

Management of NPD

Create a Design Brief

A new product development project- Virus Detector

MSc International Innovation Management (IIM)

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Synopsis:

As we all know that, our company specialises in the manufacture of electronic breathalyser system. And we know the market for these devices is predominantly to police and security forces. So In light of the current Coronavirus pandemic, the Company see great potential in developing a product and moving into the new segment that can meet both clinical and personal requirements for such virus detection and are therefore anxious to bring the new product to market.

The Company identified an opportunity through a Knowledge Transfer Partnership with a local university, to extend the chemical alcohol detector system which is at the heart of our breathalyser products to cover the detection of other organic materials, including those generated in the breath as a result of various virus infections.

This new virus detector has been trialled in the laboratory and the necessary patent application have been registered on our company name. We also have successfully completed the prototype for electronic and mechanical systems which actually form the new product and now we have to design the 'physical envelope' and appearance of the new Virus Detector.

Because of the nature of the changes to the detector system, we will have to have completely new product design. However, our company have decided to sourcing the electronics and mechanical elements of the product externally, and undertaking final assembly, testing, packing and shipping at the company's Carmarthen factory (similar strategy as breathalyser).

Our company has successfully prototyped the electronic and mechanical systems which form the new product and now we have engaged a London-based company to design the 'physical envelope' and appearance of the new Virus Detector. Also, we glad to say that our company has already gained certification for the new Virus Detect from the various medical device regulatory agencies.

So, the company wants to manufacture 500,000 virus detector in this first year of project, and then after 5 million per annum. And for achieving this target company has already made a time schedule for the project.

This design brief will give you the overall idea of the product and their requirements so we can kick off the project. This is the official authorised issued copy from NPD department for all the departments of the company. NPD department will be responsible for the future query and revision of this document. If there are any changes to this document, you will be issued a new revised copy of this document along with highlighted revised/bullet points without any discrepancy.

Aesthetics:

- The device should be aesthetically pleasing and should not be overly intrusive or obtrusive.
- The device should be modern, sleek, and sophisticated as this would be the personal as well as professional device.
- The design should emphasize clean lines, minimalistic elements, and a colour palette that is calming and non-intimidating.
- The device should appear inviting and non-threatening to users.
- The user interface should be intuitive and straightforward, with clear directions and visual cues to guide users through the process.
- The device should be designed to be accessible to users of all ages and abilities.
- A device needs to be both visually appealing and functional in order to be successful.
- The colour and shape of the device should be chosen to be inviting, while still allowing for easy identification of the device's purpose
- The display should be easy to read, and the buttons should be easy to press and navigate.
- As these devices are expected to be used in a variety of settings, it is important to also consider portability and ease of use.
- Durability and water resistance should also be taken into account, as these devices are likely to be used in a variety of environments.
- It is important to consider the materials used in the construction of the device, as these will affect both its aesthetic appeal and its ability to withstand wear and tear.
- The device should be constructed with durable materials, including a waterproof case and scratch-proof coating, to ensure long-term use and reliability.
- It should also be lightweight and portable, allowing users to take it with them wherever they go.
- The device should be audible for warning, information and instructions with good sound quality (for inputs and outputs).
- Mouthpiece should be comfortable and well design.
- Design should be suitable for all age groups as well as all genders and consider the other country

Reference documents/references-

Design/Design requirements, Size, Weight

Company Finance doc

Company's manufacturing Manual

Company's Breathalyser standard

Approved Vendors/Suppliers:

Source of electronic circuit boards –

1. China or Malaysia
2. UK or Europe

The mechanical element of the detector- TBD

The Company have not yet decided whether to source this element as a fully assembled unit (as they do for their breathalyser products), or whether to source the mouldings separately and assemble the unit in house. Preliminary research has indicated.

We should search for more/other vendors or suppliers in the market for the items, parts, outer case, detector, electronic circuit, etc. As our Company CEO and Finance Director have jointly decided to seek alternative suppliers to those currently used, partly as a means of seeing if they might, as a result, be able to drive down the manufacturing costs of their existing products.

Reference documents/references-

Company's Breathalyser standard and strategy

Company Strategy

Branding and logos:

The device should be branded with a company logo or other visual representation.

Logo should be

- on device front and back (mirror finish or radium), it should be visible
- on mouthpiece
- on device as well as reflecting on display while turning on and off the device (with sound effect)
- on packaging
- On documents-warranty card, instruction booklet, manual etc.
- on website
- While connecting- in case of connecting with any device (name/model number/logo should appear)

Reference documents/references-

Company's Breathalyser standard

Company's branding and logos catalogue (as per item size)

Finance

Aesthetic

Circular economy:

- The circular economy a virus detector would be powered by a rechargeable battery, eliminating the need for disposable batteries.
- The device should be modular, allowing for easy repair and upgrade in the event of technological advances.
- The device should be designed to be easily recyclable, further reducing its environmental footprint.
- Repair and refurbishment should involve repairing or re-calibrating existing detectors to improve their accuracy or efficiency.

Company Constraints:

- The cost of the device should be as low as possible
- The device must be profitable for business.
- The device must be designed and manufactured within two months.
- The device must meet all safety and compliance regulations.

Reference documents/references-

Costing and budget sheet

Company's manufacturing Manual

Finance

Testing results and different agencies approvals

Company Strategy:

The company have decided to adopt a similar strategy to that which they use for their current range of breathalyser products, i.e. sourcing the electronics and mechanical elements of the product externally, and undertaking final assembly, testing, packing and shipping at the company's Carmarthen factory.

The Company CEO and Finance Director have jointly decided to seek alternative suppliers to those currently used, partly as a means of seeing if they might, as a result, be able to drive down the manufacturing costs of their existing products.

Also, 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.

The mechanical element of the detector (basically the breath sample capture system) will be fabricated from injection moulded parts. The Company have not yet decided whether to source this element as a fully assembled unit (as we do for their breathalyser products), or whether to source the mouldings separately and assemble the unit in house (TBD).
Source of electronic circuit boards –

3. China or Malaysia
4. UK or Europe

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

Product design specification (PDS) will be generated soon. Individual element's data sheet will be provided, if required.

Reference documents/references-

Company's Breathalyser standard, CEO and Finance Director's approval

Company's approved vendor list

Company's costing sheet

Manufacturing process docs-Vacuum form process and injection moulding process.

Testing results and different agencies approvals

Company Finance doc, Design

Competition:

- The device should be competitively priced compared to similar products on the market.
- The device should offer features and benefits that differentiate it from similar products on the market (such as, easy to use, suitable, reliable, compatible, comfortable and user friendly for all generations, age groups, genders as well in all countries and their people).
- The device should have a competitive edge in both design and functionality.
- The device must be designed to stand out from the competition in terms of features, reliability, and usability.
- The device should be based on the latest technology and should have a high degree of accuracy and sensitivity

Design/Design requirements:

- The device should be able to detect the virus in breath samples (air blowing) taken in any temperature, humidity and in minimum air flow.
- The device should be designed to be user friendly and should have a display panel which will show the level of virus detected. The device should also have an alert signal which will be triggered when the virus is detected.
- The device should be based on the latest technology and should have a high degree of accuracy and sensitivity.
- Printer should use rechargeable batteries.
- Device should connect through smartphones as well.
- The design should also consider the environment in which it will be used. It should be able to withstand harsh conditions, such as extreme temperatures, dust, and humidity. It should also be waterproof and shockproof. The design must also be durable enough to withstand regular use.
- It should also include a rechargeable battery that can easily be replaced and recharged.
- Battery should with stand for minimum 12 hours and having long life for reuse.
- Device should have ability to remind servicing and calibration cycle.

The goal of this project is to create an ergonomic electronic corona virus detector (similar to a breathalyser) that meets the following criteria:

The device must be small and portable, while remaining easy to use.

- It should be intuitive, with clear and simple instructions for use.
- It should be designed to minimize user fatigue during use.
- It should be designed to minimize risk of cross-contamination.
- It should be designed for durability and ease of maintenance.
- It should be designed to minimize the potential for false readings.
- It should be designed for accuracy of results.
- It should be designed to provide user feedback in an easily understandable format.
- It should be designed with safety and ergonomics in mind.
- It should be designed to accommodate a wide range of user body types and sizes.
- It should be designed to be cost-effective and reliable.
- It should also be able to process a breath sample in less than 10 seconds and display the results. The device should be able to detect the presence of corona virus with a minimum false positive rate of 1%.

Languages-

- The device should have settings of different languages as per user/country.
- The device should have multilingual welcome, start guides- Written document as well as audible.
- Major countries where we sell our product- UK, India, China, Japan, Australia, France, Netherlands.
- So included languages should be- English, Welsh, Hindi, Chinese, Japanese, French, Dutch, etc. (We can add as many as possible languages and local languages of country as well for product's popularity and user friendly.)

Reference documents/references-

Aesthetics, Size, Target customer, Company Finance doc, Weight.
Company Strategy.

Documentation:

- The documentation for the virus detector should include all of the relevant information about the project, such as the design specifications, the materials used, the testing performed, and the results obtained.
- The documentation should also include a user manual that provides instructions on how to use the device.
- We should follow and produce all internal documents as per company standards and company policies.
- We should produce all the documents (such as user manual/guide, Start guide, safety information, etc.) and certifications in multiple languages (multilingual documents) as our product is going worldwide.
- Documents should be available online as well as offline.

Deliverables: A comprehensive, easy-to-understand document that contains all the necessary information for using the device.

Style/Tone: The document should be clear and concise with simple language and clear instructions.

Format: The document should be in PDF format.

Reference documents/references-

Company standards and policy

Standard list of documents

Intellectual Property:

The design of this device must include the appropriate intellectual property protection to ensure its creators are adequately protected. The following areas should be considered when designing this device:

- Patent Protection: A patent can protect the design of the device itself, as well as any unique components or processes used in the device.
- Copyright Protection: Copyright law can be used to protect the design drawings, source code, and user manuals related to the device.
- Trade Secrets Protection: Keeping the design of the device and its components confidential can help protect it from competitors.
- Trademark Protection: Trademark protection can be used to protect any logos, brand names, or slogans that are used to market the device.
- Licensing Agreement: A licensing agreement can be used to ensure that the device's creators are compensated for any commercial use of the device.

The above considerations should be taken into account when designing this device to ensure that its creators are adequately protected.

Internet Protocol:

- A microcontroller circuit can be used to detect the presence of coronavirus in the breath sample.
- The circuit should be connected to an internet-enabled device (e.g. smartphone, laptop, etc.).
- The device should be able to collect breath samples from the user, process the samples and analyse them for the presence of coronavirus/any virus.
- The device should display the results and alert the user of any potential infection.
- The device should be able to store the results for further reference.
- The device should be equipped with a security system to protect the user's data.
- The device should be equipped with a tamperproof casing to prevent unauthorized access.
- The device should be able to connect to a cloud-based platform for data storage, analysis and sharing.

Legal requirements, Legality:

Our company has already gained certification for the new Virus Detect from the various medical device regulatory agencies.

We should follow and gain all the standards, certifications and approvals from several bodies (which mentioned in the Standards, Specification, Approvals and Certifications section) as over product is going for worldwide countries.

It is important to note that the use of virus detectors can be subject to certain laws, such as those related to privacy and data protection. In particular, the use of the device may be subject to the Health Insurance Portability and Accountability Act (HIPAA), which includes rules about how patient data is collected and stored. Therefore, it is important to ensure that any electronic Corona virus detector used is in compliance with all applicable laws.

Reference documents-

Standards, Specification, Approvals and Certifications section
International requirements/codes
Company standards
Standard list of documents
Approved Supplier/Vendor's list

Life in service:

Life in service for electronic corona virus detector (similar to breathalyser) is an important and necessary job. This job provides an essential service to keep the public safe and healthy.

The job involves calibrating, maintaining, and troubleshooting the electronic corona virus detector. The individual must be knowledgeable about the inner workings of this device and be able to recognize any potential issues that could arise. They must be able to use diagnostic tools and software to properly diagnose and repair the device. They must also be able to update the device with the latest firmware and software in order to keep it up to date.

The individual must also have the ability to work with customers and explain to them how to properly use the device. This includes providing instruction on proper sanitization and storage of the device, as well as explaining the results of the test. They must also be able to answer any questions or concerns customers may have about the device or the results.

Reference documents-

Repair and maintenance
Company standards
Design/design requirements

Manufacturing facilities:

To ensure the device meets the manufacturer's specifications, our facility should include the following components:

- Clean Room.
- Testing Room
- Assembly Line
- Quality Control
- Packaging
- Storage

The facility should also have established procedures for product recalls and warranty claims, a robust security system in place to protect its personnel, assets, and products from unauthorized access and procedures in place to ensure that all waste materials are disposed of properly, and that any hazardous materials are handled in a safe and responsible manner.

Manufacturing processes:

- Design and Prototyping: The first step in the manufacturing process is to design and prototype the virus detector. This will involve the design and development of the hardware and software components of the device. This step also includes testing and validation of the design. The Company have successfully prototyped the electronic and mechanical systems and has already gained certification for the new Virus Detect from the various medical device regulatory agencies
- Component Assembly: Once the design of the device has been finalized, the components of the device must be assembled. This includes the hardware components such as sensors, microcontrollers, and circuit boards, as well as the software components such as the user interface and the software for detecting and measuring the presence of the virus.
- Testing and Quality Assurance: After the components have been assembled, the device must undergo rigorous testing and quality assurance processes to ensure that it meets all safety and performance standards. This includes testing for accuracy and reliability.
- Manufacturing: Once the device is ready for mass production, it must be manufactured in a factory. This includes the assembly of the components and the packaging of the device.
- Distribution: The final step in the manufacturing process is to distribute the device to the various markets and customers. This includes shipping, handling, and customer support.

The projected manufacturing volumes are 500,000 in the first year, and 5 million per annum afterwards

Reference documents-

Company standards and manufacturing process manual/guide, manufacturing facilities

Market constraints:

Materials-

- Sensor: Sensors that detect the presence of the virus in the breath are made from a variety of materials, including polymers, metals, and nanomaterials. The company have decided to source the electronics and mechanical elements of the product externally.
- Power Source: The power source for the virus detector should be durable and reliable. Commonly used power sources include lithium-ion batteries, which are rechargeable and can provide power for extended use.
- Display Materials: The display of the electronic coronavirus detector should be made from a material that is resistant to scratches, water, and dust. Commonly used materials include glass, plastic, and metal.
- Housing: Commonly used materials include metal, plastic, and rubber. These materials should also be resistant to corrosion and other environmental factors.
- Data Storage: Data storage materials used in the virus detector should be able to withstand the conditions of the environment. Commonly used materials include flash memory, SD cards, and hard drives.

Reference documents-

Company standards

Approved Supplier/Vendor's list

Packaging:

We should follow the company standard (breathalyser) for packaging and also follow the international norms.

Add all warnings and instructions on packaging and inside the box which we use for our breathalyser (such as warranty cards, user manual, etc.)

Reference documents-

Company standards/Breathalyser packing instruction manual

International norms

Design

Performance:

- The electronic corona virus detector should be able to accurately detect the presence of the coronavirus in a person's breath with minimal false positives or negatives.
- The device should be able to quickly and accurately detect the presence of the virus in a person's breath, with a detection rate of at least 95%.
- The device should also have a low rate of false positives and false negatives.
- The device should be able to detect the virus in a person's breath at a distance of up to 3 feet.
- The device should also have a low power consumption and be easy to use and maintain.
- The device should have a high degree of accuracy and reliability, and should be able to provide results in a timely manner.
- The device should be able to operate in a wide range of temperatures, and should be designed to be used in multiple locations and environments.

Reference documents-

Design/Design requirements

Test certificates

Repair and maintenance

Political Implications:

The implementation of such a device has major political implications. It could be used to create a more efficient system for tracking the spread of the virus, as well as for enforcing quarantine and travel restrictions. It could also be used to monitor and enforce social distancing, as well as to identify those who may have been exposed to the virus but are asymptomatic. In addition, the device could be used to create a system of surveillance that would allow government and health officials to monitor the public and track their movements, raising questions about privacy and civil liberties.

- The device should be easy to use and portable, and should be able to send its readings to a central database.
- It should also be affordable and be able to be mass produced quickly in order to meet the need of the public.
- The device should be used to create a more efficient system for tracking the spread of the virus, as well as for enforcing quarantine and travel restrictions. However, its implementation also raises questions about privacy and civil liberties.

Product life span:

- The virus detector (similar to a breathalyser) is designed to have a life span of 3 years.
- During this time, the product should remain in good working condition, with all components, such as the battery and sensors, functioning properly.
- The device should not require additional maintenance or repairs during this time.
- The detector should be able to accurately and consistently detect the presence of coronavirus in the user's breath for a period of 3 years, with minimal false positives and false negatives.

Prototyping:

The Company have successfully prototyped the electronic and mechanical systems and has already gained certification for the new Virus Detect from the various medical device regulatory agencies.

Reference documents-

Prototyping documents, test results, approval and certifications

Quality:

- The device should be designed for accuracy and reliability, and should be able to detect the virus in a single breath sample.
- It should be capable of providing accurate and reliable results in a short amount of time, and should be able to provide a clear indication of the amount of virus present in the sample.

Reliability:

- To ensure reliable performance, the detector must be able to accurately detect the presence of the virus and must be able to withstand a wide range of environmental conditions.
- The detector should be designed to be robust and resistant to shock, vibration, and changes in temperature and humidity.
- The accuracy of the detector should be tested and certified to meet the appropriate standards and regulations for medical diagnostic equipment.
- The detector should be designed to be easily maintained, with easily replaceable components, so that it can be quickly and easily serviced when necessary.

Repair and maintenance:

- Make environmental free repair and maintenance policy for this device.
- We should also be able to provide a wide range of services for customer support, including customer service, troubleshooting, and warranty services.
- Add a list of authorised service center for calibration (same as breathalyser), contact details and address.

All below points and instruction need to add in the manufacturer's instructions

- Regular maintenance of a virus detector is vital to ensure its accuracy and reliability. If any problems are noticed, it is important to contact the manufacturer or supplier for further advice and support.
- How to clean the virus detector after each use, to prevent the build-up of dirt and dust that can interfere with its accuracy.
- Refer to the manufacturer's instructions for troubleshooting.

Reference documents-

Company standards
Life in service
International norms

Safety:

- This product is for person's safety, so company and product is responsible for it.
- Product should be safe to use.
- Product should have high data security for person's data
- Product should be able to share the data to government for person's safety.
- Product should be able to save all previous data.

Shelf life and storage:

- It should be minimum 3 years.
- The detector should be tested annually to ensure continued accuracy and functionality.
- It should withstand in any environmental condition.

Shipping Requirements:

- The device should be packaged in strong, durable materials to protect it from damage during shipping.
- The package should include all necessary accessories and components, such as batteries and a power adapter.
- The package should include detailed instructions on how to use the device and interpret the results.
- The package should include contact information for customer service and technical support.
- The package should include a return policy and information about any warranties.

Reference documents-

Packaging, company transportation and supply chain doc.

Size:

- The device should be small enough to be easily carried by the user and should not be much larger than a cell phone, so anyone can use it by single hand and carry into purse or pocket.
- The device should be designed to be user-friendly and easy to understand, with a clear display of the results.

Reference documents-

Design/Design requirements:

Social & cultural:

- The device should also need to be designed with a social and cultural context in mind, as it needs to be acceptable to all users.
- It should be designed to be easy to use, with a user-friendly interface, and should be able to be used by people from all backgrounds.
- The device should be designed to be as discreet as possible, as people may be reluctant to use a device that stands out and attracts attention.

Standards, Specification, Approvals and Certifications:

This product will go worldwide, so we must need to follow and consider all standards.

The product will be design same for all the countries, however, while distributing with specific countries we can tweak and modify as per the specific country's standards as well as customer's requirements (if needed).

In summary, we need to design our product as a Platform product (commonize the requirements) and then after customisation of the product will come into the picture (if necessary or depend on demand).

Major countries where we sell our product- UK, India, China, Japan, Australia, France, Netherlands.

Approvals and Certifications

CE Certificate (Conformite Europeenne)- This is our commercial product and we are the manufacturer of this product, so we should assess the product and meet EU safety, health and environmental protection requirements.

UK Home Office Approved- The UK Home Office is the lead government department for immigration and passports, drugs policy, crime, fire, counter-terrorism and police.

EN Approved- European Standards (abbreviated EN, from the German name Europäische Norm ("European Norm")) are technical standards drafted and maintained by CEN (European Committee for Standardization).

OIML Certified- International Organization of Legal Metrology (OIML), OIML Basic Certificates are issued by Issuing Authorities appointed by OIML Member States after completing all the tests, evaluations and examinations specified in the relevant OIML Recommendation and after it is demonstrated that the type complies with the requirements of the Recommendation.

RoHS Compliant- RoHS compliance means that a product has been tested for 10 banned substances by an independent authority, and that the tests confirmed levels of the substances below the RoHS threshold.

FDA Approval- The FDA approves new human drugs and biological products.

If the FDA grants an approval, it means the agency has determined that the benefits of the product outweigh the risks for the intended use.

DoT Alcohol Screening Devices (ASD)- ASDs that meet National Highway Traffic Safety Administration (NHTSA) specifications for precision and accuracy are placed on a Conforming Products List (CPL) for Alcohol Screening Devices.

DoT Evidential Breath Tester (EBT)- An evidential breath tester or EBT is a breathalyser device that is capable of producing test results that can stand up in a court of law.

ISO standard (ISO 90001:2009)- ISO standards are standards developed by the standardisation institute ISO. ISO is an internationally recognized quality management standard. It is a set of standards that provides a framework for companies to manage their quality. The ISO standards ensure that the company's products, services, and processes are consistent with the customer's and market needs.

Relevant documents-

Market study handbook

Target customers/Audience

Organisation's Standards

Internationals norms

Company's testing processes

Testing results and different agencies approvals

Target Customers/Audience:

- The target customers/audience for this project are people concerned about the spread of viruses (coronavirus) and who want to take the necessary precautions to protect themselves and their families.

Testing:

- The detector should be tested in a variety of scenarios to ensure accuracy and reliability.
- The tests should include, but are not limited to, testing in different environments, with different types of viruses, and with different types of people.
- The tests should also include testing to ensure the accuracy of the results, the reliability of the device, and the user-friendliness of the interface.
- All these results and tests should have taken n number of times in repeat cycle (cyclic test) so we would have accurate results for it.

Time scale:

- Research & Development: completed
- Design & Prototyping: Prototyping completed with the electronic and mechanical systems, Design (including physical envelope and appearance of the new Virus Detector) yet to complete- 1-2 months
- Testing & Quality Assurance: 2-4 weeks
- Regulatory Approval & Documentation: the company has already gained certification for the new Virus Detect from the various medical device regulatory agencies. For other documentations- 2-3 weeks
- Production & Assembly: 2-4 weeks
- Distribution & Deployment: 2-4 weeks
- Maintenance & Support: Ongoing

Weight:

- The device should be designed to be as lightweight as possible and it shouldn't weigh more than 200gm.

Notes:

All requirements and specifications of this Design brief are interlink/tie up and Interdependent. So we need to consider all the standards, specification mentioned in this design brief. We have decided to adopt a similar strategy which we use for our current range of breathalyser products. So we need to consider our company's standards and specifications as well.

Please feel free to contact me (Bhagyashri Shingare) if you need any further information, your question will be answered.

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