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 VII
NBOG MD 0100

Carried out by Derek Lamb
02 / 10 / 17

VIAMED

- Stock References Review
- Supplier Review
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Stock References Review

Stock Reference	Description
0310100	APGAR Timer - Digital.
0320201	Mounting bracket - Medirail. Rev. 2.
0330502	Label Set front panel. Apgar timer.
0330503	Label top panel. Digital Apgar timer
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:

Confrimed the stock references

Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
0330242	Medirail Mounting Bracke	00009032	822	R & L Enterprises Ltd	A
0330565	PCB Spacer - Pack of 25.	00009061	146-322	Farnell	A
0360000	Hex wrench short arm 3	00009061	1552281	Farnell	A
0330240	Knurled Torque Knob	00009123	702-7557	RS Components Ltd	A
0330548	APGAR Timer Case.	00010011	84136108.LB1	Phoenix Mecano Limited	A
0330549	APGAR Timer End Cap Set	00010011	84131000.L4	Phoenix Mecano Limited	A
0330550	APGAR Timer Case Set.	00010011		Phoenix Mecano Limited	A
0330558	Battery Holder BE60 - Bl	00010011	46600000	Phoenix Mecano Limited	A
0330560	End lid.	00010011	84131000	Phoenix Mecano Limited	A
0330562	Seal - Blue. Pack of 10.	00010011	84201314	Phoenix Mecano Limited	A
0330564	Screw caps - Grey.	00010011	SCREWCAPS	Phoenix Mecano Limited	A
0330502	Label Set front panel.	00010665		Pendle Signs & Plastics	B
0330575	APGAR Timer LCD.	00012176		Varitronix (UK) Limited	B
0330580	Threaded socket for rear	00012177	TRH3896	TR Fastenings	B
0330555	APGAR Timer PCB v1.0 ass	00012189	0330555	Northern Hi-Tec - NHT	B
0330570	APGAR timer - keypad mem	00012225	C5297A	Danielson - Schurter	B

Comments on Suppliers:

all supplier reviews are in date

Sales Information

Stock Reference	Description	2011	2012	2013	2014	2015	2016	2017
0310100	APGAR Timer - Digital.	274	41	46	56	33	61	27
0320201	Mounting bracket - Medirail. Rev. 2.						22	3
0330502	Label Set front panel.							
0330503	Label top panel. Digital Apgar timer							
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 ass							
0330558	Battery Holder BE60 - Bl	4	3	6				
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 mem	7	1	1	1	1	3	
0330571	APGAR timer - keypad membrane & upper							
0330575	APGAR Timer LCD.							
0330580	Threaded socket for rear							
0330581	Threaded socket for rear panel. Single							

Comments on Sales Information:

Units selling,
Slightly higher numbers than shown due to inclusion in the 0310002 which cannot be included here as it has its own technical file 8 extra units sold in 2017

Countries Review

Country	2011	2012	2013	2014	2015	2016	2017
AU Austria		[X]		[X]			[X]
AUS Australia	[X]					[X]	
B Belgium	[X]	[X]		[X]		[X]	
CAN Canada	[X]	[X]	[X]	[X]	[X]	[X]	[X]
DE Denmark			[X]	[X]			
FI Finland							[X]
G Germany	[X]	[X]					
IRE Ireland							
IT Italy		[X]	[X]				
LEB Lebanon							[X]
MO Morrocco						[X]	
MON Mongolia				[X]			
NO Norway			[X]				
P Poland						[X]	
PO Portugal							
RU Russia			[X]				
SAU Saudi Arabia			[X]				
SWI Switzerland							
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]
USA USA	[X]	[X]	[X]	[X]	[X]	[X]	[X]

Comments on Sales to Countries:

No problems identified with selling to new countries Finland , Lebanon

Comments on Risks with Sales to Countries:

No problems identified with selling to new countries Finland , Lebanon

Returns and Q.A. Fails Review

Stock Reference	Fault	2011	2012	2013	2014	2015	2016	2017
0310100	Battery Box Refitted						1	
0310100	Battery Door Replaced							
0310100	Case Replaced							
0310100	Keyboard	1	1	1	1		1	
0310100	Keypad And Battery Door Replaced	1						
0310100	New							
0310100	No Fault Found						1	
0320201	Unchecked - Returned To Stock						8	
0330555	No Fault Return To Stock							

Comments on Returns:

Few few returns, the most being the keyboard with 0.69% failure rate.

Comments on Risks with Returns and Potential Re-work:

no risks identified in the returns system

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

No design changes

Comments on Risks with Design Changes:

No design changes

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 IFU changes,

Comments on Risks User Instructions:

No IFU changes,

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 label changes

Comments on Risks Labels:

No label changes

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
22112	VM3COP47.07 Apgar packing procedure	18/09/17
22108	VM3COP47.06 Apgar timer calibration procedure	18/09/17
22104	VM3COP47.05 Apgar technical manual	18/09/17
22100	VM3COP47.04 Apgar QA manual 0310100	18/09/17
17219	Apgar Timer 2 Post Market Surveillance	20/07/16

Comments on Document Changes:

New procedures added for packaging ./ technical manual qa manual and calibration manual.

Comments on Risks with Document Changes:

no risks found with new documentation

Internal Issues Review

Number of Issues reviewed: 26

Issue ID	Subject
85822	Office Meeting Sales Back Orders Review - By Customer Backorder 00002130 0330570 ORD84077
99195	Office Meeting Sales Back Orders Review - By Customer Backorder 00003720 0320201 ORD87450
75867	Office Meeting Sales Back Orders Review - By Customer Backorder 00006070 0310100 ORD81570
96244	Office Meeting Sales Back Orders Review - By Customer Backorder 00006194 0310100 ORD86710
97122	Office Meeting Sales Back Orders Review - By Customer Backorder 00006428 0310100 ORD86910
104037	Office Meeting Sales Back Orders Review - By Customer Backorder 00006463 0310100 ORD88547
74663	Office Meeting Sales Back Orders Review - By Customer Backorder 00007476 0310100 ORD81248
90236	Office Meeting Sales Back Orders Review - By Customer Backorder 00007476 0310100 ORD85139
90244	Office Meeting Sales Back Orders Review - By Customer Backorder 00007476 0320200 ORD85139
87961	Office Meeting Back Order Report POR11115 0330548 //
87872	Office Meeting Back Order Report POR11115 0330548 //
87692	Office Meeting Back Order Report POR11115 0330548 //
86987	Office Meeting Back Order Report POR11115 0330548 //
87962	Office Meeting Back Order Report POR11115 0330549 //
87873	Office Meeting Back Order Report POR11115 0330549 //
87693	Office Meeting Back Order Report POR11115 0330549 //
86988	Office Meeting Back Order Report POR11115 0330549 //
87963	Office Meeting Back Order Report POR11115 0330558 //
87874	Office Meeting Back Order Report POR11115 0330558 //
87694	Office Meeting Back Order Report POR11115 0330558 //
86989	Office Meeting Back Order Report POR11115 0330558 //
87236	Office Meeting Back Order Report POR11116 0330555 //
86982	Office Meeting Back Order Report POR11116 0330555 //
87153	Office Meeting Back Order Report POR11117 0330570 //

Issue ID	Subject
86981	Office Meeting Back Order Report POR11117 0330570 //
75803	Office Meeting Stock Queries Reserved Stock Request

Comments on Issues:

All order processing or customer information updates,
no non conformances or customer complaints found

Comments on Risks with Issues:

No risks identified in the Issue 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 :

www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/The-Apgar-Score
http://pediatrics.aappublications.org/content/136/4/819

Both indicate the Apgar timer is still valid technology

No risks were identified / 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 :

Only classification reports and updated found
(Confirmation the product is class 1)

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES
PART 880 -- GENERAL HOSPITAL AND PERSONAL USE DEVICES

Subpart C--General Hospital and Personal Use Monitoring Devices

Sec. 880.2930 Apgar timer.
(a) Identification. The Apgar timer is a device intended to alert a health care provider to take the Apgar score of a newborn infant.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in 880.9. The device is also exempt from the current good manufacturing practice requirements in part 820 of this chapter, with the exception of 820.180 of this chapter, with respect to general requirements concerning records, and 820.198 of this chapter, with respect to complaint files.

[63 FR 59718, Nov. 5, 1998]

Risk ISO 14971 : 2012 Summary

02 Oct 2017 File 22 Apgar Timer 2 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	Yes	Negligible	Improbable	No Action
[4]	what is the medical devices role relative to treatment NOTES: Basic timer with alarms at preset intervals	Yes	Negligible	Improbable	No Action
[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 NOTES: Use of a manual clock	Yes	Negligible	Improbable	No Action
[330]	What are the indications for use e.g. patient population	No	---	---	n/a

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

ID	Ref Question	Applys	Risk	Probability	Overall
[56]	Factors that should be considered include temperature	No	---	---	n/a
[57]	Factors that should be considered include humidity	No	---	---	n/a

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. NOTES: Only time is measured to be able to produce an Apgar Score	No	---	---	n/a

C.2.12 Is the medical device interpretative

ID	Ref Question	Applys	Risk	Probability	Overall
[62]	Factors that should be considered include whether conclusions are presented by the medical device from input or acquired data	No	---	---	n/a
[63]	Factors that should be considered include whether conclusions are presented by the medical device from the algorithms used	No	---	---	n/a
[64]	Factors that should be considered include whether conclusions are presented by the medical device from the confidence limits	No	---	---	n/a
[65]	Factors that should be considered include whether conclusions are presented by the medical device. Special attention should be given to unintended applications of the data or algorithm	No	---	---	n/a

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

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

C.2.14 Are there unwanted outputs of energy or substances

ID	Ref Question	Applys	Risk	Probability	Overall
[69]	Energy-related factors that should be considered include vibration,	No	---	---	n/a
[70]	Energy-related factors that should be considered include heat,	No	---	---	n/a

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	No	---	---	n/a
[89]	Factors that should be considered include the transport environment	No	---	---	n/a
[90]	Factors that should be considered include the storage environment	No	---	---	n/a
[91]	Factors that should be considered include light	No	---	---	n/a
[92]	Factors that should be considered include temperature	No	---	---	n/a
[93]	Factors that should be considered include humidity	No	---	---	n/a
[94]	Factors that should be considered include vibrations	No	---	---	n/a
[95]	Factors that should be considered include spillage	No	---	---	n/a
[96]	Factors that should be considered include susceptibility to variations in power	No	---	---	n/a

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

C.2.16 Does the medical device influence the environment

ID	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	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	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 NOTES: could be dropped	No	---	---	n/a
[121]	Factors that should be considered include whether the forces to which the medical device will be subjected are controlled by interaction with other persons	No	---	---	n/a

C.2.23 What determines the lifetime of the medical device

ID	Ref Question	Applys	Risk	Probability	Overall
[122]	Factors that should be considered include ageing	No	---	---	n/a
[123]	Factors that should be considered include battery depletion. NOTES: Battery life of around a year, Low battery indicator normall AA batterys - easy to replace	Yes	Negligible	Improbable	No Action

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

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

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

C.2.29.5 Does the medical device display information

ID	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
[187]	Factors that should be considered include sequence clarity and memorization problems	No	---	---	n/a

ID	Ref 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	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
[192]	Factors that should be considered are the risk of missing alarms	No	---	---	n/a

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

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

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

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

ID	Ref Question	Applys	Risk	Probability	Overall
[25]	Factors that should be considered include compatibility with relevant substances	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	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	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: IFU	Yes	Minor	Improbable	No Action
[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	No	---	---	n/a
[223]	Gravity Falling NOTES: Unit is heavy but in normal use clampped into place	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

ID	Ref Question	Applys	Risk	Probability	Overall
[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	No	---	---	n/a
[242]	Bacteria	No	---	---	n/a
[243]	Viruses	No	---	---	n/a
[244]	Other agents prions	No	---	---	n/a
[245]	Bio-incompatibility	No	---	---	n/a
[246]	Incorrect formulation chemical composition	No	---	---	n/a
[247]	Toxicity	No	---	---	n/a
[248]	Allergenicity/ irritancy	No	---	---	n/a
[249]	Mutagenicity	No	---	---	n/a
[250]	Oncogenicity	No	---	---	n/a
[251]	Carcinogenicity	No	---	---	n/a
[252]	Re and/or cross infection	No	---	---	n/a
[253]	Pyrogenicity	No	---	---	n/a

D.3.12 hygienic standards

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

D.4 Electromagnetic fields

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

D.5

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

D.7 Mistakes judgement errors

ID	Ref Question	Applys	Risk	Probability	Overall
[295]	Mistakes & judgement errors	No	---	---	n/a
[296]	Incorrect or inappropriate output or functionality	No	---	---	n/a
[297]	Erroneous data transfer	No	---	---	n/a
[298]	Loss or deterioration in function	No	---	---	n/a
[301]	Rule based failure	No	---	---	n/a
[302]	Knowledge based failure	No	---	---	n/a
[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

Returns / Service

ID	Ref Question	Applys	Risk	Probability	Overall
[1126]	0310100 Does Fault Code Keyboard Type Fault present a risk NOTES: 0.69 % Fault	Yes	Minor	Improbable	No Action
[1125]	0310100 Does Fault Code Case replaced Type Fault present a risk NOTES: 0.099 % Fault	Yes	Minor	Improbable	No Action
[1124]	0310100 Does Fault Code Battery Box or Door Type Fault present a risk NOTES: 0.296 %		Minor	Improbable	No Action

Reference Question 3
C.2.1 What is the intended use and how is the medical device to be used what is the medical devices role relative to monitoring
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By John Lamb
Assessed On 23/09/15
Further Information Issue : 0
Risk Completed

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 23/09/15
Notes :
Basic timer with alarms at preset intervals
Further Information Issue : 0
Risk Completed

Reference Question 11
C.2.1 What is the intended use and how is the medical device to be used
is special intervention necessary in the case of failure of the medical device
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By John Lamb
Assessed On 23/09/15
Notes :
Use of a manual clock
Further Information Issue : 0
Risk Completed

Reference Question 52
C.2.9 Is the medical device intended to be routinely cleaned and disinfected by the user
Factors that should be considered include the types of cleaning or disinfecting agents to be used
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 22/04/14
Notes :
IFU
Further Information Issue : 0
Risk Completed

Reference Question 123
C.2.23 What determines the lifetime of the medical device
Factors that should be considered include battery depletion.
Applys Yes
Risk Negligible
Risk Probability Negligible
Overall Risk Action : No Action
Assessed By John Lamb
Assessed On 23/09/15
Notes :
Battery life of around a year, Low battery indicator
normall AA batterys - easy to replace
Further Information Issue : 0
Risk Completed

Reference Question 1125
Returns / Service
0310100 Does Fault Code Case replaced Type Fault present a risk
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 24/09/17
Notes :
0.099 % Fault
Further Information Issue : 0
Risk Completed

Reference Question 1126
Returns / Service
0310100 Does Fault Code Keyboard Type Fault present a risk
Applys Yes
Risk Minor
Risk Probability Minor
Overall Risk Action : No Action
Assessed By Derek Lamb
Assessed On 24/09/17
Notes :
0.69 % Fault
Further Information Issue : 0
Risk Completed

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Risk Assessment Document Summary Applicable questions and Actions

Ref Question	Applys	Risk	Risk Probability	Overall Risk	Assessed By	Assessed On	Risk Completed
3	Yes	Negligible	Improbable	No Action	John Lamb	23/09/15	Yes
4	Yes	Negligible	Improbable	No Action	John Lamb	23/09/15	Yes
11	Yes	Negligible	Improbable	No Action	John Lamb	23/09/15	Yes
52	Yes	Minor	Improbable	No Action	Derek Lamb	22/04/14	Yes
123	Yes	Negligible	Improbable	No Action	John Lamb	23/09/15	Yes
1125	Yes	Minor	Improbable	No Action	Derek Lamb	24/09/17	Yes
1126	Yes	Minor	Improbable	No Action	Derek Lamb	24/09/17	Yes