

Risk Assessment iaw EN ISO 14971:2000 Annex D: Possible hazards with medical devices.

Ref.	Hazard.	Related part / Component posing	Sev of	Like of	Risk.	Solution.	Document referenced.	Sev of	Like 0f	Risk.
		risk.	Haz.	Haz.				Haz.	Haz.	
D.2	Energy hazards and con			T	Г		-T		Г	
D.2.1	Electricity	Instrument Failure	2	1	2	Inherent Design features	Manufacturers Data	1	1	1
D.2.2	Heat	Instrument Failure	2	1	2	Inherent Design features	Manufacturers Data	1	1	1
D.2.3	Mechanical force		1	1	1			1	1	1
D.2.4	Ionising radiation		1	1	1			1	1	1
D.2.5	Non ionising radiation		1	1	1			1	1	1
D.2.6	Moving parts		1	1	1			1	1	1
D.2.7	Unintended motion		1	1	1			1	1	1
D.2.8	Suspended masses		1	1	1			1	1	1
D.2.9	Patient support failure		1	1	1			1	1	1
D .2.10	Pressure (vessel rupture)		1	1	1			1	1	1
D.2.11	Acoustic pressure		1	1	1			1	1	1
D.2.12	Vibration		1	1	1			1	1	1
D.2.13	Magnetic fields	Potential component	2	1	2	Not for use within MRI	F. Instruction Leaflet	1	1	1
	(eg. MRI)	interference				scanning suites				
D.3	Biological hazards and	contributory factors								
D.3.1	Bio-contamination		1	1	1			1	1	1
D.3.2	Bio-incompatibility		1	1	1			1	1	1
D.3.3	Incorrect formulation		1	1	1			1	1	1
	(chemical composition)									
D.3.4	Toxicity		1	1	1			1	1	1
D.3.5	Allergenicity		1	1	1			1	1	1
D.3.6	Mutagenicity		1	1	1			1	1	1
D.3.7	Oncogenicity		1	1	1			1	1	1
D.3.8	Carcinogenicity		1	1	1			1	1	1
D.3.9	Re and/or cross infection	User error	2	2	4	Cleaning Information	F. Instruction Leaflet	1	1	1

E. Risk Management BS14971 Annex D_SpO2 Probes

Page 1 28/01/2005



D.3.10	Pyrogenicity		1	1	1			1 1	1	1
	Inability to maintain	General un-	2	2	4	Cleaning Information	F. Instruction Leaflet	$\frac{1}{2}$	1	2
	hygienic standards	cleanliness								
D.3.12	Degradation		1	1	1			1	1	1
D.4	Environmental hazards	and contributory fa	ctors	·						,
D.4.1	Electromagnetic fields		1	1	1			1	1	1
D.4.2	Susceptibility to		1	1	1			1	1	1
	electromagnetic									
	interference									
D.4.3	Emissions of		1	1	1			1	1	1
	electromagnetic									
	interference									
D.4.4	Inadequate supply of		1	1	1			1	1	1
	power									
D.4.5	Inadequate supply of		1	1	1			1	1	1
	coolant									
D .4.6	Storage / operation		1	1	1			1	1	1
	outside prescribed									
	environmental conditions									
D.4.7	Incompatibility with		1	1	1			1	1	1
	other devices with which									
	the product is intended to									
D 4.0	be used		-	- 1	7			-	-	,
D.4.8	Accidental mechanical		1	1	1			1	1	1
D 4.0	damage		-	-	1		_	-	-1	,
D .4.9	Contamination due to								1	1
	waste products and/or									
D.E	device disposal	in accuract output = £		 	 	•				
D.5	Hazards resulting from	incorrect output 01 (energy	anu sui	ostance 1	3	1	1 1	1	1 1
D.5.1	Electricity		1 1	1 1	1			1 1	1	1 1
D.5.2	Radiation		<u> </u>		1			<u> </u>	1	<u> </u>

E. Risk Management BS14971 Annex D_SpO2 Probes

Page 2 28/01/2005



D 5 2	Volume		1	1 1	1			1	1	1
D.5.3			1	1	1	-		1	1	1
D.5.4	Pressure		1	1	1			1	1	1
	Supply of medical gases		1	1	1			1	1	1
D.5.6	Supply of anaesthetic		1	1	1			1	1	1 1
	agents									
D.6	Hazards related to the u	ise of the medical dev	vice an	d contr	ibutor	y factors				
D.6.1	Inadequate labelling		2	1	2			1	1	1
D.6.2	Inadequate operating		2	1	2			1	1	1
	instructions									
D.6.3	Inadequate specification		1	1	1			1	1	1
	of accessories									
D.6.4	Inadequate specification		1	1	1			1	1	1
	of pre-use checks									
D.6.5	Over-complicated		1	1	1			1	1	1
	operating instructions									
D.6.6	Inadequate specification		1	1	1			1	1	1
	of service and		_	_				_	_	
	maintenance									
D.6.7	Use by unskilled /	Inadequate site	2	2	4	For use by trained / skilled	F Instruction leaflet	1	1	1
D.0.7	untrained personnel	located	_	~	,	personnel		_	1	1 1
D.6.8	Reasonable foreseeable	100000	1	1	1	personner		1	1	1
D.0.0	misuse		1	1	1			1	1	
D .6.9	Insufficient warning of		1	1	1	+		1	1	1
D .0.5	side effects		1	1	1			1	1	1
D 6 10	Inadequate warnings of		1	1	1			1	1	1
D.0.10	hazards likely with re-		1	1	1			1	1	1
	use of single use devices									
D (11	Incorrect measurement	Tachniqua Limita 1	2	-		For use by trained / slvill - 1	E Instruction leaflet	1	1	1
D.6.11		Technique Limited	2	2	4	For use by trained / skilled	r. instruction featiet	1	1	1
	and other metrological					personnel				
	aspects									

28/01/2005



D.6.12	Misrepresentation of results		1	1	1			1	1	1
D.6.13	Incompatibility with consumables / accessories / other devices	Alternative connections	2	2	4	Manufacturers use similar connectors	Colour spot identification labelling	1	1	1
D.6.14	Sharp edges or points		1	1	1			1	1	1
D.7	Inappropriate, inadequa	ate or overcomplicate	ed user	interf:	ace (ma	an/machine communication				
D .7.1	Mistakes & judgement errors	Personnel attributes	2	2	4	For use by trained / skilled personnel	F. Instruction leaflet	1	1	1
D.7.2	Lapses and cognitive recall errors	Personnel attributes	2	2	4	For use by trained / skilled personnel	F. Instruction leaflet	1	1	1
D.7.3	Slips & blunders (mental or physical)		1	1	1			1	1	1
D.7.4	Violation or abbreviation of instructions, procedures etc		1	1	1			1	1	1
D.7.5	Complex or confusing control system		1	1	1			1	1	1
D .7.6	Ambiguous or unclear device state		1	1	1			1	1	1
D.7.7	Ambiguous or unclear presentation of settings, measurement, or other information		1	1	1			1	1	1
D.7.8	Misrepresentation of results		1	1	1			1	1	1
D .7.9	Insufficient visibility, audibility or tactility		1	1	1			1	1	1



	Poor mapping of controls to action or of displayed information to actual state		1	1	1			1	1	1
D .7.11	Controversial modes or mappings as compared to existing equipment		1	1	1			1	1	1
D.8	Hazards arising from fu	nction failure, maint	tenance	e and a	geing :	and contributory factors				
D.8.1	Erroneous data transfer		1	1	1			1	1	1
D.8.2	Lack of, or inadequate specification for maintenance including post maintenance functional tests		1	1	1			1	1	1
D.8.4	Inadequate maintenance		1	1	1			1	1	1
D.8.5	Lack of adequate determination of end of device life	Will fail to function	2	1	2	No end of life set		2	1	2
D .8.6	Loss of electrical integrity	Will fail to function	2	1	2	User decision of failure, cost effectiveness of repair	F. Instruction Leaflet	1	1	1
D.8.7	Loss of mechanical integrity	Will be visible to the user	2	1	2	Constant vigilance		1	1	1
D.8.8	Inadequate packaging (contamination and / or deterioration of the device)		1	1	1			1	1	1
D .8.9	Re-use and/or improper re-use		1	1	1			1	1	1

28/01/2005



D.8.10 Deterioration in function	1	1	1		1	1	1
(gradual occlusion of							
fluid / gas path or change							
in resistance to flow,							
electrical conductivity)							
as a result of repeated							
use							



Risk Assessment iaw EN ISO 14971:2000 Annex D: Possible hazards with medical devices.

Ref.	Hazard.	Related part /	Sev	Like	Risk.	Solution.	Document referenced.	Sev	Like	Risk.
		Component posing risk.	of Haz.	of Haz.				of Haz.	0f Haz.	
D.2	Energy hazards and con		TILLI	111121				11424	11424	
D.2.1	Electricity	Instrument Failure	2	1	2	Inherent Design features	Manufacturers Data	1	1	1
D.2.2	Heat	Instrument Failure	2	1	2	Inherent Design features	Manufacturers Data	1	1	1
D.2.3	Mechanical force		1	1	1			1	1	1
D.2.4	Ionising radiation		1	1	1			1	1	1
D.2.5	Non ionising radiation		1	1	1			1	1	1
D.2.6	Moving parts		1	1	1			1	1	1
D.2.7	Unintended motion		1	1	1			1	1	1
D.2.8	Suspended masses		1	1	1			1	1	1
D.2.9	Patient support failure		1	1	1			1	1	1
D.2.10	Pressure (vessel rupture)		1	1	1			1	1	1
D.2.11	Acoustic pressure		1	1	1			1	1	1
D.2.12	Vibration		1	1	1			1	1	1
D.2.13	Magnetic fields	Potential component	2	1	2	Not for use within MRI	F. Instruction Leaflet	1	1	1
	(eg. MRI)	interference				scanning suites				
D.3	Biological hazards and c	ontributory factors					-	_		
D.3.1	Bio-contamination		1	1	1			1	1	1
D.3.2	Bio-incompatibility		1	1	1			1	1	1
D.3.3	Incorrect formulation		1	1	1			1	1	1
	(chemical composition)									
D.3.4	Toxicity		1	1	1			1	1	1
D.3.5	Allergenicity		1	1	1			1	1	1
D.3.6	Mutagenicity		1	1	1			1	1	1
D.3.7	Oncogenicity		1	1	1			1	1	1

T:\Kevin Rush\CE Files\CE files current\SpO2_Probes\SpO2 Probes_CE File_2004\E. Risk Analysis\EN 14971 Annexe D\E. Risk Management BS14971 Annex D_SpO2 Probes.doc Page 1 12/07/2004



D.3.8	Carcinogenicity		1	1	1			1	1	1
D.3.9	Re and/or cross infection	User error	2	2	4	Cleaning Information	F. Instruction Leaflet	1	1	1
D.3.10	Pyrogenicity		1	1	1			1	1	1
D.3.11	Inability to maintain	General un-	2	2	4	Cleaning Information	F. Instruction Leaflet	2	1	2
	hygienic standards	cleanliness								
D.3.12	Degradation		1	1	1			1	1	1
D.4	Environmental hazards a	and contributory fac	tors		_					
D.4.1	Electromagnetic fields		_1	1	1			1	1	1
D.4.2	Susceptibility to		1	1	1			1	1	1
	electromagnetic									
	interference									
D.4.3	Emissions of		1	1	1			1	1	1 1
	electromagnetic									
	interference									
D.4.4	Inadequate supply of		1	1	1			1	1	1 1
	power				l					
D.4.5	Inadequate supply of		1	1	1			1	1	1
	coolant									
D.4.6	Storage / operation		1	1	1			1	1	1 1
	outside prescribed									
	environmental conditions									
D.4.7	Incompatibility with		1	1	1			1	1	1
	other devices with which									
	the product is intended to									
D 10	be used		-							
D.4.8	Accidental mechanical		1	1	1			1	1	1
D 4.6	damage		1							
D.4.9	Contamination due to		1	1	1			1	1	1
	waste products and/or									
	device disposal			<u> </u>	<u> </u>					

T:\Kevin Rush\CE Files\CE files current\SpO2_Probes\SpO2 Probes_CE File_2004\E. Risk Analysis\EN 14971 Annexe D\E. Risk Management BS14971 Annex D_SpO2 Probes.doc Page 2 12/07/2004



D.5	Hazards resulting from i	ncorrect output of e	nergy a	nd sub	stances	S				
D.5.1	Electricity		1	1	1			1	1	1
D.5.2	Radiation		1	1	1			1	1	1
D.5.3	Volume		1	1	1			1	1	1
D.5.4	Pressure		1	1	1			1	1	1
D.5.5	Supply of medical gases		1	1	1			1	1	1
D.5.6	Supply of anaesthetic agents		1	1	1			1	1	1
D.6	Hazards related to the us	se of the medical dev	ice and	l contri	l ihutory	factors				
D.6.1	Inadequate labelling	oc of the incurcal dev	2	1	2			1	1	1
D.6.2	Inadequate operating		2	1	2			1	1	1
15.0.2	instructions		2	1	2			1	1	1
D.6.3	Inadequate specification		1	1	1			1	1	1
	of accessories									
D.6.4	Inadequate specification		1	1	1			1	1	1 1
	of pre-use checks									
D.6.5	Over-complicated		1	1	1			1	1	1
	operating instructions									
D.6.6	Inadequate specification		1	1	1			1	1	1
	of service and									
	maintenance						_			
D.6.7	Use by unskilled /	Inadequate site	2	2	4	For use by trained / skilled	F. Instruction leaflet	1	1	1
	untrained personnel	located				personnel				
D.6.8	Reasonable foreseeable		1	1	1			1	1	1
	misuse									
D.6.9	Insufficient warning of	•	1	1	1			1	1	1
	side effects									

T:\Kevin Rush\CE Files\CE files current\SpO2_Probes\SpO2 Probes_CE File_2004\E. Risk Analysis\EN 14971 Annexe D\E. Risk Management BS14971 Annex D_SpO2 Probes.doc Page 3
12/07/2004



D.6.10	Inadequate warnings of hazards likely with reuse of single use devices		1	1	1			1	1	1
D.6.11	Incorrect measurement and other metrological aspects	Technique Limited	2	2	4	For use by trained / skilled personnel	F. Instruction leaflet	1	1	1
D.6.12	results		1	1	1			1	1	1
D.6.13	Incompatibility with consumables / accessories / other devices	Alternative connections	2	2	4	Manufacturers use similar connectors	Colour spot identification labelling	1	1	1
D.6.14	Sharp edges or points		1	1	1			1	1	1
D. 7	Inappropriate, inadequa	ite or overcomplicate	d user	interfa	ce (ma	n/machine communication)			•
D.7.1	Mistakes & judgement errors	Personnel attributes	2	2	4	For use by trained / skilled personnel	F. Instruction leaflet	1	1	1
D.7.2	Lapses and cognitive recall errors	Personnel attributes	2	2	4	For use by trained / skilled personnel	F. Instruction leaflet	1	1	1
D.7.3	Slips & blunders (mental or physical)		1	1	1			1	1	1
D.7.4	Violation or abbreviation of instructions, procedures etc		1	1	1			1	1	1
D.7.5	Complex or confusing control system		1	1	1			1	1	1
D.7.6	Ambiguous or unclear device state		1	1	1			1	1	1

T:\Kevin Rush\CE Files\CE files current\SpO2_Probes\SpO2 Probes_CE File_2004\E. Risk Analysis\EN 14971 Annexe D\E. Risk Management BS14971 Annex D_SpO2 Probes.doc Page 4 12/07/2004



D 7.7	A1.1.		1	1	1			1 1	1 1	1 1
D.7.7	Ambiguous or unclear		ı	1	1			1	1	1
	presentation of settings,									
	measurement, or other									
	information									
D.7.8	Misrepresentation of		1	1	1			1	1	1
	results									
D.7.9	Insufficient visibility,		1	1	1			1	1	1
	audibility or tactility									
D.7.10	Poor mapping of controls		1	1	1			1	1	1
	to action or of displayed									
	information to actual									
	state									
D.7.11	Controversial modes or		1	1	1			1	1	1
D.7.11	mappings as compared to		1	1	*			1	1	1
	existing equipment									
1				I				1	l	1
D 0				1	٠		1		<u>L</u>	
D.8	Hazards arising from fu	nction failure, maint	enance	and ag	geing a	nd contributory factors	, , , , , , , , , , , , , , , , , , ,	1 -	<u> </u>	
D.8.1	Hazards arising from fur Erroneous data transfer	nction failure, maint	enance 1	and ag	1	nd contributory factors		1	1	1
	Hazards arising from fur Erroneous data transfer Lack of, or inadequate	nction failure, maint	enance 1 1	and ag	geing a	nd contributory factors		1 1	1 1	1 1
D.8.1	Hazards arising from fur Erroneous data transfer Lack of, or inadequate specification for	nction failure, mainto	e nance 1 1	and ag	1	nd contributory factors		1 1	1 1	1 1
D.8.1	Hazards arising from fur Erroneous data transfer Lack of, or inadequate	nction failure, maint	enance 1 1	and ag	1	nd contributory factors		1 1	1 1	1 1
D.8.1	Hazards arising from fur Erroneous data transfer Lack of, or inadequate specification for	nction failure, maint	enance 1 1	and ag	1	nd contributory factors		1 1	1 1	1 1
D.8.1	Hazards arising from fur Erroneous data transfer Lack of, or inadequate specification for maintenance including	nction failure, maint	enance 1 1	and ag	1	nd contributory factors		1 1	1 1	1 1
D.8.1	Hazards arising from fur Erroneous data transfer Lack of, or inadequate specification for maintenance including post maintenance functional tests	nction failure, maint	1 1	and ag	1	nd contributory factors		1 1	1 1	1 1
D.8.1 D.8.2	Hazards arising from fur Erroneous data transfer Lack of, or inadequate specification for maintenance including post maintenance functional tests Inadequate maintenance	nction failure, mainto	1	and ag	1	nd contributory factors No end of life set			1 1 1	1 1 2
D.8.1 D.8.2	Hazards arising from fur Erroneous data transfer Lack of, or inadequate specification for maintenance including post maintenance functional tests Inadequate maintenance Lack of adequate		1 1	and ag	1 1			1 1 1 2	1 1 1	1 1 2
D.8.1 D.8.2	Hazards arising from fur Erroneous data transfer Lack of, or inadequate specification for maintenance including post maintenance functional tests Inadequate maintenance Lack of adequate determination of end of		1 1	1 1 1 1 1 1	1 1			1 1 1 2	1 1 1 1	1 1 2
D.8.1 D.8.2 D.8.4 D.8.5	Hazards arising from fur Erroneous data transfer Lack of, or inadequate specification for maintenance including post maintenance functional tests Inadequate maintenance Lack of adequate determination of end of device life	Will fail to function	1 1 2	and ag	1 1 2	No end of life set	F. Instruction Leaflet	·	1 1 1	1 1 2
D.8.1 D.8.2	Hazards arising from fur Erroneous data transfer Lack of, or inadequate specification for maintenance including post maintenance functional tests Inadequate maintenance Lack of adequate determination of end of device life Loss of electrical		1 1	1 1 1 1 1	1 1	No end of life set User decision of failure,	F. Instruction Leaflet	1 1 2	1 1 1	1 1 2
D.8.1 D.8.2 D.8.4 D.8.5	Hazards arising from fur Erroneous data transfer Lack of, or inadequate specification for maintenance including post maintenance functional tests Inadequate maintenance Lack of adequate determination of end of device life Loss of electrical integrity	Will fail to function Will fail to function	1 1 2 2	1 1 1 1 1 1	1 2 2	No end of life set User decision of failure, cost effectiveness of repair	F. Instruction Leaflet	·	1 1 1 1	1 1 2
D.8.1 D.8.2 D.8.4 D.8.5	Hazards arising from fur Erroneous data transfer Lack of, or inadequate specification for maintenance including post maintenance functional tests Inadequate maintenance Lack of adequate determination of end of device life Loss of electrical	Will fail to function	1 1 2	1 1 1 1 1 1	1 1 2	No end of life set User decision of failure,	F. Instruction Leaflet	·	1 1 1 1	1 1 2

T:\Kevin Rush\CE Files\CE files current\SpO2_Probes\SpO2 Probes_CE File_2004\E. Risk Analysis\EN 14971 Annexe D\E. Risk Management BS14971 Annex D_SpO2 Probes.doc Page 5
12/07/2004



D.8.8	Inadequate packaging	1	1	1		1	1	1
	(contamination and / or							
	deterioration of the							
	device)							
D.8.9	Re-use and/or improper	1	1	1		1	1	1
	re-use							
D.8.10	Deterioration in function	1	1	1		1	1	1
	(gradual occlusion of							
	fluid / gas path or change							
	in resistance to flow,							
	electrical conductivity)							
	as a result of repeated							
	use							

T:\Kevin Rush\CE Files\CE files current\SpO2_Probes\SpO2 Probes_CE File_2004\E. Risk Analysis\EN 14971 Annexe D\E. Risk Management BS14971 Annex D_SpO2 Probes.doc Page 6 12/07/2004



Risk Assessment iaw EN ISO 14971:2000 Annex D: Possible hazards with medical devices.

Ref.	Hazard.	Related part / Component posing risk.	Sev of Haz.	Like of Haz.	Risk.	Solution.	Documen
D.2.1	Electricity	Instrument Failure	2	1	2	Inherent Design features	Manufactur
	Heat	Instrument Failure	2	1	2	Inherent Design features	Manufactur
	Mechanical force	,	1	1	1		
	Ionising radiation	<u> </u>	1	1	1		1
D.2.5	Non ionising radiation	,	1	1	1		+
	Moving parts	,	1	1	1		+
	Unintended motion	,	1	1	1		
	Suspended masses	,	1	1	1		+
	Patient support failure	,	1	1	1		
	Pressure (vessel rupture)	,	1	1	1		
	Acoustic pressure	,	1	1	1		
	Vibration	,	1	1	1		1
	Magnetic fields	Potential component		1	2	Not for use within MRI	F. Instruction
	(eg. MRI)	interference				scanning suites	
D.3.1	Bio-contamination		1	1	1		
D.3.2	Bio-incompatibility		1	1	1		
	Incorrect formulation (chemical composition)		1	1	1		
D.3.4	Toxicity		1	1	1		
D.3.5	Allergenicity		1	1	1		
D.3.6	Mutagenicity		1	1	1		
	Oncogenicity		1	1	1		
	Carcinogenicity		1	1	1		
	Re and/or cross infection	User error	2	2	4	Cleaning Information	F. Instruction
	Pyrogenicity		1	1	1	-	
D.3.11	Inability to maintain hygienic standards	General un- cleanliness	2	2	4	Cleaning Information	F. Instruction
	Degradation	,	1	1	1		
D.4.1	Electromagnetic fields		1	1	1		
	Susceptibility to	,	1	1	1		
	electromagnetic interference						

E. Risk Management BS14971 Annex D_SpO2 Probes

Page 1

28/01/2005

Severity of hazard: 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Probability of event: 1 = Improbable, 2 = Occasional, 3 = Likely, 4 = Highly likely.



D.4.3	Emissions of	1	1	1 1	1		
	electromagnetic	, 		'			
	interference		<u> </u>	'			
D.4.4	Inadequate supply of		1	1	1		
	power	<u> </u>	<u> </u>	'			
D.4.5	Inadequate supply of		1	1	1		
	coolant	<u> </u>		'			
D.4.6	Storage / operation		1	1	1		[·
	outside prescribed	1	1	'			
	environmental conditions	<u></u> '	<u> </u>	'			
D.4.7	Incompatibility with	1	1	1 1	1		!
	other devices with which	1	1	'			
	the product is intended to	1	1	'			•
	be used	 '	<u> </u>	<u> </u>	<u> </u>		<u> </u>
D.4.8	Accidental mechanical	1	1	1	1		
	damage	<u>'</u>		<u> </u>	 		<u> </u>
D.4.9	Contamination due to	1	1	1	1		•
	waste products and/or	1	1	'			
	device disposal			<u> </u>			
D 5 1				1	1		
D.5.1	Electricity	<u> </u>	1	1	1	<u> </u>	
D.5.2	Radiation	<u> </u>	1	1	1		<u> </u>
D.5.3	Volume	<u> </u>	1	1	1		<u> </u> !
D.5.4	Pressure	<u>'</u>	1	1	1		
D.5.5	Supply of medical gases	 '	1	1	1		
D.5.6	Supply of anaesthetic	1	1	1	1		
	agents	<u> </u>		'			
= 6.1	4 4 44			سيكم			
D.6.1	Inadequate labelling	 	2	1	2		
D.6.2	Inadequate operating	1	2	1	2		
	instructions	 '	<u> </u>	<u> '</u>	 		
D.6.3	Inadequate specification	1	1	1	1		
	of accessories	<u> </u>	<u> </u>	<u> </u>	<u> </u>		
D.6.4	Inadequate specification	1	1	1	1		
<u></u>	of pre-use checks	 '	<u> </u>	<u> </u>	<u> </u>		<u> </u>
D.6.5	Over-complicated	1	1	1 1	1		
	operating instructions	 	<u> </u>	<u> </u>	<u> </u>		<u> </u>
D.6.6	Inadequate specification	1	1	1 1	1		
	of service and	l		'			
	maintenance	<u> </u>	<u> </u>	<u> </u> '		<u> </u>	<u> </u>
D.6.7	Use by unskilled /	Inadequate site	2	2	4	For use by trained / skilled	F. Instruction
	untrained personnel	located	<u> </u>	<u> </u>		personnel	

E. Risk Management BS14971 Annex D_SpO2 Probes

Page 2

28/01/2005

Severity of hazard: 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Probability of event: 1 = Improbable, 2 = Occasional, 3 = Likely, 4 = Highly likely.



D.6.8	Reasonable foreseeable misuse		1	1	1		
D.6.9	Insufficient warning of side effects		1	1	1		
D.6.10	Inadequate warnings of hazards likely with reuse of single use devices		1	1	1		
	Incorrect measurement and other metrological aspects	Technique Limited	2	2	4	For use by trained / skilled personnel	F. Instructio
	Misrepresentation of results		1	1	1		
	consumables / accessories / other devices	Alternative connections	2	2	4	Manufacturers use similar connectors	Colour spot labelling
D.6.14	Sharp edges or points		1	1	1		
D.7.1	Mistakes & judgement errors	Personnel attributes	2	2	4	For use by trained / skilled personnel	F. Instructio
D.7.2	Lapses and cognitive recall errors	Personnel attributes	2	2	4	For use by trained / skilled personnel	F. Instruction
	Slips & blunders (mental or physical)		1	1	1		
D.7.4	Violation or abbreviation of instructions, procedures etc		1	1	1		
D.7.5	Complex or confusing control system		1	1	1		
D.7.6	Ambiguous or unclear device state		1	1	1		
D.7.7	Ambiguous or unclear presentation of settings, measurement, or other information		1	1	1		
D.7.8	Misrepresentation of results		1	1	1		
D.7.9	Insufficient visibility, audibility or tactility		1	1	1		

E. Risk Management BS14971 Annex D_SpO2 Probes

Page 3

28/01/2005

Severity of hazard: 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Probability of event: 1 = Improbable, 2 = Occasional, 3 = Likely, 4 = Highly likely.



D.7.10	Poor mapping of controls to action or of displayed information to actual state		1	1	1		
D.7.11	Controversial modes or mappings as compared to existing equipment		1	1	1		
D.8.1	Erroneous data transfer		1	1	1		
D.8.2	Lack of, or inadequate specification for maintenance including post maintenance functional tests		1	1	1		
D.8.4	Inadequate maintenance		1	1	1		
D.8.5	Lack of adequate determination of end of device life	Will fail to function	2	1	2	No end of life set	
D.8.6	Loss of electrical integrity	Will fail to function	2	1	2	User decision of failure, cost effectiveness of repair	F. Instruction
D.8.7	Loss of mechanical integrity	Will be visible to the user	2	1	2	Constant vigilance	
D.8.8	Inadequate packaging (contamination and / or deterioration of the device)		1	1	1		
D.8.9	Re-use and/or improper re-use		1	1	1		
D.8.10	Deterioration in function (gradual occlusion of fluid / gas path or change in resistance to flow, electrical conductivity) as a result of repeated use		1	1	1		



Risk Assessment iaw EN ISO 14971:2000 Annex D: Possible hazards with medical devices.

Ref.	Hazard.	Related part / Component posing risk.	Sev of Haz.	Like of Haz.	Risk.	Solution.	Documen
D.2.1	Electricity						
D.2.2	Heat						
D.2.3	Mechanical force						
D.2.4	Ionising radiation						
D.2.5	Non ionising radiation						
D.2.6	Moving parts						
D.2.7	Unintended motion						
D.2.8	Suspended masses						
D.2.9	Patient support failure						
D.2.10	Pressure (vessel rupture)						
	Acoustic pressure						
	Vibration						
D.2.13	Magnetic fields						
	(eg. MRI)						
D.3.1	Bio-contamination						
D.3.2	Bio-incompatibility						
D.3.3	Incorrect formulation						
	(chemical composition)						
D.3.4	Toxicity						
D.3.5	Allergenicity						
D.3.6	Mutagenicity						
D.3.7	Oncogenicity						
D.3.8	Carcinogenicity						
D.3.9	Re and/or cross infection						
D.3.10	Pyrogenicity						
	Inability to maintain						
	hygienic standards						
D.3.12	Degradation						
D.4.1	Electromagnetic fields						

T:\Kevin Rush\CE Requirements\CE Files\CE files current\SpO2_Probes\SpO2 Probes_CE File_2004\E. Risk Analysis\EN 14971 Annexe D\E. Risk Management BS14971 Annex D.doc Page 1

08/10/2004

Severity of hazard: 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Probability of event: 1 = Improbable, 2 = Occasional, 3 = Likely, 4 = Highly likely.



CE FILE

D.4.2	Susceptibility to			
	electromagnetic			
	interference			
D.4.3	Emissions of			
	electromagnetic			
	interference			
D.4.4	Inadequate supply of			
	power			
D.4.5	Inadequate supply of			
	coolant			
D.4.6	Storage / operation			
	outside prescribed			
	environmental conditions			
D.4.7	Incompatibility with			
	other devices with which			
	the product is intended to			
	be used			
D.4.8	Accidental mechanical			
	damage			
D.4.9	Contamination due to			
	waste products and/or			
	device disposal			
D.5.1	Electricity			
D.5.2	Radiation			
D.5.3	Volume			
D.5.4	Pressure			
D.5.5	Supply of medical gases			
D.5.6	Supply of anaesthetic			
	agents			
D.6.1	Inadequate labelling			
D.6.2	Inadequate operating			
	instructions			
D.6.3	Inadequate specification			
	of accessories			
D.6.4	Inadequate specification			
	of pre-use checks			

T:\Kevin Rush\CE Requirements\CE Files\CE files current\SpO2_Probes\SpO2 Probes_CE File_2004\E. Risk Analysis\EN 14971 Annexe D\E. Risk Management BS14971 Annex D.doc Page 2

08/10/2004

Severity of hazard: 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Probability of event: 1 = Improbable, 2 = Occasional, 3 = Likely, 4 = Highly likely.



CE FILE

D.6.5	Over-complicated			
	operating instructions			
D.6.6	Inadequate specification			
	of service and			
	maintenance			
D.6.7	Use by unskilled /			
	untrained personnel			
D.6.8	Reasonable foreseeable			
	misuse			
D.6.9	Insufficient warning of			
	side effects			
D.6.10	1			
	hazards likely with re-			
	use of single use devices			
D.6.11	Incorrect measurement			
	and other metrological			
	aspects			
D.6.12	Misrepresentation of			
	results			
D.6.13	Incompatibility with			
	consumables /			
	accessories / other			
	devices			
D.6.14	Sharp edges or points			
D.7.1	Mistakes & judgement			
	errors			
D.7.2	Lapses and cognitive			
	recall errors			
D.7.3	Slips & blunders (mental			
	or physical)			
D.7.4	Violation or abbreviation			
	of instructions,			
	procedures etc			
D.7.5	Complex or confusing			
	control system			
D.7.6	Ambiguous or unclear			
	device state			

T:\Kevin Rush\CE Requirements\CE Files\CE files current\SpO2_Probes\SpO2 Probes_CE File_2004\E. Risk Analysis\EN 14971 Annexe D\E. Risk Management BS14971 Annex D.doc Page 3

08/10/2004

Severity of hazard: 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Probability of event: 1 = Improbable, 2 = Occasional, 3 = Likely, 4 = Highly likely.



CE FILE

D.7.7	Ambiguous or unclear			
	presentation of settings,			
	measurement, or other			
	information			
D.7.8	Misrepresentation of			
	results			
D.7.9	Insufficient visibility,			
	audibility or tactility			
D.7.10	Poor mapping of controls			
	to action or of displayed			
	information to actual			
	state			
D.7.11	Controversial modes or			
	mappings as compared to			
	existing equipment			
D.8.1	Erroneous data transfer			
D.8.2	Lack of, or inadequate			
	specification for			
	maintenance including			
	post maintenance			
	functional tests			
D.8.4	Inadequate maintenance			
D.8.5	Lack of adequate			
	determination of end of			
	device life			
D.8.6	Loss of electrical			
	integrity			
D.8.7	Loss of mechanical			
	integrity			
D.8.8	Inadequate packaging			
	(contamination and / or			
	deterioration of the			
	device)			
D.8.9	Re-use and/or improper			
	re-use			

T:\Kevin Rush\CE Requirements\CE Files\CE files current\SpO2_Probes\SpO2 Probes_CE File_2004\E. Risk Analysis\EN 14971 Annexe D\E. Risk Management BS14971 Annex D.doc Page 4

08/10/2004

Severity of hazard: 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Probability of event: 1 = Improbable, 2 = Occasional, 3 = Likely, 4 = Highly likely.

_

CE	FIL	E
----	-----	---

D.8.10	Deterioration in function			
	(gradual occlusion of			
	fluid / gas path or change			
	in resistance to flow,			
	electrical conductivity)			
	as a result of repeated			
	use			

T:\Kevin Rush\CE Requirements\CE Files\CE files current\SpO2_Probes\SpO2 Probes_CE File_2004\E. Risk Analysis\EN 14971 Annexe D\E. Risk Management BS14971 Annex D.doc Page 5

08/10/2004

Severity of hazard: 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Probability of event: 1 = Improbable, 2 = Occasional, 3 = Likely, 4 = Highly likely.