

Management of New Product Development

Assignment – B

MSc International Innovation Management

Module Code: ACPA7006

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Product Brief – Electro-mechanical Breathalyser for Virus Detection

30th Sept 2022

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New Product Development – Electro-mechanical Breathalyser for Virus Detection

Product Brief

Customer	<i>TBC</i>
Document Level	<i>1</i>
Confidentiality	<i>Internal use only</i>
Technology	<i>Electro-Mechanical</i>
Department of Document Origin	<i>Engineering</i>
Summary: Product design brief of a new Electro-Mechanical breathalyser for detection of novel viruses.	

	Name	Function	Date and Signature
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List of Distribution

Department/ Company	Name	Function	Cover Page only	Report Body
Engg., Design				X
Engg., Stress				X
Flammability				X
Industrialisation				X
Metallurgy & Materials lab				X
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Procurement				X
Ext Supp 1				X
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Doc., Control				X
PMO				X
BoM Control				X
Finance				X
Logistics				X
Pre-Sales				X
After-Market				X

Record of Revisions

ISSUE	DATE	EFFECT ON		REASON FOR REVISION
		PAGE	PARA	
1.0	30/09/2022	ALL	ALL	New issue released

Contents

Synopsis.....	6
Who we are?	6
Our latest Innovation!.....	6
Do we have a sellable product concept?	6
How do we go about it?	6
Market.....	8
Market Potential and Target Market	8
Competitors	8
Market Constraints	9
Company Constraints.....	9
Branding	9
Sales and Marketing	10
Product cost	10
Marketing.....	10
Functionality and performance.....	10
Performance Requirements.....	11
Product Look & Feel	11
Shape, Size & weight,.....	11
Portability.....	12
Aesthetics.....	12
Ergonomics.....	12
Colour.....	12
Texture, Finish & Labelling.....	12
User Interface, Features and Accessories.....	13
Display.....	13
Data Storage, Retrieval and Analysis	13
Electronics.....	13
Mouthpiece.....	14
Battery & Charging.....	14
Product packaging and inclusions.....	14
Manufacturing.....	14
Processes and Manufacturing Facilities.....	14
Prototyping	15
Materials	15
Quantity and Inventory Control.....	15
Sustainability and Circular Economy.....	15
Cost of Manufacturing	15
Installation, Maintenance, Storage & Repair and End of life	15
Installation	15
Maintenance	15
Repair	15
End of Life	15
User Instructions, Placards and Warnings.....	16
Product Build Quality.....	16

Performance	16
Shelf Life and Storage	16
Life in Service, Durability and Product Life Span	16
Reliability and Perceived Quality	16
Logistics	16
Packaging	16
Shipping	16
Procurement	16
Legal	17
Intellectual Property & Patents	17
Law and Legislature	17
Standards & Specifications	17
Testing and Performance Evaluation	17
Politics, Social & Cultural	17
Time scale	17
Health Safety & Environment	18
Health	18
Safety	18
Environment	18
Bibliography	19

Synopsis

Who we are?

We are the only company based in Wales with specialisation in designing, producing, certifying and marketing electronic breathalyser systems. We have been predominantly serving the police and security forces for our products so far. We have the legacy and technology of designing and manufacturing of electro-chemical systems to analyse contents in human breath.

Our latest Innovation!

One of our knowledge transfer partnerships with a university has recently showed that our chemical alcohol detector system has the potential to detect other organic material, including those generated in the breath as a result of various antibacterial infections. Laboratory trials have shown high level of confidence in this system and necessary patent applications have been registered. Current studies have also shown that viruses such as Covid-19 can be successfully detected through breath samples and such device will be a game changer (Giorgia Giovannini, 2021), (Izhar Ben Shlomo, 2022), (Zi-Cheng Yuan, 2021).

Our preliminary market survey (Grand View Research, 2021) has shown that there is a large personal market in Europe where in the near future it might be a legal requirement for all drivers to have such a device as part of their mandatory safety equipments.

Also, Covid-19 situation has clearly shown a positive market trend towards increased demand for personal and commercial airborne infectious pathogen detection system. Hence it is in the company's interest to develop a product that can meet both clinical and personal requirements for virus detection system which can quickly, efficiently and reliably provide results of breath analysis.

Do we have a sellable product concept?

Through the research we know that we have the required technical knowhow of what product we intend to produce as well as have the knowledge, technology and supply chain to produce the intended product. But, the technical requirement of the new product is such that the existing in-house products cannot be either fully or partially used as basis for this virus detection product, hence necessitating a new product design.

Preliminary designs and prototypes of the new electro-mechanical system which is the heart and brain of this new product have been fairly successful. Based on this prototype product and its testing the company has been able to gain certification for the new virus detection system from various medical device regulatory agencies (Agency, 2013).

How do we go about it?

Company has engaged a London-based styling firm to design the Physical Envelope and appearance of the product with whom our product design engineering team need to work with to finalise the physical outline of the product. Intention is to use the existing supply chain to procure the fully assembled electronic (single PCB) kits for the virus detector. Whereas, a decision has to be made on the manufacturing aspects of the mechanical part of the device such as the mouth pieces, parts of the base frame and body.

The company has therefore decided to develop and commercialise this hand held personal /commercial breath based virus detection instrument herein after referred to as 'the device' in this report.

From the interest of efficient and smooth progress of the product design and development this design brief is generated and made available to all the departments, suppliers and internal/external stake holders. Unless until an initial Product Design Specification is published, this product brief will in all respect serve as the primary reference document for information pertaining to the design, marketing, procurement, testing & certification of the device.

This design brief is in no means a final version of documentation of specifications and hence is subjected to changes and amendments, albeit all the amendments are logged and revision controlled for future reference.

This design brief covers the following major aspects of the device:

- Market and Marketing strategy
- Look, Feel, Product quality, usability and user interface
- Manufacturing, Maintenance, Repair and End of life
- Issues related to Politics, Culture, Law & Legislation, Health and Safety

Market

Market Potential and Target Market

Covid-19 pandemic is far from over, at least for the near future. Statistics predict (UCL, 2022) that the next peak is just around the corner i.e., early November 2022 and the one next to it is as early as March 2023. (IHME, 2022) provides past data and future projection of various statistical analysis of Covid-19. Though the data shows flattening trend for the rate of infection and death rate, it is evident that the need for clinical trials and sample analysers of various types is far from over, especially with the emergence of new Covid-19 variants as well as any possible future pandemics.

As of April 2022, US Food and Drug Administration (FDA, 2022) has authorised first Covid-19 diagnostic test using breath samples, meaning we already have a geographical area where the market is suppose to flourish for such breathalysers. Same trend is expected in the rest of the world.

Potential market includes but not limited to:

- Law enforcement – Police, security services,
- Medical and Health Care – GPs, Hospitals, Care homes, Old age homes
- Construction – Small, medium and large scale domestic and commercial construction sites
- Manufacturing Industry – Small, Medium and Large
- Offices – Engineering offices, Software development centres, Call centres, Govt offices, Others
- Prisons, detention centres and various rehabilitation centres
- Cruise Ships, Airports, bus and train stations, public transportations
- General House Holds
- Sports – Gyms, Stadiums, Arenas, Racing Circuits, Swimming pools, Small, medium and large sporting events
- Education Institutions – Nurseries, Schools, Collages, Child Minders
- Night life – Bars, Pubs & Restaurants
- Shopping and Leisure centres – small, medium and large
- Cinema & Entertainment – Cinemas, Theatres, Circuses, Operas, Music Concerts
- Garages

Competitors

With increasing demand for viral detectors in the wake of Covid-19, several companies have mushroomed which claim to make viral detectors and hence competition from within UK as well as Europe and Asia, especially China cannot be ignored. Product build and marketing strategy has to be strong enough to place a product in market and gain a lion's share out of it. It is also important to understand and keep a tab on the competitor's activity to be aware of any possible patent infringement due to already existing technology or otherwise, as well as learning from what has already been done or discussed within the industry.

Market Constraints

- Market's perception towards a new medical device and its anxiety over its efficiency and credibility of results.
- Unavailability of market data for product future demand and trend and hence its impact on production and inventory control of spare parts.
- Lack of brand awareness as we have always been serving a niche market.
- Implication of Brexit on man and material supply, custom restrictions & tariffs and non standard regulations between the UK and Europe

Company Constraints

- We have never tried to penetrate to a market other than our niche market. Sales force needs training and learning regarding this product.
- Learning curve is expected from each department working on this product as the product is pretty new and hence this needs to be accounted for in the programme plan.
- Need for new workforce and skill. Due to increased demand for resource and their training, financial planning and appraisal of sourcing and training of resources is needed.
- Review of available resource in terms of Plant, shop floor, laboratories, testing facility, employee well being facilities is needed to understand the availability, limitations and shortfalls.

Branding

We are a brand know to a certain target market only. For this product it is imperative that creating brand awareness (Rong Huang, 2011) and increasing brand equity among the target customer is of prime importance. Brand awareness can be created by:

- Product should contain the company logo in a highly visible area, though away from the mouth piece and display.
- Product should follow any signature looks and features of its predecessors that highlights the brand uniqueness.
- Product should contain any signature sounds or music of the company on power on or shutdown.
- New branding or de-branding from parent brands to create unique brand equity can be considered.
- Signature packaging style of company or unique packaging for new branding.
- Creative advertising in all main stream media.
- Behavioural study of various consumer segments and targeted advertisement for brand awareness.
- Engagement with social media giants and collaborative social media campaign for product introduction, launch and marketing.
- Ad campaigns in educational institutions, supermarkets, malls, bill boards.

Sales and Marketing

Product cost

- Medical devices cost plays an important role based on the product placement segment (Tatiana Jurieva Kudryavtseva, 2017).
- Even before the product is designed, definition of a max ceiling, min threshold and a price bracket is of crucial importance.
- Market research for similar competing products and analysis of data is highly recommended for successful product launch and market sustenance.

Marketing

- Identification of potential marketing partners for successful launch of product.
- Gathering input on market requirement relevant to product development such as product cost, functional expectations and provide feedback to design team.
- Competitor product entrance timelines and cost analysis.
- Knowledge of new market entrants.
- Study of market trends and consumer behaviour.
- Assessment of Sales forecast.
- Compliance with regulations for medical device advertising in the UK (CMS, n.d.) and outside.

Functionality and performance

Define Standard Operating Procedure for assurance of proper functionality of the device for use with design of device parts, components and development of user and repair manual:

- For clinical use, wear proper PPE. Personal discretion advised for personal / in-house use.
- Device case retrieval from safe storage and place on a flat surface.
- Unlatch case and safely remove device from case and hold in one hand at the palm grips provided.
- Clean the mouth piece receptacle with anti bacterial / alcohol based wet wipes
- Snap fit a new unused mouthpiece from the mouth piece cartridge case into the receptacle.
- Power on the device using the power button and wait for power on self test to complete with a beep and a welcome message.
- Select test mode and programming using the touch screen, refer memory management section of the user manual for advanced user options.
- Insert the mouth piece into the mouth to cover at least 2/3 the length of it to ensure no breath leakage. Seek assistance where one is not able to handle the device on their own.
- Blow through the mouthpiece until a long beep is heard to ensure enough volume of breath is collected by the device collector for processing.
- Remove the mouth piece from mouth and check the display for results. This can take several second to a couple of minutes.
- Results are displayed on screen with Positive represented with a double red striped along the screen indicting a potential infection or a Negative result represented through a single green vertical stripe.

- Result can be stored onto the internal memory if required.
- Pull trigger in red next to the mouth piece to pop out the used mouth piece and dispose off per the medical advice. Refer (Health and Safety Executive, n.d.) for guidelines regarding disposal of waste in a clinical set up.
- Clean the mouth piece receptacle with anti bacterial / alcohol based wet wipes and ready for next use.
- Where data is needed to be stored onto an external device, connect the device through the mini USB cable or the docking station supplied with the device and plug onto the external storage device through an USB port. Device can be read on a computer as a standard USB device for data transfer.
- Press and hold the power button until a good bye message is displayed to turn the device off.
- Store the device back in the safe carry case provided.
- Store back in a cool, dry place away from sunlight, dust, chemicals, vibrations and reach of children.

Performance Requirements

- Device boot/wakeup duration is less than 10 seconds.
- Device shut down duration is less than 10 seconds.
- Standby screen off timer is user defined, default factory setting to be 5 seconds.
- Time delay between any two consecutive tests to be as minimum a possible.
- Default memory should be enough to hold data for at least a 100 tests. Provision for add on secondary semiconductor memory.
- Results accuracy and precision to be within the regulatory requirements.
- Display errors and warning regarding the device performance like battery usage, memory usage, change of mouthpiece after each use, charging indications (plug, on-charge, full).
- Device to be shock, tamper (liquid spill, abrasion, etc) and abuse proof.

Product Look & Feel

Shape, Size & weight,

- Product shape and size can be derived from one of our latest hand held breathalysers which satisfies the requirements for a standard hand held device.
- Consult in-house or external experts in the field of handheld medical device ergonomics to understand and design the basic outline shape of the device.
- Design various shapes based on ergonomics study and conduct prototype trials of the mock-up shapes from independent volunteers to collect feedback for further processing.
- Weight is a crucial factor for hand held devices. Lighter the better. It is in the best interest of the product to estimate a comfortable weight through ergonomic studies and fix a weight target. (Carolina Zingale, 2005) Recommends a maximum weight for hand held computing devices of 2.3kg and a maximum size of 4 inches.
- Most importantly, choice of material for the device body and the components has a major impact on the overall weight of the assembly and hence to be chosen with care.

- All up weight of the device along with carry case and carry on accessories should not be more than what a 50th percentile female can handle.

Portability

- Overall volumetric size of the device including the carry case should not be more than the size of the glove box of a standard hatchback car or quarter of a briefcase.
- Overall weight of the device along with carry case should be such that it can be transported by hand over a distance of 100m without strain or injury to the personal.
- Carry case must have a handle and/or lanyard for ease of transportation.
- USB charging and data transfer for easy portability and universal use.

Aesthetics

- It is important to differentiate the device as a medical equipment to avoid risk of being used as a toy. General aesthetics of the device should confirm to the standards of a portable medical device.
- Overall look should be pleasing.
- Avoid fast colouring.
- Include signature look features

Ergonomics

- Hand held medical device regulations vary across the globe. Two major regulatory bodies for device developers to comply with are (FDA, 2022) and EC Medical Device Directive 93/42/EEC.
- (Jennifer L. Martin, 2007) describes various aspects of ergonomics studies to be considered in the successful design of medical devices, such as Heuristics, Cognitive task analysis, usability tests, cognitive walkthrough and Delphi technique.

Colour

- Primarily, a distinctive colour scheme to any other household devices OR toys to avoid risk of misuse.
- Avoid fast and flashy colours unless specifically requested by customer. Avoid colours which make the device look old and used.
- Pleasing, professional and neutral colours with minimum numbers as possible. Too many colour changes on a single hand held device may not be too pleasing.
- Follow company signature colour scheme if possible to promote brand.
- Distinctive colour scheme to immediate competitor products.
- Material of the colours used should be free from toxins such as cadmium, lead and mercury and as green as possible.
- Material of colours should be hard wearing, easy to clean off greasy substances and should keep lustre over a long period of time.

Texture, Finish & Labelling

- Identify areas of grip and use suitable anti slip material or knurl if metal.
- Glossy finish is believed to be unpleasant though easy to clean, try and test would help.

- Avoid textures which might collect dust and debris during usage and pose difficulty in cleaning.
- Avoid gaps and gouges to avoid dust and debris collection. Ensure flush and smooth flow of material over the surface.
- Spill proofing to ensure 'No-liquid ingress' will improve the product quality appeal and reduces risk of shock and damage to device.
- Labelling of device parts for ease of use and maintenance to be in according to local medical advisory (U.S Food and Drugs, 2020), (Medicines and Healthcare products Regulatory Agency, 2022).

User Interface, Features and Accessories

Display

- 'High quality precision and full touch pad' display or 'partial display and push button combi interface', decision based on target cost of the device.
- Simple, colour Liquid Crystal Displays can also be considered to reduce cost as the information output on display is barely textual and less on imagery and graphics.
- Colour or monochromatic, based on either choice of customer or only one of the two to offer, based on market survey.
- Basic power on self test display.
- Data backup indicator.
- Alerts and warnings on screen.
- Battery life indicator.
- Mouth piece replacement warning.
- Device system error indication.

Data Storage, Retrieval and Analysis

- Internal memory for primary data storage.
- Extendable memory provisions for better portability.
- Store at least name, age, sex, address & cell number, name of testing clinical personal and result of the test of several hundred samples.
- Data noise reduction and noise cancellation algorithms for precision result interpretation.
- Wifi capable for direct linkage to central servers for data analytics, if need be.
- Cloud capable for direct data link to cloud storages.
- Docking station for data transfer and charging.
- Device to have minimum data analysis capabilities including.
 - Retrieval of data from last 3 months for review.
 - Generate report of positives, negative & void results for 100 samples.
 - Report of number of tests carried out in a certain defined period.

Electronics

- Advanced microprocessor and data bus for fastener data processing and result display.
- USB enabled mother boards for standard interfacing for charging and data transfer.
- Shock proof packaging.

Mouthpiece

- Both Adult and child mouthpieces are required for test comfort and adaptability of device receptacle for them both.
- Mouth pieces are single use and not to be reused. Provide clear instruction on the device and on the mouth piece cartridge of single use only.
- Instructions on safe disposal of used mouth pieces.
- Material of mouth pieces and construction to be in accordance with medical advice (Medicines and Healthcare products Regulatory Agency, 2022).
- Mouthpieces to be clean, hygiene and free from sharp edges and debris when delivered.
- Cost of single use mouth pieces is crucial as they are needed in thousand, if not in millions.

Battery & Charging

- Batteries to be essentially rechargeable to avoid landfill due to disposal batteries and ease of maintenance.
- USB recharging technology recommended for better portability.
- Choice of battery technology to be in accordance with electronic hardware to be use.
- Shape and size of battery to be in accordance with the space envelope generated by device styling or vice versa.
- On full charge battery to retain charge for a minimum of 10 hours, i.e., to provide enough charge equivalent of one shift of a day/night nurse or an overnight trip outside home for a family.
- Battery life to be in accordance with device life itself. Battery life should not necessarily drive the device life.
- Clearly specify on manuals whether the battery is user serviceable or not.

Product packaging and inclusions

- Tamper proof case, tested and certified by drop test.
- Case with latch (1 or 2) for securing device during transportation from point A to point B.
- Low or no Vibration and rattling of device within the packaging during transportation, use noise and vibration absorbers placed within packaging.
- Ease of removal from and placing back of device in the case.
- Ensure smooth surfaces to avoid rubbing and chipping of device finish.

Manufacturing

Processes and Manufacturing Facilities

- All internal metallic parts to be aluminium made – either machined or sheet metal to reduce weight.
- High wearing parts only to be steel made – either machined or sheet metal.
- Expected fully assembled devices output from the plant is anywhere from 5000-15000 units per month. Review current capacity of assembly lines for current and new product and report to plant design and maintenance to cover for future demand.
- Assess feasibility and cost implications of semi automatic and fully automatic (robotic) assembly lines.
- Generate process documents for part manufacturing and assembly.

Prototyping

- Prototype and test ergonomic designs for satisfactory results – record findings for future use. Volunteers can be used for ergonomic tests.
- Prototype functional models at different stages of device development to check adherence to design specifications and re-design where needed.
- Partial/fully functional prototypes can be used for market research and initial market feedback to improve the product before launch.

Materials

- Company approved engineering materials to be used for all parts of the device.
- Use registered suppliers for material procurement.

Quantity and Inventory Control

- High volume production expected.
- Robust ERP system is a must for smooth production and timely delivery.

Sustainability and Circular Economy

- Design optimisation for weight reduction is key to reducing carbon foot print.
- Reduce waste by using smart manufacturing and additive technology where possible.
- Design cross over parts to reduce part count and interchangeability.

Cost of Manufacturing

- Analyse which parts are cheaper to procure from suppliers than producing them in house.
- Check for over the shelf parts and standard parts for design to reduce cost of special production.
- Reduce cost of manufacturing where possible to increase profitability.

Installation, Maintenance, Storage, Repair and End of life

Installation

Product to be fully assembled in factory for customer use except for the mouth piece change, charging and computer interfacing.

Maintenance

- Manual to clearly describe procedure to sanitise the device after a positive result to reduce risk of further infections.
- User manual to include details of any user serviceable parts and maintenance guidelines.
- Low user maintenance is key to product popularity.

Repair

- Replacement parts to be identified from design and testing.
- Plan for inventory of spare parts.
- Decision needed on repair or replace based on cost analysis.

End of Life

- User manual to include clear instructions on recycling of device and it's parts at the end of life of the product.

- Update and upgradation programmes can be planned to retrieve used devices for refurbishment or use as spare parts for future production. This ensures customer loyalty and continued business.

User Instructions, Placards and Warnings

Device to have all necessary:

- Hazard Signs
- Placards for usage, temporary and long term storage
- Warning signs
- User manuals, safety instructions in English and regional languages

Product Build Quality

Performance

- Individual test durations to be as low as 5 minutes.
- Ground time between tests to be minimum to increase number of tests per hour.
- Repeatability of test results to be at 99.9%.

Shelf Life and Storage

- Shelf life is limited by the type and choice of battery –take this point into account for battery selection.
- User manual to include storage instructions.

Life in Service, Durability and Product Life Span

- Product design life to be at least a million tests or 3 years in service.

Reliability and Perceived Quality

- Accuracy of test results and reproduction of same test results every time is the key to success of this product.

Logistics

Packaging

- Packaging should be minimal and fully recyclable.
- Packaging should be just adequate to ensure safety of device during transportation.
- Packaging to include all necessary accessories, manuals and warranty instructions.

Shipping

Standard hand held medical device, no special attention needed for shipping.

Procurement

- Identify suppliers for parts and raw material.
- Long lead time items to be planned in advance.
- Dies and tools to be designed and procured in advance.

Legal

Intellectual Property & Patents

- Patent registration at different parts of the world is necessary to protect the intellectual property.
- Register both the concept and the device.

Law and Legislature

Device design should be compliant with the legislature and law of the land where it is intended to be sold and used (MHRA, 2020), (European Medicines Agency, 2022), (U.S. Food and Drugs, 2020).

Standards & Specifications

- Standards and specifications for hand held virus detectors is not set as yet by any regulatory bodies.
- For the purpose of current device design it is advisable to adhere to the company standards and specifications.

Testing and Performance Evaluation

- Test and validation team to determine and set test performance parameters.
- A full test campaign to evaluate the design performance of the new device is mandatory. In house test facility can be made use of for the test campaign.

Politics, Social & Cultural

Geo political and cultural changes are dynamic and always set to change. Requirement of one region may be different to the other in terms of design, buying pattern, religious considerations and hence it can have a direct effect on the design of the product itself, the sales and logistics. Some of these differences are:

- Religious beliefs and social stigma towards oral devices.
- Supply chain and technology issues with underdeveloped countries.
- Legislation for disposal of contaminated mouth pieces and recycling of medical waste.
- Legislation on disposal of packaging and product at end of life such as type and percentage of plastics, etc.
- Variation in taxation on medical devices very the profit margin.
- Clinical trials and public testing events regulations.

Time scale

An estimated time line from conception to first prototype successful test is expected to be at 12 months. This is in line with the marketing strategy and procurement lead times.

Health Safety & Environment

Health

- Specification of level of cleanliness and Sanitization of device.
- Dust and debris collection and removal instructions.
- Handling and disposal of used mouth pieces.

Safety

- No sharp edges
- No pinch points
- No liquid ingress
- Surface roughness level not to exceed the comfort zone.
- Delethalization of critical design features for personal safety.

Environment

- Battery replacement and safe disposal instructions.
- Instructions on safe disposal of chemical containers, canisters, etc.
- Instructions on safe disposal of manufacturing waste, effluents, gas emission.
- Safe disposal of packaging.

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