

Developing the Design Brief

ASSESSMENT B

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Synopsis:

Electronic Virus Breathalyzer systems

As part of a R&D Knowledge Transfer partnership with a local university there is an opportunity to use a similar system of chemical detection as used in our alcohol breathalyser products to detect for certain virus infections. The new technology has been successfully trialled in the laboratory and any patent applications have been registered. Due to the success of this testing, we have already gained medical certification through various agencies (MHRA, NICE)

Through our market research there is potential not only in the healthcare sector but also in certain private sector scenarios where near instant detection of a virus could be used to protect members of the public or prevent the spread of the virus. This was evident in the coronavirus pandemic, where accurate immediate results could have allowed businesses to remain open and operational without the need for lockdown scenarios. If this detection data can be recorded or uploaded to the cloud, the data could lead to accurate predictions of viral spread and used for track and trace data.

The potential market size for this type of product is 3 million per year with projected year 1 sales of 750,000 units. A recurring sales stream will be the mouthpieces into which the patients will need to blow to provide a sample. These could take several formats: single use disposable, multi-use with items where possible sterilized on site (hospital, Dental) or a business model of returning used items for sterilization and repackaging. Private use, where an individual may want to retain their own mouthpiece to be used multiple times (day or evening out). There may be opportunity for sales of accessories (lanyards, hand straps, covers, batteries).

We are engaging with a London based design consultancy to work on the physical embodiment and appearance of the product. They will be working with on the aesthetics and ergonomics of the embodiment and key operating functions, information indication, operator interaction, patient interaction.

Working prototypes of the Electronics, Software and Mechanical systems have been produced and have been successfully trialled and tested. Addition Prototypes will be required from the design consultancy to finalized layout, "feel" and check for any assembly issues.

The initial manufacturing strategy is to externally source all the electronics, and mechanical elements and perform final assembly, testing, packing and distribution from our Carmarthen factory. The CEO and Finance Director have decided that alternative suppliers are explored to potentially de-risk our supply chain but also drive down manufacturing costs of current products.

Aesthetics

- Should the design be in keeping with our current product range- clear links to our already well-established products?
- retain similar colour schemes
- size to be optimized, based on electronics and mechanical systems. But keeping ergonomics in mind. (See [Size, ergonomics.](#))
- Use of materials and colours in design to help intuitive operation.
- Is there anything distinctive or different from the competitors that can be Design protected? (see [Intellectual property](#))
-

Branding

- company branding should be evident and clear from multiple aspects of the product
- product model and version should be clear
- logo design could be in keeping with current company style or this could be used as an opportunity to try new styling.
- Fonts and images should be the same as company default style and of such a nature to allow for ease of reading and intuitive use.
- If a screen is being used company branding and logo as well as model details should be displayed at start up and on shut down.

Calibration

- Is calibration required? How do we ensure that unit is reading and outputting correct measurements? (see [Standards](#), Reliability)
- Do we need to provide the user with calibration or test equipment?
- If calibration is required at what intervals? After X number of tests? At a battery change? Once a year with servicing?
- Is there potential for a service and calibration business model.

Circular economy

- Where possible, materials used in componentry should be ethically sourced or from recycled materials.
- Where possible use materials that can be recycled or
- Design parts to be reused/refurbished
- Consider ease of disassembly for end of life or repair.
- Is there a servicing business plan, refurbished market for this product?
- Packaging – where feasible use no plastic, biodegradable / recycled material
- Single use sample collection pieces are likely to be collected via a hazardous waste stream, these tend to be incinerated, consider using / doing research into a clean burning / environmentally friendly material. Card, paper, what plastic alternative can be considered.
- Multi use sample collection parts if feasible should be manufactured out of a reusable material (Metal, Plastic, glass). that could potentially be collected and sterilized for resale / redistribution.
- ISO14001 – Are we looking to achieve this environmental standard? Are there aspects of this standard that we should consider adopting

Company Constraints

- What additional skills are required? Do we need to hire additional staff or hire temporary contract staff to fill skills gap? Do we require external consultancy to provide expert input?
- Staff, production staff, admin staff, customer services, warehouse,
- Do we have the additional manufacturing capacity required to assemble, test, and package the new product? See Manufacturing Facilities.
- Big Data. If we were to provide data collection services, do we have the necessary skills internally to manage and implement this? Do we have the necessary IT infrastructure to collect, store, manage and analyse the data collected? What will we be able to output? Who will be interested in this data? NHS, University, Government.
- Warehouse / Storage / production space. Do we have the physical space required to manufacture 3million additional products per year? What additional warehousing is needed to store additional subcomponents and finished assemblies.
- Supply chain and distribution. Are our current systems capable of handling the expected increase in throughput of goods in and goods out? Do we have suitable supply chain and distribution providers both nationally and internationally?

Connectivity

- If device is going to be used for data collection. Means on connectivity should be considered. Healthcare professional may want to enter or link more data about the patient being tested.
- How is data going to be downloaded? Wi-Fi, Bluetooth, USB,
- Should device have GPS connectivity
- How will these options affect, Price, Size, Weight, Battery life?

Competition

- Who are they?
 - <https://www.owlstonemedical.com/>
 - https://www.draeger.com/en_uk/Productselector/Alcohol-and-Drug-Testing/Breathalyzer?page=1
 - <https://alcodigital.co.uk/>
 - There are already several breathalyser companies specializing in utilizing similar technology to our existing Breathalyzer. There does not currently appear to any patent infringements for our technologies.
- What technology are they using? Each company claims its own unique way of detecting chemicals in airflo. *“They rely on a variety of technologies, including mass spectrometry and gas chromatography, but some of the most promising ones—in terms of affordability and ease of use—are based on nanomaterial-based sensors. Some sense viral particles, but most focus on compounds produced by the human body. SpiroNose contains seven metal oxide semiconductor sensors that detect thousands of volatile organic compounds in exhaled air.”* (VRIEZE, 2021)
- What do products look like?



- What markets are they selling into?
 - Most breathalysers of this variety are focused on the alcohol breath testing for work and drink driving environments.
 - Owlstone medical are looking at cancer detection by taking breath samples and analysing these for cancer biomarkers.

Customer

- there is huge potential to supply this type of testing device into many private and public sectors.
- The typical user or tester will be either a
 - healthcare professional i.e., nurse, carer, or GP. They will be doing less tests per day, 1 test every 10-20 minutes in a GP surgery or dentist. This number could be far greater in a hospital with multiple patients on wards.
 - Doorman, bouncer, events security, and entry staff. This user will be required to have fast results with very clear pass-fail indication. The test device will need to be robust and easy to operate with very quick turnaround times. They will need to get the members of the public into events or onto transport quickly and efficiently. Detailed data collection could be less critical in these scenarios. See data collection.
- Customers
 - Care Homes
 - Private user
 - Pubs, clubs, restaurants, hairdressers,
 - retailers
 - Banks
 - Gyms
 - NHS
 - Local authorities
 - Emergency services
 - Leisure centres
 - Dentists
 - Doctors' surgeries
 - Police forces
 - Transportation (aviation, Trains, Ferries, Public transport)

Data Collection

- What data do we need to collect?
 - Very basic – pass, fail
 - Basic info - sex, age, location
 - Detailed info – linked to NHS patient notes
 - Name, DOB, and above
 - GDPR risk
- Data entered in computer and then linked to tester
- Data entered on tester via touch screen keyboard
- Data scanned from QR code or barcode on patients notes

Documentation

- Technical file – As our device is Classed as a medical device (Class1) it is essential that our Quality Management team and engineering team produce and maintain a technical File. *“Before placing a medical device on the European market, manufacturers need to produce technical documentation providing evidence of conformity with the relevant legislation. Technical documentation needs to be in compliance with the Medical Devices Directive (MDD) 93/42/EEC “ (Bobela, et al., n.d.) (Standards, 2021)*
- Testing data of all critical parts of the device must be recoded and kept aligned with the requirements of the MDR. This will include software and electronics critical in the output of accurate and reliable results in testing. (See Testing)
All products should pass an end of line test before packaging.
- Subcomponent data sheets – All data sheets for critical electrical components should be recorded. Data sheets of any mechanical componentry used within the assembly shall be requested from manufacturer shall be recorded.
- Material data sheets – Material data sheets for all raw materials used in the manufacture of injected moulded components is required.
- SOPs – Standard operating procedures for all assembly and test processes need compiling and recording in line with our QMS.
- User instructions, start-up guides, training material, troubleshooting, servicing, and maintenance documents should all be created and issues. (See Standards)
- Serial numbers are required on all devices. It is essential that these can be linked to supplied subcomponents for traceability purposes.

Environment

- Indoor – it is assumed that most of the use will be in the healthcare setting, this can be assumed to be indoors within a waiting room or consulting room or ward environment. Possibility is that these will have some sort of air conditioning to keep staff and patients at a comfortable environment. 20-24 Celsius
- Outdoors – wet, cold, hot –. If the product is to be use by the emergency services or safety and security service sector, there is a chance that the product will be used outside. In outdoor environment operation there is possibility that unit may become wet. IP rating will need to be determined so as not to cause product failure.
- Extremes? Australia – Iceland. For operation in countries of extreme temperature we should consider possible exposure to extreme temperatures of approximately - 20 to 45 degrees Celsius. Exposure to these extremes could have implications to functionality and performance of mechanical fixtures, electronics, and batteries.
- These testing devices are also likely to be used in environments where other electrical equipment is in operation. This could be lifesaving / critical equipment which may be susceptible to EMC (electromagnetic compatibility) emissions. EMC testing should be conducted. (See Testing)
- Transportation and storage? What are these environments likely to be?
- Assembly environment? What are the conditions of manufacture in far east for electronics and injection moulding in Europe?

Ergonomics

Considering that some users may need to be holding the device for long periods of time,

- the tester should be comfortably held in one hand, with screen and control buttons easily controlled by other hand. Easily operated by both right- and left-handed users.
- What are the control buttons going to be made of? (See Materials)
- Is the screen going to be a touch screen? What information do we want to display? Consider size and layout of windows and data entry requirement, keyboard button size.
- Due to the nature of the viruses being tested for to prevent the accidental spread or cross contamination. Surfaces should be easily cleaned, and wipe cleanable between tests. (See Materials)
- Sample collections mouthpieces should be secure but easily attached and removed, preferably without the risk of cross contamination. Consider an ejector button?
- Protective cover? Add grip, comfort, (see Materials)
- Consider hand strap, lanyard, wrist strap, for users likely to using in prolonged operation.
- Will the device be accessible to operators and test subjects with disabilities?
- Is there anything distinctive or different from the competitors that can be Design protected? (See Intellectual Property)
- (Gupta, et al., 2003)

Installation

- What software required for data transfer to a computer, how will this software be supplied? CD, online download, via website?
- Does the device connect via cable, Wi-Fi, Bluetooth? (See connectivity)
- Should software updates be required, how will these be done?
- Will the test device need to link to a mobile phone or PDA Apps?

Intellectual property

- patents are pending on the sensing technology used with in the test device. A review of the ownership of the technology between ourselves and the University.
- There is the option to licences the technology to other manufactures and even to our competitors. This needs special consideration so as not to lose control of our IP.
- Consider applying a design register for body of unit and mouth pieces separately, is there anything in the design and layout of the test device which is worth protecting? see ergonomics and aesthetics.
- Trademarking of model name, product range.

Legal processes

- What insurances are needed? Product safety liability and insurance. (Standards, 2021)
 - International customs laws and regulations for medical devices?
 - CE Marking for sale into Europe, UKCA for sale within UK
 - MHRA registration
 - “Manufacturers and importers placing products on the UK market need to demonstrate that they comply with relevant safety requirements. This basically involves:*
 - *minimising the risks associated with the product*
 - *generating and keeping records of associated technical documentation*
 - *placing appropriate labelling on the product*
 - *providing instructions on how to use it safely”*
- (Standards, 2021)

Product life span

- It can be assumed that the need for this type of viral detection will be needed indefinitely on the assumption that the technology can be modified to test for multiple types of viral chemistries. It may mean that the physical embodiment remains the same, but the software and chemical test means change.

Life in service

Based on worst case scenario of everyday use by high volume operator is say the transport industry 24h train station. Assume a cycle time of 30 sec between tests = 2880 tests in a 24h period. By 365 days that equates to 1,051200 tests a year.

- warranty period of 1-2 years against material and manufacture failures.
- Parts should be of suitable quality to sustain up to 7 years of use. This will be dependent on the environment and conditions in which the test device is used.
- Buttons, membranes, touchscreens have a limited lifespan. We should consider making these parts be easily replaced / serviced.
- Consider circular economy when designing parts and assembly.
- Mouthpiece attachment point should be of such a design to allow for unlimited connections or ease of replacement if worn/damaged

Maintenance & Repair

- Require minimal maintenance in general use. General users should only need to replace batteries, and potentially update software.
- Should connection points become worn or damaged, we should consider being able to supply replace parts with service guide on how to replace and repair these items.
- Consideration should be made to provide repair / servicing contracts. If feasible this could be an additional income stream. Users could potentially buy x number of years' service contract, devices can be returned for routine maintenance, i.e., replacement of worn parts, software upgrades.
- [see life in service](#)
- see [circular economy](#).

Manufacturing facilities

- Are existing facilities suitable? We currently manufacture similar type of products and are planning to utilize a similar methodology to produce this range of tester.
- Do we require additional production lines? will our current lines be suitable and capable of manufacturing the increased number of predicted products.
- Are our manufacturing facilities agile enough to change quickly between supply and demand?
- What new technologies are available? What Industry 4.0 technologies can we embrace? Can and should smart factory technologies be investigated to create agile and efficient production facilities? Automation utilizing Cobots or robots. (i-SCOOP, 2020)

Market constraints

- Will the current high demand seen during the covid pandemic continue? There will always be a need for viral detection but potentially not to the same levels currently being seen.
- If the demand drops off can the technology be utilized for other viral detection?
- What are the demands in developing countries?
- How will this type of technology and device be accepted in other cultures and societies?

Materials

- Injection moulded components –
 - consider using recycled material where possible, where virgin material is required use materials that can be easily recycled.
 - Consider tooling costs, yearly projected parts should require fully hardened tools. The type of tooling, family tools? Multi cavity tools? Tool size, tool quality, where are tools going to be made, who will own tools.
- Electronics –
 - ensure electrical components are available considering potential high volumes needed for future production.
- Fasteners – how is product going to be assembled, screws, clip together, plastic welded, glued?
 - What materials are fasteners going to be made of? Treated steel, Stainless steel, plastic.
 - Do fasteners need to have anti tamper heads,
 - Metal machine screws with metal inserts or metal screws with plastic cut threads?
- What are the control buttons going to be made of? Mechanical, membrane, combination?
- Batteries – what type of batteries are going to use? (See [power supply](#))
- Packaging – See (packaging)
- RoHS compliance for materials, and components manufactured abroad.
- Consider all materials and components are in good supply, that the supply is well established or have various and easy to change alternatives.
- Material coming in contact with users and patients, should be free from materials likely to cause irritation or allergic reactions. Latex free,

Packaging (Trott, 2017)

- Protection
 - reduced/ no plastics where feasible. (de Koeijer, et al., 2017)
 - Recycled/biodegradable alternatives (See [Storage](#), [Circular Economy](#))
 - Protect device in transport and storage.
 - What information is needed?
 - Are graphics required? Storage conditions, packing orientation.
 - cost
- Containment
 - How is tester going to be sold? In a kit with spares/ accessories? Will it require a carry case to house all parts separately and securely? Will the case be purchased or bespoke?
 - Will product need displaying on shelving
 - Cost implications
- Identification - labelling
 - See Standards – Use labelling and symbols outlined by ISO standards
 -

Performance

- What are the user expectations on performance?
- How quickly does unit turn on?
- How accurate are results?
- How long do batteries last? (See [Power supply](#))
- How easy is it to do multiple tests?
 - Collect data, save data, change sample collector, clean/ disinfect unit,

Politics

- What do current Government policies say? How will government legislation and guidance change?
- Investigate not only UK but review other international government policies and guidance.

Product cost

- What is our pricing strategy?
- What is our cost of manufacture, development, and investment? How quickly to we want to recoup these costs? What are our estimated variable costs and fixed costs per unit? Can we base it on our current product ranges? Profit margins – what margin do we wish to make.
- Market research led, Are there any similar devices already on the market? (See [Competition](#)) What do these devices retail at? What are competitor prices? What can we get away with?
- Lost leader to sell mouth sample collector pieces? Do we want to sell the test devices at lower margin to gain a bigger market share to enable us to supply more sample collectors?
- Can we utilize this development to try and drive down the manufacturing cost of our current products by exploring alternative suppliers' options? We need to consider new electronics supply and plastic injection suppliers.

Prototyping

- Successful working prototypes of the electronic and mechanical systems have already been done.
- Additional prototypes from our London Based design company will explore Ergonomics and aesthetics. (See [ergonomics](#) and [aesthetics](#).)
- We should consider how many if any, preproduction prototypes we need for user trials and testing.
- Will our sales and marketing teams need prototypes?
- What prototyping processes are needed and what will they cost.

Power supply

- Batteries

Consideration into what battery technology is to be used to power our product. 500-2000 tests?

- Non rechargeable alkaline — user will be responsible to replace and supply their own batteries.
- Re-chargeable - Lithium or NiMH could be supplied. The initial up cost is higher, but batteries could provide up to 500 charge cycles— 2- 5 years' worth of tests- legislation from supply chain to safety is critical. This would potentially become a supply business.
- Potential to design the option to take different technologies.
- Consider size, weight, capacity and which technologies are best suited of our product.

- USB –

- Could the design use USB for?
 - “Emergency power supply”
 - charging – if rechargeable batteries are used, a charging unit/ power supply would need to be provided.
 - data transfer – downloading of results
 - software updates - uploading of software updates

Quality

- Does the device satisfy the customer's needs?
- Does the device adhere to the industry standards?
- customer perception of quality is crucial,
 - Is operation of quick, accurate,
 - Does material and finish portray that of a good quality product.

Quantity

- Year 1 sales are expected at 750000 units
- Further years 3 million units per year
- Mouthpieces, will be vary depending on setting,
A review of each possible setting will need to be done. A nurse may see 1 patient every 30mins, over an 8-hour day that is 16 patients. For a sporting or musical event, there could be more than 45-60 thousand single use tests required.

Reliability

- It is essential that tests are accurate and repeatable.
- Mechanical, electrical and software systems should be robust to withstand daily continuous usage.

Operating SKU's

- Quick test – simple quick test to check for viruses, possibly used where patient data collection is not necessary and quick testing is needed to determine entry to event/public transport. Simple pass/fail indication.
- Detailed test – more complex data collection. Patient key data with test result recorded. Data could be entered into tester or on a computer and then transferred between two systems via an automatic link.

Safety

- IEC60601 - technical standards for the safety and effectiveness of medical electrical equipment. Check individual country versions and legislation.
- electrical shock
- choke hazard

Shelf life

- are there any components or subcomponents that have a limited shelf life? Rechargeable batteries for example need to be charged over certain periods to avoid depletion to low level that may result in battery failure or reduction in battery life.

Shipping

- Device is to be sold worldwide. As individual items and in multiples.
- How is product going to be shipped? Air or sea freight?
- Will we utilize international distributors and resellers? How many items will be required? Can distributors hold stock?
- Are units going to be individually boxed? Or boxed in predetermined quantities?
- Are standard size boxes available do we require bespoke boxing?
- What pallet sizes are to be used? Do pallets need to conform for international transport regulations?
- What weatherproofing is required?
- What are legal requirements for international shipments? Have we considered import and export laws?
- What is the cost of all options? Is it cost effective?

Size

- Estimate 80mm x 150mm x 25mm
- Should size be optimized around required Electronics and battery size (see [power supply](#)) or designed around ergonomics with user in mind?

Social & cultural

- How will this type of device be accepted in other cultures and societies?
- Will this technology be affordable in developing countries? (Krisher, et al., 2014)
-

Spare Parts

- What spare parts are we going to supply?
 - Batteries,
 - connection clips,
 - accessories,
 - Electronics
 - Carry case

Specifications

- A detail product design specification needs to be complied in line with this design brief.
- Specifications will satisfy considerations made in this design brief and any associated standards.

Standards (ISO, 2022)

- ISO 13485 - the standard for medical device quality management systems.
- ISO 14971 - the standard for medical device risk management
- ISO 9001 - the standard for business quality management systems
- ISO 62304 - the standard for software used in medical devices
- ISO 10993 - the standard for biological evaluation of medical devices.
- ISO 15223 - the standard for symbols to be used with medical device labels, labelling, and information to be supplied.
- ISO 11607 - the standard for sterilized product packaging for medical devices.
- ISO 20417 - Medical devices — Information to be supplied by the manufacturer
- IEC 60068 (Environmental testing)
- IEC 60601 (Medical electrical equipment and systems)
- IEC 61010 (Safety requirements for electrical equipment for measurement, control, and laboratory use)
- ISO 16750 (Environmental conditions and electrical testing for electrical and electronic equipment)
- IEC 60529, ISO 20653, DIN 40050 (Degrees of protection provided by enclosures)

Storage

- Are our current storage facilities suitable for the new components and electronics?
Is there anything different from our current products?
- Do we have the additional space requirements?
- Considering the volume of products anticipated should we look to utilize Smart Factory technologies? Connected tech, IoT, Voice Picking, Vision Picking(AR), Warehouse management systems, Semi-Autonomous Machines, RFID scanning

Testing

What testing is required?

- Accelerated Life Testing
- Temperature and humidity testing (See [environment](#))
- Mechanical shock testing
- Impact testing – drop testing.
- Vibration testing -
- Ingress protection (IP) testing
- Packaging testing
- End of line testing for all devices.

Time scale

- considering the current world crisis, it is essential to deliver this project in a timely and effective manner in order to gain good market share. 3-9 months
- how long will tooling manufacture and verification take? 6-12 weeks.
- Electronic assembly and preproduction testing and verification 6-12 weeks.

Weight

- Tester should be light enough to be held and used continuously by users who are performing continuous testing, test centres, events entry,
- Assumed weight to be between 200g-600g
- Weight to be considered in the design of injection moulded parts. Keep material thickness to a minimum unless it is considered to adversely affect durability and function.
- Battery technology should be considered to reduce weight. (see [Power Supply](#))

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