



PRODUCT CONSIDERATIONS OF A NEW GENERATION OF BREATHALYSER FOCUSING ON VIRAL LOAD DETECTION

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1 Introduction

1.1 Who are we?

We, Carmarthen Breathalyzer Analytics (CBA,) are a Carmarthen-based SME, focussing on the manufacture of chemical detector systems. Commonly we place these systems within hand-held breathalysers that detect alcohol through a person's breath. These systems are provided to the Police and security services across the UK which is our core market. As we grow, we are looking to diversify into additional, complementary markets.

1.2 What problems do we currently solve?

Currently, we provide mobile, hand-held solutions to the police and security forces that allow them test alcohol levels in the field. We are proud of these products, as they help to keep the public safe by providing the Police with the right tools.

In the future, however, we recognise our technology could be used to do more, helping to protect the general public from viral infections.

1.3 What problems are we trying to solve with this product?

For the last 18 months we have engaged with a local university via the Knowledge Transfer Partnership (KTP) to build and test new chemical detection systems, designed specifically to identify viruses within a Breathalyzer system. This is in response to the COVID-19 pandemic where, as of August 2021, 572.2million people had contracted COVID and ~6.5million people had perished to the virus (WHO, 2022).

Commercially, COVID-19 represent an opportunity to increase our market share of the breathalyser market, valued at \$812.53M in 2021 and expected to grow to \$1.3B in 2022 (Mordor Intelligence, 2022). This growth is being fuelled by breathalysers, with the US FDA approving the first COVID-19 breathalyser in April 2022 (Grand View Research 2022).

Today, we are trying to provide solutions to monitor the spread of viruses by using our advances in next-generation Chemical Detection Systems to build new, more sophisticated breathalysers. These new systems will record organic content in analysed breath, which can be screened for a variety of viral signatures. This allows us to expand our offerings into the expanding breathalyser market (Fortune Business Insights, 2021).

1.4 Aims and objectives of this new product

Our aim is to expand our current breathalyser offerings and increase our market share of the breathalyser market.

To achieve this aim, we will build a new breathalyser that can detect viruses within a users breath. The objectives of this new product, the 'MK2 device' are:

- Provide protection and peace-of-mind to vulnerable people who have to take extra precautions during the COVID-19 pandemic
- Help us expand our client base outside of the police and security forces, by targeting clinical and selected public demographics, and
- Help us increase market share within an expanding breathalyser market.

1.5 Use of this document

This document is designed to be used by all departments within our business. Its core function is to define all the main elements that are to be considered when developing the 'Mk2' device. It will form a key foundation for the Product Specification phase, which will take place after completion of this document.

During the Product Specification phase, this document should be consulted by all teams tasked with specifying the Mk2 product in the first instance. This is a version controlled document, so be sure to consult to the most recent version, which will be stored centrally on our corporate MS SharePoint site.

2 New Product Design brief – Who are we building this for?

This section provides a summary overview of the Market Research phase, which has already been complete.

2.1 Customer analysis

For commercial success, this new breathalyser must appeal to a broad customer base. A clear requirement within a clinical setting (e.g., hospital) is understood. However, taking advantage of a shift in public attitude towards increased, personal health screening due to COVID-19, we believe a breathalyser dedicated to measuring viruses that can be used at home/on holiday etc. would also be attractive to the general public. As such, the potential client base of this product could be significant.

Accordingly, the aesthetics, functions and general design of this virus detecting breathalyser must:

- Appeal to clinical staff and respect the general clinical environment so that it will be appropriate in the UK (as well as Europe and the USA for example).
- Appeal to non-clinical, general populous of selected markets

We can split our potential customer base into two groups:

Clinicians

This group represents nurses, GPs, hospital doctors, consultants etc. They will be focussed on function, practicality and how robust the product is. Bold colours and large graphic designs are unlikely to be appropriate for a clinical setting

General Population

We do not believe this product will be attractive to the entire spectrum of the general public. Our target group is smaller and briefly described below

Likely demographic

Affluent, in-work men and women, 30+ years old. They will have disposable income to purchase the device as well as requirements for its use: office work, business travel etc. Affluent retiree's may also provide a large customer base, with this device helping them to keep connected to their family.

2.2 Branding

Our branding is important as it defines our company. However, we need to make sure our branding marries with what we're hoping to achieve and the customer base we hope to engage with.

Branding

Our traditional branding focusses on protection, with our breathalysers deployed within the police and security forces. These services work to serve and protect the general population and we can continue this theme within our new breathalyser units. Our new viral detection breathalysers will help people test for COVID-19 as well as other viruses, keeping themselves and others safe. Use within clinical environments will help bolster this image and will connect directly to our 'protection' branding. This should speak well to the demographics we are trying to engage.

3 New Product Design brief – product design considerations

3.1 What are we building?

In light of the recent global COVID-19 pandemic, and our own advances in Chemical Detection systems, we are expanding our range of breathalyser products to take advantage of changes in public perception to personal and public health issues. This document represents a New Product Design brief focussed on description of a '**Multi-Viral Detection System**', known as the MK2 device. This represents a whole new product, not just an update to our traditional MK1 devices issued to the police/security force industry. Accordingly, its form, functionality, aesthetics, materials etc. are described in the following sections

3.2 Overall form

The overall form of the MK2 device will be different to that of our standard MK1 alcohol detection breathalysers, marking this out as a new product. A summary of the overall MK2 device form is described as follows:

- This device will be sleek and modern, designed to be attractive and not look like a 'traditional' medical device.
- It will be rectangular, similar in size to a smartphone
- It will comprise two main parts
 - o A main body – rectangular in shape. This will house a single, integrated circuit board and comprise two injection moulded sections:
 - Section 1 will be the front housing. It will contain space for a display screen that will occupy 60% of the front of the device
 - Section 2 will be the rear housing. It will contain space for one USB-c connection on a short-axis side, space for the mouth-piece to connect to the main body, and space for a micro-SD card on the right long-axis side
 - o A mouth-piece to blow into – this will connect to the short axis of the device. It will be removable.

The functionality, aesthetics and safety/standards that the MK2 device will comply to are described below under appropriate headings.

3.3 Functionality

The principle function of the MK2 device is to measure different viral content within a user's analysed breath, screen the breath for one of a series of user selected viruses and return a 'positive/negative' result.

The MK2 device mouthpiece will be removable. It will be washable in a standard sink/bowl. This will allow it to be sterilised between uses, or between patients within a clinical setting. Additional one-use, disposable mouthpieces could also be available in a clinical setting, although this has an environmental impact. When not in use, the mouthpiece will be placed within a specific compartment within a carry case supplied with the device. See additional design brief for carrier case description.

The MK2 device will be battery powered, charged via a USB-c charging cable, and use a similar battery pack to that found within most smartphones. This is likely to be a Lithium-Ion battery, although alternatives can be reviewed during the detailed design specification phase. During the design specification phase, it will be important to refer to the Target Product Profile Rapid Breath Tests for the direct and indirect detection of SARS-CoV-2 (MHRA, 2021) document provided by the UK Gov. It will be charged via a USB-c charging cable.

Bluetooth connectivity will be built into the MK2 device, allowing it to pair/connect to a user's smartphone, relaying analytical results to a downloadable app. See section 5 for more details.

Control

The MK2 device will be controlled from a touchscreen that comprises a large proportion of the front of the device. This screen will allow a user to:

- Select what virus is being tested for
- Save/delete test results,
- Pair the breathalyser to a selected smartphone and 'push' data to our application downloaded onto the connected smartphone

Consequently, a User Interface will need to be developed that allows control of these functions.

3.4 Aesthetics

This section reviews the aesthetics of the MK2 device, including design ideas on size and weight.

Colour

The MK2 device is aimed at both the clinical market, as well as typically more affluent members of the public. It aims to reflect this aspiration through a sleek design that is also not lost in a hospital/GP surgery setting.

Bright, bold colours should be avoided, as this would not be appropriate in a medical setting. Light greys or black would be more appropriate. Furthermore, these colours are likely to show less physical wear and tear, which is likely within a clinical setting.

Shape

The MK2 device will be rectangular in shape, with its long axis X2 as long as the short axis (similar to that of modern-day smartphones). Its sides and top/base are to be flat, giving a similar appearance to

a modern smartphone. The thickness of the MK2 device should be similar to modern smartphone, not exceeding 3cm.

Size

Ideally, the short-axis of the MK2 device should sit along the width of an 'average' adult palm, similar to that of modern smartphones. Additional considerations are:

- The size should not exceed our internal injection moulding capability
- The size should allow it to be easily despatched via courier service

For clinical use:

- The size should allow the device to fit within a standard tunic or trouser pocket

For general public use:

- The size should allow it to be placed on store shelves in places such as e.g., Curries, M&S, O2 etc.
- The size should allow it to be easily stored in 'typical' handbags, or 'typical' carry-on luggage cases

These points are important as it will dictate how easily the product can be used by the general public and how accessible it may be in physical stores.

It is understood that the actual size of the MK2 device is likely to be controlled by the size of required integrated circuit board and additional electronics that will be required for Bluetooth connectivity, micro-SD card housing etc. Specific dimensions will be identified during the design specification phase.

Weight

The MK2 device should be easy to hold in a one hand. As such, weight should be kept to a minimum. Ideally, the MK2 device should not weigh more than 500g. In addition:

- The weight of the device should allow it to be easily despatched via courier service
- Its weight should not exclude it from being put on display in physical stores

For clinical use:

- The weight should not restrict it from being able to 'comfortably' be carried within a standard tunic or trouser pocket

Once again, the specific weight of the device will defined during the design specification phase.

Texture

Ideally, the rear injection moulded housing should have a more textured feel, allowing it to be more easily gripped. This is an important ergonomic design and will make it easier to held in one had whilst in operation.

Materials

Ultimately, this product should be able to operate in both a clinical (hospital/GP surgery) or domestic setting.

For clinicians:

- The material must be able to withstand high-frequency sterilisation.

For the general public:

- This product should have a 'good quality' feel. That is, it should not feel 'cheap' or made of cheap material.

To meet this criteria, the MK2 device will have to utilise a different injection moulding material than our traditional alcohol breathalyser, as the MK2 device is tailored to both clinicians and the general public rather than just the police/security forces.

Safety and Testing

To perform in both a clinical and domestic setting, the MK2 device will have undergo rigours testing.

For both clinical and domestic settings, the following tests must be considered

- Drop testing from multiple heights
- The device must be fire-rated
- The housing material must not be corrosive or fracture easily

For clinical use, additional tests on the capacity of the housing material to be frequently exposed to sterilising agents will need to be undertaken.

Packaging

The packaging must reflect our brand, but with a softer imager than we typically portray with our MK1 alcohol breathalysers which are supplied to the police/security forces. Colours such as whites, creams or light greys would be best, providing a more calming appearance.

4 New Product Design brief – Environmental considerations

To meet the expectations of our customers, environmental considerations must be taken into account when building the MK2 device.

4.1 Environment

Single use plastics are a major contributor to environmental decline. However, use of this MK2 device in a clinical setting would most likely mean use of single-use mouthpieces. Considerations to this are:

- Use of plant-based plastics to manufacture disposable mouthpieces for clinical use. These would be biodegradable and, therefore, reduce the amount of plastic going to landfill

For general public use, the mouthpieces are designed to be removed, washable and re-used. This will reduce plastic entering landfill and promote the environmental credibility of the device.

5 New Product Design brief – new digital services

5.1 Introduction

Sale of the Mk2 device to members of the general public provides an opportunity to enter a new market, extra to the Police/security force market we currently exist within. Consequently, it allows us to evaluate potentially new revenue streams that are in addition to physical sales of the Mk2 product.

COVID-19 provoked large-scale government responses across the globe. Modelling the potential spread of the virus throughout the population became critical, particularly as governments grappled with the timing and duration of large-scale stay at home orders (i.e., 'Lockdown' as experienced throughout 2020 and 2021).

In the UK, one key tool in modelling viral spread was application of the NHS 'Track and Trace' app. Users, although encouraged by government through media outlets (Radio, TV, social media etc.), freely downloaded a public app onto their smartphones and actively allowed that app to collect personal data such as:

- Positive/Negative COVID-19 infection (provided through QR code scanning of lateral flow tests and assigning a positive/negative result to test)
- Location
- Proximity to other people

This data was centralized and analysed, with results used to help model viral transmission etc. and was key to shaping the duration of national and regional 'lockdowns'.

We believe the public uptake of this App demonstrates a shift in general attitudes towards large-scale data collection, centralisation and analysis, when collection of this data is transparent and used to aid medical modelling. We believe we can utilise this shift in public attitude to generate a **new service** focussed on data collection and associated access to this data.

5.2 New Service

We propose a new service available through the Mk2 device based on large-scale data collection. The premise of this service is described below:

- Users can sign-up to share their breathalyser results with us.
- This data will be centralized, stored securely and used by 3rd parties to build 'Big Data' datasets that can be used to help model distribution and spread of certain viruses within the general population.

To perform this new service, the following workflow is suggested:

- Results of each breathalyser test are recorded and digitally stored on the Mk2 device
- Using Bluetooth technology, the Mk2 device will connect to a users mobile smartphone
- Data will then be uploaded to secure cloud storage via an App installed on the user smartphone. This App will also serve additional meta data such as:
 - Time and date
 - Sex and age (based on personal data provided by user when accessing and installing the App)

5.3 Commerciality of new service - Corporate data analysis

The commerciality of this service is based on providing clients corporate access to the compiled dataset derived from users connecting to our smartphone application or web portal. To do this, we must understand who these clients are likely to be. This work was undertaken during the Market Research phase earlier this year. A summary of the results are provided below.

Our clients are likely to be:

- Government health organisations (e.g., the NHS) – these are likely to use the data to help model viral spread between the population so that a national vaccination programme can be designed

- Pharmaceutical companies – these are likely to use the data to determine what viruses are most common, allowing them to ramp-up/reduce production of specific medicines
- Academic institutions (e.g., Universities) – these are likely to use the data to generate large models of the population, allowing them model the distribution of certain viruses through a populous and test their results against ‘ground-truthed’ data

In all cases, we will maintain IP of the data, but we will relinquish derivative IP to the client to promote access to the database.

At present there are two main commercial models:

Corporate model - subscription access

Subscription access to the centralised database is the preferred corporate model. In this case, clients (as listed above) will provide an annual fee for online access to the compiled dataset. Annual subscription allows for a more accurate prediction of revenue

Monthly rental of the database can also be provided. Again, access to data will be online.

Corporate model - One-off purchase

An alternative or complimentary business model would allow clients to download all or a portion of the dataset. In this case it will be harder to maintain IP of the data and monitor its use. However, this model might appeal to clients with limited budgets or where they cannot guarantee annual revenue will be available for subscription; e.g., a university that has been awarded a one-off grant.

5.4 Connectivity and data analysis

To provide the service described above and realise the potential new revenue stream, additional technology will have to be included within the new Mk2 device, as described in the following sub-sections.

Connectivity

Data generated by the MK2 device will have to be served to our centralised database. This is best achieved through pairing the device with a user’s smartphone. Bluetooth connectivity will be vital for this connectivity. This is likely to require:

- Additional electronics within the device, potentially directly connecting to the printed circuit board, that power and support additional hardware
- Additional hardware in the form of a Bluetooth transmitter/receiver

Considerations that should be taken into account to accommodate these additions are:

- 3rd party, printed circuit board manufacturers must be able to incorporate Bluetooth transmitter/receiver technology
- Device housing may have to be altered to accommodate additional electronics:
 - o Size/dimensions of device may have to be increased – it is important to discuss this with vacuum forming company once integrated circuit board manufacturer has been identified
 - o Weight of device may change dependant on inclusion of additional Bluetooth technology
 - o Compliance with telecommunications regulations in separate regions must be reviewed and adhered

Internal data storage

All data generated by the MK2 device will have to be locally stored. Considerations associated with internal storage are listed below:

- Internal storage on micro-SD cards is preferred as these are a proven technology which can be easily integrated into the device.
- Micro-SD cards also provide potential for physical swapping of memory between devices (if required; e.g., if a personal device fails, or breaks). This provides an additional, new function to the MK2 device compared to the Mk1.
- Manufacturing Costs can be kept low by using off-the-shelf micro-SD card readers that can connect to integrated circuits
- Integrated circuit manufacture must be informed of requirement to include micro-SD card reader, allowing connections be placed on circuit board

Internal data analysis

Data gathered by the detector must be accessible to the user. Accordingly, an internal capacity to process and interrogate data must be built into the device. Considerations for this are listed below:

- Internal processing must be powerful enough to deal with data analytics
- Processers must be able to connect to the selected integrated circuit board – this must be discussed with suppliers when sourcing any new integrated circuit board manufacturer

Data visualisations

Gathered data must be able to be displayed/visualised for user assessment. This visualisation can vary dependent on what is required:

- On-device data visualisation should be limited to simple alpha-numeric visuals; i.e., describing if a test is positive/negative in simple text form. This will provide rapid understanding of the test results
- Complicated data visualisation would be provided by connecting the device to a users smartphone via Bluetooth connection. Once connected, data will be visualised via our Application. Within the app, data will be visualised in a dashboard with the following considerations:
 - o Visualisation has to be simple, clean and results clear
 - o Graphics must be large enough to be readable
 - o Interrogation tools must be simple; e.g., using a 'slider' to determine the number of tests to include within the data analytical dashboard.

Online access

The key success and what will underpin the commercial component of this new service is connecting data to our centralised database. This will be achieved via the internet as users engage with our mobile applications and/or online portals. These are described in more detail below.

Mobile Application

This is a key component of engaging with our client base. It is likely to be the main conduit for providing data for our centralised database, as we estimate that most people will connect to our database using the smartphone Application. Accordingly, the following considerations need to be taken into account:

- The application must be free to download – we are not generating revenue from sale of the application, but by providing commercial access to the compiled dataset
- Terms of use, including the serving of selected data to our servers must be explicit and obvious when downloading the application, as well as when using the application – transparency is key as it builds trust and also taps into the same mindset people engaged when accessing NHS track and trace.
- It must be easy to connect the MK2 device to a users smartphone
- The application must be easy to use.
- The dashboard element of the application, which provides the data visualisation display must be crisp and modern. Pastel colours are suggested as these are calmer and are less likely to date quickly
- Interrogation tools on the dashboard must be simple and resultant visualisations must be easy to digest.
- Connection between the Mk2 device and a users smartphone

Website Portal

For users who do not want to download our smartphone application, but want to record their data for personal reference, adding a portal to our website is suggested. This portal will:

- Sit behind a login screen – again access to this portal should be free
- Will share similar visuals to that of the smartphone application demonstrating continuity of the brand/interactive experience
- Simple data will be manually entered by a user. This will be restricted to:
 - o Test type
 - o Result
 - o Date
 - o Time
 - o Sex

In the same way as the smartphone application, terms of use including the serving of this data to our servers must be explicit, as transparency is paramount to building this new service and associated brand.

Online security

Providing any online service that collects and stores users data must be very secure, and must adhere to all relevant legislation dependant on the country the dataset is collected from. It is likely that outsourcing this security to a 3rd party is most cost effective.

6 New Product Design brief – compliance considerations

6.1 Compliance

This section of the document provides an overview of the different types of clinical and legal compliance this product will have to adhere to. It will be the remit of the Legal team to assess that all compliance is met during the Product Specification and subsequent manufacturing phases.

Clinical compliance

The requirements for clinical compliance are likely to alter dependent on market sector. This product will launch in the UK clinical sector, with entry into the European market coming in year 3.

Both UK and European medical agencies have already provided certification for the MK 2 prototype, allowing us to move forward with this initial New Product Design brief. Consequently, the Technical, and ultimately Legal teams, must ensure that the certified chemical alcohol detector system which formed the basis of the prototype and subsequently passed clinical certification is adhered to within the Product Specification and subsequent manufacturing phases.

Legislation compliance

This product must meet the legislative compliance of both the UK and European markets.

7 References

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