

Program BioVigor

Virus breathalyser unit

Design Brief

Validation	Name and Position	Signature	Date
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A vertical line in the margin, or **highlighting**, indicates the changes.

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Distribution list		
Position/Department	Name	Delegated to
Aftermarket		
Change Manager		
Configuration Manager		
Electrical Design		
Export Control		
Finance		
Health & Safety		
Intellectual Property		
Logistics		
Manufacturing Engineer		
Sales & Marketing		
Mechanical Design		
Procurement		
Product Design		
Production		
Program Manager		
Stress		
Quality / Testing / FAI / LAI		

Note:

Document originally written in English (GB).

For translation discrepancies, please refer to the master document.

This document is for **INTERNAL** use only.

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Acronyms

FAI	First Article Inspection
IP	Intellectual Property
IP Lawyer	Intellectual property lawyer
LAI	Last Article Inspection
MU	Manufacturing Unit
PM	Program Manager
R&D	Research and Development

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1 Briefing

1.1 Scope

A new product to be brought onto the market to detect organic materials (aka virus and bacteria caused by illness/infections), to be used in clinical and personal use as an aid in the detection and thus treatment of patients. Utilising our current technology, Intellectual Property and research in the breath alcohol analysis equipment, the fuel cell technology could be changed to detect organic material instead of alcohol.

In partnership with the local University, the theory has been tested and proven achievable using our fuel cell technology in a laboratory. To progress off this success, the prototype is to be developed into a working unit for distribution into multiple areas of the healthcare system.

1.2 Use case

Product to be used in a multiple of settings, including NHS, A&E, GP's, senior care, schools, large events, prisons. Product main goal of detecting virus, like COVID-19, to assist the user with their investigation and developing a treatment plan.

1.3 Assumptions:

- Patents have been submitted, awaiting authorisation
- R&D are confident the new fuel cell sensor system can fit inside the same envelope as our current breathalyser unit
- Prototypes of the electrical and mechanical systems have been built and successful lab tested
- Existing breathalyser product cannot be upgraded to cover both alcohol and virus
- Physical envelope design to be outsourced
- Internal components to be outsourced and final assembly conducted in-house
- Electronics to be designed onto one circuit board
- Target of 750,000 units to be shipped in the first year, ramping up to 3million per year once steady state
- Preliminary use to detect COVID-19, with secondary function to test for known virus
- Target audience is both clinical and personal use
- Current supplier base to be used to source parts/components
 - Senior Management open to bringing in new suppliers to support the new project

1.4 References

No external references used during the creation of this document.

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2 Design Brief

2.1 Jurisdiction/Lawful

2.1.1 Legal

Will need to outsource legal to an expert in the field of medicine testing to ensure the product and the company are not liable for false positive/negative results as a result of using the unit. Legal implications towards the company of how the unit can be used as a means of defence if the user passes on COVID or something similar will need to be investigated.

NDA lawyer will need to be brought onto the project with **immediate effect**, current company prototype tech outside of our control, NDA's will need to be issued and controlled.

Export Control Officer to review the product, assess what licence will need to be sourced.

Intellectual property lawyer to investigate potential clashes with competitors.

See "[Competition](#)"

Legal to update program on any active sanctions limiting potential markets or importing components.

Action on Program Manager

1. Medical Legal advice to be sourced for the project
2. NDA layer to be subcontracted
3. IP Lawyer to be subcontracted

Action on Export Control Officer

1. Review what licence will be needed for the unit

Action on Legal

1. Advised on active Sanctions which will impact the Program

2.1.2 Social and Cultural

Marketing to review if the product will be accepted by the public or seen in a negative way of impeding personal freedoms. The goal of the unit is to save lives by speeding up the investigation being carried out by health care workers, this message to be pushed in any marketing messages to bring the public onto our side.

Action on Marketing

1. Carry out surveys to assess if the public will believe in the product

2.1.3 Standards and Specifications

Outsource research into "Standards and Specification" needed.

Action on Program Manager

1. Hire contractor specialising in UK and EU Standards

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2.1.4 Market constraints

R&D to research into any legal requirements set out by our proposed main customers to ensure the product can be sold into this market. Same to be done for international markets.

Actions on **R&D**

1. Assess if any constraints set out by NHS/Governments regarding the use of the product
2. Research into EU and NA medical laws

2.1.5 Company constraints

See "[Legal](#)"

Action on **Legal**

1. Program Manager to advise any company constraints that would impact the program

2.1.6 Competition

Currently in 2023, there are no known COVID breathalysers on the market however, there are a number of prototypes and lab testing being carried out.

InspectIR have been given approval in America back in 2022 for their mobile COVID screening device, the PNY-1000 which has a recorded success rate of 91%. The unit is a desk-mounted device which users provide a breath sample via a disposable straw. The unit takes up to 4min to generate results and is limited to 160 tests a day. Costing is unknown currently.

An Australian company in 2022 has developed a breathalyser prototype for detecting COVID with a reported 98% success rate.

In Washington University, a one-minute breath test has been successfully tested to detect COVID using the same fuel cell technology.

Action on **Program Manager**

1. Review if purchasing the unit to reverse engineer is beneficial to the project

Action on **R&D**

1. Look into other virus detection breathalysers on the market

Action on **Legal**

1. Assess if there is any IP infringement with the prototypes from 2022 and 2023.

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2.1.7 Circular Economy

Where possible, the use of virgin material to be heavily discouraged without affecting quality or costs. Depending on the investigation to be carried out by the Legal team regarding liability, a decision is to be made regarding if the unit can be maintained and repaired by the user or if a “*Warranty void if opened*” scenario and therefore all repairs to be carried out by approved contractors or in-house only.

Also, Legal to advise on how does calibration of the fuel cell by the end user impact liability on the company if carried out incorrectly resulting in an incorrect reading.

See “[Consumables](#)”

Action on **Program Manager**

1. Will the company support to reject maintenance to be done by the user or not?
2. Will there be planned obsolescence?

Action on **Legal**

1. Review if the company is liable if the user calibrates the product incorrectly

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2.2 Production

2.2.1 Material

Same plastic as used in manufacturing the alcohol unit. Research needed into hygienic plastics for use in hospitals. Unit be manufactured with recycled materials where possible without impacting on quality and shelf life.

Action on **Procurement**

1. Review current plastic catalogue, assess if suppliers can provide medical grade plastic
2. Review costs/life span of virgin vs recycled plastic

2.2.2 Weight

Target weight of 160g, with an ideal range of between 140-170g. However, this can be expand on to a min/max of 130-200g. Our target weight should be similar to the current alcohol unit.

Action on **R&D**:

1. Assess if NHS have a handheld weight limit

2.2.3 Size

Target size similar to the current breathalyse unit 120x60x30mm. To stay as a handheld unit, the unit can be expanded to 130x70x40mm. Alternative designs to be considered if the alcohol breathalyser shape is considered in a negative light by the end user.

Action on **R&D**:

1. Research into current handheld standards to ensure target size is still socially acceptable.
2. Confirm the proposed new fuel cell and electronics can be compressed within above dimensions.
3. Conduct public surveys to see if the current alcohol test shape will cause a negative reaction and hamper sales

Action on **Standards and Specifications** contractor to confirm the above.

2.2.4 Time scale

To bring the item onto the market, the target turnaround from 'Initial Technical Co-ordination Meeting' to first delivery is no longer than 18 months. Considering COVID detection is the target market, bringing the tech to the market within 12 months is the goal to maximise on the current customer base.

2.2.5 Manufacturing facilities

In-house final assembly using sub-assemblies manufactured off site. Target of 14.5k units a week ramping up to 57.8k units once steady state, depending on uptake by customer base.

Action on **Manufacturing**

1. Can MU support proposed target alongside current production?

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2.2.6 Environment

The product should be designed to be fully recycled where possible. The selected internal components will need to be considered regarding if they can be easily disassembled and recycled.

The product will need to work in a range of conditions, temperature range of -10/+40C and 20-80% humidity.

See "[Circular Economy](#)"

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2.3 Product

2.3.1 Key features

The display on the product should be usable in the day and night, including in direct sunlight. Care should be taken to ensure colour blind and visual impaired users are able to use the display.

The use of a speaker to be considered, giving the user verbal instructions and even providing results. It can also be used to warn the user of low power or how many test cycles remaining until calibration is needed.

For mass use, the implementation of internal or external memory to be considered to store results to be reviewed at a later date.

Option to sell a basic and advanced unit depending on the requirements of the end user, parents are only interested in standard illnesses where as doctors will require a wider range of tests therefore interested in a full spread of results. Also an option to sell a COVID only tester.

Action on **Legal**

1. Will the use of a speaker break Doctor/Patient confidentiality?
2. Does storing patient's results digitally comply with data protection laws?

Action on **Program / R&D**

1. Review if beneficial to sell the unit as basic/premier/COVID testers instead of all in one unit

2.3.2 Branding

Design to assess possible location and requirements for company logo and branding.

2.3.3 Performance

See "[Reliability](#)"

2.3.4 Product Cost

Using the current alcohol breathalyser as a baseline the target cost per unit is £500. Assuming a minimal life of 1000 tests per fuel cell, this would equate to £0.50 per test. Taking into account the £0.40 for the mouth piece (data pulled from the alcohol breathalyse unit), this would mean a test would be sub £1, a 50% reduction on the current £2 lateral flow tests.

Considering this will be the first unit onto the market, a premium could be applied of between £500-£750 to the unit until competition join the market. Discounts could be provided with bulk ordering.

Action on **Program / Finance**

1. Review the proposed unit cost to assess if this will bring the program into the black within the first year

Action on **Finance**

1. Assess if bulk discounts could be provided

Action on **R&D**

1. Carry out public surveys to assess if £500 is a good target or the unit is over/under priced

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2.3.5 Aesthetics

Colour options to be reviewed and assessed depending on the end user. For use in GP's and schools, a bright vibrant colour might be preferred, where as in hospitals, a stain resistant dark colour might be preferred.

Action on **R&D**

1. Assess if NHS have medical equipment colour requirements

2.3.6 Quality

Product to meet end users as well as the public's understanding on quality. The product needs to work in a multitude of conditions and perform the same as when first used and its 1000 use. When selecting materials, quality to be considered as a primary factor.

See "[Circular Economy](#)" regarding planned obsolesces.

2.3.7 Product life span

The unit should be able to do a minimal of 1000 test and last once opened for a minimal of three-year before the fuel cell will need replacing. With a fresh fuel cell installed, the unit will work for a minimal of 2 years before being replaced.

Service plans and extended warranty to be considered.

Action on **Legal**

1. Advise on liability to company on a product over one year old

Action on **R&D**

1. Advise program on the workings of the fuel cell, time between each test.

2.3.8 Reliability

Product to be over 90% reliable in all proposed use conditions by a trained user.

See "[Legal](#)"

2.3.9 Life in Service

See "[Shelf life and storage life](#)"

2.3.10 Shelf life and storage life

The standard of 2 years shelf life to be offered before recalibration needed. If unit has non-removable batteries, shelf life to be reassessed in line with batteries life span. Once the unit has been opened, the standard 6 months between recalibrations is proposed.

Action on **Procurement**

1. What is the current shelf life of the fuel cell?
2. What is the current shelf life of the proposed batteries?

Action on **R&D / Procurement / Legal**

1. What is the proposed recalibration time frame for the fuel cell

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2.3.11 Quantity

Due to mixture of end users, the product to be sold in one and multi packs to accommodate small and large business as well as the public (aka parents/child carers).

2.3.12 Power

The internal battery to be a rechargeable unit which can be replaced by the end user once it's usable life is up (minimal of 1 year). Depending on available internal space, the option of extra capacity batteries to be looked into as an aftermarket option.

Charging to be done via USB C. To minimise the packaging and make the unit more widely available, Wall AC to USB charging unit not to be provided, rely on customer having access to a USB port near the dock or access to a phone charger. This will allow the unit to be sold in multiple countries and where users have access to 110V or 230V AC power without needing to design the product around this limitation.

For use in the NHS facilities, replacing the battery with a capacitor system to prolong the life of the product to be reviewed. However, this option will be limited to a cradle charging device and not fully portable. This option is more of an A&E device setting where quick results are needed but the device will not leave the area.

See "[Aftermarket](#)"

2.3.13 Connectivity

Device to come with the ability to communicate via:

- Bluetooth
- WiFi
- ANT+
- NFC
- Data sim card
- USB C

This will allow the unit to be integrated into the end users digital systems, allowing data to flow quickly and to be linked directly to the patients file. This will also allow the unit to be connected to a printer if required by the customer.

The use of a data simcard to be reviewed to allow data to flow back to home base when the unit is out of the building.

Phone app to be considered to display more in-depth data to the user that the inbuilt screen cannot. However Data protection laws will need to be considered when designing the app.

Action on R&D

1. Review what is the current NHS database system and how can the device communicate with the system

Action on Program Manager

1. Bring in App designer

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2.3.14 Safety

Due to the product to be used in the NHS and other health service settings, the device needs to be designed to be safe in the hands of trained and untrained users, considering the primary users will be children and the elderly.

Design need to ensure the user or patient cannot access the electronics to cause harm or allow parts be become detached and swallowed. Any use of chemicals in the product to be reviewed for potential human consumption.

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2.4 Usability

2.4.1 Customer

Target user will primarily be within Europe and North America, branching out to Asia and other countries once steady state. First run of production will mainly aim at the UK market to allow quick return/replacement while initial manufacturing errors are processed out and our suppliers are at a steady state of production.

2.4.2 Maintenance and Repair

Due to the nature of the product, maintenance and repairs to be done in house or by approved sub-contractors.

Action on Legal

1. Advise Program the implications to the company if the user carried out unauthorised maintenance/repair

See "[Shelf life and storage life](#)" and "[Circular Economy](#)"

2.4.3 Training

Training material/manual to be provided online if possible to minimise use of paper and printing costs. Material to be generated in multiple languages to cover most of the proposed customer base. The use of videos to be assessed as alternatives to text base material to capture a wider audience.

Action on IT

1. Assess the costs associated to hosting PDF material online for life of program +5 years

2.4.4 Documentation

Documentation to be provided digitally where possible to minimise paper and ink costs. The use of images and videos to be heavily used to assist with language barriers and support with speeding up training by the end user. Media to be provided in multiple languages depending on target market location.

If printed documents are required, recycled paper over virgin paper to be preferred.

Action on Quality / Procurement

1. Assess if recycled paper can be used without impacting quality of printed media

Action on R&D

1. Assess target market to determine what languages documents to be translated into

2.4.5 Language

Unit to be programmed in a range of languages to ensure it can be sold in the majority of Europe with minimal changes to the software. During the initial set up of the device, the user will be able to select the preferred language.

Action on Program Manager

1. Bring in translator to support team

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2.4.6 Ergonomics

Unit to be designed so can be used in either hand. Design to ensure the mouthpiece can be mounted in a way to ensure above can be achieved. To support multi uses, the weight of the unit to kept to a minimal to reduce wrist issues with the user.

Action on Design

1. Ensure function can be achieved in both LH and RH use

2.4.7 Installation

Due to the system being a hand held unit, no installation is needed. Product to work out of the box with minimal input from the end user.

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2.5 Logistics

2.5.1 Packaging

Target packaging of 150x100x50mm, mainly paper and cardboard construction. Minimise the use of plastic packaging where possible. Multi-pack option to be looked into to support our larger customer (aka NHS, GP centres).

Action on **Procurement**:

1. Assess the cost impacts of virgin vs recycled packaging material

Action on **Logistics**:

1. Can cardboard packaging survive shipping impacts?
2. Look into single and multi-pack options

2.5.2 Shipping

Product to be shipped via Air/Sea/Land, therefore the product needs to be able to withstand temperature/humidity/vibration conditions from all forms of transport. Product to withstand temperature range of -45/60C, packaging to withstand exposure to direct sunlight while in transit.

Using above packaging dimensions, 7252 units per UK pallet, 5274 units per EU pallet.

Action on **Logistics**:

1. Using the above baseline figures, provide preliminary costs for shipping.

Action on **Design**:

1. Packaging design to take into account stacking up to 55 units high.

2.5.3 Distribution

Due to the new market area, current distribution avenues will not work. The customer base will need to be researched and developed.

To attract the individual users (i.e. parents/child minders), selling the product via distribution companies like Amazon to be looked into.

Action on **Logistics**:

1. Look into using Amazon as a distribution system

Action on **Marketing**:

1. Research into new market and how to distribute product

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2.6 R&D

2.6.1 Testing

Testing of the product will be similar to the testing plan developed for the alcohol units. Additional testing needed for use in the medical field.

Action on Quality:

1. Review testing requirements set out by NHS regarding handheld units.
2. Pull current testing plan, review and update.

2.6.2 Prototyping

A proof of concept has been successfully carried out in a laboratory setting. The next phase would be to compress the equipment down into a smaller package while still achieving the same results. Depending on the results, the proposed sizing can be confirmed.

Action on R&D

1. Look into carrying out tests limiting the size the prototype can use

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2.7 Aftermarket

2.7.1 Extras

To maximise on the product, while also minimising on the units packaging, aftermarket options to be sold as optional extras, including but not limited to:

- Screen protectors
- Drop/protection cases
- Additional battery packs
 - Standard and extra capacity
- Standard & Fast chargers
- Docking station for single or multiple units
- Car 12V chargers
- Solar charging kits
- Printers (Wired or wireless)

2.7.2 Consumables

Due to the nature of the test and for hygiene between patients, disposable mouthpieces are needed for each test. This mouthpiece to be offered in batches depending on target customer (100, 250, 500, 1000 units). Current Alcohol breathalyse unit charges £0.40 per mouthpiece.

Design to and use the current mouthpiece product with no changes, allowing both units to use the same mouthpiece.

Like the alcohol product, to calibrate the unit compressed gas with synthetic or active virus to be sold to ensure the unit is as accurate as possible. Due to the legal implications, calibration of the unit might only be done in house or by trained sub contractors.

Action on Legal

1. Advise the program on the implication of selling synthetic or active viruses to the public.

Action on Program Manager / Finance

1. Review the costs associated in carrying out calibration of units in house

2.7.3 Upgrades

As the lifecycle of the product progresses, the option to update the hardware/software could be provided to the user if the Program deems it beneficial. With the possible implementation of a data sim card, the unit software could be updated over the air, allowing the user to keep the unit instead of returning for rework.

Action on Program Manager

1. Review if over the air upgrades are an option or would prefer the unit to be returned to be reworked or replaced.

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2.7.4 Service Plan

Service plans to be offered as an option extra with the goal of less than 24hr turn around for a replacement unit.

Action on Program Manager / Finance

1. Review the benefits vs the cost of offering a service plan