



CDS BREATHALYSER

Design Brief

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Design Brief Summary Sheet

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1. OUR COMPANY

With our headquarters in Carmarthen, UK, Powys Laboratories Limited is a company invested in bringing safe, portable and accurate electronic breathalysers, and is proud of being one of the leading providers of this technology worldwide, with the police and security forces being our main clients. Operational since 1998, Powys Laboratories Limited has also been fully engaged with the well-being of our community in Carmarthen and has been involved in several health campaigns in the area and across Wales. Our mission is to have a safer world with the aid of technology.

Our bespoke technology is the result of more than two decades of research and collaborations with local universities. We have engaged with governmental institutions to make sure our screening instruments are of the highest standards. This has taken us to be the pioneers on the technology behind digital breathalysers for alcohol analysis.

Our technology has been used for several research projects in different universities across Wales, including several PhD theses in the medical sector. Our firm has also been involved in knowledge transfer partnerships, making innovation one of our main tools for growth.

2. OUR CURRENT MARKET

Our current market is heavily dominated by the police and security forces. We are proud to be the number one company of electronic breathalysers in the UK with the Home Office being our main client. Our top-of-the-market electronic breathalysers provide accurate measurements on alcohol levels in people. These measurements indicate great performance when comparing to studies diagnosing the accuracy of alcohol breathalysers (e.g. Ashdown et al., 2014). Our company also has strong presence in Europe, and we have also entered the market in the US and Canada with excellent performance over the past two financial years.

3. OUR FUTURE MARKET

The pandemic experienced from 2020 has strongly compromised many aspects of our society such as healthcare systems, social life and economy, and has shown how vulnerable our societies can be to outbursts of diseases. As a result of this global outbreak of SARS-CoV-2 (Covid 19), the governments have had to implement a whole series of procedures and protocols for detection of this virus and prevention of contracting it. Among those, the current mechanism used for testing if a person has contracted this virus is by obtaining a sample of mucus or saliva with a swab either from inside the nostrils or at the back of the throat. This invasive method has proven to be extremely discomforting for the patient. Hence, a lot of research focusing on the detection of SARS-CoV-2 has been taking place over the past two years (e.g. Giovanninni et al., 2021). Moreover, research involving the detection of different breath-transmitted diseases using breathalysers has been ongoing since before the Covid-19 pandemic (e.g. Krisher et al., 2014).

As pioneers in the technology behind electronic breathalysers, Powys Laboratories have been closely monitoring the ongoing research in this field and have also been involved in several studies on this matter. As a result, we have now prototyped a new chemical detection system (CDS) able to detect, via breath analysis, the presence of different diseases such as SARS-CoV-2 and pneumonia. The system has been successfully tested in the laboratory and all the patents have been registered. This opportunity will open the doors to a completely new market share that corresponds to the medical sector. In addition, a business we can be in is the use of our device as a personal piece of equipment that will provide a piece of mind to individuals by accessible and instant tests for breath-transmitted diseases. We see ourselves gaining strong presence in the market of developing countries where a need of early, accessible and affordable disease detection plays a major role in the well-being of the society.

4. SELLING PROPOSITION

We could be *breaths away* from the next pandemic. Our selling proposition is therefore that we can help having a safer world and preventing outbreaks of

respiratory diseases by the use of our technology and aid authorities to have data-driven decisions.

A London-based company has been approached to design physical container of the electronic and mechanical systems which form our new product. This design brief will provide guidelines on aspects to consider when designing the device.

5. AESTHETICS

5.1. SIZE

- A suggested dimensions of the device are 210mm x 75mm x 45mm to follow with our line of breathalysers. This has been proven to be a standard size for all types of hands. A variation of $\pm 2\%$ of this size should be permitted for fitting components inside or to reduce costs. Changes beyond these margins will need to be discussed and approved by the Board.
- Size of packaging should be kept to the allowed minimum without compromising on the integrity of the device when shipped/stored (see *8.2. Packaging* for more details).

5.2. SHAPE

- The shape of the device must be suitable for both left-handed and right-handed people.
- Grooves for fingers placement must be included on the edges of the device for ergonomics and to provide a better grip.
- The grip must allow holding the device in both directions so self-testing and testing someone else feels equally comfortable.
- The piece where the mouthpieces go must be compatible with our current mouthpieces that follow an “easy fit” design. This will enable correct placement and consistency with our additional line of products.
- Mouthpiece should be placed at the top of the device.

5.3. WEIGHT

- The device should not exceed 325g (including battery).
- The weight of the packaging must be kept to a minimum without compromising the safety of the equipment.
- It is expected that a total of the device and packaging should not exceed 600g.

5.4. COLOUR

- The colour pallet must be light greys and white, with the main colours to be used being (branding colours):
 - RGB: 247, 250, 248
 - RGB: 192, 196, 193
- Additional colours may be used but a medical look must be kept.
- Packaging and accessories must follow the same pallet of colours.

5.5. MATERIALS

- Use of polymer sourced from at least 30% recycled material is preferable to follow the green practices of the firm.
- Fire retardant properties must be considered.

5.6. DISPLAY

- The size of the display should be on the range of 15 cm to allow displaying of measurements and messages with a font size easily readable.
- Display must include “dark mode” for usage in poor light conditions.
- Avoid use of touchscreen. Use of physical buttons will be required (see below).

5.7. BUTTONS

- Rubber buttons are preferable to operate the device to aid people with sight loss.
- Buttons should be multi-functional. The device must not have more than three buttons.
- Each button must have a different raised pattern to aid visually impaired users.
- The buttons must be colour-coded for easy user guide instructions and operation.

5.8. LIGHTS

- Different indication lights must be implemented for when the device is powered on, running a test, and getting an error (e.g. green, blue, red respectively). These lights can be either as part of the buttons or on the side of the device.

5.9. BATTERY

- The device must operate with a removable battery.
- A charger needs to be included for charging the battery externally (i.e. removed from the device). This will allow continuous operation of the device by using a spare battery.
- The battery must be of high capacity to last long hours of operation.
- The Battery must withstand operational temperatures of -5°C to up to 45°C when operational.
- The battery and charger must be equipped with *fast charging* technology.

6. SAFETY & QUALITY

6.1. SAFETY

- The device must support operational temperatures between -5°C and 45°C without compromising the accuracy of the measurement the integrity of its functionality.
- In case of malfunction due to high temperatures/low temperatures, or problems with the electricals, the device must emit a warning sound and display a warning message before automatically shutting down.
- A “cool-down” period must be considered when getting an error and before the device can be turned back on.
- It must tolerate storage temperatures between -10°C and 45°C.
- Fire retardant materials should be considered for the carrying pouches (*see accessories*).

6.2. QUALITY

- The electronic parts used must be on the top end of their line. The parts will be sourced from either China or Malaysia (electronics department manager to provide input/insights).
- Moulded parts will potentially be sourced from the UK to closely verify the quality of the product.
- The device must be hermetic to protect against contamination from water and dust coming inside the electronic components. A minimum of IP54 is desirable.
- A 1-year warranty must be provided for all the parts.

6.3. RELIABILITY

- The accuracy of results must be on the high end of the ones published by Ashdown et al. (2014).
- The sensor type to be implemented must be an electrochemical fuel cell as this technology as proven to be very reliable in our other devices.
- The measuring range must cover from 0.0 to 3.0mg/L BrAC.

- The device must provide accurate measurements on an operating humidity range of 20 to 95% (non-condensing).
- The device should provide reliable results without any calibration for 6 months. A calibration adjustment is required after 6 months. If checked regularly with dry gas, a 12-months calibration cycle should be acceptable.
- A message for recalibration must be shown in the display every 6 months.

6.4. REGULATIONS

- For the UK market, the device must comply with the Medical Devices Regulation issued by the British government (MHRA, 2002).
- Likewise, the EU Medical Devices Regulation must be followed (European Medicines Agency, 2017).
- The device must comply regulations to operate in areas such as intensive care and emergency rooms.
- Additional regulations on marketing authorisations and licensing in the UK need to be followed (Medicine and Healthcare products Regulatory Agency, 2022).
- Legal team to advice on regulations outside the UK and EU.
- The calibration equipment must follow the approved design standards and specifications for pressurised fluids (Health and Safety Executive, 2005).

6.5. PERFORMANCE & USAGE

- The device must provide highly accurate results on all tests providing they have been performed in the correct form. For the expected accuracy of results see Ashdown et al. (2014).
- If the blow/sample is not enough, the device must emit a sound and a message for an additional take.
- An alert (sound/message) must be given to the user if the mouthpiece has not been placed properly.
- Processing and analysis of the blow/sample must not take more than 15 seconds.
- The device must be able to operate for continuous hours without presenting any issues with readings or temperature.

- If inactive for approximately 1:00 minute, the device must switch to standby mode to increase battery life.

6.6. SHELF LIFE AND STORAGE

- The shelf life of the device will be conditioned by the electrochemical fuel cell. This is estimated to be three years.
- The aim for the lifespan on an operational device is around eight years.
- Advice on frequency of battery replacement needs to be provided in the user manual and as a message in the display.

6.7. EXTRAS

- The device must be equipped with Wi-Fi and Bluetooth connection technology.
- The Wi-Fi technology must be able to triangulate the geo-location of the device with an option to include this in the printout of the results. Addition of GPS technology can be also considered depending on costs.
- Cloud-based storage provided.
- Subscription to online dashboards for visualisations on results, trends and performance should be considered.
- Additional services such as subscription to virtual support and advice from health specialists must be explored.

6.8. ACCESSORIES

- A lanyard must be included for holding the device around the neck if freeing up the hands of the user is required.
- Pouches must need to be designed to provide additional instrument protection. The pouch should be branded with the company logo.
- The mouthpieces must follow the standard design used in our line of breathalysers. These must be of white colour for consistency with the device and to provide a clinical look. The material used must be source

from at least 30% recycled material and must be fully recyclable when disposed.

- Calibration equipment in the form of gas cannisters must be made available. These cylinders cannot exceed a volume of 200cm³ of fluid.
- A portable printer kit with Bluetooth connexion must be designed to allow printing results more efficiently, especially if the tests are being performed in remote areas.
- A protective instrument case for carrying the device and all the additional instrument accessories (e.g. charger, spare battery, calibration equipment). Each of these components must have a designated space in the case. They must fit tightly to avoid becoming loose during transportation.
- Additional charger for connecting the device to the 12V outlet of a car must be included. This should be handy for customers such as policemen as the device can be charged in their vehicles while on shift.

7. COMMERCIAL

7.1. BRANDING

- The logo of the company must be added to the device in a visible spot.
- The logo should not be too big to provide a stylish look to the device. A grooved logo should be considered.
- The company logo and website must be displayed in the device screen when being turned on and off.
- Additional information (e.g. model reference) must be included.
- The packaging must follow the medical-oriented design and must match the pallet of colours used in the device.
- The packaging must also contain a clearly visible company logo and website.
- A product website page must include all the relevant information of the device (e.g. technical specifications) and should also display clear links to where to order accessories from.
- Customer feedback forms must be included in the website.
- Advertisement campaigns to be run in social media and relevant institutions (e.g. NHS).

7.2. CUSTOMERS

- Our main customers are expected to be from the medical sector:
 - General practitioners
 - Nurses
 - Surgeons
- Police and the Home Office
- Other personnel involved in field medical campaigns will be potential customers.
- Personnel from care homes.
- Airport security
- General security
- Personnel involved in logistics and security of public events such as concerts.
- Institutions such as the World Health Organisation can be potential customers interested in the geo-data and results obtained from our device as it will be equipped with the geo-location technology. A subscription approach to dashboards showing areas of spread or concern could be a model to consider.
- Although on a lesser extent, we also aim to release our device to the general public. It's expected that elderly people will be the main target when marketing our product.

7.3. MARKET CONSTRAINTS

- Supply chain disruption due to current geo-political problems in Europe.
- Increasing costs of transportation due to higher costs of fuel.
- Constrains on exporting to other countries (Kneller, 2013; UK Parliament, 2021).
- PESTLE analysis required for specific countries/regions where we aim to introduce our product (e.g., Southeast Asia and South America).

7.4. COMPANY CONSTRAINTS

- The size of the current facilities could be an issue for storage.

- Dependency on electronic components from China or Malaysia could create disruptions in producing our devices if local problems arise
- Financial risk on expanding our presence into Asian and South American markets must be closely monitored.

7.5. COMPETITION

- Lion Laboratories are expected to be the main competitors in the UK.
- Market intelligence campaigns must be carried out in other regions to gauge competition and evaluate the best approach to have a strong presence in the market.

7.6. SOCIAL AND CULTURAL

- Variable requirements for testing SARS-CoV-2 on different countries.
- Travel restrictions.
- Areas more prone to have outbreaks of breathing-related diseases (e.g. pneumonia with India, China and Pakistan being the main countries) (Rudan et al., 2008).
- Developing countries with areas of malnutrition.
- Culture of health monitoring and self-testing.

7.7. PRODUCT COST

- Finance department to run financial appraisals and modelling to provide a cap for the cost of manufacturing the device. Re-evaluation from the board will be required if costs of manufacturing are higher.
- Market price to be provided by the finance department following financial modelling.
- As the aim is to also release the device in other areas outside Europe, local markets must be taken into account when setting the price on each region, so we do not price ourselves out. Finance will advise on this specially by considering data from the Profitability Index, Internal Rate of Return and Benefit-Cost ratio.

7.8. PROTOTYPE

- The prototype should be able to provide the expected accuracy of the final product.
- Must be able to be used to obtain certifications on the different regulations and standards.
- Logo, lights, side ergonomics and different user-specific alerts not required in the prototype.
- Prototype should include the packaging expected to be used when put on the market.

8. SHIPPING MANUFACTURING AND REPAIR

8.1. MANUFACTURING FACILITIES

- Electronics and mechanical parts to be shipped from China or Malaysia.
- Casts and moulds to be likely sourced from the UK.
- Bar/QR code scanners coupled with conveyor belts for automatic sorting of the different components is suggested. This will increase efficiencies when assembling and storing the items.
- Additional manufacturing facilities in Asia and South America to be considered if this reduces costs of shipping and assembly. This without compromising the quality and accuracy of the product.
- Open space facilities are recommended.
- Clear access to lorries must be guaranteed to avoid problems with the delivery of parts and shipment.
- The manufacturing facilities must be accredited with ISO 14001 and 45001.

8.2. PACKAGING

- Recycled and recyclable cardboard must be used for packaging.
- Used plastic must be from at least 30% recycled material.
- The device must go inside a protective plastic mould to prevent or minimize de-calibration in case of impact when in transport.

- Plastic film to be placed in the display to prevent scratches.

8.3. SHIPPING

- Electronic components from China and/or Malaysia to be shipped via sea freight. This to reduce costs and CO2 footprint.
- Shipment to customers via ground freight (UK and Europe) and sea freight to other regions outside EU.
- Air freight to be considered if short turnaround is requested by the client. A premium delivery fee should be charged to the client to cover the additional costs.

8.4. REPAIR AND MAINTENANCE

- Basic maintenance instructions (e.g. cleaning, calibration) must be included in the user manual.
- Additional instructional videos for troubleshooting and care must be added to the website.
- Repairs must be carried out at our facilities (or authorized suppliers) to guarantee that the device is up to standards after repairment.
- Any signs of hampered devices should void the warranty.

9. LEGAL ASPECTS

9.1. STANDARDS & SPECIFICATIONS

- The device must comply with ISO 13485 (Medical Device Standards) (International Standardization Organization, 2016).
- The results must be within the highest standards provided by Ashdown et al. (2014).
- All providers must comply to ISO 9001, 14001 and 45001.

9.2. POLITICS

- Internal politics on countries outside EU may affect the shipment and commercialization of the device.
- Specific regulations for medical devices may apply in markets outside the UK/EU. Legal team to provide insights on these topics.

9.3. INTELLECTUAL PROPERTY

- All the intellectual property behind the design and operation of the device must belong to Powys Laboratories Limited.
- Results obtained from analyses using our device, including dashboards and geo-tagged data can be used for scientific purposes providing the appropriate credit to Powys Laboratories Limited is given.
- Any other commercial product or process derived from data generated using our dashboards or geo-tagged shall not be carried out without the consent of Powys Laboratories Limited. In special cases, this can be allowed but should incur a fee payment.

10. CIRCULAR ECONOMY & ENVIRONMENT

- Partnerships with companies implementing circular economy on batteries and electronics must be explored.
- Appropriate disposal information must be provided in the user manual.
- Points of collection for unused devices can be placed on hospitals and major electronics shops.
- As mentioned before packaging most consist of recycled and recyclable cardboard and plastics off at least 30% of recycled materials.
- Powys Laboratories limited is fully committed on reducing the carbon footprint of all our products, and therefore air freight must be avoided if possible.

11. USER INTERFACE

- The display must indicate the different steps for running a test.
- Option for changing brightness of backlight must be included.
- Option for changing the language of the interface must also be included.
- Font size should be allowed to be changed to aid people with sight problems (e.g. elderly).
- Icons for low battery etc. must be clearly visible.
- Links to videos of how to operate the device can be included in the user manual.

12. TIMESCALE

- Aim to launch the device before winter 2023.
- The general Gantt chart below will provide expected timeframe on the main components:

Main Milestones	Months											
	1	2	3	4	5	6	7	8	9	10	11	12
Electronics approval												
Other components approval												
components shipment for prototype												
Prototype manufacture												
Prototype testing and approval												
Certifications and legal aspects												
Initiation of production												
Marketing campaign												
Product launch												

13. BIBLIOGRAPHY

Ashdown H.F., Fleming, S., Spencer, E.A., Thompson, M.J., Stevens, R. (2014) *Diagnostic accuracy study of three alcohol breathalysers marketed for sale to the public*, BMJ Open, 4. doi: 10.1136/bmjopen-2014-005811

European Medicines Agency (2017), *medical devices regulation*. Available at: <https://www.ema.europa.eu/en/human-regulatory/overview/medical-devices>. Accessed on 14/09/2022

Giovannini, G., Haick, H., Garoli, D. (2021) *Detecting COVID-19 from Breath: A Game Changer for a Big Challenge*, ACS Sensors, 6(4), pp. 1408-1417. doi: 10.1021/acssensors.1c00312

Health and Safety Executive (2005). *Approved design standards and specifications*. Available at: <https://www.hse.gov.uk/cdg/stdcurr.htm>. Accessed on 15/09/2022.

International Standardization Organization (2016). *Medical Device Standards*. Available at <https://www.iso.org/iso-13485-medical-devices.html> Accessed on 18/09/2022.

Kneller, R. (2013) *What are the constraints on potential UK exporters? future of manufacturing project: Evidence paper 17*. Government Office for Science. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/283891/ep17-uk-exporters-potential-constraints.pdf. Accessed on 17/09/2022.

Krisher, S., Riley, A., Mehta, K. (2014) *Designing breathalyser technology for the developing world: how a single breath can fight the double disease burden*, Journal of Medical Engineering & Technology, 38(3), pp. 156-163, doi: 10.3109/03091902.2014.890678

Medicines and healthcare products regulatory agency (2002), *Medical devices regulation*. Available at:

<https://www.legislation.gov.uk/ukxi/2002/618/contents/made>, accessed on 14/09/2022

Medicines and Healthcare Regulatory Agency (2022).

<https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>. Accessed on 15/09/2022

Rudan, I., Boschi-Pinto, C., Biloglav, Z., Mulholland, K., Campbell, H. (2008) *Epidemiology and etiology of childhood pneumonia*, Bulletin of the World Health Organization, 86 (5), pp. 408–416. doi:10.2471/BLT.07.048769. PMC 2647437. PMID 18545744.

UK Parliament (2021) *Trade in goods significantly harder under Brexit deal*. Available at <https://committees.parliament.uk/committee/445/eu-goods-subcommittee/news/153116/trade-in-goods-significantly-harder-under-brexit-deal/> Accessed on 17/09/2022