

Design Inputs vs Design Outputs

Project:

Device Class: I : Iia : Iib: III

To be completed after every stage and design change Refer to QC 22 for full Risk analysis

		Description/Performance	Specification/ Comment	Validated ?	Sample Nos tested	Documentation
1		Display				
	a	Accuracy				
	b	Resolution				
	c	Usage continuous Y / N				
	d	Calibration				
	e	User controls				
	f	Stability				
	g	Response time				
	h	External conditions affecting accuracy				
2		Alarms				
3		Accessories				
4		Desired Appropriate Standards				
	a	IEC 606.01 EMC				
	b	IEC 606-02 EMC				
	c	IEC 601 Safety				
	d	MDD Essential Requirements				
5		Final Design Tests Required				
	a	In-house				
	b	External				
	c	3 rd Party testing				
	d	Special Tests				
6		Acceptance test Criteria				
7		Trial Requirements				

		Clinical trials			
8		Maintenance			
	a	Manual			
	b	On-site			
	c	Return to base			
	d	Overseas sales			
	e	Lifespan			
9		Software			
		Repeatability			
		Reliability			
10		Packaging			
	a	Breakage			
	b	Contamination			
	c	Storage conditions			
11		Accessories			
	a	Detachable components			
	b	Sterile /Single use			
12		Environment			
	a	Vibration			
	b	Noise			
	c	Radiation			
	d	Magnetic			
	e	Electrostatic			
	f	EMC IN / out			
	g	Heat			
	h	Flame			
	i	Latex			
	j	Volume			
	k	Pressure			
	l	Electric shock			
	m	Ingress of moisture			
	n	Ingress of dust			

	o	Cross infection		
	p	Frequency of patient exposure		
	q	Duration of patient exposure		
	r	Current Technology used		
	s	Construction		
	t	Current medical practices		
	u	Health & safety of patient		
	v	Health & safety of user		
	w	Intended use		
	x	Possible misuse		
	y	Possible side effects		
	z	Ergonomical features		
	aa	Ease of use		
	bb	Blood products		
	cc	Animal products		
	dd	Sterile /Single use		
	ee	Mechanical stability		
	ff	Gas supplies		
	gg	Hydrolic supplies		
	hh	Calibration		
	ii	Ageing		
	jj	Flow rates		
	kk	Reaction with other equipment		
	ll	Reciprocal interference		
	m	Disposal of product		
	m			
13		Notified Body required Y/N		
14		User manual		
	a	Cleaning		
	b	Intended purpose		
15		Clinical Benefit/Risk		

