

PRODUCT DESIGN BRIEF
COVID CHEMICAL DETECTOR SYSTEM

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Synopsis

RS Technologies is Carmarthen based SME & specialises in the manufacture of electrical breathalyser systems. We have a strong foundation developing breathalysers for the past 8 years & catering to industries like the law enforcement, heavy industries & transportation sector.

Our products mainly use alcohol detection system as the basis & are created for use in various industries for screening.

A knowledge transfer partnership was conducted with a local university following which possibility of developing a chemical detector system to detect any organic materials including virus infections such as coronavirus.

Following initial study regarding the possible developments of the chemical alcohol detector system, it was identified that similar products can be developed to detect covid-19 & other virus infections including those generated in the breath.

The product is aimed to cater both clinical & personal use – a few scenarios were explored during the initial research to explore both avenues.

The product design brief will focus on the details of the product and its functionalities & will focus on what's required to bring the product into existence. This document will focus on providing information to all internal and external key stake holders covering all the key aspects of the life cycle management of the product.

- Design of the product
- Developing key interfaces at partners
- Communicate requirements to supply chain
- Industrialize the product
- Manufacturing the product
- Quality management of the product

The following business case consideration has been made for the product:

The projected manufacturing volumes in the first year is likely to be no more than 750,000, potentially 3million per annum afterwards.

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Aesthetics

Aesthetics of a product is very important as it provides the first impression of the product. The factors that influence a user's opinion of the product is detailed below:

- Shape: The device should be a handheld one so the shape should be such that there are indentations for the fingers for ease of hold. The display should be on the top similar to handheld scanners at Asda or Tesco.
- Colour: The device needs to be monochromatic & the key colours of the device are white, black & dark blue.
- Texture: The device should be having a textured grip for people to have a tight grip while holding the device.
- Display: The display should be clear & the digits should be big enough for every to see without stressing & it must be a backlit display.
- Touch: The touch pad for the display should be soft touch & the buttons should be big enough for all finger sizes.
- Sound: Specific sounds for when the unit switched on & off & another tone for when the test is being taken.
- The charging port must be at the bottom face of the product so it can be used while charging and doesn't interfere with the tube for testing.
- Accessories:
 - The device should have a portable charger with a 1m lead to connect.
 - The device should also be provided with at least a pack of 10 breathing tubes which can be purchased in bigger quantities separately.

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Branding

Branding is a key part for the company as its preferable that the company's brand is visible on the device. The branding should be consistent with other products in the company portfolio

- The RS logo should appear on the device when the unit switches on.
- The RS logo should remain on the device on the display screen while the device is being used – on one of the corners without interfering the actual data display.
- The logo should also be available on the handheld surface.
- The box should have the logo & also on the 1st page of the instruction manual.
- The key areas of branding and marketing are the website and a web based application that can be used on all mobile devices.
- The website should display the product as the front page when accessing the site.
- A specific application should be created for the device which can be linked to the device to get instant results.
- The user should be able to use the app & the website in the language of their choice.
- The product should be displayed on medical journals.

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Circular Economy

The concept of circular economy involves sharing, reusing, repairing & recycling materials as long as possible to extend the lifecycle of the product.

- The materials to be used for the products must be recyclable, either use of recycled materials or ensure the materials are recycled at the end.
- All electrical components must be reusable at the end of the process.
- Recycling of batteries.
- The production processes of the device should focus on reducing CO₂ emissions.
- Ensure maximum components are designed so they can be repaired & replaced.
- Ensure no hazardous or toxic parts are used in the process.
- Ensure the circular economy concept is also communicated to the partners & suppliers to maintain it through the process.
- Ensure design for manufacture.
- Use only recyclable packaging methods and materials.
- Transition materials, manufacturing processes and operating systems to low carbon alternatives.
- Reduce Freshwater use and aim for zero waste.
- Reduce energy use and facilities.

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Company Constraints

- **Budget:** The budget to design & manufacture the device will be set around £100,000 subject to approval from finance & the exec team.
- **Timescale:** The timeline to design & manufacture the product will be 12 months aiming to launch the product ready for the holiday season of 2023.
- **Volume:** The manufacturing volumes in the first year is likely to be 750,000, potentially 3million per annum afterwards.
- **Research & Development:** The initial research is being done in-house however the knowledge transfer partnership will continue with the local university for some key areas of the product. Any expert partners can be provided components to research. All research partners must work under a non-disclosure agreement.
- **Industrialization:** The product development will happen in-house to keep low prototype development costs. Any electrical components can be produced at a strategic partner.
- **Production:** The initial industrialization will take place in the UK & the 1st 1000 parts will be produced in-house, following which the production will be moved to our strategic manufacturing partners in China.
- Any strategic partners or production facilities can only be used from the company's approved list of partners and any alternate partners would have to go through new partner approval process.

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Competition

- Literature Research: Carry out general literature research across the board to study & research any breathalysers in the market to design & manufacture a competitive product.
- Some of the key competition is:
 - InspectIR COVID-19 Breathalyzer: FDA approved in USA
 - Breathonix Breathalyser: Provisionally approved in Singapore
- Create a study to compare breathalysers with other testing methods like the RT-PCR test & lateral flow tests.
- Study the competition for:
 - Costs
 - Weight
 - Durability
 - User friendly nature
- Compare competitive companies which are in the market for creating similar products and their potential customers. Study the qualities of the product and compare with our product.

Components

- The product must have the following key components:
 - The device – the handheld device which will take the readings to determine the results of the test.
 - Testing tube – a tube of some sort which can be used for the patient to blow into for the device to work
 - Charger – A portable charger that can be used to connect the device to the power supply. The charger should consist of a USB cable connecting to a charging plug which can then be changed according to the country of use.
 - App: A web based app is required to support the device in which the tests can be logged in which should be capable of producing a barcode or a test certificate.
 - Database: All results must be linked to a testing database to have a record of any tests and print results.

Customer

- The product is to be designed to cater for clinical use as well as personal applications.
- The clinical areas are hospitals such as NHS & other health institutions, care homes, restaurants, airlines, airports & event establishments.
- In terms of personal applications – the product should cater for medical professionals, frequent travelers, or simply any individual who is cautious.
- Market Research: Conduct a market research in the form of surveys to study the key competition & come up with key characteristics that can be adapted from market research.
 - What does the customer want?
 - Why would the customer need our product?
 - What features are necessary for such device?
 - Do they need an app?
 - How do they get the test results?
- There should be a dedicated customer service team working solely to support the new product which should be available round the clock.
- The website & app should be user friendly for the customers to have the best experience.

Documentation

The device must be accompanied with:

- User instruction manual: The device must be provided with a traditional user manual detailing the device; installation and how to use instructions.
- App use instructions: The instruction manual should detail download of app & how to set up/ use app.
- Instructions on how to register the test and download the results.
- Instruction videos on website / official YouTube channel to use the device & use app.

Environment

- Temperature: The product must be operating under a high temperature range; ranging from -10 °C to 50 °C to ensure the device can be used in a vast number of countries.
- Humidity: Ensure the product can be used in all climate ranges.
- The product must be water resistant.
- The product must be resistant to alcohol based wipes / liquid.
- The product must be corrosion resistant.
- The product must be working in dusty/ dirty environments.
- The device must be able to withstand certain levels of vibration.
- Shock loading and drop testing from at least 6ft.
- Any changes that can occur during packaging, transportation, warehouse storage, display or use.

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Ergonomics

- Define handling characteristics.
- The device must be designed to be used in a neutral position as much as possible, with elbows relaxed below shoulders.
- The unit should be easily used by right and left handed users.
- Number of soft touch buttons must be kept to a minimum as possible.
- Is there any hand room available around the controls.
- The force to press the soft touch button should be kept to minimum.
- Visibility of the display text should be adjustable during use.

Installation

- The installation process must be covered in the instruction manual.
- The installation must be simple & explained in detailed steps.
- The device and the accessories must be clearly listed & shown on the manual in clear pictures.
- The installation must also be shown as step by step procedure on the website and the app.
- Installation of app & connecting the device to the app must also be clearly written.
- Troubleshooting steps should be on the website and manuals in case the assembly is incorrect.
- The app installation must be specified on the website and the manual.
- Instructions to record results and link them to the testing database should also be explained.

Intellectual Property

- Define all patents, trademarks, copyrights and trade secrets
- Ensure all existing patents, copyrights are reviewed.
- Any new innovations are patented as per the process.
- Ensure if any technology being used is patented by other, correct procedure is followed to avoid any copyright infringement.
- Working with the university on the knowledge transfer, ensure any common technologies / innovations are patented with both parties & the procedure is well documented.

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Legal

- EEC of product liability legislation.
- Ensure defects of specification are minimized to reduce any defects in design /manufacture which could cause legal issues in the future.
- Defects in specification account for defects of design and defect of manufacture which could cause product defect legislations.
- Ensure the product is registered with key markets.
- Ensure the product manufacture in other countries is approved by relevant authorities.
- Ensure the sale of products in multiple markets is covered legally.
- Ensure patents are registered to avoid any legal conflicts.

Life In Service

- The product should have a lifespan of 100,000 uses or 5 years whichever is sooner.
- List all key components & lifespan.
- Specify number of tests/ usage per day.
- Specify effects of overuse or underuse of the device.
- Which components would be covered for repair & replacement?
- Specify details of repair and replacement coverage.
- What's the timeline for free replacements?
- How quickly can parts be replaced?
- In country support for all high priority customers.

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Maintenance & Repair

- The product must be fully supported for maintenance or repair within the first year as standard practice.
- Any major failures with the device should result in replacement of the device with a brand new device.
- Any key components that fail within the prescribed lifespan to be repaired or replaced.
- There must be a paid 1 year, 2 year or 3 year warranty & support plan after the 1st year which would have all the benefits of the 1st year support.
- Dedicated in service issues team to monitor all issues & work on repairs & further improvements.
- Yearly calibration of devices.
- Dedicated onsite service team to be set up for clients with high sales.
- Maintenance facility to be set up for the biggest customers in key geographical areas.

Manufacturing Facilities and Assembly

- The design should use commonalities with the existing products to use the current production facilities.
- Use the current machines, tools.
- Use the current assembly setup to manufacture the new device.
- Use the current suppliers to keep commonality across other products.
- Train the existing team to manufacture the new device.
- Investigate the partner sites, the possibility of manufacture & reuse the existing infrastructure & labour at those sites.
- Create work packages for strategic partners to outsource any production work.
- Consider:
 - How much of the product will be manufactured in house
 - How will the production be managed?
 - What are the production constraints that need to be taken into account?

Assembly:

- Design phase must consider for maximum assembly using automation and if required, the final assembly on an assembly bench using operators.
- The assembly must be broken into 3 phases electrical, mechanical & final assembly.
- The electrical assembly & mechanical assembly can be automated or outsourced.
- After the final assembly, even unit must be quality tested.
- Packaging & quality testing must be a part of the final assembly process.

Market Constraints

- Feedback from the market Intel' should be considered.
- Ensure the product can be marketed & sold in all the key markets across the world.
- Is the market ready for the product?
- Are there similar products in the market which will make it hard for the product to sell?
- What would be the market share of the product when it launches.
- Is the price competitive?
- Is the market different for clinical & individual customers?

Materials

- Use renewable materials.
- Are thermoplastic required.
- Is injection moulding the method of manufacture?
- Specifications for the material.
 - Quality & Reliability “EN45000”
 - Industrial standards “BS EN 60601 1-1,1-2,1-4”
 - Industrial Standards & Specifications “MDA and/or FDA approval” etc.
 - Legal “Confidentiality Agreements etc”
- Manufacturing facilities for relevant materials & manufacturing methods.
- Materials for display & the buttons.
- Specific materials for the electronic components.
- Use recycled or renewable materials in products and maximize material efficiency, product longevity and recovery.

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Packaging

- Ensure the product is packaged using environmental friendly material.
- Ensure use of recyclable material.
- The packaging must protect against the environmental effects of shipping such as salt water, corrosion, and shock-loading.
- Do not use single use plastic/ bubble wrap in packaging.
- The packaging box should be a standard size as used to package other products in the company.
- A pallet should be able to carry at least 50 boxes.
- The packaging box must clearly identify the product details including name and part number of the product.

Performance

- The product must be able to test the presence of coronavirus & provide quick results.
- Additional things to consider:
 - Speed of results
 - Speed with which the unit can be assembled.
 - Can it perform in extreme weather conditions?
- Is there a setup time after every use?
- Is there a limit of maximum uses within 24 hrs?
- Is it weatherproof?
- Is it childproof?
- Does it have a grip or is it slippery?
- How does the unit connect to the web application?
- How does one get the results from the app?
- Is it user friendly?
- Are there any additional functions the device can perform?

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Politics; Social & Cultural

- Consider the effect of the product on the political and social structure of the market or country for which it is to be designed and manufactured.
- Knowledge of local conditions, particularly overseas, combined with a full knowledge of the market must be incorporated.
- Feedback from the market intelligence should be considered.
- Factors to consider:
 - effect of consumer movements,
 - stability of the market,
 - Avoidance of product features that can create social unrest and upset.

Processes

- Ensure processes used in the design & manufacturing is line with the existing processes in the company.
- Any processes should be linked to engineering specifications as per the business standard.
- If there are any special processes, they must be defined.
- Audit all processes as per the regulations.
- Any relevant standards - British, foreign, in-house, client's etc. - could be called upon.
- Ensure all workings staff are trained to understand the processes & use them during design and manufacture phase.
- All processes must be documented & should have work instruction or control plans to be followed during assembly. All the processes must be followed by strategic partners & key suppliers.

Product Cost

- The product cost is a key factor as revenues are the key part of the business.
- The cost range of the product should be established upfront.
- Check the price with the other existing products in the market as the final cost must be competitive.
- Cost patterns should be established and studied in detail before setting the target cost.
- Consider the selling price & identify margins to ensure profit and cope with fluctuations in material costs and exchange rates.
- Cost should be established based on
 - Processes that will be outsourced
 - Materials that will be used
 - Labour costs
 - Location of partners
 - Any other development costs

Product Life Span

- The product will be in production for at least 3 years with a further extension of another 2 years.
- The customer demand for the product will be for the next few years as the world is coming out of the pandemic.
- There shall be additional variants developed during the production phase which will be launched for production during the time period.
- Product life span would be directly related to the manufacturing processes adopted, tooling used and material used in the process.

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Prototyping

- Prototyping is a key step in any product development.
- Prototypes will be built as a part of the critical design review.
- Working prototypes are necessary to establish the working of the product and any improvements required.
- The visual prototype is key as it can be presented to a customer which can be used to get the feedback at any customer events.
- A prototype can be used to conform aesthetics, fit, form and function.
- While prototyping is key, cost spent on prototyping should be defined & worked to.
- Set up a percentage of the budget for prototyping costs.
- Prototype to be done in-house to reduce additional costs.

Quality Testing

- Quality is a key factor for any product's success & for it to be reliable in the market.
- Quality is a key part of the company's branding.
- Ensure quality is built through every step of the product.
- First article conformity would be a key step in the process to check the quality of the product during every step of manufacturing.
- Ensure quality control plans are created according to company processes.
- Verify the quality as per the product design brief.

Quantity

- The business case scenario is:
 - The projected manufacturing volumes in the first year is likely to be no more than 750,000, potentially 3million per annum afterwards.
- Consideration of quantity during design and manufacture is important.
- It has an effect on costs of raw materials, manufacturing methods, supplier costs, tooling costs etc.
- Moderate numbers may require cheap temporary tooling, while large numbers may require permanent, expensive tooling.
- Quantity of the product will help decide the method of manufacture, place of manufacture in the long term & will have an impact on the supportive investment required.

Reliability

- It's important that a product is reliable.
- Any new product in the market needs to be reliable to boost sales.
- User trials & surveys should be conducted for checking the reliability of the product.
- Quality and reliability of the product will determine the success of the product.
- Carryout reliability assurance on the electrical circuitry to increase reliability.
- Design for reliability approach can be used to increase product reliability.
- To ensure product is reliable – design, verify, review, manufacture and test.

Safety

- Ensure all safety procedures are followed in design & manufacture of the product.
- The product must conform to BS:EN 365 [generation of instructions and maintenance documentation for safety equipment] or similar regulations as per the country of manufacture.
- Follow General Product Safety Directive.
- Are there any safety instructions for the consumers before the use of the product?
- Check if the product has a safety feature or is it required.
- Assess and manage chemicals for risks to human health and environment.
- Health and Safety considerations must be built in the manufacturing facility and training must be provided on essential standards.

Shelf Life and Storage

- Define the shelf life of the product.
- How long can the product be in storage
- What kind of weather conditions can it be stored in?
- Does it need to be stored in any specific storage conditions?
- What kind of places can it be stored in. Example – Indoor storage facility, outdoors in the open yard.
- Would there be any damage to the packaging or would there be any decay.
- What happens if the units are stored past their shelf life?
- Does the storage space require temperature, moisture control?
- How long can the tubes be stored for.
- Do they need to be stored in any type of containers while being in use.

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Shipping

- Define shipping conditions.
- Would the shipping be by road, sea freight or air freight?
- How many units of the product can be put on a pallet?
- What kind of packaging should be used on the pallet?
- How long would it take to ship to key geographical areas – it might affect any customer delivery expectations.
- Is there a minimum quantity on bulk orders to keep shipping costs to a minimum?

Size

- Size of the product is very important as the device is hand held.
- The product must be able to fit in small carry cases and should be similar to the size of hand held scanner at grocery shops like tesco & asda.
- The accessories – battery, charger, tubes for testing must all be fitting into the box without taking extra space.
- The size could have some serious implications on the weight of the product.
- The shape should be as defined in aesthetics.

Standards & Specifications

- The standards of design and manufacture must be followed according to the country of development.
- Ensure all standards are considered e.g. BS, EN, AFNOR, DIN, ASTM, ISO etc
- Cross-correlation of such standards should be carried out prior to commencement of the design.
- It is difficult, costly, time consuming and inefficient to attempt retrospective matching of designs already finalised to such standards.

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Testing

- Developmental Testing
 - It's important that products are tested prior to packaging and shipping.
 - Certification testing is the part of the development process.
 - There must be electronic testing to check the display functionality.
 - There must be drop tests to see breakage limits.
 - Tests must be done to see compatibility of the accessories with the device.
 - Tests must be done for test result timings.
 - Testing of app & database testing should be done as well.

- Device testing in production
 - All devices must be tested every 3 months.
 - The units must be issued with a testing certificate.
 - Testing failures must be recorded & logged into for analysis.

Time Scale

- The time scale for the project is 12 months
- The project should be launched in phases of design, procurement, industrialization and production.
- A top level schedule is shown below which would be tracked regularly to ensure timelines are met.
- The timescale is important to launch a product in time to meet the customer demand.
- Any delays to the schedule adherence must be presented to the exec team and approved.
- The schedule must be shared with key partners and must be included as a part of the key negotiations.

Milestone	
PDS Delivery	▶ T months
Initial Design Review	▶ T + 15 days
Digital Design Review	▶ T + 100 days
Critical Design Review	▶ T + 180 days
Certification	▶ T + 250 days
First Article Conformity	▶ T + 300 days
Start of Production	▶ T + 320 days
Shipment of 1st batch	▶ T + 365 days

Weight

- The desirable weight of the device is between 450-500 gms
- The device must not be heavy for a person to carry it around with them.
- Weight would be a key factor in shipping costs.
- Weight limits must be kept in check constantly as it can increase costs.
- Weight reports must be created through every stage of the development to monitor & track any weight deviations.
- Conduct a survey to zero in an optimum weight limit.
- Compare other similar products to offer a competitive weight.

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