Post market surveillance risk assesment re-evaluation

Nova Oxygen Tents

Enclosures to enable oxygen enriched air and humidity to be supplied to the patients head only.

Class IIa
Via Rule Rule 2
Assesment Route Annex II
NBOG MD 0101

Carried out by Derek Lamb
16 / 07 / 15

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
2310000	Oxygen hood/tent - standard.
2310001	Oxygen hood/tent - standard.
2310002	Oxygen hood/tent - standard.
2310003	Oxygen hood/tent - standard.
2310004	Oxygen hood/tent - standard.
2310005	Oxygen hood/tent - standard.
2310006	Oxygen hood/tent - standard.
2310007	Oxygen hood/tent - standard.
2310008	Oxygen hood/tent - standard.
2310009	Oxygen hood/tent - standard.
2310010	Oxygen hood/tent - standard.
2310011	Oxygen hood/tent - standard.
2310012	Oxygen hood/tent - standard.
2310013	Oxygen hood/tent - standard.
2310014	Oxygen hood/tent - standard.
2310020	Oxygen hood/tent - dual port.
2310021	Oxygen hood/tent - ICN with 3 ports.
2310025	Oxygen hood/tent - no bottom.
2310026	Oxygen hood/tent - no bottom.
2310027	Oxygen hood/tent - no bottom.
2310028	Oxygen hood/tent - no bottom.
2310029	Oxygen hood/tent - no bottom.
2310030	Oxygen hood/tent - no bottom.
2310031	Oxygen hood/tent - no bottom.
2310032	Oxygen hood/tent - no bottom.
2310033	Oxygen hood/tent - no bottom.
2310034	Oxygen hood/tent - no bottom.
2310035	Oxygen hood/tent - no bottom.
2310050	Oxygen hood/tent - partial bottom.
2310051	Oxygen hood/tent - partial bottom.
2310052	Oxygen hood/tent - partial bottom.
2310053	Oxygen hood/tent - partial bottom.
2310054	Oxygen hood/tent - partial bottom.
2310055	Oxygen hood/tent - partial bottom.
2310075	Oxygen hood/tent - NICU.
2310076	Oxygen hood/tent - NICU.
2310077	Oxygen hood/tent - NICU.
2310078	Oxygen hood/tent - NICU.
2310079	Oxygen hood/tent - NICU.
2310080	Oxygen hood/tent - NICU.
2310081	Oxygen hood/tent - NICU.
2310100	Low birth weight tenthouse

Stock Reference	Description
2310101	Low birth weight tenthouse w/port
2310102	Low birth weight tenthouse top access
2310103	Low birth weight tenthouse with top &
2310104	Low birth weight tenthouse
2310105	Low birt weight tenthouse w/port.
2310106	Low birth weight tenthouse top access
2310107	Low birth weight tenthouse with top &
2310125	Double tent set
2310126	Double tent set
2310127	Double tent set
2310128	Double tent set inner no bottom
2310129	Double tent set
2310130	Double tent set
2310131	Double tent - outer tent only for use
2310132	Double tent - outer tent only for use
2310133	Double tent - outer tent only for use
2310134	Double tent - outer tent only for use
2310140	Babyshield - infant heat shield
2310141	Babyshield - infant heat shield with
2310145	Oxygen hood - no drape.
2310150	Isolation canopy - chair.
2310151	Isolation canopy - crib.
2330000	Oxygen hood/tent - standard.
2330001	Oxygen hood/tent - standard.
2330002	Oxygen hood/tent - standard.
2330003	Oxygen hood/tent - standard.
2330004	Oxygen hood/tent - standard.
2330006	Oxygen hood/tent - standard.
2330007	Oxygen hood/tent - standard.
2330010	Oxygen hood/tent - standard.
2330011	Oxygen hood/tent - standard.
2330013	Oxygen hood/tent - standard.
2330014	Oxygen hood/tent - standard.
2330020	Oxygen hood/tent - dual port.
2330021	Oxygen hood/tent - ICN with 3 ports.
2330025	Oxygen hood/tent - no bottom.
2330026	Oxygen hood/tent - no bottom.
2330027	Oxygen hood/tent - no bottom.
2330028	Oxygen hood/tent - no bottom.
2330029	Oxygen hood/tent - no bottom.
2330031	Oxygen hood/tent - no bottom.
2330032	Oxygen hood/tent - no bottom.
2330035	Oxygen hood/tent - no bottom.
2330050	Oxygen hood/tent - partial bottom.
2330052	Oxygen hood/tent - partial bottom.

Stock Reference	Description
2330053	Oxygen hood/tent - partial bottom.
2330055	Oxygen hood/tent - partial bottom.
2330075	Oxygen hood/tent - NICU.
2330076	Oxygen hood/tent - NICU.
2330077	Oxygen hood/tent - NICU.
2330078	Oxygen hood/tent - NICU.
2330080	Oxygen hood/tent - NICU.
2330081	Oxygen hood/tent - NICU.
2330100	Low birthweight tenthouse
2330101	Low birthweight tenthouse w/port
2330103	Low birthweight tenthouse with top &
2330104	Low birthweight tenthouse
2330105	Low birthweight tenthouse w/port.
2330107	Low birthweight tenthouse with top &
2330125	Double tent set
2330126	Double tent set
2330127	Double tent set
2330128	Double tent set inner no bottom
2330129	Double tent set
2330130	Double tent set
2330131	Double tent - outer tent only for use
2330132	Double tent - outer tent only for use
2330133	Double tent - outer tent only for use
2330134	Double tent - outer tent only for use
2330140	Babyshield - infant heat shield
2330141	Babyshield - infant heat shield with
2330500	Label for Oxygen hoods & plastics...
2330501	Label for Oxygen hoods & plastics...

Comments on Stock references review:

All part number correct

Supplier Review

Stock Reference	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
2310000	Oxygen hood/tent - stand	00012241	903011	Nova Health Systems	B
2310001	Oxygen hood/tent - stand	00012241	903202	Nova Health Systems	B
2310002	Oxygen hood/tent - stand	00012241	900800	Nova Health Systems	B
2310003	Oxygen hood/tent - stand	00012241	903081	Nova Health Systems	B
2310004	Oxygen hood/tent - stand	00012241	903012	Nova Health Systems	B
2310006	Oxygen hood/tent - stand	00012241	903213	Nova Health Systems	B
2310007	Oxygen hood/tent - stand	00012241	903013	Nova Health Systems	B
2310010	Oxygen hood/tent - stand	00012241	903014	Nova Health Systems	B
2310011	Oxygen hood/tent - stand	00012241	907011	Nova Health Systems	B
2310013	Oxygen hood/tent - stand	00012241	903015	Nova Health Systems	B
2310014	Oxygen hood/tent - stand	00012241	907024	Nova Health Systems	B
2310020	Oxygen hood/tent - dual	00012241	903022	Nova Health Systems	B
2310021	Oxygen hood/tent - ICN w	00012241	903092	Nova Health Systems	B
2310025	Oxygen hood/tent - no bo	00012241	903101	Nova Health Systems	B
2310026	Oxygen hood/tent - no bo	00012241	903016	Nova Health Systems	B
2310027	Oxygen hood/tent - no bo	00012241	903201	Nova Health Systems	B
2310028	Oxygen hood/tent - no bo	00012241	903082	Nova Health Systems	B
2310029	Oxygen hood/tent - no bo	00012241	903017	Nova Health Systems	B
2310031	Oxygen hood/tent - no bo	00012241	903214	Nova Health Systems	B
2310032	Oxygen hood/tent - no bo	00012241	903018	Nova Health Systems	B
2310035	Oxygen hood/tent - no bo	00012241	903094	Nova Health Systems	B
2310050	Oxygen hood/tent - parti	00012241	903049	Nova Health Systems	B
2310052	Oxygen hood/tent - parti	00012241	903019	Nova Health Systems	B
2310055	Oxygen hood/tent - parti	00012241	903020	Nova Health Systems	B
2310075	Oxygen hood/tent - NICU.	00012241	903005	Nova Health Systems	B
2310076	Oxygen hood/tent - NICU.	00012241	903008	Nova Health Systems	B
2310077	Oxygen hood/tent - NICU.	00012241	903009	Nova Health Systems	B
2310078	Oxygen hood/tent - NICU.	00012241	903006	Nova Health Systems	B
2310080	Oxygen hood/tent - NICU.	00012241	903215	Nova Health Systems	B
2310081	Oxygen hood/tent - NICU.	00012241	903007	Nova Health Systems	B
2310100	Low birth weight tenthou	00012241	903200	Nova Health Systems	B
2310104	Low birth weight tenthou	00012241	903301	Nova Health Systems	B
2310107	Low birth weight tenthou	00012241	903307	Nova Health Systems	B
2310125	Double tent set	00012241	903028	Nova Health Systems	B
2310140	Babyshield - infant heat	00012241	909028	Nova Health Systems	B
2310141	Babyshield - infant heat	00012241	909030	Nova Health Systems	B

Comments on Suppliers:

supplier review update

Sales Information

Stock Reference	Description	2009	2010	2011	2012	2013	2014	2015
2310000	Oxygen hood/tent - stand		3	3	-3	1		
2310001	Oxygen hood/tent - stand	2	7		5	4	6	1
2310002	Oxygen hood/tent - stand		10	4				
2310003	Oxygen hood/tent - stand				1	2	2	1
2310004	Oxygen hood/tent - stand	1	12		2	5	1	4
2310005	Oxygen hood/tent - standard.							
2310006	Oxygen hood/tent - stand	7	11	20	2	9	4	
2310007	Oxygen hood/tent - stand	27	60	40	25	34	18	15
2310008	Oxygen hood/tent - standard.							
2310009	Oxygen hood/tent - standard.							
2310010	Oxygen hood/tent - stand	98	82	69	60	51	44	18
2310011	Oxygen hood/tent - stand	2						
2310012	Oxygen hood/tent - standard.							
2310013	Oxygen hood/tent - stand	32	49	36	28	30	18	10
2310014	Oxygen hood/tent - stand		6	8				
2310020	Oxygen hood/tent - dual							
2310021	Oxygen hood/tent - ICN w							
2310025	Oxygen hood/tent - no bo					1		
2310026	Oxygen hood/tent - no bo						1	
2310027	Oxygen hood/tent - no bo						2	
2310028	Oxygen hood/tent - no bo						2	
2310029	Oxygen hood/tent - no bo			19		2	6	0
2310030	Oxygen hood/tent - no bottom.							
2310031	Oxygen hood/tent - no bo			5	4		2	
2310032	Oxygen hood/tent - no bo	2	1	30	21	14	31	0
2310033	Oxygen hood/tent - no bottom.							
2310034	Oxygen hood/tent - no bottom.							
2310035	Oxygen hood/tent - no bo	3	9	37	33	37	31	18
2310050	Oxygen hood/tent - parti							
2310051	Oxygen hood/tent - partial bottom.							
2310052	Oxygen hood/tent - parti				4	2	1	
2310053	Oxygen hood/tent - partial bottom.							
2310054	Oxygen hood/tent - partial bottom.							
2310055	Oxygen hood/tent - parti					2		3
2310075	Oxygen hood/tent - NICU.							
2310076	Oxygen hood/tent - NICU.		4					
2310077	Oxygen hood/tent - NICU.							
2310078	Oxygen hood/tent - NICU.		4					
2310079	Oxygen hood/tent - NICU.							
2310080	Oxygen hood/tent - NICU.							
2310081	Oxygen hood/tent - NICU.		4					
2310100	Low birth weight tenthou							

Stock Reference	Description	2009	2010	2011	2012	2013	2014	2015
2310101	Low birth weight tenthouse w/port							
2310102	Low birth weight tenthouse top access							
2310103	Low birth weight tenthouse with top &							
2310104	Low birth weight tenthou							
2310105	Low birt weight tenthouse w/port.							
2310106	Low birth weight tenthouse top access							
2310107	Low birth weight tenthou							
2310125	Double tent set							
2310126	Double tent set							
2310127	Double tent set							
2310128	Double tent set inner no bottom							
2310129	Double tent set							
2310130	Double tent set							
2310131	Double tent - outer tent only for use							
2310132	Double tent - outer tent only for use							
2310133	Double tent - outer tent only for use							
2310134	Double tent - outer tent only for use							
2310140	Babyshield - infant heat							
2310141	Babyshield - infant heat							
2310145	Oxygen hood - no drape.							
2310150	Isolation canopy - chair.							
2310151	Isolation canopy - crib.							
2330000	Oxygen hood/tent - standard.	3		1				
2330001	Oxygen hood/tent - standard.	2	1	1			1	
2330002	Oxygen hood/tent - standard.			3				
2330003	Oxygen hood/tent - standard.							
2330004	Oxygen hood/tent - standard.	2					1	
2330006	Oxygen hood/tent - standard.	1						
2330007	Oxygen hood/tent - standard.	3						
2330010	Oxygen hood/tent - standard.						1	
2330011	Oxygen hood/tent - standard.							
2330013	Oxygen hood/tent - standard.	1					2	
2330014	Oxygen hood/tent - standard.				1			
2330020	Oxygen hood/tent - dual port.							
2330021	Oxygen hood/tent - ICN with 3 ports.							
2330025	Oxygen hood/tent - no bottom.							
2330026	Oxygen hood/tent - no bottom.							
2330027	Oxygen hood/tent - no bottom.							
2330028	Oxygen hood/tent - no bottom.							
2330029	Oxygen hood/tent - no bottom.							
2330031	Oxygen hood/tent - no bottom.				1			
2330032	Oxygen hood/tent - no bottom.							
2330035	Oxygen hood/tent - no bottom.				4		1	
2330050	Oxygen hood/tent - partial bottom.							
2330052	Oxygen hood/tent - partial bottom.							

Stock Reference	Description	2009	2010	2011	2012	2013	2014	2015
2330053	Oxygen hood/tent - partial bottom.							
2330055	Oxygen hood/tent - partial bottom.							
2330075	Oxygen hood/tent - NICU.		1	1				
2330076	Oxygen hood/tent - NICU.							
2330077	Oxygen hood/tent - NICU.							
2330078	Oxygen hood/tent - NICU.							
2330080	Oxygen hood/tent - NICU.							
2330081	Oxygen hood/tent - NICU.							
2330100	Low birthweight tenthouse							
2330101	Low birthweight tenthouse w/port							
2330103	Low birthweight tenthouse with top &							
2330104	Low birthweight tenthouse							
2330105	Low birthweight tenthouse w/port.							
2330107	Low birthweight tenthouse with top &							
2330125	Double tent set							
2330126	Double tent set							
2330127	Double tent set							
2330128	Double tent set inner no bottom							
2330129	Double tent set							
2330130	Double tent set							
2330131	Double tent - outer tent only for use							
2330132	Double tent - outer tent only for use							
2330133	Double tent - outer tent only for use							
2330134	Double tent - outer tent only for use							
2330140	Babyshield - infant heat shield							
2330141	Babyshield - infant heat shield with							
2330500	Label for Oxygen hoods & plastics...							
2330501	Label for Oxygen hoods & plastics...							

Comments on Sales Information:

Items still sellings

Countries Review

Country	2009	2010	2011	2012	2013	2014	2015
B Belgium	[X]	[X]				[X]	
F France							
G Germany						[X]	
GR Greece		[X]			[X]		
IRE Ireland		[X]	[X]	[X]	[X]	[X]	
IT Italy						[X]	[X]
JO Jordan							
NE Netherlands		[X]	[X]				
P Poland	[X]		[X]	[X]			
SP Spain	[X]				[X]		
SW Sweden			[X]				
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]

Comments on Sales to Countries:

Belgium and Germany are new countries,

Comments on Risks with Sales to Countries:

No risks identified with selling to new countries

Returns Review

Stock Reference	Fault	2009	2010	2011	2012	2013	2014	2015
2310000	Unchecked - Returned to Stock							

Comments on Returns:

No returns, just a return to stock

Comments on Risks with Returns and Potential Re-work:

n/a

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

no design changes

Comments on Risks with Design Changes:

n/a

User Instructions Review

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
13626	Oxygen Hoods Instructions for Use User Manual Italian	07/04/14
8969	Nova Oxygen Tents Instructions for Use / User Manual	18/10/11

Comments on User Instructions:

no changes to the instructions

Comments on Risks User Instructions:

n/a

Labels Review

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
8961	Nova Oxygen Tents Accessory Labels List of Accessories	18/10/11
7690	Nova Oxygen Tents Labels	15/02/11

Comments on Labels:

no changes to the labels

Comments on Risks Labels:

n/a

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
14436	Nova Oxygen Tents Promotional Leaflets Single Patient Use Oxygen...	03/10/14
14010	Nova Oxygen Tents Clinical Trials Reports Reviews and Post Marke...	04/06/14

Comments on Document Changes:

promotion leaflet converted for email use (down scalled)
no other documentation updates

Comments on Risks with Document Changes:

n/a

Internal Issues Review

Number of Issues reviewed: 25

Issue ID	Subject
51770	2330013 & 0014724
54654	Backorder 00000200 2310010 ORD71482
55439	Backorder 00000290 2310010 ORD71996
54496	Backorder 00000790 2310010 ORD71373
55643	Backorder 00000790 2310010 ORD72030
54467	Backorder 00000950 2310032 ORD71254
55122	Backorder 00000950 2310032 ORD71773
55386	Backorder 00000950 2310032 ORD71973
55170	Backorder 00000950 2310035 ORD71804
55387	Backorder 00000950 2310035 ORD71977
55194	Backorder 00001415 2310028 ORD71828
55471	Backorder 00001902 2310007 ORD72002
56931	Backorder 00001902 2310007 ORD72867
57368	Backorder 00002470 2310055 ORD73177
57322	Backorder 00002471 2310055 ORD73095
56256	Backorder 00002960 2310035 ORD72460
54535	Backorder 00004113 2310001 ORD71388
56254	Backorder 00004200 2310013 ORD72450
58967	Backorder 00004200 2310013 ORD74159
58597	Backorder 00004670 2310004 ORD73931
55674	Backorder 00005250 2310035 ORD72047
53625	Backorder 00006220 2330013 ORD70892
55421	Backorder 00007385 2310035 ORD71986
59516	Backorder 00007385 2310035 ORD74481
55373	Nova hoods stock

Comments on Issues:

Just order processing Issues in the system

Comments on Risks with Issues:

no risks identified in the system

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 :

No reports found

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 :

No Reports Found

Risk ISO 14971 : 2012 Review

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

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

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

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

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

C.2.11 Are measurements taken

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

C.2.12 Is the medical device interpretative

[ID]	Reference Question	Applys	Risk	Probability	Overall
62	Factors that should be considered include whether conclusions are presented by the medical device from input or acquired data	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]	Reference Question	Applys	Risk	Probability	Overall
66	Factors that should be considered include identifying any other medical devices	Yes	Minor	Remote	Acceptable
67	Factors that should be considered include identifying any other medicines	No	---	---	n/a
68	Factors that should be considered include identifying any other medical technologies that can be involved	No	---	---	n/a

C.2.14 Are there unwanted outputs of energy or substances

[ID]	Reference Question	Applys	Risk	Probability	Overall
69	Energy-related factors that should be considered include vibration,	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

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

C.2.16 Does the medical device influence the environment

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

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

[ID]	Reference Question	Applys	Risk	Probability	Overall
102	Factors that should be considered include specifications for such consumables	No	---	---	n/a
103	Factors that should be considered include specifications for such accessories	No	---	---	n/a

[ID]	Reference Question	Applys	Risk	Probability	Overall
104	Factors that should be considered include any restrictions placed upon users in their selection of consumables.	No	---	---	n/a
105	Factors that should be considered include any restrictions placed upon users in their selection of accessories.	No	---	---	n/a

C.2.18 Is maintenance or calibration necessary

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

C.2.19 Does the medical device contain software

[ID]	Reference Question	Applys	Risk	Probability	Overall
111	Factors that should be considered include whether software is intended to be installed	No	---	---	n/a
112	Factors that should be considered include whether software is intended to be verified	No	---	---	n/a
113	Factors that should be considered include whether software is intended to be modified	No	---	---	n/a
114	Factors that should be considered include whether software is intended to be exchanged	No	---	---	n/a

C.2.2 Is the medical device intended to be implanted

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

[ID]	Reference Question	Applys	Risk	Probability	Overall
18	Factors that should be considered include the expected lifetime of the implant	No	---	---	n/a
19	Factors that should be considered include the reversibility of the implantation	No	---	---	n/a

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

[ID]	Reference Question	Applys	Risk	Probability	Overall
115	Factors that should be considered include labelling	No	---	---	n/a
116	Factors that should be considered include indicators	No	---	---	n/a
117	Factors that should be considered include disposal of such medical devices	No	---	---	n/a

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

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

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

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

C.2.23 What determines the lifetime of the medical device

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

C.2.24 Is the medical device intended for single use

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

C.2.29.4 Does the medical device have a control interface

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

C.2.29.5 Does the medical device display information

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

C.2.29.6 Is the medical device controlled by a menu

[ID]	Reference Question	Applys	Risk	Probability	Overall
182	Factors that should be considered include complexity and number of layers	No	---	---	n/a
183	Factors that should be considered include awareness of state	No	---	---	n/a
184	Factors that should be considered include location of settings	No	---	---	n/a
185	Factors that should be considered include navigation method	No	---	---	n/a
186	Factors that should be considered include number of steps per action	No	---	---	n/a
187	Factors that should be considered include sequence clarity and memorization problems	No	---	---	n/a

[ID]	Reference Question	Applys	Risk	Probability	Overall
188	Factors that should be considered include importance of control function relative to its accessibility and the impact of deviating from specified operating procedures.	No	---	---	n/a

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

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

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

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

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

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

C.2.30 Does the medical device use an alarm system

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

[ID]	Reference Question	Applys	Risk	Probability	Overall
195	Factors that should be considered are the medical staffs possibility of understanding how the alarm system works	No	---	---	n/a

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

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

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

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

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

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

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

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

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

[ID]	Reference Question	Applys	Risk	Probability	Overall
25	Factors that should be considered include compatibility with relevant substances	No	---	---	n/a
26	Factors that should be considered include compatibility with tissues	No	---	---	n/a
27	Factors that should be considered include compatibility with body fluids	No	---	---	n/a

[ID]	Reference Question	Applys	Risk	Probability	Overall
28	whether characteristics relevant to safety are known	No	---	---	n/a
29	is the device manufactured utilizing materials of animal origin	No	---	---	n/a

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

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

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

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

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

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

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

[ID]	Reference Question	Applys	Risk	Probability	Overall
46	Factors that should be considered include whether the medical device is intended for single use	No	---	---	n/a

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

D.2 Energy hazards and contributory factors

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

D.3 Toxic hazards and contributory factors

[ID]	Reference Question	Applys	Risk	Probability	Overall
241	Bio-contamination	No	---	---	n/a
242	Bacteria	No	---	---	n/a

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

D.4 Electromagnetic fields

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

D.5

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

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

[ID]	Reference Question	Applys	Risk	Probability	Overall
279	Inadequate operating instructions	No	---	---	n/a
280	Inadequate description of performance	No	---	---	n/a
281	Inadequate specification of intended use	No	---	---	n/a

[ID]	Reference Question	Applys	Risk	Probability	Overall
282	Inadequate disclosure of limitations	No	---	---	n/a
283	Inadequate specification of accessories	No	---	---	n/a
284	Inadequate specification of pre-use checks	No	---	---	n/a
285	Over-complicated operating instructions	No	---	---	n/a
286	Inadequate specification of service and maintenance	No	---	---	n/a
287	Use by unskilled / untrained personnel	No	---	---	n/a
288	Reasonable foreseeable misuse	No	---	---	n/a
289	Insufficient warning of side effects	No	---	---	n/a
290	Incorrect measurement and other metrological aspects	No	---	---	n/a
291	Inadequate warnings of hazards likely with re-use of single use devices	No	---	---	n/a
292	Misrepresentation of results	No	---	---	n/a
293	Incompatibility with consumables / accessories / other devices	No	---	---	n/a
294	Sharp edges or points	No	---	---	n/a

D.7 Mistakes judgement errors

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

D.8

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

Risk ISO 14971 : 2012 Summary

Nova Oxygen Tents Risk Assessment Document Summary Applicable questions

Reference Question	Applys	Risk	Risk Probability	Overall Risk	Assessed By	Assessed On	Risk Completed
4	Yes	Minor	Occasinal	Acceptable	John Lamb	07/05/14	Yes
56	Yes	Minor	Remote	Acceptable	John Lamb	07/05/14	Yes
57	Yes	Minor	Improbable	Acceptable	John Lamb	07/05/14	Yes
58	Yes	Minor	Remote	Acceptable	John Lamb	07/05/14	Yes
66	Yes	Minor	Remote	Acceptable	John Lamb	07/05/14	Yes
132	Yes	Minor	Improbable	Acceptable	John Lamb	07/05/14	Yes