CONFIDENTIAL

Centre For Sustainability and Development

Business plan

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Centre For Sustainability and Development

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The big problem

Problem Statement

The project addresses the need for reliable, reusable, high-grade personal protection equipment (PPE) for Health-care workers (HCW) and people in emergency rooms. The specific aim is to satisfy the public need exacerbated by the COVID19 pandemic. In the U.K., one in four doctors is off work because they are either sick or in self-isolation, according to the Royal College of Physicians. In Italy, most infections occurred in hospital emergency rooms due to volume&traffic of people without masks. Overall, 10% of those infected with COVID19 were HCWs. This increases the strain on the NHS and other National Health organizations, especially during a pandemic.

Problem Analysis

Who has the problem?

The face mask request cannot be satisfied from the current level of face mask production.

Causes

- COVID-19
- Lack of face mask production.

Consequences

The pandemic background created an unstable system since the local governments cannot satisfy the massive demand of face masks.

Current Solution

The current face mask market appears to be virtually saturated, as there are not enough manufacturers/suppliers capable of meeting the staggering demand for these products during the COVID-19 period. The industry needs a breakthrough in terms of production and supply of masks since they are used in two main areas:

- COVID-19 protection: cases on a global scale have been growing again for about a month (source: WHO).
- Protection for doctors in environments with high bacterial risk.

The Unique Solution

Our Solution

The specific innovation is a face mask for protection against viruses and bacteria. The mask's novelty is created by its utilization of a pulsating High-Frequency Electric Field (" **HFEF**") device. This device allows the mask not to filter out harmful pathogens, but inactivate them, rendering viruses incapable of pathogenesis. The approach is unique because it combines the best aspects of the two main types of PPE:

a) Typical filter based face masks -- light and portable, value for money, offers reusable models;

b) SCBA-based PPE (for example, hazmat suit) -- provides the highest grade of personal protection, suitable for work in high-risk environments.

The current invention is light and portable while also offering enhanced protection like SCBA-based PPE. The invention solves the drawbacks of filter-based masks (ssRNA viruses are 6-10X smaller than the filters in the highest grade surgical masks, like N95) and SCBA equipment, single-use, and exceptionally expensive.

Our primary target market

Our Primary market will be A&E staff and G.P.s in the U.K. and the U.S. We use the fabless business model, allowing us to benefit from lower capital costs while

concentrating their research and development resources on the end market. Our team members have experience in implementing **Horizon 2020** projects and offer a unique combination of skills in business and strategy, marketing & sales, engineering, product design, and serial entrepreneurship.

The Horizon 2020 Project

Horizon 2020 (H2020) is the European Union (EU) Framework Program for research and innovation for 2014-2020. The Framework Programs, lasting seven years, are the main instrument with which the European Union (EU) finances research in Europe.

Horizon 2020 unifies three previous programs (2007-2013) aimed at supporting research, innovation and technological development in a single financial instrument: the Seventh Framework Program (FP7), the Competitiveness and Innovation Framework Program (CIP) and the European Institute of Innovation and Technology (EIT). Its elaboration was started in 2011, when the EU heads of state and government invited the European Commission, for the period 2014-2020, to integrate into a common strategic framework the various instruments dedicated to supporting research and innovation.

The Commission launched a broad consultation that involved all the leading players in the research field and led to the establishment of the Program.

The Market

Market Opportunity

According to Grand View Research Institute (Source: Grand View Research: Disposable Face Mask Market, 2020), the global disposable face mask market size exceeded a value of USD 74.90 billion in Q1 of 2020 (USD 307.2 billion in 2020) and is expected to grow at a compound annual growth rate (CAGR) of 53.0% from 2020 to 2027. The unprecedented spread of coronavirus worldwide, most notably in Europe and North America, is driving the demand for disposable face masks. Disposable face covers are extensively used in the healthcare sector. The proliferating OPD sessions and surgeries on a daily basis across the globe are anticipated to drive product demand within the healthcare sector. The function of disposable face masks is to reduce or eliminate the chances of being affected by potential environmental contaminants. Disposable face covers are typically made from non-woven fabric and are usually available in a multi-layer (two- or three-layer) form.

Additional Market Insights

Disposable face masks are popular among health care professionals who constantly attend patients or perform surgeries. These masks protect health care professionals from harmful bacteria that may ooze out either in the form of aerosols and liquid droplets from the patient's mouth. The virus or harmful bacteria can also get spread in the form of body fluids or infectious blood. Thus, these masks act as a protective barrier and help eliminate or reduce the chances of cross-contamination among surgeons and patients.

The demand for disposable face masks is likely to be driven by the rising popularity of online shopping platforms. In this regard, Amazon.com, Inc. and eBay Inc. are among the biggest online players contributing significantly to the distribution of the product. Furthermore, the popularity of online sales has been creating a healthy demand for disposable designer face masks, most notably among affluent consumers worldwide. Such trends are expected to sustain throughout the forecast timeframe.

A key factor challenging the growth of the industry is the rising prevalence of counterfeit products both in physical stores and on online platforms. The counterfeit masks are usually made in unsterile sweatshops that were previously used to manufacture designer jeans or fake handbags. In this regard, there have been instances of numerous producers labeling their products with fake brand names of reputed medical supply manufacturers, such as 3M. Such factors are expected to restrain market growth throughout the forecast period.

Rising consumer awareness regarding airborne infections has been creating a healthy demand for the product, most notably for personal use. In this respect, a rise in outbreaks as regards airborne diseases in the recent past has been contributing significantly to the demand for disposable face masks among the general public. A trend that has been gripping the market is the increasing consumption of surgical masks for personal use.

Product Insights

Among products, protective face masks segment dominated the overall industry, accounting for a share of 35.8% in 2019. This type of disposable face cover also includes air-purifying respirators. The other two segments that make up the overall disposable face masks market are dust masks and non-woven masks.

Protective face covers have certain advantages for users with respiratory issues such as asthma or lung disease. Users with cardiovascular diseases also prefer them. Protective masks such as N95 are known to offer more protection to health care workers performing medical procedures that expose them to patients' respiratory secretion.

Non-woven masks are manufactured using plastic variants such as polypropylene to provide protection against various types of infections at workplaces. These masks do not contain latex, PVC, and DEPH material. Non-woven face covers are principally used in the hospital industry and are manufactured using two to three layers of protection. Users prefer these masks for the superior protection they offer against allergic reactions to consumers with sensitive skin.

Distribution Channel Insights

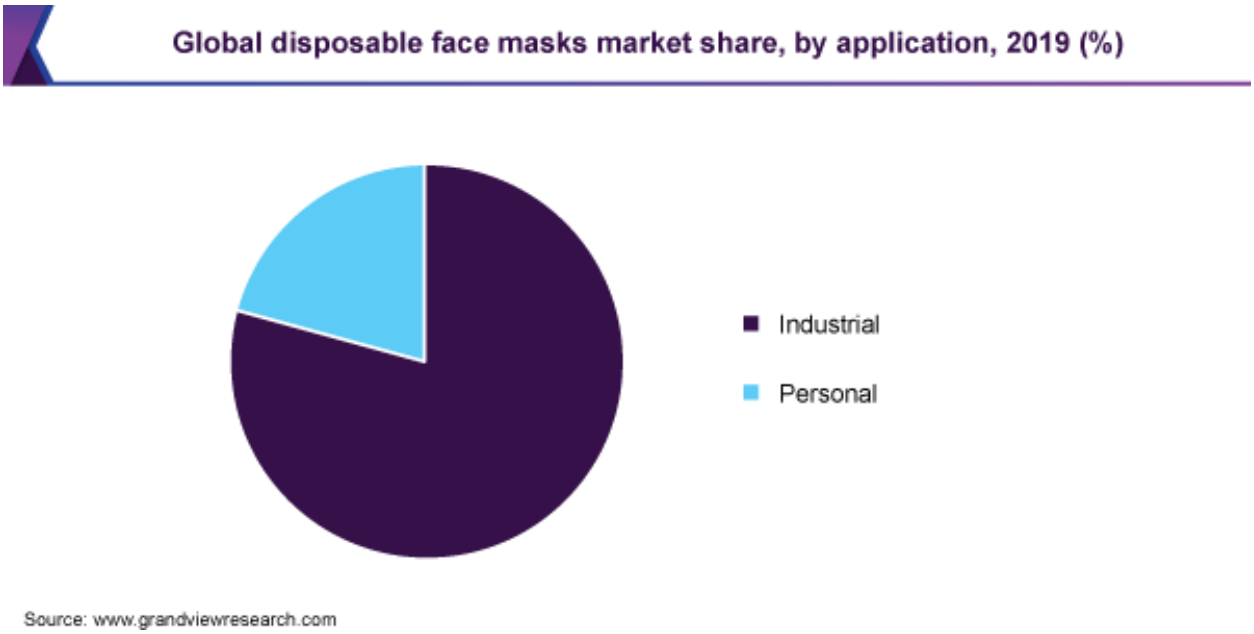
The offline segment emerged as the largest in 2019, with a market share of 80.7%. This segment is likely to retain its pole position throughout the forecast period. Numerous brands prefer to sell their products through drug stores and pharmacies

as these stores showcase a wide variety of disposable face masks. From a consumption standpoint, visiting these stores helps consumers compare different products in terms of material used and quality.

E-commerce has significantly changed the shopping habits of people as it offers benefits such as door-step delivery, substantial discounts, and availability of a wide range of products through one platform. Key players in the market are increasingly launching e-commerce websites, most notably in emerging markets owing to the rising popularity of online shopping among millennials and young population.

Application Insights

By application, the industry is segmented into two categories, namely industrial and personal, wherein the industrial segment dominated the overall industry revenues in 2019, with a share of over 80.0%. This segment is also anticipated to retain its prominent position throughout the forecast timeframe. Disposable face covers intended for industrial applications are principally used by healthcare professionals and workers at agricultural and construction sites. The growth of this segment is driven by the mushrooming of hospitals across the globe.



The global rise in the frequency of air-borne diseases and pollution levels has been encouraging a sizable number of consumers to opt for personal disposable face masks. With consumers looking out for options to keep themselves safe from virus-related pandemics, prominent manufacturers are focusing on increasing their scale of operation in regards to the manufacturing of disposable face masks for personal use.

Regional Insights

Asia Pacific emerged as the largest market for disposable face masks in 2019, having accounted for a market share of 33.7% in 2019. Manufacturers operating in this region are benefiting from the presence of a large customer base, most notably in

countries such as China and India. China and India are also among the most substantial disposable face masks' manufacturing countries in the world.

North America is forecast to progress at the highest CAGR over the projected timeframe. Led by countries such as the U.S. and China, the demand for disposable face masks in North America is driven by an expanding consumer base, backed by rising awareness regarding health and personal hygiene. The coronavirus outbreak is likely to contribute massively to the growth of the market in North America with various governments, encouraging the habit of personal hygiene among consumers.

Number of Users Segmentation

During the COVID-19 pandemic, face masks were employed as a public and personal health control measure against the spread of SARS-CoV-2. Their use is intended as personal protection to prevent infections and as a source, control to limit the transmission of the virus in a community or healthcare setting.

The use of masks has received several recommendations from various public health agencies and governments, including prominent Western countries such as Europe, the United Kingdom, South Korea, and the United States of America.

The World Health Organization and other public health organizations agree that masks can limit the spread of respiratory viral diseases such as COVID-19. However, the topic has been the subject of debate, with some public health agencies and governments initially disagreeing on a protocol for wearing face masks.

Since the beginning of May 2020, 88% of the world's population lives in countries that recommend or enforce the use of masks in public; more than 75 countries have imposed the use of shows, and therefore it is estimated that from April 2020 to today (30 August 2020) there have been approximately 4.3 billion users. Debates have arisen over whether masks should also be worn when socially walking away at 2 meters (6 feet) and whether they should be worn during anaerobic exercise. (Source: Grand View Research: Disposable Face Mask Market, 2020).

Besides, the public health agencies of some countries and territories have changed their recommendations on face masks over time. Face masks have been shortages, and not all have been certified. Especially in the month of April, the entire globe suffered from the lack of masks as few companies were specializing in producing these consumer goods. The shortage situation is still present (September 2020).

Also, inadequate masks with significantly reduced performance have been reported on the market.

Types of Face Masks Segmentation

There are several types of face masks, including:

- cloth face masks
- complete medical or surgical masks

- Face seal filtering face masks, including non-certified dust masks and certified breathing masks (with respirator certifications such as N95 masks, N99 masks, and FFP masks)
- other respirators, including elastomeric respirators, some of which are also N95 / FFP / N99 masks, etc

Transparent face shields, medical goggles, and other personal protective equipment are sometimes used along with face masks.

We can deepen this differentiation as follows:

Fabric masks

They are fabric masks produced for non-sanitary hygienic use and are not certified. Many companies have reconverted their production lines to market masks for clean use at a time of great demand and scarce supply of shows. This is because it is crucial to protect yourself and still wear a fabric barrier that allows you to breathe easily and prevent the propagation of potentially contagious droplets. These masks must completely cover the nose and mouth and must be used, like all other masks except PPE, keeping a safe distance of at least one meter from other people. They are washable and reusable masks and are suitable for going out in compliance with all the World Health Organization's preventive hygiene requirements.

So they are not a medical device, but they still help to fight the spread of the virus due to their filter function compared to the bulk of the droplets expelled from the mouth and nose. More and more states (including America and England) are inviting the population to wear any mask, even homemade, to limit the infection's extent. For the gradual reopening of commercial activities (so-called Phase 2), the European Union also provides for the use of "fabric" masks. Therefore, fabric masks for non-sanitary use are a form of collective protection, compatible with their low cost and their mechanical barrier function against the virus's propagation. They also help reduce the enormous production of waste to be disposed of connected with the mass use of disposable masks and gloves.

Surgical masks

Surgical masks are among the most widespread and worn during the COVID-19 epidemic. They are masks with a typical blue color and were usually worn by doctors and dentists. The surgical mask aims to protect the operated patient from possible contact with bacteria and viruses exhaled by the wearer. Their value lies in filtering the air coming out of the nose and mouth very well. They have a very high filtering capacity towards the outside, equal to 95%. For this reason, they are considered an excellent way to severely limit the spread of droplets that are spread by talking or through coughing and sneezing.

FFP3 and FFP2 masks

Medical staff in hospitals wear them. They are masks considered by law as PPE (personal protective equipment), and for this reason, they guarantee a much higher filtering capacity of the inhaled and exhaled air. The abbreviation FFP stands for "facial filters for individual protection" and indicates that the mask was produced in compliance with the EN 149-2001 standard. The progressive numbering (FFP1, FPP2, FFP3) shows the different device types' developed air filtering capacity. The FFP1 masks have a limited filtering capacity. They only stop the most massive particles in the breathed air and are not the most suitable for protecting the wearer from harmful micro particles such as those containing the virus.

The FFP2 and FPP3 masks have a filtering capacity of tiny particles (including those containing the virus) equal to 92% for FPP2 and 98% for FFP3. The most effective masks for protecting oneself and others are FFP2 masks and FFP3 masks without valves, as they guarantee maximum protection for both the wearer and those around them. The valves expel the air exhaled by the wearer, but without filtering it. Therefore, their use is not recommended, especially if you have symptoms or are suspected of being contagious. A feature of FFP3 masks is that, given the high level of filtering and the layering of the materials used to make them, they can be uncomfortable to breathe for prolonged periods. These masks also have a limited cycle of use. They are manufactured to ensure protection for about 6 hours, after which the filtering effectiveness is no longer guaranteed and must be disposed of.

N95 and KN95

The abbreviations N95 and KN95 accompany the masks that have been produced and certified in China (KN95) and in America (N95), according to quality standards similar to those that certify the European FFP2 masks. Here we need to clarify: in order for the effectiveness of masks with these abbreviations to be officially equated to FFP2; the CE mark must have been affixed. This means that the mask's effectiveness has been tested and has been evaluated in compliance with the standards adopted in the European Union. If the N95 and KN95 masks bear the CE mark, these masks' effectiveness concerning filtering microparticles and viruses is comparable to that of FFP2 masks.

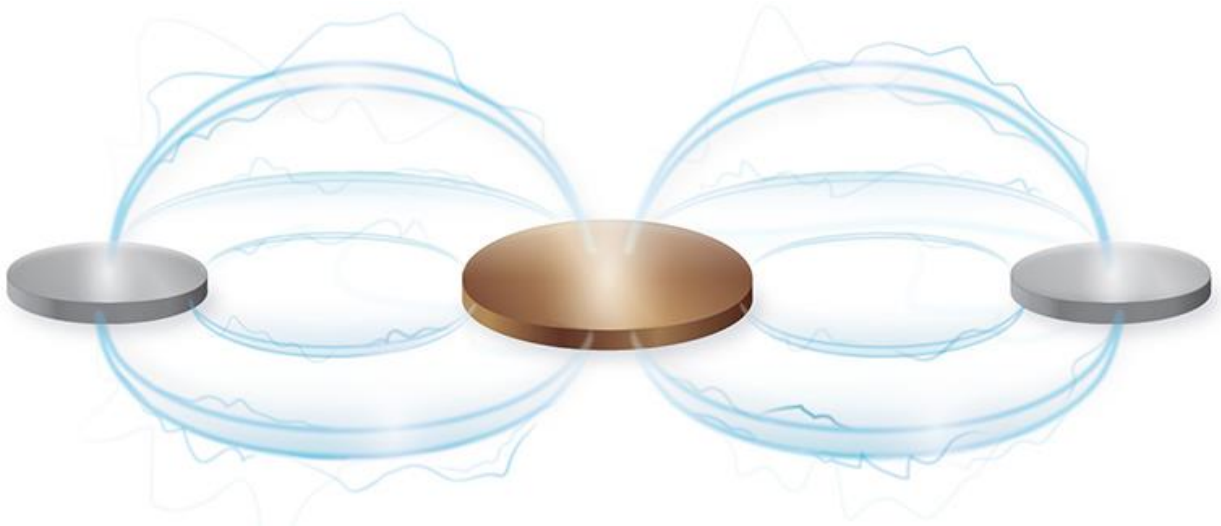
Electric Face Masks

As the wearing of face masks has become ubiquitous in public places, people end up reusing these devices as they go from place to place. Pathogens get deposited on the exterior of the masks and within the fabric. Considering that many pathogens, including that which causes COVID-19, can reside on surfaces for a long time, the masks themselves may be a way for diseases to spread.

Researchers at Indiana University believe that electricity can be used to deactivate pathogens on face masks and they recently showed that an “electroceutical” fabric kills coronavirus particles on contact and may be highly useful to help guarantee the safety of face masks and potentially make them properly reusable.

The material, already commercialized by Vomaris, an Arizona firm and FDA cleared for the treatment of wounds, consists of an array of tiny batteries that work together to generate an electric field across a fabric. When moisture is present, a current is evoked within it and any pathogens within the moisture are affected.

The technology, called V.Dox, seems to be particularly suited for coronaviruses because they use electrostatics to bind to a host and to take on an infective form. Sending a current through where the viral particles are attached may be disrupting these processes.



In their laboratory tests, the Indiana team were able to kill coronaviruses within a minute of activating the V.Dox fabric. Since it's already being safely used as an

antimicrobial electroceutical for the treatment of serious wounds, it may soon be green lit by the FDA for other applications.

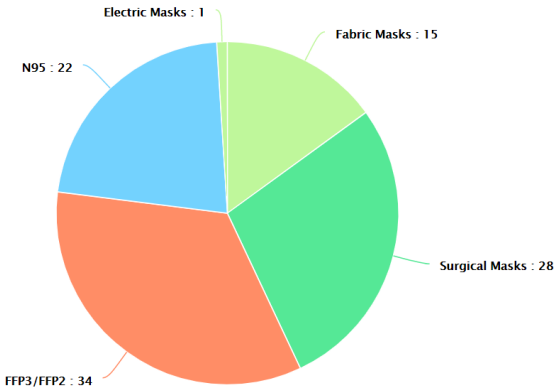
“This work presents the first evidence demonstrating that the physical characteristic features of coronaviruses may be exploited to render them non-infective following contact with low-level electric field-generating electroceutical fabric,” said Chandan Sen, principal author of the study which has been preprinted in *ChemRxiv*.

The electric face mask entered in the market during the last month (August 2020) with a donation from LG Electronics to the Severance Hospital in Seoul. Several actors are depositing their patents for the development and production of electric face masks, but - as the reader can imagine - there are no available data and insights about these products, since their market niche is totally new.

Speaking now in terms of face mask segmentation, we can resume the following percentages of market shares in the global scale:

1. Fabric masks: 15% of the shares
2. Surgical masks: 28% of the shares
3. FFP3/FFP2: 34% of the shares
4. N95: 22% of the shares
5. Electric face masks (a new trend).: 1% of the shares, but their potential growing rates will be equal to +89% during the next 14 months. (Source: Grand View Research, Disposable Face Mask Market, 2020).

PRODUCT SEGMENTATION (%)



Grand View Research

Customer Analysis

Customer Overview

Our target groups are:

* A&E staff, Advanced Paramedic and Emergency Medical Technicians;

* G.P.s during an epidemic;

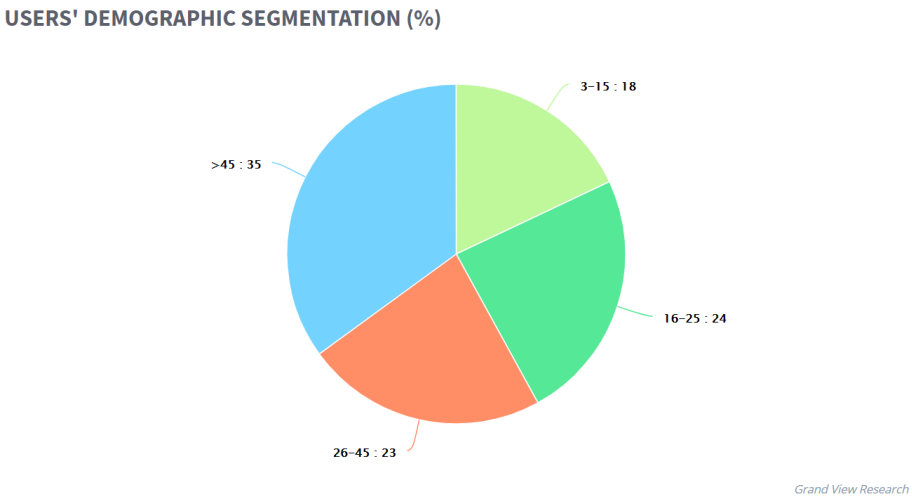
* All other HCWs;

* Visitors to A&E.

Demographics

We can divide the total target market under the following groups (by including the percentages of each target market):

- 3–15 years old: 18%
- 16–25 years old: 24%
- 26–45 years old: 23%
- > 45 years old: 35%.



Additional Insights

We have to consider a great portion of potential target market with the following categories:

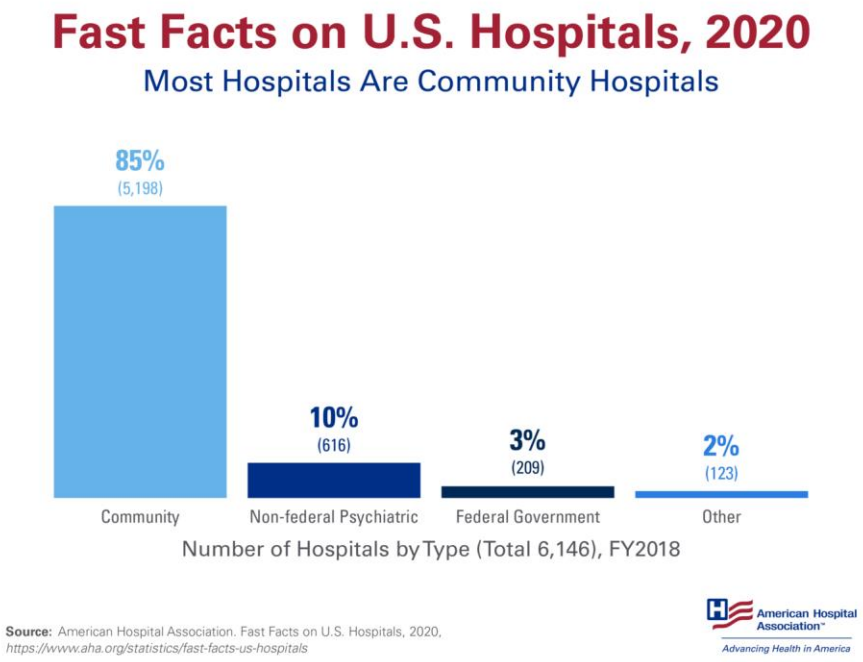
- **Hospitals and Medical Centers** (UK/USA)
- **Emergency Departments** (UK/US)
- **General Practitioners** (UK/US).

Hospitals and Medical Centers in the USA

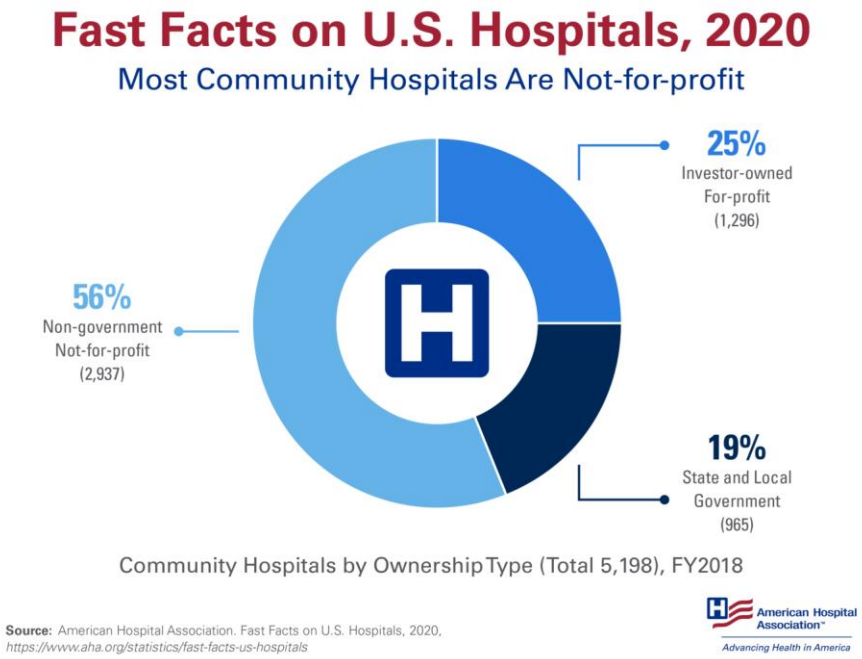
The American Hospital Association conducts an annual survey of hospitals in the

United States. The data below, from the 2018 AHA Annual Survey, are a sample of what you will find in *AHA Hospital Statistics*, 2020 edition. The definitive source for aggregate hospital data and trend analysis, *AHA Hospital Statistic*s includes current and historical data on utilization, personnel, revenue, expenses, managed care contracts, community health indicators, physician models, and much more.

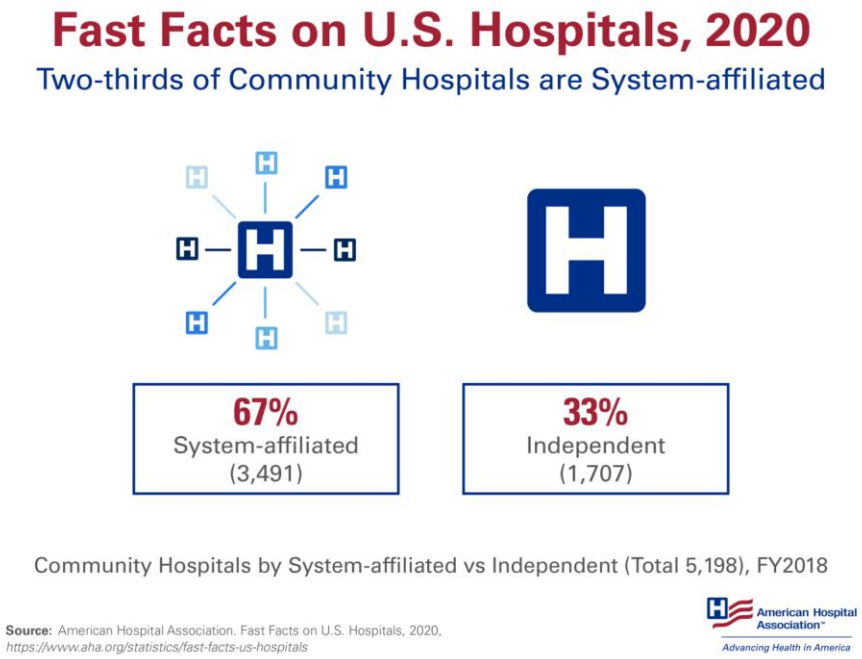
- The majority of US hospitals are community hospitals, followed by Non-Federal centers, and Federal Government-based hospitals.



- Most community hospitals are no-profit organizations.



- 2/3 of the community hospitals are system-affiliated centers.



- 65% of them are situated in urban areas.

Total Number of All U.S. Hospitals	6,146
Number of U.S. **Community** [1] Hospitals	5,198
Number of Nongovernment Not-for-Profit Community Hospitals	2,937
Number of Investor-Owned (For-Profit) Community Hospitals	1,296
Number of State and Local Government Community Hospitals	965
Number of Federal Government Hospitals	209
Number of Nonfederal Psychiatric Hospitals	616
Other [2] Hospitals	123

- Additional US hospital insights:

Total Staffed Beds in All U.S. Hospitals	924,107
Staffed Beds in Community [1] Hospitals	792,417
Intensive Care Beds [3] in Community Hospitals	
Medical-Surgical Intensive Care [4] Beds in Community Hospitals	55,663
Cardiac Intensive Care [5] Beds in Community Hospitals	15,160
Neonatal Intensive Care [6] Beds in Community Hospitals	22,721
Pediatric Intensive Care [7] Beds in Community Hospitals	5,115
Burn Care [8] Beds in Community Hospitals	1,198
Other Intensive Care [9] Beds in Community Hospitals	7,419
Total Admissions in All U.S. Hospitals	36,353,946

1. **Community hospitals** are defined as all nonfederal, short-term general, and other special hospitals. Other special hospitals include obstetrics and gynecology; eye, ear, nose, and throat; long term acute-care; rehabilitation; orthopedic; and other individually described specialty services. Community hospitals include academic medical centers or other teaching hospitals if they are nonfederal short-term hospitals. Excluded are hospitals not accessible by the general public, such as prison hospitals or college infirmaries.

2. **Other hospitals** include nonfederal long term care hospitals and hospital units within an institution such as a prison hospital or school infirmary. Long term care

hospitals may be defined by different methods; here they include other hospitals with an average length of stay of 30 or more days.

3. Note that **intensive care bed counts** are reported on the AHA Annual Survey by approximately 80% of hospitals. Therefore, we have supplemented the Intensive care bed counts based on FY2018 data reported in the CMS Healthcare Cost Report Information System (HCRIS). Total intensive care beds are not summed because the care provided is specialized..

4. **Medical-surgical intensive care.** Provides patient care of a more intensive nature than the usual medical and surgical care, on the basis of physicians' orders and approved nursing care plans. These units are staffed with specially trained nursing personnel and contain monitoring and specialized support equipment for patients who because of shock, trauma or other life-threatening conditions require intensified comprehensive observation and care. Includes mixed intensive care units.

5. **Cardiac intensive care.** Provides patient care of a more specialized nature than the usual medical and surgical care, on the basis of physicians' orders and approved nursing care plans. The unit is staffed with specially trained nursing personnel and contains monitoring and specialized support or treatment equipment for patients who, because of heart seizure, open-heart surgery, or other life-threatening conditions, require intensified, comprehensive observation and care. May include myocardial infarction, pulmonary care, and heart transplant units.

6. **Neonatal intensive care.** A unit that must be separate from the newborn nursery providing intensive care to all sick infants including those with the very lowest birth weights (less than 1500 grams). NICU has potential for providing mechanical ventilation, neonatal surgery, and special care for the sickest infants born in the hospital or transferred from another institution. A full-time neonatologist serves as director of the NICU.

7. **Pediatric intensive care.** Provides care to pediatric patients that is of a more intensive nature than that usually provided to pediatric patients. The unit is staffed with specially trained personnel and contains monitoring and specialized support equipment for treatment of patients who, because of shock, trauma, or other life-threatening conditions, require intensified, comprehensive observation and care.

8. **Burn care.** Provides care to severely burned patients. Severely burned patients are those with any of the following: (1) second-degree burns of more than 25% total body surface area for adults or 20% total body surface area for children: (2) third-degree burns of more than 10% total body surface area; (3) any severe burns of the hands, face, eyes, ears, or feet; or (4) all inhalation injuries, electrical burns, complicated burn injuries involving fractures and other major traumas, and all other poor risk factors.

9. **Other intensive care.** A specially staffed, specialty equipped, separate section of a hospital dedicated to the observation, care, and treatment of patients with life-threatening illnesses, injuries, or complications from which recovery is possible. It

provides special expertise and facilities for the support of vital function and utilizes the skill of medical nursing and other staff experienced in the management of these problems.

UK Hospitals

Number of NHS hospitals

Correct as of September 2019, there are 1,257 hospitals in the UK. This includes the NHS trust-managed hospitals and the additional private hospitals that are currently in use.

Largest hospital

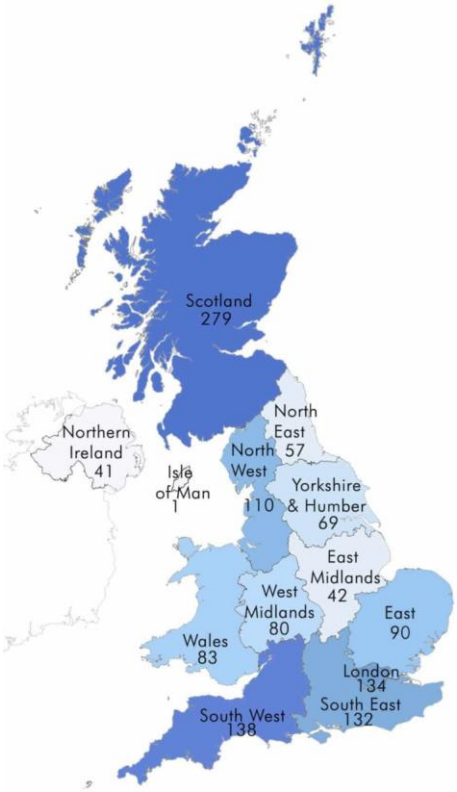
St George's Hospital is the largest in the UK, looking after 1.3 million people in southwest London and significant populations in Surrey and Sussex, totaling approximately 3.5 million. It has 1,300 beds and around 8,500 staff, as well as several centres of excellence, such as its stroke care and cardiology unit.

Number of NHS trusts

An NHS trust is a healthcare provider, set up to deliver hospital and community services, and other aspects of patient care. As of October 2019, there were 223 trusts in the UK. However, this statistic doesn't correlate to the number of hospitals, as many trusts run more than one hospital, e.g. Manchester University

NHS Foundation Trust runs nine. The number is constantly changing due to mergers but as of April 2019, there were 191 CCGs in England.

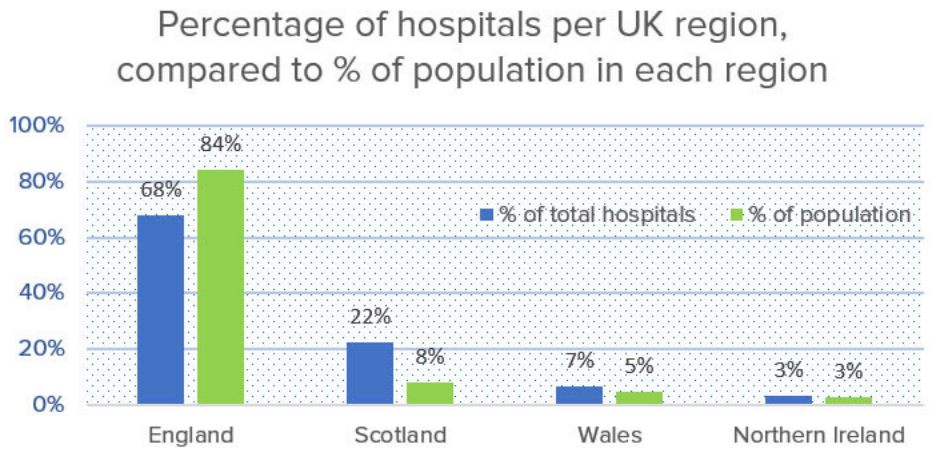
Looking at the different regions, 68% of all hospitals are in England (854 hospitals) and Scotland has 22% of the hospitals at 279. Wales has 7% with 83 hospitals and Northern Ireland has just 3% with 41 hospitals.



In more detail, here's the full list of hospital numbers per district: Scotland 279, South West 138, London 134, South East 132, North West 110. East of England 90,

Wales 83, West Midlands 80, Yorkshire & Humber 69, North East 57, East Midlands 42, Northern Ireland 41, Channel Islands 1 and finally the Isle of Man has 1 hospital.

When considering the number of patients and hospitals in each region, there's a huge disparity between regions. For example, England is home to 84% of the UK population, but there's only 68% of the total number of hospitals. However, there are very large multi-discipline hospitals serving large communities all across England. Whereas there are many more smaller hospitals, serving communities in the less populated, remote areas of Scotland and Wales.



General Practitioner in the USA

Of the 624,434 physicians in the United States who spend the majority of their time in direct patient care, slightly less than one-third are specialists in primary care. Primary care physicians consist of family physicians and general practitioners, general internists, general pediatricians, and geriatricians. Of the nearly 956 million

visits that Americans made to office-based physicians in 2019, 51.3% were to primary care physicians.

According to the 2019 American Medical Association Physician Masterfile, there are slightly more than 246,000 primary care physicians in the United States. This number, however, overestimates the number of practicing physicians and needs to be adjusted because the AMA Physician Masterfile includes some retired physicians and others who have left the workforce and a substantial number of primary care trained physicians now practice in non-primary care settings, including as hospitalists and in emergency departments. After adjusting for these two factors, the number of practicing primary care physicians in the U.S. is estimated to be approximately 209,000.

Type of practice	Primary care physicians in direct patient care*	Adjusting for retirement	Percent estimated to be practicing	Practicing primary care physicians
FP	87,650	84,033	95%	79,831
GER	3,260	3,157	95%	2,999
GP	11,883	9,557	100%	9,557
GIM	93,655	89,359	80%	71.487
PD	49,642	47,297	95%	44,933
Total	246,090	233,403		208,807

* From the AMA Physician Masterfile 2019.

Abbreviations: FP = Family Practice, GER = Geriatrics, GP =General Practice, GIM= General Internal Medicine, PD = General Pediatrics.

General Practitioners in the UK

Of the 290 thousand doctors registered in the United Kingdom in 2018, around 61.5 thousand are registered as general practitioners. In the last ten years the ratio of patients per GP practice has been deteriorating, indicating a stretch on the health service. In 2008, there was, on average, approximately 6.4 thousand patients to each GP practice in the UK, by 2017 this figure had climbed to over 7.6 thousand.

All GPs: **33,515 Full-time equivalent** (1.8% (600) **fewer** than June 2019), **44,041 Headcount** (1.2% (529) **fewer** than June 2019).

Fully qualified GPs (excludes Registrars): **27,605 Full-time equivalent** (2.3% (651) **fewer** than June 2019), **37,996 Headcount** (1.5% (585) **fewer** than June 2019).

Qualified permanent GPs (excludes Registrars and Locums): **26,435 Full-time equivalent** (1.9% (506) **fewer** than June 2019), **34,753 Headcount** (1.2% (399) **more** than June 2019).

Emergency departments in the USA

According to the Center of Disease Control and Prevention (www.cdc.gov), we can provide the following insights:

- Number of visits: 139.0 million
- Number of injury-related visits: 40.0 million
- Number of visits per 100 persons: 43.3
- Number of emergency department visits resulting in hospital admission: 14.5 million
- Number of emergency department visits resulting in admission to critical care unit: 2.0 million
- Percent of visits with patient seen in fewer than 15 minutes: 40.4%
- Percent of visits resulting in hospital admission: 10.4%
- Percent of visits resulting in transfer to a different (psychiatric or other) hospital: 2.2%

- As of 2019, there were more than 5,200 documented emergency departments and rooms in the whole of the country. As we are speaking today, the number is estimated to have increased by more than 25% according to a recent research conducted by the National Emergency Department. By 2022 the number of emergency rooms is projected to be at more 10,000 if the current trend is anything to go by. There are emergency rooms mushrooming on every street corner and the services are getting closer to people. This is a positive sign and Americans should be glad because quicker services are coming closer to them.

Emergency departments in the UK

There are three main types of A&E departments in England.

Type 1 departments are what most people might traditionally think of as an A&E service. They are major emergency departments that provide a consultant-led 24-hour service with full facilities for resuscitating patients, for example patients in cardiac arrest. Type 1 departments account for the majority of attendances (63 per cent in 2018/19).

Type 2 departments are consultant-led facilities but for single specialties, for example, dedicated to treating only eye conditions or only dental problems.

Type 3 departments treat minor injuries and illnesses, such as stomach aches, cuts and bruises, some fractures and lacerations, and infections or rashes. Type 3

departments, which can be routinely accessed without an appointment, include minor injury units and walk-in centers.

Major (type 1) and specialist (type 2) departments are operated by NHS trusts. Type 3 departments are operated by the NHS and by the independent sector.

As of March 2020, there were 132 NHS trusts operating type 1 A&E departments. Each trust may operate more than one type 1 A&E department, and, based on audit data from the Royal College of Emergency Medicine, there are approximately 180 individual type 1 emergency departments in England.

Competitors

Competitive Landscape

A

The disposable face masks industry houses both international and domestic market players. Prominent market participants compete on the basis of price and product quality. Small and medium-sized market players are expected to show considerable improvements in the foreseeable future, given the moderate level of capital expenditure needed to set up a business. The large-sized companies, however, are likely to aim for global expansion, in a bid to gain a more considerable brand reputation. Capacity expansion is expected to remain as the preferred competitive strategy for prominent market participants to stay competitive. For instance, In March 2020, Honeywell expanded its production capabilities in Phoenix to produce N95 face masks in support of the U.S. government's response to the novel coronavirus pandemic. Some of the prominent players in the disposable face mask market include:

Honeywell

Honeywell is a Fortune 100 company that invents and manufactures technologies to address tough challenges linked to global macrotrends such as safety, security, and energy. With approximately 110,000 employees worldwide, including more than 19,000 engineers and scientists, they have an unrelenting focus on quality, delivery, value, and technology in everything they make and do.

The PM 2.5 **masks** from **Honeywell** are specially designed to protect the user from probable respiratory ailments and allergies originating from the polluted air in the cities and common allergens like pollen in the environment. These **masks** have **a** 3 layer filter media which ensures the best protection.

3M

3M touches virtually every part of your life. Their people and technology make the impossible, possible. Every day they apply their science to enhance people's lives. This is 3M Science. Applied to Life.

3M Health Care Particulate **Respirators** and **Surgical Masks3M** Health Care Particulate **Respirators** and **Surgical Masks** provide you the respiratory protection you desire. Every day you put yourself at risk to ensure your patients are cared for.

Moldex

Moldex is one of the world's leading manufacturers of respiratory and hearing protection products. Founded in California in 1980, Moldex Germany was established five years later with the aim of developing and producing products to European standards. Today Moldex is a global company with 750 employees in 24 countries. In addition to safety, usability and quality, the foremost objectives of product development are sustainability and design.

The **Moldex** disposable Respirator rangeFFP-**Masks**, also called Respirators, provide optimum protection from airborne particles. **Moldex** offers **a** wide

Respirator range in all protection levels and for **a** variety of applications. Due to the filter technology, **Moldex masks** are very easy to breath through.

Kimberly Clark

Wherever you go, Kimberly-Clark brands are among the best known in the world

Kimberly-Clark creates essential products for a better life through renowned brands, necessary in everyday life: at home, at school, at work, and on the go.

Throughout our 142 years of history, they have challenged conventional ideas to innovate products while best-meeting consumers' needs. They have created new categories with top brands like Kleenex and redefined the categories with Huggies® and U by Kotex®.

As they continue to expand our $ 19 billion global business, they contribute to professional growth through teamwork where traditional boundaries are redefined, engaging experiences, and countless opportunities to work with some of the world's best-known brands. Their 43,000 employees are changing the world to make it a better place, including generous donations to charitable organizations and projects worldwide.

Their masks feature **a** protective three-layer construction for adequate protection when exposure to blood or bodily fluids is not **a** risk.

SAS Safety Corp.

SAS Safety Corp. (a Bunzl, PLC subsidiary) is committed to providing its customers with quality products and services through continued improvement in technology, process and personnel. Being ISO certified is more than just a certificate; it is about maintaining a quality management system that assures valued customers that they can rely on SAS Safety products. They offer a complete line of head-to-toe personal protective equipment solutions for all industries: Respiratory, Hearing, Eye, Hand/Body Protection, Ergonomic/Traffic Safety, First Aid Kits and Spill Control. They understand the importance of meeting customer's needs from the distributor to the end-user. Commitment to your satisfaction is our #1 priority.

Electric Face Masks

As we have already introduced and analyzed in the**Market** chapter, there is a new interesting trend that is raising during the last month (July 2020): the electric face masks. As we have already seen, this type of masks uses a particular technology called V.Dox. It seems to be particularly suited for coronaviruses because they use electrostatics to bind to a host and to take on an infective form. Sending a current through where the viral particles are attached may be disrupting these processes.

We are going to analyze the top companies that are providing/developing their electric face masks:

- **LG Electronics**: The mask has two H13 HEPA filters that are replaceable and a user can inhale air through the filters. Under the filters, there is a tiny fan that can control the amount of air. The fan is applied with an algorithm that raises the fan speed to let in more air when the user breathes in.

- **Xiaomi Group**: Xiaomi started the development of its electric face mask since March 2020 and introduced them into the market during the last July 2020. The working process is similar to the LG-based masks.

- **Keshiwo**: the product is similar to the masks proposed by Xiaomi and LG.

- **LIGC**: This is another type of electric face masks. With its graphene filtration system the Guardian G-Volt is 99 per cent effective against particles over 0.3 micrometers, and 80 per cent effective against anything smaller, claims LIGC Applications.

For comparison, a N95 respirator mask blocks 95 per cent of particles over 0.3 micrometers. Viruses such as COVID-19 can be transmitted through tiny droplets of water. A low level electrical charge will pass through Guardian G-Volt when it is plugged in to a portable battery pack via a USB port. This charge would repel any particles trapped in the graphene mask. At home, a docking system will allow the mask to be fully sterilized so it can be worn again.

Risks

Key Risks

We should consider the following key risks:

- High number of new competitors: Since the market results are profitable, we should expect a tremendous number of new competitors during the next months. As we have explored in the market chapter, the industry size will start its fall from 2021, but it will be slow and gradual.
- Complexity for the mask logistics: An external outsourced production (China and South Korea is the best solution in terms of direct expenses), but we should consider the potential logistics-based barriers to place a manufacturing center in these regions. The shipments in the US and UK targets may register high delay times. Differently, a manufacturing center established in Europe or the USA will bring higher direct production costs and lower logistics issues and expenses.

Required patents and permissions

USA

According to Troutman Insights, in April, the Centers for Disease Control and Prevention (“CDC") began recommending that the public wear face masks as “source control" to limit the spread of COVID-19. In response to this recommendation, the Food and Drug Administration (“FDA") extended its prior

Emergency Use Authorization (“EUA") to cover face masks intended for use as source control. In May 2020, FDA again updated its guidance documents and defined face masks used for source control as medical devices subject to FDA regulation and requirements. To aid in increasing the availability of products intended to help curb the spread of COVID-19, the Department of Health and Human Services (“HHS") issued a declaration that provides potential manufacturers of countermeasures with immunity from liability in certain cases. Now that FDA has defined face masks used for source control as medical devices covered by its EUA, face mask manufacturers may be able to claim protection under these immunity provisions. FDA regulation and potential civil products liability still pose legal risks, and would-be manufacturers should understand the regulatory requirements, immunities, and protections surrounding face mask manufacturing before wading into this highly regulated industry.

In response to the CDC's recommendations that members of the public use face masks to cover their noses and mouths, FDA issued a Letter of Authorization for the use of face masks (hereafter “Authorization Letter"). Under FDA's most recent guidance, all face masks intended for use as “source control" are considered medical devices. In this context, source control “refers to the use of a face mask or cloth face covering over the mouth and nose to contain that individual's respiratory secretions to help prevent transmission from infected individuals who may or may not have symptoms of COVID-19." Simply put: manufacturers producing even

simple cloth face coverings are now producing medical devices regulated by FDA and must therefore comply with certain regulatory requirements.

Although this may sound daunting, FDA's Authorization Letter makes compliance very straightforward. First, manufacturers acting under the Authorization Letter may only produce masks intended for source control. In other words, the Authorization Letter does not permit a manufacturer to produce a face mask intended for another medical purpose, like a surgical mask or respirator. Second, they must comply with the following labeling requirements:

1. The product is labeled accurately to describe the product as a face mask and includes a list of the body contacting materials (which does not include any drugs or biologics);
2. The product is labeled accurately so that it does not claim to be intended for use as a surgical mask or to provide liquid barrier protection;
3. The product labeling includes recommendations against use in a clinical setting where the infection risk level through inhalation exposure is high;
4. The product is not labeled in such a manner that would misrepresent the product's intended use; for example, the labeling must not state or imply that the product is intended for antimicrobial or antiviral protection or related uses or is for use such as infection prevention or reduction;
5. The product is not labeled as a respiratory protective device, and therefore should not be used for particulate filtration; and
6. The product is not labeled for use in high risk aerosol generating procedures.

Finally, they must comply with the Conditions of Authorization as detailed in the Authorization Letter. The Conditions of Authorization reiterate the labeling requirements while also requiring the manufacturer to (1) take steps to ensure that the labeling information is available to the end user; (2) include instructions regarding the recommended cleaning of the materials; (3) implement a process to report adverse events; (4) maintain records related to the Emergency Use Authorization; (4) maintain records related to the production and distribution of the masks; and (5) comply with certain requirements for advertising and promoting the masks.

Despite FDA's efforts to simplify regulatory compliance for face mask manufacturers, liability and regulatory risks remain. Those interested in producing face masks should seek guidance from an attorney experienced in FDA and regulatory compliance to ensure full compliance with FDA's requirements, as well as an attorney experienced in issues surrounding products liability to ensure that the immunity protections provided by HHS will apply to the manufacturer's actions in producing face masks.

UK

In the United Kingdom, the regulations are different depending on the type of products.

Surgical Face masks

These are mainly intended for healthcare staff to wear to protect patients during surgical procedures and other medical settings.

If you make a surgical mask, intended to protect the patient, they are Class I medical devices. They must meet the design and safety requirements of the Medical Device Regulations (MDD/MDR) and be CE marked before you can sell them in the UK.

If they are not CE marked you must apply for exemption from the regulations. We may authorise you to supply a non-CE marked device in the interest of protecting health.

If the surgical masks you want to supply are sterile, then you also need a CE certificate from a notified body for the sterility aspects. We regulate these types of masks and the Guidance on Class 1 Medical Devices gives further information.

Face masks intended to protect the wearer (PPE)

If your masks are intended to protect the wearer, they are regulated as personal protective equipment and need to meet the regulations covering PPE products. They will need a notified body to verify the relevant requirements are met. They are not medical devices.

If you need advice on these regulations, see the OPSS coronavirus guidance for business and local authorities.

Face coverings intended for use by the general public are not PPE or medical devices. As such they do not carry a CE mark and should not be sold or donated as PPE or medical devices.

If you wish to sell face coverings or supply them to others outside your household or family, the face coverings must meet the existing requirements of the General Product Safety Regulations 2005 (GPSR).

The GPSR sets out the responsibilities of the producers and distributors of these products.

As face coverings are not medical devices, we do not regulate these products. There is guidance for makers and suppliers of face coverings from the Office for Product Safety and Standards.

Requirements for medical staff protection in the pandemic background

We can apply the same set of considerations for the UK and US-based backgrounds. The standards are defined by WHO (www.who.int):

Infection prevention and control measures include, among other measures: hand hygiene, personal protective equipment and waste management materials.

The Protective equipment consists of garments placed to protect the health care workers or any other persons to get infected.

These usually consist of standard precautions: gloves, **mask**, gown. If it is blood or

airborne high infections, will include: **Face protection**, goggles and mask or face shield, gloves, gown or coverall, head cover, rubber boots.

According to **Health and Safety Executive UK**, medical employers have duties concerning the provision and use of personal protective equipment (PPE) at work.

PPE is equipment that will protect the user against health or safety risks at work. It can include items such as safety helmets, gloves, eye protection, high-visibility clothing, safety footwear and safety harnesses. It also includes respiratory protective equipment (RPE).

Making the workplace safe includes providing instructions, procedures, training and supervision to encourage people to work safely and responsibly.

Even where engineering controls and safe systems of work have been applied, some hazards might remain. These include injuries to:

- the lungs, eg from breathing in contaminated air
- the head and feet, eg from falling materials
- the eyes, eg from flying particles or splashes of corrosive liquids
- the skin, eg from contact with corrosive materials
- the body, eg from extremes of heat or cold

PPE is needed in these cases to reduce the risk.

When selecting and using PPE:

- Choose products which are CE marked in accordance with the Personal Protective Equipment (Enforcement) Regulations 2018 – suppliers can advise you
- Choose equipment that suits the user – consider the size, fit and weight of the PPE. If the users help choose it, they will be more likely to use it
- If more than one item of PPE is worn at the same time, make sure they can be used together, eg wearing safety glasses may disturb the seal of a respirator, causing air leaks
- Instruct and train people how to use it, eg train people to remove gloves without contaminating their skin. Tell them why it is needed, when to use it and what its limitations are.

Maintenance

PPE must be properly looked after and stored when not in use, eg in a dry, clean cupboard. If it is reusable it must be cleaned and kept in good condition.

Think about:

- using the right replacement parts which match the original, eg respirator filters
- keeping replacement PPE available
- who is responsible for maintenance and how it is to be done
- having a supply of appropriate disposable suits which are useful for dirty jobs where laundry costs are high, eg for visitors who need protective clothing

Employees must make proper use of PPE and report its loss or destruction or any fault in it.

Monitor and review

- Check regularly that PPE is used. If it isn't, find out why not
- Safety signs can be a useful reminder that PPE should be worn
- Take note of any changes in equipment, materials and methods – you may need to update what you provide.

According to the **FDA** (Food and Drug Administration USA), all personal protective equipment (PPE) that is intended for use as a medical device must follow the FDA's regulations and meet specific performance standards for protection. Other government agencies, including those listed below provide guidelines for use of PPE:

The U.S. Department of Labor's Occupational Safety and Health Administration (OSHA) assures the safe and healthful working conditions for working men and women by setting and enforcing standards and providing training, outreach, education, and assistance. OSHA requires employers to provide appropriate PPE for workers who could be exposed to blood or other infectious materials (such as bloodborne pathogens). OSHA may also require employers to provide PPE to protect against other hazards at work. Although OSHA requires the use of specific equipment, it does not regulate the marketing of these devices nor grant claims of disease prevention. OSHA regulations are as follows:

- **29 CFR 1910.1030 Bloodborne pathogens:**

  When there is occupational exposure, the employer shall provide, at no cost to the employee, appropriate personal protective equipment such as, but not limited to, gloves, gowns, laboratory coats, face shields or masks and eye protection, and mouthpieces, resuscitation bags, pocket masks, or other ventilation devices. Personal protective equipment will be considered "appropriate" only if it does not permit blood or other potentially infectious materials to pass through to or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used.

As part of CDC, The National Institute for Occupational Safety and Health (NIOSH) is the U.S. Government agency responsible for the certification and approval of respiratory protective devices for occupational use. It also addresses quality assurance requirements for the manufacturing of respiratory protective equipment. The approach to approval is that anybody can manufacture and sell any type of respiratory protective device, but only those that meet or exceed all of the requirements established in the 42 CFR 84 standards are acknowledged by NIOSH, and only those that have been NIOSH-certified may be marketed as a NIOSH-approved respirator.

Logistics

The logistics component of the PPEs doesn't present relevant issues since the following factors compose it:

- **Phase 1**: Prototyping. We will design and prototype the final product that will be introduced into the market during this phase.
- **Phase 2**: Production. During the second phase, we will produce the final product by using an externalized outsourcing manufacturer.
- **Phase 3**: Logistics. This is maybe the most challenging phase in our business model. We have to penetrate the market properly during this phase by introducing our products through a strong logistics network. We will use third-party freight management companies to ship the end-goods from the manufacturing point to the end-markets (US and UK). Speaking in terms of manufacturing operations, we have selected Körfez Güvenlik, a manufacturer specialized in the production of PPE as a manufacturing partner.

Market Barriers

Perceived severity: Perceived severity refers to how much an individual fears a disease or an outbreak, and how worried he/she is that his/her place of residence would become a quarantine city. During the early SARS outbreak, the results of a telephone survey showed that perceived susceptibility, perceived benefits and cues to action were significant predictors of facemask use. Perceived severity was not found to be a significant predictor of the use of facemasks. The authors, Tang et al,

attributed this finding to the individuals' underestimation of the disease's potential to become a global epidemic. During the early stage of the local outbreak, the disease mainly affected healthcare workers, a few index patients, and the two mentioned groups' close contacts. The dire outcome of the disease with increasing prevalence and fatalities could have been overlooked. However, perceived severity did not affect the wearing of facemasks when going out in cases of ILI. Although 88.7% of the respondents had initially stated they would wear facemasks when having ILI symptoms, only 36.6% of respondents self-reported that they had often or always worn facemasks in public areas when having symptoms of ILI, a few months after the outbreak. Among those with ILI symptoms, respondents were found to be more likely to wear facemasks when going out if they perceived the impact of bird-to-human H5N1 to be worse than that SARS (OR 3.21, 95% CI 1.21–7.91, $p < 0.05$).

In a study by Syed et al, the authors described their journey from the United Kingdom to Thailand during the 2003 SARS scare. They observed that the prevalence of mask-wearers in Thailand rose during the outbreak and hypothesised that the perceived severity of SARS as a threat to the economy and public health was associated with the increased social acceptance of facemasks. In Australia, Taylor et al found that individuals who reported to be extremely or very concerned for self and/or family in the event of a pandemic influenza were more willing to wear facemasks (OR 1.94, $p < 0.001$). A 2009 study by Eastwood et al, in which

interviews were conducted with adult Australians, found that an increase in anxiety was associated with an increase in the willingness to wear facemasks.

A lack of adequate knowledge about a disease may also hinder mask-wearing compliance. The street survey in Taiwan traditional markets by Kuo et al found that individuals who lacked correct knowledge about the fatality rate of avian influenza were four times less likely to practise appropriate AI preventive behaviour, including mask-wearing. Factors associated with correct AI preventive behaviour included having correct knowledge about the fatality rate of AI (adjusted OR 4.18) and knowing severe AI (adjusted OR 2.13).

Perceived barriers: In the present context, perceived barriers refer to factors that potentially prevent or discourage individuals from using facemasks. In a cluster-randomised trial by MacIntyre et al, households in Australia were given either (a) P2 masks, which are the equivalent of N95 masks; (b) surgical masks; or (c) no facemasks. Households given facemasks (either P2 masks or surgical masks) were instructed that the facemasks were to be worn at all times in the presence of a child infected with respiratory infection. In that study, more than half of the mask-wearers voiced concerns about the discomfort associated with mask-wearing. Other barriers to compliance were that the children of mask-wearers disliked their parents wearing facemasks, forgetfulness, ill fit of the facemasks provided, and the impracticality of wearing facemasks in certain situations, such as during meal times and while sleeping. Other than that, the study found that participants with three or more adults in the house were less likely to wear facemasks.

Ferng et al's study, which aimed to evaluate the barriers to mask-wearing among Hispanic households of Northern Manhattan, involved 'think-aloud' activities and focus group discussions. The study found that discomfort resulted from poor fit of the facemasks, which was due to certain facial structures of the wearer. For instance, facemasks tend to slide down the faces of wearers with low cheekbones and small nose bridges. It was also reported that ill individuals might find it unpleasant to wear facemasks, especially if the user suffers from nasal congestion or rhinorrhoea. Facemasks also tend to become damp after a period of time in warm environments, further contributing to mask-wearing discomfort. In a study by Weiss et al, the authors identified four barriers that may discourage individuals from wearing facemasks: (a) discomfort, especially in hot weather; (b) the presence of chronic lung disease; (c) inconvenience, due to the need to remove facemasks when eating or drinking; (d) young age, as facemasks are generally not designed for children, and even if they were, children were found to be unlikely to wear them for long periods of time.

In Hong Kong, Tang et al found that perceived barriers was not a significant factor affecting mask-wearing compliance during SARS. During epidemics, perceived susceptibility and perceived severity outweighed the effect perceived barriers had with regard to facemask use. The authors postulated that since facemasks are relatively easy to put on and remove, as well as cheap and accessible (except during the early stages of the SARS outbreak), they present as less of a barrier, despite the discomfort and inconvenience associated with their use.

The cost of facemasks was a factor that was not thoroughly covered in any of the studies that investigated the determinants of mask-wearing compliance. Nevertheless, monetary cost to the individual has been found to affect compliance with other health measures. In a study by Campbell et al, which studied the effect of asthma medication price changes on asthma medication use, the authors found that even a slight increase in medication costs led to a severe decline in medication use. In Taiwan, it was reported that N95 masks that originally cost 85 cents each were sold for USD 20 each during the SARS outbreak in 2003. However, the report did not elaborate on the impact of cost on an individual's decision to don masks, which may be significant, particularly during outbreaks when the demand for masks may outstrip the supply.

Executive Team

Personnel

Management Team

Our management team will be formed by the following professionals:

- **The owner** Mihail Mitev: CEO and responsible for managing the daily operations of the company. He is experienced in commercial finance and capital requirements of R&D activities. He is personally accountable for the project HFEF face mask and delegates the rights to:
- a) Strategy consultant – PM Dimitar Mitev. E*xperience*: Commercial Strategy Senior Manager, KPMG; Sales Consultant, Large Customer Sales TMT & Retail, Google UK; Commercial & Pricing Strategy;

- b) Chief Engineer and IPR lead – Eng. Gancho Mitev. An experienced entrepreneur, having taken two start-ups from zero to successful exit experience in product design and electrical engineering;
- c) CMO – Lili Dikova – Marketing Director Bionic, Sales Manager at the Telegraph;
- d) Commercialization –Alexandar Maximov. 8 capability improvement initiatives in financial planning, analysis, and decision support.

Executive Team

The business will not hire direct personnel until 2021.

From 2021, we will hire the following professionals:

- x4 R&D engineers, who will develop and implement PPE-based products. They will also prototype the final product that will be introduced into the market.
- Market research analyst, who will analyze and schedule our production according to the market demand.

We will also collaborate and contribute to 2 Ph.D. research projects with Leeds University that can enable additional future applications of our innovation.

Potential Key Partners

We can individuate the following key partners:

- **Shipping partners**: they will transport the masks from the production centers to the logistics/distribution points located in Europe and the USA.

- **Local Couriers**: they will supply the masks from the logistics points to the retailing centers.

- **Retailing Centers**: they are the core of our business success since they represent the direct contact between our products and our end-customer-target. They include hospitals, clinics, retail shops, et al.

- **Marketing partners**: we may decide to include some marketing partners that will facilitate our marketing promotion. They may include influencers, doctors, clinics, hospitals, and medical professionals.

Personnel Table

	2021	2022	2023	2024	2025
R&D Engineers (4)	$150,000	$150,000	$150,000	$150,000	$150,000
Market Research Analyst	$35,000	$35,000	$35,000	$35,000	$35,000
Owner	$50,000	$50,000	$50,000	$50,000	$50,000
Strategy Consultant	$35,000	$35,000	$35,000	$35,000	$35,000
Chief Engineer	$40,000	$40,000	$40,000	$40,000	$40,000
CMO	$40,000	$40,000	$40,000	$40,000	$40,000
Marketing & Sales Specialist	$40,000	$40,000	$40,000	$40,000	$40,000
Totals	**$390,000**	**$390,000**	**$390,000**	**$390,000**	**$390,000**

Strategy

Positioning

As we have already stated multiple times, we position our firm in the PPE production and delivery segment.

We have in mind to operate and penetrate into the US and UK markets.

Revenue Model

We will generate our revenues by selling our PPEs.

We will apply a competitive selling price equal to USD 140 per unit by registering an estimated production cost equal to USD 35 per unit (25%).

Marketing Penetration Strategy

Given the similarities between the UK and US markets, we can apply the same set of considerations for both target markets during this paragraph.

- **Price Adjustment**: We will adjust our prices to take a specific competitive advantage versus our direct competitors. As we have already explored in the previous paragraph, we will apply a price equal to USD 140 per unit by registering an estimated production cost equal to USD 35 per unit.
  Increase promotion: Our competitors treat the face masks as a standard medical product by not following many marketing channels, like digital

media marketing. We have in mind to follow a different marketing approach by implementing an innovative marketing plan. It will include the massive use of social networks, Google SEO optimization, and a set of straightforward procedures by including introductory letters, brochures, and frontal meetings with stakeholders.

- **A strong distribution network**: As we have already described, we will implement a robust logistics approach. First of all, we will use third-party-based shipment services to transport the masks from the production point (we have selected a Turkish PPE manufacturer named Körfez Güvenlik) and the distribution centers (located in Europe and the USA). As the second step, we will distribute the distribution centers' masks to the retail points/hospitals by using third-party-based couriers.
- **Market development**: We should implement a specific set of strategies to attract potential customers that usually don't use our provided products. Given the pandemic background that is struggling with the entire Globe, face masks are required by the worldwide population. We won't have to implement massive market strategies under these circumstances since the demand already has a considerable size.

Identification of needed partners for market penetration

We can individuate the following companies as our partners:

- Manufacturing partner: Körfez Güvenlik, specialized in the production of PPE - already selected.

- UK certification partner - to be selected.

- Trade partner - large distributor of medical and PPE equipment in UK - to be selected.

Marketing Strategy

Marketing Strategy

We have to implement a fantastic marketing approach based on digital marketing that will promote the business with a short amount of costs. Marketing methods useful to spread a firm dramatically changed during these last years. Ten years ago, the business promotion was led by flyers, radio/TV advertising techniques, and small alerts on newspapers or magazines.

Thanks to social networks and the digital market, we can cover the same range of potential customers, spending half of the time used in the last years and a quarter of the total money spent before.

The company will use a specific Facebook Advertisement professional campaign to spread out the firm rapidly in the near zone where it will operate.

Second, we will use a dedicated website to spread our promotions and our entire brand. As the next action, we will create an Instagram profile, where we will quickly spread out our firm through the usage of stories and posts (videos and pictures). Following this way, we will cover an extensive range list of potential clients, spending a moderate amount of money.

Finally, we will also apply traditional marketing methods as flyers dispatching in the main points of interest.

Therefore, below are the strategies we intend to adopt in marketing our various customers:

- We will send introductory letters and emails to hospitals, clinics, retail centers, and other stakeholder categories.
- We will place adverts on print (community–based newspapers and magazines) and electronic media platforms.
- We will sponsor relevant community programs.
- We will make leverage on the internet and social media platforms like Instagram, Facebook, Twitter, to promote our face mask brand.
- We will engage in roadshow from time to time in targeted communities.
- We will distribute our fliers and handbills in target areas.

The estimated cost for the startup marketing plan is approximately near to $25,000.

Distribution Strategy

As we have already stated in the previous chapters, we will use third-party freights to bring the end-goods from the production points to the end-points (US and UK).

As second step, we will use third-party couriers to supply each selling/using point by including hospitals, clinics, retail centers, et al.

SWOT Analysis

In this specific section, we are going to use a power tool of analysis to further understand and classify the current business under four significant aspects, Strengths (S), Weaknesses (W), Opportunities (O), and Threats (T).

Strengths:

- The specific market segment results to be stable and profitable in the operating countries (US and UK).

- Moderate production cost.

- Massive demand for the provided products during the current and incoming years.

- Easiness of business management.

- Short hierarchical line.

- Scaling the business is easy as the foundations will already be in place.

Weaknesses:

- High presence of substitute products/companies in the area.

- A major weakness that may count against us is the fact that we are a new face mask production company and we don't have the financial capacity to engage in the

kind of publicity that we intend giving the business especially when big companies holding the largest market share in the industry.

- High market entry barriers.

Opportunities:

- Possibility to escalate with-in the market sector by introducing innovative services and products.

- Opportunity to use digital tools to spread out the business and improve its activities.

- The opportunities available to face masks manufacturing companies with a wide range of products are enormous. This is due to the fact that face masks have been a subject of shortages, and have also been made compulsory in some countries especially in a period where COVID – 19 is a global pandemic.

Threats:

- Possibility of new competitors' entrance in the specific market branch.

Financial Projections

Key Assumptions

In this chapter, divided into Profit & Loss, Cash Flow, and Balance Sheet parts, we will analyze the firm's economic/financial situation for a forecast period of 3 years. Any data is a forecast considering the method of Accrual Basin accounting technique mixed with the Statistical Method of Confidence. First, we will explore the Profit & Loss section, where we will see the capacity to generate real incomes.

These incomes will cover the fixed total cost per year in business (formed by personnel salaries, third-party services costs, and other startup related costs) and, finally, the productions' direct cost. As we can see from numeric data, the company will generate positive net incomes from the first business year. The cash will remunerate the starting investment (see the next paragraph for a detailed investment total cost data) with a minimum attractive return (MARR).

Second, we will find the Cash Flow Statement, a useful instrument that allows us to see the net value between adequate monetary income and less effective financial outcomes. As a direct consequence of Profit & Loss data, we will have a good Cash Flow situation from the first year in business.

Startup Capital

As we can see from the following graph, we have to cover $1,248,000 as direct startup expenses.

THE STARTUP CAPITAL

Experimental development	100000
Prototyping "Cartridge with HFEF device"	380000
Laboratory testing	100000
Field testing	200000
Cost for services	6000
IPR	78000
Insurances for field tests	60000
Rent	24000
Marketing	300000

By requiring $1,200,000 as startup capital, we can reimburse it with an interest rate equal to 7% and 120 monthly payments.

Your estimated monthly payment is **$13933.02***

Total amount to be repaid (with interest):	$1,671,962.40
Total interest to be repaid:	$471,962.40 Interest Principal

Methods of Calculus

We used the tool provided by LivePlan to calculate financial projections professionally. In particular, the tool has taken the following step for the calculation:

1) It required the total startup expenses shown in the previous paragraph of this plan. The entire startup expenses show the dimension of the firm.

2) Once we have declared the firm's dimension, the tool required us additional parameters, such as the market where the firm would have operated, its market branch, the country/countries where the business would have worked, and the number of active employees.

3) Once we have entered these parameters, the tool used the verified method of confidence Ranges. This method provides a numeric interval for each year in a business where the sufficient revenues occur, with a probability (" confidence") equal to 95%.

4) In conclusion, the method considers various aspects of the firm, including its size, the future economic trend of the country/countries where the business operates, the future patterns of the market segment/market branch/niche, providing a robust set of financial revenues estimation.

Cost estimations

Speaking in terms of expenses / startup capital forecasts, we have used authoritative references as the Euromonitor Dataset (https://go.euromonitor.com/passport.html) and US Census (https://www.census.gov/data.html).

TAM & SAM

We have used the PubMed Electric Face Mask Insights as valid base of TAM calculation. The SAM (*Service Addressable Market*) is calculable as 5.2% for the UK and 8% for the US since the second market segment results to have a more considerable set of professional operating in medical industry. We assumed 5.2% and 8% as SOM, since they represent the percentages of electric face masks on the total medical face mask industry. **Speaking in technical terms**, the TAM and SAM don't directly depend by the specific enterprise, but from the type of the market segment/industry where the company will operate.

TAM Market							
Location	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**
UK	$5,400,000,000	$5,700,000,000	$5,820,000,000	$5,750,000,000	$5,700,000,000	$5,640,000,000	$5,520,000,000
USA	$6,160,000,000	$6,350,000,000	$6,420,000,000	$6,380,000,000	$6,240,000,000	$5,980,000,000	$5,830,000,000
Authoritative Source: PubMed Electric Face Mask Insights, Sept. 2020.							
SAM Market %							
Location	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**
UK	0.00%	0.00%	5.20%	5.40%	5.80%	6.10%	6.30%
USA	0.00%	0.00%	8.00%	8.20%	8.70%	9.00%	9.40%
SAM Market							
Location	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**
UK	$0	$0	$302,640,000	$310,500,000	$330,600,000	$344,040,000	$347,760,000
USA	$0	$0	$513,600,000	$523,160,000	$542,880,000	$538,200,000	$548,020,000

SOM

We will cover, as SOM, 0.009% and 0.004% of the UK and US-based SAM during 2022 since we will only sell 341 models as a **pilot series**. The UK percentage is higher than the US one since we will achieve a more consistent amount of sales in the domestic market.

0.009% and 0.004% represent the percentages of SOM on the SAM assumptions.

The **SOM** directly depends by the influence and technical capabilities of the singular company. We estimate a SOM equal to 0.3% and 0.15% in 2023 since we will start the on-trade sales during this year.

% Market Shares (Shares of the SOM component)							
Location	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**
UK	0.000%	0.000%	0.009%	0.300%	1.200%	1.800%	1.800%
USA	0.000%	0.000%	0.004%	0.150%	0.450%	1.000%	1.260%
Markets Revenues							
Location	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**
UK	$0	$0	$27,238	$931,500	$3,967,200	$6,192,720	$6,259,680
USA	$0	$0	$20,544	$784,740	$2,442,960	$5,382,000	$6,905,052
Total	$0	$0	$47,782	$1,716,240	$6,410,160	$11,574,720	$13,164,732
Number of Masks Sold							
Location	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**
UK	0	0	195	6,654	28,337	44,234	44,712
USA	0	0	147	5,605	17,450	38,443	49,322
Total	0	0	341	12,259	45,787	82,677	94,034

We can expect a good growing from 2023, since we will have acquired a good market penetration in the UK and US markets by representing 0.3% and 0.15% as SOM % on the SAM.

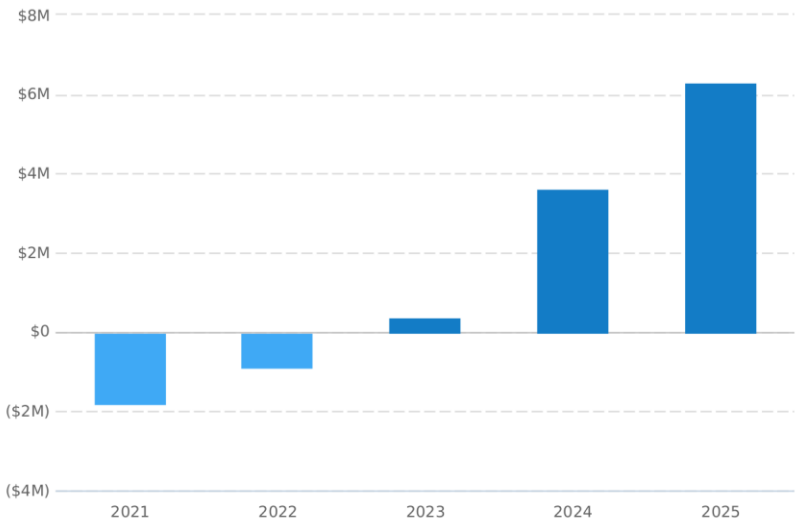
Profit & Loss

Projected Profit and Loss

	2021	2022	2023	2024	2025
Revenue	**$0**	**$47,880**	**$1,716,260**	**$6,410,180**	**$11,574,780**
Direct Costs	**$0**	**$11,970**	**$429,065**	**$1,602,545**	**$2,893,695**
Gross Margin	$0	$35,910	$1,287,195	$4,807,635	$8,681,085
Gross Margin %	**0%**	**75%**	**75%**	**75%**	**75%**
Operating Expenses					
Salaries & Wages	$390,000	$390,000	$390,000	$390,000	$390,000
Employee Related Expenses	$78,000	$78,000	$78,000	$78,000	$78,000
Experimental Development	$100,000				
3D Design Software	$4,000	$4,000	$4,000	$4,000	$4,000
3D Printer	$5,000				
Cost For Services	$6,000	$6,000	$6,000	$6,000	$6,000
Insurance	$2,400	$2,400	$2,400	$2,400	$2,400
Rent	$24,000	$24,000	$24,000	$24,000	$24,000
Marketing	$300,000	$120,000	$120,000	$90,000	$90,000
Prototyping “Cartridge with HFEF device”	$380,000	$40,000	$45,000	$45,000	$50,000
Laboratory testing	$100,000	$50,000	$50,000	$60,000	$75,000
Field Testing	$200,000	$60,000	$50,000	$35,000	$30,000
IRP	$78,000	$40,000	$45,000	$50,000	$50,000

Insurances for field tests	$60,000	$25,000	$30,000	$30,000	$35,000
Total Operating Expenses	**$1,727,400**	**$839,400**	**$844,400**	**$814,400**	**$834,400**
Operating Income	**($1,727,400)**	**($803,490)**	**$442,795**	**$3,993,235**	**$7,846,685**
Interest Incurred	$74,736	$75,602	$68,980	$61,880	$54,267
Depreciation and Amortization					
Gain or Loss from Sale of Assets					
Income Taxes	$0	$0	$0	$308,549	$1,480,559
Total Expenses	**$1,802,136**	**$926,972**	**$1,342,445**	**$2,787,374**	**$5,262,921**
Net Profit	**($1,802,136)**	**($879,092)**	**$373,815**	**$3,622,806**	**$6,311,859**
Net Profit / Sales		**(1,836%)**	**22%**	**57%**	**55%**

Net Profit (or Loss) by Year



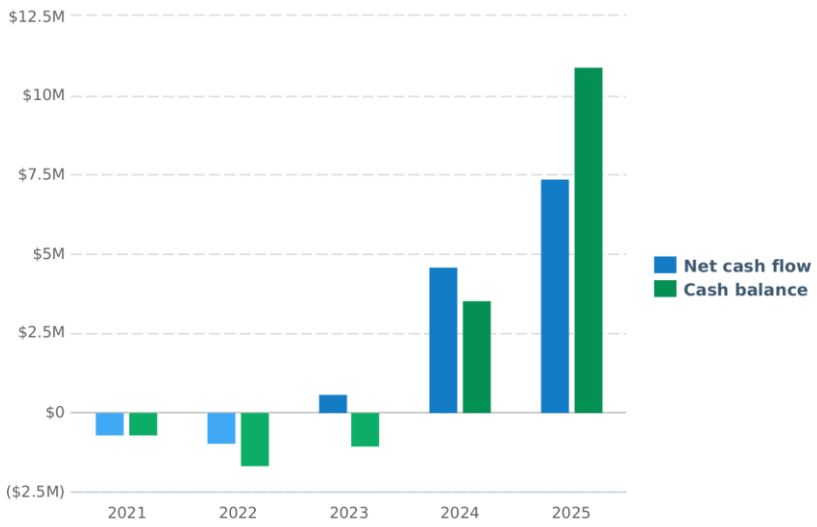
Cash Flow

Projected Cash Flow Statement

	2021	2022	2023	2024	2025
Net Cash Flow from Operations					
Net Profit	($1,802,136)	($879,092)	$373,815	$3,622,806	$6,311,859
Depreciation & Amortization					
Change in Accounts Receivable	$0	$0	$0	$0	$0
Change in Inventory					
Change in Accounts Payable	$0	$0	$0	$0	$0
Change in Income Tax Payable	$0	$0	$0	$186,854	$183,420
Change in Sales Tax Payable	$0	$9,097	$316,993	$891,844	$981,274
Change in Prepaid Revenue					
Net Cash Flow from Operations	**($1,802,136)**	**($869,995)**	**$690,808**	**$4,701,504**	**$7,476,553**
Investing & Financing					
Assets Purchased or Sold					
Net Cash from Investing					
Investments Received					

Dividends & Distributions					
Change in Short-Term Debt	$91,594	$6,621	$7,100	$7,613	$8,164
Change in Long-Term Debt	$1,029,879	($98,216)	($105,316)	($112,929)	($121,093)
Net Cash from Financing	**$1,121,473**	**($91,594)**	**($98,216)**	**($105,316)**	**($112,929)**
Cash at Beginning of Period	$0	($680,663)	($1,642,252)	($1,049,660)	$3,546,528
Net Change in Cash	($680,663)	($961,589)	$592,592	$4,596,188	$7,363,624
Cash at End of Period	**($680,663)**	**($1,642,252)**	**($1,049,660)**	**$3,546,528**	**$10,910,152**

Cash Flow by Year



Balance Sheet

Projected Balance Sheet

	2021	2022	2023	2024	2025
Cash	($680,663)	($1,642,252)	($1,049,660)	$3,546,528	$10,910,152
Accounts Receivable	$0	$0	$0	$0	$0
Inventory					
Other Current Assets					
Total Current Assets	**($680,663)**	**($1,642,252)**	**($1,049,660)**	**$3,546,528**	**$10,910,152**
Long-Term Assets					
Accumulated Depreciation					
Total Long-Term Assets					
Total Assets	**($680,663)**	**($1,642,252)**	**($1,049,660)**	**$3,546,528**	**$10,910,152**
Accounts Payable	$0	$0	$0	$0	$0
Income Taxes Payable	$0	$0	$0	$186,854	$370,274
Sales Taxes Payable	$0	$9,097	$326,090	$1,217,934	$2,199,208
Short-Term Debt	$91,594	$98,216	$105,316	$112,929	$121,093
Prepaid Revenue					
Total Current Liabilities	**$91,594**	**$107,313**	**$431,406**	**$1,517,717**	**$2,690,575**
Long-Term Debt	$1,029,879	$931,663	$826,347	$713,418	$592,325
Long-Term Liabilities	**$1,029,879**	**$931,663**	**$826,347**	**$713,418**	**$592,325**
Total Liabilities	**$1,121,473**	**$1,038,976**	**$1,257,753**	**$2,231,135**	**$3,282,900**

Paid-In Capital					
Retained Earnings		($1,802,136)	($2,681,228)	($2,307,413)	$1,315,393
Earnings	($1,802,136)	($879,092)	$373,815	$3,622,806	$6,311,859
Total Owner's Equity	**($1,802,136)**	**($2,681,228)**	**($2,307,413)**	**$1,315,393**	**$7,627,252**
Total Liabilities & Equity	**($680,663)**	**($1,642,252)**	**($1,049,660)**	**$3,546,528**	**$10,910,152**

Financial Highlights by Year