

BREATHALYSER NEW PRODUCT DEVELOPMENT

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NEW PRODUCT BRIEF GUIDELINE

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VERSION HISTORY

Version	Revised By	Date of Revision	Approved by	Approval Date	Description
1	Maria Shipman	27/10/2022			Initial brief created

PROJECT BACKGROUND AND DESCRIPTION

i The Company has identified a potentially large personal market in France and Germany where it is becoming a legal requirement for all drivers to have a such a breathalyser as part of their mandatory safety equipment (*Jarvis, 2020*)(e.g., 'gilet jaune', red warning triangle etc.) to be carried in each vehicle.

The research team identified that the French and German markets would need more stock due to laws changing and it is becoming a legal requirement for drivers to have mandatory safety equipment in each vehicle. Furthermore, with drink-driving on the rise, potential customers are choosing to invest in breathalyser systems to keep themselves, and those around them, safe.

A secondary potential market has been uncovered with the outbreak of the COVID-19 pandemic. Rapid sample testing became mandatory in almost every country and with the added complexity of mutating viruses, a self-testing device that could pick up all strains could have a great impact on global safety and health as well as be lucrative for the company.

A knowledge-transfer partnership has also identified that this breathalyser machine could be used to detect organic substances in a person's breath which will then alert the user of possible viruses and other illnesses. Due to the coronavirus pandemic from 2020 to 2021, the potential market for detecting organic particles that can travel through water vapour in the breath, enabling the identification of viruses and bacterial infections and other illnesses has never been greater.

Due to the company never having worked in the medical breath test field, a new product design is required, along with rigorous and complicated testing. This brief will set out all legislation to be considered and followed.

This is a live document that will outline the manufacturing and rollout of a new breathalyser for the medical market. It will outline the development and adaptations needed to transform the ABV testing breathalyser into a medical device.

The company has developed a successful prototype, with different variations of capability and price range in comparison to its ABV traditional tester. This document will give focus on the aesthetic feel and functionality of the breathalyser to test if it is fit for purpose and maintains the high standards of products that have come before.

1. Design

- 1.1. Material
 - 1.1.1. Plastics
 - 1.1.2. Carbon
 - 1.1.3. Aluminum
- 1.2. Silhouette
 - 1.2.1. Consistent form between other model's companies provides (please see figure 1)
- 1.3. Controls
 - 1.3.1. Soft touch buttons
 - 1.3.2. Touchscreen screen
 - 1.3.3. Controlled via APP
 - 1.3.3.1. Software compatibility
 - 1.3.3.2. Ease of use for all age demographics
 - 1.3.3.3. Access to app for all social and economic sectors



Figure 1 CAD mockup of breathalyser

- 1.4. Finish
 - 1.4.1. Smooth/ polished
 - 1.4.2. Matte/ easy grip
- 1.5. Weight
- 1.6. Colour
 - 1.6.1. Branding
- 1.7. Cost to environment
 - 1.7.1. Disposable breath sampling tubes
 - 1.7.2. Biodegradable breath sampling tubes
- 1.8. Energy adaptation
 - 1.8.1. Compatible charging points
 - 1.8.2. Charging points
 - 1.8.3. Charge/ battery life
- 1.9. Electrics
- 1.10. Weight
- 1.11. Audio
 - 1.11.1. Audio for battery levels
 - 1.11.2. Audio for setting selection
- 1.12. Cost per unit
- 1.13. Distinction from competitors
 - 1.13.1. Branding
- 1.14. Is there further outreach?

2. Circular economy

- 2.1. Life span of the product
 - 2.1.1. Expected usage time frame
 - 2.1.2. Returns and spare parts
 - 2.1.3. Storage implications and life span
- 2.2. Materials used are recycled plastics
 - 2.2.1. Recycling of product available
 - 2.2.2. Recycling of batteries if used
- 2.3. Supply chain ethics
 - 2.3.1. Suppliers' values towards sustainability
 - 2.3.2. Quality of parts outsourced
- 2.4. Safe waste disposal
 - 2.4.1. Following regulations for a different part of the product
 - 2.4.1.1. Solvents
 - 2.4.1.2. Electrical
 - 2.4.1.3. Plastic
 - 2.4.1.4. Batteries

3. Legislation, Legal and political

- 3.1. Medical
 - 3.1.1. EN approval (Shelburne, 2022)
 - 3.1.2. CEN (CEN, 2022)
 - 3.1.3. CENELEC (CENELEC, 2014)
 - 3.1.4. ETSI (ETSI, 2008)
 - 3.1.4.1. Qualifying medical boards for EU
 - 3.1.4.2. Quality management for required regulations– ISO 13485: 2016 (ISO, 2016)
 - 3.1.4.3. Risk management for required
 - 3.1.4.4. Qualifying medical boards for the UK
 - 3.1.5. Medical performance testing
 - 3.1.5.1. Post-market market monitoring and surveillance testing
 - 3.1.6. Medical Registration
- 3.2. Intellectual property
 - 3.2.1. Trademarks (GOV, 2012)
 - 3.2.2. Copyright (GOV, 2022)
 - 3.2.3. Registration of product
 - 3.2.4. Product liabilities
 - 3.2.5. Patents
- 3.3. Software regulations
 - 3.3.1. Data protection (GOV, 2018)
 - 3.3.2. GDPR (Intersoft, 2018)
- 3.4. Electrical legislation (GOV, 2016)
 - 3.4.1. Electrical testing tolerances
- 3.5. Solvent's legislation (HSE, 2014)
- 3.6. Battery legislation (GOV, 2015)
- 3.7. Customs (gov, 2021)
 - 3.7.1. Border tariffs
 - 3.7.2. Could differ for region and countries
 - 3.7.3. Implications of Brexit (rapidly evolving custom requirements)

4. Technical and Market testing

- 4.1. Testing tolerance
 - 4.1.1. Pass and failure rates
- 4.2. Travel guidelines
- 4.3. Product testing on focus groups

5. Social and cultural implications

- 5.1. Potential to be rolled out to underdeveloped countries where medical help and advice is scarce
 - 5.1.1. Specific pricing for underdeveloped countries
 - 5.1.2. Cost implications swallowed by the company to provide for underdeveloped countries and to create fair pricing
 - 5.1.3. Medical attention and aftercare access for underdeveloped countries.
 - 5.1.4. Market stability between regions and countries
- 5.2. Manufacturing staff within the UK and outsourced globally
 - 5.2.1. Labour cost
 - 5.2.2. Time
 - 5.2.3. working conditions
 - 5.2.4. jobs creation for local communities
- 5.3. Legal tolerances for alcohol differ between regions and countries
- 5.4. Consumer differentiations and buying habits between regions and countries

6. Marketing and branding

- 6.1. Website
- 6.2. Social media
 - 6.2.1. Twitter
 - 6.2.2. Facebook
 - 6.2.3. Instagram
 - 6.2.4. Tik Tok
 - 6.2.5. Reddit
- 6.3. Advertising campaign
 - 6.3.1. Television adverts
 - 6.3.2. Sponsored internet searches
 - 6.3.3. Radio adverts
- 6.4. Consistent branding
 - 6.4.1. Colour
 - 6.4.2. Logo
 - 6.4.3. Packaging (please refer to figure 2)
 - 6.4.3.1. Sustainable
 - 6.4.3.2. Educational
 - 6.4.3.3. On brand
- 6.5. Educational marketing
 - 6.5.1. Demonstrations
 - 6.5.2. Tradeshow
 - 6.5.2.1. Medical
 - 6.5.2.2. Dental
 - 6.5.2.3. Alcohol
 - 6.5.3. Personal relations
 - 6.5.3.1. Market research
 - 6.5.3.2. Consumer surveys



Figure 2 Sample packaging

7. Funding, Grants and Loan

- 7.1. Grants
 - 7.1.1. Medical grants
 - 7.1.2. Dental grants
 - 7.1.3. Research and development grants
 - 7.1.3.1. Knowledge transfer partnerships (KTP, 2022)
 - 7.1.3.2. Kes students
- 7.2. Loans

8. Effected departments

- 8.1. Directors and project managers
 - 8.1.1. Decision making
 - 8.1.2. Market readiness
 - 8.1.3. Market competitors
 - 8.1.4. Unit Costing
 - 8.1.5. Competitiveness within the market and sector
- 8.2. Logistics
 - 8.2.1. Time scale of parts coming into the company
 - 8.2.2. Time scale of parts finished
 - 8.2.3. Time scale of orders being shipped/ part shipped
 - 8.2.4. Communications to all departments to
- 8.3. Manufacturing
 - 8.3.1. Manufacturing completed/ part completed in house
 - 8.3.2. Quality assessing and testing breathalyser
 - 8.3.3. Prototyping and testing
- 8.4. Marketing
 - 8.4.1. Educating the customer
- 8.5. Sales
 - 8.5.1. Communicating with the target audience
 - 8.5.2. Customer service and aftercare
- 8.6. Research and development
 - 8.6.1. Continued research and development to expand the product range
 - 8.6.2. Continued product testing to broaden product capabilities

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