

Developing the Design Brief

By

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Product Design Brief – Cover Sheet

PROJECT CODE:	PROJECT NAME:	PRODUCT DESCRIPTION:	MODEL:
RMT	RMT MY25	VIRUS DETECTION DEVICE	VIROSENSE LIGHT

Product Design Brief to be circulated and approved by each head of function listed below before design freeze.

	Head of Function	Approval	Date
Innovation Management	Ryan Thomas		
Research & Development	Alan Mumby		
Programme Management	Henry Gantt		
Logistics	Malcolm McLean		
Manufacturing	Henry Ford		
Procurement	Jeff Bezos		
Sales & Marketing	Richard Branson		
Quality	Genichi Taguchi		
Engineering	Elon Musk		
Finance	Martin Lewis		

It is necessary to update the Product Design Brief during the new product development review. Any updates to the design brief must be recorded on below revision history table.

Revision History

SIGN	FUNCTION	DATE	REVISION	SYMBOL	HISTORY
RYAN THOMAS	INNOVATION MANAGEMENT	22.09.23	N		NEW DESIGN BRIEF CREATED

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1. Synopsis

1.1 SME Ltd - the business we are in today

The company (**SME Ltd**) is a renowned manufacturer of electronic breathalyser devices, a product that has been developed to analyse the level of alcohol in the end user's breath. For many years, the product has been supplied to the police, who use the device to test the general public that appear to be under the influence of alcohol whilst driving a motor vehicle. This has been enforced by the government since introducing the Road Safet Act in 1967 giving the police force the power to test. The procurement is the police force itself, and over the years of supply, there has been no requirement to change the product design.

(Lion Laboratories, 2023)

1.2 Emerging opportunity for a new product

During the year 2020, the world suffered from a global pandemic where all aspects of the modern day life was affected. Lockdowns were enforced by the local governments costing the economy billions, peoples mental health and wellbeing were impacted and education slowed with home schooling. From this the company has identified an opportunity to extend the chemical alcohol detector system which is at the heart of our product portfolio, to cover the detection of other organic material including those generated in the breath as a result of various virus infections.

Through the Knowledge Transfer Partnership with a local university, the design of a virus detection system has been developed to meet the company's objective. The new system has been trialled successfully in the laboratory and the necessary patent applications have been registered. The company has also gained certification for the new virus detector from the various medical device regulatory agencies. Now the company wants to drive the design forward by developing the 'physical envelope' and appearance of the new Virus Detector Device for personal domestic use.

This Product Design Brief outlines the requirement to bring the Virus Detector Device from concept to mass production. It's a communication document to be shared with all the head functions withing the company, where everyone's input is required before the product is launched.

1.3 Company constraints

Financial: Investment required to cover the cost of various engineering activities, jigs and tooling required for the new components / assemblies. See Section 7 for summary of all costs involved.

Master Schedule: A project timing plan has been set by the company to achieve key milestones within the development of the new product. See section 2.4 for key dates.

Quality Control: Procedures have been applied in line with ISO 9001 to control the quality of end product, both from external suppliers and in house assembly. See section 6 for quality assurance.

Product testing: A test plan is scheduled to verify the design and to validate the new equipment and processes that are developed for the manufacture of new product. The new product is required to pass all physical testing (in line with test specification developed by the company) before start of mass production. See section 4 for product testing.

Production Volume: Floor space required for a high volume. There is a big increase in volume from year 1 to year 2 (an additional 2,250,000 assemblies forecasted), therefore floor space needs to be constrained and future proofed.

2. Sales & Marketing

2.1 Marketing Sensing

The company has applied various marketing techniques to the business to help determine the direction required for the development of the new virus detector device. From the study, the new device has been targeted towards the NHS staff, as they are mostly exposed to various viruses within their working environment. Having the NHS staff test on a regular basis would help identify the virus early on and to stop spreading further towards people who are vulnerable.

See below for the Value Proposition Canvas tool used to determine the features required on the new product based on customer values and needs. The job of the device is firstly defined, then the pains for the customer is listed based on current knowledge and predicted outcomes. From this, ideas on how the product / service should be designed are listed to help overcome the pains, making the customer experience better.

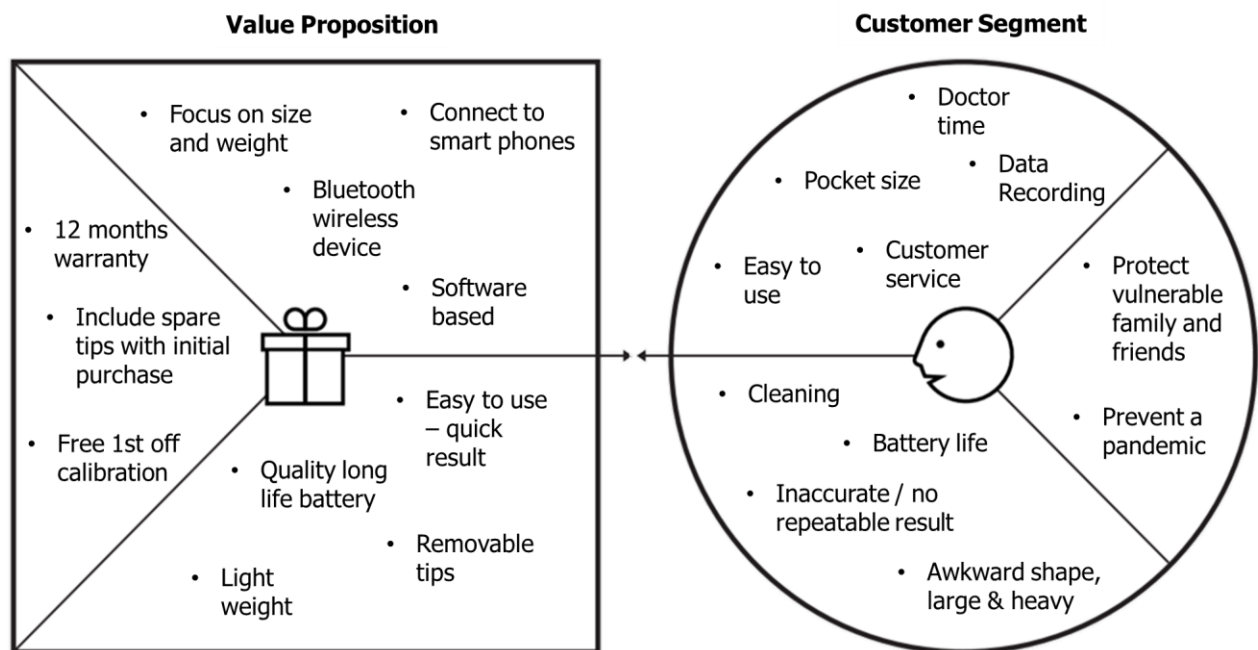


Figure 2a – Value Proposition Canvas for a domestic use Virus Detection Device

(The Value Proposition Canvas, 2023)

Customer Jobs:

- To protect vulnerable family and friends.
- To help prevent a global pandemic.

Pains:

- Cleaning the product where it has been exposed to users mouth.
- Short battery life – device doesn't function when user has no access to charging port.

- Inaccurate result where device result is non repeatable.
- Awkward shape – large and heavy device that is difficult to carry around / transport.

Gains:

- Saves time and effort to go and see doctor to understand what virus the user has. At the same time would save the doctors time so he could focus on other issues.
- Pocket size device so that user could easily carry or store, for example, in a handbag.
- Simple and easy to use.
- Record results onto an app to see if there's any trend.
- Customer service to absorb and rectify any issues

Pain Relievers:

- Easy to use – quick result.
- Quality long life battery
- Removable tips where users mouth is exposed.
- Light weight

Products & Services:

- 12 months warranty
- Include spare tips with initial purchase
- NHS discount
- Free 1st off calibration

Gain Creators:

- Device to include Bluetooth technology to be able to connect to smartphone app
- Software based so that cost for future updates is kept to minimal
- Focus on weight and size

2.2 Customer Experience

- Design product that is simple to use so that end user enjoys the experience of obtaining a virus detection result
- Use a clever brand name so end user is fully aware of product detail.

Product Virus Detection Device	Pricing Premium
Place Retail: Boots Hospitals (order through NHS discount)	Promotion Hospital display boards Media

Figure 2b – Market Mix of domestic virus detection device

(Batad, Wided 2020)

2.3 Production Forecast

- 750,000 units per annum – FY25 (Year 1).
- 3 million units per annum – FY26, FY27, FY28, FY29 (Year 2, 3, 4 and 5).
- End of production planned after 5 years (based on design updates to current model).
- Service parts to be available for 10 years after end of production.

2.4 Key Milestones

- Prototype Build: October 2023
- Design Freeze: December 2023
- Off Tool Build: May 2024
- Off Process Build: September 2024
- Start of Production: January 2025

2.5 Market Constraints

- Brexit – importing/exporting parts to and from UK.

2.6 Branding

Model name given for the virus detection device is **'ViroSense Light'**.

'Viro' is derived from the word virus.

'Sense' gives the user an indication that the device senses a particular input.

'Light' is to indicate that the hand held device is light in weight, therefore practical to carry around for personal use.

Below is the **'ViroSense Light'** logo that will be printed on each device.

The logo for ViroSense Light. 'ViroSense' is written in a stylized, italicized font where the 'V' and 'S' are larger and more prominent. Below it, the word 'light' is written in a smaller, lowercase, italicized font.

Figure 2c – Brand logo

2.7 Competitors

Figure 2d below shows the Raman-based breathalyzer module designed by Nanyang Technological University, which is based around surface-enhanced Raman scattering (SERS). The device offers point-of-care covid diagnosis able to screen for a virus in 5 minutes. The person breathes into device for 10 seconds, where the covid biomarkers in breath chemically interact with the sensors.



Figure 2d – Raman-based breathalyzer image

(Raman-based breathalyzer, 2023)

Figure 2e below shows an image of SARS-CoV-2 detection device, which has been developed by scientist at Washington University in St. Louis to produces a result in less than a minute. Its aim is to quickly identify strains of COVID-19 or other airborne pathogenic disease by screening people at public events and to help prevent outbreaks where people are withing close proximity.



Figure 2e – SARS-CoV-2 detection device image

(SARS-CoV-2 detection device, 2023)

3. Product Concept

3.1 General Overview

Figure 3a below is an image of design concept for the new virus detector device, labelled with key features;

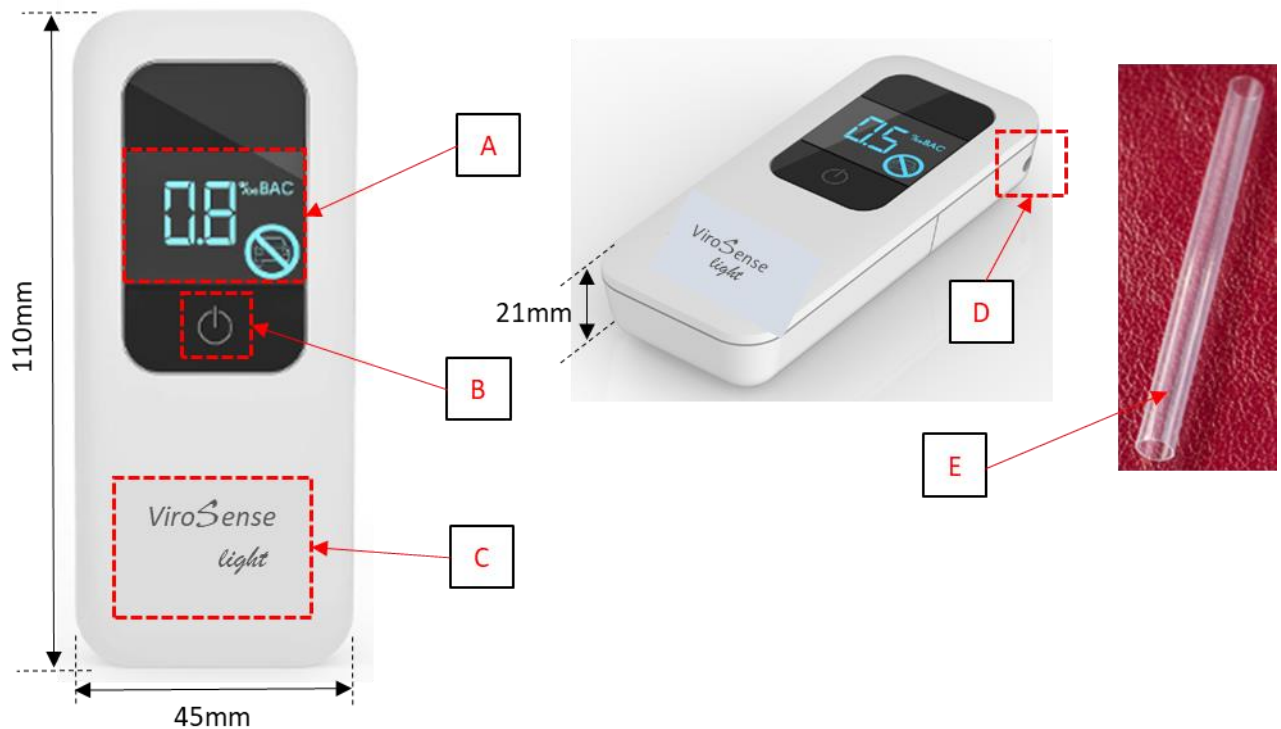


Figure 3a – Virus Detector Device – Design Concept

Description of key features labelled on figure 3a above;

- A:** LCD screen to display result and battery life.
- B:** ON / OFF button to power the device ON / OFF and to enable Bluetooth pairing.
- C:** Brand & Model location – ViroSense light printed.
- D:** Blow tube locator – user insert Blow Tube (labelled E) into the hole then blows through tube for device to analyse breath and display result
- E:** Blow tube – supplied separately with device on purchase and also available to purchase as a stand-alone product in a batch of 20 as spares.

Design intent at a glance;

- Pocket size (HxWxD): 110 x 45 x 21mm.
- Easy to use – the only operating button is the on/off button (labelled as B above)
- Product includes Bluetooth technology that connects to a smart phone app.

- Quickly displays virus result clearly on LCD screen (labelled A above)

(AlcoSens Lite 2a, 2023), (Ma, Li. Shao, Yun-fei, 2020).

3.2 Technical details

- Safety rating: RoHS, ISO 9001
- Virus Detector Weight: 84 g
- SME Top Level Part Number for Virus Detector: 21410 RMT0A—A
- Batteries fitted internally – device to be charged using USB C charger plug.
- Housing Colour: White

(AlcoSens Lite 2a, 2023)

For further technical detail of each component, please refer to the technical drawings (see drawing number for each part on figure 3b part list below)

3.3 Material Selection

Below is the material selection process followed to determine the material required for the virus detector device (housing);

Design Requirement -> Selection method -> Materials

Design requirements (the required inputs for the product);

Technical – high impact, tough and unbreakable, durable,

Aesthetic – brightly coloured white, transparent smooth feel.

Selection Method used for material;

Analysis - technical datasheets of material properties, performance metrics, screening of a database of materials and their properties

Synthesis – exploring knowledge of other similar products who have already solved the problem for above design requirements

Material decided from the above research;

Polycarbonate (PC)

(Ashby, Mike and Johnson, Kara. 2010)

3.4 Parts List / Bill of Material

Figure 3b below show the bill of material with new part numbers generated for each component / assembly along with drawing part numbers. Make / Buy column added to show if component or assembly is bought in from external supplier or made in house.

BOM Level	Part No / Revision	Part Description	Qty	Drawing number / Revision	Estimate weight (grams)	Material	Make or Buy
1	21410 RMT0A--A	Virus Detector – Final Assy	1	21410 RMT0A-01	83	N/A	Make
2	21411 RMT0A--A	Virus Detector – Sub Assy	1	21411 RMT0A-01	74.2	N/A	Make
3	21412 RMT0A--A	Housing – Lower Assembly	1	21412 RMT0A-01	50.9	N/A	Make
4	21413 RMT0A--A	Housing - Lower	1	21413 RMT0A-01	17.7	PC	Buy
4	21414 RMT0A--A	Electronic Control Module	1	21414 RMT0A-01	29.2	N/A	Buy
4	21415 RMT0A--A	M3 Fastener	4	21415 RMT0A-01	4	N/A	Buy
3	21416 RMT0A--A	Housing - Upper	1	21416 RMT0A-01	22.5	PC	Buy
3	21417 RMT0A--A	Adhesive	1	21417 RMT0A-01	0.8	Araldite 2023-60	Buy
2	21418 RMT0A--A	Housing - Side	1	21418 RMT0A-01	8.2	PC	Buy
1	21419 RMT0A--A	Blow Tube	1	21419 RMT0A-01	13.6	Recycled HDPE	Buy
1	21420 RMT0A--A	Charging Cable	1	21420 RMT0A-01	24.8	N/A	Buy

Figure 3b – Product Part List

3.3 Performance

- Can be used re-used 300 times before calibrating. Reminder is programmed in device to calibrate after 300 tests or 12 months
- Bluetooth technology: When ON/OFF button is held down for more than 3 seconds, the device becomes visible for Bluetooth pairing. LED behind ON/OFF button flashes to indicate device is ready to pair, when paired the light remains ON.
- Blow tube has rough interior surface to help reduce condensation build up inside the virus detector device and improve accurate reading
- Battery life: 6 hours

(AlcoSens Lite 2a, 2023)

3.4 Circular Economy

- Blow tube 21419 RMT0A—A component listed in figure 3b is made in recycled material as part of an all-important global drive towards reducing contamination, landfill volume and saving natural resources. There is no requirement for a specific colour on this component and it's not fixed permanently to the device, therefore there is no design implication for using recycled material.

(BASF, Design Solution Guide)

4. Product Testing

- Prototype testing in laboratory already completed to prove the virus detector system design (electronic control module).
- Further physical testing below required to prove out the new envelope design and manufacturing tools and equipment;
 1. Verify the new envelope design (physical verification phase). Parts produced from rapid 3D printing. See key milestones in section 2.4 for build dates.
 2. Validate the new tooling (off tool phase). See key milestones in section 2.4 for build dates.
 3. Validate the new assembly process (off process phase). See key milestones in section 2.4 for build dates.

4.1 Physical Verification Testing

Below are the proposed test items for physical phase;

- Heat Cycle Test (-40°C~80°C cycles)
- High temperature (when device is left in direct sunlight)
- Performance (Electronic Control Module function within new mould assembly)
- Vibration Durability
- Impact Test
- Strength and Rigidity
- Ergonomics (to have a feel of the new shape physically)

4.2 Off Tool Validation Testing

Below are the proposed test items for off tool phase;

- Heat Cycle Test (-40°C~80°C cycles)
- High temperature (when device is left in direct sunlight)
- Performance (Electronic Control Module function within new mould assembly)
- Attach / Detach (Housing Side fitment to device for service)
- Fastener Torque (fastener assembly of Electronic Control Module to Housing Lower)
- Vibration Durability
- Impact Test
- Strength and Rigidity

4.3 Off Process Validation Testing

Below are the proposed test items for off process phase;

- Heat Cycle Test (-40°C~80°C cycles)
- High temperature (when device is left in direct sunlight)
- Performance (Electronic Control Module function within new mould assembly)
- Attach / Detach (Housing Side fitment to device for service)
- Fastener Torque (fastener assembly of Electronic Control Module to Housing Lower)
- Vibration Durability
- Impact Test
- Strength and Rigidity
- Internal Cleanliness (analysing the cleanliness of assembly are within SME)

Above tests have been developed internally within SME for electronic devices validation.

(Above test items are estimated based on experience in current industry)

5. Manufacturing & Logistics

5.1 Manufacturing Process Flow

The company's current in house capabilities include assembly, testing, packaging and shipping of breathalyser component, with the electronics and mechanical elements of the product sourced externally. The company have therefore decided to adopt the same strategy for the new virus detection device. Figure 5a below is the manufacturing process flow for both bought out and in house parts;

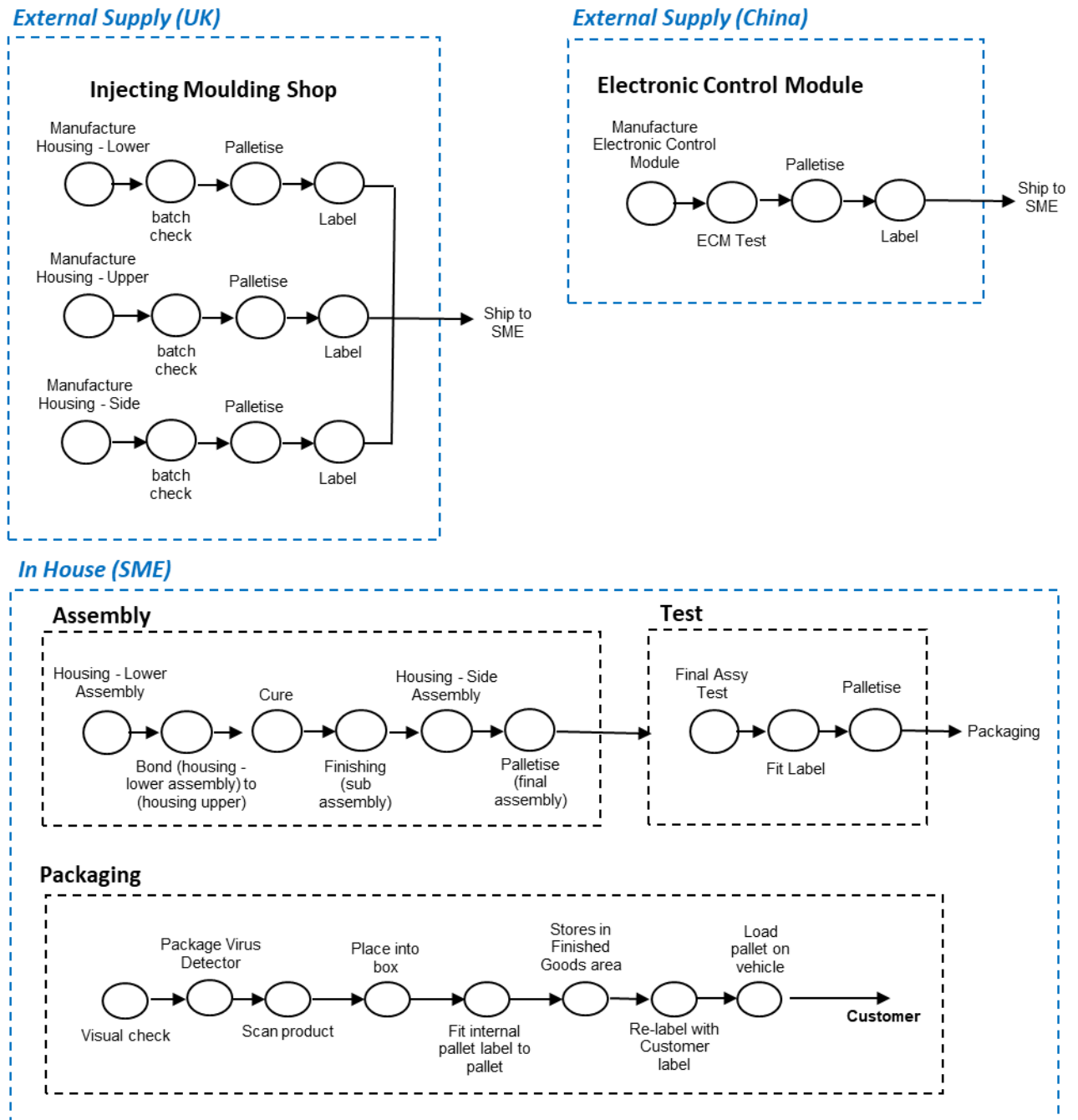


Figure 5a – Manufacturing Process Flow

5.2 Design For Manufacture

- R&D to chair a Design For Manufacture (DFM) review with the project team (manufacturing, engineering, program management, logistics, procurement, sales and marketing, quality) before design freeze. Any input to the design from the manufacturing perspective must be captured and drawings to be updated before design freeze. See key milestones in section 2 Sales & Marketing for design freeze timing.
- Suppliers to submit a feasibility document for bought out components to confirm latest design is feasible, any updates to design must be captured with design freeze timescale.

(BS EN ISO 9001, 2008)

5.3 Assembly Requirements

Fastener standard for Sub Assembly 21411 RMT0A—A;

All fasteners specified shall include the size, pitch, length and threaded length and are to be taken from the component drawing listed in figure 3b part list.

- Socket Cap Screws: ISO 4762

5.4 Packaging

- Each device is packed into a plastic mould, then fitted into a cardboard box (stage 2 within package manufacturing flow in figure 5a). Cardboard box is designed to be stored on the shelving at retailer and includes the various product information.



(AlcoSens Lite 2b, 2023)

- 20 of the above package to be boxed for transportation (stage 4 within package manufacturing flow in figure 5a).
- Packaging designed safe to ship and at the same time small enough to fit a large quantity in 1 box

- Spare blow tubes are available to purchase separately as spare parts and are therefore boxed separately, as shown in below image. Each box contains 20 blow tube parts.



5.5 Service

- Housing - Side (21418 RMT0A—A) is designed to unclip to allow access to the electronic ports during calibration.

6. Quality Assurance

6.1 Continual Improvement

- Continual improvement of the quality management must be adhered to as per the BS EN ISO 9001
- The methodology known as 'Plan Do Check Act' (PDCA) obtained from BS EN ISO 9001 is to be applied to all processes.

6.2 Supplier Quality Control

- If there are any concerns with dimensions that are outside of the specified tolerance, then result must be reported to SME R&D.
- Any concessions required for dimensions that are outside specified tolerance must be agreed by SME R&D. If agreed, component drawings must be updated to reflect the change in tolerance.

Injection moulded components

- During development, supplier to submit the following dimension report based on the key dimensions identified for fit and function on component drawings, as part of tool and part buy off before start of production;
Off Tool: measure 5 parts after tool is manufactured and submit results to SME QA for approval.
Off Process: measure 30 parts from final manufacturing process and submit results to SME QA for approval.
Note: See figure 3b part list in section 3 for drawing part number for each component, to review the key dimensions for approval.
- After start of production, supplier to check a sample from each batch of parts (as identified on process flow shown in figure 5a) before shipment to SME

Electronic Control Module

- During development, supplier to submit the following dimension report based on the key dimensions identified for fit and function on component drawings (PCB mounting holes)
Off Tool: measure 5 parts after tool is manufactured and submit results to SME QA for approval.
Off Process: measure 30 parts from final manufacturing process and submit results to SME QA for approval.
Note: See figure 3b part list in section 3 for drawing part number for ECM component, to review the key dimensions for approval.

- During development and after start of production, each final assembled electronic control module to be 100% tested end of line, (as identified on process flow shown in figure 5a) before shipment to SME.

6.3 Inhouse Quality Control

- During development, SME QA to measure assembled (sub and final assembly) components based on the key dimensions identified for fit and function on assembly drawings
Off Tool: measure 5 assemblies and submit result to SME R&D for approval
Off Process: measure 30 assemblies and confirm CPK value to see if manufacturing process is capable. Submit result to SME R&D for approval.
Note: See figure 3b part list in section 3 for drawing part number for assemblies, to review the key dimensions for approval.

(BS EN ISO 9001, 2008)

7. Finance

7.1 Engineering Cost

BOM Costings

Labour		
	Description	Rate
Design	2D & 3D Drawings	£ 36.00
Software	Software for smartphone app	£ 36.00
Programming	Test Machine and Label Print	£ 36.00
Testing	Product Validation	£ 28.00
Assembly	Manufacturing Work Instructions	£ 36.00
Bonding	Bonding 1st off	£ 19.00
Project management	Overview of the project	£ 36.00

All Components

Time	Cost
117	£ 4,212.00
78	£ 2,808.00
17	£ 612.00
234.0	£ 6,552.00
78	£ 2,808.00
8	£ 152.00
60	£ 2,160.00

Total Labour 397.00 £19,304.00

Total Cost £19,304.00

Selling Price (ex.works) £24,130.00

7.2 Assembly Jigs and Tooling Cost

BOM Costings

Labour		
	Description	Rate
Design	Bonding and Test Fixture	£ 36.00
Machining	Bonding and Test Fixture	£ 19.00
Painting	Bonding and Test Fixture	£ 16.00
Assembly	Bonding and Test Fixture	£ 36.00
Inspection	Bonding and Test Fixture	£ 36.00

All Jigs

Time	Cost
39	£ 1,404.00
39	£ 741.00
8	£ 128.00
17	£ 612.00
8	£ 288.00

Total Labour 72.00 £ 3,173.00

Materials

	Description	Unit	Unit cost
Tooling	Housing - Lower + Shipping	Each	£ 15,499.32
Tooling	Housing - Upper + Shipping	Each	£ 15,191.83
Tooling	Housing - Side + Shipping	Each	£ 8,264.97
Tooling	Blow Tube + Shipping	Each	£ 9,412.64

Required	COST
1	£ 15,499.32
1	£ 15,191.83
1	£ 8,264.97
1	£ 9,412.64
	£ -

Total Materials (+10%) £ 53,205.64

Total Cost £ 56,378.64

Selling Price (ex.works) £112,757.27

7.3 Manufacturing Cost

Manufacturing costs below are calculated per assembly;

BOM Costings

Labour

Description	Rate
Housing - Lower Assembly	£ 16.00
Bonding (housing lower assembly to housing upper)	£ 16.00
Finishing (sub assembly)	£ 16.00
Housing - Side Assembly & Palletise	£ 16.00
Final Assembly Test & Palletise	£ 16.00
Inspection	£ 36.00
Packaging	£ 16.00
Delivery Preparation	£ 16.00

Virus Detector Assembly

Time	Cost
0.017	£ 0.27
0.05	£ 0.80
0.017	£ 0.27
0.033	£ 0.53
0.05	£ 0.80
0.167	£ 6.00
0.083	£ 1.33
0.083	£ 1.33

Total Labour

0.48

£

11.32

Materials

Description	Unit	Unit cost
Housing - Lower + Shipping	Each	£ 3.66
Housing - Upper + Shipping	Each	£ 3.53
Housing - Side + Shipping	Each	£ 2.87
Electronic Control Module + Shipping	Each	£ 24.08
M3 Fastener + Shipping	Each	£ 0.05
Adhesive + Shipping	1 tub	£ 18.20
Blow Tube + Shipping	Each	£ 2.43
Charging Cable + Shipping	Each	£ 8.53
cardboard box + Shipping	Each	£ 1.87
Label paper + Shipping	Each	£ 0.02

Required	COST
1	£ 3.66
1	£ 3.53
1	£ 2.87
1	£ 24.08
4	£ 0.20
0.1	£ 1.82
1	£ 2.43
1	£ 8.53
0.05	£ 0.09
3	£ 0.06
	£ -
	£ -

Total Materials (+10%)

£

52.00

Total Cost

£

63.32

Selling Price (ex.works)

£

126.64

Note: The above labour stages are in line with SME manufacturing flow for Virus Detector Assembly shown in figure 5a. The above material costs are in line with part list shown in figure 3b.

All material costs are based on the volume stated in section 2.3

(Above costs are estimated based on experience in current industry)

7.4 Cost Summary

Non recurring costs

Engineering Costs

Change 1	£ 24,130.00	1	£ 24,130.00
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Assembly Jig Costs

Assembly 1	£ 112,757.27	1	£ 112,757.27
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NRC Total Cost

£

136,887.27

Part costs

Component Costs

Unit Cost	QTY	Sub Total
Virus Detector Assembly £ 126.64	1	£ 126.64

7.5 Legal & Intellectual Property Costs

- Consider the cost of patent registration identified in section 8 Legal & Intellectual Property.
- Registering a patent in 8 European countries alone for 10 years can cost up to £40,000.

(Trott, Paul. 2016)

7.6 Strategy to drive down manufacturing cost

Research has indicated that Asian countries, such as China, Taiwan and Vietnam, remain the most favourable for manufacturing electronic circuit boards. This is due to the low hourly compensation costs for labour, where a printed circuit board assembly involves extensive labour time. Therefore, the manufacturing of the new Electronic Control Module (21414 RMT0A—A) is proposed to be produced and assembled externally by a supplier based in China.

(Cost of manufacturing, 2020)

8. Legal & Intellectual Property

- Patents for similar products to be checked to see whether the company's new product design concept (electronic and mechanical system) has any concerns over intellectual property.
- Consider a copyright registration for software design for the new phone app.
- Consider a registration of a patent for the new system that has been designed to detect organic materials in the breath as a result of various viruses (20 year monopoly).
- Consider a trademark registration for the new brand name 'Virosense light' created for the new product.
- Suppliers to sign an NDA (non-disclosure agreement) before any data of new product design is shared to ensure the design is protected.

(Trott, Paul. 2016)

9. Politics, Social & Culture

9.1 Political Insight

- Advised that government to be informed of the new technology targeted towards NHS staff. The technology could enforce the government to introduce a new law that would force NHS staff to test on a regular basis.
- Data gathering from the app could potentially be shared with the World Health Organisation (WHO), which will need to be supported by the local government. Funding could be made available by the government to help progress the idea forward.

9.2 Social and Culture

- Vision for the new detection device is to change the culture in how people respond when they are feeling unwell, or when they plan to visit friends and family who are vulnerable to viruses.
- The change in culture will have a positive impact to how people live their lives, by having a reduced number of viruses spreading which will enable people to be part of social activities.
- Data gathering from the new device would help prevent another pandemic by recording the results on the app and potentially sharing with the World Health Organisation to see if there are any trends. This would not only have a positive impact socially, but to protect the global economy from any downturns.

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