



MANAGEMENT OF NEW PRODUCT DEVELOPMENT DEVELOPMENT

Assessment – Creating the design brief

Prepared for – Mr Alan Mumby

Author – Colin Jones 2125470

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Product design brief

<u>Prepared by</u>	<u>Date</u>	<u>Department</u>
Colin Jones	03/05/2023	Engineering Development

The signatures below confirm that this Product Design Specification is accepted for use.

<u>Approved by</u>	<u>Date</u>	<u>Department head</u>
A Rse	03/05/2023	Finance
E Lbow	03/05/2023	Sales
N O Clue	03/05/2023	Production
O M God	03/05/2023	Legal
I N Spiration	03/0/2023	Logistics

Revisions

Revision Number	Revision details	Date

General Introduction



Please note that information contained in this document is commercially sensitive and until otherwise advised its contents should not be disclosed to any party not actively involved in its generation, evolution or evaluation.

Further to sustained efforts in gaining market intelligence is has become apparent that a substantial opportunity is available to the company. This opportunity involves the supply of a **virus detection unit** to both a clinical and personal customer base, this detection unit is based around the existing range of alcohol detection units we currently manufacture, however, it will require substantial enhancements to be supplied to the new marketplace.

It is estimated that this new marketplace will require 750,000 units in the first year, increasing to 3,000,000 units annually thereafter.

The overriding purpose of this document is to offer a portfolio for any aspect that needs to be considered to guarantee as far as possible the smooth running of the project and a worthwhile outcome for all parties involved.

It is worth considering the relevance of this product design brief and it's importance, especially in light of a recent publication:

"The telehealthcare sector has been expanding steadily in the UK. However, confusing, complex and unwieldy designs of telehealthcare devices are at best, less effective than they could be, at worst, they are potentially dangerous to the users".

Yang, & Renda, G. (2019). The design briefing process matters: a case study on telehealthcare device providers in the UK. *Disability and Rehabilitation: Assistive Technology*, 14(1), 91–98.

<https://doi.org/10.1080/17483107.2018.1428372>

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Synopsis

noun syn·op·sis \sə-'näp-səs\

a short description of the most important information about something : a summary or outline

SYNOPSIS.

Purpose.

The general use of this new product is simple, it will be a market leader in equipment designed for the rapid detection of a range of viral templates from within a sample of breath. It should be appropriate for use within both the clinical or personal use environments and offer a platform for the user to replace for example existing LFT or PCR test kits

Non negotiables.

Market intelligence has indicated that to compete in the proposed market places the following should be considered non-negotiable in the brief.

- The colour will be dictated by the potential requirements of clinical use.
- The general finish will be dictated by the sanitary requirements of clinical use.
- The overall design will be resistant to the general cleaning regime dictated by clinical use.

Performance.

As a minimum level of performance, the unit should be able to offer:

- Rapid and accurate sampling
- Methodology that will not in any way put the user at risk from third party infection
- Ease of use

Features.

While benefiting from the company's experience in the design and manufacture of alcohol detection units it is anticipated that this new product will be able to stand alone with a full range of market leading features:

- Ergonomic design
- Cost competitive
- Accurate and rapid sampling
- High recycling percentage
- Bluetooth compatible
- Appropriate for both clinical and personal use

Image courtesy of The Bath Novel Awards



POTENTIAL COMMERCIAL BENEFIT.

It is anticipated that the production requirement in the first year will be circa 750,000 units.

It is further estimated that including initial expenditure we will generate a cost price of £404 per unit and a retail value of £412. This offers the rarity of a gross margin of circa 2% inclusive of anticipated development costs.

This equates to an increase in turnover of £309,000,000 however with a gross profit on this increase of just 2%. This may be hugely sacrificial to the existing manufacturing capacity, especially considering the existing profit margins on the current product range. If we take into account an expected annual unit requirement of 3,000,000 units with our standard levels of profit, the expected increase in turnover in year two would be £1.4 billion with a gross profit of £423 million.

Image courtesy of Adobe stock



AESTHETICS.

It should be considered what this item should look like, however, as noted in the “non-negotiables” the general colour may be dictated by the requirements of the clinical end user rather than the fashionable requirements of alternative users.

www.team-consulting.com/insights/the_role_of_colour_in_medical_devices (20 July 2017)

“Colour plays an important part in the design of medical devices, through carefully considered colour schemes it can help us tackle both practical and emotional design challenges.” “Where possible the use of pre-approved colour and material combinations will help to reduce risk during the manufacturing process”

“Colour options can be influenced by the materials chosen, the processes required through the manufacturing path” (Sibley (2001): Schepman et al (2018)

“Each person will make for himself the kind of nude he wants, with the nude that I will have made for him. He’ll put everything where it belongs, with his own eyes.”

– Pablo Picasso

As such maybe we should consider should we offer two colour schemes, one for clinical use and one for non-clinical.

The use of colour also has potential impacts in different countries or cultures, we should consider these for non-clinical applications. A selection of examples would be as follows:

Yellow - This is seen as being warm and happy in most Western Cultures, it is the colour of envy in Germany. In France it can be seen as meaning weakness and betrayal.

In Egypt yellow signifies happiness and good fortune while in China it is the colour that represents harmony and in Thailand it is a lucky colour. All in all, it is one of the colours that is least likely to cause offense.

Blue - Although it is often associated with sadness, blue doesn’t have many negative cultural implications in different parts of the world.

Red – In African countries it can be associated with death and aggression. It is classed as the colour of mourning in South Africa, while in Russia it is strongly linked to communism and the Motherland.

White - In Western countries this colour is used to represent purity. Alternatively, Korea is one of several countries where it is used during mourning. White is linked to death and bad luck across much of Asia.

Branding

BRANDING.

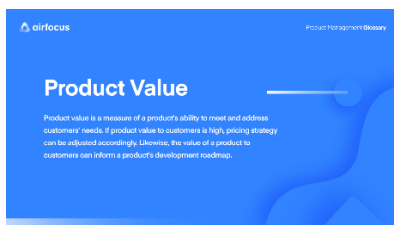
We have an existing brand identity; however, this may not be appropriate for the proposed markets. If we feel that we require a new branding concept to differentiate the new product range from the old, then we should consider the following:



Image – What image are we attempting to portray.



Message – What message are we attempting to convey.



Values – What values are we attempting to imply.

“Successful brand management requires both an understanding of how the brand strategy is implemented and communicated to the customer and how consumers respond to this”
(Goodyear 1996; Kapferer 1997; Young and Rubicam 1994)

Images courtesy of Daily news Egypt, Imaginasium and Airfocus.



COMPANY CONSTRAINTS

We should consider any influence that we will have to contend with to execute this new business strategy. The following are a selection of basic influences that may be apparent and subject to consideration.



Time – Business is essentially a way of putting assets to work over time.



Capacity – Do we have adequate capacity to engage in this new project?



Materials – Are the materials required currently available in the global supply chain?



Manpower – Do we have enough or can we employ suitable additional staff.



Capital – Do we have adequate funding in place to make this venture commercially viable?



Resources – Do we have everything that we need to conduct this additional business?

“A business related condition or event that prevents the project from fully delivering the ideal solution to customers and end users.” www.bablocks.com/business-constaint (2020)

Images courtesy of Vecteezy, the OU, Youtube, Sweetynational, Office for students, ABS.



COMPETITION

At present there is no evidence that we have any viable competitors in this new field, however, it is not anticipated that this will be the case for a sustained period of time. Every effort should be made to take full use of any market advantage that we may have, this emphasizes the need to make full use of this brief and use the intelligence it provides to format a full and fundamentally effective product specification. It also emphasized the need for confidentiality regarding this document and its findings.

“Commercial Competitor means any Person who engages or participates in, or manages or controls, directly or indirectly, in any capacity (including as an individual, partner, shareholder, joint-venturer (whether by Contract, acquisition of Equity Interests or otherwise), officer, director, principal, trustee or consultant), a Competing Commercial Business, and any of such Person’s Affiliates or successors in interest.”

www.lawinsider.com/dictionary/commercial-competition (2020)



COMPLIANCE

While we are well aware of the requirement for us to comply with standard and regulatory compliance throughout our existing product range, we should consider the additional requirements that may be required in the new area of interest.

Following the UK's exit from the European Union (EU), the Medicines and Healthcare products Regulatory Agency (MHRA) has a unique opportunity to improve how medical devices and in vitro diagnostic medical devices (IVDs) are regulated in the UK. As such certification of compliance may take time and this potential delay may need to be factored into timescale estimations.

An example of standards that we may need to consider would include:

[“BS EN ISO 13485-2012 Quality management for medical devices”](#)

[“BS EN ISO 14871-2012 Application of risk management for medical devices”](#)

[“BS EN ISO 14155-2011 Clinical investigation of medical devices for human subjects”](#)

Image courtesy of Forbes



CUSTOMER

Significant effort has already been employed in the use of market intelligence to evaluate who we propose to sell this product to.

We propose to market this product to effectively sell it to the following:

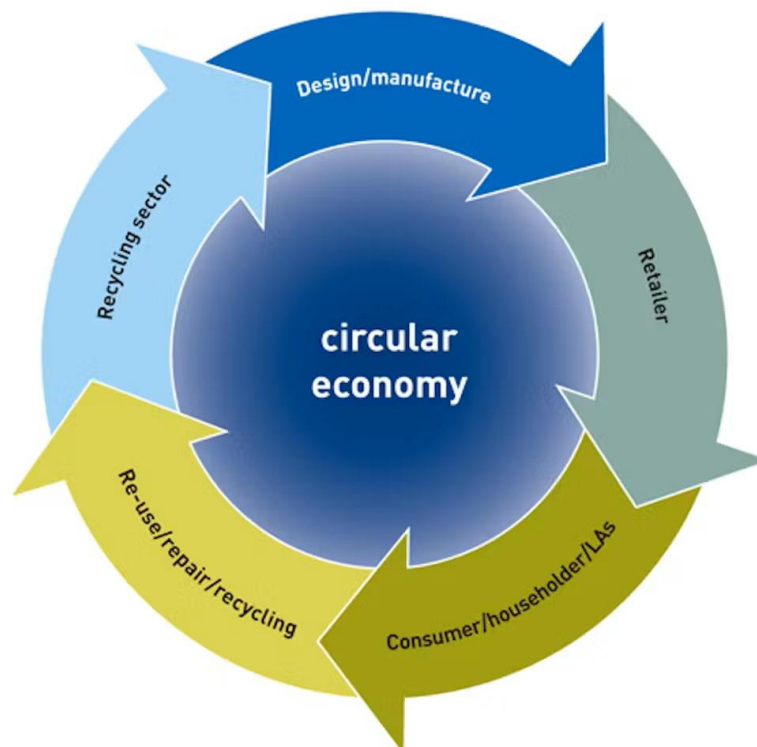
- What we could politely term as the “General Public”, however considering the potential for cultural and social limitations (this will be covered later in this document)
- Employers throughout all aspects of industry
- Clinical end users within the health industry
- Travel operators, cruise operators and airlines

Perhaps we should consider if a single design will be acceptable for all the target customer types or if small modifications on a base design will be more sensible in order not to compromise.

“Put simply, the more you know about your customers the better informed each and every one of your decisions will be”

<https://www.boomandpartners.co.uk/articles/why-is-understanding-customer-needs-important>

Image courtesy of Bullhorn



THE CIRCULAR ECONOMY

With a proposed output of 3 million units per annum from year two this product carries a considerable weight when it comes to what happens to it at the end of its life cycle. As such we should consider the re-cyclability of all materials involved in the construction of the product. I would propose that we look at the latest information regarding possible requirements for re-cycling of the materials based on a product lifespan of 3 years. The following would be a suitable example of the latest thinking:

Requirement for disposal of electrical/electronic items

Citation: Boudewijn, A.; Peeters, J.R.; Cattrysse, D.; Dewulf, W.; Campadello, L.; Accili, A.; Duflou, J.R. Systematic Quantification of Waste Compositions: A Case Study for Waste of Electric and Electronic Equipment Plastics in the European Union. *Sustainability* 2022, 14, 7054.
<https://doi.org/10.3390/su14127054>

There is also the consideration of our responsibility for potentially 3 million disposable straws at least once per day, these would in all probability go to into plastics re-cycling from public use or some form of clinical waste regime for a clinical end user.

Image courtesy of The Conversation



ENVIRONMENTAL

While the environmental impact of this product can be somewhat incorporated into the Circular Economy section, there are some direct impacts that should be considered. These are possibly the more “day to day” considerations.

We may need to look into the creation of an Environmental Product Declaration, the general process for the writing of this declaration would be to complete the following stages:

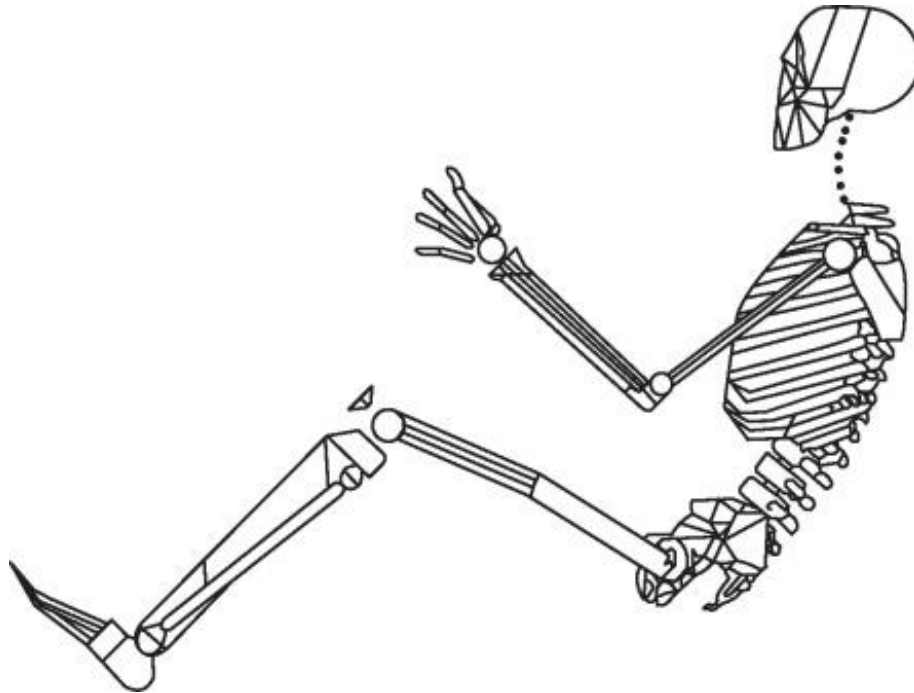
1. Collect and relevant data.
2. Conduct a life cycle assessment.
3. Prepare a background report.
4. Secure third party verification.
5. Publish to the public domain.

In any case, the extract below shows some of the most modern thinking regarding the integration of environmental impacts into product design:

“A trend towards greater awareness of environmentally related restrictions on human activities can be identified in the industrialised world of today. This development concerns also industry and its product development efforts. The environmental adaptation of products becomes an explicit intention, driven by the competition of customers and societal responsibility. In order to realise environmental adaptation, new knowledge and new considerations are needed in product development.”

S Ritzen, Integrating Environmental Aspects into Product Development (2000)

Image courtesy of Forage



ERGONOMICS

We should consider the fit and interaction between the product and the end user. This interaction should include considerations of the following aspects:

1. The general safety of the product when in use using the correct practices. We should also take into account the potential for user safety if the unit is being used incorrectly.
2. The level of comfort available to both the person taking the sample and the person giving the sample.
3. How easy is it to use the product, how easy is it to understand the operating instructions.
4. Will the unit operate at the level of performance intimated by us and expected by the end user.
5. Is the unit as aesthetically pleasing as expected and will this aesthetic performance continue for an acceptable period of time.

Bligård, Lars-Ola & Simonsen, Eva & Berlin, Cecilia. (2017).

“Ergonomics activities in the product development process. Ergonomics and human factors (E/HF) has an important role throughout the whole product development process, but the scope and content of E/HF work differs depending on the phase of the project.”

Image courtesy of Science Direct



INSTALLATION

While there is little probability that this new piece of equipment will require installation, there is the potential for the clinical or other commercial end user to require operator training and certification of operator competence. In this instance we should perhaps consider if we have the following:

1. Sufficient staff to be able to offer this facility.
2. Sufficient time to be able to offer this facility.

If we do not have adequate in house resources or the commercial will to be able to facilitate this function, then perhaps this could be offered to a suitable external supplier and result in mutual commercial gain. We should perhaps consider the importance of training from the perspective of the operator, this is summarized by (Jehanzeb and Basir, 2013) with the following comment:

“Individual Benefits: Training and development programs help individuals in learning the soft, functional, and technical skills necessary to perform their jobs. They achieve higher level of job satisfaction, because they feel they are investing in their own future”

<https://www.coursehero.com/file/186240983/Journal-The-Importance-of-Training-and-Development>

Image courtesy of Omkar Engineering



INTELLECTUAL PROPERTY

The importance of securing intellectual property rights on this design cannot be under estimated.

As a company we stand to reap greater benefits from this innovation if we consider the full range of intellectual property issues in this new product design brief.

The area of IP and the laws and restrictions surrounding it are intensely complex and while we as a Company have IP rights in place on our existing range of products it would be foolish not to consider re-visiting our requirements via a specialist in the field, especially when we consider that the much increased turnover may require additional elements such as manufacturing under license and marketing or sales through vastly new pathways such as Amazon.

“The law’s role in innovation is to help new products come to market—not in helping with the actual initial design of the product.”

http://www.wipo.int/sme/en/documents/ip_innovation_development_fulltext.html



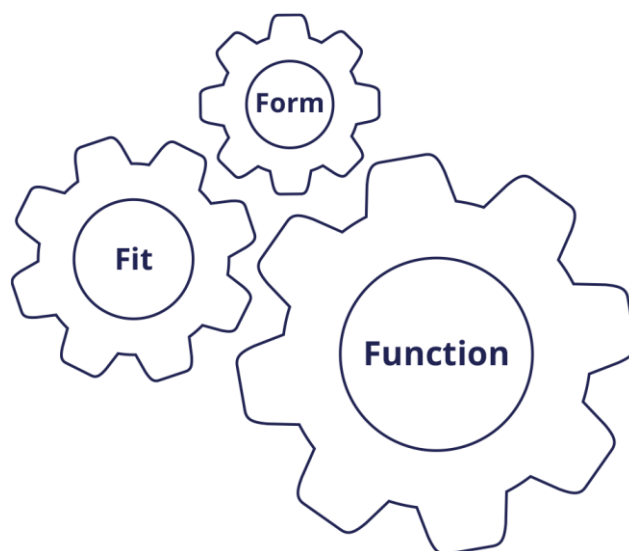
LEGAL

There will be numerous legal considerations with this new line of products, it will be far more beneficial to investigate these at the earliest possible stage of this process. There is little point in furthering the development of these new products only to find that there are legal issues that either stall or even worse, reverse the development process.

Possible issues that we may need to consider via legal specialists could include:

- Product liability.
- Consumer protection.
- Intellectual Property rights.
- Supply chain issues.
- Advertising and marketing.
- Product naming and marketing

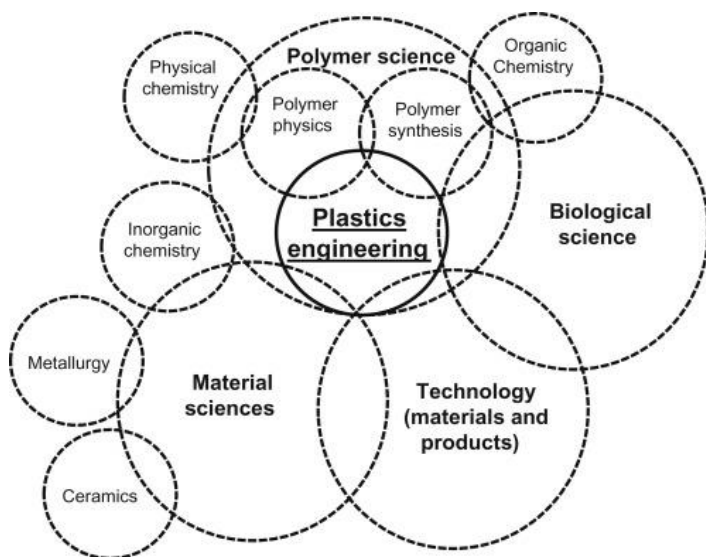
Image courtesy of Cal Matters



MATERIALS

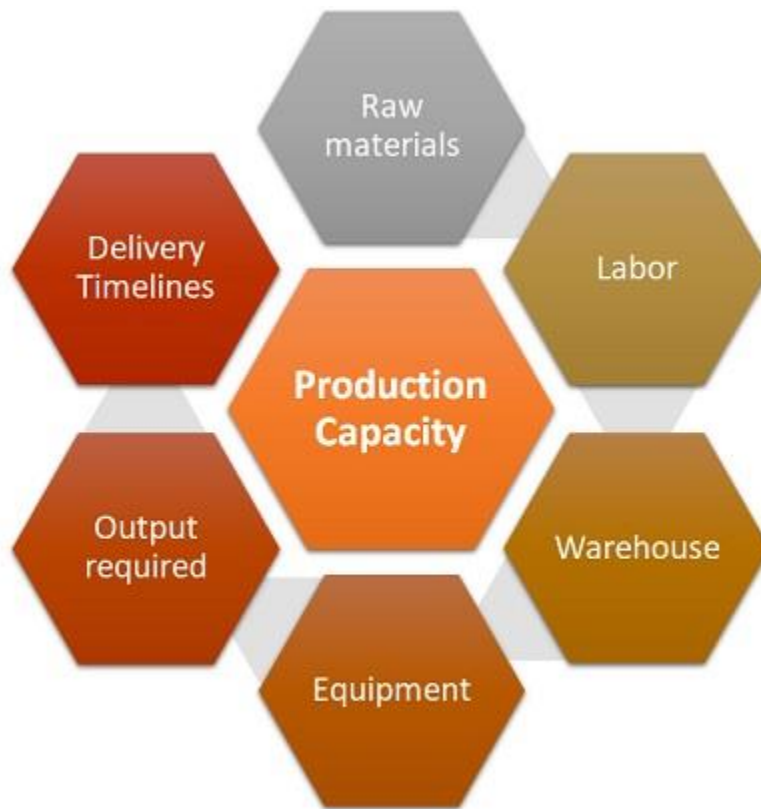
The range of materials used in the manufacture of our existing range have been extensively researched to establish their suitability within their prescribed scope of use, the required properties are reasonable biased toward durability rather than aesthetics, however, with the possible introduction of the general public as an end user, the aesthetic element may require further consideration. A further consideration may be the rapid increase in cost of engineering plastics, this will obviously have a major impact on the cost of the item, it may also (if this cost is a limiting factor) reduce the options regarding which materials are viable.

It is crucial that any engineering plastic chosen satisfies the 3F's, these being Form, Fit and Function.



Anshuman Shrivastava, an Introduction to Plastics Engineering, 2018

Image courtesy of Arena Solutions



MANUFACTURING FACILITIES

Based on our existing assembly capacity of 1.1 million units per year (running at 78% of maximum capacity) we have a maximum assembly capacity of 1.35 million units. Existing capacity cannot cope with either the increased requirement in the first year or the estimated requirement of an additional 3 million units from year two.

We should consider the following options regarding increasing our overall capacity:

1. Use of the existing surplus floor area to install additional inhouse facilities, this would obviously require additional manufacturing staff to facilitate it.
2. Investment into additional production facilities.
3. Use of external manufacturing facilities and staff.

“Strategic capacity planning refers to the determination of the sequence and the timing of tool purchases and, possibly, retirements, which is a multi-criteria decision-making process involving trade-offs among finance, throughput, cycle time and risk.”

(Na Geng and Zhibin Jiang, December 2007)



MARKET CONSTRAINTS

When forecasting our potential market, we should consider the potential external (and potential internal) factors that may contribute to a constrained market. We are currently forecasting potential sales of 3 million units per annum, however, this may be affected by any or all of the following at any time and some may be almost impossible to pre-determine.

- Increase of number of competitors or improvement in performance of existing competitors.
- Legal issues.
- Internal budgetary restrictions.
- Change in customer profiles or requirements.
- Economic turbulence leading to restricted spending levels.
- Regulatory or standards change.
- Unforeseen increases in costs.
- Changes in the pathway to the customer.
- Changes to the way the product can be marketed or promoted.

We should look at measures that would limit where possible the potential impact of the above or similar constraining elements.

[“Recognizing, understanding and addressing contextual constraints impacting the effectiveness of the standard development process is more challenging than addressing project specific failures and barriers”](#)

[Gurtner, Spanjol and Griffin, Leveraging Constraints for Innovation \(2018\)](#)

Image courtesy of Business 101



MAINTENANCE AND REPAIR

It is anticipated that both the major elements of the new unit:

- Control circuit and display
- Carcass

With be maintenance free from the perspective of the end user, however, with an expected lifespan of 3 years and an expected warranty period of 1 year there is an opportunity to be able to offer a “return to the manufacturer” option for both a general inspection and debug or potential repair if required.

It may be worth taking into consideration setting up a new department to cater for these options or the possibility of offering this aspect of the business to a third party.

“Reliability of products is becoming more and more important due to tough competition in the product market. The effective ways to ensure reliability are consider design, manufacturing and after sales services.”

Rahman and Chattopadhyay, Long Term Warranty and After Sales Service (2015)

Image courtesy of Student Lesson

PRODUCT PACKAGING DESIGN



PACKAGING

Packaging, especially excess and unnecessary packaging are fundamentally discredited in most modern cultures, in essence it is there primarily to offer an aesthetically pleasing product before you even get to see it for itself and protection during shipping and while on the shelf. The more industrial and clinical end use will probably have a lower interest in the visual impact of the packaging and more interest in the functionality, while the home user is more used to more of an “Easter egg” approach where the visual impact of the packaging offers a potential insight into the value and quality of the product within.

We should also consider the implications of the style and type of packaging from a waste perspective and also, should request that the original packaging be used for transportation if the product is returned for maintenance or repair.

“Packaging and it’s design has come to play an increasingly prominent role in the branding exercise as the scope and extent of branding has grown; it is no longer merely concerned with the need to contain and protect a product”

Ambrose, Harris, *Packaging the Brand* (2011)

Image courtesy of Shopify



PERFORMANCE

Performance is the standard bearer for so many other attributes of equipment, product performance terminology has mutated in many areas as a measurement of sales conversions in relation to sales cost, however, we should concentrate on the physical performance of this new item and leave the fluffy stuff to those who know. We should consider such attributes that may be of general interest to the end user such as:

- How accurate the result will be.
- How speedy the result will be available.
- How consistent the results will be.
- How easy the unit is to operate.
- What is the battery life of the unit.
- What is the recharge duration.
- How long will the unit last before it requires replacement.
- What happens if the unit breaks down

This list is by no means exhaustive and there will be numerous other considerations to take into account, however, all have a potential impact on the product design.

[“It is seldom clear which general dimensions of product performance are important to the consumer and how these are related to satisfaction”](#)

[Swan, Combs, AMA Journal Vol.40 Iss.2 Product performance and consumer satisfaction \(1976\)](#)

Image courtesy of Talen Team



POLITICAL IMPACT

Political change and variation offers possibly the least predictable element of unforeseen risk in new product development. The changes could be economic, social, legal or a combination of them all, however, we should be able to react where possible to these potential changes and attempt to minimize the impacts that they have on the project.

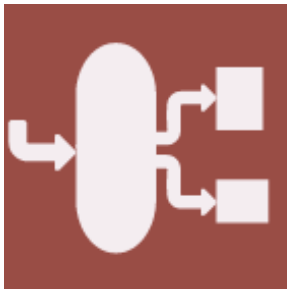
Elements that we may wish to consider would include:

- Bureaucracy
- Corruption level
- Freedom of the press
- Tariffs
- Trade control
- Employment law
- Discrimination law
- Data protection law
- Environmental Law
- Health and safety law
- Competition regulation
- Regulation and deregulation
- Tax policy (tax rates and incentives)
- Government stability and related changes
- Government involvement in trade unions and agreements
- Import restrictions on quality and quantity of product
- Intellectual property law (Copyright, patents)
- Consumer protection
- Laws that regulate environment pollution

“According to the political perspective on strategic decision making, political decisions are the results of a process in which the preferences of the most powerful dominate over those of the less powerful.”

M. Dayan, S. Elbanna and A. Di Benedetto, "Antecedents and Consequences of Political Behavior in New Product Development Teams," in *IEEE Transactions on Engineering Management*, vol. 59, no. 3, pp. 470-482, Aug. 2012, doi: 10.1109/TEM.2011.2166078.

Image courtesy of IRMI



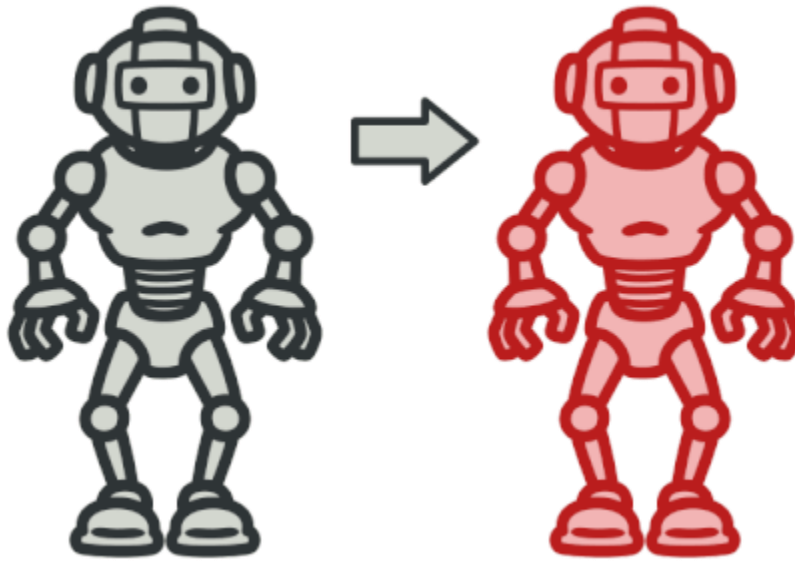
processes

PROCESSES

The processes involved in the manufacture of these items will be similar to those currently used for our breathyliser units, however we should consider that due to the substantial increase in output requirement the processes will need to be slicker and more efficient. In general, there is usually one process within the chain that becomes a “bottle neck”, this simply cannot be the case for this future requirement. We should consider all process elements within the chain to establish any points of concern, these elements may include:

- Ordering of bought in items
- Progress chasing of bought in items
- Pre-assembly
- Final assembly
- Testing
- Packaging
- Warehousing
- Shipping

These elements are somewhat easier to keep on top of when all processes are “in house” but we should also consider the implications of them if processes are handed over to third party companies.



PROTOTYPING

The importance and benefits that a functional prototype can offer are huge, the opportunity to have a tactile working evaluation of a concept offers a selection of opportunities to interrogate the design. Examples of these aspects may include but not be limited to the following:

- Testing and subsequent refinement of the existing design
- Double check the material specification for durability, cost, form and fit
- Evaluate manufacturing options including who by and where will it be manufactured, confirm the correct manufacturing processes and confirm suitability of the design for mass production
- Confirmation of quality assurance to include that the product meets requirement, check for design weaknesses or errors and check suitability for production
- Confirm estimated production costs are viable
- Look into possible savings in cost

Consider that every loose specification has the potential to be a failed prototype, along with the attached loss of finance and time that goes with it.

“Prototypes serve several purposes: they function as guiding milestones; show tangible progression or demonstrative specific features; and enable systems integration, ensuring components and subsystems work together as planned”

Chua, C. K., Leong, K. F. and Lim, C. S., Rapid prototyping principles and applications. Singapore: World Scientific Publishing Co. Pte. Ltd, 2003

Image courtesy of Refacturing Guru



PRODUCT COSTS

All market studies indicate that a competitive sales price for this item is £421, this is similar to the sales price of our existing range of equipment. In order to establish a projected sales price we need to consider elements such as:

- Design management costs
- Pre-prototype design costs
- Prototype costs
- Electronic component engineering costs
- Mechanical component and tooling costs
- Certification and testing costs
- Packaging costs
- Sales and marketing costs
- Shipping costs

Most of the costs listed above will variable in nature, as such it makes it very awkward to establish an accurate product cost at the design/development stage, however, the closer you can get to an accurate figure the less the opportunity for increasing risk at a later stage. We should perhaps consider a comprehensive cost system fir the longer term as indicated below:

"A comprehensive product-cost system, incorporating the long term variable costs of manufacturing and marketing each product or product line, should provide a much better basis for managerial decisions on pricing, introducing, discontinuing and reengineering product lines. The cost system may even become strategically important for running the business and creating sustainable competitive advantages for the firm (Bruns, et. al. 2007)"

Image courtesy of Price2spy



PRODUCT LIFE SPAN

Product life span has two general meanings, these being:

1. The length of time product can safely be left on a shelf (shelf life)
2. The length of time that a product can be marketed and supported

The industrial digital analyser market defines the lifetime of a unit to be 5 years from the date of manufacture, shelf life has no real impact on this timespan as the items are rarely sat in the warehouse for an extended period of time..

Adhesives, polymers and other materials used in the construction of the analysers can affect other components they come into contact with. This along with normal wear and tear, contribute to the degradation of a unit's performance over time.

It would be safe to say that the retail market would expect a shorter lifespan of 3 years and the duty of use to be somewhat lighter than the industrial sector, it could also be expected that the retail user would take more care of their purchase than an industrial user, as such any item designed and developed for industrial use should comfortably cater to the retail end user.

The understanding of a product's life cycle, can help a company to understand and realize when it is time to introduce and withdraw a product from a market, its position in the market compared to competitors, and the product's success or failure.

Komninos, I., 2002. Product life cycle management. *Thessaloniki: Aristotle University of Thessaloniki*, pp.1-26.

Image courtesy of Investopia

PRODUCTION CAPACITY



QUANTITY

At present our maximum in house manufacturing capacity is 1.35 million units per year, we currently run at an operational capacity of 1.1 million units per year (78% capacity) and in all honesty that is probably as high as we can comfortably go utilizing our existing plant and staff.

It is estimated that we will require the manufacture of 750,000 additional items in the first year, this on its own would outstrip our current capacity and would require either addition plant or staff.

The estimation that in year two that this requirement will increase to 3 million items will no doubt delight the sales and financial contributors to this design study, however, it will no doubt have those with more production based responsibilities swallowing deeply.

It is a huge increase and we should consider the viability of continuing to manufacture in house or utilize the facilities of an external manufacturing option.

“When launching a new product, the manufacturing and marketing functions of a firm are required to jointly take critical decisions concerning the amount of manufacturing capacity to be acquired, and to elaborate policies for managing it over the product's life cycle”.

Marco Cantamessa, Carlo Valentini, Planning and managing manufacturing capacity when demand is subject to diffusion effects, International Journal of Production Economics, Volume 66, Issue 3, (2000),

Image courtesy of Marketing91



SAFETY

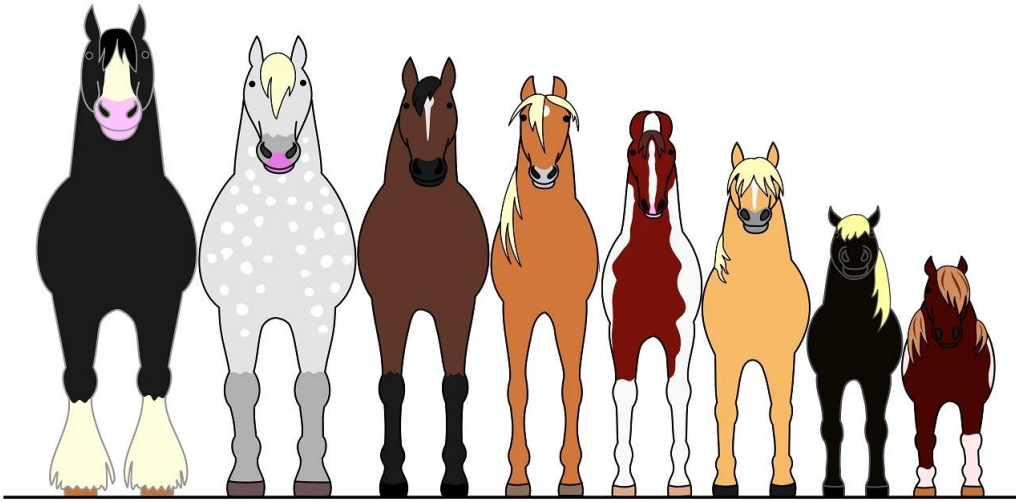
Safety is paramount, non negotiable, essential, integral and a primary concern in the development of this new product. The following statement indicates the level of compliance that is both expected and required under Government legislation, these are not negotiable or pliable.

[“If you make, import, distribute or sell consumer products in the UK, you are responsible for making sure they are safe for consumers to use and following the legal requirements in relation to labelling.”](#)

[HM Government Office for product safety and standards \(March 2019\)](#)

We should consider the safety standards and regulations that the new product will require to be compliant to, specific standards are covered under the standards and specifications section.

Image courtesy of Linley and Simpson



SIZE AND WEIGHT

In line with both the aesthetic and ergonomic requirement of the unit we must consider the dimensional and weight elements. Further to our market intelligence we have an outline proposal of the following specification:

- General dimensions 60mm x 150mm x 32mm
- General weight including battery 150g

There is a possibility that we may also be looking at options including Bluetooth, the options may increase the weight by approximately 10%.

Other aspects that may affect both the size and weight of the unit are final material specifications, final printed circuit specifications. The target weight and dimensions have been estimated with considerations for both packaging and shipping requirements.

[“It is important to remember the human factor”](#)

[Miller, Dorsey, Jacobs, The Importance of ergonomics to sustainability \(2012\)](#)

Image courtesy of Shutterstock



SHELF LIFE AND STORAGE

There are no items other than the battery and sampling tube in the proposed design that would be considered as consumable. As such there is no real anticipated shelf life limitation. The product life span section indicates that the “shelf life” consideration is generally based on the length of time that an item can safely be left on the shelf pending sale, our consideration would be that the warranty period is initiated at point of sale and not date of manufacture, as such the shelved period should be kept as short as possible. The packaging is designed to offer aesthetics and protection in line with the full expected life span of the product.

“Shelf life planning and execution allows you to identify and plan for risks throughout your supply chain that could impact your ability to deliver your product while minimizing the risk of carrying obsolete inventory”.

<https://www.bevsource.com/news/importance-understanding-your-shelf-life-while-navigating-supply-chain-uncertainty>

Image courtesy of Recipal



SHIPPING

Based on item dimensions of 60 x 150 x 32 we have based our initial packaging dimensions at 80 x 170 x 150mm. This should allow for adequate protective material between the item and the external box, it should also allow enough room for voids to accept both battery and charging elements. It is estimated that using a standard full Euro pallet with dimensions of 145 x 800 x 120 and stacking in a standard format 20 packs high we will have enough space available for 1400 boxes per pallet.

This format will utilize 98.84% of the available pallet capacity and will still have enough room for security tracking if required. Tracking and freight insurance are something we should consider as a full pallet will have a value approaching £588k.

A full pallet is estimated to have a net weight of 308kg, so is easily moved with either manual pallet truck or forklifts.

[“Correctly sizing a package eliminates excess material in production and waste. It also reduces amount of space the package takes up in the freight truck, and therefore reduces the shipment's carbon footprint.”](#)

[Steve Foster, Packaging 101, The importance of right sizing your package \(2019\)](#)

Image courtesy of Fedex

PESTLE Analysis

P	E	S	T	L	E
POLITICAL	ECONOMICAL	SOCIAL	TECHNOLOGICAL	LEGAL	ENVIRONMENTAL
Example: • Current tax policy • Brexit • Trade policies • Political stability • Government policy	Example: • Inflation rate • Exchange rates • Economic growth • Interest rates • Disposable income • Unemployment rate	Example: • Lifestyle attitudes • Cultural barriers • Population growth • Population age • Health consciousness • Target demographics	Example: • Level of innovation • Automation • Technological awareness • Cybersecurity • Technological change • Internet availability/speed	Example: • Employment laws • Discrimination laws • Health and safety • Copyright protection • Consumer safety	Example: • Weather • Climate change • Environmental policies • NGO pressure • Recycling • Pollution • Sustainability

SOCIAL AND CULTURAL

We should consider gaining an insight into the ingrained values into the cultures of our target end user. We should then be able to perceive the design elements that are of particular importance, these elements may include the following:

- Symbols and colours
- Language of display and instructions
- Social conditions
- Local terminology
- Social and cultural sensitivities
- Cultural practices and customs.

The earlier these potential impacts are identified the less impact they are likely to have on the design of the project. Even considering the general diversity in the population the social and cultural impacts in the UK market are not expected to be great, however, this may not be the case for the European and wider markets.

“the model can be used for the evaluation of the market and the industry especially before entering a new market”

Cadle, et al, (2010)

Image courtesy of Impact innovation

STANDARDS & SPECIFICATIONS

STANDARDS AND SPECIFICATIONS

Another massively important aspect of this design brief is the requirement to meet all the required standards and specifications. We will find ourselves under the guidance of multiple standards from multiple directions, these will include pathways such as:

- Electrical and electronic equipment regulations
- CE and UKCA regulations
- Medical equipment directives

While the requirements of all the pathways may contain common elements there will also be elements peculiar and particular to individual elements, this area is massively complex and we no doubt have adequate, existing knowledge and expertise, it may be worth considering using external specialists to assist. It is an area that also seems to be evolving continually and an element of “future proofing” should be looked into, as an example of this as of May 2021 a new regulation covering the placement of new medical devices on the market was initiated this replaced the two existing directives (93/42/EEC and 90/385/EEC).

“A medical device manufacturer should design and manufacture a product that is safe and effective throughout its life cycle”.

[Deep, Medical device regulations, A complete guide \(2022\)](#)

Image courtesy of LRWRT



TESTING

We have a superb test facility for our existing product range, however, the testing for alcohol on site is far less complex than testing for the presence of virus contaminants. We will still have internal facilities that enable the testing of many elements ie construction, fit, form, electronic function, durability etc, however, we may have to utilize the facilities of an external test site where certification and calibration are available.

We should consider:

- Are such services available
- What are the associated costs
- What is the associated time frame
- Should this testing be carried out at the prototype phase

“Before allowing any product to go on sale, it must be proven that it is completely safe. For example, product testing can prove that household tools or appliances are safe for use, or find any defects that could potentially be unsafe before the products are available for sale”.

Deep, Medical device regulations, A complete guide (2022)

Image courtesy of Tech Beacon



TIME SCALE

The temptation to place unacceptable limitations on the time frame to complete this brief and a possible full specification are huge, most of the elements considered in this brief are affected by time and data and may change as the project evolves, however, the more data that is considered and evaluated in this brief, the more effective and accurate its effect on it's input into the design specification.

This brief offers the opportunity to iron out any potential issues and concerns at an early stage, thus reducing the opportunity for risk and limited potential expense.

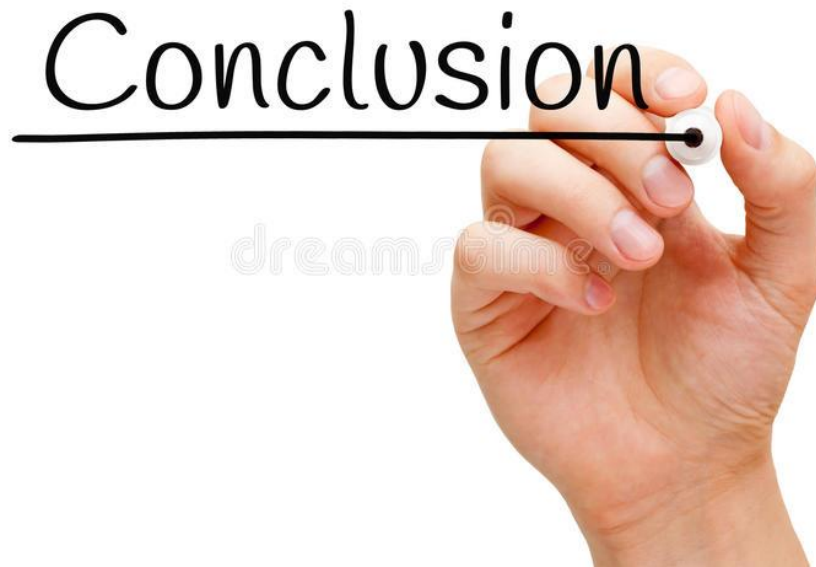
We would expect the following to be a viable time line for this new product:

Design brief and associated research	4 weeks
Design specification and associated research	20 weeks
Design concepts	4 weeks
Concept decision making	1 week
Technical design and development	6 weeks
Prototyping and testing	12 weeks
Prototyping and testing decision making	2 weeks
Manufacturing data and tooling	12 weeks
Allowance for slippage and unexpected issues	10 weeks
Final evaluation	2 weeks
Total	73 weeks

"In general, a project timeline provides an overview of a project with all the various elements including important milestones, dependencies, priority tasks, and delivery dates".

<https://www.prioritymanagement.com.au/why-are-project-timelines-important>

Image courtesy of Pay Forex



CONCLUSION

This design brief offers us the opportunity to investigate multiple aspects of the new product from multiple points of view, departmentally you will no doubt have particular areas of interest and your efforts will no doubt be polarized within these, however, while commercially some of the points covered have critical importance to the viability of this project, the importance of each aspect cannot be underestimated.

We have the chance to evaluate individual aspects in depth with minimal time constraints, this should enable us to minimize potential risk and design out potential faults at the earliest possible opportunity.

Let us make the most of it and deliver the best product we can.

Image courtesy of Dreamstime

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