

**BUSINESS PLAN FOR AN INNOVATIVE FEMININE
MEDICAL DEVICE**

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*What prevents knowledge is neither time nor intelligence, but only the absence of curiosity.
O que impede o saber não são nem o tempo nem a inteligência, mas somente a falta de curiosidade.*

Agostinho da Silva

RESUMO

A área ginecológica relacionada com as infeções vaginais apresenta-se pouco explorada do ponto de vista prático do paciente. O leque de opções de testes de auto-diagnóstico é limitado e pouco divulgado, o que leva a que as mulheres tenham o hábito de consultar o médico quando sentem algum desconforto ou comprar um medicamento sem receita médica. Assim, surge uma oportunidade no mercado de colmatar a falta de informação do público sobre esta área da sua saúde pessoal, muitas vezes negligenciada, sem ter de recorrer a uma consulta médica.

Esta tese explora os mercados das Femtech e Medtech, em Portugal e no resto da Europa. O plano de negócios desenvolvido diz respeito ao lançamento de um dispositivo médico inovador para auto-diagnosticar infeções vaginais. Este tem conexão com uma app móvel, de forma a criar um histórico e analisar analiticamente os resultados dos testes. O objetivo deste produto é, assim, promover o bem-estar e a saúde da mulher, aliando-se à tecnologia para a informar e, conseqüentemente, a ajudar a tomar decisões no que diz respeito à sua saúde ginecológica.

Palavras-chave: *Femtech*, Plano de Negócios, Vaginites, Dispositivos Médicos

Classificação JEL:

M130 Novas empresas; *Startups*;

L110 Produção, *Pricing*, e Estrutura de Mercado; Distribuição por Dimensão das Empresas

ABSTRACT

The gynecological area related to vaginal infections is not very explored from the practical point of view of the patient. The range of options of self-testing kits is limited and little publicized, so women tend to go to the doctor whenever they feel any discomfort, or they simply buy medicine without a prescription. Therefore, a market opportunity arises to fill the lack of public information about this often neglected area of their personal health, without having to consult a doctor.

This thesis explores the Femtech and Medtech market in Portugal and Europe. The business plan is about the launching of an innovative medical device to self-test vaginal infections and which connects to a mobile app to create records and analytically analyse the test results. This product's aim is therefore to promote women's well-being and health, allying with technology to inform them and subsequently help them to make decisions regarding their gynecological health.

Key-words: Femtech, business plan, vaginites, medical device

JEL Classification:

L110 Production, Pricing, and Market Structure; Size Distribution of Firms

M130 New Firms; Startups

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GLOSSARY

BV – Bacterial Vaginosis

CAE – Portuguese Economic Activities Classification

CAPM – Capital Asset Pricing Model

CAGR – Constant Annual Growth Rate

EU – Europe

EVA – Economic Value Added

FCFF – Free Cash Flow to the Firm

FCFE – Free Cash Flow to Equity

GDP – Gross Domestic Product

HIV - Human Immunodeficiency Virus

IRR – Internal Rate of Return

NPV – Net Present Value

p.p. – Percentage points

PI – Profitability Index

ROA – Return On Assets

ROE – Return On Equity

ROIC – Return on Invested Capital

SME – Small and medium sized enterprises

STD – Sexually Transmitted Disease

US/USA – United States of America

VAT – Value added tax

Vs. – versus

WACC – Weighted Average Cost of Capital

WC – Working Capital

EXECUTIVE SUMMARY

The concept of this business plan is based on the incidence of gynecological infections.

This thesis explores the development, market launch and viability of a portable medical device which is used to detect vaginal infections in advance, and prevent heavier drug prescription treatments. The device will connect to a mobile app via Bluetooth to help the users to establish patterns between internal and external factors of their body and the measurements done by the device, in order to help them to accurately diagnose of a vaginal infection. It is specially designed for women more susceptible to contract vaginal infections.

Will be explored the market potential of Femtech and health-related technologies, which are having a great acceptance by the female public. Both markets are growing steadily, Femtech is expected to reach a volume of \$50 billion by 20205 and the European Medtech market has been growing at a CAGR of 4,3% since 2008, having reached a sales volume of 115 billion euros in 2018. This is a result of the urge of the consumer to know more about what is happening within his body, and that pushes brands to get into the digital market, to include new sensors and create strategic partnerships.

There are already some alternatives in the market to self-assess vaginal infections: swab tests and pH test strips. Both methods are colorimetric, disposable and restricted to adult women who are not pregnant or in menopause. The device which is object of this thesis doesn't restrict the life stage, but it is more worthy for recurrent users since it costs nearly 7 times more than the top sales swab tests; nevertheless it also lasts longer because it is reusable.

Taking advantage of the e-commerce trend, the device will be sold online through the brand's website at a price of 84,52€+VAT. This price is the result of a gross margin of 50% from the production, which will be fully externalized. In fact, almost all the value chain will be externalized, only the administration and marketing team will be part of the company. This was the most simple and effective way to be sure that the product had quality and was marketed fast, with no hassle and benefiting from the know-how of the involved entities.

Strategically, the product will be initially launched in Portugal and then in Europe. This will be made using a communication line targeting firstly the national consumers and then international ones. This product follows a differentiation focus strategy, by offering a new solution to a specific market segment. Therefore on the first years the objective will be to inform and advertise the existence of the product, and to create awareness to the prevention of vaginitis.

Starting with an issuance of 2000 shares, which amounts to 62 988€, the investment year's expenses with investment with fixed assets, the costs of developing and testing the device and the working capital needs will be covered. On the next year, a second round of financing aims for an investment of 30 350€ to cover the clinical tests and the investment in fixed assets. The funding sources will be Business Angels and Venture Capital. After these two rounds of investment the founder will still have ownership majority with 58% share.

All the parameters of viability of the project point on the “go” direction. The business model also presents some robustness when tested in the sensitivity analysis with variations of 20% on key-assumptions, creating optimistic and pessimist scenarios. On the realistic scenario the Net Present Value of the project is 105 184€; the Internal Rate of Return is higher than the discount rate, nearly 3 times higher; the project generates a profit of 1,67€ for each euro invested; and the payback period is shorter than the projections horizon, not exceeding 5 years.

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1. INTRODUCTION

Motivation

The lack of information on gynaecological infections lead women to neglect that area of their health or take incorrect medicine. In order to diagnose a vaginal infection women can go to the doctor to do the tests, or can self-test at home with the help of self-testing kits sold at the pharmacy or online. Nowadays, in a woman's busy life, it is not always easy to have time to go to the doctor whenever she feels any discomfort, so the most practical solution can be to buy the mentioned kits. These products are not reusable, meaning they only allow a single use and are non-recyclable. Thus, this is a short-term "solution" that doesn't allow mistakes in the use and produces "easy waste".

The motivation is to develop a reusable product that allows women to self-diagnose vaginal infections, with low total cost of ownership due to its long term added value.

Objectives

The first objective is to explore the pregnancy and menopausal segments, because they are often excluded and present a big potential. The existing vaginal infections self-test kits are not designed for women in those life stages because their vaginal flora presents different characteristics. They are designed for a standard use.

Another objective is to encourage the prevention. By giving women a tool that helps them to detect vaginal pH level changes they can check if it is created a good environment for infections to proliferate and reverse the situation without heavy drug prescriptions. This only applies to women who are more susceptible to develop vaginitis.

Outline

In first place it is identified the innovative proposal, in a brief text explaining the creation of the concept of the medical device.

Follows the literature review, where is explored the gynecological infections incidence. Right after explaining the problem comes a description and justification of the proposed solution.

On the next chapters is performed a market search and different analysis to the internal and external factors of the business environment of the project. The intention is to have a

general overview of the main market trends on the present and short-term as well as the factors to which the business will have to adapt, such as competition. With this information is outlined the market strategy conducting line, which will mold the rest of the business plan choices and assumptions.

The business model is defined on chapters 10 to 12, where all the assumptions, choices and implementation resources are presented and justified, as well as the projects chronogram and value chain.

Lastly, the project is evaluated and the business model is submitted to sensitivity tests in order to evaluate its robustness.

2. IDENTIFICATION OF THE INNOVATIVE PROPOSAL

This concept was initially created and developed on the final project of Finance and Accounting Bachelor Degree: Business Project in Finance (2016); a collaboration between the Faculty of Science of Lisbon's University (FCUL) and ISCTE University Institute of Lisbon (ISCTE-IUL). It first occurred because of the vulnerability of women with cancer. Because of the chemotherapy and drugs they take during the treatment their defenses weaken and they develop infections more easily. This leads to more drug prescriptions and an overall discomfort.

Because of environmental matters, the initial product suffered a big twist to what it is now – initially it was a sanitary pad for daily use.

It was developed the idea of a medical device that is used to measure the vaginal pH to assess the emergence of vaginitis. Vaginal acidity is linked to the health of the vaginal flora and is a good indicator for checking if an infection is developing. This level of acidity changes throughout a women's life – puberty, pregnancy, menopause - and is sensitive to internal and external factors – like chemicals in hygiene habits, unprotected intercourse, antibiotics or hormonal changes – so the device will be associated with a mobile app that will allow women to interconnect all those factors with their pH level. Thus, they can understand if their pH level is normal or not. The product's target is women who are more susceptible to develop vaginal infections: with chronic disease, heavy drug prescriptions, pregnant or naturally more vulnerable to develop this type of infections.

3. LITERATURE REVIEW

3.1. Description of the problem - Infections of the Gynaecological Tract

“Vulvovaginitis is an inflammation or infection of the vulva and vagina. Other names for this condition are vulvitis and vaginitis” (Blake & Watson, 2018). The three most common infection’s triggers are *Candida albicans*, *Candida sp* (Candidiasis – yeast infection), *Gardnerella Vaginalis* (Bacterial Vaginosis – bacterial infection) and *Trichomonas vaginalis* (Trichomoniasis – parasite). These lead to infections that are highly characterized by an abnormal vaginal discharge, which is a frequent reason why women consult a gynaecologist (Raugust & Ribeiro Duarte, 2013).

Agent	Type	Infection’s name
<i>Candida albicans, Candida sp</i>	Yeast	Candidiasis
<i>Gardnerella Vaginalis</i>	Bacterial	Bacterial Vaginosis
<i>Trichomonas vaginalis</i>	Parasitic	Trichomoniasis

Table 1 - Most common gynaecological infection's triggers. Source: Author

3.1.1. Incidence

This is a widespread problem in society. It is estimated that 75% of women at some stage of life have candidiasis, of whom 50% present the case more than one time and 5% have four or more episodes in one year – a so called recurrent vaginal candidiasis (Raugust & Ribeiro Duarte, 2013). Despite this high numbers, *Candida*’s caused infections are just the second most frequent, representing 17% to 39% of the clinical cases of vaginal infections (Raugust & Ribeiro Duarte, 2013). It is Bacterial Vaginosis (BV) the most common diagnosis, representing 40% of the cases of vaginal complaints (Achkar & Fries, 2010)¹ – yeast infections and *Trichomonas* have an occurrence rate of 20% (Monistat, 2018).

Regarding the abnormal discharge, *Gardnerella vaginalis* is the main agent - responsible for causing 45% of the cases - followed by *Candida* which is accountable for 20% to 25% of the complaints (Raugust & Ribeiro Duarte, 2013).

3.1.2. Morphology of the female reproductive tract

The bacterial flora of the vagina is mostly composed by microorganisms called Döderlein bacilli, or lactobacilli, which are responsible for keeping the normal balance of bacteria in the vagina (Tua Saúde, 2019) – that is keeping the pH at a low level/acidic and that

¹ These numbers refer to statistics of the United States of America.

prevents the outgrowth of disease-causing bacteria that can lead to gynaecological infections and STDs (WebMD, 2018). The vaginal flora has a naturally acidic pH.

3.1.3. Connection with pH

“An average of 78% of the BV cases will be accompanied by a pH level of 4,7 or greater” (VS-SENSE, 2018). The pH level is often used as a diagnostic method, but it requires other parameters to assure a diagnosis, meaning **it doesn’t point out an objective result per se** (Achkar & Fries, 2010): it is an indicator.

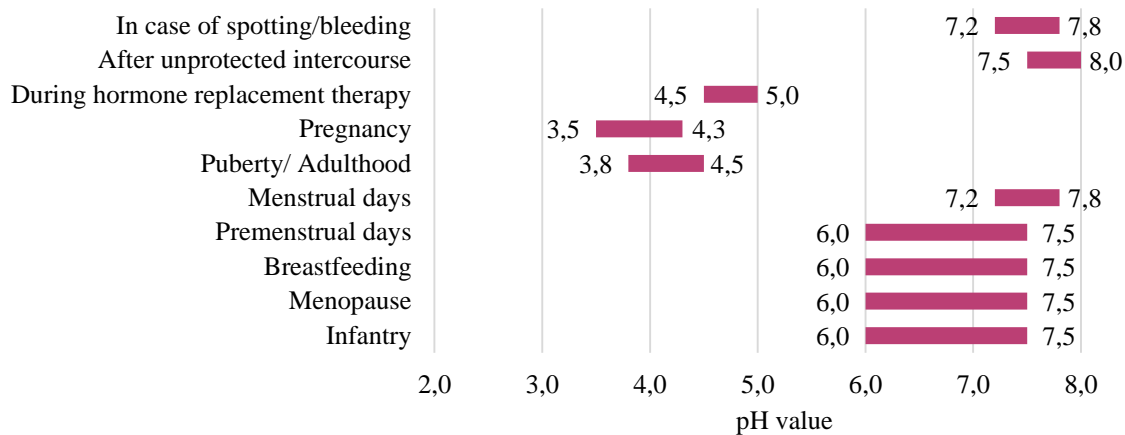
pH level	May indicate...
<3.8	Candidiasis
3.8 - 4.5	Normal
>4.5	Bacterial Vaginosis Trichomoniasis (up to 8, but generally in pH values between 6 and 6.5)

Table 2 – pH as an indicator of vaginitis, adapted from Raugust & Ribeiro Duarte (2013) and Achkar & Fries (2010). Source: Author.

The pH can vary due to the stage of life: blood or low levels of estrogen rise the pH of the vagina, amongst others. So, a healthy pH before menstruating and after menopause is higher than 4.5. Estrogen plays an important role in the regulation of the natural pH because as it floats the pH floats inversely, meaning that peaks of estrogen production lead to low pH levels and vice versa (Nordqvist, 2017). This is to reinforce the subjectivity of pH screening if the circumstances of the individual are not taken into consideration.

The acidity of the vagina may be affected by: vaginal infections, blood, semen, antibiotics or other drugs, estrogen (perimenopause, menopause, pregnancy, menstrual cycle), douching frequently – hygiene habits (Nall, 2018) -, stress, weak immune system and diseases like diabetes or HIV.

Vaginal acidity variation according to stage of life



Graph 1 – Variation of the vaginal acidity according to women’s stage of life. Source: Adapted from *BeyonDevices Report* (s.d.).

3.1.4. Treatments and prescriptions

The treatment of vaginal infections involves the use of specific drugs, commonly in the form of pills, creams or gels. Many of the necessary medicines to treat gynaecological infections are available over the counter (OTC) (Virtual Medical Centre, 2011), and this leads to individuals taking drugs based on self-diagnosed symptoms. “Ready access to these products is associated with wasted financial expenditures, unfulfilled expectations, and a delay in correct diagnosis for a substantial number of women.” (Ferris, et al., 2002)

In the study “Over-the-counter antifungal drug misuse associated with patient-diagnosed vulvovaginal candidiasis” (Ferris, et al., 2002), a sample of symptomatic women were buying OTC fungal infection’s drugs for a self-diagnosed candidiasis. After professional examination and tests, the actual pathologies were: “vulvovaginal candidiasis 33.7%, bacterial vaginosis 18.9%, mixed vaginitis 21.1%, normal 13.7%, other diagnoses 10.5%, and trichomonas vaginitis 2.1%”. So, almost 70% of the women were going to take medicine that would not treat their complaints (of these nearly 14% were healthy); thus prolonging their discomfort and contaminating their bodies with needless substances, possibly aggravating the pathology, not to mention the money waste. The motivation behind buying these OTC drugs is the time and money waste of scheduling a doctor’s appointment.

Antibiotics may damage the human health and weaken the immunity system, once they make no distinction between killing off the bad bacteria or the good. So, the use of antibiotics sometimes lead to other health issues hence the body becomes more exposed to the growth of other pathogens (WebMD, 2018). At a gynaecological level, by killing the lactobacilli, the pH gets higher and bacterial infections may proliferate as well as some STDs.

When a bacteria proliferates in the gynaecological tract, the pH tends to be higher, more alkaline, thus creating a good environment for different infections to spread out - bacterial, parasite (Raugust & Ribeiro Duarte, 2013). This type of infections is generically treated with antibiotics (Annex I - Resume board on the types of infections), consequently killing the majority of the bacteria present. By “cleaning out” the vaginal flora bacteria, the pH starts to low down becoming more acidic again and depending on the strength of the women’s immunity and regulating system, once more a good environment for infections may be created, in this case fungal infections (Achkar & Fries, 2010).

In Portugal, the usual diagnostic procedures includes visual analysis of the vaginal channel with the help of a speculum and a cytology exam which is sent to laboratory (it can take up to one week to get the results).

3.1.5. Groups more susceptible to contract/develop vaginitis

The most susceptible group to gynaecological infections is women during reproductive years, mostly due to the hormonal changes and sexual contact, which are amongst the main causes for this infectious diseases. However, a weak immunity system is an open door for infections to proliferate, regardless of the age (Monistat, 2018).

The complex balance of the microorganisms in the vaginal flora is more easily guaranteed with a strong immunity system. The natural defences of the body deteriorate, amidst others, as a result of antibiotics prescriptions, cancer treatments (chemo and radiotherapy), corticosteroid therapy or as a condition/symptom/cause of an autoimmune disease (Monistat, 2018).

To include the vaginitis treatment in the daily routine of an individual that already has defences below the normal levels can be challenging not only for its body but psychologically as well. If the infection is caught/detected in an early stage, the treatment will be softer and heavier drugs might not be necessary (HARTMANN, 2018).

Pregnant women also beneficiate of an early diagnosis since during pregnancy hormonal changes can disrupt the pH balance of the vagina (Tobah, 2018). If an infection caused by bacteria or *trichomonas* (most common types during pregnancy) is not detected and treated appropriately it can generate delivery issues including preterm labour, premature rupture of the amniotic membrane or post-labour complications and infections (Soper & Sims, 2018). A clinical trial published in 2000 concluded that “frequent vaginal pH testing during pregnancy resulted in more frequent diagnosis and treatment of bacterial vaginosis” (Gjerdingen, 2000).

In sum, early detection helps – with a regular pH check, risks can be mitigated and the treatments are simpler (HARTMANN, 2018).

3.1.6. Safety assessment and development stages of a medical device

Generally products must fulfil certain requisites of consumer safety. The level of control of the product, from its components to the customer usage, depends on the type of product. A premarket safety assessment approach regularly adopted is the exposure-based quantitative risk assessment (QRA) to assure the safety of the product (Woeller & Hochwalt, 2015). It includes the following steps (Bae, et al., 2018):

- **Hazard identification** - Identify the presumable toxic/chemical components used in the manufacture/industrial process which have potential effects on human health and environment;
- **Hazard characterization** – Determine the effects of the components with toxic/chemical properties as well as it's tolerated doses, and the human body response;
 - Usually the effects are dermatological: skin irritation, hypersensitivity caused by the materials and residual chemicals.
- **Exposure characterization** - Determine the exposure to the pertinent components of the products, the duration and frequency of contact/ the consumer use and the type of contact;
- **Risk characterization** - Compare the results with a safe benchmark;
 - If the components used and respective measured exposure are similar to those already incorporated in products with long history of safe use, then these should meet that same safety level as well.
- **Clinical evaluation** – Clinical tests and trials.
- **Risk assessment** - Propose measures to mitigate the risks assessed, and of how to monitor those risks;
 - This consists of giving the consumer information needed to prevent the misuse of the product, to repair any damage or answer to any possible doubt about it– include instructions of use, possible risks and risk groups, emergency contact numbers, customer care contact number/website/e-mail address;
 - After marketing the product the post-market surveillance step begins, which as the name says consists on monitoring the satisfaction of the customer, “to further substantiate safe use in the marketplace, and to be alerted to any unanticipated issues or unusual trends” (Woeller & Hochwalt, 2015). This stage/step takes years of

permanently search for measures to improve the product in respect to the customer experience assessment.

The general quality certification is ISO 9001, which ensures the quality of the services and operations of an organization. For medical devices sector the certification of quality management systems is ISO 13485. It can be granted to organizations in one or more of the value-chain stages of the medical device or even associated services (APCER, n.d.).

On Figure 1 it is shown the steps that a medicine should follow, but it can be extrapolated for the medical device industry. It starts by validating the technology and design behind the product, then testing it and evaluate safety levels of usage and emergency measures in case of misuse/breakdown of the medical device; the next step is the approval by the respective regulatory entity and market; on the following years (post-market) the product will be monitored by the regulatory entity (FDA, 2018).

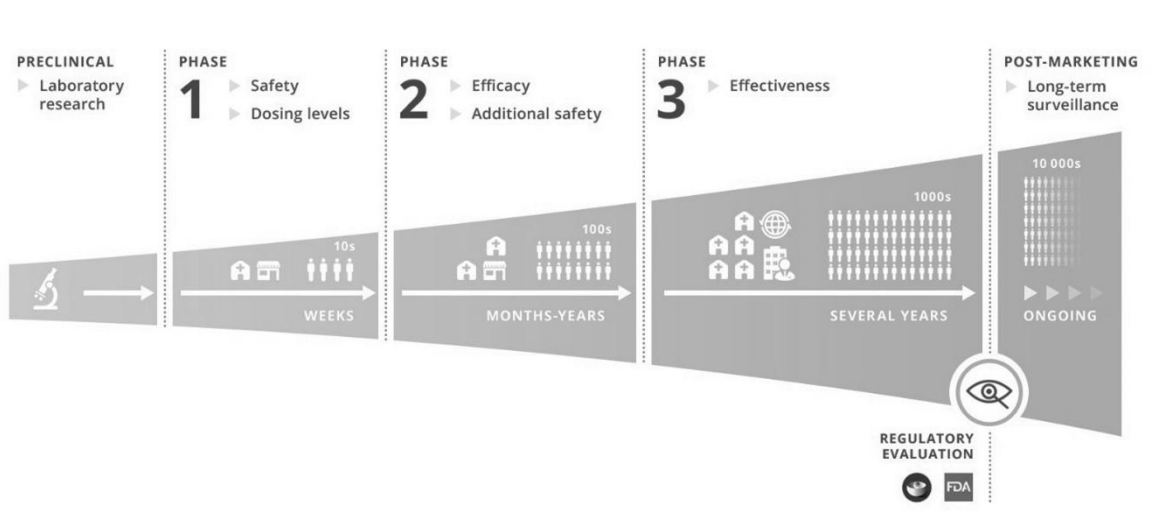


Figure 1 - Drug development process. Source: FDA (2018)

4. REFERENCE FRAMEWORK

The rational sequence for the literature review was progressive from the problem identification and how it arises, to the solutions already existing for diagnosis, to the potential consumers/target, and to the solution identification. The following topic summarizes the key-points to retain and that will sustain the reasoning for the proposed solution.

4.1. Description of the proposed solution

Problem 1: Women self-diagnose vaginitis wrongly and end-up taking non-pertinent OTC drugs (Ferris, et al., 2002).

Problem 2: Some vaginitis are asymptomatic, or at least at the beginning.

Scientists estimate that 20% of women have *candida* yeast without even suspecting (CDC, 2019) and 50% of those infected with BV don't have any symptoms (Harvard Health, 2019).

Fact 1: The vast majority of women have vaginitis at least once in their lifetime (Raugust & Ribeiro Duarte, 2013).

Fact 2: Vaginal pH level is directly linked to vaginal infections.

Self-testing the vaginal pH is a reliable indicator to find if the gynaecological flora is healthy (Nyirjesy, et al., 2017).

Fact 3: Correctly self-screening the vaginal pH can reduce the number of medical visits.

In cases where the pH is above the expected normal values, indicating a possible bacterial or parasite infection, it is advisable to consult a health technician. However, a yeast infection emergence doesn't require a medical appointment - it can be treated with homemade medicine or OTC medication depending on the circumstance (consult 3.1.4. Treatments and prescriptions).

Fact 4: Late detection of vaginitis leads to more aggressive treatments and may affect other body organs (consult 3.1.5. Groups more susceptible to contract/develop vaginitis).

Solution: A reusable pH device used to self-measure the vaginal pH level precisely allowing the monitoring of its changes in order to detect possible vaginitis

How does it work? It consists on a pen-shaped probe which tip has an electrode and is held still against the vaginal wall. It uses electrical signals to measure the hydrogen ions concentration and give back the pH level. The higher the concentration the more acidic the pH will be.

How to do the diagnosis? Crossing the symptoms (i.e. vaginal discharge and itching) with the pH level and comparing it to the chart in the product's package.

How often should the vaginal pH level be measured? Whenever there are symptoms. For regular monitoring it depends on the frequency of vaginitis development, pregnancy or disease. Women with recurrent vaginitis (>4 times a year), pregnant or with a weakened immunity system should measure it regularly, for instance once a week, but it should be discussed further with their health professional.

See Doctor if these symptoms persist: itching, burning, foul odor, unusual discharge.

Second phase of the solution: Bluetooth connectivity between the pH device and an interactive app for the mobile phone (Android, iOS and Windows)

How does it work? All the measurements can be recorded in the app, making a chronological history of pH levels. It will alert the user for abnormal levels based on their history of recordings and analytics, always considering the symptoms as well. The app gives the possibility for the user to add notes that may justify the changes in the pH level.

Important: it will be an indicator and is highly dependent on the correct use and sensibility of the user to analyse their symptoms.

5. MARKET ANALYSIS

5.1. Overview on Femtech market

Over decades, tech world, healthcare products and solutions didn't always consider the physiological differences in gender, that reflects in different needs regarding healthcare (Das, 2018). The urge to design gender-specific technologies, feminine in particular, has developed a niche and expanded to the creation of a new market: Femtech.

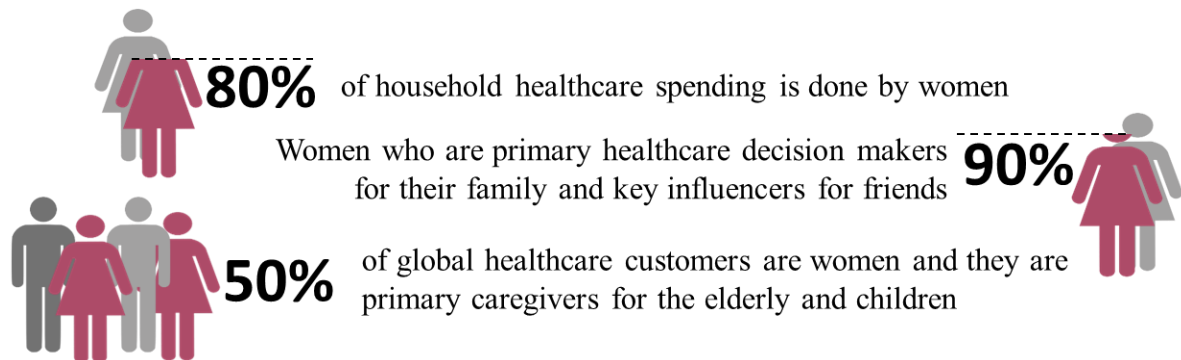


Figure 2 – Statistical data that supports the growth and appearance of Femtech market – household healthcare, healthcare decision makers, healthcare customers - adapted from Frost & Sullivan (2018). Source: Author.

Femtech market, which is included in the Women's Health market, is recent and presents a big potential. It was "created" in 2016 because of the need to better phrase the products specifically designed to address women's needs (Forsyth & Muska, 2018). Etymologically it means Female Technology and comprises products, services, software and diagnostics that use technology to improve and manage women's health and well-being. It is expected to reach a volume of \$50 billion by 2025 (Frost & Sullivan, 2018).

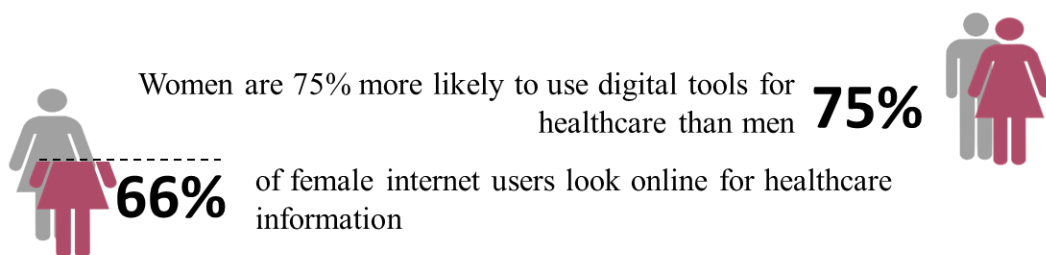


Figure 3 - Statistical data that support the growth and appearance of Femtech market – digital tools and internet use - adapted from Frost & Sullivan (2018). Source: Author.

	Volume (in million USD)						CAGR			
	2017	2018	2019	2024	2025	2026	2008 - 2018	2017- 2024	2018 - 2023	2018 - 2026
Global Feminine Hygiene Products Market	24 350			37 700				6,4%		5,7%
Femtech Market					50 000					
Investment in Femtech companies/startups		400	1000 (p)							
Global Digital Healthcare Market								11,8%		
Women's Health Market (USA)						54 600				4,2%
European Medtech Market		115 000					4,3%			
World Medtech Market		425 930 (c)								

Legend: (p) predicted; (c) calculated.

Table 3 – Market figures on some relevant markets related do medical devices and Femtech. Adapted from sources: ReportBuyer (2018), Credence Research (2018), Reuters (2019), Grand View Research (2019) and Meditech Europe (2019).

The urge to combine wearables and health data is matching with the rise of Femtech. Wearable health monitoring devices, like sport watches, are declining once the users want more features besides “tracking” their steps or heart rate, they want information about their body and what is happening within it (Forsyth & Muska, 2018). Some other market trends are:

- **Increase of the e-commerce** - one can find online the products that are not available in retail stores (Business Wire, 2017). The sector expanded by 11,4% in September 2018 (Wertz, 2018);
- **Ethical consumerism** – Sustainable, organic, green, fair-trade, cruelty-free, eco, these are all labels that consumers are valuing. A portion of the consumers is trying to include sustainable behaviours on their lifestyle. People care about sustainability, and is up to the brands to help (National Geographic, 2014);
- **Brands-as-a-culture** – consumers care about the company positioning considering corporate responsibility, social consciousness, and more. Company’s culture has become more important than ever (Wertz, 2018);
- **Awareness for feminine hygiene** – The increasing openness to discuss personal hygiene and health issues has generated more conscious about it on the general female public, hence creating demand on feminine hygiene products. “The number of blogs that create awareness on female health issues has surged due to this open environment, and they are instrumental in creating demand for feminine hygiene products,” says Amber Chourasia, a lead analyst at Technavio for health and wellness research (Technavio, 2017);
- **Early onset of puberty** – this affects positively the global feminine hygiene and sanitary products market (Technavio, 2017);

- **Evolving lifestyles of women** - The increase in the working women population and financial independence created demand for feminine hygiene products (Business Wire, 2017). This facilitates the targeted marketing, focusing directly on women and influencing their purchasing power (Business Wire, 2017).

In sum:

Market drivers – Rising awareness for feminine hygiene and related products, early onset of puberty, evolving lifestyles of women

Market trends – Ethic consumerism, e-commerce market, brands-as-a-culture

However, there isn't much awareness created about the potential of Femtech applications to improve well-being of women. "Insights into the drivers and motivating factors that increase usage, enhance patient perception, and encourage better engagement, will be critical for Femtech to reach its maximum potential" (Das, 2018).

There are over 200 Femtech startups worldwide. The main fields of Femtech are menstruation care, fertility/reproductive tracking and solutions, pregnancy and nursing care, sexual health and general wellness (HITLAB, 2019). However, startups are developing other issues that address women such as breast cancer, endometriosis, osteoporosis, anxiety, depression or thyroid issues.

5.2. Gynaecological infections in Portugal – Market study

In order to assess the market openness to a product like this device, for this thesis a market study was conducted between 10th June and 11th July of 2019, with a total number of 314 participants, with ages from 18 to 84. The enquiry's target was women with more than 18 year old who live in Portugal. The age's average is 38. No segmentation was made regarding the economical class. The sample is random.

Main results:

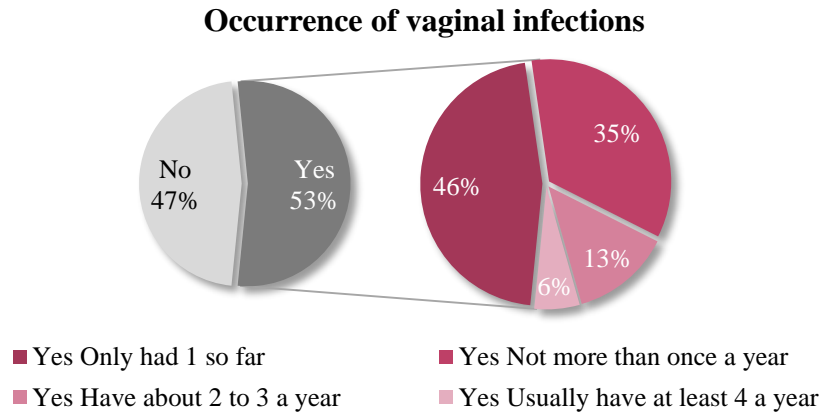
- 167 participants have already had a type of vaginal infection (53% total); from this, 6% have recurrent vaginitis (4 or more times a year recurrence) and 13% have 2 to 3 infections of this type a year, as illustrated on Graph 2;

- Nearly 11% of the participants didn't have any symptoms when diagnosed the infection. The majority (66%) scheduled a medical appointment after having any sort of symptoms and 22% self-diagnosed because they were already familiar with the symptoms;

- Percentage of women who self-diagnosed and bought over-the counter medicine: 16%;

- Women who had vaginal infections tend to care more about themselves to avoid recurrence/ occurrences.

- The electronic device was the most popular method to measure the vaginal pH regularly at home. The percentage of participants that had preference for this method rose according to the recurrence of vaginal infections, as shown in Graph 3.

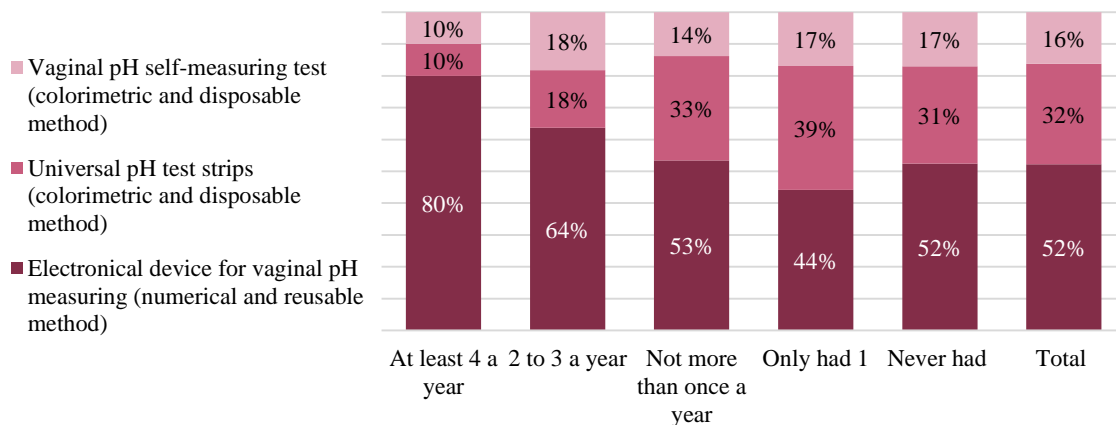


Graph 2 – Occurrence of vaginal infections. Answers to the questions “Have you ever had a vaginal infection? (Do not confuse with urinary)” and “Regarding the occurrence of vaginal infections, what option fits you better?”. Source: Author

Main conclusions:

- Vaginitis is a predominant infection;
- Women who had vaginitis are more aware to avoid them;
- The electronic device is well-perceived by the targeted public (women who have “2 to 3 infections a year” and “4 or more”);
- The only type of products sold and specifically designed for measuring vaginal pH (“Vaginal pH self-measuring test”) scored poorly of the participants preferences.

Method chosen for regular measurement of pH by infection recurrence



Graph 3 – Method chosen for regular measurement of pH by infection recurrence. The device is the favourite method, especially for the surveyed that suffer the most from this type of infections. Source: Author.

5.3. Medical Technology Market in Europe

X-ray scanners, contact lenses, dental equipment, breast implants, heart valve replacements, prostheses, pregnancy tests, condoms, orthopaedic soles and wheel chairs, are all encompassed in the Medical Devices market, a branch of Medical Technology. The so called Medtech, is one of the biggest growing segments in Europe: it was the major field in patent applications in 2017, with 13 000 patents filled in European Patent Office (EPO); it represents 7,2% of the total healthcare spending in Europe, from which 90,3% respect to Medical Devices - 6,5% of the total healthcare spending in Europe (MedTech Europe, 2019).

According to Medtech Europe, in EU the annual sales reach 115 billion euros, which is 27% of the world market volume, following USA with 43% of it. USA is also the biggest export destination for European medical devices, reaching 40,7%; followed by China with 9,6% and Japan with 6,6%. The opposite trading flux (imports) follows the same order: USA 52,6%; China 12,2% and Japan 6,2%. The European average spending per capita on medical technology is 213€ (weighted average), an average of less than 1% of the GDP is spend on it. The medical device trade balance of Portugal is negative by 559€ million (MedTech Europe, 2019).

Over 27 000 companies in EU operate in this market, employing more than 675 000 persons. Germany is the country with the highest employment: about 200 000 employees in this industry, but is also where most of the companies on this sector are based. These numbers are highly dependent on the SMEs of this segment, which account for 95% of the total companies (MedTech Europe, 2019), being most of them micro and small-sized - Annex III - SME.

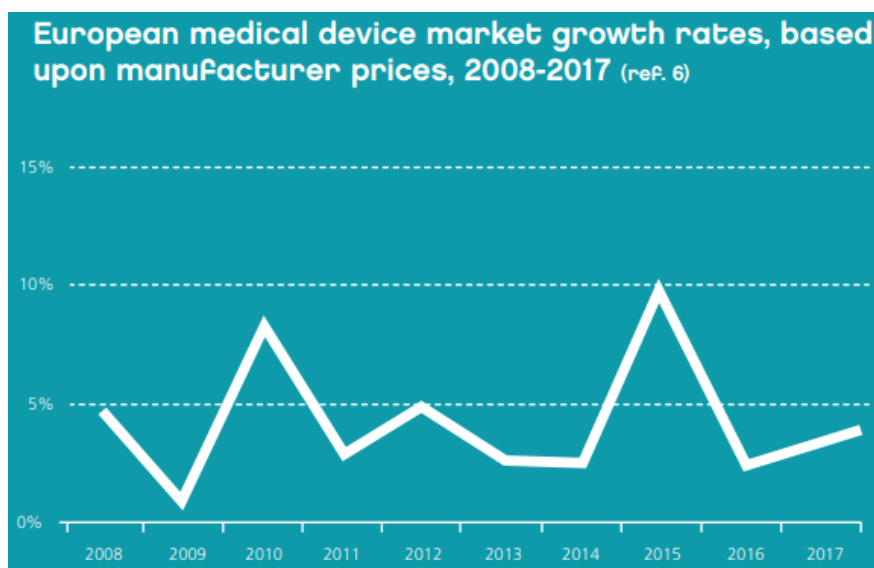


Figure 4 – “European medical device market growth rates, based upon manufacturer prices, 2008-2017”. Source: The European Medical Technology Industry – in figures 2019, Medtech Europe (2019).

The average fluctuation on medical devices market is 2% to 5% since 2009 economic crisis. 4,3% is the average annual growth over the past decade (MedTech Europe, 2019).

5.4. Competition and top players

The top product devices for vaginal pH measuring are:

- **Swab tests** – small swab-like instrument with a pH sensitive tip, which is inserted in the vagina. According to the pH level the tip turns into a different colour. Usually they have a small spectrum (4 to 7) and the package brings 1 to 2 swabs. Examples of some of the most common products:
 - Gyno-Canestest®, from Common Sense™ but distributed by Bayer in Portugal. Allegedly detects any change in the vaginal pH with a precision of more than 90% (Gyno-Canestest, 2018). This is the top sales test in Portugal. Price: 9,34€ to 12,99€.
 - VS-SENSE™, from Common Sense™, which has a high accuracy of 92% (Geva, et al., 2017). Same manufacturer of Gyno-Canestest®, but not sold in Portugal.
 - Monistat® Care™, from Monistat®, not available in physical stores in Portugal.
 - VagiSense®, not available in physical stores in Portugal.
 - Ferlidona™, from Actavis. This is made thinking about pregnant women to monitor their acidity twice a week, to avoid premature birth or other complications. It is a swab test and doesn't consider pH levels lower than 4. Is sold in Portugal, but is very rare.
- **pH test strips** – Colorimetric method consisting of small paper pH sensitive strips, used for urine, saliva, water and mostly all substances. According to the pH of the substance it changes its colour. Some strips are designed for specific type of substance and include detailed information about it, as well as a more indicated spectrum of colours.

Product type	Pros	Cons
Swab Tests	<ul style="list-style-type: none"> - Designed specifically to identify infections - Small and discrete - Easy to read results 	<ul style="list-style-type: none"> - Usually expensive (relation between money and usage) - Usually only include 1 or 2 swabs per kit - The presence of blood or any colour-tinged vaginal discharge may distort the results - Disposable
pH test strips	<ul style="list-style-type: none"> - Inexpensive - Readily available - Easy to use and read results - Usually one pack includes several strips 	<ul style="list-style-type: none"> - Accuracy depends on the visual acuity of the user/person who checks the colour displayed in the strip - The presence of blood or any colour-tinged vaginal discharge may distort the results - May have a wide spectrum of pH levels (1 to 14), reducing the accuracy of the test - Disposable

(continues)

(continuation)

Product type	Pros	Cons
pH meter	<ul style="list-style-type: none"> - Precise measuring (quantitative) - Non-dependent of the visual acuity of the user/person who checks the test results - Possibility of monitoring frequently - Reusable and therefore long-lasting 	<ul style="list-style-type: none"> - Expensive - Only available online - The models available are not designed for the purpose of being small, light and discrete. There are mostly lab equipment.

Table 4 – Pros and Cons of already existing products for vaginal pH screening and for pH meter. Source: Author.

This industry is growing fast as women’s health awareness is increasing and funding constraints are slowly dropping – currently only 4% of the funding for research and development for healthcare products and services in the world is invested in women’s health (Das, 2019). Considering the market of female technologies, some of the most popular apps/gadgets are:

- **Ava**, a fertility monitoring bracelet, which keeps record of pulse rate, sleep, breathing rate, heat loss and skin temperature. It connects with a mobile app, where this info is displayed. This device helps tracking menstrual cycle, fertility and pregnancy. Price of the last version: 299€.

- **Elvie Trainer**, which is a pelvic floor exerciser device to help with pelvic floor problems recovery (bladder control, postnatal recovery and intimacy). It connects with a mobile app in real time with biofeedback of the training. Recently partnered with NHS. Elvie raised \$42 million in funding on April of this year (HITLAB, 2019). Price: 199€.

- **Clue**, period and ovulation tracker, it is a mobile app in which the user takes note of their mood and any physical symptoms in order to create a panorama of its reproductive health (Clue, 2019). Price: normal subscription is free, the upgrade is 9,99€/year

- **Daysy**, an intelligent fertility tracker device, centred on basal body temperature measured in the mouth. It syncs with the mobile via Bluetooth. Using an algorithm that learns through time it predicts accurately the menstrual cycle (Daysy, 2019). Price: 299€.

- **Madorra**, non-hormonal solution to treat vaginal atrophy/dryness. It’s a medical device that uses therapeutic ultrasound to create heat and increase vaginal blood flow without the need to insert it. It is still under clinical trials and studies (Madorra, 2019).

- **Clearblue Digital Ovulation Test**, indicates the fertile window by measuring the hormones in urine. If a specific hormone is present in the urine means that the user is in fertile stage of the menstrual cycle. It is reusable, each kit brings 10 tests that are attached to the measuring device (Clearblue, 2019). Price: 21,22€- 34,70€

Other products encompassed on Femtech market are:

- **MenoGenix**, non-hormonal treatment for menopausal symptoms through the administration of MNGX-100 a naturally-occurring human blood protein. Still under clinical trials.

- **Flex menstrual disc, Think, Cora**, are disruptive products/concepts for menstrual flow. The last one got \$7,5 million in funding (HITLAB, 2019). US based.

5.5. Hygiene Sector in Portugal

Hygiene sector industry's growth has inherent the subliminal trend that population is giving more importance to personal care habits. That personal care is also associated with the health field – wellness -, which leads to the reasoning of associating hygiene sector and some of the Femtech areas. In 2017, the hygiene and cosmetic products had a weight of 4,3% out of the 10th main products of the retail commerce (which represent 53% of the total business volume – 47 products). Regarding the category of pharmaceutical, medical, hygiene and cosmetic products, it rose 6,6% on the specialized retail stores and 6,8% on non-specialized retail stores, reaching a business volume of nearly 800 and 1342 million euros. See annex IV – Hygiene Sector in Portugal.

5.6. Business environment analysis

5.6.1. PESTEL

Since the product's premature market target is Portugal, PESTEL analysis is focused on the country. It allows an overview on the political, legal, social, technological and environmental matters on a present and short-term future analysis.

Political-legal context

Medical device classification

In Portugal, the introduction of medical devices in the market is regulated and supervised by INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde (National Authority of Drugs and Healthcare Products). As the name suggests, this entity assures the quality standards of the drugs and healthcare products as well as their efficacy and safety for human use (INFARMED, I.P., s.d.). Some INFARMED's attributions are:

- To regulate, evaluate, authorize, supervise, analytically verify and ensure the monitoring and control of research, production, distribution, marketing and use of human medicines and health products, including medical devices and cosmetic and body care products;
- To manage the National System for the Evaluation of Health Technologies (Sistema Nacional de Avaliação de Tecnologias de Saúde - SiNATS²).

In Europe, the European Commission regulates the medical devices classification which is based on the risk from low to high, from Class I, IIa, IIb and III, in the same order of risk. There are four essential features for this classification, namely the time in contact with the human body, the invasiveness of the human body, the anatomy affected by the use of the device and the potential risks concerning the design and manufacturing of the device. The definition of the classification rules may be consulted in Annex V. The new Regulation on medical devices – Regulation (EU) 2017/745 – will only entry into force on the spring of 2020.

According to Article 2 (1) of the *REGULATION (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices*, the product which is theme of this thesis, is considered as medical device:

“(…)‘Medical device’ means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: — diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease (…)” (European Parliament and Council, 2017)

Regarding the mobile app, it is regulated independently of the device and its connection with it, and may be considered as medical device:

“(19) It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, qualifies as a medical device, while software for general purposes, even when used in a healthcare setting, or software intended for life-style and well-being purposes is not a medical device. The qualification of software, either as a device or an accessory, is independent of the software's location or the type

² The evaluation of health technologies (ATS – Avaliação de Tecnologias de Saúde) aims to support the decision to use and finance health technologies.

of interconnection between the software and a device.” (European Parliament and Council, 2017)

Other regulations that are directly or indirectly linked to the marketing of a medical device in Europe and Portugal:

- *Annex VIII of the REGULATION (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices* which establishes the rules for the classification of medical devices;
- *Annex I of the REGULATION (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices* which regulates the essential requirements the product and manufacturer should meet;
- *Annex XIV of the REGULATION (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices* which establishes the clinical evaluation requirements and conditions;
- *Decree-law 145/2009 emitted by the Portuguese Ministry of Health of 17 June 2009* that establishes the rules for investigation, manufacture, marketing, market entry and advertising to which medical devices and respective accessories should follow;
- *Law 21/2014 of 16 April emitted by the Portuguese Republic Assembly* which regulates clinical trials in Portugal.

To launch the product to the market it is mandatory to have a CE mark, which is the certification that the product is manufactured according to the essential applicable requirements and that it is safe to use. The entity responsible for the CE evaluation and authorization of class I medical devices with measuring functions, class IIa, IIb and III, and active implantable medical devices is the Notified Organism (INFARMED, I.P., 2019). Other legal requisites may be consulted in Annex V.

Intellectual property

In Portugal, the only entity that gives exclusiveness rights on inventions is Instituto Nacional da Propriedade Industrial (INPI) – National Institute of Industrial Property. There are two ways to protect technology: patent or utility model. The second one has a more simplified process (INPI, 2019). There is another procedure called provisional patent application which allows the applicant to delay for one year the formal patent application while assuring the secrecy and confidentiality and the priority of patent request (Justiça.Gov.PT, 2018). The rights INPI gives are only valid on national territory. An international or European request

is required to get protection beyond borders, but only patent protection is possible. The request can be made through World Intellectual Property Organization (WIPO), but for European request it can be done through European Patent Office (EPO), but is only approved after a copy of the patent is delivered in each country's institute, in its official language (Justiça.Gov.PT, 2019).

Economic-demographic context

Portugal is a country of ancient population. For every young person there are approximately 58 old persons and the life expectancy is 81 years old (PORDATA, 2019). Due to lack of incentives to inhabit the interior continental regions most of the young and labour force is moving to the coast and main cities. Thus the interior regions have the higher ancient index, achieving 197% in Centre area and 201% in Alentejo (PORDATA, 2019). The majority of the 10,2 million of residents is female gender (53%) and the total labour force represents about 51% of the total resident population.

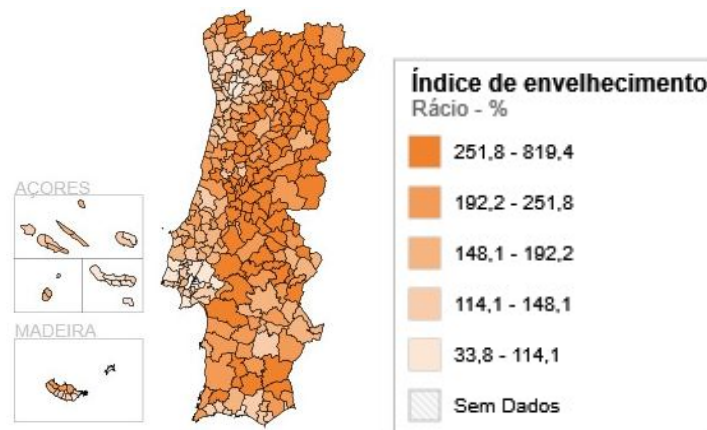


Figure 5 – Aging index per district in Portugal, 2018. Source: PORDATA (2019).

Portuguese economy is slowing down the expansion pace, gradually converging to the Euro Area average. After a variation to some extent below expectations in 2018 (2,1%), the Portuguese GDP will continue to grow, despite the slowdown. Banco de Portugal's growth projections for the national GDP are 1,7% in 2019 and 1,6% in 2020 and 2021. These are higher rates than the Euro Area average of 1,2% and 1,4%, respectively (Banco de Portugal, 2019).

It is expected a decrease on the inflation rate in 2019 (0,9%) and in 2020 it will rise again to the value of 2018 (1,2%). In the Euro Area the fluctuation follows the same path, a decrease of 5 p.p. to 1,3% in 2019 and a rise to 1,4% in 2020.

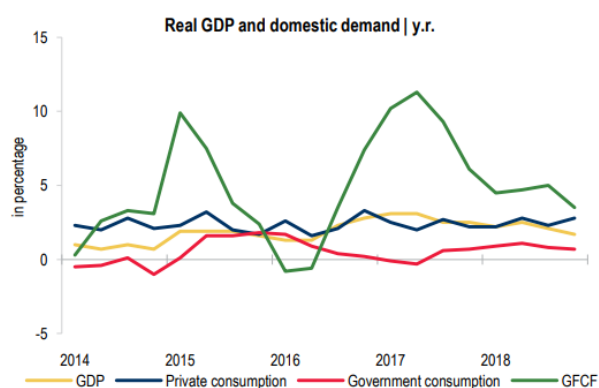
	% of GDP	EB June 2019				EB March 2019			
		2018	2018	2019 (p)	2020 (p)	2021 (p)	2018	2019 (p)	2020 (p)
Gross domestic product	100	2.1	1.7	1.6	1.6	2.1	1.7	1.7	1.6
Private consumption	65	2.5	2.6	2	1.7	2.5	2.7	1.9	1.6
Public consumption	17	0.8	0.5	0.5	0.5	0.8	0.3	0.2	0.2
Gross fixed capital formation	17	4.4	8.7	5.8	5.5	4.4	6.8	5.8	5.2
Domestic demand	100	2.8	3.5	2.3	2.2	2.7	3.0	2.3	2.0
Exports	44	3.6	4.5	3.1	3.4	3.7	3.8	3.7	3.6
Imports	43	4.9	8.0	4.3	4.4	4.9	6.3	4.7	4.1
Contribution to GDP growth, net of imports (in p.p.)									
Domestic demand		1.3	1.3	1.1	1	1.3	1.3	1.1	1.0
Exports		0.8	0.4	0.5	0.5	0.8	0.4	0.6	0.7
Employment (b)		2.3	1.3	0.8	0.4	2.3	1.5	0.9	0.4
Unemployment rate		7.0	6.3	5.7	5.3	7.0	6.1	5.5	5.2
Current plus capital account (% of GDP)		0.4	0.1	0.2	0.2	0.4	0.6	0.6	0.9
Goods and services account (% of GDP)		1.0	-0.5	-0.7	-1.1	1.0	0.2	-0.2	-0.4
Harmonised index of consumer prices		1.2	0.9	1.2	1.3	1.2	0.8	1.2	1.3

Notes: (p) – projected, (p.p.) – percentage points. For each aggregate, this table shows the projection corresponding to the most likely value, conditional on the set of assumptions considered. (a) The demand aggregates net of imports are obtained by subtracting an estimate of the imports needed to meet each component. The import content calculations were based on 2015 data. Differences between GDP growth rate and the sum of the contributions is due to rounding effects. (b) Total employment, in number of persons, according to the national accounts concept.

Table 5 – Banco de Portugal's Projections 2018-2021 for Portugal, yearly change rate. Source: Banco de Portugal, Economic Bulletin, June (2019).

As consequence of a global commercial deceleration for 2019 the external demand for Portuguese goods and services is going to ease, however an average growth of nearly 3% is expected over the projection horizon. Globally, commercial activity is expected to grow more steadily again in 2020 and 2021.

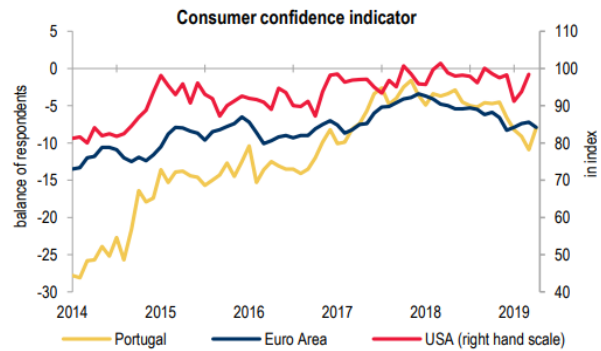
In 2018 the domestic demand contributed considerably for the economic growth and it is expected to continue playing a bigger role than exports for the evolution of the GDP. Private consumption decreased in the first quarter of this year 0,4 p.p., and Gross Fixed Capital Formation (GFCF) rose quite significantly on the same period, by 7,6 p.p. – rather influenced by construction sector, machinery and equipment manufacturers. This is reflected on the economic activity, with a rise of 0,1pp on the GDP. Regarding GFCF variation rate, the business



Graph 4– Bank of Portugal's Statistics on the Real GDP and domestic demand relation 2014-2018. Source: Banco de Portugal, June (2019).

sector is the major contributor. However, investors are concerned about the evolution of the global economy and its projected deceleration and it may condition their decisions to invest as they see a less optimistic on sight future.

Private consumption projected evolution has an underlying growth on the increase of families real disposable income. This is in part due to the increase of the minimum wage, overall raises on salaries and on the decrease of the unemployment rate. The low level of the prices also contributes to the degree of confidence of the consumers and thus to the willing to spend more money (families saving rate is 5% and in Euro Area is 13%). With the rise of inflation rate for 2020 and 2021, and the loss of the minimum wage increase effect, among others, the private consumption will slow its pace. On the projection horizon, the private consumption weight of the total GDP is expected to reach 65%, which is fairly above 53%, the Euro Area average.



Graph 5 - Bank of Portugal's Statistics on Consumer Confidence level 2014-2019. Source: Banco de Portugal, June (2019).

Regarding the exports of goods excluding fuel, automobile segment had a significant rise in exports, and the smallest segment was chemical products. Projections point out an average growth of 3,6% over the projection horizon for goods and services exports which is lower than the observed in previous years, implicitly accusing the smaller market share gains for 2020-2021 and the maturation of the economic cycle for the main commercial partners.

Imports of goods excluding energetic goods presented a high dynamism in the first quarter of 2019, and are expected to keep strong growth throughout the year, comparing to 2018. A more moderated evolution is expected for the following years of projection, with an average growth of 4,3%, getting closer to the weighted global demand. Balance of trade deficit which had a gradual recovery in previous years, accentuated in 2018 and this year's first quarter.

Joint current plus capital account will decline driven by the deterioration of the goods and services account, in particular in the goods. In 2021, the return by the European Financial Stabilization Fund of amounts paid by Portugal under the Economic and Financial Assistance Program will help stabilize the joint current and capital accounts in about 2% of the GDP.

Financing conditions should continue positive and favourable for all the economic sectors. Interest rates are in historically low levels both short and long term. These levels are fruit of the monetary policy of BCE of buying sovereign bond.

On the first quarter of the current year, unemployment rate set an historical minimum since 2003, of 6,5%. This trend is expected to continue moderately, because of job offer constraints and the maturation of the cycle, and also the increase in labour force – currently 5,2 millions, gender proportional.

Socio-cultural context

The minimum salary raise and the increase in employment has gradually improved the quality of life in the Portuguese families. Higher disposable income leaves financial breach for families and individuals to care about health and wellness, once food and housing needs are satisfied (Figure 6). According to a report from the Organization for the Economic Cooperation and Development (OECD) 60,1% of the Portuguese belong to middle class, 16,8% have low income, 12,4% are in the poor level and 10,6% have high income (Paula, 2019).



Figure 6 – Maslow’s Hierarchy of Needs. Theory about the priority of the human needs: only when lower levels of needs are fulfilled individuals can attend higher levels. Source: Author, based on Simply Psychology’s website article (2018).

The schooling rate increase (illiteracy of citizens with 15 or more years old dropped from 12% to 6,7% on the past 10 years (PORDATA, 2019)) and the access to information (3 in 4 citizens between 16 and 74 years old use internet (Ferreina, 2018)) developed the population thinking, translating into a greater interest on certain matters. Informed citizens know better their options so they take more time to consider and evaluate them, is the so called “society of information”.

The #MeToo movement³ created a domino effect unblocking barriers for women in many contexts, seeking for gender equality and breaking from the oppression of past times generations. The feminist movement is spreading, and one of the “mottos” is the

³ Social media movement, encouraging women to expose in their social media pages discriminatory situations or behaviours, sexual assault/harassment and other physical or violent actions which they experienced in first person. The posts use the hashtag #MeToo.

demystification of the taboos over the female body and to talk about it freely. This incites women to openly share their views about their personal hygiene products, creating awareness about wellbeing and thus feminine hygiene (Business Wire, 2017). “Women are keenly taking a proactive role in decisions concerning their day-to-day life such as their education, career, marriage, family planning, management of chronic conditions and elderly care” (Frost & Sullivan, 2018).

Individuals are gaining consciousness and getting interested not only on themselves and their moral beliefs but also how it affects others and the environment. In sum, they are pickier on their consumer choices. Euromonitor International released a report highlighting the 10 global consumer emerging trends for 2019 (Euromonitor International, 2019), which are the following:

1. The perception of old age has changed (“old” is a more advanced stage)
2. Authentic products, simplicity and quality over materialism
3. Ethical and conscious consumerism
4. Digital remote experiences
5. Much more informed shopper (many information sources)
6. Mental wellbeing and disconnection from technology
7. Self-sufficient, no need to consult professionals
8. Plastic-free
9. Instant gratification
10. Independent lifestyles

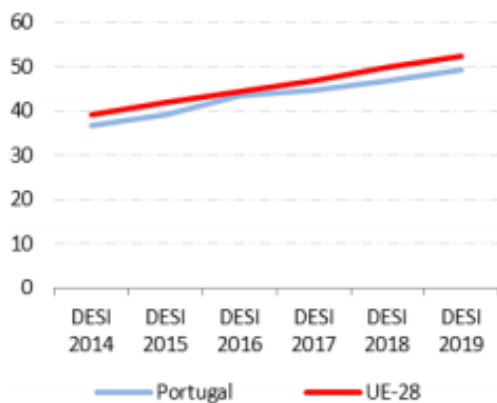
So, essentially, there is a shift towards ethic, self-sufficiency and lifestyle consumer focus.

Technological context

Digitalization, Artificial Intelligence (AI) and Internet of Things (IoT) are trends for plenty of sectors from services to goods, from industry to healthcare. Health industry companies/health facilities are changing to keep up with the speed of the technology wave and harness the benefits they can get from it: according to Global Digital Health Index “Integrating technologies such as mobile phones, tablets, remote patient monitoring devices, and sensors into health systems can save lives, extend the reach of healthcare services, and reduce healthcare costs” (Global Digital Health Index, 2018). The digital disruption goes way beyond optimizing

procedures already done; eHealth⁴ extends to the citizen in its personal daily life with gadgets or apps which allow them to self-monitor health indicators whether within the scope of fitness or medical or even just user’s personal curiosity (Vinagre, 2018). Portugal is making efforts to embrace eHealth, from communication (telemedicine lines), to web based services to citizens, decision support systems and to the Public Health System Integration, among other actions (Monteiro, et al., 2019) – however, there is still a long path to follow to transform health services in terms of quality and personalization. Tech companies are partnering with health organizations in order to cope with the demand, for example Google worked together with World Health Organization (WHO) and American Heart Association (AHA) to develop new features and user goals for Google Fit (WHO, 2019).

All the information gathered and stored represents a huge amount of data that is useful to analyse and determine patterns on a population or a single individual. Businesses take those amounts of information as precious assets to understand market trends, improve their reach, and built their strategies – this is called Big Data, the volume of records that impact on businesses operational level. Big Data allows a large amount of information from a variety of sources to be processed in high speed, and aggregates it to help mitigate risks regarding strategic moves (SAS, n.d.). One source of information is through IoT which merges information



technology with operational technology, collecting data in real time from “things” with sensors, systems, or networks (Bradicich, 2018).

Graph 6 - Digital Economy and Society Index (DESI)⁵ – evolution of Portugal through time. In an overall look, Portugal is positioned in 19th place, just below EU average. Source: European Commission DESI Country Profile Report (2019).

In a more digital era, engagement of consumers is changing: the big trend is Digital Marketing. “There is significant growth potential in the healthcare industry when it comes to digital channels of engagement. Patients are increasingly researching the Internet before they seek medical care from healthcare professionals” (Frost&Sullivan, 2018). Digital marketing brings a shift on how to reach consumers: information is no longer random and general but

⁴ eHealth definition by World Health Organization (WHO) is “eHealth is the use of information and communication technologies (ICT) for health” (WHO, n.d.).

⁵ Composite index that measures 5 indicators - connectivity, human capital, use of internet services, integration of digital technology, digital public services – of EU member states and tracks their evolution.

specific and targeted. Social networks are the most powerful channels nowadays for businesses to reach their target, and generate leads. It is such a need from companies that it even created jobs as, for instance, digital influencer – a person with many followers on social networks and that uses products/services and advertises it on their profile.

Alongside, the budget on SEO⁶ is increasing fast. Google is responsible for 94% of total organic traffic and 96% of mobile search traffic. From the smartphone users, 51% have discovered a new product/company while searching on their smartphone (HubSpot, 2019). Therefore, to include specific keywords on the content of the website or advertisement is halfway to succeed in lead generation.

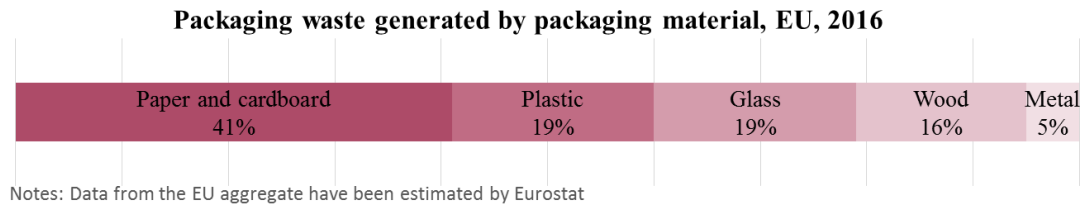
Environmental context

On a global scale the climate change situation is quite alarming once the window for the governments and population to act and carry out eco-friendly measures is very small. Portugal is one of the countries which signed the Paris Agreement and is taking measures to achieve the agreed upon results. Youth is forcing the Estate to declare environmental emergency, inspired in the School Strike for Climate movement started in Sweden by Greta Thunberg.

One of the biggest concerns after greenhouse emissions is plastic, since it takes several years to decompose and has a wide range of usage. In Portugal, only 42% (2016) of the plastic is recycled (Eurostat, 2018) – Portugal is aligned with the EU average. Subsequently it is estimated that nowadays a human ingests about 250 grams of plastic (microplastics) per year (WWF, 2019). This creates opportunities for innovative greener solutions to enter the scene; solutions that incorporate polymers and materials made from biodegradable/compostable components (like corn – bioplastics -, seaweed, mushroom, sugarcane bagasse, among others), emit less greenhouse gases in the manufacturing and create circular economy mechanisms (Greenway, 2018).

Regarding recycling of paper and cardboard, Portugal had the worst rate from the countries considered by Eurostat (EU28) of 70% versus the average of 85%; and on the recycling of glass Portugal occupies the third worst place on the same group, having a rate of recycling of 58% versus 74% (Lusa, 2018). According to Eurostat data the recycling rate of municipal waste for Portugal was 28,4% in 2017, way below the EU average of 46,4% (Eurostat, 2018). Words of order are: Reduce, Reuse and Recycle.

⁶ Search Engine Optimization. Aims to increase the visibility of a website or page through non-paid means that is organic search results.



Graph 7 – “Packaging waste generated by packaging material, 2016”, adapted from Eurostat Statistics Explained. Source: Author based on Eurostat (2019).

5.6.2. Porter’s Five Forces

The following analysis helps to assess the Femtech industry’s attractiveness and competition enhancers, in particular the health self-monitoring devices and, when possible, addressing pH self-testing kits. Industry structure is constantly changing, so the analysis comprehends the present time. The five forces will be measured from very low to very high with a numerical scale of power from 1 to 5.

- Barriers to the entry of new players

Funding is more challenging to find in Femtech industry because the potential investors don’t understand the issues that Femtech is trying to solve. However, 76% of venture capitalists consider that a **patent** influences positively their decision. **Intangible assets** like “database rights, copyright, know-how, trade secrets as well as trademarks and brand associated goodwill” (Forsyth & Muska, 2018) are perceived as well as valuable and investment appealing.

Clinical trials and approvals are a protracted process that also depend on the budget but mostly on the type of product: if it is a medical device, or an app, or a drug/supplement, a wearable, clothing, etc.

Power force: 3

- Competitive rivalry enhancers

The spectrum of technology applicability to health data monitoring is still wide enough. Nowadays the concept is still being worked in several areas, however many brands already feel the pressure to “do more”⁷ because otherwise the users lose interest – the users want to know what is happening within the body **more than just tracking** activities (Forsyth & Muska,

⁷ i.e. Fitbit, a brand of sport watches was “forced” to include more features and sensors for different vital signs monitoring; in a recent collaboration with Clue (menstrual tracking app) it now allows women to collect their health data on their wrists and cross it with menstruation tracking; Another example: in 2015 Apple launched a new version of an health app (HealthKit) and was criticized for not including menstrual cycle tracker.

2018). Given that there is a big possibility to create differentiation and this market has very unexplored branches, the power of this force for now is low: 2 – it is still a blue ocean.

Power force: 2

- **Threat of substitute products or services**

Since this market is in expansion phase with projected high growth rates, it is an attractive place to create a business, and it is starting to be noticed. With the possibility of a boom of new entrants, it is likely that some will try to respond better to the same need than an existing player. However, it is common that products that are more sophisticated to market (legal framework and clinical trials) get a patent or some protection for its intellectual property, making any copy difficult.

Online shopping presents the customer with a panoply of brands that sell cheaper products or products that are not sold in home country. This possibility of not having purchasing boundaries is a market trend also in Portugal: approximately 40% of the resident population bought something online in 2018, which is 20 p.p. below the European Union (EU-28) average (INE, 2018), motivated by the easiness and convenience allied to low cost products and promotions (Calado, 2018). Regarding pH measuring, products with the same purpose can be found at very low prices – universal pH paper strips are the cheapest. However the features and accurateness are considerably different.

Power force: 4

- **Bargaining power of suppliers**

For a small company, the easiest and fastest way to produce a product is by subcontracting the manufacturing. There are some companies that offer turn-key solutions and others that just put together the different pieces/components of the final product – assembly -. So, for small companies, the suppliers have a high bargaining power. Big companies, on the other hand, can benefit from their presence in the market, financial capability and from scale economies, and for that they can bargain with the suppliers, getting discounts, mitigating their power. The same logic follows for distributors and material suppliers.

Online selling is a market trend. It requires some IT, different logistics and new suppliers. The main suppliers will be related to:

- Landing page and website storage – highly fragmented market;
- Database SQL server - Database-as-a-Service (DBaaS) is a very competitive market;

- App Store – Google, Apple and Microsoft each have their own so they have the monopoly of app download. Unless one app is downloaded through a cloud or drive or website, but usually doing it shows safety alerts for the user, and some of those users may give a step back on proceeding to download.

Power force: 4

- Bargaining power of customers

If the client is not the end-customer and has the money, he can buy the patent – **upstream integration**. In this industry the sales volume is small comparing for instance with feminine pads, so a smaller value chain represents possibility to make higher margins.

The regular customer has **access to information** to compare the product with others on the market. Similar products (with different functions – i.e. menstrual cycle tracking) are expensive and a comparison might be made despite the lack of correctness. The customer may have plenty of choices but can't change the price directly, so the bargaining power is really small.

Force Power: 1

- Conclusions

Next there is a summary of the force's power and the industries attractiveness which is 2,2 out of 5.

Force	Power	Attractiveness
Barriers to the entry of new players	3	2
Competitive rivalry enhancers	2	3
Threat of substitute products or services	4	1
Bargaining power of suppliers	4	1
Bargaining power of customers	1	4
Average result	2,8	2,2

Table 6 – Summary table of the Porter's Five Force analysis. Source: Author

6. INTERNAL ANALYSIS

SWOT

On the following table is presented an analysis on the internal aspects of the business (left side) and an outlook on the market/external environment (right side). SWOT framework is a strategic analysis that gives a “bigger picture” viewpoint. It helps to analyse less positive points and to take advantage of market opportunities, improving and developing towards success.

Strengths	Opportunities
<ul style="list-style-type: none"> - The results are numerically precise - Reusable product - Connectivity with electronic devices like smartphone and laptop - Broader target than other pH screening tests -Disease diagnosis is less explored; Main advances are made in reproductive matters 	<ul style="list-style-type: none"> - Women don't have much time to take care of their health (so, avoiding medical consults is a plus) - 51% of the world population is women, in Portugal is almost 53% (PORDATA, 2017) - There isn't much investment/inventions in Femtech for menopausal women, so it is quite unexplored. The global menopause market was valued at almost US\$4 billion in 2014 (Forsyth & Muska, 2018) - The ethical consumerism is market trend
Weaknesses	Threats
<ul style="list-style-type: none"> - Requires electricity (batteries) - Requires maintenance – cleaning with the antiseptic solution before and after use - Most worthy on the long-term - Depends on the correct use of the user - There are plenty of patented products that have the same aim to detect vaginitis - May be too invasive for some women 	<ul style="list-style-type: none"> - Women don't have much time to take care of their health (so, adding another routine may create stress in some potential users) - Some persons are technology averse - Doctors may not approve/may discourage the use of the product - Lack of visibility and communication about Femtech applications to users and healthcare professionals (Das, 2018) - Companies that make medical claims with no clinical trial support, creating trust issues in the users (Knowles, 2019) - Vast majority of investors are men - Privacy concerns about the data collection

Table 7 – SWOT analysis. Source: Author

7. COMPETITIVE ANALYSIS

Qualified SWOT

Crossing the market Opportunities and Threats with the business's Strengths and Weaknesses previously identified on the SWOT analysis, helps to assess the main challenges, constraints, warnings and risks that the future may bring. Also, with this analysis one can possibly create solutions to face any undesirable point/ predictable outcome.

	Opportunities	Threats
	Challenges	Warnings
Strengths	<p><u>S4 vs. O3</u> – Possibility of exploring the menopausal segment, because the device doesn't consider the average normal values to give a result/indication.</p> <p><u>S2 vs. O4</u> – The device is worth it at other levels than health-related only, like: less time wasted with doctor appointment, not a short life-cycle product (is durable), made to be more cost-effective than the existing self-testing alternatives.</p>	<p><u>S3 vs. T2</u> – The device may be used without the connection, because it has a display.</p> <p><u>S5 vs. T3</u> – The product needs to be backed up with clinical tests and opinions from known doctors (on a more advanced stage).</p>
	Constraints	Risks
Weaknesses	<p><u>W2 vs. O1</u> – The sanitation of the product may not be a skipped step. The cleaning wipes that are included on the pack are formulated for the most fast and convenient use.</p>	<p><u>W2 vs. T1</u> – Incorrect use of the product or factor that drives away a potential customer.</p> <p><u>W3 vs. T4</u> – May not seem legit - people are averse to give a certain amount of money for things they don't know/ don't have information.</p>

Table 8 – Qualified SWOT Analysis, as a sequence of “Table 7 – SWOT analysis”. The capital letters S, W, O and T correspond to whether it is a Strength, Weakness, Opportunity or Threat; and the number indicates the order it shows on Table 7. Source: Author.

8. GOALS OF THE PLAN

The first point to be settled when building a strategy is to define the final objective, or small ones across the path. The definition of that objective keeps companies on track, cohesive and far from measures that diverge from the mission fulfilment aim. For this business the objectives are the following:

Qualitative:

- Promote and raise awareness for women's health and well-being;
- Raise awareness for specific care of gynaecological tract pathologies;
- Promote prevention of diseases and their treatment on early stages;
- Give women the possibility of knowing better their body and act accordingly to signs it gives;
- Prevent that women take inadequate medicine due to lack of information – promote self-knowledge.

Quantitative:

- Success rate among the users of more than 99%;
- Reach a volume of sales representing at least a market share close to 2%;
- Remunerate the shareholders;
- Pay the initial investment up to year 5;
- Internal rate of return of at least 20%;
- Achieve a minimum profit of 1,5€ for each euro invested – profitability index of 2,5 minimum.

9. DEVELOPMENT STRATEGY

9.1. Mission, Vision and Values

These will be the guidelines and moral conduct rules of the business. Success will be ultimately measured by the achievement of the vision, by practicing the mission.

Mission	To promote the health and well-being of women by using technology that allows them to detect changes on their vaginal health through pH screening and prevent them from undergoing longer and heavier treatments.
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Vision	Be the top-of-mind medical device that promotes vaginal health.
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Core Values - Accuracy, honesty, consciousness, safety.

9.2. Critical Success Factors and Competitive Advantages

Critical Success Factors

Easy to use – complexity may be dangerous if it leads to inadequate handling or use. These are practical tools, to use in a quick and convenient way, it is not supposed to be necessary much thinking during the process of self-testing. Also, costumers are attracted to simplicity in use.

Quick to use and get the results – Women buy self-testing kits to save time (and money) from medical appointments or clinical exams. A self-testing kit must be worth the trade.

Gives precise results – If the outcomes are not precise there can be a misinterpretation of the results. A product should be effective and reliable to carry out its purpose.

Small and discrete – Like most products that involve the human's body reproductive system, there is some taboo about showing/using them. So the process of using, getting the results and disposing/storing the self-testing kit should not draw unwanted attentions.

Competitive Advantages

Precision – Colorimetric tests may lack accuracy by the user. Using a numeric scale the result is exact;

Reusable – Besides ecological matters, this product allows the user to re-test how many times she needs/wants without spending more money. Ultimately, it helps the user to decifre patterns between the pH value and daily life habits.

Bluetooth incorporation – This feature is innovative, and allows a connection with the mobile phone and with the specially designed mobile app.

Broader target - Doesn't exclude women based on their life stage. By monitoring the pH the user gets to know herself and how their habits affect the vaginal pH, allowing her to calculate her personal "normal" pH level. Thus, it is possible to detect abnormal changes on that considered level.

9.3. Certification

The CE marking enables the commercialization of the product in 32 European countries, indicating that it complies with the EU regulations (Emergo, 2019). The European Medical Devices Regulation (MDR) will be updated in May 2020.

For the CE marking, first the product has to be classified as a medical device, following the rules of *Annex VIII of the REGULATION (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices* as seen on Figure 7.

Duration of use	Transient
Invasiveness	Penetrates inside the body through a body orifice
Active medical device	No. Despite depending on an electrical source of energy it doesn't cause significant changes in the patient
Measuring function	Yes. It measures a physiological parameter and the result is displayed in legal units within the meaning of the legally accepted

Figure 7 – Parameters for classification of the medical device following European Parliament and Council regulations (2017) and European Commission's Guidance Document on Medical Devices (1998). Source: Author.

According to the aforementioned Classification Rules regulation's from Annex VIII⁸ this device is classified as class I medical device with measuring function. Regarding the mobile application, the following rule applies: "3.3. Software, which drives a device or influences the use of a device, shall fall within the same class as the device" (European Parliament and Council, 2017, p. 140). The software associated (mobile app) doesn't drive or influence the use of the device – it is an extra feature to help the user to save the measurements and establish patterns.

The following stages on CE marking process are related to the technical file, which is a file where the device's technicalities and design are exhaustingly described and all the data about tests, clinical and non-clinical, is gathered – Clinical Evaluation Report (CER).

⁸ "5.1. Rule 5 - All invasive devices with respect to body orifices, other than surgically invasive devices, which are not intended for connection to an active device or which are intended for connection to a class I active device are classified as: — class I if they are intended for transient use (...)" (European Parliament and Council, 2017, p. 142)

It is then submitted and approved. With this approval, a number from European Database on Medical Devices (EUDAMED) is attributed to the medical device, is called the Single Registration Number. After this, the Declaration of Conformity must be prepared by the manufacturer, stating that the product is in compliance with the MDR and the CE marking can be affixed, from this point on. The last step is register the device on EUDAMED database as well as its Unique Device Identifier (UDI).

9.4. Testing

The designing of the product is usually attached to two lists of requisites: the company's or marketing's list - technical details about the performance and specifications that the product should have - and the client's "needs" list - usability and user's perspective and feedback -. After the first final design, comes the verification and validation phases. The verification phase gives respect to the first list and consists on testing the prototypes and the chemical requisites; the validation is related to the second list and may count with the collaboration of volunteers (user study) and the results of it should be statistically relevant.

Both verification and validation have an estimated duration of 2 to 3 months and may be outsourced. This is a process that is strongly linked to the product's design because, according to the results, changes might be needed and consequently impact on the materials used and shape of the device.

Some crucial points about this stage are:

- Product's robustness – when dropped if it breaks, cracks or opens in a way that the inside of the product is reachable, if it is waterproof, among others. It is called drop-off test;
- Use of electric energy – the risk of electrocution or starting a fire;
- Dangerous substances/materials – understand if there are no materials or substances that exceed the maximum level stated in RoHS's list (Restriction of Hazardous Substances Directive 2002/95/EC) and that are in conformity with COSHH (Control of Substances Hazardous to Health) Regulations 2002. See Annex VII – RoHS's list

To ensure the efficacy of the product, clinical evaluation tests are carried out and small clinical trials. This is very important for credibility and consumer confidence as well.

9.5. Market entry

The market entry will be simplified at the most. Ideally there is going to be one entity responsible for the design of the product and the technical validation and verification; programmers that will develop the mobile app and the company's website; designers for creation of media content and website design; another entity (manufacturer) responsible for the clinical evaluation and the production, assembly and packaging of the final product; another entity that will help with the CE certification and, if it justifies, will also give a hand with the intellectual property process; and another responsible for the logistics from when the product leaves the factory until it reaches the customer.

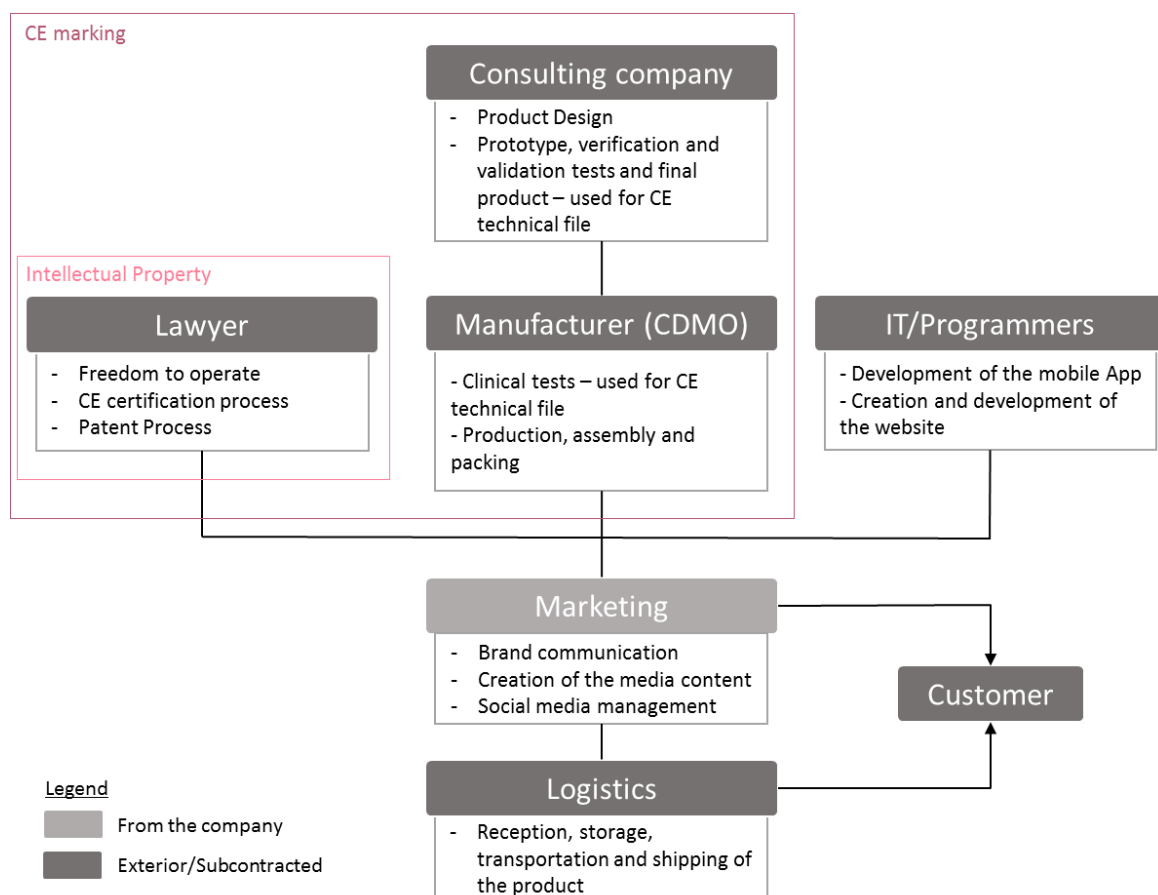


Figure 8 - Business organization framework: entities involved from design to first sale. Source: Author.

The first step will be to validate the information and concept/principle of the product with experts of gynaecological infections and biomedical engineers, and to confirm the freedom to operate with a lawyer's office. After this, the development of the device and the app can begin and since they have independent designs and development stages their development can also be independent. The process of validation and verification of the product will start 1,5 months (6 weeks) after, once it is the estimated period for conclusion of the first prototype of the device. This process will test the prototype, and this often requires adjustments on the

design. For that reason, the period concerning the design of the product is extended until the very end of the tests.

The negotiations with the manufacturers will start right after. The manufacturers chosen have the means to do the clinical evaluation, and it is part of the plan to negotiate that. In the meantime, the process to get the CE marking will begin, with an estimated duration of 9 months, in which all the information regarding further tests and evaluations made will be gathered and submitted. Only after the approval the product can be marketed.

Lastly, the media content creation and the development of the website and social media pages, just before the market release, on November of 2021. The chronogram is in Annex VIII – Business plan chronogram.

To have intellectual property protection will not be a priority until it is really viable to market it, and that is why it is only considered after CE approval. However, a provisional patent will be requested, because it is not very expensive and gives some protection for 1 year (which is expected to end when the CE marking is approved). Until then, non-disclosure agreements and confidentiality contracts will be used for that purpose.

9.6. Strategy definition

The sales strategy is to introduce the product online and disseminate it through social media platforms. On a first phase, the communication will aim to attract potential Portuguese costumers, mostly. This is a product with a certain risk, and the idea is that Portugal works like a “trial”, to assess how the public responds to it and have some users’ feedback. European market follows, with a more international communication strategy.

There are no products of this type, and the market study made shows that the target customers have predisposition for it. According to Porter’s competitive strategies model (1985), the competitive advantage that better suits the project is differentiation, while aiming for a narrow target. This combination results in a differentiation focus strategy – this means that it seeks to fulfil a specific segment with particular needs through a differentiated and unique product offer.

10. DEFINITION OF IMPLEMENTATION POLICIES

10.1. Segmentation, Target and Positioning

Having in consideration the characteristics of the device, as well as some statistics, it is possible to delineate a target group through the following **segmentation criterion**:

- Demographic: women in child-bearing age and beyond;
- Social: middle to upper class (with basic needs satisfied); best if they have a mobile phone;
- Physiological: more prone to contract/develop gynaecological infections; who want to prevent the development of vaginal infections;
- Behavioural: Care about personal health and well-being; responsible.

So, the **target** is defined as women more susceptible to develop vaginitis and that want an affordable indicator that allows them to easily know when they have an infection without the need of a medical consult and in order to treat it as soon as possible. The only direct competitor in Portugal is Canestest®, so the **positioning** will have that product as a starting point reference.

Identification: Portable vaginal pH probe with digital connection to a mobile app, which allows women to regularly monitor and keep record of their pH value, using it as a health indicator of the gynaecological tract.

Specialized market product – niche and well-differentiated: The product follows a specialization strategy since it serves a market niche and the perspective of evolution of the product doesn't cross over other segments. The objective is to monitor the pH, so it doesn't exclude menopausal neither pregnant woman, like most products.

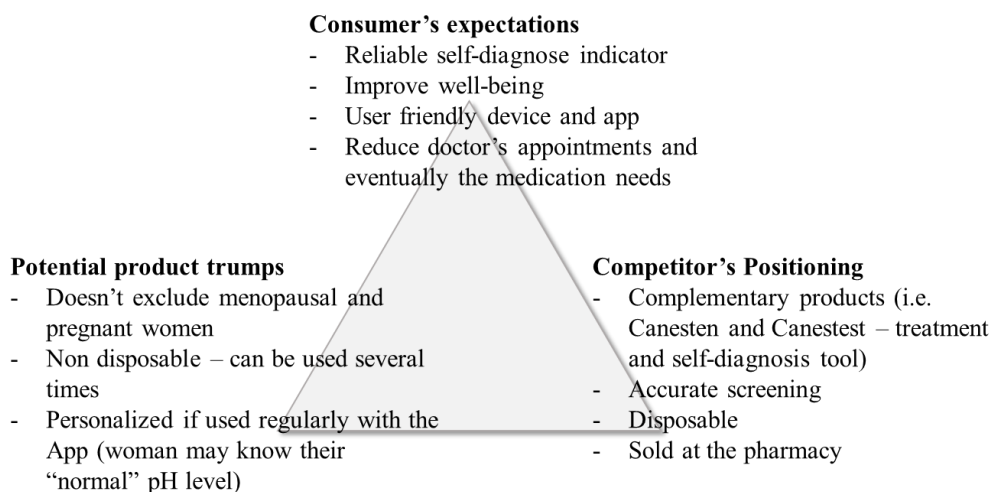


Figure 9 – Positioning gold triangle. Source: Author

10.2. Marketing mix

It is cautious to first look to what already exists in the market. There are pH measuring devices that are used for liquid solutions and for solids like food (meat and cheese, for instance) or biologic tissue (skin and scalp) (Consult Annex IX – Existing pH meters). The product that is object of this thesis will follow the same aesthetic. The pack's details on design, components, price, communication and selling channels will be explained on this chapter.

10.2.1. Product

Pack and components characteristics

The product itself is sold as a “pack” including: device, cleaning wipes for disinfection and maintenance, and solutions for calibration of the device.



Figure 10 - Pack composition: device, cleaning wipes and buffer solutions, under the suggested name of VagiPro (not on scale). Source: Beatriz Janes, for this project.

Device: It is the core of the pack. It will be responsible for assessing the vaginal pH when inserted in the vaginal canal and displaying the value for information of the user. The device can be divided in two parts: the “head” and the probe. The conductor (as may be seen on Figure 11) is the part that needs to be in touch with the vaginal canal and mucous – it is the key to electrically measure hydrogen ions concentration because of its conductivity. After measuring, the information will be processed and displayed on the device and on the mobile app.

App: Mobile application which will be available for download on the application stores of the main operating systems (Android, iOS and Windows). It will allow the user to keep record of the data collected by the device as well as other data inserted by the user and that can help to establish a correlation between the pH floating levels and the user's behaviour.

First thing after downloading the mobile app the user will be asked to introduce a code that was previously sent to the e-mail address introduced on the purchasing act. This code “unblocks” the app and the user can start introducing its personal data. Data that will be used and stored is:

- Name or nickname – for personalized messages on the app and personalization of the frontend;
- Stage of life and age– pregnant, menopause, pre-menopause;
- Daily factors that may change pH like menstruation, sexual activity, drug prescriptions, stress, mood, hygiene and general health. The user may keep track of that in order to get a bigger picture of factors that influence their vaginal state and health (optional but recommended feature);
- pH level – automatically displays on the app after measuring, it will be stored with the calendar date and time of the mobile;
- E-mail address – The user’s data will be associated with their e-mail address mostly for data recovery in case the user changes/losts its mobile phone or the device gets broken.

Cleaning wipes: For easy and convenient cleaning and sterilisation of the device a pack of specially formulated cleaning wipes will be endorsed to the product pack. The wipes will be soaked in an antiseptic solution with electrolytes designed for the pH sensor care.

Another characteristic of the cleaning wipes will be the disintegration in water, meaning that the wipes are flushable – this is not only convenient but also comfortable for the user because of the discretion of not having to throw away any garbage after use. The aim is that the wipe by itself is biodegradable and the eventual remains of it can be cleaned at the wastewater treatment plants and the water can be purified. In sum, the disposal of this wipes must not harm the environment.

Calibration solutions: Before a probe is used for the first time it needs calibration in order to assure correct measuring. For that purpose, two small bottles with pH buffer solutions will be included in the pack to allow a two-point calibration (bracketing). The standard pH buffer solutions in the market have values of 4,01; 7,01 and 10,01; and it is advisable that the calibration is done with pH values close to the ones of the sample (RS Calibration Services, 2017). So, the buffer solutions to be included in the pack will have an acidity of 4 and 7.

Brand	Volume	pH 4,01	pH 7,01	Source
Hanna	500mL	26€+VAT	26€+VAT	Hanna Catalog
Hach	500mL	31,60€	31,60€	Hach Catalog
VDL	300mL	4,50€	4,50€	eBay
Water Master	250mL	6,00€	6,00€	“A loja da maria” online store

Table 9 – Brief benchmark of existing buffer solutions. Sources: Hanna Instruments (2019), Hach (2019), eBay (2019) and “a loja da maria” (2019).

Design

Main concerns over the design of the device are the weight, size and usability, besides the technical requisites. It is crucial that the device is inserted in the vaginal canal effortlessly – slim arm – and that the tip is in contact with the vaginal wall without trouble. The tip should be made of a conductive material so that the pH is easily assessed. The intention is that the product has a clean and simple/uncomplicated appeal but also that is small (portable). Keeping the battery out from the part that will be inserted is also something to have in consideration.

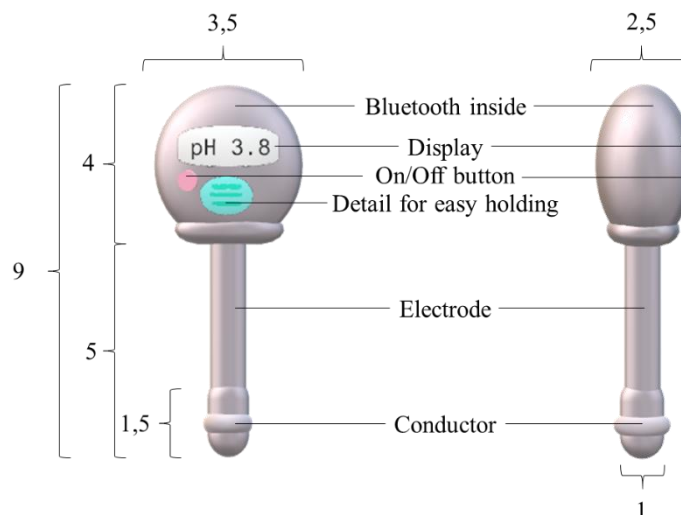


Figure 11 – Front and right side elevation of the device (units are in centimetres). Source: Author

The portability is defined by two aspects: size and weight. For the weight, it is anchored to the materials nature; for the size, it is a matter of shape and dimension of the electronic components. Detailing the size: the electrode has to be slim in order to be easily inserted; the tip should be a bit wider to facilitate the contact with the vaginal wall; the length of the electrode plus the tip should be a little less than the index finger average length (the cervical height is often measured using the index finger’s phalanges); the “head” of the device should contain all the mechanical components inside as well as a battery, and the display has to present the measurement result legibly.

The wipes will be sold on a pack similar to makeup remover wipes. Closed hermetically after each use in order to keep the moist and properties of the solution in which they are soaked. Both pH buffer solutions should be labelled in harmony with the image of the pack.

Materials

Materials used must be safe, effective and function properly while meeting specific requirements like: resistance to sterilization and chemicals that may come across, compatibility with body fluids, skin and tissues (Sastri, 2014, pp. 33-54), in the short and long term. Other considerations to be taken into account are the storage conditions, processing and transport, and how they may affect the materials chosen, and, finally, regulatory requirements (Smithers Rapra, 2017). The product must be waterproof (not immersion or jet proof) and have a classification in accordance with International Protection Rating (IP) Code which classifies the degree of protection the device offers against certain external factors (DSM&T, 2018).

The probes are usually made of glass because of its conductivity. However, glass may not pass the drop-off test, so it is safer to use plastic on the arm of the device and invest on a metal component or mixed material for better conductivity on the tip.

By using a material that has already been tested and that is commonly used makes the safety assessment easier to pass. For that, and the fact that “over 75% of all plastics used in medical device applications use commodity thermoplastics” (Sastri, 2014, pp. 73-120) the device will be made using this type of plastics. Thermoplastics are plastics that become soft and moldable when heated at a certain high temperature and harden again when cooled, see examples in Annex XI

The choice of the specific type of plastic (or plastics) will be at the responsibility of the consulting company responsible for the design of the product.

Package

The pack's package will have inside the device, the two bottles of buffer solution, a pack of the special cleaning wipes plus a bag to store the device away from bacteria and dirt and informative paper documents.

There is some info/symbols that should be displayed on the outside of the pack's package, like the type of material, the recycling info, the distributor, the manufacturer, the CE marking, UDI, the responsible entity in EU, the minimum suitable age and the conditions for storage, besides the info on what is included in the pack.

Package leaflet

Will be provided information and illustrations/photographs regarding the use of the device: calibration, handling and utilization, cleaning and maintenance of the device, storing

conditions, disposal instructions and emergency contact numbers in case of poisoning or other accident caused by the device. These instructions will be in Portuguese and English.

A small vaginitis awareness guide will also be included. Examples of the kind of topics to be included on the guide: Information about the correlation between the vaginal pH level and the occurrence of vaginitis; tips about what to do in case of abnormal pH level and how to prevent it in some cases; advices about healthy eating habits to keep a healthy vaginal flora, for instance: take probiotics, consumption of healthy fats and exempt sugar (HARTMANN, 2018); Tips about daily habits, for instance to use mainly cotton underwear, to avoid intimate sprays, vaginal washes and give preference to pH neutral gels for the intimate area hygiene (HARTMANN, 2018).

The App will also have a chapter reserved on the brochure explaining its functionalities and how to connect it.

The package, the leaflet and the guide will be made of paper sources. Whenever is possible, all the cardboard and paper should come from recycled sources – further details on the type of material should be assessed by the consulting company responsible for the design.

10.2.2. Price

If the price follows the benchmark of Femtech devices, it can go up to as much as 300€ (Table 10). It is a concern for the author that it is affordable but also that the consumer doesn't perceive it as low-quality product. One of the world's top market player has margins of 40% to 60% on their digital devices, selling over 5 million worldwide. So, the criteria chosen for establishing the price is the company's costs but attending to the top players' strategy on margin.

Product	Price
Gyno-Canestest	9,34€-12,99€
Clearblue Digital Ovulation Test	21,22€- 34,70€
Ava	299 €
Elvie Trainer	199 €
Daysy	299 €

Table 10 – Price benchmark of the type of Femtech devices considered similar to the pH monitor device, mentioned in 5.4 - Competition and top players. Source: Author.

Resuming, the main criteria for the price are:

- Affordable, less than half of Ava's, Elvie's and Daysy's devices price;
- Worth the purchase when comparing to Gyno-Canestest, it would compensate the money spent after a certain number of uses.
- Average margin of the mentioned top player, 50%.
- **This results in a price of 84,52€+VAT, which resumes a total of 103,96€, per pack.**

The product will be taxed with a VAT rate of 23%. According to Decree-Law 102/2008 of the Portuguese VAT Code (2008), this type of medical device is not covered by the reduced tax and a normal 23% VAT rate should be applied. In the case of exports, following the EU VAT Directive on VAT compliance, the tax rate to be applied will be the Portuguese (origin of the goods) unless “the supplier’s annual sales are above the threshold applied by the customer's Member State” (European Commission, 2018). The threshold limit values can be consulted in Annex XIII – Threshold limit to the application of VAT of the origin country in Intra-Community sales.

Regarding the externalized production (outside Portugal) the VAT rate to be applied is the one of buyer, in this case, Portugal's (European Commission, 2018).

10.2.3. Place

The company will have its headquarters address at Labs Lisboa. A virtual incubation service will be subscribed until the beginning of the media content creation. After that, a small space for 2 persons will be rented (approximately 4m²).

	Type of space	Price/month	What is included
Until launching	Virtual incubation	25€	- Information and mail centralization - Attendance to Labs Lisboa events
		40€	- All the above - Use of the Lab meeting room (with wi-fi) up to 4 hours/month
After launching	Physical incubation	10€/m ²	- Information and mail centralization - Common rooms (meeting rooms, small kitchen, training rooms) - 24-hour availability - WC - Air conditioning - Internet - Workshops and mentoring programs

Table 11 – Incubation at Labs Lisboa – prices and services. Source: Labs Lisboa (2019)

The channel for sales will be online. On the company’s website the internet user will have information about the product and the possibility to buy it as well as blog-like content on relevant topics related with gynaecological infections. Despite the focus of the marketing being on the Portuguese costumer, and once the website information is accessible worldwide, there can be potential sales from outside of the Portuguese border. So the pack will be available to a broader target and allow purchases from foreign countries’ costumers. The website will be available in Portuguese and English.

	Cost
Website + E-mail address domain	9,00€ /month
Online store	16,00€/ month
Website storage	2,07€/month

Table 12 – Components of the website and respective price. The prices are in accordance with the pricing table of Dominios S.A. (2019).

10.2.4. Promotion

To inform the market that the product exists, how it works, its features and the benefits of having it; to show the welfares of prevention and lighter medical prescriptions; and to reach the targeted public as well as possible investors and influencers, requires a strong and efficient communication strategy.

It will be used a *pull* promotion strategy, by trying to reach and engage the costumer. The methods that will be used are advertising, sponsorship and sales promotions. Since this product is in an introductory stage of its lifecycle, the promotional campaigns must be more aggressive and mostly informative – about the product, its characteristics and benefits.

Communication Axis: the aim will be to promote above all the quality of life, the well-being based on a smart and rational solution. Transmit the idea that this product will simplify certain aspects of life that are often unspoken topics and that women don’t give top priority attention; that this is not just a “pretty” female product, but a smart purchase, rational and an investment on health; that there is an easy answer for the (sometimes) frequent question that drives women to make a gynaecology appointment; the idea of technology made thinking about women, at the tip of the finger.

Communication Message: the main message will be not to neglect the signs of the body, and use them instead, write them down and track them in favour of quality of living and wellness. This will be the conductor line between the product and the mission of the company.

Communication Goals:

- Reach the maximum number of potential customers;
- Show the product, its purpose and characteristics;
- Clearly state the benefits of measuring the vaginal pH;
- Generate leads and engage potential customers;
- Create awareness for the importance of gynaecological symptoms;
- Show that vaginal pH measuring can be more ecological, without disposable products.

Communication channels are divided in *above the line* and *below the line* according to the means used – digital or not. The starting marketing strategy will be to take advantage of the use of social networks and mass media means: present the product and create brand awareness. At a more mature stage, brochures will be distributed in health-related establishments.

***Above the line* promotion:**

- Social media pages – creation of an Instagram account and a Facebook page that will have periodically scheduled posts promoting the product, the mission that the company aims to achieve and other interesting contents. This will be the biggest channel for reaching potential customers, because of its mass dissemination and low costs.

- Dynamic posts on the website – besides being the sales platform, the website will work as a blog, with interesting informative or interactive posts and news. An important point is to have a SEO (Search Engine Optimization) strategy, so that the website can “climb” on search engine pages. The online shopping conversion rate for “Medical” category is 10%, for “Health and Beauty” is 10% as well (Much Needed, 2018)

- Google Ads – Create small ads that will appear on internet users’ pages according to their searches, and that will forward them to the brand’s website, if they click on it.

- Advertising on periodic journals and/or magazines – press publications that are related to the target public or from the gynaecological/health professional field. This channels have a specific and frequent target so, whether it is a sponsored article or just a visual commercial ad, the journals/magazines must be chosen with some criteria.

***Below the line* promotion:**

- Representation in fairs and events – opportunities to establish direct contact with the potential customers (clients and users) and to keep up to date with the innovation on the field. Examples of events of interest: Portugal eHealth Summit, Digital Health Summit in Las Vegas, Med-Tech Innovation Expo in Birmingham.

- Distribution of brochures on health-related establishments – on a later stage, in which the product will have a solid base, with more certifications, and a broader list of active users with positive feedback, the following step is to turn the product into a recommendation of the doctor. So, there should be information about the device on the health units, mostly the ones with gynaecological unit.

Communication platform	Budget
Google Ads	50€-200€ (month)
Sponsored post on Instagram	30€-100€ (month)
Press publication	Up to 4 000€ (year)
Budget for fairs and events	Up to 500€ (year)

Table 13 – Budget for communication. The Press publication budget is based on “Activa” (Portuguese magazine) advertising rates (IMPRESA, 2017) and “Expresso” advertising rates (IMPRESA, 2019). Source: Author.

10.3. Intellectual property protection

For protection of the design of the product, a legal shield will be needed most probably. This protection can begin closer to the end of the market launch time line if the communication about the product is restricted and confidentiality/non-disclosure agreements are used whenever having a meeting with someone new. The patentability of the device’s design will only be certain after the *Freedom to operate* request, but for the business plan a utility model will be considered necessary as well as a provisional patent application.

	Provisional patent	Patent	Utility model
Protection period	1 year	20 years	10 years
Cost of application in paper (national)	21,33€	213,21€	213,21€
Cost of application online (national)	10,67€	106,61€	106,61€
Conversion to patent	149,23€		
Maintenance cost (Annual)		(Online and paper) Progressive 5 th year - 52,57€ 20 th year - 735,95€	(Online/paper) Progressive 5 th year – 31,99€/ 47,97€ 10 th year – 37,30€/ 53,30€
Maintenance cost (Accumulated - considering the total protection period)		6 860,10€	207,87€/ 303,81€

Table 14 – Base costs for provisional patent, patent and utility model application in Portugal. Source: Author based on Justiça-GOV.PT (2019).

	Price
European Search (Freedom to Operate)	1 300€
Transmittal Fee (online filling)	10,77€
International request of the utility model (online)	53,81€

Table 15 – Base costs for European industrial property protection. Source: Author based on European Patent Office online page (2019) and the Portuguese Statement of Rectification No. 32/2019 (Diário da República, 2019).

10.4. Production process

Manufacturing

To take advantage of the know-how of companies and professional teams that are in the manufacturing and molds business for decades the production will be carried out by a Contract Development and Manufacturing Organization (CDMO). This way the industrialization is faster once they already have the means and structures to create turn-key solutions; and risks associated with the development of the manufacturing process are mitigated because of the specialized staff and years of knowledge. *A-priori* this might be a very expensive choice, however it is a solution that will work with high certainty. It saves time and money from failed attempts of getting the product, or the materials, or the molds in the pretended and correct way; plus they aggregate up to 4 other way needed suppliers (tests, materials, assembly, packing), making the value-chain much smaller and easier to control.

Requisites for choosing the manufacturer:

- Quality management system in accordance with the EU law specified in *Annex IX of the REGULATION (EU) 2017/745*, conformity evaluation procedure;
- Makes the tests required for the technical file needed for the CE marking process;
- One-stop shop solutions: responsible for producing, assembling, packing and labelling.

Three possible manufacturers would be Stevanato Group (Italian multinational), Gerresheimer AG (German multinational), Gemü (Switzerland), they all meet the required characteristics. Given the size of these companies, and the variables that make the price for their service change, it is not easy to assess the true costs of contracting them as suppliers. For costs clearance, a gross margin of 50% will be assumed for the supplier for the base scenario.

Consulting company

For the design of the product the priority will be to choose a Portuguese company with skills for a project of this kind. Some possibilities are: Almadesign (Lisbon), Pharmadvance (Coimbra) or BlueScience (Lisbon). This service of product design plus some non-clinical tests (technical verification and validation) will take 4 to 6 months and the cost may reach 50 000€ - this value includes the prototype mold which have a cost of 20 000€ to 30 000€.

Note: The prototype mold might be used for the production stage afterwards if the production has low-volume. Prototype molds usually have fewer cavities (only few pieces are injected) than the production molds (which can be 10 times more expensive) and last for an average of 10 000 injections. However these are highly recommended for shortening and

optimizing the design and build phases of a medical device because they allow engineers and designers to correct any issues (Lomax, 2012).

Development of the App

Two IT technicians will be hired to create and develop the mobile application and website. It is estimated a development period of 6 months, with a 500€/month wage. On the long-term, for updates on the app and the website, a bank of hours will be negotiated, for the equivalent of 3 months per year, and with a remuneration of 250€/month.

IT team	Development	Updates/New features
Period of time	6 months	3 months/year
Remuneration policy (month)	500€	250€

Table 16 – IT Team remuneration and expected workload. Source: Author.

In order to have the App available in each app store, it must be uploaded using a Developer Account subscription. Uploading has no cost.

	Android	iOS	Windows
Developer Account registration	25€ one time	99€ per year	75€ one time

Table 17 – Cost of the Developer Account registration in each operating system. Sources: Play Console Help (2019), Apple Developer (2019) and Microsoft Windows Dev Center (2018).

For storing all the data, there are many data base options on the market. The parameters to have in account are: availability, support, backup/disaster recovery, amount of data stored in Gigabyte, connectivity speed in Mbps and type of programming accepted. It was decided that FireBase (from Google) will be subscribed. It works as a Data Base as a Service (DBaaS) and the storage needs can be adjusted throughout time. To start, the Spark Plan will be subscribed – it is free and offers enough conditions; when needed the plan will be updated to Blaze Plan which has pay-per-use conditions (for the financial evaluation, the plan with the biggest/longest range will be considered after Year 0 – Flame Plan).

Shipping

There are 3 major logistic needs after the product is ready on the manufacturer: transport to the warehouse, stock maintenance, expedition to the costumer. The stock will be kept at one point only. Ideally, the pack should be delivered to the customer within a week.

A shipping platform service will be used with the intention of benefitting from better deals on the shipment rates they have negotiated and taking advantage of already existing routes of distribution. The platform chosen is Shiptimize, which is Portuguese. When using a shipping

platform there is no need to have contracts with any carrier, which gives more freedom and flexibility to change.

The transport from the factory to the warehouse will be made by other operator, Merkur, which offers better conditions, and also offers the storage and handling service. All the costs are detailed further on Table 26 – Estimation of the costs of shipment, storage, handling and distribution, for this specific product – Logistics.

10.5. Organizational structure

The company’s organizational structure will be simple, because the majority of the processes will be externalized. There will be a manager that will coordinate the activities and be the top contact of the company; two IT programmers, which are external hiring and will give technical support for the app and website; one media content designer, for the creation of fresh and appealing custom images and advertising for social media and website, also called as marketing or marketing department.

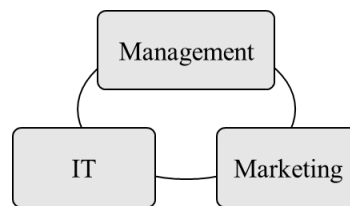


Figure 12 - Organizational chart. Source: Author.

As shown in Figure 12, all the areas are connected and communicate. Despite the more strategic level of the manager, at the operational level it is expected that the employees also promote and care for the business – ownership culture. Giving freedom to each area to create and develop new ideas enables management to focus on strategic points, while promoting an environment of trust.

Area	Management	Marketing	IT
Employees	1	1	2
Main functions	- customer support - stakeholder management	- brand’s communication - marketing promotion - social media management	- app maintenance - website maintenance - development of new features for the app/website
Remuneration policy (month)	900€	700€	Year 0: 500€ Long-term: 250€

Table 18 – Remuneration policy and main functions of employees, including external hiring (IT). Source: Author.

11. REQUIREMENTS FOR IMPLEMENTATION

On this chapter will be presented the “skeleton” of the implementation and the company’s activities in order to do so: constitution of the company, development of the product up to the market launch (activities and needed processes) and the value chain of the operating company.

Constitution of the company

The company will be private limited liability company, this way the owner’s personal property is safe disregarding the company’s activity and results and he has full control over the business.

Firm	pHmonitor, Limited
Legal nature of the company	Private limited company
Minimum share equity	5 000€
CAE number	46690 - Wholesale of other machinery and equipment

Table 19 – Requirements for constitution of the company. The name is just a suggestion, no database was searched to see if it already exists or not. Sources: INE (2007), and author.

Activities and duration

The following board includes the summarized process of developing and marketing the product. All the value chain was carefully prepared to be the safest way to launch the product, not the cheapest, but the one with less chances of setbacks and maximum quality possible. So, the estimated duration of the activities described next doesn’t count on delays. This table gave origin to a Gantt diagram, which can be consulted in Annex VIII – Business plan chronogram.

Activity	Estimated duration
Technical evidence validation	3 months
Design of the Product + verification	1,5 + 6 months
Development of the App	6 months
Product validation and verification	3+3 months
Negotiations with the manufacturers and distributors	11 months
Clinical Evaluation/Studies (ISO 14155)	3 months
CE Marking	9 months
Appoint a person responsible for regulatory compliance	1 day
Determine classification of the device	
Implement QMS (quality management system)	
Prepare CE technical file with CER according to Annex II	
Appoint an Authorised Representative in EU (EC REP)	
Obtain a Single Registration Number from EUDAMED	
Prepare Declaration of Conformity	
Register de device and its UDI in the EUDAMED database	
Keep updating the clinical evaluation	

(continues)

(continuation)

Activity	Estimated duration
Intellectual Property	10 months
Freedom to operate	2 days
Provisional Patent request (1y)	1 month
Utility Model Request (10y)	9 months
Delivery of the formal request	1 day
Formal exam	1 week
Request's publishing on the Industrial Property Bulletin	6 months
Deadline for interested parties to oppose	2 months
Invention examining (optional)	1 week
Decision	1 week
Creation of the media content	1,5 months
Market launch	

Table 20 – Summarized process of developing and marketing the product - Activities and duration. Source: Author.

Value chain

It was defined that the manufacturing will be externalized, allowing the focus to be shifted towards the other activities such as innovation, market surveillance, customer support, contacts with potential clients and other administrative tasks. When the product is fully ready to sell, it will be transported to a warehouse, until it is purchased and shipped to the customer. Transport, storage and distribution of the finished product will also be outsourced. The sale “happens” on the website and is processed afterwards. The customer will be able to write reviews on the website or send a message to the company through that platform – this is part of the post-market surveillance as well. On Figure 13 only the main information fluxes are represented.

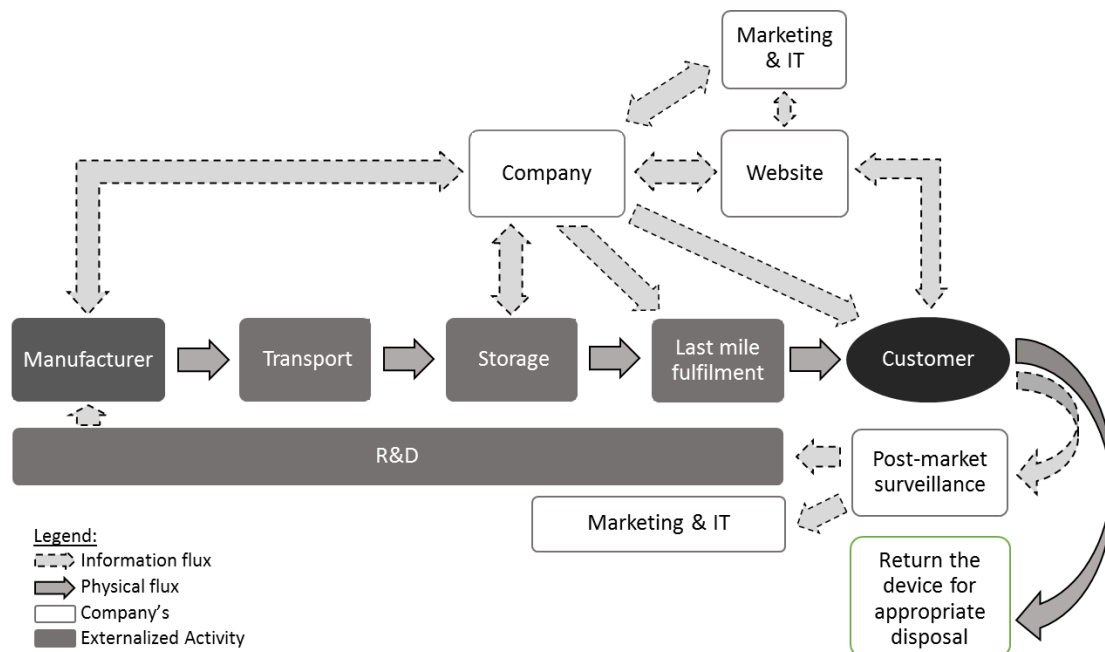


Figure 13 – Value chain from the manufacturer to the final consumer. Note: marketing and IT are repeated for design purposes only. Source: Author.

The return of the device for appropriate disposal/recycling is something that will be taken into consideration for environmental reasons, given the durable and non-degradable materials likely to be used in the device components. According to the European Law, producers of medical devices that “are expected to be infective prior to end of life” (European Parliament and Council, 2012) are excluded from financing the waste management. However, if the product is effectively sterilised it might be recyclable, obtaining secondary raw material with economic value. This step will be explored after gauging the materials to be used.

12. ECONOMIC AND FINANCIAL EVALUATION

For all the tables shown in this chapter, is important to mention that every value highlighted with light orange colour is an assumption.

12.1. Main assumptions

- The project's temporal horizon is 8 years total, because at year 7 it is when the effects of the reinvestment on molds are felt. This way is possible to evaluate the performance of the company facing a big cost like the molds. Besides, the company only starts the sales at the end of year 1, so 5 years in total would be considered a short period of time to evaluate the feasibility of the project and achieve the projected goals.
- Assumed a growth of 7,81% (g rate) after the end of the projected horizon, the same as the calculated market average growth rate.

12.1.1. Sales

- The criteria to calculate the **obtainable market** was: female gender population, in active age (between 15 and 64 years old, employed or unemployed), that belong to the middle and upper class with recurrent vaginitis and that would buy the product (according to the market survey conducted). A last indicator was added, the conversion rate at online shopping businesses for medical sector (10%). The criterion used to forecast the obtainable market was the same for Europe and Portugal, however they are separated for strategic and logistics purpose. Regards on this segmentation:

- Total **population** remains the same over the projection horizon, even though the Portuguese population is expected to decrease; the same was considered for the active age population. This population was then filtered by social class (middle and upper)
- The **recurrent vaginitis percentage** was generated considering the candidiasis literature review - 5% of women have recurrent candidiasis, from the 50% that have it more than once in a lifetime, from the 75% of the population that will have it at some stage of life. This represents nearly 2% of the total population of the female gender. Which is a small number because, like mentioned, only considers recurrent candidiasis.
- For the calculation of the 5th segmentation criterion was considered the group of the market survey participants who answered about the recurrence of vaginitis "have about 2 or 3 times a year" and "at least 4", that rated the importance of measuring the vaginal pH (3 and 4 on the 1-4 scale) and that would prefer to buy the medical device (when

compared to the other available choices) is 59,4%, and that is considered the **obtainable market** (discriminated on Annex XIV – Calculations for the obtainable market value).

	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
EU except PT								
Female gender population	256.192.909	256.192.909	256.192.909	256.192.909	256.192.909	256.192.909	256.192.909	256.192.909
In active age	111.506.600	111.506.600	111.506.600	111.506.600	111.506.600	111.506.600	111.506.600	111.506.600
Middle and upper class	86.417.615	86.417.615	86.417.615	86.417.615	86.417.615	86.417.615	86.417.615	86.417.615
Recurrent vaginitis	1.620.330	1.620.330	1.620.330	1.620.330	1.620.330	1.620.330	1.620.330	1.620.330
Obtainable market	962.476	962.476	962.476	962.476	962.476	962.476	962.476	962.476
Conversion rate	96.248	96.248	96.248	96.248	96.248	96.248	96.248	96.248
PT								
Female gender population	5.423.800	5.423.800	5.423.800	5.423.800	5.423.800	5.423.800	5.423.800	5.423.800
In active age	2.572.100	2.572.100	2.572.100	2.572.100	2.572.100	2.572.100	2.572.100	2.572.100
Middle and upper class	1.818.475	1.818.475	1.818.475	1.818.475	1.818.475	1.818.475	1.818.475	1.818.475
Recurrent vaginitis	34.096	34.096	34.096	34.096	34.096	34.096	34.096	34.096
Obtainable market	24.106	24.106	24.106	24.106	24.106	24.106	24.106	24.106
Conversion rate	2.411	2.411	2.411	2.411	2.411	2.411	2.411	2.411

Table 21 – Segmentation of the market, in Portugal and rest of Europe. Source: Author.

- On the **first year of sales a market share** of 3% was assumed in Portugal, and the first year of sales in Europe the market share was delimited at 0,5%, given the dimension of the potential costumers and the project's strategy of dissemination in the rest of Europe.

- For the following years, a growth rate of two and three times the market growth rate are assumed for Portugal and the rest of Europe, respectively.

- Another important note considers the date of the product launching in Portugal: before Christmas (see Annex VIII – Business plan chronogram), which is a consumerism season. For that reason, the number of sales is relatively high for a product in the beginning of its life, and that has been sold solely for 1,5 months. So, on the second year the sales are six times higher than the first year volume in number, and on top of that is added the growth rate (two times the market).

- First year of sales on the rest of Europe is not expected to be on "full mode", so the sales of the 2nd year will double the forecast of the 1st year plus the constant market growth.

Sales Plan								
	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Sales in Europe	-	-	481	1 188	1 467	1 810	2 235	2 759
Sales in Portugal		72	502	580	671	776	897	1 037
Total sales		72	983	1 768	2 137	2 586	3 132	3 796
Total market share		0,1%	1,0%	1,8%	2,2%	2,6%	3,2%	3,8%
Growth			1259%	80%	21%	21%	21%	21%
Share in EU		0,0%	0,5%	1,2%	1,5%	1,9%	2,3%	2,9%
Share in PT		3,0%	20,8%	24,1%	27,8%	32,2%	37,2%	43,0%
Growth in EU				146,9%	23,4%	23,4%	23,4%	23,4%
Growth in PT			593,8%	15,6%	15,6%	15,6%	15,6%	15,6%
Unit Cost		42	42	42	42	42	42	42
Logistics Unitary cost (average)		13	18	20	20	20	21	21
Unit Price		85	85	85	85	85	85	85
Sales in Volume		6 112	83 082	149 455	180 660	218 581	264 700	320 830
Inflow from sales (Sales volume+Distribution)		7 088	101 147	185 130	224 083	271 474	329 170	399 464
Production costs of sold products		3 056	41 541	74 728	90 330	109 291	132 350	160 415
Distribution costs		975	18 066	35 675	43 423	52 892	64 470	78 634

Table 22 – Sales plan. Source: Author.

- For the **market growth rate**, seven relevant market growth rates were taken into account, some are real market data and other are forecasts, resulting in a value for the average market CAGR of 7,81%.

7,81%	Average market CAGR
4,20%	Women's Health Market CAGR 2026
6,00%	National demand for women's health care 2020 (US)
11,80%	Global Digital Healthcare Market (2018-23)
5,70%	Global Feminine Hygiene Products Market (2018-26)
4,30%	Medtech in Europe (2008-2018)
6,70%	Retail sale of pharmaceutical, medical, hygiene and cosmetic products in Portugal (2016-2017)
16,00%	How fast the healthcare ecommerce market is growing annually (2018)

Table 23 – Sales Growth Rate calculation. This table shows the rates considered to calculate the CAGR of the market (since no rate was found that suited the project), which is considered to calculate the sales growth and is also considered to be the growth rate g, used to calculate the continuity of the project. Source: Author.

12.1.2. Price and development of the product

- The **production, assembly and packing costs** were calculated has a proportion of the market share. One of the biggest top player's has 47% of the European market and a production cost for digital devices from 1,50\$ to 2,10\$, for a production of 5 million devices (worldwide). A 2% market share was taken into consideration for the company, which is 23,5 times less than the 47%. Then the average production cost of the top player was multiplied for that proportion, obtaining an average unitary production cost of 42€ for the company's pack.

Estimate sales cost through a top player Electronic device	2018
Average worldwide sales of top player's Electronic device (units)	200 000
European % of the market (Medtech)	27%
Europe volume (units)	54 000
Top player (estimated) market share	47%
Top player profit margin	40%-60%
Average production cost of electronic device	1,50\$-2,10\$
Average production cost of visual device	0,45\$
Company's assumed market share	2,00%
Proportion of market share vs. top player	23,48
Average cost of production of electronic device top player	1,80\$
Assumption for cost of production of the pack	42,26 €

Table 24 - Estimate sales cost through a top player Electronic device. Source: Author.

- When production reaches the 10 000 units it's when the **molds** reach their end of life, so it is when new ones must be bought. Amortization costs are discriminated in Annex XV.

- The **price of the pack** was fixed as 50% margin from the production costs, based on the average margin of one of the market's top players.

Production Cost	Margin	Pack's price
42,26 €	50,00%	84,52 €

Table 25 – Price of the pack considering the 50% margin assumed. Source: Author.

- The product design, testing and prototype molds that will be at charge of the **consulting company** have a joint cost of 50 000€, which is an approximate estimate made by a design engineer that works on the medical device's sector.

- **Clinical tests** tend to be more expensive that verification and validation, so they cost an extra 10 000€, ascending to a total of 30 000€.

12.1.3. Logistics

- The geographic sales distribution is needed because of the different **shipment costs**. The reason why Spain and the Portuguese islands have a special highlight is that the distribution costs are different from the two big groups, Portugal (continent) and Europe.

- Merkur doesn't make the distribution from warehouse to customers' door, so Shiptimize's service will cover that need.

- Final **inventory** is equivalent to 2 months of the average annual monthly sales. This is based on the contract condition with Merkur of having that equivalent quantity in stock.

- All the values are from costumed budgets from Merkur and Shiptimize.

Logistics budget with costs		Merkur	Shiptimize	(operators)
1 box Transport cost (70€+VAT/m ³)		0,11 €		
Shipment of 30 boxes per month		3,44 €	29,93 €	UPS
Storage + handling maximum cost (mandatory 2 months of sales in stock)		300,00 €		
Per delivery	Distribution PT (continent)		3,37 €	GLS
	Distribution PT (islands)		10,44 €	UPS
	Distribution EU (Spain)		4,61 €	GLS 72h
	Distribution EU (Rest)		13,47 €	DHL

Table 26 – Estimation of the costs of shipment, storage, handling and distribution, for this specific product – Logistics. Source: direct contact with Merkur and Shiptimize.

Regarding the information on Table 26, the transport from the factory and the storage and handling will be done by Merkur, and the distribution will be carried out contracting Shiptimize services, for pricing and coverage motives.

12.1.4. Staff

- **Staff** is going to be a relatively small team. Marketing department will only start working on the last 5 months of Year 1, and the Management will only get paid when the company starts to operate. IT department is expected to work 6 months on Year 0 and 3 months on the following years, in hour bank system. Regarding the employee charges, the insurance cost is going to be 1,50% of the gross salary. Detailed costs are on Annex XV.

12.1.5. Legal, R&D and other costs

- The **lawyer** will be needed to help handle the intellectual property and CE marking processes. A base cost of 500€ was assumed and doubled on Year 1 because it is when the CE marking process begins.

- An annual budget of 500€ is reserved for **Research and Development (R&D)**.

- **Marketing budget** on the first year is low, because it only considers 3 months of advertising using Instagram sponsored posts (the last three months of the year). Then the promotion of posts will be used 6 months/year. Google Ads will only be subscribed at the time of expansion to the rest of Europe, with a maximum yearly budget of 50€. The Press publication is considered if there is profit and it is viable to spend that amount of money on that year.

- The **budget for office supplies** considers the purchase of any material needed for the office day-to-day life and any software licensed that might be needed. The assumption was based mostly on the price of Adobe Illustrator software which has an annual cost of 295€. The rest of the budget is assumed to be for consumable items (like pens, paper and so), so the depreciation rate will then be 100% for the whole cost.

12.1.6. Discount rate

- Assumptions to calculate the **real discount rate** were made using the data available on the most similar markets (similar to Femtech/medical devices) - On Damodaran’s website, the two most relevant industries are “Healthcare Products” and “Healthcare Information and Technology”, and they have an **Unlevered Beta** of 1,12 and 0,92 respectively.

- The rate of return was calculated using the CAPM Model.

Project's Rates		Healthcare products	Healthcare Information and Technology
Tax rate	t	21,00%	21,00%
Risk free rate	rf	0,19%	0,19%
Country risk premium	E(rm)-rf	9,02%	9,02%
Unlevered β	β_U	1,12	0,92
Project's risk premium		10,10%	8,30%
Nominal discount rate		10,29%	8,48%
Inflation	i	1,20%	1,20%
Project's real discount rate	rP	8,98%	7,20%
Growth rate	g	7,81%	7,81%
VAT PT		23,00%	23,00%
Cost of Equity	rE	13,52%	11,15%
Cost of Debt	rD	0%	0%
Debt β	β_D	-0,02	-0,02
Levered β of the project	β_L	1,48	1,22
WACC	WACC	9,60%	7,92%
Capital Structure	D/E	0,398	0,398

Table 27 – Project rates for viability analysis. Source: Author.

Notes on Table 27:

- Risk free rate: Germany's 10 year bond yield average since Oct17 (Investing, 2019). Germany is a country which presents 0% country risk premium and is rated Aaa by Moody’s.
- Country risk premium: Portugal's Equity Risk Premium.
- Unlevered Beta of the project: European Market Damodaran, using Marginal Tax Rate of 21%, value for Portugal 2018 (Damodaran, 2019).
- Inflation: Economic Boletim June 2019 (Banco de Portugal, 2019).
- The project is analysed in constant prices, so the discount rate must have into account the inflation effect.
- Cost of Equity: Was used the levered beta because WACC must reflect the financial risk of the project, despite the financing sources it has.
- Cost of Debt: considered 0% because the financing sources are Business Angels and/or Venture Capital.

12.2. Investment and Financing

The main investments will be with the molds, product verification and validation, clinical tests and the legal processes, as showing on Table 28.

INVESTMENT								
	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Capex	30.000	350	350	350	350	350	30.350	350
Supplies and Services	28.460	53.104	66.841	120.461	140.180	169.303	204.787	248.082
From which the bigger costs yearly are:								
- App development	6.000							
- Testing and design	20.000							
- Legal		11.263						
- Tests		30.000						
- Production		7.131	44.389	80.259	92.930	112.451	136.193	165.092
WC	4.528	- 5.099	3.333	2.812	1.769	1.720	8.988	- 4.366
TOTAL	62.988	48.355	70.524	123.623	142.299	171.374	244.125	244.066
Amount to ask for financing	62.988	30.350						

Table 28 – Capex, supplies and services and working capital variation – assets and resources for the business. Investment to ask for. Source: Author.

The financing sources will be Business Angels and/or Venture Capital. There are two rounds of financing planned: the first one aims to get funds to start the implementation of the business, covering the Capex investment and services costs associated with the implementation; the second one includes the tests made by the manufacturer (clinical tests) and the Capex investment of that year.

Share issue					
Angel round (Year 0)	Total value (€)	Per share (€)	No. of shares	% Pre-money	% Post-money
Pre-money valuation	122.893	31,49	3.902	100%	66%
Equity raised/needed	62.988	31,49	2.000	51%	34%
Post-money valuation	185.881	31,49	5.902		100%
2nd round (Year 1)	Total value (€)	Per share (€)	No. of shares	% Pre-money	% Post-money
Equity raised/needed	30.350	31,49	964	16%	14%
Post-money valuation	216.231	31,49	6.866		100%

Table 29 – Pre-money and post-money valuation. Source: Author.

The pre-money valuation on Year 0 is the sum of the discounted cash flows of the project, the Net Present Value. Then it was given a random number of shares to be correspondent to the equity raised value (2 000 shares), and then the value per share was calculated.

Capitalization table			
Angel round (Year 0)	Capital (€)	No. of common shares	% Ownership
Founder		3.902	66%
Employees	-		0%
Investor A	47.241	1.500	25%
Investor B	15.747	500	8%
Total	62.988	5.902	100%
2nd round (Year 1)	Capital (€)	No. of common shares	% Ownership
Founder		3.902	57%
Employees	-		0%
Investor A	47.241	1.500	22%
Investor B	15.747	500	7%
Investor C	30.350	964	14%
Total	93.338	6.866	100%

Table 30 – Capitalization Table. Capital dilution over the two investment rounds. Source: Author.

It is important to take into account the post-money percentage of ownership of the founder – to keep majority, because, as seen on Table 30, the shares are common shares and so give voting rights to their owners. On the second year that was specially taken into account because of the dilution of the first round, but there was no reason for concern because the founder still has 56,8% ownership.

For the short-term treasury balance was assumed a credit line with an Annual Percentage Rate (APR) of 5% and a Deposit rate of 1%.

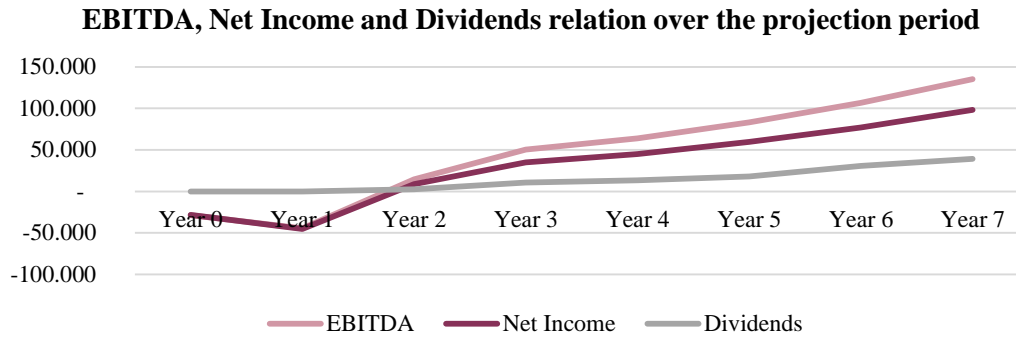
12.3. Income Statement

On the first line of Table 31, “Sales” comprises only the inflow from sales, meaning it doesn’t include the distribution costs. These costs, which are supported by the buyer, will be added separately from the variable costs total, for a clearer analysis.

Income Statement								
	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Sales	-	6.112	83.082	149.455	180.660	218.581	264.700	320.830
COGS	-	3.056	41.541	74.728	90.330	109.291	132.350	160.415
Gross margin (without distrib.)	-	3.056	41.541	74.728	90.330	109.291	132.350	160.415
Gross margin (%)		50%	50%	50%	50%	50%	50%	50%
Distribution inflow from sales	-	975	18.066	35.675	43.423	52.892	64.470	78.634
Inventory of finished product	-	4.075	2.848	5.531	2.600	3.160	3.843	4.677
Variable costs	-	2.000	19.047	37.298	44.346	53.949	65.690	80.053
Contribution Margin	-	6.106	43.408	78.635	92.008	111.394	134.974	163.673
Fixed costs	28.460	43.972	3.404	2.904	2.904	2.904	2.904	2.936
Staff	-	6.394	25.140	25.140	25.140	25.140	25.140	25.140
Other expenses	-	90	230	230	230	230	230	230
Other earnings								
EBITDA - 28.460	-	44.350	14.634	50.361	63.734	83.121	106.700	135.367
Amortization and depreciation	-	856	3.501	6.047	6.947	8.333	10.018	12.070
EBIT - 28.460	-	45.207	11.133	44.314	56.787	74.788	96.682	123.297
Interest Income	13	13	12	127	332	574	795	1.099
Interest Expenses	-	109	109	-	-	-	-	-
Financial result	13	- 96	- 97	127	332	574	795	1.099
EBT - 28.448	-	45.303	11.036	44.440	57.120	75.362	97.477	124.396
Tax	-	-	2.318	9.332	11.995	15.826	20.470	26.123
Net Income - 28.448	-	45.303	8.718	35.108	45.125	59.536	77.007	98.273
Payout	30%	30%	30%	30%	30%	30%	40%	40%
Dividends	-	-	2.616	10.532	13.537	17.861	30.803	39.309
Retained net income - 28.448	-	45.303	6.103	24.575	31.587	41.675	46.204	58.964

Table 31 – Income Statement. Source: Author.

As expected from the project’s chronogram, the first two years present negative results that are compensated over the following business years. The investment of 30.000€ on new molds on year 6 slightly slows the growing pace of the interest income from short-term applications, but is not a significant shake on the Net Income.

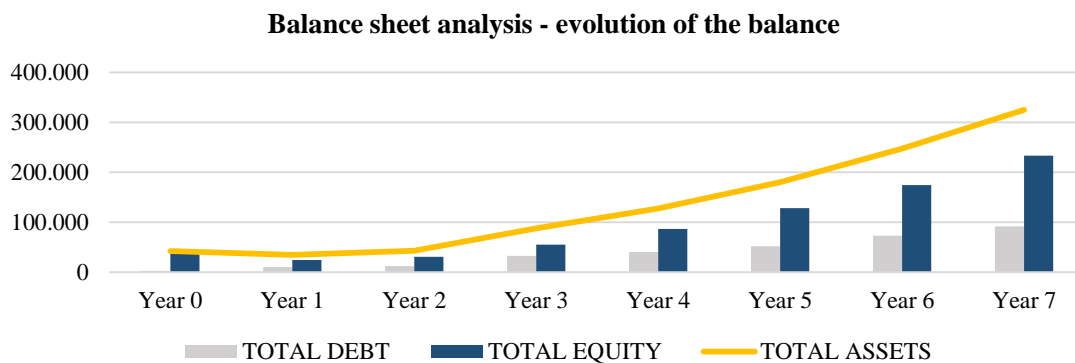


Graph 8 - EBITDA, Net Income and Dividends relation over the projection period. Source: Author.

On Graph 8, is possible to see the evolution of the Net Income, EBITDA and Dividends. The boost on sales is notable with the “entrance” of European costumers. After Year 3 the growing pace starts to ease and be more constant. Because of the good results, the dividends distribution will rise to 40% of the NI in Year 6.

12.4. Balance Sheet Analysis

Equity value is what stands out the most in Graph 9, Year 0. Equity includes the paid-up capital for constitution of the firm, the equity raised in funding rounds, the retained earnings (NI) and the transited results. The type of funding of the project is the main reason for the low levels of Debt - on the first year it only comprises payment of services.



Graph 9 - Balance sheet analysis - evolution of the balance. Source: Author.

The capital structure oscillates throughout the horizon of the project. On year 0 and 1 it this fluctuation is attributed to the beginning of the activity (mostly the equilibrium loan effect on debt). On the following years the main factors are the increase of nearly 45% in the suppliers and the rise in dividends payment in Year 6 (from 30% to 40%). Presented on Table 32 are the variations in some rubrics of the balance sheet, to better assess the fluctuation on D/E ratio.

Variation in some rubrics to explain the capital structure fluctuation								
	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Suppliers		46%	21%	45%	14%	17%	17%	17%
State and Other Public Entities		100%	42%	0%	0%	0%	0%	0%
Equilibrium Loan		100%						
Dividends to pay			100%	75%	22%	24%	42%	22%
Taxes to pay			100%	75%	22%	24%	23%	22%
Debt		72%	18%	62%	19%	21%	29%	20%
Equity		-61%	20%	44%	36%	32%	26%	25%
Current Year Retained Net Income		37%	842%	75%	22%	24%	10%	22%
Capital Structure ratio	0,074	0,421	0,409	0,597	0,468	0,403	0,418	0,392

Table 32 - Variation in some rubrics to explain the capital structure fluctuation. In green are the variations which contribute the most for the result of the D/E ratio oscillation. Source: Author.

Despite the strong component of the intellectual property there are no intangible assets considered in the balance - its value is implicit on the cash flow generation. All the costs related to the legal processes are considered as fixed costs. The Balance Sheet may be consulted in Annex XV.

12.5. Evaluation of the project

The project presents positive cash flows from operations on Year 2, which is when the company really starts to operate, and that is a good indicator, despite the low value.

CASHFLOWS MAP								
	Years							
	0	1	2	3	4	5	6	7
EBITDA	- 28.460	- 44.350	14.634	50.361	63.734	83.121	106.700	135.367
Amortization and Depreciation	-	856	3.501	6.047	6.947	8.333	10.018	12.070
EBIT (Net Operating Profit)	- 28.460	- 45.207	11.133	44.314	56.787	74.788	96.682	123.297
Adjusted taxes	-	-	2.338	9.306	11.925	15.705	20.303	25.892
NOPLAT	- 28.460	- 45.207	8.795	35.008	44.862	59.082	76.378	97.405
Operational Cash Flow	- 28.460	- 44.350	12.296	41.055	51.809	67.415	86.396	109.474
Working Capital variation	4.528	- 5.099	3.333	2.812	1.769	1.720	8.988	- 4.366
Cash Flow from Operations	- 32.988	- 39.252	8.962	38.243	50.040	65.695	77.408	113.840
CAPEX	30.000	350	350	350	350	350	30.350	350
Divestment in CAPEX								
Tax on divestment								
Net Cash Flow (also FCFE)	- 62.988	- 39.602	8.612	37.893	49.690	65.345	47.058	113.490
Accumulated FCFE	- 62.988	- 102.590	- 93.978	- 56.085	- 6.395	58.950	106.008	219.498
Discounted FCFE	- 62.988	- 36.338	7.251	29.276	35.227	42.507	28.089	62.160
Accumulated Discounted FCFE	- 62.988	- 99.327	- 92.075	- 62.799	- 27.573	14.935	43.024	105.184

Table 33 – Cash Flows Map. Source: Author.

On the lower level of the cash flows map, Table 33, was calculated the Free Cash Flow to the Firm (FCFF) discounted and accumulated at the project's discount rate r_P . From that is possible to perceive that the payback period is within the goal of “up to year 5” (when the accumulated FCFE changes to positive). It was not considered any divestment because the project will continue – five years of sales for such an amount of time, processes and money invested to start the business and the positive cash flows it generates, sustain the decision of continuation (see continuity value in Annex XV).

Investment decision

To know if its viable to invest in a project, an investor will look at certain parameters such has if the project will remunerate the shareholders and generate a surplus of capital, the expected growth rate of the product, the relation between the initial capital invested and the project's NPV, and when is predictable that the project pays itself. The viability analysis done is summarized on the following table:

Indicator	NPV	IRR	PI	PBP
Condition for accepting	>0	>rP	>1	< project horizon
With project's value	>0	>8,98%	>1	<7
Project's values	105.184	27%	2,67	4,10 ; 4,65
Decision	Accept	Accept	Accept	Accept

Table 34 – Main parameters for the investment decision. Source: Author.

The conclusion is that the project is viable for each parameter of the analysis. The project will pay its shareholders and remunerate them and generate a surplus of cash (NPV>0), will generate a profit of 1,67€ for every euro invested (PI=2,67), will pay back in less than 5 years - 4 years 1 month and 5 days for the accounting PBP and 4 years 7 months and 24 days for the finance PBP (PBP=4,10 ; PBP=4,65).

12.6. Financial Indicators

To easily analyse the performance of a company and to be able to eventually compare it to others, financial indicators are used. Some of the most common are presented on Table 35.

Performance indicators	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Return on Sales (ROS)		-740%	13%	30%	31%	34%	37%	38%
ROIC	-82%	-156%	30%	134%	210%	390%	172%	343%
Gross ROA	-67%	-129%	26%	50%	45%	41%	39%	38%
Net ROA	-67%	-130%	20%	40%	35%	33%	31%	30%
ROE	-72%	-184%	28%	64%	52%	46%	44%	42%
Financial Autonomy	93%	70%	71%	63%	68%	71%	71%	72%

Table 35 – Indicators of the company's performance. Source: Author.

The first five are profitability indicators: Return on sales indicates the return on EBIT from each sale - that is the contribution of each sale for the company's operating profit, the capability of paying the producing costs and capital expenditure costs – On the first year it is negative because the sales volume is very low but on year 2 for each euro in sales there is an operating profit of 13 cents, increasing continuously; Return on Invested Capital (ROIC) is higher than WACC in the operating years meaning the company is investing well its capital - year 0 and year 1 are for investment and development, so it is *a priori* expected that the company is not able to generate profit or to repay the shareholders at any demanded rate on those years –; Gross Return on Assets (Gross ROA) gives an idea of how well the assets are being used to

generate profit, it uses the total assets and confronts them with the company's operating profit (EBIT), it is decreasing but still represents a solid value; Net ROA is the same as Gross ROA but uses the Net Income instead of EBIT, so it includes taxes and financial costs/earnings; Return on Equity (ROE) reflects the return on the money invested in the firm, under the assumption that earnings that are not distributed as dividends are reinvestments in the business. The last indicator indicates the balance of equity in the assets total, which is increasing, because equity is remaining stabilizing and assets' volume is growing.

12.7. Sensitivity analysis

This is the last analysis performed and it studies how variations in key assumptions change the viability parameters of the project. The main assumptions made for this project are the selling price, the production cost and the sales in quantity. Regarding the last one, for the sensitivity analysis was only considered the sales from year 2 because it is when the project is fully implemented. Five different scenarios were created in order to see how the business model behaves under negative, positive and terrible circumstances. Two of the scenarios reproduce possible choices for the products costs and price based on benchmark and top player's numbers, and that were considered when developing the business plan. On Table 36 is the reasoning behind each scenario and variation; and on Table 37 is the resume board of the variations according to the scenario (variable cells) and the conclusions (result cells).

Scenario variations		Reasoning for the variations
Pessimistic / Optimistic		Equivalent changes on some of the most determinant variables.
Selling price	-20% / 20%	Pessimistic: positive changes on the variables that affect negatively the results, and vice-versa; Optimistic: positive changes on the variables that affect positively the results, and vice-versa.
Production cost	20% / -20%	
Sales in quantity (year 2)	-20% / 20%	
Terrible		Unlikely negative
Selling price	-29%	Negative change to resemble the selling price of 60€ (the first idea before assessing the costs of the project)
Production cost	0%	The current price of 42€ is believed to be close to the maximum possible, so no changes were considered
Sales in quantity (year 2)	-15%	Bigger variation than in the pessimistic scenario, the product may not be so well-received by the costumers
Top Player (low cost)		Production costs similar to the top player's
Selling price	-29%	Negative change to resemble the selling price of 60€ (the first idea before assessing the costs of the project)
Production cost	-95%	To make the production cost similar to the 2,10€ of the top player
Sales in quantity (year 2)	0%	No changes are considered
Top Player (benchmark cost)		Selling price closer to the benchmark and top player's production cost
Selling price	16%	To make the selling price be close to 100€
Production cost	-95%	To make the production cost similar to the 2,10€ of the top player
Sales in quantity (year 2)	0%	No changes are considered

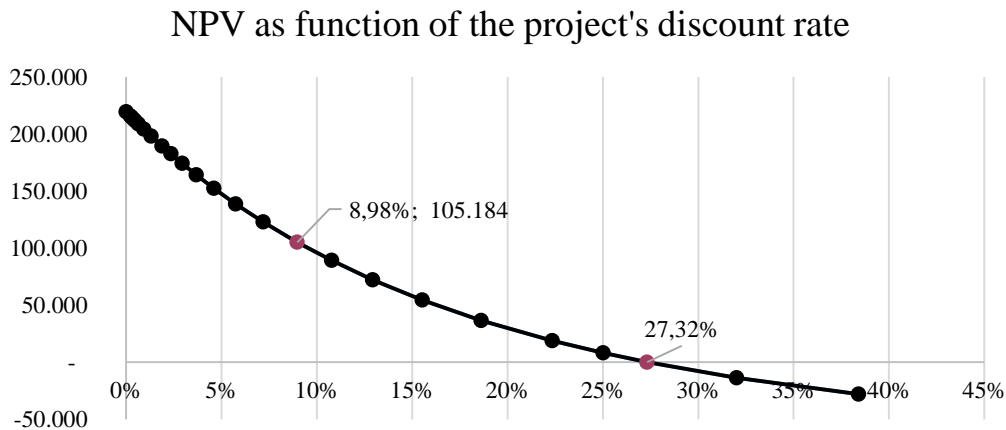
Table 36 – Reasoning behind each scenario and variation. Source: Author.

Scenario Summary	Realistic	Pessimistic	Optimistic	Terrible	Top Player (low cost)	Top Player (benchmark cost)
Variable Cells:						
Selling price	0%	-20%	20%	-29%	-29%	16%
Production cost	0%	20%	-20%	0%	-95%	-95%
Sales in quantity (year 2)	0%	-20%	20%	-15%	0%	0%
Result Cells:						
NPV	105.184	13.341	148.106	-80.551	-234.578	-216.797
Goingconcern Value	5.987.846	3.468.013	6.536.650	611.496	246.334	225.333
IRR	27%	12%	34%	-13%	#NUM!	#NUM!
Profitability Index	2,67	1,21	3,35	-0,28	-2,72	-2,44

Table 37 – Summary of the sensitivity analysis scenarios. Source: Author.

The business model is robust for variations of 20%, however it fails on the other scenarios. On the top player related scenarios all the cash flows generated are negative so it is impossible to calculate an IRR.

Lastly, was analysed the NPV's sensitivity to changes in r_P , which is demonstrated on the following graph:



Graph 10 – NPV as a function of the project's discount rate. In purple is the NPV with $r_P=8,98\%$ and IRR, which is when $NPV=0$, i.e. when the function crosses the horizontal axis. Source: Author.

Other sensitivity analysis were performed and can be consulted on Annex XV.

13. CONCLUSION

Femtech market is booming, not showing clear signs of slowing its pace and women are open to new options that promise to improve their lives.

According to the market survey results, the participants show preference for a product like the electronic device to measure the vaginal pH and, in relative percentages, the target public has the highest score. It is a very positive point since it shows that the need is recognized and the proposed solution seems indeed pertinent to the eyes of the targeted potential consumers.

There is no paved road to introduce a product like this device, specially in Portugal, where there is only one product of one brand sold in pharmacies. Thus the potential costumers may not be willing to pay much because they don't recognize added value yet, and in this case the lack of information on gynaecological health is a risk. On the other hand, women who are pregnant or in menopause are now included on the scene: the product is suitable for any pH level, and with the support of the mobile app the users can also track their pH level history. Exploring the menopausal segment is in fact one of the identified challenges for the business, since the product is suitable for this segment and it is quite unexplored.

Initially, the price of the product was thought to be close to 60€, however, a medical device requires a considerable investment of money (and time) and the production process is expensive without scale economies, so that price was quickly discarded. For sure the options made to create the value chain didn't take into consideration the final cost, so the production value could be lower, but then the whole process would take more time and there could be dramatic setbacks. The value chain chosen is the safer choice for the business to run with no hassles. For being a class I medical device, the process to get the CE mark is easier. On this thesis the total time to market is almost 2 years, and it is mainly because of the legal processes of the CE marking, tests and intellectual property.

Overall, the financial model doesn't have many pure assumptions, only on the initial market share and share issue. All the information on values and costs was gathered using real sources and custom data whenever possible. Thus, it is reasonable to say it is a realistic model.

By considering Business Angels/Venture Capital funding the financial charges arising from the initial investment needs drop to zero, and that has a considerable impact on the financial plan, balance and overall result.

For the sensitivity analysis the business model thrives on three of the six scenarios created. Considering the realistic scenario the NPV is 105 184€, the project generates a profit of 1,67€ for each invested euro, the IRR is 27% and the payback period is shorter than 5 years.

The final result could be more interesting if the gross margin was improved. The value of the production is very high when comparing to the top player, so there is a window to upgrade that value. With the sales upwind, a new contract can be negotiated with the manufacturer, the same or other (depending on the switch cost), in order to get a price lower than the current 42€ unitary cost.

Considering the results of this business plan, the conclusion is the viability of the project, with margin for changes on the key-assumptions.

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15. ANNEXES

Annex I - Resume board on the types of infections

Type	Infections	Description	Causes	Symptoms	Diagnostic method	Treatment
Bacterial	- Bacterial Vaginosis	When there is an outbalance of bad bacteria (e.g. Gardnerella Vaginalis) over good bacteria (lactobacilli) in the vagina. (Hardy, et al., 2017) Is common for bacterial vaginosis to come back a few months after treatment. (NHS, 2018)	Excessive hygiene (e.g. douching frequently; perfumed products) Having more than one/having a new sex partner (Healthwise, 2018)	- Abnormal vaginal discharge with odor	- Papanicolaou - Microbiological analysis	- Antibiotics (creams/gels or pills) Duration: approx. 7 days (Healthwise, 2018)
	- Sexually Transmitted Diseases (STDs): - Gonorrhea - Chlamydia	Infectious diseases that spread through sexual contact. Chlamydia may take longer to present any apparent symptoms (from 1 to 3 weeks). (WebMD, 2017)	Sexual contact with someone with the infection.	Most common for infectious STDs: - Abnormal vaginal discharge - Burning or itching in or around the vagina - Pain/burning sensation when urinating - Pain when having sex - Unusual bleeding - Painful periods - Abdominal pain with fever		- Antibiotics (pills) - In case the disease is antibiotic-resistant other drugs are prescribed (pills). (CDC, 2016)

Type	Infections	Description	Causes	Symptoms	Diagnostic method	Treatment
Fungal Infections /Candida	- Vaginal yeast Infection/ Vaginal Candidiasis	Originated by the abnormal growth of the yeast cells that normally live in the vagina. It is such a common disease that approximately 75% of women will have it at least one of this infections, and 40% to 45% will have multiple incidences. (WebMD, 2017)	- Hormonal changes - Non controlled diabetes - Antibiotics - Vaginal sprays or douches - Weakened immune system - Can also be spread through sexual contact	- Abnormal vaginal discharge with odor - Burning, redness and soreness/swelling of the vagina and vulva; - Pain/burning sensation when urinating - Pain when having sex	- Vaginal culture - Cytology - Microbiological analysis (Raugust & Ribeiro Duarte, 2013)	- Anti-fungal creams or ointments (creams) - Anti-fungal pills or vaginal suppositories (pills). - Eating probiotics (lowers the risk of infection and slows down its growth) (Hopkins Medicine, s.d.)
Parasite	- Trichomoniasis (also an STD, caused by the parasite Trichomonas vaginalis)	A protozoan parasite that is transmitted through sexual intercourse Only about 30% of the people with this STD develop any symptoms (CDC, 2017) . If they do, they appear on a later stage 5 to 28 days after a person is infected. The probability of being infected again in the next 3 months after treatment is 1/5.	Sexual contact with someone with the parasite. (Healthline, 2016)	- Abnormal vaginal discharge with odor - Itching, burning, redness or soreness of the vagina; - Pain/burning sensation when urinating	- Papanicolaou - Cytology - Microbiological analysis (Raugust & Ribeiro Duarte, 2013)	- Antibiotic and antiprotozoal medication (pills) (CDC, 2017)
Viral Vaginitis	- Herpes Simplex Virus (HSV)	A type of virus often associated with stress or emotional distress (Cleveland Clinic, 2018). It is very common and highly contagious.	- Usually spreads through sexual contact - Stress - Emotional distress	- Cold sores on the vulva and/or vagina - Itching - Pain/burning sensation when urinating		There is no cure, however there is medicine to prevent outbreaks and heal the sores faster, and the spreading risk can be minimized with oral antiviral medication (pills) (CDC, 2017)

Type	Infections	Description	Causes	Symptoms	Diagnostic method	Treatment
	- Genital Human Papillomavirus (HPV)	There are more than 150 types of this virus. (CDC, 2017) Even though the majority of the HPV infections disappear by themselves in a period of 2 years, never giving any symptoms or health issues, others may lead to cancer. (CDC, 2018)	Sexual contact	- Warts in the genital area that begin as small bumps. (CDC, 2017)		Vaccine for prevention (vaccine) Treatments with creams/gels applied directly in the warts (cream) Surgical methods (surgery) (Mayo Clinic, 2018)
Non-infectious	- Reactions or allergies	Allergic reactions/irritations caused by products or the environment that manifests in the genital area.	Amongst the more commons are: - Perfumed products - Fabric detergents or softeners - Douches - Vaginal sprays/spermicides	- Abnormal vaginal discharge - Irritation and sensitive skin - Itching or burning sensation on the vagina; (Cleveland Clinic, 2018)		- Estrogen creams or oral tablets (creams or pills) (Columbia Doctors, 2017) - Identify the cause and avoid it

Adapted by the author from the different sources referenced in the table.

Annex II – Market survey

The questionnaire was made in *Typeform* digital platform and shared through a link which allowed the participants to answer on their mobile phone or computer. The structure was made using a logic jump between the questions as consequence of the answers. Following there are the survey's questions. The answers given may be consulted on the following tables on this same annex.

1 - Age

2 - Have you ever had a vaginal infection? (do not confuse with urinary)

3 - You knew you had an infection because...

4 - "Other". Which?

5 - Regarding the occurrence of vaginal infections, what option fits you better?

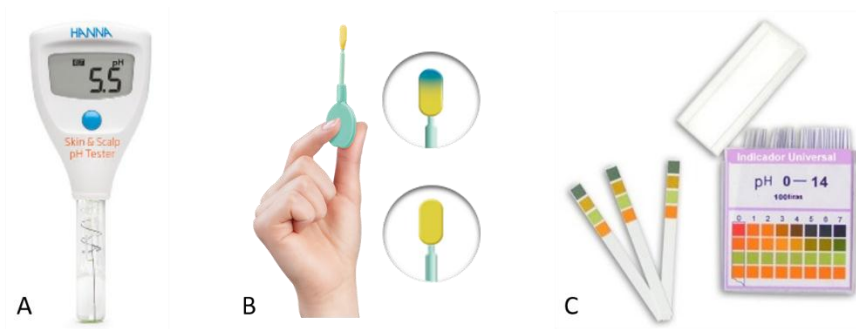
6 - To treat the infection...

7 - What natural/homemade methods did you use?

8 - Do you have any special care to avoid vaginitis? (for instance, type of hygiene, underwear type, intercourse, among others)

9 - By measuring vaginal pH, a woman can measure whether she is more likely to develop/contract a vaginal infection and can act to prevent it. How important do you think this prevention is? (4 very important; 1 not important)

10 - Suppose your doctor proposes that you measure your vaginal pH regularly, at home and over the long term. Which method would you rather use?

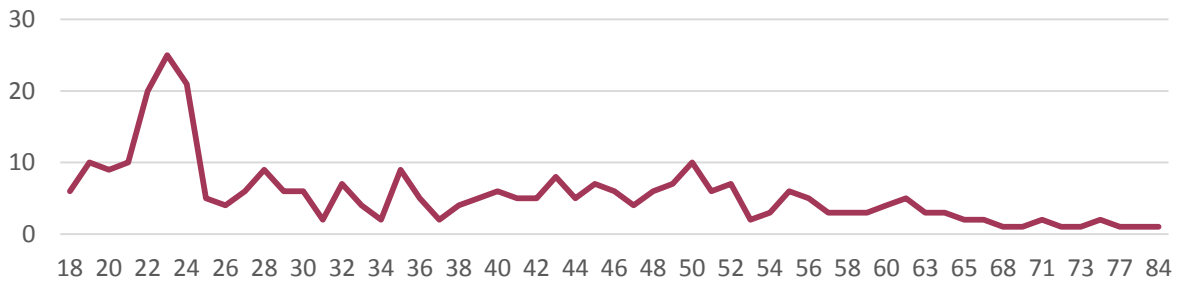


11 - Suppose the electronic vaginal pH meter allows a connection to a mobile application - so that the user can record their measurement history as well as some factor that may have fuelled changes in their pH. How relevant do you think this feature is? (4 very relevant; 1 unnecessary)

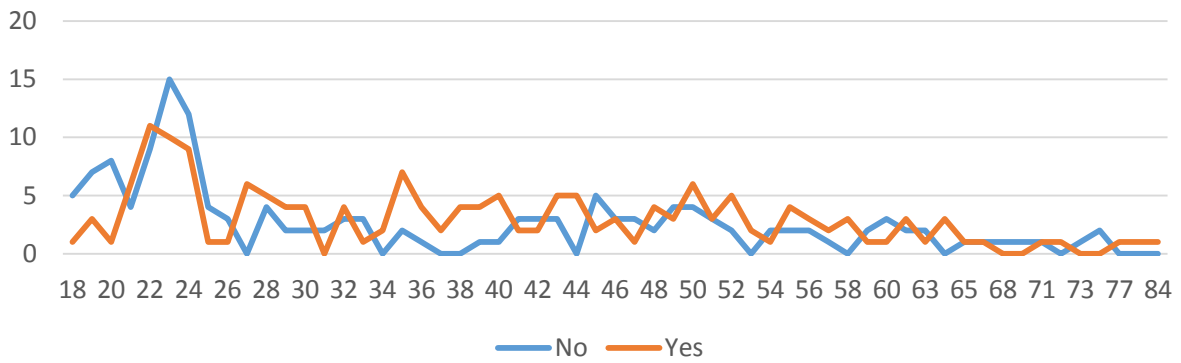
12 - If you would like to leave a comment, please do it in this section

The following section presents some worked data retrieved from the survey's results.

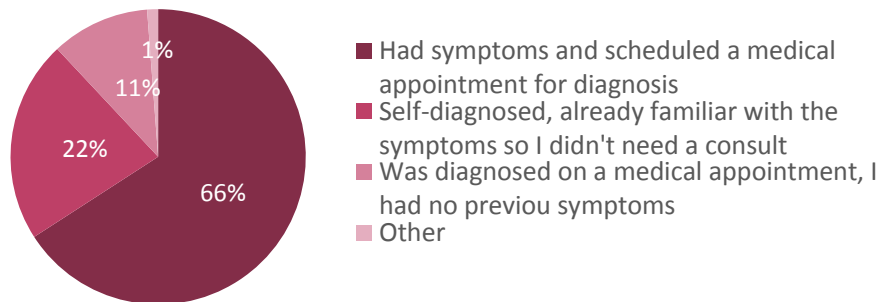
Distribution of the participants by age



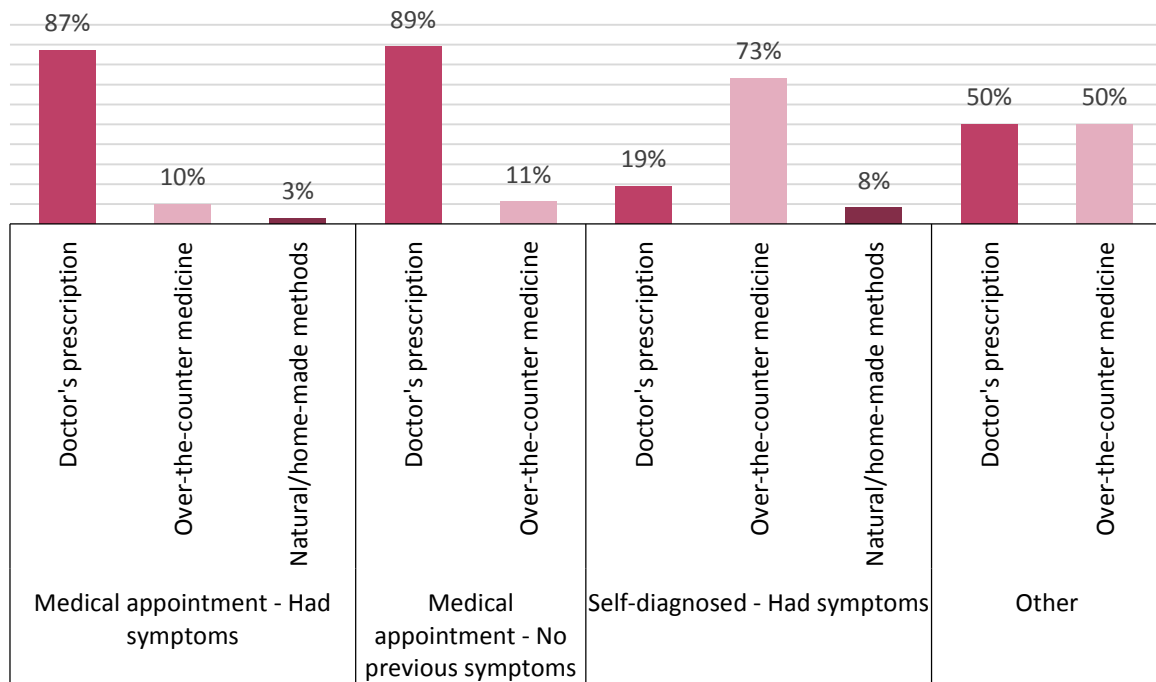
"Have you ever had a vaginal infection?" by age



How the participants discovered they had a vaginitis

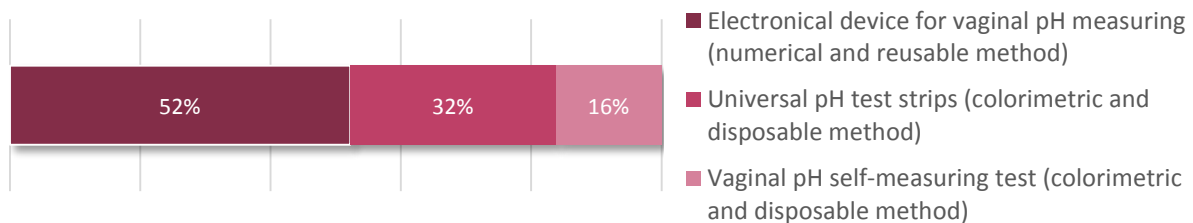


Treatment used according to the diagnostic method



Do you have any special care to avoid vaginal infections?			Ever had a vaginal infection?			
	In number	In %		In number	In %	In % of Total
No	64	20%	No	39	61%	12%
			Yes	25	39%	8%
Yes	250	80%	No	108	43%	34%
			Yes	142	57%	45%
Total	314	100%	Total	314		100%

Method chosen if the doctor suggested measuring the vaginal pH regularly and at home



Here follows all the questions from the market study and its results (number of answers and percentage of answers from the total). It was made using logic jumps and that is why there is “(blank)” in some answers.

Have you ever had a vaginal infection? (do not confuse with urinary)		
No	147	46,8%
Yes	167	53,2%
Total	314	100,0%

You knew you had an infection because...		
Had symptoms and scheduled a medical appointment for diagnosis	110	35,0%
Self-diagnosed, already familiar with the symptoms so I didn't need a consult	37	11,8%
Was diagnosed on a medical appointment, I had no previous symptoms	18	5,7%
Other	2	0,6%
(blank)	147	46,8%
Total	314	100,0%

"Other". Which?		
Antibiotic side-effect	1	0,3%
I'm a doctor	1	0,3%
(blank)	312	99,4%
Total	314	100,0%

Regarding the occurrence of vaginal infections, what option fits you better?		
Have about 2 to 3 a year	22	7,0%
Not more than once a year	58	18,5%
Only had 1 so far	77	24,5%
Usually have at least 4 a year	10	3,2%
(blank)	147	46,8%
Total	314	100,0%

To treat the infection...		
I used natural / homemade methods	6	1,9%
Went to the pharmacy for the doctor's prescription	120	38,2%
Went to the pharmacy to buy an over-the-counter medicine	41	13,1%
(blank)	147	46,8%
Total	314	100,0%

What natural/homemade methods did you use?		
Drink much water	1	0,3%
Drink much tea		
I waited for it to mature and then burst on its own - Bartholin's gland	1	0,3%
Hygiene	1	0,3%
Natural homemade yogurt and apple cider vinegar	1	0,3%
Naturopathy	1	0,3%
Vinegar and natural yogurt	1	0,3%
(blank)	308	98,1%
Total	314	100,0%

Do you have any special care to avoid vaginitis? (for instance, type of hygiene, underwear type, intercourse, among others)		
No	64	20,4%
Yes	250	79,6%
Total	314	100,0%

By measuring vaginal pH, a woman can measure whether she is more likely to develop / contract a vaginal infection and can act to prevent it. How important do you think this prevention is? (4 very important; 1 not important)		
1	7	2,2%
2	9	2,9%
3	60	19,1%
4	238	75,8%
Total	314	100,0%

Suppose your doctor proposes that you measure your vaginal pH regularly, at home and over the long term. Which method would you rather use?		
Electronic device for vaginal pH measuring (numerical and reusable method)	164	52,2%
Universal pH test strips (colorimetric and disposable method)	99	31,5%
Vaginal pH self-measuring test (colorimetric and disposable method)	51	16,2%
Total	314	100,0%

Suppose the electronic vaginal pH meter allows a connection to a mobile application - so that the user can record their measurement history as well as some factor that may have fuelled changes in their pH. How relevant do you think this feature is? (4 very relevant; 1 unnecessary)		
1	24	7,6%
2	41	13,1%
3	93	29,6%
4	156	49,7%
Total	314	100,0%

If you would like to leave a comment, please do it in this section	
The decision between 8B and 8C was strongly influenced by the ergonomics (admitting that only a part of the 8B is disposable). Option 8A was not considered because it was admitted that 1) the value of the device is bigger than the others and 2) the equipment is less eco-friendly than the others.	1
The option I chose depends on the price.	1
To have in consideration the costs for the consumer associated to the different analysis methods.	1
I think it is very important to have a type of examination that serves as a control to do at home.	1
I find it very important to focus on women's health especially on an intimate issue where very little information is shared even by gynecologists	1
Very relevant subject, with little information disclosed	1
Good work!!	1
As I only had one infection in my life, it turns out not to be something that I find relevant on a particular level. Given that most women are more susceptible, I believe it can be an asset.	1
I am having this issue currently, I found the test very interesting and well-timed.	1
Interesting questions	1
In my case I had once with symptoms and again without symptoms, in one of the questions where this can be answered we can only answer once when there may be more answers.	1
Option to keep the records on the computer.	1
For treatment I recurred to all the available options. Regarding the application I don't believe it would be that useful given that an application may become an obligation and may not be the most convenient thing.	1
It would be very interesting to be able to do a follow up and, after all, a prevention of this kind.	1
Interesting subject, good work.	1
Anything to help avoid these situations is positive.	1
Yes is going to be useful to many women.	1
(blank)	297
Total	314

Note: this section was fully translated from the original inputs of the participants.

Annex III - SME

Company category	Staff headcount	Turnover	or	Balance sheet total
Medium-sized	< 250	≤ € 50 m		≤ € 43 m
Small	< 50	≤ € 10 m		≤ € 10 m
Micro	< 10	≤ € 2 m		≤ € 2 m

Source: Adapted from European Commission's website (2018).

Annex IV – Hygiene Sector in Portugal

Country - Subcategory - Category	Volume in thousand €; % of the category's total		Source: INE , “Estatísticas do comércio”, 2016 and 2017
	2016	2017	
PT - Total Hygiene and cosmetic products - main retail products	2.107.656 (4,6%) Annual variation of 0,1p.p.	2.114.652 (4,3%) Annual variation of -0,2p.p.	From a set of 47 products that make up the nomenclature in use, the top 10 products in this sector generated 53.0% of the overall business volume. Source: Table 2.1.3.2 - Top 10 Products of Retail Trade Companies, 2016 Table 2.3.2 - Top 10 Products of Retail Trade Companies, 2017
PT - Toiletries, cosmetics, pharmaceuticals and medical-surgical instruments - Food Retail	897.312 (7,4%)	910.999 (7,4%)	Source: Tables 39 and 40 - UCDR - Sales Volume of Food retail or food predominantly, by Product Category, by NUTS II, 2016 Table 3.12 and 3.13 - UCDR - Sales Volume of Food or Food-predominant Retail Trade, by Product Category, by NUTS II, 2017
PT - Toiletries, cosmetics, pharmaceuticals and medical-surgical instruments - Non Food Retail	134.855 (2,6%)	146.146 (2,6%)	Source: Tables 52 and 53 - UCDR - Distribution of Sales Volume in Non-food retail or without food predominance, by product category, by NUTS II, 2016 Table 3.25 - UCDR - Distribution of Sales Volume in Non-food retail or without food predominance, by Product Category, by NUTS II, 2017
PT - Pharmaceutical, medical, hygiene and cosmetic products - Specialized Retail	793.536 (7,1%)	779.748 (6,6%)	- Other retail sale of goods in specialized stores (group 477). Source: Table 22 - IECOM - Main products of retail trade of other products in specialized stores (CAE Group 477), 2016 Table 2.17 - IECOM - Main products of Retail trade of other products in specialized stores (CAE Group 477), 2017
PT - Pharmaceutical, medical, hygiene and cosmetic products - N. Specialized Retail	1.321.117 (7,3%)	1.341.816 (6,8%)	- Retail sale in non-specialized stores (group 471). Source: Table 16 - IECOM - Main products of retail trade enterprises in non-specialized stores (CAE Group 471), 2016 Table 2.11 - IECOM - Main products of retail trade enterprises in non-specialized stores (CAE group 471), 2017

Annex V – Classification rules for medical devices

Definitions for the classification rules, based on Section 1 of the Annex VIII of the REGULATION (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Definitions for the classification rules

Duration	Transient	Normally intended for continuous use for less than 60 minutes
	Short term	Normally intended for continuous use for not more than 30 days.
	Long term	Normally intended for continuous use for more than 30 days.
Risks	Based on the literature review and clinical evaluation report	
Invasiveness	Surgically invasive device	An invasive device which is placed into the body, through a body orifice, with the aid of or in the context of a surgical operation.
	Implantable device	Any device which is totally introduced into the human body by surgical intervention which is intended to remain in place after the procedure.
	Reusable surgical instrument	Instrument intended for surgical use without connection to any active medical device and which can be reused
Active medical devices	Any medical device operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices. Stand-alone software is considered to be an active medical device.	
Devices with a measurable function	Active device for diagnosis	Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.

Source: European Parliament and Council regulations (2017)

Annex VI – Requirements regarding design and construction

COUNCIL DIRECTIVE 93/42/EEC

of 14 June 1993

concerning medical devices

ANNEX I

ESSENTIAL REQUIREMENTS

II. REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION

10. Devices with a measuring function

10.1. Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer.

10.2. The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.

10.3. The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC.

12. Requirements for medical devices connected to or equipped with an energy source

12.1. Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks.

12.1a For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.

12.4. Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.

12.9. The function of the controls and indicators must be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.

13. Information supplied by the manufacturer

13.3. The label must bear the following particulars:

- (a) the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorised representative where the manufacturer does not have a registered place of business in the Community;
- (b) the details strictly necessary to identify the device and the contents of the packaging especially for the users;
- (c) where appropriate, the word ‘STERILE’;
- (d) where appropriate, the batch code, preceded by the word ‘LOT’, or the serial number;
- (e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month;
- (f) where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community;
- (g) if the device is custom-made, the words ‘custom-made device’;
- (h) if the device is intended for clinical investigations, the words ‘exclusively for clinical investigations’;
- (i) any special storage and/or handling conditions;
- (j) any special operating instructions;
- (k) any warnings and/or precautions to take;
- (l) year of manufacture for active devices other than those covered by (e). This indication may be included in the batch or serial number;
- (m) where applicable, method of sterilization;

13.6. Where appropriate, the instructions for use must contain the following particulars:

- (a) the details referred to in Section 13.3, with the exception of (d) and (e);
- (b) the performances referred to in Section 3 and any undesirable side-effects;
- (c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination; 1993L0042 — EN — 11.10.2007 — 005.001 — 31
- (d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times;

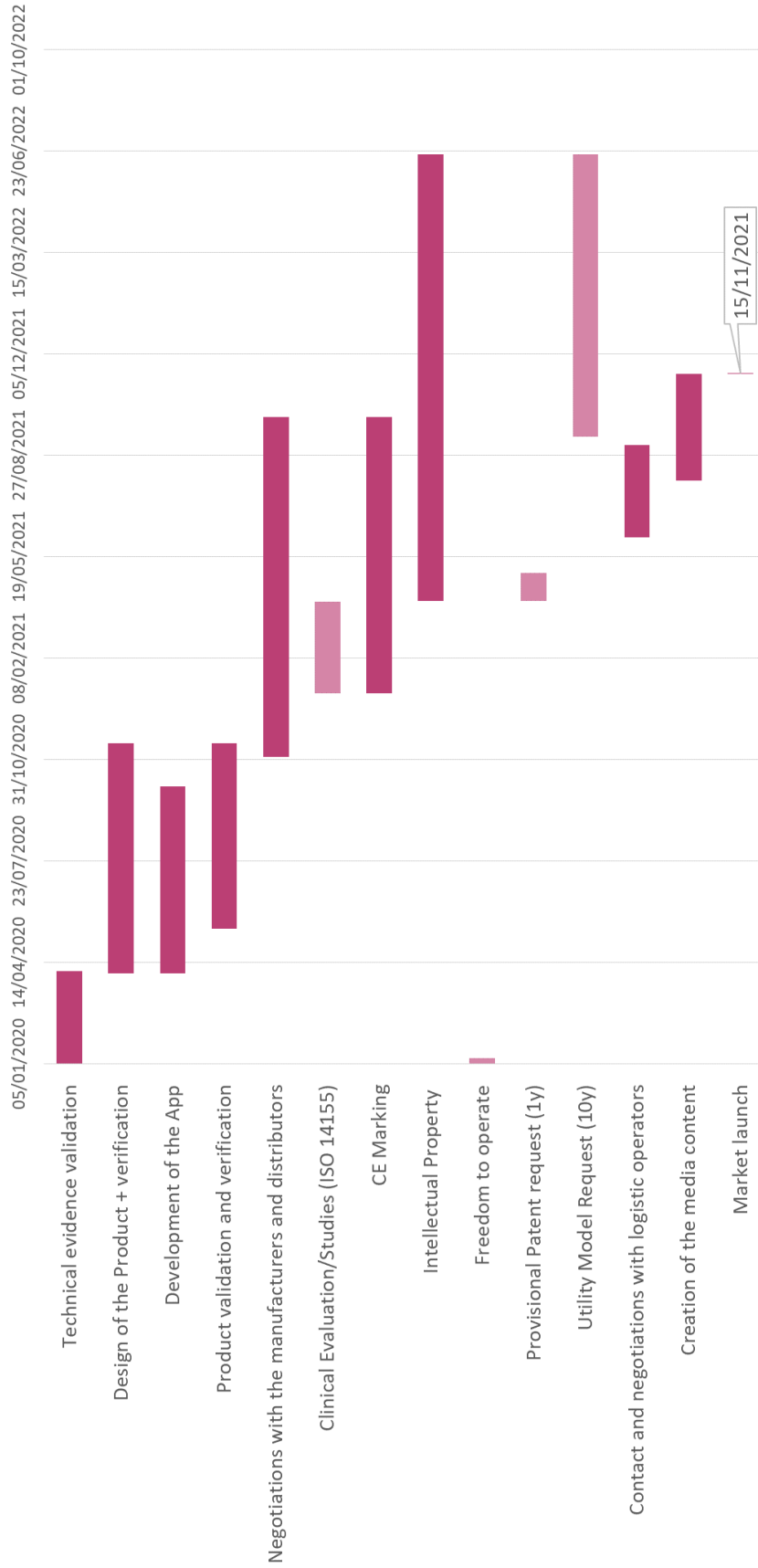
- (e) where appropriate, information to avoid certain risks in connection with implantation of the device;
- (f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment;
- (g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;
- (h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be resterilized, and any restriction on the number of reuses. Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I.
- (i) details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.);
- (j) in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.
- (l) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;
- (m) adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered;
- (n) precautions to be taken against any special, unusual risks related to the disposal of the device;
- (p) degree of accuracy claimed for devices with a measuring function;
- (q) date of issue or the latest revision of the instructions for use.

Annex VII – RoHS’s list

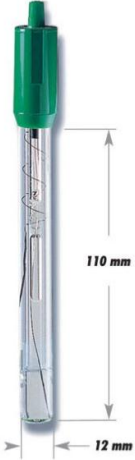



Substance	Maximum Levels
Cadmium (Cd)	< 100 ppm
Lead (Pb)	< 1000 ppm
Mercury (Hg)	< 1000 ppm
Hexavalent Chromium (Cr VI)	< 1000 ppm
Polybrominated Biphenyls (PBB)	< 1000 ppm
Polybrominated Diphenyl Ethers (PBDE)	< 1000 ppm
Bis(2-Ethylhexyl) phthalate (DEHP)	< 1000 ppm
Benzyl butyl phthalate (BBP)	< 1000 ppm
Dibutyl phthalate (DBP)	< 1000 ppm
Diisobutyl phthalate (DIBP)	< 1000 ppm

Source: RoHS Guide (2019).

Annex VIII – Business plan chronogram

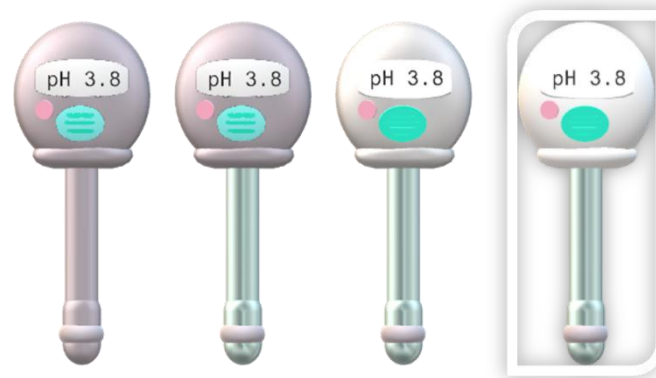


Annex IX – Existing pH meters

Name	HI-1413B Glass Bodied Flat pH Electrode, BNC Connector	HI10532 Wireless HALO® pH electrode for emulsions	HI981036 Foodcare Meat pH Pocket Meter	HI981037 Skin and Scalp pH Pocket Meter
Brand	Hanna Instruments	Hanna Instruments	Hanna Instruments	Hanna Instruments
Image				
Materials	Glass body	Ceramic tip Glass body	Glass tip Polyvinylidene fluoride (PVDF) plastic body	Glass body
Range	0 to 12 pH; -5 to 50°C	0 to 12 pH; -5 to 70°C	0 to 14 pH; 0 to 50°C	0 to 14 pH; 0 to 50°C
Used for	Skin, leather, paper, emulsions	Emulsions, pastes and other viscous samples	Meat	Skin and scalp
Other features	Viscolene (hard gel) electrolyte layer that is free of silver chloride (AgCl) between the sample to be measured and the internal reference cell. BNC Connection	Bluetooth 4.0 with a 10 metres range; The electrode connects with the App Hanna Lab, transforming a smart device on an operational pH measurer; Temperature sensor	Battery indication; Pattern recognition; Automatic shut-off; Removable sleeve for clean-up and to add electrolyte gel.	Automatic shut-off;
Price (excluding VAT)	£146,50	241,00€	109,00 €	109,00 €

Source: Hanna Instruments (Hanna Instruments, n.d.) (Hanna Instruments, n.d.) (Hanna Instruments, n.d.) (Hanna Instruments, n.d.), adapted by the author.

Annex X – Modifications on the device’s colour and material



Source: Author

Annex XI – Common types of plastic

Most common types of plastic and correspondent characteristics, common uses and utility after recycling.

Abbreviation	Full name	Characteristics	Commonly used in	Utility after recycling
PET	Polyethylene terephthalate	Infinitely recyclable, thermoplastic	Drinking bottles, food packaging	Carpet fibre, fabric, diverse accessories, cleaning product's package, brooms
PEAD (HDPE)	High density polyethylene	Light, sturdy, waterproof, very versatile	Liquid cleaning products, sanitary products, telecommunications products	Cleaning product's bottles, motor oil, sewage pipe, urban furniture
PVC	Polyvinyl chloride	High density material, very sturdy, thermoplastic	Window rails, pipes, toys, hoses	Water hose, sewage pipe, traffic cones, cables
PEBD (LDPE)	Low density polyethylene	Light, flexible, waterproof, cheap	Flexible packaging of food, cosmetics, bags and agriculture materials, cling film	Envelopes, films, plastic bags, garbage bags, irrigation pipes
PP	Polypropylene	Light, waterproof, thermoplastic	Airtight food packaging, medical syringes, tampons, carpet and upholstery fibre	Boxes and cables for car batteries, brooms, brushes, oil funnel, boxes, trays
PS	Polystyrene	Light, thermoplastic	Single use objects (like cups or food trays), toys, household appliances	Thermal insulation boards, office supplies, trays
Mixed	Combined plastics for specific electronic or engineering components.			Non-recyclable

Source: adapted by the author from Coca-Cola (2018) e eCycle (2013).

Annex XII – Characteristics of the Website Server

Storage	
Plan's name	Startup
Capacity	15 GB SSD PRO
No of websites	1
MySQL Databases	15
E-mails	Unlimited
Monthly traffic	Unlimited
Memory	1 vCPU/768MB RAM
Backup	30 days
Online Store	
Plan's name	Business
Capacity	10 000 products
Languages	2
Payment methods	ATM reference, Bank transfer, PayPal
Product attributes	1 000
Client's data	Possibility to import/export the data to csv. file
Orders	Possibility to import/export the data to txt. file
Other features	Discount coupons, search suggestions, 1 000 pages/categories
Compatible with	Amazon, Ebay, AppStore

Source: Adapted from Dominios.pt (2019)

Annex XIII – Threshold limit to the application of VAT of the origin country in Intra-Community sales

Country	National Coin	Equivalent in euros
Austria	35 000 EUR	
Belgium	35 000 EUR	
Bulgaria	70 000 BGN	35 791 EUR
Cyprus	35 000 EUR	
Czech Republic	1 140 000 CZK	44 873 EUR
Germany	100 000 EUR	
Denmark	280 000 DKK	37 595 EUR
Estonia	35 000 EUR	
Greece	35 000 EUR	
Spain	35 000 EUR	
Finland	35 000 EUR	
France	35 000 EUR	
Croatia	270 000 HRK	36 291 EUR
Hungary		35 000 EUR
Ireland	35 000 EUR	
Italy	35 000 EUR	
Lithuania	35 000 EUR	
Luxemburg	100 000 EUR	
Leetonia	35 000 EUR	
Malta	35 000 EUR	
Netherlands	100 000 EUR	
Poland	160 000 PLN	37 859 EUR
Portugal	35 000 EUR	
Romania	118 000 RON	25 305 EUR
Sweden	320 000 SEK	31 390 EUR
Slovakia	35 000 EUR	
Slovenia	35 000 EUR	
United Kingdom	70 000 GBP	80 197 EUR

Source: Translated from Europa.EU (2018)

Annex XIV – Calculations for the obtainable market value

Recurrence of vaginal infections	Importance given to measuring the vaginal pH (4 very important; 1 not important)	Method chosen for regular measurement	Number of answers
		Subtotal	22
Have about 2 to 3 a year	1	Electronic device	2
	3	Electronic device	2
	4	Electronic device	10
		Universal pH test strips	4
		Vaginal pH self-measuring test	4
		Subtotal	10
Usually have at least 4 a year	2	Electronic device	1
	3	Universal pH test strips	1
	4	Electronic device	7
		Vaginal pH self-measuring test	1
Total			32

Data from the market survey, organized to give the value of women with regular vaginitis who give importance to the pH measurement and chose the electrical device.

Source: Author.

SOM - Service Obtainable Market	
1- Women who have regular vaginitis	32
2- Women who give importance of 3 or 4 to the measurement of pH	29
3- Women who chose the electronic device	19
Women with regular vaginitis who give importance to the pH measurement and choose the electrical device (=3/1)	59,4%

Service Obtainable Market (SOM) calculations. Percentage of women who give importance to the pH measurement and choose the electrical device from the total of women who have regular vaginitis. Source: Author

Annex XV– Supporting Maps for the Economic and Financial Evaluation

Staff								
STAFF SALARY	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
TOTAL	-	4.850	19.200	19.200	19.200	19.200	19.200	19.200
Working months								
Marketing	1	5	12	12	12	12	12	12
Manager/Owner	1	2	12	12	12	12	12	12
Base Salary								
Marketing	700	3.500	8.400	8.400	8.400	8.400	8.400	8.400
Manager/Owner	900	1.350	10.800	10.800	10.800	10.800	10.800	10.800
With subsidies								
Marketing	817	4.083	9.800	9.800	9.800	9.800	9.800	9.800
Manager/Owner	1.050	1.575	12.600	12.600	12.600	12.600	12.600	12.600

	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Total Salaries	-	4.850	19.200	19.200	19.200	19.200	19.200	19.200
Vacancy allowance	-	808	3.200	3.200	3.200	3.200	3.200	3.200
Total annual salary	-	5.658	22.400	22.400	22.400	22.400	22.400	22.400
Food Allowance	-	651	2.404	2.404	2.404	2.404	2.404	2.404
Accident Insurance	-	85	336	336	336	336	336	336
Social Security (SS) Employer	-	1.344	5.320	5.320	5.320	5.320	5.320	5.320
Total charges with employees	-	2.080	8.060	8.060	8.060	8.060	8.060	8.060
Total staff charges	-	7.738	30.460	30.460	30.460	30.460	30.460	30.460
SS Employee	-	534	2.112	2.112	2.112	2.112	2.112	2.112
IRS retention*	-	180	431	431	431	431	431	431
	-	184	1.474	1.474	1.474	1.474	1.474	1.474
Total charges with employees	-	897	4.017	4.017	4.017	4.017	4.017	4.017

*According to Taxrates (IRS) tables for the Portugal (continent) 2019

Total staff charges (resume)	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Remuneration		6.394	25.140	25.140	25.140	25.140	25.140	25.140
Charges on remuneration		2.241	9.337	9.337	9.337	9.337	9.337	9.337
Total staff charges		8.636	34.477	34.477	34.477	34.477	34.477	34.477
Payment to the employee	-	6.394	25.140	25.140	25.140	25.140	25.140	25.140
Employee cost for the entity	-	7.738	30.460	30.460	30.460	30.460	30.460	30.460

Costs Breakdown									
A - App									
TOTAL		Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
		6.000	1.749	1.899	1.899	1.899	1.899	1.899	1.899
Developer account registration			199	99	99	99	99	99	99
Google Playstore	25		25						
Apple App Store	99		99	99	99	99	99	99	99
Windows Phone Store	75		75						
Upload app	-								
FireBase Database Server (DBaaS)	25	-	50	300	300	300	300	300	300
Programmer	500	6.000	1.500	1.500	1.500	1.500	1.500	1.500	1.500
W- Website									
TOTAL	monthly	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
		-	125	300	300	300	300	300	300
Domain (Website + E-mail)	9		45	108	108	108	108	108	108
Online store	16		80	192	192	192	192	192	192
Website storage	2		10	25	25	25	25	25	25
C - Consulting									
TOTAL		Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
		50.000	- €	- €	- €	- €	- €	- €	- €
Product Design		20.000							
Testing									
Molds (prototype)		30.000							
P - Production									
TOTAL		Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
		-	37.131	44.389	80.259	92.930	112.451	166.193	165.092
Clinical tests			30.000						
Production, assembly and packing	42,26	-	7.131	44.389	80.259	92.930	112.451	136.193	165.092
Molds		-	-	-	-	-	-	30.000	-
L - Logistics									
TOTAL		Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
		-	1.707	10.624	19.209	22.242	26.914	32.596	39.513
Transport	0,11	-	19	120	218	252	305	370	448
Storage + stock maintenance + labelling	10,00	-	1.687	10.504	18.991	21.990	26.609	32.227	39.065
Distribution		-	244	8.123	17.789	21.804	26.735	32.794	40.240
M- Marketing budget									
TOTAL		Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
		-	90	230	230	230	230	230	230
Instagram sponsored post	30 €-100 €		90	180	180	180	180	180	180
Google Ads	50 €-200 €			50	50	50	50	50	50
Press Publication	4.000 €								

Supplies and Services									
	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	
TOTAL	28.460	53.104	66.841	120.461	140.180	169.303	204.787	248.082	
F Office	300	375	480	480	480	480	480	480	Others
F R&D		500	500	500	500	500	500	500	
F Programmer	6.000	1.500	1.500	1.500	1.500	1.500	1.500	1.500	App
F Developer accounts	-	199	99	99	99	99	99	99	
V Database Server (DBaaS)	-	50	300	300	300	300	300	300	
F Website + E-mail address domain	-	45	108	108	108	108	108	108	Website
F Online store	-	80	192	192	192	192	192	192	
F Website storage	-	10	25	25	25	25	25	25	
F Product Design	20.000	-	-	-	-	-	-	-	Consulting company
F Testing									
F Clinical tests	-	30.000	-	-	-	-	-	-	Production
V Production, assembly and packing	-	7.131	44.389	80.259	92.930	112.451	136.193	165.092	
V Transport	-	19	120	218	252	305	370	448	
V Storage + stock maintenance + labelling	-	1.687	10.504	18.991	21.990	26.609	32.227	39.065	Logistics
V Distribution	-	244	8.123	17.789	21.804	26.735	32.794	40.240	
F Legal	2.160	11.263	500	-	-	-	-	32	Legal
F Patent (total)	-	263	-	-	-	-	-	32	
F Provisional patent (online)		11							
F Utility Model		107						32	
F Exam		81							
F International patent request		65							
F Lawyer	500	1.000	500						
F Freedom to Operate	1.300								
F CE mark		10.000							
F Company name registration	360								
TOTAL excluding production	28.460	45.972	22.451	40.202	47.249	56.852	68.594	82.989	
TOTAL fixed costs	28.460	43.972	3.404	2.904	2.904	2.904	2.904	2.936	
TOTAL variable costs	-	9.132	63.437	117.557	137.276	166.399	201.883	245.146	

F - Fixed cost; V - Variable cost

Investments								
	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
TOTAL	30.000	350	350	350	350	350	30.350	350
T Office supplies		350	350	350	350	350	350	350
T Molds (prototype)	30.000	-	-	-	-	-	-	-
T Molds (production)	-	-	-	-	-	-	30.000	-
TOTAL intangible assets	-	-	-	-	-	-	-	-
TOTAL tangible assets	30.000	350	350	350	350	350	30.350	350

T - Tangible; I - Intangible

Logistics

Support for logistics calculations		Logistics budgets with costs		Merkur	Shiptimize	(operators)
1 box size (cm)	18x13x7	1 box Transport cost (70€+VAT/m³)		0,11 €		
1 box volume (cm³)	1.638	Shipment of 30 boxes per month		3,44 €	29,93 €	UPS
1 box volume (m³)	0,00164	Storage+handling		300,00 €		
Average weight (gr)	500	Per delivery	Distribution PT (continent)		3,37 €	GLS
			Distribution PT (islands)		10,44 €	UPS
			Distribution EU (Spain)		4,61 €	GLS 72h
			Distribution EU (Rest)		13,47 €	DHL

Geographic sales distribution	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
In %								
Portugal		100%	51,04%	32,81%	31,38%	29,99%	28,64%	27,32%
PT (continent)	99%	100%	99,00%	99,00%	99,00%	99,00%	99,00%	99,00%
PT (islands)	1%		1,00%	1,00%	1,00%	1,00%	1,00%	1,00%
Europe		0%	48,96%	67,19%	68,62%	70,01%	71,36%	72,68%
EU (Spain)	2%		2,00%	2,00%	2,00%	2,00%	2,00%	2,00%
EU (Rest)	98%		98,00%	98,00%	98,00%	98,00%	98,00%	98,00%
Total		0%	100%	100%	100%	100%	100%	100%
In distribution costs								
Portugal (units)		72	502	580	671	776	897	1037
PT (continent)	3,37 €	244 €	1.674 €	1.936 €	2.238 €	2.588 €	2.992 €	3.460 €
PT (islands)	10,44 €	- €	52 €	61 €	70 €	81 €	94 €	108 €
Europe (units)		0	481	1188	1467	1810	2235	2759
EU (Spain)	4,61 €	- €	44 €	110 €	135 €	167 €	206 €	254 €
EU (Rest)	13,47 €	- €	6.353 €	15.684 €	19.360 €	23.899 €	29.502 €	36.418 €
Total	- €	244 €	8.123 €	17.789 €	21.804 €	26.735 €	32.794 €	40.240 €
In sales volume								
Portugal (units)		72	502	580	671	776	897	1037
PT (continent)	84,52 €	6.112 €	41.983 €	48.544 €	56.131 €	64.903 €	75.046 €	86.775 €
PT (islands)		- €	424 €	490 €	567 €	656 €	758 €	877 €
Europe (units)		0	481	1188	1467	1810	2235	2759
EU (Spain)		- €	814 €	2.008 €	2.479 €	3.060 €	3.778 €	4.664 €
EU (Rest)		- €	39.862 €	98.413 €	121.483 €	149.962 €	185.118 €	228.515 €
Total	- €	6.112 €	83.082 €	149.455 €	180.660 €	218.581 €	264.700 €	320.830 €

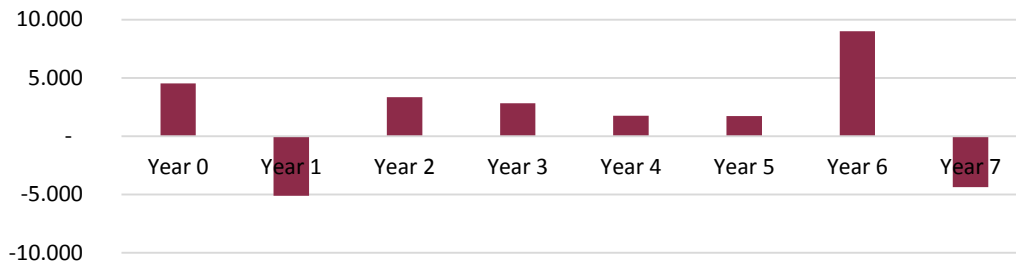
Inventory

Pack - Final product inventory	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Initial inventory			96	164	295	356	431	522
Production		169	1.050	1.899	2.199	2.661	3.223	3.907
Sales		72	983	1.768	2.137	2.586	3.132	3.796
Final inventory		96	164	295	356	431	522	633
Final inventory (€)	-	4.075	6.923	12.455	15.055	18.215	22.058	26.736

Working Capital

	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Clients (with VAT)	-	182	2.592	4.744	5.742	6.957	8.435	10.236
Inventory	-	4.075	6.923	12.455	15.055	18.215	22.058	26.736
VAT to recover	7.445	1.064	877	1.502	1.694	2.025	9.328	2.921
Ciclical Needs	7.445	5.321	10.392	18.701	22.491	27.196	39.822	39.893
Suppliers (incl. production)	2.917	5.443	6.851	12.347	14.368	17.354	20.991	25.428
State + VAT to pay	-	448	778	778	778	778	778	778
Ciclical Resources	2.917	5.891	7.629	13.125	15.147	18.132	21.769	26.207
Working capital needs	4.528	-	570	2.763	5.575	7.344	18.053	13.687
WC variation	4.528	-	5.099	3.333	2.812	1.769	8.988	-

WC variation



Average payment periods	In months	Times/year
Suppliers payment	1	12
Receipt term	0,25	48
Stock	2	6
Estate	1	12

State + VAT

State TOTAL	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
SS	-	375	619	619	619	619	619	619
IRS	-	73	159	159	159	159	159	159
VAT -	7.445	- 1.064	- 877	- 1.502	- 1.694	- 2.025	- 9.328	- 2.921
Inflow	7.445	1.064	877	1.502	1.694	2.025	9.328	2.921
Outflow	-	448	778	778	778	778	778	778
Total	7.445	616	99	724	915	1.247	8.550	2.143
State - to receive	7.445	616	99	724	915	1.247	8.550	2.143
State - to pay	-	-	-	-	-	-	-	-

VAT	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Sales	-	1.630	23.264	42.580	51.539	62.439	75.709	91.877
Production	-	1.640	10.210	18.460	21.374	25.864	31.324	37.971
Supplies and Services	6.546	10.574	5.164	9.247	10.867	13.076	15.777	19.088
Investments	6.900	81	81	81	81	81	6.981	81
Inflow	-	1.630	23.264	42.580	51.539	62.439	75.709	91.877
Outflow	13.446	12.294	15.454	27.787	32.322	39.020	54.082	57.139
Total (inflow-outflow) -	13.446	- 10.664	7.810	14.793	19.217	23.419	21.628	34.737
VAT to receive	13.446	10.664	-	-	-	-	-	-
VAT to pay	-	-	7.810	14.793	19.217	23.419	21.628	34.737

VAT (with payment periods)	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Clients	-	34	485	887	1.074	1.301	1.577	1.914
Suppliers (incl. production)	545	1.018	1.281	2.309	2.687	3.245	3.925	4.755
Investment	6.900	81	81	81	81	81	6.981	81
Inflow	-	34	485	887	1.074	1.301	1.577	1.914
Outflow	7.445	1.098	1.362	2.389	2.767	3.325	10.906	4.835
Total (inflow-outflow) with payment period	- 7.445	- 1.064	- 877	- 1.502	- 1.694	- 2.025	- 9.328	- 2.921
VAT to receive	7.445	1.064	877	1.502	1.694	2.025	9.328	2.921
VAT to pay	-	-	-	-	-	-	-	-

Amortization and Depreciation

Molds	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Production	-	169	1.050	1.899	2.199	2.661	3.223	3.907
Production accum	-	169	1.219	3.118	5.317	7.978	11.201	15.107
Depreciation rate	0,00%	1,69%	10,50%	18,99%	21,99%	26,61%	32,23%	39,07%
Depreciation	-	506	3.151	5.697	6.597	7.983	9.668	11.720
Reinvestment	-	-	-	-	-	-	30.000	-
Residual value	30.000	29.494	26.343	20.645	14.048	6.066	26.398	14.678

Note: Depreciation is based on the production. 10 000 units are considered the maximum limits of the mold, which only has one injecton cavity.
Depreciation rate is based on production 10.000 units = 100%

Reinvestment in Molds

Molds (prototype)	30.000	-	-	-	-	-	-	-
Molds (production)	-	-	-	-	-	-	30.000	-

Office supplies	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Value of annual investments	-	350	350	350	350	350	350	350
Depreciation rate	100%	100%	100%	100%	100%	100%	100%	100%
Depreciation	-	350	350	350	350	350	350	350
Residual Value	-	-	-	-	-	-	-	-

Total dep	-	856	3.501	6.047	6.947	8.333	10.018	12.070
Total reinvestment	30.000	350	350	350	350	350	30.350	350

Goingconcern Value

NOPLAT	97.405
g	7,81%
rP	8,98%
WACC	10%
Investment	30.350
Goingconcern Value w/ WACC	5.987.846
Goingconcern Value w/ rP	9.174.856

Financial Plan									
Money origins	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	
EBITDA	- 28.460	- 44.350	14.634	50.361	63.734	83.121	106.700	135.367	
Capital for constitution of the firm	5.000								
Obtained fundings (Equity=share issue)	62.988	30.350							
Working Capital Desinv.	-	5.099	-	-	-	-	-	-	4.366
Application recovery		5.013	-	4.857	45.921	87.380	142.713	176.261	
Financial income		13	-	12	115	218	356	440	
Total from origins	39.528	- 3.877	14.634	55.230	109.770	170.719	249.769	316.433	
Money applications	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	
Investment CAPEX	30.000	350	350	350	350	350	30.350	350	
Working Capital Inv.	4.528	-	3.333	2.812	1.769	1.720	8.988	-	
Tax on profit payment	-	-	-	2.318	9.332	11.995	15.826	20.470	
Dividends payment	-	-	-	2.616	10.532	13.537	17.861	30.803	
Equilibrium loan reimbursement	-	-	4.458	-	-	-	-	-	
Interest from equilibrium loan		-	109	-	-	-	-	-	
Total from applications	34.528	350	8.250	8.095	21.983	27.603	73.025	51.623	
Annual treasury balance	5.000	- 4.227	6.384	47.134	87.786	143.116	176.744	264.810	
Cash and Banks BOY		-	122	1.662	2.989	3.613	4.372	5.294	
Safety treasury reserve	-	122	1.662	2.989	3.613	4.372	5.294	6.417	
Potential balance	5.000	- 4.227	6.506	48.796	90.776	146.729	181.115	270.104	
Difference	5.000	- 4.349	4.845	45.807	87.162	142.357	175.821	263.688	
Balance to be financed	-	4.349	-	-	-	-	-	-	
Balance for application	5.000	-	4.845	45.807	87.162	142.357	175.821	263.688	
Application interest	13	-	12	115	218	356	440	659	
Final application	5.013	-	4.857	45.921	87.380	142.713	176.261	264.347	
Loan to request		4.458	-	-	-	-	-	-	
Loan interest		109	-	-	-	-	-	-	
Cash and Banks EOY	-	122	1.662	2.989	3.613	4.372	5.294	6.417	
APR Loans		5%							
APR Applications		1%							

Balance Sheet								
	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
ASSETS								
Non-current Assets								
Fixed Tangible Assets	30.000	30.350	30.700	31.050	31.400	31.750	62.100	62.450
Intangible Assets	-	-	-	-	-	-	-	-
Depreciation and Amortization	-	856	4.357	10.405	17.352	25.684	35.702	47.772
Total Non-current Assets	30.000	29.494	26.343	20.645	14.048	6.066	26.398	14.678
Current Assets								
Inventory	-	4.075	6.923	12.455	15.055	18.215	22.058	26.736
Accounts receivable short-term								
Clients	-	182	2.592	4.744	5.742	6.957	8.435	10.236
Others								
State	7.445	1.064	877	1.502	1.694	2.025	9.328	2.921
Total Accounts receivable ST	7.445	1.246	3.469	6.246	7.436	8.981	17.763	13.158
Cash and Bank Accounts	-	122	1.662	2.989	3.613	4.372	5.294	6.417
Financial Applications	5.013	-	4.857	45.921	87.380	142.713	176.261	264.347
Deferrals								
Total Current Assets	12.458	5.443	16.911	67.611	113.484	174.281	221.377	310.657
TOTAL ASSETS	42.458	34.937	43.253	88.257	127.533	180.347	247.774	325.335
EQUITY								
Capital for constitution of the firm	5.000	5.000	5.000	5.000	5.000	5.000	5.000	5.000
Share issue	62.988	93.338	93.338	93.338	93.338	93.338	93.338	93.338
Reserves and retained Earnings		- 28.448	- 73.750	- 67.647	- 43.072	- 11.485	30.190	76.394
Current Year Retained Net Income	- 28.448	- 45.303	6.103	24.575	31.587	41.675	46.204	58.964
TOTAL EQUITY	39.541	24.588	30.691	55.266	86.854	128.529	174.733	233.696
DEBT								
Total Non-current Debt	-	-	-	-	-	-	-	-
Current Debt								
Suppliers	2.917	5.443	6.851	12.347	14.368	17.354	20.991	25.428
State and Other Public Entities	-	448	778	778	778	778	778	778
Funding								
Bank Loan	-	-	-	-	-	-	-	-
Equilibrium Loan	-	4.458	-	-	-	-	-	-
Dividends to pay	-	-	2.616	10.532	13.537	17.861	30.803	39.309
Taxes to pay	-	-	2.318	9.332	11.995	15.826	20.470	26.123
Total Current Debt	2.917	10.349	12.562	32.990	40.679	51.818	73.042	91.639
TOTAL DEBT	2.917	10.349	12.562	32.990	40.679	51.818	73.042	91.639
TOTAL DEBT + EQUITY	42.458	34.937	43.253	88.257	127.533	180.347	247.774	325.335

Project's viability				
	NPV with rP	105.184	122.893	Healthcare Products (left) and Healthcare Information and Technology (right)
	NPV with WACC	99.468	115.501	
	NPV with rE	67.985	86.121	

	IRR	27%	>1, so it will generate profit of 1,67€ for each euro invested 4 years 1 months and 5 days 4 years 7 months and 24 days By setting the NPV=105.184€ to zero
	Profitability Index	2,67	
	Pay Back Period (accounting)	4,10	
	Discounted Pay Back Period (finance)	4,65	
	Sales break-even point	70,35 €	

Valuation Models								
	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Invested Capital (asset view)	34.528	28.923	29.106	26.221	21.393	15.130	44.451	28.365
Invested Capital (resource view)	34.528	28.923	29.106	26.221	21.393	15.130	44.451	28.365
Return on Invested Capital (ROIC)	-82%	-156%	30%	134%	210%	390%	172%	343%
EVA MODEL								
Spread (ROIC-WACC)	-92%	-166%	21%	124%	200%	381%	162%	334%
Economic Value Added (EVA)	-31.775	-47.984	6.000	32.490	42.808	57.630	72.111	94.681
Market Value Added (MVA)	5.473.164							
FCFF MODEL								
	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
FCFF	-62.988	-39.602	8.612	37.893	49.690	65.345	47.058	113.490
EV	6.575.864							
Firm Value	6.580.877							
EQV	6.580.877							
FCFEMODEL								
	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Free Cash Flow to Equity (FCFE)	-52.627	-32.266	10.749	58.421	57.642	76.937	68.910	132.955
Debt variation	10.349	7.432	2.213	20.428	7.689	11.139	21.223	18.597
Discounted FCFE	129.655							
EQV	1.112.919							

Performance indicators								
	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Profitability								
Return on Sales (ROS)		-740%	13%	30%	31%	34%	37%	38%
ROIC	-82%	-156%	30%	134%	210%	390%	172%	343%
Cash ROIC	-82%	-149%	37%	112%	134%	165%	108%	144%
Gross ROA	-67%	-129%	26%	50%	45%	41%	39%	38%
Net ROA	-67%	-130%	20%	40%	35%	33%	31%	30%
ROE	-72%	-184%	28%	64%	52%	46%	44%	42%
Tax effect	99,956%	100,21%	99,13%	100,29%	100,59%	100,77%	100,82%	100,89%
ROE without tax effect	76%	120%	85%	37%	16%	5%	15%	6%

Risk								
	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Degree of Operational Leverage	0,00	-0,14	3,90	1,77	1,62	1,49	1,40	1,33
Degree of Financial Leverage	1,00	1,00	1,01	1,00	0,99	0,99	0,99	0,99
Degree of Capital Leverage	0,00	-0,13	3,93	1,77	1,61	1,48	1,38	1,32
Turnover	0%	20%	234%	210%	176%	151%	133%	123%

Others								
	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Financial Autonomy	93%	70%	71%	63%	68%	71%	71%	72%
General liquidity	427%	53%	135%	205%	279%	336%	303%	339%
Times Interest Earns (TIE)	2277	-470	115	-350	-171	-130	-122	-112

Sensitivity Analysis

Sensitivity of NPV to changes of 10% on the production cost and selling price

	105.184	34	38	42	46	51
68		45.062	17.196	-14.297	-45.790	-80.432
76		101.269	73.541	42.732	11.739	-22.903
85		163.720	135.993	105.184	74.376	40.486
93		226.172	198.445	167.636	136.828	102.938
102		294.869	267.142	236.333	205.525	171.635

Sensitivity of Goingconcern value, NPV, IRR and PI to 10% changes on the Market average growth rate

	Goingconcern Value	NPV	TIR	Profit. Index
Average market growth rate	5.987.846	105.184	27,3%	2,67
4,15%	834.449	29.906	15,9%	1,47
4,61%	1.007.570	38.165	17,5%	1,61
5,13%	1.249.433	47.655	19,2%	1,76
5,70%	1.604.325	58.601	21,1%	1,93
6,33%	2.577.388	73.237	22,9%	2,16
7,03%	3.672.189	87.971	25,0%	2,40
7,81%	5.987.846	105.184	27,3%	2,67
8,60%	12.247.809	123.321	29,5%	2,96
9,46%	156.067.486	144.388	31,9%	3,29

Continuity as a function of the growth rate

	Goingconcern Value (WACC)	Goingconcern Value (rP)
g rate	5.987.846	9.174.856
6,33%	2.807.808	3.998.967
7,03%	3.465.868	5.467.091
7,81%	4.670.895	9.174.856
8,60%	7.123.476	27.937.009
9,46%	16.632.225	-22.776.834