Post market surveillance risk assesment re-evaluation

COT Lids

Acrylic Sheet: hinged with or without louvers, to be used in conjunction with a basinet, to retain heat and humidity.

Class I
Via Rule 1
Assesment Route Annex II
NBOG MD 0100

Carried out by Derek Lamb
02 / 10 / 17

VIAMED

- Stock References Review
- Supplier Review
- Sales Review
- Countries Review
- Returns Review
- Design Changes Review
- User Instructions Review
- Labels Review
- Document Updates Review
- Internal Issues Review
- Clinical / FDA Incidents online search
- Risk ISO 14971 : 2012 Review

Stock References Review

Stock Reference	Description
0392060	Leaflet - Cot Lids
0450120	Packing box - Cot Lids
0490051	Instructions for use - Viamed cot lids
PP8116	Cot Lid with Louvres *
PP8118	Cot lid special
PP8120	Cot lid upgrade kit - 08/03
PP8583	1 Piece Cot Lid With Stoppers*
PP8690	Cot lid
PP8711	Hoskins Cot Lid
PP8712	Bristol Maid Cot Lid
PP8713	Nesbit Evans Cot Lid
PP8776	Hoskins Cot Lid - One Piece
PP8777	Bristol Maid Cot Lid - One Piece
PP8778	Nesbit Evans Cot Lid - One Piece
PP8787	Bristol Maid Cot Lid
PP8788	Bristol Maid Cot Lid - One Piece
PP8789	Arjo-Huntleigh Cot Lid
PP8790	Arjo-Huntleigh Cot Lid - One Piece

Comments on Stock references review:

part number correct

Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
PP8711	Hoskins Cot Lid	00009022	PP8711	Tanda Engineering Ltd	A
PP8712	Bristol Maid Cot Lid	00009022	PP8712	Tanda Engineering Ltd	A
PP8713	Nesbit Evans Cot Lid	00009022	PP8713	Tanda Engineering Ltd	A
PP8777	Bristol Maid Cot Lid - O	00009022	PP8777	Tanda Engineering Ltd	A
PP8778	Nesbit Evans Cot Lid - O	00009022	PP8778	Tanda Engineering Ltd	A
PP8787	Bristol Maid Cot Lid	00009022	PP8787	Tanda Engineering Ltd	A
PP8788	Bristol Maid Cot Lid - O	00009022	PP8788	Tanda Engineering Ltd	A
0450120	Packing box - Cot Lids	00009353	BOC531	Rajapack Ltd	B
PP8690	Cot lid	00011873	PP8690	Rossendale Plastics	B

Comments on Suppliers:

supplier reviews upto date

Sales Information

Stock Reference	Description	2011	2012	2013	2014	2015	2016	2017
0392060	Leaflet - Cot Lids							
0450120	Packing box - Cot Lids							
0490051	Instructions for use - Viamed cot lids							
PP8116	Cot Lid with Louvres *							
PP8118	Cot lid special							
PP8120	Cot lid upgrade kit - 08/03							
PP8583	1 Piece Cot Lid With Stoppers*							
PP8690	Cot lid							
PP8711	Hoskins Cot Lid	4	2	1			3	2
PP8712	Bristol Maid Cot Lid	22	11	17	3	5	1	5
PP8713	Nesbit Evans Cot Lid	2	4	4	1	1	2	
PP8776	Hoskins Cot Lid - One Piece							
PP8777	Bristol Maid Cot Lid - O		4	6	6	12	18	2
PP8778	Nesbit Evans Cot Lid - O			1	2			
PP8787	Bristol Maid Cot Lid				1	4		2
PP8788	Bristol Maid Cot Lid - O					1		
PP8789	Arjo-Huntleigh Cot Lid							
PP8790	Arjo-Huntleigh Cot Lid - One Piece							

Comments on Sales Information:

Very low sales,
Decided to discontinue the product range.
letters are being assembled to inform current customers

Countries Review

Country	2011	2012	2013	2014	2015	2016	2017
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]

Comments on Sales to Countries:

Only sell to the UK

Comments on Risks with Sales to Countries:

Returns and Q.A. Fails Review

Stock Reference	Fault	2011	2012	2013	2014	2015	2016	2017
PP8712	Unchecked - Returned To Stock		4					

Comments on Returns:

No faults, just a return to stock item

Comments on Risks with Returns and Potential Re-work:

no

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

No product changes

Comments on Risks with Design Changes:

no

User Instructions Review

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
14537	PP8711 Hoskins Cot Lid User Instructions	10/11/14
14535	PP8712 Bristol Maid Cot Lid User Instructions	10/11/14
14533	PP8713 Nesbit EvansCot Lid User Instructions	10/11/14
14531	PP8776 Hoskins (One Piece) Cot Lid User Instructions	10/11/14
14529	PP8777 Bristol Maid (One Piece) Cot Lid User Instructions	10/11/14
14527	PP8778 Nesbit Evans (One Piece) Cot Lid User Instructions	10/11/14
14525	PP8787 Bristol Maid Cot Lid User Instructions	10/11/14
14523	PP8788 Bristol Maid (One Piece) Cot Lid User Instructions	10/11/14
14521	PP8790 Arjo Huntleigh (One Piece) Cot Lid User Instructions	10/11/14
14519	PP8789 Cot Lid for use with Arjo Huntleigh Cots Instructions for...	10/11/14
9637	Instruction For Use - Reusable Oxygen Hoods	13/12/11
7510	COT Lids Instructions for Use User Manual Cot Lids background i...	21/01/11
1898	Instructions For Use / Cleaning Cot Lids superceeded	18/06/07

Comments on User Instructions:

no IFU changes

Comments on Risks User Instructions:

no

Labels Review

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
16792	Head Box Oxygen Hoods Labels	20/04/16
9169	No accessory labels	18/10/11
7523	COT Lids Labels	21/01/11
1899	Cot Lid Labels	18/06/07

Comments on Labels:

no label changes

Comments on Risks Labels:

no

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
17288	COT Lids Clinical Trials Reports Reviews and Post Market Surveil...	18/08/16

Comments on Document Changes:

only new file last yeasrs version of this document

Comments on Risks with Document Changes:

no

Internal Issues Review

Number of Issues reviewed: 29

Issue ID	Subject
76352	Office Meeting Sales Back Orders Review - By Customer Backorder 00000290 PP8711 ORD81723
100243	Office Meeting Sales Back Orders Review - By Customer Backorder 00000290 PP8711 ORD87684
100467	Office Meeting Sales Back Orders Review - By Customer Backorder 00000290 PP8711 ORD87749
93648	Office Meeting Sales Back Orders Review - By Customer Backorder 00001040 PP8787 ORD86052
97998	Office Meeting Sales Back Orders Review - By Customer Backorder 00003500 PP8777 ORD87061
101215	Office Meeting Sales Back Orders Review - By Customer Backorder 00003880 PP8777 ORD87902
86639	Office Meeting Sales Back Orders Review - By Customer Backorder 00003910 PP8712 ORD84253
86640	Office Meeting Sales Back Orders Review - By Customer Backorder 00003910 PP8712 ORD84254
101658	Office Meeting Sales Back Orders Review - By Customer Backorder 00003910 PP8712 ORD87787
100593	Office Meeting Sales Back Orders Review - By Customer Backorder 00003910 PP8712 ORD87796
100586	Office Meeting Sales Back Orders Review - By Customer Backorder 00003910 PP8787 ORD87787
82276	Office Meeting Sales Back Orders Review - By Customer Backorder 00005030 PP8777 ORD83012
76859	Office Meeting Back Order Report POR10883 PP8711 //
82900	Office Meeting Back Order Report POR11015 PP8777 //
82893	Office Meeting Back Order Report POR11015 PP8777 //
82392	Office Meeting Back Order Report POR11015 PP8777 //
86841	Office Meeting Back Order Report POR11108 PP8712 //
86837	Office Meeting Back Order Report POR11108 PP8712 //
93806	Office Meeting Back Order Report POR11253 PP8787 //
93790	Office Meeting Back Order Report POR11253 PP8787 //
98176	Office Meeting Back Order Report POR11337 PP8777 //
98170	Office Meeting Back Order Report POR11337 PP8777 //
100690	Office Meeting Back Order Report POR11387 PP8711 //
100691	Office Meeting Back Order Report POR11387 PP8712 //

Issue ID	Subject
100693	Office Meeting Back Order Report POR11387 PP8787 //
101919	Office Meeting Back Order Report POR11410 PP8712 //
101544	Office Meeting Back Order Report POR11410 PP8712 //
101920	Office Meeting Back Order Report POR11410 PP8777 //
101545	Office Meeting Back Order Report POR11410 PP8777 //

Comments on Issues:

only Order Processing issues,
nothing found int he non conformance or customer complaints headers

Comments on Risks with Issues:

no risks identified

Clinical / FDA Incidents online search

Clinical Investigation online review

Do any of the Results indicate a Risk / Problem : No
Do any of the Results indicate outdated Technology : No
Comments on Clinical Search :

Nothing found, its only a simple cot lid so results are not forth coming

Review of online FDA Incident reports

Do any of the Results indicate a Risk / Problem : No
Do any of the Results indicate outdated Technology : No
Comments on Clinical Search :

Nothing found, its only a simple cot lid so results are not forth coming

Risk ISO 14971 : 2012 Summary

02 Oct 2017 File 53 COT Lids Risk Assesment Questions

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	Yes	Negligible	Improbable	No Action
[5]	what is the medical devices role relative to alleviation of disease	Yes	Negligible	Improbable	No Action
[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	Yes	Negligible	Improbable	No Action
[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	Ref Question	Applys	Risk	Probability	Overall
[56]	Factors that should be considered include temperature NOTES: Contains the preffered environment	Yes	Negligible	Improbable	No Action
[57]	Factors that should be considered include humidity NOTES: Humidity can be administered	Yes	Negligible	Improbable	No Action

ID	Ref Question	Applys	Risk	Probability	Overall
[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	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 NOTES: Humidified gas	Yes	Negligible	Improbable	No Action
[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

ID	Ref Question	Applys	Risk	Probability	Overall
[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 NOTES: Should not be sealed to allow CO2 to be vented	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

ID	Ref Question	Applys	Risk	Probability	Overall
[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	No	---	---	n/a
[103]	Factors that should be considered include specifications for such accessories	No	---	---	n/a
[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	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 NOTES: Some have hinges which should be checked.	Yes	Negligible	Improbable	No Action
[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	Ref 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	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
[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 NOTES: Cot lid fits over basinet	Yes	Negligible	Improbable	No Action

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 NOTES: Cracks harbour bacteria See CE file Risk analysis reports	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	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	No	---	---	n/a

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	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	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	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	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	Ref 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	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

ID	Ref Question	Applys	Risk	Probability	Overall
[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	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	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

ID	Ref Question	Applys	Risk	Probability	Overall
[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	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	Ref Question	Applys	Risk	Probability	Overall
[191]	Factors that should be considered are the risk of false alarms	No	---	---	n/a

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

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, NOTES: Fits over basinet	Yes	Negligible	Improbable	No Action
[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 NOTES: Has lips to prevent falling off or into the basinet	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	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	Ref 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	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: Usually Humidity and/or oxygen	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

ID	Ref Question	Applys	Risk	Probability	Overall
[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	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 NOTES: Some substances may craze the acrylic CE file Risk report	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	Ref Question	Applys	Risk	Probability	Overall
[222]	Mechanical force NOTES: Cot lid can be knocked into bastinet	Yes	Serious	Improbable	No Action
[223]	Gravity Falling NOTES: Cot lid can be knocked into bastinet	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
[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 NOTES: Cracks in lid	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

ID	Ref Question	Applys	Risk	Probability	Overall
[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
[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	Ref 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 NOTES: Cot lid knocked into cot	Yes	Minor	Improbable	No Action
[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
[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	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

D.9 Fire Risk

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

D.10 Explosion Risk

ID	Ref 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	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

Reference Question 4
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 treatment
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By John Lamb
Assessed On 06/10/15
Further Information Issue : 0
Risk Completed

Reference Question 5
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 alleviation of disease
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By John Lamb
Assessed On 06/10/15
Further Information Issue : 0
Risk Completed

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 Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By John Lamb
Assessed On 06/10/15
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 John Lamb
Assessed On 06/10/15
Notes :
Usually Humidity and/or oxygen
Further Information Issue : 0
Risk Completed

Reference Question 56
C.2.10 Is the medical device intended to modify the patient environment
Factors that should be considered include temperature
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By John Lamb
Assessed On 06/10/15
Notes :
Contains the preffered environment
Further Information Issue : 0
Risk Completed

Reference Question 57
C.2.10 Is the medical device intended to modify the patient environment
Factors that should be considered include humidity
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By John Lamb
Assessed On 06/10/15
Notes :
Humidity can be administered
Further Information Issue : 0
Risk Completed

Reference Question 67
C.2.13 Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies
Factors that should be considered include identifying any other medicines
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By John Lamb
Assessed On 06/10/15
Notes :
Humidified gas
Further Information Issue : 0
Risk Completed

Reference Question 106
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 operator
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 25/02/14
Notes :
Some have hinges which should be checked.
Further Information Issue : 0
Risk Completed

Reference Question 121
C.2.22 To what mechanical forces will the medical device be subjected
Factors that should be considered include whether the forces to which the medical device will be subjected are controlled by interaction with other persons
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By John Lamb
Assessed On 06/10/15
Notes :
Cot lid fits over basinet
Further Information Issue : 0
Risk Completed

Reference Question 201
C.2.33 Is the medical device intended to be mobile or portable
Factors that should be considered are the necessary grips,
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By John Lamb
Assessed On 06/10/15
Notes :
Fits over basinet
Further Information Issue : 0
Risk Completed

Reference Question 222
D.2 Energy hazards and contributory factors
Mechanical force
Applys Yes
Risk Serious
Risk Probability Serious
Overall Risk Action : No Action
Assessed By John Lamb
Assessed On 02/03/14
Notes :
Cot lid can be knocked into bastinet
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 John Lamb
Assessed On 02/03/14
Notes :
 Cot lid can be knocked into bastinet
Further Information Issue : 0
Risk Completed

Reference Question 288
D.6 Hazards related to the use of the medical device and contributory factors
Reasonable foreseeable misuse
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By John Lamb
Assessed On 02/03/14
Notes :
Cot lid knocked into cot
Further Information Issue : 0
Risk Completed

02 Oct 2017 File 53 COT Lids
Risk Assessment Document Summary Applicable questions and Actions

Ref Question	Applys	Risk	Risk Probability	Overall Risk	Assessed By	Assessed On	Risk Completed
4	Yes	Negligible	Improbable	No Action	John Lamb	06/10/15	Yes
5	Yes	Negligible	Improbable	No Action	John Lamb	06/10/15	Yes
10	Yes	Negligible	Improbable	No Action	John Lamb	06/10/15	Yes
36	Yes	Negligible	Improbable	No Action	John Lamb	06/10/15	Yes
56	Yes	Negligible	Improbable	No Action	John Lamb	06/10/15	Yes
57	Yes	Negligible	Improbable	No Action	John Lamb	06/10/15	Yes
67	Yes	Negligible	Improbable	No Action	John Lamb	06/10/15	Yes
106	Yes	Negligible	Improbable	No Action	Derek Lamb	25/02/14	Yes
121	Yes	Negligible	Improbable	No Action	John Lamb	06/10/15	Yes
201	Yes	Negligible	Improbable	No Action	John Lamb	06/10/15	Yes
222	Yes	Serious	Improbable	No Action	John Lamb	02/03/14	Yes
223	Yes	Minor	Remote	No Action	John Lamb	02/03/14	Yes
288	Yes	Minor	Improbable	No Action	John Lamb	02/03/14	Yes