

Management of New Product Development
Assessment 2 – Creating the Product Design Brief

Virus Detection System Product Design Brief

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Product Design Brief

Virus Detection System

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VERSION HISTORY

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SYNOPSIS

Company Profile & the Story So Far

The company is a leading manufacturer of electronic breathalyser products, which utilise chemical alcohol detector systems, and has predominantly targeted the police and security forces market.

Always developing with the latest technology, the company strives to provide users with new products to satisfy a wide array of requirements. With increasing technological advancements and a focus on innovative solutions, the company aims to provide solutions for ever growing social and clinical issues.

In light of the Coronavirus pandemic and through a Knowledge Transfer Partnership, the company has identified the possible commercial opportunities that may exist if the flagship alcohol detection system was adapted to include the detection of organic material, such as those found in the breath. New technologies that utilise machine learning algorithms can identify certain diseases through people's breath, by identifying patterns in subtle chemical changes (Anthes, 2021).

Several studies have proved the concept of virus detection through breath analysis (Exline et al. 2021; Liang et al. 2021; Haelle, 2021), which has been corroborated by the company's own in-house validation. Following this, the company has greenlit the project to develop and commercialise a handheld virus detection system suitable for use in a variety of clinical and personal settings. From here on out, the to-be-developed virus detection system shall be referenced as 'the device'.

The company has approached a London-based company to design the physical casing of the new device, and this Product Design Brief will serve as the central source of information for the design company and various internal departments and provide the location for their contributions. The development of this product design brief early in the project will ensure a smooth-running project with successful product outcome (Zarney, 2002; Phillips, 2004). The brief shall include elements of the following:

- Market and commercial considerations
- Technical and material requirements
- Manufacturing requirements
- Time scales and budget

Current Problem

Although two years on, COVID-19 is still causing disruption around the world, and while several initiatives have been put in place there is still a strong need for people to be tested. Many countries require passengers to be vaccinated, or have proof of a negative test, however the spread of the virus still poses a risk, and additional testing can be a barrier to this. Large scale events have similar testing requirements, and there are risks when coming into close contact with elderly or at-risk friends, loved ones, colleagues, or simply strangers, that would benefit from additional testing.

Current test methods are commonly in the form of lateral flow tests or PCR tests, which are more invasive, uncomfortable, time-consuming, and often difficult for patients to use, especially for people with learning disabilities and autism. PCR tests also require samples to be analysed in a lab, often taking several days for patients to receive results requiring more planning and preparation when a test is needed for a particular activity.

Our Goal & Product Overview

Our goal is to develop a device that solves these issues many people face. The internal virus detection system has been prototyped, validated and is available for utilisation, however the handheld, commercialised product must be designed and developed in accordance with this design brief.

The device will be considered a success if it allows the 'user' (the person using the test on someone else) to quickly, easily and to a high degree of accuracy test a patient (the person being tested) for the presence of a virus in a non-invasive manner. This must be achieved by a patient blowing into the device through a mouthpiece, where the internal system will analyse the breath sample for key biomarkers before providing a positive, negative, or error result on a display within the specified period. The device must be able to store patients' results data through cloud-based storage.

The device must be easily sanitised to prevent cross contamination, which will be through an interchangeable, disposable mouthpiece. One mouthpiece must be used only once, by one patient. The device must be suitable for personal and clinical use, and such potential markets will be discussed later in the brief.

The company has projected first year manufacturing volumes to be 750,000 units, increasing to 3 million units per annum the following years. Mouthpiece quantity is yet to be determined at this stage.

Due to the ongoing circumstances surrounding the Coronavirus pandemic, the company are anxious to launch the new product as soon as possible, and as such, the board have determined a deadline of 12 months to launch.

Company Constraints

- Time
 - Due to the ongoing pressures of COVID-19, time-to-market has been defined as 12 months
- Financing
 - Limited budget available for R&D, production, and marketing activities
- Manufacturing facility
 - Assembled in house using existing facilities
 - For future expansion – explore building new facilities in target locations to reduce transportation costs and expand capacity
- Production capacity
 - No issues for years 1-3 (750,000 – 3,000,000 units)
 - Further sales will require expansion investigation
 - CapEx exploration and business case justification must be provided for all investments
- Sourcing
 - Cost of polypropylene increasing, thereby reducing margin on final project (Statista, 2022)
 - Supplier agreements must consider following ICIS for changing costs of polypropylene (ICIS, 2022)
- Marketing
 - Wide array of possible market that could be explored
 - Diligence must be done to ensure focus is targeted on the right markets
- Future investment
 - Bank loans and/or Government support for expansion
 - For all externally produced components, consider future possibility of internal manufacture to improve cost margins

- Quality control
 - For all components manufactured externally – agreements, prior testing, and declaration of conformity must be received
 - For internal components and final product – thorough QA testing is required

COMMERCIAL

Target Market: Buyers, Users & Patients

Initial market research has shown there are strong markets available for the device. A range of potential markets have been identified in both personal and clinical fields, offering large market sizes.

The best uses the device is for large-scale screening of patients for clinical testing, event testing and vehicle boarding. Non-clinical testing can also be performed without a healthcare worker present. Previous experience of this type of testing would be done using a lateral flow test.

Further market research is required, but examples of the possible markets below:

- Airports
- Border control
- Large scale events
- Mass screening
- Festivals
- Schools
- Enforced testing
- Pre-event testing
- Vehicle boarding
- People with learning disabilities and autism
- People who are housebound and cannot travel independently
- Hospitals
- GPs
- Private healthcare
- Home use

Consideration must be given to different stakeholders within a market and their differing requirements, for example:

Market	Buyer	User	Patient
Airport	Supply chain staff	Staff	Passengers
Festivals	Festival organisers	Staff	Attendees
Education (schools/universities)	School administration	Teachers	Students
Hospitals / GPs	Supply chain staff	Doctors, nurses	Patients

Developing personas

For each targeted market, make use of Emic and Etic research (Batat, 2019) for the preparation of personas to define what customers look like, to gain further insights into their needs and

requirements. Creating perspectives helps to provide a clear understanding of how and why a consumer is using a product. Tools that may prove useful are the Value Proposition Canvas (Strategyzer, 2017) and the Empathy Map (Gray, 2017).

Competitors

Must consider price, intellectual property, ranges for what is already on the market for the device and each of its components.

Considerations:

- Virus detection system
 - For future expansion, has new technology been developed that could be implemented?
 - Smaller, cheaper, quicker results, etc?
- Mouthpiece
 - Cheaper, more ergonomic, more readily available?
 - Could an existing solution be modified to fit the device?
 - Could the device be redesigned to fit an existing mouthpiece?
- Handheld casing
 - What are other handheld medical devices doing?
 - Are specific colours, shapes, sizes, features, being used?
- Printed Circuit Board (PCB)
 - Are cheaper or smaller PCBs available?

Competitor devices:

Deep Sensing Algorithms - DSA BreathPass™



Silver Factory Technology - TracieX Breathalyser, Singapore



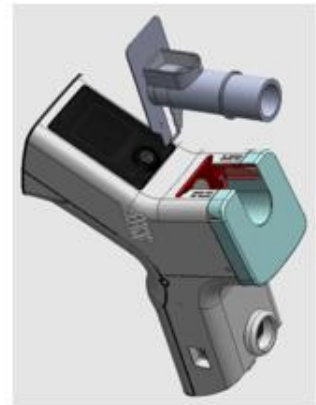
Canary Global Inc. - ASU
Detect CV-19™



Rutgers Institute for Translational
Medicine and Science, USA



Exhalation Medical
Technology – CoronaCheck™



Market Constraints

- Supply chain, customs and border tariffs, regulations, and workforce implications of Brexit (Scott, 2021)
- User perception of efficacy and acceptance of COVID-19 breathalyser device

Political, Social & Cultural Implications

Requirements from region to region will vary, which may affect the design, logistics, or sale of the device. Such differences may include:

- Clinical or public event testing requirements
- Disposal protocols for potentially contaminated mouthpieces
- Material conditions and taxes e.g. plastic packaging tax on parts with less than minimum required recycled polyprop percentage
- Demand stability of markets affected due to possible negative implications of future COVID-19 outbreaks
- Capability of cloud-based storage for underdeveloped countries

Branding

The device must include branding added directly to the device, including company logo, product name, reference number, product code. Other considerations:

- Website link
- Advertisement
- Model name and logo
- Consistency
- New branding for new markets (different from alcohol breathalysers)
- Packaging design
- Product literature (usage and testing – medical trial journals, expert opinions, key opinion leaders)
- Dedicated FAQ page

Purchasing & Pricing

Orderable unit configurations and pricing to be defined for device and mouthpiece, for example:

Unit

- One off payment available per unit, with MOQ of 1 unit
- One off payment available per carton of units, with MOQ of 1 carton
- Price per level of orderable unit to be determined at design freeze sign off

Mouthpiece

- One off payment available per bag of mouthpieces, with MOQ of 1 unit (1 unit may contain several mouthpieces)
- One off payment available per carton of mouthpieces, with MOQ of 1 carton
- Price per carton of mouthpieces to be determined at design freeze sign off

LEGAL

Intellectual Property & Patents

- Due diligence required to ensure no conflicts or infringements of existing patents, trademarks, or registered designs (Whittle, 2020)
- Application for IP of developed product if deemed suitable – utilise company solicitors
- Professional and associated renewal fees must be considered
- Associated documentation preparation
- NDA must be signed with design agency

Legal

- Testing tolerances for pass/failure rate
- Registration of product as medical due to 'diagnosis of virus' (MDD, 2017)
- Data protection of user's information and results (Data Protection Act, 2018)
- Product liability for product defects (EEC, 1985)

Standards & Specifications

It is essential that the device fully complies with the specified standards of quality. Preliminary research suggests the below standards are applicable, however, further research is needed:

ISO 13485	Medical devices — Quality management systems — Requirements for regulatory purposes
ISO 14971	Medical devices — Application of risk management to medical devices
IEC 62304	Medical device software — Software life cycle processes
ISO 15223-1	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
ISO/TR 24971	Medical devices — Guidance on the application of ISO 14971

ISO 17664-1	ISO 17664-1 - Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices
ISO 14971:2019	Medical devices — Application of risk management to medical devices
BSI Kitemark	UK Product and Service Quality Certification Mark
ISO 24552:2020	Ergonomics — Accessible design — Accessibility of information presented on visual displays of small consumer products
ISO/IEC 27001	Information Security Management
ISO 10993-1:2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
ISO 11607-1:2019	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems

Documentation

- Instruction for use manual required by MDD (2017) for medical devices
 - To be available with each orderable unit of the device
 - To be available for PDF download from company website
- Consider ISO 15223-1 for general labelling requirements
- Risk management activity
- Verification and validation of developed product

QUALITY

Safety

- Minimal possible contamination from one mouthpiece to the next
- Instructions for use must indicate safe practise of device
- Guidance must be provided on disposal of mouthpieces – subject to local guidance
- Electronic elements must be PAT tested (battery charging unit only)

Regulatory

- Certification already been obtained from required regulatory agencies through initial prototypes
- Medical Devices Directive 93/42/EECMedical Devices Regulation (EU) 2017/745
- General Product Safety Directive
- In-vitro Diagnostic Medical Devices
- CE Marking Directive

Shelf Life and Storage

- Accelerated age testing to determine shelf life of device (Eurofins, 2021)
- Seal stability testing and packaging performance for mouthpieces
 - Mouthpieces must be in sterilised packaging to avoid potential contamination prior to testing

Quality

- Must be made from quality materials, within budget
- Colours, size, and other elements should be aligned to avoid device appearing cheap
- Colour must be in alignment with medical device guidelines
- Must be easy to use and deliver quickly, requiring minimal effort from customer
- Must be traceable through GS1 barcoding system (GS1, n.d.)
- Audible or light alert to indicate product failure/error
 - Digital display to indicate specific error message to determine next steps
- Drop test performance to ensure product is safe

Life in Service

- Test duration
- Mouthpiece changeover time
- Number of tests per day
- Quantity of tests before recalibration
- Average usage per day (max per day)
- Comms to customers on expectations

Testing

- Verification and validation testing required for proof of concept and design freeze
- Regular QC testing from production samples
- All devices require calibration prior to distribution
- Acceptable Quality Limit (AQL) to determine sample size and acceptance number
- Data collection of all test results

Risks

- Large potential consequences if results of device are inaccurate (e.g. false positives/negatives)
- Acceptable rate must be communicated to customers

DESIGN

Please note: all design considerations must be discussed and reviewed from the outset of the project, and must come from internal stakeholder opinion and expertise, as well as external customer feedback. Cycles of feedback must be obtained throughout the project.

Ergonomics

- 'Handle' of the device must be designed targeting the 5th percentile female hand to the 95th percentile male hand to accommodate the physical range of grasp, motion, and flexion (Rutter, 2018)
- Must allow for user to comfortably and without interference hold the device while testing patient

- Functional aesthetic aspects must provide visual or tactile clues to the user to encourage best interaction practice (Rutter, 2018)
- Display must be in location that allows easy access from thumb of the hand holding the device – all one-handed operation
- When holding the device, the user must easily be able to see the display screen
- Mouthpiece connection must be easy to attach and remove – must not have sections where dirt or contaminants can gather
- Shape of the device must allow for comfortable holding – single handed operation

Materials

- Outer casing must be made from thermoplastics suitable for injection moulding
 - Consideration given to regrind or recycled material for carbon emission impact
- Touch screen digital display
- Mouthpiece – plastic or cardboard?
- Packaging material considerations – plastic film, cardboard shipping cartons, cardboard consumer cartons – consideration to reduce materials where possible
- Internal electronics – quality tested predelivery to Carmarthen site
- Regulatory considerations
 - ASTM, DIN, BS, ISO considerations
 - Quality & Reliability “EN45000”
 - Legal “Confidentiality Agreements etc”
 - Industrial standards “BS EN 60601 1-1,1-2,1-4”
 - Industrial Standards & Specifications “MDA and/or FDA approval” etc.
 - Manufacturing facilities

Weight

- Device must be as lightweight as possible for:
 - Transportation considerations
 - User consideration – holding for long periods of time if mass screening
- Carton weights must be set within manual handling weight limit guidance (HSE, 1992)

Prototyping

- Fully realised prototype must be available for design freeze sign off (e.g. 3D printing)
- Several concepts may be prototyped to aid with development
 - Form, shape, colour, compatibility with predetermined components
- Budget available for prototyping requirements

Product Life Span

- No unstable materials or components that would indicate a short shelf life
- Minimum 5 years – accelerated age testing to determine product life span

AESTHETICS

Colour

- Handbook of Human Factors in Medical Device Design (Weinger, Wiklund & Gardner-Bonneau, 2010) considerations / important factors:
 - Colour choice, consistency, and number of colours
 - Red, green, yellow, orange and blue are the most easily recognized colours
- Colours should be consistent throughout the product, but also with company brand colours (Stipe, 2014)
 - Note – using company colours should not be used if deemed inappropriate for the context
 - Tint or shade could be used
- What are the characteristics and values the user will associate the product with?
- Colour must have clinical, intelligent, and professional colour scheme
- Must be different colour scheme to other company product range (own breathalyser range) to clearly differentiate product family
- Cool, calming colours, consistent with medical devices
- For consideration – historically and commonly medical devices are green and blue

Surface Finish

- Surface finish must not be so rough that they provide areas for contaminants to be stored
 - Infection Control requires easy to clean and disinfectable surfaces
- Must not be so smooth or shiny that they show fingerprints or smudges clearly
- Higher textured finish must be applied around the devices 'holding' area (for the hand and fingers) – act as guidance for the user

Size

- Size must be suitable for range of different users (hand sizes) to comfortably hold the device (Rutter, 2018)
- One size fits all approach
- Consideration given to reduction in size for reduction in materials (cost)
- Must be designed around predetermined components

Shape

- Shape of the device must allow for comfortable holding – single handed operation
- Must be clearly identifiable, where the user holds the product
- Must allow for user to comfortably and without interference hold the device while testing patient
- When holding the device, the user must easily be able to see the display screen

ACCESSORIES & FEATURES

Mouthpiece

- Detachable single use mouthpiece – One mouthpiece per patient, per test

- Made from moulded plastic or cardboard – benefits of both
- Must be big enough that no possibility of cross contamination onto main device
- Must be small enough for packing, transportation, and storage considerations (mass screening requires many mouthpieces)
- Must be easy to attach/detach
- Disposal guidance must be written into instructions for use
- New design or explore existing mouthpieces and design device for compatibility
- Device must include sensor to sense when mouthpiece is attached – device will not ‘run’ unless mouthpiece is attached

Battery

- Device must be equipped with rechargeable batteries
- Mains charged or separate charging dock
- Target usable battery life of 12 hours minimum (common nurse/doctors shift)
- Device must be able to clearly indicate when device is:
 - a) Running low on battery
 - b) Out of battery

Display

- Touch screen digital display required
- Size must allow for clear identification of results, error/warning messages, charging status, readiness for sample collection
- Text size and font to be determined through development
- Screen must have backlight for use in dark environments

Data Storage

- Device must incorporate a cloud-based storage database
- Multiple devices must be linked to designated reference database
- Possible to review data on external computer
- Device must have internal storage capabilities of storing a to-be-set number of results e.g. last 100 results

Portability

- Device must have element of portability that allows travel from one location to another – prerequisite for clinical usage
- Possible accessories:
 - Attachable lanyard
 - Carry case

Alerts

- Audible alerts during operation
- Visual lighting alerts during operation
- Possible alerts:
 - Device ready for (next) sample connection
 - Device completed sample collection
 - On/off sounds
 - Errors or warnings

USER EXPERIENCE

Instructions for Use (IFU)

- Device must be easy to use that requires little training without need for trained personnel
- Physical IFU must be available with each orderable unit
- Digital IFU must be available for download from the company website
- IFU must clearly demonstrate all operational usage of the device, including:
 - Performing test
 - Attaching and detaching mouthpiece
 - Interface and digital display guidance
 - Charging method and usage guidance
 - Mouthpiece disposal recommendations
 - Troubleshooting
- Contact information for customer care teams for further discussion

Installation

- Mains power required for charging
- Regional power cables for different markets
- Ability to create user profiles that can be registered on the device and cloud-based system

Performance

- Device must be compatible with:
 - Mouthpiece
 - Charger
 - Lanyard
 - Carry case
- Device will not run unless mouthpiece is attached
- Removing mouthpiece from device must trigger a data reset for next sample collection
- Target operational timings have been set based on prototype performance:
 - Power on to ready-for-sample-collection time 60 seconds
 - Sample collection time ('blowing' time) 10 seconds
 - Analysis of sample collection time (results) 30 seconds
 - Next patient time:
 - Data reset time 10 seconds

- Mouthpiece changeover time 15 seconds

Maintenance & Repair

- All devices require calibration prior to distribution
- Low expectation that devices will need recalibration
- Replacement or repair services
- Ability to open casing for inspection or tamperproof casing
- Determine whether parts will be replaceable for returned faulty products

Reliability

- Quality testing of prototypes have indicated a successful detection rate of 99.7%
- Quality materials and components from accredited and reliable suppliers must be used to maintain proven performance reliability
- Perform regular audits on suppliers to ensure consistent manufacturing
- IFU must be provided to users to ensure correct usage – incorrect usage may negatively affect reliability
- If the test fails, an indication of why must be indicated as this could be due to the device requiring calibration. Possible failure modes:
 - Insufficient breath collection
 - Out of environmental tolerances
 - Low battery
 - Faulty product

Environment (Product Use)

For many medical devices that are manufactured from metals and robust plastics, the evaluation time for a product's shelf life can be significantly shortened by aging the materials at elevated temperatures (often as high as 55°C).

- Digital display backlight must allow user to clearly read screen in dim lit conditions
- Light alerts must be incorporated to inform users of things, when being used in a loud area
- Audible alert sound level must be in accordance with IEC 60601-1-8 Alarms, Sound level measurement
- Device may get contaminated through repeated use so materials must allow for disinfecting

Languages

- Device must be programmed with Interface language packs
- Digital display of the device must be easily configurable
- Documentation and IFUs must be available in a range of languages:
 - All available in PDF format from the company website
 - Physical Multilanguage IFU to reduce number of SKUs

TRANSPORTATION

Packaging (Formats)

- Packaging for variety of product configurations – formats will vary depending on market of use
- Example of possible configurations:

Product	Quantity	Packaging	Contents
The device	1	Consumer carton for 1 device	1 device, 1 charging system, 1 IFU
The device	50	Wholesale carton of 50 devices	50 consumer cartons of 1 device (see above)
Mouthpiece	10	Small consumer carton of 10 mouthpieces	10 mouthpieces
Mouthpiece	100	Medium consumer carton of 100 mouthpieces	100 mouthpieces
Mouthpiece	1000	Wholesale carton of 1000 mouthpieces	1000 mouthpieces

- Packaging must be developed to contain the device safely and securely
- Elements of user experience must be considered when developing packaging (Earl, 2022)
- For sustainability considerations, source recycled cardboard and reduce single use plastics where possible
- Dimensions of cartons should allow for optimised palletisation (e.g. cartons covering whole footprint of pallet)
 - UK and Euro pallets
- Packaging must be validated to ensure adequate protection of product during transportation (drop and impact testing, load stability, shock and fragility testing, compression testing, etc.)
- Notable standards for packaging durability:
 - ISTA 1A drop test procedure
 - ISTA 2A: Packaged-Products weighing 150 pound (68 kg) or Less
 - ASTM: D7386-16 Standard Practice for Performance Testing of Packages for Single Parcel Delivery System 150 lbs or less
- Obtain regulatory compliance where evidence of optimised packaging is required (FDA, MRHA)
- All packaging levels must have required labelling in accordance with medical device guidance for safe handling
 - ISO 15223-1: Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

Shipping

- Global online purchasing availability
- Development and implementation of eCommerce systems prior to launch
- Stock management considerations for products to reduce leadtimes for customers
- Weight considerations to shipping cartons
- Dimensions of cartons should allow for optimised palletisation

MANUFACTURING REQUIREMENTS

Device Construction / Format

Developed product must consist of:

- Internal virus detection system
- Plastic mechanical element – injection moulded
 - Explore manufacturing internally or sourcing externally
 - UK or Europe would, for now, be seen as favoured source for the moulded parts
- Product electronics contained in a single PCB (delivered fully tested prior to delivery at Carmarthen)
 - Preliminary research indicates China or Malaysia remain the most favourable source of PCBs
- Digital display

Sustainability & The Circular Economy

- Material considerations:
 - Recycled cardboard for product packaging
 - Minimal single use plastics
 - Recycled thermoplastics for casing where possible
 - Cardboard or recycled plastic mouthpiece
- Process considerations
 - Offer collection services for disposed plastic mouthpieces to regrind and use in manufacture of new parts

Manufacturing Facilities & Environment

- Final assembly, testing, packing, and shipping at the Carmarthen factory
- Where possible, utilise existing machinery
- New injection moulded tooling required for device casing – must be multi-impression for cycle time optimisation
 - Internal toolroom or external toolmakers for manufacture
 - Large, expected forecasts requires durable material e.g. 420 stainless steel
- Consider replicability of new equipment for future expansion – localised production of products
- Implement lean practices to ensure optimisation of onsite production process
- CAPEX budgeting activity for new equipment to improve processes
- Cost comparisons of internal and external manufacture of applicable components
 - E.g. injection mould company or source injection mould machine for internal manufacture
- Consider opportunities for professional development for employees by providing training on new systems

Quantity

- Expected year 1 sales: 750,000 devices
 - Expected 8-hour/5-day working week: 360 devices to be made hourly
- Expected year 2 sales: 3,000,000
 - Expected 8-hour/5-day working week: 1442 devices to be made hourly
- Annual forecasts expected to increase
- Quality material required for injection mould tool due to high volumes
- Multiple tools and machines may be needed
- Business case to determine inhouse or external manufacture

Processes

- Consider collection services for disposed plastic mouthpieces to regrind and use in manufacture of new parts

Sourcing

- Supplier audits for all new suppliers, with supplier agreements in place
- Stock and material quantities, cost, and safety must be discussed and agreed
- Explore alternative suppliers for cost management activity and secured supply

Disposal

- Utilise recyclable materials (in product and packaging) where possible for circular economy considerations
- IFU must state correct disposal practice in accordance with local guidance

Cost

- Review of competitor costs to determine target price
- Agree with board on target profit margin
- Research on aspects affecting regional costs (local regulations, taxes, importing costs, etc.)
- Supplier agreements for materials to protect against fluctuating costs
- Budget available for development and prototyping fees
- Business cases and proposal for key manufacturing and material decisions
- Capital costs such as tooling, additional plant, and machinery
- Distribution costs such as warehousing, freight, import or export taxes
- Cost considerations for possible IP protection (design registrations, trademarks)

PROJECT DELIVERABLES

A fully realised, commercially available device, matching the specification based off this design brief is required. Product validation, user testing, technical drawings, packaging design, logistics, instruction manuals, supply chain agreements must be signed off prior to launch

TIMESCALES

Due to the ongoing circumstances surrounding the Coronavirus pandemic, the company are anxious to launch the new product as soon as possible, and as such, the board have determined a deadline of 6 months to launch. With the internal virus detection system developed, main time constraint is the device casing.

Project will be taken through a modified Stage-Gate process (Cooper, 2011), with duration for key milestones detailed below:

Stage gate 1 – opportunity screening

- Duration: 2 months

Stage gate 2 – concept development

- Duration: 4 months
- Including proof of concept prototype

Stage gate 3 – product development

- Duration: 3 months
- Design freeze

Stage gate 4 – implementation and launch

- Duration: 3 months

Total project duration: 1 year

Proposed release date: June 2023

Time critical aspects:

- Design freeze sign off
- Injection mould tooling manufacture
- Injection moulding machine sourcing
- Determine manufacturing plan for entire process, including inhouse/external production

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