

DEVELOPING THE DESIGN BRIEF – A CORONOVIRUS CHEMICAL DETECTOR SYSTEM

ASSESSMENT B
ACPA 7006 - MANAGEMENT OF NEW PRODUCT
DEVELOPMENT
INTERNATIONAL INNOVATION MANAGEMENT



MANUFACTURE
ADVANCED
DESIGN
ENGINEERING

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Acronyms

Acronym	Acronym Description
BS	British Standards
CDS	Chemical Detector System
EN/EU	European
EUA	Emergency Use Authorisation
FDA	Food and Drugs Administration
ISO	International Organisation for Standardisation
KTP	Knowledge Transfer Partnership
NHS	National Health Service
NPD	New Product Development
PDB	Product Design Brief
PDS	Product Design Specification
R & D	Research and Development
WHO	World Health Organisation

Document Information

This document is the PRODUCT DESIGN BRIEF for Project Chemical Detector System (CDS).

Document Classification: CONFIDENTIAL – CATEGORY C1

Document Storage: This document and associated reference documentation will be handled in line with the companies [Data Management Procedure \(PROC DM001\)](#), and will be stored in the following network location:-

S DRIVE >> PROJECTS >> NPD >> PROJECT CDS >> 01: PROJECT DOCUMENTATION >> DESIGN >> PDB

The above link can be accessed via the company's Business Management System (BMS).

Due to the confidential nature of this document, access to the above network drive is strictly controlled and only granted to permitted staff members. Access can be requested via the IT team, once approval by the companies NPD Manager has been authorised.

Document Control

Document Title	Product Design Brief – Project Chemical Detector System (CDS)
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Table 1 - Document Control

Version Control

Document Revision	Date Modified	Updated By	Summary of Changes
1.0	May 2022	Harish Rama (NPD Manager)	Initial Issue of Document

Table 2 - Version Control and History

An updates to this document from the last released version will be summarised in Table 2 above. All changes made will be highlighted in red ink.

PRINTED COPIES OF THIS DOCUMENT, SHOULD BE HANDLED IN A CONTROLLED MANNER, IN ACCORDANCE WITH OUR COMPANIES POLICIES AND PROCEDURES.

Reference Documents

Document Title	Document Reference No
Data Management Process	DM001
Supply Chain Management	SC001
Marketing Strategy	MR001
Company Branding	BR001
Commercial Process	CM001
Project Financials	FIN001
Business Case	BC001
Sales Document	SAL001
Sustainability policy	STB001

Table 3 - Reference Documents

Synopsis

This document has been created, as the Product Design Brief for Project Chemical Detector System (CDS). Project CDS has been launched at our Carmarthenshire facility and focuses on the development of a new product, for the detection of viruses and other organic materials. The hand held, portable device will target both clinical and personal use, and will be formed using our patented Chemical Alcohol Detector technology (currently utilised in our range of breathalyser products).

Through working closely with a local University via a Knowledge Transfer Partnership (KTP), the opportunity to extend our CDS technology for detection of viruses/other organic materials has now been validated

Following on from successful laboratory trials, prototyping and filing of patent applications, next steps for this project involves bringing the product to the market. This design brief will facilitate the process of bringing this new product into existence and will serve as the initial touch point for all of our company's managers. The aim of the document is to provide all functions with information on where their input and insight will be required.

This product will be marketed as a high performing, lightweight, reliable and accurate device that is portable and easy to use. The individual elements of the product will be sourced externally (electronics, mechanical parts, casing), before being assembled, tested, packaged and shipped at our Carmarthenshire site. Product quality must be of the highest level, to ensure our reputation as a company is maintained, whilst also securing product sales in future markets. In line with the current Coronavirus pandemic, demand for this product will be significant; therefore, it is essential the product enter the market as soon as possible (expected sales of 3,000,000 units in year 2).

All of the key aspects, required for consideration during the design of this new product are captured within this brief. This includes consideration to externally sourced elements of the product, through our global supply chain. The layout of this brief outlines each aspect in alphabetical order, as opposed to using a hierarchal structure. The aim of this is to provide a structured framework, for the users of this document. Each aspect outlined in this brief is a critical part of the New Product Development (NPD) process and requires equal consideration in terms of priority.

This document is intended to be viewed electronically and therefore makes use of an interactive contents page and clickable hyperlinks. Cross-references have also been included throughout this document, to highlight key dependencies between aspects of the design brief.

This document is formally controlled, in line with the companies Data Management process. It makes use of both version and revision control, and requires formal sign off and approval, prior to release. An updates made to this document from the last released version will be summarised and all changes will be highlighted in red ink. It is expected that this document will be updated frequently during the NPD process, and ultimately support the creation of the Product Design Specification (PDS) (*Mumby, 2022*).

Aesthetics

Product Aesthetics should reflect a precise, intelligent, durable, sophisticated, quality product. An aesthetics workshop(s) shall be held with our design partners and focus group users, to investigate the following:-

Colour

Product colour section must be in accordance with the company's corporate branding policy (BR001).

- Colour selection should be consistent with our existing product range (breathalyzers).
 - Review colour temperature, value, brightness, saturation and hue (**Stipe, 2022**).
- The selected colour scheme of this products should reflect the medical nature of this device, for **clinical** and **personal** use.
- Colour selection and application methods will need to withstand the [product life in service](#) requirements.
 - Ensure cleaning/sterilization methods do not affect product colour.
 - Consider the impact of radiation on colour (hospital settings)
 - Consider effects of the [environment](#) on the perception of product colour (medical lighting)
- Master samples of colour swatches shall be obtained during the selection process.
Consider the cost implications of each colour and its application process.
 - Final master samples shall be signed off by the design house and branding manager.
- There is a significant future market for our product in Europe/Asia.
 - Colour selection should involve cultural considerations – certain colours denote negativity. (**Tidd and Bessant, 2018**)
- The selected colour shall be easily applied on future products.
- Colour selection will be supported through prototypes/focus groups.

Finish

- The product finish should reflect a sleek and sophisticated, high quality product.
- The product will require a smooth ergonomic finish that allows ease of cleaning/sterilization.

Form

- The form of this product will be consistent with our existing products and shall make consideration to future products.

Shape

- Product shape should support a portable, hand held device.
- Product shape should allow for ease of device storage, packaging and transportation.

Touch and Feel

- The product aesthetics should make the user feel calm (neutral colours) (**Stipe, 2022**).

“Most medical products currently/historically use greens, blues and colours in the neutral space of whites/greys. Blues and greens are calming colours, which is what you want in the anxious environments of hospitals and clinics”. (Stipe, 2022).



Figure 1 - Example Colour Scheme (Stipe, 2022)

- Ensure the product has no sharp edges.
- The product must feel smooth to touch (no unusual textures).
- Consider the touch application of the product (buttons/touch screen display).
- Ensure the product does not make use of any exterior materials, colours, paints or finishes that could harm the user (close proximity of product to user's mouth).

Differentiation from Competitors

- Ensure the product is sufficiently different from any of our competitor products.

Consideration will be made to Human Engineering factors, for all aesthetic considerations (**Trott, 2016**).

CROSS REFERENCES

- [Ergonomics](#)
- [Life in Service](#)
- [Manufacturing Facilities and Systems](#)
- [Materials](#)
- [Product Cost](#)
- [Quality](#)
- [Weight](#)

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Branding

Branding of this new product should ensure alignment with the companies branding across our existing products.

Company Values and Ethos

- There is a need to create a strong and positive perception of our company (**Oberlo, 2021**), as one that focuses on:-
 - Product Quality, Accuracy and Reliability
 - Strong Customer Service
 - Safety
 - Sustainability
 - Improving the quality of life of our users.
- Our **Mission statement** should be considered during the design of this product.
- Ensure branding conveys a **consistent theme** across our product ranges.
- Ensure branding is **consistent with the marketing** of this product and all marketing communications ([Refer to Marketing Strategy document MR001](#)).

Logo

- The company's **logo** must be applied on the product, spareable parts, the carry case, associated packaging and documentation.
- Consider application of the company's logo on the device start screen.

Refer to the companies [Branding Policy \(BR001\)](#) for additional information on Branding.

CROSS REFERENCES

- [Packaging](#)
- [Performance](#)
- [Maintenance and Repair](#)
- [Sustainability](#)

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Circular Economy and Sustainability

The end-to-end product life cycle of the CDS product must take into account circular economy considerations, (company's values and ethos).

Product Design

- Ensure product design is completed in line with the 3R's (Recycle, Re-use and Reduce) (**Satell, 2017**).
- Product design must consider design for disassembly/decommissioning.
- Ensure materials selected for use on the product and its **packaging** are fully recyclable where possible (aim for 100% recyclable materials)
- Where recycling is not possible, consider the use of biodegradable materials.

Product Manufacture and Assembly

- Injection moulded parts used for the mechanical element of the detector, must be fully recyclable.
- Investigate the carbon footprint associated with sourcing of injection moulded plastic components from the supply chain vs sourcing the moulding separately.

Supply Chain and Logistics

- Consider carbon footprint with a view to minimising the cradle to grave carbon lifecycle.
- Pay particular attention to the decommissioning of product batteries/electronic components.
- Ensure components cause no damage to the environment when sourced/disposed.

Refer to the companies [Sustainability policy](#) for additional information. (STB001).

CROSS REFERENCES

- [Branding](#)
- [Product Cost](#)
- [Life in Service](#)
- [Maintenance and Repair](#)
- [Manufacturing Facilities and Systems](#)
- [Performance](#)
- [Safety](#)
- [Supply Chain](#)

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Company Constraints

There is a need to review and discuss the constraints of our company's current practices.

Research and Development

- Research and Development (R&D) into this product will be facilitated through a University KTP.
- Consider recruitment of staff with knowledge of the medical sector/development of products in this sector.
- Investigate competitor R & D.
- Focus group

Financials

- A considerable budget has been allocated to PROJECT CDS, however consider the following funding routes:-
 - Crowd Funding
 - Government Subsidies/Grants in R & D
 - Phased payment approach with suppliers to support cash flow.
 - Additional KTP's.

Manufacture and Assembly

Investigate constraints linked to manufacture/assembly.

- Ensure co-development between all partners:-
 - **Casing** – London
 - **Electronics** – China/Malaysia
 - **Moulded Plastics** – Europe
 - **Assembly** – Carmarthenshire
- **Production Facility and Resources**
 - Is the facility floor plan sufficient to meet the needs of the assembly process?
 - Is there sufficient capacity, to ramp up production, to meet the rate of 3,000,000 units in year 2?
 - Do we have all the relevant skilled staff to support assembly?
 - Do we have sufficient machinery and tooling to support assembly?

Certification and Approval

- Are there any additional constraints linked to product regulatory requirements or certification (Certification already gained).

In Service Support

- Are we enabled to provide in-service support?
- Are agreements required to be in place with our partners, for in- service support?

CROSS REFERENCES

- [Product Cost](#)
- [Ergonomics](#)
- [Manufacturing Facilities and Systems](#)
- [Supply Chain](#)

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Competition

A thorough analysis of competitors and their products must be carried out. This will include sourcing competitor products for reverse engineering and reviewing competitor literature.

Technology

- Competitors have made use of various technologies, to solve the problem of virus testing, to date:
 - Saliva testing methods
 - Lateral Flow/PCR Testing
 - Blood Testing
 - Anti-Body testing

IP/Patents

- Consider competitor IP and patents, to avoid legal implications associated with the design of our product.

Market Share

- A thorough investigation of the market for virus detector products must be carried out.

Key Competitor Products

- **Cue Health – Portable Covid-19 Diagnostic Test Kit (Cue Health, 2022)**
 - American based health care company has developed a Covid-19 detector, which combines accuracy, ease of use and speed.
 - Device fits into the palm of the users hand and provides results via an app.
 - Product makes use of a saliva testing and provides lab quality results (97.8% accuracy) within 20 minutes.
 - Device requires change of cartridge, after each use. Cartridges have a limited shelf life.
 - Product is Food and Drug Association (FDA) certified **(Cue Health, 2022)**.



Figure 2 - Competitor Product - Cue Health Covid-19 Test Kit (Cue Health, 2022)

- **ID NOW – Portable Covid-19 Virus Detection Machine (*ID Now, 2022*)**
 - US based product, which delivers test results in 5 minutes.
 - Device is portable, but not hand held.
 - Device uses a molecular technology, to produce test results via saliva based testing.
 - This system does not use cartridges, but requires sterilization after each use.
 - Approved and certified by the EUA (Emergency Use authorisation) (*ID Now, 2022*).



Figure 3 - Competitor Product - ID Now Covid 19 Detector (*ID Now, 2022*)

Product Differentiation

- Ensure there is sufficient differentiation from competitor products.
- There is currently no virus detector product on the international market, that does the following:-
 - Performs virus detection through a breath specimen.
 - Is hand held and portable
 - Works without the need for cartridge replacement
 - Provides accurate results that can be stored electronically and viewed in real time or retrospectively

CROSS REFERENCES

- [Aesthetics](#)
- [Branding](#)
- [Product Cost](#)
- [Ergonomics](#)
- [Intellectual Property](#)
- [Legal](#)
- [Supply Chain](#)

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Compliance

This new product will be primarily used for virus detection by medical clinicians, alongside personal use at home.

Regulations, Directives and Initiatives

Compliance with the following regulations, directives and initiatives is therefore required (**Mumby, 2022**).

- General Product Safety Directive 2001/95/EC (**European Commission, 2021a**)
- Product Liability and Safety Directive 85/374/EEC (**Freeman, 2021**)
- In-vitro Diagnostic Medical Devices Regulations (EU)2017/746 (IVDR) (**European Commission, 2022**).
- Medical Devices Directive (EU) 2017/745 (**European Commission, 2016**).
- Measuring Instrument Directives 2014/32/EU (**National Standards Authority, 2022**)
- Radio and Telecommunications Equipment Directive 2014/53/EU (**European Commission, 2014**)

Other directives require consideration, in line with our company's core principles, ethos, brand and long-term goals around sustainability.

- EU emissions Trading Systems Directive (**European Commission, 2021b**)
- The Batteries Directive 2006/66/EU (**European Commission, 2019**)
- Waste from Electronic components directive (**European Commission, 2012**)

Regulatory Bodies and Authorities

Compliance with criteria from regulatory bodies/authorities also requires consideration. Approval from the following bodies will be essential.

- World Health Organisation (WHO)
- The National Health Services (NHS)
- US Food and Drug Administration (FDA)

Sales Regulations

There is great potential to sell this device internationally.

- Research will need to be completed, to ensure compliance to specific regulations in all of the countries and markets of sale:-
 - Europe
 - Asia
 - USA
 - UK

CROSS REFERENCES

- [Branding](#)
- [Life in Service](#)
- [Maintenance and Repair](#)

- [Performance](#)
- [Safety](#)
- [Supply Chain](#)

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[Customers and Markets](#)

[Initial Customer Base](#)

The product we are developing is required to meet both clinical/personal requirements for virus detection. In line with this, our target customers for the device are:

- **Medical Clinicians - Testing patients prior to administering medical care/treating patients with illnesses.**
 - Nurses/Doctors/Paramedics/GP's
 - Dentists
 - Healthcare workers
 - Covid-19 Test Centre Staff
- **Members of the General Public – Use of the CDS product for personal testing or testing of family and friends.**

[Future Customers and Markets](#)

Despite focusing on the above customer sectors initially, there is scope for extending our footprint in other markets. Market Research, coupled with use of tools such as the Empathy Map and Customer Valuation Proposition Canvas (**Harris, 2022**) has indicated a requirement for this product in the following sectors:-

- **Travel Sector** – Screening prior to travel.
 - Use at Airports and borders, by Airlines, Ferries, and Cruise Ships etc.
 - This is particularly appealing, due to the forecasted growth in air travel over the next 15 years (**Airbus, 2021**).
- **Events Sector** – Virus screening to facilitate attendance to large events, such as concerts.
- **Sporting Sector** – Virus screening for large sporting events.
- **Education Sector** – Virus screening at Universities, Schools and Colleges.
- **Government Organisations** – Use in government organisations such as the Military and Police.
- **Business Sector** – Screening for large office spaces.

In order to future proof our customer base, it is essential that the technology used and developed in this CDS product is also adaptable, to detect future viruses and support any new pandemics.

- A full analysis of market constraints, for each of the above future markets will be conducted.

CROSS REFERENCES

- [Performance](#)

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Disposal and Recycling

Sustainability is one of our core values, therefore product disposal and recycling are key considerations.

- Ensure product design is in line with the 3R's (Recycle, Re-use and Reduce).
- Product design must consider design for disassembly/decommissioning.
- Ensure materials selected for use on the device and its **packaging** are fully recyclable (aim for 100% recycled materials)
- Where recycling is not possible, consider the use of biodegradable materials.
- Carbon footprint reduction shall be considered at all levels of the product lifecycle.

Refer to the company's [sustainability policy](#) for additional information (STB001).

CROSS REFERENCES

- [Circular Economy](#)

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Documentation and Manuals

Development of this product requires creation of various documentation and manuals. All documentation created shall be generated and approved formally.

The following documentation will need to be supplied with the packaged product, at the point of sale:-

Product Information

- Product Manual
- Key Product Information sheet (Serial no.)
- Customer Quick Start Guide
- Warranty Information
- App Download/Usage Instruction Sheet
- Troubleshooting Guide
- Safe Usage Guidelines

Product Maintenance and Repair

- Maintenance manual
- Software update guidelines
- List of spare parts and sourcing
- Approved repair/maintenance vendors

Company Information

- Company Information with link to website
 - Information around our full range of products
- Consider the use of providing documentation electronically (website links/apps), to avoid cost and reduce wastage.

CROSS REFERENCES

- [Performance](#)
- [Life in Service](#)
- [Maintenance and Repair](#)

[RETURN TO CONTENTS PAGE](#)**Environment**

An investigation into all aspects of the products likely environment will need to be considered.

Product Environment - In Use (Operational)

- **Temperature** - The product must withstand operation in a temperate range of -10C to 55C.
 - This will enable the product to be sold in global markets, where temperatures can reach extreme highs and lows.
- **Pressure and Humidity** – An investigation shall be made into acceptable pressure/humidity ranges.
- **Impact/Shock Loading** – The device must be able to withstand a uniform impact loading force of 3N, which equates to the user dropping the device from a height of 2m ([Refer to Testing and Calibration section](#)).
- **Cyclic Loading** – The device must withstand cyclic loading of up to 10,000 cycles, before failure. (10,000 on/off cycles including operation of buttons and display)
- **Ingress** – The device must be fully sealed to ensure there is no damage by dirt, dust and water.
- **Sanitisation** – The nature of this device means regular cleaning and sanitisation is required. Ensure the device and its appearance does not become damaged when sanitized.

Product Environment - Manufacture, Assembly, Storage, Transportation, Display

A full investigation shall be made into the environment the product will encounter during the stages listed below:-

- **Manufacture** – exposure to range of cutting fluids, fluxes etc.
- **Assembly** – exposure to human workforce.
- **Storage** – exposure to elements in the warehouse.
- **Packaging** – exposure to human workforce.
- **Transportation** – exposure to weather elements (rain, snow, etc.)
- **Display** – exposure to customers viewing the product.

CROSS REFERENCES

- [Performance](#)
- [Life in Service](#)
- [Maintenance and Repair](#)
- [Safety](#)

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Ergonomics

This aim of this product is to be an easy to use, portable, hand held device. The following user considerations will be required:-

- **Buttons** – The device will require buttons to be operational. Consider the following characteristics, to ensure button usage is pleasant:-
 - Location/Position on device
 - Feel
 - Size
 - Feedback (When pressed).
 - Colour
 - Hand/Finger room around buttons.
- **Display Panel** – The device will require a panel, to display results. Evaluate the following:-
 - Location/Position on device (For ease of reading test results).
 - Backlight options
 - Visibility - Panel Brightness, contrast and resolution must be modifiable.
 - Consider the use of a touch screen display, as opposed to buttons.
 - Display Text size – Device must allow for text size to be increased/decreased.
 - Language – The device must be operational in various languages (English, Welsh, French, Spanish, Hindi, and Japanese).
- **Sound**
 - Audio warnings – positive test results
 - Low battery warnings
 - Start-up/shut down tone
 - Adjustable device volume
- **Casing**
 - Handling – easy to hold
 - Portability – easy to transport.
- **Mouth piece**
 - Attachment/Detachment.
 - Sanitization/sterilisation.
 - Maintenance – easy to replace.
 - Proximity of mouth piece to device
 - Feel of mouth piece
- **Other**
 - Software Updates
 - Access to historic test data

CROSS REFERENCES

- [Product Cost](#)
- [Compliance](#)
- [Documentation and Manuals](#)
- [Intellectual Property](#)
- [Legal](#)
- [Life in Service](#)
- [Manufacturing Facilities and Systems](#)

- [Maintenance and Repair](#)
- [Performance](#)
- [Size](#)
- [Weight](#)

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[Installation and Production Registration](#)

A detailed analysis will need to be conducted into product installation and registration.

[Installation](#)

Despite being a portable product, there is potential to install this device in fixed locations at hospitals, covid test centres and in other settings such as schools.

- Analyse methods of installation that would allow this device to be used in fixed locations.

[Registration](#)

- A route for customer product registration will be required, via the company's website (use of the product serial no.).
- Product registration shall be used to activate the products extended warranty.
- Product registration will be used to access historical test data (option for this to be sold as a separate service).
- The company website will be used for product software updates (via secure portal).

CROSS REFERENCES

- [Compliance](#)
- [Documentation and Manuals](#)
- [Legal](#)
- [Life in Service](#)
- [Maintenance and Repair](#)
- [Performance](#)

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[Intellectual Property](#)

The companies NPD team shall complete a thorough review around Intellectual property (IP). This will ensure this product does not infringe any existing patents/IP.

- Review of product design against existing patents.
- Review of competitor trade marks
- Registering any newly developed property as a trade mark (*USPTO, 2022*).
- Filing of new global patents for novel features, technologies or designs developed for this product.

Development of this product, involves working with the local University via the KTP. Clear guidance on the ownership of any IP developed as part of the KTP, is required, contractually.

CROSS REFERENCES

- [Compliance](#)
- [Competition](#)
- [Legal](#)
- [Performance](#)

[RETURN TO CONTENTS PAGE](#)**Legislation and Legal**

All relevant legislation and legal requirements must be fully adhered too, during the cradle to grave lifecycle of this product.

Further analysis will be required around the following:-

Data Protection

- General Data Protection Regulation (GDPR) Legislation
- Data storage and management, including use of cloud based storage systems.

Trade

- Import and export laws
- Export control
- Trade tariffs, embargos and fees
- Supply chain contracts, terms and conditions

Financial

- Financial legislation around accounts, tax payments, profit declarations etc.

Product Performance

- Production Liability Directive 85/374/EEC (**Freeman, 2021**).
- Product safety legislation.
- Product warnings
- Product warranty legislation.
- Company Insurance.

CROSS REFERENCES

- [Compliance](#)
- [Intellectual Property](#)
- [Supply Chain](#)

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Life in Service

The following items will need to be considered, for the product, during its life in service.

- The device shall perform 10,000 individual refer cycles, prior to any component failure.
 - This will ensure the device performs in clinical settings, where usage is likely to be high.
 - Analysis shows, that the device may be used up to 50 times per day in clinical settings.
- The device battery shall be sufficient to last for 50 individual testing cycles, before re-charging is required.
- A safe usage notice shall be included within the products manual, to manage user expectation (battery life).
- A study of the product mouthpiece will be required, to ensure this part meets all life in service performance requirements.
- Device calibration (Chemical Detector System) will need to be investigated, to ensure this can be done, whilst the product is in service.
- Options to perform in-service software updates, shall be considered.

CROSS REFERENCES

- [Performance](#)
- [Shelf life and Storage](#)
- [Shipping and Transportation](#)
- [Supply Chain](#)
- [Maintenance and Repair](#)
- [Quality](#)

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Maintenance and Repair

Regular maintenance and/or repair is not desirable.

Maintenance

- The product will be designed for maintenance free operation.
 - A fully sealed and tamper proof casing will enable this.
- Consider the shelf life of the CDS used within the product and maintenance/calibration of this ([See Testing and Calibration](#)).
- Maintenance information shall be included on our website.

Repair

- A list of approved repair workshops, shall be provided to the customer. This shall also be made available on the company website.
- Warehouse space will be required for spare parts provision.
- Any faulty devices will be replaced for new, during the warranty period.

CROSS REFERENCES

- [Compliance](#)
- [Performance](#)
- [Legal](#)

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Manufacturing - Processes, Facilities and Systems

This development of this new product should make use of existing manufacturing processes, facilities and systems, wherever possible.

Facilities and Systems

- Consider the use of our existing Carmarthenshire facility for Production. This will be facilitated through:-
 - o A review of site suitability, for the assembly of this new product.
 - An assembly area of 400 sq. ft. will be required.
 - o A Review the current load within this facility vs capacity.
 - o A shop floor layout analysis.
 - o Review of existing machinery and tooling
 - o Review of staff skill sets (use existing labour)
 - o A review of storage
 - o Review of the logistics team capacity
 - o Review of transportation and shipping routes
- In line with expected volumes, the facility will require capacity to ramp up production in year 2 (3,000,000 units expected to be produced).
 - o Review the use of two production lines or multiple shifts
 - o Consider out-sourcing all/part of the assembly work.
 - o Consider the production and provision of spareable/maintenance parts (clinical usage devices will require up to 6000 mouthpieces per year).
- Review the use of potential new facilities, as a contingency.

Processes

All special processes required should be carefully defined and documented.

Consider the following:-

- Special processes linked to the products electronic components
 - o Soldering, wiring and cable routing.
- Special processes for sealing the product.
- Special processes required for testing of the product.
- Other relevant processes should be investigated.

It is essential all special processes comply with the relevant standards (British standards etc.).

CROSS REFERENCES

- [Materials](#)
- [Supply Chain](#)

[RETURN TO CONTENTS PAGE](#)**Materials**

An in-depth material study will need to be considered for all elements of the product. Evaluate the following:-

- **Casing**
 - Thermoplastics
 - Review a range of plastics
 - Consider grade of plastic against performance requirements
 - Consider formability
 - Consider cost and material availability
- **Buttons**
 - Assess options for buttons
 - Plastic preferable
- **Mechanical Parts**
 - Injection moulded parts
 - Consider various plastics for injection moulding
 - Consider moulds required and cost
 - Consider time and effectivity of moulding process
- **Electronics**
 - Review electrical component needs for this product
 - Consider availability of electronic components
 - Consider dual sourcing options
- **Mouth piece**
 - Paper, plastic or metal
- **Display**
 - Evaluate screen options vs performance requirements
 - Review the use of a touch screen vs buttons
- **Battery**
 - Battery selection should meet performance needs
 - Consider disposal of the battery including battery acid
- **Packaging**
 - Select environmentally friendly packaging materials that meet packaging performance needs
- **Transportation**
 - Evaluate all materials required for transportation
 - Transportation media – crates, pallets, forklifts etc.
- **Assembly/Manufacture Materials**
 - Consider use of sealants, fluxes and fluids etc.
 - Review the use of assembly materials such as tooling, fasteners, washers etc.

For all of the elements and materials outlined above, a study will also need to be conducted into the following (*Tidd and Bessant, 2018*):-

- Material properties (strength, weight, durability)
- Material standards (ISO, BS, DIN, ASTM etc.)
- Material specifications/grades
- Material processes
- Material sourcing agreements, lead times and availability

Ensure there is no use of corrosive materials, or those than can be harmful for the customers of this device, during usage or decommissioning.

CROSS REFERENCES

- [Compliance](#)
- [Product Cost](#)
- [Environment](#)
- [Life in Service](#)
- [Maintenance and Repair](#)
- [Packaging](#)
- [Performance](#)
- [Safety](#)
- [Standards, specifications and tolerances](#)
- [Supply Chain](#)

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Packaging

This product will need to be sufficiently packaged to avoid damage in storage, transit and usage.

- The packaging solution for the product must have a NTE weight of 400g
- Product Packaging must be sufficiently rigid, durable and shockproof, to withstand impacts and exposure to elements such as rain water, corrosion and salt water.
 - Drop testing will be required against multiple drops from a height of 2m on a range of surfaces.
 - Water ingress testing will be required on the packaging.
- Packaging must be consistent with the company's branding.
- Highlight the products Unique Selling Point (USP) on the packaging.
- Perform a trade-off study against internally supplied packaging/out sourcing.
- Consider re-use of packaging designed for the company's breathalyser products.

CROSS REFERENCES

- [Branding](#)
- [Compliance](#)
- [Product Cost](#)
- [Disposal and Recycling](#)
- [Performance](#)
- [Sustainability](#)

- [Testing](#)
- [Weight](#)

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[Performance](#)

The following performance targets have been set:-

- **Start Up** – This product must be ready to function, within a 30-second period from being powered on.
- **Accuracy** – The device shall detect viruses and other organic substances, to a high level of accuracy.
 - Detection must be possible for a specimen sample, with a viral load of 0.1% or greater.
 - The user shall be notified of an invalid breath specimen, within 10 seconds of sample collection (audio warning/message).
- **Reliability** - This product will function to a high level of accuracy (1 false test in 1,000 permitted).
- **Speed** – The device must provide the user with accurate test results, within 45 seconds of sample collection.
- **Calibration** – The device must notify the user, when calibration is required (message on display).
- **Durability** – The device must be sufficiently robust, to withstand a uniform impact loading force of 3N.
- **Battery** – The product must have a suitable battery that provides sufficient power for the product to function.
 - **Battery Capacity** – Battery life must ensure the device is powered for a minimum of 50 test cycles, from full charge.
 - **Charging** – The battery must be able to be regularly charged. Charge time should be from 0 to 80%, within 4 hours.
 - **Battery Life** – The battery must be sufficient to be fully charged and drained 1,000 times (1,000 full charges x 50 test cycles per charge = 50,000 tests per battery).
 - **Battery replacement** - should be designed for specialist replacement only.
- **Memory** – The device must have sufficient memory to allow users to review historical test data:-
 - Review results of the last 25 tests, on the device.
 - Review results of the last 100 tests, via connection to a PC - consider USB/Bluetooth connection.
- **Software** – Device software must be compatible with software updates, via the company's website or app.
- **Display** – The display must be sufficiently legible, to display test results and other relevant messages.
 - A minimum character length of 30 characters is required to be displayed
 - Display size must vary between types 8 to type 16 size font.
 - A touch screen display shall be considered.

CROSS REFERENCES

- [Compliance](#)
- [Product Cost](#)
- [Materials](#)
- [Supply Chain](#)

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Political, Social and Cultural Considerations

Political, social and cultural considerations need to be made around this new product and its introduction into global markets.

Political

- Local governments stance on Covid-19 virus testing varies, based upon political parties in power (both UK and overseas).
- Closely monitor the ever-changing covid restrictions globally, including Covid passports and travel certificates.

Social

- Social acceptance of regular virus testing and detection will be required.
- Consider implications of anti-vaxers and conspiracy theorists on social acceptance of the product.

Cultural

- Acceptance of virus testing is not acceptable in some cultures (stigma around testing).
- Consider the impact of product design characteristics on some cultures (e.g. colour connotations) (*Satell, 2017*).

CROSS REFERENCES

- [Aesthetics](#)
- [Customers](#)
- [Compliance](#)

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Pricing

Detailed information around product pricing can be found in the PROJECT CDS business case document (BC001).

Pricing is strictly confidential and will vary, based on the products market.

Pricing – Personal Use

- A finalised retail price for the product, for personal use, will be made in the Product Design Specification.
 - Estimated costing will be used to determine the product retail price. This will be completed through analysis of the product Bill of Materials (BoM).

Pricing – Clinical Use

- Pricing for the product in the clinical sector will be managed by the Sales and Business Development Teams and will be generated in line with customer contracts.
- All customers will be required to keep pricing information confidential through Non-Disclosure Agreements (NDA).

Pricing – International Markets

- Foreign exchange rates will need to be considered/tracked.

CROSS REFERENCES

- [Aesthetics](#)
- [Ergonomics](#)
- [Customers](#)
- [Performance](#)
- [Product Cost](#)
- [Materials](#)

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Product Costs and Target Costs

Product cost will need to be evaluated vs price, to ensure target margins are met, as per the business case (Refer to BC001).

- **An initial target unit cost £20 has been established (based on our previous products/historical data).**
- A full review of competitor costs is required.
- This cost will be regularly reviewed as design evolves.
- The PDS document will contain the final approved cost.

CROSS REFERENCES

- [Aesthetics](#)
- [Competition](#)
- [Ergonomics](#)
- [Intellectual Property](#)
- [Maintenance and Repair](#)

- [Manufacturing Facilities and Systems](#)
- [Materials](#)
- [Performance](#)
- [Safety](#)
- [Standards, Specifications and Tolerances](#)
- [Supply Chain](#)

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[Product Life Span](#)

- This new product is likely to remain in production, for a minimum of 5 years after its launch in 2023.
- Sales have been forecasted for years 1 and 2. ([Refer to quantity and volume section](#)).
- The product is likely to continue to be a marketable entity, as part of a wider product range, for the next 15 years. This is based on future development of its core technologies (refer to Customers section).
 - It is essential that the technology used and developed in this product is adaptable, to detect future viruses.
 - There is scope for extending our footprint in other markets.

CROSS REFERENCES

- [Compliance](#)
- [Performance](#)
- [Maintenance and Repair](#)

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[Prototyping](#)

Prototypes shall be used throughout the design phase of this project.

- **Concept Stage** - Initial Prototypes used, to down select product concepts
- **Detailed Design Stage** – Prototypes used to aid the detail design of elements of the product.
- **Final Design Stage** – A series of full scale prototypes, to test the final design solution, prior to product manufacture.

A focus group of target users will test all prototypes, in order to aid the consumer feedback process.

CROSS REFERENCES

- [Aesthetics](#)
- [Ergonomics](#)

- [Performance](#)
- [Testing and Calibration](#)

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Quality and Reliability

Quality Considerations

- Image and reputation will be a big driver for sales of this product, therefore no compromise on product quality is permitted.
- The product must have a smooth and sleek, professional finish ([Refer to Aesthetics section](#)).
- The end-to-end manufacturing process will require analysis, to ensure maximum build quality.
- Testing will be completed, to ensure product quality, prior to launch.

Reliability Considerations

- Product reliability is a mandatory requirement of this product.
- Virus test results provided by the product should have a very high reliability rate (only 1 false result in 1,000 tests is permitted).
- The device must notify the user when calibration/maintenance is required.

CROSS REFERENCES

- [Aesthetics](#)
- [Branding](#)
- [Ergonomics](#)
- [Materials](#)
- [Prototyping](#)
- [Testing and Calibration](#)

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Quantity and Volume

Demand for this new virus detector product is expected to be significant:-

- 750,000 units are required in year 1
- 3,000,000 units are required in year 2

In order to meet these volumes and ramp up in demand, review the following:-

- Manufacturing/Assembly Facility Space
- Work force availability (skilled labour)
- Assembly process automation
- Component/part/material availability
- Tooling (Temporary/permanent tooling)
- Cash flow/working capital

- Storage of finished goods and components
- Transportation/Freight

CROSS REFERENCES

- [Materials](#)
- [Performance](#)
- [Product Cost](#)
- [Manufacturing Facilities and Systems](#)
- [Supply Chain](#)
- [Shelf Life and Storage](#)
- [Shipping and Transportation](#)

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[Safety](#)

This product must be designed with safety in mind, to ensure the user is safe. It is expected that the product will be used by young adults **aged 16 and above.**

[Product Safety](#)

Product safety must be ensured through the following:-

- Avoid use of corrosive, irritant or hazardous materials.
- A fully sealed and tamper proof CDS.
- Use of zero small parts/zero easily detachable parts (choking hazard)
- Design of a child friendly mouthpiece.
- Design of a childproof battery compartment.

[Other Safety Considerations](#)

- Use of relevant PPE, for all colleagues.
- Lifting plans.
- Waste management (safely dispose of hazardous materials)

CROSS REFERENCES

- [Performance](#)
- [Materials](#)
- [Sustainability](#)
- [Testing and Calibration](#)

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Shelf Life and Storage

The shelf life of this new product and its associated components will need to be analysed, tested and documented.

Consider the following:-

- Shelf life of the CDS element (when will the CDS become ineffective?)
- Review the shelf life of the detachable mouthpiece (material dependant – paper, plastic or metal).
- Battery shelf life shall be considered (battery acid can become corrosive).
- Investigate the effect of storing the product for long periods (without use).
- Consider the impact of storage of the product (warehouse environment).
 - o The product battery shall be activated upon first use.

CROSS REFERENCES

- [Performance](#)
- [Shipping and Transportation](#)
- [Prototyping](#)
- [Testing and Calibration](#)

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Shipping and Transportation

Shipping and Transportation routes will need to be established for this product, globally.

Review freight options for 750,000 units in year 1 and 3,000,000 units in year two.

- Analyse all modes of freight (sea, air and road).
- Consider shipping options for one off orders (personal use) and bulk orders (clinical).
 - o Ensure fully packaged products, fit into standard sized shipping containers/pallets (ISO standards).
 - o Estimated weight of one ready to ship, fully packaged product, shall be no more than around 2.5kg.
 - o A maximum of 100 fully packaged products, shall be stored on standard size pallet (250kg weight).
- Investigate shipping and transportation of spareable parts.
- Shipping routes will need to be established for the return faulty items (under warranty).

Note: There is currently a global delay in shipping and freight, due to the Covid-19 pandemic. Considerations shall be made in line with this.

CROSS REFERENCES

- [Life in Service](#)
- [Packaging](#)
- [Materials](#)
- [Product Cost](#)
- [Shelf Life and Storage](#)

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Size

Product size should be consistent with similar hand held, portable medical devices.

Particular attention should ensure the product is:

- Consistent with sizing of our existing hand held breathalyser products
- Sized to align with the products ergonomic requirements.
- Suitability sized, to store in personal and clinical environments, such as desk drawers, or first aid kits.
- Sized with transportation, shipping and storage in mind (abnormal sizing is not acceptable).

CROSS REFERENCES

- [Aesthetics](#)
- [Performance](#)
- [Prototyping](#)
- [Storage](#)
- [Weight](#)

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Supply Chain

The development of this new product relies heavily on the use of our external supply chain, therefore relationships with new and existing suppliers are essential.

- Prior to supplier selection, a full Make vs Buy analysis for all elements of the product, shall be completed.
- Electronic components will be sourced externally
 - China
 - Malaysia
- Mechanical elements of the product will be sourced externally
 - UK
 - Europe
- London Based Design House – responsible for the product casing.

- Product Assembly will be completed in-house

Consider the following:-

- Interface management between suppliers.
- Evidence of supply chain compliance to rules, regulations, standards and special processes.
- Dual sourcing considerations (to eliminate single points of failure within the supply chain).
- Ensure all suppliers are reviewed against the company's code of conduct and ethics policies.

Refer to the companies [supply chain strategy \(SC001\)](#), for additional details.

CROSS REFERENCES

- [Compliance](#)
- [Performance](#)
- [Materials](#)
- [Product Cost](#)

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Standards, Specifications and Tolerances

This new product will be sold globally and will need to comply fully with all standards, specifications and tolerances within the country of purchase.

Copies of all relevant documentation shall be obtained. A cross-correlation activity of all standards, specifications and tolerances will be performed during the project kick-off phase (**Mumby, 2022**).

Standards

- International Organisation for Standardisation - (ISO) Standards
 - ISO 13486 – Medical Devices (**ISO, 2019**)
- European Standards - (EN) Standards
- British Standards (BS) Standards

Specifications

- Government Specifications
 - NHS Approval
 - FDA Approval

Tolerances

- Component tolerances
- Assembly Tolerances
- Finished device tolerances

CROSS REFERENCES

- [Compliance](#)
- [Performance](#)
- [Legal](#)

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Testing and Calibration

Testing

Testing will be required from the initial concept phase, through to manufacture of the final product.

- Test plans will be created, to capture all testing requirements, including test type, frequency and set up. Testing will include:-
 - Impact Testing
 - Cyclic load testing
 - Stress testing
 - Component/material testing
 - Assembly/Manufacture process testing (*Mumby, 2022*).
- A combination of prototype testing and full scale testing will be carried out, as per test plan requirements.
- As this is a new product, 1 in 50 finished products will be tested. This sample size will be reduced/increased based on test results.
- All test data shall be recorded and electronically stored. This includes the storage of test data sheets/other relevant information from suppliers (certificates of conformity)
- User focus group and feedback testing will take place.
 - Use feedback will be incorporated into the final product design.

Calibration

- Calibration of the products CDS will be required, prior to distribution of the device.
- User calibration may be required, due to the shelf life of chemicals used in the CDS.

CROSS REFERENCES

- [Supply chain](#)
- [Compliance](#)
- [Performance](#)

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Time Scales

An initial schedule for the introduction of this new device is outlined below.

	Task/Activity	PROJECT CDS - PROGRAMME PLAN																			
		2022								2023											
		May-22	Jun-22	Jul-22	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23	Sep-23	Oct-23	Nov-23	Dec-23
CONCEPT PHASE	Define project scope and requirements																				
	Create and release Product Design Brief																				
	Initial product workshops																				
	Draft concepts																				
INITIAL DEISGN PHASE	Create initial prototypes and down select concepts																				
	Select Final Concept																				
DETAIL DESIGN PHASE INCLUDING PROTOTYPE AND TEST PHASE	Create product detailed design																				
	Detailed design workshops																				
	Generate full scale prototypes																				
	User Testing and Feedback																				
	Product Changes																				
	Generate full scale prototypes																				
	User Testing and Feedback																				
	Product Changes																				
MANUFACTURE PHASE	Design Freeze and Lock																				
	Launch Manufacture																				
	Source Parts via Supply Chain																				
	Internally Manufactured Parts																				
PRODUCTION PHASE	Product Assembly																				
CERTIFICATION PHASE	Certification Phase																				
	Final Product Testing																				
DELIVERY PHASE	Product Packaging, Transportation and Storage																				
	Delivery of first units to customers																				
AFTER MARKET PHASE	Provide In-service support																				

Figure 4 - NPD Programme Plan - Timescales

- A timeline of 20 months has been established, from the start of this project, to delivery. This timescale has been expedited, due to maturity of our CDS technology and certification agreement.
- In order to deliver this new product as per Figure 4, consideration will need to be made on the following elements:-
 - Supply chain lead times :-
 - Electronics
 - Plastic parts
 - Casing
 - Mouth piece
 - Assembly processing times
 - Tooling lead times
 - Availability of materials
 - Testing requirements and facilities
 - Shipping routes
 - Contingency time based on project gate failure (Go/No-Go Gates) (*Mumby, 2022*).

CROSS REFERENCES

- [Supply chain](#)

[RETURN TO CONTENTS PAGE](#)

Weight

Product Weight

- The desirable weight of this product should be no more than 1.5 - 2kgs (portable device).
- The device is likely to be held for long periods when used by clinicians (anthropological considerations required) (*Mumby, 2022*).

Transportation and Shipping

- Weight of the product, in its fully packaged state should be considered, to ensure transportation costs are minimised.
 - The product packaging should not weight more than 400g.

CROSS REFERENCES

- [Size](#)
- [Ergonomics](#)
- [Packaging](#)
- [Shipping and transportation](#)
- [Manufacturing Facilities and Systems](#)

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