



VIA MED

Apgar Timer 2

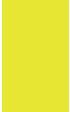

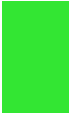








Start Freeze Reset timer used to gauge a given time interval when scoring newborn infants based on their vital signs and response to stimulus.

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

Carried out by Derek Lamb
18 / 03 / 21



VIA MED

-  Stock References Review
-  Supplier Review
-  Sales Review
-  Countries Review
-  Returns Review
-  Design Changes Review
-  User Instructions Review
-  Labels Review
-  Document Updates Review
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-  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:

No longer produced part numbers are correct

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	B
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 produced, no requirments to review the suppliers in relation to apgar

Sales Information

Stock Reference	Description	2015	2016	2017	2018	2019	2020	2021
0310100	APGAR Timer - Digital.	33	61	41	30	19		
0320201	Mounting bracket - Medirail. Rev. 2.		21	4	15	7	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					1		
0330558	Battery Holder BE60 - BI				1	5		3
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	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 produced,
only spares being sold until stocks run out

Countries Review

Country	2015	2016	2017	2018	2019	2020	2021
AU Austria			[X]				
Australia							
Austria							
Australia		[X]					
Belgium		[X]		[X]	[X]		
Canada	[X]	[X]	[X]	[X]			
Denmark				[X]			
Finland			[X]	[X]			
Germany					[X]		
Ireland					[X]		
Italy				[X]			
Lebanon			[X]				
MON Mongolia							
Morocco		[X]					
Norway							
Qatar					[X]		
Saudi Arabia							
Scotland	[X]						
Switzerland							
UK	[X]	[X]	[X]	[X]	[X]	[X]	
UK United Kingdom		[X]					
United Kingdom				[X]			
USA					[X]		[X]
USA USA	[X]	[X]	[X]				

Comments on Sales to Countries:

No longer produced,
only spares being sold

Comments on Risks with Sales to Countries:

Returns and Q.A. Fails Review

Stock Reference	Fault	2015	2016	2017	2018	2019	2020	2021
0310100	All new internals and some casing parts						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 longer produced, repairs not a problem

Comments on Risks with Returns and Potential Re-work:

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

No longer produced, 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 longer produced, no cha

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 longer produced, no cha

Comments on Risks Labels:

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
31960	Apgar Timer 2 Post Market Surveillance	21/01/20

Comments on Document Changes:

No longer produced, no changes

Comments on Risks with Document Changes:

Internal Issues Review

Number of Issues reviewed: 5

Issue ID	Subject
175292	Backorder 00002570 0320201 123614
197781	Product Failures New Codes Review (750)
164153	Production In Production List (556)
164001	Production In Production List (556)
194809	Web Site Question ID 8229

Comments on Issues:

No longer produced, no issues found

Comments on Risks with Issues:

- Sales Back Orders Review - By Customer
Backorder 00002570 0320201 123614
Issue ID #175292
Date Created 01/Jan/1970
Issued To:
Completed Status: 01 May 2020
Stock Ref: 0320201
Order Number: 123614

Notes:

Issues:175292

VIAMED Management Meeting - VIAMED Management Meeting

Product Failures New Codes Review (750)

Issue ID #197781

Date Created 18/Sep/2020

Issued To: Derek Lamb

Completed Status: 23 Sep 2020

Notes:

System Generated
Task To be Completed

Review Intrastats Page:

Returns-> Repair codes Clean up

If New Faults have entered the system,

Review the Stock Repairs and apply a clean code and tag Fault / user or No Fault.

Complete all Stock References until the list is empty

18 Sep 2020 Derek Lamb

0012106 requires Cleaning!

Unable to repair - faded screen, as we no longer supplier these a replacement part number was offered in its place.

0015013 requires Cleaning!

No Fault Found

0110020 requires Cleaning!

No Fault Found

0110039 requires Cleaning!

No Fault Found

0110049 requires Cleaning!

No Fault Found

0110435 requires Cleaning!

No Fault Found

0310100 requires Cleaning!

PCB Fault

8010050 requires Cleaning!

Low output,

oxygen sensor normal fail type, no cap required

Issues:197781

VIAMED Stock Meeting - VIAMED Stock Meeting

Production In Production List (556)

Issue ID #164153

Date Created 03/Feb/2020

Issued To: Catherine Spence

Completed Status: 15 Feb 2020

Notes:

Added by Derek Lamb sent to Catherine Spence
0310100 Over 40 days

8000004 Over 40 Days

whats the reason, (iso review came up)

04 Feb 2020 Catherine Spence
0310100, waiting to be packed up, have asked for this to be done.

8000004 was being made up and has just landed back with me, will be put into stock tomorrow, these ones will sit idel sometimes. These ones are all in hand

07 Feb 2020 Derek Lamb

Issues:164153

VIAMED Stock Meeting - VIAMED Stock Meeting

Production In Production List (556)

Issue ID #164001

Date Created 03/Feb/2020

Issued To: Derek Lamb

Completed Status: 07 Feb 2020

Notes:

System Generated

Task To be Completed

List any production jobs started more 30 Days ago.

List any production jobs which QA date is more 30 Days ago.

03 Feb 2020 Derek Lamb
Created Related Issue #164153
Added by Derek Lamb sent to Catherine Spence
0310100 Over 40 days

8000004 Over 40 Days

whats the reason, (iso review came up)

03 Feb 2020 Derek Lamb
0310100 Over 40 days

8000004 Over 40 Days

asked in follwup issue as to the reason

Issues:164001

Non Conforming Stock Transfers. (QC19) - Web Site Updates

Web Site Question ID 8229

Issue ID #194809

Date Created 24/Aug/2020

Issued To: Steve Hardaker

Completed Status: 26 Aug 2020

Notes:

Web Site Question ID 8229

24/08/20

leosheridan@nhs.net

Information Request to Viamed Limited at the <https://www.viamed.co.uk/uk/> WebSite

Leo Sheridan

Ninewells Hospital

Medical Physics

leosheridan@nhs.net

Scotland EU

Type: Pricing

Could you please quote the price for the main board for a Apgar timer Part number 0310100 (serial number 00137) or give me the price of a new unit.

Thanks for your help

Leo

Request further Information on

25 Aug 2020 Kate Griffiths

Next Action Changed From Kate Griffiths To Steve Hardaker

25 Aug 2020 Steve Hardaker

Advised him that the main board is not available separately as there is a high probability of damaging the device when attempting to replace it. Also advised that the APGAR Timer can no longer be supplied as new but we can offer a fixed-cost repair, which is effectively almost a complete rebuild at a far lower cost than the original would have cost.

This is available as follows:

- 0380017 - APGAR Timer fixed cost service inc. parts @ Â£110.00+VAT

- Return Carriage @ Â£10.00+VAT

Asked him to let us know if he wants to return it so we can issue a returns number.

26 Aug 2020 Kate Griffiths

done

Issues:194809

Clinical / FDA Incidents online search

Clinical Investigation online review

Do any of the Results indicate a Risk / Problem : No

Do any of the Results indicate outdated Technology : No

Comments on Clinical Search :

No longer produced, no review

Review of online FDA Incident reports

Do any of the Results indicate a Risk / Problem : No

Do any of the Results indicate outdated Technology : No

Comments on Clinical Search :

No longer produced, no review