

Job Description & Specification

Page 2

Project:				
Requested By				
Name / Position				
Address				
Telephone No				
Origination Date				
Device Class: I : Iia : Iib: III				
		Description/Performance	Specification/ Comment	Predicted Risks
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	Hydraulic supplies		
	hh	Calibration		
	ii	Ageing		
	jj	Flow rates		
	kk	Reaction with other equipment		
	ll	Reciprocal interference		
	mm	Disposal of product		
13		Notified Body required Y/N		
14		User manual		
	a	Cleaning		
	b	Intended purpose		
15		Clinical Benefit/Risk		