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Management of NPD
MSc International Innovation Management

Developing the Design Brief

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1. Synopsis

New 'virus detect' product overview.

The COVID pandemic highlighted the devastation caused by respiratory virus and disease, with total global deaths attributable to COVID-19 exceeding 6.9 million (World Health Organization, 2023). The unprecedented social and economic disruption, restricted travel, constrained business and leisure and impacted healthcare and emergency services.

The ability to perform quick, reliable testing and diagnosis, proved vital in isolating cases, reducing the spread of the virus. A lack of preparedness, innovation and awareness resulted in a race to provide testing devices that could be manufactured, distributed and used quickly and accurately. Nucleic acid amplification tests (NAATs) and antigen tests became the two main forms of testing, with antigen self-test kits emerging as the most widely used form of personal testing.

Although these testing methods proved highly effective, the following points highlight some of the challenges associated with these approaches.

1. **Plastic pollution** – multiple contents contained in many testing kits are single use, throw away items. When considering the scale of use globally, this presents a serious environmental issue. During the COVID-19 pandemic several billion single-use diagnostics were used each year, usually made of unsustainable plastics, with some containing toxic chemicals (University of Edinburgh, 2022).
2. **Ease of use/ user experience** – assembly of many different components contained in each self-test kit and the necessity to correctly follow various steps to administer accurate testing, means they are not best suited for 'on the go' use. Uncomfortable test procedures, swabbing throat or nasal passages, proved unpleasant and undesirable.
3. **Acquiring reliable diagnosis** – reduction in professional testing (reduction of NHS testing facilities), means accurate testing is now reliant on correctly administering a self-test or visiting a health professional.

Adopting the principles of the alcohol breathalyser detection system, a new handheld covid detection breathalyser, will be designed to detect the presence of organic materials, including those generated in the breath as a result of a viral infection.

The new product will target the UK consumer market as a health and wellbeing product, offering a more environmentally sustainable, reliable, rapid user-friendly alternative to PCR testing and antigen self-test kits.

The product will be environmentally conscious and designed for longevity and ease of repair, incorporating recycled or sustainable materials and reducing the use of virgin materials, helping reduce waste to landfill.

Components will be designed and manufactured modularly, to simplify user maintenance and repair. Mechanical working parts and casing will be fabricated using injection moulding methods. Electronics used in the device will be contained in a single circuit board and received in a fully assembled and tested form.

The device will look professional, clean, sterile and reliable. The device will have a visual digital display that will deliver easily interpreted instructions to the user.

The device will be designed so that the user can securely and comfortably grip the device, while operating using one hand. The device will be lightweight and portable for use during normal daily activities.

Preparing the test will be quick and simple. The device will have minimal parts to assemble before use, reducing test time and simplifying the process. The device should couple with a single use, recyclable mouthpiece tube, which the user will blow through. The digital display will provide rapid, concise diagnosis results. The reusable device can be recharged using a USB charging cable.

Product analysis - elements and architecture

2. Aesthetics

Colour

- Must be aesthetically appealing with careful consideration given to how colour could emotionally impact users.
- The product should look clean and sterile, bright white should be used as the main casing colour to signify cleanliness purity and light weight (Park, 2015a).
- Lighter colours, such as pale pastels blue and greens, should be used to add contrast to white colours. Pale colours should draw the eye and differentiate working parts such as buttons, mouthpiece housing points and charging ports and cables.
- The colour selection should create a calming feel to help reduce stress, anxiety or frustration while in use.

- The colour of the digital display should project instructions clearly. The display background should contrast numbering/lettering on the display and the casing. Consider using a blue or orange device background against black lettering and numbering.
- The colour of branding will contrast with the product colouring. Consider darker reds, blues and black against the lighter colouring of the device. Darker colours in branding will help draw the attention of the user, promote and advertise the device.

Shape

- The device's shape must be one that's easily cleaned to prevent the ingress of dirt and foreign objects. Device texture will be smooth, joining parts should have even, tightly mating surfaces to prevent dirt ingress and maintain the sterile appearance of the product.
- Display and push buttons should be proportionate to device casing and should sit flush with the device casing for easy of cleaning.
- Display and button positioning should look balanced and central on the device to express a product quality.
- The form of the device should portray simplicity and comfort. Surfaces that are gripped by the palm should have smooth rounded edges to help give a comforting look.
- Product shape should be considered to minimise packaging materials and must fit inside packaging that maximises stacking and loading capacity for distribution.
- Consider a rectangular shape with smooth rounded edges.

3. Branding

Device branding

- Branding should reflect the product's purpose and functionality, aligning the product with brand identity. It should inform the user of its purpose.
- Typography and wording will be easy to interpret, the font used and spacing should portray the product and company as professional and trustworthy.

- The colour of the logo and branding will add contrast to the product colouring. Consider darker reds, blues and black against the lighter colouring of the device. The contrast in colouring will help draw the attention of the user to the branding, helping promote and advertise the device.
- Branding size should be in proportion to product size and will be positioned on the device to promote maximum visibility and impact. Areas of the device covered when in use, such as those gripped by the palm should be avoided.

Packaging branding

- Branding should be easily identifiable and memorable, instilling confidence and trust in the product, and should help establish brand recognition.
- The company logo should feature in a prominent position on the front face of the box and should stand out from the packaging design. Company and product name should also feature prominently on the packaging.
- The QR coding will be placed on the packaging, providing the user with supplementary information about the company, product, instruction for use, maintenance, trouble shooting and limitations.
- The QR code will transfer the user to the website, which will feature links to social media platforms that the company / product information is advertised on.
- Company contact details should be included on the packaging.

4. Company constraints

Budget

- Financing the project, consider:
 - Government funding eligibility.
 - Debt financing options- effect on cash flow / net profits.
 - Equity financing options- effects on decision making within the business.
 - Venture capital options- effects on the direction and control of the business.
- Arrange good credit agreements with new suppliers to maximise cash flow.

People

- Current resource availability and expertise required to design, produce, market and sell new product.
 - Recruitment of additional operations, finance, commercial and logistics staff.

- Requirement to outsource elements of the project.
- Must use a cross functional working model to overcome constraints.

Supply chain

- Capacity and capability of existing supply chain.
 - Capacity to cope with project's sales growth.
 - Sourcing new suppliers with capacity to supply materials.

Logistics

- Current capabilities of logistics and network.
 - Type of vehicles required/ methods of transport required.
 - Current fleet size capacity vs future requirements.
 - Number of drivers vs future requirements.
 - Cost of purchase of new vehicles.
 - Recruitment of new drivers.

Machinery and Infrastructure

- Limitations of existing machinery and infrastructure required to produce new product.
 - Warehouse capacity.
 - Assembly line capacity/capability.
 - Size of existing facility.
 - Production line capacity/capability.
- Investment required increase/ improve infrastructure and machinery.

Time

- Time sensitivity.
 - Are competitors developing similar products at the same time?
 - Commodities prices, utility costs for time period- impact to project.
 - Potential reduced time to market.

5. Competition

- Research current competition, consider their market, investigate when/if they are launching new products, review their customer value proposition? understand their market share.
- Research companies such as:
 - **Breathonix** - <https://breathonix.com/science-and-technology>

- Aeonose - https://www.enose-company.com/wp-content/uploads/2021/03/Wintjens2020_Article_ApplyingTheElectronicNoseForPr.pdf

- Risk of foreign competition/ imports – carry out market diligence.
- Consider IP and patents.
- Identify points of parity, points of difference and points of contention (Anderson, Narus and van Rossum, 2006).
- Review and compare competitors pricing.

6. Customer

- Explore market sources – management information systems, market research, market intelligence, cross disciplinary tools .
- Target health conscious, UK household consumers.
- Understand the market size.
- Research market segments, focus on mass markets.
- Consider etic and emic perspectives:
- Create a research, data driven customer value proposition.

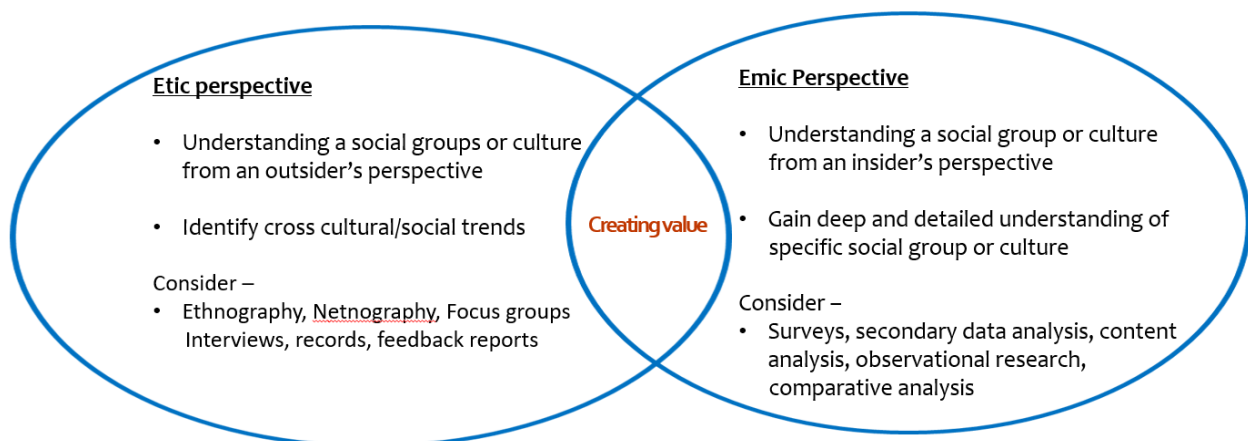


Fig 1. Etic and Emic research considerations (Williams, Lawrence and Barlea, 2023)

7. Circular economy / Sustainability

- Product will be an alternative to single use throw away test kits.
- Consider material selection. Select best suited materials for performance, manufacturing, cost, availability, durability, reliability, consider:
 - Post consumer recycled materials.
 - Post industrial recycled materials.
 - Bio Plastics.
 - Hybrid plastics.
 - Composable materials.
 - Recyclable materials
 - Mouthpiece tubes.
 - Packaging.
- Consult with a materials scientist.
- Consider products as a service.
 - Could product be leased during periods of high infection rates?
 - Could product be leased to companies who issue to employees?
- Design for longevity, importance of correct material selection.
- Consider product sharing. Device can be shared and reused amongst household members as opposed to using individual throw away tests.
- Focus on ease of repair and maintenance.
 - Parts must be easily available.
 - Must be designed to repair.
 - Must be designed to recycle.

Closed loop systems

- Consider company buy back of old items.
 - Standardising components across product range.
 - Component reuse in other products offerings.
- Regulations and legislation. Seek consultation from a legal professional.

8. Documentation

- Ensure all documentation is captured, communicated to relevant stakeholders, securely stored and easily accessible to those who require them, throughout the project.
- Document processes should be audited.

9. Environment

- Material selection
 - Assess environmental impact of extracting and processing raw materials.
 - Aim to reduce plastics to landfill. Consider the use of:
 - Post consumer waste.
 - Post industrial waste.
 - Bioplastic.
 - Composable plastics.
 - Carboard tubes.
 - Consult with a materials scientist.
- Reduce carbon footprint, consider the energy required in manufacturing the product:
 - Review feasibility of wind, solar and turbine power generation.
 - Assess the and energy required to recycle the product.
- Review the impact to the environment in transporting raw materials and product.
 - Aim to reduce exhaust emissions.
 - Consider biofuels.
 - Consider electric vehicles.
 - Product weight reduction.
- Design for longevity, repair, reuse, recycle product.
- Control noise pollution in manufacturing.
- Regulations and legislation. Seek consultation from a legal professional.
- Ensure international and national suppliers are environmentally responsible, review policy.
- Consider ISO14001 accreditation.

10. Ergonomics

- Consider anthropometry.

- The device should fit comfortably in the shape of a gripped hand.
 - Consider grip strength required against product weight.
 - While gripping in one hand, device buttons should be operated with a thumb.
 - Device should also be operable by gripping with one hand and operating with the finger of the other hand.
 - Device should be operable using right or left hand.
 - Device mouthpiece should be proportionate and sized so that user can blow comfortably without the face/mouth contacting the device body.
 - Device should be held in line with mouth, chin area when in use (blowing).
 - The device's digital display should be positioned so the user can grip the device, view the digital display and operate with one hand.
- Hand size
 - Research average UK hand dimensions.
 - Consider dimensions A, C and D, and grip position illustrated in figure 2 for holding the device.

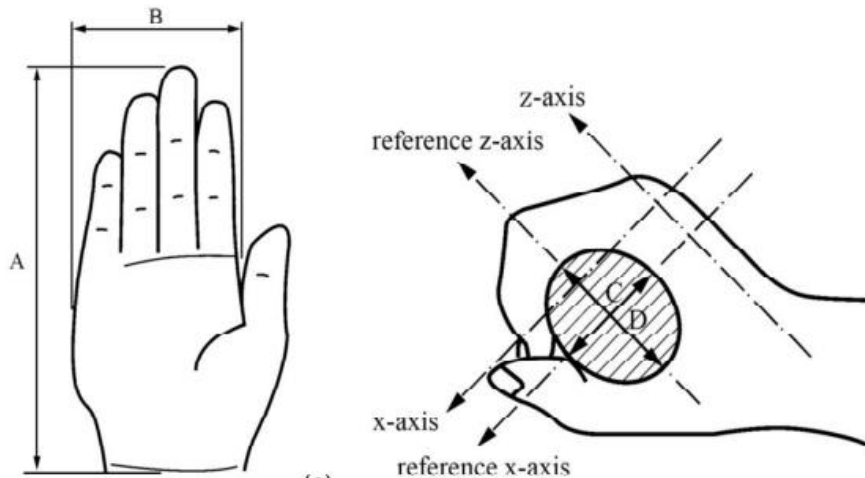


Figure 2. (Wang and Cai, 2023)

- Comfort
 - The device buttons should be positioned to allow the user to comfortably grip the device and operate using one hand.
 - The device's digital display should be positioned so the user can view the screen, without twisting the wrist or head into a strenuous position.
 - Product should be light enough for the user to operate without causing strain.

11. Installation

- Minimise complexity of assembly.
 - Minimise the number of parts to assemble before operation. Make the product quicker and simpler than home testing kit assembly, assembly should consist of:

- Removal of new tube from internal housing.
 - Fit mouthpiece onto device.
 - Fit charging cable into device (when required)
- The product should contain clear, concise instructions to the prepare the device before use, disassemble after use, fitting the charging cable and maintenance.
- The product should be simple enough to assemble, by users of all competence levels.
- Pre-use assembly and after-use disassembly should require no specialist tools or skills.
- Maintenance installations
 - The device should be designed for basic maintenance to be carried out by the user.
 - Ensure ease of disassembly for maintenance, repair and installation of replacement parts, with basic household tools, such as screw drivers.
- Charging installation
 - Insertion of a USB charging lead, USB/ TYPE A micro.
 - Female charging port should be easily identifiable on device.

12. Intellectual property (IP)

- Patent
 - Ensure patented design does not infringe on existing products or other patents.
 - Ensure parts sourced and manufactured in China/Malaysia do not infringe on existing patents, are not counterfeit and the supplier owns the IP for the parts they are supplying.
- Copyright
 - Review copywriting of artwork, pictures, literature, sound recordings, website, and marketing material.
- Trademark
 - Company name, logo, product name, logo and slogans.
- Social media
 - Verification required on social media platforms such as twitter (Blue tick), copywrite of protection of content from scammers, copycat accounts and spam bots.
- Trade secrets
 - Could be required if work is outsourced. Consider non-disclosure agreements.
- Outsourcing
 - Agreement with any contractor conducting work on the project, for ownership of IP rights of any works they create.
- Consult patent consultant.

- Consult trademark consultant.

13. Legal

- Product liability.
 - Liability insurance will be required, to cover consider the following scenarios:
 - Death or injury caused by a fault with the device.
 - Faulty device causing loss or damage to possessions or property.
 - To avoid liability claims due to misuse of the device, the company must:
 - Ensure that instruction for operation and maintenance are clear and comprehensive.
 - Ensure the correct quality control procedures are in place to identify and contain defects.
 - Ensure that the product meets required safety standards.
- Export and import regulations.
 - Ensure the correct import duties and taxes are identified and paid for any parts imported.
 - Ensure the correct customs charges and tariffs are identified when importing parts.
 - Consult a custom's broker.
- IP
 - Ensure product or media does not infringe on existing products or other patents.
 - Ensure imported parts or services do not infringe on existing patents and the suppliers' own the IP for their offerings.
 - Consult patent consultant.
 - Consult trademark consultant.
- Regulatory compliance and legislation.
 - Product must be compliant with Office for Product Safety and Standards (OPSS) and the Trading Standards Institute (TSI) regulations.
 - Product must comply with Medical Devices Regulations (MDR).
 - Product must comply with Medicines and Healthcare products Regulatory Agency (MHRA).
 - Seek guidance from the Department of Health and Social Care (DHSC).
- Contractual obligations, consider:
 - Outsourcing of work/services.
 - Supply chain contracts.
 - Customer contracts.
- Seek consolation from a legal expert.

14. Life in service

- Product offers an alternative to single use throw away plastic (unique selling point).
- Create a product with a long useful working life compared with products currently on the market (unique selling point).
- Generate brand trust and recognition, by offering a sustainable, durable and long-lasting product.
- Consider materials that will prolong the products useful working life.
- Create a product with high reliability and low failure rates.
- Product can be easily maintained, parts can be replaced, spare parts are easily obtained.

15. Materials

- Must be easily available, must be recycled, must be recyclable and must be cost effective.
- Must be able to be injection moulded.
- Device material properties must include:
 - Durability- withstand wear and tear of everyday use.
 - Toughness- must withstand impact if dropped from the height of an average adult.
 - Hardness / abrasion resistance – must withstand abrasion, scratches or general wear throughout its useful life, helping maintain a clean appearance, helping maintain a smooth surface for clean.
 - Chemical resistance – must withstand degradation from alcohol and general sterilising/ cleaning fluids.
 - Temperature resistance – must withstand changes in temperature in different environments. Device may be used during travel. Materials must maintain properties during varying operating conditions.
 - Dimensional stability – must maintain structure, shape and dimensions during changes in environment, temperature and humidity.

Fig 3. Device casing material selection.

Device casing material selection, consider:			
Material	Recycled Polyethylene Terephthalate (PET)	Recycled Polypropylene (PP)	Acrylonitrile Butadiene Styrene (ABS)
Properties	• High strength and toughness. • Good abrasion and heat resistance. • Good thermal and chemical resistance. • Excellent dimensional stability • Can be injection moulded.	• High impact strength • Good elasticity and toughness. • Good fatigue resistance. • High chemical resistance • Can be injection moulded.	• High strength and Toughness. • Good temperature resistance. • Ease of moulding can be injection moulded. • High quality surface finish. • good chemical resistance (although poor resistance to Alcohol- consider coatings). • Good abrasion resistance.

Fig 4. Digital screen material selection.

Digital screen material selection, consider:	
Material	Recycled Polycarbonate (PC)
Properties	• Lightweight. • Transparent plastic, good clarity. • High tensile and impact strength. • High chemical and moisture resistance.

Fig 5. Mouthpiece tube material selection.

Mouthpiece tube material selection, consider:			
Material	Polylactic acid (PLA)	Polyhydroxyalkanoates (PHA)	Recycled paper or carboard pulp
Properties	• Low cost • Safe for use in applications such as medical devices. • Biodegradable and compostable • Durable. • Good mechanical strength • Uses significantly less energy to produce than conventional plastic. • Generates significantly less greenhouse gases than conventional plastics. • Can be injection moulded.	• Compostable and biodegradable • Non-toxic • Can be used in medical applications. • Renewable material. • Can be Injection moulded. • Good water vapor barrier.	• Recyclable. • Biodegradable and compostable. • Abundance of material supply. • Low cost. • Sustainable. • Significantly effected by water absorption – consider Cellulose fibre additives to improve barrier.

16. Manufacturing facility

- Consider any new machinery required to produce the device.
- Calculate the facility size required to produce the new device, including housing:
 - Increased number of employees.
 - R&D facility.
 - Additional injection moulding lines required.
 - New moulds.
 - Increased loading and vehicle traffic.
 - Warehouse size, stock holding.
 - Goods in department.
- Facility size to facilitate forecasted growth.
- Utilisation of existing machinery.
- Consider if manufacturing facility location-
 - is best located for new market.
 - is best located for supply chains.
- Quality control processes and testing equipment requirement.
- Review existing assembly line, assess addition resource required, consider:
 - Assembly of device components.
 - Electronics into casing.
 - Buttons.
 - Display.
 - Casing.
- Consider additional picking and packing requirements.
 - Picking and packing machines.
 - Wrapping equipment.
 - Stacking/ loading.
 - Forklift trucks.
 - Palletizers.
 - Weighing.

17. Market constraints

Sustainability and circularity.

- Sustainable material availability.
 - Competition for post-consumer recycled material.
 - Sourcing reliable, consistent recycled material supply.
 - Creating circular supply chains.
 - Material cost fluctuations.
- Sustainable materials impact on cost per unit compared to using virgin materials.
 - Can the product be produced cost effectively and sustainably?

Legislation

- Compliance with governing bodies regulations such as OPSS and TSI.
- Regulations effect on product design, production, marketing and sales.
- IP – Infringement on existing patents.
- New or future legislation – Market intelligence required.

Competition

- Assess the competition.
 - How well known/ established is the competition. What is their market share?
 - Establish our points of parity and points of difference (Anderson, Narus and van Rossum, 2006) against a competitor's products.

Economic factors

- Inflation, Cost of living – effect on consumer spend. Is it a good time to launch? Gather market intelligence.
- Utilities, Commodities costs – assess impact of inflated costs.
- International conflict, trade sanctions – consider potential effects on supply chains.
- Understand the market - is covid still provoking enough attention to warrant this product now that restrictions have eased?

Innovation and technological advancements

- Disruptive technology.
 - gather market intelligence, is their innovation that will affect the success of our product.
 - Research technological advancements that we need to be aware of.

Consumer behaviour

- Track changes in markets trends – market intelligence required.

- Changes in consumer preferences - market intelligence required.

18. Maintenance and repair

- Design for longevity - Carry out rigorous prototyping and testing of different materials, during design phase to identify best suited materials, unearth potential design flaws and faults to reduce defects and failure rates.
- Ease and accessibility
 - Packaging should contain trouble shooting guide to help user identify defects.
 - Packaging should contain basic cleaning and maintenance instructions and warning instructions, that are easily interpreted by the consumer.
 - Device packaging should contain comprehensive repair instructions, recycling and disposal instructions that are easy to interpret by the consumer.
 - Device component parts should be easily removable with basic household tools.
 - Component parts should be modular in design, for ease of replacement.
 - Modular electronics.
 - Modular display screen.
 - Modular casing (splits into 2 halves).
 - Batteries should be standard rechargeable.
 - Maintenance and repair instructions should detail how to order spare parts and contact customer service support.
 - Spare parts should be readily available to order, within a reasonable lead time.
- Standardisation of components.
 - Where possible consider standardising parts across the product range to reduce the amount of spare stock held.

19. Packaging

- Shelf appeal.
 - Consider how the product will appeal to the consumer when stacked on store shelves with other products.
 - Packaging should draw consumers to device over other products.
 - Packaging should be considered a significant part of the purchasing experience, consider how packaging emotionally impacts the customer.
 - Create sense of quality, trust and reliability in brand and product.
 - Branding should be visible and prominent on packaging when stacked. Consider positioning, colours textures and typography.
 - Packaging must be stable when stacked.

- Product protection.
 - Packaging must protect the device throughout storage, transportation and potentially when purchased and stored.
 - Device should be secured inside packaging, prevented from movement within packaging and protected from damage and defect.
 - Product packaging should consist of a box, a tray and a box wrap to prevent from ingress of water and contaminants.
 - Include a tamper sticker/seal to box.
- Distribution.
 - Design to be stable and uniformly stacked.
 - Consider a rectangular shape, remove unnecessary material to reduce weight, and increase the number of items that can be distributed on a standard 1200mm X 1000mm UK pallet.
 - Packaging should be quick and easy to pack and wrap.
- Sustainability.
 - Packaging should be environmentally responsible, consider:
 - Recycled cardboard material in box
 - Recycled High-Density Polyethylene (HDPE) or PET, for device tray.
 - Biodegradable plastics for device trays.
 - Recycled Low-Density Polyethylene (LDPE) – LDPE and PET for plastic film wrapping of box.
 - Consult materials scientist to advise on material selection.
 - Consider outsourcing packaging manufacture and design.
- Information
 - Packaging should include compliance approvals and standards.
 - ISO compliance or other accreditations
 - Compliance with Medicines and Healthcare products Regulatory Agency (MHRA).
 - Seek advice from compliance and legal experts.
 - Packaging should provide a short, punchy description of product and its claims.
 - More sustainable alternative to disposable home testing kits.
 - Robust, reliable, accurate, portable.
 - Ease of operation, rapid testing.

20. Performance

- Refer to the unique selling points when considering performance.
- Must be a more sustainable, rapid, long lasting, user friendly, alternative to traditional single use test kits.

- Design to perform in everyday situations and 'on the go' use.

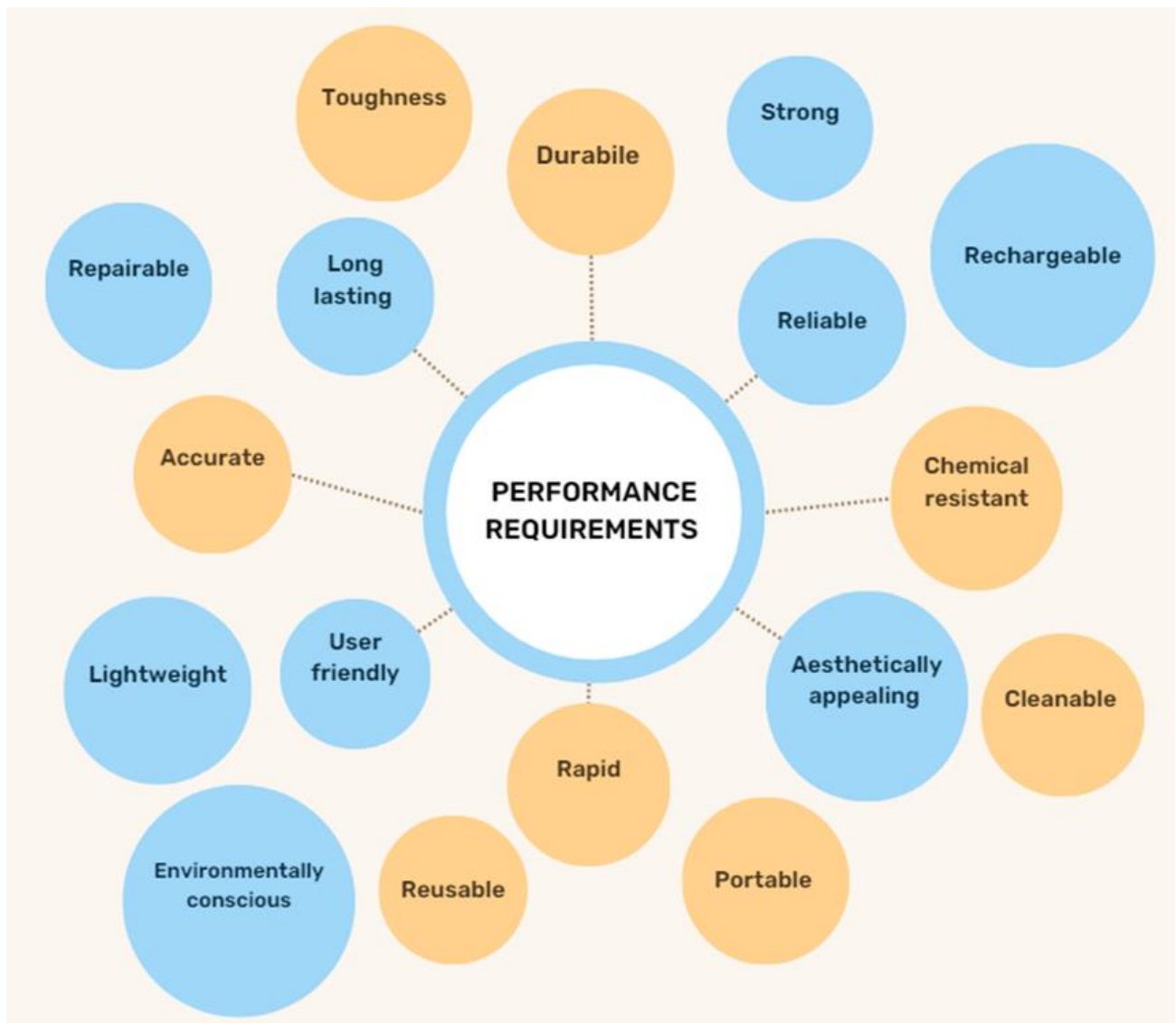


Figure 6. Performance requirements

21. Prototyping

Carry out rigorous prototyping and testing, collaborating with consumers and key stakeholders during design phase, to identify potential design flaws and faults and validate for, fit, function, and fabrication (Krishnan and Ulrich, 2001)

- . Consider the following methods to reduce prototype cost:
 - Computer aided design (CAD).
 - Additive manufacturing (3D printing).

- Simulation and modelling.
- Gather customer feedback throughout all stages of the NPD processes, ensure the product meets the needs of the customer and market before manufacturing and product launch.

22. Politics

- Consider how the new product is impacted by, or may effect:

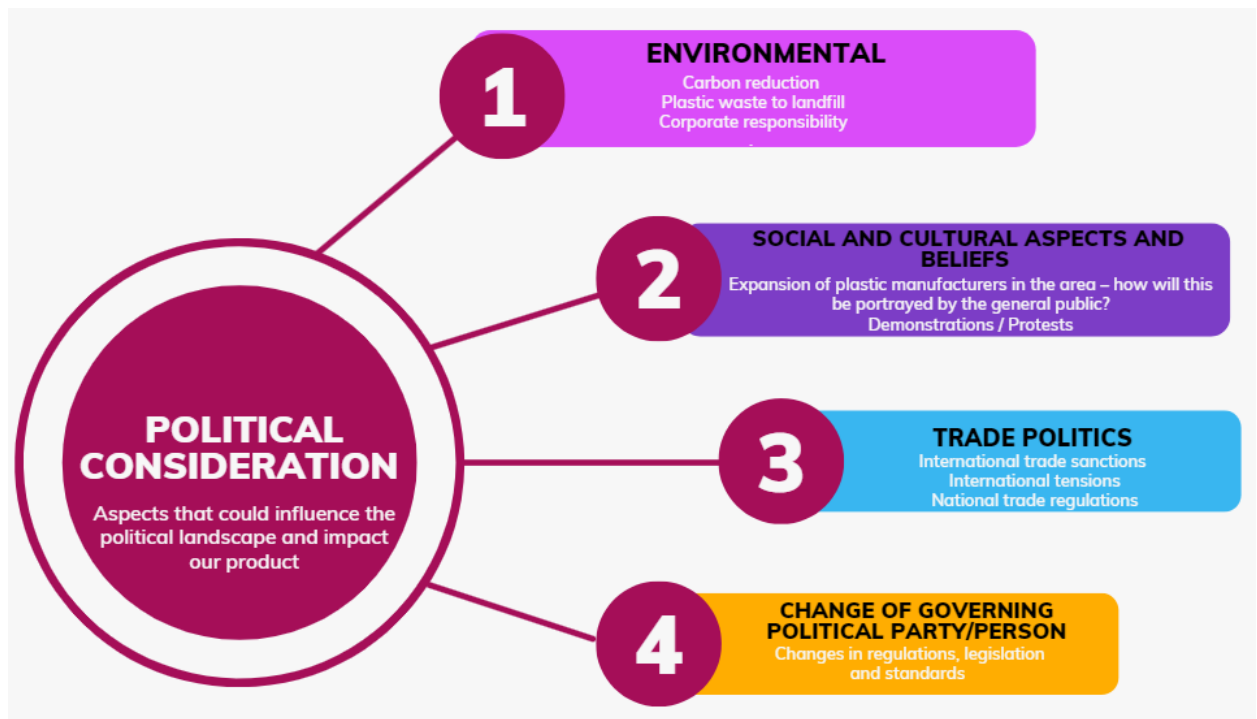


Fig 7. Political considerations

23. Processes

- Specialist processes required include, injection moulding, assembly of printed circuit boards, battery manufacturing, packaging, tube manufacturing and assembly of device.
- Robust processes must be created through the lifecycle of the product, consider developing processes in the following areas:

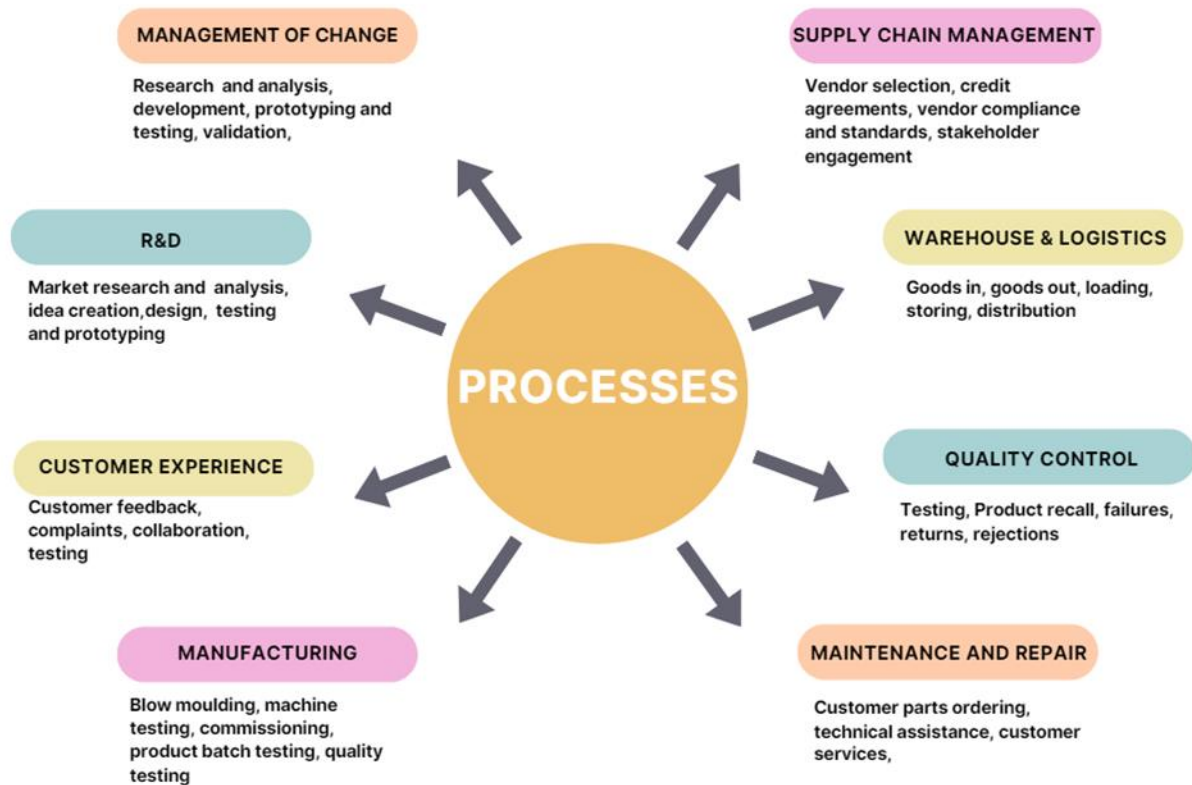


Fig 8. Process considerations

24. Product cost

- Balance cost. Product must be a more sustainable alternative to single use, throw away test kits, however, consider material cost impact. Product must be affordable.
- Reduce cost without compromising product safety or quality.
- Consider the use of automation in manufacturing machinery, compared to more manual processes.
- Compare virgin material costs against, post-industrial, post-consumer recycled materials and bioplastics.
- Circularity – how can we re-use components/ material over producing new?
- Review production/ operations processes – optimise wherever possible.

- Track utility and commodities prices. Consider negotiating better materials and utility contracts, or generating own electricity (solar, gas turbine, wind turbine).
- Minimise waste.

25. Product lifespan

- Design for longevity.
 - Test and create prototypes during the design phase to identify and correct potential faults.
 - Select materials for durability and reliability.
 - Extend working life by making spare parts readily available to the customer, at an affordable price.
 - Follow design to repair methodology and provide clear instruction to replace components.
- Product end of life
 - Understand the market/ customer, what are consumer habits and trends. Understand how long other similar products are deemed desirable by the customer, how does innovation effect the market.
 - Consider product usefulness lifespan Vs desirable lifespan.
 - Consider how the product will be phased out-
 - Upgrade.
 - New product launch.
 - Discontinue.

26. Quality

- Conduct quality control and testing processes for the following:

During manufacture

- Raw material quality testing.
- Process running conditions.
- Batch sampling.
- Dimensional check.
- Visual inspection for imperfections.

Finished products

- Visual inspection for imperfections.
- Dimensional stability
- Impact testing
- Thermal stability

- Visual inspection for imperfections
- Colour consistency

After sales

- Containment, segregation, recalls, customer complaints, quality investigations

27. Quantity

- Consider customer minimum orders, make to order, inventory size.
- Establish optimum number of units per tool change for efficiency, cost effectiveness/ greater profit margins.
- Plan for scalability and increase in volume-
 - Budget and plan for ramp up in production. 750,000 units in the first year and 3 million per annum afterwards, timeline for additional resource required.
- Consider spare parts inventory size for customer orders (repairs).
- Review suppliers' quality control processes (national and international).
- Consider ISO 9001 accreditation.

28. Reliability

- Create and test prototypes during the design phase to identify and correct potential faults.
- Select materials for durability and reliability.
- Components and finished product should pass quality control testing.
- The device's electronics should be protected to IP54
 - Dust protected.
 - Splashes of water from any direction.
- Design to repair - provide instruction for basic customer maintenance and repair.
- Make spare parts readily available to the customer.
- Conduct product reviews, listen to customer feedback and continuously improve product.

29. Safety

- The product must be compliant with Office for Product Safety and Standards (OPSS).
- The device should minimise risk of injury to the user, the device should have no sharp or jagged edges.
- The user should be protected from contact with electrical components and wiring.
- The mouthpiece should be secure when fitted to the device to prevent swallowing.
- Consider the device's weight.
- Seek guidance from a compliance and health and safety consultant to ensure all safety regulations and standards are identified and adhered to, regarding the product design and health and safety at work.
- Consider ISO 45001 accreditation.

30. Size

- Consider the following factors relating to product size:
 - Must be aesthetically pleasing.
 - Must be proportioned to suit the functional requirements of the product.
 - Small enough to be carried and transported in a large pocket or handbag.
 - Material costs.
 - Manufacturing processes.
 - Size must be ergonomically proportionate.
 - Product must be lightweight and comfortable to use, how will size impact weight?

31. Shelf life and storage

- Balance inventory to maintain better inventory rotation, consider component shelf life:
 - Batteries around 10 years (Walker, 2020).
 - Electronics hot air soldered (HAS) lead free PCB around 12 years (Fineline-global, 2023).
 - Packaging.
- Store in dry, safe, dust free location.
 - In warehouse.
 - On wrapped pallets.
 - On racking

- Keep product dry to avoid water damage of packaging and corrosion of electronics and fasteners.

32. Shipping

- Product shape should minimise packaging materials and must fit inside packaging that maximises stacking and loading capacity for distribution for bulk deliveries.
- Establish vehicle fleet requirement when production volumes increase.
- Consider environmental impact/ carbon emissions-
 - Biofuels.
 - Electric vehicles.
- Ship direct to customers in small quantities and distributors in bulk shipments throughout the UK.
- Determine number of units per standard 1200mm X 1000mm UK pallet.
- Consider rectangular shape packaging, remove unnecessary material to reduce weight.
- Calculate shipping costs.

33. Social and cultural

- Consider social and cultural aspects and beliefs of manufacturing and launching product.
 - Anti vax movements, covid hoax beliefs.
 - Plastic pollution.
 - Expansion of plastic manufacturers in the area.
 - Bad publicity in press/social media.
 - Demonstrations.
- Develop marketing campaign, focussing on:
 - Creating employment.
 - Health/wellbeing.
 - More sustainable, environmentally conscious product offering.
 - Customer value proposition.
 - Points of parity and points of difference (Anderson, Narus and van Rossum, 2006).

34. Standards and specification

- The device will:
- Be classified as a Class IIa medical device.
- ISO 13485: international standard for quality management systems specific to medical devices.
- Comply with the European In Vitro Diagnostic Regulation (IVDR) – sets out requirements for vitro diagnostic medical devices (including Covid breathalyser kits).
- Comply with the UK Rapid Test Consortium (UK-RTC) Protocol.
- Comply with the Office for Product Safety and Standards (OPSS).
- Comply with the trading Standards Institute (TSI) regulations.
- Comply with the BS EN 60335-1 Covering the safety requirements for household electrical devices.
- Part and services delivered by international suppliers should also meet the required standards, required for sale in the UK.
- Comply with the BS 1363-1 British Standard for 13 A plugs, adaptors and connection units. Applicable to devices charger.
- Comply with the BS EN 62133 Standard for safety requirements for portable rechargeable lithium-ion batteries used in electrical products. Applicable to devices rechargeable batteries.
- CE marking.

35. Time and scale

- Follow an agile/scrum project management methodology, to effectively manage time and how the project is scaled.
- Use sprint planning, daily stand-up meetings, sprint reviews and retrospect meetings to assign work packages to track progress of work packages.
- Project scalability should be considered in sprint planning. The processes, resources and work packages required to scale production to ship 750,000 units in the first year and 3 million per annum afterwards, should be divided into smaller sprints and managed following scrum methodologies.

36. Testing

- Throughout product concept, design, manufacture, and distribution testing must be carried out in the following areas:
 - Feasibility testing – ensure project is affordable, scalable, desirable, producible, profitable.
 - Prototype testing - test material options, test performance, examine aesthetics, test ergonomics.
 - Quality testing and inspecting during production x1 sample every 2 hrs.
 - Safety testing.
 - Functional testing.
 - Performance testing- rigorously/ repeatedly test all functions, measure performance in exaggerated circumstances.
 - Acceptance testing – testing by consumer / distributor (maybe more suitable in built order from a distributor).
 - User/consumer testing – gather feedback on product.

37. Weight

- Consider the following factors relating to product weight:
 - Weight must be proportioned to suit the functional requirements of the product.
 - Material costs.
 - Manufacturing processes
 - The product must be lightweight and comfortable to use.
 - The product's weight must be assessed against:
 - transportation cost.
 - carbon emissions.
- Production must be safe and light enough to carry and operate without causing a strain injury.

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