UNIVERSIDAD DEL ROSARIO

EADA BUSINESS SCHOOL

AIRESS

Trabajo de Grado

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Rodrigo Muralles
Lorenzo Paolini
Paolo Figueroa

Barcelona, España

2020

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2020

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TABLE OF CONTENTS

TABLE OF FIGURES

TABLE INDEX

Glossary

Medical devices: an article, instrument, apparatus, or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting, or modifying the structure or function of the body for some health purpose. (Virta, 2022)

Airmony: device that helps people with sleeping apnea.

Sleep apnea: is a potentially serious sleep disorder in which breathing repeatedly stops and starts. (Mayo Clinic Staff, 2020)

First aid: basic medical treatment that is given to someone as soon as possible after they have been hurt in an accident or suddenly become ill. (Cambridge University Pres, 2022)

CPR maneuver: Cardiopulmonary Resuscitation is a lifesaving technique that is useful in many emergencies, such as a heart attack or near drowning, in which someone´s breathing or heartbeat has stopped.(Mayo Clinic Staff, 2020)

Cardiorespiratory arrest: is the cessation of adequate heart function and respiration and result in death without reversal.(Sharabi & Singh, 2021)

Ventilation: Rescue breathing can be mouth-to-mouth breathing or mouth-to-nose breathing if the mouth is seriously injured or can´t be opened (Mayo Clinic Staff, 2020).

Compression: use of hands to push down hard and fast in a specific way on the person´s chest.(Mayo Clinic Staff, 2020)

Defibrillator: are devices that restore a normal heartbeat by sending an electric pulse or shock to the heart, they are used to prevent or correct an arrhythmia, a heartbeat that is uneven or that is too slow or too fast. (National Heart, Lung, and Blood Institute, 2020)

Abstract

TBIOM is a Catalan start-up that offers high-tech medical devices. The company had already developed a successful device which is called Airmony and helps people with sleeping apnea. Now based on the technology of that device they are willing to enter new markets and one of them is the first aid market, with a device that helps paramedics and common people with the CPR maneuver. So TBIOM has decided to develop a new product called AIRESS, which intends to save the lives of people who are suffering cardiorespiratory arrest or cardiac arrest.

The main problem in this industry is that 90% of cardiac arrests that occur outside the hospital end in loss of life due to lack of training and First Aid Equipment. In Spain, ambulances can take about 10 minutes to arrive at the emergency site, while in the villages it takes much longer, and the survival ratio is 10%. The CPR maneuver consists of two parts, chest compressions, and ventilation, this process can be exhausting, emergency personnel and doctors can be forced to perform CPR for at least 35 minutes in patients suffering from cardiac arrest outside the hospital. In addition, it must also be considered that people during CPR may be uncomfortable doing mouth-to-mouth breathing ventilation.

The solution to this problem is to decrease the percentage of death from cardiac arrest with equipment easy to use, transportable, and hygienic. The product gives the necessary ventilation and will help the person who is doing the CPR to give the compressions at an adequate rate. There is not a product like AIRESS in the market and other products related to the CPR maneuver are too expensive and complicated to use.

Key words

Cardiopulmonary resuscitation (CPR), medical device, AIRESS, compressions, ventilation, cardiac arrest.

Resumen

TBIOM es una start-up catalana que ofrece dispositivos médicos de alta tecnología. La empresa ha desarrollado un dispositivo de éxito que se llama Airmony y ayuda a las personas con apnea del sueño. Ahora, basándose en la tecnología de ese dispositivo, están dispuestos a entrar en nuevos mercados y uno de ellos es el de los primeros auxilios, con un dispositivo que ayuda a los paramédicos y a la gente común con la técnica de RCP. Así que TBIOM ha decidido desarrollar un nuevo producto llamado AIRESS, el cual busca salvar la vida de las personas que sufren una parada cardiorrespiratoria o un paro cardíaco.

El principal problema de este sector es que el 90% de los paros cardíacos que se producen fuera del hospital acaban con la pérdida de la vida debido a la falta de formación y de equipos de primeros auxilios. En España, las ambulancias pueden tardar unos 10 minutos en llegar al lugar de la emergencia, y para llegar a los pueblos se tarda mucho más, y el ratio de supervivencia es del 10%. La maniobra de RCP consta de dos partes, compresiones torácicas y ventilación, este proceso puede ser agotador, el personal de emergencias y los médicos pueden verse obligados a realizar la RCP durante al menos 35 minutos en pacientes que sufren un paro cardíaco fuera del hospital. Además, también hay que tener en cuenta que las personas durante la RCP pueden sentirse incómodas al realizar la ventilación con respiración boca a boca.

La solución a este problema es disminuir el porcentaje de muertes por paro cardíaco con un equipo fácil de usar, transportable e higiénico. El producto proporciona la ventilación necesaria y ayudará a la persona que realiza la RCP a dar las compresiones a un ritmo adecuado. No existe

un producto como AIRESS en el mercado y otros productos relacionados con la maniobra de RCP son demasiado caros y complicados de usar.

Palabras Claves

Reanimación cardiopulmonar (RCP), dispositivo médico, AIRESS, compresiones, ventilación, paro cardíaco.

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TBIOM Medical Devices

EXECUTIVE SUMMARY

What is this project about?

TBIOM is a Catalan start-up that offers high-tech medical devices. The company had already developed a successful device which is called Airmony and helps people with sleeping apnea. Now based on the technology of that device they are willing to enter in new markets and one of them is the first aid market, with a device that helps paramedics and common people with the CPR maneuver. So TBIOM has decided to develop a new product called AIRESS, which intends to save lives of people who are suffering a cardiorespiratory arrest or cardiac arrest.

Problem

90% of cardiac arrests that occur outside the hospital end in loss of life due to lack of training and First Aid Equipment. In Spain, ambulances can take about 10 minutes to arrive at the emergency site, while in the villages it takes much longer, and the survival ratio is 10%.

The CPR maneuver consists in two parts, the chest compressions and the ventilation, this process can be exhausting, emergency personnel and doctors can be forced to perform CPR for at least 35 minutes in patients suffering from cardiac arrest outside the hospital (H et al., 1982). Also, normally two people who have knowledge of first aid should assist this maneuver and should be performed with a certain time sequence making it difficult to accomplish effective CPR. In addition, it must also be considered that people during a CPR may be uncomfortable to do mouth-to-mouth breathing ventilation.

Solution

Decrease the percentage of death from cardiac arrest with equipment easy to use, transportable, and hygienic. The product gives the necessary ventilation and will help the person who is doing the CPR to give the compressions at an adequate rate. There is not a product like AIRESS in the market and other products related to the CPR maneuver are too expensive and complicated to use.

Research

Interviews:

In general, all the people surveyed answered us that the product is a “nice to have”. Both doctors and nurses agreed that the product would be a good complement to the defibrillator and the characteristics that they valued the most are portability, which is easy to use and hygienic.

As for the use, they believe that anyone who is previously trained can perform the maneuver, without the need for additional help. The buyers said that if there is no law that forces you to have it in their facilities, they would not buy it. Furthermore, the probability of cardiac arrest emergencies is very low, based on their experiences in office. They agreed that it is important that the product is reliable, that it has certifications and a good price. They see it as interesting to prevent deaths and always be prepared.

Surveys:

According to the surveys to the target established in the first investigation, the results obtained were the following:

According to the selected positions, among the total of respondents, 53% of the Managers and 78% of the CEOs are willing to pay between 400 and 600 euros for a unit of AIRESS. We focus on Managers and CEOs specifically since these charges are those that will pay for the product.

Plus, in Spain, which will be the central country in the first five years of sales, people show that the probability of buying the product according to the price they chose is approximately 74%.

Regarding the potential target that we established and the probability of buying the product, the surveys show us that Mall Centers have a 50% probability of purchase, being the lowest percentage, Sports facilities 78%, retirement homes for the elderly 86%, and medical transport companies 88%.

Additionally, with the surveys, it was possible to observe an approximate size of the companies in number of people and the type of training they receive. In companies that have less than 50 people, between 50 and 100 and between 501 and 1000 people, the percentage of CPR training is more than half, being 55%, 83% and 60% respectively. While companies between 101-500, and more than 1,000 people present a lower percentage of training, being 30% and 50% respectively.

Market Opportunity

Through our primary and secondary research, we have concluded that our target is big enough to be profitable for AIRESS.

We obtained the potential market size of 98,118 units of AIRESS. Therefore, the market size is sufficient. In Spain, there is a law that requires places with an agglomeration of 500 people to

have a defibrillator. Considering the research, we carried out, in the interviews with doctors, everyone agreed that it would be a good complement to the defibrillator.

The targets are Spanish companies (defibrillator law) that have an agglomeration and want to prevent respiratory arrest accidents. Such as the Mall Centers due to the high amount of people that goes into these places, increasing the probability of having a cardiac arrest emergency, then other market could be ambulances that are always present at events with many people, the third target are the sports facilities due to the high level of physical activity that athletes have and 84% of non-traumatic deaths that happen are caused by a cardiovascular cause and the last target would be the retirement homes for the elderly where the risk of having a cardiac arrest is of 76% to people over 60 years old.

Financials

After the analysis and assumptions that we made for the project, we concluded that this project is viable.

In the last two years, TBIOM has had losses in their P&L because they have done a lot of research, so our analysis is based when the company is capable to reach the market with AIRESS. The price of the product is 600 € (VAT Inc.) and includes device, training, and maintenance.

The base scenario has shown successful results in terms of cash flow, P&L and Balance Sheet and all these give results of a good valuation of the company. Some results are shown in the graph below.

Tabla 1

Financial Results

	Year 1	Year 2	Year 3	Year 4	Year 5
Revenues	971,416 €	1,023,872 €	1,706,532 €	2,086,171 €	2,563,409 €
Net Income	-79,582 €	-66,400 €	106,707 €	166,509 €	253,323 €
Cash Flow	-87,652 €	262,217 €	570,701 €	1,038,844 €	1,572,668 €
Enterprise Value	*1,663,084 €*				

Source: Own elaboration – Final Project Team AIRESS

Recommendation

Product

AIRESS offers a unique value to the customer, but to ensure a good performance of the product, the user must be trained in the CPR maneuver.

Operations

TBIOM should have all the manufacturing and assembling outsourced. This will allow the company to focus on some key partners and increase the sales team quality inside the company to sell this product through the different targets selected.

Marketing mix

To increase the brand awareness and develop a long relationship with the customers, TBIOM should always increase their marketing budget according to sales and keep promoting the product through fairs, exhibitions, and digital channels.

The recommended price of the product is 600 € (VAT inc.) and this should include: training and maintenance.

Financials

The company should continue investing in R&D and innovation. To do this, they may invest the resulting cash in the balance or maybe could ask for more investors.

To become a profitable business and obtain a 21.4% of CAGR of sales, TBIOM should focus their investment for AIRESS in Spain, divided in five main regions: Catalunya, Madrid, Andalucía, Castilla y León y Valencia.

1. INTRODUCTION

1.1.PROJECT BACKGROUND

TBIOM is a Catalan start-up that offers high-tech medical devices. The company had already developed a successful device which is called Airmony and helps people with sleeping apnea. Now based on the technology of that device they are willing to enter new markets and one of them is the first aid market, with a device that helps paramedics and common people with the CPR maneuver. To analyze the potential of this new product and to develop a business plan this project starts.

This project came through by the cooperation of EADA Business School Barcelona and TBIOM. With this cooperation both parties have benefits, the start-up company with a high technical background can get an impressive business plan and alumni from EADA can put in practice their new theoretical knowledge of business into a real-life business environment.

1.2.PRODUCT INTRODUCTION

TBIOM is developing a new product called AIRESS which intends to save lives of people who are suffering a cardiorespiratory arrest or cardiac arrest. (See Exhibit 1 for differences

between cardiac arrest and heart attack.) This product is a complement for people who are doing the CPR maneuver. AIRESS is a device that helps the person who is doing the heart massage to give them the right air flow to the patient. In addition, AIRESS, thanks to a light that marks the blows that the person in charge of doing the heart massage must do. So, we can define it as an apparatus that helps both in the part of breathing and in the part of time of how to perform the massage, in which it gives the rhythm of the heart massage.

"The 2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care" increased the focus on methods to ensure that high-quality cardiopulmonary resuscitation (CPR) is performed in all resuscitation attempts. There are 5 critical components of high-quality CPR: minimize interruptions in chest compressions, provide compressions of adequate rate and depth, avoid leaning between compressions, and avoid excessive ventilation"(Meaney et al., 2013)

AIRESS will help with two of the 5 critical components mentioned before. The product will give the necessary ventilation and will help the person who is doing the CPR to give the compressions at an adequate rate.

More than 350,000 cardiac arrests occur outside of the hospital each year, which 18.8% OHCA in adults and 13.3% OHCA in children happen in public spaces, so this product is aimed to be in public spaces, to be able to prevent a respiratory attack. (Virani et al., 2020)

1.3.PURPOSE AND OBJECTIVE OF THE PROJECT, COMPANY, AND CUSTOMERS

The first objective of the project is to determine what type of users the product could be used by. In the market research, it will be validated if the use of the product will be exclusively for health professionals or ordinary people. Once these results are obtained, we can define the potential of the product in the market, which was B2B from the beginning and will not have variations.

After obtaining the results of the market, a comprehensive business plan will be proposed where marketing, operations, and management strategies will be proposed that will finally give a financial result.

2. MARKET ANALYSIS

2.1.COMPANY

2.1.1. Vision and mission

Vision

TBIOM´s vision is to focus on accelerating biotechnology and bioengineering projects with the aim to bring new progress to society while they guarantee profit for their investors.

Mission

TBIOM is a company that offers medical devices that contribute to improving people's health and quality of life in a sustainable way (Nordics, 2020).

2.1.2. Location, facilities, and resources

TBIOM has its headquarters located in Sant Adrià del Besòs (Barcelona), where they have specialized electronic equipment and a team of people who study, innovate, and develop products to improve biomedical respiratory health techniques.

2.1.3. Core values and purpose

The TBIOM values are the purposes that guide the attitudes of each collaborator and keep them linked to the common objectives established within the organization. On the other hand, these values are the maximum expression of TBIOM's mission and vision.

Innovation

TBIOM is a company willing to adopt changes when necessary and this availability to change, is defined as innovation, introducing new ideas and using technology to improve processes and offer new products that improve the quality of life and health of people, and at the same time, these actions generate a profit in the market.

Community

At TBIOM people work for the same objective, they share passions, ideas, wishes, respecting each member of the company and a communication environment is developed where each one gives the best of himself, which generates a maximum contribution and a social contribution.

Adaptability

We currently live in an environment that is continually changing, which is why at TBIOM the ability to adapt is essential, and changes are necessary and are part of the process of transformation and growth of the company because only through a renovation is continuous improvement guaranteed.

Diversity

At TBIOM, employee diversity is promoted, taking advantage of the talent of each individual and carrying out responsible management of human capital, guaranteeing equal opportunity, and thus achieving greater efficiency, innovation, access to new markets, and recruitment and retention of human talent. For the organization, proper diversity management allows turning differences into a source of opportunities.

2.1.4. Culture

Based on the vision and values that have and define the company, which is the axis for its growth, TBIOM builds its organizational culture where the effort of each worker is valued and direct contact with team members is maintained. On the other hand, by having specialists in each field such as electronics, mechanics, software, quality, among others; organizational and generational diversity is generated, which brings experience and enthusiasm to the company and this leads to generating new ideas, innovative proposals and with different points of view which adds value to creative processes and helps in decision making.

2.1.5. Company offering

TBIOM explores and studies the unmet needs in the respiratory health market and at the same time evaluates new biotechnology and bioengineering projects. Thus, offering disruptive, proven, and protected technology to deliver to the world and cover that space in the market satisfying the needs of people who suffer from respiratory problems and, also, facilitating techniques and procedures for all those who work in the health area.

2.1.6. Key to success

At TBIOM teamwork and the opinion of each person within the company is valuable. For them, taking risks seem it as opportunities for growth, without being afraid to try new things and fail, because each failure is a new learning and a step closer to reaching the established goal. That is why one of the phrases that represent the key to success for TBIOM is:

"Twenty years from now you will be more disappointed by the things that you didn't do than by the ones you did do. So, throw off the bowlines. Sail away from the safe harbor. Catch the trade winds in your sails. Explore. Dream. Discover."

Mark Twain

2.2.PRODUCT ANALYSIS

2.2.1. Applications

The main application for AIRESS is to provide a constant and enough supply of oxygen to the brain when someone is in the middle of cardiopulmonary resuscitation. This type of application is called Continuous Positive Airway Pressure (CPAP) and is used to help breathe a person and in the case of a CPR is to provide the oxygen needed along with the chest compressions.

2.2.2. Trends

In the field of medical devices, the innovations and changes in demand are constant and are something you cannot predict like in other industries due to the variety and unknown trends of diseases. However, as this year has shown, the trend for 2020 and next year will be devices related to breathing diseases. COVID-19 has shown the impact that a pandemic can have in the World and our limited healthy systems.

Related to CPR, there is a trend for a device that can perform the resuscitation and avoid the human error in these types of maneuvers. Some products look for the whole maneuver to be performed by a machine and others like AIRESS offer a product that is something complementary with the help of a person.

The use of new materials becoming more sustainable is a trend in almost industry and medical devices are part of it. New synthetic materials and the use of 3-D printers are already helping with the design and will become more important in the future to the manufacturing of new and better medical devices.

"Europe's elderly is projected to reach approximately 29% of the population by 2060, making it the world's oldest region" (Rajbhandary & McLeod, 2019). The tendency will be the same in other continents, life expectancy is higher each year and this affects the general demand of medical devices due to the risks of having more people exposed to different diseases.

2.2.3. Product development and lifecycle

The product development and lifecycle of medical devices are divided in five steps[1]. (See Figure 1)

Concept

The concept must be clear to start the process in the design of a medical device. It can start by using data and similar products in the market to improve the mechanism or also by the identification of a clinical need, for example, the COVID-19 pandemic that is moving the market towards the creation of new and better breathing apparatus. The point is to have the idea and fulfill the market needs.

Research and development

This phase gathers all the technical information about the product and to look at all the regulatory points to take in count related to the product. This phase is also about a deeper analysis of the competition and the market the product is aiming for. Part of this stage is for engineers and scientists develop different models and prototypes, all this to understand the technology and not violate any legal problem, for example a patent already designed. This phase helps to know which type of strategy the company will have with the product. Another important part of the strategy is to know the required investment, the company needs to know if they can get an external investment or sponsorship to finish the project.

Validation and regulatory approval

[1] Representation of the development process of medical devices in Europe. (Santos et al., 2012)

After the plan and the designs and prototypes, to reach this phase the product must be almost ended. The product is put to test with different trials, all this to determine if it works compared to previous results in the laboratory and ensure that the device is safe and effective. Also, as a medical device, it must accomplish any regulatory audit to be manufactured in a place. The last part after the technology is validated and before the launch, if it is possible the company needs to look for a patent to avoid competitors offering the same type of quality and technology in their products. This is something to keep a competitive advantage in the market.

Launch

After the product is validated and has passed all the trials, the product enters the launch stage. The device is offered to different possible buyers, like hospitals, doctors, clinics, governments, etc. This is to start positioning the product and see how the public reacts to the final product and in some companies also the brand if this is something new.

Update and improvements

Once the device is in the market, the company must control how the product is developing. Post-market activities divide into two categories:

Post Market Surveillance (PMS)

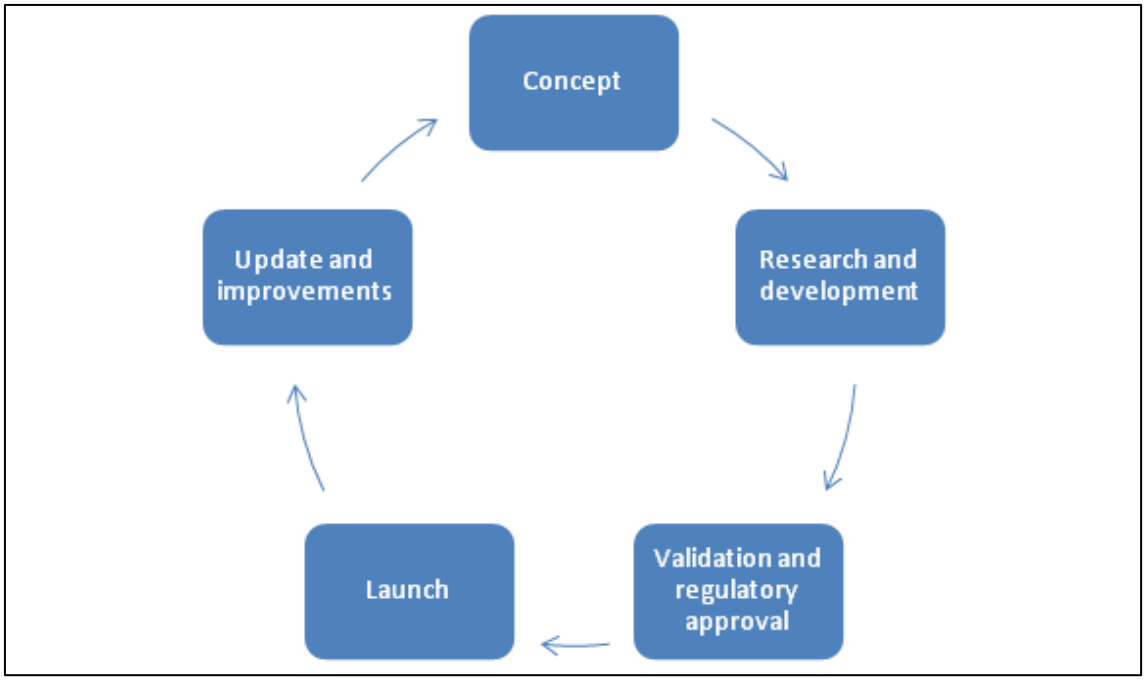
Vigilance

The first one is about the collection of data about the device in categories such as quality, performance, sales, and how the market is acting. The second part is the vigilance, focus on any trouble related to the device that may be caused an injury, any aggravation of the treated disease or injury, and in the worst-case scenario any death of a patient.

These activities allow the company and the R&D department to keep working in any improvement that the device needs, and the data collected may help to the development of new technology because in this field the change is constant, and technology tend to become obsolete faster.

Figure 1

Development Process of Medical Devices in Europe[2]



Source: EADA TBIOM TEAM

2.3.CONTEXTANALYSIS

[2] Stages of the medical device life cycle. (Guru, 2022)

2.3.1. PESTEL

Political factors

- European healthcare system:

According to the Thematic Factsheet Health System of the European Commission Healthcare[3] in Europe is provided through a wide range of different systems managed nationally, gives equal access to all its patients. Each country has solved its own way of organizing their insurance companies, doctors, and hospital systems. Many European countries (and all European Union countries) offer their citizens a European health insurance card which provides insurance for emergency medical care when they visit other participating European countries. Therefore, for the political part of this project, it will have to be analyzed the Spanish healthcare system as an example and have a vision of how other European countries can be analyzed.

- Spanish healthcare system

According to the Spain Health[4] system review of the European Observatory on Health System and Policies, Spain has both public and private healthcare systems. The public system provides free basic healthcare to those who contribute to the Spanish social security system and their families. The public system provides free healthcare for every citizen, including those from other EU countries. The Sistema Nacional de Salud is a national health system based on the principles of universality, free access, and equity of financing, and is mainly funded by citizens' taxes. It is organized at two levels, national and regional, and health competencies are transferred to the 17

[3] European semester thematic factsheet. (European Commision, 2017)
[4] (Bernal-Delgado et al., 2018)

Autonomous Communities. The Spanish healthcare system is a network made up of nearly 800 hospitals, which include public and private. The public system, since 2002, has a decentralized health system under national coordination, so this means that the organization and delivery of health services have been devolved to 17 regional health administrations. Each community organizations and finances by themselves through social security contributions that all Spanish citizens pay. Spain has made that autonomy of management involves the transfer of responsibility to hospitals and, therefore, each hospital has the autonomy to purchase all the tools and materials necessary to obtain better use of its resources. Subsequently, this autonomy creates inequalities between communities since the money is not distributed equally. Important variations arise across regions, not only in health spending but also in the supply of doctors and other health workers, health care activities, and waiting times. Nowadays in Spain, but as other European countries, it is facing privatization problems with some hospitals converting from the public to private, or facilitating private hospitals, which will increase problems in public health.

Economic factors

- European Economy

According to The Economy of the official website of the European Union, Europe is formed by 44 countries with 741 million people but operating as a single market with 27 countries (European Union, 2020), the EU is a major world trading power. EU economic policy focuses on creating jobs and increasing growth by making smarter use of financial resources and providing visibility and technical assistance to investment projects. In terms of GDP, the EU GDP is bigger than the US economy, considering that in 2017 was €15.3 trillion. The EU is one of the 3 largest

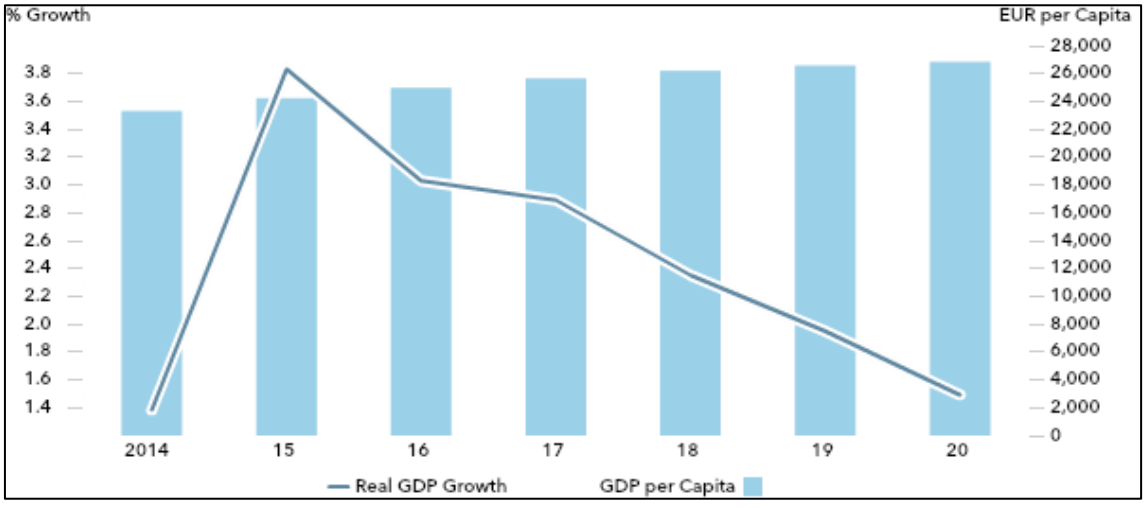
global players in international trade and EU countries had the second-largest share of global imports and exports of goods in 2016.

- Spanish Economy

According to the Spanish economic vision of the Euromonitor, Spain's economy will weaken in 2020. Gains in private final consumption will be subdued and domestic demand will remain the main driver of growth. Employment growth is projected to slow, but the unemployment rate is set to decline. The growth of real GDP will increase to 1.5% in 2021. The economy will decelerate in later years, falling to about 1.2% per year by 2027. Real GDP should increase by 1.5% after gains of 2.0% in 2019.

Figure 2

Real Spain GDP Growth and Per Capita GDP 2014-22



Source: (Euromonitor Internacional, 2020)

Following the economic crisis, health spending per capita in Spain decreased relative to the EU average. “In 2015 the health expenditure per capita has reached €2,374 (purchasing power parity), compared to the EU average of €2,797, and 9.2% as a share of GDP, also below the EU average of 9.9%. Around 71% of health spending in Spain is publicly funded, while out-of-pocket payments account for 24% of total health spending, a much higher share than the EU average of 15%.” (OECD & European Observatory on Health Systems and Policies, 2017)

- The global economy and COVID-19

According to the Spanish economic vision after the Covid-19 of the Euromonitor the economy was expected to grow at a similar rate in 2020 as in 2019. The COVID-19 disease caused by a new strain of coronavirus started rapidly rising in China and spreading around the world. These events resulted in disrupted supply chains, economies effectively shutting down for an indefinite period and financial markets panicking. In April 2020, a few months after the first reported cases, the global economy is expected to enter a recession. The COVID-19 pandemic has forced governments to quarantine entire countries, disrupted global supply chains, reduced business, and consumer confidence and affected financial markets (Stalenis et al., 2020). In this most extreme scenario Global GDP growth of -9.0% to -5.5% in 2020.

Social factors

- Europe

In October 2017, according to the European Resuscitation Council (ERC)[5], together with national resuscitation registries and resuscitation councils declared sudden OHCA is the third

[5] International European project. (European Resuscitation Council, 2022)

leading cause of death in industrialized nations. In Europe, more than 350,000 patients are affected every year. And 100.000 could be saved if lay resuscitation – giving chest-compressions immediately and before the arrival of the emergency medical services (EMS) – was improved all over Europe.

- Spain

According to the Spanish Society of Intensive, Critical Medicine and Coronary Units (SEMICYUC), every year around 30,000 people die in Spain due to cardiorespiratory arrest (Lourido, 2016). In many cases, death would have been preventable if someone had started a cardiopulmonary resuscitation (CPR) maneuver immediately in situ and had used a public defibrillator immediately. If the cardiac massage is started during the 4 minutes immediately after the cardiorespiratory arrest, the probability of the patient's survival increases in a situation in which a citizen had to initiate a resuscitation maneuver, which means that he knows how to act quickly and effectively is key.

Legal factors

- **Article 20**. Emergency measures.

According to Ley 31/1995, de 8 de noviembre, de prevención de Riesgos Laborales[6] of the BOE the entrepreneur, taking into account the size and activity of the company, as well as the possible presence of outsiders, must analyze possible emergency situations and adopt the necessary measures regarding first aid, firefighting and evacuation of the workers, appointing for it the personnel in charge of putting these measures into practice and periodically checking, if

[6] (*Ley 31 de 1995, de 8 de noviembre, de prevención de Riesgos Laborales.*, 2014)

appropriate, their correct operation. The personnel must have the necessary training, be sufficient in number, and have the appropriate material, depending on the circumstances. For the application of the measures adopted, the employer must organize the relationships that are necessary with services outside the company, particularly in first aid, emergency medical assistance, rescue, and firefighting, so that speed is guaranteed. and their effectiveness.

According to NTP 458[7]: Primeros auxilios en la empresa: organization of the Instituto Nacional de seguridad e higiene en el trabajo, one lifeguard for every 50 workers per shift (always considering the need for alternate lifeguards). This number should be considered as a minimum in all other situations. Sometimes it is desirable to have two lifeguards per workgroup (e.g., work with dangerous machines or tools).

According to Royal Decree 486/1997, de 14 de abril[8], por el que se establecen las disposiciones mínimas de seguridad y salud en los lugares de trabajo, of the BOE without prejudice to the provisions of the preceding sections, every workplace must have, as a minimum, a portable medicine cabinet that contains authorized disinfectants and antiseptics, sterile gauze, cotton wool, bandage, adhesive plaster, adhesive dressings, scissors, tweezers, and disposable gloves.

Workplaces with more than 50 workers must have a place for first aid and other possible health care. They must also have the workplaces of more than 25 workers for whom the labor authority so determines, taking into consideration the dangerous nature of the activity carried out and the possible difficulties of accessing the nearest medical assistance center.

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[7] (Solé Gómez & Moliné Marco, 1997)

[8] (*Real Decreto 486/1997, de 14 de abril, por el que se establecen las disposiciones mínimas de seguridad y salud en los lugares de trabajo*, 1997)

The first aid premises will have, as a minimum, a first-aid kit, a stretcher, and a source of drinking water. They will be close to the workstations and will be easily accessible for the stretchers.

Technological factors

There are several companies and startups that are developing new products in the field of CPR heart massage, for example like the ZOLL company with AutoPulse which provides uninterrupted high-quality CPR. According to ZOLL's self-animation system the resuscitation system provides high-quality mechanical CPR to sudden cardiac arrest victims. Easy to use and battery-powered, the AutoPulse system compresses the patient's entire chest to improve blood flow to the heart and brain(Zoll an Asahi Kasei company, 2020). Designed for patient handling and transportation by placing the stabilizing table of the AutoPulse resuscitation system on a soft stretcher or a transport sheet, rescuers can continue to practice high-quality CPR even while descending steep stairs, making tight turns, or in a tiny lift.

Environmental factors

The environmental effects of the AIRESS product will be limited as they affect a software program. The amount of energy used to run the software is close to zero compared to other energy consumers because a rechargeable battery is used.

Plus, after the coronavirus pandemic, there will be more controls on hygiene in all facilities and we will take better care of hygiene in general, therefore we will try to avoid contact with unknown people.

2.3.2. Porter's 5 Competitive Forces

The search for Porter's 5 forces will focus on the Healthcare Medical Devices industry.

Bargaining power of the buyers

- There are several options when offering this type of products. Like the example of AIRESS, the industry offers other options that can be used to help someone and treat any emergency or disease, so the buyers have various types of options depending on the budget they have and the level of preparation and qualification the people that will use the product. So, this creates a more competitive industry where each product differentiation and competitive advantage is helpful, all these factors, gives more power to the buyer.
- The client is not fully trained in this type of subject. In this industry, the buyer is not the final user of the product, thus in the moment of selling or offering a medical device, the buyer does not have a preparation to use the device. This gives more power to the seller; it means that this point is more in favor of the medical companies.
- Number of buyers within the Spanish health care equipment & supplies. The market is limited, this meaning that leading specialists are competing to assure purchases, so buyers hold a certain degree of power over market players.
- The implementation and effectiveness of this product could be important. As a product in the medical industry, the effectiveness is important because we are dealing with the life and wellness of a human being and any trouble related to the medical device will be crucial. This part gives more power to the buyer that will require different license and certifications that supports the product.

*These 4 insights give as a result a **medium** bargaining power of the buyer.*

The rivalry between competitors

- The health care equipment & supplies market is characterized by the presence of large-scale international specialists, increasing the level of rivalry. These companies are large and benefit from scale economies, meaning they can negotiate more intensely on price.
- Many players operate in a wide range of markets, this diversification reduces the company's dependence upon any one area of operations, reducing rivalry.
- There is a large and fragmented market with many products of different kinds. Medical devices industry is big and the variety results in a high competition between the companies where the differentiation in technology and certifications is important.
- A possible merger of another competitor product, this means that is a big industry and the budget each company has, at the end will have a bigger impact compared to other type of products. The more budget the company has, more will spend in research and development. This increases the competition because each new product that emerges in the market, is at greatest risk of being imitated.

*The last 4 points supports the conclusion that the rivalry between company is **high** in the medical devices industry.*

New entrant threats

- The investment required for the development of a medical device is high. The initial investment to start a medical devices company is high and requires a lot of knowledge and

time. To offer a final medical device the company must have different certifications that proves the product works and is an industry where the R&D budget cannot be limited.

- The technical knowledge and regulatory requirements for the approval of a medical product are more demanding compared to other industries. When a product has a direct impact in the life of a person it takes more importance, that is why the good manufacturing practices are more demanding, this part is key to have all the license to manufacture and will take time and money.

*In conclusion, the risk for a new entrant threat is **low** because not all the companies have the knowledge, facilities, certifications, and time to invest in this industry.*

The threat of substitute products

- Relatively high entry barrier to producing the device. The technology for each product in the medical devices industry normally involves a patent, these create a high barrier to produce a similar device.
- There are no viable alternatives to health care equipment and supplies due to their specialization.
- Large companies that are manufacturing respirators for COVID-19 could adapt them as CPR respirators. Due to the COVID-19 pandemic most of the companies are focused on the development of solutions and devices that can help the people affected by the virus. As the focus of the industry is on other type of products, the risk of substitute product can be affected by decreasing in the industry.

*These three points results as **low** risk for substitutes due to the specialized nature each healthcare equipment has.*

Bargaining power of suppliers

- There is a wide variety of suppliers and different types of products. The variety of products and suppliers in the industry is large, but at the same time each supplier can offer something different and specific to each product, this gives a high power of bargaining to the suppliers.
- There are many specific suppliers of specific materials. Suppliers are large companies that can negotiate in different terms, and in terms of price and supply are better positioned compared to the medical device's companies.
- Long-term contracts are made with suppliers, so the presence of contracts usually indicates penalties upon termination of a contract, imposing switching costs and increasing supplier power to some extent.
- Commodities can have various price fluctuations, which can adversely affect a company's profitability, therefore market participants can buy inputs on the open market, but by doing so they can lose control over prices.

*These four points results as **medium** risk for supplier power in this market.*

Conclusion: It is a profitable and saturated market. The success of companies depends on the level of investment in innovation and quality of their products.

2.4.CUSTOMERS

Emergencies are unexpected because we do not know when occurring. Therefore, we must be prepared for the correct performance at any time.

Firstly, possible emergency situations will be classified according to their severity:

Emergency classification[9]

- Emergency attempt:

An emergency that can be easily and quickly neutralized and controlled by the personnel, plus the means of protection available in the place where it occurs. In general, it does not require the evacuation of personnel from the affected area.

- Partial emergency:

An emergency that cannot be immediately controlled as an outbreak and requires the action of the sector's special emergency teams. The effects of the situation are limited to the sector where the emergency begins, without affecting the neighboring sectors or third parties. In general, it does not require the evacuation of the company, but only, and in any case, the affected sector.

- General emergency:

An emergency that exceeds the capacity of the human and material resources against fire and emergencies established in the industrial plant and requires the action of all the company's emergency teams and the help of rescue and rescue means outdoor. In general, it requires the general evacuation of the company in an orderly and controlled manner.

[9] (Remón, 2012)

2.4.1. Customer behavior

- Untrained people in medical services:

Confusion, anxiety, paralysis, hysterical screaming, and panic.

During emergency planning and protection, human behavior plays a critical role.

Most people have not had the experience of facing an imminently dangerous situation and when this occurs, some people make decisions that increase the danger for themselves and others. Thus, the behaviors that occur range from a calm attitude to real panic.

It seems a constant fact in the history of the major casualties that the fear of dying has suffered far more victims than the casualty itself. It is stated, for example, that in the event of a catastrophe of regular proportions, whatever its nature (fire, explosion, flood, etc.), panic causes more damage and casualties than the catastrophe itself.

- Trained people in medical services:

Leader, committed, calm, cautious, knowledge

They assess the patient to determine the type of assistance they need. When the situation cannot be resolved without the intervention of a doctor, the paramedic oversees stabilizing and transferring the patient to the hospital, while observing him during the trip.

They provide the patient with certain life-saving procedures to stabilize them, such as oxygen administration and cardiac defibrillation. Other specific tasks that these professionals can carry out are the supply of intravenous and oral medications, endotracheal intubation, the interpretation of electrocardiograms, and the practice of minor surgeries, as well as the use of equipment of

medium and high complexity. This shows that they must have a solid base of knowledge, both theoretically and practically.

- Buyers:

Warning, careful

The lives of many people are in the hands of the decisions of the owners of places with crowds of people or governments. Therefore, they must prevent emergency situations with all the necessary equipment and trained personnel. Otherwise, they can have a remarkably high fine and even go to jail.

2.4.2. Market needs

We live in a world where we all seek fast, effective, efficient, and practical responses. In emergency situations, the same applies, as well as equipment easy to use. Due to many small companies or startups, it is possible to achieve all this and at a competitive price. They need to have the equipment to feel safe and protected.

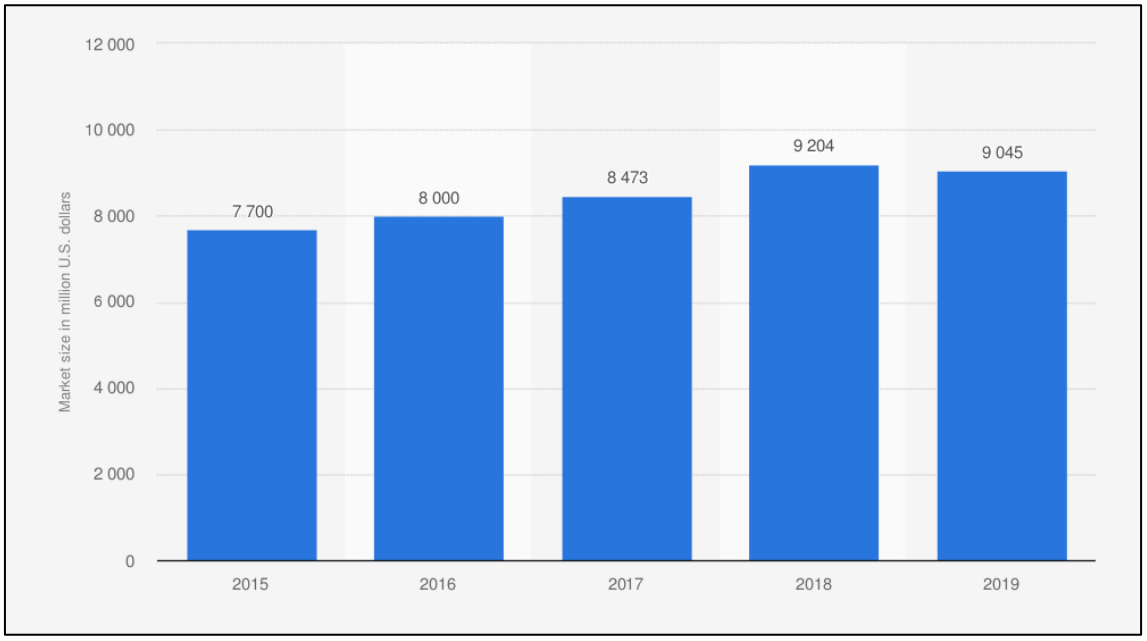
The market looks for disruptive technologies, that manage to be efficient and profitable.

2.4.3. Market trends

The size of the market for the medical technology industry in Spain is growing every year, that means an opportunity for TBIOM/AIRESS.

Figure 3

Market size of the medical technology industry in Spain from 2015 to 2019

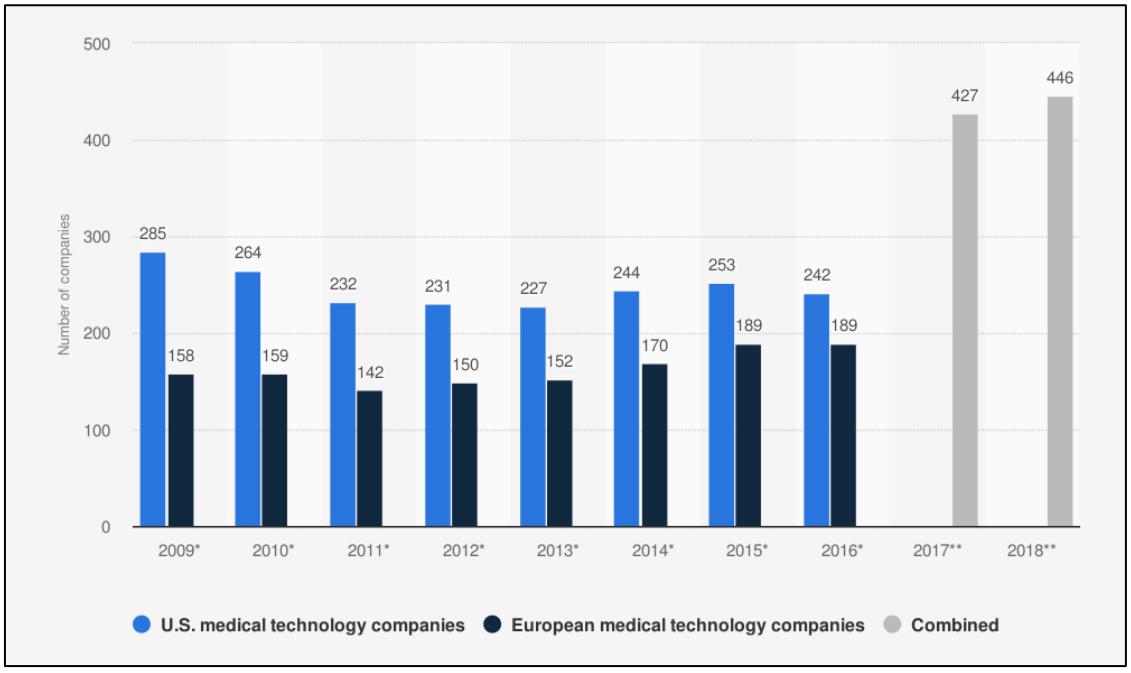


Source: (Statista, 2021)

The growth of medical technology companies is also on the rise, although it is slow, it is an important factor.

Figure 4

Number of U.S and European medical technology companies from 2009 to 2018



Source: (Statista, 2020b)

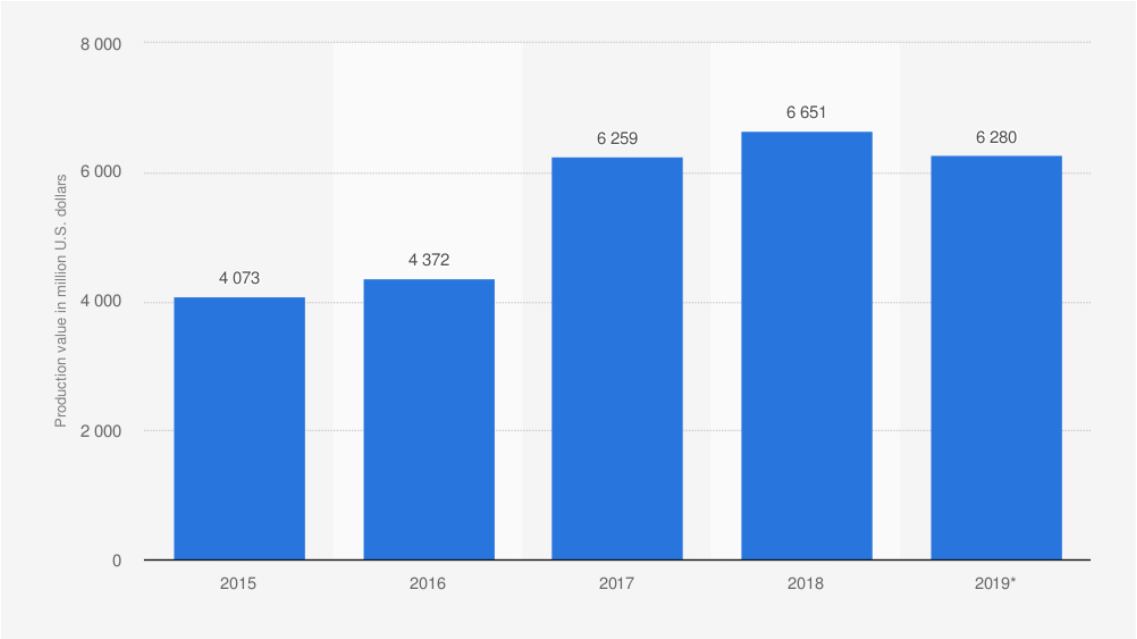
2.5.COMPETITORS

In this industry the investment and knowledge required are high. The market size of the medical technology industry in Spain has gone from 7.7 billion in 2015 to 9 billion U.S. dollars in 2019. The market is growing and there a lot of companies specialized in specific areas of the medical field, the technology is always changing, and these factors create a high competition where each product need to differentiate by the quality of their results. In terms of production, the annual production value for the medical technology industry in Spain was 6.3 billion U.S.

dollars, with the same tendency of going up since 2015. The mentioned data can be appreciated in graphs 1 and 2. (See Figure 3 and Figure 4)

Figure 5

Annual production value of the medical technology industry in Spain from 2015 to 2019



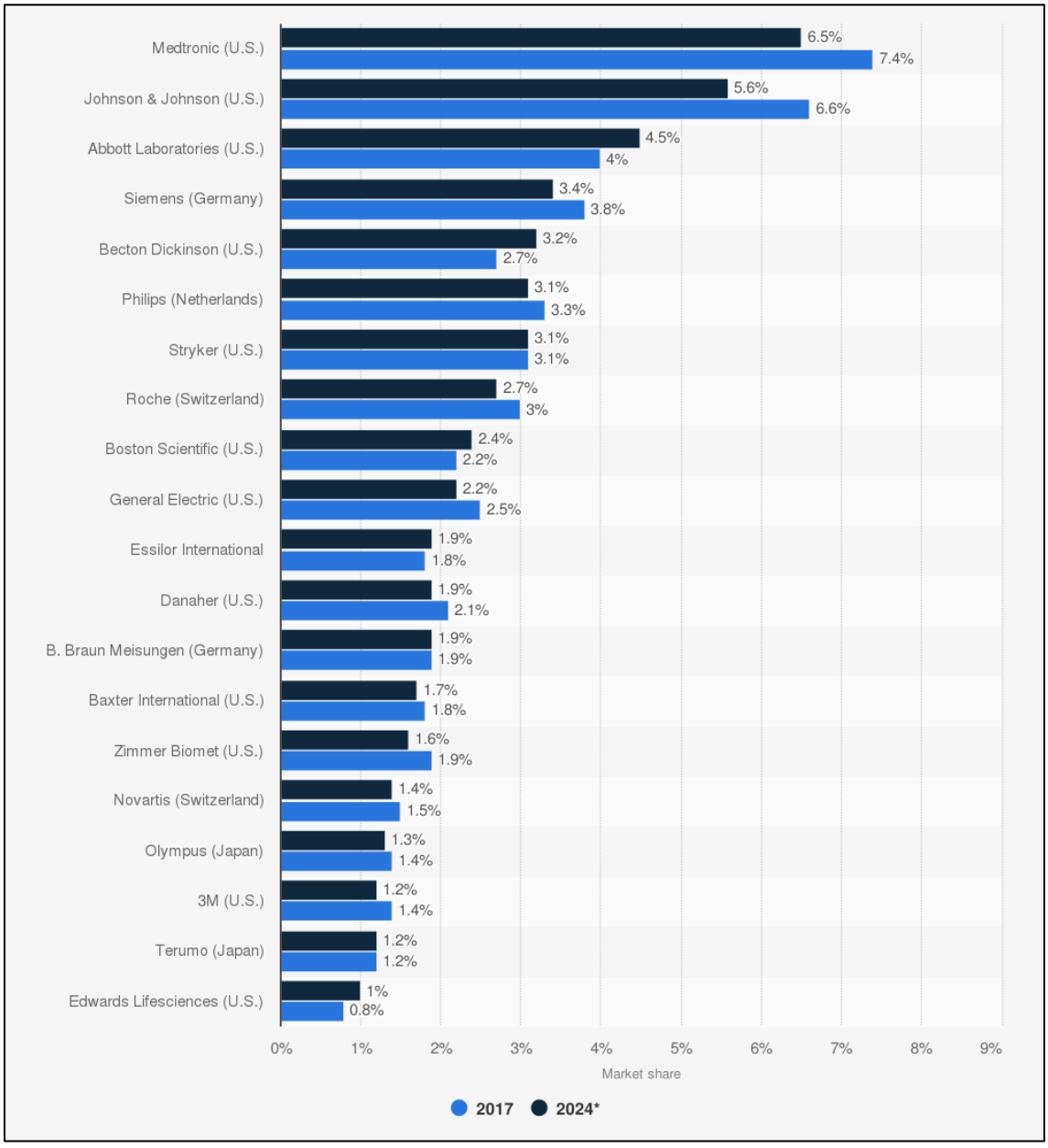
Source: (Oficina de Análisis de la Industria, 2021)

2.5.1. Market Share

To illustrate an overview of the market we did some research based on general medical technology companies and the companies that can offer similar products to TBIOM, in this case, would be medical respiratory devices. As you can see in the first graph, the biggest company on medical technology is projected to have 6.5% of the global market share by 2024 and the smallest company, 1%. (See Figure 6)

Figure 6

Top 20 companies based on medical technology revenue market share in 2017 and 2024



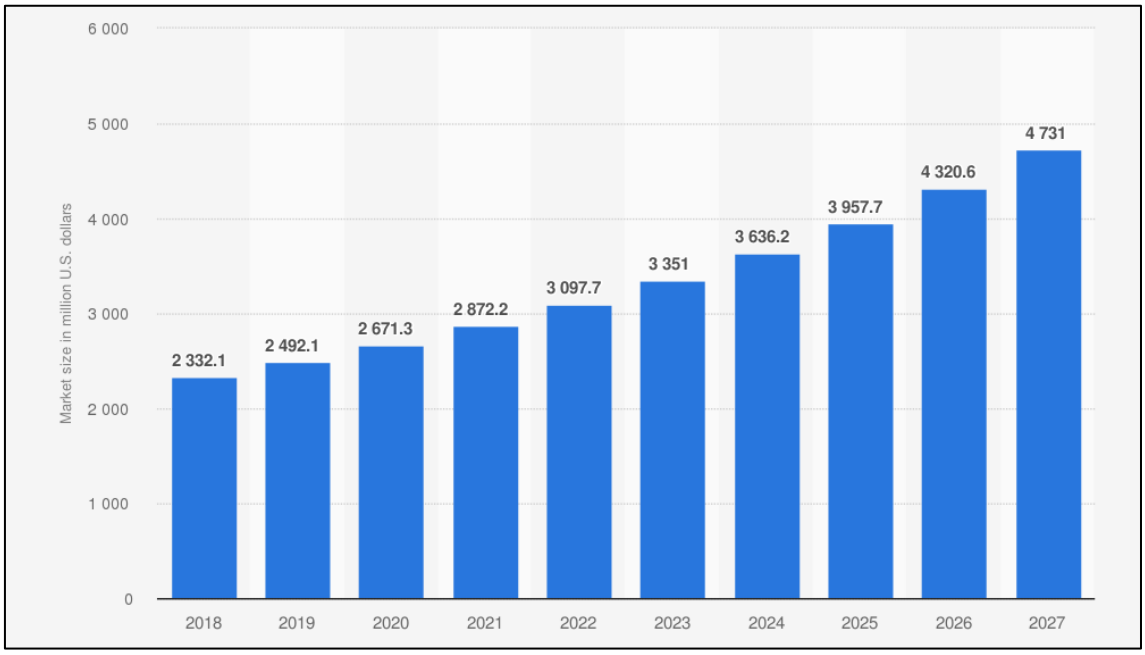
Source: (Statista, 2018)

There is no clear leader on the market, meaning that there is a lot of competitors with small shares on the global market. One reason may be the specialization each company can have at which diseases or medical treatments want to focus on.

By the year 2027 is expected that the market size in the global positive airway pressure devices market is going to be 4.7 billion U.S. dollars. It is a market expected to keep growing in the next years, and an opportunity for companies like TBIOM to increase their market share in this type of equipment. The whole prediction for the market shows in the next graph. (See Figure 7)

Figure 7

Size of the global positive airway pressure devices market from 2018 to 2027



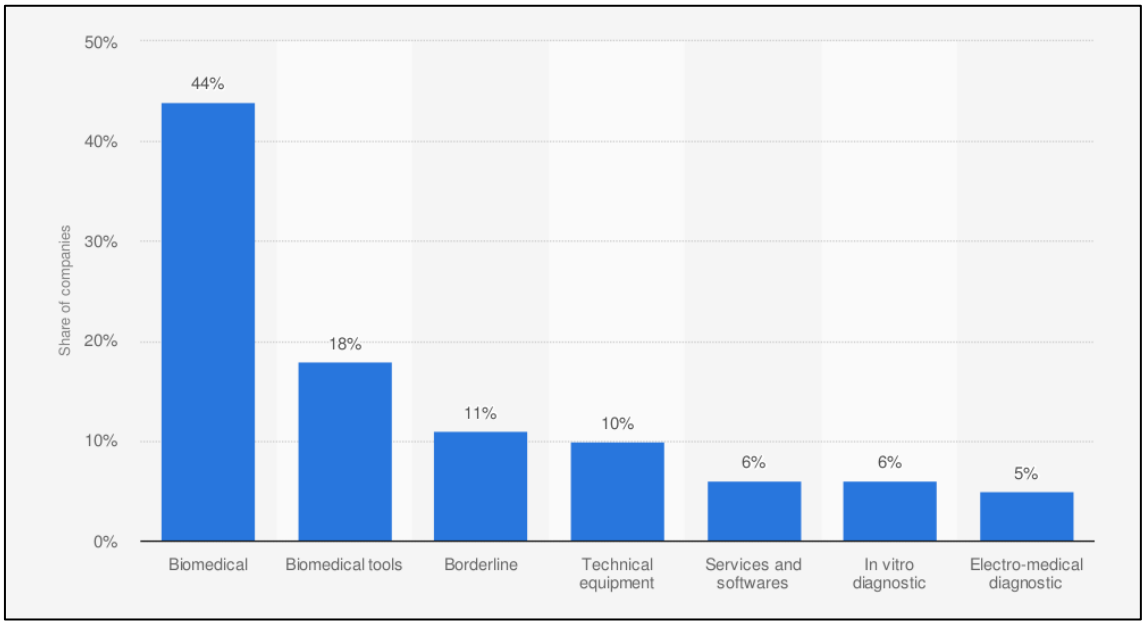
Source: (Statista, 2019)

2.5.2. Degree of concentration

The companies focused on the development of medical technology can be divided into different areas according to the type of equipment they want to work. As the last section mentioned, the market value for the positive airway pressure devices (CPAP) market is growing, in 2020 the estimated value is 2.7 billion U.S. dollars. So, it is a big market but not the biggest among the different areas medical technology can be. In Italy, data shows the next areas and sizes for medical technology. (See Figure 8)

Figure 8

Distribution of companies in the medical technology sector in Italy by category



Source: (Statista, 2020a)

In Italy, the main category with 44% is the Biomedical category in companies inside the medical technology sector. The category for TBIOM and its product AIRESS would fit in the technical equipment, and as you can see in the graph, in Italy this category is the 10%.

Based on this data, and with the assumption that Italy medical technology market is similar to the Spanish one, the concentration is high, being small with high value, and despite the fact that most of the companies are on categories such as biomedical, the concentration is high with a lot of companies offering similar or complementary products.

2.5.3. Direct Competitors

Competition is high in the medical industry, and as the previous points already explained, it is a broad market. For AIRESS there is no direct competition in terms of product functionality, there are other products that focus on the CPR maneuver, but they are more complicated, or they perform the maneuver by themselves. AIRESS is a complementary device that helps one person performing the CPR. So, the research was focus only on the direct competitors, those that offer a similar catalog of products focus on respiratory problems and cardiopulmonary resuscitation (CPR). Based on the companies that can have different respiratory devices that also can be modified as ventilators by emergency use authorizations, the potential direct competitors are:

Resmed

Resmed[10] is a company founded in 1989, with a presence in 120 countries and they specialize in the development of devices and treatments for sleep apnea, COPD, and other chronic

[10] (ResMed, 2021)

respiratory diseases. They are considered as pioneers in this area and type of treatments. Their investment in R&D is high; they have an annual growth rate of 16.4% in this department (Statista, 2020c), showing their compromise to keep working on new alternatives and improve their products. It is not among the biggest companies with a lot of revenue market share in the EU, but they are the ones that have more similar products and technologies compared to TBIOM and their products, offering 24 respiratory devices.

Philips

This Dutch company was founded in 1891 (Philips, 2022). They are global and been working on the health industry with different solutions. On medical technology, it is expected that their market share revenue in 2024 is 3.1%. Currently, in their portfolio, they have 12 respiratory devices.

Fisher & Paykel healthcare

This company with 86 years of experience has a presence in 50 countries with manufacturing facilities around the world (Fisher & Paykel Healthcare, 2020). They focus on treatments for sleep apnea and other respiratory solutions, they do not manufacture mechanical ventilators, that is why they also are an indirect competitor.

General Electric

GE is an American corporation that started in 1892(Editors of Encyclopaedia Britannica, 2020). Now has a lot of different solutions in different industries, including the healthcare

industry. According to the figure 6, the revenue market share expected for GE in 2024 is 2.2%. General Electric has 6 similar devices that can be modified to function as a respiratory device.

Johnson and Johnson

This company founded 130 years ago is now one of the biggest and most profitable corporations in the whole World. J&J offers a diverse medical devices and other products focus on human health and well-being (Johnson & Johnson, 2020). As figure 6 shows, the revenue market for this company is on the second highest spot and is expected to have 5.6% of the market share in 2024 and puts it as one of the most powerful companies inside this industry.

2.6.SWOT ANALYSIS

Strengths:

- Technology patents & certifications.

TBIOM have the patents of the technology that they have developed, and they are already certified some of their products with the CE Marking that is mandatory for all products that want to be sell in the UE.

- Less bureaucracy in decision making because TBIOM is a small company.

TBIOM is an SME, so they do not have many people in their organizational structure, and this mean less hierarchy. Their policy of open door is comfortable for all the employees so all can give their opinions in the decision-making process.

- Pioneers in transportable ventilation solutions.

There are many CPR automatized solutions in the market but all of them are focus on the chest compressions and after deep research we got the conclusion that there are not solutions for the ventilation, that is why we consider TBIOM as pioneers in transportable ventilation solutions.

Weaknesses:

- Is not a company with a large presence in the market.

As mentioned before the companies that are into the medical devices industry are huge with a long financial backup and constantly investment in R&D.

- Weak Marketing & Sales Team.

Currently TBIOM is not selling any units of AIRESS or AIRMONY, so they do not have a specific team for sale or marketing in comparison with their huge competitors.

Opportunities:

- Low competition in the CPR market (respiratory solutions).

This is related with the strength of being pioneers in CPR respiratory solution.

- Development and improvement of OSH laws and now even more because of the COVID-19.

Now a days due to different issues the OSH laws are getting stronger and more important to the communities and governments and even more now because of the new coronavirus where social distance should be keeping every time.

Threats:

- Competitors with large presence in the market.
- This is related with the weak of not having large presence in the medical devices market.
- Due to the COVID-19 a lot of new companies are starting to explore the health market (respiratory solutions).

Now a days due to the new coronavirus all the government are helping companies who are trying to develop new respiratory solutions, so there is a new wave of medical devices companies which are trying to develop solutions.

3. MARKET RESEARCH & ANALYSIS

3.1.RESEARCH METHODOLOGY OVERVIEW

The main objective of this chapter is to show the market research techniques used to better understand the total market and the potential, the effectiveness of the product, its profitability, and its valuation.

Secondary and primary market research was conducted to obtain the greatest amount of useful and valuable information.

The primary research was qualitative and focused primarily on physicians, nurses, safety experts, and employers with an average of 500 employees and with this we discovered several insights.

In secondary research, we obtained a better overview of the market and that of other competitors in this area.

Scientific documents, online databases, articles, business social networks and others were used to get more information about the health care business.

3.2.AIMS AND OBJECTIVES

The main objective of the research was to gather as much information as possible about the market and competitors, to further expand the knowledge of TBIOM, to verify the profitability of the product, the potential and total market.

Primary research was used to discover new insights, the real need of the market and to verify if the AIRESS solution is really valued by the target.

However, the most important part of the secondary research was to better understand the potential market and the competitive advantage of TBIOM/AIRESS within this environment.

3.2.1. Primary research

The main objective of the primary research was to assess the real need of doctors, nurses, security experts and businessmen (buyers), focusing on the problem rather than the product. To understand if AIRESS really would be an interesting product for them. Since the product is not a need, but rather a nice to have.

Therefore, a qualitative investigation (interviews) was carried out to discover the attitude and thoughts of trainer people in emergencies situations.

With the buyers, in addition to their opinion on emergencies, this qualitative research was also a good opportunity to collect information on the amount that they invest annually in first aid kits, training, personnel and training. To measure the availability to pay for a CPR equipment.

3.2.2. Secondary research

The objective of the secondary research was to obtain information on the total and potential market. Where there really is a greater need for a solution like AIRESS. It is important to know who the current competitors are and what are possible threats to TBIOM.

We also analyze competitive forces, to carry out a competitive strategy.

By better understanding the market, we can truly find AIRESS's competitive advantage so that when it comes to entering, it can be more successful.

3.3.DATA COLLECTION AND ANALYSIS METHODS

3.3.1. Primary research

The investigation began with in-depth interviews with 7 Doctors, 2 nurses, 4 security experts and 3 CEO´s.

The second part of the primary research was carried out using an anonymous survey with the help of the Qualtrics platform. Online surveys were conducted where a total of 70 responses were obtained, of which 8 were from people who work in Health transport services, 10 from workers in shopping centers, 14 from Residence centers, 23 from Sports facilities, and 15 from other sectors.

With these surveys, it was possible to obtain a clearer opinion of the potential markets regarding the product, its characteristics, its operation, and its price. Likewise, questions were

asked about the knowledge that companies have about CPR. To establish a more consistent business plan.

3.3.2. Secondary research

Secondary research was conducted using databases such as Statista, Passport, MarketLine, and Google.

3.4.RESULTS

3.4.1. Primary Research

Interviews

In general, all the people surveyed answered us that the product it is a “nice to have”.

Both doctors and nurses agreed that the product would be a good complement to the defibrillator. The characteristics that they valued the most are portability, which is easy to use and hygienic.

As for the use, they believe that anyone who is previously trained can perform the maneuver, without the need for additional help.

The buyers say that if there is no law that forces you to have it in their facilities, they would not buy it. Furthermore, the probability of cardiac arrest emergencies is extremely low, based on their experiences in office.

They agreed that it is important that the product is reliable, that it has certifications and a good price. They see it as interesting to prevent deaths and always be prepared.

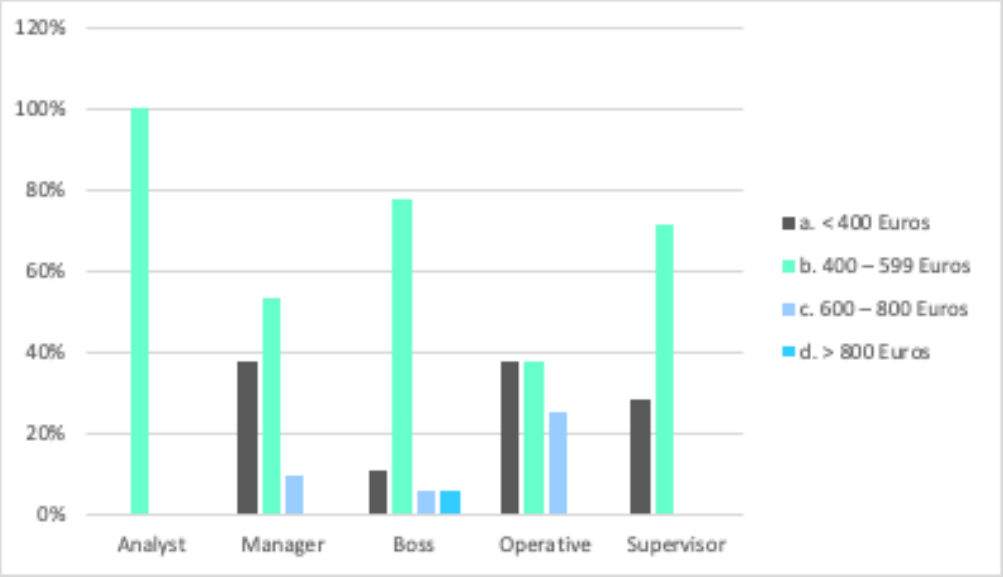
Surveys

According to the surveys carried out during the second part of the primary research to the target established in the first investigation, we asked the country from which they come, the position they have in the company where they work and the sector which they work or worked. Base on this information the results obtained were the following:

As can be seen in the graph, according to the selected positions, among the total of respondents 53% of the Managers and 78% of the Bosses are willing to pay between 400 and 600 euros for a unit of AIRESS, while 38% and 11% of Managers and Bosses respectively would be willing to pay less than 400 euros. Considering that the price includes CPR training and product maintenance. We focus on Managers and Chiefs specifically since these charges are those that will pay for the product.

Figure 9

Willingness to pay

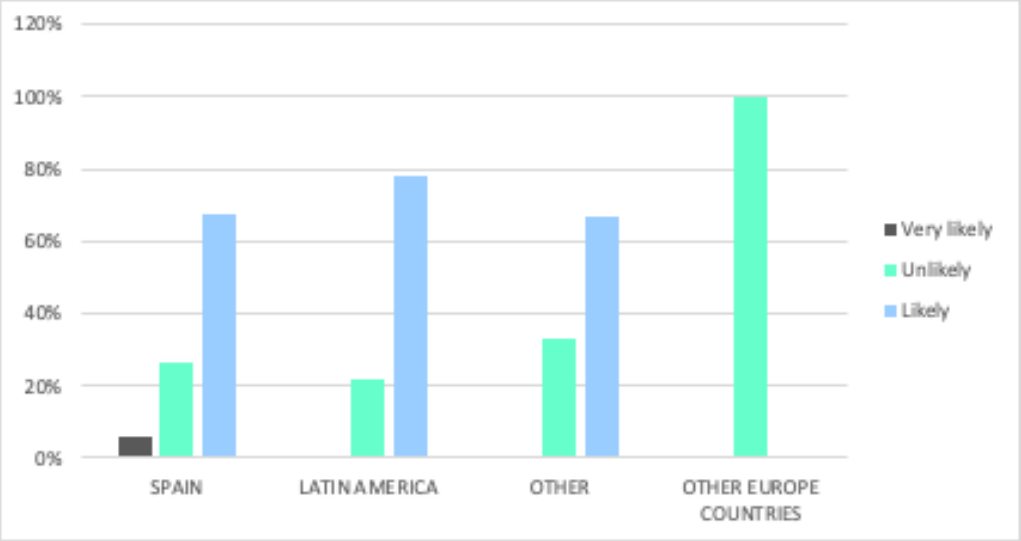


Source: Own elaboration – Final Project Team AIRESS

On the other hand, surveys also show us that, in Spain, which will be the central country in the first five years of sales, people show that the probability of buying the product according to the price they chose, which can be seen in the previous graph, it is approximately 74%. Likewise, the probability in Latin American countries is 78%.

Figure 10

Probability of purchase

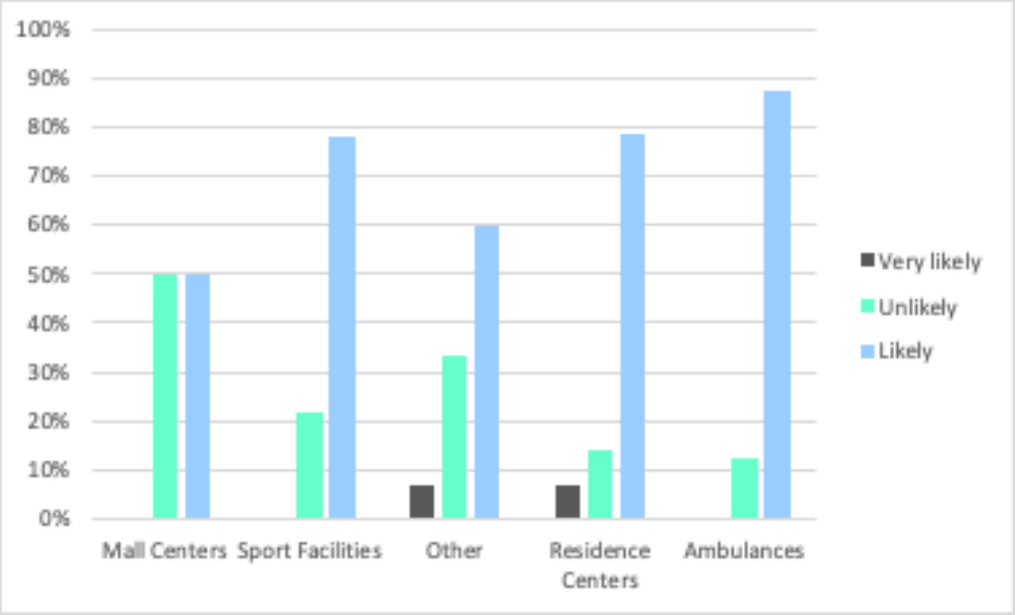


Source: Own elaboration – Final Project Team AIRESS

Regarding the potential target that we established and the probability of buying the product, the surveys show us that Mall Centers have a 50% probability of purchase, being the lowest percentage, Sports facilities of 78%, Residence centers of 79%, and medical transport companies of 88%.

Figure 11

Probability of buying - potential markets

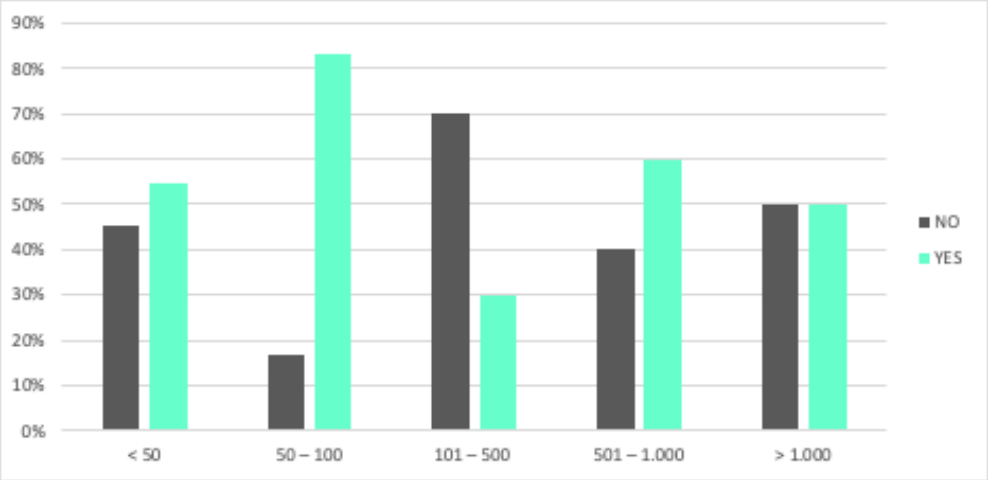


Source: Own elaboration – Final Project Team AIRESS

Additionally, with the surveys it was possible to observe an approximate size of the companies in number of people and the training they receive, as shown in the graph, in companies that have less than 50 people, between 50 and 100 and between 501 and 1000 people, the percentage of CPR training is more than half, being 55%, 83% and 60% respectively. While companies between 101-500, and more than 1,000 people present a lower percentage of training, being 30% and 50% respectively.

Figure 12

CPR training - by company size



Source: Own elaboration – Final Project Team AIRESS

On the other hand, it wondered about what is most valued when buying a first aid kit. The results obtained showed that the reliability of the product comes first, followed by the ease of use and the ease of transporting, then hygiene and price, and finally the reputation of the product.

After showing the product, the respondents rated its characteristics from 1 to 4, one being the most important. According to the answers, what is most valued about AIRESS is hygiene, followed by ease of use, ease of transport and finally the durability of the device.

3.4.2. Secondary Research

In Spain, 76% of people over 60 dies from cardiac arrest, there are more than 5,200 nursing homes, with more than 366,000 rooms, which gives us an average of 69 places per center[11].

[11] Informes Envejecimiento en red. (Abellán García et al., 2019)

As AIRESS could be a complement to the defibrillator, the ambulance market is interesting, since in Spain there are more than 350 ambulances and they have more than 13,000 units (Ballfugó, 2019). Covering events and places where there is an influx of people.

The mall center is also a potential market, due to the large influx of people cardiac arrests are likely to occur, in Spain there are more than 560 Mall centers, where around 1,900 M people visit each year (Torres, 2019).

In Spain 1.6 out of every 100,000 athletes with high physical effort performance die from sudden death, in total there are more than 176,000 sports centers, where 84% die from charity arrest. (Boraita, 2002)

3.5.LIMITATIONS

Due to the current situation of the pandemic, both the interviews and the surveys were hampered. Still, we managed to reach the amount of information necessary to continue moving forward with the project.

3.6.TIMELINE OF DATA COLLECTION

For the first stage of the investigation, the data collection time took approximately two months, where interviews were conducted with specialists in medicine, security, and possible

buyers of the product. A total of sixteen interviews were obtained, where nine are part of the nursing and medicine area, four of security, and three CEOs from different companies.

The second stage of the investigation began with the surveys through Qualtrics platform, the data collection and response time took approximately one month and a half, obtaining a total of 70 responses, the following tables show the countries and sectors from which responses were received.

Table 2

Surveyed countries

COUNTRY	QUANTITY
Spain	34
Latin America	32
Other European countries	3
Other	1
TOTAL	70

SECTOR	QUANTITY
Medical Transport	8
Retirement Centers	14
Sport Facilities	23
Mall Centers	10
Other	15
TOTAL	70

Source: Own elaboration – Final Project Team AIRESS

4. BUSINESS STRATEGY

After considering all AIRESS's strengths, but also the weaknesses, opportunities and threats, the next part will highlight how AIRESS should take advantage of the market opportunity.

It illustrates the proposed product concept and strategy, as well as the factors to be taken into consideration for success in the healthcare sector.

4.1.STAKEHOLDER ANALYSIS

First, we need to identify the stakeholders who will be divided into the following categories:

Collaborators: employees, team members, manufactures, distributors and financial entities (Bank).

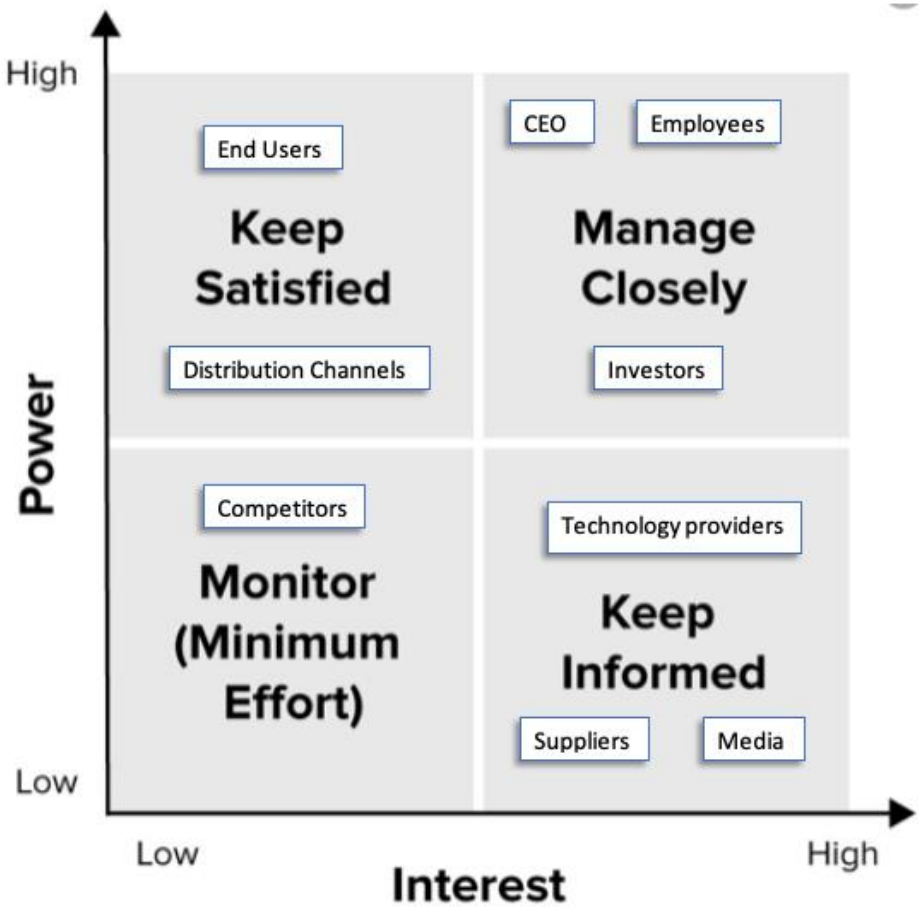
Beneficiaries and users: first aid rescuers, mall centers, sport centers, gyms and swimming pools, ambulance companies and retirement homes.

Consultants: Business advisor (EADA), consultor, legal consultor, and medical consultor.

It must be necessary for AIRESS to have a clear vision of what the power and interest of internal and external stakeholders should be, given that they play a vital role in the corporate strategy. The following table illustrates the relationship AIRESS should have with each stakeholder.

Figure 13

Stakeholder Analysis



Source: Own elaboration – Final Project Team AIRESS

Based on the one previously written, we have identified what values AIRESS wants to give to each of its stakeholders. For users who use the product we want to make them understand that we are offering a product that can save lives in an emergency. Another important aspect is that it is quick to use, hygienic and easy to transport. Instead taking into consideration all the buildings identified as target where we would like to put AIRESS, what we want to transmit is the main good that would be to provide an increasingly healthy environment to grow, and that people and

workers who are inside the building feel it more security and well-being. What we would like to give to the AIRESS team would be to take advantage of a product that could penetrate the respirator market by helping the CPR maneuver and the awareness of sell a new product.

4.2.PRODUCT CONCEPT

90% of the people that suffer a cardiac arrest outside a hospital end in loss of life due to lack of training and good first aid equipment. Even when people have a qualification to perform cardiopulmonary resuscitation, it is difficult to have an efficient maneuver without the help of equipment because the person in the emergency needs to receive constant ventilation usually performed mouth to mouth and chest compressions.

The process is exhausting for the user and without the help of equipment can be in vain and do not help the person involved. AIRESS is a transportable respiratory assistant that substitutes the mouth-to-mouth part of the CPR. The first benefit this product offers is to provide enough flow of air needed during the CPR; at the same time, it improves the hygienic part because you do not need to perform mouth to mouth.

4.2.1. Value proposition

AIRESS offers the possibility to perform a CPR during a larger period and increases the effectiveness of the maneuver. This product helps people outside the hospital to keep a person alive during the period an ambulance takes to arrive.

When someone performs a CPR, it needs to be effective because every time the person does not respond, it can have future problems related to neurologic outcomes. The time and effectiveness are something crucial and the product can help during the ventilations and at the same time marks the rhythm of compressions on the chest needed.

4.2.2. Technology / Licenses

Quality standards are high in this industry. TBIOM need to have certifications and different audits to manufacture and sell a product like AIRESS. As a company TBIOM required a license from the Spanish Agency for Medicines and health products (AEMPS in Spanish) this organization is responsible for guaranteeing society, from the perspective of public service, the quality, safety, efficacy, and correct information of medicines and health products. This license is something TBIOM has in its portfolio.

For the product, they need to have different types of certifications from the UNE[12] or Normalización Española in Spanish. This organization contributes to the competitiveness and safety of companies, their products and services, and processes. They look for total standardization and this helps to ensure the safety of the people. Like UNE that is focused on the Spanish market, another important entity in Europe is CEN, they are the European Committee

[12] (UNE Normalización Española, 2021)

for Standardization[13], their focus is also the standardization of different processes, materials, products, and services. Both entities are in different types of industries, and they provide support through these norms, materials and documents, and technical reports.

To be more specific the UNE and CEN norms that apply to AIRESS are the following ones:

- UNE-EN 60601-1:2008+ERR:2008+CORR:2010+A12:2015
- UNE-EN 60601-1-12:2015
- UNE-EN 60601-1-2:2015
- UNE-EN 60601-2-12:2007
- UNE-EN 794-3:1999+A2:2010
- EN 301 489-1
- EN 301 489-17

4.3.COMPETITIVE ADVANTAGE

TBIOM has characteristics that competing products do not possess, which allows raising the sale price, obviously if they are appreciated and valued by customers. So, they are specialists.

4.4.BUSINESS MODEL CANVAS

[13] (Cen Celenec, 2020)

This tool helps us shape the TBIOM/AIRESS business model.

TBIOM's competitive advantage is that they are pioneers in CPR ventilation solutions. The product adds a lot of value since it reduces the percentage of death due to cardiac arrest with easy-to-use, transportable, and hygienic equipment.

The relationship with customers must be long-term, where TBIOM provides post-Sales service, maintenance, and training to companies constantly.

The sales channels would be through a distributor.

The market segments are divided into two steps, firstly in -Ambulances Sport Center, Mall Center, Retired people center, and them Manufacturing Centers, Enterprise Buildings when the brand has already gained recognition and trust.

Design, innovation, and engagement are key activities for the brand to last over time. While in resources, intellectual, human, economic, and physical must be key.

Strategic allies are suppliers that provide you with production, warehousing, and product testing (3D).

5. MARKETING STRATEGY

Marketing builds the image of the brand and drives communication aimed at potential customers, thus driving sales growth.

TBIOM's marketing strategy should focus on attracting the attention of the Potential target, creating value, and thus acquiring customers who ask distributors for the AIRESS product.

AIRESS's marketing strategy will be elaborated through segmentation, targeting, and positioning, focused on the 4P of marketing: product, price, promotion, and place.

The marketing plan will evolve over time and will be constantly influenced by the market.

5.1.MARKET OPPORTUNITY

We analyze the following questions, to see if there is a market opportunity or not:

1. Is there an unmet need in this market?

Based on the research we carry out, we discovered that AIRESS does not cover a need in the market. If there is no law that compels companies to buy it, they will not. So, in hindsight it would be a nice to have product, which makes the site where it will be placed a safer place for the people who work there or who are passing through.

2. Is this market large enough?

Although the product does not meet any need on the market, it could be used as a complement to the defibrillator. In secondary research, we obtained the potential market size of 98,118 units of AIRESS. Therefore, the market size is sufficient.

3. Does the company have the resources to satisfy this need?

Currently, TBIOM does not have the production capacity but could make alliances to reach the necessary production.

5.2.STP

5.2.1. Segmenting

A market segment is a subgroup of people or organizations that have one or more characteristics in common that makes them have the same product needs. Market segmentation must be identifiable, substantial, accessible, stable, differentiable, and actionable.

In Spain there is a law that requires places with an agglomeration of 500 people to have a defibrillator. Considering the research, we carried out, in the interviews with doctors, everyone agreed that it would be a good complement to the defibrillator.

So, who would buy from TBIOM?

Spanish companies (defibrillator law) that have an agglomeration and want to prevent respiratory arrest accidents. Such as the Mall Centers, the ambulances that are always present at events with many people, sports facilities (due to the high level of physical activity that athletes

arrive at) and retirement homes for the elderly (the risk of cardiac arrests increase from 55 years old).

5.2.2. Targeting

By segmenting we can address a more specific market, where marketing is much more direct, and the investment and resources will be used profitably.

5.2.3. Positioning

To position AIRESS in the market, we have carried out an analysis based on the strategic circles and the value pyramid.

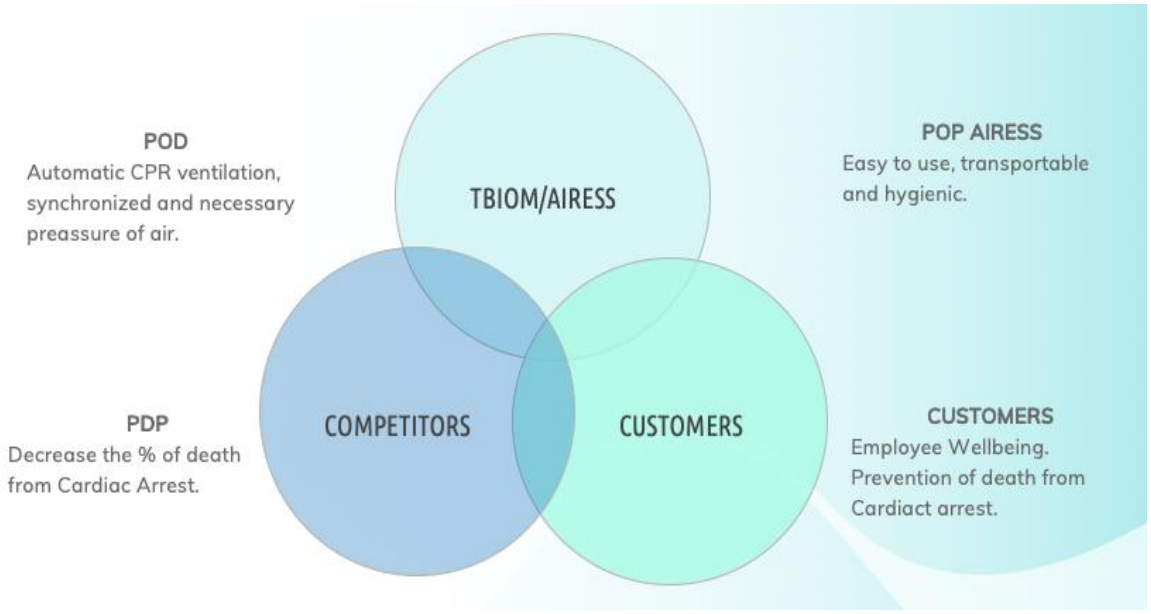
Strategic Circles

"The 3 Circles Model is an analysis tool that helps to visually represent through 3 overlapping circles what the company offers, what customers want, and what the competition is located, connecting, and integrating these key concepts. that directly affected the business results" (Cámara Madrid, 2020).

The objective of this diagram is to provide a frame of reference to evaluate the strategic market segments (company, clients, and competition) and to develop a growth strategy according to the differentiation points detected during the analysis, which, in turn, must be aligned with the skills and assets of the company.

Figure 14

Strategic Circles



Source: Own elaboration – Final Project Team AIRESS

After analyzing each one, we can identify the point of differentiation for AIRESS, the point of parity (POP), and the point of differentiation (POD) for competitors.

POP is important because it will be the benchmark for AIRESS to meet current market standards.

POD is what makes AIRESS stand out, as there is no value in being a product that offers the same as competitors.

POD will allow AIRESS to offer additional value.

Value Pyramid

The value pyramid is used to define the position of the company in the consumer's mind.

The following figure shows us, starting from the bottom up, the attribute of the product, the functional and emotional benefits, as well as the value that AIRESS brings to the client according to the research carried out (Interviews and surveys).

Figure 15

Value Pyramid

Source: Own elaboration – Final Project Team AIRESS

5.3.MARKETING MIX

TBIOM/AIRESS needs to take into consideration the product, promotion, place, and price, to be able to properly approach the target market.

5.3.1. Product

AIRESS is a respirator that intends to save the lives of people who are suffering a cardiorespiratory arrest or cardiac arrest. This product it is a compliment for people who are doing the CPR maneuver.

“The 2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care" increased the focus on methods to ensure that high-quality cardiopulmonary resuscitation (CPR) is performed in all resuscitation attempts(Meaney et al., 2013). There are 5 critical components of high-quality CPR: minimize interruptions in chest compressions, provide compressions of adequate rate and depth, avoid leaning between compressions, and avoid excessively

AIRESS will help with two of the 5 critical components mentioned before. The product will give the necessary ventilation and will help the person who is doing the CPR to give the compressions at an adequate rate.

According to the American Heart Association, more than 350,000 cardiac arrests occur outside of the hospital each year which 18.8% OHCA in adults and 13.3% OHCA in children happens in public spaces, so this product is aimed to be in public spaces.

5.3.2. Price

There are three pricing methods, which are: cost-based, positioning based, and customer value-based.

After the research we carry out, we recommend that AIRESS fix prices based on customer value, as they are specialists.

We proposed a price of 600€, VAT included, per product, which includes training, customer service and annual maintenance. They could also charge an annual fee for the customer still receiving these services and thereby create long-term relationships.

5.3.3. Place

In the short term, AIRESS would focus on the Spanish market with a potential market of 98,118 AIRESS units in step one. In the long term, AIRESS could go out to the rest of the world, once it has gained brand recognition and experience, and Europe is recommended as an expansion as it is the closest market to the Spanish one.

5.3.4. Promotion

To AIRESS reach the customer in the best way, they will need to:

- Contact the key opinion leaders. In this case Nurses, Doctors, Firefighters, lifeguards, security people, and CEO´S.
- Develop an AIRESS area in the TBIOM website, which will provide all the relevant information about the product and benefits (training, product service and customer support) and the importance of being prepared for emergency situations, showing interesting data to generate consciousness and credibility. The website should have chat

boxes to communicate and provide high- quality customer support and maintain a good customer relationship.

- Attend fairs such as medical, technological fairs and labor union events as they can influence companies to adopt TBIOM/AIRESS.
- Attend Magazines such as Occupational Safety & Health, Medicine, and First Aid.
- Arrange one-to-one meetings with potential customers.
- Perform digital marketing, such as SEO/SEM. To Appear on the seekers with keywords and banners on pages that are related to our product.
- Create social networks on Facebook and Instagram, where they share interesting content about the importance of being forewarned, interesting data to inform and raise awareness. In such a way that the brand gains strength and credibility.

5.3.5. People

To achieve a long-term relationship with customers, it will be necessary for the sales team to be very well trained, with the necessary knowledge about the product, always highlighting the characteristics that they value (Hygiene, easy to use and transport), in addition, providing after-sales care.

5.3.6. Process

The way in which a service is offered, and its effectiveness is part of AIRESS. It is especially important to carry out a correct process. For AIRESS it could be the correct positioning in the

search results. Thus, the user knows our product and our services more quickly, requesting the product from the seller.

The main basic steps of the activities to successfully deliver the AIRESS product to the customer once they buy through the supplier are the following:

1. AIRESS installation

This should be done by a TBIOM team technician who has knowledge of the team.

2. Training

The training must be done by a person from the TBIOM team.

In case the client pays for an annual fee, they would have access to one training every year.

3. Maintenance

Maintenance must also be carried out by the TBIOM team technicians, to check that everything is in order.

In case the client pays for an annual fee, they would have access to one maintenance every year.

4. Customer service

Customer service is a crucial part of customer relationship management, to building long-term relationships.

5.3.7. Physical Environment

It´s help shape customer's perceptions of the product and service.

In the case of AIRESS, it is important that it be recognized as a good product and above all reliable. Work on building a good brand reputation.

5.4.KPI's

5.4.1. Customer Acquisition Cost

To know the economic investment that TBIOM will make per year to ensure that a potential customer becomes an end consumer and acquires the AIRESS product, the formula used was CAC = Marketing expenses and Commission (year) / number of Customers Acquired (per year). The following table show the calculation and results of the costumer acquisition cost for TBIOM in the next five years.

Table 3

Customer Acquisition Cost AIRESS/TBIOM

	Year 1	Year 2	Year 3	Year 4	Year 5
Cost of Sales	609,274 €	642,175 €	1,070,341 €	1,308,451 €	1,607,776 €
Marketing expenses	48,571 €	51,194 €	85,327 €	104,309 €	128,170 €
Commission	48,571 €	51,194 €	85,327 €	104,309 €	128,170 €
# Mall centers	4	4	5	3	1
# Sport facilities	744	744	1,004	428	621
# Residence Centers	56	56	49	25	54
# Ambulances	176	176	207	123	59
CAC	***721.19 €***	***104.53 €***	***134.88 €***	***359.83 €***	***348.65 €***

Source: Own elaboration – Final Project Team AIRESS

5.4.2. Customer Lifetime Value

To know the value/profit that each client will represent, in this case, each small center, sport facility, residence center and ambulance, for the next five years for the company, the formula used was: CLV = Revenue per customer / Cost of Acquisition. The following table show the customer lifetime value for TBIOM per year.

Table 4

Customer Lifetime Value AIRESS/TBIOM

	Year 1	Year 2	Year 3	Year 4	Year 5
Revenue per customer	992 €	1,045 €	1,349 €	3,598 €	3,486 €
Cost of Acquisition	721.19 €	104.53 €	134.88 €	359.83 €	348.65 €
CLV	***1.38 €***	***10.00 €***	***10.00 €***	***10.00 €***	***10.00 €***

Source: Own elaboration – Final Project Team AIRESS

5.5.MARKET ENTRY STRATEGY

Every company in any sector has only one possibility when it enters a market with a new product, therefore it must be done in the most strategic way. Since AIRESS should be accompanied with a defibrillator or even sold as a single product, the marketing of the product will be entrusted to the sellers' team. So, the sale of the product will be introduced into the market thanks to a team of sellers. The sales team will have to focus on the beginning of the sale of the product in the Catalan region since TBIOM is based in Barcelona, and then, the sales will be directed to the other regions that we consider main in the sale of AIRESS.

By averaging the number of malls centers, ambulances, sports facilities, and rest centers for the elderly, we discovered the Spanish regions with the highest rate of these facilities, to direct

the sales team to these five regions. As seen above, we identified Catalunya as the first region to start selling AIRESS with 12.465 facilities, after Madrid in the second year, in the third year Andalucia with 12,652 facilities, Castilla y Leon in the fourth year with 7.352 and Comunidad Valenciana in the fifth year with 5.798 facilities. Starting with two sellers the first year focused only on the sale of AIRESS in Catalunya to the predetermined target explained above, in the second year one more seller will be added to support the work and increase the sales team in the Catalan and Madrid regions.

In the third, fourth and fifth years, depending on how many sales can be produced, it is recommended to add as many sellers as are required to support sales for each year in the regions of Andalucia, Castilla y Leon and Comunidad Valenciana.

Table 5

Potential markets - by communities in Spain

	Potencial	Potencial + Probabilidad de Compra	5 Comunidades	Cataluña	Madrid	Andalucia	Valencia	Castilla y Leon
Mall Centers	563	282	167	24	48	53	30	13
Sport Facilities	79,059	61,872	35,405	9,765	5,106	10,042	4,284	6,208
Retirement Centers	5,295	4,160	2,413	790	335	491	255	542
Ambulances	13,201	11,551	7,407	1,885	1,637	2,067	1,229	589
Total	**98,118**	**77,865**	**45,392**	**12,465**	**7,125**	**12,652**	**5,798**	**7,352**

Source: Own elaboration – Final Project Team AIRESS

6. OPERATIONS

6.1.VALUE CHAIN

In this part of the project, we analyze the recommended value chain of the company based on Porter's Value Chain (See Exhibit 3 for full Value Chain)

6.1.1. Primary activities

Inbound Logistics

TBIOM inbound logistics are managed by PROMAX their main key partner. All the raw materials and supplies go directly to PROMAX warehouses, and they manage the stocks and material requirements.

Operations

TBIOM as they do with their inbound logistics, they also outsource the operations and production of their products through their key partner PROMAX.

The two parties involved in operations have developed a procedure and guidelines to optimize operations and maintain product quality. (See Exhibit 4 for the full guidelines)

Outbound Logistics

PROMAX as the main partner of the company also managed its outbound logistics. When TBIOM have a sale all the information goes to PROMAX, so they know all the details and after finishing the production they hired companies who deliver the products to the distributors who finally sell to end customer.

Marketing and Sales

The intention of TBIOM at the beginning is to reach the Spanish market, so to achieve this they will have alliances and associations with distributors of medical and health devices, these companies must have a medium-large presence in the market and with them a strong sales force and with this TBIOM can be leveraged to reach all sectors.

Service

The services offered by TBIOM are two: training and maintenance. The purchase of the product includes maintenance (quarterly) and a training course (groups of 15 people) all this only in the first year. Training course is composed of how AIRESS works and how heart massage is performed. After the first year, TBIOM offers an annual fee which includes the same maintenance and training.

Another service is an open line / mail where people can ask for information about the product and provide feedback on their use and how we can improve it.

6.1.2. Support activities

Firm Infrastructure

The firm infrastructure is a flat one because TBIOM is a small company where employees and chiefs can interact daily and exchange opinions in their daily work.

Human Resource Management

The HRM in TBIOM is based on three pillars: effort recognition, diversity, and specialization.

Effort recognition is based on how much the employees do to achieve their objectives and depending on it, the company gives different types of recognition (money, studies, public, etc.).

Diversity in the company is important, in fact, TBIOM is a small company but in all the areas there are people of different ages, cultures, and gender. This helps with creativity and improve the work environment.

In each area of the company, TBIOM has specialized people who can accomplish the most difficult works the most important are doctors and engineers.

Technology Development

This is the main pillar of the company, TBIOM is always researching, developing, and innovating in new technologies, and each time they achieve something new they patent the technology. The technology developed by TBIOM are software and hardware with the highest standards of quality.

Procurement

TBIOM managed all the procurement with key partners and suppliers, the main companies are FARNELL for electronics; FIMSA for general supplies; PANTUR for 3D parts; and FAULHABER for the motor.

7. ORGANIZATIONAL MANAGEMENT

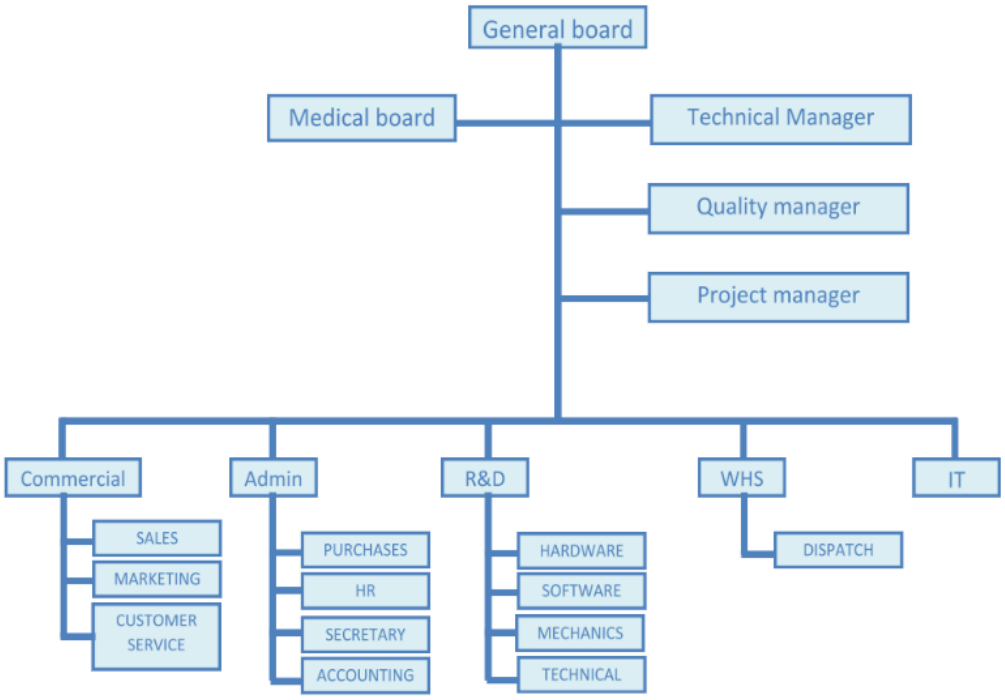
7.1.ORGANIZATIONAL STRUCTURE

At TBIOM workers are the main key to carry out the product to be developed, within the company it has a varied team where they have experts in different areas, this allows them to have a broader perspective of each product, as well as experience and new ideas with a different point of view.

TBIOM in its organizational hierarchy has the Medical Director in charge of advising other professionals in the organization on medical aspects and aims to coordinate medical activity. (See Figure 16)

Figure 16

TBIOM Organizational Hierarchy



Source: EADA TBIOM TEAM

Within this direction, a Responsible Technician participates, in charge of giving support within the established policies, recommending actions that lead to optimizing the performance of information technology (IT) devices, and programming and supervising the preventive maintenance of technology devices information ensuring its correct operation. On the other hand, there is a quality control team that enforces all the procedures of the quality system and guarantees that the products and services meet the quality standards. And the project management branch oversees administrate, planning, and coordinating the monitoring and

control of all the activities and resources assigned for the execution of each project so that the scope is met within the established time and budgeted costs.

Besides, the company has a commercial, management, innovation and development, production, warehouse, and information technology team, who work giving their best effort to carry out the objectives of the organization and continue to provide products that help improve people's health.

7.2.REQUIRED FUTURE STAFF

As part of our recommendations, TBIOM should have in their plans to bring together a team to sell the equipment AIRESS to the different targets and communities that have been selected to sell the product in the five years proposal that has been developed.

For the first year, the company should hire two different salesmen in charge of selling the product in Catalonia and, in the second year, one salesman more in charge of selling the product in Madrid. Then in the third year, TBIOM should hire one more employee for the task of sales force. This team should then go and work in the other 3 regions that have been selected, these are Andalucía, Castilla y León and Valencia.

7.3.RECRUITMENT, SELECTION, AND TRAINING

For TBIOM to grow as a company and take advantage of all the human talent they have working in all the different projects developed, they must establish a process for recruitment, selection, and training.

Recruitment

This part is something important, especially for this industry. To attract the best talent, TBIOM must start recruiting from the universities where young professionals are looking for a first opportunity in the medical device industry.

TBIOM should start some internships programs that allow the company to work in different projects faster and better. The recruitment should focus on developing a complete team, with some people in charge of the R&D and the technology part of the project, but also have other people in charge of the investigation of the market and other areas like project management, marketing, and finance parts.

Selection

After attracting the different candidates, the selection process is formed by some evaluations depending on the role of the company and interviews. In this part TBIOM must focus on the attitudes they value the most and based on the results of this part the selection is done.

As a tech start-up, where the R&D is important TBIOM should have different ways to evaluate the capacity of the persons to know they have the qualifications to work and develop this type of tech projects. The interviews must be designed according to the role the person will

have inside TBIOM but at the same time should be managed with objectivity, so all the candidates have the same opportunity.

Training

As the recommendation is to TBIOM on work with new and young talent to develop new ideas focused on innovation, the company must offer a training program that will allow the interns to get better in their abilities. First, TBIOM should focus on the strategy that the company wants to follow, to develop a good training program. The idea of having a clear strategy is to create a "culture" inside the organization. "The culture is what maintains the organization united in three aspects"

- It generated consistency inside the organization.
- It put forward action guidelines
- It channels the energy

This culture will help the next steps the company has because based on what TBIOM is looking for everyone inside the organization will work to accomplish these goals.

As something general the training programs for employees should encompass

- Team building
- Technical knowledge and skills
- 360° Feedback

Team building

This part is key to improve the results, all employees, and teams in charge of a specific project should know what their role inside the organization is and how they can contribute to

accomplishing all the goals. So TBIOM should always perform some team meetings and workshops to improve this part.

Technical knowledge and skills

As we mentioned before for this company the preparation and skills a candidate has is something important because of all the different abilities and knowledge necessary to develop a medical device. The R&D is the first part when the organizations start a new project and some workshops and training programs related to new technology and innovation should be performed by the company to improve the preparation of each employee.

360° feedback program

To keep a good communication inside the organization a 360° feedback program should be implemented to know all the opinion of the persons involved in every part of the project, this is something TBIOM should be looking to implement in every level of the organization chart, so supervisors are aware of how they are managing their goals and working on the team building.

8. FINANCE

8.1.SALES FORECAST

The sales forecast has been made from the introduction of communities during the 5-year project projection. In years 1 and 2 it begins with Catalonia and Madrid and Andalusia, Valencia and Castilla y Leon are added.

Table 6

Sales Forecast TBIOM

	Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**
Revenues Und	1,959	2,065	3,442	4,207	5,170
Revenues EUR	971,416 €	1,023,872 €	1,706,532 €	2,086,171 €	2,563,409 €
Direct Materials	550,503 €	580,231 €	967,096 €	1,182,237 €	1,452,690 €
Direct Labor	58,771 €	61,944 €	103,245 €	126,213 €	155,086 €
Contribution Margin	362,142 €	381,697 €	636,191 €	777,720 €	955,633 €

Source: Own elaboration – Final Project Team AIRESS

8.2.BREAK-EVEN ANALYSIS

The company reaches the break-even point every year of the forecasted operations. The detailed fixed costs and variable costs can be checked on the P&L Statement. The variable costs are made of direct materials and direct labor.

Table 7

Break-even analysis AIRESS/TBIOM

Price	**496 €**	**496 €**	**496 €**	**496 €**	**496 €**
Fixed Costs	148,305 €	150,945 €	165,638€	168,624 €	171,671 €
Contribution Margin	135 €	135 €	135 €	135 €	135 €
BEP Units	1,096	1,116	1,224	1,247	1,269

Source: Own elaboration – Final Project Team AIRESS

8.3.PROFIT & LOSS STATEMENT

Due to high amortization that the company have because of the patents, what is the most important asset, TBIOM got loss the first two years because the sales are not enough. The following years TBIOM is obtaining profits and it should continue increasing unless there develop a new patent or new R&D project, or their sales dramatically go down.

Table 8

Profit & Loss Statement AIRESS/TBIOM

	Year1	**Year2**	**Year3**	**Year4**	**Year5**
Sales Und	1,959	2,065	3,442	4,207	5,170
Revenues	971,416€	1,023,872€	1,706,532€	2,086,171€	2,563,409€
COGS	-609,274€	-642,175€	-1,070,341€	-1,308,451€	-1,607,776€
Gross Margin	362,142€	381,697€	636,191€	777,720€	955,633€
Administrative Expenses					
Rent	-12,000€	-12,000€	-12,000€	-12,000€	-12,000€
Light	-415€	-415€	-415€	-415€	-415€
Telephone	-190.00€	-190.00€	-190.00€	-190.00€	-190.00€
Insurance	-2,500€	-2,500€	-2,500€	-2,500€	-2,500€
General Supplies	-1,200€	-1,200€	-1,200€	-1,200€	-1,200€
Salaries	-110,000€	-112,200€	-126,444€	-128,973€	-131,552€

Selling Expenses					
Marketing	-48,571€	-51,194€	-85,327€	-104,309€	-128,170€
Commission	-48,571€	-51,194€	-85,327€	-104,309€	-128,170€
Other Operating Expenses	-22,000€	-22,440€	-22,889€	-23,347€	-23,814€
EBITDA	116,695€	128,365€	299,900€	400,478€	527,621€
Depreciation	-4,320€	-4,320€	-4,320€	-4,320€	-4,320€
Amortization	-183,770€	-183,770€	-183,770€	-183,770€	-183,770€
EBIT	-71,394€	-59,724€	111,811€	212,389€	339,532€
Financial Expenses	-8,187€	-6,676€	-5,104€	-3,469€	-1,768€
EBT	-79,582€	-66,400€	106,707€	208,920€	337,764€
Taxes	-€	-€	-€	-42,411€	-84,441€
Net Income	-79,582€	-66,400€	106,707€	166,509€	253,323€

Source: Own elaboration – Final Project Team AIRESS

8.4.CASH FLOW STATEMENT

In the first year the cash statement of the company goes negative, so they must answer for a loan or investment. Our suggestion is to go 50% Loan and 50% Investment in exchange of shares. After that, the company will be profitable in term of cash flow all the following years forecasted in the project.

Table 9

Cash Flow Statement TBIOM

	Year 1	Year 2	Year 3	Year 4	Year 5
EBIT	- 71,394 €	- 59,724 €	111,811 €	212,389 €	339,532 €
less Income taxes	- €	- €	- €	- €	- €
= EBIAT (NOPAT)	- 71,394 €	- 59,724 €	111,811 €	212,389 €	339,532 €
plus Depreciation expense	188,089 €	188,089 €	188,089 €	188,089 €	188,089 €
= Gross Cash Flow	116,695 €	128,365 €	299,900 €	400,478 €	527,621 €
less CAPEX	- €	- €	- €	- €	- €
+/- A/R	- 205,209 €	- 12,934 €	- 168,327 €	- 93,609 €	- 117,675 €
+/- Inventory	- 50,077 €	- 2,704 €	- 35,192 €	- 19,571 €	- 24,602 €
+/- A/P	90,040 €	5,408 €	70,383 €	39,141 €	49,204 €
+/- Taxes payable	- €	- €	- €	- €	- €
= Free Cash Flow	- 48,552 €	118,135 €	166,765 €	326,439 €	434,548 €
less Loan repayments	- 37,790 €	- 39,301 €	- 40,874 €	- 42,508 €	- 44,209 €
less Interests (net of taxes)	- 6,140 €	- 5,007 €	- 3,828 €	- 2,602 €	- 1,326 €
= Cash Flow	- 92,482 €	73,827 €	122,064 €	281,330 €	389,013 €
CASH PAST YEAR	4,830 €	188,390 €	448,637 €	757,515 €	1,183,655 €
FINAL CASHFLOW	- 87,652 €	262,217 €	570,701 €	1,038,844 €	1,572,668 €

Source: Own elaboration – Final Project Team AIRESS

8.5.BALANCE SHEET

The company balance sheet shows that they have financials resources but not the enough to keep going the business after the first year because of the negative cash flow. In here we can see that they have intangible assets around 900,000 euros which is mainly the patents and R&D investment, which highly impact in the P&L.

Also, here we can see that the company does not have operations in the year zero because they do not have inventories, A/R, A/P or cash.

8.6.COMPANY VALUATION

After doing the forecast of the P&L we decided to do a valuation of the company because we are asking for an investment of 45,000 euros. The valuation of the company assuming no grow in the future is for 1,663,084 euros and if we are going to ask for that investment it will be in exchange for the 2.70% of the shares of the company.

Table 10

Company Valuation – TBIOM

	Year 1	Year 2	Year 3	Year 4	Year 5
EBIT	- 71,394 €	- 59,724 €	111,811 €	212,389 €	339,532 €
Taxes	- €	- €	- €	- 48,270 €	- 84,883 €
NOPAT	- 71,394 €	- 59,724 €	111,811 €	164,119 €	254,649 €
Depreciation	183,770 €	183,770 €	183,770 €	183,770 €	183,770 €
CAPEX	- €	- €	- €	- €	- €
OWC Variation	- 165,247 €	- 10,230 €	- 133,135 €	- 74,039 €	- 93,073 €
Free Cash Flow	- 52,871 €	113,815 €	162,445 €	273,849 €	345,346 €
Terminal Value					2,348,729 €
Total FCF	**- 52,871 €**	**113,815 €**	**162,445 €**	**273,849 €**	**2,694,074 €**
Discounted Cash Flow	- 46,093.99 €	86,505.94 €	107,640.76 €	158,199.48 €	1,356,832.06 €
PV (FCF)	480,181 €				
PV (TV)	1,182,904 €				
Enterprise Value	**1,663,084 €**				

Source: Own elaboration – Final Project Team AIRESS

8.7.FINANCIAL CONCLUSION

In general lines the company have a strong financial situation. The only must ask for a loan/investment in the first year. In terms of P&L they seem to be bad the first two years but if we exclusively have a look into the EBITDA is positive all the years which means that the profits for the main operations give good results.

Also, the valuation of the company in our opinion is positive because the company is not selling any AIRESS currently and we are valuing the company without having any sales and give a good result of 1.6 M.

Although, all the positive things mentioned before we have to advice to the company to invest in R&D or patents carefully because those items have negative impact in the P&L due to the high level of investment, so in the case they would ask for a loan or investment a negative net income is not a well looking thing.

9. LEGAL ISSUES

9.1.INTELLECTUAL PROPERTY PROTECTION

This industry is extremely competitive and full of big companies, so when a start-up like TBIOM launches a new product, it must offer a different solution to an existent problem, like the case of AIRESS. At the same time the company is looking to improve their product and technology they must deal with the danger of a company copying their product not only in the way to solve the problem, but also in aspects like design and technology.

Patents and licenses are ways to differentiate and add value to the product, but also to protect the intellectual property of the company. AIRESS already has a patent related to the technology used to provide the air flow and this is something important, especially in this industry. Patents and certifications can be a lot of time consuming but is important to protect the future of the company, also is something that as a start up in the health industry should take into account in the initial investment of a new product because this is also that consume financial resources of the company.

9.2.DEFIBRILLATOR STATE LAWS AND LEGISLATION

Currently in Spain, there is one law, the decree 151-2012 that mentions the requirements for the installation and use of external defibrillators outside the health field and for the authorization of training entities for this equipment.

The use and installation of emergency aid kits and equipment in public places is something that governments are taking more seriously, that is why these types of laws can be a benefit to equipment like AIRESS. As it is already mentioned before, these defibrillators can be a complemented with a product like AIRESS and help in mouth-to-mouth breathing ventilation's part needed during a CPR, therefore is always to be aware of the different state laws and legislations related to defibrillator and other similar equipment.

10. CONCLUSION

Research clearly shows that there is no product that can provide the right flow of oxygen during the CPR maneuver.

To perform a proper heart massage, there should be at least two people, one person for the heart massage and another person who can help him during the rescue since it can last up to half an hour. In addition, we must consider the fact that assistance may arrive late, so people who perform the CPR maneuver must be aware of the time. This takes time and is subject to errors due to expert fatigue.

Current automated solutions do not achieve acceptable accuracy and therefore are not used by experts in the field; therefore, they are forced to use defibrillators and respirators for resuscitation. However, experts in the CPR maneuver still use these tools as they have no better alternatives.

TBIOM has found a solution to this problem by developing a device that allows the person in charge to do the heart massage not to worry about breathing, but only concentrate on chest massage. The product called AIRESS helps the expert in heart massage also thanks to the fact that the same device gives you the rhythm to do the heart massage with a flashing light, and thanks to this light it also tells you when to stop, so that the device can give the right flow of oxygen to the patient.

The solution, AIRESS, can be a product that can give security to public or private buildings, given that cardiac arrests that occur outside the hospital occur with an 18% frequency in adults every year. The first goal was to collect as much data as possible through cooperation with

doctors and nurses, so that they could give us their opinion. And then, our main purpose it would be to contract experienced salesmen in the sector who can help sell the product giving the product a vision of scalability in Spain.

11. RISK MITIGATION PLAN

There are many risks that could affect the development and success of TBIOM and its product AIRESS. As we have already mentioned before, it is a competitive market and there are big competitors and other factors to consider.

Legal

AIRESS, is in the medical device segment and here all the legal factors, patents, and medical trials are important so the product can be in the market. Failing to complete any legal process that is required for these types of devices could have a negative impact not only on the product but also for the company. To mitigate this risk, TBIOM should always hire a lawyer with experience in this field. Also, keep in the general board a doctor and any other professional that knows about the value all these legal requirements have.

Competitors

TBIOM is competing in a market where big companies with a higher monetary capacity can invest in a similar idea to AIRESS, change the market for this product affecting the sales and market share. To avoid this risk, AIRESS should focus on and launch this product as soon as possible for the targets we have proposed (retirement centers, sports centers, shopping malls, and ambulances).

Reputation

As a company that is still working its place in the medical device market, TBIOM should keep in mind to have a good reputation when anyone talks about the products they have developed. Any malfunction or failure for the product can be catastrophic because human life is at risk. To avoid this risk, like the legal part of this risk mitigation plan mentions, the company should always keep the focus on the talent and experience their employees have. A board with an experienced doctor and engineer can increase the reputation and reduce any failure possibility for their devices.

Funding

For any startup, the funding is a key part to keep working until the launch of a product. While there is still money to keep investing, the company will have more chances to carry out its business plan. To avoid any risk of losing any funding, TBIOM should always keep applying to any incubator's programs, keep working on their networking with possible investors and different institutes and universities that may have an interest in medical devices.

People

As the reputation part previously says, as a product developer, TBIOM employees are an important part of any chance of success. Without doctors and engineers to develop the product and a sales team capable of distributing the product, the risk of failure increases. To avoid this risk, they should keep hiring talented employees to develop products and to sell the products because this is as important as the product itself.

Exit strategy

If the resulting sales and success of AIRESS or the company are not the expected, TBIOM should always keep any exit strategy. This normally would be the acquisition by a bigger company that is in this market. Another option could be the change of strategy to become just a product developer to other companies.

Is always recommended to keep working on any risks that may affect the company, as a startup that is in the medical industry and as this year has already taught us with the Covid-19 pandemic, the change in this industry can be unexpected and the needs of the market can change from one day to other.

12. RECOMMENDATIONS

Product

AIRESS offers a unique value to the customer, but to ensure a good performance of the product, the user must be trained in the CPR maneuver. AIRESS has been defined as a complementary product and that has the right post-Covid-19 hygiene requirements and can also guarantee a 10-year life product.

Operations

TBIOM should have all the manufacturing and assembling outsourced. This will allow the company to focus on some key partners and increase the sales team quality inside the company to sell this product through the different targets selected.

Marketing mix

To increase the brand awareness and develop a long relationship with the customers, TBIOM should always increase their marketing budget according to sales and keep promoting the product through fairs, exhibitions, and digital channels.

The recommended price of the product is 600 € (VAT Inc.) and this should include: training and maintenance.

Financials

The company should continue investing in R&D and innovation. To do this, they may invest the resulting cash in the balance or maybe could ask for more investors. With a break-even point of 684 units and that the company starts to have profits starting from year 3 and a positive cash flow starting from year 2.

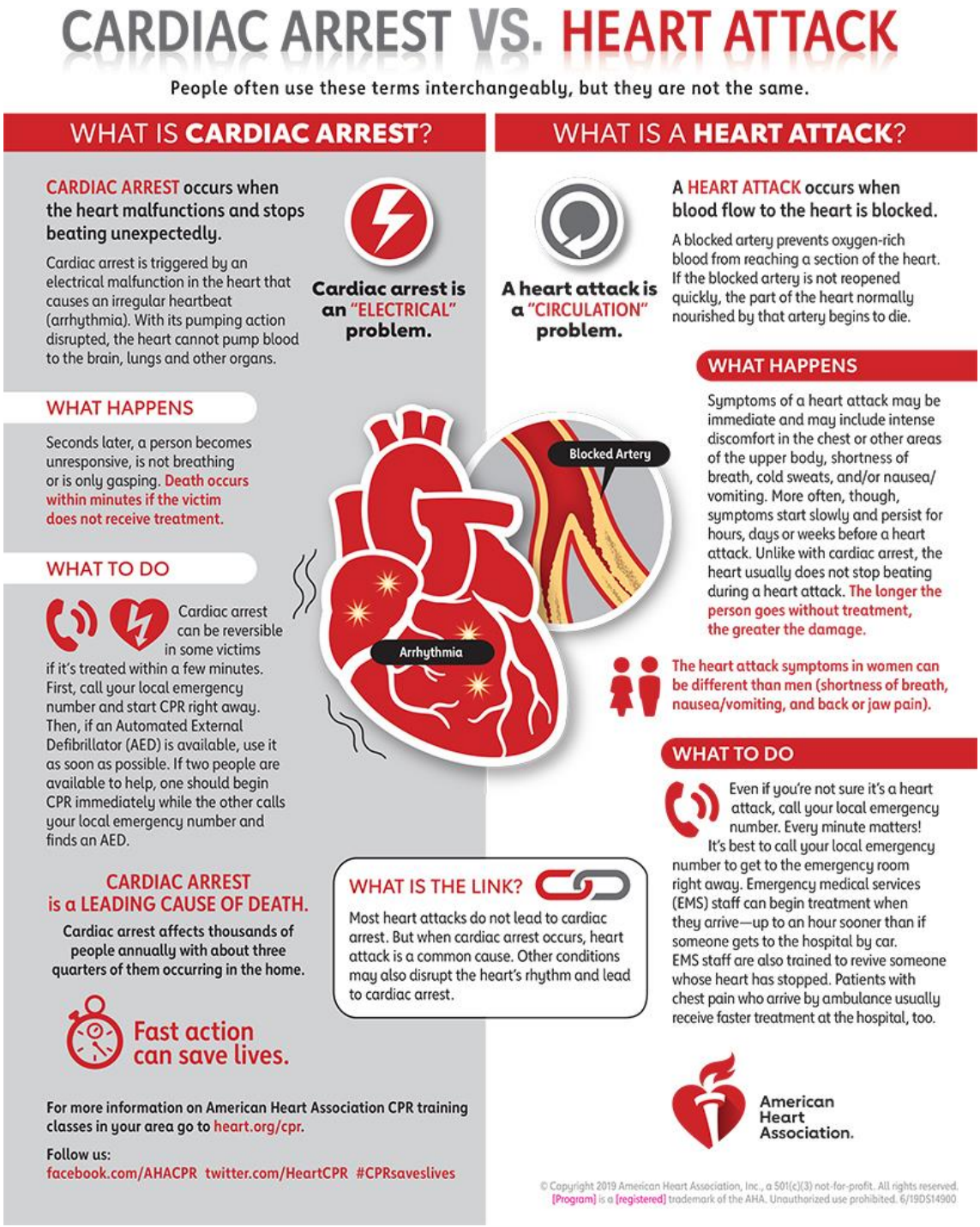
To become a profitable business and obtain a 21.4% of CAGR of sales, TBIOM should focus their investment for AIRESS in Spain, divided in five main regions in five years: Catalunya, Madrid, Andalucía, Castilla y León and Valencia.

Opportunity

AIRESS, as we have seen in the analysis, does not have a direct competitor, only indirect ones that perform different functions than that which AIRESS performs. There is also an opportunity that the medical device sector is growing more and moreover, there are 10 million people in Spain with diseases and conditions related to the heart. Moreover, 18.8% OHCA in adults and 13.3% OHCA in children happen in public spaces, therefore a great opportunity as we have already analyzed before.

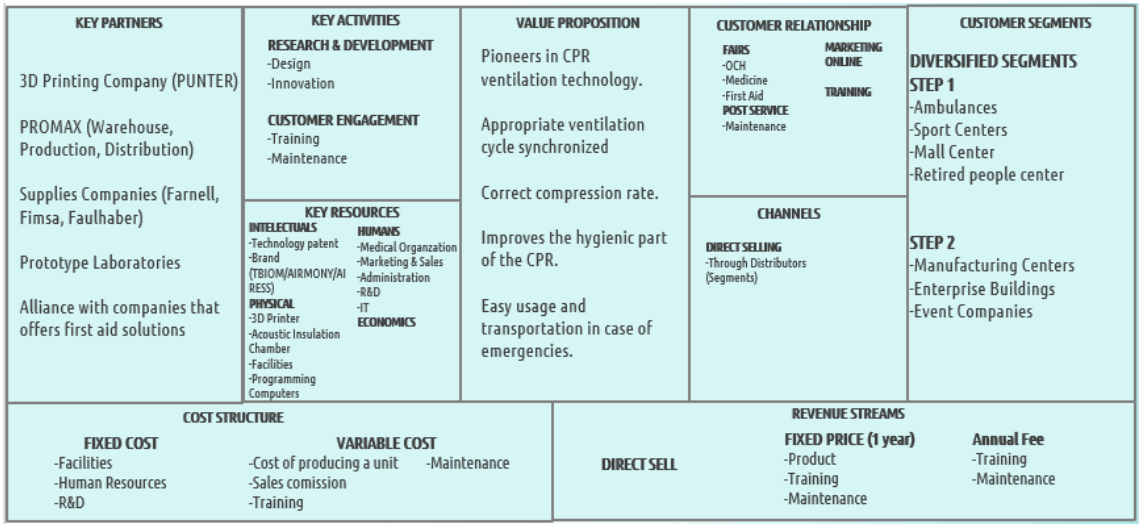
13. EXHIBITS

Exhibit 1 Cardiac Arrest vs Heart Attack



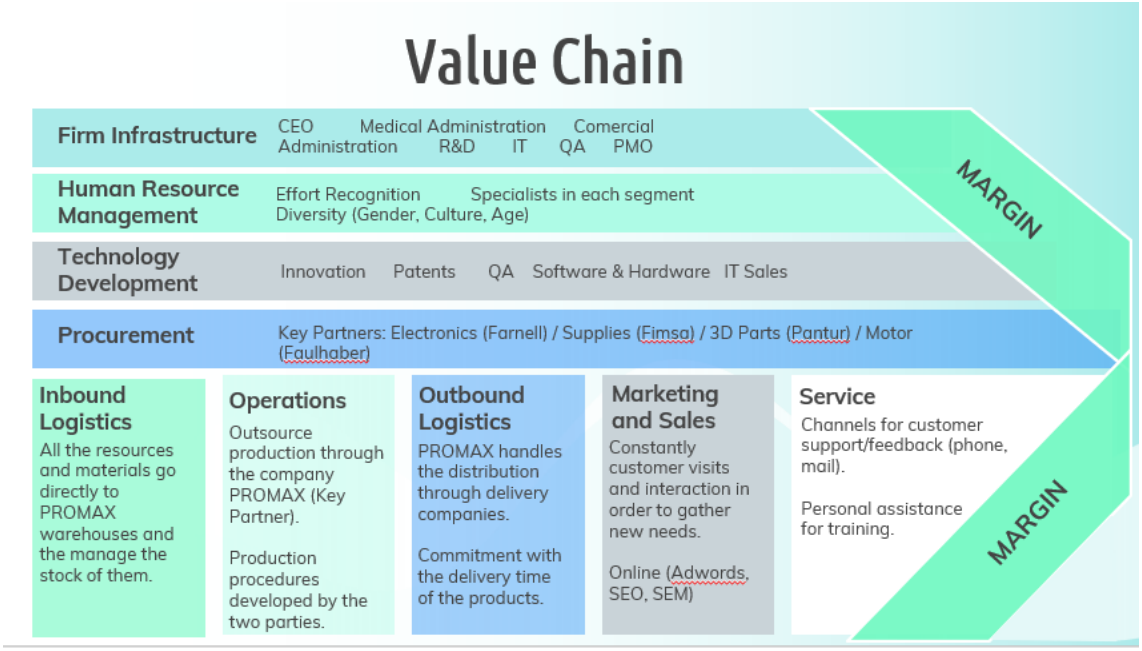
Source: (American Heart Association, 2019)

Exhibit 2 TBIOM AIRESS Business Model Canvas



Source: Own elaboration – Final Project Team AIRESS

Exhibit 3 TBIOM Porter's Value Chain



Source: Own elaboration – Final Project Team AIRESS

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