

NPD product brief

Viral testing device

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Aesthetics

(See also user experience / interaction, company constraints)

- The device should align with the existing company products, matching the style to create a 'family' of products.
- However should be sufficiently different so as not to confuse it with the existing alcohol only device.
- The parts which the user must to interact with should be obvious through the use of semiotics to ensure a good User experience/ Interaction (UX/ UI).

Installation

- The device is to be portable and handheld, therefore installation is only applicable to a potential changer.
- Parallel products use AA batteries or charge using desk or wall mounted chargers.

Training

- Minimal training for the operative, ideally an image based instruction manual
- Training resources will be available for those in a more technical role

Performance

- The device must provide a result reading from the breath test in under 1 minute.
- It's battery life should be a minimum of 8 hours.
- It should function independent of a WIFI or internet network connection.
- Withstand cyclical loading of 100s of changes to the breath sample chamber in a single day
- The accuracy must comply fully with DOT model specification for evidential breath testing devices (EBTs).

Safety

(See installation, training)

- Should not cause cross contamination between users.
- Must be no risk of electric shock,
- Should minimise the risk of repetitive strain injury (RSI) caused to the operator.

Branding

(See Company constraints)

- the device should clearly be identified as a Lion Laboratories device.
- Focusing on accurate reliable readings.
- It is a durable device that can be used in the field.
- Public and private sector use, professionals who are involved in public safety
- It should be positioned as a key device in assisting with reducing the spread of a pandemic.

Intellectual property

- Patent application has been submitted using the bench prototype.
- there is potential for the device names could be trademarked.
- a patent search needs to be completed for the competitor products.

Politics

(See also *Legal*)

- Government guidance for the countries that the device is to be sold in should be monitored for changes and updates.
- currently there are no mandates in place for monitoring for COVID.

Size

(See aesthetics, ergonomics, manufacturing, materials)

- Must be single handed use. (210mm x 75mm x 45mm) approx.
- Must enclose circuit board (dims required).
- Must incorporate breath sample capture system. (Dims required)

Company Constraints

(See performance, aesthetics, branding)

- Assembly will be completed in house (Welshpool), with parts shipped from external suppliers that meet the correct requirements.
- The product must meet the minimum test requirements which will be conducted during quality control at Welsh pool
- The product will be packed using the existing methods for protection and delivery
- Shipping will increase to become worldwide, initial shipments will be UK and EU.

Legal

Medical device legislation

In Vitro Diagnostic Medical Devices Directive 98/79/EC.

- part 4 of the Medical Devices Regulations 2002, other than solely by virtue of regulation 39(2) approved under the Coronavirus Test Device Approvals (CTDA) legislation or listed on the protocol.
- Medical Devices Regulations 2002 (SI 2002 No 618, as amended) in relation to in vitro diagnostic medical devices
- The Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021

Marks,

- UKCA - for UK markets
- CE - for rest of world
- Portable electronics regulations - varies by country
- Medical equipment regulations - see table 1 for guidance
- ETSI EN 303 645 - Cyber Security for Consumer Internet of Things: Baseline Requirements
- It must pass bluetooth qualification
- The product must meet Waste Electrical and Electronic Equipment Regulations 2013
- BPA free plastic for mouth piece

Table 2. Tools and general requirements of the five members of the GHTF

COUNTRY/REGION	PRE-MARKET	PLACING ON-MARKET		POST MARKET
	Product control Tools for acknowledging product cleared for the market	Medical device establishment control	Advertising control	Vendor after-sale obligations Examples of common requirements
Australia*	ARTG number	Enterprise Identification (ENTID)	Generally, prohibition of advertisement before a device is cleared to enter the market. Prohibition of any misleading or fraudulent advertisement	1. Problem reporting 2. Implant registration 3. Distribution records 4. Recall procedure 5. Complaint handling
Canada	Device licence	Establishment licence		
European Union	Compliance label (CE mark)	Responsible person registration		
Japan**	Shounin (approval) or Todokede (notification)	Seizo-Gyo (Manufacturer Licence) Yunyu Hanbai-Gyo (Import Licence) Hanbai Todoke (Sales notification)		
United States of America	Approval Letter (PMA) or Marketing Clearance (510k)	Establishment registration		

* Australia's new medical devices legislation was passed by the Australian Parliament in April 2002 (see www.health.gov.au/tga/)
 ** Japan's PAL (Pharmaceutical Administration Law) revision is scheduled for 2005.

TABLE 1 MEDICAL DEVICE REGULATIONS: GLOBAL OVERVIEW AND GUIDING PRINCIPLES (2003) WORLD HEALTH ORGANIZATION. AVAILABLE AT: [HTTPS://FCTC.WHO.INT/PUBLICATIONS/I/ITEM/9241546182](https://fctc.who.int/publications/i/item/9241546182) (ACCESSED: 25 AUGUST 2023).

Competitors

Device	Image	URL
Inspect IR	 A black Pelican hard-shell case with a handle. The lid is open, revealing a device with a screen and a keyboard. The screen displays the 'INSPECT IR' logo and some text. The device is labeled 'INSPECT IR' and 'PELICAN'.	https://inspect-ir.com/
Canary Breath Detect CV19	 A black, rectangular device with a silver-colored top section. It has a small screen and several buttons. The word 'canary' is printed vertically on the side. It is shown next to a silver-colored mounting bracket.	https://www.canarydetect.com/about
Breathonix breathalyzer	 A breathalyzer system consisting of a black and silver base unit, a white sensor probe on a stand, and a computer monitor on a black stand displaying a graph. The base unit has a small screen and buttons.	https://breathonix.com/wp-content/uploads/2023/01/Breathonix-BreFence-GO-Testing-Station.pdf
SpiroNose	 A white, cylindrical device with a large circular opening at one end and several smaller circular openings along its side. It is shown against a teal background.	www.breathomix.com/spironose-2/

Device	Image	URL
Sotech		https://www.sotechhealth.com/
Breath Pass		https://dsa.fi/dsa-breathpass
ETL Corona Check		https://exhalationtechnology.com/etl-coronacheck/

Processes

(See company constraints, manufacturing facilities)

- Injection moulded parts are to be outsourced, the suppliers are to be selected. Appropriate quality controls will need to be agreed and in place.
- Printed Circuit board (PCB) parts to be manufactured by a supplier. The suppliers are to be selected, Appropriate quality controls will need to be agreed and in place.
- The final assembly of the product will take place at Welshpool. Including final testing and certification.
- The packaging for the product must provide sufficient protection for international shipping. It must minimise waste. It should be fully recyclable and made from recycled content.

Product

(See aesthetics, training, size, performance, safety, installation)

- The product will be used multiple times per day, with a high number of users. The operators will be trained in the correct use.
- The breath capture system cannot be used by more than one user, as this will cause cross contamination. So will need to be removable.
- When the product has reached the end of its service life it should be returned to us for re-manufacture. And must meet WEEE regulations.
- The device could have a removable battery to allow for longer periods in the 'field' I.e. 2 x AA alkaline batteries

Shelf life and storage

- The shelf life needs to be a minimum of 2 years.
- The parts and labour warranty will be 2 years.
- The operating temperature of the product must be -10 to +50 degrees. In humidity 20-95%

Life in Service

(See shelf life and storage, life span, UX/UI)

- The product will be used in a range of situations 'in the field', such as large capacity venues, transport hubs and vehicles.
- Operators may not be using the device every day.
- Operators may be wearing gloves

Prototyping

- Function testing is complete, the final PCB size needs to be confirmed. The critical dimensions must be communicated as soon as practicable.
- Breath sample capture system critical dimensions are required, estimations from existing parts can be used for prototyping.
- Prototyping of device will be managed via a design studio, also design management to be controlled by them until sign off is complete.

Shipping

(See size, processes - packaging, quantity)

Year 1 - 750,000 units shipped,

Year 2 - scaling up to 3,000,000

- The freight partner must be able to deal with international shipping of products. Collecting from the factory at Welshpool, including all the correct documentation for shipping.

- Domestic shipping should be within 2 working days maximum. International shipping within 10 days.

Customer

The initial customer segments have been identified as.

- security type customers i.e. Law Enforcement, venue security staff. (Extension to current market)
- Mass transport operators (train, aeroplane, metro, bus). Operators are expected to be managers, check-in staff. With the purchasing being done by a centralised department
- Small transport operators (taxi, minibus), individuals and small operators that are involved in people transport.

Materials

- a) The injection moulded plastics used in the product body must withstand;
 - strong alcohol based cleaning products
 - the operating temperatures (-10 to +50degrees)
 - daily use in the field

- b) The handle should have tactile grip to improve handling, provide semiotic interaction and reduce potential drops.

- c) The breath sample system parts must be suitable for being used in the mouth, with no negative impact on the user.
 - Where possible the plastics must be recyclable.

Inner electrics

- should be possible for the OEM to disassemble components so that replacement parts can be installed.
- The components should be made from materials that can be easily separated and recycled at the end of life.

Screen

- the impact on planet should guide the selection of the screen.
- LCD screens have proven good reliability and longevity in the past, so should be a good choice.
- It should be illuminated so that the product can be used in low light conditions.

Product Cost

- Final cost including shipping should be less than £350 per unit, to achieve 50% margin. Whilst remaining competitive with the market.
- The system could be sold through a service type model. Where the customer pays monthly for the support, and products required to achieve Covid breath testing, the pricing structure of this is to be confirmed.

Social and Cultural

- Within the UK it is required to meet GDPR rules if the samples are to be captured alongside personal identifiable information. Which is then kept on record.
- Other countries will have similar legislation in place.

Circular Economy

(See also, materials, life in service, shelf life, product, performance, product cost)

- It must be possible to service the product to ensure that it has the longest possible lifespan.
- At the end of life it must be possible to disassemble the product so that the parts can be re-used or recycled.
- A service model for the product will ensure the best possible circular economy performance. As a singular product could have a much longer life, through multiple different contracts.

Manufacturing facilities

(See also, company constraints, processes, standards and specifications)

- Printed circuit board (PCB) manufacturing is to be out sourced, contractors in China or Malaysia have been identified as the best value.
- Injection moulding is to be outsourced to companies in Europe.
- The Welshpool site is to complete final assembly and commissioning tests.
- All contractors / manufacturing sites must have ISO 9001 and 14001 certification. As a minimum.

Product Life Span

(See also service life)

- the product must last a minimum of 2 years in the field (under warranty)
- With the total expected life span to be 5 years minimum

Standards and Specifications

(See also legal,)

- ISO 9001 for product quality, this is required from suppliers as well as the Welshpool factory.
- EN15964 can be used for guidance, however this is based on alcohol testers.
- No clear standards for breath based covid testing however ISO/TS 5798 provides recommendations for the design, development, verification, validation of swab type testing.

Documentation

- there will need to be a user Instruction manual and supporting videos
- Certificate of conformance, and proof of calibration
- throughout the lifespan there will need to be recorded calibrations of the device
- the patent application will require documentation of the design, key characteristics etc.
- A maintenance and repair manual will be required before final product shipping

Market Constraints

(See also Product cost, standards, competitors, performance)

- Competitive retail Price
- Device performance
- Time frame for certified product
- The device will need to meet any certification requires of the country that is to be sold in.

Quality

(See also aesthetics, standards and specifications)

- all sub assemblies must meet tolerances for fitment to surrounding assemblies
- Plastics must be of sufficiently high grade
- Quality checks to be completed at all key milestones during manufacturing

Testing

(See also calibrations, standards and specifications, quality)

- Key subassemblies must have a certificate of conformance based on relevant operational testing
- the device will need to be pass a 2m drop test
- the drives should pass an IP54 immersion test
- if used in hospitals it will need to pass an Electrical interference test

- an initial batch of 20 units will need to be field tested before general release of the product
- If it is fitted with bluetooth it must meet bluetooth test requirements.

Environment

(See also materials, circular economy, life span)

- the Material and component impact on planet must be considered
- the device must meet WEEE disposal guidance (UK) or equivalent in destination country
- the disposable mouth piece must have the correct recycling marking on it.

Maintenance and Repair

(See also documentations, lifespan)

- No user maintenance or repair due to calibration certificates
- Components can be replaced by the OEM
- the General maintenance should aligned with calibration period
- A repair service should be offered through return to base scenario

Quantity

(See also shipping)

- Year 1: 750,000
- Year 2 +: 3,000,000
- Shipped in batches to minimise warehousing required.

Time Scales

(See also quantity, prototyping, legal)

- the bench test is complete, therefore search for new suppliers needs a time limit
- Suppliers need to be found that have 10 week or less lead time
- Development of training material, service network, etc should be run in parallel to reduce the time to market.

Ergonomics

(See also dimensions, materials)

- Hand held - by user / operator
- Clearly Readable screen
- Non-handed
- Less than 350g

User interaction / experience

(See also aesthetics, ergonomics)

- the displayed messages must be clear, with simple interaction to navigate between information screens
- there must be indicative sounds to provide feedback during use
- there should be lights to indicate device status
- Software updates must be kept to a minimum, if updates are needed these should require minimal technical knowledge and be possible for the operator to conduct at their premises.
- It should be possible to change the language to match the country in which the product has been shipped to.

Packaging

(See also environment, circular economy, shipping)

- must provide protection during shipping
- must be of minimal size.
- should have semiotics that align with the product quality.
- Identify each serial number for warehousing
- can be grouped into 'cartons'
- Cartons can be palletised.
- make use of recycled cardboard and plastics, and be recyclable.

Reliability

(See also Performance, life span, product life)

- it will experience multiple uses in quick time frame, so cyclical wear is a concern
- should the device encounter an error it should be possible for an operator to conduct a 'basic' reset.
- the device should run start up self checks, to prevent in-accurate tests.
- batteries should be changeable
- there must be reliable storage of test results which can be backed up
- the device will potentially be stored for a long period,

Weight

- One product - 350g (including batteries) approx.
- One carton - 20Kg max. Due to manual handling
- Pallets should be standard size 800 x 1200mm

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