

BIIM Innovation Management Level 7

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Product Design Brief

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(Vi-P project)

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Synopsis

Over 6.3 million people to date have died from the Coronavirus COVID-19 outbreak (World Health Organisation, 2022) and rapid and accurate diagnostic testing is critical in patient isolation and treatment. Exhaled breath is a rich source of biomarkers and is starting to be used in the context of medical and health-related issues. Volatile Organic Compounds (VOCs) are produced as the result of metabolic processes throughout the body and reach the breath via the bloodstream. The 'rapid, cost-effective and non-invasive nature of VOCs make them a strong candidate as a COVID-19 biomarker' (Ibrahim,W et al, 2021).

Through a Knowledge Transfer Partnership, we have identified the opportunity for an extension of our chemical alcohol detector system to cover the detection of other organic materials, including those generated in the breath as a result of various virus infections. Laboratory testing has now been concluded resulting in the registration of patent applications and certification of the new detector from medical device regulatory agencies.

The device will be a portable, hand-held device for the in vitro detection of VOCs from a breath sample. Electronics and mechanical elements are to be sourced externally and we will be collaborating with an external company in the design of the physical envelope and appearance of the device. A decision is to be made as to whether to source the complete device as a fully assembled unit (as per current products) or to source the mouldings and assemble the units in-house.

The project presents new market opportunities (sectors and geographical locations) with specific legal requirements which must be fully researched and understood to minimise potential negative reputational and financial impacts. Potential markets have been identified as:

- Medical environment - hospitals, care facilities and diagnostic centres and clinics
- Entertainment industry - controlling entry to venues
- Travel industry - testing pre-travel in airports, ferry and cruise ship ports
- Public home/personal use

Consideration must be given to the customer pains/triggers for each sector with the use of customer value proposition canvases. Knowledge of local Government policies and customer procurement processes must be researched.

Competition for COVID-19 diagnostic devices is increasing and this must be researched to maximise market share. This competition will drive the required time to market launch.

This Product Design Brief requires input from all areas of the business and gives consideration to the requirements of this NPD project. Cross referencing between sections is provided. The document is held and updated electronically with revision control and latest changes are to be highlighted.

[Return to Contents](#)

Aesthetics, Colour and Finish

- Colour:
 - Light colour around periphery with darker colour at the interior - perception of cleanliness, low weight and size (Stipe, D)
 - Contrasting colours (warm colours) to highlight areas of for user interface - buttons
 - Consider competitor products - consistency or differentiation
 - Carry case to be dark colour - minimise effect of damage
 - Implement brand identity from developed brand pad
 - Material availability, batch sizes, shelf life
 - Standardisation across product range
 - Legal requirements
- Shape:
 - Handheld device - consider right and left handed use
 - Single handed use
 - Contoured edges with impact protection
 - Grip
 - Consider existing company product ranges for potential consistency for brand recognition
 - Buttons to be shaped for ease of use and accessibility
 - Touch screen interface
 - Carry case to be carried by single handle
 - Manufacturability
- Use of accessories:
 - Charging
 - Mouthpiece
 - Data transfer port
 - Sealable ports (IP64)
 - Mitigate risk of damage
- Finish:
 - Allow for easy cleaning
 - No areas for ingress and accumulation of dirt
 - Anti-shock protection
- Consultation:
 - Internal subject matter experts - sales, marketing, production, engineering
 - User workshops
- Antiviral protection or cover

[Cross reference:](#)

- [Ergonomics](#)
- [Materials](#)
- [Branding](#)

Branding

- Brand pad:
 - Logo
 - Font type
 - Font size
 - Colours
 - Icons
- Brand recognition:
 - Review existing product ranges
 - Consistency
 - Use of logo - labelling, software, packaging
 - Manuals
 - Literature
- Brand awareness:
 - Social media
 - Website
 - Trade Associations
 - Product launch
 - Trade Shows
- Labelling in compliance with ISO 15223-1:2016 (Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements)

[Cross reference:](#)

- [Aesthetics, Colour and Finish](#)
- [Documentation](#)

Circular Economy

- Collaboration with supply chain:
 - Application of BS8001:2017 Circular Economy Principles
 - Return of parts for reuse - technical metabolism
 - Product life in service expectations
- Design for disassembly:
 - Recycling of components, batteries and packaging
 - Establish process for return of products and batteries at end of life
- Packaging:
 - Consider full life-cycle including manufacturing processes and transit packaging
 - Use of packaging through manufacturing stages
- Battery:
 - Replaceable
 - Extend device life

Cross reference:

- [Materials](#)
- [Manufacturing Facilities](#)
- [Maintenance and Repair](#)
- [Disposal and Recycling](#)

Company Constraints

- Manufacturing facility:
 - Review of in-house processes vs subcontract
 - Year 1 and year 2+ volume predictions and implications on:
 - Physical factory space - manufacturing, component storage, WIP and finished goods
 - Machinery, tooling and equipment to include for manufacturing, materials handling, test and packaging
 - Distribution networks
 - Supply chain management
 - Business Continuity plans - manufacturing and supply chain
 - Space for support functions
 - Testing facilities
- IT infrastructure - possible consideration for supply chain interfaces
- Personnel:
 - Staff development
 - Recruitment of specific skills across all disciplines
 - Knowledge of standards relating to medical devices
- Business processes and additional certification requirements
- Financing:
 - Government grants - Innovate UK grants would be a consideration
 - Bank loans
 - Potential for investor support
- Knowledge of export/import controls
- International distribution

Cross reference:

- [Manufacturing Facilities](#)
- [Product and Project Cost](#)
- [Standards and Specifications](#)

Competition

Competition identified in the marketplace:

1. Handheld breath analysis device developed by Dallas-based SOTECH Health in collaboration with The University of Texas (figure 1). The device was submitted to the

Food and Drug Administration for emergency use as reported in September 2021 (Fontenot, 2021)



Figure 1 - The Breath Analyser Device designed by SOTECH Health

2. Consortium formed by DeepVerge (formally Integumen) with Modern Water and Avacta and Aptamer Group to develop a system to detect the COVID-19 virus in a personalised breath test (DeepVerge, 2021).
3. The Inflammacheck developed by Exhalation Technology Ltd (ETL) in Cambridge. Clinical study announced January 2021 (Scialom, 2021)



Figure 2 - The Inflammacheck

- Determine product launch and/or research status
- Attempt to procure devices for detailed analysis of components and software
- Research testing methods
- Patents:
 - European Patent Office
 - Current and expired
 - Proposed and adjacent product areas

- Market research:
 - Example Grand View Research, 2022
 - Prominent players in COVID-19 diagnostics market
 - Size of market - total and by geographical area
- Continued analysis for reporting to the Project Team for risk management
- Conduct competitor SWOT analysis

Cross reference:

- [Patents and Trademarks](#)
- [Market Constraints](#)

Components

- Packed into carry case:
 - Hand-held device
 - Touch screen
 - Interface points for mouthpiece and data connectivity either physically using supplied interface cable or wirelessly
 - Software on device
 - Injection moulding for main body
 - Internal circuit board
 - Buttons
 - Fixings
 - Internal memory to hold up to 2 weeks worth of test data (144 tests per day) and space for future software updates - specification to consider size and cost
 - Serialised
 - Battery pack
 - Replaceable to extend product life
 - Power block and power cord
 - Software for test database supplied via CD or separate download
 - Manuals
- Consumables:
 - Mouthpiece:
 - Sterile
 - Single-piece
 - Single-use or multi-use for different use cases
 - Positive and negative control material
 - Antiviral cover
- Not supplied with device, but required for use:
 - PPE - Disposable gloves, disposable gown, face shield or safety goggles
 - Power source/supply - countries and variation within hospital areas
- Spares:
 - No customer requirements
 - Spares required for the Service team

Cross reference:

- [Materials](#)
- [Performance and Features](#)

Customers

- Target market sectors:
 - Medical environment - hospitals, care facilities and diagnostic centres and clinics
 - Entertainment industry - controlling entry to venue
 - Travel industry - testing pre-travel in airports, ferry and cruise ship ports
 - Public home/personal use
 - Consider training and customer support requirements (note level of users' medical training will vary), device maintenance service and device registration for each use case
- Target geographical locations - further research regarding country specific legal and documentation and software language requirements.
- Procurement teams:
 - Sector specific
 - Country specific
 - Processes and requirements, with potential barriers, for tender and supply contracting
 - Government bodies v private sector organisations v public
- Business to business and Business to consumer economic engines differences
- Customer pains/triggers - customer value proposition canvas

Cross reference:

- [Market constraints](#)

Disposal and Recycling

- Mouthpiece - single use or multi-use
- Recyclable finished goods packaging
- Recyclable components
- Returnable transit packaging for supply chain:
 - Standardisation across product ranges
 - Durability
 - Item placement and removal
 - Protection during transit
 - Kanban systems
 - Quantity required
 - Use during assembly
- Battery:
 - Replaceable
 - Recyclable via return/replacement service
 - Waste Batteries and Accumulators (Amendment) Regulations 2015

- Compliance with Waste electrical and electronic equipment (WEEE) Directive (2012/19/EU)

Cross reference:

- [Circular Economy](#)
- [Materials](#)
- [Manufacturing Facilities](#)
- [Packaging](#)

Documentation

- User manual:
 - Start up
 - Test process
 - Quick reference fault finding guides
 - Software set up and use
 - Cleaning
 - PPE requirements
 - Charging
 - Mouthpiece change, disposal and/or maintenance
 - Data extraction
 - Language selection
- Technical manual:
 - Detailed product specification
 - Calibration
 - Software installation and updates
 - Detailed troubleshooting
 - For support staff
- Patient/user instructions:
 - Pre-test (guidelines on eating, drinking, use of tobacco products)
 - During test
 - Post test
- Accessibility:
 - Electronically via portal for customer access only
 - Hard copy format with the device
- Language:
 - Target geographical locations
 - Translation services for manuals and software
- Branding
- Process for updates/revisions
- Durability

Cross reference:

- [Branding](#)
- [Customers](#)

Environment

- Temperature range
 - Use 0-35 degrees Celsius
 - Storage -10-55 degrees Celsius
- Relative humidity
 - Use 40-60%
 - Storage below 90%

Considering manufacturing, storage, assembly, packaging, transportation

- Pressure range
- IP64 rating - totally dust tight and protected against water splashes from all directions
- Shock loading and drop test in and out of packaging from 1-1.5m desk height - replicate use environment
 - Identify standards for drop testing
- Corrosion from device battery fluids
- Noise levels
- Vibration
- Cleaning fluids - test and specify
- Likely level of abuse during use

Cross reference:

- [Customers](#)
- [Testing](#)
- [Manufacturing Facilities](#)
- [Standards and Specifications](#)

Ergonomics

- Single handed use and operation - consider left and right handed use and male and female anthropometric measurements (Robinette et al, 1999)
- Grip
- Buttons:
 - Operational force
 - Ease of use
 - Prevent inadvertent operation
 - User experience
 - Illumination
- Touch screen:
 - Visible and readable during test - 12-18 inches from the eye, 4-5 inches below eye level
 - Illumination
 - Operational force
 - Font type and size

- Interface points:
 - Mouthpiece
 - Charging
 - Data connectivity
- Case:
 - Carry handle
 - Device placement and removal
- Charging
- Battery replacement
- Design for accessibility
- User design audit
- Legal requirements
- Consideration for manufacturing, assembly and packing

Cross reference:

- [Size](#)
- [Weight](#)
- [Materials](#)

Installation

- Charging:
 - Required before first use
 - Power inverter and plug connection to AC/DC power
 - Portable Appliance Testing by customer
- Connectivity:
 - Wifi connection for software setup and updates
- Registration of the device by the customer with the manufacturer
- Mouthpiece:
 - Single use or multi use
 - Insertion and removal
- Registration of test result data with client or Government bodies
 - Consider local laws regarding data protection and privacy (EU: General Data Protection Regulation)

Cross reference:

- [Documentation](#)

Intellectual Property

- Patents:
 - Research existing and expired patents in the European Patent Register for potential competitor products
 - Fees
 - EPO Guidance (EPO, 2022)

- Patent new device
- Register Design rights:
 - Professional fees, registration fees, increasing renewal fees every 5 years (£70-£140)
- Register Trademark for product/brand name
- Verify for existing products:
 - Brand logo - registered design, trademark, copyright
 - Company name and product/brand name - trademark
 - Invention - patents
 - Databases - copyright, database right, confidential information
- Non Disclosure Agreements with all collaborators and suppliers
- Consultation meetings are taking place with our legal teams to discuss:
 - Consideration for a Collaboration or Joint venture agreements, as applicable, for design collaboration
 - Identification of ownership and protection of IP resulting from the KTP project
 - Create agreement with design company to protect IP

[Cross reference:](#)

- [Legal](#)
- [Branding](#)

Legal

- Standards and specifications:
 - Market sectors
 - Geographies
 - Government bodies
- Contractual:
 - Brief legal team
 - IP ownership from KTP partnership
 - Design company collaboration - IP ownership
- Data protection and privacy legislation
- Brand identity
- Patents
- Design Registration
- Warranty
- Liability insurance
- Legal limitations on manufacturing processes
- Non Disclosure Agreements
- Classification and registration of medical device (MHRA, 2020)
- Medical Device UK Approved bodies (MHRA, 2020)

[Cross reference:](#)

- [Standards and Specifications](#)
- [Intellectual Property](#)

Life in Service (Product)

- Service life to be 5-10 years
- Typical usage for medical sector:
 - Seven days a week
 - Up to 144 tests per 12 hour working period
- Battery charge time:
 - 1 to 2 hours to full charge
 - Full charge to power the device for 12 hours
- Annual calibration and maintenance requirements
- Warranty period - consider high and low usage range

Cross reference:

- [Maintenance and Repair \(including Calibration\)](#)
- [Documentation](#)
- [Testing](#)
- [Performance and Features](#)

Maintenance and Repair (including Calibration)

- Device and battery charging unit:
 - Factory tested prior to shipment
 - Tamper proofing labelling
- PAT testing of battery charging unit - customer responsibility
- Service team:
 - Establish considering predicted volumes
 - Communicate contact details
 - Fault diagnostics and support
 - Repair and calibration service
 - 24/7 support
 - 24/48 hour response time for repairs
 - Viability of on-site support to reduce device downtime (global)
 - Customer repair will invalidate the warranty (state in manuals)
 - Stock of spares to support service
 - Scheduled calibration
 - Device to show due date
 - Show on manufacturer's device register
 - Alarm and disabling of device when calibration overdue
 - Language skills
- Customer maintenance:
 - Daily test of control material
 - Cleaning
 - PAT testing
 - Arranging annual calibration
- Software updates:

- Automatically released
- Software and apps updated through wifi connection
- Devices updated via wifi

Cross reference:

- [Documentation](#)
- [Quantity](#)

Manufacturing Facilities

Projected manufacturing volumes:

750,000 year 1	(14,700 per week)
3 million per annum year 2+	(59,000 per week)

- Production:
 - Prototypes and production capacity
 - Footprint availability
 - Existing or new tooling
 - Assembly lines
 - Headcount
 - Shift patterns
 - Training
- Current factory:
 - IT infrastructure
 - Component, WIP, packaging and finished goods storage
 - Impact on other product lines with introduction
 - Environmental management
 - PPE
 - Manual handling
 - Standard Operating Procedures
- Suppliers:
 - Circuit board from Asia
 - Injection mouldings from UK or Europe
 - Tooling and test - production volumes and maintenance plans
 - Assembly - make-v-buy decision, training, capital expenditure
 - Export/import control
 - Supplier communication - time difference, language
 - Part approval process
 - Shipping method - cost, batch size, lead-time and stocking implications
 - Contingency planning - single source
- Management:
 - Production management - shift patterns
 - Staff levels - all departments
 - Just In Time planning and manufacturing

- Training
- Cost

Cross reference:

- [Quantity](#)
- [Product and Project Cost](#)
- [Components](#)

Market Constraints

- Global COVID-19 diagnostics market size (Grand View Research, 2022) valued at USD 97.4 billion in 2021 and expected to expand at a compound annual growth rate of 7.7% from 2022 to 2030
 - Market size value in 2022 = USD 95.2 billion
 - Revenue forecast in 2030 = USD 50.1 billion
 - Consideration of this required for Product Life Span
- Share by end use in 2021 - Figure 3

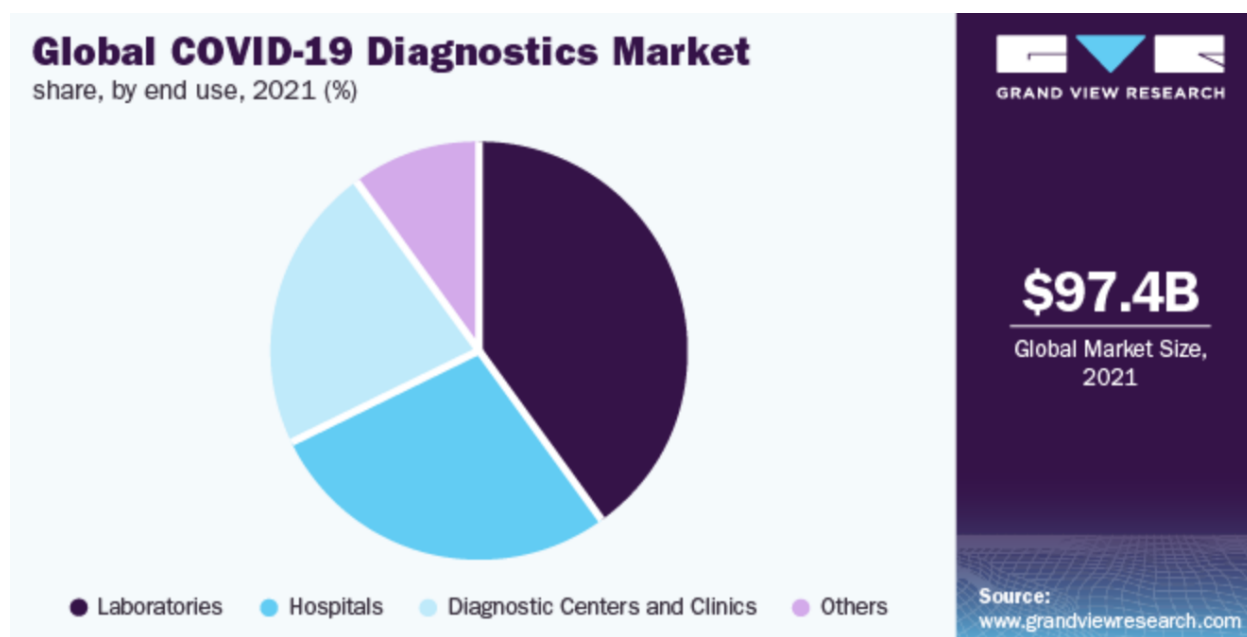


Figure 3 - Global COVID-19 Diagnostics Market

- Report identifies that the need to eliminate the risk of acquiring COVID-19 in hospitals is boosting the growth of the diagnostic centres and clinics segment
- Prominent players in the COVID-19 diagnostics market are detailed and should be considered in the Competitors section
- Geographical data to be analysed to determine target markets locations
- Sources of market knowledge:

- Management information systems
 - Finance, HR, Purchasing, Sales
 - Government departments
 - Trade associations
 - Social media
 - Educational institutions
 - Commercial data provider
- Marketing research
 - Survey
 - Focus groups
 - Interviews
- Marketing intelligence
 - Secondary research
 - Political
 - Economic
 - Social
 - Legal
 - Technological
 - Environmental
 - Industry and consumers
- Customer pains/triggers - customer value proposition canvas

Cross reference:

- [Competition](#)
- [Product Life Span](#)

Materials

- Thermoplastic for moulded parts:
 - ISO, ASTM, DIN, BS standards
 - Medical grade polymers
 - Finished product must be impact and corrosion resistant, to withstand high use and sterilisation cycles
 - Polycarbonate potential for prototype
 - Device will have limited or no contact with bodily fluids
 - Finite element analysis during design
- Acrylonitrile butadiene styrene (ABS) for carry case:
 - Lightweight
 - Tough
 - Endure accidental impacts
- Touch screen
 - Durability
 - Corrosion resistance
 - Scratch resistant
 - Sterilisation cycles
- Buttons

- Durability
 - Labelling
- Industrial standards and specifications - including:
 - Printed circuit board - IPC-A-600
 - Assembly - IPC-A-630
- Battery and charging unit
- Mouthpiece
- Chemical resistance for cleaning
- Circular economy
- Define characteristics and properties of materials - existing skills or employ Material Scientist
- Batch sizes and material shelf-life
- Material obsolescence
- Packaging - returnable/recyclable

[Cross reference:](#)

- [Components](#)
- [Circular Economy](#)
- [Performance and Features](#)
- [Standards and Specifications](#)
- [Aesthetics, Colour and Finish](#)

Packaging

- Carry case:
 - Device and accessories
 - Protection during movement
 - Ease of device removal
 - Durability
 - Manuals
- External packaging for retail:
 - Branding
 - Quality
 - Appearance
- Transit packaging:
 - Standardisation
 - Maximise units per pallet
 - Export packaging
 - Discuss with logistics team
- Labelling:
 - Device labelling in line with ISO15223-1:2016
 - Serial number
 - Calibration status
- Supply chain:
 - Part protection
 - Use at assembly line

- Discuss with procurement team
- Returnable and/or recyclable:
 - Supplier and customer location
 - Cost
 - Materials
 - Life
- Branding

Cross reference:

- [Circular Economy](#)
- [Disposal and Recycling](#)
- [Components](#)

Patents and Trademarks

- Patents:
 - Protect invention
 - Investigate and research using European Patent Office
 - Possible patent clashing
 - Similar products
 - Competition
 - Testing methods
 - What they are made of
 - How they are made
- Trademarks:
 - Company name, brand name, brand logo and product name
 - Registered or unregistered
 - Distinction
 - Graphic representation
 - Not describe goods, service or characteristics
 - Not be offensive, deceptive, have become customary or contain a specially protected emblem
 - Geographical limitations
 - Standardised registration categories

Cross reference:

- [Intellectual Property](#)
- [Legal](#)

Performance and Features

- Use frequency - likely staccato
- Device powered by electrical, rechargeable battery:

- Charge to last 12 hour working period
 - Support up to 144 tests (assuming a 5 minute test time)
 - Charging between shifts
 - Second battery option to support increased working patterns
 - Display battery charge status on the device
 - Display battery charge status when charging
- Software:
 - Determine which VOCs are present
 - Analyse ratios
 - Give positive or negative result
- Built in data logger:
 - Hold test data from up to 14 working days in case of data export delay
 - Data exported via wifi or external device connection - subject to client local policies
- Repeatability
- Accuracy
- Consider economic implications of targets
- Easy connection and removal of mouthpiece
- Performance targets:
 - Device start up within 30 seconds of power on
 - Breath sample:
 - 0.25L breath sample collected and tested
 - Display countdown of time for patient to exhale during sample collection - 10 second countdown
 - If suitable breath sample not supplied, report on device within 5 seconds
 - Pass or fail test result displayed on unit within 3 minutes
 - Time to test result to be displayed
 - Results shown with RED (Fail) or GREEN (Pass) identification
 - Time from startup to test result to not exceed 4 minutes - allowing 1 minute for mouthpiece insertion and removal
- Design for disassembly
- Establish realistic expectations of users and optimise user interactions (Weinger, M.B. et al. (2011))

[Cross reference:](#)

- [Environment](#)
- [Circular Economy](#)
- [Materials](#)

Political, Social and Cultural

- PESTLE analysis
 - Tax and NI rises increase national healthcare funding
 - Tariff implications for import and export
 - Stability of financial markets
 - Energy price rises
 - National and International events destabilising supply chains

- Advances in manufacturing technology and material science
 - Compliance and approval processes for medical devices - country specific
- Government Policies
- Consumer movement
- Feedback from market intelligence
- Cultural and religious considerations
- Engagement with Government departments
- Customer purchasing teams and processes

Cross reference:

- [Customers](#)

Product Life Span

The product life is anticipated to be 20+ years for COVID-19 with the potential for this to be increased with development for breath analysis for other viruses. This is to be considered when planning tooling (manufacturing and test), manufacturing facilities and all stages of the supply chain. This must also be considered when specifying materials to reduce potential for obsolescence.

Cross reference:

- [Market Constraints](#)
- [Competition](#)
- [Manufacturing Facilities](#)

Product and Project Cost

- Development costs
- Prototyping and testing costs
- IP protection costs - patents, design registrations, trademarks
- Capital costs - tooling, plant, machinery
- Material costs - including predicted fluctuations in costs and exchange rates
- Manufacturing costs - labour, training, overheads
- Distribution costs - warehousing, freight, import/export taxes
- Competitor pricing analysis
- Selling price expectations of retailers
- Establish cost patterns and study before setting target cost

Cross reference:

- [Manufacturing Facilities](#)
- [Prototyping](#)
- [Intellectual Property](#)

- [Competition](#)

Prototyping

- Electrical and mechanical systems:
 - Successfully prototyped
 - See Project team for costs and reporting outcomes
 - No further design changes anticipated
- Physical envelope:
 - Collaboration with external company to design
 - Prototyping of the injection moulding parts:
 - 3D printing for initial samples before progressing to injection moulding tooling
 - Aluminium tooling for prototypes - lower cost, low runs and allow for modifications
 - Assume 100 off sets
 - Anticipated cost £50k
 - Lead-time for tooling
- Assembly:
 - 50 sets of all components required - anticipated cost £10k
 - SOPs to be drafted and tested during prototype assembly for productionisation
 - Planning of production personnel and capacity discuss with planning and manufacturing teams
 - Set up production area
 - 25 off sets to be passed through for test and quality inspection
 - Prove fit, form and function and aesthetics

Cross reference:

- [Manufacturing Facilities](#)
- [Testing](#)
- [Timescales](#)

Quality and Reliability

- Rugged
- Anti-shock protection in case of device being dropped
- Appearance of quality and cleanliness - instil patient and user confidence
- Must not appear complicated
- Display and software must be clear and easy to understand
- Appearance in keeping with our company brand values
- Reliability is paramount for maintaining a positive brand image
- Customer support must be considered
- Look appealing - increased user vigilance and job satisfaction (Weinger, M.B. et al. (2011))

Cross reference:

- [Branding](#)
- [Aesthetics, Colour and Finish](#)

Quantity

Projected manufacturing volumes are 750,000 in the first year and 3 million per annum thereafter. This equates to:

14,700 per week year 1

59,000 per week year 2 onwards

- Supplier discussions:
 - Circuit board:
 - Manufacturing method - automation, hand placement
 - Automated inspection and testing
 - Injection moulded parts
 - Temporary tooling for prototypes
 - Multi-cavity production tooling
 - Tool life and maintenance plan
 - Stock levels and ordering process (forecasting, call-offs, maximum stock liability)
 - Batch sizes
 - Lead-time
- Internal reviews:
 - Manufacturing engineering team:
 - Assembly jigs and tooling
 - WIP control
 - Line-side stock
 - Traceability control
 - Stores personnel:
 - Kanban
 - Stock control
 - Packaging

Cross reference:

- [Components](#)

Safety

- Production:
 - Manual handling
 - PPE
 - COSHH
 - Environmental considerations
 - SOPs with care points

- Testing
 - Packing and distribution
 - Training
- Device use:
 - Documentation
 - PPE
 - Environmental considerations - mouthpiece, battery
 - Standards and Specifications
 - Device registration
 - Data registration
 - PAT testing
 - Calibration

Cross reference:

- [Documentation](#)
- [Standards and Specifications](#)

Shelf-Life - Storage

- Target and means to combat decay
- Link to performance for storage conditions
- Storage and transport in any orientation
- Date coding of device
- Battery implications
- Documentation
- Testing

Cross reference:

- [Performance and Features](#)

Shipping and Distribution

- Packaging:
 - Shipping method requirement - road, air, sea
 - Processes for returnable packaging
 - Stacking for transit and storage
 - Maximum stack height and load
 - Centre of gravity
 - Lifting aids/devices (safe working loads)
- Cost:
 - Combine deliveries with existing product ranges
 - Maximise products on pallet footprint
- Logistics partners:

- Capacity of existing with potential volumes
 - Geographical locations
 - Stock hubbing
 - Licensing for transporting batteries
- Processes for returned devices (end of life)

Cross reference:

- [Weight](#)

Size

- Single-handed operation
- Approximately the same size as the Lion alcolmeter® 900 (Lion Laboratories, 2022) - 210mm x 75mm x 45mm
- Carry case to be approximately 450mm x 300mm x 100mm
- Ergonomics
- Usability

Cross reference:

- [Weight](#)
- [Ergonomics](#)

Special Processes

Initial analysis of the components required for the device have determined that no special processes will be required (Special process being a process which puts some kind of stress on the product or part of the product due to mechanical, chemical or thermal operations).

Conformal coating may be required to protect the circuit board from the environment and corrosion and this may be considered to be a special process.

The Design Team must identify any special processes and reflect these in the PDB. Special processes must be identified on drawings and discussions held with suppliers with regards to controls.

Cross reference:

- [Components](#)

Standards and Specifications

- Regulatory marking:

- CE marking, UKCA marking or CE UKNI marking
- Reporting of device problems to MHRA using the Yellow card scheme
- Medical Devices Regulations 2002 - definition as an in vitro diagnostic medical device (IVD)
 - UK MDR fall under the Consumer Protection Act 1987
 - MHRA (2020) Guidelines - Medical Devices: how to comply with the legal requirements in Great Britain
 - Classification:
 - Class IIa device
 - Active device for diagnosis - see figure 4 (UK MDR 2002)

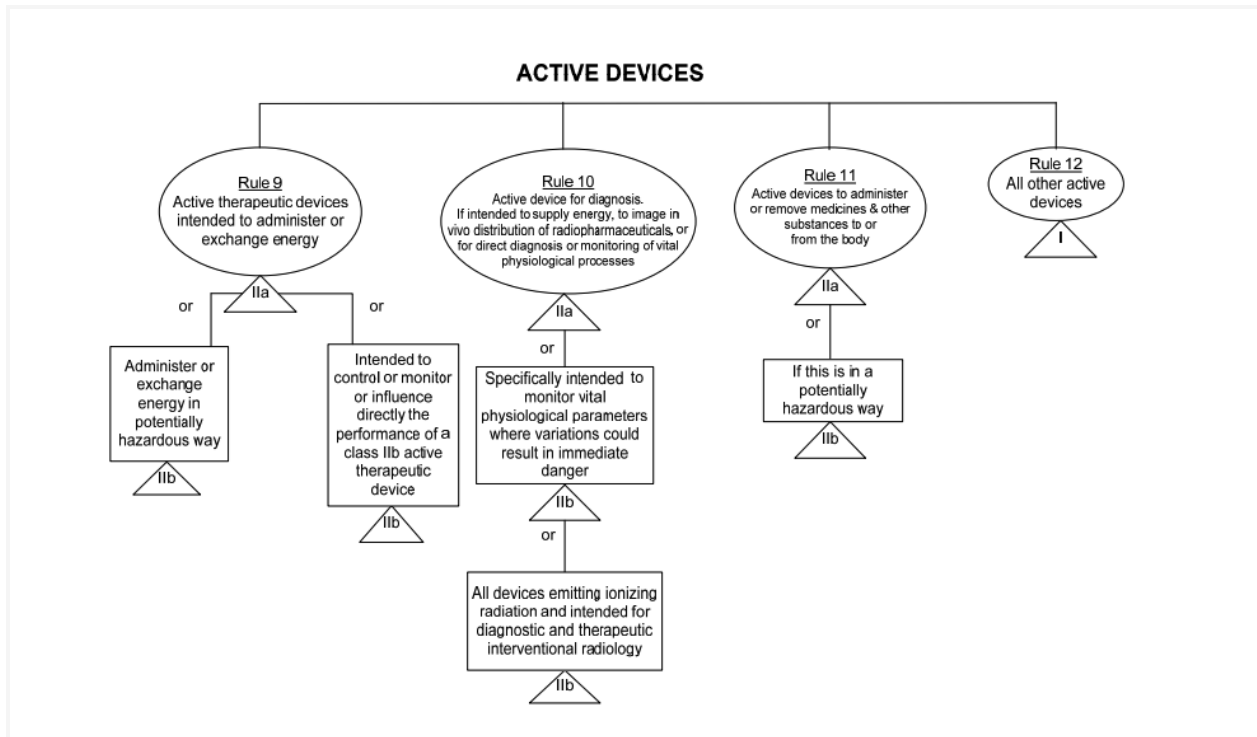


Figure 4 - Classification of Medical Devices

- UK Approved Body:
 - Conformity assessment for the specific classification (MHRA UK Approved bodies, 2022)
 - Issue UKCA certificate which can be placed on the device (MHRA Guide conformity assessment and the UKCA mark, 2020)
 - All medical devices on the Great Britain market must be registered with the MHRA
- Clinical data must be held and be based on clinical investigations
- Design to current International and British Standards
 - Research to ensure compliance with standards which are requisite within the country of purchase.
 - Conform to all industrial standards including those shown in Table 1.

ISO13845:2016	Medical devices — Quality management systems — Requirements for regulatory purposes (applicable to the full supply chain)
EN60601	Medical electrical equipment and systems - Group of standards which cover the safety, essential performance and electromagnetic compatibility of medical electrical equipment and related systems
ISO 15223-1: 2021	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
ISO 14971:2019	Medical devices — Application of risk management to medical devices
ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer (includes requirements for identification and labels)
IEC 62304:2006	Medical device software — Software life cycle processes
ISO/TR 20416:2020	Medical devices — Post-market surveillance for manufacturers
ISO/TR 80002-2:2017	Medical device software — Part 2: Validation of software for medical device quality systems
ISO 15378:2017	Primary packaging materials for medicinal products
ISO 16142-2:2017	Medical devices — Recognized essential principles of safety and performance of medical devices

Table 1 - Applicable International/British Standards

- Additional CE Marking Legislation:
 - Low Voltage Directive (LVD) (2014/35/EU)
 - Electromagnetic Compatibility (EMC) (2014/30/EU)
- Environmental considerations:
 - Batteries and Accumulators (Placing on the Market) (Amendment) Regulations 2012 and Waste Batteries and Accumulators (Amendment) Regulations 2015
 - Waste electrical and electronic equipment (WEEE) Directive (2012/19/EU)
 - ISO14001:2015 Environmental Management Systems:
 - Held by our organisation
 - All suppliers (Except COTS parts) to have certification or demonstrate controlled processes and a plan towards certification
- ISO9001:2015 Quality Management Systems:
 - Held by our organisation

- All suppliers (except COTS parts) to have certification
- Additional research to be conducted and regularly reviewed to ensure that the Product Design Brief contains a comprehensive list of international standards relevant to the device
- Liaison with sector bodies and technical committees to stay abreast of sector changes:
 - ISO/TC 210 Quality management and corresponding general aspects for medical devices - focus on products with a medical purpose with deliverables including standards, guidance documents and white papers
 - UK Medicines and Healthcare Products Regulatory Agency (UK MHRA)

Cross reference:

- [Disposal and Recycling](#)
- [Market Constraints](#)

Testing

Pre-production release:

- Repeatability
 - Demonstrate agreement between multiple measurements from samples
- Reproducibility
 - Operator to operator, day to day or site to site
- Interfacing substances
 - Substances which may be present in exhaled breath do not affect the test result
- Drop test
- Shock and vibration
- EMC

Clinical performance:

- Good clinical practice for the design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the clinical performance or effectiveness and safety of medical devices
- ISO14155:2020 Clinical Investigation of medical devices for human subjects - Good clinical practice

Production:

- Circuit board:
 - Automated Optical Inspection (AOI) in conjunction with:
 - In Circuit Testing (ICT) or Flying Probe testing
 - Discuss cost and coverage differentials
 - Provide volume information
 - Parts serialised with traceability to component level
- Injection moulded parts:
 - Test strategy to be discussed with supplier
 - Frequency of testing - first off, last off and one in 50 (dependant on batch run size)

- Statistical Process Control
 - Parts serialised for traceability to batch level
- Other components (buttons, touch screen etc):
 - Commercial off the shelf (COTS) items
 - Control processes to ensure 100% quality and delivery
 - Batch traceability via assembly records
- Assembly testing:
 - Devices uniquely identified by serial number label
 - 100% functional test
 - PASS marked on the device label
 - Non-conformance process for identification of FAIL devices
 - 100% Visual inspection
 - Recorded electronically
 - SOPs for inspection criteria

All test data is to be retained for a minimum of 10 years following the production date by suppliers and after the final device test.

Cross reference:

- [Quantity](#)
- [Manufacturing Facilities](#)

Timescales

- Appointment of Project Manager and define organisation roles and responsibilities (PRINCE2 methodology)
- Gantt chart
 - Key milestones:
 - Market research
 - Design
 - Prototyping
 - Supply chain management
 - Manufacturing and assembly
 - Intellectual Property
 - Branding
 - Tasks with ownership
 - Target dates
 - Budget costs
- Use gated process (Cooper, 1990) with Go/No-go decisions by Project Board

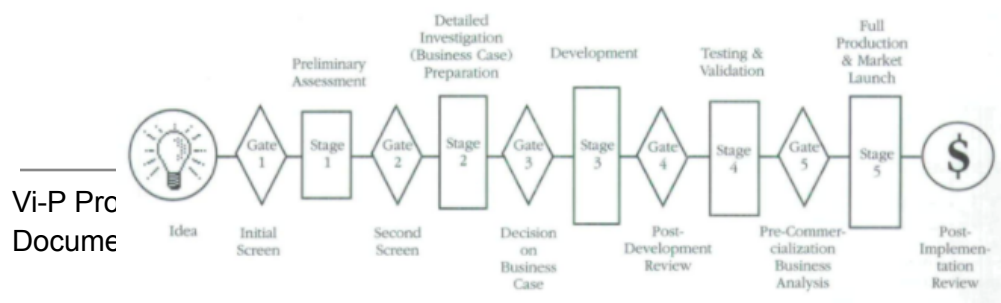


Figure 5 - Cooper's Stage-Gate System

- Market intelligence to determine target launch date

Cross reference:

- [Market Constraints](#)

Weight

- Device use:
 - Held at arm's length
 - Single hand use
 - Test duration of 5 minutes
- Device to be approximately the same weight as the Lion alcolmeter® 900 (Lion Laboratories, 2022):
 - 210g without battery
 - Battery weight to be considered
- Fully packed case to weigh no more than 1kg
- Plastic material specification:
 - Durability;
 - Cost; and
 - Weight
- Manual handling:
 - Manufacture
 - Assembly
- Logistics

Cross reference:

- [Components](#)
- [Materials](#)
- [Size](#)

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