10 Nov 2017 File 16 Tom Thumb Risk Assesment Questions

Severity Key

Negligible Inconvenience or Temporary discomfort
Minor: Results in temp injury not requiring Prof. Med. Intervention
Serious: Results in injury requiring requiring Prof. Med. Intervention
Critical: Results in permanent impairment or life threat. injury
Catastrophic: Results in Death

Probability Key

Improbable
Remote
Occasional
Probable
Frequent

Risk Action

	Negligible	Minor	Serious	Critical	Catastrophic
Improbable	No Action	No Action	No Action	Risk Benefits	Unacceptable
Remote	No Action	No Action	Risk Benefits	Unacceptable	Unacceptable
Occasinal	No Action	Risk Benefits	Unacceptable	Unacceptable	Unacceptable
Probable	Risk Benefits	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	Ref 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	No	---	---	n/a
[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 NOTES: Device itself on its own does not support life, rather it enables the Operator to support life using the Tom thumb, in the same way the resuscitation bag supports life with the help of the operator.Needs Two major faults and operator error to impose any risk to patient	Yes	Serious	Improbable	No Action

ID	Ref Question	Applys	Risk	Probability	Overall
[11]	is special intervention necessary in the case of failure of the medical device NOTES: In case of failure the operator would need to resort to the old resuscitation bag method.However the Tom thumb unit has a secondary safety value mechanism in case of primary valve failure.Needs Two major faults and operator error to impose any risk to patient. Main risk is not connecting the Tom Thumb into the circuit	Yes	Negligible	Remote	No Action
[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	Ref 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 NOTES: Tom Thumb device is only used to remove the risk of excessive pressure.It needs four major component failures incorrect including set up and misuse by operator.	Yes	Critical	Improbable	Risk Benefits
[60]	Factors that should be considered include light	No	---	---	n/a

C.2.11 Are measurements taken

ID	Ref 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	Ref 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	No	---	---	n/a
[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	Ref 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	Ref Question	Applys	Risk	Probability	Overall
[69]	Energy-related factors that should be considered include vibration,	No	---	---	n/a
[70]	Energy-related factors that should be considered include heat,	No	---	---	n/a
[71]	Energy-related factors that should be considered include radiation,	No	---	---	n/a
[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	No	---	---	n/a
[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	Ref Question	Applys	Risk	Probability	Overall
[88]	Factors that should be considered include the operational environment	No	---	---	n/a

ID	Ref Question	Applys	Risk	Probability	Overall
[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
[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	Ref 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	No	---	---	n/a

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

ID	Ref Question	Applys	Risk	Probability	Overall
[102]	Factors that should be considered include specifications for such consumables NOTES: Breathing Circuit, and T-Piece	Yes	Minor	Remote	No Action
[103]	Factors that should be considered include specifications for such accessories NOTES: Breathing Circuit, and T-Piece	Yes	Minor	Remote	No Action
[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. NOTES: Breathing Circuit, and T-Piece Selected by the user	Yes	Serious	Remote	Risk Benefits

C.2.18 Is maintenance or calibration necessary

ID	Ref 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

ID	Ref Question	Applys	Risk	Probability	Overall
[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 NOTES: Main Pressure is user selectable. Safety Value is Fixed. Yearly Calibration is essential.	Yes	Minor	Remote	No Action
[109]	Factors that should be considered include are special substances or equipment necessary for proper maintenance	No	---	---	n/a
[110]	Factors that should be considered include are special substances or equipment necessary for proper calibration NOTES: Main Pressure is user selectable. Safety Value is Fixed. Yearly Calibration is essential.	Yes	Minor	Remote	No Action

C.2.19 Does the medical device contain software

ID	Ref 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	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	Ref 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

ID	Ref Question	Applys	Risk	Probability	Overall
[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	Ref 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	No	---	---	n/a

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

ID	Ref 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	Ref 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	Ref 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.	No	---	---	n/a

C.2.24 Is the medical device intended for single use

ID	Ref 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 NOTES: Positive Pressure device, No patient contamination during use	No	---	---	n/a

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

ID	Ref 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 NOTES: Unit made of Brass, completly recycable	Yes	Minor	Remote	No Action

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

ID	Ref Question	Applys	Risk	Probability	Overall
[130]	Factors that should be considered include the novelty of the medical device	No	---	---	n/a
[131]	Factors that should be considered include the likely skill and training of the person installing the device.	No	---	---	n/a

C.2.27 How will information for safe use be provided

ID	Ref 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 NOTES: Information supplied in the instructions for use	Yes	Negligible	Improbable	No Action
[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	Ref 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	Ref Question	Applys	Risk	Probability	Overall
[142]	such as the user interface NOTES: Human interaction is required to use the device. there is no risk to this as the method it replaces - the resuscitation bag also requires	No	---	---	n/a

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

ID	Ref 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
[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	Ref Question	Applys	Risk	Probability	Overall
[153]	Factors that should be considered include the consequence of use error NOTES: Used in maternity, level environment distractions will be High,however there will one to one nursing if the Tom Thumb is in use.	Yes	Negligible	Improbable	No Action
[154]	Factors that should be considered include whether the distractions are commonplace NOTES: Used in maternity, level environment distractions will be High, however the number one patient will be the infant if the Tom Thumb is in use.	Yes	Minor	Remote	No Action

ID	Ref Question	Applys	Risk	Probability	Overall
[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	Ref Question	Applys	Risk	Probability	Overall
[156]	Factors that should be considered include the possibility of wrong connections NOTES: Tom Thumb design to avoid incorrect connections	Yes	Minor	Remote	No Action
[157]	Factors that should be considered include similarity to other products connections,	No	---	---	n/a
[158]	Factors that should be considered include connection force, NOTES: Unit made from Brass,	Yes	Minor	Remote	No Action
[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. NOTES: Possibility of connection being disconnected, due to flowing gas, and immediate non functioning of the device, this scenario should be immediate obvious	Yes	Minor	Remote	No Action

C.2.29.4 Does the medical device have a control interface

ID	Ref 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
[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	Ref Question	Applys	Risk	Probability	Overall
[174]	Factors that should be considered include visibility in various environments NOTES: Mechanical Pressure gauge clear display, bought in standard component as used by multiple medical manufacturers	Yes	Negligible	Improbable	No Action
[175]	Factors that should be considered include orientation NOTES: Mechanical Pressure gauge clear display from all angles	Yes	Negligible	Improbable	No Action
[176]	Factors that should be considered include the visual capabilities of the user NOTES: Clear legible display, Black text on white background	Yes	Negligible	Improbable	No Action
[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 NOTES: Clear legible display, Black text on white background	Yes	Negligible	Improbable	No Action
[179]	Factors that should be considered include units NOTES: Clear legible display, Black text on white background, standard units for this application	Yes	Negligible	Improbable	No Action
[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	Ref 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	Ref 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	Ref 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	Ref 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 NOTES: Device is used in conjunction with a patient circuit which is covered by its own CE mark. device itself does not touch the patient	Yes	Negligible	Improbable	No Action
[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	Ref 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	Ref Question	Applys	Risk	Probability	Overall
[196]	Factors that should be considered are incorrect use of connectors	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 NOTES: routine servicing should be maintained. However, after 25 Years we have not seen a problem of a unit non functioning due to lack of servicing. Even if the device develops leaks it should still perform the function for which it is intended.	Yes	Minor	Remote	No Action

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

ID	Ref 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	Ref 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	Ref 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	Ref Question	Applys	Risk	Probability	Overall
[25]	Factors that should be considered include compatibility with relevant substances NOTES: Oxygen,Uses Brass,and Doc 2338 Fomblin Oxygen Friendly grease.No electronic or other form of ingnition source	Yes	Negligible	Improbable	No Action
[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	Ref Question	Applys	Risk	Probability	Overall
[30]	Factors that should be considered include the type of energy transferred NOTES: The Tom THumb is used to prevent pressure problems Four faults are required to defeat it	Yes	Negligible	Improbable	No Action
[31]	Factors that should be considered include the type of energy its control NOTES: Pressure relief valves.	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	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	Ref Question	Applys	Risk	Probability	Overall
[36]	Factors that should be considered include whether the substance is delivered NOTES: Delivers gas, which is the primary function of the device	Yes	Negligible	Improbable	No Action
[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	Ref 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	Ref 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 NOTES: Can be re-used indefinably, made of brass can be cleaned and sterilized if required, however the device itself does not come into contact with the patient	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
[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	Ref Question	Applys	Risk	Probability	Overall
[52]	Factors that should be considered include the types of cleaning or disinfecting agents to be used	Yes	Minor	Remote	No Action
[53]	Factors that should be considered include any limitations on the number of cleaning cycles.	Yes	Minor	Remote	No Action
[54]	Factors that should be considered include The design of the Medical device can influence the effectiveness of routine cleaning and disinfection	Yes	Minor	Remote	No Action
[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	Ref Question	Applys	Risk	Probability	Overall
[222]	Mechanical force	No	---	---	n/a
[223]	Gravity Falling NOTES: Clamped into place	Yes	Minor	Remote	No Action
[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

ID	Ref Question	Applys	Risk	Probability	Overall
[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	Ref 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
[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	Ref 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	Ref 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	Ref Question	Applys	Risk	Probability	Overall
[274]	Volume	No	---	---	n/a

ID	Ref Question	Applys	Risk	Probability	Overall
[275]	Supply of medical gases	No	---	---	n/a
[276]	Pressure NOTES: Unit has Safety Value to stop over pressure	Yes	Minor	Remote	No Action
[277]	Supply of anaesthetic agents	No	---	---	n/a

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

ID	Ref Question	Applys	Risk	Probability	Overall
[279]	Inadequate operating instructions NOTES: operating instructions are adequate and usage is covered by standard hospital protocols and clinical training of the users	Yes	Minor	Remote	No Action
[280]	Inadequate description of performance NOTES: operating instructions are adequate and usage is covered by standard hospital protocols and clinical training of the users	Yes	Minor	Remote	No Action
[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 NOTES: operating instructions are adequate and usage is covered by standard hospital protocols and clinical training of the users	Yes	Negligible	Improbable	No Action
[285]	Over-complicated operating instructions NOTES: operating instructions are adequate and usage is covered by standard hospital protocols and clinical training of the users	Yes	Minor	Remote	No Action
[286]	Inadequate specification of service and maintenance	No	---	---	n/a
[287]	Use by unskilled / untrained personnel	Yes	Minor	Remote	No Action
[288]	Reasonable foreseeable misuse	No	---	---	n/a
[289]	Insufficient warning of side effects	No	---	---	n/a
[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	Ref 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

ID	Ref Question	Applys	Risk	Probability	Overall
[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	Ref Question	Applys	Risk	Probability	Overall
[317]	Loss of mechanical integrity NOTES: Safety Value	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	Ref Question	Applys	Risk	Probability	Overall
[332]	Somebody Adjusts Pressure to zero NOTES: Reducing the pressure would have to be a premeditated deliberate act. Effects of reducing the pressure to Zero would be picked up by trained personnel both 1 / In the quick test before use - Block the outlet and check the pressure setting. and 2 / visually in normal use as the baby is not receiving and positive pressure when the T Occlude is blocked by the users thumb. i.e the chest will not rise.	Yes	Minor	Improbable	No Action

X.2

ID	Ref Question	Applys	Risk	Probability	Overall
[333]	Somebody Adjusts Pressure to Maximum NOTES: Tom Thumb still works correctly, and within maximum limit of 45. 45cmH20 was used as a limiting pressure set by physicians to prevent accidental Pulmonary barotrauma See ISO 10651-4:2002 Section 6.7.2.1 as the 45cmH2O limit for weights under 10Kg	Yes	Negligible	Remote	No Action

D.9 Fire Risk

ID	Ref Question	Applys	Risk	Probability	Overall
[334]	In terms of the device itself NOTES: Risk due to being suitable for use with Oxygen Gas. To limit the risk of Fire the Tom Thumb uses Special O Rings and Oxygen compatible grease (Fomblin). In actual use over 25 years there has not been a single report of any form of fire caused by a Tom Thumb device.	Yes	Negligible	Improbable	No Action
[335]	In term of materials used to clean	No	---	---	n/a

D.9 Fire Risk

ID	Ref Question	Applys	Risk	Probability	Overall
[336]	In terms of Materials passing through the device NOTES: Oxygen can be passed through the device if the hospitals only have piped Oxygen. There is no electrics within the device, there is not an ignition source. Units have been in used for over 20 years and there has never been a reported indecent of a fire caused by a tom thumb unit	Yes	Minor	Improbable	No Action

D.10 Explosion Risk

ID	Ref Question	Applys	Risk	Probability	Overall
[337]	In terms of the device itself NOTES: Risk due to being suitable for use with Oxygen Gas. To limit the risk of Fire the Tom Thumb uses Special O Rings and Oxygen compatible grease (Fomblin). In actual use over 25 years there has not been a single report of any form of fire caused by a Tom Thumb device.	Yes	Negligible	Improbable	No Action
[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	Ref 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

Pressure Measurement in CmH20

ID	Ref Question	Applys	Risk	Probability	Overall
[341]	80/181/EEC does not allow cmH20 as a Legal Reading, NOTES: The Tom thumb has been Using cmH20, since 1993. Many NHS Trusts the use of CMH2O is in the Guidelines.	Yes	Negligible	Improbable	No Action

Returns / Service

ID	Ref Question	Applys	Risk	Probability	Overall
[467]	Does Fault Code Replaced Gauge Face Type Fault present a risk NOTES: User Damage,0.417 % 0310034 0.933 % 0310030	Yes	Minor	Improbable	No Action
[463]	Does Fault Code Damaged Pressure Gauge Type Fault present a risk NOTES: User Damage,0.417 % 0310034 0.933 % 0310030	Yes	Minor	Improbable	No Action
[1123]	0310094 Does Fault Code Replaced Gauge Face Type Fault present a risk NOTES: User Damage,0.417 % 0310034 0.933 % 0310030	Yes	Minor	Improbable	No Action
[1122]	0310080 Does Fault Code Replaced Gauge Face Type Fault present a risk NOTES: User Damage,0.417 % 0310034 0.933 % 0310030	Yes	Minor	Improbable	No Action
[1121]	0310034 Does Fault Code Damaged Pressure Gauge Type Fault present a risk NOTES: User Damage,0.417 % 0310034 0.933 % 0310030	Yes	Minor	Improbable	No Action
[1120]	0310033 Does Fault Code Replaced Gauge Face Type Fault present a risk NOTES: User Damage,0.417 % 0310034 0.933 % 0310030	Yes	Minor	Improbable	No Action
[1119]	0310032 Does Fault Code Damaged Pressure Gauge Type Fault present a risk NOTES: User Damage,0.417 % 0310034 0.933 % 0310030	Yes	Minor	Improbable	No Action
[1117]	0310030 Does Fault Code Service Type Fault present a risk NOTES: Service not a Fault	No	---	---	n/a
[1116]	0310030 Does Fault Code Damaged Pressure Gauge Type Fault present a risk NOTES: User Damage,0.417 % 0310034 0.933 % 0310030	Yes	Minor	Improbable	No Action
[1275]	Does Fault Code Clamp Broken Type Fault present a risk NOTES: User Damage,0.072 %	Yes	Negligible	Improbable	No Action
[1336]	0310030 Does Fault Code Stuck Gauge Type Fault present a risk NOTES: 2 Unit 0.14% can be caused during maintenance.	Yes	Negligible	Improbable	No Action
[1450]	Unit that will not go above 10 cmh20 NOTES: Unit will not pass initial test or user setup	Yes	Minor	Improbable	No Action

Reference Question 10
C.2.1 What is the intended use and how is the medical device to be used
does the medical device support life
Applys Yes
Risk Serious
Risk Probability Serious
Overall Risk Action : No Action
Assessed By John Lamb
Assessed On 09/11/17
Notes :
Device itself on its own does not support life, rather it enables the Operator to support life using the Tom thumb, in the same way the resuscitation bag supports life with the help of the operator.Needs Two major faults and operator error to impose any risk to patient
Further Information Issue : 0
Risk Completed

Reference Question 11
C.2.1 What is the intended use and how is the medical device to be used
is special intervention necessary in the case of failure of the medical device
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By John Lamb
Assessed On 09/11/17
Notes :
In case of failure the operator would need to resort to the old resuscitation bag method.However the Tom thumb unit has a secondary safety value mechanism in case of primary valve failure.Needs Two major faults and operator error to impose any risk to patient. Main risk is not connecting the Tom Thumb into the circuit
Further Information Issue : 0
Risk Completed

Reference Question 21
C.2.3 Is the medical device intended to be in contact with the patient or other persons
Factors that should be considered include the nature of the intended contact surface contact
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 30/09/15
Notes :
Device is used in conjunction with a patient circuit which is covered by its own CE mark.
device itself does not touch the patient
Further Information Issue : 0
Risk Completed

Reference Question 25
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
Factors that should be considered include compatibility with relevant substances
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 24/09/17
Notes :
Oxygen,Uses Brass,and Doc 2338 Fomblin Oxygen Friendly grease.No electronic or other form of ingnition source
Further Information Issue : 0
Risk Completed

Reference Question 30
C.2.5 Is energy delivered to or extracted from the patient
Factors that should be considered include the type of energy transferred
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By John Lamb
Assessed On 09/11/17
Notes :
The Tom THumb is used to prevent pressure problems Four faults are required to defeat it
Further Information Issue : 0
Risk Completed

Reference Question 36
C.2.6 Are substances delivered to or extracted from the patient
Factors that should be considered include whether the substance is delivered
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 30/09/15
Notes :
Delivers gas, which is the primary function of the device
Further Information Issue : 0
Risk Completed

Reference Question 52
C.2.9 Is the medical device intended to be routinely cleaned and disinfected by the user
Factors that should be considered include the types of cleaning or disinfecting agents to be used
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 21/02/14
Further Information Issue : 0
Risk Completed

Reference Question 53
C.2.9 Is the medical device intended to be routinely cleaned and disinfected by the user
Factors that should be considered include any
limitations on the number of cleaning cycles.
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 21/02/14
Further Information Issue : 0
Risk Completed

Reference Question 54
C.2.9 Is the medical device intended to be routinely cleaned and disinfected by the user
Factors that should be considered include The design of the Medical device can influence the effectiveness of routine cleaning and disinfection
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 21/02/14
Further Information Issue : 0
Risk Completed

Reference Question 59
C.2.10 Is the medical device intended to modify the patient environment
Factors that should be considered include pressure
Applys Yes
Risk Critical
Risk Probability Critical
Overall Risk Action : Risk Benefits
Assessed By John Lamb
Assessed On 09/11/17
Notes :
Tom Thumb device is only used to remove the risk of excessive pressure.It needs four major component failures incorrect including set up and misuse by operator.
Further Information Issue : 0
Risk Completed

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 Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 24/02/14
Notes :
Breathing Circuit, and T-Piece
Further Information Issue : 0
Risk Completed

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 Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 24/02/14
Notes :
Breathing Circuit, and T-Piece
Further Information Issue : 0
Risk Completed

Reference Question 105
C.2.17 Are there essential consumables or accessories associated with the medical device
Factors that should be considered include any restrictions placed upon users in their selection of accessories.
Applys Yes
Risk Serious
Risk Probability Serious
Overall Risk Action : Risk Benefits
Assessed By Derek Lamb
Assessed On 10/10/17
Notes :
Breathing Circuit, and T-Piece Selected by the user
Further Information Issue : 0
Risk Completed

Reference Question 108
C.2.18 Is maintenance or calibration necessary
Factors that should be considered include whether maintenance or calibration are to be carried out by the specialist
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 21/02/14
Notes :
Main Pressure is user selectable.
Safety Value is Fixed.

Yearly Calibration is essential.
Further Information Issue : 0
Risk Completed

Reference Question 110
C.2.18 Is maintenance or calibration necessary
Factors that should be considered include are special substances or equipment necessary for proper calibration
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 21/02/14
Notes :
Main Pressure is user selectable.
Safety Value is Fixed.

Yearly Calibration is essential.
Further Information Issue : 0
Risk Completed

Reference Question 129
C.2.25 Is safe decommissioning or disposal of the medical device necessary
Factors that should be considered include is the material recyclable
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 21/02/14
Notes :
Unit made of Brass, completly recycable
Further Information Issue : 0
Risk Completed

Reference Question 132
C.2.27 How will information for safe use be provided
Factors that should be considered include whether information will be provided directly to the end user by the manufacturer
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 30/09/15
Notes :
Information supplied in the instructions for use
Further Information Issue : 0
Risk Completed

Reference Question 153
C.2.29.2 Is the medical device used in an environment where distractions can cause use error
Factors that should be considered include the consequence of use error
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By John Lamb
Assessed On 09/11/17
Notes :
Used in maternity, level environment distractions will be High,however there will one to one nursing if the Tom Thumb is in use.
Further Information Issue : 0
Risk Completed

Reference Question 154
C.2.29.2 Is the medical device used in an environment where distractions can cause use error
Factors that should be considered include whether the distractions are commonplace
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 21/02/14
Notes :
Used in maternity, level environment distractions will be High,
however the number one patient will be the infant if the Tom Thumb is in use.
Further Information Issue : 0
Risk Completed

Reference Question 156
C.2.29.3 Does the medical device have connecting parts or accessories
Factors that should be considered include the possibility of wrong connections
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 30/09/15
Notes :
Tom Thumb design to avoid incorrect connections
Further Information Issue : 0
Risk Completed

Reference Question 158
C.2.29.3 Does the medical device have connecting parts or accessories
Factors that should be considered include connection force,
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 30/09/15
Notes :
Unit made from Brass,
Further Information Issue : 0
Risk Completed

Reference Question 160
C.2.29.3 Does the medical device have connecting parts or accessories
Factors that should be considered include over- and under-tightening.
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 30/09/15
Notes :
Possibility of connection being disconnected,
due to flowing gas, and immediate non functioning of the device, this scenario should be immediate obvious
Further Information Issue : 0
Risk Completed

Reference Question 174
C.2.29.5 Does the medical device display information
Factors that should be considered include visibility in various environments
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 30/09/15
Notes :
Mechanical Pressure gauge clear display,
bought in standard component as used by multiple medical manufacturers
Further Information Issue : 0
Risk Completed

Reference Question 175
C.2.29.5 Does the medical device display information
Factors that should be considered include orientation
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 30/09/15
Notes :
Mechanical Pressure gauge clear display from all angles
Further Information Issue : 0
Risk Completed

Reference Question 176
C.2.29.5 Does the medical device display information
Factors that should be considered include the visual capabilities of the user
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 30/09/15
Notes :
 Clear legible display, Black text on white background
Further Information Issue : 0
Risk Completed

Reference Question 178
C.2.29.5 Does the medical device display information
Factors that should be considered include clarity of the presented information
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 30/09/15
Notes :
Clear legible display, Black text on white background
Further Information Issue : 0
Risk Completed

Reference Question 179
C.2.29.5 Does the medical device display information
Factors that should be considered include units
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 30/09/15
Notes :
Clear legible display, Black text on white background, standard units for this application
Further Information Issue : 0
Risk Completed

Reference Question 198
C.2.31 In what ways might the medical device be deliberately misused
Factors that should be considered are neglect of manufacturer`s recommended maintenance
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 21/02/14
Notes :
routine servicing should be maintained.
However, after 25 Years we have not seen a problem of a unit non functioning due to lack of servicing.

Even if the device develops leaks it should still perform the function for which it is intended.

Further Information Issue : 0
Risk Completed

Reference Question 223
D.2 Energy hazards and contributory factors
Gravity Falling
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 21/02/14
Notes :
 Clamped into place
Further Information Issue : 0
Risk Completed

Reference Question 276
D.5
Pressure
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 21/02/14
Notes :
Unit has Safety Value to stop over pressure
Further Information Issue : 0
Risk Completed

Reference Question 278

Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 21/02/14
Further Information Issue : 0
Risk Completed

Reference Question 279
D.6 Hazards related to the use of the medical device and contributory factors
Inadequate operating instructions
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 30/09/15
Notes :
operating instructions are adequate and usage is covered by standard hospital protocols and clinical training of the users
Further Information Issue : 0
Risk Completed

Reference Question 280
D.6 Hazards related to the use of the medical device and contributory factors
Inadequate description of performance
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 30/09/15
Notes :
operating instructions are adequate and usage is covered by standard hospital protocols and clinical training of the users
Further Information Issue : 0
Risk Completed

Reference Question 284
D.6 Hazards related to the use of the medical device and contributory factors
Inadequate specification of pre-use checks
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 30/09/15
Notes :
operating instructions are adequate and usage is covered by standard hospital protocols and clinical training of the users
Further Information Issue : 0
Risk Completed

Reference Question 285
D.6 Hazards related to the use of the medical device and contributory factors
Over-complicated operating instructions
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 30/09/15
Notes :
operating instructions are adequate and usage is covered by standard hospital protocols and clinical training of the users
Further Information Issue : 0
Risk Completed

Reference Question 287
D.6 Hazards related to the use of the medical device and contributory factors
Use by unskilled / untrained personnel
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 30/09/15
Further Information Issue : 0
Risk Completed

Reference Question 332
X.1
Somebody Adjusts Pressure to zero
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 11/08/15
Notes :
Reducing the pressure would have to be a premeditated deliberate act.
Effects of reducing the pressure to Zero would be picked up by trained personnel

both
1 / In the quick test before use - Block the outlet and check the pressure setting.
and
2 / visually in normal use as the baby is not receiving and positive pressure when the T Occlude is blocked by the users thumb. i.e the chest will not rise.

Further Information Issue : 0
Risk Completed

Reference Question 333
X.2
Somebody Adjusts Pressure to Maximum
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 11/08/15
Notes :
Tom Thumb still works correctly, and within maximum limit of 45.
45cmH20 was used as a limiting pressure set by physicians to prevent accidental Pulmonary barotrauma
See ISO 10651-4:2002 Section 6.7.2.1 as the 45cmH2O limit for weights under 10Kg
Further Information Issue : 0
Risk Completed

Reference Question 334
D.9 Fire Risk
In terms of the device itself
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 28/09/15
Notes :
Risk due to being suitable for use with Oxygen Gas.

To limit the risk of Fire the Tom Thumb uses Special O Rings and Oxygen compatible grease (Fomblin).

In actual use over 25 years there has not been a single report of any form of fire caused by a Tom Thumb device.

Further Information Issue : 0
Risk Completed

Reference Question 336
D.9 Fire Risk
In terms of Materials passing through the device
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 11/08/15
Notes :
Oxygen can be passed through the device if the hospitals only have piped Oxygen.

There is no electrics within the device, there is not an ignition source.

Units have been in used for over 20 years and there has never been a reported indecent of a fire caused by a tom thumb unit

Further Information Issue : 0
Risk Completed

Reference Question 337
D.10 Explosion Risk
In terms of the device itself
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 28/09/15
Notes :
Risk due to being suitable for use with Oxygen Gas.

To limit the risk of Fire the Tom Thumb uses Special O Rings and Oxygen compatible grease (Fomblin).

In actual use over 25 years there has not been a single report of any form of fire caused by a Tom Thumb device.
Further Information Issue : 0
Risk Completed

Reference Question 341
Pressure Measurement in CmH20
80/181/EEC does not allow cmH20 as a Legal Reading,
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 18/08/17
Notes :
The Tom thumb has been Using cmH20, since 1993.
Many NHS Trusts the use of CMH2O is in the Guidelines.

Further Information Issue : 0
Risk Completed

Reference Question 463
Returns / Service
Does Fault Code Damaged Pressure Gauge Type Fault present a risk
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 24/09/17
Notes :
User Damage,0.417 % 0310034 0.933 % 0310030
Further Information Issue : 0
Risk Completed

Reference Question 467
Returns / Service
Does Fault Code Replaced Gauge Face Type Fault present a risk
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 24/09/17
Notes :
User Damage,0.417 % 0310034 0.933 % 0310030
Further Information Issue : 0
Risk Completed

Reference Question 1116
Returns / Service
0310030 Does Fault Code Damaged Pressure Gauge Type Fault present a risk
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 24/09/17
Notes :
User Damage,0.417 % 0310034 0.933 % 0310030
Further Information Issue : 0
Risk Completed

Reference Question 1119
Returns / Service
0310032 Does Fault Code Damaged Pressure Gauge Type Fault present a risk
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 24/09/17
Notes :
User Damage,0.417 % 0310034 0.933 % 0310030
Further Information Issue : 0
Risk Completed

Reference Question 1120
Returns / Service
0310033 Does Fault Code Replaced Gauge Face Type Fault present a risk
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 24/09/17
Notes :
User Damage,0.417 % 0310034 0.933 % 0310030
Further Information Issue : 0
Risk Completed

Reference Question 1121
Returns / Service
0310034 Does Fault Code Damaged Pressure Gauge Type Fault present a risk
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 24/09/17
Notes :
User Damage,0.417 % 0310034 0.933 % 0310030
Further Information Issue : 0
Risk Completed

Reference Question 1122
Returns / Service
0310080 Does Fault Code Replaced Gauge Face Type Fault present a risk
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 24/09/17
Notes :
User Damage,0.417 % 0310034 0.933 % 0310030
Further Information Issue : 0
Risk Completed

Reference Question 1123
Returns / Service
0310094 Does Fault Code Replaced Gauge Face Type Fault present a risk
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 24/09/17
Notes :
User Damage,0.417 % 0310034 0.933 % 0310030
Further Information Issue : 0
Risk Completed

Reference Question 1275
Returns / Service
Does Fault Code Clamp Broken Type Fault present a risk
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 24/09/17
Notes :
User Damage,0.072 %
Further Information Issue : 0
Risk Completed

Reference Question 1336
Returns / Service
0310030 Does Fault Code Stuck Gauge Type Fault present a risk
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 03/10/17
Notes :
2 Unit 0.14% can be caused during maintenance.
Further Information Issue : 100173
Risk Completed

Reference Question 1450
Returns / Service
Unit that will not go above 10 cmh20
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 27/10/17
Notes :
Unit will not pass initial test or user setup
Further Information Issue : 104434
Risk Completed

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Risk Assessment Document Summary Applicable questions and Actions

Ref Question	Applys	Risk	Risk Probability	Overall Risk	Assessed By	Assessed On	Risk Completed
10	Yes	Serious	Improbable	No Action	John Lamb	09/11/17	Yes
11	Yes	Negligible	Remote	No Action	John Lamb	09/11/17	Yes
21	Yes	Negligible	Improbable	No Action	Derek Lamb	30/09/15	Yes
25	Yes	Negligible	Improbable	No Action	Derek Lamb	24/09/17	Yes
30	Yes	Negligible	Improbable	No Action	John Lamb	09/11/17	Yes
36	Yes	Negligible	Improbable	No Action	Derek Lamb	30/09/15	Yes
52	Yes	Minor	Remote	No Action	Derek Lamb	21/02/14	Yes
53	Yes	Minor	Remote	No Action	Derek Lamb	21/02/14	Yes
54	Yes	Minor	Remote	No Action	Derek Lamb	21/02/14	Yes
59	Yes	Critical	Improbable	Risk Benefits	John Lamb	09/11/17	Yes
102	Yes	Minor	Remote	No Action	Derek Lamb	24/02/14	Yes
103	Yes	Minor	Remote	No Action	Derek Lamb	24/02/14	Yes
105	Yes	Serious	Remote	Risk Benefits	Derek Lamb	10/10/17	Yes
108	Yes	Minor	Remote	No Action	Derek Lamb	21/02/14	Yes
110	Yes	Minor	Remote	No Action	Derek Lamb	21/02/14	Yes
129	Yes	Minor	Remote	No Action	Derek Lamb	21/02/14	Yes
132	Yes	Negligible	Improbable	No Action	Derek Lamb	30/09/15	Yes
153	Yes	Negligible	Improbable	No Action	John Lamb	09/11/17	Yes
154	Yes	Minor	Remote	No Action	Derek Lamb	21/02/14	Yes
156	Yes	Minor	Remote	No Action	Derek Lamb	30/09/15	Yes
158	Yes	Minor	Remote	No Action	Derek Lamb	30/09/15	Yes
160	Yes	Minor	Remote	No Action	Derek Lamb	30/09/15	Yes
174	Yes	Negligible	Improbable	No Action	Derek Lamb	30/09/15	Yes
175	Yes	Negligible	Improbable	No Action	Derek Lamb	30/09/15	Yes
176	Yes	Negligible	Improbable	No Action	Derek Lamb	30/09/15	Yes
178	Yes	Negligible	Improbable	No Action	Derek Lamb	30/09/15	Yes
179	Yes	Negligible	Improbable	No Action	Derek Lamb	30/09/15	Yes
198	Yes	Minor	Remote	No Action	Derek Lamb	21/02/14	Yes
223	Yes	Minor	Remote	No Action	Derek Lamb	21/02/14	Yes
276	Yes	Minor	Remote	No Action	Derek Lamb	21/02/14	Yes
278	Yes	Minor	Remote	No Action	Derek Lamb	21/02/14	Yes
279	Yes	Minor	Remote	No Action	Derek Lamb	30/09/15	Yes
280	Yes	Minor	Remote	No Action	Derek Lamb	30/09/15	Yes
284	Yes	Negligible	Improbable	No Action	Derek Lamb	30/09/15	Yes
285	Yes	Minor	Remote	No Action	Derek Lamb	30/09/15	Yes
287	Yes	Minor	Remote	No Action	Derek Lamb	30/09/15	Yes
332	Yes	Minor	Improbable	No Action	Derek Lamb	11/08/15	Yes
333	Yes	Negligible	Remote	No Action	Derek Lamb	11/08/15	Yes
334	Yes	Negligible	Improbable	No Action	Derek Lamb	28/09/15	Yes
336	Yes	Minor	Improbable	No Action	Derek Lamb	11/08/15	Yes
337	Yes	Negligible	Improbable	No Action	Derek Lamb	28/09/15	Yes
341	Yes	Negligible	Improbable	No Action	Derek Lamb	18/08/17	Yes
463	Yes	Minor	Improbable	No Action	Derek Lamb	24/09/17	Yes
467	Yes	Minor	Improbable	No Action	Derek Lamb	24/09/17	Yes
1116	Yes	Minor	Improbable	No Action	Derek Lamb	24/09/17	Yes
1119	Yes	Minor	Improbable	No Action	Derek Lamb	24/09/17	Yes

Ref Question	Applys	Risk	Risk Probability	Overall Risk	Assessed By	Assessed On	Risk Completed
1120	Yes	Minor	Improbable	No Action	Derek Lamb	24/09/17	Yes
1121	Yes	Minor	Improbable	No Action	Derek Lamb	24/09/17	Yes
1122	Yes	Minor	Improbable	No Action	Derek Lamb	24/09/17	Yes
1123	Yes	Minor	Improbable	No Action	Derek Lamb	24/09/17	Yes
1275	Yes	Negligible	Improbable	No Action	Derek Lamb	24/09/17	Yes
1336	Yes	Negligible	Improbable	No Action	Derek Lamb	03/10/17	Yes
1450	Yes	Minor	Improbable	No Action	Derek Lamb	27/10/17	Yes