

Management of NPD

Assessment B

Creating the Design Brief

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1. Synopsis

Following on from the Coronavirus (Covid-19) pandemic, 4 in 10 of adults today mention they are 'very or somewhat worried about new variants of Covid-19' (ONS,2022). The UK alone have seen over 23 million cases of Covid, and around 189,000 deaths (WHO,2022).

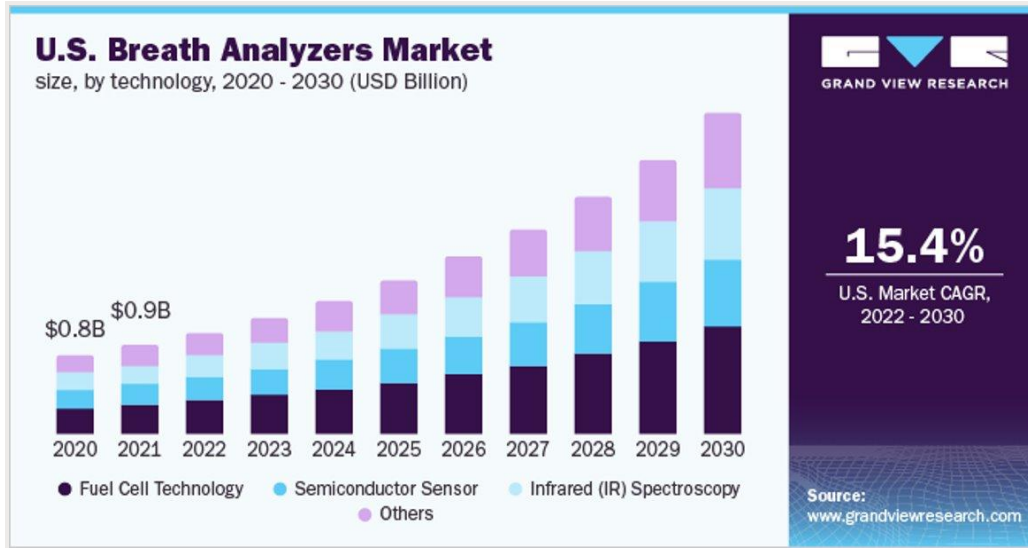
We specialise in the manufacturing of electronic breathalyser systems. Our current market is used for medical purposes, where the hand held, portable device has rapid measurement of the alcohol concentration in the breath. There's an opportunity here in developing a product for such virus detections which can meet both clinical and personal requirements.

The new product development (NPD) is a chemical detector system. This innovational product will have the ability to detect viruses, helping reduce the risk of an outbreak which could lead to a pandemic. Based on our experience and expertise, developing this new product will grow the business, increase revenue and develop our technological capabilities.

Opportunity came through a Knowledge Transfer Partnership with a local university where it identified that our current breathalyser products could cover the detection of other organic materials. These include those generated in the breath of various virus infections.

"When markets shift, technologies proliferate, competitors multiply, and products become obsolete almost overnight, successful companies are those that consistently create new knowledge, disseminate it widely throughout the organization, and quickly embody it in new technologies and products." Slater, S et al. (2012, p18). This design brief will outline the specific elements of the new product for a successful journey to market.

2. Customer



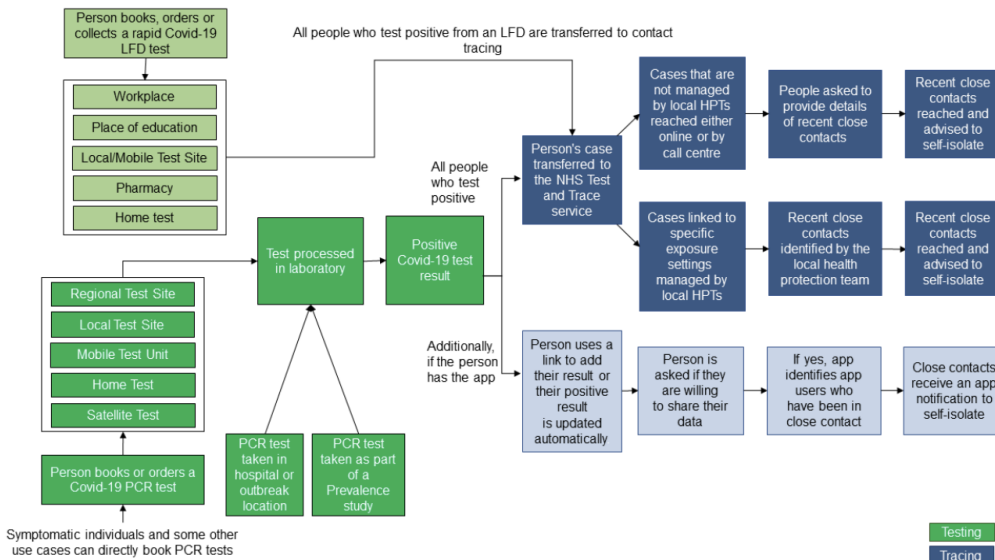
In 2021, the global breath analyzers market size was valued at USD 2.38 billion. According to Grand View Research (2022) it is estimated to expand at a compound annual growth rate (CAGR) of 16.5% from 2022 to 2030.

Callaway (2022) mentions, “tracing the source of one potential variant — among the thousands probably circulating globally — might help researchers to understand the biological factors that caused variants such as Omicron to emerge.”. If people are able to reduce the possibility of another outbreak, help the healthcare system and protect themselves and others, this device is the essential product for improvement on lives, mental health and scientific knowledge. There is an opportunity here. This is a product which customers could want in the future, or in some cases, need. ‘While it is important for the firm to keep customers satisfied by responding to their articulated needs, customer delight is secured through the creation of successful ‘really new products’ that address customers’ latent needs.’ Slater, S et al. (2012, p22).

New business opportunities allow for new revenue streams. There is potential for us to grow our customer base through expanding our product range. Based on the urgency that we saw to adapt lifestyle and living structure over the pandemic, we are hoping to lean into Business to Government (B2G). Prospect to see a positive impact worldwide for countries mental state, and reduce the severity of another outbreak. The governments Track and Trace app demonstrates a clear shift in data acquisition

with a clear increase in individuals willingness to provide data to large datapools.

Figure 1. Flowchart showing how people move through NHS Test and Trace



UK Health Security Agency. (24 March 2022).

Another customer avenue of business to business (B2B) possibility includes of testing specific viral loads at different venues from ports of entry to large events at stadiums / closed spaces. This could go hand in hand with the breathalyser for alcohol detection and increase the safety of customers. This would need consideration of training security personnel.

Testing at different venues can also apply to workplace, and with technology developments, there is scope to create an automated system to reduce accidents and viral spreads. Benefits of avoiding loss of staff due to illnesses, improve safety around the workplace and ability to track the overall health situation of the business. After the decline and business loss from the pandemic, there is greater demand for the wellbeing of employees and to avoid absences as much as possible.

3. Marketing Intelligence

Using the SWOT analysis to identify key factors that are favourable or unfavourable to the businesses objective (CIPD, 2021 b), the strength findings for this product is that we already have a pre-existing supply chain and manufacturing set up for breathalysers as well as relevant contacts in the right market or industry.

Weaknesses for us is the lack of internal expertise on viral identification, as well as additional markets. The opportunity here is to complete new revenue within new markets and add diversification into our products which reduces commercial exposure. Threat for this product is the potential size of market reducing quick due to the reduction of concern in Covid-19 as well as Government health legislation could increase and the product would not oblige or be to the right standard.

There needs to be an efficient and easier method of testing to ensure reduction in transmitting and spreading a virus, keeping people safer and avoiding another outbreak. Singapore ministers speak about a faster and easier method which is “in the pipeline, where a breathalyser which can produce a result in about one to two minutes (Regan, H. 2021).

Marketing knowledge has been done for this NPD and we will follow Piercy, N.F., (2009) process of going to market through creativity, innovation and reinvention. From this marketing intelligence our strategic sensitivity and agility to react quickly from a global pandemic will benefit the business but also build customer value if done right.

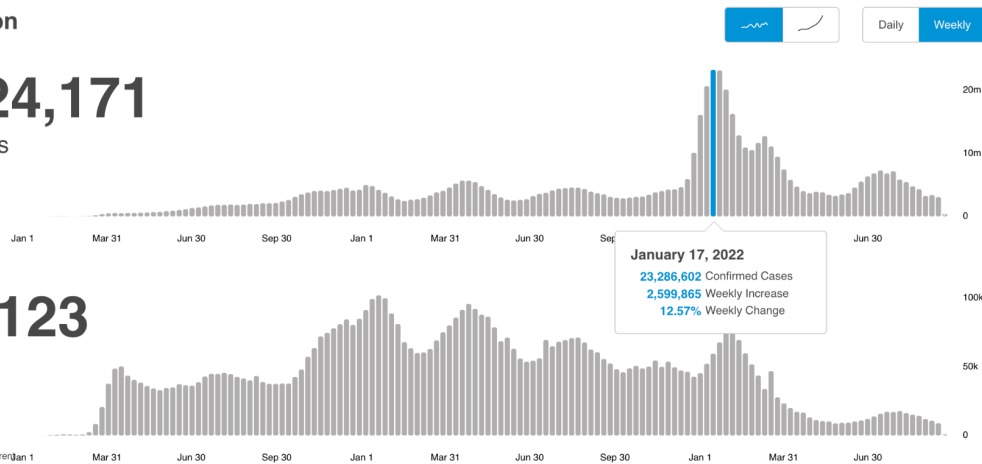
4. Coronavirus Statistics (Covid-19)

Global Situation

612,724,171
confirmed cases

6,517,123
deaths

Source: World Health Organization
Data may be incomplete for the current day or week.



(WHO, 2022)

Global confirmed cases of Covid-19 reported were nearly 613 million on 27th September 2022, including 6.5 millions deaths according to the World Health Organization (2022). The impact which the pandemic has had on the economy, travel, wellbeing, society and healthcare is detrimental.

According to ONS (Office for National Statistics, 2022), when asked between 31 August to 11 September 2022, “around half (48%) of adults aged 70 years and over were very or somewhat worried about new COVID-19 variants, compared with around 3 in 10 (29%) adults aged 16 to 29 years.”. The pandemic has created uncertainty and worry. According to Mind (2021), “a total of 1 in 4 adults and more than 1 in 6 young people experienced mental distress for the first time during the pandemic”.

In May 2022, visits to the UK by overseas residents was estimated at 2.7 million, which is down 21% on pre-coronavirus (Covid-19) times, compared to 3.4 million visits in May 2019. Although down, it is still an

improvement from April 2022 where the numbers were down 33% (ONS, 2022). This strengthens the target market of B2B at large venues and portland how beneficial it would be for people to feel safe.

We have experienced 13 named variants from Covid-19. Omicron being the most recent. This is from the coronavirus rapidly mutating which leads to variants that spread quickly and evade immunity (Advisory Board, 2022). Although there has not been a new variant for over 10 months, there is concern that the virus may have entered a new stage, and David Robertson, a virologist at the University of Glasgow suggests that future SARS-CoV-2 will evolve from Omicron (Advisory Board, 2022).

5. Performance

This device should be a handheld, portable device. Accuracy of result is important. Task completion time from breath to result received should be no longer than 3 minute waiting duration. A single device should have the memory to record up to 3,000 tests. Analytical response time should be within 30 seconds and recovery time should be around 22 seconds at 0.35mg/L.

When the device is turned on, the screen should display similar to the following :

Serial Number - to record for data analytics on the performance of the device and for legal standards

Date and time - to ensure if data is collected that this is set up correctly

Remaining Test Memory - how many tests which are left on the device

Function Selection - clear communication on the following steps, for example could be New Test / Recall Last Test / Switch Off.

This product must be user friendly with clear instructions. Depending on the market, there is potential for this product to be sold globally. Based on this, we would need to have multiple language options.

“Scientists have long been interested in creating portable devices that can quickly and painlessly screen a person for disease”, simply from a persons breath (Anthes, E. 2021). We need to ensure we achieve this with clear interaction efficiency from a performance perspective.

The new product’s electronics will be contained in a single circuit board. This will need to be sourced in a fully assembled and tested form. Two central tasks for performance strategy (Tidd, J. & Bessant, J. 2009) can be followed :

1. Identify and develop the range of disciplines that must be combined into a functioning technology.
2. Identify and explore the new competencies that must be added if the functional capability is not to become obsolete.

IEC 60529 standard will be followed to ensure the device is resistant from dust and liquids and that the enclosure of the electronics is safe. The reliability of the device will be crucial for the credibility of this product to ensure the results are correct for the safety of the customer and others. To measure the level of functional performance in this product, review must take place in the design, development, manufacture and performance of the product. (Tidd, J. & Bessant, J. 2009)

6. Aesthetics

“The term design aesthetics is employed in two ways: it may refer to the objective features of a stimulus (e.g. colour of a product) or to the subjective reaction to the specific product features.” Sonderegger, A & Sauer, J. (2010).

The aesthetics of the device will be similar to our current handheld breathalyser devices. A standard handheld device which is universal from size, shape and form. The finish of the material can be discussed with manufacturing in consideration of usability. The device screen will display the results and complete interaction with the user. In regards to offerability, the screen should be central, allowing the user to be left or right handed.

We will be striving towards an aesthetically pleasing device. The colour could be distinctively different to standard handheld medical devices. Practice Growth Pras (2017), mention that the colour blue is “typically associated with credibility, trust, knowledge, power, professionalism, cleanliness, calm and focus.” There is opportunity here to find a credible aesthetic USP for the device and possibly an approachable colour for the consumer.

Branding for the design will be outsourced along with the packaging. This needs to include a specific logo for the device, a device name, business name, and all standard specifications needed on a medical device. To be identifiable as a product from our business, but also distinguishably different to our current product offering.

7. Size and Weight

As it is a handheld device, the dimensions should be around 125mm height x 65mm width x 30mm depth. There is possibility to slightly amend due to specifications from standards or manufacturing but shouldn't go anymore than 5mm on each dimension.

The device needs to be lightweight and ergonomic. Desirable weight would be 140g including batteries. Overall weight with packaging etc is to be determined once the design specifications are finalised. Weight is restricted for this device. If the device is too heavy it would make the product difficult to handle and become an inefficient cost for shipping.

The size and weight of the device should consider the overall ergonomics of this product for customers.

8. Materials

Materials for this device will be similar to our current products, but thorough testing will be applied to ensure standards are met. There may be parts of the device which will need altering and adapting to fall in line with the aesthetics and ergonomics, as well as the target market or certain customer. This would

be based on manufacturing capabilities and demand. In addition from a health and safety perspective, the certified operating temperature range needs to withstand the materials.

The device will comply with the British Standards Institution, (BSI Group, 2022). ASTM (American Society for Testing and Materials) standards will also need to be met, these are to be discussed and confirmed with manufacturing and the health device agencies. From researching, there are many standards that need to be met, from plastic, environmental, quality control to medical device.

On the basis of the prototype product testing, the company has already gained certification for the new Virus Detect from the various medical device regulatory agencies.

The mechanical element of the detector (basically the breath sample capture system) will be fabricated from injection moulded parts. Battery will be reusable and can be recharged.

Mouthpiece - to be single use and disposable, but continued research on this should be done to lower our environmental impact. From an environmental aspect, these are recyclable.

Quality and design of the device should have a clear direction and can follow something similar :

- Is applicable to the purpose of the device and organisation
- Complies with customer needs for efficiency and accuracy
- All legal standards are met through the quality assurance
- Sustainability considerations are covered

9. User Interface.

The performance interaction should display similarly to our current Alcohol breathalyser device.

When new test is selected, screen should display instructions to attach a new mouthpiece following with instructions on taking the breath. Results displayed will be different to our alcohol reading. Research and development on what the screen will display post test to be complete, for example the below graphics could be displayed :

- × positive result symbol
- negative result symbol
- ↔ inconclusiveresult symbol

The product will illuminate and display instructions. The screen will display the reading.

Battery life will be displayed. The product needs to have a beeper which will provide various messaging to the operator.

If there is an error display, this needs to have clear instructions in the packaging on how to resolve, for example - 'Hold down green button for 10 seconds to reset device'.

10. Product Lifespan

Lifespan for this product should be a minimum of 5 years. The device can report up to 3000 tests. Depending on the design demand of the interface, it is possible to follow the same power unit for our current electronic breathalyser systems. Providing a rechargeable battery which is fitted within the device.

There may be a possibility of the lifespan of the product reducing based on change in healthcare, demand, technological developments and innovation through scientific research. Keeping this in mind, there needs to be a flexible approach to the design structure. This also creates urgency for us to get to market as soon as possible - ensuring all standards are met.

11. Maintenance & Repair

Maintenance for the device will need to be tested to weigh out all possibilities of what this would be. All maintenance and repairs should be done in house by the business for legal and safety regulations. Instructions for repairs will be included in the packaging. Length of repair needs to be considered and communicated to the customer and manufacturing team.

The rechargeable battery could be replaced if faulty. Consideration should be given to see if necessary to provide a spare battery on purchase. This will increase the product cost, but could increase the length of the device.

Warranty of the product will be confirmed once testing and sign off is completed. This will be included in instructions on the packaging. Ideally at the end of life, there will be opportunity here for the device to be sent back for us to recycle, upcycle or repair to be used in another technology or device. This will ensure the environmental impact is reduced through minimising waste through as many avenues possible.

12. Product Cost

Current cost of a hand-held breathalyser range from £45 (AlcoSense, 2022) to £550 for a Lion 500 Alcolmeter (Breathalyser Direct, 2022). At current there aren't any similar devices out in the market to compare prices.

In comparison to our current hand-held breathalysers, this product includes a new innovational technology with greater complexity which warrants a higher price point. Price will be competitive and high enough to achieve profit. Modelling a project and working out the potential IRR and NPV for this device could be beneficial to forecast.

Consideration on the cost also needs to apply to taxes, shipping, freights and import fees, as well as fluctuation in exchange rates and material costs. These may have an impact on selling depending on the customer and potential of reaching worldwide markets. Price sensitivity will come from packaging, designing through to development and prototype costs.

The product will have 5 disposable mouth pieces, and a higher price point if more mouth pieces are offered.

13. Quantities

For the first year in market, the projected manufacturing volumes are 500,000, with a large increase to 5 million per annum afterwards.

Based on the scalability projections, these volumes need to be considered from a manufacturing, storing, shipping aspect. Investment into permanent tooling may need researching for these high quantities to ensure production capabilities are possible.

14. IP protection / patents

Leading from a successful trial of the new system in the laboratory, the necessary patent applications have been registered.

We will be patenting the invention as we believe our device has a point of difference to the competition that is out there. Once design and aesthetics are confirmed, we will need to register a design as well as a trademark. By applying for these we are protecting our intellectual property and makes it easier to take legal action against anyone who steals or copies it (Gov UK, 2022). Patent protection can be a strong detriment of the relative commercial benefits to innovators and imitators (Tidd, J. & Bessant, J. 2009).

Some factors which will help influence and need to consider :

Secrecy - If the NPD is to be kept a secret, NDA will need to be signed.

Product complexity - The aesthetics and ergonomics of the device is in line with specifications. The complexity of the technology is where we need to ensure imitation is complex.

Strength of patent protection - ensuring all possible features have been covered to avoid law implications

15. Packaging and Shipping

Design of the packaging, labelling and 'physical envelope' will be outsourced by a London-based company, who we've already engaged with. A clear brief on the direction for this is needed as also mentioned in aesthetics.

Labelling needs to be clear and simple and to include instructions for use, technical description, intended purpose, and proper use of the medical device. Shipping documents will be separate (International Organization for Standardization, 2022).

When it comes to shipping the product, they will need to be in a compact packaging that would protect the device, avoid any disruptions and reduce the risk of damaging the product. Shipping size will

depend on import and duty fees. Considering a postal box size which is universal could benefit from a financial perspective.

A protection sleeve if selling individual which is durable and waterproof will be needed, and must be recyclable. External casing will depend on the final form of the product as generated by the product design company.

16. Accessories and Add-ons

Additional accessories for the device could include a carry case or a protective pouch. Material of this could be leather as current or can explore sustainable materials such as pinatex or mylo leather. Choice of colour, material, print design can be offered to be made completely unique to the customer from a personalisation pathway.

To ensure the highest level of portability, there's potential to offer electronic chargers for motor vehicles. There is opportunity to provide an optional printer unit where a permanent record of each test will be produced at the relevant time.

From a hygiene and cleaning point of view, cleaning products could be offered. This could be an additional product that can help with sales but also to ensure the highest level of cleanliness for the medical device, especially with transmittable viruses being tested.

With the urgency that was adapted to create the track and trace app, this is something that could be built for the device. If the app is targeted for personal or business use, it could build data collection and advise the customer on improving their health and lifestyle by creating suggestions through AI. This could be done on a subscription type offer,

As mentioned in 'customer', there's possibility of designing a fully automated system that could restrict access based on the chemical detector. If negative, the employee / customer is refused entry. This could be outsourced with an AI designer and offered as an additional service or programme.

17. Calibration

From a health, safety and medical perspective, the calibration of this device will need to follow a stricter, higher standards to ensure accuracy in results.

If selling for personal use, recalibration of the device will need to happen annually. For medical requirements, the device may need to be recalibrated every 6 months, or 1000 uses, whichever comes first. Calibration should be performed by a trained technician or through the manufacturer. If selling globally, or to certain markets, there's possibility that training can take place to ensure a technician is qualified to calibrate their devices.

18. Standards & Specifications

There will be certain standards and specifications that need following from a national and international requirements. From manufacturing, to testing and calibration. We will ensure all aspects of the device is covered to a high standard, and keeping in line with our current products.

This device will follow the ISO 13485 and ISO 14971 standards. ISO 13485 focuses on quality and customer requirements for medical devices, and ISO 14971 focuses primarily on safety, security, and risk associated with the use of medical devices. We are aware that ISO 14971 does not have certification requirements, from a manufacturing point of view, it will be good practice to follow. (International Standard, 2021).

CE (European conformity) compliance requirements needs to be met and the business will need to delve further into the FCC (Federal Communications Commission) once design is finalised to check if the specifications apply based on the oscillation level.

Other standards and specifications that may need including would be environmental testing, shock test for the durability and quality of the product, following the MHRA guidance.

19. Time-scales

Ideal scenario would be to get the product to market within the next 12 months. Being a competitive market, there is pressure to achieve a high level of quality and accuracy, and to be the first to market to avoid losing potential customers. A review within 6 months will allow us to reschedule if needed, and create a new pathway, perhaps focussing on a specific market segment to soft launch the product.

We've already gained certification for the new Virus Detect from the various medical device regulatory agencies from the prototype. Testing will need to be achieved following the right standards. With our current manufacturing abilities and the connection with the university there is scope to achieve this time scale, with room for error considered.

20. Manufacturing Facility

Similar strategy to what we currently use for our breathalyser, the manufacturing of the electronics and mechanical elements will be outsourced. Our Carmarthen factory will be doing the final assembly, testing, packing and shipping.

The business has decided from a financial standpoint that alternative suppliers are to be explored. There's opportunity to lower the manufacturing cost, on both existing and new products and offer a competitive price for the launch of this new product.

The mechanical element of the detector (basically the breath sample capture system) will be fabricated from injection moulded parts. It is to be confirmed whether the device should be sourced from a fully assembled unit (as we currently do for our breathalyser products), or to source the mouldings separately and assemble the unit in house.

From our preliminary research China or Malaysia remains the most favourable source of electronic circuit boards. The UK or Europe would, for now, be seen as favoured source for the moulded parts but we are open to explore suppliers based on financial considerations as well as quality and manufacturing ability to meet our growth expectations of units.

Specifying and sourcing the external casing will depend upon the final form of the product as generated by the product design company

Constraints could arise if sourcing separate due to different timelines of production, as well as following the final assembly of the device. From a health and safety, environment and quantity perspective, there may be difficulty sourcing separate, but we must ensure that all possibilities are exhausted before making a final decision.

21. Environment

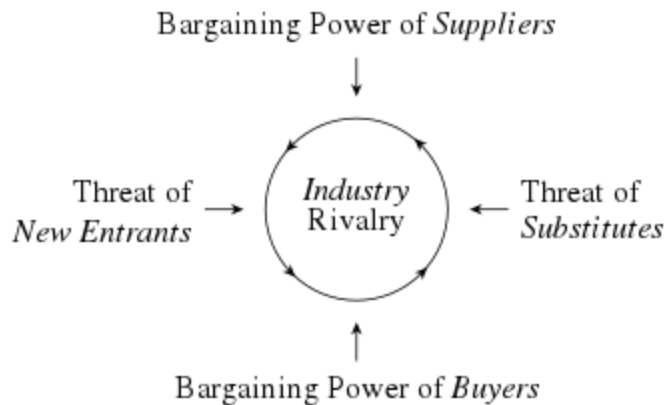
Environmental elements of the device should be considered from a temperature and pressure range, humidity, shock loading and corrosion. Not only are these important factors from a health and safety perspective but also from a sustainable perspective.

To reduce the carbon footprint of the device, measuring the manufacturing, packaging and transportation impact would provide learnings, and the most impactful place to focus on reduction. There needs to be thorough research on the disposing of the mouthpieces, and if possible to change to a lower impact material which is better for the environment.

For this product launch, there is opportunity to follow the Sustainable Development Goals (SDGs) to ensure that all aspects of the product from design to manufacturing are being considered from an environmental angle. Focus on the environmental, social and governance (ESG) areas, and understanding the right goals suitable to help benefit (Eccles, R. 2018).

22. Competition

According to Grand View Research (2022), 'the breath analyzers industry is competitive in nature but also highly fragmented.' Companies which are entering with innovative products have great scope for growth as the demand for innovative products is high.



Porter's Five Forces Analysis (Satell, 2017).

Following Micheal Porter's theory, to achieve sustainable competitive advantage we should minimize threats of substitutes and new entrants, at the same time maximize bargaining power from buyers and suppliers (Satell, 2017). This relates back to the urgency of getting to market first, along with exploring new manufacturing avenues, keeping in mind Porters five forces analysis.

The United States 'have given the green light to a Covid-19 breathalyser according to Macmillan, (2022) with the hope that 'breath testing could eventually be used to detect and monitor other conditions, such as cancer'.

InspectIR Systems were the first to develop a Covid-19 breathalyzer test and it was approved by the U.S. FDA in April 2022. A test which 'provides results within three minutes and detects five volatile organic compounds (VOCs) associated with COVID-19.' (Grand View Research, 2022)

Hound Labs, based in Canada, originally design easy-to-use, ultra-sensitive technology for their cannabis breathalyser. In 2020, they adapted their business model and created the Hound Covid-19 breathalyser. Designed to meet the needs of hospitals and clinics as a solution with patients care specifically in mind. It has the ability to measure Covid-19 in breath of both symptomatic and asymptomatic individuals.

They are hopeful, after additional research that the device would be able to identify whether the presence of SARS-CoV-2 in breath can help to identify 'super spreaders' (Hound Labs, 2022). This is not a personal use device, and development is still in place for completion on a point-of-care product.

The importance of patenting our design and features is crucial for successful product to market. As Ikujiro Nonaka (1991, p. 96) argues: 'In an economy where the only certainty is uncertainty, the one sure source of lasting competitive advantage is knowledge.'

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