

COMPANY OPERATING PROCEDURES

Post Market surveillance

VM3/COP/18

Post Market Surveillance

1. This is obtained and monitored by many methods and is a continuous process. will be represented and the following subjects discussed and progress monitored.

Item	Subject	Meeting	Meeting No.	Recurring Issue
1	Quality	Management Meeting	23.2	
2	Production	Stock Meeting	2.3	
3	Supplier problems	Management Meeting	11.1	
4	Review of Stock to order	Stock Meeting	2.1	
5	Review of supplier orders	Stock Meeting	2.1	
6	Review of customers orders	Stock Meeting	2.2	
7	Complaints File monitoring	All Meetings		75
8	Repair File monitoring	Stock Meeting	11.2	
9	Goods returned File	Stock Meeting	8.1	69
10	Goods returns to customers	Stock Meeting	9.1	69
11	Goods returns to suppliers	Stock Meeting	8.1	69
12	Staff resources and requirements	Management Meeting	26.0	

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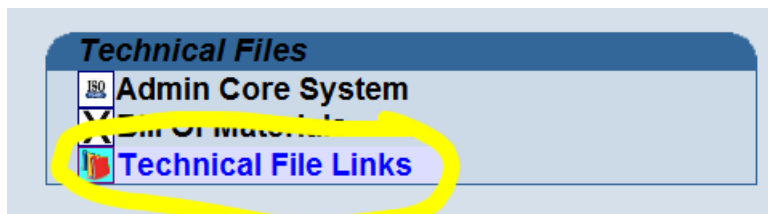
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13	Physical resources space, equipment, procedures	Stock Meeting	2.3	
14	Post surveillance enquiry cards	Sale Marketing Meeting	1.6	
15	Sales Warnings	Monthly Review Lost sales		55 / 56 / 57 / 58
16	Yearly Technical File PMS / Risk Review			50

2. Intrastats : Yearly PMS / Risk Assessment

ISO



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Existing Technical Files			
CE File Name	Technical File Type	Tools	
Apgar Timer 2	Viamed Product	    	
COT Lids	Viamed Product	    	
Heat Shields	Viamed Product	    	
Light Shields	Viamed Product	    	
Microstim MkIII	Viamed Product	    	
Nova Oxygen Tents	Viamed Product	    	
Oxygen Hoods	Viamed Product	    	
Resuscitation Unit and TC400	Viamed Product	    	
T Adaptors	Viamed Product	    	
Tom Thumb	Viamed Product	    	
Tube Holder	Viamed Product	    	

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Post market Surveillance and Risk Assesment Re-evaluation

Apgar Timer 2

Last Reviewed by Derek Lamb on 25/01/11

Associated Stock References

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

B I U ABC    

Scroll down the Page,

Stock references

check Stock references are up to date and current,

Check via, searching

Production Statistics, Find last Production run, Confirm Stock scanned to end Unit
Search Stock File for main Keywords (e.g. APGAR)

Fill in any Comments on Stock References, Should a further action be required tick the
Further Action Box,

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Suppliers

All suppliers of the above Stock references

Supplier Information Main and Component Parts				
Stock_Reference	Description	Supplier AC	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

B *I* U ABC    

Further Action Required ☐

Each supplier should have a Rating, Click account number to see recent activity, Click the Rating to update / change the supplier Rating, (DO NOT refresh the page as above comments will be lost.)

Sales Information

All sales of related stock references will be shown since 2001,

Note high sales of component parts can indicated a possible problem with the products.

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New Countrys

New Countrys											
Country	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
AU Austria											
AUS Australia											
B Belgium											
CAN Canada											
DE Denmark											
G Germany											
IRE Ireland											
PO Portugal											
SWI Switzerland											
UK United Kingdom											
USA U.S.A.											

Green squares indicate that product has been sold into the related country,

Comments can be made on sales

a separate box is provided to comment on any potential risks selling to the newer countries may pose.

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Returns Information

Returns Information												
Stock Ref	Fault	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
0310100	Battery door replaced							1				
0310100	Case replaced										1	
0310100	Keyboard								1		1	

Comments on Returns

B *I* U ABC     

Further Action Required ☐

Returns / New Re-Work Risks?

All returns of related stock references will be show, separated into fault codes,

2 input boxes provided,

1. Comment on the returns in general
2. comment on any risks that may be associated with Re-working the repairs

Design Changes

Design Changes / Product Changes		
Showing Documents Filed in Y 14 Design Changes Red lines are New Since last review : 25/01/11		
Added On	Added By	Document Description
08/03/11	Derek Lamb	Apgar Timer 2 Design Changes HiTec Capacitor Change
04/03/11	John Lamb	Apgar Timer 2 Design Changes
20/05/08	John Lamb	Apgar Timer 2 Design Reviews QC24 04-03-2004 At Rens VET Box
20/05/08	John Lamb	CE FILE Apgar Timer 2 Design Changes APGAR Engineering Change Order Number AP 0310100-001
09/05/07	Derek Lamb	CE FILE Apgar Timer V1r Product Changes

From the **Technical Files** all documents from section Y 14 highlighted in RED have been added or updated since the last review, all blue files were in place prior to the last review.

2 input boxes provided,

- 1 Comment on the documents in general
- 2 Comment on any risks that may be associated with the new documents

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All other Documentation

From the **Technical Files** all documents highlighted in RED have been added or updated since the last review, all blue files were in place prior to the last review.

2 input boxes provided,

- 1 Comment on the documents in general
- 2 Comment on any risks that may be associated with the new documents

Issues

Any Issues from the Intrastats Issue system that contains any of the relevant stock references, will be high-lighted.



27585 Stock Meeting Sale or Returns
Returned Items SOR416
Added by Jonathan Connor sent to Jonathan Connor
SOR ID416 Originally added by Lisa leggoe Loughton Ambulance Station John Boon Rectory Lane Loughton Essex IG10 3RU Returned : 0012105 31000359 Returned : 0012160 30001349 Returned : 0014751 EAB01329 Returned : 0022191 Tracking46
07 Mar 2011 Jonathan Connor
complete
07 Mar 2011 Jonathan Connor
27275 Stock Meeting Sale or Returns
Request
Added by jonathan Connor sent to jonathan Connor

This list can be Huge as all day to day Issues will be shown,

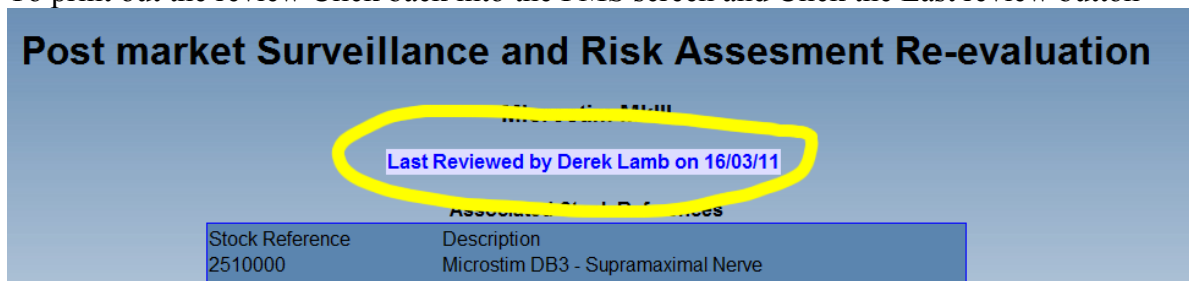
Sign off the Review

Action Required ☐

Sign off review Derek Lamb

The review is stored,

To print out the review Click back into the PMS screen and Click the Last review button



Post market Surveillance and Risk Assessment Re-evaluation	
Last Reviewed by Derek Lamb on 16/03/11	
Associated Stock References	
Stock Reference	Description
2510000	Microstim DB3 - Supramaximal Nerve
2510001	Microstim DB3 - Supramaximal Nerve