



VIA MED

Apgar Timer 2

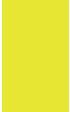

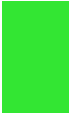








Start Freeze Reset timer used to gauge a given time interval when scoring newborn infants based on their vital signs and response to stimulus.

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

Carried out by Derek Lamb
27 / 11 / 18



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:

part number upto date

Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
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	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
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:

supplier reviews up to date

Sales Information

Stock Reference	Description	2012	2013	2014	2015	2016	2017	2018
0310100	APGAR Timer - Digital.	41	46	56	33	61	41	30
0320201	Mounting bracket - Medirail. Rev. 2.					22	4	15
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							
0330558	Battery Holder BE60 - BI	3	6					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 mem	1	1	1	1	3		
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, in low numbers

Countries Review

Country	2012	2013	2014	2015	2016	2017	2018
AU Austria	[X]		[X]			[X]	
AUS Australia					[X]		
B Belgium	[X]		[X]		[X]		[X]
CAN Canada	[X]	[X]	[X]	[X]	[X]	[X]	[X]
DE Denmark		[X]	[X]				[X]
FI Finland						[X]	[X]
G Germany	[X]					[X]	
IRE Ireland							
IT Italy	[X]	[X]					[X]
LEB Lebanon						[X]	
MO Morrocco					[X]		
MON Mongolia			[X]				
NE Netherlands							[X]
NO Norway		[X]					
P Poland					[X]		
PO Portugal							
RU Russia		[X]					
SAU Saudi Arabia		[X]					
SC Scotland			[X]	[X]	[X]		
SLA Slovakia						[X]	
SWI Switzerland							
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]
USA USA	[X]	[X]	[X]	[X]	[X]	[X]	

Comments on Sales to Countries:

Comments on Risks with Sales to Countries:

no risks identified with countries and apgar timer

Returns and Q.A. Fails Review

Stock Reference	Fault	2012	2013	2014	2015	2016	2017	2018
0310100	Battery Box Refitted					1		
0310100	Battery Door Replaced							
0310100	Case Replaced							
0310100	Keyboard	1	1	1		1		
0310100	Keypad And Battery Door Replaced							
0310100	New							
0310100	No Fault Found					1		1
0320201	Unchecked - Returned To Stock					8		
0330555	No Fault Return To Stock							

Comments on Returns:

no faulty returns in 2years

Comments on Risks with Returns and Potential Re-work:

no risks with reworks as non existant

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

no changes

Comments on Risks with Design Changes:

no 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:

IFU still fit for purpose

Comments on Risks User Instructions:

no risks identifies with user manuals

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:

no changes

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
28066	Apgar Timer Leaflet (email)	30/10/18
26435	Apgar Timer 2 Specifications of Materials casing	14/06/18
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
25622	Apgar Timer 2 Classification rationale 2008	19/03/18
25620	Apgar Timer 2 Device Classification rules	19/03/18
24682	Apgar Timer 2 Flammability and Fire Risks	18/12/17
24615	Apgar Timer 2 Product usability	11/12/17
23976	Apgar Timer 2 Specifications Casing Notes	16/11/17
23157	Apgar Timer 2 Specifications of Materials Boplar Parts	23/10/17
23010	Apgar Timer 2 Quotations APGAR Timer parts - casing quote 2017-1...	20/10/17
23002	Apgar Timer 2 Manufacturing route 0330548 0330549 0330558 APGAR ...	19/10/17
22996	Apgar Timer 2 Data Sheets Screw Cover Material Datasheet 031010...	19/10/17
22994	Apgar Timer 2 Data Sheets Powder coating safety datasheet 0310...	19/10/17
22992	Apgar Timer 2 Data Sheets 0310100 Technical datasheet for powde...	19/10/17
22990	Apgar Timer 2 Data Sheets Gasket datasheet 0310100 Badaflex® TP...	19/10/17
22988	Apgar Timer 2 Data Sheets Casing material datasheet 0330548	19/10/17
22986	Apgar Timer 2 Data Sheets Casing end caps material datasheet 0...	19/10/17
22984	Apgar Timer 2 EC Declaration of Conformance 0310100 Bobla case	19/10/17
22931	Apgar Timer 2 Specification Brief Apgar Timer - User design inp...	18/10/17
22811	V1000 Foetal Heart Simulator Specifications Hardware specdicat...	16/10/17
22771	Apgar Timer 2 Software APGAR Software Outstanding Issues V1	16/10/17
22765	Apgar Timer 2 Specifications Hospital specification	16/10/17
22759	Apgar Timer 2 Specifications Hardware Specification V1.0	16/10/17
22747	Apgar Timer 2 Design Input Device Design Theory Hardware Desig...	16/10/17
22743	Apgar Timer 2 Circuit Diagrams Circuit Operation V1.0	16/10/17
22736	Apgar Timer Circuit Diagrams Circuit Operation V1.0	16/10/17
22385	Apgar Timer 2 Post Market Surveillance	02/10/17

Comments on Document Changes:

Comments on Risks with Document Changes:

Internal Issues Review

Number of Issues reviewed: 38

Subject

Office Meeting Other	0310100 APGAR Timer parts - casing notes
Office Meeting Other	0310100 APGAR Timer parts - casing notes
Office Meeting Other	0310100 APGAR Timer parts - casing quote 2017-10-16
Office Meeting Other	0310100 APGAR Timer parts - casing quote 2017-10-16
Office Meeting Other	0310100 APGAR Timer parts - Datasheet for casing
Office Meeting Other	0310100 APGAR Timer parts - Datasheet for casing
Office Meeting Other	0310100 APGAR Timer parts - Datasheet for casing end caps
Office Meeting Other	0310100 APGAR Timer parts - Datasheet for casing end caps
Office Meeting Other	0310100 APGAR Timer parts - Datasheet for gasket
Office Meeting Other	0310100 APGAR Timer parts - Datasheet for gasket
Office Meeting Other	0310100 APGAR Timer parts - Declaration of Conformity
Office Meeting Other	0310100 APGAR Timer parts - Declaration of Conformity
Office Meeting Other	0310100 APGAR Timer parts - Material datasheet for screw cover
Office Meeting Other	0310100 APGAR Timer parts - Material datasheet for screw cover
Office Meeting Other	0310100 APGAR Timer parts - Powder Coating Paint
Office Meeting Other	0310100 APGAR Timer parts - Powder Coating Paint
Office Meeting Other	0310100 APGAR Timer parts - Powder Coating Paint Safety Data Sheet
Office Meeting Other	0310100 APGAR Timer parts - Powder Coating Paint Safety Data Sheet
Office Meeting Production	0310100 APGAR Timer brackets - 0320201
Office Meeting Any other business	0310100 APGAR Timer leaflet edits required
Office Meeting Sales Back Orders Review - By Customer	0310100 Backorder 00000112 0310100 ORD93197
Office Meeting Sales Back Orders Review - By Customer	0310100 Backorder 00004260 0320201 ORD90471
Office Meeting Sales Back Orders Review - By Customer	0310100 Backorder 00006421 0310100 ORD90921
Office Meeting Sales Back Orders Review - By Customer	0310100 Backorder 00006428 0310100 ORD88760

Subject

Office Meeting Sales Back Orders Review - By Customer
ackorder 00006463 0310100 ORD88547

Office Meeting Sales Back Orders Review - By Customer
ackorder 00006466 0310100 ORD88658

Office Meeting Sales Back Orders Review - By Customer
ackorder 00007359 0310100 ORD91725

Office Meeting Sales Back Orders Review - By Customer
ackorder 00007586 0310100 ORD90931

Office Meeting Document Control Amendments needed
Document Update Request (2573) Resuscitation Unit Instructions for Use / User Manual Apgar Timer II Instructions for use Apgar Timer

Office Meeting VIAMED Stock Meeting
Production Statistics (551)

Office Meeting VIAMED Stock Meeting
Production Statistics (551)

Office Meeting Sale or Returns
Returned Items SOR756

Office Meeting Stock Queries
Stockroom 1, old or discontinued stock

Office Meeting Web Site Updates
Web Site Question ID 1112

Office Meeting Web Site Updates
Web Site Question ID 1139

Office Meeting Web Site Updates
Web Site Question ID 1148

Office Meeting Web Site Updates
Web Site Question ID 1219

Office Meeting Web Site Updates
Web Site Question ID 1257

Comments on Issues:

mainly sales or stock issues,
no nonconformities or customer complaints

Comments on Risks with Issues:

non found

VIAMED Management Meeting - Other
0310100 APGAR Timer parts - casing notes

Issue ID #106068

Date Created 19/Oct/2017

Issued To: Derek Lamb

Completed Status: 04 Dec 2017

Notes:

Copy Issue Main Issue #106067

Added by Steve Nixon sent to John Lamb

0310100 APGAR Timer

Casing parts are manufactured by BOPLA in Germany and supplied via their distributor in the UK. Phoenix Mecano Ltd.

0330548 APGAR Timer Case

84136108.LB1

Bopla ref. Albus 1330 split, machined.

Includes:

1 x Front panel (machined & painted white RAL 9016)

1 x Rear panel (machined & painted white RAL 9016)
with 2 x Hank bushes.

NOTE: From June 08 powdered coated finish.

Previously enamelled finish.

0330549 APGAR Timer End Cap Set

84131000.L4

Bopla ref. ABD 1300

Includes:

1 x End cap (painted white RAL 9016)

1 x Seal, blue (for end cap)

2 x Screws (for end cap)

2 x Screw caps, grey (for end cap)

NOTE: From June 08 powdered coated finish.

Previously enamelled finish.

0330558 Battery Holder BE60 – Black

Bopla ref. 46600000

16 Nov 2017 Derek Lamb

added to apgar file

Issues:106068

VIAMED Management Meeting - Other
0310100 APGAR Timer parts - casing notes

Issue ID #106067

Date Created 19/Oct/2017

Issued To: John Lamb

Completed Status: 10 Apr 2018

Linked Files

20 Oct 2017 0310100 APGAR Timer - Casing Notes 2017-10-20

20 Oct 2017 0310100 APGAR Timer - Casing Notes pdf 2017-10-20

Notes:

Added by Steve Nixon sent to John Lamb

0310100 APGAR Timer

Casing parts are manufactured by BOPLA in Germany and supplied via their distributor in the UK. Phoenix Mecano Ltd.

0330548 APGAR Timer Case

84136108.LB1

Bopla ref. Albus 1330 split, machined.

Includes:

1 x Front panel (machined & painted white RAL 9016)

1 x Rear panel (machined & painted white RAL 9016)
with 2 x Hank bushes.

NOTE: From June 08 powdered coated finish.

Previously enamelled finish.

0330549 APGAR Timer End Cap Set

84131000.L4

Bopla ref. ABD 1300

Includes:

1 x End cap (painted white RAL 9016)

1 x Seal, blue (for end cap)

2 x Screws (for end cap)

2 x Screw caps, grey (for end cap)

NOTE: From June 08 powdered coated finish.

Previously enamelled finish.

0330558 Battery Holder BE60 – Black

Bopla ref. 46600000

23 Oct 2017 John Lamb

Added to file T1

09 Apr 2018 John Lamb

Issues:106067

VIAMED Management Meeting - Other

0310100 APGAR Timer parts - casing quote 2017-10-16

Issue ID #106144

Date Created 20/Oct/2017

Issued To: Derek Lamb

Completed Status: 21 Oct 2017

Notes:

Copy Issue Main Issue #106142

Added by Steve Nixon sent to John Lamb

See attached quote.

Carried out as a pricing review and to verify part numbers. Opera has been checked and updated.

0330548 price the same at £26.43

0330549 price increased from £7.43 to £7.95.

The increase is acceptable.

0330558 price the same at £2.76

20 Oct 2017 Derek Lamb

ok

Issues:106144

VIAMED Management Meeting - Other

0310100 APGAR Timer parts - casing quote 2017-10-16

Issue ID #106142

Date Created 20/Oct/2017

Issued To: John Lamb

Completed Status: 10 Apr 2018

Linked Files

20 Oct 2017 0310100 APGAR Timer parts - casing quote 2017-10-16

Notes:

Added by Steve Nixon sent to John Lamb
See attached quote.

Carried out as a pricing review and to verify part numbers. Opera has been checked and updated.

0330548 price the same at £26.43

0330549 price increased from £7.43 to £7.95.
The increase is acceptable.

0330558 price the same at £2.76

23 Oct 2017 John Lamb

09 Apr 2018 John Lamb

Issues:106142

VIAMED Management Meeting - Other

0310100 APGAR Timer parts - Datasheet for casing

Issue ID #106061

Date Created 19/Oct/2017

Issued To: Derek Lamb

Completed Status: 21 Oct 2017

Notes:

Copy Issue Main Issue #106060

Added by Steve Nixon sent to John Lamb

Applies to part:

0330548

19 Oct 2017 Derek Lamb

done

Issues:106061

VIAMED Management Meeting - Other

0310100 APGAR Timer parts - Datasheet for casing

Issue ID #106060

Date Created 19/Oct/2017

Issued To: John Lamb

Completed Status: 15 Jan 2018

Linked Files

19 Oct 2017 Casing material datasheet

Notes:

Added by Steve Nixon sent to John Lamb

Applies to part:

0330548

23 Oct 2017 John Lamb

Added to file T1

28 Dec 2017 John Lamb

Issues:106060

VIAMED Management Meeting - Other

0310100 APGAR Timer parts - Datasheet for casing end caps

Issue ID #106063

Date Created 19/Oct/2017

Issued To: Derek Lamb

Completed Status: 21 Oct 2017

Notes:

Copy Issue Main Issue #106062

Added by Steve Nixon sent to John Lamb

Applies to part: 0330549

19 Oct 2017 Derek Lamb
done

Issues:106063

VIAMED Management Meeting - Other

0310100 APGAR Timer parts - Datasheet for casing end caps

Issue ID #106062

Date Created 19/Oct/2017

Issued To: John Lamb

Completed Status: 15 Jan 2018

Linked Files

19 Oct 2017 Casing end caps material datasheet

Notes:

Added by Steve Nixon sent to John Lamb

Applies to part: 0330549

23 Oct 2017 John Lamb

Added to File T1

28 Dec 2017 John Lamb

Issues:106062

VIAMED Management Meeting - Other

0310100 APGAR Timer parts - Datasheet for gasket

Issue ID #106053

Date Created 19/Oct/2017

Issued To: Derek Lamb

Completed Status: 14 Nov 2017

Notes:

Added by John Lamb sent to Derek Lamb

19 Oct 2017 Derek Lamb
done

Issues:106053

VIAMED Management Meeting - Other

0310100 APGAR Timer parts - Datasheet for gasket

Issue ID #106040

Date Created 19/Oct/2017

Issued To: John Lamb

Completed Status: 15 Jan 2018

Linked Files

19 Oct 2017 Gasket datasheet

Notes:

Added by Steve Nixon sent to John Lamb

Applies to:

0330549 The gasket is part of this set.

We also two part numbers to cover the gasket (seal) as a speparate part.

0330562 Seal - Blue, pack of 10, ref 84201314

0330563 Seal - Blue, single

19 Oct 2017 John Lamb

Created Related Issue #106053

Added by John Lamb sent to Derek Lamb

28 Dec 2017 John Lamb

Issues:106040

VIAMED Management Meeting - Other

0310100 APGAR Timer parts - Declaration of Conformity

Issue ID #106054

Date Created 19/Oct/2017

Issued To: Derek Lamb

Completed Status: 14 Nov 2017

Notes:

Added by John Lamb sent to Derek Lamb

19 Oct 2017 Derek Lamb

Issues:106054

VIAMED Management Meeting - Other

0310100 APGAR Timer parts - Declaration of Conformity

Issue ID #106039

Date Created 19/Oct/2017

Issued To: John Lamb

Completed Status: 15 Jan 2018

Linked Files

19 Oct 2017 Declaration of Conformity

Notes:

Added by Steve Nixon sent to John Lamb

Applies to:

0330548

0330549

0330549

19 Oct 2017 John Lamb

Created Related Issue #106054

Added by John Lamb sent to Derek Lamb

28 Dec 2017 John Lamb

Issues:106039

VIAMED Management Meeting - Other

0310100 APGAR Timer parts - Material datasheet for screw cover

Issue ID #106049

Date Created 19/Oct/2017

Issued To: Derek Lamb

Completed Status: 14 Nov 2017

Notes:

Added by John Lamb sent to Derek Lamb

19 Oct 2017 Derek Lamb
done

Issues:106049

VIAMED Management Meeting - Other

0310100 APGAR Timer parts - Material datasheet for screw cover

Issue ID #106046

Date Created 19/Oct/2017

Issued To: John Lamb

Completed Status: 15 Jan 2018

Linked Files

19 Oct 2017 Screw Cover Material Datasheet

Notes:

Added by Steve Nixon sent to John Lamb

Applies to parts:

0330549 screw covers are included in with this set.

We also have a part number for the screw cover (cap) as a separate item:

0330564 Screw caps - Grey

19 Oct 2017 John Lamb

Created Related Issue #106049

Added by John Lamb sent to Derek Lamb

28 Dec 2017 John Lamb

Issues:106046

VIAMED Management Meeting - Other

0310100 APGAR Timer parts - Powder Coating Paint

Issue ID #106051

Date Created 19/Oct/2017

Issued To: Derek Lamb

Completed Status: 14 Nov 2017

Notes:

Added by John Lamb sent to Derek Lamb

19 Oct 2017 Derek Lamb
done

Issues:106051

VIAMED Management Meeting - Other

0310100 APGAR Timer parts - Powder Coating Paint

Issue ID #106041

Date Created 19/Oct/2017

Issued To: John Lamb

Completed Status: 15 Jan 2018

Linked Files

19 Oct 2017 Technical datasheet for powder coating

Notes:

Added by Steve Nixon sent to John Lamb

Technical datasheet for Fine Texture Powder Coat Type F 5904, manufactured by Brillux.

Colour we use is white: RAL 9016

Applies to parts:

0330548

0330549

19 Oct 2017 John Lamb

Created Related Issue #106051

Added by John Lamb sent to Derek Lamb

28 Dec 2017 John Lamb

Issues:106041

VIAMED Management Meeting - Other

0310100 APGAR Timer parts - Powder Coating Paint Safety Data Sheet

Issue ID #106050

Date Created 19/Oct/2017

Issued To: Derek Lamb

Completed Status: 14 Nov 2017

Notes:

Added by John Lamb sent to Derek Lamb

19 Oct 2017 Derek Lamb
done

Issues:106050

VIAMED Management Meeting - Other

0310100 APGAR Timer parts - Powder Coating Paint Safety Data Sheet

Issue ID #106043

Date Created 19/Oct/2017

Issued To: John Lamb

Completed Status: 15 Jan 2018

Linked Files

19 Oct 2017 Powder coating safety datasheet

Notes:

Added by Steve Nixon sent to John Lamb

Safety datasheet for Fine Texture Powder Coat Type F 5904, manufactured by Brillux.

Colour we use is white: RAL 9016

Applies to parts:

0330548

0330549

19 Oct 2017 John Lamb

Created Related Issue #106050

Added by John Lamb sent to Derek Lamb

28 Dec 2017 John Lamb

Issues:106043

Production - Production

Apgar Timer brackets - 0320201

Issue ID #112412

Date Created 16/Jan/2018

Issued To: Jonathan Connor

Completed Status: 17 Jan 2018

Notes:

Added by Steve Hardaker sent to Jonathan Connor

We need to start a production job for more Apgar timer brackets, we will have just 3 left after the next order for 4 cabinets goes out.

It looks like the sub-components may need re-stocking, we are showing 0 stock of the mounting plate 0330242. Thanks.

17 Jan 2018 Jonathan Connor
Done, thanks

17 Jan 2018 Steve Hardaker

Issues:112412

VIAMED Sales And Marketing - Any other business

APGAR Timer leaflet edits required

Issue ID #130004

Date Created 10/Oct/2018

Issued To: Catrin Hird

Completed Status: 10 Oct 2018

Linked Files

10 Oct 2018 Apgar Timer Leaflet 2018-10-10

10 Oct 2018 Apgar Timer Leaflet 2018-10-10v2

Notes:

Added by Steve Nixon sent to Catrin Hird

Do we have an updated APGAR Timer leaflet. The Neonatal catalogue has been updated, but it looks like the leaflet has not been updated:

0320200 change to 0320201. The picture also needs updating. The catalogue also has the old picture. Web site picture OK.

0121199 discontinued

0121200 old picture, needs updating. See the catalogue.

Web site also needs the updated leaflet.

10 Oct 2018 Catrin Hird

0320201 - catalogue already has the right image, website is incorrect. - Website has now been updated.

0121199 removed

0121200 image updated on leaflet.

When leaflet signed off will upload to website.

Please find attached updated leaflet. Hard copy with proof sheet provided.

10 Oct 2018 Catrin Hird

My apologies, mounting bracket 1 piece image was never taken. Have altered my image taken in 2015, I have updated leaflet and updated website.

Hard copy given to SN for sign off.

10 Oct 2018 Catrin Hird

Sn signed off. Updated Intrastats and added to Z for L.

Issues:130004

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00000112 0310100 ORD93197

Issue ID #125141

Date Created 01/Aug/2018

Issued To: General

Completed Status: 09 Aug 2018

Stock Ref: 0310100

Opera A/c: 00000112

Order Number: ORD93197

Notes:

01 Aug 2018 12:23:37 PM Kate Griffiths

See Attached Notes

Checking serial number with customer. KG 31.7.18

Issues:125141

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00004260 0320201 ORD90471

Issue ID #113193

Date Created 26/Jan/2018

Issued To: General

Completed Status: 29 Jan 2018

Stock Ref: 0320201

Opera A/c: 00004260

Order Number: ORD90471

Notes:

26 Jan 2018 08:18:31 AM Catherine Spence
Shipping Fri 26 Jan 2018

Issues:113193

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00006421 0310100 ORD90921

Issue ID #115742

Date Created 07/Mar/2018

Issued To: General

Completed Status: 27 Jun 2018

Stock Ref: 0310100

Opera A/c: 00006421

Order Number: ORD90921

Notes:

07 Mar 2018 08:00:21 AM Catherine Spence
Back Order - Production

14 Mar 2018 07:39:11 AM Catherine Spence
Shipping Wed 14 Mar 2018

Issues:115742

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00006428 0310100 ORD88760

Issue ID #105201

Date Created 12/Oct/2017

Issued To: General

Completed Status: 23 Oct 2017

Stock Ref: 0310100

Opera A/c: 00006428

Order Number: ORD88760

Notes:

12 Oct 2017 07:44:10 AM Catherine Spence
Back Order - Production

Issues:105201

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00006463 0310100 ORD88547

Issue ID #104037

Date Created 29/Sep/2017

Issued To: General

Completed Status: 11 Oct 2017

Stock Ref: 0310100

Opera A/c: 00006463

Order Number: ORD88547

Notes:

29 Sep 2017 09:14:19 AM Catherine Spence
Back Order - Supplier

Issues:104037

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00006466 0310100 ORD88658

Issue ID #104753

Date Created 06/Oct/2017

Issued To: General

Completed Status: 11 Oct 2017

Stock Ref: 0310100

Opera A/c: 00006466

Order Number: ORD88658

Notes:

06 Oct 2017 08:24:02 AM Catherine Spence
Back Order - Production

Issues:104753

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00007359 0310100 ORD91725

Issue ID #118435

Date Created 18/Apr/2018

Issued To: General

Completed Status: 30 Apr 2018

Stock Ref: 0310100

Opera A/c: 00007359

Order Number: ORD91725

Notes:

18 Apr 2018 07:42:05 AM Catherine Spence
Back Order - Production

Issues:118435

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00007586 0310100 ORD90931

Issue ID #115177

Date Created 26/Feb/2018

Issued To: General

Completed Status: 27 Jun 2018

Stock Ref: 0310100

Opera A/c: 00007586

Order Number: ORD90931

Notes:

26 Feb 2018 08:07:28 AM Catherine Spence
Shipping Mon 26 Feb 2018

Issues:115177

BS EN ISO 13485:2003 - Document Control Amendments needed

Document Update Request (2573) Resuscitation Unit Instructions for Use / User Manual A

Issue ID #116924

Date Created 26/Mar/2018

Issued To: Derek Lamb

Completed Status: 06 Apr 2018

Notes:

Added by Catrin Hird sent to Derek Lamb

Controlled Document (2573) Resuscitation Unit Instructions for Use / User Manual Apgar Timer II

Instructions for use Apgar Timer 0310100 Requires Updating

Unsure if this is still valid as we have the new manual just being updated in the system.

I have also added the email version to my leaflets section so will appear in the doc index.

06 Apr 2018 Derek Lamb
archived it

06 Apr 2018 Catrin Hird
ok thanks

Issues:116924

VIAMED Stock Meeting - VIAMED Stock Meeting

Production Statistics (551)

Issue ID #131498

Date Created 05/Nov/2018

Issued To: Derek Lamb

Completed Status: 05 Nov 2018

Notes:

System Generated

Task To be Completed

Review recent 30-40 Days completed Production runs,

Check the last 3 Completed runs.

1. Check the pick parts (Audit Button) against the previous builds pick parts.

List any where the quantities dont match

List production jobs any where Days to complete are greater than 30 Days.

05 Nov 2018 Derek Lamb

PR02649Viamed100310100APGAR Timer - Digital.20/Sep/2018

Catherine Spence02/Oct/2018

Catherine Spence05/Nov/2018

Robert Connor34.14

all audit productions matched ok

Issues:131498

VIAMED Stock Meeting - VIAMED Stock Meeting

Production Statistics (551)

Issue ID #125521

Date Created 06/Aug/2018

Issued To: Derek Lamb

Completed Status: 09 Aug 2018

Notes:

System Generated

Task To be Completed

Review recent 30-40 Days completed Production runs,

Check the last 3 Completed runs.

1. Check the pick parts (Audit Button) against the previous builds pick parts.

List any where the quantities dont match

List production jobs any where Days to complete are greater than 30 Days.

06 Aug 2018 Derek Lamb

Checked

0320201 APGAR mounting bracket Rev2 Previous 3 builds

0310097 Tom Thumb TT480 (TG) Previous 3 builds

0110232 Oxygen Sensor R-22VAN Previous 3 builds

Only tom thumbs in the build list over 30 days to complete

Issues:125521

VIAMED Stock Meeting - Sale or Returns

Returned Items SOR756

Issue ID #117331

Date Created 03/Apr/2018

Issued To: Ryan Swaine

Completed Status: 03 Aug 2018

Notes:

Added by Emma Clark sent to Ryan Swaine

SOR ID756

Originally added by :Ryan Swaine

Mediq Suomi Oy

Juha Leppasalo

Luomanportti 3

Espoo

02200

Returned : 0310030 0401324

sold on ord914585

Returned : 0310100 00855

Returned : 3210071 Tracking896198_68

03 Apr 2018 Ryan Swaine

Issues:117331

VIAMED Stock Meeting - Stock Queries
Stockroom 1, old or discontinued stock

Issue ID #117338

Date Created 03/Apr/2018

Issued To: Derek Lamb

Completed Status: 16 Apr 2018

Notes:

Added by Robert Connor sent to Derek Lamb

While sorting stock down in Stock Room 1 I noticed we have a huge number of parts and components for stuff we don't make anymore but may still need to hold on to for a while. There's also a fair amount of very old stock which could possibly be disposed of.

I was wondering how best to proceed with this as I thought it might be better to scan and pack these into location-barcoded boxes and put them somewhere out of the way to make space for sellable stock, so we still have access to them, and they are on the system should they be needed.

I started writing down a list of part numbers but it basically amounted to 3/4 of everything on the duckets wall so I thought it better to wait for a firm decision on the fate of the stock.

03 Apr 2018 Derek Lamb

its possible the fate of the stock has already been sealed,
can you send me a part number of anyone of them i'll see where in intrastats you can see if i've already written the stock off,
as if its already written off, as far as i'm concerned they can be thrown in a box for disposal

03 Apr 2018 Derek Lamb

if you search the stock in the magnify glass, and click the i for information, look for stock tag,
normal stock it should say Stock, most written off stock say written off 20xx
the written off stock can go in a box, it does not really need further scanning as i can automate that bit.

04 Apr 2018 Robert ConnorOk had a quick peek at a few part numbers and some stuff like 0030685 is already written off, but there's also some stock that looks very old, but still appears to be tagged as stock like the OXY-SL3.

04 Apr 2018 Derek Lamb

guess best option now is make a list of items still tagged as stock,
remove the rest of the stuff,
i'll process the list update the tag where appropriate

05 Apr 2018 Robert ConnorOk, I have removed the following stock off the shelf, all of it was tagged as write-off in stock info but still has live barcodes.

PP8310
0010133
0030789
0030785
0018777
0038697
0009688
0010707
0030786
0010181
0024011
0031258
0010600
0031255
0031244

0231000
0031202
0031201
0030685
0018617
0038647
0038587
0018567
A-182
A-220
D22F10
0330551
0031239

I'll box these up for disposal and then go over what's left in the ducket wall and make a list of stock that looks extremely old.

05 Apr 2018 Derek Lamb

Using Stock location 33679 to move items before i kill the live codes,
all the above partnumbers have now been moved to the new location

16 Apr 2018 Robert ConnorOk, thank you

Issues:117338

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

Web Site Question ID 1112

Issue ID #107181

Date Created 02/Nov/2017

Issued To: Zoey Teal

Completed Status: 03 Nov 2017

Notes:

Web Site Question ID 1112

02/11/17

Jonathan.petersson@vll.se

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

0310100 Apgar Digital Timer

Jonathan Petersson

University Hospital of Umeå

Medical Engineering

Jonathan.petersson@vll.se

Sweden EU

Type: Pricing

Hi,

I would like to know the price of the Apgar Digital Timer with and without the mounting options, and also if you ship to Sweden.

Thanks in advance.

Request further Information on

03 Nov 2017 Zoey Teal

COMPLETED

03 Nov 2017 Zoey Teal

COMPLETED

Issues:107181

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

Web Site Question ID 1139

Issue ID #112130

Date Created 11/Jan/2018

Issued To: Sarah Walton

Completed Status: 11 Jan 2018

Notes:

Web Site Question ID 1139

10/01/18

daniel.beug@unitypoint.org

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

0310100 Apgar Digital Timer

daniel beug

unity point health/trinity moline

biomed

daniel.beug@unitypoint.org

United States

Type: General

Price request of timer

Request further Information on

Medical Apgar Timer

11 Jan 2018 Sarah Walton

Done

Issues:112130

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

Web Site Question ID 1148

Issue ID #113089

Date Created 25/Jan/2018

Issued To: Sarah Walton

Completed Status: 29 Jan 2018

Notes:

Web Site Question ID 1148

24/01/18

monique.oijen@airmed.nl

Information Request to Viamed Limited at the [https://www.viamed.co.uk/uk/ WebSite](https://www.viamed.co.uk/uk/WebSite)

0310100 Apgar Digital Timer

Monique Oijen

AirMed

monique.oijen@airmed.nl

Netherlands, The EU (Holland)

Type: Pricing

Good afternoon,

We are a medical distribution company based in the Netherlands specialised in neonatal and infant products.

In the past we have ordered a few times Apgar timers true your distributor in Belgium but the prices are not competitive any more.

For one of our customers we have to make an offer for 16 x apgar timers, can we purchase these direct true you?

What would be the conditions?

Looking forward to your reply.

Kind regards,

Monique Oijen

AirMed

GSM: +31623145168

Request further Information on

29 Jan 2018 Sarah Walton

Done

Issues:113089

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

Web Site Question ID 1219

Issue ID #125047

Date Created 31/Jul/2018

Issued To: Kate Griffiths

Completed Status: 02 Aug 2018

Notes:

Web Site Question ID 1219

31/07/18

anggaprasetyo87@yahoo.com

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

0310100 Apgar Digital Timer

Angga

PT BUMI INDAH SARANAMEDIS

Marketing

anggaprasetyo87@yahoo.com

Indonesia

Type: General

Good Morning

I want to ask

Distributor merck Viamed in indonesia

Request further Information on

02 Aug 2018 Kate Griffithsreplied with leaflet

Issues:125047

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

Web Site Question ID 1257

Issue ID #129994

Date Created 10/Oct/2018

Issued To: Kate Griffiths

Completed Status: 10 Oct 2018

Notes:

Web Site Question ID 1257

10/10/18

leitner@geisenhoferklinik.de

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

Leitner

Frauenklinik Dr. Geisenhofer

leitner@geisenhoferklinik.de

Germany EU

Type: Pricing

Can you please offer us: Apgar Digital Timer 0310100

Mounting Bracket Rev 2 -Medirail 0320201

Universal Mounting Clamp 0121200

Many thanks for
your trouble, I look forward to hearing from you shortly.

Kind regards,
Elfi Leitner

Request further Information on

10 Oct 2018 Kate Griffithsdone. Referred to Christoph Boehle, Inspiration Medical as per RS. KG 10.10.18

Issues:129994

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 :