



16/May/2012

Post market Surveillance and Risk Assessment Re-evaluation

Resuscitation Unit and TC400
Viamed Product
Post market Surveillance
Risk Assessment
Stock References Review
Supplier Review
Sales Review
Country Sales Review
Stock Returns Review
Design Changes Review
User Manuals Review
Labels Review
Document Updates Review
Internal Issues Review
Clinical Information Review
FDA Incidents Review
Carried out by Derek Lamb on 16 / 05 / 12

Stock References Reviewed

Stock Reference	Description
0120140	Adapter 15mm I.D. - 15mm I.D
0310001	Infant resuscitation cabinet.
0310002	Infant resuscitation cabinet.
0310003	Wall mounted cabinet including :
0310004	Cabinet - Type 2 no suction.
0310007	Infant resuscitation cabinet.
0310008	Infant resuscitation cabinet.
0310012	Infant resuscitation cabinet.
0310013	Infant resuscitation cabinet.
0310020	Storage bins size 3 blue.
0310025	Radiant warmer with double hinged arm
0310037	Rail mounted low suction controller
0310051	Infant resuscitation cabinet.
0310052	Infant resuscitation cabinet.
0310054	Infant resuscitation cabinet.
0310055	Infant resuscitation cabinet.
0310056	Infant resuscitation cabinet.
0320010	Universal rail clamp with `V`
0320021	Resuscitation Bed 14 flat.``
0320023	Resuscitation Bed rotating.
0320039	Mattress octaganol - infant
0320043	Mattress large - infant resuscitation.
0320200	Mounting bracket - Medirail. For use
0330005	Resuscitation Cabinet Type 1
0330006	Door pad - for use with resus cabinet
0330007	Resuscitation Cabinet Door Hinge RHS.
0330008	Resuscitation Cabinet Door Hinge LHS.
0330009	Resuscitation Cabinet Door Catch
0330035	Suction clear tubing (1m)
0330105	Resuscitation Cabinet Type 2
0330106	Resuscitation Cabinet Type 3.
0332037	Resucitation Cabinet Rail - Spacer 15mm
0332038	Resucitation Cabinet Rail - Spacer 15mm
0332039	Resucitation Cabinet Rail - Spacer 20mm
0332040	Resucitation Cabinet Rail - Spacer 20mm
0332041	Resucitation Cabinet Rail - Screw 35mm
0332042	Resucitation Cabinet Rail - Screw 35mm
0332043	Resucitation Cabinet Rail - Lock nut
0332044	Resucitation Cabinet Rail - Lock nut
0332045	Resucitation Cabinet Rail - Washer
0332046	Resucitation Cabinet Rail - Washer
0332055	Resucitation Cabinet Rail - 0.3m length
0332056	Resucitation Cabinet Rail - 0.4m length
0332057	Resucitation Cabinet Rail - 0.4m length
0332058	Resucitation Cabinet Rail - 0.3m length

Stock Reference	Description
0332059	Resuscitation Cabinet Rail - 0.4m length
0332060	Resuscitation Cabinet MediRail ENDCAP
0332100	Resuscitation Cabinet Door Catch
0340010	Labour - Resuscitation Cabinet.
0340011	Training - Resuscitation Cabinet.
0350100	Packing box for resuscitation cabinet.
0380010	Annual service - Resuscitation cabinet.
0390000	B/W Resuscitation Cabinet Side 2
0390053	Label: Infant resuscitation cabinet.
0390100	Leaflet - Infant Resuscitation Cabinet.
0391055	Service sheet - Resuscitation Cabinet
3210071	Single use silicone round facemask
3833-007	Tapered connectors 10 per pack.
3833-132	1l VacSax canister - V mount.
9910-340	1l VacSax standard bore liners.Box of 25
9910-340S	1l VacSax standard bore liner - Single
9950050	Battery 1.5V AA 2700 mAh.

Comments on Stock references review:

stock reference ok

Supplier Information on Main and Component Parts

Stock Reference	Description	Supplier A/C	Supplier Name	Rating
0310025	Radiant warmer with double hinged arm	00007785	Nufer Medical AG	B
0320019	Resuscitation Bed 12 Flat.``	00009022	Tanda Engineering Ltd	A
0320021	Resuscitation Bed 14 flat.``	00009022	Tanda Engineering Ltd	A
0320023	Resuscitation Bed rotating.	00009022	Tanda Engineering Ltd	A
0332055	Resucitation Cabinet Rail - 0.3m length	00009022	Tanda Engineering Ltd	A
0332056	Resucitation Cabinet Rail - 0.4m length	00009022	Tanda Engineering Ltd	A
0332059	Resucitation Cabinet Rail - 0.4m length	00009022	Tanda Engineering Ltd	A
0332056	Resucitation Cabinet Rail - 0.4m length	00009032	R & L Enterprises Ltd	B
0332058	Resucitation Cabinet Rail - 0.3m length	00009032	R & L Enterprises Ltd	B
0332059	Resucitation Cabinet Rail - 0.4m length	00009032	R & L Enterprises Ltd	B
0310020	Storage bins size 3 blue.	00009061	Farnell	A
0330006	Door pad - for use with resus cabinet	00009061	Farnell	A
0332046	Resucitation Cabinet Rail - Washer	00009061	Farnell	A
0360000	Hex wrench short arm 3/6.``	00009061	Farnell	A
9950051	Batteries 1.5V AA. Procell.	00009061	Farnell	A
0350040	Patient circuit (single patient use).	00009082	Intersurgical Ltd	B
0310037	Rail mounted low suction controller	00009150	Therapy Equipment Ltd	A
0320010	Universal rail clamp with `V`	00009150	Therapy Equipment Ltd	A
0320030	1/2 litre suction jar and holder.	00009150	Therapy Equipment Ltd	A
0330035	Suction clear tubing (1m)	00009150	Therapy Equipment Ltd	A
0330055	Universal clamp - 44mm horizontal	00009150	Therapy Equipment Ltd	A
0390000	B/W Resuscitation Cabinet Side 2	00009360	Print Centre	B
0390100	Leaflet - Infant Resuscitation Cabinet.	00009360	Print Centre	B
0390100	Leaflet - Infant Resuscitation Cabinet.	00009363	Impress Print	B
0332056	Resucitation Cabinet Rail - 0.4m length	00009365	WEC Machining	B
0332058	Resucitation Cabinet Rail - 0.3m length	00009365	WEC Machining	B
0332059	Resucitation Cabinet Rail - 0.4m length	00009365	WEC Machining	B
0310035	Low suction controller	00009450	Oxylitre	B
0310141	Injector low suction controller.	00009450	Oxylitre	B
0330040	Suction hose assembly (3m)	00009450	Oxylitre	B
3210071	Single use silicone round facemask	00009602	Bunzl Healthcare	C
3210071	Single use silicone round facemask	00009721	Marshall Products Limited	B
0330238	Rectangular Bracket (G+R)	00010160	KSJ Engineering Limited	B
0330005	Resuscitation Cabinet Type 1	00010220	Bristol Maid	B
0330105	Resuscitation Cabinet Type 2	00010220	Bristol Maid	B
0390053	Label: Infant resuscitation cabinet.	00010665	Pendle Signs & Plastics Ltd.	B
0332040	Resucitation Cabinet Rail - Spacer 20mm	00011727	Plastic Parts Centre Ltd.	B
3833-007	Tapered connectors 10 per pack.	00011810	Vacsax Ltd.	B
3833-132	1l VacSax canister - V mount.	00011810	Vacsax Ltd.	B
9910-340	1l VacSax standard bore liners.Box of 25	00011810	Vacsax Ltd.	B
0350100	Packing box for resuscitation cabinet.	00011818	Macfarlane Group	B
0120140	Adapter 15mm I.D. - 15mm I.D	00011844	Instrumentation Industries Inc	B
0320039	Mattress octaganol - infant	00012180	Park House Healthcare Ltd.	C
0320042	Mattress small - infant resuscitation.	00012180	Park House Healthcare Ltd.	C
0320043	Mattress large - infant resuscitation.	00012180	Park House Healthcare Ltd.	C
9950051	Batteries 1.5V AA. Procell.	00012264	H-Squared Electronics Ltd	B

Stock Reference	Description	Supplier A/C	Supplier Name	Rating
0330009	Resuscitation Cabinet Door Catch	00012266	R P Hardware Ltd	B
0330105	Resuscitation Cabinet Type 2	00012407	W Shuttleworth & Co	B

Comments on Suppliers:

supplier review uptodate

Sales Information

Stock Reference	Description	2006	2007	2008	2009	2010	2011	2012
0120140	Adapter 15mm I.D. - 15mm I.D		2	36	39	31	26	5
0310001	Infant resuscitation cabinet.							
0310002	Infant resuscitation cabinet.	12		21	16	31	21	7
0310003	Wall mounted cabinet including :							
0310004	Cabinet - Type 2 no suction.							
0310007	Infant resuscitation cabinet.							
0310008	Infant resuscitation cabinet.		1		3	13		
0310012	Infant resuscitation cabinet.							
0310013	Infant resuscitation cabinet.							
0310020	Storage bins size 3 blue.				3			
0310025	Radiant warmer with double hinged arm	1			5	23		
0310037	Rail mounted low suction controller	1					1	
0310051	Infant resuscitation cabinet.							
0310052	Infant resuscitation cabinet.							
0310054	Infant resuscitation cabinet.		1					
0310055	Infant resuscitation cabinet.		1					
0310056	Infant resuscitation cabinet.			6				
0320010	Universal rail clamp with `V`		2		16	1		4
0320021	Resuscitation Bed 14 flat.`	2		2	9	6	5	14
0320023	Resuscitation Bed rotating.			1				
0320039	Mattress octaganol - infant			1				
0320043	Mattress large - infant resuscitation.	1				7	1	7
0320200	Mounting bracket - Medirail. For use	7	7	7	8	4	12	4
0330005	Resuscitation Cabinet Type 1							
0330006	Door pad - for use with resus cabinet							
0330007	Resuscitation Cabinet Door Hinge RHS.		1					
0330008	Resuscitation Cabinet Door Hinge LHS.		1					
0330009	Resuscitation Cabinet Door Catch	11	34	11	18	7	3	
0330035	Suction clear tubing (1m)		1		200			
0330105	Resuscitation Cabinet Type 2	2				1		
0330106	Resuscitation Cabinet Type 3.							
0332037	Resucitation Cabinet Rail - Spacer 15mm							
0332038	Resucitation Cabinet Rail - Spacer 15mm							
0332039	Resucitation Cabinet Rail - Spacer 20mm							
0332040	Resucitation Cabinet Rail - Spacer 20mm							
0332041	Resucitation Cabinet Rail - Screw 35mm							
0332042	Resucitation Cabinet Rail - Screw 35mm							
0332043	Resucitation Cabinet Rail - Lock nut							
0332044	Resucitation Cabinet Rail - Lock nut							
0332045	Resucitation Cabinet Rail - Washer							
0332046	Resucitation Cabinet Rail - Washer							
0332055	Resucitation Cabinet Rail - 0.3m length				12			
0332056	Resucitation Cabinet Rail - 0.4m length							
0332057	Resucitation Cabinet Rail - 0.4m length				12	40		36
0332058	Resucitation Cabinet Rail - 0.3m length							
0332059	Resucitation Cabinet Rail - 0.4m length							

Stock Reference	Description	2006	2007	2008	2009	2010	2011	2012
0332060	Resuscitation Cabinet MediRail ENDCAP							
0332100	Resuscitation Cabinet Door Catch							
0340010	Labour - Resuscitation Cabinet.							
0340011	Training - Resuscitation Cabinet.							
0350100	Packing box for resuscitation cabinet.							
0380010	Annual service - Resuscitation cabinet.							
0390000	B/W Resuscitation Cabinet Side 2							
0390053	Label: Infant resuscitation cabinet.							
0390100	Leaflet - Infant Resuscitation Cabinet.				25			
0391055	Service sheet - Resuscitation Cabinet							
3210071	Single use silicone round facemask		1	95	201	1037	1681	1240
3833-007	Tapered connectors 10 per pack.		1					
3833-132	1l VacSax canister - V mount.	5			17			
9910-340	1l VacSax standard bore liners.Box of 25					2		3
9910-340S	1l VacSax standard bore liner - Single			25	16	18		
9950050	Battery 1.5V AA 2700 mAh.		12	12	72	7		

Comments on Sales Information:

units still selling

New Countries

Country	2006	2007	2008	2009	2010	2011	2012
B Belgium	[X]	[X]	[X]	[X]	[X]	[X]	[X]
C China	[X]						
CAN Canada						[X]	
DE Denmark	[X]		[X]				
F France		[X]			[X]		
FI Finland				[X]			
G Germany				[X]			[X]
IRE Ireland	[X]	[X]					
IT Italy			[X]		[X]		
MA Malaysia				[X]			
RU Russia				[X]	[X]	[X]	[X]
SWI Switzerland				[X]	[X]		
UAE U.A.E.				[X]			
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]

Comments on Sales to Countries:

no new countries

Comments on Risks with Sales to Countries:

no risks identified in the country sales

Returns Information

Stock Reference	Fault	2006	2007	2008	2009	2010	2011	2012
0310025	Tested					10		
0320021	Unable to repair				1			

Comments on Returns:

not failures,

Comments on Risks with Returns and Potential Re-work:

n/a/

Design Changes / Product Changes

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

updated installation instructions

Comments on Risks with Design Changes:

no risks with updated documents

User Instructions

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
9525	Tom Thumb Instructions for Use User Manual Resuscitation Cabine...	18/10/11
9241	Resuscitation Unit and TC400 Instructions for Use / Mobile Cerat...	18/10/11
8510	Resuscitation Unit and TC400 Instructions for Use User Manual O...	06/07/11
8509	Resuscitation Unit and TC400 Instructions for Use User Manual O...	06/07/11
8508	Resuscitation Unit and TC400 Instructions for Use User Manual T...	06/07/11
8507	Operators manual for Inspiration Blender Resuscitation Unit and ...	06/07/11
8179	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	24/03/11
8178	Resuscitation Unit Instructions for Use / Installation Ceratherm...	24/03/11
8176	Resuscitation Unit and TC400 Instructions for Use User Manual T...	24/03/11
8175	Resuscitation Unit and TC400 Instructions for Use User Manual A...	24/03/11
8170	Resuscitation Unit and TC400 Instructions for Use User Manual O...	24/03/11
8126	Resuscitation Unit and TC400 Instructions for Use TC400/W mkl	23/03/11
8124	Resuscitation Unit and TC400 Instructions for Use / User Manual	23/03/11
4128	Resuscitation Unit and TC400 Instructions for Use TC400 prevent...	09/07/08
4127	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	09/07/08
4121	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	09/07/08
4120	Resuscitation Unit and TC400 Instructions for Use / Therapy Equi...	09/07/08
4119	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	09/07/08
4118	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	09/07/08
4117	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	09/07/08
4115	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	09/07/08
4114	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	09/07/08
4113	Resuscitation Unit and TC400 Instructions for Use / Ceratherm Ch...	09/07/08
4112	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	09/07/08
4101	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	09/07/08
3977	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	08/07/08
3976	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	08/07/08
3975	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	08/07/08
3974	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	08/07/08
3973	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	08/07/08
3972	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	08/07/08
2573	Resuscitation Unit Instructions for Use / User Manual Apgar Time...	17/08/07
1511	User Manual Apgar Smiths NS 22G CE FILE Apgar Timer V1r Instruct...	09/05/07
1312	Resuscitation Unit Instructions for Use / User Manual Nufer Wall...	19/03/07
1308	Resuscitation Unit Instructions for Use / Operator Manual Cerat...	19/03/07
1303	Resuscitation Unit Instructions for Use / User Manual Oxytitre S...	19/03/07

Comments on User Instructions:

user manuals cleaned up and sorted out,had multiple versions, only latest version now active

Comments on Risks User Instructions:

no risks with user manuals

Labels

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
8127	Resuscitation Unit and TC400 Labels	23/03/11
4110	Resuscitation Unit and TC400 Labels Caution 2006	09/07/08
4109	Resuscitation Unit and TC400 Labels cabinet labels	09/07/08
4108	Resuscitation Unit and TC400 Labels 1989	09/07/08
3983	TC400 Rear Label original.pdf CE FILE Resuscitation Unit and TC4...	08/07/08
3981	Resuscitation Unit and TC400 Labels TC400 2001 (5).pdf	08/07/08
3980	Resuscitation Unit and TC400 Labels TC400 2001.pdf	08/07/08
3918	Resuscitation Unit Labels rotating bed	23/06/08
1319	Resuscitation Unit Labels Apgar Timer (2002)	19/03/07
1318	Resuscitation Unit Labels Thermacot 2	19/03/07
1317	Resuscitation Unit Labels Ceratherm 2006 Weee	19/03/07
1316	Resuscitation Unit Labels Thermacot	19/03/07
1315	Resuscitation Unit Labels Caution Label	19/03/07

Comments on Labels:

Comments on Risks Labels:

no risks identified with labels

Documentation Updates / Changes

Comments on Document Changes:

no comments on new documents, file has been massively tidied up, so its registering lots of changes, most are archiving old version of files, leaving only the latest version accessible

Comments on Risks with Document Changes:

no risks identified with new documents

Review of Issues

Number of Issues reviewed: 34

Issue ID	Subject
30332	Returned Items SOR478
28434	Eden Medical
28433	Eden Medical
35285	New Medirail supplier - R&L Enterprises
29844	3210077 stock fro sales order
36522	Document Update Request
34451	Instruction sheet required
34450	Instruction sheet required
27617	Controlled Documents require Attention
31064	Resus cabinets for Royal Bolton
31063	Production order required
31062	Production order required
28086	
28085	
30868	0330006 stock adjustment
28873	Watford adaptors
28872	Adaptor
34968	Low suction controllers required
34966	Cabinet bodies required
34102	More medirail required
30859	Medirails coming in for customer order.
30751	Medirails required - see drawing
28076	Size 3 cabinet bins from Farnell
28075	Therapy Equipment low suction controllers
33643	JSC Pro-forma invoice PRO01841
33642	JSC Pro-forma invoice PRO01841
33641	JSC Pro-forma invoice PRO01841
33133	Lost Customers System
32978	Lost Customers - Infant Resus and Blenders
32977	Lost Customers
34156	0310002 Steve Hardaker Sales Forecasts
32872	3210071 Steve Hardaker Sales Forecasts
32638	Neopeep & masks requirements for 2012
32637	Neopeep & masks requirements for 2012

Comments on Issues:

lots normal day to day issues,

Comments on Risks with Issues:

no risks identified with issues

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 :

cabinates are a collection of already well established devices,
its still upto date and valid technology.

no risks have been identified

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 reports found