



24/Oct/2011

Apgar Timer 2

Apgar Timer 2
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
0330548	APGAR Timer Case.	00010011	Phoenix Mecano Limited	B
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	101
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	2
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]			[X]
B Belgium		[X]	[X]	[X]		[X]	[X]
CAN Canada					[X]	[X]	[X]
DE Denmark	[X]	[X]	[X]	[X]		[X]	
G Germany					[X]		[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]	[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	1
0330555	No Fault Return to Stock							

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	Description
9212	Apgar Timer 2 Design Reviews QC24 04-03-2004 At Rens VET Box
9209	Apgar Timer 2 Design Changes APGAR Engineering Change Order Numb...
7913	Apgar Timer 2 Design Changes HiTec Capacitor Change
7871	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

Document ID	Description
9508	Apgar Timer 2 Specification Brief QC 22 Job Spec
9507	Apgar Timer 2 Specifications of Materials Hardware Design Detail...
9506	Apgar Timer 2 EMC rationale
9505	Apgar Timer 2 Classification rationale
9492	Apgar Timer 2 EN ISO 14971:2001 Annex D updated
9460	Apgar Timer 2 EN ISO 14971:2001 Annex D 2008
9458	Leakage and Liquid damage BLANK
9457	Generic CE File Attached to All Medicinal Substances None
9456	Generic CE File Attached to All Ionising Radiation None
9455	Carcinogenic Substances
9442	Apgar Timer 2 Essential requirements 200747ec
9356	Apgar Timer 2 Pre-Clinical Trials Data
9222	Apgar Timer 2 Final Costings APGAR Timer Project Costs
9221	Apgar Timer 2 Specification Brief Y.02 Specification Brief_Apgar...
9220	Apgar Timer 2 Specification Brief O.02 Device Specification_QC22...
9219	Apgar Timer 2 Specification Brief st7 Programming Manual
9218	Apgar Timer 2 Test Reports APGAR II Power Consumption
9217	Apgar Timer 2 Design Reviews QC24 Returned membranes 21-03-2005
9216	Apgar Timer 2 Design Reviews QC24 Phoenix Mecano 20041122
9215	Apgar Timer 2 Design Reviews QC24 Northern Hi-Tec 01-06-2005
9214	Apgar Timer 2 Design Reviews QC24 Estimate of APGAR Timer Produc...
9213	Apgar Timer 2 Design Reviews QC24 Danielson 21-04-2005
9212	Apgar Timer 2 Design Reviews QC24 04-03-2004 At Rens VET Box
9211	Apgar Timer 2 Validation CE FILE
9210	Apgar Timer 2 Validation QC 30 Project Validation
9208	Apgar Timer 2 Design Input Device Design Theory Y.01 Device The...
9207	Apgar Timer 2 Design Input Device Design Theory Y.01 Design His...
9206	Apgar Timer 2 Design Input Device Design Theory O.01 Design His...
9205	Apgar Timer 2 Design Input Device Design Theory APGAR Power Con...
9204	Apgar Timer 2 Design Output OEM Files QC 29 Documentation
9203	Apgar Timer 2 Accessories Photographs S. Photographs_Accessories...
9202	Apgar Timer 2 Sterilisation O. Sterilisation_Apgar Timer
9201	Apgar Timer 2 Circuit Diagrams N. Quality plan Viamed_Apgar Time...
9200	Apgar Timer 2 Packaging Trials and validation M Apgar Timer ii 2...
9198	Apgar Timer 1 Work Instructions and Tests Procedure to re-work
9197	Apgar Timer 2 Manufacturing route Apgar Timer II 2005
9196	Apgar Timer 2 Location of responsibilities 2004
9195	Apgar Timer 2 Clinical Trials Clinical Trials_Apgar Timer 2005
9194	Apgar Timer 2 Analysis of complaints HI. Customer Complaints_Apg...
9193	Apgar Timer 2 Product Life G. Product Life_Apgar Timer 2004
9192	Apgar Timer 2 Service Manual G. Service Statement_Apgar Timer
9191	Apgar Timer 2 Instructions for Use / User Manual 2002
9190	Apgar Timer 2 Description of Device Description of Device_Apgar ...
9189	Apgar Timer 2 Risk analysis reports design risks 2004
9188	Apgar Timer 2 Risk analysis certificate unsigned

Document ID	Description
9187	Apgar Timer 2 Location of Documents 2004
9186	Apgar Timer 2 Location of Documents 2003
9185	Apgar Timer 2 Index of Documentation 2003
9184	Apgar Timer 2 Preliminary Outline Introduction
9169	No accessory labels
9140	Notified Body Certificate Not Required
9098	No 510k Required
9096	EU representative
9080	No Animal Tissues No Animal Substances
8519	Apgar Timer 2 Labels
8517	Apgar Timer 2 Labels 0330505
8487	Apgar Timer 2 Specifications specification
8453	Apgar Timer 2 Instructions for Use User Manual - print version
8451	Apgar Timer Instructions for Use German
8450	Apgar Timer 2 Instructions for Use User Manual
8315	Human Blood & derivatives Statement of non use
8171	Apgar Timer 2 Risk analysis reports PMS Report
8043	Machinery Directive Not Applicable
7883	Apgar Timer 2 Specifications of Materials Membrane
7878	Apgar Timer 2 Drawings
7877	Apgar Timer 2 Specification Brief QC22 Specification brief
7876	Apgar Timer 2 Final Costings
7874	Apgar Timer 2 Analysis of complaints Battery leakage
7873	Apgar Timer 2 Software
7872	Apgar Timer 2 Preliminary drawings Case layout
7870	Apgar Timer 2 Quotations
7869	Apgar Timer 2 Design Reviews QC24 Membrane 2004
7868	Apgar Timer 2 Design Reviews QC24 De Nammplaat front panel
7867	Apgar Timer 2 Design Reviews QC24
7866	371-4652 Farnell Integrated Circuit SMD SOT-23 ZXRE125FFTA Speci...
7865	Apgar Timer 2 Specifications of Materials speaker
7864	Apgar Timer 2 Specifications of Materials Washer M3
7863	VI421-DP4.0-RC-12 Varitronix (UK) Limited LCD TH VI421-DP4.0-RC-...
7862	114-1620 350-655 Farnell Potentiometer TH Cermet 10k 1W 20% Spec...
7861	119-295 Farnell Integrated Circuit SMD SOT-23A-6 TC1072-3.0VCH S...
7860	150-242 Farnell Switch Red Single pole Push to make Specificatio...
7859	Apgar Timer 2 / tek ox Specifications of Materials
7858	Apgar Timer 2 Specifications of Materials Flash memory
7856	110-7593 110-7594 110-7596 388-7479 388-7492 Farnell Socket hous...
7855	486-1048 486-1050 Farnell Connector SMD M22 Right-angled Pin hea...
7854	486-1292 Farnell Connector SMD M20 Right-angled Pin header SIL 1...
7853	Apgar Timer 2 Specifications of Materials SMD 0.5mm FFC Molex-2
7852	Apgar Timer 2 Specifications of Materials SMD 0.5mm FFC Molex-1
7851	Apgar Timer 2 Specifications of Materials switches
7850	353-0863 Farnell Quartz Crystal SMD Ceralock 4MHZ 0.5% Specifica...
7848	316-0312 Farnell Quartz Crystal SMD 85SMX 32768Hz 20% Specificat...
7845	392-1165 Farnell Piezo Transducer SMD SFM-1740 Specification
7844	Integrated Circuit SMD SOT190-1 PCF8576CT Specification Apgar Ti...
7843	149-682 Farnell Nut Steel Bright zinc M4 Specification

Document ID	Description
7842	Blu-OX Specifications of Materials CN3 Apgar Timer 2 Specificati...
7841	473-613 955-6672 Farnell Transistor SMD MMUN2214LT1G Specificati...
7840	Apgar Timer 2 Specifications of Materials Membrane specification
7839	Apgar Timer 2 Specifications of Materials MAX4410
7838	LTC3459ES6#PBF Linear Technology Integrated Circuit SMD ThinSOT-...
7837	Apgar Timer 2 Specifications of Materials
7835	LTC1877EMS8 LTC1877 Specification LTC1877EMS8#PBF Linear Technol...
7834	Apgar Timer 2 Specifications of Materials Loctite 243
7833	Apgar Timer 2 Specifications of Materials LM185 volt regulator
7832	510-920 Farnell Jumper socket 2.0mm Blue Specification
7831	388-7042 965-0857 Farnell Connector SMD 1.25mm Right-angled Pin ...
7829	Apgar Timer 2 Specifications of Materials FPC SMD R-A Bottom con...
7827	Apgar Timer 2 Specifications of Materials clover display
7826	110-7603 Farnell Crimp socket 28/32 AWG Specification
7825	108-1203 354-7024 Farnell Diode SMD SOT-23 BAT754 Specification ...
7824	942-5829 Farnell Integrated Circuit SMD SO20 AD7801BR Specificat...
7823	BT00355 BT02404 CPC Battery AA Alkaline PC1500 2700mAh Specifica...
7821	952-7800 471-6760 952-7788 Farnell Capacitor SMD 1210 47uF 6V3 1...
7814	471-6747 Farnell Capacitor SMD 1210 22uF 16V 15% X5R Apgar Timer...
7811	471-6735 952-7796 Farnell Capacitor SMD 1210 10uF 10V 10% X5R Sp...
7810	521-2819 521-2820 521-2832 Farnell Capacitor SMD 0805 4.7uF 6V3 ...
7809	Apgar Timer 2 Specifications of Materials 0805 50V 5pc COG EPCOS
7803	471-6656 952-7702 Farnell Capacitor SMD 0805 2.2uF 25V +80/-20% ...
7802	471-6619 952-7710 Farnell Capacitor SMD 0805 1uF 16V 10% X7R Spe...
7799	Farnell 744 Sealant White Specification
7793	952-7699 471-6607 Farnell Capacitor Specification SMD 0603 1uF 6...
7790	MCR03EZPFX294k MCR03EZPFX365k MCR03EZPFX976k MCR03EZPFX280k MCR0...
7786	Apgar Timer 2 Specifications of Materials enclosure
7783	Apgar Timer 2 Drawings Apgar II membrane
7782	Apgar Timer 2 Drawings Front a.Nammplaat
7781	Apgar Timer 2 Drawings Front a.
7780	Apgar Timer 2 Drawings LCD design
7779	Apgar Timer 2 Drawings Apgar Timer 2 Drawings
7777	Apgar Timer 2 Preliminary drawings Cut outs
7776	Apgar Timer 2 Design Reviews QC24 Preliminary info
7775	Apgar Timer 2 Software System IP
7774	Apgar Timer 2 Preliminary drawings Front Panel
7773	Apgar Timer 2 Preliminary drawings Apgar Prelim diag
7772	Apgar Timer 2 Final Costings January 4 2006 Apgar Timer 2 Final ...
7771	Apgar Timer 2 Design Input Time Scale
7770	Apgar Timer 2 Work Logs Time
7769	Apgar Timer 2 Parts List
7768	Apgar Timer 2 Analysis of complaints Quality Investigation repor...
7765	Apgar Timer 2 Labels front membrane
7764	Apgar Timer 2 Test Reports
7763	Apgar Timer 2 Test Reports Membranes prototypes
7762	Apgar Timer 2 Description of Device
7751	Training Information
7734	Apgar Timer 2 Product Changes C7 C8 Component Change

Document ID	Description
7704	Apgar Timer 2 Residual Risks

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: 13

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