



Pro-Fion New Product Development

Design Brief

Project: **FORWARD**

Overview:

Development of a new product or product range that will implement the recently trialled Pro-Fion breath-based viral infection detection system, internal name ***"AirDiag"***. This product will aim to capitalise upon the recent changes in the market that have occurred due to the increased importance of rapid testing methods for viral infections such as COVID-19. This project brings significant implications for the future of the company's current market as it will be the first product to be developed outside of the current categorisation of "Breath Alcohol Analysis Instrumentation".

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1. Required Context

From 2019 to 2023, the COVID-19 outbreak transformed all business markets. These transformations led to significant adverse reactions in some industries and massive positive reactions in others. Two notable benefiting industries are “Big Pharma”, as a result of the distribution of the vaccines required to combat COVID-19 and drug screening specialists such as “SureScreen Diagnostics” (Pegden, 2022).

As a reaction to the changes in the market, Pro-Fion has identified that there may be a possible business opportunity in using the existing expertise in chemical-based alcohol detection systems to develop a new patented product which would be able to detect a broader range of organic materials, most notably those that imply viral infection.

The first stage of this concept development has been completed through a “Knowledge Transfer Partnership” with a local university. The method of detecting the new range of materials has been developed through the partnership, and patent applications have begun. This brief is for developing the product that would implement this detection method.

2. Potential Market Scale

As this project aims to introduce a new product family into the existing range and introduce an entirely new product into the industry, the predicted scale of the market opportunity is difficult to quantify. As Pro-Fion has a strong position within the breath alcohol analysis instrumentation market and due to the market behaviour as a result of the COVID-19 outbreak, refer to section 1; this new product range is anticipated to perform well. The product development investment justification should be met through the expected manufacturing volumes. Currently, it is expected that 750,000 units are to be sold in the first year, with 3 million units per annum continuing.

3. Product Development scale

To parallel our existing product range of breath alcohol analysis instrumentation products, there is potential for this product development project to lead to the development of a new product “family” encompassing a range of individual products meeting varying levels of function. This level of development may come during the project or after the post-launch review stages.

4. Design specification development process

The design process must collaborate the efforts of all stakeholders. This includes:

- The NPD department, managers and engineers.
- Suppliers of both components and materials.
- The Product Manager and Sales team.
- Manufacturing engineers.
- Factory assembly staff.
- Procurement.
- Customers, end users
- Customers, distributors.
- Etc

All stakeholders will have valuable contributions to the development of this product. Collaboration between all areas will allow for all aspects of the proposed product to be considered and thoroughly developed to meet the specifications to be established further into the development cycle.

Contributions to the specifications are as follows:

- The NPD department. Primary coordinators for the project, producing project deliverables, communicating with other stakeholders, and leading the design development.
- Suppliers. Influence the design of externally sourced components and material selection. Can assist with the design for manufacture.
- The Product Manager and Sales team. Primary deciding group for the products specifications. They will ultimately dictate the specifics of what the product achieves for our customers and the Pro-Fion business strategy.
- Manufacturing engineers. Influence the design for manufacture and assembly process within the Pro-Fion factory.
- Factory assembly staff. Has the most knowledge of how Pro-Fion products behave during assembly and testing. Can provide valuable feedback on the processes and design.
- Procurement. The supply chain development process will influence the outsourcing of components, and therefore procurement should be consulted when interacting with suppliers.
- Customers, end users. From our customer feedback surveys, notable design ideas and feedback can be considered to appeal to our customer base.
- Customers, distributors. Similar to the end user. Can provide valuable feedback through surveys.

Informed department managers: NPD, Sales, Product Management, Marketing, Manufacturing Engineering, Procurement

5. Functionality Requirements

5.1 Base function

This product range is to encompass the newly developed breath-based viral infection detection system, internal name **“AirDiag”**, within an accessible testing platform akin to what Pro-Fion currently provide with the breath alcohol analysis instrumentation product range. A product that utilises the AirDiag system to provide rapid test results to its user for various organic viral infections.

5.2 Performance Specification Requirements

The product is to be designed to meet expected performance levels in a number of criteria. These should be used to describe the overall performance of the unit and should be specified prior to the primary design development phase. These include:

- Accuracy of measurement.
- Average result delivery period.
- Ambient functioning conditions.
- IP Protection class.
- Data storage capacity.
- If designed to be charged, the number of measurements per charge.
- If designed to be battery operated, the number of measurements per battery set.

- Energy usage.

5.3 Physical Function, Customer

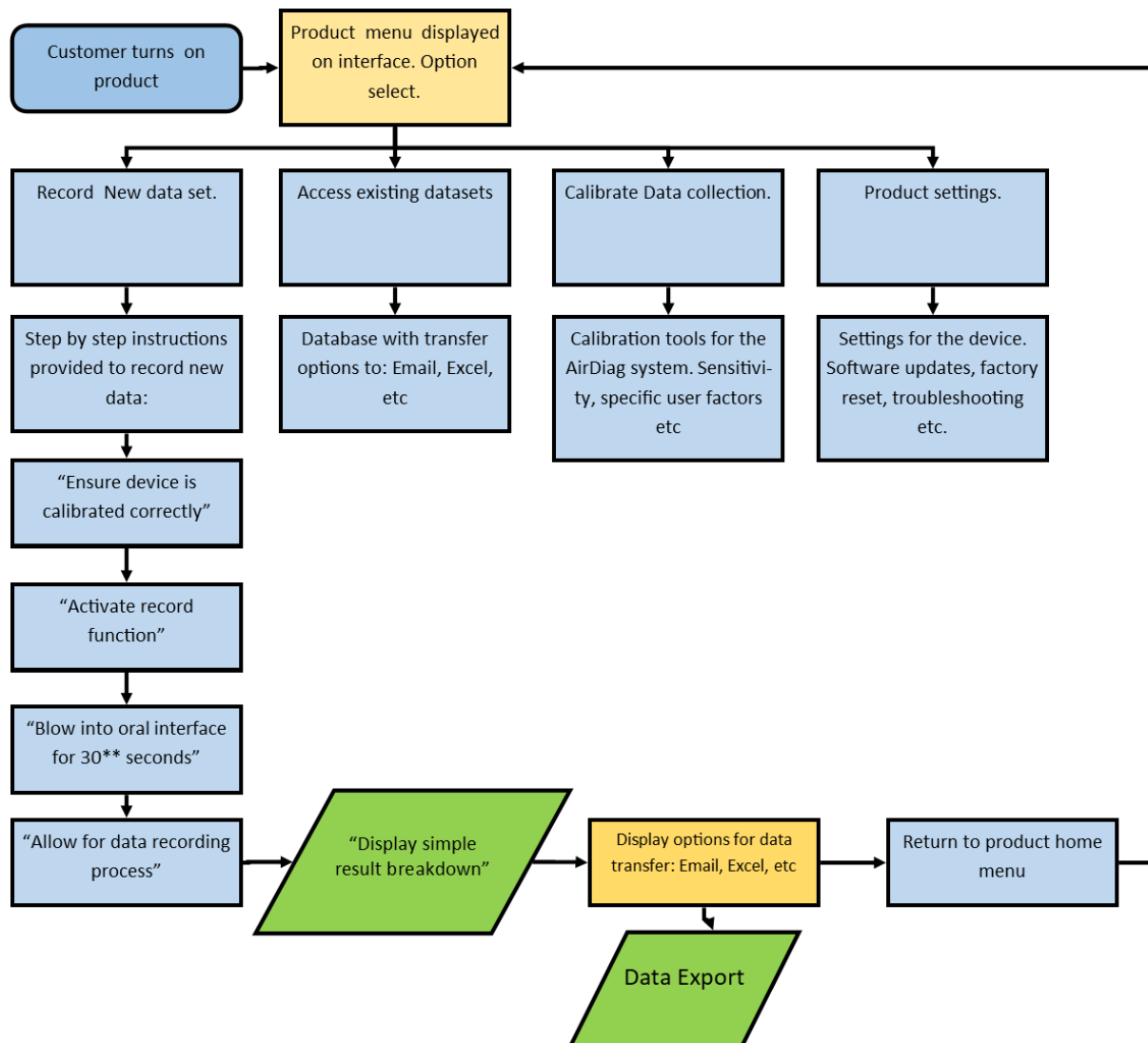
The product is to follow a similar design direction as the existing Pro-Fion range of breath alcohol analysis instrumentation products. This includes the following:

- Handheld:
 - To be held in one hand while operated with the other with ease.
 - Ergonomics must not prioritise either left or right handed individuals.
 - Must accommodate ergonomics and human factor ranges of all genders. (Karwowski, 2005)
 - Weight must be manageable by the user.
 - It must be comfortable to hold and operate.
- Accessibility of controls and interfaces:
 - Controls must be operatable using one hand.
 - Controls must be intuitive.
 - Controls must be suitably labelled.
 - The labelled text must be in a clear typeface and legible from a suitable distance.
 - Controls must be responsive.
 - Interfaces must be clear and legible.
 - Interfaces must not strain the user's vision after prolonged use.
 - Infaces and controls must function collaboratively and coherently.
- Storage and handling while not in use:
 - The product must be easily and securely stored while not in use.
 - The product must be supplied with an appropriate method of carry, either integrated into the device or separately.
 - Methods of carrying must be comfortable and non-intrusive.
- Testing platform (oral interface):
 - The oral interface must be accessible to all potential users.
 - The oral interface must be easily cleaned.
 - The oral interface must be removable.
 - The oral interface must be non-intrusive.
- User Maintenance:
 - Power supply, either battery or via mains supply, must be provided in a way that is accessible to the user.
 - The product must be easy to charge/replace the battery.
 - Errors in interface function and data recording should be easily indicated.
 - Methods for finding the solutions to errors must be provided.
- Risk management:
 - During the event of electrical failure, the product must not allow the user to be put at risk.
 - During the event of the product being dropped from a notable height, the product should be designed to minimise damage/not introduce risk to the user.
 - Charging and power systems should be designed not to put the user at risk.
- Quality:
 - The product must be designed to meet the expected level of material, design and user interface quality expected of Pro-Fion products.

- The level of physical quality demonstrated by the product should not significantly reduce over prolonged use.
- Aesthetics
 - The product must be designed to fit within the existing Pro-Fion product ranges while keeping a distinct design motif that distinguishes it into its own family.
 - This design motif must focus on achieving functionality and accessibility while maintaining the Pro-Fion brand.

5.4 Product Operation

To provide the function noted above in section 4.1, the product use should follow the flow chart depicted below. This chart should be reviewed throughout the NPD process as the design is developed:



5.5 Interface for data storage

Collection of data should be more expansive than that of the current Pro-Fion range of breath alcohol analysis instrumentation products. The data that can be recorded via AirDiag consists of more variables than alcohol level, and a variety of results can be obtained. Therefore, it is more necessary to have a method of storing and transferring the dataset to an external device for further analysis. This may be achieved through a number of methods:

1. Digital transfer. The product features an internal memory that can hold datasets before transfer to another device through digital systems such as Wi-Fi connectivity, Bluetooth connectivity or even file transfer to an email address.
2. Transfer through a physical memory device. The product features an insert slot for an external memory device, such as a micro SD card, which can then be used to transfer to another device.

5.6 Accessories

It should be considered if various accessories can be provided either within the sold package alongside the product or as independent items. These should include components that provide additional functionality outside of the primary product or replace perishable components of the test system. For example, carrying accessories such as straps, cases and bags, additional control interfaces, memory storage devices or replacement oral interfaces.

5.7 Prototyping

Prototyping should occur throughout the NPD process to physically represent design development and encourage design reflection based on a physical presentation. Prototypes of the mechanical and structural component families can be constructed utilising the additive manufacturing facilities in the Pro-Fion design laboratory. This should assist with the development of the aesthetic, ergonomic, and design for assembly aspects via live feedback from the various stakeholders. Prototypes of components manufactured by suppliers can also introduce design reflection and assist with the development.

Informed department managers: NPD, Sales, Product Management, Marketing, Manufacturing Engineering, Procurement

6. Manufacturing

The manufacturing process will consist of several stages and the collaboration of a number of key stakeholders. These stages include:

- Outsourcing components from external suppliers.
 - Adopting a similar strategy to the current product range. Electronic, mechanical, chemical, and structural components will be outsourced.
 - The selection of these suppliers will be determined with minimisation in manufacturing cost as a driving factor.
 - This may result in the use of new suppliers over those with existing relationships with Pro-Fion
- Assembly in-house.
 - Assembly of the components is aimed to occur within the Pro-Fion factory.
 - This process will aim to be similar to that of the current product range to minimise disruption to existing manufacturing operations and reduce the need for excessive training.
 - The number of components required for assembly in-house is unconfirmed. (Mechanical components may require external assembly or addition to the in-house process)
 - Assembly capacity may require expansion depending on product range performance.
- Testing In-house.
 - End-of-line tests will be employed to maintain product quality.
 - This process will aim to be similar to that of the current product range to minimise disruption to existing testing operations.
 - Testing for interface operation, detection process, quality of build, etc
- Packing and distribution in-house.
 - Packaging capabilities will likely not require significant expansion.
 - Distribution and stock capacity may require expansion depending on product range performance.

Informed department managers: NPD, Product Management, Manufacturing Engineering

7. Materials

Product materials are a driving factor in both cost and performance. The selection of materials for each component should be driven by a hierarchy of prioritised factors as follows:

Mechanical components:

1. Materials our suppliers have access to.
2. Material guidelines and standards.
3. Material properties, strength, density, elastic modulus.
4. Cost.
5. Other factors etc.

Justification: As the mechanical components are to be purchased through an external supplier, the material selection is limited to what is on offer from each supplier. Costs should be minimised but not at the expense of performance and safety. Costs will drive what supplier is chosen; however, the materials that said supplier has access to will limit the final decision.

Electrical components:

1. Materials our suppliers have access to.
2. Cost.
3. Other factors etc.

Justification: Knowledge of the materials that are used in our electrical components is limited within our existing product supply chain. Because of this, it is appropriate to allow the expertise of the supplier to guide this decision. Therefore, as per advice from the supplier, costs should be prioritised.

Structural components

1. Materials our suppliers have access to.
2. Material guidelines and standards.
3. Manufacturing process.
4. Application requirements, strength, inert interfaces, product longevity etc.
5. Cost.
6. Life cycle, reuse, and Embodied carbon
7. Other factors etc.

Justification: Structural components include; the main casing to house mechanical and electronic components, the outer surfaces the customer will interact with, and the internal structures to provide rigidity. These components are likely to be mass-produced, homogenous components manufactured by our suppliers through high-quantity processes like injection moulding. The material selection for these components will be heavily driven by what is standard in the design of handheld electronic devices, similar to that of the existing Pro-Fion product ranges. The suitability for application is also heavily influential, followed then by the minimisation of costs. Additionally, thought must be put towards the lifecycle of these components, specifically end of life and how the components can be recycled, this is more achievable for homogenous products.

Chemical components:

1. Application requirements.
2. Cost.
3. Abundance of materials
4. Other factors etc.

Justification: The AirDiag system has been specifically designed to utilise materials for the function of the detection process. This means that materials are not subject to changes to fulfil the function and safety requirements. Cost minimisation will drive the decision-making somewhat, but significant changes are unexpected.

Informed department managers: NPD, Product Management, Manufacturing Engineering, Procurement

8. Suppliers

The decision has been made to use this new product development as an opportunity to investigate new suppliers separate to the existing supply chains. The drive for this decision was manufacturing cost minimisation. New suppliers for all components should be explored, and current findings conclude that the Chinese market for printed circuit boards, sensors and other electronic components is still the most economically viable option; however, this does not appeal fully to the general move towards reducing the embodied carbon in Pro-Fion products. For more details, see section 14.

Informed department managers: NPD, Procurement

9. Packaging

Packaging should be designed to fulfil similar offerings to that of the other Pro-Fion products. This includes single-unit packs with space to accommodate all required accessories. Depending on the developing sales strategy, the option for multiple units per package may be required. The packaging scale is to be confirmed further into the product development process; pallet packing will be addressed once the size is confirmed. The packaging supply chain is likely to follow the existing product range and use established suppliers.

Informed department managers: NPD, Marketing, Manufacturing Engineering, Procurement

10. Transit

As the completed product assembly will occur within the Pro-Fion assembly factory, safety stock will be kept on site. Therefore, the factory distribution centre will be utilised to distribute the product through the existing channels. Unlikely that new transit links will be required.

Informed department managers: NPD, Logistics

11. Shelf life Storage

Packaging should provide adequate protection from prolonged shelf storage. This includes protection from external factors such as UV light and also internal factors such as battery degradation.

Informed department managers: NPD, Product Management

12. Product Lifespan

The product should be designed to provide service for a suitable lifespan. This includes mechanically but also the function of the AirDiag system. If the AirDiag system requires the use of chemicals that degrade, that degradation must be designed for and should not impede the suitable advertised life span of the product. This degradation should be clearly displayed for the customers understanding.

Informed department managers: NPD, Sales, Product Management

13. Environmental Factors

13.1 Circular economy

As part of the Pro-Fion pledge of waste reduction, in accordance with ISO 14001 (NQA, GLOBAL CERTIFICATION BODY, 2022) in our products, circular design must be considered within the design

development process. At all possible stages of the design, consideration of how the product may be deposited responsibly should influence design choices such as materials, fixtures, and disassembly.

Informed department managers: NPD

13.2 Embodied Carbon

Embodied carbon is currently a key point of discussion within all manufacturing sectors (A. Alsabri and S. G. Al-Ghamdi, 2020). Driving to reduce the carbon embodied within Pro-Fion products should be considered at all design stages. However, material and supplier selection is the most impactful. Costs should be prioritised, but embodied carbon should not be ignored.

Informed department managers: NPD

13.3 Hazardous substances

The product is likely to include hazardous substances such as chemicals and batteries. Any substance that could be considered hazardous should be reported, and the product must meet the appropriate compliance and directives, see section 14.

14. Compliance

As the product in development is to feature electronic components it must comply fully with the Electromagnetic Compatibility Directive 2014/30/EU (European Commission, 2014), including all relevant standards enclosed and the Waste Electrical and Electronic Equipment Regulations 2013 (GOV.UK No date). Additionally, compliance with the Restriction of Hazardous Substances Directive 2002/95/EC (THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, 2003) and REACH compliance (ECHA, No date) will be required due to the inclusion of potential hazardous materials within the product.

14.1 Standards

Review of the following European standards should be performed while reviewing the functionality and design specifications for this project:

- CSN EN 15964 “Breath alcohol test devices other than single-use devices - Requirements and test methods” (European Standards, 2011)
- CSN EN 16280 “Breath alcohol test devices for the general public - Requirements and test methods” (European Standards, 2012)

Design testing to show compliance with the relevant standards is required. Further testing to validate performance may be required.

14.2 Declaration of Conformity

Conformity of the appropriate standards and directives should be openly declared and updated when changes are made to the legislative documents.

Informed department managers: NPD, Product Management

15. Patents

As of the writing of this report, the necessary patent applications have been registered for the AirDiag system. As this system is fundamental to the function of the proposed product, the patent progress should be monitored and reviewed.

Informed department managers: NPD, Product Management

16. Risk Assessment

All necessary risk assessments must be carried out to ensure the product is safe within the following scenarios:

- Manufacturing and assembly.
- Transportation.
- Usage.
- Maintenance.
- Disassembly.
- Disposal/Recycling.

Informed department managers: NPD, Manufacturing Engineering

17. Documentation

All necessary documentation for the product should be provided digitally. This includes.

- Instructions of use and maintenance.
- Datasheet
- Declaration of conformity

The following documentation should also be provided physically with the purchase of the product:

- Instructions of use and maintenance.

Informed department managers: NPD, Product Management, Marketing

18. Marketing

The marketing strategy for this product should aim to highlight the key features of this new range. These include:

- A unique way to test for various viral infections.
- Quick result delivery.
- Compact and easy to carry.
- Accessible.
- Reusable.

The aesthetics of the product will largely be determined by the function. However, several factors can be under the control of the marketing team. These include:

- Colour scheme.
- Labelling.
- Logo placement.
- Some aspects of shape and structure.

Informed department managers: NPD, Product Management, Marketing

19. Target Costs

Final costs will be determined by the total variable costs of the complete product, including assembly. To produce a target cost, a rough bill of materials must be formed with informed assumptions made around the price of individual components, assembly time, and expected requirements for specialist labour or expertise.

Informed department managers: NPD, Sales, Product Management, Manufacturing Engineering, Procurement

20. Competitor response and comparison

As this product is intended to be a new arrival to the viral testing market, comparisons are predicted to be difficult. However, with this product release, a competitor response may occur.

Informed department managers: NPD, Sales, Product Management

21. Timescale

A timescale in the form of a Gantt chart should be utilised to plan the successful completion of this design development project and product release. Defined milestones and a reactive deadline system should be employed to ensure a successful product launch.

Informed department managers: NPD, Sales, Product Management, Marketing, Manufacturing Engineering, Procurement

22. References

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