Microstim MkIII Risk Assesment Questions

Risk Key

	Negligible	Minor	Serious	Critical	Catastrophic
Improbable	Acceptable	Acceptable	Acceptable	Acceptable	Unacceptable
Remote	Acceptable	Acceptable	Acceptable	Unacceptable	Unacceptable
Occasinal	Acceptable	Acceptable	Acceptable	Unacceptable	Unacceptable
Probable	Acceptable	Unacceptable	Unacceptable	Unacceptable	Unacceptable
Frequent	Unacceptable	Unacceptable	Unacceptable	Unacceptable	Unacceptable

C.2.1 What is the intended use and how is the medical device to be used

ID	Reference Question	Applys	Risk	Probability	Overall
[1]	what is the medical device`s role relative to diagnosis,	No	---	---	n/a
[2]	what is the medical device`s role relative to prevention	No	---	---	n/a
[3]	what is the medical devices role relative to monitoring NOTES: Relies on bio feedback to anaesthetist to judge depth of anaesthesia.	Yes	Minor	Remote	Acceptable
[4]	what is the medical devices role relative to treatment	No	---	---	n/a
[5]	what is the medical devices role relative to alleviation of disease	No	---	---	n/a
[6]	what is the medical devices role relative to compensation for injury or handicap	No	---	---	n/a
[7]	what is the medical devices role relative to replacement or modification of anatomy	No	---	---	n/a
[8]	what is the medical devices role relative to control of conception	No	---	---	n/a
[9]	does the medical device sustain life	No	---	---	n/a
[10]	does the medical device support life	No	---	---	n/a
[11]	is special intervention necessary in the case of failure of the medical device	No	---	---	n/a
[330]	What are the indications for use e.g. patient population	No	---	---	n/a

C.2.10 Is the medical device intended to modify the patient environment

ID	Reference Question	Applys	Risk	Probability	Overall
[56]	Factors that should be considered include temperature	No	---	---	n/a
[57]	Factors that should be considered include humidity	No	---	---	n/a
[58]	Factors that should be considered include atmospheric gas composition	No	---	---	n/a
[59]	Factors that should be considered include pressure	No	---	---	n/a
[60]	Factors that should be considered include light	No	---	---	n/a

C.2.11 Are measurements taken

ID	Reference Question	Applys	Risk	Probability	Overall
[61]	Factors that should be considered include the variables measured and the accuracy and the precision of the measurement results.	No	---	---	n/a

C.2.12 Is the medical device interpretative

ID	Reference Question	Applys	Risk	Probability	Overall
[62]	Factors that should be considered include whether conclusions are presented by the medical device from input or acquired data NOTES: Relies on bio feedback to anaesthetist to judge depth of anaesthesia.	Yes	Negligible	Improbable	Acceptable
[63]	Factors that should be considered include whether conclusions are presented by the medical device from the algorithms used	No	---	---	n/a
[64]	Factors that should be considered include whether conclusions are presented by the medical device from the confidence limits	No	---	---	n/a
[65]	Factors that should be considered include whether conclusions are presented by the medical device. Special attention should be given to unintended applications of the data or algorithm	No	---	---	n/a

C.2.13 Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies

ID	Reference Question	Applys	Risk	Probability	Overall
[66]	Factors that should be considered include identifying any other medical devices	No	---	---	n/a
[67]	Factors that should be considered include identifying any other medicines	No	---	---	n/a
[68]	Factors that should be considered include identifying any other medical technologies that can be involved	No	---	---	n/a

C.2.14 Are there unwanted outputs of energy or substances

ID	Reference Question	Applys	Risk	Probability	Overall
[69]	Energy-related factors that should be considered include vibration, NOTES: Protection diode Doc 3354	Yes	Negligible	Improbable	Acceptable
[70]	Energy-related factors that should be considered include heat,	No	---	---	n/a
[71]	Energy-related factors that should be considered include radiation, NOTES: Only applies to patients with pacemakers. Possibility of interference with heart rate, if the wires are placed near the pacemaker. Risk is well known and is referred to in the instruction manual.	Yes	Minor	Improbable	Acceptable

ID	Reference Question	Applys	Risk	Probability	Overall
[72]	Energy-related factors that should be considered include noise,	No	---	---	n/a
[73]	Energy-related factors that should be considered include ionizing radiation,	No	---	---	n/a
[74]	Energy-related factors that should be considered include non-ionizing radiation,	No	---	---	n/a
[75]	Energy-related factors that should be considered include ultraviolet/ radiation,	No	---	---	n/a
[76]	Energy-related factors that should be considered include visible radiation,	No	---	---	n/a
[77]	Energy-related factors that should be considered include infrared radiation,	No	---	---	n/a
[78]	Energy-related factors that should be considered include contact temperatures	No	---	---	n/a
[79]	Energy-related factors that should be considered include leakage currents	No	---	---	n/a
[80]	Energy-related factors that should be considered include electric fields	No	---	---	n/a
[81]	Energy-related factors that should be considered include magnetic fields	No	---	---	n/a
[82]	Substance-related factors that should be considered include substances used in manufacturing	No	---	---	n/a
[83]	Substance-related factors that should be considered include substances used in cleaning NOTES: The instrument case and leads can be cleaned using isopropyl alcohol. The instrument and leads are not intended to be sterilized. Do not autoclave.	Yes	Negligible	Improbable	Acceptable
[84]	Substance-related factors that should be considered include substances used in testing	No	---	---	n/a
[85]	Other substance-related factors that should be considered include discharge of chemicals	No	---	---	n/a
[86]	Other substance-related factors that should be considered include waste products	No	---	---	n/a
[87]	Other substance-related factors that should be considered include body fluids	No	---	---	n/a

C.2.15 Is the medical device susceptible to environmental influences

ID	Reference Question	Applys	Risk	Probability	Overall
[88]	Factors that should be considered include the operational environment	No	---	---	n/a
[89]	Factors that should be considered include the transport environment	No	---	---	n/a
[90]	Factors that should be considered include the storage environment	No	---	---	n/a
[91]	Factors that should be considered include light	No	---	---	n/a
[92]	Factors that should be considered include temperature	No	---	---	n/a
[93]	Factors that should be considered include humidity	No	---	---	n/a
[94]	Factors that should be considered include vibrations	No	---	---	n/a
[95]	Factors that should be considered include spillage	No	---	---	n/a
[96]	Factors that should be considered include susceptibility to variations in power	No	---	---	n/a

ID	Reference Question	Applys	Risk	Probability	Overall
[97]	Factors that should be considered include susceptibility to variations in cooling supplies	No	---	---	n/a
[98]	Factors that should be considered include susceptibility to variations in electromagnetic interference	No	---	---	n/a

C.2.16 Does the medical device influence the environment

ID	Reference Question	Applys	Risk	Probability	Overall
[99]	Factors that should be considered include the effects on power and cooling supplies	No	---	---	n/a
[100]	Factors that should be considered include the emission of toxic materials	No	---	---	n/a
[101]	Factors that should be considered include the generation of electromagnetic disturbance NOTES: See Technical File EMC rationale	No	---	---	n/a

C.2.17 Are there essential consumables or accessories associated with the medical device

ID	Reference Question	Applys	Risk	Probability	Overall
[102]	Factors that should be considered include specifications for such consumables NOTES: Standard ECG Electrodes, cables can be replaced with standard ECG wires	Yes	Negligible	Improbable	Acceptable
[103]	Factors that should be considered include specifications for such accessories NOTES: Standard ECG Electrodes, cables can be replaced with standard ECG wires	Yes	Negligible	Improbable	Acceptable
[104]	Factors that should be considered include any restrictions placed upon users in their selection of consumables.	No	---	---	n/a
[105]	Factors that should be considered include any restrictions placed upon users in their selection of accessories.	No	---	---	n/a

C.2.18 Is maintenance or calibration necessary

ID	Reference Question	Applys	Risk	Probability	Overall
[106]	Factors that should be considered include whether maintenance or calibration are to be carried out by the operator	No	---	---	n/a
[107]	Factors that should be considered include whether maintenance or calibration are to be carried out by the user	No	---	---	n/a
[108]	Factors that should be considered include whether maintenance or calibration are to be carried out by the specialist	No	---	---	n/a
[109]	Factors that should be considered include are special substances or equipment necessary for proper maintenance	No	---	---	n/a

ID	Reference Question	Applys	Risk	Probability	Overall
[110]	Factors that should be considered include are special substances or equipment necessary for proper calibration	No	---	---	n/a

C.2.19 Does the medical device contain software

ID	Reference Question	Applys	Risk	Probability	Overall
[111]	Factors that should be considered include whether software is intended to be installed	No	---	---	n/a
[112]	Factors that should be considered include whether software is intended to be verified	No	---	---	n/a
[113]	Factors that should be considered include whether software is intended to be modified NOTES: Possible variations in software at manufacturing stage. Not by user	No	---	---	n/a
[114]	Factors that should be considered include whether software is intended to be exchanged	No	---	---	n/a

C.2.2 Is the medical device intended to be implanted

ID	Reference Question	Applys	Risk	Probability	Overall
[12]	Factors that should be considered include the location of implantation,	No	---	---	n/a
[13]	Factors that should be considered include the characteristics of the patient population	No	---	---	n/a
[14]	Factors that should be considered include the characteristics of the patient age	No	---	---	n/a
[15]	Factors that should be considered include the characteristics of the patient weight	No	---	---	n/a
[16]	Factors that should be considered include the characteristics of the patient physical activity	No	---	---	n/a
[17]	Factors that should be considered include the effect of ageing on implant performance	No	---	---	n/a
[18]	Factors that should be considered include the expected lifetime of the implant	No	---	---	n/a
[19]	Factors that should be considered include the reversibility of the implantation	No	---	---	n/a

C.2.20 Does the medical device have a restricted shelf-life

ID	Reference Question	Applys	Risk	Probability	Overall
[115]	Factors that should be considered include labelling	No	---	---	n/a
[116]	Factors that should be considered include indicators	No	---	---	n/a
[117]	Factors that should be considered include disposal of such medical devices NOTES: in accordance with WEEE regulations	Yes	Negligible	Improbable	Acceptable

C.2.21 Are there any delayed or long-term use effects

ID	Reference Question	Applys	Risk	Probability	Overall
[118]	Factors that should be considered include ergonomic effects	No	---	---	n/a
[119]	Factors that should be considered include cumulative effects	No	---	---	n/a

C.2.22 To what mechanical forces will the medical device be subjected

ID	Reference Question	Applys	Risk	Probability	Overall
[120]	Factors that should be considered include whether the forces to which the medical device will be subjected are under the control of the user	No	---	---	n/a
[121]	Factors that should be considered include whether the forces to which the medical device will be subjected are controlled by interaction with other persons	No	---	---	n/a

C.2.23 What determines the lifetime of the medical device

ID	Reference Question	Applys	Risk	Probability	Overall
[122]	Factors that should be considered include ageing	No	---	---	n/a
[123]	Factors that should be considered include battery depletion. NOTES: Instrument has battery level indicator	No	---	---	n/a

C.2.24 Is the medical device intended for single use

ID	Reference Question	Applys	Risk	Probability	Overall
[124]	Factors that should be considered include does the medical device self-destruct after use	No	---	---	n/a
[125]	Factors that should be considered include Is it obvious that the device has been used	No	---	---	n/a

C.2.25 Is safe decommissioning or disposal of the medical device necessary

ID	Reference Question	Applys	Risk	Probability	Overall
[126]	Factors that should be considered include the waste products that are generated during the disposal of the medical device itself	No	---	---	n/a
[127]	Factors that should be considered include does it contain toxic material	No	---	---	n/a
[128]	Factors that should be considered include does it contain hazardous material	No	---	---	n/a
[129]	Factors that should be considered include is the material recyclable	No	---	---	n/a

C.2.26 Does installation or use of the medical device require special training or special skills

ID	Reference Question	Applys	Risk	Probability	Overall
[130]	Factors that should be considered include the novelty of the medical device	No	---	---	n/a

ID	Reference Question	Applys	Risk	Probability	Overall
[131]	Factors that should be considered include the likely skill and training of the person installing the device. NOTES: Only used by a specialist	No	---	---	n/a

C.2.27 How will information for safe use be provided

ID	Reference Question	Applys	Risk	Probability	Overall
[132]	Factors that should be considered include whether information will be provided directly to the end user by the manufacturer	No	---	---	n/a
[133]	Factors that should be considered include will it involve the participation of third parties such as installers	No	---	---	n/a
[134]	Factors that should be considered include will it involve the participation of third parties such as care providers	No	---	---	n/a
[135]	Factors that should be considered include will it involve the participation of third parties such as health care professionals	No	---	---	n/a
[136]	Factors that should be considered include will it involve the participation of third parties such as pharmacists	No	---	---	n/a
[137]	Factors that should be considered include will it involve whether this will have implications for training	No	---	---	n/a
[138]	commissioning and handing over to the end user and whether it is likely/possible that installation can be carried out by people without the necessary skills	No	---	---	n/a
[139]	based on the expected life of the device, whether re-training or re-certification of operators or service personnel would be required	No	---	---	n/a

C.2.28 Will new manufacturing processes need to be established or introduced

ID	Reference Question	Applys	Risk	Probability	Overall
[140]	Factors that should be considered include new technology	No	---	---	n/a
[141]	Factors that should be considered include new scale of production.	No	---	---	n/a

C.2.29 Is successful application of the medical device critically dependent on human factors

ID	Reference Question	Applys	Risk	Probability	Overall
[142]	such as the user interface	No	---	---	n/a

C.2.29.1 Can the user interface design features contribute to use error

ID	Reference Question	Applys	Risk	Probability	Overall
[143]	Factors that should be considered are user interface design features that can contribute to use error	No	---	---	n/a

ID	Reference Question	Applys	Risk	Probability	Overall
[144]	Examples of interface design features include control and indicators,	No	---	---	n/a
[145]	Examples of interface design features include symbols used,	No	---	---	n/a
[146]	Examples of interface design features include ergonomic features	No	---	---	n/a
[147]	Examples of interface design features include physical design and layout,	No	---	---	n/a
[148]	Examples of interface design features include hierarchy of operation	No	---	---	n/a
[149]	Examples of interface design features include menus for software driven devices	No	---	---	n/a
[150]	Examples of interface design features include visibility of warnings,	No	---	---	n/a
[151]	Examples of interface design features include audibility of alarms	No	---	---	n/a
[152]	Examples of interface design features include standardization of colour coding	No	---	---	n/a

C.2.29.2 Is the medical device used in an environment where distractions can cause use error

ID	Reference Question	Applys	Risk	Probability	Overall
[153]	Factors that should be considered include the consequence of use error	No	---	---	n/a
[154]	Factors that should be considered include whether the distractions are commonplace	No	---	---	n/a
[155]	Factors that should be considered include whether the user can be disturbed by an infrequent distraction	No	---	---	n/a

C.2.29.3 Does the medical device have connecting parts or accessories

ID	Reference Question	Applys	Risk	Probability	Overall
[156]	Factors that should be considered include the possibility of wrong connections	No	---	---	n/a
[157]	Factors that should be considered include similarity to other products connections,	No	---	---	n/a
[158]	Factors that should be considered include connection force,	No	---	---	n/a
[159]	Factors that should be considered include feedback on connection integrity	No	---	---	n/a
[160]	Factors that should be considered include over- and under-tightening.	No	---	---	n/a

C.2.29.4 Does the medical device have a control interface

ID	Reference Question	Applys	Risk	Probability	Overall
[161]	Factors that should be considered include spacing,	No	---	---	n/a
[162]	Factors that should be considered include , coding,	No	---	---	n/a
[163]	Factors that should be considered include grouping,	No	---	---	n/a
[164]	Factors that should be considered include mapping,	No	---	---	n/a
[165]	Factors that should be considered include modes of feedback	No	---	---	n/a

ID	Reference Question	Applys	Risk	Probability	Overall
[166]	Factors that should be considered include modes of blunders	No	---	---	n/a
[167]	Factors that should be considered include slips	No	---	---	n/a
[168]	Factors that should be considered include control differentiation	No	---	---	n/a
[169]	Factors that should be considered include visibility	No	---	---	n/a
[170]	Factors that should be considered include direction of activation	No	---	---	n/a
[171]	Factors that should be considered include direction of change	No	---	---	n/a
[172]	Factors that should be considered include whether the controls are continuous or discrete	No	---	---	n/a
[173]	Factors that should be considered include the reversibility of settings or actions	No	---	---	n/a

C.2.29.5 Does the medical device display information

ID	Reference Question	Applys	Risk	Probability	Overall
[174]	Factors that should be considered include visibility in various environments	No	---	---	n/a
[175]	Factors that should be considered include orientation	No	---	---	n/a
[176]	Factors that should be considered include the visual capabilities of the user	No	---	---	n/a
[177]	Factors that should be considered include populations and perspectives	No	---	---	n/a
[178]	Factors that should be considered include clarity of the presented information	No	---	---	n/a
[179]	Factors that should be considered include units	No	---	---	n/a
[180]	Factors that should be considered include colour coding	No	---	---	n/a
[181]	Factors that should be considered include accessibility of critical information	No	---	---	n/a

C.2.29.6 Is the medical device controlled by a menu

ID	Reference Question	Applys	Risk	Probability	Overall
[182]	Factors that should be considered include complexity and number of layers	No	---	---	n/a
[183]	Factors that should be considered include awareness of state	No	---	---	n/a
[184]	Factors that should be considered include location of settings	No	---	---	n/a
[185]	Factors that should be considered include navigation method	No	---	---	n/a
[186]	Factors that should be considered include number of steps per action	No	---	---	n/a
[187]	Factors that should be considered include sequence clarity and memorization problems	No	---	---	n/a
[188]	Factors that should be considered include importance of control function relative to its accessibility and the impact of deviating from specified operating procedures.	No	---	---	n/a

C.2.29.7 Will the medical device be used by persons with special needs

ID	Reference Question	Applys	Risk	Probability	Overall
[189]	Factors that should be considered include the user, their mental and physical abilities, skill and training, ergonomic aspects, the use environment, installation requirements, and the patient`s capability to control or influence the use of the medical device. Special attention should be paid to users with special needs, such as handicapped persons, the elderly and children. Their special needs might include assistance by another person to enable the use of a medical device. Is the medical device intended to be used by individuals with various skill levels and cultural backgrounds	No	---	---	n/a

C.2.29.8 Can the user interface be used to initiate user actions

ID	Reference Question	Applys	Risk	Probability	Overall
[190]	Factors that should be considered include the possibility of initiatinig a deliberate action for the user to enter a controlled operation mode, which enlarges the risks for the patient and which creates awareness for the user for this condition.	No	---	---	n/a

C.2.3 Is the medical device intended to be in contact with the patient or other persons

ID	Reference Question	Applys	Risk	Probability	Overall
[20]	Factors that should be considered include the nature of the intended contact	No	---	---	n/a
[21]	Factors that should be considered include the nature of the intended contact surface contact	No	---	---	n/a
[22]	Factors that should be considered include the nature of the intended contact invasive contact	No	---	---	n/a
[23]	Factors that should be considered include the nature of the intended the period of contact	No	---	---	n/a
[24]	Factors that should be considered include the nature of the intended the frequency of contact	No	---	---	n/a

C.2.30 Does the medical device use an alarm system

ID	Reference Question	Applys	Risk	Probability	Overall
[191]	Factors that should be considered are the risk of false alarms	No	---	---	n/a
[192]	Factors that should be considered are the risk of missing alarms	No	---	---	n/a
[193]	Factors that should be considered are the risk of disconnected alarm systems	No	---	---	n/a
[194]	Factors that should be considered are the risk unreliable remote alarm systems	No	---	---	n/a
[195]	Factors that should be considered are the medical staffs possibility of understanding how the alarm system works	No	---	---	n/a

C.2.31 In what ways might the medical device be deliberately misused

ID	Reference Question	Applys	Risk	Probability	Overall
[196]	Factors that should be considered are incorrect use of connectors NOTES: Used for nerve location	No	---	---	n/a
[197]	Factors that should be considered are disabling safety features or alarms	No	---	---	n/a
[198]	Factors that should be considered are neglect of manufacturer`s recommended maintenance	No	---	---	n/a

C.2.32 Does the medical device hold data critical to patient care

ID	Reference Question	Applys	Risk	Probability	Overall
[199]	Factors that should be considered include the consequence of the data being modified	No	---	---	n/a
[200]	Factors that should be considered include the consequence of the data being corrupted.	No	---	---	n/a

C.2.33 Is the medical device intended to be mobile or portable

ID	Reference Question	Applys	Risk	Probability	Overall
[201]	Factors that should be considered are the necessary grips,	No	---	---	n/a
[202]	Factors that should be considered are the necessary handles,	No	---	---	n/a
[203]	Factors that should be considered are the necessary wheels,	No	---	---	n/a
[204]	Factors that should be considered are the necessary, brakes,	No	---	---	n/a
[205]	Factors that should be considered are, mechanical stability	No	---	---	n/a
[206]	Factors that should be considered are,durability	No	---	---	n/a

C.2.34 Does the use of the medical device depend on essential performance

ID	Reference Question	Applys	Risk	Probability	Overall
[207]	Factors that should be considered are the characteristics of the output of life-supporting devices	No	---	---	n/a
[208]	Factors that should be considered are the operation of an alarm	No	---	---	n/a

C.2.4 What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device

ID	Reference Question	Applys	Risk	Probability	Overall
[25]	Factors that should be considered include compatibility with relevant substances	No	---	---	n/a
[26]	Factors that should be considered include compatibility with tissues	No	---	---	n/a
[27]	Factors that should be considered include compatibility with body fluids	No	---	---	n/a
[28]	whether characteristics relevant to safety are known	No	---	---	n/a
[29]	is the device manufactured utilizing materials of animal origin	No	---	---	n/a

C.2.5 Is energy delivered to or extracted from the patient

ID	Reference Question	Applys	Risk	Probability	Overall
[30]	Factors that should be considered include the type of energy transferred	No	---	---	n/a
[31]	Factors that should be considered include the type of energy its control	No	---	---	n/a
[32]	Factors that should be considered include the type of energy its quality	No	---	---	n/a
[33]	Factors that should be considered include the type of energy its intensity NOTES: Maximum setting would produce a Mild electric shock.	No	---	---	n/a
[34]	Factors that should be considered include the type of energy its duration	No	---	---	n/a
[35]	Factors that should be considered include whether energy levels are higher than those currently used for similar devices	No	---	---	n/a

C.2.6 Are substances delivered to or extracted from the patient

ID	Reference Question	Applys	Risk	Probability	Overall
[36]	Factors that should be considered include whether the substance is delivered	No	---	---	n/a
[37]	Factors that should be considered include whether the substance is extracted	No	---	---	n/a
[38]	Factors that should be considered include whether it is a single substance	No	---	---	n/a
[39]	Factors that should be considered include whether it is a range of substances	No	---	---	n/a
[40]	Factors that should be considered include maximum transfer rates and control thereof	No	---	---	n/a
[41]	Factors that should be considered include minimum transfer rates and control thereof	No	---	---	n/a

C.2.7 Are biological materials processed by the medical device for subsequent

ID	Reference Question	Applys	Risk	Probability	Overall
[43]	re-use,	No	---	---	n/a
[44]	transfusion	No	---	---	n/a
[45]	transplantation	No	---	---	n/a

C.2.8 Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable

ID	Reference Question	Applys	Risk	Probability	Overall
[46]	Factors that should be considered include whether the medical device is intended for single use	No	---	---	n/a
[47]	Factors that should be considered include whether the medical device is intended for re-use packaging	No	---	---	n/a
[48]	Factors that should be considered include shelf-life issues	No	---	---	n/a
[49]	Factors that should be considered include limitation on the number of re-use cycles	No	---	---	n/a

ID	Reference Question	Applys	Risk	Probability	Overall
[50]	Factors that should be considered include method of product sterilization	No	---	---	n/a
[51]	Factors that should be considered include the impact of other sterilization methods not intended by the manufacturer	No	---	---	n/a

C.2.9 Is the medical device intended to be routinely cleaned and disinfected by the user

ID	Reference Question	Applys	Risk	Probability	Overall
[52]	Factors that should be considered include the types of cleaning or disinfecting agents to be used NOTES: Poor cleaning. Used in OR	No	---	---	n/a
[53]	Factors that should be considered include any limitations on the number of cleaning cycles.	No	---	---	n/a
[54]	Factors that should be considered include The design of the Medical device can influence the effectiveness of routine cleaning and disinfection	No	---	---	n/a
[55]	Factors that should be considered include the effect of cleaning and disinfecting agents on the safety or performance of the device.	No	---	---	n/a

D.2 Energy hazards and contributory factors

ID	Reference Question	Applys	Risk	Probability	Overall
[222]	Mechanical force	No	---	---	n/a
[223]	Gravity Falling NOTES: Dropping onto hard floors	No	---	---	n/a
[224]	Suspended masses	No	---	---	n/a
[225]	Stored energy	No	---	---	n/a
[226]	Torsion,Shear & Tensile	No	---	---	n/a
[227]	High Pressure Fluid injection	No	---	---	n/a
[230]	Moving parts	No	---	---	n/a
[231]	Moving & positioning patient	No	---	---	n/a
[232]	Unintended motion	No	---	---	n/a
[233]	Patient support failure	No	---	---	n/a
[234]	Pressure vessel rupture	No	---	---	n/a
[235]	Acoustic pressure	No	---	---	n/a
[236]	Ultrasonic energy	No	---	---	n/a
[237]	Infrasound energy	No	---	---	n/a

D.3 Toxic hazards and contributory factors

ID	Reference Question	Applys	Risk	Probability	Overall
[241]	Bio-contamination	No	---	---	n/a
[242]	Bacteria	No	---	---	n/a
[243]	Viruses	No	---	---	n/a
[244]	Other agents prions	No	---	---	n/a
[245]	Bio-incompatibility	No	---	---	n/a
[246]	Incorrect formulation chemical composition	No	---	---	n/a
[247]	Toxicity	No	---	---	n/a

ID	Reference Question	Applys	Risk	Probability	Overall
[248]	Allergenicity/ irritancy	No	---	---	n/a
[249]	Mutagenicity	No	---	---	n/a
[250]	Oncogenicity	No	---	---	n/a
[251]	Carcinogenicity	No	---	---	n/a
[252]	Re and/or cross infection	No	---	---	n/a
[253]	Pyrogenicity	No	---	---	n/a

D.3.12 hygienic standards

ID	Reference Question	Applys	Risk	Probability	Overall
[254]	Degradation	No	---	---	n/a
[255]	Chemical	No	---	---	n/a
[256]	Acids or Alkalis	No	---	---	n/a
[257]	Contaminates	No	---	---	n/a
[258]	Processing aids	No	---	---	n/a
[260]	Testing aids	No	---	---	n/a
[261]	Medical gases	No	---	---	n/a
[262]	Anaesthetic products	No	---	---	n/a

D.4 Electromagnetic fields

ID	Reference Question	Applys	Risk	Probability	Overall
[268]	Operation outside prescribed environmental conditions	No	---	---	n/a
[270]	Accidental mechanical damage	No	---	---	n/a
[271]	Contamination due to waste products and/or device disposal	No	---	---	n/a

D.5

ID	Reference Question	Applys	Risk	Probability	Overall
[274]	Volume	No	---	---	n/a
[275]	Supply of medical gases	No	---	---	n/a
[276]	Pressure	No	---	---	n/a
[277]	Supply of anaesthetic agents	No	---	---	n/a

D.6 Hazards related to the use of the medical device and contributory factors

ID	Reference Question	Applys	Risk	Probability	Overall
[279]	Inadequate operating instructions	No	---	---	n/a
[280]	Inadequate description of performance	No	---	---	n/a
[281]	Inadequate specification of intended use	No	---	---	n/a
[282]	Inadequate disclosure of limitations	No	---	---	n/a
[283]	Inadequate specification of accessories	No	---	---	n/a
[284]	Inadequate specification of pre-use checks	No	---	---	n/a
[285]	Over-complicated operating instructions	No	---	---	n/a
[286]	Inadequate specification of service and maintenance	No	---	---	n/a
[287]	Use by unskilled / untrained personnel	No	---	---	n/a
[288]	Reasonable foreseeable misuse	No	---	---	n/a
[289]	Insufficient warning of side effects	No	---	---	n/a

ID	Reference Question	Applys	Risk	Probability	Overall
[290]	Incorrect measurement and other metrological aspects	No	---	---	n/a
[291]	Inadequate warnings of hazards likely with re-use of single use devices	No	---	---	n/a
[292]	Misrepresentation of results	No	---	---	n/a
[293]	Incompatibility with consumables / accessories / other devices	No	---	---	n/a
[294]	Sharp edges or points	No	---	---	n/a

D.7 Mistakes judgement errors

ID	Reference Question	Applys	Risk	Probability	Overall
[295]	Mistakes & judgement errors	No	---	---	n/a
[296]	Incorrect or inappropriate output or functionality	No	---	---	n/a
[297]	Erroneous data transfer	No	---	---	n/a
[298]	Loss or deterioration in function	No	---	---	n/a
[301]	Rule based failure	No	---	---	n/a
[302]	Knowledge based failure	No	---	---	n/a
[303]	Routine violation	No	---	---	n/a
[304]	Violation or abbreviation of instructions, procedures etc	No	---	---	n/a
[308]	Misrepresentation of results	No	---	---	n/a
[311]	Controversial modes or mappings as compared to existing equipment	No	---	---	n/a

D.8

ID	Reference Question	Applys	Risk	Probability	Overall
[317]	Loss of mechanical integrity	No	---	---	n/a
[318]	Inadequate packaging contamination and / or deterioration of the device	No	---	---	n/a
[320]	Deterioration in function gradual occlusion of fluid / gas path or change in resistance to flow, electrical conductivity as a result of repeated use	No	---	---	n/a

X.1

ID	Reference Question	Applys	Risk	Probability	Overall
[332]	Somebody Adjusts Pressure to zero	No	---	---	n/a

X.2

ID	Reference Question	Applys	Risk	Probability	Overall
[333]	Somebody Adjusts Pressure to Maximum	No	---	---	n/a

D.9 Fire Risk

ID	Reference Question	Applys	Risk	Probability	Overall
[334]	In terms of the device itself	No	---	---	n/a
[335]	In term of materials used to clean	No	---	---	n/a

D.9 Fire Risk

ID	Reference Question	Applys	Risk	Probability	Overall
[336]	In terms of Materials passing through the device	No	---	---	n/a

D.10 Explosion Risk

ID	Reference Question	Applys	Risk	Probability	Overall
[337]	In terms of the device itself	No	---	---	n/a
[338]	In term of materials used to clean	No	---	---	n/a
[339]	In terms of Materials passing through the device.	No	---	---	n/a

Use By Dates

ID	Reference Question	Applys	Risk	Probability	Overall
[340]	Does the device have and time limitation on the safe use of the device. Note the USE-BY time limit refers to the period before the first use of the device, It does not relate to the number or period of subsequent uses (Lifetime) of the device	No	---	---	n/a

Risk Assessment Document Summary Applicable questions

Reference Question	Applys	Risk	Risk Probability	Overall Risk	Assessed By	Assessed On	Risk Completed
3	Yes	Minor	Remote	Acceptable	Derek Lamb	29/07/15	Yes
62	Yes	Negligible	Improbable	Acceptable	Derek Lamb	29/07/15	Yes
69	Yes	Negligible	Improbable	Acceptable	Derek Lamb	21/09/15	Yes
71	Yes	Minor	Improbable	Acceptable	Derek Lamb	21/09/15	Yes
83	Yes	Negligible	Improbable	Acceptable	Derek Lamb	21/09/15	Yes
102	Yes	Negligible	Improbable	Acceptable	Derek Lamb	29/07/15	Yes
103	Yes	Negligible	Improbable	Acceptable	Derek Lamb	29/07/15	Yes
117	Yes	Negligible	Improbable	Acceptable	Derek Lamb	29/07/15	Yes

Reference Question 3
C.2.1 What is the intended use and how is the medical device to be used what is the medical devices role relative to monitoring
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Acceptable
Assessed By Derek Lamb
Assessed On 29/07/15
Notes :
Relies on bio feedback to anaesthetist to judge depth of anaesthesia.
Risk Completed Yes

Reference Question 62
C.2.12 Is the medical device interpretative
Factors that should be considered include whether conclusions are presented by the medical device from input or acquired data
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Acceptable
Assessed By Derek Lamb
Assessed On 29/07/15
Notes :
Relies on bio feedback to anaesthetist to judge depth of anaesthesia.
Risk Completed Yes

Reference Question 69
C.2.14 Are there unwanted outputs of energy or substances
Energy-related factors that should be considered include vibration,
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Acceptable
Assessed By Derek Lamb
Assessed On 21/09/15
Notes :
Protection diode
Doc 3354
Risk Completed Yes

Reference Question 71
C.2.14 Are there unwanted outputs of energy or substances
Energy-related factors that should be considered include radiation,
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Acceptable
Assessed By Derek Lamb
Assessed On 21/09/15
Notes :
Only applies to patients with pacemakers.
Possibility of interference with heart rate, if the wires are placed near the pacemaker.

Risk is well known and is referred to in the instruction manual.

Risk Completed Yes
Supporting Document ID 3280

Reference Question 83
C.2.14 Are there unwanted outputs of energy or substances
Substance-related factors that should be considered include substances used in cleaning
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Acceptable
Assessed By Derek Lamb
Assessed On 21/09/15
Notes :
The instrument case and leads can be cleaned using isopropyl alcohol. The instrument and leads are not intended to be sterilized. Do not autoclave.
Risk Completed Yes

Reference Question 102
C.2.17 Are there essential consumables or accessories associated with the medical device
Factors that should be considered include specifications for such consumables
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Acceptable
Assessed By Derek Lamb
Assessed On 29/07/15
Notes :
Standard ECG Electrodes, cables can be replaced with standard ECG wires
Risk Completed Yes

Reference Question 103
C.2.17 Are there essential consumables or accessories associated with the medical device
Factors that should be considered include specifications for such accessories
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Acceptable
Assessed By Derek Lamb
Assessed On 29/07/15
Notes :
Standard ECG Electrodes, cables can be replaced with standard ECG wires
Risk Completed Yes

Reference Question 117
C.2.20 Does the medical device have a restricted shelf-life
Factors that should be considered include disposal of such medical devices
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Acceptable
Assessed By Derek Lamb
Assessed On 29/07/15
Notes :
in accordance with WEEE regulations
Risk Completed Yes