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Design and Professional Practice 2

Product Specification Document

Dr Ian Radcliffe

Aims and Objectives

The aim of this session is to provide you with a basic understanding of the Product Specification Document and what is required for your project submission.

Intended Learning Outcomes

- Understand the role of the PSD in the product development process.
- Identify the key sections within a PSD and appreciate the level of content required within them.
- Formulate a PSD, as a group, for your project.

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Product Development Process

The PSD captures the expected specification and requirements of a product yet to be designed.

This helps the designers, manufacturers and even the users understand more about the product.

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Product Development Process

User Requirements

4.0 System Features

4.1 The system will consist of two handheld devices, differing only by the size and arrangement of the electrodes. The primary device will consist of a more extensive number of electrodes and will be used to produce planes of coagulated tissue in highly vascular organs. The secondary device will be used to coagulate small vessels or areas of tissue that have not been coagulated by the primary device.

4.2 Each device's handle will be constructed from a medical grade polymer which will provide thermal and electrical insulation. The handle design will be comfortable and practical.

4.3 For the primary device, multiple electrodes will issue from the handle in an array that will be designed to coagulate a volume of tissue at depths of up to 20cm, with a length of more than 2cm and widths of 1 cm. Each volume of tissue will be coagulated in less than 5 minutes.

4.4 For the secondary device, electrodes will issue from the handle in an array that will be designed to coagulate tissue at depths of up to 5 cm , lengths of 2cm and widths of 1 cm. Each volume of coagulated tissue will be achieved in 3 minutes.

4.5 Both devices will be supplied sterile and for single use only.

4.6 Each alternate electrode on a device will act as the ground return for the active electrode; hence the RF energy will be delivered bipolar. This substantially reduces the measured impedance, allowing for a more efficient power delivery, and eliminating the risk of ground electrode burns.

4.7 The electrodes on each device will be made from a material that will provide mechanical strength compatible with multiple insertions into soft tissue without significant deformation of the electrodes. The electrodes will have suitable conductive properties. The electrodes will have a non-stick surface preparation to facilitate insertion and removal from the liver or other soft vascular tissue. The electrodes will be designed to allow easy insertion into soft tissue.

4.8 The devices will have cables and connectors for connection to an RF generator outside of the sterile field. The RF generator will supply the RF energy in the frequency range 200-800kHz to the electrodes. The device will operate with 200W generators such as the Radionic's RF generator.

Technical Specification

Device		A: Long Probe	B: Short Probe
Total Number of Needles		4	4
Needle Diameter	mm	2.0	1.5
Total Length	mm	210	70
Useable Needle Length below plate	mm	190	50
Insulated Length	mm	150	0
Non insulated (active) length (distal portion)	mm	40	50 (full length)
Arrangement of needle array		2 x 2 (2 pairs)	2 x 2 (2 pairs)
Separation to sideways neighbour (centre-centre)	mm	6.0	6.0
Separation to next pair (centre-centre)	mm	7.0	7.0

1 Problem Definitio

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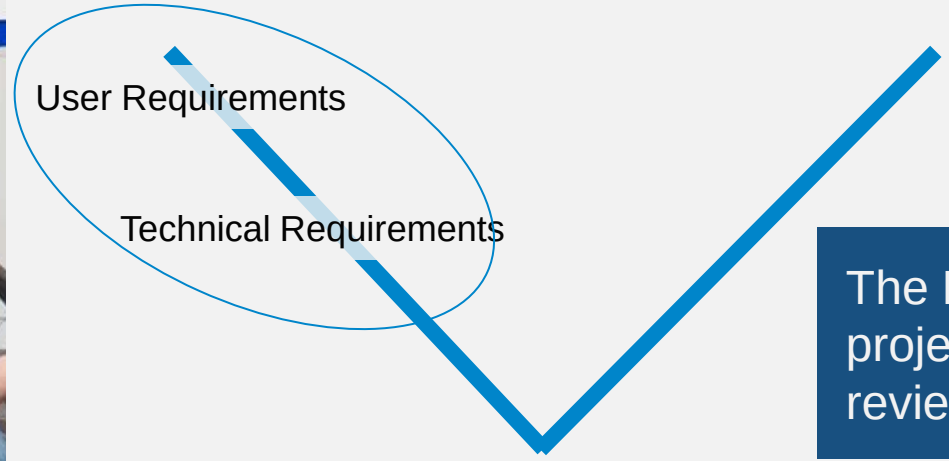
Product Development Process

The V-Model



The PSD is defined early in the project (although may be reviewed at key stages).

1 Problem Definition

2 Concept Generation

3 Technical Development

4 Detail Design

5 Manufacture Realisation

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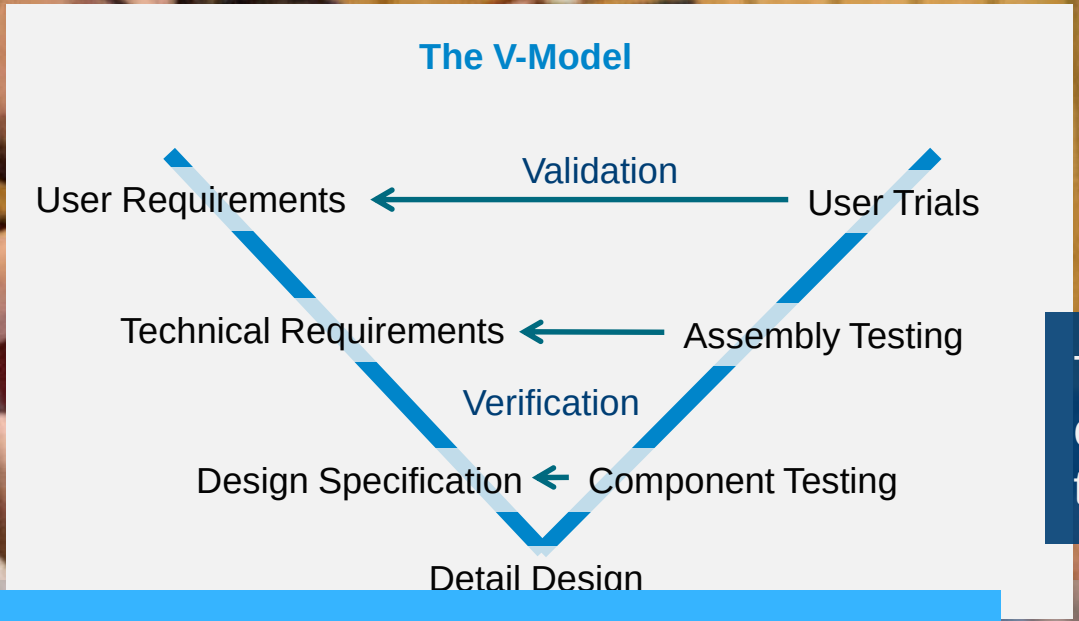
Product Development Process



The PSD provides criteria to assess the product against.

Validation against the User Requirements:
Are we building the right product?
Verification against the Technical Requirements:
Are we building the product right?

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Product Specification Document

There is a PSD Template prepared for you along with examples from last years projects.

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Product Specification Document

Product·Specification·Document¶

¶

Project·Name:¤	¤
Date:¤	¤
Release·Number:¤	¤

¶

No.¤	Aspect¤	Objective¤	Specification¤	Test·Method¤
¤	Functionality·and·Performance¤	¤	¤	¤
¤		¤	¤	¤
¤		¤	¤	¤
¤		¤	¤	¤
¤		¤	¤	¤
¤	Size·and·Weight¤	¤	¤	¤
¤		¤	¤	¤
¤		¤	¤	¤
¤		¤	¤	¤

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Product Specification Document

Product Specification Document

Project Name:	Use the shortened project name (and number)
Date:	The date
Release Number:	Allows you to keep track of changes you make (1, 2, 3, A etc.)

No.	Aspect	Objective	Specification	Test Method
	Functionality and Performance			
	Size and Weight			

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¤	Functionality·and·Performance¤	¤	¤	¤
¤		¤	¤	¤
¤		¤	¤	¤
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¤		¤	¤	¤
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	Functionality and Performance	A short line which describes what this particular specification is. (e.g.: weight, maximum load, energy consumption, power supply, cost, fire retardant.)		
	Size and Weight			

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	Size and Weight			

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	Size and Weight			

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No.	Aspect	Objective	Specification	Test Method
	Functionality and Performance			
	Size and Weight			

Functional requirement - detail the intended behaviour of the device, such as services, tasks or functions it is required to perform.

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	Size and Weight			

Functional requirement - detail the intended behaviour of the device, such as services, tasks or functions it is required to perform.

The physical attributes that the device needs to have, size, weight also potentially material and strength characteristics

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	Usability, Interface and Ergonomics	Any specific requirements related to how the how the user interacts with the device, does it need a button, touch screen, comfortable seat?		
	Environmental			
	Portability			
	Safety & Security			

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Product Specification Document

	Usability, Interface and Ergonomics	Any specific requirements related to how the how the user interacts with the device, does it need a button, touch screen, comfortable seat?		
	Environmental	Not is it recyclable and compostable. This means aspects that relate to the use environment in which the device will be used. Is it humid or dry, is it hot or cold, is it going to be in a hospital ward and therefore need to be cleaned in an autoclave?		
	Portability			
	Safety & Security			

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	Usability, Interface and Ergonomics	Any specific requirements related to how the how the user interacts with the device, does it need a button, touch screen, comfortable seat?		
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	Portability	Do you need to move it – in many ways links into the size and weight aspects as well as ergonomics. Will it be carried, will it be on wheels etc.		
	Safety & Security			

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Usability, Interface and Ergonomics	Any specific requirements related to how the how the user interacts with the device, does it need a button, touch screen, comfortable seat?
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Portability	Do you need to move it – in many ways links into the size and weight aspects as well as ergonomics. Will it be carried, will it be on wheels etc.
Safety & Security	Anything related to safety and security, such as flammability, electric shock / insulation, data storage / GDPR.

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	Life, Reliability and Maintenance	How long will it be used for, what is it's life span, how accurate will it be, what is the allowable failure rate, what maintenance is required?		
	Costs			
	Legal and Regulatorys			

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Product Specification Document

	Life, Reliability and Maintenance	How long will it be used for, what is it's life span, how accurate will it be, what is the allowable failure rate, what maintenance is required?		
	Costs	What is the acceptable target market price? What do competitor / similar products cost.		
	Legal and Regulatorys			

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Product Specification Document

Life, Reliability and Maintenance	How long will it be used for, what is it's life span, how accurate will it be, what is the allowable failure rate, what maintenance is required?
Cost	What is the acceptable target market price? What do competitor / similar products cost.
Legal and Regulatory	Any specific legal issues and regulatory issues that need to be adhered to, Medical Device certification, Toy Safety standards, Electrical standards, sporting or health guidelines and rules, laws.

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Summary

The PSD is a legal document that explains what the product needs to do, but not how it needs to do it.

It provides the criteria against which you will evaluate your design.