



MANAGEMENT OF NPD ASSESSMENT B CREATING THE DESIGN BRIEF

Lecturer: Alan Mumby

Abstract

The design brief will include considerations for efficient production methods, scalability, and cost-effectiveness to ensure the product's commercial viability. The project will be managed with a focus on meeting the 12-month timeline and delivering the initial 500,000 units to market, with plans for scaling production to meet the 5 million unit per annum requirement.

Joshua Evans

0452686@student.uwtsd.ac.uk

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Synopsis

Company Profile

The company is a leading manufacturer of electronic breathalyser devices, which are predominantly used by UK police and security to detect traces of alcohol in a person's respiratory system. However, with the ongoing impact of COVID-19 on the economy, Company A has decided to shift its focus from alcohol detection products to developing a detection system for traces of coronavirus. The demand for fast and effective testing is high due to the inconvenience faced by both individuals and businesses during COVID outbreaks.

Problem

Although the pandemic appears to be coming to an end, Covid outbreaks still have the potential to cause significant disruption and health risks if not contained properly. Despite widespread vaccination efforts, the virus remains highly contagious and early detection is crucial to prevent further spread. However, the current test methods, including lateral flow and PCR tests, are often uncomfortable, complicated, time-consuming, and impractical for many individuals. Additionally, the accuracy of these tests is questionable, particularly with the rising number of self-tests being conducted. This puts the responsibility on the medically untrained user to conduct the test correctly, increasing the likelihood of errors and reducing the overall reliability and accuracy of the results.

Goals

The objective is to create a revolutionary product that addresses the shortcomings of current COVID testing procedures. This will be achieved through the development of a non-intrusive device that enables fast, accurate, and reliable testing by having the patient blow into it, similar to an alcohol detection breathalyser. This will take some of the pressure off the user when it comes to getting accurate results, unlike the lateral flow tests.

The accuracy of lateral flow tests has been widely debated with some research stating that lateral flow tests are more than 80 per cent effective at detecting any level of Covid-19 infection and are more than 90 per cent effective at detecting Covid when people are at their most infectious (Petersen, Crozier, Buchan, & Mina, 2021).

However there have also been studies that support that lateral flow tests detect an average of 72 per cent of symptomatic cases and 58 per cent of asymptomatic ones (UCL, 2021).

The electrical internals of the virus detection system have been prototyped, validated and are available for utilisation. However, a commercialised handheld version must be designed and developed based on this new product design brief before it can be launched in the market.

The aim of this product design brief is to highlight the points that need to be considered by the design team in order to produce and manufacture a successful product within the following company constraints:

Objectives

- To develop a product that enables fast, accurate, and reliable testing for COVID-19 in a non-intrusive manner through the use of a portable breathalyser.
- To address the shortcomings of current COVID-19 testing procedures with the development of a new and innovative device.
- To design and develop a handheld version of the COVID breathalyser tester for commercialised use.
- To ensure the product is financially viable and profitable by budgeting finances across areas such as marketing, research and development, and production costs.

- To meet the manufacturing capabilities required for large-scale production, ensuring the design is fundamentally viable for mass production.

Main Goal

- To launch the product in the market within a 12-month timeframe for the initial 500,000 units, with a requirement for 5 million units per annum after the initial 12-month period.

Team Roles

To ensure that the constraints in the previous section are overcome during the development of the new product, it is essential that a substantial team is formed, each with different roles and tasks that will contribute to producing a successful product.

A team with different roles and tasks is essential to overcome the constraints during the development of a successful COVID-19 Breathalyser product. The NPD and Innovation Manager coordinates the teams, while the design, manufacturing, finance, logistics, and marketing teams are responsible for their respective tasks, such as producing a reliable, accurate, and easy-to-use device, ensuring financial viability, steady distribution, and promoting the product to the target market.

Aesthetics

The design of the COVID breathalyser should be modern and attractive to appeal to customers.

Some factors to consider for the design of the device include:

- Shape
 - Fit the profile of the hand for comfort while holding.
 - Smooth edges, avoid any sharp corners. Smooth edges will reduce damage if dropped.
 - The device should be ergonomically designed for ease of use and comfort.
- Colour
 - Bright colours
 - Maintain consistency with the company's branding image and aesthetics.
- Finish
 - smooth plastic surfaces, easy to keep clean.
 - Include ribbed/lined section on the handle area for grip enhancement.
- Longevity
 - Include more material around circuit board and screen for added protection.
 - Make the product simple to take apart in the event of maintenance/repairs i.e. accessible screws, small slot or groove to split sections in half.

Cost analysis will be required amongst the teams to ensure that the design is cost effective and beneficial to the product.

Branding

Branding is a vital part of creating a successful, marketable product.

- The device should have a strong and recognisable brand identity
- The branding should accurately reflect the purpose and benefits of the device
- The brand image should be consistent across all marketing materials and packaging, as well as websites, advertisements, brochures.

Teams must work together to work towards building a brand that adds credibility to the product, within budget.

Links:

- Marketing

Circular Economy

- The COVID breathalyser should be designed with sustainability in mind, using materials that are environmentally friendly and recyclable where possible.
- The manufacturing process should also focus on minimising waste and emissions, and should be optimised for energy efficiency.
- The product should be designed with end-of-life considerations, including recyclability and repurposing potential. This could be achieved by offering discount on next purchase if old handsets are sent back to the company, the company can then explore the possibilities of reusing circuit boards or components.
- The handset material can be cleaned and shredded, with the plastic chippings possibly being used for future mouldings.

Links:

- [Environment](#)
- [Manufacturing](#)

Costs

- Production - The cost of producing the COVID breathalyser must be minimised where possible to ensure profitability.
- Manufacturing – Ensure that the manufacturing facility is running lean with minimal waste to reduce costs.
- Sales - The cost of the device should be competitive in the market to attract customers.
- R&D - The budget for research and development must be allocated appropriately to ensure the successful development of the product.
- Marketing and Distribution - The cost of marketing and distribution should be considered to ensure that the product is available and accessible to customers.
- Materials
- Prototype

Links:

- [Manufacturing Facilities](#)

Customers

According to market intelligence, there is a strong customer base for the device in both the private and public sectors. To optimise sales, the company should be targeting both sectors, with a particular focus on securing regular contracts with public sector institutions such as the NHS, GP practices, and schools. This device is likely to be more popular during the winter months when COVID rates are typically at their highest.

Current trends indicate that COVID rates fluctuate throughout the year, but as the most popular time for holiday makers and the private sector is during the summer months, there is a market for testing in the build up to the summer period. This presents an opportunity to target high-demand locations such as airports, cruise ships, hotels, festivals, and sports events. Other potential targets include hospitals, ferry services, and schools.

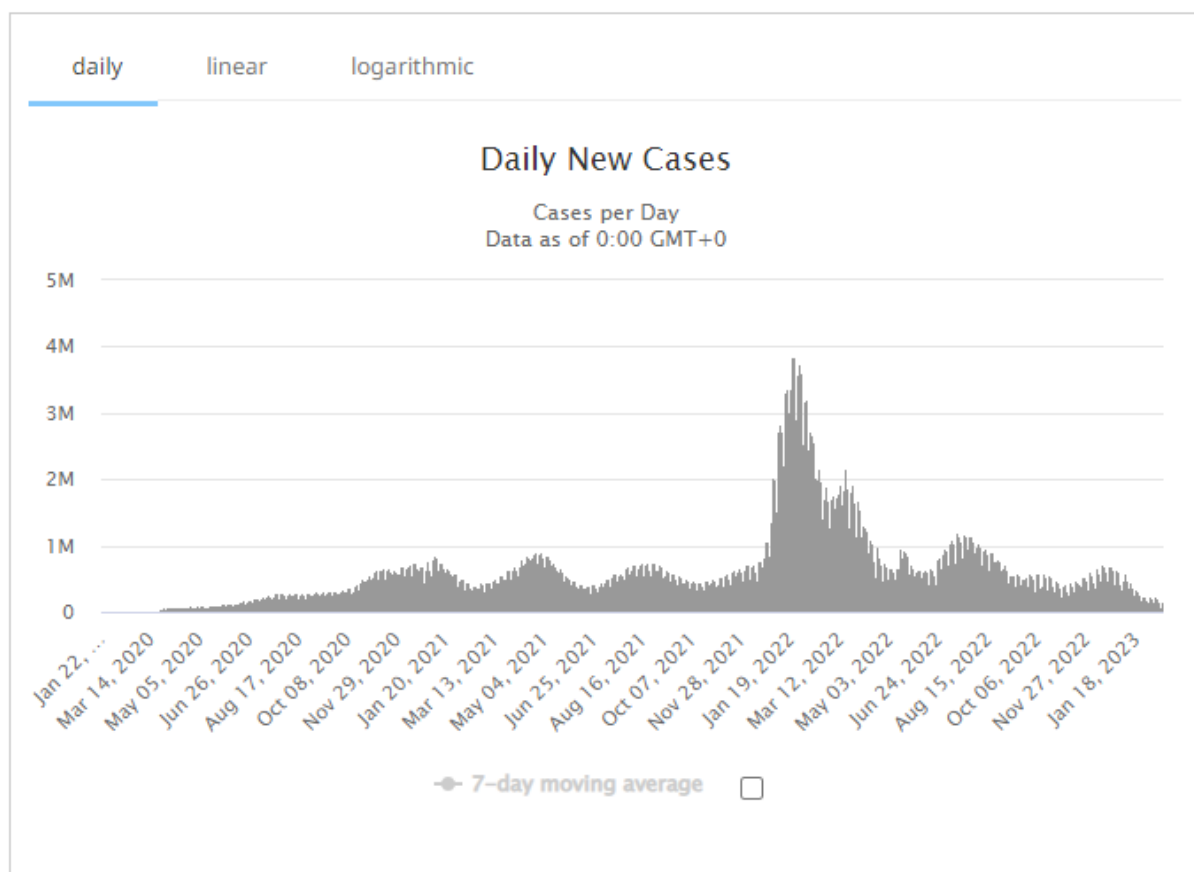


Figure 1 – Covid cases by date (Worldometer, 2023)

Design

Materials

- Must be light to ensure comfort for the user and reduce the risk of injury. Repetitive strain injury
- Must be easily formable to mould to the shape of the device casing required. Materials with higher melting points will require more energy, thus increasing the costs present to manufacture.
- Disposable tubes – Must be non-toxic and FDA approved.

Practicality

- The breathalyser should be easy to use, with clear instructions and a simple, intuitive design.
- Develop the handle so the product is comfy to hold and grip, making the product easier to hold and reducing the chances of it being dropped.

Portability

- The breathalyser should be small and lightweight, with a design that is convenient for on-the-go use.

Durability

- The breathalyser should be able to withstand daily use and be able to function in a variety of environments.
- The device should be able to withstand any shock to a degree as a result of it being dropped during use. Shock absorbing rubber could also be added to any areas that may be prone to damage.
- Inclusion of more material around vulnerable areas such as the screen or buttons for additional protection should be considered by the design engineer.
- Drop tests on a prototype could be conducted to highlight these areas and ensure that they are well focused on for the final product.

Expansion

- Data storage and tracking: Consider whether the breathalyser should have the ability to store and track results over time, potentially through a connected app or other digital platform.

Links:

- Quality
- Value

Documentation

- Detailed technical specifications and design drawings should be created for the COVID breathalyser.
- A comprehensive user manual should be developed to ensure that the device is easy to use and understand.
- All relevant certifications and approvals required for the product should be obtained and documented.

Links:

- Legal

Environment

- The design and manufacturing process for the COVID breathalyser should take into account environmental sustainability.
- The device should be designed to minimise its carbon footprint and waste during use and disposal of tubes and the device at the end of its life.
- The product should be packaged in an environmentally friendly manner to reduce waste.
- Consideration should be given to the environmental impact of the breathalyser, including the materials used in its construction and any potential disposal concerns.

Temperature

- The device should be designed to operate effectively in different temperature and humidity conditions to ensure consistent and accurate results.
- The device should undergo rigorous testing to ensure that it can operate effectively in a range of different environmental conditions.
- The UK police issued Dräger Alcotest® 6820 can provide full analysis at temperatures ranging from -5 °C to +50 °C (Dräger, 2022). If possible, the device should be rated following the same specifications as the trialled and proven unit being used by the UK police.

Humidity

- Product must be rated to be able to form with moisture in the air if humid. Ensure circuit board is protected.

Exposure

- Given the potential environments this device may be used in (rainy, cold), the device will need to comply with IP standards. A protection class of IP54 would be sufficient, allowing the product to be weather resistant but not able to be fully submerged. This is the standard adhered to for the police issued Dräger Alcotest® 6820 (Dräger, 2022).

Links:

- Design
- Quality

Ergonomics

- The device should be designed to be ergonomic and easy to use, even for individuals with limited mobility or dexterity.
- The device should be designed to be comfortable to hold and use for extended periods of time.
- The ergonomics of the design can be trialled on a prototype and any concerns or improvements can be fed back to the design team to consider for the final design.

Links:

- Design

Legal

- The device must comply with all relevant legal and regulatory requirements, including but not limited to data protection, privacy, and intellectual property laws.
- The device should be CE marked, indicating that it meets European Union health, safety, and environmental protection requirements.
- Any patents or trademarks required for the product should be secured.
- Non-disclosure agreements (NDAs) should be implemented to any companies used to subcontract any part of the manufacturing or assembly process.

Intellectual Property

According to (Trott, 2008), there are four types of intellectual property that can be applied to a product design or idea to protect creative efforts:

- Patents - Offers a 20-year control.
- Copyright - Provides exclusive rights to creative individuals for the protection of their literary or artistic productions.
- Registered designs - As protected by registration, is for the outward appearance of an article and provides exclusive rights for up to 15 years.
- Registered trademarks - A distinctive name, mark or symbol that can be identified with a company's products.

Assign a legal team to safeguard IP of the design to protect it from competitors, considering all of the above factors to ensure the best protection for the product.

Legislation

- The device must comply with all relevant FDA and international regulations for medical devices.
- The device must comply with all relevant health and safety legislation, including but not limited to medical device regulations.
- The device should be designed and manufactured in accordance with good manufacturing practices (GMP).
- Any relevant certifications and licenses required for the product should be obtained.

Maintenance/Calibration

- The device should be designed for easy maintenance and repair.
- Develop a comprehensive maintenance manual to facilitate routine maintenance and repairs by users.
- Clearly document calibration procedures and include them in the user manual.
- Create a spare parts list to ensure that replacement parts are readily available.
- Keep the user interface simple, with a low number of buttons for ease of use.

- Consider making the sensor removable, allowing for easy replacement after 200-300 tests. This can allow for the sensor can be replaced so the device can continually be used.
- Ensure that calibration techniques protect the circuit board from extreme weather conditions, both hot and cold
- Advise users to store the tester in optimal conditions, such as indoors and in a dry place, and not in a cold, damp car during winter.
- Consider implementing a calibration schedule to ensure that the device remains accurate and reliable.
- Calibration procedures should be clearly documented and provided to users as part of the user manual.

Manufacturing Facilities

Manufacturing Goal: To launch the product in the market within a 12-month timeframe for the initial 500,000 units, with a requirement for 5 million units per annum after the initial 12-month period.

To ensure that the device can be manufactured at scale with minimal disruptions to production, it is important to carefully consider the manufacturing process. One critical element is finding a manufacturing facility that can meet the demands of the project while adhering to any necessary non-disclosure and copyright agreements.

To optimise the manufacturing process and minimise potential delays, consider sourcing the work to a dedicated manufacturing facility that will solely focus on producing the breathalyser device. This will help ensure that workers and management are not distracted by other contracts or projects. Losing manufacturing slots due to unexpected delays or issues could significantly impact production and should be avoided if possible.

Achieving Production Targets

Achieving production demands is critical so will require a streamlined and fully functional assembly process. To achieve this, the following factors should be considered:

- JPH (Jobs Per Hour) targets: The workforce must be capable of maintaining an appropriate JPH score on a consistent basis.
- Shift patterns: Consideration should be given to implementing continental or semi-continuous shift patterns with overtime to maximise productivity.
- Workforce size: The size of the workforce should be appropriate to meet production targets.
- Line layout: The assembly line layout should be either loop or continuous, depending on the nature of the manufacturing process. The manufacturing team will be required to extensively review to decide on the optimal line layout and processes.
- Line size/quantities: The line size and quantities will depend on the available floorspace of the unit, with the aim of maximising production efficiency within budget.

Production/Assembly Plan

The production timeline for manufacturing the first 500,000 units is 16 weeks. Based on this timeframe, the following calculations were made:

Parts per week: To achieve the target of 500,000 units in 16 weeks, the production rate needs to be 31,250 units per week ($500,000 / 16 = 31,250$).

Shifts per week: Assuming a 4-shift pattern with 12-hour day and night shifts, the total number of shifts per week would be **14**.

Parts per shift: Dividing the weekly production rate by the number of shifts ($31,250 / 14$) yields a result of **2,323 parts per shift**.

Working hours per shift: Each shift is 12 hours long, but assuming 1 hour for breaks and shift handover, the effective working time per shift is **11 hours**.

Jobs Per Hour: Dividing the parts produced per shift by the working hours per shift ($2,323 / 11$) gives a rate of 212 units per hour (JPH). To ensure that the desired JPH (jobs per hour) can be achieved despite any downtime, the production capacity should exceed the target. Considering a 10% downtime rate, equating 90% uptime, the total production capacity of the assembly lines needs to be 236 JPH.

$$\frac{212}{90} \times 100\% = 236 \text{ JPH}$$

- **Workforce size:** Assuming an operator can assemble 1 unit in 4 minutes, they can achieve 15 JPH at 100%. At 90% uptime, this would equate to 13 JPH per person. $236/15 = 15.7$, $212/13 = 16.3$ therefore a workforce of 16 assembly workers would be required. In addition to assembly workers, managers, maintenance personnel, and supervisors should also be considered when determining the overall workforce size.

The layout and size of the production line can be analysed and optimised to accommodate the 16 assembly workers. During the trial phase, different trials can be conducted to identify the most efficient processes and layouts.

Full Scale Production

Assuming the previous section's assumptions, producing 31,250 units per week, would result in an annual production of 1,468,750 units (47 working weeks). To produce 5 million units using one manufacturing facility with 16 assembly workers, it would take approximately 3.5 years. However, this production goal could be achieved in 1.75 years by utilising two identical facilities.

Market constraints

- The COVID breathalyser should be designed to meet the needs and requirements of the target market.
- The product should be competitively priced while still maintaining profitability.
- The device should be designed to be easy to use and understand, with a user-friendly interface.

Materials

- To achieve the ideal product, materials used to manufacture must be cheap, durable and lightweight.
- The device should be designed using high-quality materials to ensure durability and reliability, allowing the device to withstand daily use and be able to function in a variety of environments.
- The device should be designed to minimise its environmental impact, using materials that are recyclable and/or biodegradable where possible.
- The materials used should be compliant with relevant health and safety regulations.

Packaging

- Focus on using recyclable materials for packaging, minimising the use of single use plastics where possible.
- Consider how many boxes can be included per crate, and how many crates per pallet. This will increase the number of items per shipment, thus reducing the carbon footprint.
- The packaging for the device should be designed to protect the device during transportation and storage.
- When developing the packaging process, drop tests on the packaging should be included to ensure that the goods cannot be damaged if dropped from 2m or less.
- The product should be packaged in an environmentally friendly manner to reduce waste.
- The packaging should include clear and concise instructions on how and how not to use the device during both operation and storage.

Patents

- The device should be protected by relevant patents to ensure that the company has exclusive rights to the product.
- Any necessary patents or trademarks should be secured to protect the company's intellectual property.

Performance

- The device will likely be used intermittently, with short to medium periods of continuous use, followed by periods of dormancy in storage.
- Offers fast, repeatable, and easy use, with more accurate results than lateral flow tests and faster results than PCR tests.
- If possible, use biodegradable straws to reduce environmental impact.
- Operates through light notification system: green light for negative result, red light for positive result.
- Offer Wi-Fi/Bluetooth result certificates for easy access to test results.
- Design prioritises ease of use with minimal buttons.
- Designed to meet or exceed performance requirements for intended use.
- Rigorous performance testing to validate product's performance during development process.

Processes

The device should be designed using a lean manufacturing process to minimise waste and increase efficiency, speeding up manufacturing times whilst simultaneously reducing the costs involved to produce.

The device should be designed with an emphasis on easy maintenance and repair.

- The COVID breathalyser should be designed and manufactured using streamlined and efficient processes to ensure cost-effectiveness.
- The device should be manufactured using good manufacturing practices (GMP) to ensure that it is of high quality.
- The manufacturing process should be audited to ensure that the product meets all relevant health and safety requirements.

Product Cost/Projected cost

The device should be designed to minimise production costs without compromising on quality and performance. The following categories should be considered when budgeting for this product:

- Marketing – costs associated with advertising and promotional material.
- Prototyping – assign a set budget to the prototyping phase, keep costs minimal and essential as multiple prototypes may be required.
- Manufacturing and Distribution – Consider employee wages, costs of opening a 2nd manufacturing facility, or to bring in a specialist third party manufacturing/shipping/distribution company to meet the high volume demands in the given time frame in the event that the current facilities cannot cope with the demand.

LINKS:

- [Manufacturing Facilities](#)
- [Distribution](#)

Product Lifespan

Designate a set amount of usage before the product needs to be replaced i.e. 250 tests before replacing to ensure

The device should be designed for long-term use and should have a product lifespan of at least 2 years with regular maintenance.

- The device should be designed to have a long lifespan to ensure that it provides good value for money to the user.
- The device should be designed to be easily repairable and maintainable to extend its lifespan.
- The product should be designed with end-of-life considerations in mind, with recyclable or biodegradable materials used where possible.

LINKS:

- [Circle economy](#)
- [Environment](#)

Prototyping

Phase 1

- Select the right components for the breathalyser, including sensors, screen, and batteries. Ensure that they meet the product's requirements and are easy to replace or maintain.
- Start with a basic prototype that can test the device's functions and accuracy. This can be done using a breadboard or other prototyping platform. Use this prototype to identify and address any issues with the device's design and functionality.
- Trial the prototype to determine if factors such as size, weight, layout are appropriate.

Phase 2

- Produce a fully functional prototype that is close to the final design.
- Deploy in real world scenarios to help with the final development of the product.

Trial phase

- Implement a prototype phase that will deploy the product in a controlled environment e.g. schools, GP, hospital (avoiding areas that would receive negative feedback for a positive test i.e. football match). Use any feedback from this trial period to determine both the areas of the product that can be kept the same, and the aspects that will need redeveloping and/or changing.
- It is quite possible that modifications are made depending on the feedback from the prototype phase. Any potential lean manufacturing process changes after the trial phase should be reviewed thoroughly to cover all aspects of risk vs reward of any post-trial phase changes taking place. (Risk = Trying to fix something that's not broken, Reward = something that could take the product to the next level).

Quality

Objective: To design and produce a part that is durable, fit for purpose, marketable and within budget.

- The COVID breathalyser should be designed and manufactured to meet the highest quality standards.
- The device should be designed to be reliable, accurate, and easy to use.
- The product should be manufactured using good manufacturing practices (GMP) to ensure that it meets all relevant health and safety requirements.

Reliability

- Removable sensor, every 200-300 tests, sensor can be replaced, and the device can continually be used.
- The breathalyser should have a long battery life to allow for multiple uses without the need for frequent recharging.
- The device must be reliable and accurate. The product must perform consistently over its lifespan and provide consistent results.

- The device should be designed to be compatible with personal protective equipment, such as masks and gloves, to allow for use in the typical test conditions.

LINKS:

- Design
- Cost
- Manufacturing

Safety

- The device should be designed with safety and hygiene in mind, with features such as single-use disposable mouthpieces to prevent the spread of infection.
- Smooth, crack and crevice free internals on the product to avoid any bug traps (areas where bacteria can become trapped and fester) to reduce the chances of cross contamination between tests and reduce the possibility of false readings.
- The device must be safe for all users. The product must meet all regulatory standards for medical devices and be tested extensively to ensure that it poses no risk to the user.

LINKS:

- Ergonomics
- Design

Shipping

- The device must be able to be distributed globally, with logistics in place to ensure timely delivery.
- The device should be designed for easy packaging and shipping to minimise the risk of damage during transportation.
- The packaging should be designed to be environmentally friendly and cost-effective.
- The device should be designed to meet the relevant shipping regulations and standards.

Size

- The size of the Covid Breathalyser must be compact and portable. The product must be easy to use and carry and must not take up too much space.
- The size of the device will be influenced by the size of the electronic components and the ergonomics for user comfort.

LINKS:

- Design
- Ergonomics
- Shipping

Testing

- The device must undergo extensive testing before release. The product must meet all regulatory standards and customer expectations.
- The device must be tested thoroughly both in lab and in real-world conditions to ensure its performance and reliability, as well as in various weather conditions.

LINKS:

- [Prototype](#)
- [Timescales](#)

Timescales

- Concept development: 6 weeks
- Design and prototyping (Phases 1 and 2): 10 weeks
- Testing and validation: 12 weeks
- Trial Phase: 5 weeks
- Final development: 3 weeks
- Production: 16 weeks

Total time: 52 weeks.

LINKS:

- [Manufacturing facilities](#)
- [Prototype](#)
- [Design](#)

Weight

- The device should be as lightweight as possible without compromising the product.
- Topology optimisation – can weight be reduced without compromising the structure?
- The weight of the Covid Breathalyser must be minimal. The product must be easy to use and carry and must not be too heavy.

Value

In order to future-proof the product, the base features of the breathalyser should be designed in a way that allows for easy upgrades. For example, the screen type could be designed with a modular system that allows for different types of screens to be easily installed in the future. Similarly, the charging/battery functions could be designed in a way that allows for easy replacement or upgrade of batteries and charging components. By designing the product in this way, it reduces the likelihood of it becoming obsolete and increases its value to customers over time.

It is important to keep the fundamental aspects of the product, such as its shape, manufacturing process, and material, consistent in order to ensure that any future upgrades or modifications do not compromise the core functionality. By maintaining the core aspects of the product, it becomes easier to implement upgrades or modifications that build upon the existing design.

In addition to future-proofing the product, it is important to ensure that the COVID breathalyser provides value to customers. This means that the product must be affordable, accurate, and reliable. These objectives should be tied into the overall objectives of the new product development process.

Finally, it is important to consider potential future mutations of the COVID virus that may lead to new pandemics. The product design should be flexible enough to accommodate any new features that can be added to account for mutations that may emerge, either through software updates or hardware upgrades. By considering potential future scenarios, the product can be designed to address future needs and ensure its continued relevance and usefulness.

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