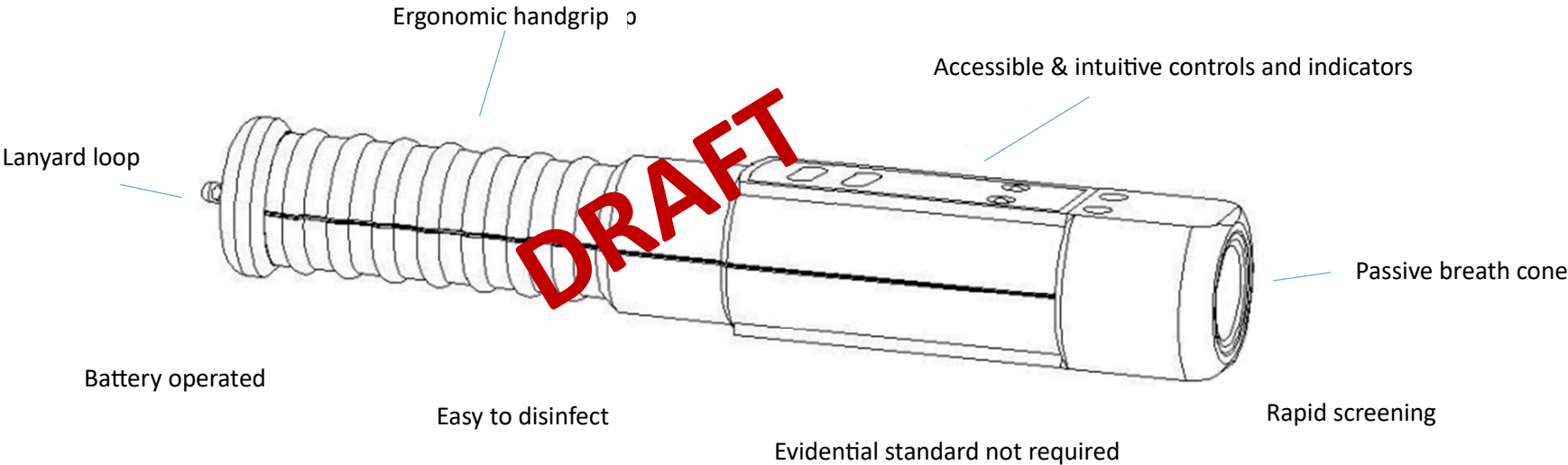


CovBlow

handheld Covid-detecting breath sensor

ID	123/456
Version	1.0
Status	Issued
Date	22/09/2023



Product Owner	Dimensions	Process & materials	Volume	Cost	Launch date
Hannah Verrall	265mm x 48mm x 48mm 300 g including batteries	Case: blow-moulded plastic	Y1: 750,000 units Y2+: 3,000,000 units	Production: £57.50 Retail: £250	TBC

Document overview

This document captures the evolving design for the product. It is intended to:

- Be a living document, with regular updates as the design is developed
- Capture a wide range of information needed by different parts of the business to carry out their responsibilities in relation to the development and launch of the product

The design references the accompanying smartphone application; however, a separate Design Brief will be developed to cover the detail of the application.

Print instructions

This document features a front and back cover, designed to summarise key points of interest for different audiences:

- The front cover summaries the product, including information about the Product Owner
- The back cover summarises information about the current state of the project to launch the product, including status information from the involved parties

WARNING: This document becomes uncontrolled when printed: newer versions may be available in SharePoint.

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Product specifications

Product detailed description

A handheld portable device for use by the public and professionals to test for the presence of Coronavirus. The device can be used in standalone mode or used with the supporting app to share data with wider groups, e.g., in schools or businesses.

The device:

- Provides a pass/fail for virus detection: shows a clear, unambiguous result
- Is simple to use: requires no user training
- Provides rapid, accurate results: quickly gives peace of mind to users, even when testing large groups
- Uses contact-free detection: minimises transmission of the virus or other germs; does not require disposable mouthpieces
- Is similar in concept to the AlcoBlow® Rapid Test, but has higher aesthetic values: it needs to appeal to the wider market
- Is at least small enough to be kept in a handbag or briefcase, ideally small enough to fit in a pocket

The app:

- Records readings over time: users can document consistent absence of the virus (e.g., before coming out of isolation after contracting the virus)
- Allocate readings to different app accounts: one device can be used for multiple people
- Connect with other user accounts: alert registered members of a wider group if the virus is detected, prompting others to re-test
- Uses geo-location functionality on users' phones: can anonymously alert users if they have been in proximity to someone who tests positive, even outside their registered network of users
- Shares anonymous information with medical officials in the jurisdiction: aids detection and response to outbreaks

The device is new to the market, but other companies will no doubt be developing similar devices of their own:

- We need to bring the device to market as soon as possible
- We will need to protect our Intellectual Property and rigorously defend it
- Our marketing campaign should seek to rapidly achieve high saturation in the market, and build a reputation for high quality and accuracy, so that our market position becomes almost unassailable
- The design should be flexible so that we can calibrate it to detect additional variants, and have the potential to evolve to detect other illnesses

Product summary specifications

The device needs to balance portability with perceptions of quality: whilst it is possible to make an extremely lightweight device, this may be perceived as low quality or cheap and undermine the trust in the results.

Size and weight

	Ready for use	With lid/in travel case	In Primary retail packaging
Height	approx. 265mm		
Width	approx. 48mm		
Depth	approx. 48mm		
Weight	approx. 300 g including batteries		

Safety, ergonomic and aesthetic requirements

This is a critical safety device. It must:

- Be easy to hold and operate by the majority of users in the operating age bracket (10-100), including by older children, women and the infirm
 - Shaped to be held easily and comfortably, by hand or in a stand (e.g., similar to a microphone stand, for use when testing large volumes of people)
 - Sized for people with a smaller stature
 - Not require strong grip to hold the device or operate buttons
 - Not require user to perform multiple operations, such as holding two buttons simultaneously
- Be accessible, and therefore use visual, haptic, and audible indicators to confirm pass/fail. Visual indicators must not rely on colour to avoid misinterpretation by people with colour sensing conditions.

In addition, most users will feel that the price of the device is high and will therefore expect a high-quality product. The aesthetics of the device must reflect both the price, and the level of trust the users place in the results.

Market geography

The device will initially be marketed in the UK, but will later be extended into the EU, the United States, and other regions.

Materials

Different materials and production methods will be used during prototyping, test production runs and main production.

	Prototype	Test production run	Production
Casing	3D printed: • Polypropylene (PP) • Polycarbonate (PC) • Acrylonitrile butadiene styrene (ABS)	Low-volume sample of Production casing	Blow-moulded thermoset plastic. TBC, but likely one of: • Fluoropolymer • Polymethylmethacrylate (PMMA) • Polypropylene (PP) • Polycarbonate (PC) • Phenol formaldehyde • Styrene • Acrylonitrile butadiene styrene (ABS) • ABS/polycarbonate blend
Fuel cell	n/a	n/a	Platinum; acid-electrolyte
Circuit board	n/a	n/a	FR4 fire-retardant fibreglass; copper; solder, electronic components
Mouthpiece/sample cone	As casing	As casing	TBC from list above. May be different material to casing.
On/off switch	TBC		
Indicator lights	TBC		
Audible alarm	TBC		
Display screen	Not applicable: LED indicators shows pass/fail. Device can be connected to a smartphone for detailed information		
Bluetooth module/chip	Integrated into the circuit board		
Travel case	TBC		
Cone lid/dust protector	TBC		
Power supply	4x 1.5 V batteries (type LR06, AA)	4x 1.5 V batteries (type LR06, AA)	4x 1.5 V batteries (type LR06, AA)
Labels & surface printing	TBC		

Technical specifications and operating conditions

Name and model	TBC
Software	TBC
Display system	2 Tri-colour LEDs
Power supply	4 batteries 1.5 V (type LR06, AA)
Battery life	~10,000 readings
Expected lifespan	~15 years
Expected failure rate	<2% annual failure rate
Expected warranty returns	<5% annual warranty returns
Accuracy	>99.5% accuracy
Measuring range	TBC
Response time	approx. 5 seconds
Display hold time	2 seconds
Audible alarm	Advises of change in display status
Automatic switch off	2 minutes after the last operation
Device temperature range	Ambient to ambient + 5°C
Operating temperature range	-5°C to +40°C
Storage temperature range	-15°C to +55°C
Humidity	30% to 60% relative humidity (RH)
Water-resistance grading	None
Shock resistance range	Up to 1.2 m
Calibration frequency	Annually for commercial use
Warranty	2 years

Product volumes

Year 0	0 units
Year 1	750,000 units
Year 2	3,000,000 units
Year 3+	3,000,000 units

Production costs

The following cost schedule defines the indicative cost envelope for each activity, based on a retail price of £250 per unit.

Area	Includes	Percentage	Actual
Research and Development (R&D)	- Product Development (design, prototyping, hardware/software development) - Testing (prototype testing, app beta testing, safety evaluations, certifications)	5%	£12.50
Manufacturing	- Components (materials and components) - Labor (assembly process)	23%	£57.50
Packaging	- Materials (packaging materials) - Design (graphic design for packaging)	5%	£12.50
Logistics	- Transportation (freight and shipping) - Warehousing (storage before reaching retailer)	5%	£12.50
Marketing and Sales	- Advertising (promotion and advertising costs) - Public Relations (PR campaigns)	10%	£25.00
Retailer Margin	Retail Margin (retailer's markup for operating costs and profit)	30%	£75.00
Corporate Overheads and	Overheads (corporate overheads and administrative costs)	5%	£12.50
Profits	Profit (company profit margin)	15%	£37.50
After-Sales Service and Warranty	- Customer Service (customer support and service) - Warranty (warranty services)	2%	£5.00
Retail price		100%	£250.00

Detailed requirements and specifications

Safety

The device must protect against:

- Radiation
- Electromagnetic interference
- Electrical shock
- Overheating of the device and/or power source
- Battery leakage
-

Ergonomics and accessibility

- User age range
 - The device will be used by responsible older children and adults: the user age range is 13-100
 - The device may be used with or without an assistant, for example to test younger children
- Overall size and shape
 - Designed for smaller stature (not primarily an adult male) so that it can be used easily by as wide a range of users as possible
 - Curved to fit in the hand in use, either by the user or an assistant (e.g., a parent of a young child)
 - No sharp corners
 - Lightweight for portability, but with sufficient 'heft' to imbue a sense of quality
 - Weight should be balanced when in use: the device must not be top-heavy
- Surface finish
 - Surface finish should continue the sense of quality, as well as provide grip
 - Surface finish must be easy to clean (not a finish that attracts and holds lint, etc.)
 - Surface finish must withstand strong anti-bacterial cleaning fluids, sprays, foams, and wipes
- Buttons
 - Single button operation, for ease of use especially by users at the extremes of the age range or with mobility issues
 - Buttons should have some form of haptic feedback (vibration, click, etc.) when used
 - Buttons should be at least 10mm x 10mm, to ensure users are able to press them easily (not too small)
 - Buttons should be separated by at least 5mm, to ensure that only one button is pressed at a time
 - Buttons should be easy to press, without requiring significant force

- Indicators
 - Indicators should use a variety of feedback methods: visual, audible, and haptic, to ensure that users of all abilities can safely and accurately use the device
 - Visual indicators must not rely on colour to avoid misinterpretation by people with colour sensing conditions such as protanopia, deuteranopia, tritanopia, achromatopsia, protanomaly, deuteranomaly, tritanomaly, or achromatomaly.
 - Visual indicators must be clearly visible in daylight, artificial light and in low light conditions
- Power saving
 - Device will power down after 30 seconds of inactivity to preserve battery power
- Accessories
 - As the device is portable, we should offer an optional protective travel case to minimise physical damage and contamination by dust or water.
 - Some applications may benefit from a 'skin' for the device, to provide additional drop protection and/or alter the colour or grip properties

Device aesthetics

The following table records the aesthetic features of the device and, for reference, two comparable products: the AlcoBlow® Rapid Test and the Lumen keto sensor.

	AlcoBlow® Rapid Test	Lumen	Virus sensor
Whole unit			
Width	approx. 48mm	approx. 42mm	
Height	approx. 265mm	approx. 102mm	
Depth	approx. 48mm	approx. 38mm	
Weight	approx. 300 g including batteries	75 g	
Casing body			
Casing body shape	Designed primarily for handheld use: round cross-section; wider to house cone for sample collection; flat area for label and LEDs; loop at bottom for a lariat	Designed for handheld use and for standing on a surface: flat bottom for standing in the charger or on a surface; curved body front to back; tapered from bottom to top; oval cross-section	Designed for handheld use, standing on a surface, and being mounted in a stand
Casing body weight			
Casing body colour	- Yellow and black - Black	Black	TBC
Casing body surface finish	Shiny	Matt	TBC
Casing body surface tactile feel	Smooth and hard	Velvety, warm to touch	TBC
Controls & indicators			
On/off and other buttons	2x tactile button	1x mechanical button integrated into the base component of the casing	TBC
Button width		12mm	
Button height		18mm	
Display	Not applicable	Not applicable: connects to a smartphone app	Not applicable: connects to a smartphone app

	AlcoBlow® Rapid Test	Lumen	Virus sensor
Visual indicator	2x 3-colour LED	Colour changing, animated illuminated ring under the skin (not visible when off) to indicate: • Steady white: ready for use • Steady red: requires charging • Steady purple: measuring • Rotating purple: charging • Steady green: fully charged	TBC
Haptic indicator	None	Haptic feedback	TBC
Audible indicator	Single tone	None	TBC
Labelling and branding	Labelled button & LED panel with AlcoBlow® Rapid Test branding	Brand name in white on dust cover (facing user when about to use) and top front of charger	TBC
Mouthpiece			
Mouthpiece shape	Not applicable	Curved from body to shallow, wide oval opening	TBC
Mouthpiece weight			
Mouthpiece colour	Not applicable	Black	TBC
Mouthpiece surface finish	Not applicable	Shiny, metallic	TBC
Mouthpiece tactile feel	Not applicable	Cool, smooth	TBC
Cone lid/dust cover	Not applicable		
Cone lid/dust cover shape	Not applicable	Reflects mouthpiece shape	TBC
Cone lid/dust cover weight	Not applicable		
Cone lid/dust cover colour	Not applicable	Black	TBC
Cone lid/dust cover surface finish	Not applicable	Shiny, metallic, secured with a magnet for a satisfying audible click and 'pull' into position	TBC Mechanism to reduce loss, e.g., attached to body via short lanyard or can be secured while in use (similar to a pen lid)
Cone lid/dust cover tactile feel	Not applicable	Cool, smooth	TBC

	AlcoBlow® Rapid Test	Lumen	Virus sensor
Exhaust vent			
Exhaust vent shape		Recessed elongated oval in base	
Exhaust vent weight		TBC	
Exhaust vent colour		Dark grey metallic	
Exhaust vent surface finish		Dark grey metal mesh (potentially tungsten or titanium)	
Exhaust vent tactile feel		Light texture, but not meant to be touched in normal use	
Travel case			
Travel case shape	Not applicable	Not applicable	TBC
Travel case width			
Travel case height			
Travel case depth			
Travel case weight	Not applicable	Not applicable	
Travel case colour	Not applicable	Not applicable	TBC
Travel case surface finish	Not applicable	Not applicable	TBC
Travel case tactile feel	Not applicable	Not applicable	TBC
Charger			
Charger shape	Not applicable	Oval cross section, proportionate to device body; 'socket' for device to sit in for charging; magnet to 'pull' into position; cable exit at rear	Not applicable
Charger width		75mm	
Charger height		15mm	
Charger depth		67mm	
Charger weight		118 g	
Charger cable length		800mm	
Charger colour	Not applicable	Black	Not applicable
Charger surface finish	Not applicable	Textured plastic	Not applicable
Charger tactile feel	Not applicable	Slight friction, hard	Not applicable

	AlcoBlow® Rapid Test	Lumen	Virus sensor
Other features			
Disinfection		None	Consider UV or other disinfection functionality, possibly integrated into the travel case
Lanyard loops	At the bottom of the device for a wrist or neck lanyard	None	2x loops: - To secure the dust cover to the device - For a wrist lanyard

Consumables and optional accessories

	Required	Optional	Not required/not available
Consumables	Batteries	Approved cleaning products	Disposable mouthpieces
Accessories	None	- Travel case - Additional 'skins' - Spare cone lid/dust cover - Wrist lanyard - Neck lanyard - Stand	Charger
Peripherals	None	Smartphone, if using the app	Not applicable

Primary packaging and printed guidance

The packaging should also reflect similar aesthetic values to those defined for the device, whilst also providing retailers with an attractive product to sell on and offline.

- Retailers will buy in bulk: cartons should contain at least 12 devices
- Consumers will often buy devices remotely, shipped to them by the retailer as a single device: the Primary retail packaging must afford adequate protection during final shipping as well as look attractive on sale in bricks and mortar shops
- Opening the Primary retail packaging should be a similar 'unboxing' experience to mid-range mobile phones
- The device must include detailed, easy to read printed guidance to ensure accurate reading
- All packaging must be recyclable using kerbside collection, excluding the seal

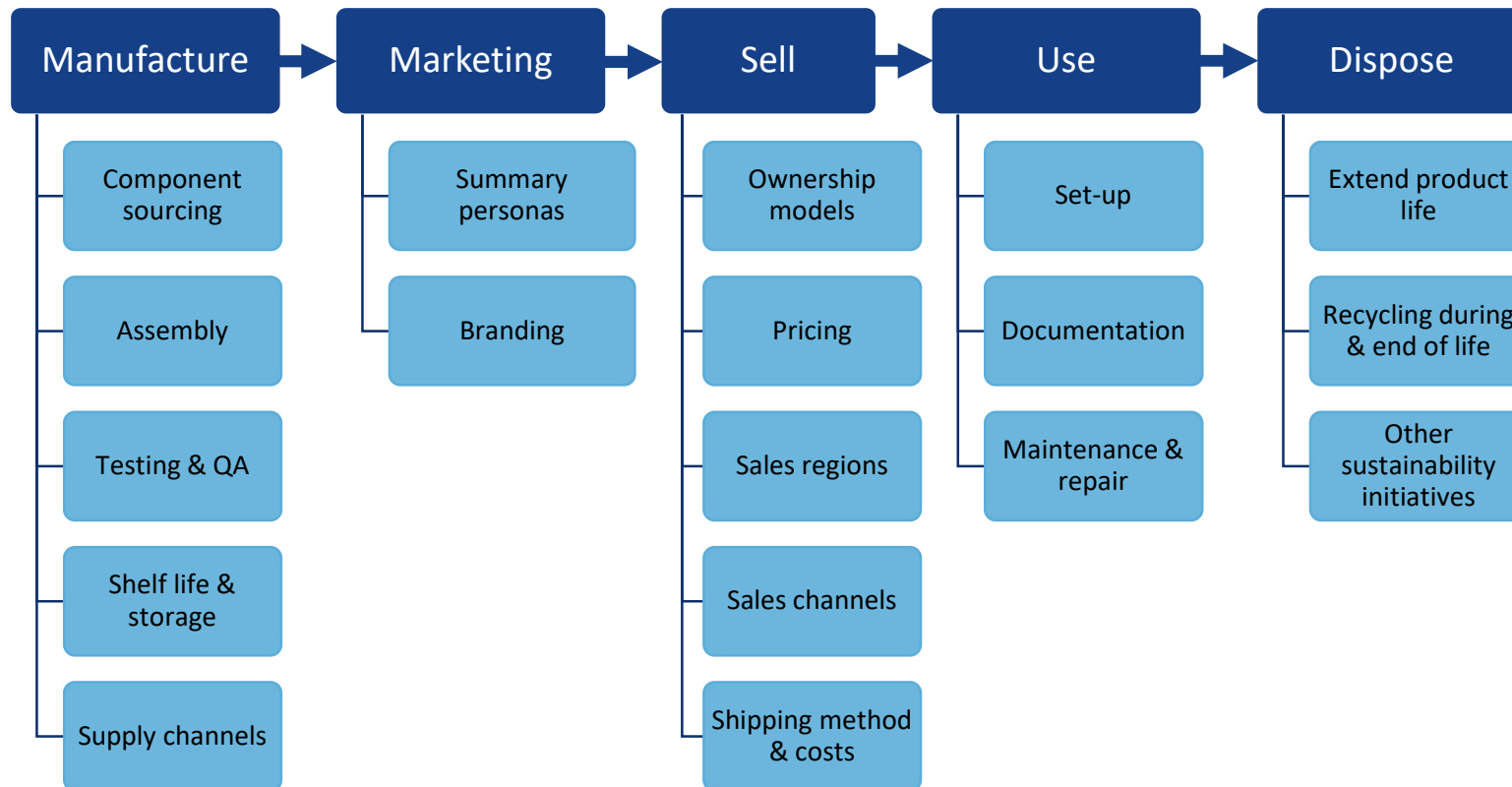
	AlcoBlow® Rapid Test	Lumen	Virus sensor
Primary retail packaging			
Width		approx. 140mm	
Height		approx. 160mm	
Depth		approx. 75mm	
Weight			
Box contents			
		• Device • Charging dock • USB-C cable • User guide	• Device • Batteries (packed separately) • Dust cover
Outer carton			
Lid		3mm thick card lid 42mm deep. Satin black with logo, name and tag line printed in colour, white and glazing (shine with no colour)	
Base		3mm thick card base 28mm deep with a 3mm thick card shoulder extending a further 27mm. 3mm thick card inner lip 5mm below the shoulder to hold the device tray. Satin black. Contents and company information printed on underside. Adhesive label with SKU, serial number, and 2D and QR barcodes	
Packaging inner components			
Device tray		Black plastic tray with single cavity and fingerhole piercing. Printed with white text.	
Accessory tray		Black plastic tray with three cavities. No printing	
Protective material		Black foam lining the lid	

	AlcoBlow® Rapid Test	Lumen	Virus sensor
Printed guidance			
Slip envelope		200 gsm satin card A6 glued slip envelope. Full colour printing on outside only	
Quick start guide		120 gsm gloss A6 stapled booklet with 4 pages, full colour printing on both sides	
User guide		80 gsm gloss A3 folded into 12 (3 by 4) with full colour printing on both sides. Includes safety instructions, CE & recycling marks, FCC & CE conformity declarations, warranty, trademarks	
Thank you note		200 gsm gloss card. Full colour printing to one side only	
Social media invitation		120 gsm gloss, full colour printing on both sides	

Secondary and tertiary packaging

	Width	Height	Depth	Maximum weight	Actual weight	Count per container
Pallet (tertiary package)	1200 mm	1600 mm	1000 mm	1500 kg		Not applicable
Carton (secondary packaging)	400 mm	400 mm	500 mm	60 kg		24 per pallet
Retail package (primary packaging)	200 mm	100 mm	100 mm	1.5 kg		40 per carton

Product lifecycle



Manufacture and distribution

Component sourcing

	Source company	Model ID	Indicative price
Casing	TBC	TBC	TBC
Fuel cell	Made in-house	TBC	TBC
Circuit board	TBC	TBC	TBC
Mouthpiece/sample cone	TBC	TBC	TBC
On/off switch	Included with circuit board		
Indicator lights	Included with circuit board		
Audible alarm	Included with circuit board		
Display screen	Not required		
Bluetooth module/chip	Included with circuit board		
Travel case	TBC	TBC	TBC
Cone lid/dust protector	TBC	TBC	TBC
Power supply	TBC	TBC	TBC
Labels & surface printing	TBC	TBC	TBC
Point-of Sale packaging (box, foam or another insert)	TBC	TBC	TBC
Print documentation (handbook, warranty, etc.)	TBC	TBC	TBC
Online documentation	TBC	TBC	TBC
Package seal	TBC	TBC	TBC
Outer carton	TBC	TBC	TBC

Manufacturing and assembly capacity and responsibility

	Current available capacity	Required capacity	Alternative source
Circuit board	None	Not applicable	TBC
Casing			
Assembly			
Testing			
Product packing			
Shipping packing			

Product testing and quality assurance

	Technical testing	User testing	Frequency
Prototype	TBC	TBC	
Circuit board	Tested before delivery		Not applicable
Casing	TBC		TBC
Assembled product	TBC		TBC

Shelf life & storage

- Packaged device must be stored in dry conditions away from sunlight and within a temperature range of -15°C to +55°C
- Batteries will be packed separately to minimise damage from battery leakage
- Device requires calibration annually for commercial use: devices should be returned to the manufacturer if stored unsold for more than 12 months

Supply channels

	Current supplier	Current channel	Proposed supplier	Proposed channel
Circuit board				
Casing				
Other components				
Product packing				
Shipping packing				

Marketing

Summary customer personas

		Buyer	User	
Commercial and state institutions, including: • Medical institutions • Police & judiciary • Public transport • Social venues • Education		Reg Singer, 63, male Headteacher • Reduce student & staff absence • Minimise transmission at his school		Mary Jones, 47, female Teacher • Minimise disruption to normal class life • Simple to learn and use
Consumers		Sarah Adams, 34, female Parent • Protect her family • Minimise impact on her job		Sam Brown, 14, male Child • Avoid using invasive lateral flow tests • Wants to have fun, in a normal childhood, without COVID stress

Full personas available separately, including additional personas specific to other industries.

Branding

The device, while it has its similarities with our Breathalyser devices, will be purchased by a much wider market, including by consumers.

- We should devise and trademark a brand name for the device, as part of the mission to become the leading brand in the market (the Google or Hoover of Covid breath sensors)
- Branding does not have to be closely tied with existing product lines
- Branding must appeal to consumers, not just institutional or commercial buyers
- The brand must
 - Leverage our existing heritage and reputation, to demonstrate accuracy and trustworthiness
 - Not dilute or undermine our existing products
 - Be appealing to consumers and commercial users alike

Sales & distribution

Ownership model

Traditionally, we have sold using the outright ownership model. However, we should consider additional models for this device, such as:

- Deposit scheme: customers receive a payment when end-of-life devices are returned to us, enabling us to refurbish and/or recycle more effectively
- Rental scheme: customers pay a subscription which includes the device and a service element to cover calibration and repairs
- Subscription: customers buy the device outright (or another model) and pay an additional monthly or annual fee for the app*

*Subscription services also can include consumables and/or accessories, not relevant for this device.

Pricing

As this is a new and innovative product with no established competitors, the market has not yet set an expected price range. There are a variety of pricing models used, depending on the market, product, and perceived position.

Pricing will be value-based, rather than calculated using the cost-plus method. We will conduct research using Van Westendorp's Price Sensitivity Meter to estimate the Optimal Price Point. [ref needed]

Point of Marginal Cheapness (PMC)	Point of Marginal Expensiveness (PME)	Optimal Price Point (OPP)	Indifference Price Point (IPP)	Price
				TBC, but working estimate is £250

Sales regions

The device will be piloted in the UK. It will be rolled out to other regions after three months, with a focus on EU and the US.

Sales channels

	AlcoBlow® Rapid Test	Lumen	Virus sensor
Direct			
Tender	Yes	No	Yes
Online	No	Yes	Consider
Offline	No	No	No
Indirect			
General retailer	No	No	Consider
Specialist retailer	Yes	No	Yes
Wholesaler	Yes	No	Yes

Shipping methods and costs

	Count of devices	Shipping method	Company	Total shipping cost	Shipping cost per unit
Single	1	Courier			
Carton	40	Courier			
Pallet	960	Pallet distribution			

Use

Set up

1. Install batteries & replace battery cover
2. Create app account and sync device (optional)
3. Take reading

Documentation

Printed guidance			
Slip envelope		200 gsm satin card A6 glued slip envelope. Full colour printing on outside only	
Quick start guide		120 gsm gloss A6 stapled booklet with 4 pages, full colour printing on both sides	
User guide		80 gsm gloss A3 folded into 12 (3 by 4) with full colour printing on both sides. Includes safety instructions, CE & recycling marks, FCC & CE conformity declarations, warranty, trademarks	
Thank you note		200 gsm gloss card. Full colour printing to one side only	
Social media invitation		120 gsm gloss, full colour printing on both sides	

Maintenance & repair

'Right to repair' legislation in the UK and EU mandates the availability of spare parts and manuals to enable 'professional repairers' to repair household goods (Conway, 2021). This device is not currently governed by that legislation, but the trend is clear: we must ensure that the device can be repaired, albeit using protocols that do not impair its effectiveness as a trusted medical device

	Our facilities	Authorised repairer network	Unauthorised repairer network	User
Calibration	Annual	Annual	No	No
Maintenance	Ad hoc	Ad hoc	No	No
Repair for at least 10 years after purchase	Ad hoc	Ad hoc	No	No

Disposal

Extend product life

Disposal is a last resort, instead we should aim to increase the useful life of the product:

- Components that can be replaced, to extend the total life of the device
- Repairability of components
- Switching to rechargeable batteries and/or enabling the device to be recharged using a standard USB-A or USB-C cable (to avoid creating proprietary charging mechanisms)
- Opportunities for owners to return devices at the end of life
- Supporting the consumer to recycle at home, including labelling and disassembly instructions to separate components for recycling in kerbside collection
- Extending the usefulness of the device by testing for additional diseases
- Enable and encourage the retail packaging to be reused for other purposes

Recycling during & end of life

To maximise the recyclability of waste and reduce harm to the environment, we should eliminate or minimise:

- Non-recyclable materials
- Materials that are not recycled or bio-sourced
- Carbon black
- Flexible and multi-layer plastics, especially foil-lined, that are difficult to recycle mechanically
- Single-use secondary and tertiary packaging
- Single-use component packaging, especially Electrostatic Discharge (ESD) bags
- Lightweight, small plastic fastenings that might be dropped or blown from refuse collection and enter the wider environment
- Contamination and/or mixing of waste, to avoid increasing the cost of recycling and/or its overall viability
- Power consumption, especially on standby
- Lower-footprint transport, for example by sea rather than by air
- Minimising energy and water use, and production of waste during manufacturing and shipping throughout the product's lifecycle

We should establish clear, proportionate waste handling mechanisms in place along the device lifecycle to ensure waste is re-used, repurposed, or recycled:

Design	Make	Sell	Use	Dispose
• Unwanted mock-ups and prototypes • Discarded design prints • 3D printing sprues • Print proofs	• Faulty devices • Offcut materials • Worn machinery and moulds • Component packaging	• Secondary and tertiary packaging • Damaged unsold or returned units	• Primary packaging • Paper documentation • Batteries • Other consumables • Packaging used to return the device for repair or calibration	• Device • Worn component parts replaced during repair or refurbishment • Redundant travel cases and lanyards

Other sustainability initiatives

We should also consider:

- Conducting and publishing a Life Cycle Analysis of the device, including calculating the carbon footprint, the flexible plastic footprint and other areas of concern or comparison
- Certifying as a B-Corp or equivalent

Processes

- Competitors' inaccuracies and failures will undermine trust in the entire market
- Force majeure events including war (e.g., Ukraine), natural disasters and disease may affect the supply chain, from delivery of components through to distribution to retailers and buyers

See also relevant sections on competitors, legislation, and intellectual property.

The internal and external landscape

Company constraints

The introduction of an entirely new product line raises questions:

- Can the product be delivered under the existing organisational structure, or is this a new Line of Business with a separate structure?
- Do our existing team have both the capacity and the skills to support the new product, or do we need to train and/or recruit staff? This will affect all business capabilities, but especially Sales and Marketing, who will need to engage with consumers as well as businesses.
- What changes to our processes do we need to implement? How will we operate effectively with multiple different processes?
- Are some activities, for example the app development, best delivered by partners?
- How do we extend and manage our relationships with third parties, e.g., for research, business partnerships, and suppliers?
- What support do our partners and suppliers need from us?
- Do we require additional funding or other support from our investors?

Intellectual Property

Claiming Intellectual Property rights

	Potential	Considerations	UK cost and timescale
Patents	• Sensor function and other utility patents • Sensor shape and other design patents	• Balance the high level of protection against disclosing trade secrets during application process, even if unsuccessful • Apply in which jurisdictions? • Cost of defending patents • Lion hold 37 patents	• £310 application fee • Protects for 5 years, renewable every 5 years up to 20 years • ~5-year application process • Will need professional support, which may cost several thousand pounds
Trademarks	• Logo and protected terms, such as 'Alcoblow' and 'Alcostop' • Sensor shape, packaging, and other design trademarks	• Trademarking is cheaper than applying for patents • Trademarking may help recognition as the leading brand • Lion hold 18 active, 5 dead and 1 cancelled trademarks	• £170+ application fee, depending on how many types are applied for • Protects for 10 years, renewable indefinitely • 4-month application process

	Potential	Considerations	UK cost and timescale
Copyright	• App • Printed documentation • Online documentation • Marketing materials and other collateral, including audio and video	• Copyright needs to be declared as part of publishing material, but there are no other costs	• Not applicable
Unregistered Industrial Design Rights	• Shape, arrangement, and appearance (colour, pattern, etc.)	• Automatic shape and arrangement protection in UK & EU for 15 or 10 years after creation or first sale, respectively • Automatic appearance protection in UK & EU for 3 years after first making the design public • Recommend lodging designs with a solicitor as proof of creation or publication date, in case of a dispute	• Not applicable, other than any costs associated with lodging proof
Registered Industrial Design Rights	• As above	• Registering helps provide proof of ownership and date	• Costs range from £50-150 per application, for 1-50 designs • Protects for 5 years, renewable every 5 years up to 25 years
Non-disclosure agreements (NDA)	• All proprietary information including designs, processes, data, etc.	• Sign NDA with all suppliers and partners before revealing proprietary information	• Legal costs drawing up agreement • Applicable period specified within the agreement

Licensing and partnerships

Alongside manufacturing and selling products ourselves, we may wish to consider licensing partners to use some or all of our intellectual property as an additional income stream.

We do not have strong app-developing capabilities: we should consider partnering with a third party to reuse and extend an existing app.

External PESTLE analysis

Political	Policy	- Government policy will change as the disease becomes more/less prevalent or dangerous - Medtech strategy and application schedule
	Taxes	What taxes might apply? What tax relief or other schemes?
	Tariffs and subsidies	- What UK tariffs or subsidies might apply? - What import tariffs do other countries apply? - How long will the current import duty and VAT exemption for COVID equipment apply?
	Political direction and stability	- How long will the current government stay in power? - How different is the likely direction of the next government?
	Government or other funding	Is there any funding available from state functions, e.g., from health services
Economic	Global and national GDP	- Are economies growing or shrinking? - Are there shifts in how people are earning or spending?
	Inflation	- What are the global and national interest rates? - Are they likely to change? - What would cause a change in interest rates?
	Exchange rates	- What are the current exchange rates with key currencies such as the euro and the dollar? - Are they likely to change? - What would cause a change in exchange rates?
	Economic trend and cycle	- Are the global and national economic trends up or down? Where in the economic cycle are we? - What might cause shifts in the trend?
Sociological	Attitude to COVID	- What is the level of public concern about COVID? - Are current COVID reduction measures perceived to have a large or a mild impact on normal life?
	Vaccination	- What is the current rate of vaccination? - What is the current rate of vaccine boosters? - What is the public attitude towards COVID vaccination?

	Personal responsibility	• Is there high acceptance of personal responsibility for COVID testing? • Is there high acceptance of personal responsibility for COVID reduction?
Technological	Breath sensing innovation	•
	COVID detection innovation	•
	Smartphone and app capabilities innovation	•
	Materials, power source and other environmental impacts innovation	•
	Wider technological innovation, e.g., AI	•
Legal	Legislation and regulation	• What legislation affects us? • What upcoming legislation might affect us? See also list below
	Standards	• What standards apply to us? • What upcoming standards might apply to us? See also list below
	Voluntary practices and codes of conduct	• Which voluntary practices, associations or codes of conduct might be relevant to us?
Environmental	Environmental impact and sustainability	• How can we minimise the environmental impact of producing, using, and disposing of the device? • How can we make the device more sustainable? • What material swaps could we consider? • How can we reduce transportation impact?
	UN Sustainable Development Goals (SDGs)	• Which goals should we support? How do we contribute to those goals?

Potentially applicable legislation, regulations, and standards

- *BS EN 55032:2015+A11:2020 Electromagnetic compatibility of multimedia equipment. Emission Requirements.* (British Standards Institution, 2020)
- *ETSI EN 301 489-1 ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard for ElectroMagnetic Compatibility* (ETSI, 2019)
- *ETSI EN 301 489-17 ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard for ElectroMagnetic Compatibility* (ETSI, 2020)

- *Guidance on the regulations for electronic instructions for use of medical devices* (Gov.UK, 2013)
- *Medical devices: how to comply with the legal requirements in Great Britain* (Gov.UK, 2021)
- *Medical devices: information for users and patients* (Gov.UK, 2020a)
- *Guidance: Pay no import duty and VAT on medical supplies and protective equipment brought in due to coronavirus (COVID-19)* (Gov.UK, 2022)
- *Regulating medical devices in the UK* (Gov.UK, 2023)
- *Regulations: Waste Electrical and Electronic Equipment (WEEE)* (Gov.UK, 2018)
- *Regulatory guidance for medical devices* (Gov.UK, 2020b)
- *IEC 62304:2006 Medical device software — Software life cycle* (International Electrotechnical Commission, 2006).
- *IEC 62311:2019 Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz to 300 GHz)* (International Electrotechnical Commission, 2019)
- *IEC 62321-2:2021 Determination of certain substances in electrotechnical products - Part 2: Disassembly, disjointment and mechanical sample preparation* (International Electrotechnical Commission, 2021)
- *IEC 62366-1:2015 Medical devices — Part 1: Application of usability engineering to medical devices* (International Electrotechnical Commission, 2015)
- *IEC 62368-1:2023 Audio/video, information, and communication technology equipment - Part 1: Safety requirements* (International Electrotechnical Commission, 2023)
- *IEC 62479:2010 Assessment of the compliance of low-power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)* (International Electrotechnical Commission, 2010)
- *ISO 11135:2014 Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices* (International Standards Organisation, 2014)
- *ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes* (International Standards Organisation, 2016)
- *ISO 14971:2019 Medical devices — Application of risk management to medical devices* (International Standards Organisation, 2019)
- *ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements* (International Standards Organisation, 2021)
- *MDCG 2021-24 Guidance on classification of medical devices* (Medical Device Coordination Group, 2021)

Competitor analysis

Testing method	Manufacturer	Pros	Cons
Lateral flow tests (lower standard)	Various	• Available in many retail outlets • 15-minute results • At-home testing	• Circa £2 per test • Mid-range accuracy • Unsuitable for travel
Lateral flow tests (higher standard)	Various	• 15-minute results • At-home testing • Suitable for travel	• Around £10-15 per test
Polymerase chain reaction (PCR)	Various	• Higher accuracy than Lateral Flow tests ○ 90% sensitivity ○ Nearly 100% specificity	• Circa £70-90 per test • Clinical testing only • 3–7-day results • False positives
BreFence™ Go COVID-19 Breath Test System	Breathonix, Singapore	• Uses mass spectrometry for high accuracy ○ 85.5% sensitivity ○ 97% specificity	• Non-portable device • Clinical testing only
TracieX	Silver Factory Technology, Singapore	• Portable device • 95% accuracy	• Two-part device • Single use, disposable component creates waste
GeNose C19	Kesumapramudya Nurputra, D. and Triyana, K., Indonesia	• 3-minute results • Accuracy comparable to PCR ○ 89-92% sensitivity ○ 95% specificity • US\$0.7-1.7 per test	• Uses a breath bag • Portable, but not pocket sized • Requires laptop

Testing method	Manufacturer	Pros	Cons
VOX	Scentech Medical, Israel	• 10 second results	• Uses gas chromatography, mass spectrometry and ReCIVA breath collecting device (Staff and Solomon, 2020) • Not portable • Not yet FDA approved (Uriel-Beeri, 2021) • Not available for public use • Requires an operator
TeraBioStation	TeraGroup, Israel	• Uses mass spectrometry for high accuracy • 1–3-minute results • Extending to include other illnesses • Connects to user, medic, and government systems	• Uses a tube to collect breath • Not portable • Pending FDA approval
Breath Biopsy™	Owlstone Medical, UK	• Range includes the ReCIVA handheld device • Awarded ‘Exhaled Breath Diagnostics’ research project by U.S. Defense Innovation Unit (DIU)	• Designed for research, not diagnosis • ReCIVA collects sample but additional equipment is needed to diagnose • ReCIVA is handheld but not pocket-sized
SpiroNose	Breathomix, The Netherlands	• 1-minute results • €2 per test, excluding staff costs • Low false-negative results, but 70% false-positives	• Requires specific six breath pattern • Incorrect use causes false negative results • Requires trained operator • Not portable • Uses disposable mouthpieces and filters

Project overview

Responsibilities and deliverables

Capability	Responsibilities and deliverables
Strategy	• Company strategy and direction, including innovation focus • Market and competitor analysis
Corporate social responsibility	• ESG strategy • Sustainability goal setting
Research and Development (R&D)	• Identify new technology opportunities • Develop design specifications and prototypes • Prove accuracy and effectiveness of new products
Finance and procurement	• Cost modelling • Budget management • Partner management
Human resources	• Recruitment • Training
Legal and compliance	• Obtaining certifications and authorisations • Overseeing ongoing compliance • Protecting Intellectual Property
Manufacturing	• Sourcing and supplier management • Manufacture • Quality assurance
Marketing	• Develop branding collateral • Establish brand position in market
Sales and distribution	• Ownership and pricing strategy • Logistics and inventory management • Managing customer relationships
Support and maintenance	• Customer support • Repairs, calibration, and warranty claims

Project ID/name:		Week 1 Week 2 Week 3 Week 4 Week 5 Week 6 Week 7 Week 8 Week 9 Week 10 Week 11 Week 12												Overall status:	
123/456														Not started	
CovBlow handheld Covid-detecting breath sensor															
Target date:														Report date:	
TBC														22/9/2023	
Project Manager														Commentary	

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