



Management of New Product Development

Assessment 2 – Developing the Design Brief

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1 Synopsis

1.1 Background (Company Profile)

Welshpool Breathalyser Ltd (WBL) is a leading manufacturer of electronic breathalyser systems responsible for prosecuting drink drivers. They have initially pursued their products for the use in the law enforcement industries but have since seen an increase in business within the medical industries with their products being used for critical diagnosis and monitoring.

Being global leaders in the electronic breathalyser market, WBL have continuously invested in the development of their internal research and development teams which led to a strong focus on pursuing advanced technologies which aims in providing innovative solutions. Through a Knowledge Transfer Partnership (KTP) with University Trinity Saint Davids, WBL have identified an opportunity in extending the capabilities of their chemical alcohol detector system by expanding the technology to detect organic materials which are generated from the breath.

The identification of the opportunity to develop and enhance the chemical alcohol detector system has led WBL to initiate a project to develop and commercialise a portable handheld virus breath detection device suitable for both self-care and clinical-care environments. A successful prototype of the electronic and mechanical system has already been developed to prove the concept of the device performance. The initial stages of the project have been initiated for the commercial and insights team to understand the scope of the market for such product.

This Product Design Brief (PDB) document is aimed as a controlled piece of documentation to emphasize the requirements of the project. Furthermore, this document aims to provide the required information for the internal and external teams designated to contribute to the development of the product. The development of a product design brief ensures that the success criteria for the product are understood by the stakeholders involved in the project and provides confirmation that the project has reached a suitable design solution (Mazur, 2023).

1.2 Current Problem

COVID-19 is an illness first discovered in 2019 and is caused by a respiratory coronavirus (UK Health Security Agency, 2022), the discovery of the illness has caused a widespread pandemic for 2 years with more variants of the viruses continuously emerging (VanStratt, 2023). Several developments to prove the concept of a breath-based virus detection system are continuously being investigated, the emergence of such technology could provide a less invasive method of analysing viruses such as COVID-19 and could go a long way with healthful, responsible self-care (Giovannini, et al., 2021).

Existing methods of testing such as a lateral flow tests (LFTs) have permitted an unprecedented scale of global testing in both clinical and public health due to their simplicity, low costs, accessibility, and rapid results (Nature Reviews Bioengineering, 2023). Despite this, problems with current LFTs have been identified which includes the device being a single use device, it is also commonly manufactured using plastic which inevitably leads to the development of non-biodegradable plastic wastes. Another aspect of consideration is portability, LFTs are commonly used indoors and aren't often used outdoors. Lastly, LFT results are not often captured and cannot be compiled as datasets which on the onset could provide early alerts of virus outbreaks and help detect infectious diseases earlier.

1.3 Design Intent & Product Overview

The design intent of the project is to develop a device that can resolve the current issues surrounding existing virus detection devices (i.e., LFTs) outlined in section **1.2 Current Problem** and produce a product that can disrupt the virus detection market whilst enabling a breakthrough innovation strategy (Satell, 2017) for WBL. The successful laboratory trials of the new system have initiated the early stages of patent applications for the technology to be registered, securing the overall architecture of the technology to WBL.

To enable the measurement of the success of the product, key factors must be identified and targeted. The early stages of the New Product Development (NPD) process, with the use of this document will lead to the development of a User Requirement Specification and Product Requirement Specification which aim to provide details on the key factors for the product.

Project Success Factors	
Success Factors	Critical Reasoning
Project must be delivered on time and budget	Critical to the expectations of the business as well as the desired release of the product to the market
Project cost does not exceed value of product offering	Critical to ensure profit is generated
Project has appropriate resources both internally and externally	Critical to developing a design which successfully address the technical requirements of the device
Product is sufficiently tested and trialled before release to the marker	Critical to prevent risk of product failure, poor sales performance, and potential damage to the brand
User Success Factors	
Success Factors	Critical Reasoning
Product performs as designed	Critical to market performance, brand reputation, and user satisfaction
User needs remains the same, and or changes are identified and addresses throughout the development of the product	Critical to ensure development of a successful product
User realises and appreciates the additional benefits from the product	Critical to user engagement which related to increase in user satisfaction and market share
Intended users realise and appreciates the additional benefits of the product	Critical to user engagement which related to increase in user satisfaction and market share

1.4 Business Constraints

- Time:
 - Reflecting on the recent COVID-19 pandemic, the development timeframe for the project is defined as **12 months**.
- Finance:
 - A budget of **£200,000** has been provided for the development of the project (R&D, Production, and Marketing activities included)
- Manufacturing:
 - To be in-house assembled within existing production facility
 - Increase demand within the UK and Internationally – may require the consideration of external partners for the assembly of the devices in specific market sites.
- Production Operations:
 - No initial issues identified regarding assembly capacity within the first year of production – 750,000 volumes.
 - Concerns identified with the year two of production with volumes increasing to 3 million.

- Business case and Capital Expenditure (CAPEX) proposal required for possible site expansion and automated machine acquisitions.
- Sourcing and Procurement:
 - Rising prices of raw materials such as polypropylene may impact the overall Cost of Goods (COGs) of the product (Segen, 2023).
- Marketing:
 - Market positioning and new business opportunities regarding the product must be clearly defined by the product managers, commercial and insights team.
 - Clear Marketing Requirement Specification (MRS) must be developed to outline the marketing considerations for the device.
- Future Investment:
 - Potential future investment may be acquired through SMART Innovate UK grant programme focusing on disruptive innovations with significant potential for rapid economic return to the UK (GOV.UK, 2023).
 - Externally fabricated and sourced components could be contemplated to be manufactured internally for improved COGs.
- Quality Control and Quality Assurance:
 - Declaration of Conformity document must be acquired from external suppliers (Halton, 2022).
 - Risk Assessments must be clearly documented and defined for both internal and external components.
 - Quality Assurance procedures must be in place for all internal components and final assembly checks.

2 Commercial

2.1 Target Market

Initial market research has identified a strong market availability and new market positioning for the product which includes opportunity to disrupt the COVID testing kit market, wireless portable device market, and medical device market.

The portability of the product will be best used for both indoor and outdoor use with an evident benefit of the device catering for testing mass crowd gatherings. Self-care testing can also benefit users who are always on the move which require to obtain real time diagnostic of their health.

Further market sensing activities are required to classify the market for the device, monitor existing competitions, develop a customer value assessment, and acquire early customer feedbacks (Tu Cao, et al., 2012). Initial investigation has indicated the possible markets consisting of mass gathering, concerts, festival events, airports, hospital, and home use.

Value proposition canvas toolkit must also be used to understand the value proposition of the device in relation to the brand, user experience, and overall makeup of the product (Strategyzer, 2023).

2.2 Users Personas

User personas must be generated to support with the user catered design considerations for the product. The personas will help the design team to ask questions about a specific users' motivations and needs, build up the required requirements for the product, and ensuring that the users needs are met within the overall design of the product (Stolze, 2010).

2.3 Existing Competitors

Consideration must be made on what is currently in the market as well as existing methods of testing viruses. Competitor product price points as well as existing filed intellectual properties (IP) must be understood.

Competitor research must focus on the below considerations:

Breath based testing methods:

- Who are the existing companies developing breath-based virus detection systems?
- What existing IP's have been filed regarding such methods and technologies?

Device Types:

- What type of devices do existing competitors have developed/are developing? (i.e. portable or benchtop devices)
- What price ranges do existing competitor devices are marketing their devices?

- How accessible are the devices of our existing competitors?

Customer Reception:

- How are the competitor devices being received by customers and users?
- Any early indications of user and market concerns regarding the method of testing?
- What are the main key take aways we could consider for the marketing of our product?

Device Design:

- What key features do competitor devices have?
- How are their devices manufactured?
- What are the key design considerations we should consider differentiating our device from competitors?

2.4 Competitors Devices

Competitors with existing breath base technologies ranges from university led research and development and startup companies with pre-clinical trial devices. Further information required to understand trial and FDA review results.



IMEC – Proof of Concept Breath Sampler



Breathomix – BreathBase



SOTECH – Rapid Breath Test for COVID-19



OPTEEV – Vira Warn



BreFence – Go COVID-19 Breath Test System



Canary – Breath Detect

2.5 Market Constraints

- Varied medical device reimbursement scheme in different markets outside of the UK. (Castle & Cowlshaw, 2022)
- Supply chain issues regarding raw materials, delivery delays, and higher prices of components (Institute of Government, 2021)

2.6 Social, Political, and Cultural Implications

Social and cultural considerations are based on demographic situation of different countries which varies from each other. The product may be impacted by such implications, thus key factors must be considered:

- Device adherence to the correct medical device directive of a specific country (i.e., EU MDR, and FDA).
- Clinical evidence to back up the efficacy of the medical device.
- Sustainability and disposal considerations of the device and its components.
- Device packaging consideration due to plastic tax regulations as per EU Green Deal (KPMG, 2021)

2.7 Product Pricing and Configurations

Product pricing, configurations and accessories must be stated, examples of possible considerations:

- Device x1 with x4 mouthpiece boxed – Orderable unit and drug tariff availability.
- Device individually boxed units – Orderable box of x50 for shopfront retailers and pharmacies.

Accessories Configurations:

- Box of x20 mouthpiece accessories – Orderable unit and drug tariff availability.
- Mouthpiece accessories boxed units – Orderable box of x50 mouthpiece accessories.
- Device chargers and other accessories to be defined throughout the design of the device.

Finalised device and accessories COG's to be fully defined for the design freeze of the device within the Stage 4 of the NPD process.

2.8 Branding

- The device must include the required branding as well as required locations of the product brand logo, and company logo.
- The PRS will outline the locations and symbols required to be used within the device as per ISO 15223-2021 medical device symbols.
- The packaging specification must define each requirement for the device product code, GS1 barcoding, product descriptions, and required medical device symbols as per ISO 15223-2021.

3 Legal

3.1 Intellectual Property & Patents

- NDA's must be in place prior to engagement with any external companies, suppliers, and consultancies.
- IP applications and any new submissions must ensure the consultation of the business's IP lawyers.
- Identification of new ideas must follow the required IP procedures of the company.
- Development of IP documentation for submission must be as per the requirements of the IP lawyers.

3.2 Conformity Requirements

- Device certification of conformity must be developed by the QA team.
- Device must adhere to the requirements of a Class IIa medical device.

3.3 Standards and Specifications

The development of the product must ensure compliance with the specified standards to ensure quality. Preliminary research has indicated the requirements to adhere to the relevant medical device standards for the development of the virus breath detection device.

Standard Number	Standard Descriptions
ISO 13485	<i>Medical devices — Quality management systems — Requirements for regulatory purposes</i>
ISO 14971	<i>Medical devices — Application of risk management to medical devices</i>
IEC 62304	<i>Medical device software — Software life cycle processes</i>
ISO 62322-1	<i>Medical device — Part 1: Application of usability engineering to medical devices</i>
ISO 15223-1	<i>Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements</i>
ISO/TR 24971	<i>Medical devices — Guidance on the application of ISO 14971</i>
IEC/TR 80002-1	<i>Medical device software — Part 1: Guidance on the application of ISO 14971 to medical device software</i>
IEC/TR 80002-2	<i>Medical device software — Part 2: Validation of software for medical device quality systems</i>
IEC/TR 80002-3	<i>Medical device software — Part 3: Process reference model of medical device software life cycle processes (IEC 62304)</i>
EU MDR 2017/745	<i>The European Union Medical Device Regulation</i>
ISO 11607-1	<i>Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems</i>
IVD 2017/746	<i>Vitro Diagnostics Regulation</i>
BSI Kitemark	<i>BSI Kitemark Certification</i>

3.4 Documentation

- Development of technical documentation as per ISO 13485.
- Design history file to be develop and detail the process of the design and development of the product.
- Instruction for Use required for medical device products.
- Risk management documentations to be developed as per ISO 14971.

4 Quality

4.1 Regulatory

- Certification acquired from regulatory bodies regarding the device prototype.
- Further certification may be required for the design freeze device.
- Device development process must adhere to the requirements of ISO 13485.
- Requirements for In-Vitro Diagnostic Medical Device must be identified as per IVD 2017/746.
- Medical device classification must be defined as per EU MDR 2017/745.

4.2 Safety

- Instruction for use must detail the correct use and practice in the use of the device.
- Correct labelling must be included in the device and it's packaging as per ISO 15223-1.

- Disposal requirements and guidance must be indicated within the instruction for use.
- Device must consider testing under safety requirements of medical electronic devices as per ISO 60601-1

4.3 Shell Life and Storage

- Accelerated aging testing to accurately predict the changing in properties of materials used in the product (Hemmerich, 1998).
- Accelerated aging testing of device in its packaging must also be considered.
- ISTA testing of packaging to ensure the desired outcome of the product packing and storage performance (ISTA.Org, 2023).

4.4 Quality

- Must comply with EU MDR requirements.
- Must be traceable at all levels through GS1 data matrix system requirements (GS1 UK, 2023).
- Device must undergo user and clinical trials to support its performance.
- Device and packaging drop and water resistance testing performance.
- Must be design and made with quality materials.
- Device design and development must be within budget.
- Device ease of use must be considered to ensure minimal effort from the users.

4.5 Life in Service

- Test device accelerated aging duration *Reference accelerated testing requirements **4.3 Shell Life and Storage**
- Frequency of mouthpiece replacement.
- Customer feedback and expectations *Reference **2 Commercial**.
- Quantity of daily testing required.
- Average battery life duration.
- Expected battery performance overtime.

4.6 Testing

- Verification activities required to ensure outputs meets the design inputs (Lyons, 2023).
- Validation activities required to prove that device design meets the user needs and intended use specified (Lyons, 2023).
- Calibration testing and certificates require prior to supply.
- Determine required sample size to be tested via production quality checks.
- Testing and quality procedures must be in place for device checks.

4.7 Risks

- Potential risks associated with malfunctioning devices which can lead to false results.
- Potential risks of device not passing the requirements of EU MDR.
- Risk analysis and FMEA's to be developed and updated throughout the project.

5 Design

The design stage of the project will fall under the Stage B and C of WBL internal R&D process. The design processes must ensure that full documentations are developed to support the QMS for the device. All concepts and designs must be formally presented and signed off via a design review prior to the progression to the next stage of the process. The project lead must ensure constant communication with internal and external stakeholders throughout the design process.

5.1 Ergonomics

- Device must consider human factors consideration in its design.
- Device must consider neutral wrist posture and alternate hands use.
- Consideration of finger reachability for controls of touchscreens and buttons.
- Device must allow for single handed use.
- Screen displays must be easily visible during use.
- Device must not be too bulky to hold and touch.
- Device centre of gravity during use must be considered.
- Device must not consist of deep contour grips or textures.
- Device must not have sharp edges that can injure the users.

5.2 Materials

- Outer casings must be made with plastic polymers suitable for injection moulding.
- Considerations must be given to possible use of recycled plastic masterbatch.
- Externally assembled electronic components must ensure quality and must adhere to ISO 60601-1.
- Piezoelectric components – Possible consideration of haptic cues
- Mouthpiece accessories – Possible alternative materials (compostable, paper based)
- Touchscreen display – Consideration required (resistive touch, projected capacitive, infrared) (ViewSonic, 2021).

5.3 Weight

- Device weight must be considered:
 - Lightweight – consider use within clinical environments and portability.

5.4 Portability

- Physical dimensions for the device must be based on the size of existing products and existing population of users.
- Device must be able to fit within backpacks and handbags.
- Device must easily be stored and fit within clinicians and nurse scrub pockets.

5.5 Functional Prototypes

- Functional prototypes of the device must be developed as part of the final design review.
- Suitable functional prototype methods must be used (3D Printing, Arduino, Soft Tool Mouldings).
- Concept development stages of the project will require the development of several concepts and prototypes.
- Concept development must consider the form, ergonomics, aesthetics, and component fit.
- Appropriate prototyping budget will be accommodated for each stage of the project for both internal and external activities.

5.6 Intended Use

- Device intended use must be considered during the concept development stages of the product.
- Intended use must ensure consideration of **5.1 Ergonomics, 5.3 Weight, 5.4 Portability**
- **8 User Experience** must also be considered.

5.7 Product Life Span

- Material and component longevity must be able to withstand lifespan of used.
- Accelerated testing must be conducted to identify life span of device (e.g., battery, composite, and electronics).
- Device must consider life span minimum of 5 years.

6 Aesthetics

6.1 Colour

- Colours must consider current market trends (medical devices, handheld devices)
- Choices in device colours must consider making the product look current (Park, 2015).
- Colour choices must consider the company's brand identity.
- Device colours must be easily distinguishable to be WBL's device.
- Device must be easily recognisable from up close and far (Park, 2015).
- Button colours must consider usability enhancement through visual understanding (Park, 2015).

6.2 Surface Finish

- Product surface finish consideration must consider infection control.
- The device surface finish must prevent the device slipping out of the users' hands during use (Zingale, et al., 2005).
- Consideration of a non-slip surface finish which is shaped with the device (Zingale, et al., 2005).

6.3 Size

- Device size must consider the impact of user interaction when used (must not impact application to the user's mouth).
- Device size should consider appropriate dimensions to fit within a user's hands.
- Size must consider the portability of the device and must fit everyday storage (bags, and pockets).
- Device size must not impact its suitability to be used within its intended work environments (Zingale, et al., 2005).

6.4 Form and Shape

- The form and shape of the device must allow ease of use and comfort during use.
- Form and shape of the device must consider single arm operation.
- When used, the user must have a legible view of their results (screen size must be clear and legible for all ages).

7 Accessories and Features

7.1 Mouthpiece

- Single use and detachable after use by a single patient.
- Must consider biodegradable materials as it's a single use accessory.
- Must be small enough to be packed in multiples especially during use in mass screening environments.
- Each mouthpiece must be bagged separately to prevent cross contamination.
- Must consider compostable packaging for each mouthpiece.
- Disposal guidance must be clear and visible within the instruction for use.
- Mouthpiece design must be thoroughly considered for its ergonomics and ease of fit within the device.

7.2 Battery

- Device must be designed to be operated by rechargeable batteries (As used in mobile phones).
- Device must be able to be charged via conventional mains electricity (As used in mobile phones).
- Device must provide clear and legible indications of battery life (Fully charged, battery percentage, battery low).

7.3 Display

- Device display must be clear and legible to show user results.
- Device display must consider legibility for all environments (daylight, and night-time).
- Device display must consider readable text sizes and easy to read typeface.

7.4 Alerts

- Device must consider tone alerts to inform users of test completions or errors.
- Device must consider haptic and vibrations to indicate test completions or errors.

7.5 Storage

- Device must incorporate suitable internal storage size for user data.
- Device must incorporate the use of microSD cards for internal storage.
- Device must consider the use of cloud-based storage and database.
- Device must consider the ability to share data to doctors and clinicians.

8 User Experience

8.1 Instruction for Use

- Device must be easy to use.
- Device must be intuitive and required minimal training.
- Digital IFU must be available and accessible through the company website.
- Printed IFU must be packaged within each boxed device.
- Compliance symbols must be highlighted within the IFU.
- IFU must outline a step-by-step operation for the device:
 - Initial setup
 - Calibration
 - Test setup
 - Alert and display settings
- IFU must also indicate correct disposal methods for mouthpiece accessories.

8.2 Getting Started

- User profile creation must be accessible via mobile phone app.
- Setup must be easy through the connectivity via Bluetooth.
- Device built in app must allow for initial setup and device troubleshoot.
- Built in app must provide options to user on their current and previous readings.

8.3 Performance

- Device must provide accurate reading at all times and must be visible within the device.
- Device must be compatible via Bluetooth for both Android and iPhone devices.
- Device cannot be used without the use of its mouthpiece accessory.
- Device must provide a traffic light system to provide easy to understand testing protocol.
- Device must also provide haptic and sound alerts to indicate successful or failure results.

8.4 Maintenance

- Device software must be able to be updated using the mobile phone app.
- Device calibration must be initiated prior to each testing.
- Device maintenance optional if required, otherwise device care must be available.
- Warranty period for device must be for 1 year.

8.5 Reliability

- Prototype testing should indicate success rates for each reading (successful reading rate to be confirmed).
- Purchasing team must ensure that suppliers are reliable and are accredited to maintain component quality.
- Device IFU must ensure that users can easily understand the use of the device.
- Charging maintenance must be indicated within the IFU to increase battery life performance.

8.6 Environment

- Device must be usable within different environments and scenarios.
- Device must be able to perform at high temperature environments greater than 30°C.
- Screen display must be visible at both bright and dark environments.
- Device must be drop tested to ensure its survival within rough environments.

8.7 Translation

- The device and its mobile phone app must be available in different languages.
- IFU must be available in different languages accessible online via the company website.

9 Packaging

9.1 Packaging Design

- Packaging design should consider structural integrity of the carton (Mackie & Hill, 2023).
- Packaging should protect the device at all levels of its configuration.
- Consideration for 'frustration-free packaging should be considered to build patient confidence (Mackie & Hill, 2023).
- Packaging should provide the opportunity to reduce patient anxiety and user errors (Mackie & Hill, 2023).
- Consider the integration of a quick start guide illustration within the packaging design.
- User experience should be considered when designing the packaging for the device.
- Packaging configurations must be validated for the compliance to the packaging standards:
 - ISTA transit testing standard compliance (ISTA, 2023).
 - Refer to ISTA standard for non-simulation, simulation, and enhanced simulation testing of packaging throughout the design process.
- Packaging must be traceable at all levels:
 - Unique Device Identification must be included within the level of packaging of the device.
The use of GS1 data matrix must be used for the identification of the device and its packaging (O'Leary, 2014).

9.2 Configurations

- Configuration availability format must consider market requirements:
 - Direct to retailer.
 - Direct to user.
 - Online retailer to user.
- Device configuration examples as follows:
 - Packaging A = Device + Accessories + IFU (Direct to user).
 - Packaging B = Packaging A x6 + Wholesale Carton x1 (Direct to retailer).
 - Packaging C = Packaging A x1 + Over box carton x1 (Online retailer to user).
- Accessories and spare parts to be shipped with separate cartons.
- Accessory quantities to be confirmed by product manager through insights and research.

9.3 Shipping

- Device availability through online retailers must be considered (i.e., Amazon EU, and International).
- Established company courier service must cater for the shipment of direct to user and direct to retailer configurations.
- Online ecommerce shop availability through company website must be considered.
- International shipping or international courier service must be put in place.

- Packaging B configuration must be designed and optimised to fit within the standard palletisation requirements and dimensions.

10 Manufacturing Requirements

10.1 Device Production

- Electronics of the device to be sourced externally:
 - Supplier audits must be conducted to chosen suppliers and manufacturers.
 - Preliminary investigation suggests that the electronic components are to be sourced from China or Malaysia.
- Plastic mechanical components:
 - Manufacturing must consider internal or external sourcing of plastic moulded components.
 - Sourcing the moulded components locally within the UK must be favoured to ensure control of quality of parts.
- Device final assembly to be undertaken internally within the company's production facilities:
 - Electronic single circuit boards to be tested and assembled to the plastic components internally.
 - Device to be tested internally prior as per the procedure set out the quality assurance team.

10.2 Sustainability / Circular Economy

- Fabrication of electronic parts possibly coming all the way from China or Malaysia must only be used as a short-term plan due to carbon footprint considerations.
- Material considerations must include:
 - Packaging must consider single use plastics.
 - Recycled injection moulded plastic polymers must be considered.
 - Biodegradable plastic use consideration.
- Company must consider the implementation of repair service to prevent disposal of broken / non-working devices.

10.3 Manufacturing Facilities & Environmental

- Device final assembly, testing, packing, and shipping will all be at the Welshpool production facility.
- Existing processes and machinery must be used for the device (assembly and testing).
- Short-term and long-term production plan must be considered for optimisation.
- Consideration for Welshpool site expansion:
 - Provide internal injection moulding expertise and facilities.

- Provide internal tool room expertise for maintenance and support.
- Consider the development of an internal electrical experts and engineers.
- Review cost reduction activities of current parts for possible reduction of cost of goods.

10.4 Quantity

- Projected year 1 volumes = **750,000** devices.
- Projected year 2 volumes = **3,000,000** devices.
- Possible volumes increase during year 3 and 4 to be expected.
- External suppliers must be notified for increase in volumes after year 1.
- Possible shift to internal fabrication must be planned for year 2 if possible.
- Business case proposal must be generated to propose internal fabrication.

10.5 Sourcing

- Supplier audits must be conducted within both the chosen internal suppliers.
- Minimum order quantity for all materials and components must be in place and delivered within agreed durations.
- Cost exercises must be conducted continuously to assess possible cost reduction in cost of goods and components.

10.6 Disposal

- Device repair programme must be considered to provide support with broken devices as part of circular economy plans.
- Mouthpiece materials should consider biodegradable materials for ease of disposal.
- IFU must indicate correct disposal procedures for the device.

10.7 Costs

- Device selling costs must be agreed by top management.
- NHS tariff costs must be agreed separately from the initial selling costs by top management.
- Courier service agreement must be in place for delivery of devices to customers and retailers.
- Competitor device costs must be considered during selling costs determination.
- New equipment's and machinery costs must be submitted for review and approval.
- Possible import tax for externally sourced components must be outlined.
- CAPEX costs of injection moulding tools.
- External consultancy fees for both device design and tool development.

11 Project Deliverables

The project is expected to deliver a commercially available breath detection device capable of detecting organic materials and viruses. The device in development must ensure the subsequent adherence to the design brief in ensuring all the requirements are considered for the device. The development processes of the device must ensure the compliance with ISO 13485 ensuring the development of a design file and technical file which covers traceability of product validation, user testing, risk management, DFMEA's, product specification and user requirements etc.

12 Project Timescales

12.1 Project Activities and Timeframes

Due to the on-going circumstances relating to COVID-19 and its subsequent variants, WBL are anxious to bring the new product to market as soon as possible. Therefore, a project timeframe of 12 months has been proposed by the management team as a deadline to launch the product.

As part of the existing development processes of the company and to ensure the correct design activities are captured as part of ISO 13485, the project will run using the internal R&D teams Stage Gate process. Indication of project time frame is indicated below:

Stage A – Project Strategy and Identification (5 Months)

Stage B – Design and Development Inputs (4 Months)

Stage C – Design and Development Outputs (6 Months)

Stage D – Design and Process V&V (4 Months)

Stage E – Product Launch (5 Months)

Estimated launch date: Summer of 2024.

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