

Developing the Design Brief

Management of NPD

Assessment B

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Contents

1. Introduction	3
2. Synopsis of the Product.....	3
3. Potential as an NPD Project.....	5
3.1. Objectives.....	5
4. Analysis of the Elements and Architecture	5
4.1. Functional Requirements (FR).....	6
4.1.1. Product Description	6
4.2. Operational Requirements (OPR).....	7
4.2.1. Intended Use	7
4.2.2. Indications.....	7
4.2.3. Contraindications.....	8
4.2.4. Intended User Profile	8
4.2.5. Level of Usage.....	9
4.3. Performance Requirements (PR).....	9
4.4. Accessories (AR).....	10
4.5. Safety and Regulatory Compliance.....	11
4.6. Intended Markets (IM)	11
4.7. Marking and Labelling Requirements (MR).....	12
4.8. Alarms	12
4.9. Interface Requirements (IF)	13
4.10. Mechanical and Form Requirements (MER)	13
4.11. Cleaning and Disinfection Requirements (CD).....	14
4.12. Component and Material Requirements (CM)	15
4.13. Maintenance Requirements (MAIN).....	16
4.14. Data Storage and Presentation Requirements (DS)	16
4.15. Graphic User Interface Requirements (GUI).....	17
4.16. Cost Requirements (CR)	17
4.17. Copy Protection and Commercial Aspects Requirements (IPR)	18
5. References	20
Figure 1 - Example of a Lateral Flow Test	4

Table 1 – Product Description	7
Table 2 - Intended Use	7
Table 3 - Indications	7
Table 4 - Contraindications.....	8
Table 5 - Intended User Profile	9
Table 6 - Level of Usage.....	9
Table 7 - Performance	10
Table 8 - Accessories	11
Table 9 - List of International Standards.....	11
Table 10 - Intended Markets.....	11
Table 11 - Marking and Labelling	12
Table 12 - Alarms	13
Table 13 - Interface	13
Table 14 - Mechanical and Form	14
Table 15 - Cleaning and Disinfection	15
Table 16 - Components and Materials.....	15
Table 17 - Maintenance.....	16
Table 18 - Data Storage and Presentation	17
Table 19 - Graphic and User Interface	17
Table 20 - Cost	18
Table 21 - Intellectual Property	19

1. Introduction

This document outlines the design considerations and requirements of a new breath virus detection system to inform senior management, design and engineering, manufacturing, finance, marketing and logistics of the project scope so they can effectively input and plan to enable a successful product launch.

Successful product development results from careful planning and execution that fits organisational goals and strategy. The development of this new product is aligned organisationally with the new product development pillar. It is disruptive (Trott, 2021) and enables access to new markets and revenues (Ansoff, 1965). The post-launch performance will be monitored via the New Product Vitality Index (NPVI) (Goldense, 2015).

This document does not lay down precise product specifications but provides input to the development process.

2. Synopsis of the Product

The company's current product portfolio covers core markets within Breath Alcohol Analysis, serving rapid screening, screening, and vehicular mounted and evidential-based products. These products are sold into several market sectors, and revenues are spread across these core markets. However, an opportunity has been identified to leverage several base technologies and extend the platform to cover virus detection.

Effective and early detection of viral infections is of interest, as it can relieve the impact on individuals by allowing them access to treatment and reduce the burden on healthcare providers by initiating preventative measures such as isolation in the event of pandemics and administering anti-viral medications.

Viruses and viral outbreaks cause significant health damage globally. In the UK, it is widely accepted that viral infections are seasonal and circulate at higher levels during winter months. Most commonly, viral infections affect the upper respiratory tract, such as the common cold. They significantly burden society regarding both human suffering and economic burden. They are highly contagious by their nature (Heikkinen and Järvinen, 2003). Other types of viruses include Human Immunodeficiency Virus (HIV), which is among the most dangerous viral infection in the UK, with estimates of around 105,000 people living with the condition (Gov.UK, 2022).

For the extreme example, International Health Regulations (IHR) govern the framework for health security globally and declare the presence of Public Health Emergencies of International Concern (PHEIC). Six such events have been declared between 2007 and 2020 (Wilder-Smith and Osman, 2020), including;

- 2009 – H1N1 Influenza pandemic
- 2013 – Ebola (*West Africa outbreak*)
- 2014 – Poliomyelitis
- 2018 – Ebola (*Democratic Republic of Congo outbreak*)
- 2016 – Zika
- 2020 – COVID-19

Various types of tests are used to detect viruses and may require the involvement of laboratories. No single test can identify every microorganism, and tests that work well for one microorganism often do not work well for another. Tests must then be chosen on which microorganism is thought most likely to cause the signs and symptoms of infection.

For the target viruses for this new product development, existing solutions take particles from fluid secretions of the nose and throat via swabs to detect genetic material via a nucleic acid-based test (Dagli, 2021). Lateral flow tests such as these are manufactured by Global Access Diagnostics, Omega Diagnostics Group and SureScreen Diagnostics and are an immunoassay which is a technology that is around 60 years old. Lateral flow immunoassays can efficiently achieve the goal of rapid, point-of-care diagnosis by point-of-care testing (Park, 2022). Test results come within 10-30 minutes, are inexpensive to deploy, and have an easy-to-interpret results system. The sensitivity of these tests varies depending on the target virus, with false positives being rare. Laboratory testing may be used to validate preliminary results.

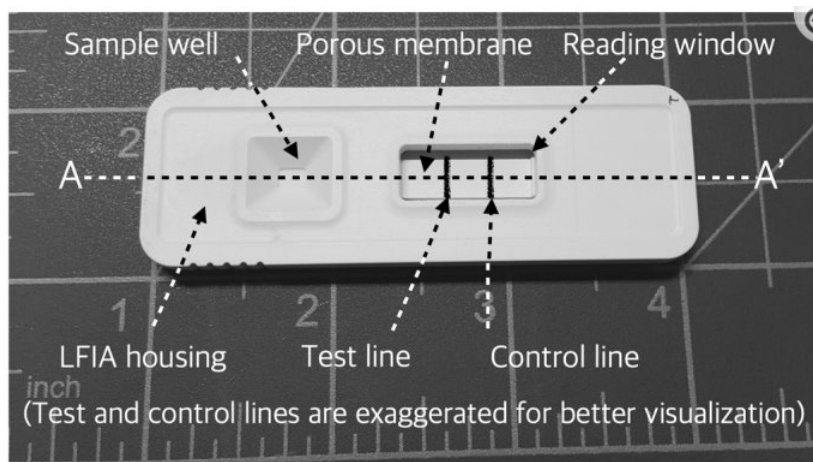


Figure 1 - Example of a Lateral Flow Test

However, Lateral Flow tests have several limitations and drawbacks. They are not as sensitive as laboratory testing, therefore introducing the chance of false-negative or false-positive results. They can be limited in the detection, especially in the earlier stages of infection. Sample collection is invasive and, without the proper technique, may lead to incorrect results. While generally more affordable than laboratory testing, their single use and disposable nature means that costs can quickly add up and create a significant waste problem.

Introducing a reusable breathalyser-type diagnostic device would be disruptive, allowing the organisation to access new revenue opportunities globally.

The product would be unique by not requiring invasive sampling to occur. Users would breathe into a single-use disposable mouthpiece, eliminating the need for uncomfortable and invasive sample collection. The results would be rapid, enabling immediate detection and timely intervention. Users could perform the tests themselves without needing specialised training or used by others to diagnose those with symptoms.

The sensor uses proprietary sensor technology and algorithms to accurately detect virus infections, with the possibility of future developments to offer versatility beyond the target viruses. This adaptability makes it valuable for future sustaining innovation (Trott, 2021). Due to its reusable nature, the device quickly becomes a cost-effective alternative to lateral flow tests, and consideration of circular design means it is manufactured from sustainable sources with a clear end of life.

Furthermore, its connectivity enables continuous monitoring and tracking of viral infections as it can integrate with mobile applications. This integration allows for real-time data analysis supporting public health interventions.

3. Potential as an NPD Project

3.1. Objectives

- I. Develop a new product based on the chemical alcohol detection system platform to detect viral infections.
- II. Engage with the London-based company for the physical design work.
- III. Source electronics and mechanical elements externally. Alternative suppliers to those currently used should be sought as a potential cost-saving exercise for the existing portfolio (out of scope for this project).
- IV. Plan and prepare for the final assembly, testing, packing and shipping internally.

Conformity assessment as a Class 2a medical device via the notified body is already established.

While market sizing is complicated, the global lateral flow assays market has been valued at \$10.69 billion in 2022 and is expected to grow at a CAGR of 4.26% (Grand View Research, 2023).

Based on initial forecasts manufacturing quantities are projected to be 750,000 pieces in year one, rising to 3 million per annum. Design and manufacture should consider the importance of scalability.

4. Analysis of the Elements and Architecture

The system architecture has been broken down into pertinent sections that impact the effective organisational development of the device. Each section will display a reference, individual product requirement, a description and a cross-reference, highlighting their interdependencies on each other* to ensure transparency across the multidisciplinary team. During the product development stage, each of these references will need to be;

- Considered – *are they still relevant*
- Defined – *what is the specification*
- Agreed upon – *against project objectives and to avoid scope creep*

**Standards are not cross-referenced as they apply to the whole device.*

4.1. Functional Requirements (FR)

All functional requirements are listed to define the development project's scope considering how the product is used and what claims are desired to be made.

4.1.1. Product Description

Reference	Requirement	Description	Cross-References
FR1	Quick and easy to use.	Design for rapid deployment with intuitive, ergonomic GUI, LEDs and button configuration.	FR3,6,7,8,11,14 OPR2,3,17 PR4,5 MR4,9 IF5 MER1,2,3,6,7,8,10 CD1,3,5 CR10,11
FR2	Accurate and trustworthy results.	Proven effectiveness providing confidence in its use.	FR1,3,13 OPR1,4 Alarm1,2,3,4,5
FR3	Easy-to-understand results.	Clear and legible results display.	FR1,2,13 OPR1 MR4
FR4	Connectivity.	Several options to transfer test results to a database and sample giver.	FR5,12 MR4 CR10,11
FR5	GPS.	Sample GPS tagging function.	FR4,12 MR4
FR6	Mobile and portable.	The device is handheld and battery-powered (rechargeable or disposable will be specified during development).	FR1 CR10,11
FR7	Easily assembled.	All accessories and modular components are assembled via the Poka-Yoke method.	FR1,8 MR4
FR8	Single-use mouthpiece.	Single-use, disposable manufactured from sustainable sources. The level of cleanliness prevents sample contamination. Determine whether the mouthpiece requires sterilisation. If so, by what route, i.e., gamma, EtO.	FR1,7
FR9	Sample containment.	Protecting the sample taker from viral exposure and potential cross-contamination.	FR8 OPR1 MR4
FR10	Prevents contamination.	IP rating prevents external contaminants from affecting the results or performance of the device.	FR9 CR10,11
FR11	Easy to clean and decontaminate.	Protects the following user from potential infection and cross-contamination.	FR9,10 CD1,2,3 MR4
FR12	Compliant.	The device must conform to all identified standards, be clearly labelled on the device (where necessary) and be published in the IFU.	FR2,10 MR4

FR13	Error reporting.	Informs the user when an error has occurred.	FR1,2 Alarm1,2,3,4 MR4 CR10,11
FR14	Used in varying environments.	The device can be used indoors and outdoors and in specified environmental conditions.	FR4,6,10 PR3,4,6 MR4
FR15	Recognisable design.	The device should be recognised as part of the company's product portfolio. Reinforcing branding guidelines. Naming, logos and aesthetics should be prominent visual features.	CR10,11
FR16	Sustainable materials.	Manufactured from raw materials from sustainable sources with disposal and end-of-life routes considered and communicated to users.	FR8,14 CR10,11

Table 1 – Product Description

4.2. Operational Requirements (OPR)

A list of requirements that serve as inputs for product specifications.

4.2.1. Intended Use

Reference	Requirement	Description	Cross-References
OPR1	Infection diagnosis.	The device will diagnose targeted viruses and provide user feedback on the test outcome.	FR1,2,3,14 OPR4 MR4 CR10,11
OPR2	Use in any indoor setting.	Suitable for use in any indoor setting.	FR1,2,4,6,14 MR4 CR10,11
OPR3	Use in controlled outdoor settings.	Suitable for use in outdoor settings, so long as they are within manufacturers' guidance.	FR1,2,4,6,14 PR3,4,6 MR4 CR10,11

Table 2 - Intended Use

4.2.2. Indications

Reference	Requirement	Description	Cross-References
OPR4	Target Viruses.	A complete list of target viruses should be provided, including those not diagnosed by the device.	FR2,3,9 OPR1 MR4 CR10,11
OPR5	Signs and Symptoms of target viruses.	Many viruses present similar signs and symptoms. A complete list of signs and symptoms should be provided.	FR2 OPR1,4

Table 3 - Indications

4.2.3. Contraindications

Reference	Requirement	Description	Cross-References
OPR6	Smoking.	Smoking may mask detection and should be discouraged for at least 24hrs before the test.	MR4
OPR7	Alcohol Consumption.	Alcohol may mask detection and should be discouraged for at least 24hrs before the test.	MR4
OPR8	Non-target viruses.	A complete list of target viruses should be provided, including those not diagnosed by the device.	OPR1,4 MR4
OPR9	Existing disease states.	Information should be provided highlighting what existing disease state may interfere with results.	MR4
OPR10	Inability to produce a suitable sample.	Conditions that may cause consequences if aggravated by forced expiration, e.g. aortic aneurism, current pneumothorax, recent surgery including ophthalmic, thoracic and neurosurgery.	MR4
OPR11	Recovering from past positive diagnosis.	False positives may occur if a previous infection has been diagnosed within four weeks.	MR4
OPR12	General Condition.	The person is too unwell to perform expiration.	MR4
OPR13	Communication Problems.	Any person with learning disabilities or confusion.	MR4

*Table 4 - Contraindications***4.2.4. Intended User Profile**

Reference	Requirement	Description	Cross-References
OPR14	Trained – Experienced.	Medically trained individuals experienced in the preparation, use, and end-of-use of multiple types of medical devices. Including diagnostic equipment. These users will pass their knowledge on to the trained novice users.	FR1,3,7,8,9,13,14 MR4 Alarm1,2,3,4,5 CR10,11
OPR15	Trained – Novice.	Medically trained but unfamiliar with using similar types of devices due to speciality area or tenure. These users will be expected to be proficient, so they must acquire the technical skill base quickly.	FR1,3,7,8,9,13,14 MR4 Alarm1,2,3,4,5 CR10,11
OPR16	Untrained – Professionals.	Not medically trained, but their level of education or profession means they use complex machinery or data regularly. The use of this device will be familiar or introduce familiar stress levels or application of skills.	FR1,3,7,8,9,13,14 MR4 Alarm1,2,3,4,5 CR10,11

OPR17	Untrained – Unskilled.	Not medically trained, and their level of education and profession results in a high level of unfamiliarity and understanding of the device and its intended use.	FR1,3,7,8,9,13,14 MR4 Alarm1,2,3,4,5 CR10,11
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Table 5 - Intended User Profile

4.2.5. Level of Usage

Reference	Requirement	Description	Cross-References
OPR18	Ad-hoc – <i>Infrequent use (single-person use)</i>	Only be used when feeling unwell, symptomatic, or supporting relatives or siblings. The device should have a trouble-free start-up after periods of being idle. Use level: 7 - 10 times per year	FR6,7 CR10,11
OPR19	Multiple times per day – <i>Frequent use (multiple persons)</i>	In professional environments such as healthcare settings, the device may be used multiple times per day. Use level: 5 - 10 times per day	FR6,7 CR10,11
OPR20	Ad-hoc – <i>infrequent use – (multiple persons)</i>	Use within a family environment where the device may be used frequently for a short period across several family members before being stored for future use. Use level: 28 - 50 times per year	FR6,7 CR10,11
OPR21	Placebo/increased periods of vigilance.	Increased use during times of national or local outbreaks where proactive and routine screening may be wanted during a short but intense period. Use level: 50+ times per year	FR6,7 CR10,11

Table 6 - Level of Usage

4.3. Performance Requirements (PR)

All requirements that the product must meet to perform its intended function

Reference	Requirement	Description	Cross-References
PR1	Measuring Range and detection limits.	Minimum and maximum viral loading should be specified. Tolerance should be defined.	FR2 OPR1 MR4
PR2	Accuracy of results.	Specify accuracy and communicate tolerances.	FR2,3 OPR1 MR4
PR3	Viral categories.	The device should accurately detect helical, envelope and icosahedral viruses.	FR2,3 OPR1 MR4
PR4	Speed.	Determine the speed and response time for the diagnosis to occur	FR1,6,7

PR5	Power Up Time.	Quick start-up times via a one-button operation: targeted at 4 seconds at 20 degrees Celsius.	FR1
PR6	Operating Temperature Range.	The device will be used throughout the year across all seasons. Consideration should be given to the target markets identified in Table 11 and the extremes in temperature geographically and seasonally.	FR2,14 MR4
PR7	Operating Humidity Range.	10 – 95% Relative Humidity Consideration should be given to the target markets identified in Table 11 and the extremes in humidity geographically and seasonally.	FR2,14 MR4
PR8	Memory.	Should retain test records securely on the device.	FR4,5 MR4
PR9	Atmospheric Pressure Range.	Consideration should be given to the target markets identified in Table 11 and the atmospheric pressure range geographically and seasonally.	FR2,14 MR4
PR10	Ingress Protection.	Design should prevent fluid and dust ingress that may interfere with correct use or interfere and contaminate sample integrity.	FR10,14 MR4
PR11	Durability.	Design and materials should be durable to withstand use over expected product life.	FR10,16
PR12	Power consumption and battery life.	Optimise battery life and specify expected life under typical usage scenarios.	FR7 MR4
PR13	Noise and interference.	As quiet and unobtrusive as possible and reject interference to maintain data and test integrity.	FR1

Table 7 - Performance

4.4. Accessories (AR)

All listed accessories with a description of their function

Reference	Requirement	Description	Cross-References
AR1	Mouthpieces.	Replacement mouthpieces in varying quantity pack sizes, i.e., bulk purchases for higher use and smaller for personal	FR1,7,8,9,16 MR4
AR2	Carry Bag.	Convenient for the user to transport in between uses	FR1,7,16 MR4
AR3	Carry case.	Protects the instrument in busy commercial and professional environments	FR1,7,16 MR4
AR4	Printer.	Local printout of results for immediate record keeping	FR1,7,16 MR4
AR5	Cross-Contamination Prevention Kit.	A kit containing personal protective equipment (PPE) and cleaning aids to protect the sample taker during and after use.	FR1,7,8,9,10,12 MR 4

AR6	Calibration kits.	Provision of equipment required to calibrate the device in specified frequencies and modes adequately.	FR1,7,12 MR4
AR7	Replacement components.	Such as replacement filters, cables (chargers)	FR1,7 MR4
AR8	Mounting or fixation.	Mounting brackets may be required to ensure secure placement in commonly used locations.	FR1,7 MR4
AR9	IFUs.	Replacement IFUs should be made available online.	FR1,8 MR4

Table 8 - Accessories

4.5. Safety and Regulatory Compliance

The device's design and manufacturing processes should comply with applicable requirements in the following standards and regulations.

International Standard Reference	Standard Title
MDR 2017/745	EU medical device regulation
ISO 10993-1:2018	Biological Evaluation of Medical Devices. Part 1: Evaluation and Testing.
ISO 10993-5:2018	Biological evaluation of medical devices. Part 5: Tests for in-vitro cytotoxicity.
ISO 13485:2016	Quality Management Systems for Medical Devices
ISO 15223-1:2016	Medical devices -- Symbols to be used with medical device labels, labelling, and information to be supplied -- Part 1: General requirements
ISO 14971:2019	Medical devices – Application of risk management to medical devices

Table 9 - List of International Standards

4.6. Intended Markets (IM)

Target market segments and geographies where the device will be marketed.

Reference	Requirement	Description	Cross-References
IM1	Direct to Consumer – Personal Use.	Online retail via Amazon or companies own e-commerce store.	FR14 CR10,11
IM2	Professional Use – Healthcare	Direct sales team.	FR14 CR10,11
IM3	Retail.	Traditional sales route, filling in the gaps remaining from online sales activity.	FR14 CR10,11
IM4	Fee-for-Service.		FR4,5,14 CR10,11
IM5	Subscription.	Consumable elements of the detection system should be regularly replenished, at an agreed level and frequency, for professional users to reduce transactional friction and improve customer experience.	FR4,5,14 CR10,11
IM6	Geographies.	UK, EU, USA	FR4,5,14 CR10,11

Table 10 - Intended Markets

4.7. Marking and Labelling Requirements (MR)

Consider all information that is to be displayed on the device and packaging.

Reference	Requirement	Description	Cross-References
MR1	Branding.	Clear presentation of company and device naming and logos.	FR15 MR4 CR10,11 AR1,2,3,4,5,6,7,8,9
MR2	Symbols.	Where possible, avoid the use of English. Instead, using globally recognised symbols and logos to instruct use as per international standards.	ISO 15223-1:2016 MR4 AR1,2,3,4,5,6,7,8,9
MR3	Compliance.	Include all mandatory and desirable compliance logos, i.e., CE, UKCA, waste disposal, and classification.	FR2,4,5 IM1,2,3,4,5,6 MR4
MR4	Instructions for Use.	Clear and compliant.	FR3,8,11,13 MR1,2,3 Alarm1,2,3,4 AR1,2,3,4,5,6,7,8,9
MR5	Model and serial number.	Providing traceability and servicing information.	AR1,2,3,4,5,6,7,8,9
MR6	Safety symbols and warnings.	Alerts users to potential risks and hazardous situations. Information should be contained within the IFU.	FR2 MR4 Alarm1,2,3,4,5
MR7	Barcodes and QR codes.	Facilitating tracking, inventory management and device registration processes.	AR1,2,3,4,5,6,7,8,9
MR8	Manufacturer and contact information.	To comply with regulations and to enable users to access support or to report adverse events.	MR4 AR1,2,3,4,5,6,7,8,9
MR9	Legible, durable and well-placed.	It should provide access and visibility to users.	FR15 MR4

Table 11 - Marking and Labelling

4.8. Alarms

Consideration should be given to alarms required to alert users of undesirable situations or abnormal conditions.

Reference	Requirement	Description	Cross-References
Alarm1	Inadequate Sample.	Notification to the user that an inadequate sample has been provided. Corrective action should be provided on the screen and within the IFU.	FR2,4,13 OPR1 MR4
Alarm2	Software Error.	Audible and visual error notifications can happen at any time. Corrective action should be provided on the screen and within the IFU.	FR4,13 OPR1 MR4
Alarm3	Start-Up Error.	Error notification to the user that a fault has occurred upon start-up.	FR4,13 OPR1 MR4

		Corrective action should be provided on the device screen and within the IFU.	
Alarm4	Low Battery.	Notification to the user that the device has a low battery. Corrective action should be provided on the device screen and within the IFU.	FR4,13 OPR1 MR4
Alarm5	Recalibration, Maintenance.	The device is scheduled for routine maintenance or recalibration.	FR4,13 OPR1 MR4 MAIN1

Table 12 - Alarms

4.9. Interface Requirements (IF)

Physical and remote connections to devices made by the user or organisation during maintenance activities.

Reference	Requirement	Description	Cross-References
IF1	Wired interfaces.	Physical connections such as USBC to transfer data or firmware updates. It could also be used to connect to printers. This connection can also be used for diagnostic purposes in case of a device error.	MR4
IF2	Wireless interfaces.	Enable communication with smartphones and tablets to facilitate remote monitoring, data transfer and integrations with other systems.	FR4 MR4
IF3	Data storage interfaces.	Internal memory to store and retrieve data.	FR4, MR4
IF4	Power interfaces.	A rechargeable battery port or battery compartment should be included. To be specified.	MR4
IF5	User feedback interface.	OLED or LCD screen to provide feedback to the user. Visual indicators (LED lights), display messages, audible alarms, and haptic feedback will enhance the operation and ensure correct device use.	MR4 CR10,11

Table 13 - Interface

4.10. Mechanical and Form Requirements (MER)

Reference	Requirement	Description	Cross-References
MER1	Handheld.	Should allow for single-handed use (both left and right-handed).	FR1,6
MER2	Lightweight.	Be portable and mobile to allow for easy carrying and handling during operation.	FR1,6 CM1,2,3,4,5,6,7,8,9
MER3	Weight.	Design considerations that reduce weight while maintaining structural integrity.	FR1,6 CM1,2,3,4,5,6,7,8,9
MER4	End of life.	The product should allow for easy deconstruction to segregate different material types at the end of its life.	FR8,16 MR4 CM1,2,3,4,5,6,7,8,9

MER5	Prevent fluid and dust ingress.	Providing a protective enclosure safeguards internal components from environmental factors, including dust, moisture or accidental damage.	FR9,10,11 MR4 CM1,2,3,4,5,6,7,8,9
MER6	Allow for suitable and effective cleaning and decontamination.	Minimise cavities, crevices, and stagnant areas to join lines and avoid porous materials to enable suitable cleaning and decontamination, as outlined in Table 16.	FR11 MR4 CM1,2,3,4,5,6,7,8,9
MER7	Multi-press buttons.	All buttons must be able to withstand repeated use in different environments.	FR1, MR4 CM1,2,3,4,5,6,7,8,9
MER8	Multi-function buttons.	To reduce the number, buttons may have more than one feature, i.e., press and hold and may provide feedback on their correct use with audible beeps or vibrations.	FR1 MR4 CM1,2,3,4,5,6,7,8,9
MER9	Support I.P.	Buttons should support the ingress protection rating of the device, i.e., not be a fluid entry path and allow for easy cleaning.	FR10 CD1,2,3,4 CM1,2,3,4,5,6,7,8,9
MER10	Intuitive.	Undergo usability assessment to ensure ease of use.	FR1,2
MER11	Integrated sensors and ports.	Facilitating poka-yoke systems to ensure device functionality and prevents accidental disconnection during use.	
MER12	Mounting and attachment options.	Features such as hooks, clips or brackets.	AR1,2,3,4,5,6,7,8,9

Table 14 - Mechanical and Form

4.11. Cleaning and Disinfection Requirements (CD)

Reference	Requirement	Description	Cross-References
CD1	Cleaning.	The device will be cleaned by mechanical cleaning, i.e., soap and water via a cloth.	FR1,2,10,11 MR4 CM1,2,3,4,5,6,7,8,9 AR1,2,3,4,5,6,7,8,9
CD2	Disinfection.	The device will be chemically disinfected via various agents including, but not limited to, Chlorine, Alcohols, Phenolics, Aldehydes, Iodine, Halogens, Ethylene oxide, and Quaternary ammonium compounds. Each chemical may be used in varying strengths depending on the perceived level of contamination risk. Appropriate warnings should be provided.	FR1,2,10,11 MR4 CM1,2,3,4,5,6,7,8,9 AR1,2,3,4,5,6,7,8,9
CD3	Disposal of Consumables.	Consideration should be given to the disposal of consumables (<i>such as used</i>	FR8,11,16 MR4 CM1,2,3,4,5,6,7,8,9

		<i>mouthpieces</i>) as to the most appropriate route, i.e., general or medical waste.	AR1,2,3,4,5,6,7,8,9
CD4	Validation testing.	Evaluate the device's compatibility with a range of cleaning agents.	CM1,2,3,4,5,6,7,8,9 MER1,2,3,4,5,6,7,8,9, 10,11,12
CD5	Training.	Appropriate protocol guidance should be provided if any specific techniques are required.	MR4 CM1,2,3,4,5,6,7,8,9

Table 15 - Cleaning and Disinfection

4.12. Component and Material Requirements (CM)

Reference	Requirement	Description	Cross-References
CM1	Power Supply.	To be specified based on further needs assessment.	MR4 CD1,2,3,4
CM2	Sensor Type.	Proprietary Electrochemical fuel cell.	MR4 CD1,2,3,4
CM3	Durable Materials.	The device will be reused multiple times in different environments. Its design should withstand severe treatment, such as being dropped during use.	FR8 CD1,2,3,4
CM4	Sustainability.	Materials, while durable, should, where possible, be derived from sustainable sources. Including, but not limited to; I. Polymers of non-virgin sources. II. Cardboard and paper from FSC and recycled sources.	FR8 CD1,2,3,4
CM5	End-of-Life Disposal.	All materials used in the manufacturing and shipping of the device should be recyclable or reusable.	FR8 MR4 CD1,2,3,4
CM6	Chemical Resistance.	It should withstand the cleaning and decontamination requirements described in Table 16.	FR8,10,11 MR4 CD1,2,3,4
CM7	Smooth and non-porous.	Minimising adherence to contaminants and facilitating easier cleaning.	FR8,11 CD1,2,3,4
CM8	Disassembly and accessibility.	The device design should allow for easy disassembly of components that require cleaning to ensure effective device use.	FR8 MR4 CD1,2,3,4
CM9	Resistance to environmental factors.	Can withstand anticipated environmental conditions and cleaning processes.	FR8,10,11 CD1,2,3,4

Table 16 - Components and Materials

4.13. Maintenance Requirements (MAIN)

Reference	Requirement	Description	Cross-References
MAIN1	Calibration.	The frequency and method of sensor calibration should be defined. Guidance should be given on the device's level of use as defined in Table 6.	FR13 MR4 Alarm5
MAIN2	Warranty.	24 months, parts and labour.	MR4 CR3,4,7
MAIN3	Component replacement.	Identify components that may require regular replacement and provide instruction (aftermarket) on their correct installation. These should be provided as accessories.	FR1,8,13 MR4
MAIN4	Firmware and software updates.	Firmware and software updates should occur when connected by a wired or wireless means to the database, i.e., during data transfer. User authorisation should be sought.	FR1,4,13 MR4
MAIN5	User-replaceable parts.	User-replaceable parts will help to minimise downtime in the event of failure, such as replaceable batteries, filters, and other items that do not need specialised expertise.	FR1,8,13 MR4
MAIN6	Service and support.	Technical support should be available where users can seek assistance for device maintenance, troubleshooting or repair services.	FR13 MR4
MAIN7	Record keeping.	The device should keep a log of service and maintenance.	DS4

Table 17 - Maintenance

4.14. Data Storage and Presentation Requirements (DS)

Reference	Requirement	Description	Cross-References
DS1	Data access and retrieval.	Design to allow authorised persons access to stored data when needed.	FR12 MR4
DS2	GDPR/HIPAA.	Robust security measures, such as encryption, access controls and authentication, protect any patient data recorded.	FR12 MR4
DS3	Errors and maintenance.	A record is kept on device maintenance and error recording.	FR12,13 MR4
DS4	Storage and capacity.	Consider the volume of data generated per patient and frequency of use to ensure adequate storage space. Minimum 1000 results.	FR12 OPR23,24,25 MR4
DS5	Retention policies.	Align to regulatory requirements and organisational policy.	FR12 CR11

DS6	Data Disposal.	Define procedures to protect patient data when securely erasing or destroying stored data.	FR12 DS5
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Table 18 - Data Storage and Presentation

4.15. Graphic User Interface Requirements (GUI)

Reference	Requirement	Description	Cross-References
GUI1	User research.	Understand user requirements to meet specific needs.	FR8
GUI2	Usability testing.	Ensure that chosen GUI is intuitive, efficient and meets user needs.	FR2,7
GUI3	Button Interface.	Providing tactile feedback and precise control and navigation of GUI navigation.	FR2,7
GUI4	Intuitive Menu.	Using a hierarchical menu and submenus to navigate through features. Users should not need to remember sets of commands.	FR2,7 MR4
GUI5	Multi-colour display.	LCD or OLED screen. Presenting information in a visual format.	
GUI6	Battery life.	Displays battery life and warnings when to recharge or replace.	CM1
GUI7	Environmental conditions.	Indicating whether the device is being used within specified environmental conditions	
GUI8	Status.	If the device is ready for use or whether other steps need to be taken.	MR4
GUI9	Instructional.	Providing guidance on the next stage of operation.	FR8,9
GUI10	User friendly.	Ability to guess your way around the options without any prior knowledge.	FR1,
GUI11	Mobile App interface.	Connections with IOS and Android devices.	
GUI12	Multilingual support.	Users can interact with the device in their preferred language.	

Table 19 - Graphic and User Interface

4.16. Cost Requirements (CR)

Consideration of critical aspects related to the cost of the device.

Reference	Requirement	Description	Cross-References
CR1	Target Price.	Understanding the target average selling price and required organisational profit margin will provide inputs into operational and design, and manufacturing cost requirements.	FR8
CR2	Cost of Materials and Components.	Cost-effective options should be sought without compromising quality or performance.	FR8,11
CR3	Manufacturing.	Adopt lean manufacturing principles to streamline processes, reduce and eliminate waste and improve efficiency.	FR8,16

CR4	Volume production.	Consideration of production scalability as volumes grow. Determine ideal production volumes based on market demands.	FR8,16
CR5	Regulatory and compliance.	Cost of initial and ongoing regulatory compliance.	FR12
CR6	Tooling and equipment.	Costs of initial and ongoing maintenance of tooling, moulds and equipment needed to manufacture the device.	FR8
CR7	Packaging and labelling.	Packaging and labelling costs should be considered during design to optimise shipping and storage costs.	FR8,11
CR8	Clinical efficacy reporting (post-market surveillance).	Initial and ongoing clinical study costs associated with post-market clinical follow-up obligations.	OPR1 PR1,2,3
CR9	Distribution and logistics.	Evaluate costs associated with shipping across distances (into different countries), import and export costs and transport methods (sea vs air).	FR8
CR10	Marketing and advertising	Ongoing operational expenditures are planned to promote the device to target user groups suitably.	IPR1,2,3,4,5,6,7
CR11	Intellectual property and enforcement.	Costs associated with filing new patents and potentially enforcing them in target markets.	IPR1,2,3,4,5,6,7

Table 20 - Cost

4.17. Copy Protection and Commercial Aspects Requirements (IPR)

Considerations on how to protect innovation and investment.

Reference	Requirement	Description	Cross-References
IPR1	Patents.	Protect novel inventions and innovative features.	OPR1 CR10,11
IPR2	Freedom to Operate (FTO).	Understanding what technology is already patented within the device's intended use to mitigate the risk of infringement.	CR10,11
IPR3	Trademarks.	Obtain trademark coverage in all target markets as defined in Table 11.	CR10,11
IPR4	Copyrights.	Providing exclusive rights to reproduce, distribute and display owned intellectual property.	CR10,11
IPR5	Trade secrets.	Protection of valuable processes, formulas, and algorithms that pertain specifically to the device that is not wanted in the public domain.	CR10,11
IPR6	Non-disclosure agreements (NDA).	Ensure NDAs are in place with all suppliers and third-party manufacturers.	CR10,11

IPR7	International considerations.	Assess IP protection in markets where the device is to be sold.	CR10,11
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Table 21 - Intellectual Property

Word Count – 4701

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