



NPD

Developing the Design Brief

Assessment B

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Note: In electronic format, use interactive contents table and cross references to navigate the document.

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Introduction

The following document outlines the design brief intended to outline what needs to be considered to bring the product into existence and will be used to inform the various managers within the company of the elements of the Product Design Brief that will need to be appreciated. The product is a virus protection system with an injection moulded device body with preconfigured electrical components. The components and material are not yet assigned to a specific supplier and the brief should help determine favourable attributes of the components and supply chain. Volumes are expected to be no more than 750,000 in the first year, potentially 3 million per annum afterwards.

Life in service

- Main device body can be used repetitively
- Mouthpiece will be disposed of after each use
- Materials for mouthpiece should be taken into specific consideration, particularly the recyclability and cost in order to manage cost and environmental impact of disposable components.
- Rate of electronic equipment development should be considered as not to outdate the device, offers to replace devices at cost after 2-3 years of use could be a solution for keeping platforms up to date and users serviced with the most up to date and cost effective technology.
- Depreciation in performance should also be considered, 2-3 years is a reasonable amount of time to suggest replacements.
- The device is not expected to be used continuously, only intermittently, this should safeguard the product's life in service.
- The device should operate at full performance for up to the advised replacement time, performance of the device may depreciate after this time

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Product lifespan

- Cyclical release of new models, 2 years is a reasonable amount of time for cyclical design and release process.
- Cyclical release for updated model will influence consumers to buy the updated models, this supports renewal of life in service performance
- 2 year cyclical design offers the opportunity to implement improvements in hardware, software and aesthetics in each model release and use this for marketability
- 2 year cycle of model releases help to remain current and present in the market

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Reliability and Warranty

- Expected product life should be 4 years, this covers the x2 model releases as it's unreasonable that all customers will upgrade at each model cycle.

- Production supply chain reliability should be considered. Use standard hardware, materials, and components which are available on general markets and have a low risk of becoming unavailable over the life cycles of the product.
- A fair warranty period is 12months
- Any failures or performance issues within the warranty period should be repaired or replaced accordingly

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Ease of repair

- The product should be designed as a non-maintenance item to prevent users tampering with critical components
- Product should be IPX5 rather for water resistance to enable wipe down and clean/ disinfect in the event of contamination.
- Mouthpieces should be disposable and replaceable and do not require maintenance
- The main body should be sealed, including the battery.
- The product should be fitted with a tamper seal to identify if the product has been tampered with in the event of a warranty claim
- Repairs should only be carried out in-house by the manufacturer, this is to control quality of repairs but also to capture any quality issues and understand the root cause to be carried into future developments.

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Quality

- The product should be CE and UK Kite marked to show adherence to product quality for electronic and safety regulations.
- Suppliers of components must be audited and registered as strategic suppliers and scored on their quality and delivery in order to maintain confidence in quality and on-time delivery of components.
- An design failure mode and effect analysis (DFMEA) should take place to identify the areas of design with require particular attention due to potential risk of failure.
- Control plans must be in place to ensure specific characteristics are controlled and the risk of failure is sufficiently managed.
- Each manufacturing process should be documented and visually illustrated in order to maintaining a standard operating procedure of work.
- Training must be giving to any personnel working on a standard operating procedure.

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Target Cost

Price expectations

- Cost must be relative to target market spending

- Subscription cost models could be applicable for mouth pieces
- One-off payments are preferred but finance terms and instalments can be attractive for bulk buys
- B2C Sales: Profit target 40% of cost to make
- B2B Sales: Profit target 20% of cost to make – must meet minimum order quantity

Material Costs

- Take into account fluctuations in raw material costs to protect against price increases
- Child Parts
- Standard components
- can you cope with any fluctuations in material costs, exchange rates etc.

Development costs

- Costs of product development and the creation of prototypes should be considered, i.e. the use of 3D design software and rendering plug-ins can be used to view the design in a virtual environment with a good level of real world similarity.
- Use of 3D printing should be used to understand the physical weight, size, and aesthetics before proceeding on to any tooling expenses .
- During the design process, opportunities to minimise the number of components should be carefully considered. By reducing the number of components the material, tooling and manufacturing cost will inevitably be reduced.
- Assembled components should be 3D printed to understand the interface and how it translates into the manufacturing assembly process. This could dictate whether any additional assembly equipment may be required to achieve a repeatable and ergonomic process.
- Testing a validation can be carried out in-house where possible with basic measurement equipment. Not until all inhouse testing is complete should specialist external tests be carried out.
- Where IP protection is required the risk of competitor adoption should be assessed, a team should be formed to identify the most cost effective course of action for the specific design area i.e. IP copyright, patents, design registration or trademarking

Capital costs such as tooling, additional plant and machinery

- Considerable effort should be taken to ensure components are well designed for manufacture.
- Consult toolmakers and tooling specialists on opportunities to reduce tooling cost through good design practices. Well considered design for manufacture can reduce tooling cost by up to 50%.
- Where plant and machinery is required for manufacture of components these should be justified by a clear demonstration of design considerations within the project documentation.
- Prototype tooling should be produced at low cost for low volume production, this can help give production representative parts at lower cost.
- Assess all capital spend with the a total target ROI (return on investment) within 24months.

Manufacturing costs

- Consider the development of manufacturing equipment such as Jigs and Fixtures
- Simplify the manufacturing process through the product design process

- Identify simplified assembly methods through design geometry and material selection

Testing and Validation

- Consider jigs and fixtures for measuring and testing in order to validate the geometry and any other part specifics
- Consider costs of external testing and the use of specialised test facilities if applicable.

Logistic Costs - such as warehousing, freight, import or export taxes

- Consider minimum and maximum stock levels to identify ideal order quantities
- Account for import taxes and tariffs when purchasing components from overseas
- Consider the risks of late deliveries due to logistic issues when importing any goods and components

Other Opportunities for cost saving

- Carry over components from previous models into new development where reasonably practicable
- Build supplier relationships and identify benefits of both bulk and scheduled ordering options
- Use existing tooling, plant, and equipment where possible, and when developing following models to minimise capital spend.

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Timescale

- Design team must identify adequate design time before presenting a timing plan, ensuring consideration for all items within the design brief.
- The timescales considered should be in-line with current market forecasts. Study trends within the market and identify the best time for product launch. The launch must be planned in coordination with cyclical released of competitors to ensure arrival in the market in time with cyclical buying patterns. For example, consider NHS buying patterns, and whether they buy in bulk or regularly replace equipment or a rolling basis.
- Consider contract that may be help by target customers with competitors, if primary target customers have contracts expiring at similar time this would be a good time to launch.
- Down timing plans into micro details to better manage task accountability and delivery
- Use planning tools like gantt charts to show this following:
 - Initial planned timing target, i.e. a baseline
 - Actual timing, how the project is currently running
 - Slippage – how the actual compares with the base line and the areas where delays have occurred
 - Corrective actions – actions in place to bring task back on time
 - Clear due dates for delivery
 - Responsible persons
 - Potential Roadblocks
 - The critical path
 - Project milestones

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Size

- The size of the product should be limited to within the following range, this include the hand held device but does not include accessories such as the mouthpiece, charging cables, or protective cases.
 - Length 100 - 150mm
 - Width 50 - 70mm
 - Depth 25 - 50mm
- Effort should be made to make the device smaller than the maximum allowed sizes whilst still being comfortable to hold and easily handled.
- The size must be suitable for housing the internal components in-line with performance requirements
- The size of any auxiliary equipment must be considered, for example the mouthpiece must be suitable for storage whilst considering handling and compatibility with the device interface.
- Charging equipment must be sized in line with common market devices.

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Weight

- Overall weight of the hand held device should be no more than 200g
- There is no minimum weight for the device, however the weight of the components required to meet performance specifications should be considered closely and weight should be saved where possible.
- The weight of the casing for the device should be kept to a minimum in order to reduce material costs, consider the following
 - Material selection – low density and lightweight polymer selection
 - Material volume – consider wall thickness of injection moulded components both for weight and manufacturability. The wall thickness should be kept to a nominal size uniformly across the part, ensure there are no thick sections. Strength can be maintained in structurally critical areas by using ribbed and webbed features.
- The mouthpiece weight should be minimised to reduce weight and therefore reducing the materials consumption. Consider manufacturing methods used for thin walled polymer parts, notably; injection moulding, blow moulding and vacuum forming.
- Consider other materials for the mouthpiece, could this be a paper/ card based material and if so what are the cost benefits?
- The overall weight of device and mouthpiece must not compromise the usability of the product.

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Ergonomics

- The user must be able to handle the device with one hand
- The user must be able to operate and interface with the device with one hand
- The buttons on the device should be operational with the thumb of the hand holding the device.

- The buttons on the device must be distinguishable from each-other
- The device must have a screen which clearly displays the resulting information to the user from a minimum of 300mm away from the user's vision.
- It should be possible to hold the device up at face level for an amount of time reasonable for the interaction with the device to take place.
- The mouth piece must be easily accessible to the user's mouth when applied to the device
- The mouth piece must cause minimal discomfort in use
- The device charging points must be easily locatable and accessible
- Charging equipment must be identifiable as the device brand by design
- Charging equipment must be easily identifiable and handle comfortably
- The exterior surfaces of the device must produce reasonable grip so as to hold the device in one hand without it sliding free.

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User Interface

- Various options on the interface should not crowd the screen from the resulting information
- The user should be able to interact with the device controls without straining eyesight or hand movements.
- Where any physical interface with the device is required it should be clearly identifiable, i.e. charging ports or mouthpiece application. Consider the use of part marking by means of tooling design to show symbols or text on the device where applicable.
- Device menus must be clearly interpreted and be navigable for users un-familiar with electronic technology.
- Language options
- The device should clearly display an audible and visual indication when:
 - the mouthpiece is connected
 - the charger is connected
 - the battery is low
 - the battery has ran out
 - the test result is shown

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Aesthetics

- The aesthetics of the components will be driven by the practicability and of the design for the application whilst still remaining visually attractive to the user.
- Colour
 - The product colour should remain in greyscale as not to create a market bias
- Shape
 - The shape must fit the indicated size and be in-line with good handling requirement without.
 - The shape must remain simple yet elegant in its design as to remain functional and attractive to the user
- Form

- The form of the device should be comfortable to hold without the use of extreme contours
 - The form of the device buttons should clearly distinguish the buttons from the main body of the device.
- Texture
 - Matt surface texture can be used to improve grip without implementing extreme contours
 - Matt texture can be used to improve the visual appearance of the product by hiding or disguising blemishes or surface marks from the manufacturing processes.
- Efforts should be made to obtain opinions from both internal and external sources during the design and styling of the product, it is important that numerous functions have an input so that the styling is not bias in favour of the engineering teams working on the project.
- Milestone design reviews should take place involving stakeholders for other functions to review the design and give feedback as it progresses, to ensure the styling is still in line with expectations. During these design reviews there should also be review of manufacturing feasibility to ensure that the design has not be altered and features have not been added that may compromise the manufacturability.

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Performance

When considering performance it needs to be designed to within space or aesthetic restrictions, so it's important to consider the impact of other elements of the brief.

Hardware

- The electronic components must be able to fit in the confines limited by the size and aesthetics of the device
- The electronic components must deliver performance that satisfies the useability without being over specified for the task.
- The electronic components must operate within practicable temperature ranges such as in both hot and cold environments
- The device should have a speaker that can give audible feedback when required.
- The device should have a backlight for the display
- The device battery must last for a minimum of 4 hours in continuous use

Software

- User friendly interface
- The software must have the option to adjust volume of system sounds
- Software must present an option to enable or disable a backlight on the display
- Audible feedback must be provided to indicate a failed or successful test
- Audible feedback must be provided to indicate initiation of a test
- The test result must be clearly legible on the device display
- The device must have a power off, standby or low power mode sustain battery life when not in use

Physical

- The attachment of the mouthpiece to the device must be guided, i.e. with a user friendly interface.
- The docking of the mouthpiece should give a positive feedback when in place such as an audible or physical click into place
- Device buttons must give positive feedback when presses, in audible or physical form.
- Device buttons must be clearly distinguishable from the device body with both vision and touch
- The device form must not have areas that are difficult to clean in case of contamination
- The device must be water resistant in order to wipe clean and disinfect in case of contamination.
- The device must be drop tested to ensure it is robust in the event of being dropped
- Materials must be resistant to chemicals present in the manufacturing process
- Materials must not degrade or lose quality of properties whilst in storage and within shelf life
- Assembly design must not require excessive force as to avoid damage in assembly

Network

- Device must be able to connect to the internet as to backup data in cloud storage
- Consider Bluetooth connectivity for use with smartphone apps and other device integration that can benefit ease of use and data collection
- Consider an automated data management system where data is backed up and stored in the event that results would need to be presented or used for analysis.

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Competition

- Investigate competitor products
- Research quality and function of customer products by purchasing the devices and using them
- Get an understanding of user feedback, what they like and don't like about competitor products, by analysing review of online stores or specific review platforms
- Research patents on similar technology and existing products
- Research competitors product prices
- Obtain an understanding of product technologies used by customers and the range of products from basic to advanced models
- What is the extent of the current market, i.e, number of competitors, typical price ranges and market value

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Footprint/ Market Reach

- Consider opportunities overseas and if there a market there for the product.
- Consider how the product would be transported from the country

- Consider the related costs of shipping overseas and how that would impact the profit margin of the product.

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Packaging

- Calculate proper package box carton and pallet size
- Consider designing the product to suit predesigned packaging.
- Use smallest practicable packaging to maximise the number of products per shipment
- Ensure the product is sufficiently protected from damage within it's packaging
- Include all packaging costs when assessing product margin, including additional protection from elements of shipping conditions such as, reinforced pallets, wooden crates, sealed bags, anti-rusting agents, lubricating fluids and protective sprays.

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Shipping

- Consider the best transport method for the required volumes
- Consider delivering the product to a distribution centre to minimise trips from the manufacturing location.
- Consider using 3rd parts distribution to minimise own transport but be aware of additional costs.

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Environment, Shelf Life and Storage

- Take into account storage facilities, third party storage i.e. distribution warehouses or retail stores may differ from environments to internal company storage
- The product must have sufficient packaging to counter elements such as
 - Temperature ranges, extreme highs and extreme lows
 - moisture rich or humid environments
 - Dusty environments

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Company Constraints

- Evaluate the risks of new innovations and impact they may have on the business, for risks consider:
 - Available human resource – do people have capacity in time to spend on adequate research and development
 - Available skills – Do people in the business have the skills to operate in the way that the innovation demands. A skill gap in a new technology could render it inefficient and ineffective
 - Available plant and equipment resource – consider if business has the infrastructure available already and if not then is a large capital investment justified

- Market position – consider whether the current market that the company operates in is aligned with the market for the new product, if they are aligned this might streamline the process of bringing the product to market and raising awareness around the product. If the existing market is detached from the new product this could require much energy to bring the product to the target market.

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Quantity

- Prototype tooling should be developed to support low volume tooling, low volumes can support design and development before moving into full volume production. Creating and running low volume tooling will also buy time to assess the market opportunity, this assessment can help identify the extent of budget that should be set for serial tooling.
- The production quantity will be driven by market demand, if sales are consistent and frequent then it may serve best to invest in automated system which inspect and guarantee quality at a steady and continuous rate. Alternatively, if order are infrequent or sporadic it may serve to make to order in batch quantities. If making batches it is important to calculate set up time. For example if making 1000 units in a batch and the set up time for each batch is 2hrs at 30 £/hr, the setup cost would be attributed as $60/1000 = £0.060$ per part.
- The stock quantity will be driven by the production quantity. If parts are made in mass production it will likely be necessary to hold more stock at times of low demand. Conversely batch product should require less storage space because volumes are made to order and should only need to be stored for short amounts of time, like when awaiting transport.

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Circular Economy

- Consider the moral obligations of product development, these product must align with environmental concerns both to satisfy regulations but also to satisfy consumer expectations.
- Consider recyclability code for plastic products. Not currently mandatory but assists and promotes recycling.
- Consider ISO 14001 Environmental Management System as an investment in the brand values and a genuine dedication to positive change.

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Material Selection

- The material selection must be considered alongside the process, for example if the design geometry requires that the part should be injection moulded then it is important that the materials selected can be processed as such.
- Various fillers, blends and additives can be used to alter material properties to achieve particular specifications, ensure the material chosen is good enough to meet the required performance but is not over specified adding unnecessary cost.

- Material suppliers should be closely monitored and audited to ensure that they comply with standard and at a minimum possess ISO9001 and 14001 accreditations.
- Keeping scorecards on supplier is good practice, this provides a running rating for the suppliers and provides a platform to manage their performance upon.

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Processes

- In line with material selection the processes must be considered and outlined where applicable
- Processes for particular features may be required. Consider the assembly of intricate electrical components like stacked PCBs, LCD screens and the management of associated wiring. What do these processes require, is it specific tooling, materials or standards that should be adhered to?
- Consider tools and equipment that can remove risk from processes. Use tools like PFMEA, Process Failure Mode and Effect Analysis, to identify high risks and implement equipment and specific processes that can reduce those risks.
- Consider if the team has the right skills to analyse and evaluate these risks or if a third party should be involved in the process design

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Manufacturing facility

- Consider the existing facility and available machinery, what exists that can be utilised to save of capital spend.
- Does the development warrant a new plant, or should a new plant be developed from a cultural perspective to start fresh in the face of a new venture.
- How much of the product needs to be manufactured at plant, can there be a number of sub supplier processes that remove process from the plant operations
- How much stock will be held, this will dictate the required warehouse sizing
- Consider location, is there benefits in localising the manufacture for regional supply

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Testing

- Consider all elements that will require testing and why they will require testing
- Does the product require testing to prove structural performance
- Does it require testing to prove digital performance
- Does the product require testing to confirm a successful assembly process or operation
- Will the testing and validation be required in plant
- Will testing be in process or offline
- Will some tests need to be provided by specialist external resources

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Documentation

- Ensure documentation is in place to manage the product development and the project, correct and well managed documentation is not only good practice but is essential for satisfying standards and compliance awards.

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Standards

- Research applicable standard required to supply in the industry
- Consider the criteria for the required standards and what it will take to meet them
- ISO 13485 Quality Management for Medical Devices
- ISO 13485 is the internationally recognized standard designed to help manufacturers comply with regulatory systems and understand what they need to do to place compliant devices on markets throughout the world.
- Consider CE marking, CE mean that the manufacturer or importer affirms the good's conformity with European health, safety, and environmental protection standards

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Compliance

- Consider consultancy companies to assist with ensuring the product is compliant. Companies offer a compliance service in the medical industry, their job is to make sure you comply with all regs and builds your specification to ensure to comply.
- Consider the directives that apply to product and the market such as the medical devices directive
- Also consider the what applies to the components within the device such as the battery directive.

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Political, social and cultural implications

- Political, cultural and social implications can have a big effect on the market, in some cases it can be the driving factor behind market behaviour.
- Consider the likely effect of the product on the political and social structure of the market or country which it is to be designed and manufactured should be considered.
- Consider consumer movements, the stability of the market, and social unrest around the nature of the product.
- Consider feedback from market intelligence

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Patents, literature and product data

- Research similar products to gain an understanding of specific features that could be considered as intellectual property

- Carry out in depth research into registered patents and how they could affect the product development

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Legal

- Consider the implications of product liability and consumer law if the good of manufacture are not fit for purpose:
 - How long does the period of liability extend
 - What does the liability cover
 - What are the components affected
 - What is the potential cost of poor quality of these liabilities are evoked

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