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.	Document referenced.	Sev of Haz.	Like 0f Haz.	Risk.
D.2	Energy hazards and contributory factors									
D.2.1	Electricity	N/A	1	1	1			1	1	1
D.2.2	Heat	If battery polarity	2	1	2	Protection diode added in	(YZ) Design File	1	1	1
D.2.3	Mechanical fa	N/A	2	1	2			2	1	2
D.2.4	Ionising radiation	N/A	1	1	1			1	1	1
D.2.5	Non-ionising radiation	N/A	1	1	1			1	1	1
D.2.6	Magnetic	N/A	1	1	1			1	1	1
	Magnetic fields									
						Easy to clean – cleaning instructions in user				
	Incorrect formulation									

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D 3.5	Allergenicity	N/A	1	1	1		Manufacturers Data	1	1	1
D 3.6	Mutagenicity	N/A	1	1	1		Manufacturers Data	1	1	1
D 3.7	Oncogenicity	N/A	1	1	1		Manufacturers Data	1	1	1
D 3.8	Carcinogenicity	N/A	1	1	1		Manufacturers Data	1	1	1
D 3.9	Re and/or cross infection	Instrument & Leads	1	1	1		Manufacturers Data	1	1	1
D 3.10	Pyrogenicity	N/A	1	1	1		Manufacturers Data	1	1	1
D 3.11	Inability to maintain	Instrument & Leads	2	2	4	Easy to clean – cleaning	E. User Instructions	2	1	2
D 3.12			2	1	2	Care Instructions given in		1	1	1
	Susceptibility to electromagnetic									
	Emissions of electromagnetic									
	Inadequate supply of									
	Inadequate supply of									
	Storage / operation outside prescribed					No specific environmental storage / operating				
	Incompatibility with other devices with which the product is intended to					Standard sized ECG press				

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D.4.8	Accidental mechanical damage	Instrument & Leads	2	1	2	Relatively robust material used. If damaged, user to assess level of damage – return for repair or spares parts available	E. User Instructions	1	1	1
D.4.9	Contamination due to waste products and/or device disposal	Instrument & Leads	1	1	1	No special disposal required. Alkaline batteries used		1	1	1
[illegible]	[illegible]									
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]			[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]			[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]			[illegible]	[illegible]	[illegible]
	Supply of anaesthetic									
						Product easy to use.				
	Inadequate operating					Product easy to use.				
	Inadequate specification									
	Inadequate specification	User Instructions /				Product easy to use	E. User Instructions			
	Over-complicated					Product easy to use				

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D.6.6	Inadequate specification of service and maintenance	N/A	1	1	1	Instrument set up at manufacturer. Does not require regular service. Maintenance only required if performance degrades		1	1	1
D.6.7	Use by unskilled / untrained personnel	Instrument & Leads	3	2	6	Product easy to use. Warning in user manual – not for use by untrained	E. User Instructions	2	1	2
D.6.8	Reasonable foreseeable	Instrument & Leads	3	2	6	Product easy to use. Warning in user manual – not for use by untrained	E. User Instructions	2	1	2
	Insufficient warning of									
	Inadequate warnings of hazards likely with re-									
	Incorrect measurement and other metrological									
	Misrepresentation of					Only for use by qualified & trained personnel – warning & in-depth				
	Incompatibility with consumables / accessories / other					Standard battery used. Leads colour coded				

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D.6.14	Sharp edges or points	Instrument & Leads	2	2	4	Only if damaged, user to assess level of damage – return for repair or spares parts available	F User Instructions	1	1	1
D.7	**Inappropriate, inadequate or overcomplicated user interface (man/machine communication)**									
D.7.1	Mistakes & judgement errors	N/A	1	1	1	No complex user interface		1	1	1
D.7.2	Lapses and cognitive	N/A	1	1	1	No complex user interface		1	1	1
D.7.3	Slips & blunders (mental	N/A	1	1	1	No complex user interface		1	1	1
D.7.4	Violation or abbreviation of instructions,	N/A	1	1	1	No complex user interface		1	1	1
	Complex or confusing									
	Ambiguous or unclear									
	Ambiguous or unclear presentation of settings, measurement, or other									
	Misrepresentation of									
	Insufficient visibility									
	Poor mapping of controls to action or of displayed information to actual									

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D 7 11	Controversial modes or mappings as compared to existing equipment	N/A	1	1	1	No complex user interface		1	1	1
D 8	**Hazards arising from function failure, maintenance and ageing and contributory factors**									
D 8 1	Erroneous data transfer	N/A	1	1	1			1	1	1
D 8 2	Lack of, or inadequate specification for maintenance including post maintenance	N/A	1	1	1			1	1	1
						Instrument set up at manufacturer. Does not require regular service. Maintenance only required				
	Lack of adequate determination of end of					User decision based on damage or cost				
	Loss of electrical					Failure of any electrical component will result in loss of audio or visual				
	Loss of mechanical					User decision based on damage or cost				
	Inadequate packaging (contamination and / or					Boxed in protective plastic case. Bubble wrap /				

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D 8 9	Re-use and/or improper re-use	Instrument & Leads	1	1	1	User decision on suitability for next use based on pre-use check & tolerable damage to casing		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	Instrument & Leads	1	1	1	Degradation of electrical components will eventually result in loss of audio or visual output		1	1	1

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