



VIA MED

Apgar Timer 2

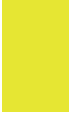
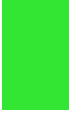
Start Freeze Reset timer used to gauge a given time interval when scoring newborn infants based on their vital signs and response to stimulus.

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

Carried out by Derek Lamb
02 / 12 / 22



VIA MED

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

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:

upto date

Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
0330558	Battery Holder BE60 - BI				Needs Grading
0330242	Medirail Mounting Bracke	00009032	A5090	R & L Enterprises Ltd	A
0330565	PCB Spacer - Pack of 25.	00009061	146-322	Farnell	B
0360000	Hex wrench short arm 3	00009061	609-635	Farnell	B
0330240	Knurled Torque Knob	00009123	702-7557	RS Components Ltd	B
0360000	Hex wrench short arm 3	00009123	609-635	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		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
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:

no longer being manufactured,
supplier reviews no longer required

Sales Information

Stock Reference	Description	2016	2017	2018	2019	2020	2021	2022
0310100	APGAR Timer - Digital.	61	41	30	19			
0320201	Mounting bracket - Medirail. Rev. 2.	21	4	15	7			
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				1			
0330558	Battery Holder BE60 - BI			1	5			
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	3						
0330571	APGAR timer - keypad membrane & upper							
0330575	APGAR Timer LCD.				1			
0330580	Threaded socket for rear							
0330581	Threaded socket for rear panel. Single							

Comments on Sales Information:

no longer selling units

Countries Review

Country	2016	2017	2018	2019	2020	2021	2022
AU Austria		[X]					
Australia							
Austria							
Australia	[X]						
Belgium	[X]		[X]	[X]			
Canada	[X]	[X]	[X]				
Denmark			[X]				
Finland		[X]	[X]				
Germany				[X]			
Italy			[X]				
Lebanon		[X]					
MON Mongolia							
Morocco	[X]						
Norway							
Qatar				[X]			
Saudi Arabia							
Scotland	[X]						
Switzerland							
UK	[X]	[X]	[X]	[X]			
UK United Kingdom	[X]						
United Kingdom			[X]				
USA				[X]			
USA USA	[X]	[X]					

Comments on Sales to Countries:

no longer selling units

Comments on Risks with Sales to Countries:

Returns and Q.A. Fails Review

Stock Reference	Fault	2016	2017	2018	2019	2020	2021	2022
0310100	All new internals and some casing parts					2	2	
0310100	Battery Box Refitted	1						
0310100	Battery Door Replaced							
0310100	Case Replaced							
0310100	Keyboard	1			1			
0310100	Keypad And Battery Door Replaced							
0310100	New				1			
0310100	No Fault Found	1		1	2			
0310100	Replaced PCB				1			
0320201	Unchecked - Returned To Stock	8						
0330555	No Fault Return To Stock							

Comments on Returns:

no new risks with returns

Comments on Risks with Returns and Potential Re-work:

no new risks with returns

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

no changes

Comments on Risks with Design Changes:

User Instructions Review

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
25764	Apgar Timer 2 Instructions for Use User Manual (+5mm bleed).	05/04/18
25762	Apgar Timer 2 Instructions for Use User Manual (High)	05/04/18
9191	Apgar Timer 2 Instructions for Use / User Manual 2002	18/10/11
8451	Apgar Timer Instructions for Use German	28/06/11

Comments on User Instructions:

no changes

Comments on Risks User Instructions:

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

Comments on Risks Labels:

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
75434	Apgar Timer 2 Risk analysis reports	18/11/21
75430	Apgar Timer 2 Post Market Surveillance	18/11/21

Comments on Document Changes:

no changes,
just the normal yearly reviews

Comments on Risks with Document Changes:

Internal Issues Review

Number of Issues reviewed: 2

Issue ID	Subject
247834	0310100 Digital APGAR Timer CE Mark
62033	Leaflet Infant Resuscitation A5 Catalogue PDFs generated for L

Comments on Issues:

no problems found in the issue system

Comments on Risks with Issues:

VIAMED Stock Meeting - Stock Queries

0310100 Digital APGAR Timer CE Mark

Issue ID #247834

Date Created 12/Jan/2022

Issued To: Steve Nixon

Completed Status: 02 Aug 2022

Notes:

Added by Catrin Hird sent to Steve Nixon

Hello

Are we able to sell these without CE mark if customer aware, although I can see the CE mark on the product.

If not, please can this be discontinued and the memo updated.

Thanks

Issues:247834

Marketing Job Logger - Marketing Job Logger

Leaflet Infant Resuscitation A5 Catalogue PDFs generated for L

Issue ID #62033

Date Created 19/Aug/2015

Issued To: Derek Lamb

Completed Status: 02 Dec 2022

Linked Files

19 Aug 2015 Infant Resuscitation A5 Catalogue 2015-08-19

Notes:

Catrin Hird 19/08/2015 Issue Generated

Leaflet Infant Resuscitation A5 Catalogue PDFs generated for L

19 Aug 2015 Catrin Hird

Next Action Changed From To Derek Lamb Please add to intrastats

9990080 catalogue

0310100 apgar

24 Aug 2015 Derek Lamb
done

Issues:62033

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 :

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 :