



24/Mar/2011

Apgar Timer 2

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Viamed Product
Post market Surveillance
Risk Assessment
Stock References Review
Supplier Review
Sales Review
Country Sales Review
Stock Returns Review
Design Changes Review
Document Updates Review
Internal Issues Review
Clinical Information Review
FDA Incidents Review
Carried out by Derek Lamb on 24 / 03 / 11

Stock References Reviewed

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 listing seems to be complete

Supplier Information on Main and Component Parts

Stock Reference	Description	Supplier A/C	Supplier Name	Rating
0330565	PCB Spacer - Pack of 25.	00009061	Farnell	A
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
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 reviews are upto date

Sales Information

Stock Reference	Description	2005	2006	2007	2008	2009	2010	2011
0310100	APGAR Timer - Digital.	1	10	24	20	16	85	12
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				5	2	1	1
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.				2	1	1	
0330571	APGAR timer - keypad membrane & upper			1				
0330575	APGAR Timer LCD.							
0330580	Threaded socket for rear panel. Pack 100							
0330581	Threaded socket for rear panel. Single							

Comments on Sales Information:

units are still selling

New Countries

Country	2005	2006	2007	2008	2009	2010	2011
AU Austria					[X]		
AUS Australia			[X]	[X]			
B Belgium		[X]	[X]	[X]		[X]	
CAN Canada					[X]	[X]	[X]
DE Denmark	[X]	[X]	[X]	[X]		[X]	
G Germany					[X]		
IRE Ireland		[X]					
PO Portugal			[X]				
SWI Switzerland					[X]	[X]	
UK United Kingdom		[X]	[X]	[X]	[X]	[X]	[X]
USA U.S.A.					[X]	[X]	

Comments on Sales to Countries:

Units are still selling internationally

Comments on Risks with Sales to Countries:

No new countries, and no risks with existing countries have been identified

Returns Information

Stock Reference	Fault	2005	2006	2007	2008	2009	2010	2011
0310100	Battery door replaced			1				
0310100	Case replaced						1	
0310100	Keyboard				1		1	

Comments on Returns:

Returns are low

Comments on Risks with Returns and Potential Re-work:

no risks identified with returns or reworked units

Design Changes / Product Changes

Showing Documents Filed in Y 14 Design Changes

Document ID	Added on	Added By	Description
7913	08/03/11	Derek Lamb	Apgar Timer 2 Design Changes HiTec Capacitor Change
7871	04/03/11	John Lamb	Apgar Timer 2 Design Changes

Comments on Design Changes:

Unit had a capacitor change,

Comments on Risks with Design Changes:

No risks identified with capacitor change

Documentation updates / Changes

Materials Membrane

nts

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SMD SOT-23 ZXRE125FFTA Specification

Materials speaker

Materials

) Limited LCD TH VI421-DP4.0-RC-12 Specification

meter TH Cermet 10k 1W 20% Specification Apgar Timer 2 Specifications of Materials

SMD SOT-23A-6 TC1072-3.0VCH Specification Apgar Timer 2 Specifications of Materials

pole Push to make Specification Apgar Timer 2 Specifications of Materials

s of Materials

Materials Flash memory

7479 388-7492 Farnell Socket housing 1.25mm 9-way Specification Apgar Timer 2 Specifications of Materials

ector SMD M22 Right-angled Pin header SIL 2-way 2.0mm

M20 Right-angled Pin header SIL 15-way 2.54mm Specification

Materials

Materials

Materials switches

MD Ceralock 4MHZ 0.5% Specification

MD 85SMX 32768Hz 20% Specification Apgar Timer 2 Specifications of Materials

SMD SFM-1740 Specification

PCF8576CT Specification Apgar Timer 2

nc M4 Specification

Materials CN3 Apgar Timer 2 Specifications of Materials

or SMD MMUN2214LT1G Specification Apgar Timer 2 Specifications of Materials

Materials

Materials

ogy Integrated Circuit SMD ThinSOT-6 LTC3459ES6#PBF Specification

Materials

tion LTC1877EMS8#PBF Linear Technology Integrated Circuit SMD MS8 LTC1877 Specification

Materials Loctite 423

Materials LM185 volt regulator

mm Blue Specification

ector SMD 1.25mm Right-angled Pin header 6-way Specification Apgar Timer 2 Specifications of Materials

ons of Materials Hardware Design Detail Xstal

Materials

materials clover display

32 AWG Specification

SMD SOT-23 BAT754 Specification Apgar Timer 2 Specifications of Materials

SMD SO20 AD7801BR Specification Apgar Timer 2 Specifications of Materials

A Alkaline PC1500 2700mAh Specification

ell Capacitor SMD 1210 47uF 6V3 15% X5R SMD 1210 47uF 6V3 15% X5R Capacitor SMD 1210 22uF 16V 10% X5R Specification

210 22uF 16V 15% X5R Apgar Timer 2 Specifications of Materials

for SMD 1210 10uF 10V 10% X5R Specification Apgar Timer 2 Specifications of Materials

Cell Capacitor SMD 0805 4.7uF 6V3 10% X5R Specification

Materials

tor SMD 0805 2.2uF 25V +80/-20% Y5V Specification

for SMD 0805 1uF 16V 10% X7R Specification Apgar Timer 2

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tor Specification SMD 0603 1uF 6V3 10% X5R

365k MCR03EZPFX976k MCR03EZPFX280k MCR03EZPFX287k MCR03EZPFX887k MCR03EZPFX8k06 Rutronik Resistor SMD 06

materials enclosure

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ings January 4 2006 Apgar Timer 2 Final Costings

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7 C8 Component Change

User Manual V1.3

71:2001 Annex D updated

Comments on Document Changes:

Various documents have been updated / reviewed due to march 2010 amandments

Comments on Risks with Document Changes:

no risk identified with updated documents

Review of Issues

Number of Issues reviewed: 10

Comments on Issues:

No issues since last review

Comments on Risks with Issues:

No issues since last review

Review of online clinical reports

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

Do any of the Results indicate outdated Technology : No

Comments on Clinical Search :

[http://www.anestesia-dolor.org/repositorio/Anestesia-en-](http://www.anestesia-dolor.org/repositorio/Anestesia-en-obstetricia/La%20escala%20de%20Apgar%20ha%20sobrevivido%20la%20prueba%20del%20tiempo.pdf)

[obstetricia/La%20escala%20de%20Apgar%20ha%20sobrevivido%20la%20prueba%20del%20tiempo.pdf](http://www.anestesia-dolor.org/repositorio/Anestesia-en-obstetricia/La%20escala%20de%20Apgar%20ha%20sobrevivido%20la%20prueba%20del%20tiempo.pdf)

<http://www.nejm.org/doi/full/10.1056/NEJM200102153440701#t=articleBackground>

Apgar Score and there for the Apgar Timer is Still relevant today

Review of online FDA Incident reports

Do any of the Results indicate a Risk / Problem :

Do any of the Results indicate outdated Technology :

Comments on Clinical Search :

No incident report were found relating to Apgar Timers