



VIA MED

Apgar Timer 2

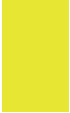
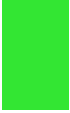
Start Freeze Reset timer used to gauge a given time interval when scoring newborn infants based on their vital signs and response to stimulus.

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

Carried out by Derek Lamb
20 / 07 / 16



VIA MED

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Stock References Review

Stock Reference	Description
0310100	APGAR Timer - Digital.
0320201	Mounting bracket - Medirail. Rev. 2.
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:

Stock references uptodate

Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
0330242	Medirail Mounting Bracke	00009032	822	R & L Enterprises Ltd	B
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	B
0330548	APGAR Timer Case.	00010011	84136108.LB1	Phoenix Mecano Limited	B
0330549	APGAR Timer End Cap Set	00010011	84131000.L4	Phoenix Mecano Limited	B
0330550	APGAR Timer Case Set.	00010011		Phoenix Mecano Limited	B
0330558	Battery Holder BE60 - BI	00010011	46600000	Phoenix Mecano Limited	B
0330560	End lid.	00010011	84131000	Phoenix Mecano Limited	B
0330562	Seal - Blue. Pack of 10.	00010011	84201314	Phoenix Mecano Limited	B
0330564	Screw caps - Grey.	00010011	SCREWCAPS	Phoenix Mecano Limited	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:

supplier review upto date

Sales Information

Stock Reference	Description	2010	2011	2012	2013	2014	2015	2016
0310100	APGAR Timer - Digital.	101	192	41	46	56	33	31
0320201	Mounting bracket - Medirail. Rev. 2.							13
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 - BI	2	3	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	1	5	1	1	1	1	1
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 still selling appear to be increasing sales in 2016

Countries Review

Country	2010	2011	2012	2013	2014	2015	2016
AU Austria			[X]		[X]		
AUS Australia		[X]					[X]
B Belgium	[X]	[X]	[X]		[X]		[X]
CAN Canada	[X]	[X]	[X]	[X]	[X]	[X]	[X]
DE Denmark	[X]			[X]	[X]		
G Germany		[X]	[X]				
IRE Ireland							
IT Italy			[X]	[X]			
MON Mongolia					[X]		
NO Norway				[X]			
P Poland							[X]
PO Portugal							
RU Russia				[X]			
SAU Saudi Arabia				[X]			
SWI Switzerland	[X]						
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]
USA USA	[X]	[X]	[X]	[X]	[X]	[X]	[X]

Comments on Sales to Countries:

Still selling to multiple countries,

Comments on Risks with Sales to Countries:

new country poland does not have any additional risks

Returns Review

Stock Reference	Fault	2010	2011	2012	2013	2014	2015	2016
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 non existant since 2014

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:

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 changes to user 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
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 labels

Comments on Risks Labels:

n/a

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
16118	Apgar Timer 2 FDA Approval Listing Details	24/12/15
15730	Apgar Timer 2 Software software validation check list	24/09/15
15728	Apgar Timer 2 Software Apgar Timer software validation	24/09/15
15422	Apgar Timer 2 Risk analysis reports	11/08/15
15418	PPE Equipment	11/08/15
15291	Apgar Timer 2 EC Declaration of Conformance 2008	29/07/15
15183	No risks disposal	21/07/15
15113	Apgar Timer 2 Post Market Surveillance	25/06/15

Comments on Document Changes:

no major document changes

Comments on Risks with Document Changes:

no risks identified in new documentation

Internal Issues Review

Number of Issues reviewed: 13

Issue ID	Subject
62062	APGAR Timer parts list
63177	Apgar Timer software validation
71284	Backorder 00001500 0330570 ORD80201
68191	Backorder 00006070 0310100 ORD79032
71805	Backorder 00007359 0320200 ORD80371
71893	Backorder 00007359 0320201 ORD80371
63284	Backorder 00007476 0310100 ORD76277
74663	Backorder 00007476 0310100 ORD81248
71582	Backorder 00012477 0310100 ORD80310
62033	Leaflet Infant Resuscitation A5 Catalogue PDFs generated for L
68751	Parts Disposed of
15272	Quote accepted?
68752	Stock to delete

Comments on Issues:

mainly normal ordering issues and sales

Comments on Risks with Issues:

no risks found 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 :

Class 1 product, simply a timer. no clincical 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 :

Class 1 product, simply a timer. no FDA reports found