

Product Design Brief

Multi-Detector Breathalyser – Business Case

By

James Scorgie

Student Number: 2113853

Student Email: 2113853@student.uwtsd.ac.uk

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A Product Design Brief

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1 Company Introduction

Cymru Analytics are a small, yet growing company, that specialises in providing high-grade detection equipment to public and private enterprises for use.

We aim to be a one-stop shop for the detection needs of the mass market, whether it be for drugs, alcohol, or diseases. By improving our existing products and modifying them slightly, we believe that we can serve a wider audience than we do currently.

By partnering with outside organisations and Universities, we have had a successful business model in the past of developing new product features within existing products to serve the mass market, and this is our intention with the development of our new 'Virus Detect Model' that expands our current breathalyser capability to detect a larger number of organic substances, including: illicit substances, infectious diseases and poisonous substances.

This document outlines the product design brief to deliver this product to market.

1.1 What we do:

- We assist companies/agencies with their detection needs and provide, quick, reliable detector machines that are portable and easy to use.
- We provide digital devices that allow for 'barriers' to be put in place, whether it be to prevent drink-driving or preventing infectious people moving freely past 'bio-barriers'

1.2 The problem we solve (use cases):

- Current use cases include mainly Government Agencies (Police/Military Organisations) to either test personnel for alcohol or drugs content.
- With upgrades to software and firmware, we believe our 'virus detect model' will be able to quickly detect other organic materials, such as infectious diseases.
- Additionally, the device will also be able to be able to test for a wider range of illicit substances, further enhancing its current use cases.
- Reducing the spread of infectious diseases by providing instant rapid testing and automated feedback to general practices (GPs).

1.3 Who we are building the product for:

- Car hire & retailers (illicit substances)
- Events sector (illicit substances; infectious diseases)
- Hospitality sector (illicit substances; infectious diseases)

- Individual consumers (illicit substances; infectious diseases)
- Medical professionals (illicit substances testing; poisoning testing; infectious diseases)
- Military (illicit substances testing; poisoning testing; infectious diseases)
- Police (illicit substances testing)
- Travel sector (illicit substances; infectious diseases)

We aim to engage with the aforementioned sectors to ensure that the product satisfies each niche with no compromise to the customer satisfaction and effectiveness.

1.4 Rationale

By developing our existing products into an expanded market, it ensures that as a company we stand out from a relatively niche, yet crowded sector with a unique and exciting product.

Furthermore, by increasing the existing capabilities of our product, we offer the opportunity for clients to save significant amounts on what would otherwise be spent on disposable tests that are not environmentally friendly long-term. An example of this would be the 7-panel drugs test (used for the testing of illicit substances) or lateral flow tests (used for the rapid testing and identification of infectious diseases). By reducing the need to non-reusable tests, we can reduce the amount of tests that are needlessly sent to landfill.

2 Product Scope & Acceptance Criteria

Currently our product is able to reliably test for alcohol and certain drug testing in the breathe samples given to the device via a blown sample.

Generally speaking, we wish to be able to test for all common drugs according to the NIDA (<https://nida.nih.gov/research-topics/commonly-used-drugs-charts>) and NHS (<https://www.ons.gov.uk/peoplepopulationandcommunity/crimeandjustice/articles/drugmisuseinenglandandwales/yearendingmarch2020>) that are outlined as commonly misused.

2.1 Product Requirements (Prototype Version 1)

The prototype (version 1) should include the outlined features below and will be used for initial product testing, refinement, and auditing purposes.

- Testing for the “7-panel test”¹, including marijuana, cocaine, opiates, PCP, amphetamines, benzodiazepines, & barbiturate.
- Functioning readings for infectious virus types, including Influenza; Coronavirus; Norovirus; SARS; Common Cold.
- Functioning readings for infectious bacterium types, including strep throat; tuberculosis; meningitis; lyme disease; tetanus.
- Shall feature a small digital screen to display results.
- USB connectivity to allow for access of data from device to be downloaded by the appropriate medical professional.
- Password protected and encrypted to AES 256-bit encryption standards to ensure data is protected.
- Branding will be adjusted slightly to ensure visibility with our current product line when being shown to consumers/auditors/companies.
- Basic body will reuse the existing design and firmware that has been modified.

2.2 Product Audit/Testing

Following this the product shall first be internally tested against international standards and conventional testing. For this, we will ensure that testing is carried out with our partner Universities (Trinity St David and University of Liverpool School of Tropical Medicine) for manufacturing and medical input.

¹ The 7-panel test is a common drugs test that uses testing methods to identify the following drugs: marijuana, cocaine, opiates, PCP, amphetamines, benzodiazepines, & barbiturate. It is common in prisons and workplaces where drugs are an extremely controlled/high-risk substance. Usually a urine kit is used for this purpose at an expense of around £5-10 per testing kit.

The following testing should be performed:

- Internal testing against known substances to ensure detection using ISO/TC 212 and the future ISO [ISO/TS 5798](#) as guides, prior to sending for external testing. [ISO/IEC 17025](#) will ensure that calibration standards are met by our device.
- External testing from partner Universities.
- Full clinical testing programme provided by the University of Liverpool's School of Tropical Medicine (LSTM). The agreed testing programme will see 50 prototype devices delivered to LSTM to use in clinical trials. The 50 devices will be used as follows:
 - 40 Devices (Controlled Clinical Trials); trials where 20 individuals are subjected to a known virus/bacterial with an expected infectious response, being tested 4 times each day from the day prior to infection to post-infection. This will allow for accurate mapping of the device's accuracy during the whole of a disease infection period. A further 20 individuals will also repeat the test, however, they will be exposed to placebo diseases to ensure that the test results are not anonymous.
 - 10 Devices (Real Life Use); trials where 10 individuals will use the device on a day-to-day basis. People selected for the trials include ex drug-offenders who are required to test each week, drink-driving convicted individuals who are also required to test and selected law enforcement bodies.
 - The results will be collected alongside conventional testing methods to ensure accuracy of the product. These will be tested to the ISO standards: TC 212, TS5798 and IEC 17025 to ensure the product is ready for the International Standards Committee.
 - Results of the trials will be published in a redacted form and presented at the International Conference on Medical, Biological and Pharmaceutical Sciences.
- Following the clinical testing period, the initial product will be presented to the International Standards Committee for clinical laboratory testing and our device will be tested to ISO standards: TC 212, TS5798 and IEC 17025. If this step is approved and ISO standards are given, the test (Version 1) will be approved, and Version 2 will be developed.
- Once version 1 testing is completed, a small focus group including clients from the Travel, Medical, Police and Events industry will be taken at our head office. Feedback from this event will help assist in the final product development of version 2.

2.3 Final product (Version 2) should include:

Following the success of the testing of Version 1, the following elements will be designed and engineered in more specific details to change the product from the existing breathalyser into the new product. Elements of feedback from the focus group will be taken into consideration during this stage.

Aesthetics, Ergonomics and Size & Weight

- Aesthetically the product will be similar to the existing breathalyser.
- The size of the device will be similar to that of an iPhone, with dimensions of 15cm tall, 7cm wide, and 3cm wide.
- The weight of the device will be 200g, which is roughly comparable to that of a standard mobile phone. The additional weight accounts for the weight required for the detector.
- The screen on the device shall be 4 inches wide diagonally and will allow for access to different testing procedures and visual instructions on how to operate it.
- The touchscreen shall be made of the highest-grade Gorilla-Glass and will be made to be used in all weather conditions as it may be used in the field. The device will be a 1080p full-colour OLED screen to ensure maximum battery life.
- The product shall feature a detachable ergonomic grip that will be interchangeable for either right or left-handed operators to ensure that proper ergonomics are followed whilst using the device.
- The ergonomic grip shall be rubberised and textured to ensure users can have a good grip.
- A quick sample button shall be placed on the side of the device, to allow for a sample to be analysed within 30 seconds of button pressing even when locked- this allows for samples to quickly be taken and then processed afterwards according to firmware analysis.
- The colour of the device will be orange to make the product distinguishable from other devices such as competitor breathalysers and even radio devices.
- 20 reusable blow tubes are delivered that can be washed using a high-temperature dishwasher (>60 degrees centigrade), will be delivered with each device. There will be an option for biodegradable pasta-based blow tubes to also be purchased for contractors that require it.

Branding

- Branding will be consistent with the current company branding, with the device being made as a bright orange and black to distinguish from other detectors.
- A logo will be present on the back of the device, with a removable name tag applied for users to attach their details to the device.
- Custom colours will be available on request (as the detachable ergonomic grip can be multi-coloured), however, this will increase costs.

Connectivity

- Device will have full Wi-Fi B/G/N connectivity, with additional Bluetooth and USB-C connectivity to allow for results to be communicated back to a central server.
- An additional model will include cellular data option (reduced battery life to 6 hours) that will allow for live reporting back, where Wi-Fi isn't available.

- The device will include a basic camera to serve as a QR code reader and also to take an image of the person being sampled to ensure that the correct person is being analysed.

Design

- The main design will consist of one full size screen, a removable blow detector with a quick sample button and an off/lock button.
- This will be designed in collaboration with our London-Based Partners and our manufacturers across the various supply chains.

Digital Design

- The device will contain an internal small lithium battery that is charged by the main battery to maintain a date and time stamp (set at factory level). This will last for the life of the device (5 years) and will require replacement after then.
- After each sample is taken a user will be required to enter their details (such as: Name, Date of Birth, Address, National Health Service Number or Similar, Phone Number and Email).
- Public bodies will be allowed to integrate databasing APIs to allow for a cellular search of people, example: NHS Numbers will attribute test data back automatically to the relevant Government server.

Documentation

- Full documentation will be included in 13 languages initially, including: English, Chinese, Arabic, Spanish, French, German, Japanese, Korean, Portuguese, Hindi, Arabic and Russian; this will ensure that as many user languages are reached as possible.
- Documentation will also be graphic to ensure that if someone can't speak the initial language offering, that they are still able to operate the device (this would be useful in the travel industry where guests may have to take their own reading).
- Documentation will include details on how to operate the devices for each use: illicit substance detection; medical illness (infectious diseases) detection and poisonous substances detection.
- Documentation will include details on how to store the device safely and maintain the batteries given with the device.

Languages

- Full language support will be given in 13 languages initially, including: English, Chinese, Arabic, Spanish, French, German, Japanese, Korean, Portuguese, Hindi, Arabic and Russian; this will ensure that as many user languages are reached as possible.

- Menus will also include graphic descriptions to allow for users to visually follow the guide.
- Taking inspiration from other devices such as the Sony A7iV camera, all menus will be sequential, and colour coded back to the documentation so that the device and documentation easily align to another.

Packaging & Shipping

- Packaging will be delivered in a Pelicase (that will serve as the hardcase) that will contain: two batteries; the charger station; device itself; holster; two standard tubes.
- The Pelicase will contain an outer cardboard slide containing branding that will be delivered when the device is new. (This will be biodegradable within 2 years).
- The device will include a reusable silicon pouch that can be recharged in a microwave to ensure the device detector remains dry in the Pelicase.
- Shipping will be conducted by our worldwide partners UPS, with sales made from our offices in Wales, Germany and Japan. Alternative sales agents will be sourced in other countries such as Australia, China and the US.

Quality

- The device shall be manufactured to be 15m waterproof to allow for the weather conditions used. These will be tested to IP68 standards (dustproof and waterproof). A further device for marine and military uses will be designed to IP69K standard.
- High-quality Japanese capacitors to be used for internal electronics.

Safety and Reliability

- Each time the device is hard switched on (when the quick analysis button is not depressed) an automated standard will be taken (if the device has not already been switched on). This will use an internally stored within the device and will be tested in the factory prior to delivery. This standard will be taken every additional 20 analysis, and if an erroneous standard result is returned then the device will display a warning.
- Two additional standards that can be externally analysed will be delivered with the device at delivery with a shelf life of 5 years. These standards should be used at least once per month to ensure that the device is working correctly.
- The device will also be IEC 60079 rated to ensure that the device does not become damaged when dropped from a height of 10 metres or more, or when crushed.
- The device will also be waterproof as previously mentioned to allow for disinfectant usage.

Shelf Life & Battery Life

- The device is designed to last for 10 years, with an extended warranty option of 7 years being offered on delivery of the device (3 years standard manufacturer's warranty, and 7 years assuming that the maintenance contract is taken at a cost of £120 per year).
- Battery life is designed for each device to last for 18 hours continuous use.
- A solar supplied charger will be available for devices that are operating in areas of lower economic standing to ensure that remote 'off-grid' locations can be reached.
- Batteries are interchangeable and two batteries are supplied with each device to ensure continuous use throughout the day.

Storage

- The device should be stored in either the provided holster or Pelicase.
- Devices should be dried prior to storage in the holster or Pelicase to prevent damage to

Environmental and Recycling Commitment

- Batteries will be recycled at no cost (if returned directly to our Wales Factory),
- The device will be continually upgradable and if a newer version is released, sizing will be allowed for increased motherboard sizes to allow for older bodies to incorporate a larger electronic board.
- Trade ins will be accepted, with a refurbishment plant being established

3 Manufacturing and materials

3.1.1 Materials Source

- Electronics will be sourced from premium manufacturers in South Korea and Japan. Electronical capacitors and components will be sourced in Japan, assembled in South Korea prior to being sent to our factory for final assembly in South Korea. Initial testing will be performed with partners in South Korea.
- A local office will be started in South Korea for close cooperation with South Korean Manufacturers and to ensure a quality control space prior to being sent to the UK. This will also Head Asian Region Sales. An additional office will be started in a European Nation within the EU (likely Germany or France) to allow entry into EU markets..
- Rubberised body and plastic body parts will be sourced from Germany and the UK, with moulded bodies being manufactured in two locations for increased redundancy and to bypass any Brexit implications should one location be compromised by political implications.

- Batteries will be sourced directly from Ukraine, however, with the ongoing conflict suppliers in China will be sourced to increase redundancy and to offset some of the backlog caused from the war.
- Pelicases will be supplied directly from Pelicon, with pre-cut foam inserts designed with their team directly.
- The holster mount and charging port will be designed with our partner company in London, with moulds being produced for completion in China.

3.1.2 Final Manufacturing Location

- Due to the confidentiality of the product, only selected partners in South Korea, Japan and the UK will have access to the final product details and assembly.
- Final assembly will be conducted at our Carmarthen Factory, if capacity is exceeded external contractors locally shall be used to increase capacity short term.

3.1.3 Patenting Decision/IP Protection

- Due to the nature of the product, it has been decided that patenting the product contains suitable risks to the products integrity worldwide. As we do not wish to compromise our idea, it is recommended that the product is assembled in house. A patent application for the UK, US and Europe will be submitted in due course prior to market release of Version 2, will NDAs signed between our partners in Japan and South Korea.
- No assembly of potentially IP contentious material (such as software or electronic motherboards are to be conducted within China, as the risk of IP copying is too great). This may result in restricted output capacity, however, this is required to protect the IP of the product.

4 Competitors

4.1 Direct Competition Companies

Direct competitors include:

- FEI
- Thermofisher
- Ametek
- Olympus
- Shimadzu
- Bruker
- Spectrics
- Zeiss Group
- Hitachi
- Nikon
- Tecan

All companies listed above account for some of the top 20 analytical device producers worldwide and should be considered direct competition. Whilst our product is not protected by a patent they should be considered at risk.

4.2 Similar Products

- ICP-GS (Gas Spectrometry Analysis)
- Lateral Flow Tests

No similar product exists for the size and range of operations as our device will currently have.

4.3 Indirect competition

Indirect competition includes the following companies that currently manufacture similar breathalyser technology to ourselves and should be considered as potential future rivals should they decide to also develop their own multi-analytical detector.

- Drager
- Alcosense
- Lion

5 Potential Target Markets

Several markets exist for our product and will require thorough research. As we are the only product available, we can reduce public sector outgoings being spent on multiple different detection methods currently in use. Using a single device will save money and increase reliability.

For private sector and individual consumers, we will offer a new product that will provide them with additional safety and reduce anxiety in a post-pandemic world.

5.1 Public Sector

- Police
- Military
- Civil service
- Medical (NHS and GPs)
- Dental practices
- Large public travel hubs (train stations, airports, etc.)

5.2 Private Sector

- Car manufacturers
- Car hire
- Travel sector (cruise lines and airline operators)
- Hospitality sector
- Retail sector
- Events management companies

5.3 Consumers

- Individual consumers (Germany and France, requirement for breathalysers currently)

5.4 Market Knowledge Requirements

Further market knowledge will be required, such as the size of any market and any additional certifications that may be required in individual countries.

6 Financial Mechanisms and Political Situation

6.1 Manufacturing Funding

Funding for the design and manufacturing of the device has been secured from increased private equity holding (buy-in from our London-Based Partner Company) and projected increased income from the sales of our new products supported by the loans.

6.2 Income

Income will be in the form of two mechanisms, a direct sale cost, subscription and maintenance subscription for those purchasing a device directly (Maintenance will be included in subscription style purchases).

Our currently breathalyser costs a total of £775 per device to market, with a manufacturing cost of £250 all-inclusive. With the new device this is expected to increase slightly to £400 all-inclusive to account for additional features.

6.2.1 Sales Price

Due to the increased capability of the device, it is proposed that the direct purchase price of the device is costed at £4995 per device as a one-off cost. This will give the user all analytics of the latest version of firmware at the time of purchase. For the cellular model, a cost of £7495 is anticipated with a £30 per month cellular subscription (covering cloud data storage up to 1tb and cellular usage).

A basic version for consumers will be released at £795 which will include alcohol detection and basic indication of whether or not the user is currently infectious with: flu, coronavirus or norovirus.

6.2.2 Subscription Price

As the direct sales costs of £4995 and £7495 will shock a lot of our users. We wish to propose options for subscription-based purchase that will allow users to unlock certain analytical features at a set cost.

For example, a subscription cost of £2000 per annum would cover all features and provide the user with the upgraded cellular device, at the higher end (this would cover poisonous substance analysis, illicit substances, or infectious diseases).

At the value-end, some companies/bodies may not require such full features and therefore may opt for a value-based subscription. For instance, law enforcement may opt for just illicit substances at a cost of £500 per annum, with no cellular connectivity, whilst medical professionals may wish to have all features available & devices connected to a cloud-based database for patient records.

6.2.3 Maintenance Subscription

Maintenance subscriptions will be based of a cost of 10% per annum of the direct sales cost.

6.2.4 Policy Advice

Attention will also be given to influence public policy at home and abroad. In some countries such as France, detectors such as ours have been made mandatory by law to be carried by individuals in private vehicles. Should this be the case elsewhere we could agree special discounts to supply our detectors at a slightly discounted price in bulk or offer subscriptions to Governments overseas.

7 Timeline and Budget

Currently the concept is in the Alpha-Testing stage, with production ready to be completed on the prototype Version 1.

It is proposed that in 6 months time, final design of Version 2 will be completed with the manufacturing of the first 500,000 devices being delivered by the end of month 12.

These will be marketed and sold with capacity increased as sales and subscriptions worldwide increase.