



30/Jul/2013

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 30 / 07 / 13

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 octagonal - 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	Resuscitation Cabinet Rail - Spacer 15mm
0332038	Resuscitation Cabinet Rail - Spacer 15mm
0332039	Resuscitation Cabinet Rail - Spacer 20mm
0332040	Resuscitation Cabinet Rail - Spacer 20mm
0332041	Resuscitation Cabinet Rail - Screw 35mm
0332042	Resuscitation Cabinet Rail - Screw 35mm
0332043	Resuscitation Cabinet Rail - Lock nut
0332044	Resuscitation Cabinet Rail - Lock nut
0332045	Resuscitation Cabinet Rail - Washer
0332046	Resuscitation Cabinet Rail - Washer
0332055	Resuscitation Cabinet Rail - 0.3m length
0332056	Resuscitation Cabinet Rail - 0.4m length
0332057	Resuscitation Cabinet Rail - 0.4m length
0332058	Resuscitation 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:

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	Resuscitation Cabinet Rail - 0.3m length	00009022	Tanda Engineering Ltd	A
0332056	Resuscitation Cabinet Rail - 0.4m length	00009022	Tanda Engineering Ltd	A
0332059	Resuscitation Cabinet Rail - 0.4m length	00009022	Tanda Engineering Ltd	A
0332056	Resuscitation Cabinet Rail - 0.4m length	00009032	R & L Enterprises Ltd	B
0332058	Resuscitation Cabinet Rail - 0.3m length	00009032	R & L Enterprises Ltd	B
0332059	Resuscitation Cabinet Rail - 0.4m length	00009032	R & L Enterprises Ltd	B
0320043	Mattress large - infant resuscitation.	00009054	Angel Healthcare Solutions Ltd	Needs Grading
0310020	Storage bins size 3 blue.	00009061	Farnell	A
0330006	Door pad - for use with resus cabinet	00009061	Farnell	A
0332046	Resuscitation 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	Resuscitation Cabinet Rail - 0.4m length	00009365	WEC Machining	B
0332058	Resuscitation Cabinet Rail - 0.3m length	00009365	WEC Machining	B
0332059	Resuscitation 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	Resuscitation 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

Stock Reference	Description	Supplier A/C	Supplier Name	Rating
9950051	Batteries 1.5V AA. Procell.	00012264	H-Squared Electronics Ltd	B
0330009	Resuscitation Cabinet Door Catch	00012266	R P Hardware Ltd	B
0330105	Resuscitation Cabinet Type 2	00012407	W Shuttleworth & Co	B

Comments on Suppliers:

Angel Healthcare Solutions Ltd, supplier questionnaire qc06 has been sent, will formally rate the company upon its return.

Follow up Issue #44489

Sales Information

Stock Reference	Description	2007	2008	2009	2010	2011	2012	2013
0120140	Adapter 15mm I.D. - 15mm I.D	2	36	39	31	26	38	82
0310001	Infant resuscitation cabinet.							
0310002	Infant resuscitation cabinet.		21	16	31	21	15	18
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			5	23			
0310037	Rail mounted low suction controller					1		
0310051	Infant resuscitation cabinet.							
0310052	Infant resuscitation cabinet.						1	
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	9	6	5	23	3
0320023	Resuscitation Bed rotating.		1					
0320039	Mattress octaganol - infant		1				1	
0320043	Mattress large - infant resuscitation.				7	1	17	3
0320200	Mounting bracket - Medirail. For use	7	7	8	4	12	12	19
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	34	11	18	7	3		
0330035	Suction clear tubing (1m)	1		200				
0330105	Resuscitation Cabinet Type 2				1		5	
0330106	Resuscitation Cabinet Type 3.							
0332037	Resuscitation Cabinet Rail - Spacer 15mm							
0332038	Resuscitation Cabinet Rail - Spacer 15mm							
0332039	Resuscitation Cabinet Rail - Spacer 20mm							
0332040	Resuscitation Cabinet Rail - Spacer 20mm							
0332041	Resuscitation Cabinet Rail - Screw 35mm							
0332042	Resuscitation Cabinet Rail - Screw 35mm							
0332043	Resuscitation Cabinet Rail - Lock nut							
0332044	Resuscitation Cabinet Rail - Lock nut							
0332045	Resuscitation Cabinet Rail - Washer							
0332046	Resuscitation Cabinet Rail - Washer							
0332055	Resuscitation Cabinet Rail - 0.3m length			12				
0332056	Resuscitation Cabinet Rail - 0.4m length							
0332057	Resuscitation Cabinet Rail - 0.4m length			12	40		59	12
0332058	Resuscitation Cabinet Rail - 0.3m length						4	
0332059	Resuscitation Cabinet Rail - 0.4m length						8	

Stock Reference	Description	2007	2008	2009	2010	2011	2012	2013
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	1514	442
3833-007	Tapered connectors 10 per pack.	1					1	
3833-132	1l VacSax canister - V mount.			17			1	
9910-340	1l VacSax standard bore liners.Box of 25				2		4	
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:

0310002 is the main part number, still selling, increasing sales on last year already.

New Countries

Country	2007	2008	2009	2010	2011	2012	2013
B Belgium	[X]	[X]	[X]	[X]	[X]	[X]	[X]
C China							
CAN Canada					[X]		
DE Denmark		[X]					[X]
F France	[X]			[X]			[X]
FI Finland			[X]				
G Germany			[X]			[X]	
IRE Ireland	[X]						[X]
IT Italy		[X]		[X]		[X]	[X]
MA Malaysia			[X]				
NO Norway							[X]
RU Russia			[X]	[X]	[X]	[X]	
SWI Switzerland			[X]	[X]			[X]
UAE U.A.E.			[X]				
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]

Comments on Sales to Countries:

New country Norway,

Not a product that gets repeat sales from the same end user so consistency of sales hard to judge.

Comments on Risks with Sales to Countries:

No new risks identified in country sales

Returns Information

Stock Reference	Fault	2007	2008	2009	2010	2011	2012	2013
0310025	Control Board Replaced							1
0310025	Tested				10			
0320021	Unable to repair			1				

Comments on Returns:

0310025 refers to the Nufer radiant warmer.

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:

No new documents to design changes

Comments on Risks with Design Changes:

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:

no new user instructions

Comments on Risks User Instructions:

n/a

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:

n/a

Documentation Updates / Changes

Comments on Document Changes:

Main document of concern is Doc ID #12732

Relating to Infection Control.

Contains the original observations made by Mr Bamton st Marys hospital,

and the response by Mr Steve Hardaker.

Comments on Risks with Document Changes:

Review of Issues

Number of Issues reviewed: 37

Issue ID	Subject
30332	Returned Items SOR478
43497	0330242 Mediral Mounting Plate
38237	PPQ and supporting info for 0310302
44269	Opera description to amend
37995	Part to add to Opera -catches for resus cabinets
37061	Corrections to Opera descriptions - medirail
43780	0310050 - PPQ required
40556	stock check
40549	stock check
38960	Peto / GHX spreadsheet corrections
37380	Ceratherm-2 models upgraded to Ceratherm 600-3 variant
37379	Ceratherm-2 models upgraded to Ceratherm 600-3 variant
37378	Ceratherm-2 models upgraded to Ceratherm 600-3 variant
37377	Ceratherm-2 models upgraded to Ceratherm 600-3 variant
37376	Ceratherm-2 models upgraded to Ceratherm 600-3 variant
37375	Ceratherm-2 models upgraded to Ceratherm 600-3 variant
37374	Ceratherm-2 models upgraded to Ceratherm 600-3 variant
37373	Ceratherm-2 models upgraded to Ceratherm 600-3 variant
37372	Ceratherm-2 models upgraded to Ceratherm 600-3 variant
37371	Ceratherm-2 models upgraded to Ceratherm 600-3 variant
37370	Ceratherm-2 models upgraded to Ceratherm 600-3 variant
37369	Ceratherm-2 models upgraded to Ceratherm 600-3 variant
36833	Shipment of Ceratherm radiant warmers
36832	Shipment of Ceratherm radiant warmers
36831	Shipment of Ceratherm radiant warmers
36830	Shipment of Ceratherm radiant warmers
36829	Shipment of Ceratherm radiant warmers
36828	Shipment of Ceratherm radiant warmers
36827	Shipment of Ceratherm radiant warmers
36826	Shipment of Ceratherm radiant warmers
37850	Backorder 00002609 0332057 ORD58324
34968	Low suction controllers required
34966	Cabinet bodies required
42522	0330190 for Mediprema?
32978	Lost Customers - Infant Resus and Blenders
36006	Sales Targets Warmers MD200 SpO2
41861	Sales Enquiry

Comments on Issues:

No problems identified in the Issues system

Comments on Risks with Issues:

n/a

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 :

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 :