Post market surveillance risk assesment re-evaluation

VIAMED

Apgar Timer 2

Start Freeze Reset timer used to gauge a given time interval when scoring newborn infants based on their vital signs and response to stimulus.

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

Carried out by Derek Lamb
30 / 05 / 14

VIAMED

- Stock References Review
- Supplier Review
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Stock References Review

Stock Reference	Description
0310100	APGAR Timer - Digital.
0330548	APGAR Timer Case.
0330549	APGAR Timer End Cap Set
0330550	APGAR Timer Case Set.
0330551	APGAR Timer Case Front - Machined &.
0330552	APGAR Timer Case Rear - Machined &.
0330553	APGAR Timer Case End cap. Painted.
0330554	APGAR Timer PCB v1.0 & LCD assembly.
0330555	APGAR Timer PCB v1.0 assembly.
0330558	Battery Holder BE60 - Black
0330560	End lid.
0330561	Seal - Black. Single unit.
0330562	Seal - Blue. Pack of 10.
0330563	Seal - Blue. Single unit.
0330564	Screw caps - Grey.
0330565	PCB Spacer - Pack of 25.
0330566	PCB Spacer - Single unit.
0330567	M3 Hex Full Nut zinc plated.
0330568	Screws for end caps.
0330569	Screw caps - Black.
0330570	APGAR timer - keypad membrane assembly.
0330571	APGAR timer - keypad membrane & upper
0330575	APGAR Timer LCD.
0330580	Threaded socket for rear panel. Pack 100
0330581	Threaded socket for rear panel. Single

Comments on Stock references review:

parts list is correct

Supplier Review

Stock Reference	Description	Supplier A/C	Supplier Name	Rating
0330565	PCB Spacer - Pack of 25.	00009061	Farnell	A
0330548	APGAR Timer Case.	00010011	Phoenix Mecano Limited	B
0330549	APGAR Timer End Cap Set	00010011	Phoenix Mecano Limited	B
0330550	APGAR Timer Case Set.	00010011	Phoenix Mecano Limited	B
0330558	Battery Holder BE60 - Black	00010011	Phoenix Mecano Limited	B
0330560	End lid.	00010011	Phoenix Mecano Limited	B
0330562	Seal - Blue. Pack of 10.	00010011	Phoenix Mecano Limited	B
0330564	Screw caps - Grey.	00010011	Phoenix Mecano Limited	B
0330575	APGAR Timer LCD.	00012176	Varitronix (UK) Limited	B
0330580	Threaded socket for rear panel. Pack 100	00012177	TR Fastenings	B
0330555	APGAR Timer PCB v1.0 assembly.	00012189	Northern Hi-Tec	B
0330570	APGAR timer - keypad membrane assembly.	00012225	Danielson (UK) Limited	B

Comments on Suppliers:

Supplier review upto date,
Varitronix iso 14001 certificate has just expired,
however its within a few days so more than likly not updated the web site at this point.

Sales Information

Stock Reference	Description	2008	2009	2010	2011	2012	2013	2014
0310100	APGAR Timer - Digital.	30	17	127	133	57	85	42
0330548	APGAR Timer Case.			82	118	54	125	
0330549	APGAR Timer End Cap Set			87	235	114	250	
0330550	APGAR Timer Case Set.			9				
0330551	APGAR Timer Case Front - Machined &.							
0330552	APGAR Timer Case Rear - Machined &.							
0330553	APGAR Timer Case End cap. Painted.			4				
0330554	APGAR Timer PCB v1.0 & LCD assembly.							
0330555	APGAR Timer PCB v1.0 assembly.	40		71	123	57	115	
0330558	Battery Holder BE60 - Black	5	2	120	120	57	131	
0330560	End lid.							
0330561	Seal - Black. Single unit.							
0330562	Seal - Blue. Pack of 10.							
0330563	Seal - Blue. Single unit.			8				
0330564	Screw caps - Grey.			10	2			
0330565	PCB Spacer - Pack of 25.			203	10	3	11	
0330566	PCB Spacer - Single unit.	80		44	12	10		
0330567	M3 Hex Full Nut zinc plated.	80		38	90	76	172	
0330568	Screws for end caps.							
0330569	Screw caps - Black.							
0330570	APGAR timer - keypad membrane assembly.	42	1	117	123	58	126	
0330571	APGAR timer - keypad membrane & upper							
0330575	APGAR Timer LCD.	40		123	110	54	125	
0330580	Threaded socket for rear panel. Pack 100							
0330581	Threaded socket for rear panel. Single							

Comments on Sales Information:

Units still selling,
component sales are down to zero which appears out of the ordinary
will create Issue to chase up why
Follow up Issue #50439

Countries Review

Country	2008	2009	2010	2011	2012	2013	2014
	[X]	[X]	[X]	[X]	[X]	[X]	
AU Austria		[X]			[X]		
AUS Australia	[X]			[X]			
B Belgium	[X]		[X]	[X]	[X]		
CAN Canada		[X]	[X]	[X]	[X]	[X]	
DE Denmark	[X]		[X]			[X]	[X]
G Germany		[X]		[X]	[X]		
IRE Ireland							
IT Italy					[X]	[X]	
MON Mongolia							[X]
NO Norway						[X]	
PO Portugal							
RU Russia						[X]	
SAU Saudi Arabia						[X]	
SWI Switzerland		[X]	[X]				
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	
USA USA		[X]	[X]	[X]	[X]	[X]	[X]

Comments on Sales to Countries:

New country Mongolia
Also seem to have a blank country appearing in the list,
will create Issue to see why
Follow up Issue #50438

Comments on Risks with Sales to Countries:

No risks identified with new countries

Returns Review

Stock Reference	Fault	2008	2009	2010	2011	2012	2013	2014
0310100	Battery door replaced							
0310100	Case replaced			1				
0310100	Keyboard	1		1	1	1	1	
0310100	Keypad and battery door replaced				1			
0310100	No Fault Found			1				
0330555	No Fault Return to Stock							

Comments on Returns:

Returns are Very low,

Comments on Risks with Returns and Potential Re-work:

No risks identifed with returns

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

No design changes have taken place since the last review

Comments on Risks with Design Changes:

no risks

User Instructions Review

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
9191	Apgar Timer 2 Instructions for Use / User Manual 2002	18/10/11
8453	Apgar Timer 2 Instructions for Use User Manual - print version	28/06/11
8451	Apgar Timer Instructions for Use German	28/06/11
8450	Apgar Timer 2 Instructions for Use User Manual	28/06/11

Comments on User Instructions:

No user instructions have been changed

Comments on Risks User Instructions:

no risks

Labels Review

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
9169	No accessory labels	18/10/11
8519	Apgar Timer 2 Labels	13/07/11
8517	Apgar Timer 2 Labels 0330505	13/07/11
7765	Apgar Timer 2 Labels front membrane	04/03/11
4779	0310100 APGAR Timer - Digital. (1134 / 992) label top	16/10/08
4767	0310100 APGAR Timer - Digital. (1134 / 992) label bottom	16/10/08
3798	Apgar Timer 2 Labels Apgar I labels	19/05/08

Comments on Labels:

No changes to lables

Comments on Risks Labels:

no risks

Documentation Updates / Changes

Comments on Document Changes:

Upto date EMC report has been added
no significate documents have been added / updated

Comments on Risks with Document Changes:

no risk identified with documentation

Internal Issues Review

Number of Issues reviewed: 7

Issue ID	Subject
43289	Returned Items SOR520
43497	0330242 Mediral Mounting Plate
47328	PAQ for resus cabinet required asap
44857	PPQ glitch on PDF
49404	0330580 Quotation
49280	Purchase orders from Phoenix Mecano
48701	APGAR component production parts

Comments on Issues:

No Issues identified in the Issues system

Comments on Risks with Issues:

No risks identified in the Issues 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 :

Seems we now have Apgar APPS on the play store

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 :

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	Unacceptable	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	Yes	Negligible	Improbable	Acceptable
4	what is the medical devices role relative to treatment	No	---	---	n/a
5	what is the medical devices role relative to alleviation of disease	No	---	---	n/a
6	what is the medical devices role relative to compensation for injury or handicap	No	---	---	n/a
7	what is the medical devices role relative to replacement or modification of anatomy	No	---	---	n/a
8	what is the medical devices role relative to control of conception	No	---	---	n/a
9	does the medical device sustain life	No	---	---	n/a
10	does the medical device support life	No	---	---	n/a
11	is special intervention necessary in the case of failure of the medical device	No	---	---	n/a
330	What are the indications for use e.g. patient population	No	---	---	n/a

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

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

C.2.11 Are measurements taken

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

C.2.12 Is the medical device interpretative

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

C.2.14 Are there unwanted outputs of energy or substances

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

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

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

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

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

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

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

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

Apgar Timer 2 Risk Assessment Document Summary Applicable questions

Reference Question	Applys	Risk	Risk Probability	Overall Risk	Assessed By	Assessed On	Risk Completed
3	Yes	Negligible	Improbable	Acceptable	Derek Lamb	22/04/14	Yes
52	Yes	Minor	Improbable	Acceptable	Derek Lamb	22/04/14	Yes
123	Yes	Negligible	Improbable	Acceptable	Derek Lamb	22/04/14	Yes