

Assessment B - Developing the Design Brief (ACPA 7006)

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Synopsis

Recently, through a knowledge transfer partnership with a local university, the organisation has successfully identified an opportunity to extend the chemical alcohol detector system used within current breathalyser products to cover the detection of other organic materials, including those generated in the breath as a result of various virus infections.

Specifically, the organisation has developed and prototyped the electrical and mechanical system, resulting in a new product that is capable of detecting volatile organic compounds (VOCs), generated during the body's immune response to COVID-19. This new product is to be known as 'Virus Detect'

Based on this emerging technology and following successful trials of the prototype, approval has been given from the Medicines and Healthcare products Regulatory Agency (MHRA), The Food and Drug Administration (FDA) and the European Medicines Agency (EMA), with ongoing applications continuing in Asia and Africa. All necessary patent applications have also been registered. In light of the current Coronavirus pandemic, the organisation would like to drive the product to market as soon as possible.

Owing to the modifications required on the detector system, it is not possible to re-use/ re-purpose existing breathalyser products for Virus Detect, thus, a completely new product design is necessary.

This product design brief document will consider and outline the requirements for the whole physical envelope of Virus Detect, and will contain information for/ require information from all stakeholders within the business.

The new product's electronics will be sourced in a fully assembled and tested form, contained in a single circuit board. The mechanical element of the detector (the breath sample capture system) will be fabricated from injection moulded parts. Assembly of Virus Detect will take place at Carmarthen HQ, following review and approval of this document.

The key performance indicators of this product are:

- Reach 85% of healthcare settings within two years
- Average length of contact with patient being tested is less than one minute
- Manufacture and deliver 750,000 units in year one, rising to 3,000,000 for years afterward
- Manufacture and deliver Virus Detect with a net zero carbon footprint
- Increase growth to 30%



The purpose of Virus Detect is to transform the lives of those who require testing, or who work in a Covid-19 testing environment (not only healthcare). This device will deliver quick, accurate results at the point of testing, without the requirement for an uncomfortable nose/throat swab. In turn, this should increase the number of tests the public are willing to take, whilst saving time on analysis in a laboratory.

To be successful, Virus Detect must be accurate, easy to use, robust, reliable and portable.

Following the approval of this document, the product design specification (PDS) will be made available

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Documentation Control

This document is considered confidential and should not be distributed externally. This document becomes uncontrolled when printed.

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Version	Date	Title	Modified By	Amendments
0.1	13.05.2022	NPD & Innovations Manager	A. Collier	Draft
0.2	20.05.2022	Environmental Manager	J Huxton	Minor amendments to circular economy and environment section
1.0	24.05.2022	NPD & Innovations Manager	A Collier	Version for approval

Market Potential

Through market intelligence (see slides [here](#)), our Carmarthen based SME, along with our local university using a knowledge transfer partnership (KTP) has identified numerous opportunities that our handheld breathalyser style products could be repurposed to detect. Some of these include:

- Viruses (Covid-19, Zika etc.)
- Diseases (Diphtheria, HIV/Aids etc.)
- Specific Cancers (Engelland, 2021)
- A persons level of fitness (Health online, 2020)
- Food intolerances (John Hopkins Medicine, (2022)

With a current global Coronavirus Covid-19 pandemic ongoing, our SME have decided to focus efforts into developing and manufacturing a 'Virus Detect' device. The device will be available to all industries that require personal testing devices, as well as the general public.

Virus Detect has been prototyped at laboratory scale, and as a result, has been granted approval by all regulatory authorities within Europe and USA.

The impact of this device going to market could shift the path of the pandemic, by delivering fast, live results at the point of contact. This makes time to market a key driver.

Elements and architecture of the product that need to be considered

This document is relevant to all stakeholders within the organisation, with relevant insight and feedback required on each of the below elements.

This document is live and should be modified as necessary, ensuring that the version control is updated and all amendments clearly noted.

No priority is given to the following elements unless otherwise stated.

Aesthetics

- Shape
 - Handheld device with display screen
 - Must be able to operate with one hand (left or right)
 - Consistent with other products where possible
 - Simple for manufacture and sanitisation
- Form
 - Should follow company branding (colour, logo etc.)
- Feel

- Touch screen display with familiar menu/ layout
- Edges to be rounded with a smooth surface finish
- Robust
- Easy to sanitise
- Accessories
 - Protective cover should be considered at design phase to include child friendly finish/ characters etc. (externally manufactured)
 - Anchor point should be available for a wrist strap/ lanyard etc.
 - Bamboo/ paper/ copper plated steel sampling tube
 - Wireless and wired charging points

See also:

Branding, Manufacturing facilities, Materials, Size

Branding

- Colour
 - As per current breathalyser products
- Shape
 - Consistent with current products
- Logos
 - Please ensure new, updated company logo is used (as below)



- Display/ Menus/ Text
 - Familiar to any existing customers
- Packaging
 - In line with all the above
- Services & support

See also:

Aesthetics, Maintenance & repair

Circular economy

- Provide a return and replacement service for all products (including chemical detector system)
- Re-use parts/ components where compatible from current breathalyser systems in new Virus Detect product

- Consider the ease of recycling for all internal and external components
- Ensure that sampling tube is not made from stiffened paper, bamboo or copper plated steel (anti-microbial) – not single use plastic
- Source materials locally where possible to reduce CO₂ emissions
- Follow BS8001 (2017) wherever possible

See also:

Environment, Life in service, Materials, Packaging

Company constraints

- Expertise in this market
 - Buy in these services
 - Train staff to have greater knowledge
 - Poach employees from competitors
- Finances
 - Government grants/ loans
 - Knowledge Transfer Partner to complete R&D
 - Bank support
 - R&D tax credits
- Manufacturing
 - Possible new facility required to deal with volume of units
 - Develop robust new supply chain (ethically resourced)
 - Develop distribution networks internationally
- Employees
 - Staff numbers must grow with production (from year 2)
 - Sales, Quality technicians, etc.

See also:

Circular economy, Competition, Manufacturing facilities, Market

Competition

- Determine current 'best in the business' devices
 - Procure devices and distribute to design/ R&D/ emerging technologies teams (each team to report with findings. Advantages, limitations etc.)
 - Please note price of devices in this document ([here](#))
- Literature review

- Emerging VOC detecting technologies (Nanotechnology Biomarker Tagging, Electrochemical etc.)
- Direct and indirect testing methods
- Patent search
- Known competition
 - InspectIR (US) (FDA, 2022)
 - 91.2% sensitivity
 - 99.3% specificity
 - 100 instruments per week manufactured
 - 160 samples per day
 - E.Co.Tech (US & UAE) (Banga et al, 2022)
 - 100% sensitivity
 - 87.04% specificity
 - 30 seconds to complete analysis
 - Detects in parts per billion (ppb)
 - Deepverge Microtox BT (Ireland) (Staines, 2021)
 - 100% specificity
 - Measures at 40 femtograms per millilitre (0.000000000000000001 kilograms)
 - AI-based water contamination detection system

See also:

Company constraints, Intellectual property, Leg, Market, Product cost, Reliability

Customer

The target customers for this device are:

- National Health Service (NHS)
 - Virus testing centres
 - Pre-appointment/admission/ A&E
 - GP surgery
- Private health and social care settings
 - Nursing homes
 - Care homes
 - Private healthcare settings
 - Organisational based occupational health
- Border security
 - Health screening of migrants

- Events management and hospitality
 - Large indoor/ outdoor events
- General population (after initial role out)

See also:

Branding, Market, Safety

Documentation

- Consumer instruction manual with company branding (Fonts, colours, logos etc.)
 - Quick start user guide
 - Technical manual
 - Troubleshooting
 - Multiple languages
 - English (UK)
 - English (US)
 - Spanish
 - French
 - German
 - Italian
 - Other languages for key markets to be available on website
- Returns policy
- HSE information
- Connectivity information via WiFi to relevant databases (NHS, Track & trace etc.)
- Warranty Registration
- FAQs
- Internal documentation
 - Calibration procedure
 - Technical manuals
 - Electrical drawings
 - Health Safety and Environment information
- Waste Electrical and Electronic Equipment (WEEE, 2012) regulations
 - Offer return scheme on end-of-life products
 - Battery to be returnable to supplier for recycling

See also:

Branding, Customer, Environment, Installation, Safety

Environment

- Organisational responsibilities in line with company branding
 - All employees who must travel (Sales team, Quality and service engineers etc.) will drive electric company cars only
 - Batteries from all devices are returnable to the organisation for end of life recycling
 - All packaging is returnable to the organisation for re-use (free of charge)
- For use of Virus Detect
 - Operable between 2°C and 35°C
 - Waterproof and dustproof to IP65 (BS EN 60529)
 - Resistant to alcohol based cleaning fluids
 - Should be suitable for both high and low pressure ranges for use at altitude or during air travel
 - Resistant to repeated drops from head height
 - Backlit display for use in low light

See also:

Circular economy, Life in service, Quality testing

Ergonomics

- For single handed use for left or right handed people
 - Ensure the size of the product is appropriate for different hand sizes
 - Ensure the product weight is suitable for single handed use by both children and pensioners
- Simple touch screen display with easy to navigate menus
 - Consider icon sizes
 - Consider sensitivity control
- Breath sample tube should seal onto the patients mouth comfortably
- Virus detect should be smooth to hold with no sharp edges

See also:

Aesthetics, Branding, Customer, Size

Installation

- Each device should be registered to the organisations data base to share information with government controlled testing services
- Device will 'buggy' to other smart devices to share information through WiFi

- Each device will require a full charge before becoming operational
- Consumer instruction manual with company branding to be included
- One wrist strap will be provided per device with instruction on how safely attach to anchor
- For commercial use, portable appliance testing (PAT) will be required

See also:

Documentation, Processes, Safety

Intellectual property

- Patent searches for similar products
- Purchase of competitor product and ethically deconstruct to determine processes and technologies
- Control of internal documentation related to Virus Detect
- Trademark of 'Virus Detect'
- Protect IP in line with current organisational systems
- Sign NDA with potential suppliers

See also:

Branding, Competition, Leg

Legal & legislation

- Ensure compliance with general product safety regulations (GPSR, 2005), including end-of-life
- Continue to liaise with MHRA, FDA and EMA ensuring compliance
- Ensure compliance with data protection legislation
- When de-constructing competitor products, ensure this is done in a way that is legal

See also:

Synopsis, Competition, Intellectual property

Life in service

- Determine time to failure and calculate service intervals
 - Time/ cycles/ periodically etc.
- All component parts must be fully replaceable/ exchangeable
 - Determine what could be exchanged/ replaced by user and what would require technician
- Provide a return and replacement service for all products (including breathalyser)

- Determine calibration frequency based on results of slope from prototypes

See also:

Circular economy, Maintenance & repair, Product life span,

- To be determined on completion of Life in service, performance, quality and safety testing
 - Virus Detect product
 - Mouthpiece sample tube
 - Chemical detector system
- Product is not expected to have similar lifespan to breathalyser products (due to frequency of uses)

See also:

Life in service, Performance, Quality testing, Safety

Prototyping, Quality testing

[Maintenance & repair](#)

- All component parts are replaceable/ exchangeable
 - Determine what could be exchanged/ replaced by user and what would require technician
 - Display screen to display fault codes if issue arises
 - Fault code to determine cause of action required (by user or organisation)
- If machine must be replaced, this must be complete in a timely manner
- Ensure quality and service technician team grows into year two (with demand)

See also:

Company constraints, Documentation, Life in service, Product life span, Quality testing

[Manufacturing facilities](#)

- Manufacturing facilities must be cohesive
 - Virus Detect products must flow through the business, to avoid building WIP
 - Components and other stock must be Just In Time (JIT)
 - Existing plant machinery should be upgraded/ updated to deal with demand in year 2
 - New production/ assembly lines to be established, encouraging flow of product with very high levels of automation for assembly
 - Packaging/ despatch should pull product

- Quality is critical
 - Right first time philosophy to be implemented
 - No waste forward
- Large focus on continuous improvement
 - To scale production in year 2, we cannot do the same as in year 1
 - Lean principles to be established among Process team
- Warehouse to be upgraded with robots and automated case pickers
- Protected covers will and wrist straps/ lanyard will be supplied externally
- The mouthpiece will be supplied externally
- Facilities should be able to manufacture ~15,000 Virus Detect products per week in year 1
- This operation will grow to ~60,000 units per week in year 2 onwards (new production/ assembly lines available)
- The site will operate 24/7 for 51 weeks of the year (1 week shutdown at Christmas)
 - Production staff will be expected to operate a 4 crew/ 5 crew continental shift pattern (Operations manager to advise on which)

See also:

Company constraints

Market

-
- Please refer to market research presentation [here](#) (log-in required)
 - Surveys
 - Focus groups
 - Field trials
 - Competitor research
 - Ethnographic evaluation
 - Complete Political, Economic, Sociological, Technological, Legal and Environmental (PESTLE) analysis and update all relevant sections in this document
 - Credible markets include but are not limited to:
 - Healthcare settings
 - Police
 - Security forces
 - Hospitality
 - Education
 - Pull on KTP for information about market research they have completed

See also:

Competition, Customer, Market Potential

Materials

- Components
 - Printed Circuit Board (PCB)
 - Rechargeable batteries (Li-Ion)
 - Touch screen display
 - Fixture and fittings (anchor, screws etc.)
 - Chemical detector system
 - Internal electronics
 - Mouthpiece
 - Bamboo
 - Stiffened paper
 - Copper plated steel
- Injection moulded thermoplastic
- Software packages with licenses
- Packaging materials
 - Recycled cardboard
 - Ethically/ Sustainably sourced bamboo fibre and bagasse (sugar cane fibre)

See also:

Circular economy, Environment, Intellectual property, Quality testing, Packaging

Packaging

- Virus Detect will be packaged as per current alcohol breathalyser products (Packaging manager)
 - Packaged in recycled cardboard
 - Ensure branding is clear on packaging
 - Consumer should be able to re-fold packaging for return to organisation
- Packaging will contain
 - 1 Virus Detect device
 - 1 wired battery charger
 - 1 wireless battery charging pad
 - All consumer documentation
 - 1 protective cover
 - 1 lanyard/ wrist strap

- Future development should include a change of material from cardboard to bamboo fibre and bagasse (fully recyclable and re-usable with improved protection during transit)
- Bulk boxes should be utilised to send larger orders/ orders from the same location

See also:

Branding, Circular economy, Materials, Shipping

Performance

The performance of this Virus Detect is critical. From data collected as a result of the prototypes, the following performance target have been set:

- Chemical Detector System
 - Must detect viral particulates in parts per trillion (PPT)
- Product
 - From powered down, the device should be ready to use within 20 seconds as per breathalyser products
 - Total sample analysis should be complete within 20 seconds as per breathalyser products
 - Results should be displayed within 10 seconds of sample analysis, as per breathalyser products
 - A void sample should be displayed within 10 seconds of sample analysis, as per breathalyser products
 - When mouthpiece is removed and replaced, the next test should be ready to use within 20 seconds
 - Target 480 cycles per day
- Battery
 - Targeted standby battery life should be 36 hours
 - Targeted number of uses per fully charged should be 480 cycles
 - The device should be able to charge using 240v power supply both wired and wirelessly
 - Charging status of the battery should be clearly indicated on the touch screen display
 - Future models should incorporate fast charging technologies

See also:

Materials, Reliability, Shelf life and storage

Politics

Please add notes that may be relevant

Processes

- Process flow mapping to complete when manufacturing route is defined
- Ensure compliance with MHRA, FDA & EMA throughout
- Calibration process will be carried out by trained, competent Quality Technician
- Warehouse automated picking process to be established

See also:

Manufacturing facilities, Quality testing

Product cost

- Dependant on:
 - Material selection
 - Mouthpiece sample tube material/ supply
 - Cost of upgrading facilities
 - Packaging and shipping costs
 - Specialist processes required
 - Supply chain costs

To be complete following approval of product design brief document

See also:

Manufacturing facilities, Materials, Circular economy, Environment, Processes

Product life span

- To be determined on completion of Life in service, performance, quality and safety testing
 - Virus Detect product
 - Mouthpiece sample tube
 - Chemical detector system
- Product is not expected to have similar lifespan to breathalyser products (due to frequency of uses)

See also:

Life in service, Performance, Quality testing, Safety

Prototyping

- This stage is complete
 - MHRA, FDA and EMA certification granted as a result
 - Single circuit board (sourced fully assembled)
 - Injection moulded thermoplastic

See also:

Synopsis, Competition

Quality testing

- Chemical detector system accuracy
 - Must detect at low level concentrations (PPT)
 - Will be serviced and calibrated by a quality technician, at a frequency driven by data from prototype
 - Must be tested at a range of temperatures to ensure accuracy
- Product
 - Must withstand repeated drops from 'head height' (to be determined)
 - Surface finish must not degrade with repeated use (wear test method to be determined)
 - Branding must remain intact or be easily replaceable during service visits
 - Should be IP65 rated (BS EN 60529)
 - Anchor point for lanyard must withstand 10G repeatedly (drop and stop test)
- Mouthpiece
 - Must withstand wet, humid environments for a minimum of 120 seconds
- Follow BS EN ISO19001 – Quality Management System (QMS)

See also:

Aesthetics, Branding, Environment, Life in service, Maintenance & repair, Performance, Reliability, Standards and specifications

Quantity

- Year 1
 - 750000 units (maximum 480 cycles per day/ per unit)
 - 360 million mouth pieces to be manufactured from most suitable material
- Year 2 onwards
 - ~3 million units
 - 1.4 billion mouth pieces per annum

- Supply chain to ensure wrist strap/ lanyard supply is secure
- Supply chain to ensure protective cover supply is secure

Circular economy, Safety

Reliability

This is critical for Virus Detect to be successful

- Each consumer will require this device to be operational each time they require it
 - If unavailable, replacement Virus Detect device must be swift
 - Technical help must be available 24/7
- Full reliability study to be determined on completion of Life in service, performance, quality and safety testing
 - Virus Detect product
 - Mouthpiece sample tube
 - Chemical detector system
- Product must be more reliable than current breathalyser products

See also:

Life in service, Performance, Quality testing, Safety, Life in service

Safety

-
- Manufacturing Facilities
 - Ensure compliance to Health and Safety at Work Act 1974
 - Training must be available for all operatives
 - Risk Assessments RA must be complete for each manufacturing process
 - Personal Protective Equipment (PPE) will be determined from this
 - Standard Operating Procedures (SOPs) will be determined from this (higher risk tasks)
 - Each RA must be verified by team leader, unit manager and a Safety, Health and Environment (SHE) team member
 - Each SOP must be verified by team leader, unit manager and a Safety, Health and Environment (SHE) team member
 - Ensure compliance to Control of substances hazardous to health (COSHH) regulations
 - Training must be available for all operatives
 - Ensure all portable appliance testing (PAT) equipment is routinely inspected
 - Ensure suitable mitigation is put in place for all hazards arising from RAs

- Safe levels of stock holding are to be determined by warehouse manager
- Virus Detect
 - Touch screen display should be shatter proof
 - As a portable appliance, the device must be PAT tested
 - The device will have no sharp edges
 - The mouthpiece sample tube used should cause no harm to health
 - Must be tested under stress and strain (should not shatter or splinter, as this could cause a choking hazard)
 - Must be waterproof and dustproof to IP65 (BS EN 60529)
 - Physical envelope must be shatter proof (sharp edges could cause lesions)
- Documentation
 - The Electrical Equipment (Safety) Regulations 2016 implemented EU Directive (2014/35/EU)
 - WEEE regulations (2012)

Circular economy, Documentation, Maintenance & repair, Manufacturing facilities, Materials, Standards and specifications

Shelf life and storage

- See Product life span for information on shelf life
- Storage
 - Virus Detect should be kept in protective case at all times
 - The device must not be stored in direct sunlight
 - Stored at temperature that is within operating temperatures
 - Virus detect should not be kept on charge for over 12 hours at a time

See also:

Environment, Product life span

Shipping

- As this product will be sold internationally, new shipping routes will need to be determined.
- Shipping to:
 - United States of America
 - United Kingdom
 - EU countries
 - European countries (not in EU)

- Approval of Virus Detect is pending from Asia, Africa and South America, please establish these supply routes
- All Virus Detect products will be shipped from SME Carmarthen HQ
- Bulk boxes should be utilised wherever possible to ship multiple products to the same country

See also:

Packaging

Size

-
- As per current range of alcohol breathalyser products (example below)



- Approximately the size of a mobile phone (when sample tube is disconnected)
- Final product size to be defined in the product design specification on approval of this document

See also:

Aesthetics, Packaging, Shipping, Size

Social & cultural

-
- No known social or cultural factors affecting manufacture or use of Virus Detect
 - Feedback required from filed trial data

See also:

Market

Software

- Device Firmware as per breathalyser products
([TANGO_PCI_E_Application_V47pe.hex](#))
- Operating system – upgraded breathalyser software using [AVIAA v12.6.py](#)
- Compatible with:
 - Microsoft Windows 10 applications (PC)
 - IOs applications for all Apple iPads and iPhones
 - Mac OS application for Apple Mac
 - Android/ Linux devices
- As per breathalyser products, multiple languages should be available
- Future models should try to incorporate blockchain technology
- Device WiFi should allow remote access to technicians to diagnose issues

See also:

Branding, Documentation, Intellectual property

Standards and specifications

- As per breathalyser products:
 - BS EN 60529, Degrees of protection provided by enclosures
 - DIR 2004/108/EC Electromagnetic Compatibility (CE Marking)
 - BS EN ISO9001 – 2015 Quality Management System
 - BS EN 8001, Framework for implementing the principles of the circular economy in organizations
 - BS EN 61010-1 Safety Requirements for Electrical Equipment, Measurement, Control & Laboratory Use

See also:

Circular economy, Documentation, Quality testing, Safety

Supply Chain

- The organisation is developing new relationships with different suppliers. The following are currently most favoured:
 - Printed Circuit Board – China or Malaysia
 - Physical envelope – Carmarthen
 - Injection moulded parts - The United Kingdom (UK) or Europe are the currently most favourable
 - Mouthpiece sample tube:

- Stiffened paper – UK
- Copper plated steel – UK
- Bamboo – China/ India
- Packaging:
 - Recycled Cardboard – UK
 - Bamboo fibre and bagasse – China/ Australia
- To meet environmental targets, more work must be done to find more local suppliers
- The suppliers selected Virus Detect should be adhering to the ISO9001 standard.

See also:

Environment, Circular economy, Materials, Packaging, Shipping

Time scale

This is a key driver for the success of Virus Detect

- For this reason, the time scale can only be defined as, '**as soon as possible**'

Weight

- The weight of the product should be suitable to hold in one hand by a wide range of users (children to pensioners)
- The product should be approximately the weight of a mobile phone

See also:

Aesthetics, Packaging, Size

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