

Synopsis

What is the product? - A Handheld breath tester which can detect organic viral materials.

“Company see great potential in developing a product that can meet both clinical and personal requirements for such virus detection”. Taken from assignment brief.

The breathalyser can detect organic materials and define if someone has a viral infection. This will be predominantly for the healthcare sector to reduce the risk of infection spreading. It is key reduce the risk of a virus spreading to reduce the need for additional resources such as isolation rooms, additional medicines, and additional staff for the healthcare customer.

The target market is largely healthcare businesses such as the NHS or private hospitals such as BUPA. This device will be designed to be used by the nursing staff / healthcare assistants to assess patient conditions both on the way into the hospital and whilst in hospital.

In addition, this device can be used in care homes and assessed living where medically vulnerable people are cared for.

This device will be handheld, simple to use and suitable for a healthcare environment.

“The projected manufacturing volumes are 750,000 in the first year, and 3 million per annum afterwards.” taken from assignment brief.

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1. Aesthetics

1.1 consider a look simple with minimal buttons.

1.2 Should have a large enough screen to read outputs.

1.3 Consider including the company branding.

1.4 Consider a cover that can be interchangeable for different markets? An interchangeable cover can give the product a premium feel and possibly increase potential sale price. This may also provide a competitive edge.

Possibly a silicone skin or leather case?

1.5 Consider colours with a positive psychological effect on user. Consider colour effects on diverse cultures to prevent offense. Below shows blue as an all-round colour that promotes trust and positivity in multiple cultures. Also used within the NHS and hygiene brands such as Boots and Oral-B.

Cultures	Red	Black	Blue	Green	Yellow
Western	Love Danger Action 	Intimidation Death Mourning 	Depression Trust Calm 	Luck Jealousy Greed 	Happiness Joy Caution 
Far Eastern	Property Good Fortune Vitality 	Health Prosperity Stability 	Healing Relaxation Feminine 	Fertility Hope Life 	Sacred Royalty Masculinity 
Middle Eastern	Danger Caution Evil 	Mystery Mourning Rebirth 	Heaven Spirituality 	Strength Hope 	Happiness Prosperity 
Indian	Beauty Wealth Power 	Evil Darkness Negativity 	Sports Strength 	Harvest Hope Virtue 	Sacred Auspicious 

Figure 1 - Mall, K. (2021). Color psychology in UX. [online] Medium. Available at: <https://bootcamp.uxdesign.cc/color-psychology-in-ux-b371fde795d3>.



Figure 2 - Mall, K. (2021). Color psychology in UX. [online] Medium. Available at: <https://bootcamp.uxdesign.cc/color-psychology-in-ux-b371fde795d3>.

Cross References	
3 –Customer / Market	4 - Environment
5 - Ergonomics	10 – Materials
12 - Performance	13 - Politics / Social / Cultural
14 – Product costs	

2. Circular Economy / disposal

- 2.1** Consider the re-use of the unit, a refurbish program by replacing the battery and the sensor. These could be donated to health charities to benefit poorer communities.
- 2.1.2** consider easy reworkable internal parts – clips and plugs rather than soldered joints for replaceable parts with a short life span.
- 2.2** Consider the recycling of the components at end of life. Can these be used to produced new units I.e. re-using the circuit boards.
- 2.3** Consider the material of the breath tube – is this biodegradable / recyclable?
- 2.4** Consider European Commission's guidance in relation to circular economy further referenced in section 16.

Cross References	
3 – Customer / Market	4 - Environment
10 – Materials	12 - Performance
13 - Politics / Social / Cultural	16 - Safety, standards and compliance testing

3. Customer / Market

- 3.1** Consider competitive products and manufacturers could these be incorporated into our marketing options? Are there any further aspects that can be unique selling points for our product? Consider using key features of competitive items:
- 3.1.1** Accessory offer silicone skins / leather cases
 - 3.1.2** Competitor product life span – fuel cell typically 5 years, AA batteries.
 - 3.1.3** Function over looks – not particularly stylised
 - 3.1.4** Fast accurate results
 - 3.1.5** Fully quantitative breath analysis
 - 3.1.6** Can be used anywhere
 - 3.1.7** Robust and durable
 - 3.1.8** Next day Delivery
- 3.2** Competitive pricing:
- 3.2.1** Similar breathalyser cost – low-cost cheap home use breathalysers £50-£100 accurate mid-range industrial use £600-£800 high end highly accurate laboratory use £1000-£3000
 - 3.2.1** Plastic mouth pieces approx £100 per 250.
- 3.3** Consider current customer base for sales, Health care customers, customers wants' and needs for unit. Using a Value Proposition Canvas, a business model tool that helps you make sure that a company's product or service is positioned around customers' values and needs. The tool has been created by Alexander Osterwalder, Yves Pigneur, and Alan Smith.

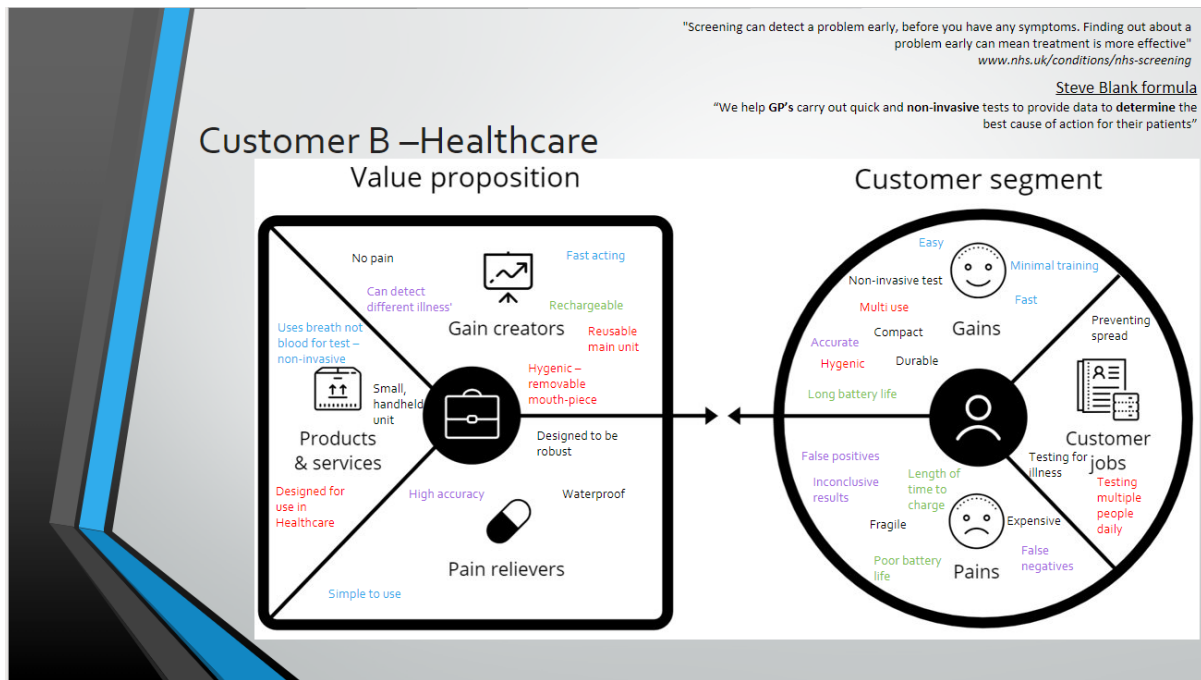


Figure 3 - Value Proposition Canvas. Extract from team Conwy Assignment A 2023.

3.4 Consider circular economy as a competitive edge.

3.5 Consider using current customer base for marketing research and testing of trial components to gain feedback.

3.6 Growth in the breathalyser sector is expected to increase with an 8.5% Compound annual growth rate from 2023 to 2028. North America holds the largest market share, consider researching sales to North America. New innovative products being introduced to the market by competitors, consider the purchase and review of their technology. (source: Mordor Intelligence, 19.09.2023).

Cross References	
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6 – Installation	7 – Legal / Patent
8 – Life in service / Maintenance / Service life	10 – Materials
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18 – Size and Weight	19 - Timescale

4. Environment

4.1 Consider the use of raw materials versus the use of recycled or reclaimed materials

4.2 Consider the biodegradability of the mouthpiece. The mouth pieces need to be disposed of as clinical waste.

4.3 Consider the regulations surrounding wastes (see section 16).

4.4 The environment the unit needs to operate in will be:

4.4.1 Clinically clean environment, the unit must be sealed and the buttons free from dirt ingress.

4.4.2 The working temperature and humidity according to Hospital hub and research by Rotronic Uk is quoted as "in the summer is between 23°C and 27°C, while in the winter it is recommended to keep

the temperatures slightly lower with a guide range of 24°C to 26°C. Humidity-wise, the report recommends 50-60%rh throughout the hospital.” Why temperature control and air quality vital for the healthcare sector - Hub Publishing, accessed 21.09.2023

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5. Ergonomics

5.1 77% of the NHS workforce are Women and worldwide (study from 104 countries) 70% of workers in the health and social care sectors are Women. The device should be able to be held comfortably by the average women's hand. NASA define the average women's hand size below:

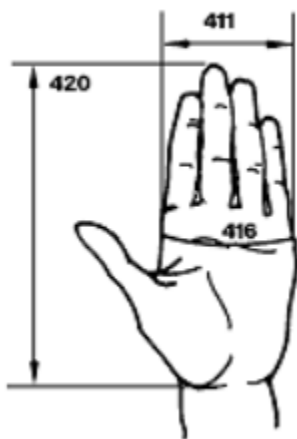


Figure 4 <https://msis.jsc.nasa.gov/sections/section03.htm>

420	Hand length	15.8 (6.2)	17.2 (6.8)	18.7 (7.3)
411	Hand breadth	6.9 (2.7)	7.8 (3.1)	8.6 (3.4)
416	Hand circumference	16.5 (6.5)	17.9 (7.0)	19.3 (7.6)

Figure 5 <https://msis.jsc.nasa.gov/sections/section03.htm>

5.2 Users will be both left and right-handed. Consider universal button location and hand grip.

5.3 Hand grips must be considered to enable a good grip and prevent dropping. Indentations where the fingers and thumb sit.

5.4 Consider a wrist strap for the user.

5.5 Weight must be balanced and not 'top-heavy'.

5.6 Button position to allow the most dexterous fingers to work them (Thumb, index and middle fingers).

5.7 Consider pips on buttons to indicate which buttons are which with touch rather than vision.

5.8 Consider a docking station so user does not need to carry continuously.

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6. Installation

6.1 Consider a Battery charging station. A charging station would give a location point for the device in a busy environment where multiple people would use the device. It would also enable the device to be safely charged.

6.2 Consider making the charging Plug type universal to enable the consumer to use a single common cable. Mobile phones use a universal plug (USB type-C port), reference the EU radio equipment directive, see section 16.

6.3 Software compatibility should be considered and the ability and format for downloading data. Data may be required to be downloaded to a PC or laptop with windows capability. Consider if a standard program such as excel can receive the data or if the software should be bespoke.

Cross References	
8 – Life in service / Maintenance / Service life	9 – Manufacturing facilities / Processes / Assembly
12 - Performance	13 - Politics / Social / Cultural
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7. Legal / Patents

7.1 Consider consulting with an intellectual property lawyer to ensure there have been no breaches of patents in the design of this product.

7.2 Consider registering the design or technology to protect the innovation, this would be based on the advice of the intellectual property lawyer.

7.3 consider the relationships with suppliers and the intellectual property, does this need to be protected.

7.4 As there has been a Knowledge Transfer Partnership with a local university consider the intellectual property ownership.

7.5 Consider contractual agreements with suppliers in relation to intellectual property.

Cross References	
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8. Life in service / Maintenance / Service life

8.1 Battery care what is best practice, what advice should be given to the consumer to prolong the life as long as possible.

8.2 battery overall life expectancy - Battery life – 1000 charges on average for Li-ion batteries, approximately 3 years. Consider alternatives with longer life expectancies.

8.3 Consider calibration / service requirements and service. At what point does the unit become unstable or too inaccurate? Set the calibration at that point. Standard breath testers have a 12-month calibration period.

8.4 Consider the fuel cell life expectancy. Standard breathalyser fuel cells have a life expectancy of 5 years. Consider life expectancy and method of replacement.

8.5 The casing of the unit should be screwed together to enable the internal components to be serviced and replaced.

8.6 The mouthpiece is disposable and removed after every test – consider cleaning advice of the mouthpiece connection to the main unit to prevent cross contamination.

8.7 Consider advice for suitable cleaning materials. Antibacterial wipes would be common in a healthcare setting but may affect the functionality of the unit.

Cross References	
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9. Manufacturing facilities / Processes

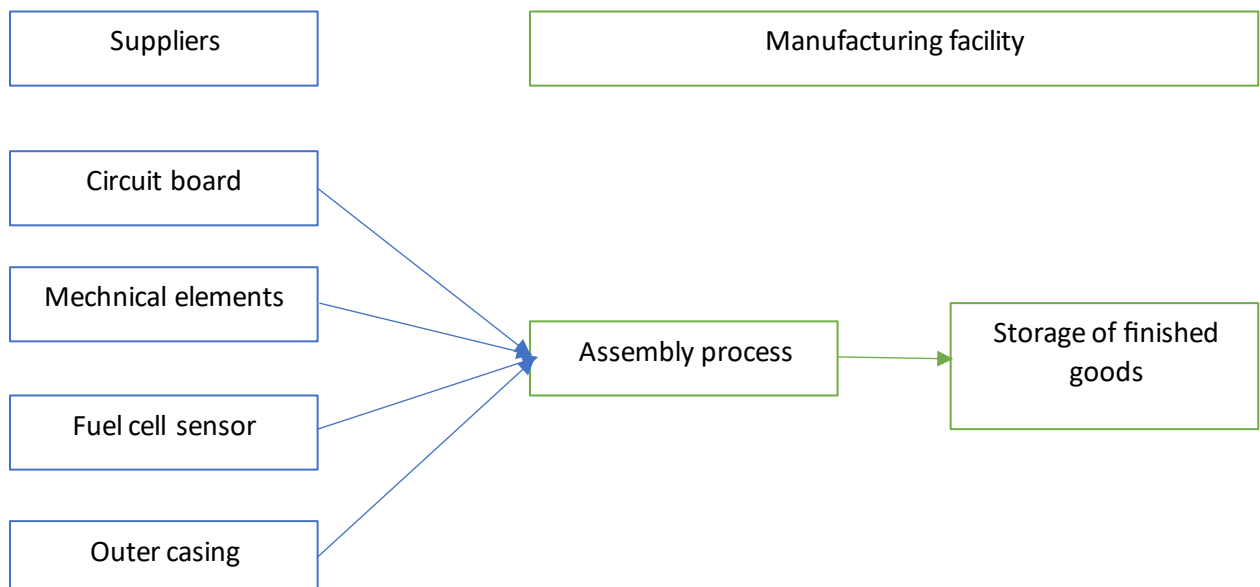


Fig 6 manufacturing sourcing diagram

9.1 Consider externally manufactured components such as the electronics and mechanical elements:

“Preliminary research has indicated that China or Malaysia remains the most favourable source of electronic circuit boards - and that the UK or Europe would, for now, be seen as favoured source for the moulded parts.”

9.1.1 Do the suppliers conform to regulatory standards?

9.1.2 Are the suppliers reliable, is there a contingency for dual supplying?

9.1.3 Is there a packaging standard to ensure the component is safely transported.

Specifically consider circuit boards and their ESD protection requirements.

9.1.4 *“The new product’s electronics will be contained in a single circuit board. This will need to be sourced in a fully assembled and tested form.”*

9.1.5 Is a goods inwards inspection required?

9.1.6 Have lead times for components been agreed?

9.1.7 Consider what stock holding is required of components based on lead times and MOQ (minimum order Quantities) of components to ensure the assembly process is not held up.

What warehouse space would this require?

9.2 *“The mechanical element of the detector (the breath sample capture system) will be fabricated from injection moulded parts.”*

9.2.1 Consider common tooling with other products to reduce costs

9.2.2 Consider the use of one tooling with blanker plates to produce the front and back components.

9.3 internal manufacturing considerations:

9.3.1 consider assembly instruction manuals to ensure all operative assemble parts consistently and correctly to specifications.

9.3.2 Are there any specialist tools or fixtures needed to assemble the unit?

9.3.3 Consider training of operatives to both assemble and test units.

9.3.4 Consider assembly and test traceability documentation, its details and retention periods. Where will it be stored? How will the units be individually identified, consider serial numbers of units.

9.3.5 Are the manufacturing areas suitable for electronic device assembly. Consider if clean room is required? Is there enough assembly area for the new units.

9.3.6 Consider how units are stored and transported within the factory prior to packing.

9.3.7 Consider testing of the unit. Test instructions will be required which may need to test compliance against a standard.

9.3.8 Is any specialist test equipment needed to test the unit that needs to be considered.

Cross References	
8 – Life in service / Maintenance / Service life	10 – Materials
12 - Performance	14 – Product costs
16 – Safety, Standards and Compliance testing	17 – Shipping and Storage
19 - Timescale	

10. Materials

10.1 For the moulded outer casing, consider a plastic:

10.1.1 that has a heat resistance that would allow a battery to get warm whilst charging but not melt.

10.1.2 that will not cause a flame if heated, to prevent fire spread.

10.1.3 with antibacterial properties, this may require a special addition to the material.

10.1.4 that has an impact resistance of a tabletop height drop.

10.1.5 that is light weight enough to make the unit handheld.

10.2 The company has indicated that *“China or Malaysia remains the most favourable source of electronic circuit boards”*

10.2.1 the circuit boards must comply with relevant regulations such as ROHS and EMC, see section 16.

10.3 The screen must be able to wipe clean.

10.4 the buttons should be flush with the casing, consider using touch screen buttons.

10.5 Consider the Fuel Sensor and its life span. Are there any sensors that have a longer lifespan.

10.6 Consider a protective cover as an accessory. Protective cover could be made of silicone which would increase the impact resistance of the unit.

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11. Packaging

11.1 Consider graphics and information required on the packaging:

11.1.1.2 Contains batteries consider labelling with cautions.

11.1.1.3 Label with the manufacture date – to aid shelf life and traceability.

11.1.1.4 label with product branding and explanation of product and contents.

11.2 Recycling of packaging material to be considered as a environmental impact. Consider packaging regulations listed in section 16

11.3 Packaging should prevent product damage:

11.3.1 Package to prevent damage to the screen.

11.3.2 Ensure package does not egress into cable connection slots.

11.4 Consider the product weight and size to ensure the product is secure when packaged.

11.5 Square boxes to enable stacking and palletising.

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12. Performance

- 12.1 Unit should be able to work under ‘normal conditions’ with temperature and humidity as defined in section 4 for the UK market. When looking at other markets, consider their working conditions.
- 12.2 The unit should be a sealed unit, not allowing dust egress and should be wipeable.
- 12.3 The unit should be reliable with minimal charging time as it will likely be used daily on multiple patients.
- 12.4 The test should be fast and accurate; the accuracy should be able to be held for a 12 month period between calibrations.
- 12.5 The unit should be able to store results and give a clear pass / fail read out with a measurement. Results should be downloadable to a PC. See section 6 installation. Result parameters will need to be established with a medical expert to be set as pass or fail.
- 12.6 Consider connectivity of the unit – could it use WIFI or Bluetooth to connect to a printer or PC.
- 12.7 The unit should be simple to operate with minimal buttons. The mouthpiece should be easy to install.
- 12.8 Consider defining the period of breath time needed to perform an accurate test – this should be included on the instructions and flagged on the unit with an error code if not enough breath present for an accurate test.
- 12.9 the unit test specifications must not be adjustable externally.
- 12.10 The charger should be a standard charger, see section 6 installation.

Cross References	
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13. Politics / Social / Cultural

- 13.1 consider traditional working hours or shutdowns of any country that is supplying components e.g China.
- 13.2 Consider communication methods with suppliers to ensure accurate detail is passed on.
- 13.3 Colours of products as per section 1 – Aesthetics, colours can represent different things in different cultures.
- 13.4 Consider the name of the product so it is not offensive in other languages or can be translated easily.
- 13.5 consider compliance to other countries legal and regulatory requirements where the product is to be marketed.

Cross References	
1 - Aesthetics	3 – Customer / Market
16 – Safety, Standards and Compliance testing	

14. Product Costs

- 14.1** As the WHO (World Health Organization) has defined bacterial illnesses as a world threat with a focus to improve detection, research if further research funding is available.
- 14.2** consider costing for fixtures or test rigs in the manufacturing facility
- 14.3** consider tooling for mouldings, could these be reduced by having a universal moulding?
- 14.4** consider raw material cost and cheaper alternatives that would meet the criteria.
- 14.4** consider buying components in bulk – fewer shipments and shipping costs but may add to warehousing costs.
- 14.5** consider the costs of external testing to prove product meets standards.
- 14.6** source components from alternative countries with cheaper overheads such as China or Malaysia.

Cross References	
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15. Prototyping

- 15.1** The Company have successfully bench type prototyped the electronic and mechanical systems
- 15.2** use current customer base for feedback on prototype.

Cross References	
1 - Aesthetics	3 – Customer / Market
12 - Performance	14 – Product costs

16. Safety, standards and compliance testing

- 16.1** Government policies and regulations

16.1.1 Circular economy consider:

16.1.1.1 government's Policy paper on Circular Economy Package policy statement

16.1.1.2 European Commission's guidance on circular economy which is adopted by the UK government.

16.1.1.3 European Commission's proposal for Rules promoting the repair of goods (DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on common rules promoting the repair of goods and amending Regulation (EU) 2017/2394, Directives (EU) 2019/771 and (EU) 2020/1828)

16.1.1.4 European Commissions Communication – EU policy framework on biobased, biodegradable and compostable plastics.

16.1.1.5 European Parliament directive for radio equipment (DIRECTIVE 2014/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC).

16.1.2 Consider Government waste and disposal regulations such as:

16.1.2.1 The Waste Electrical and Electronic Equipment Regulations 2013

16.1.2.2 Waste Batteries and Accumulators Regulations 2009

16.1.2.3 For countries outside the UK consider waste recycling and waste regulations.

16.1.3 Packaging regulations: The Packaging (Essential Requirements) Regulations 2015

16.2 Testing requirements:

16.2.1 Consider British standards such as:

BS EN 50436-2:2014+A1:2015 Alcohol interlocks. Test methods and performance requirements - Instruments having a mouthpiece and measuring breath alcohol for preventive use.

BS EN 50980-1:2019 Remote alcohol monitoring devices. Test methods and performance requirements - Instruments for assessment programmes.

BS EN 15964:2011 Breath alcohol test devices other than single use devices. Requirements and test methods.

BS EN 16280:2012 Breath alcohol test devices for general public. Requirements and test methods.

- Note these standards are based upon the testing device checking for alcohol, similar testing may be required for test units testing for organic materials.

16.2.2 Safety and compliance standards such as:

16.2.2.1 UKCA marking is required as this a measuring instrument, more information on specific requirements can be found on the government website. As a medical device, regulations are required by the Medicines and Healthcare products Regulatory Agency (MHRA) under The Medical Devices Regulations 2002.

16.2.2.2 For markets outside the UK consider the safety requirements for that specific country or region.

16.2.2.3 Consider if there are any EMC requirements under The Electromagnetic Compatibility Regulations 2016

16.2.2.4 consider ROHS compliance requirements - Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 .

16.3 Approvals

16.3.1 Dependant on specific market and region, local approvals may be required such as the UK home office, local healthcare trusts or specific police forces etc.

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17. Shipping and Storage

17.1 consider the shelf life of the units, stock rotation and FIFO (First in first out) methodology should be used. consider outer labels of boxes to include manufacturing dates for shelf life / stock rotation purposes and traceability purposes.

17.2 Store large quantities on standards pallets, to enable them to be stored on racking in warehouses. Consider the product weight and a full pallet weight.

17.3 consider storage locations at the manufacturing plant and if a bulk storage warehouse is required.

17.4 Consider minimum order quantities when bulk shipping to distributors to reduce breaking into whole boxes when picking.

17.5 No per box, number per pallet etc. Make quantities efficient to reduce shipping costs.

17.6 Consider commodity codes and hazard notices required to ship internationally.

17.7 Consider different shipping boxes for local and international shipping. Consider the pallet material to be used, does the pallet need to be treated to be shipped to its destination.

Cross References	
8 – Life in service / Maintenance / Service life	10 – Materials
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18. Size / Weight

18.1 The device should be handheld see section 5 ergonomics for guidance on hand sizes. The device should be approximately 200 x 700 x 30 mm, similar to competitive products.

18.2 the device should weigh no more than 300g, this is based on competitive products and the ability to maintain the device in a held position during testing.

Cross References	
1 - Aesthetics	3- Customer / Market
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17 – Shipping and Storage	

19. Timescale

19.1 The exact timings are to be determined once the design and complexities are established, however there is a sequence to which the steps of the process are to be completed. See diagram below:

Assessment B – Design Brief

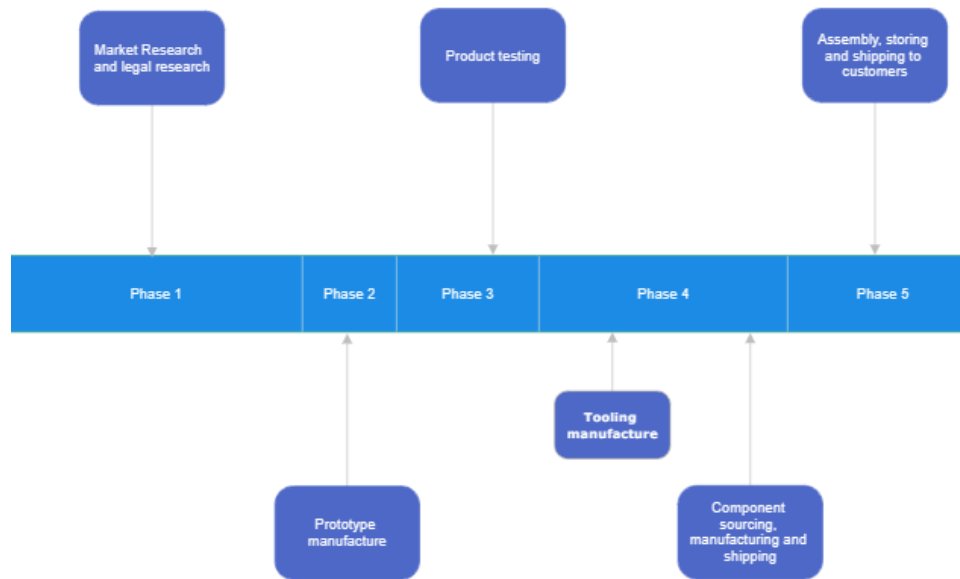


Figure 7 Project process steps

Cross References	
3 – Customer / Market	7 – Legal / Patent
10 – Materials	14 – Product costs
15 - Prototyping	16 – Safety, Standards and Compliance testing
17 – Shipping and Storage	

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