



Product Design Brief

New Product Development
Assessment B

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Version 1

Synopsis

Following comprehensive research and development through open innovation partners at the University of Wales, a proof-of-concept prototype for a Chemical detector system (CDS) has been produced, and pre-defined test parameters passed.

Authorization has been acquired from board of directors to proceed with NPD. Throughout NPD, product viability will be assessed and only if economic benefit is identified, will development proceed to project design specification (PDS) phase.

The aims of this product design brief (PDB) are to collate and consider all requirements for the development of the CDS including but not limited to design, finance, market, manufacture, and dispatch, in a transparent document for the attention of all internal stakeholders throughout the design and development process.

The CDS should enable quick, non-invasive detection of organic molecules in the user's breath and provide reliable, clear diagnosis of Coronavirus, with potential to expand into additional health issues.

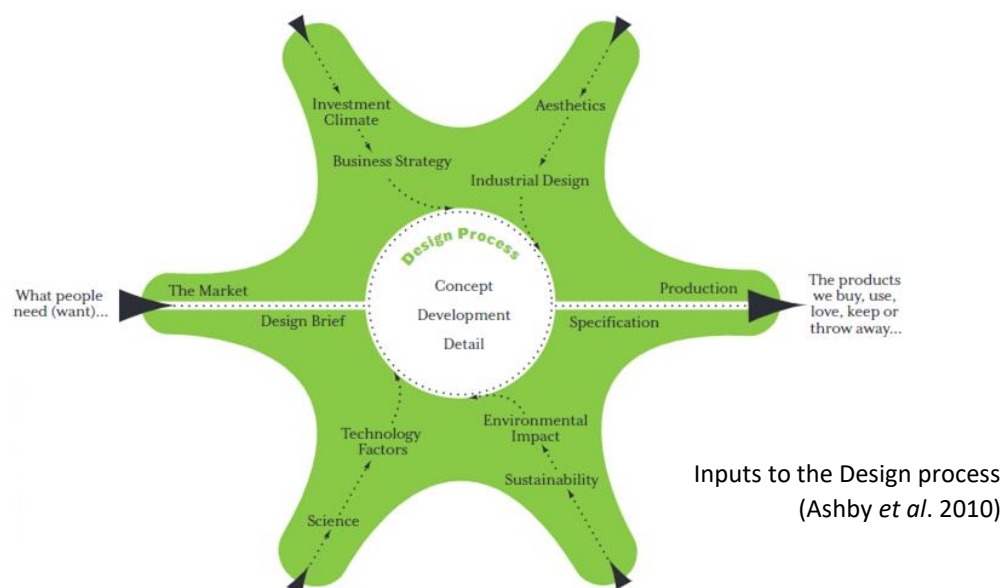
Primary goal:

Provide customer with a safe, secure, and certain solution to Coronavirus testing.

PDB will establish the following.

- Ensure design scope is consistent with performance, legal regulations, time requirements and achievable under company constraints.
- High quality performance under a variety of environmental conditions and use cases reflected by the principal markets including clinical, entertainment and personal.
- Development of a portable, handheld device consistent with brand in aesthetics and ethos.
- Manufacture and supply chain required to support a capacity of 750,000 units in first year, expanding to 3,000,000 in subsequent years.

[Hyperlinks](#) embedded throughout this PDS provide a navigation structure ensuring fluid understanding of inter-related elements throughout the design process.



Document control

Version	Date	Description	Responsible Person
1.0	27/05/2022	Initial release for comments from Chief Product Developer (Alan Mumby)	Jennie Bull

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Performance

Primary Objective

The product will successfully complete the following objectives under a range of [use environments](#).

- Provide clear diagnosis of health issues detectable in user breath profile ([technical](#)).
- Provide a non-invasive alternative to test for the presence SARS-CoV-2.
- Performance demands attained under [company constraints](#).

Responsiveness

Standard responsiveness at 20°C.

- From cold start, test ready in less than 60 seconds.
- From satisfactory sample, test results available in less than 60 seconds.
- From unsatisfactory sample, error prompt in less than 10 seconds.
- From result display, re-test ready in less than 30 seconds.
- From warm start, full cycle, and re-test ready in less than 120 seconds.

Use

The product is subject to variation in use dependent on [social and political](#) factors and should therefore maintain high quality performance under a range of use cases.

- High use case (see [Battery Life](#), [Durability](#)).
 - 20 tests in any 1-hour timeframe
 - 240 tests in any 24-hour timeframe.
- Low use case (see [Power](#)).
 - Standby up to 24 hours.

Features

- [Environmentally](#) considerate.
- Comforting in contrast to invasive testing products ([aesthetics](#), [ergonomics](#)).
- Easily cleaned ([sanitisation](#)).
- Water-resistant and non-slip ([materials](#)).

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Finance

Pricing

Prior to definition of a specific price point, the following criteria will be investigated.

- Acceptable expenditure (see [company constraints](#)).
- Cost patterns
- Comparable product costs
 - internal
 - external ([competitor](#)).

Price point:

- Product aimed at mid-range price point.
- Pricing structure should allow an average 8% profit margin in the first 6 months of production with progressive increase thereafter (see [success metrics](#)).
- R&D costs recouped in the first year of sales.
- [Legal and legislative](#) costs.
- [Manufacturing](#) costs including additional machinery and skill base.
- Distribution costs ([transportation, storage, taxation](#)).

Early estimates suggest a price range from £30 to £50.

Alternative economic models including subscription models facilitated through [platform/application](#) access.

Success metrics

Following initial profit margin of 8% in first 6 months, incremental increase in profit is expected in step with increase efficiency and upscaling.

- 10% profit expected end of first year production.
- 12% profit expected in following years.

If profit margin figures are not reached or sustained in line with the above success case, with given consideration of fluctuations in material costs and external pressures ([politics](#)), escalate to board.

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Company constraints

Funding

Funding availability.

- Existing capital
- Government support
- Funding through covid development
- Innovate UK Grants (UKIR)
- Loans and bank support
- Shareholder support
- Investment – financing rounds

Resources

Internal market research carried out to identify opportunities within Lion Laboratories for application to the development of the CDS.

Internal skillset.

- Underutilized potential to be repurposed.
- Compare expenditure associated with upskilling through knowledge transfer partnerships versus recruiting.
- Identify knowledge required in association with the new product line.
 - [*Intellectual property*](#) specialism.
 - [*Technical*](#) specialism.
 - [*Software*](#) development skills.

Market

Principal target markets.

- Individual use.
- Entertainment e.g entry requirements
- Clinical use

Establish understanding of potential market size and growth trends (Mordor Intelligence, 2022).

Continued analysis of market trends required to ensure product continues to provide a valuable development opportunity.

Customers

Focus group research and surveys utilized at strategic intervals throughout process to ensure the product continues to attain perceived needs and wants across customer spectrum.

- Individual; minimal training and guidance
- Entertainment; range of training levels
- Clinical; moderate to high level training

Customer environments ([environments of use](#))

- Home
- Entertainment venues
- Sports venues
- NHS facilities
- Care facilities

Customer [support](#) department strengthened to maintain [brand](#) values.

Device accessible to all customers independent of ability (multi-sensory results, [hardware](#)).

Brand

Logo and aesthetic continuity throughout;

- Unit housing
- Device loading screen
- Packaging
- Website
- Secondary products and accessories
- Documentation.

Brand identify as...

- an innovative company - reinforced by increase in scientific publications.
- a conscious company – reinforced by [environmental](#) ethics.
- A kind company – reinforced by [safety](#) and [support](#)



Branding System
(Trott [2017])

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Competition

Direct and indirect competitor analysis in technological sectors including alternative solutions, improvements and developments.

- Literary review
- Patent review
- Product literature

Competitor research report produced regularly to assess risk vs reward.

Initial competitor analysis suggests that no single device satisfies all desired attributes i.e cloud [connectivity](#), hand-held ([ergonomics](#), [weight](#)) and results in no more than 60 seconds ([response](#)).

Company	Flagship	Handheld?	Price	Size	response	Status	Cloud connected	Cloud calibrated
Breathomix	SpiroNose	No	"Affordable"	-	60 seconds	Released	Y	Y
Deepverge PLC	Microtox	-	-	-	60 seconds	Trial	-	-
Owlstone medical	ReCIVA	Yes	-	120 x 100 x 140	15 minutes	Released	N	N
InspectIR Systems LLC	PNY-1000	No	-	-	3 minutes	Released	N	N

Political, Social and Cultural

Political factors:

- Tariffs, Taxation, Legislation
- International politics
 - Impact on [supply chain](#)
 - Impact on [distribution](#) centres
 - Ethics and customer perception ([Brand](#))
- Specific Coronavirus response
 - Grants ([finance](#))
 - Variation in legislation ([legal](#))
- Inflation
 - Economic impact
 - Reduction in entertainment and travel

Social factors:

- Rise in health-conscious consumers
 - increase market value in health and wellbeing sector (May, 2018)

Cultural factors:

- Written style, [language](#), colloquialisms
- Cultural implications of [colour and design](#) (Bruce *et al.*, 2007).
- [Connectivity](#), cloud access and broadband mobile communications

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Timeline

Timeline should consider:

- Open innovation partnerships
- Development process
- Legal research
- Design and third-party consultation
- Sourcing parts
- Testing
- Iterative market research
- Manufacture
- Launch

Decision gates build into timeframe to prevent unsatisfactory outcomes.

- Potential time loss in development
- Defective products
- Market mismatch
- Overpowering competition.

Clear and transparent understanding of timeline required.

- Internal or external project management software
- Develop Gantt chart

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Legal

Intellectual property

Seek legal advice and support through third-party, university synergies, patent library.

Assess the benefit against the financial impact of hiring a patent attorney.

Legal team (internal or external) will review:

- Implementation of NPAs with open innovation partnerships
- Existing patents to ensure no conflicts or overlap
 - Intellectual Property Office (IPO)
 - European Patent Office (EPO)
 - United State patent and trademark office (USPTO)
- Copyright on existing products
- Trademark conflicts
- Register and trademark new product name and design
- Costs associated ([finance](#)).

Compliance

Awareness and compliance with regulations and documentation including, but not limited to:

- Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)
- Consumer Protection Act 1987
- UKCA conformity
- Medical device vigilance system (MEDDEV 2.12/1 rev 8)
- EEC Product liability legislation
- Medicines & Healthcare products Regulatory Agency (MHRA)

Fully investigate and register with required organizations. Registration process specifications as follows:

- Risk classification – Class 1 (Medical Devices Regulations 2002 [SI 2002 No 618])
- UDI-DI number via FDA Accredited issuing agency.
- Global Medical Devices Nomenclature (GMDN) code and device description

Specific requirements around Covid-19 testing devices with particular focus on time limit on new regulations and therefore impact on launch [timeline](#).

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Standards and Specifications

Product design in accordance with international standards including BS, EN, AFNOR, DIN, ASTM, ISO.

Including but not limited to:

- IEC 82079: Manuals and [Documentation](#)
- ISO 10993: Biological evaluation in medical devices
- ISO 13485: Medical Device [quality](#) management systems
- ISO 14971: Medical device risk management
- ISO 15223: Medical device labels
- ISO 294: Plastic – Injection molding of [thermoplastic](#) materials
- ISO 62304: Software use in medical devices
- MDR 2017/745/EU: [Language](#) requirements
- [EN 60529: Ingress protection](#)

Adherence to data security standards in line with improved [connectivity](#) and [data](#) usage.

- General Data Protection regulation (GDPR)
- Data security in accordance with Gramm-Leach-Bliley Act.
- ISO/IEC 27001 – Information security management

Time requirements for any certification will be reviewed as priority to ensure minimal impact on launch [timeline](#).

Copies of all required documentation will be obtained, and detailed review carried out within design process to ensure product development is viable.

Terms of contract

Product intended to be covered by standard legal warranty for up to 1 year [in service](#) to capture defective devices, managed [customer](#) expectations and reinforce [brand](#) values.

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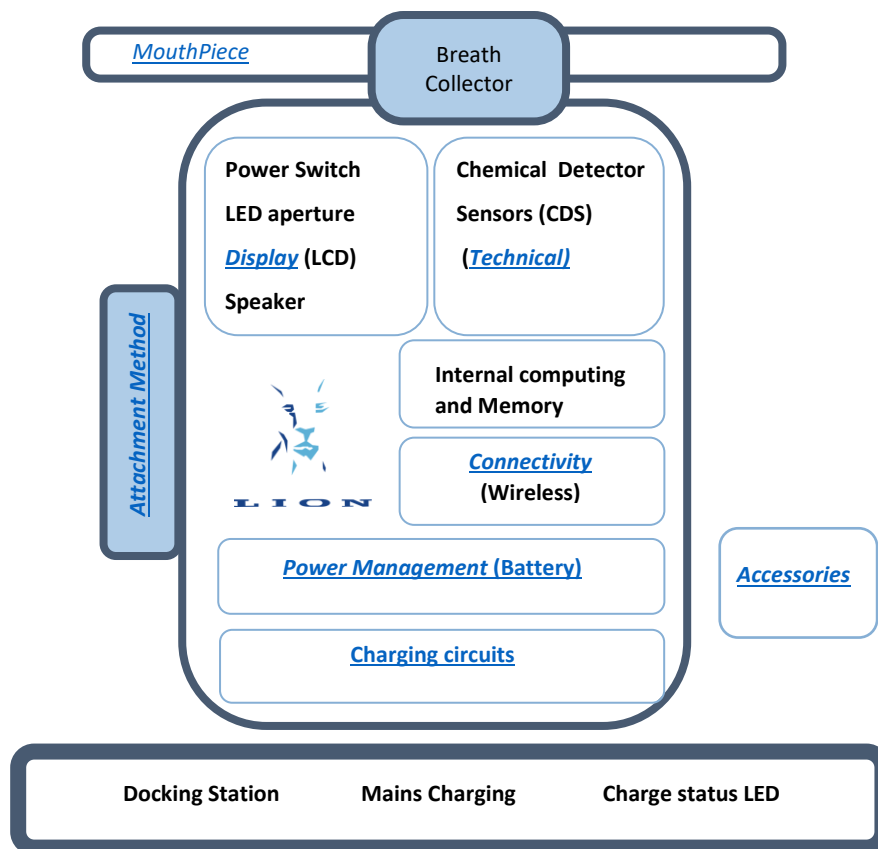
Waste

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Hardware

Summary of hardware architecture components



Housing

Main housing and dock will be injection molded (see [shape](#)).

Finger grips ([ergonomics](#)) included either in the shape of the housing or as added elements.

Attachment method, either lanyard or belt, built into housing design (pending [weight](#)).

Tamperproof to minimize [maintenance](#) and ramifications for [terms of contract](#).

Calibration data stored on device therefore no requirement for external label space.

Housing to include LED aperture for multi-sensory result notification ([customers](#)).

Dock to include LED aperture for clear charge status visibility.

Perforations in housing to enable audible result notification.

Technical specifications

- Utilize Lion fuel cell technology to minimize risk and legal implications ([patents](#)).
- Semiconductor oxide sensor technology
- Technical specifications to adhere to all legislation and standards ([legal](#)).

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Memory

Device will not be memory intensive.

RAM capacity required to run and update [OS](#) and single [platform application](#).

Estimate RAM requirements – 2 GB

Connectivity

Device will contain wireless communication hardware

- Wireless network interface card (WNIC)

Wireless connectivity will support multiple processes (see [Software](#))

Display

Touch screen LCD display with resolution no less than 300 pixels per inch (PPI) to ensure clarity ([materials](#)).

Display will comply with accessibility regulations ([Legal](#)).

Text parameters set by [software](#) and platform/application.

Speaker

Micro speakers build into device to enable audible noises prompt at 50 decibels for:

- Startup
- Test ready
- Error test
- Results received
- Power down.



Mouthpiece

Mouthpiece consistent in [shape](#) to existing product line (Lion Alcolmeter ® 900 [above]), emphasizing [brand](#) and product line connections.

In multi-user, high-[use](#) case; 240 mouthpieces per product per 24 hour (1,680 per week) will be used. This requirement results in high waste, incompatible with [environmental](#) aims.

Comprehensive review of mouthpiece materials required to assess potential to reuse. This would require [sterilisation](#) which may impact component [life-in-service](#).

Reusable mouthpiece would require material testing and product use testing in both normal and vigorous multi-user scenarios.

Under normal use mouthpiece intended to last up to 6 months, with regular sterilization, prior to disposal/recycle process.

Accessories

All accessories to be included in customer focus group forum

- Thin injection molded thermoplastic protective case.
- Wrist strap for use when device is in operation.
- Carry accessories (pending [weight](#) and customer focus groups)
 - Lanyard or wrist strap – implications for [durability](#) and [maintenance](#) due to increased likelihood of impact forces in everyday use ([testing](#)).
 - Belt attachment to improve security and reduce risk of damage.

Implications for [sales pack contents](#)

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Power

A full and detailed budget of power will be available in the PDS.

Run time

Full charge should allow device usage, at defined [use cases](#) for no less than;

- High use: 12 hours
- Average use: 12-72 hours
- Low use: 72-120 hours

After 15 minutes of inactivity battery saver settings will be initiated.

Battery Life

End-of-life at 20% capacity loss

Target charge cycles until end of useful life 400-500

Battery replacement

Replacement batteries will not be a requirement of the user experience.

On balance expected wear and tear over the duration of the full battery life would make replacement and continued use less desirable in a clinical setting.

As user will not require access, the aesthetics and ergonomics of the battery covering and less of a consideration.

Trained product technician only will require access to internal hardware and battery.

Battery Charging

Charger/dock design to be portable ([weight](#)).

Charger/dock as storage ensuring use ready charge levels.

Primary charge mechanism with be mains to ensure access to charge mechanism independent of environment.

- Standard plug socket or USB plug
- Charge adapter with wide range voltage input

Wireless charging capability will be considered following detailed customer research focused on wireless signals in clinical settings (see [hardware](#)).

From less than 5% charge, under satisfactory charging setup, full charge in less than 2 hours.

Automatic maximum charge thresholds (smart charging) to extend battery life.

Clear charge status indicator (see [Housing](#)).

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Software

Connectivity

Device hardware to enable connectivity to wireless networks allows:

- Device support
- Application access
- Cloud connectivity for data upload
- Connectivity with centralized government organisations
- Connectivity with alternate devices.
- Operating system updates
- [Calibration](#) updates and support
- Fault diagnosis

Operating system

Operating system chosen from one of the following after comprehensive review with implications for device software and hardware functions and user interface.

- Microsoft Windows
- Apple iOS
- Google Android OS
- Linux

PDS will contain full operating system specification.

Platform/Application

Application developed for both Apple iOS and Android OS to ensure compatibility with secondary devices.

Development to consider accessibility requirements ([legal](#)) and [customer/market](#) range when defining text choices including font and size.

Text Size:

- Body fonts no less than 16px
- Secondary fonts no less than 14px.

Text Font short list:

- Times new roman
- Arial
- Calibri
- Verdana

Text font and size will be clearly legible when viewed at [display](#) resolution.

Application will offer text size variation function to ensure accessibility.

Application [colour](#) scheme reflecting [branding](#).

Application available in alternate [languages](#).

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Data (BlockChain)

All data generation through the CDS will be uploaded to cloud supported by wireless [hardware](#) consistent with data management [legislation](#) and [terms of contract](#).

Cloud compatibility and cloud calibration is critical to market advantage ([competition](#)).

Cloud data storage will allow:

- Integration with government systems
 - track and trace
 - Covid passports
 - patient records
- Internal market research
- Personal records and breath profile breakdown
- Valid result certification

Languages

Language is a consideration in user interface, documentation, and labelling.

First phase production will be focused on European and US market (through sister company CMI) to reduce time to market.

Default language bundles will include:

- English (UK)
- English (US)
- French
- German
- Italian
- Spanish
- Welsh

Second phase production will develop language bundles to maintain inclusivity with broad user base, facilitating market expansion focused around existing [distribution](#) network.

Font choice to support all alphabets including Cyrillic, Arabic, Devanagari, Hanzi, Katakana etc.

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Support

Development customer support department and infrastructure in line with increasing [market](#) size and [brand](#) values in addition to digitalizing [documentation](#)

Support departments emphasis brand values and customer care through:

- Phone
- Live chat
- Email
- Web Support
 - Interactive content
 - Video tutorials (with subtitles option)
 - FAQ
- Administrative support in association with [Repair](#) services
 - Regular maintenance request
 - Outside warranty repair
 - Parts order online
 - Return of device at end-of-life
 - Return of used mouthpieces (pending review)
- Support embedded in platform/application.
 - Update prompts
 - Tool tips

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Footprint

Size

Device should be comfortably handheld ([ergonomics](#)):

- no more than 180mm x 120mm x 220mm
- no less than 100mm x 100mm
- Size variation in accordance with display pack size and [hardware](#).

Display pack:

- compatible with UK and EU standard pallet.
- minimal waste space on full pallet ([packaging](#)).
 - width no more than 198mm (2mm allowance) - 5/4 (UK/EU) to pallet.
 - height no more than 238mm (2mm allowance) – 4 (UK/EU) to pallet.
 - depth no more than 148 (2mm allowance) - 14 (UK/EU) layers to pallet.

Weight

Ideal weight 1kg or less to ensure comfortable hold position for the duration of test cycle with weight distributed evenly or towards base of device ([ergonomics](#)).

Full loaded pallet weights ([packaging](#)) – max weight per [sales pack](#) - 5kg.

Environment...

...of use

Moisture:

- Water resistance (IP65 - [Legal](#)) not expected to be submerged ([materials](#)).
- Suitable for continuous use in expected humidity range (40% - 60%).
- [Tested](#) to 20% - 80% humidity conditions.

Temperature:

- Operating temperatures consistent with existing product range (-5°C to 40°C).

Pressure:

- Operating pressure between 11psi and 15psi.

Shock loading:

- Drops expected in everyday use ([drop testing](#)).

Cleanliness:

- Clinical – sanitary environment
- Entertainment, sport and leisure – unsanitary environment.
- Device will be “dust tight” (IP65 - [Legal](#))
- Investigate [sanitization](#) solution

Corrosion:

- Expected fluid in day-to-day use:
 - Water
 - Saline
 - Grease and oil
 - Alcohol
 - Hand creams
 - Alcohol gels
 - Off-shelf cleaning fluids
 - Bleach
- Testing of [sanitization](#) fluid impact

Noise:

- Device [sound](#) set at 50 decibels to ensure audibility under normal environment conditions (10-90 decibels).

Vibration:

- Minimal vibration expected under regular use.

Degree of abuse:

- Emphasis on strength and durability in:
 - Touch screen
 - Buttons
 - Mouthpiece – resistance to bite

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...of manufacture

Temperature:

- Thermoplastic melting temp 3500°C to 4000°C

Corrosion:

- Cutting fluids
- Solvents
- Fluxes (flow soldering)
- Acids (plating and cleaning).
- Sweat
- Oils

Shock loading:

- Assembly forces

...of storage and transport

Moisture:

- Packaging damage due to moisture ingress.

Light:

- Excess light resulting in fading of display packaging.

Shock loading:

- Damage and movement in transport

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Materials

All material choices will comply with [quality](#) and [standards and specifications](#).

Thermoplastics

Thermoplastics will be used throughout production

- Injection molding ([housing](#))
- Re-usable, recyclable ([environmental](#))
- Comparatively light [weight](#).
- Chemical resistance ([environment of use](#))

Soft touch components

- Buttons and hand grips
- Research recyclable rubber solutions
- Rubber alternatives (plastic coatings)

Paper-based

Where possible recycled paper products will be used ([environmental](#)):

- Packaging
- Internal administration
- [Documentation](#) digital and not applicable
- Heavy cardboard protective setting in display [packaging](#)

Electronics:

- Silicon
- Rare metals
- Metal

[Display](#) LCD screen

- Light [weight](#)
- LED backlight
- Long lasting
- Energy efficient ([Battery](#), [Environmental](#))
- [Touch](#) screen (limited button requirement)

Supply chain

- Develop international procurement.
- Stock and component control issues due to new parts.
- Develop relationships with suppliers to support growth

Environmental

Product manufacture will comply with ISO 14001 (see [Legal](#))

Sustainability

Committed to reduce environmental impact, carbon usage and waste associated with this product with emphasis on sustainable, recyclable materials.

Alternative materials will be investigated in line with company financial limitations.

Research team and open innovation partners advance material science to reduce operational waste and increase recyclability, reinforcing innovative [brand](#).

Circular economy

Components and packaging made from recycled [materials](#) where possible throughout [supply chain](#).

Product designed with reclamation of parts in mind. Return of part or whole of device at end-of-life through [support](#) team.

Reuse parts where possible

- Reuse thermoplastic housing
- Battery refurbishment

Recycling if reuse not an option

- Research green rubber or alternative

No part intended to be consumable

If reclamation, re-use, recycle is not possible - safe and appropriate disposal in line with [waste management](#) procedure.

Aesthetics

Both internally and externally opinions will be sort through feedback routes prior and during the design process.

- [Customer](#) survey
- Focus group
- [Market](#) research

[Cost](#) implications of aesthetics choices considered.

Colour

Product colour scheme should represent a single palette suitable for all market sectors.

Any colors pertinent to environment of use or market sector considered.

Primary colour of unit light (white, cream) allowing clear visual assessment of cleanliness, reinforcing perception of sterility.

Existing product line ranges in colour (black, grey, yellow) with minimal brand continuity.



Colour highlights:

- minimal to streamline [manufacturing](#).
- consistent with company [branding](#) and two-tone logo.
 - Light Blue (RGB 92;176;214)
 - Dark Blue (RGB 24;66;134)

Figurehead CDS product will represent the type aesthetics for the clinical product line.

Shape and Form

Emphasis on design principles of naturalness and simplicity.

- Simple, classic, shape to improve injection-molding capacity.
- Mouthpiece shape consistent with existent mouthpiece to minimize manufacturing costs, not specific to user face and therefore no limitation on customer.
- Mouthpiece connection position and design under review.
- Type shape for clinical product line.
- Shape designed to fit well in palm, including grip strips.
- Display and buttons on the same side
- Display positioned towards the user when breath sample is being taken.

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Finish and Feel

Smooth, wipe clean, finish to aid in cleaning ([material](#)).

Smooth lines and rounded edges for comfortable grip and handling.

Satin finish.

[Display](#) touch screen minimizes button requirement. Where present buttons soft touch and rounded.

Ergonomics

Display screen used as control ([touch screen](#)).

- Touch screen large enough to maintain comfortable use for all hand sizes.
- Display screen and buttons on same side, facing user during test.
- Minimum key center spacing no less than 20mm.
- Touch screen pressure [testing](#).
- Touch screen to improve cleanliness and [sanitation](#)

Anthropometry (Lewis *et al.*, 2008)

- Device held and operated with the same hand.
- Device will fit in the hand comfortably
- Distribution of [weight](#) equally or towards the bottom of the device to improve handling.
- Sides of the device should include finger grips either directly on [housing](#) or via addition in design phase.
- Grip strip position suited to both left and right-handed use.

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Manufacturing

Facilities

Initial production focused on the existing site (Ty Verion, Barry) utilising: facilities, staff, machinery, tools, infrastructure.

Facility parameters:

- Operations 5 days a week (Monday to Friday)
- 8 hours shift patterns:
 - 6am – 2pm
 - 2pm to 10pm
- UK Bank holidays
- 1 week shutdown over the Christmas season.

Under these parameters, manufacture quantities required to target [sales volumes](#):

- 375 units an hour in the first year
- 1,500 units an hour in subsequent years.

To facilitate these high levels of production, automation throughout production line is required.

- Research required into automation equipment and skill requirements.
- Following assumptions of [product lifespan](#) subcontracting manufacture will be investigated to reduce cap ex and fixed costs.
- Develop production and assembly lines

Addition machinery purchase may be required ([Finance](#), [company constraints](#)).

Processes

Retain existent processes to minimize expenditure of resources ([company constraints](#)) and in consideration of [time frame](#).

Manufacturing processes will be in line with relevant internal and external quality [standards](#).

Regular review of manufacturing technology to reduce overheads

Sales Volume

First year = 750,000 units

In [success case](#), second and successive years = 3 million units.

Documentation

Documentation creation as follows:

- Instruction manuals (customer)
- Data Sheets
- Technical manuals (internal staff)
 - Repair
 - Testing
 - Calibration
- Terms and conditions

Product manuals will be digital and downloadable, available through:

- Web [Support](#)
- [Platform/application](#)

Documentation will:

- Strive for simplicity, in clear, understandable language.
- Be available in multiple [language](#) options
- Will comply and address [safety](#) and [legal](#) elements.
- Additional interactive [support](#) available

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Life

Shelf Life

Minimize defects related to intermittent usage and extended [storage](#):

- [Battery](#) thresholds
- Moisture resistance display unit packaging to minimize moisture ingress and perish of paper-based components.
- Packaging to be enclosed, no plastic window, to reduce risk of discolouration due to light exposure.

Consider [terms of contract](#) and warranty conditions to ensure good care of device.

Life-in-service

Service life of product defined primarily by [battery life](#).

- High [use](#) case: no less than 2 years
- Low [use](#) case: more than 3 years.

Warranty timeframe set at 1 year to cover defect device ([legal](#)).

Product lifespan

Under the assumption of continuous improvement and technological advancement the product lifespan of this manufacturing line is estimated at 4 years.

Implications for but not limited to:

- [Market](#)
- [Competition](#)
- [Manufacture](#)

Quality

As Lion Laboratories is ISO 9001 accredited all quality management expectations will be met ([standards](#)).

Durability

Use of thermoplastics result in strong and durable character

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Testing

Prototyping

Proof-of-concept prototype complete.

Following ideation phase additional prototype development will encompass:

- Minimum viable product (MVP) to review core functionality.
- Design prototype will provide valuable benefit through focus groups (*aesthetics*).

Testing frequency

Testing frequency will follow 3 phase approach.

New: in the first week of any manufacturing change 1 in 10 products will be tested.

Intermediate phase: 1 in 50 items tested.

Established phase: 1 in 100 items tested.

If over 90% of tested items pass acceptable threshold testing will move into the next phase.

If at any point pass rate falls below acceptable limits testing will drop down a phase.

Data collection will be fed back into this system and thresholds adjusted in keeping with testing requirement.

Product-use tests

Focus groups with design prototype to access customer uses to feed back into [documentation](#), manuals and [maintenance](#) servicing.

- Testing touch screen
- Mouthpiece
- Attachments
- Ergonomics
- Aesthetics

Drop test performance

Factor test to ensure compliance with PDS

Display packaged product should withstand a corner drop from 1.5m

Portable appliance testing (PAT)

Charger is subject to PAT Testing, not required on low voltage portable device category.

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Distribution

Utilise existing distribution network facilities in following countries (see [languages](#)):

- United Kingdom (7)
- Europe (27)
- Russia (1)
- Middle East (6)
- United States (1)
- Africa (10)
- Asia (2)

Packaging

Requirements:

- Protect from damage in distribution and storage ([environment](#))
- Correct labelling in compliance with [regulations](#) including certifications UKCA, serial numbers and unique identifiers.
- Consistent with [aesthetic](#) and [brand](#).

Display packaging

Tamper proof packaging - customer perception of cleanliness and authenticity.

Molded setting made from recycled cardboard ([materials](#)) to minimize movement.

Investigate recyclable waterproof package cover to protect from transport [environments](#) and extend [shelf life](#) prior to sale.

Transport packaging

Multiple display units packaged into a single sales unit compatible with standard European pallet (1200mmx800mm) (UNE-EN-13698) and standard UK pallet (1200mmx1000m).

- Pallet load height 210m
- Loaded equally distributed.
- loaded pallet will not exceed 1500kg ([weight](#)).

Under display pack [size](#) estimates:

- Full UK standard pallet (280 units).
- Full EU standard pallet (224 units).

Sales pack content

- Device and protective case accessory
- Mouthpiece x 10
- Docking station
- Charging cable
- USB Plug
- Carry accessories.

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Maintenance

Maintenance and repair as standard for defective items, unless invalidated by customer interference ([terms of contract](#)).

- Tamperproof casing ([Housing](#)) incorporated in design
- Service department costs factored into [pricing](#) model.

If repair not possible within 5 working days, replacement item dispatch.

Outside of warranty repair shop available ([support](#)).

Development of maintenance department as required utilizing internal skill ([company constraints](#)).

Investigate maintenance models and policies.

Calibration

Device calibration:

- Prior to distribution.
- Regular pre-set intervals during active use
- During maintenance by Lion repair team if necessary.

Device calibration certificates stored internal to device in accordance with ISO 13485

Installation

Installation process should be as simple as possible.

On first start device will prompt manufacturer registration.

- Registration details stored on device (under data security [compliance](#)) for use in result certificate generation.
- Product to product connection facilitated through [platform/application](#).

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Safety

Security

Device design will consider tamper-proof housing to minimize risk to customer.

Data security and management in compliance with all standards and specification ([legal](#)).

Sanitisation

Research into re-usable [mouthpiece](#) will be undertaken in relation to [environmental](#) policy.

Robust and reliable sanitisation process required to ensure safety.

Methods to be researched:

- UV-C disinfection (FDA, 2021)
- Fluid disinfection

Risks and implications:

- Significant risk associated with improper use of sterilization equipment.
- Impact on [customer](#) perception of device and [brand](#) values
- User perception of end-of-life for each mouthpiece impact on [quality](#)
- sanitisation equipment impacting *footprint* of standard [sales pack](#).

Waste

All components will be reclaimed, re-used, recycled ([environmentally](#)).

If no further option items will be disposed of under good practice and in compliance with standards and regulatory agencies ([legal](#)).

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