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Management of New Product Development

Assessment 2- Creating the Design Brief.

Virus detection system. Product Design Brief

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Product Design Brief

Virus Detection System

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1. Synopsis

Synopsis-

This design brief outlines the research and development needs for the adaptation of our companies existing technology in breathalysers, currently used for the detection and measurements of alcohol in a sample of breath mg/l. The development of this technology will lead us and allow us to lead the way in viral infection detection by measurement of breath, specifically the detection of volatile organic compounds (VOC's), concentrating on the to seven viruses around the world-

- | | | | | |
|----------------|----------------|----------------------|--------------|------------------|
| i. Covid. | ii. Ebola. | lii, H1N1 Influenza. | Iv. Measles. | V, Poliomyelitis |
| Vi. Monkeypox. | Vii. Smallpox. | | | |

This design brief is an aid to guide us (the company) through the strategic requirements and to aid with the ergonomic development and successful launch of the new CDS (Chemical Detector System).

Working closely with our local university we have identified an opportunity and exploited our current experience in manufacturing to react to the Covid-19 pandemic. We have proved the system works and trailed the technology in a laboratory setting, registrations for patents have been submitted via our legal team. This brief explores and outlines the considerations and needs to further develop this unit into a handheld portable unit, initially targeted at the NHS market, hospitals, emergency serviced (paramedics) and healthcare workers. Sales are conservatively estimates at 500,000 units in the first full 12 months of production growing to circa 1.5 million in year 2 and 2.5 million in year 3.

Considerations have been given to the recyclability of the unit as to minimise the environmental impact within its production and repurpose at end of life, where possible and practicable recycled plastics will be used either within the body of the unit or its components.

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We expect our customers to gain the ability to detect virus infections quickly and easily. This can help with early detection and prevention of the spread of diseases. Ease and convenience of use of our system compared to swab testing methods. Socially our customers will be regarded as conscientious members of society. More likely to adopt our value proposition due to low investment, accurate test reporting and high-quality goods that are environmentally responsible compared to swabs.

2. Social & Equality

At times technological focus can be prevalent, we need to be mindful of the “human” factors and not lose sight that the unit and its promotions need to be socially considerate and respectful.

a. Public health

- The project aims to improve public health by providing a rapid and accurate virus detection solution. Consideration is given to different languages.

b. Accessibility and Equity

- The product will be designed to ensure affordability and accessibility for diverse socioeconomic groups.
- The product design and marketing will consider diverse cultural perspectives on health monitoring.
- User opinions and concerns will be actively assessed through surveys and focus groups to inform product development.
- Be considerate of cultural sensitivities and adapt the design to be culturally sensitive and respectful.

c. Community engagement

- Local communities, healthcare professionals, and advocacy groups will be engaged to build support and address concerns.
- Design the user experience to be as simple as possible to minimize anxiety and stress.
- Ensure clear instructions are given to the recyclability of the unit, free returns to ourselves at end of life are preferred and some parts may be salvageable.

d. Education and Awareness

- A public education campaign will inform users about the technology's benefits and proper use.
- Collaboration with healthcare providers will ensure seamless integration into clinical settings.
- Clear instructions for use (picture format on unit or box) 3 easy steps.
- A feedback system will be established to address emerging social issues and gather user input for improvements.

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3. Political considerations

The development of this project will involve navigating a complex political landscape below are points for consideration.

- **Regulatory Approval and Compliance**
- Address the need for regulatory approvals and compliance with local, national, and international regulations for medical devices and public health technologies. Highlight plans for working closely with regulatory bodies to ensure product approval.
- **Political Stability:** Assess the political stability of the regions where the product will be deployed. Political instability can impact market entry and long-term operations.
- a. **Government bodies and support**
 - Consider how government policies and support can influence the project. Identify potential government incentives, grants, or funding opportunities to facilitate research, development, and deployment.
 - Stay abreast of any impending legal challenges of the accuracy or integrity of the technology.
- b. **Public health policy alignment**
 - Ensure that the project aligns with public health policies and priorities at both the national and regional levels. Highlight how technology can contribute to government efforts to combat infectious diseases.
- c. **Interagency Collaboration**
 - Explore opportunities for collaboration with government agencies responsible for public health, healthcare infrastructure, and emergency response. Consider how the project can complement existing government initiatives.
- d. **Trade and tariffs**
 - Evaluate trade policies and tariffs that may affect the import/export of components or finished products. Develop contingency plans for potential trade disruptions.
- e. **Data and Privacy security Regulations**
 - Address political considerations related to data privacy and security regulations. Ensure that the product complies with any relevant legislation, such as GDPR or HIPAA.

4. Design, aesthetics and ergonomics

A handheld unit, slightly bigger than the palm of the hand (see image 1 below), predominately made of rigid plastic (HDPE/PVC) with a soft grip outer.

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a. Hygienic by design

- Easy to clean and resilient to chemicals and sanitisers.
- Minimize areas with deep gaps that can harbor dirt.
- All external charge points or data transfer connections (USBC) to have a dust repellent tethered cap.
- Keep the unit dark grey or black, no bright colours as this will be difficult to maintain and impede recyclability.
- Ingress rating of IP44 minimum.

Image 1:



b. Users' specifics

- Easy to hold in one hand.
- Provided with an anti-slip grip.
- Can be used by left or right-handed people.

c. Unit components

- Quality plastics.
- Additional sale of personalized soft grip cases?
- Packaged with USBC cable to USB, inclusive of 3 pin UK plug.
- Replaceable rechargeable battery.
- Unit sold with two clip on breath sample tubes, washable.

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5. Transportation

Transport and logistic considerations, including supply chain resilience, environmental credentials, and security.

a. Distribution Logistics

- Discuss and formalise the logistics of distributing to various locations, including hospitals, clinics, airports, public spaces, and retail outlets. Explore the most efficient distribution channels and partnerships with logistics providers.
- Transportation Infrastructure: Assess the transportation infrastructure in target regions or countries. Ensure that transportation networks are reliable and capable of handling the movement of goods, especially if the project has a global scope.
- Temperature and Storage Requirements: Identify any specific temperature or storage requirements for the virus detection devices. Ensure that the transport and storage conditions comply with these requirements to maintain product integrity.
- Customs and Import Regulations: Address customs and import regulations for the transportation of the devices across borders. Consider import duties, customs clearance procedures, and any documentation required for international shipments.
- Supply Chain Resilience: Evaluate the resilience of the supply chain, particularly regarding the availability of essential components and materials. Develop contingency plans for potential disruptions, such as delays in shipments.
- Transport Safety and Security: Consider the safety and security of the transported products. Implement measures to protect the devices from damage, theft, or tampering during transit.
- Environmental Impact: Assess the environmental impact of transportation and develop strategies to minimize it. Explore eco-friendly transportation options and packaging materials.
- Reverse Logistics: Plan for the return and disposal of devices at the end of their lifecycle, ensuring compliance with environmental regulations and responsible recycling practices.
- Emergency Response and Disaster Preparedness: Consider how the transportation network can support emergency response and disaster preparedness efforts, such as rapid deployment of virus detection devices during outbreaks.

6. Key Performance Parameters.

Ensuring that the new product performs effectively and efficiently is essential for its success. Here is key performance considerations

a. Speed, Sensitivity, Accuracy, Range, Battery Life, Calibration.

- Sensitivity and Specificity: Define the required sensitivity and specificity levels for virus detection. The device should accurately identify the presence of viruses while minimizing false positives and false negatives.

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- **Speed of Detection:** Specify the desired speed of virus detection. Determine the maximum time it should take for the device to provide results, considering the need for rapid testing in healthcare and public settings
- **Accuracy and Precision:** Set performance standards for accuracy and precision, ensuring that the device consistently provides reliable results under various conditions.
- **Detection Range:** Define the range of viruses the device should be capable of detecting. Consider the adaptability of the technology to detect emerging viruses or variants.
- **Ease of Use:** Prioritise user-friendliness to ensure that healthcare professionals and individuals can use the device effectively, with minimal training
- **Battery Life:** If the device is battery-powered, establish acceptable battery life standards to ensure uninterrupted operation during testing.
- **Data Handling:** Define how the device will handle and store test data securely. Consider data encryption and compliance with data protection regulations.
- **Integration with Information Systems:** If applicable, ensure that the device can seamlessly integrate with healthcare information systems to record and share test results.
- **Maintenance and Calibration:** Develop a plan for device maintenance, including regular calibration to maintain accuracy over time.

7. Scalability

Availability of material resources need to be considered, especially in time of outbreaks, scarcity of mobile chip sets have been experienced in the pandemic of 2019, alternative supplies should be sourced at this stage.

a. Production, Quality, Cost Management, Continuous Improvement.

- **Production Capacity:** Assess the current production capacity and scalability of manufacturing processes. Determine the potential bottlenecks and constraints that may limit the volume of devices produced.
- **Supply Chain Scalability:** Ensure that the supply chain can scale to meet increased demand. Establish relationships with multiple suppliers for critical components to avoid single-source dependency.
- **Resource Allocation:** Plan for resource allocation, including personnel, equipment, and facilities, to accommodate higher production volumes. Consider hiring and training additional staff as needed.
- **Modular Design:** Develop a modular design for the device that allows for easy scaling. Modular components can be quickly assembled to meet increased demand without major redesign.
- **Manufacturing Flexibility:** Implement agile manufacturing processes that can adapt to fluctuations in demand. Consider flexible manufacturing lines that can switch between different product variants or configurations.

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- **Global Expansion:** If applicable, strategies for global expansion. Identify key international markets and navigate regulatory, logistical, and cultural challenges for international scaling.
- **Quality Control and Assurance:** Strengthen quality control and assurance processes to maintain product consistency and reliability as production scales up.
- **Technology Transfer:** If manufacturing is outsourced or involves multiple facilities, ensure a smooth technology transfer process to maintain product quality and performance across different locations.
- **Warehousing and Distribution:** Plan for expanded warehousing and distribution networks to accommodate larger inventories and timely product deliveries to end-users.
- **Testing and Validation:** Establish efficient testing and validation processes for a larger volume of devices, maintaining the same level of accuracy and reliability.
- **Regulatory Compliance:** Address regulatory considerations associated with increased production volumes. Ensure that the manufacturing processes and quality systems align with regulatory requirements.
- **Cost Management:** Continuously monitor and optimise production costs to ensure cost-effectiveness, even at scale. Consider strategies such as bulk purchasing and cost-efficient logistics.
- **Sustainability:** Integrate sustainable practices into scalability plans, including eco-friendly materials, energy-efficient manufacturing, and responsible waste management.
- **Demand Forecasting:** Implement advanced demand forecasting models to anticipate fluctuations in demand and plan production accordingly.
- **Risk Assessment:** Conduct risk assessments to identify potential challenges and disruptions that may affect scalability and develop mitigation strategies.
- **Collaboration:** Collaborate with partners, contract manufacturers, and distributors to align their capabilities with your scalability plans.
- **Continuous Improvement:** Establish a culture of continuous improvement to optimize processes, reduce waste, and enhance efficiency as production scales.
- **Post-Market Surveillance:** Develop a robust post-market surveillance system to monitor device performance and address any issues promptly, especially as the user base expands.

8. Assembly Process Design

Smart process design to optimise production and achieve the 3-year projected target is crucial, we have considered the following-

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a. Assembly process, Component compatibility, Quality control, Training, Worker safety, Tooling, Documentation.

- **Assembly Process Design:** Define the assembly process for the virus detection devices. Consider whether the assembly will be manual, automated, or a combination of both.
- **Component Compatibility:** Ensure that all components used in the assembly are compatible and well-suited for the intended purpose. Address any potential issues with component sourcing and compatibility.
- **Quality Control:** Develop robust quality control measures at each stage of assembly to maintain product consistency and reliability. Implement inspections and testing protocols to identify and address defects promptly.
- **Worker Training:** Train assembly workers thoroughly to ensure they have the necessary skills and knowledge to assemble the devices correctly. Continuously monitor and update training programs as needed.
- **Ergonomics and Worker Safety:** Prioritise ergonomic workstation design to enhance worker comfort and safety during assembly. Minimize repetitive tasks and potential ergonomic hazards.
- **Workstation Layout:** Optimize the layout of assembly workstations for efficient workflow, minimizing unnecessary movement and reducing assembly time.
- **Component Handling:** Implement appropriate handling procedures for sensitive components, especially if the assembly involves delicate sensors or electronic parts.
- **Material Management:** Establish efficient material handling and inventory management systems to ensure the availability of components and minimize production delays.
- **Tooling and Equipment:** Select and maintain appropriate assembly tools, equipment, and fixtures to facilitate efficient and accurate assembly processes.
- **Documentation:** Create detailed assembly instructions and documentation, including diagrams, schematics, and step-by-step guides, to assist assembly workers and ensure consistency.

9. Environmental Considerations

These environmental considerations in our design brief, demonstrate a commitment to responsible and sustainable product development. Adhering to environmentally friendly practices not only benefits the environment but can also enhance the product's reputation and appeal to environmentally conscious consumers.

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a. Materials, Recyclability, Efficiency, Emissions, Waste, Packaging, Certifications, Compliance, Renewables.

- **Eco-Friendly Materials:** Specify the use of environmentally friendly and sustainable materials for device construction whenever possible. Avoid hazardous substances and prioritize materials with low environmental impact.
- **Recyclability:** Design the product with recyclability in mind. Ensure that components can be easily disassembled and recycled at the end of the device's lifecycle.
- **Energy Efficiency:** Optimize the device for energy efficiency, especially if it's battery powered. Minimise energy consumption during use and develop low-power modes to conserve energy.
- **Reduced Emissions:** If the device involves any emissions (e.g., during testing or operation), design it to minimise these emissions and meet emissions standards.
- **Waste Reduction:** Implement strategies to reduce waste generated during manufacturing and assembly processes. Aim for efficient material usage and waste minimization practices.
- **Packaging Sustainability:** Consider eco-friendly packaging materials that minimise waste and can be recycled or repurposed by end-users. Use minimal packaging to reduce environmental impact.
- **Lifecycle Assessment:** Conduct a lifecycle assessment to analyse the environmental impact of the product from raw material extraction to disposal. Identify opportunities for improvement.
- **Carbon Footprint Reduction:** Develop strategies to reduce the carbon footprint associated with the device's production and distribution. Consider options for carbon offset programs.
- **Compliance with Environmental Regulations:** Ensure that the product complies with relevant environmental regulations and standards, such as RoHS (Restriction of Hazardous Substances) and WEEE (Waste Electrical and Electronic Equipment) directives.
- **Environmental Certifications:** Explore opportunities to obtain environmental certifications, such as ENERGY STAR, EPEAT (Electronic Product Environmental Assessment Tool), or eco-labels, to demonstrate the product's sustainability.
- **Supply Chain Sustainability:** Encourage suppliers to adopt sustainable and ethical practices in their operations. Consider suppliers' environmental certifications and commitments to responsible sourcing.
- **Recycled Materials:** Incorporate recycled materials into the product's design whenever feasible. Use recycled plastics, metals, or other components to reduce the demand for virgin materials.
- **End-of-Life Recycling:** Develop a plan for the responsible disposal and recycling of devices at the end of their lifecycle. Offer guidance to users on proper disposal methods.

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- **Renewable Energy Usage:** If applicable, consider using renewable energy sources in manufacturing facilities to reduce the carbon footprint of production.
- **Environmental Impact Assessment:** Conduct an environmental impact assessment to identify potential environmental risks associated with the product's production, use, and disposal.
- **Green Marketing:** Consider incorporating environmental sustainability into your marketing strategy, emphasizing the product's eco-friendly features and benefits.
- **Compliance Reporting:** Develop a system for reporting and tracking environmental performance metrics, including energy usage, emissions, and waste generation.

10. Shelf life/storage

a. Drop test, Temperature ranges, IP

- Temperature variations could exceed 50c, consideration to the life of battery and components should be detailed in the user manuals to manage expectations.
- Ip testing should be performed in the extremities.
- Certification against a recognized drop test standard should be considered, such as drop and impact test procedures include IEC 60068 and ASTM specifications for drop testing.

11. Quality

By addressing these quality considerations we set the foundation for the development of virus detection devices that meet high-quality standards, ensuring their reliability and effectiveness in healthcare and public health applications. Quality assurance and control are essential components of responsible product development.

a. Standards, Testing and Validation, Statistical Process Control.

- **Quality Standards:** Define the quality standards and specifications that the virus detection devices must meet. Ensure alignment with industry-specific standards and regulations, especially as the devices are intended for medical or public health use.
- **Design for Quality:** Integrate quality into the product design process. Emphasize factors such as reliability, accuracy, and durability in the design and engineering phases.
- **Testing and Validation:** Establish comprehensive testing and validation procedures to ensure that each device meets performance and quality specifications. Include verification and validation at various stages of development.

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- **Statistical Process Control:** Implement statistical process control methods to monitor and maintain consistent quality during manufacturing. Use statistical tools to identify and address variations in production.
- **Quality Control Measures:** Define quality control measures at each stage of manufacturing and assembly to detect and address defects promptly. Develop protocols for the rejection of non-conforming components or devices.
- **Traceability:** Implement a robust traceability system that tracks components and materials used in each device. This enables product recalls or investigations if quality issues arise.
- **Employee Training:** Invest in ongoing training and development for employees involved in product design, manufacturing, and quality control. Ensure that they are well-versed in quality processes and procedures.
- **Customer Feedback:** Establish mechanisms for collecting and analyzing customer feedback. Use this information to make continuous improvements to the product.
- **Post-Market Surveillance:** Implement a robust post-market surveillance system to monitor device performance and safety once it's in use. Address any reported issues promptly.
- Should undergo rigorous testing and validation to ensure it matches the claimed performance.
- Use a wide range of diverse individuals to get the most accurate results.

b. Integration

- Consider how this will be integrated and trained with current healthcare systems.

c. Emergency response due to quality issues

- Establish emergency response protocols for different scenarios such as-
Device malfunctions
False results
Faulty materials.

12. Maintenance (User)

Regular user maintenance is required to ensure continued accuracy of the device.

a. Unit design, Cleaning, Service, Software, Warranty, Replacement parts, Support.

- Removable parts for cleaning should be clipped in/out, no tools required.
- No easy to lose micro components.
- Simple, clear unambiguous instructions.
- Service & Calibration plan available.
- Software downloadable via USB-C.
- Standard warranty offered with an option to extend.
- Spare parts available to order via website.
- Manned help desk required for common trouble shooting.

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13. Market Share / Competition

The chance of pandemic is increasing (Dodds W. 2019 Dec 3:31–44.) this is our opportunity and threat, we need to ensure that we remain focused on the below to maximise our market share.

a. Target Customers, Unique Selling Point, Monitoring the Market, Cost.

- Start with target sectors but monitor all areas for distribution.
- USP- Quality, Cost, Service, Environmental credentials, ease of use, service.
- Discount on consumables for subscriptions.
- Competitive costing over current methods of detection.
- Horizon scan competition.
- Utilize current channels of distribution.
- Combine and utilise current sales and marketing teams.

14. Materials

All of the components that make up the unit will be environmentally responsible sourced, while balancing quality, cost and durability.

a. Mouthpiece

- Without sharp or harsh edges.
- Lightweight but not brittle.
- Easy to clean but not easy to scratch as this could harbor bacteria.

b. Main unit

- Durable
- Ergonomically designed to be secure in one hand.

c. User interface

- Clear and bright.
- Washable
- Unambiguous as this could be used by infrequent tech users.

d. Environmental

- Compliant with our environmental claims.
- Be mindful of our future net zero targets.

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15. Company Branding

We have a strong brand reputation to uphold, having worked with government agencies for many years we must protect this relationship. Our launch must be right first time, and delivered intime in full.

a. Brand values

- Maintain brand values- intime in full, accurate results, reliable units, strong customer relationships.
- Communicate our brand values and live them.

b. User experience

- Design and marketing centered around brand values.
- Accurate, reliable, first time, every time.

c. Branding extensions

- Merchandise centered around the confidence of testing results. **“Don’t chance it should be OK, test with us and know its OK!”**
- Extend to sectors outside of our initial focus.
- Value added warranties and unit extras.

16. Circular economy

Companies see adopting the circular economy (CE) model as an opportunity to become more sustainable and aligned to the growing demand for more environmentally friendly products...
(Barón Dorado, Giménez Leal, & Castro Vila, 2021)

a. Durability, Modularity, Material, Logistics, PaaS, Refurbishment, Supply chain.

- Design for Durability and Longevity: Create virus detection devices with a focus on durability and extended product lifecycles. Durable products can be used for a longer period, reducing the need for frequent replacements.
- Modularity and Upgradability: Design devices with modular components that can be easily upgraded or repaired. This extends the useful life of the product and reduces electronic waste.
- Material Selection: Prioritize the use of sustainable and recyclable materials in device construction. Ensure that materials are easy to disassemble and separate for recycling at the end of life.
- Recycled Materials: Incorporate recycled materials into the manufacturing process, reducing the demand for virgin resources and minimizing environmental impact.

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- Reverse Logistics: Develop a system for the collection, refurbishment, and resale of used devices. This can include trade-in programs or take-back initiatives to recover and reuse components.
- Eco-Friendly Packaging: Use eco-friendly and minimal packaging materials that are easily recyclable or biodegradable. Minimize packaging waste and encourage responsible disposal.
- Product as a Service (PaaS): Consider offering the virus detection devices as a service rather than a product. Users pay for access to the technology and benefit from updates and maintenance, while you retain ownership and responsibility for the device's lifecycle.
- Sharing and Collaborative Consumption: Explore models that encourage device sharing among multiple users or organizations. This approach can maximize the utility of each device and reduce the total number needed.
- Remanufacturing and Refurbishment: Establish processes for remanufacturing or refurbishing devices to extend their operational life. This can involve upgrading software, replacing worn components, and ensuring quality control.
- End-of-Life Management: Develop plans for responsible disposal or recycling of devices at the end of their life. Partner with recycling facilities to recover valuable materials and minimize waste sent to landfills.
- Waste Reduction: Implement lean manufacturing and production practices to minimize waste during the manufacturing and assembly process.
- Circular Supply Chain: Collaborate with suppliers and manufacturers that embrace circular economy principles, ensuring that materials and components are sourced and produced sustainably.

17. Legal & Intellectual Property

Protecting our brand and intellectual property is paramount, as this is a legal minefield, we recommend sourcing a professional to be consulted on the following areas-

a. Regulatory Compliance

- Medical legislation.
- GDPR
- Certification against quality standards,

b. Patent protection

- Robust intellectual property secured.
- Trademarking.
- Adherence to all copyrighting.

c. Understanding further trial requirements

- Requirements for continued validation and verification.

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- Work closely with WHO to understand emerging threats (viral)

d. Information sharing

- Signed none disclosure agreements with all supply and trading partners.

18. Costings

Starting with the end (cost) in mind is imperative, RRP should be agreed and then reverse engineer/cost all associated parts, transport, testing, compliance, staffing, helpdesks, insurances, legal support, future NMW, taxes, cost of environmental commitments, future packaging and waste regulations (extended producer responsibilities EPR

<https://www.gov.uk/government/consultations/packaging-and-packaging-waste-introducing-extended-producer-responsibility>

- Best quality materials against cost.
- Utilise transport and load sharing.
- Outsourced helpdesk rather than internal hire.
- Renewable energy in manufacturing site.

19. Risks, Mitigations, Time scale & Constraints

a. Risks-

- **Development Timeline:** Define the overall timeline for the project, including key milestones and deadlines for different phases, such as research and development, prototyping, testing, manufacturing setup, and product launch.
- **Regulatory Approval Time:** Consider the time required to obtain regulatory approvals and certifications for medical or public health devices. Factor in potential delays in the approval process.
- **Research and Development Time:** Estimate the time needed for research, design, and development of the new virus detection technology. Account for iterations and testing phases.
- **Manufacturing Setup:** Consider the time needed to set up manufacturing processes, secure suppliers, and establish production lines for the devices.
- **Supply Chain Lead Times:** Account for lead times in sourcing components and materials, especially if some components are specialized or require long lead times.
- **Production Ramp-Up:** Allow time for the gradual ramp-up of production to reach full manufacturing capacity, considering the initial learning curve and optimization.
- **Logistics and Distribution:** Include time for logistics, distribution, and market entry strategies, especially if your project involves international markets.
- **Market Entry:** Plan for the time required to enter the market, establish partnerships, and build brand awareness and distribution channels.
- **Competitive Pressures:** Consider competitive pressures and time constraints related to being an early mover or keeping up with industry innovations.

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- **Economic Factors:** Economic factors, such as fluctuating costs of materials or currency exchange rates, can impact the project's timeline. Monitor these factors and adapt accordingly.
- **Market Demand and Urgency:** Assess the urgency of addressing the market demand for virus detection devices. Depending on the context, rapid deployment may be critical.
- **Regulatory Changes:** Be aware of potential regulatory changes or updates that could affect the project timeline. Stay informed about evolving standards.
- **Public Health Emergencies:** Recognize that public health emergencies, such as disease outbreaks, can create urgent demand and influence project timelines.
- **Resource Availability:** Ensure that the necessary human and financial resources are available throughout the project to meet time constraints.
- **Risk Mitigation Time:** Allocate time for addressing unforeseen challenges, risks, and disruptions that may arise during the project.

20. Documentation & Certification

As a starting point we should be working towards the following (expert should be consulted for further requirements)

a. Medical, environmental, Laboratory, RoHS, EMC, FCC, CE, ISO 10993

Data taken from the following website indicates the following should be considered.

<https://www.breathalyzer.co.uk/breathalyzer-product-approvals/>

- **Medical Device Certification (e.g., FDA 510(k) or CE Mark):** If your virus detection device is intended for use in a medical or healthcare setting, you may need to obtain medical device certifications. In the United States, FDA 510(k) clearance is often required, while the CE Mark is common in Europe. These certifications demonstrate compliance with safety and performance standards for medical devices.
- **ISO 13485 Certification:** ISO 13485 is an international standard for quality management systems for medical devices. It covers various aspects, including design, development, production, installation, and servicing. Achieving ISO 13485 certification can help ensure the quality and safety of your device.
- **ISO 9001 Certification:** ISO 9001 is a broader quality management system standard that applies to a wide range of industries. While not specific to medical devices, it can still be valuable in demonstrating your commitment to quality processes and continuous improvement.
- **UL Certification:** Underwriters Laboratories (UL) certification is recognized worldwide for safety testing and certification. UL certification can be important for ensuring the safety of electrical and electronic components in your device.

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- **RoHS Compliance:** The Restriction of Hazardous Substances (RoHS) directive restricts the use of certain hazardous materials in electrical and electronic equipment. Complying with RoHS is essential for products with electronic components.
- **EMC Certification:** Electromagnetic Compatibility (EMC) certification ensures that your device does not interfere with other electronic equipment and can operate safely in different electromagnetic environments.
- **FCC Certification:** If your device includes wireless communication capabilities, you may need certification from the Federal Communications Commission (FCC) in the United States to ensure it complies with radio frequency regulations.
- **Environmental Certifications (e.g., ENERGY STAR):** If your device is designed to be energy-efficient, consider certifications like ENERGY STAR. These certifications can appeal to environmentally conscious consumers and organizations.
- **CE Marking (Non-Medical):** If your device is not intended for medical use but is sold in Europe, it may still require the CE Mark to demonstrate compliance with safety and environmental protection standards.
- **Local and Regional Certifications:** Depending on your target markets, there may be additional certifications required by local or regional authorities. Research the specific requirements for each market you plan to enter.
- **Biocompatibility Testing (ISO 10993):** If your device comes into contact with the human body, such as through sampling or testing bodily fluids, you may need to perform biocompatibility testing to ensure it is safe for use.
- **Good Manufacturing Practices (GMP):** Adhering to GMP standards is crucial for maintaining consistent product quality and safety during manufacturing.
- **In Vitro Diagnostic (IVD) Certification:** If your device is specifically intended for diagnostic purposes, you may need IVD certification, which is subject to specific regulations and standards.

21. Quantity

Epidemics and pandemics exist, this could have a negative impact on our company should one occur in our infancy stage, we should consider outsourcing manufacturing partners as a business contingency plan, if sales suddenly spike beyond a sustainable and realistic requirement, this should be agreed prior to launch not post.

22. Bibliography

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