



VIA MED

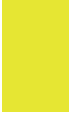
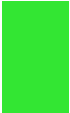
Resuscitation Unit and TC400

Class IIb
Via Rule Rule 9
Assesment Route Annex II
NBOG MD 1100

Carried out by Derek Lamb
18 / 04 / 16



VIA MED

-  Stock References Review
-  Supplier Review
-  Sales Review
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-  Returns Review
-  Design Changes Review
-  User Instructions Review
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-  Internal Issues Review
-  Clinical / FDA Incidents online search
-  Risk ISO 14971 : 2012 Review

Stock References Review

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.
0310302	Radiant warmer with double hinged arm
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	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

Stock Reference	Description
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
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:

parts list upto date

Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
0310025	Radiant warmer with doub	00007785	521A-60022OND	Nufer Medical AG	B
0310302	Radiant warmer with doub	00007785	521A-60022-3-OND	Nufer Medical AG	B
0320019	Resuscitation Bed 12 Fl	00009022	PP8720	Tanda Engineering Ltd	A
0320021	Resuscitation Bed 14 fl	00009022	PP8674	Tanda Engineering Ltd	A
0320023	Resuscitation Bed rotat	00009022	PP8762	Tanda Engineering Ltd	A
0332055	Resuscitation Cabinet Ra	00009022	PP8765	Tanda Engineering Ltd	A
0332056	Resuscitation Cabinet Ra	00009022	PP8766	Tanda Engineering Ltd	A
0332059	Resuscitation Cabinet Ra	00009022	PP8768	Tanda Engineering Ltd	A
0332056	Resuscitation Cabinet Ra	00009032	PP8766	R & L Enterprises Ltd	B
0332058	Resuscitation Cabinet Ra	00009032	PP8767	R & L Enterprises Ltd	B
0332059	Resuscitation Cabinet Ra	00009032	PP8768	R & L Enterprises Ltd	B
0332037	Resuscitation Cabinet Ra	00009045		Essentra Components	B
0320043	Mattress large - infant	00009054	0320043	Angel Healthcare Solutio	Needs Grading
0310020	Storage bins size 3 bl	00009061	274-227	Farnell	A
0330006	Door pad - for use with	00009061	1165061	Farnell	A
0332046	Resuscitation Cabinet Ra	00009061	1580684	Farnell	A
0360000	Hex wrench short arm 3	00009061	1552281	Farnell	A
9950051	Batteries 1.5V AA. Proce	00009061	MN1500 PACK 10	Farnell	A
0350040	Patient circuit (single	00009082	INT-6181	Intersurgical Ltd	B
0310037	Rail mounted low suction	00009150	4725-3M	Therapy Equipment Ltd	A
0320010	Universal rail clamp wit	00009150	2003	Therapy Equipment Ltd	A
0320030	1/2 litre suction jar an	00009150	4508	Therapy Equipment Ltd	A
0330035	Suction clear tubing (1m	00009150	4302	Therapy Equipment Ltd	A
0330055	Universal clamp - 44mm h	00009150	2002	Therapy Equipment Ltd	A
0390000	B/W Resuscitation Cabine	00009360	0390000	Print Centre	B
0390100	Leaflet - Infant Resusci	00009360		Print Centre	B
0390100	Leaflet - Infant Resusci	00009363		ACI Print Group Impress	B
0332056	Resuscitation Cabinet Ra	00009365	PP8766	WEC Machining	B
0332058	Resuscitation Cabinet Ra	00009365	PP8767	WEC Machining	B
0332059	Resuscitation Cabinet Ra	00009365	PP8768	WEC Machining	B
0310035	Low suction controller	00009450	S714916	Oxylitre	B
0310141	Injector low suction con	00009450	S801/L	Oxylitre	B
0330040	Suction hose assembly (3	00009450	S6666-3	Oxylitre	B
3210071	Single use silicone roun	00009602	M6200500D	Bunzl Healthcare	C
3210071	Single use silicone roun	00009721	M6200500D	Marshall Products Limite	B
0330238	Rectangular Bracket (G+R	00010160	0330238	KSJ Engineering Limited	B
0330005	Resuscitation Cabinet T	00010220	BA/10 TYPE 1	Bristol Maid	B
0330105	Resuscitation Cabinet Ty	00010220	SPRC11	Bristol Maid	B
0390053	Label: Infant resuscitat	00010665		Pendle Signs & Plastics	B
0332040	Resuscitation Cabinet Ra	00011727	1111630000VR	Plastic Parts Centre Ltd	B
3833-007	Tapered connectors 10 p	00011810	3833-007	Vacsax Ltd.	B
3833-132	1l VacSax canister - V m	00011810	3833-132	Vacsax Ltd.	B

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
9910-340	1l VacSax standard bore	00011810	9910-340	Vacsax Ltd.	B
0350100	Packing box for resuscit	00011818		Macfarlane Group	B
0120140	Adapter 15mm I.D. - 15m	00011844	PF 1515	Instrumentation Industri	B
0320039	Mattress octaganol - in	00012180	0320039	Park House Healthcare Lt	C
0320042	Mattress small - infant	00012180		Park House Healthcare Lt	C
0320043	Mattress large - infant	00012180	0320043	Park House Healthcare Lt	C
9950051	Batteries 1.5V AA. Proce	00012264	MN1500 PACK 10	H-Squared Electronics Lt	B
0330009	Resuscitation Cabinet Do	00012266	B344-12	R P Hardware Ltd	B
0330105	Resuscitation Cabinet Ty	00012407	SPRC11	W Shuttleworth & Co	B

Comments on Suppliers:

Supplier reviews upto date, still a problem getting certificates out of angel health care, so not purchased any since 2014

Sales Information

Stock Reference	Description	2010	2011	2012	2013	2014	2015	2016
0120140	Adapter 15mm I.D. - 15m	41	27	38	120	57	149	22
0310001	Infant resuscitation cabinet.							
0310002	Infant resuscitation cabinet.	42	31	15	38	10	7	6
0310003	Wall mounted cabinet including :							
0310004	Cabinet - Type 2 no suction.							
0310007	Infant resuscitation cabinet.							
0310008	Infant resuscitation cabinet.	25						
0310012	Infant resuscitation cabinet.							
0310013	Infant resuscitation cabinet.							
0310020	Storage bins size 3 bl							
0310025	Radiant warmer with doub	46						
0310037	Rail mounted low suction		2					
0310051	Infant resuscitation cabinet.							
0310052	Infant resuscitation cabinet.			1				
0310054	Infant resuscitation cabinet.							
0310055	Infant resuscitation cabinet.							
0310056	Infant resuscitation cabinet.							
0310302	Radiant warmer with doub					3		
0320010	Universal rail clamp wit	1		4				
0320021	Resuscitation Bed 14 fl	8	8	23	13	22	9	2
0320023	Resuscitation Bed rotat							
0320039	Mattress octaganol - in			1				
0320043	Mattress large - infant	11	0	17	3	8	5	
0320200	Mounting bracket - Medirail. For use	7	19	12	23	3	5	
0330005	Resuscitation Cabinet T							
0330006	Door pad - for use with							
0330007	Resuscitation Cabinet Door Hinge RHS.							
0330008	Resuscitation Cabinet Door Hinge LHS.							
0330009	Resuscitation Cabinet Do	13	3					
0330035	Suction clear tubing (1m				2	7	6	
0330105	Resuscitation Cabinet Ty	2		5	1	9	5	
0330106	Resuscitation Cabinet Type 3.							
0332037	Resuscitation Cabinet Ra							
0332038	Resuscitation Cabinet Rail - Spacer 15mm							
0332039	Resuscitation Cabinet Rail - Spacer 20mm						19	
0332040	Resuscitation Cabinet Ra							
0332041	Resuscitation Cabinet Rail - Screw 35mm						19	
0332042	Resuscitation Cabinet Rail - Screw 35mm							
0332043	Resuscitation Cabinet Rail - Lock nut						19	
0332044	Resuscitation Cabinet Rail - Lock nut							
0332045	Resuscitation Cabinet Rail - Washer						19	
0332046	Resuscitation Cabinet Ra							

Stock Reference	Description	2010	2011	2012	2013	2014	2015	2016
0332055	Resuscitation Cabinet Ra							
0332056	Resuscitation Cabinet Ra							
0332057	Resuscitation Cabinet Rail - 0.4m length	40		59	34	36		20
0332058	Resuscitation Cabinet Ra			4	1	9	5	
0332059	Resuscitation Cabinet Ra			8	2	18	11	
0332060	Resuscitation Cabinet MediRail ENDCAP							
0332100	Resuscitation Cabinet Door Catch							
0340010	Labour - Resuscitation Cabinet.							
0340011	Training - Resuscitation Cabinet.							
0350100	Packing box for resuscit							
0380010	Annual service - Resuscitation cabinet.							
0390000	B/W Resuscitation Cabine							
0390053	Label: Infant resuscitat							
0390100	Leaflet - Infant Resusci				10	20		
0391055	Service sheet - Resuscitation Cabinet							
3210071	Single use silicone roun	1460	1798	1514	874	648	734	188
3833-007	Tapered connectors 10 p			1			1	
3833-132	1l VacSax canister - V m			1		10		
9910-340	1l VacSax standard bore	4		4	3		2	
9910-340S	1l VacSax standard bore liner - Single	18						
9950050	Battery 1.5V AA 2700 mAh.	7						

Comments on Sales Information:

Still selling small numbers

Countries Review

Country	2010	2011	2012	2013	2014	2015	2016
B Belgium	[X]	[X]	[X]	[X]			
C China					[X]		
CAN Canada		[X]				[X]	
CZ Czech Republic					[X]		
DE Denmark				[X]			
F France	[X]			[X]			
FI Finland							
G Germany			[X]				
IRE Ireland				[X]			
IT Italy	[X]		[X]	[X]			[X]
MA Malaysia							
NO Norway				[X]			
RU Russia	[X]	[X]	[X]	[X]			
SRI Sri Lanka						[X]	
SWI Switzerland	[X]			[X]			
T Turkey				[X]			
UAE U A E							
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]

Comments on Sales to Countries:

SRI Sri Lanka new country,
was never a big export market due to weight of shipping

Comments on Risks with Sales to Countries:

no risks with selling to other countries

Returns Review

Stock Reference	Fault	2010	2011	2012	2013	2014	2015	2016
0310025	Control Board Replaced				1			
0310025	No fault found				1			
0310025	Tested	10						
0320021	Unable to repair							
0320021	Unchecked - Returned to Stock							
0320043	Unchecked - Returned to Stock							

Comments on Returns:

little to no returns,
as the product is a cabinet to hold other active devices, any returns would be logged under the respective part numbers,

Comments on Risks with Returns and Potential Re-work:

no risk to returns

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

no design changes

Comments on Risks with Design Changes:

User Instructions Review

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
14847	Resuscitation Cabinet Operator Manual (without appedices)	11/03/15
14789	Instruction Manual - Air Oxygen Blenderl	19/02/15
14688	Ceratherm 300 Installation Instructions for modified casing part...	16/01/15
12878	0310140 - S8 series injector suction Operating Instructions	15/08/13
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 Oxylitre S...	19/03/07

Comments on User Instructions:

sub component parts have had instructions updated, these are CE by the originating companies.

Comments on Risks User Instructions:

no risks with the instruction manuals

Labels Review

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
15598	Resuscitation Unit and TC400 Labels (2)	07/09/15
8127	Resuscitation Unit and TC400 Labels (1)	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:

Added the labels for the anti bacteri coatings

Comments on Risks Labels:

no risks with the labels

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
16774	Resuscitation Unit and TC400 Risk analysis reports	18/04/16
16427	Resuscitation Unit OES (OEM) CE Certificate Oxilite 9001	04/03/16
16404	Therapy Equipment ISO 13485 CE Certificate Therapy Equipment ISO...	01/03/16
16342	Inspiration Healthcare Limited Blenders Certification ISO 13485:...	18/02/16
15970	Radiant Warmers Leaflet Ceratherm 600-3 (email)	18/11/15
15681	Service Manual Tom Thumb Valves v1.1	21/09/15
15668	Tom Thumb Infant Resus Leaflet (email)	18/09/15
15667	Infant Resuscitation Catalogue A5	18/09/15
15666	Infant Resuscitation Cabinet Leaflet (email)	18/09/15
15598	Resuscitation Unit and TC400 Labels (2)	07/09/15
15540	Steri-Touch Test Report - Test Report - Powder Coat 5 yrs ageing...	25/08/15
15539	Steri-Touch Test Report - Test Report - 10 yrs aged paint	25/08/15
15538	Steri-Touch Test Report - Test Report - 5 yrs old cover	25/08/15
15504	Infant Resuscitation A5 Catalogue	24/08/15
15418	PPE Equipment	11/08/15
15291	Apgar Timer 2 EC Declaration of Conformance 2008	29/07/15
15183	No risks disposal	21/07/15
14937	Resuscitation Unit Maintenance Viamed Service Contract.	15/04/15
14853	Resuscitation Unit and TC400 Service Manual Ceratherm 600-3	12/03/15
14847	Resuscitation Cabinet Operator Manual (without appendices)	11/03/15
14845	Radiant Warmer Leaflet AMENDED MODEL NUMBER ON 0310305 (+5mm ble...	10/03/15
14844	Radiant Warmer Leaflet AMENDED MODEL NUMBER ON 0310305 (High)	10/03/15
14843	Radiant Warmer Leaflet AMENDED MODEL NUMBER ON 0310305 (email) ...	10/03/15
14817	Resuscitation Unit and TC400 EC Declaration of Conformance Gmail...	26/02/15
14816	Resuscitation Unit and TC400 EC Declaration of Conformance Decla...	26/02/15
14815	Resuscitation Unit and TC400 EC Declaration of Conformance Decla...	26/02/15
14814	Resuscitation Unit and TC400 EC Declaration of Conformance DoC_H...	26/02/15
14813	Resuscitation Unit and TC400 Certification CE CE-d-Acrobat2000_2...	26/02/15
14789	Instruction Manual - Air Oxygen Blenderl	19/02/15
14697	Infant Resuscitation Catalogue Brochure 9990080	27/01/15
14688	Ceratherm 300 Installation Instructions for modified casing part...	16/01/15
14643	Drawings ceratherm weights and dimensions	31/12/14
14630	Declaration of Conformity 0310304 Stand	30/12/14
14433	Resuscitation Unit and TC400 Promotional Leaflets Tom Thumb Infa...	03/10/14
14431	Resuscitation Unit and TC400 Promotional Leaflets Radiant Warmer...	03/10/14
14407	Resuscitation Unit and TC400 Specifications PTFE Tape Specificat...	03/10/14
14259	Resuscitation Unit and TC400 Drawings Description 0332041 033204...	09/09/14
14257	Resuscitation Unit and TC400 Drawings Description 0332043 033204...	09/09/14
14255	Resuscitation Unit and TC400 0332037 0332038 Description	09/09/14
14253	Resuscitation Unit and TC400 Drawings 0332037	09/09/14
14185	Notified body certification TUV Nufer ISO 13485 : 2003 Nufer ISO...	26/08/14
14184	Resuscitation Unit EC Declaration of Conformance Nufer Ceratherm...	26/08/14

Document ID	Description	Date Added/Updated
14183	Resuscitation Unit and TC400 Clinical Trials Reports Reviews and...	22/08/14

Comments on Document Changes:

no comments

Comments on Risks with Document Changes:

no risks to updated documentation

Internal Issues Review

Number of Issues reviewed: 106

Issue ID	Subject
9630	
9066	
12290	
63834	0121190 & 0121191 DEHP, Phthalates, PVC declaration
57375	0310002 opera stock
64921	0310025 - Solution to intermittent alarms
64920	0310025 - Solution to intermittent alarms
52278	0332037 0330332041 0332043 description
64616	3x resuscitation cabinets for QEK, Kings Lynn
50286	Angel Healthcare 0320043
69082	Backorder 00000170 0120140 ORD79433
66222	Backorder 00000262 0320021 ORD78006
67197	Backorder 00000262 0320021 ORD78568
52911	Backorder 00000262 0330105 ORD70402
53993	Backorder 00000262 0330105 ORD71015
59922	Backorder 00000550 0320021 ORD74743
62208	Backorder 00000550 0380010 ORD75501
57083	Backorder 00000590 0120140 ORD72963
62212	Backorder 00000780 0380010 ORD75500
69206	Backorder 00000970 0310002 ORD79492
69207	Backorder 00000980 0310002 ORD79493
62274	Backorder 00001350 3210071 ORD75765
59960	Backorder 00001466 0120140 ORD74746
61991	Backorder 00001910 0120140 ORD75657
59413	Backorder 00001910 0310002 ORD74357
57279	Backorder 00002040 3210071 ORD73102
58130	Backorder 00002040 3210071 ORD73620
58925	Backorder 00002040 3210071 ORD74128
58926	Backorder 00002040 3210071 ORD74130
59889	Backorder 00002040 3210071 ORD74720
61327	Backorder 00002040 3210071 ORD75402
62115	Backorder 00002040 3210071 ORD75756
66091	Backorder 00002040 3210071 ORD77945
66831	Backorder 00002040 3210071 ORD78377
68438	Backorder 00002040 3210071 ORD79141
69153	Backorder 00002040 3210071 ORD79465
64907	Backorder 00002400 0310002 ORD77149
59868	Backorder 00002400 0320021 ORD74698
63878	Backorder 00002570 0330105 ORD76701
59965	Backorder 00002600 0120140 ORD74758
62362	Backorder 00002609 0330105 ORD75905
58316	Backorder 00003540 9910-340 ORD73713

Issue ID	Subject
51553	Backorder 00003581 0310002 ORD69490
51941	Backorder 00003785 0320021 ORD69750
52025	Backorder 00003785 0320021 ORD69859
60524	Backorder 00003785 0320021 ORD75016
61684	Backorder 00003785 0320021 ORD75510
64224	Backorder 00003930 0320021 ORD76879
52374	Backorder 00004042 0310002 ORD70113
66249	Backorder 00004260 0332057 ORD77627
69339	Backorder 00004260 0380010 ORD79454
66162	Backorder 00005520 0310002 ORD77784
66890	Backorder 00006777 0120140 ORD78403
58852	Backorder 00012774 0120140 ORD74086
63097	Backorder 00012829 0332045 ORD76197
68974	Cabinet parts for urgent order - North Cumbria Hospitals NHS Trust
51211	Ceratherm 600-3 Radiant Warmer & Wall Brackets - 0310302
57327	Ceratherm 600-3 Service Manual v14.176.C
56926	Ceratherm mounting bracket - earth bonding
16187	Ceratherm safety check
55399	Ceratherm weights and dimensions
55398	Ceratherm weights and dimensions
65577	Certificates and article information sheet - Duracell batteries
65578	Datasheet AA batteries
63147	Document Update Request (1807)
55888	Document/Picture (DOCID14677) Update Request
55889	Document/Picture (DOCID14678) Update Request
55887	Document/Picture (DOCID14679) Update Request
69243	FDA numbers for Instrumentation Industries Inc products
57401	GHX Brands
13432	Medical Essentials - Resuscitation Cabinet
66093	Missing off shelf
66092	Missing off shelf
56029	Nufer Ceratherm 600-3 Radiant Warmer failure
59314	ORD74357 James Paget order for 7 x 0310002
59313	ORD74357 James Paget order for 7 x 0310002
59312	ORD74357 James Paget order for 7 x 0310002
45229	PETO/GHX Export - Requires sending
69776	POR10664 0310302 12/04/2016
57945	Price requires increasing - 0310008
60975	QA test procedure for 0310302
60952	QA test procedure for 0310302
57453	Repair prices
57248	Resus cabinet Operators Manual v10.01
53390	Resus cabinet order - Royal Preston - ORD70679
53389	Resus cabinet order - Royal Preston - ORD70679
44855	Resus cabinets service training - Fairfield General

Issue ID	Subject
66094	Resus upgrade rail kits
62910	Resuscitation cabinet production procedures
52614	Revised buying price for Shuttleworths cabinet
65598	Sales areas - Nufer Ceratherm 600-3 Radiant Warmers
65597	Sales areas - Nufer Ceratherm 600-3 Radiant Warmers
65596	Sales areas - Nufer Ceratherm 600-3 Radiant Warmers
65595	Sales areas - Nufer Ceratherm 600-3 Radiant Warmers
65594	Sales areas - Nufer Ceratherm 600-3 Radiant Warmers
65593	Sales areas - Nufer Ceratherm 600-3 Radiant Warmers
65592	Sales areas - Nufer Ceratherm 600-3 Radiant Warmers
65591	Sales areas - Nufer Ceratherm 600-3 Radiant Warmers
65590	Sales areas - Nufer Ceratherm 600-3 Radiant Warmers
65589	Sales areas - Nufer Ceratherm 600-3 Radiant Warmers
65588	Sales areas - Nufer Ceratherm 600-3 Radiant Warmers
62125	Steri-Touch antibacterial coating
65927	Web Site Question ID 805
67717	Web Site Question ID 838
67718	Web Site Question ID 839
68342	Web Site Question ID 846

Comments on Issues:

No problems found in the Issue system,
only customer complaint was regarding the Nufer wand Arm, and this was deemed to be customer abuse
rather than product fault (deemed by nufer).

Comments on Risks with Issues:

no risks identified in the Issues system

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 :

Product is a empty cabinet, there will not be any clinical reports.

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 :

Product is a empty cabinet, there will not be any FDA Reports