



VIA MED

Tom Thumb

Hand held, gas powered resuscitation unit.

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

Carried out by Derek Lamb
10 / 10 / 17



VIA MED

-  Stock References Review
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Stock References Review

Stock Reference	Description
0310027	Tom Thumb Infant Resuscitator (Air).
0310029	Tom Thumb Infant Resuscitator (Air).
0310030	Tom Thumb Infant Resuscitator.
0310031	Tom Thumb Infant Resuscitator (Oxygen).
0310032	Tom Thumb Infant Resuscitator (Oxygen).
0310033	Tom Thumb Infant Resuscitator (Oxygen).
0310034	Tom Thumb Infant Resuscitator (Oxygen).
0310072	Tom Thumb Infant Resuscitator.
0310074	Tom Thumb Infant Resuscitator.
0310075	Tom Thumb Infant Resuscitator.
0310076	Tom Thumb Infant Resuscitator.
0310080	Tom Thumb Infant Resuscitator (RO).
0310082	Tom Thumb Infant Resuscitator (RO).
0310092	Tom Thumb Infant Resuscitator (TG).
0310093	Tom Thumb Infant Resuscitator.
0310094	Tom Thumb Infant Resuscitator.
0310096	Tom Thumb Oxygen Vent with Pole Mount
0310097	Tom Thumb Infant Resuscitator (TG).
0310098	Tom Thumb Oxygen Flow.
0310099	Tom Thumb Oxygen Vent.
0310250	Tom Thumb Conversion Kit.
0320102	Tom Thumb Rectangular Mounting Block.
0320103	Tom Thumb Rectangular Mounting Block.
0330185	Wing Nut Screw Black 25mm Thread
0330190	Universal clamp - 44mm horizontal
0330191	Clamp Spacer
0330193	Pressure gauge: 63mm dial -5 to +60 cmWG
0330200	TT460 MAIN Body Block
0330201	TT480/490 MAIN Body Block
0330202	TT495 MAIN Body Block
0330203	Pressure gauge for `Tom Thumb` Infant
0330204	Flowmeter (air) 0-15 Lpm
0330205	Flowmeter Meter Bolt
0330206	Blocking Bolt And Nut
0330207	Blanking Bolt
0330208	Inlet 10 mm
0330209	Outlet 15mm
0330210	Precision Valve
0330211	Adjustable Valve
0330212	Gauge Seal
0330213	O Ring Thick
0330214	O Ring Thin

Stock Reference	Description
0330215	Clamp Spacer
0330216	Screws For Clamp
0330217	Oxygen hose 1m. C/W indirect probe &
0330218	Oxygen Hose 3m. C/W indirect probe &
0330219	Right Angle For Hose
0330220	Fomblin OT20 Grease 100g tube
0330221	Lock Tight
0330222	Precision Valve Spring
0330223	Adjustable Valve Spring
0330224	Precision Valve Body
0330225	Precision/Adjustable Valve Seating
0330227	Precision/Adjustable Valve Seat
0330228	Precision Valve Adjustment Screw
0330229	Adjustable Valve Body
0330230	Adjustable Valve Screw
0330231	Adjustable Valve Internal Stop
0330232	Adjustable Valve Collar
0330233	Adjustable Valve Centre Screw
0330234	Adjustable Valve Side Screw
0330235	Inlet Restrictor
0330236	Replacement Gauge Face.
0330241	TT480/490 MAIN Body Block
0330242	Medirail Mounting Bracket
0330243	Adjustable Valve Side Screw. Bag 100
0330246	Blocking Bolt And Nut
0330247	Blanking Bolt
0330248	Inlet 10 mm
0330249	Outlet 15mm
0330250	Oxygen hose 1.5m. C/W DIN fitting:
0330251	Oxygen hose 3.0m. C/W DIN fitting:
0330263	Oxygen Hose 2m. C/W indirect probe &
0330268	Air Hose 3m. C/W indirect probe &
0330291	Inlet 10mm Thumbelina Inlet
0330292	Outlet 15mm Thumbelina
0330295	Outlet 10mm do not use
0330296	Blanking Bolt
0330297	Clamp Spacer - dove tailed.
0330300	Key Ring chain 1 inch ball
0330800	Label - pressure control for Tom Thumb
0340000	Labour - Tom Thumb infant resuscitator.
0340001	Training - Tom Thumb infant resuscitator
0340002	Training - Tom Thumb infant resuscitator
0350120	Packing box for Tom Thumb TT480.
0350121	Packing box for Tom Thumb TT490 Series.
0380000	Annual service - Tom Thumb

Stock Reference	Description
0380030	Tom Thumb Infant Resuscitator.
0390003	Tom Thumb Instruction Manual
0390004	Leaflet - Tom Thumb Infant Resuscitator.
0390005	Tom Thumb Training Manual
0390006	Tom Thumb Instruction Manual
0390007	Tom Thumb Instruction Manual
0390008	Tom Thumb Serial Number Label
0390009	`Tom Thumb` Label
0390011	Tom Thumb CE Label
0390015	Tom Thumb label
0390016	Address label for Tom Thumb gauge.
0390017	Gauge label - Tom Thumb
0390020	Tom Thumb Service Manual
0390021	Tom Thumb Service Manual TT460
0390022	Tom Thumb Service Manual TT480
0390023	Tom Thumb Service Manual TT490-15
0390024	Tom Thumb Service Manual TT496
0390060	Tom Thumb Instruction Manual - TT495

Comments on Stock references review:

Part number upto date

Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
0320221	Pole Clamp without slide	00007317	IHCPC1-SPECIAL	Inspiration Healthcare L	A
0320103	Tom Thumb Rectangular Mo	00009022	PP8694	Tanda Engineering Ltd	A
0330185	Wing Nut Screw Black 2	00009032	3335	R & L Enterprises Ltd	A
0330190	Universal clamp - 44mm h	00009032	A4916	R & L Enterprises Ltd	A
0330191	Clamp Spacer	00009032	A4917	R & L Enterprises Ltd	A
0330201	TT480/490 MAIN Body Bloc	00009032	0330201	R & L Enterprises Ltd	A
0330205	Flowmeter Meter Bolt	00009032	0330205	R & L Enterprises Ltd	A
0330206	Blocking Bolt And Nut	00009032	0330206	R & L Enterprises Ltd	A
0330208	Inlet 10 mm	00009032	0330208	R & L Enterprises Ltd	A
0330209	Outlet 15mm	00009032	0330209	R & L Enterprises Ltd	A
0330224	Precision Valve Body	00009032	0330224	R & L Enterprises Ltd	A
0330225	Precision/Adjustable Val	00009032	0330225	R & L Enterprises Ltd	A
0330227	Precision/Adjustable Val	00009032	0330227	R & L Enterprises Ltd	A
0330228	Precision Valve Adjustme	00009032	0330228	R & L Enterprises Ltd	A
0330229	Adjustable Valve Body	00009032	0330229	R & L Enterprises Ltd	A
0330230	Adjustable Valve Screw	00009032	0330230	R & L Enterprises Ltd	A
0330231	Adjustable Valve Interna	00009032	0330231	R & L Enterprises Ltd	A
0330232	Adjustable Valve Collar	00009032	0330232	R & L Enterprises Ltd	A
0330233	Adjustable Valve Centre	00009032	0330233	R & L Enterprises Ltd	A
0330234	Adjustable Valve Side Sc	00009032	0330234	R & L Enterprises Ltd	A
0330242	Medirail Mounting Bracke	00009032	822	R & L Enterprises Ltd	A
0330216	Screws For Clamp	00009061	483-9616	Farnell	A
0330234	Adjustable Valve Side Sc	00009073	0330234	Modern Screws	B
0330243	Adjustable Valve Side Sc	00009073	020865070206020	Modern Screws	B
0330193	Pressure gauge: 63mm dia	00009097	74656	GNW - Gauges North West	B
0330210	Precision Valve	00009117	9901-40	JNK Tooling	C
0330211	Adjustable Valve	00009117	9901-18	JNK Tooling	C
0330224	Precision Valve Body	00009117	0330224	JNK Tooling	C
0330227	Precision/Adjustable Val	00009117	0330227	JNK Tooling	C
0330228	Precision Valve Adjustme	00009117	0330228	JNK Tooling	C
0330230	Adjustable Valve Screw	00009117	0330230	JNK Tooling	C
0330234	Adjustable Valve Side Sc	00009117	0330234	JNK Tooling	C
0330235	Inlet Restrictor	00009117	0330235	JNK Tooling	C
0330207	Blanking Bolt	00009123	0330207	RS Components Ltd	A
0330213	O Ring Thick	00009123	129-050	RS Components Ltd	A
0330214	O Ring Thin	00009123	129-044	RS Components Ltd	A
0330216	Screws For Clamp	00009123	483-9616	RS Components Ltd	A
0330220	Fomblin OT20 Grease 100	00009123	666-4893	RS Components Ltd	A
0330221	Lock Tight	00009123	514-515	RS Components Ltd	A
0330296	Blanking Bolt	00009123	367-6098	RS Components Ltd	A
0320060	Flowmeter (Oxygen) 0-15	00009150	6501	Therapy Equipment Ltd	B
0330030	Dovetail (male)	00009150	4505	Therapy Equipment Ltd	B

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
0330055	Universal clamp - 44mm h	00009150	2002	Therapy Equipment Ltd	B
0330204	Flowmeter (air) 0-15 Lpm	00009150	6502	Therapy Equipment Ltd	B
0330212	Gauge Seal	00009150	6650-05	Therapy Equipment Ltd	B
0330217	Oxygen hose 1m. C/W indi	00009150	ZZ HOSE 1M	Therapy Equipment Ltd	B
0330218	Oxygen Hose 3m. C/W indi	00009150	ZZ HOSE 3M	Therapy Equipment Ltd	B
0330250	Oxygen hose 1.5m. C/W DI	00009150		Therapy Equipment Ltd	B
0330251	Oxygen hose 3.0m. C/W DI	00009150		Therapy Equipment Ltd	B
0330263	Oxygen Hose 2m. C/W indi	00009150	ZZ HOSE 2M	Therapy Equipment Ltd	B
0330268	Air Hose 3m. C/W indirec	00009150	ZZ HOSE 3M	Therapy Equipment Ltd	B
0390006	Tom Thumb Instruction Ma	00009345		Duffield Printers	A
0390007	Tom Thumb Instruction Ma	00009345		Duffield Printers	A
0350120	Packing box for Tom Thum	00009353	RPT10B	Rajapack Ltd	B
0350121	Packing box for Tom Thum	00009353	RPT17B	Rajapack Ltd	B
0390004	Leaflet - Tom Thumb Infa	00009360		Print Centre	B
0390004	Leaflet - Tom Thumb Infa	00009363		ACI Print Group Impress	B
0390003	Tom Thumb Instruction Ma	00009366		Warwick Printing	B
0390006	Tom Thumb Instruction Ma	00009366		Warwick Printing	B
3210011	NeoPEEP neonatal single	00009602	M6800100/BLU	Bunzl Healthcare	B
3210071	Single use silicone roun	00009602	M6200500D	Bunzl Healthcare	B
3210011	NeoPEEP neonatal single	00009721	M6800100/BLU	Marshall Products Limite	B
3210071	Single use silicone roun	00009721	M6200500D	Marshall Products Limite	B
0330800	Label - pressure control	00009930		Renlim Labels	B
0330200	TT460 MAIN Body Block	00010160	0330200	KSJ Engineering Limited	B
0330201	TT480/490 MAIN Body Bloc	00010160	0330201	KSJ Engineering Limited	B
0330202	TT495 MAIN Body Block	00010160	0330202	KSJ Engineering Limited	B
0330205	Flowmeter Meter Bolt	00010160	0330205	KSJ Engineering Limited	B
0330206	Blocking Bolt And Nut	00010160	0330206	KSJ Engineering Limited	B
0330208	Inlet 10 mm	00010160	0330208	KSJ Engineering Limited	B
0330209	Outlet 15mm	00010160	0330209	KSJ Engineering Limited	B
0330215	Clamp Spacer	00010160	9901-22	KSJ Engineering Limited	B
0330241	TT480/490 MAIN Body Bloc	00010160	9901-01	KSJ Engineering Limited	B
0330246	Blocking Bolt And Nut	00010160	9901-06	KSJ Engineering Limited	B
0330248	Inlet 10 mm	00010160	4701-61	KSJ Engineering Limited	B
0330249	Outlet 15mm	00010160	9901-34	KSJ Engineering Limited	B
0330295	Outlet 10mm do not use	00010160	0330295	KSJ Engineering Limited	B
0330203	Pressure gauge for `Tom	00010395	611.10.063	Wika Instruments Ltd	B
0330236	Replacement Gauge Face.	00010395	1391682	Wika Instruments Ltd	B
0390015	Tom Thumb label	00010665	TT IR	Pendle Signs & Plastics	B
0390016	Address label for Tom Th	00010665	TT ADR	Pendle Signs & Plastics	B
0390017	Gauge label - Tom Thumb	00010665	TT VIA	Pendle Signs & Plastics	B
0330200	TT460 MAIN Body Block	00010725	0330200	MAJ Hi-Spec Ltd	B
0330201	TT480/490 MAIN Body Bloc	00010725	0330201	MAJ Hi-Spec Ltd	B
0330202	TT495 MAIN Body Block	00010725	0330202	MAJ Hi-Spec Ltd	B
0330205	Flowmeter Meter Bolt	00010725	0330205	MAJ Hi-Spec Ltd	B
0330206	Blocking Bolt And Nut	00010725	0330206	MAJ Hi-Spec Ltd	B

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
0330207	Blanking Bolt	00010725	0330207	MAJ Hi-Spec Ltd	B
0330208	Inlet 10 mm	00010725	0330208	MAJ Hi-Spec Ltd	B
0330209	Outlet 15mm	00010725	0330209	MAJ Hi-Spec Ltd	B
0330219	Right Angle For Hose	00010770	2020	Chelmer Pneumatics Ltd	B
0120140	Adapter 15mm I.D. - 15m	00011844	PF 1515	Instrumentation Industri	A
0330222	Precision Valve Spring	00012028	C6409	Harlow Springs Limited	B
0330223	Adjustable Valve Spring	00012028	9968	Harlow Springs Limited	B
0330300	Key Ring chain 1 inch ba	00012395	BC6	Seton	B

Comments on Suppliers:

Suppliers up to date,
new instruction manual printers needs official review

Sales Information

Stock Reference	Description	2011	2012	2013	2014	2015	2016	2017
0310027	Tom Thumb Infant Resuscitator (Air).							
0310029	Tom Thumb Infant Resuscitator (Air).							
0310030	Tom Thumb Infant Resuscitator.	171	259	94	129	67	48	44
0310031	Tom Thumb Infant Resuscitator (Oxygen).							
0310032	Tom Thumb Infant Resuscitator (Oxygen).			3				
0310033	Tom Thumb Infant Resuscitator (Oxygen).							
0310034	Tom Thumb Infant Resuscitator (Oxygen).	3		1	2	1		
0310072	Tom Thumb Infant Resuscitator.							
0310074	Tom Thumb Infant Resuscitator.							
0310075	Tom Thumb Infant Resuscitator.							
0310076	Tom Thumb Infant Resuscitator.							
0310080	Tom Thumb Infant Resuscitator (RO).		2					
0310082	Tom Thumb Infant Resuscitator (RO).							
0310092	Tom Thumb Infant Resuscitator (TG).							
0310093	Tom Thumb Infant Resuscitator.	6						
0310094	Tom Thumb Infant Resuscitator.	4		9		6	1	1
0310096	Tom Thumb Oxygen Vent with Pole Mount			1				
0310097	Tom Thumb Infant Resuscitator (TG).			5	7	18	18	1
0310098	Tom Thumb Oxygen Flow.							
0310099	Tom Thumb Oxygen Vent.			1	1			
0310250	Tom Thumb Conversion Kit.		6	6	28	3	33	
0320102	Tom Thumb Rectangular Mounting Block.							
0320103	Tom Thumb Rectangular Mo							
0330185	Wing Nut Screw Black 2							
0330190	Universal clamp - 44mm h			2	100	50		43
0330191	Clamp Spacer			1				1
0330193	Pressure gauge: 63mm dia					19	22	17
0330200	TT460 MAIN Body Block							
0330201	TT480/490 MAIN Body Bloc	1						1
0330202	TT495 MAIN Body Block			1				
0330203	Pressure gauge for `Tom	23	10	21	9		1	
0330204	Flowmeter (air) 0-15 Lpm							
0330205	Flowmeter Meter Bolt							
0330206	Blocking Bolt And Nut	16	12	10				
0330207	Blanking Bolt							
0330208	Inlet 10 mm	46	12	10		5		
0330209	Outlet 15mm					15	7	5
0330210	Precision Valve	6		3	2	3	8	7
0330211	Adjustable Valve	3	2	3	3	5	7	7
0330212	Gauge Seal	71	40	28	28	69	65	73
0330213	O Ring Thick	119	8	34	193	90	95	59
0330214	O Ring Thin	650	48	227	137	534	541	476

Stock Reference	Description	2011	2012	2013	2014	2015	2016	2017
0330215	Clamp Spacer							
0330216	Screws For Clamp							2
0330217	Oxygen hose 1m. C/W indi			6	6	2	4	13
0330218	Oxygen Hose 3m. C/W indi	25	2	7	17	14		2
0330219	Right Angle For Hose	2						
0330220	Fomblin OT20 Grease 100					1		
0330221	Lock Tight							
0330222	Precision Valve Spring		1					
0330223	Adjustable Valve Spring		2		1			
0330224	Precision Valve Body							
0330225	Precision/Adjustable Val							
0330227	Precision/Adjustable Val		2	1		2	3	
0330228	Precision Valve Adjustme							
0330229	Adjustable Valve Body			1			1	
0330230	Adjustable Valve Screw					4		
0330231	Adjustable Valve Interna							
0330232	Adjustable Valve Collar							
0330233	Adjustable Valve Centre							
0330234	Adjustable Valve Side Sc				3			
0330235	Inlet Restrictor					3		
0330236	Replacement Gauge Face.	18	5	13	14	24	10	17
0330241	TT480/490 MAIN Body Bloc							
0330242	Medirail Mounting Bracke							
0330243	Adjustable Valve Side Sc							
0330246	Blocking Bolt And Nut							
0330247	Blanking Bolt							
0330248	Inlet 10 mm							
0330249	Outlet 15mm							
0330250	Oxygen hose 1.5m. C/W DI							
0330251	Oxygen hose 3.0m. C/W DI							
0330263	Oxygen Hose 2m. C/W indi			3	12	2		2
0330268	Air Hose 3m. C/W indirec							
0330291	Inlet 10mm Thumbelina Inlet							
0330292	Outlet 15mm Thumbelina							
0330295	Outlet 10mm do not use					8		
0330296	Blanking Bolt							3
0330297	Clamp Spacer - dove tailed.							
0330300	Key Ring chain 1 inch ba							
0330800	Label - pressure control							
0340000	Labour - Tom Thumb infant resuscitator.							
0340001	Training - Tom Thumb infant resuscitator							
0340002	Training - Tom Thumb infant resuscitator							
0350120	Packing box for Tom Thum							
0350121	Packing box for Tom Thum							
0380000	Annual service - Tom Thumb							

Stock Reference	Description	2011	2012	2013	2014	2015	2016	2017
0380030	Tom Thumb Infant Resuscitator.							
0390003	Tom Thumb Instruction Ma							
0390004	Leaflet - Tom Thumb Infa	6		50		10		
0390005	Tom Thumb Training Manual							
0390006	Tom Thumb Instruction Ma	9			20			
0390007	Tom Thumb Instruction Ma	9						
0390008	Tom Thumb Serial Number Label							
0390009	`Tom Thumb` Label							
0390011	Tom Thumb CE Label							
0390015	Tom Thumb label						5	
0390016	Address label for Tom Th							
0390017	Gauge label - Tom Thumb							
0390020	Tom Thumb Service Manual							
0390021	Tom Thumb Service Manual TT460							
0390022	Tom Thumb Service Manual TT480							
0390023	Tom Thumb Service Manual TT490-15							
0390024	Tom Thumb Service Manual TT496							
0390060	Tom Thumb Instruction Manual - TT495							

Comments on Sales Information:

Units still selling albeit in low numbers

Countries Review

Country	2011	2012	2013	2014	2015	2016	2017
B Belgium		[X]	[X]				[X]
BRA Brazil							
C China				[X]			
CAN Canada							
CZ Czech Republic				[X]	[X]		
F France	[X]	[X]	[X]	[X]	[X]	[X]	[X]
HK Hong Kong	[X]						
IN India			[X]				
IT Italy						[X]	[X]
MA Malaysia							
NE Netherlands				[X]	[X]		
NG Nigera				[X]			
PA Pakistan					[X]		
PO Portugal						[X]	
RU Russia	[X]	[X]	[X]	[X]		[X]	[X]
SAU Saudi Arabia		[X]	[X]				
SRI Sri Lanka					[X]		
SWI Switzerland					[X]		
T Turkey		[X]	[X]				
UAE U A E							
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 new countries , therefore no new risks

Returns and Q.A. Fails Review

Stock Reference	Fault	2011	2012	2013	2014	2015	2016	2017
0310030	Needs Evaluating							1
0310030	Adjusted Factory Set Valves			3			1	1
0310030	Calibrated Gauge					1		
0310030	Converted To TT480		1					
0310030	Customer Declined Quotation						2	
0310030	Damaged Pressure Gauge				1	1		2
0310030	N/a							
0310030	New			1		2		1
0310030	No Fault Found						2	
0310030	No Fault Return To Stock							
0310030	Repaired Clamp And Serviced						1	
0310030	Replace Gauge And Service				1	1	4	3
0310030	Replaced Gauge Face And Service						1	
0310030	Serviced						1	9
0310030	Serviced / Adjusted Factory Set Valves		3	11	11	10	12	2
0310030	Stuck Gauge							1
0310030	Tested					1	1	
0310031	Needs Evaluating							1
0310031	Serviced						2	
0310032	Adjusted Factory Set Valves							
0310032	Calibrated Gauge							
0310032	Converted To TT480		1					
0310032	Damaged Pressure Gauge							
0310032	New							1
0310032	Replaced Gauge Face And Service							2
0310032	Serviced							
0310032	Serviced / Adjusted Factory Set Valves			1				
0310032	Serviced and Upgraded							3
0310032	Tested			1				
0310033	Replace Gauge And Service					1		
0310033	Serviced							
0310034	Adjusted Factory Set Valves							
0310034	Converted To TT480					1		
0310034	Damaged Pressure Gauge							
0310034	New							1
0310034	Serviced			1				
0310034	Serviced / Adjusted Factory Set Valves	1	1	2		5		1
0310034	Unchecked - Returned To Stock							
0310076	New							
0310080	Replace Gauge And Service				1			
0310094	Converted To TT480			9				
0310094	Not Delivering More Than 10cm						1	

Stock Reference	Fault	2011	2012	2013	2014	2015	2016	2017
0310094	Replace Gauge And Service							1
0310094	Replaced Gauge Face And Service							1
0310097	Serviced							1
0310097	Serviced / Adjusted Factory Set Valves				1	1	1	1
0310098	Serviced / Adjusted Factory Set Valves				3	1		
0310099	Serviced / Adjusted Factory Set Valves				2			
0330193	Needs Evaluating							2
0330201	Needs Evaluating					10		
0330217	Unchecked - Returned To Stock				8			
0380030	Needs Evaluating						3	
0390023	Serviced							

Comments on Returns:

new return type stuck gauge,
single unit failure, no reproducible. appears to be a one off unit

Comments on Risks with Returns and Potential Re-work:

Stuck gauge added to Risk File.

Do to comments from auditing body. have added all unique types to risk file. (mostly broken face plates)

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

No design changes

Comments on Risks with Design Changes:

No design changes no new risks

User Instructions Review

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
15572	Tom Thumb Instructions for Use / User Manual TT490-15	01/09/15
15571	Tom Thumb Instructions for Use User Manual TT480	01/09/15
15570	Tom Thumb Instructions for Use User Manual 0310027	01/09/15
15511	Tom Thumb Instructions for Use User Manual TT480 Instructions D...	24/08/15
15510	Tom Thumb Instructions for Use User Manual TT480 Instructions D...	24/08/15
15509	Tom Thumb Instructions for Use User Manual TT480 Instructions D...	24/08/15
13047	Tom Thumb Instructions for Use User Manual French	14/10/13
12211	Tom Thumb Instructions for Use User Manual TT495-15	30/11/12
11732	Tom Thumb Instructions for Use User Manual	23/03/12
8512	Tom Thumb Instructions for Use User Manual NeoPEEP	06/07/11
8506	Instructions For Use Tom Thumb TT495	06/07/11
5107	Instructions For Use Tom Thumb TT480	23/02/09

Comments on User Instructions:

No user instructions updates currently.

Comments on Risks User Instructions:

Labels Review

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
20970	Tom Thumb Labels Top Box Sticker example	17/07/17
15638	Tom Thumb Labels Original labels	16/09/15
11748	Tom Thumb Labels 0390016 Address Sticker Round outside Gauge	27/03/12
11747	Tom Thumb Labels Caution Label 0390018 Top Block	27/03/12
11746	Tom Thumb Labels 0390017 Front of Gauge Sticker	27/03/12
11745	Tom Thumb Labels 0390015 Front Block Logo Sticker	27/03/12
11744	Tom Thumb Labels 0390010 Adjustable Value Sticker	27/03/12
11743	Tom Thumb Labels Part number to Label	27/03/12
11742	Tom Thumb Labels TT491 Serial	27/03/12
11741	Tom Thumb Labels TT490 Serial	27/03/12
11740	Tom Thumb Labels Serial TT480	27/03/12
5922	Tom Thumb Labels mediprema labels	14/05/09
2254	Tom Thumb Parts List Adj label 04	19/06/07
2204	Tom Thumb Labels Tomb Thumb Infant Resuscitator	19/06/07

Comments on Labels:

added top box sticker as it was missing from the tech file due to being produced via the system at point of requirement,

Comments on Risks Labels:

no risks identified with lable

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
23431	VM3COP50.14 Calibration / Test Sheet Blank Tom Thumbs	26/10/17
23423	VM3COP50.20 TT Component Inspection	26/10/17
23108	Tom Thumb OES (OEM) CE Certificate Wika ISO 9001:2008	22/10/17
22982	Tom Thumb Description of Accessories NeoPeep File Location	19/10/17
22910	Tom Thumb Product Life Background Notes for Tom Thumb Life expect...	18/10/17
22906	Tom Thumb Design Input Device History Tom Thumb Design	18/10/17
22902	Tom Thumb Design Input Device History Background Notes for Tom ...	18/10/17
22898	Tom Thumb Description of Accessories Background Notes for Tom Th...	18/10/17
22860	Tom Thumb Location of responsibilities JK. Location of Responsi...	18/10/17
22531	Tom Thumb Sterilisation Tomb Thumb Sterility	12/10/17
22519	Tom Thumb Expected Life of Products Tom Thumb life Rationale (...)	11/10/17
22494	Tom Thumb Purchase specifications Flowmeter	10/10/17
22492	Tom Thumb Purchase specifications Fomblin RT15	10/10/17
22490	Tom Thumb Purchase specifications Wika 6111.10 gauge	10/10/17
22488	Tom Thumb Specifications of Materials Nitrile O rings	10/10/17
22486	Tom Thumb Background Notes for Tom Thumb	10/10/17
22482	Tom Thumb Post Market Surveillance	10/10/17
22480	Tom Thumb Literature reviews NewbornLifeSupportClinicalGuideline...	10/10/17
22478	Tom Thumb Risk analysis reports Risk assessment	10/10/17
22240	Tom Thumb Work Instructions and Tests GNW 21_09_2017 (4)	26/09/17
22238	Tom Thumb Work Instructions and Tests GNW 21_09_2017 (3)	26/09/17
22236	Tom Thumb Work Instructions and Tests GNW 21_09_2017 (2)	26/09/17
22234	Tom Thumb Work Instructions and Tests GNW 21_09_2017 (1)	26/09/17
22120	VM3COP50.19 TT480 service manual	18/09/17
21995	Tom Thumb Product Life User feedback old tom thumbs	11/09/17
21738	Tom Thumb PPE Equipment	04/09/17
21722	Tom Thumb Notified Body Reports 8348484 Final Assessment E-Repor...	04/09/17
21720	Tom Thumb Machinery Equipment	04/09/17
21716	Tom Thumb Design Input Device History BS EN 60601-1-6 2015 Non ...	01/09/17
21712	Tom Thumb Design Input Device History BS EN 62366-1 2015 non co...	01/09/17
21694	Product Control Tom Thumb	31/08/17
21625	Tom Thumb QA Procedures Example QA Report Barcode 1009081	27/08/17
21623	Tom Thumb QA Procedures Example QA Records Tom Thumb 0310030	27/08/17
21556	VM3COP02.02 Viamed Company Responsibility's organisation chart s...	22/08/17
20970	Tom Thumb Labels Top Box Sticker example	17/07/17
20968	Tom Thumb Expected Life of Products Proof2	17/07/17
20966	Tom Thumb Expected Life of Products Proof1	17/07/17
20916	QC 33b Tom Thumb TT480 Service Sheet	11/07/17
19538	Tom Thumb Purchase specifications GNW Instrumentation - Tom Thum...	07/04/17
19534	Tom Thumb EC Declaration of Conformance	06/04/17
18139	Tom Thumb Work Instructions and Tests NWG test certificates 2	29/11/16
18138	Tom Thumb Work Instructions and Tests NWG test certificates	29/11/16

Document ID	Description	Date Added/Updated
18115	Tom Thumb Purchase specifications Tom Thumb parts cost compariso...	21/11/16

Comments on Document Changes:

Mainly added supporting files for remote audit by notified body.

Comments on Risks with Document Changes:

No risks with documentation additions

Internal Issues Review

Number of Issues reviewed: 118

Issue ID	Subject
92966	Office Meeting Any other business Mediprema and orders for 0330190.
106558	Office Meeting Any Other Business 0330203 quotation from Wika
106557	Office Meeting Any Other Business 0330203 quotation from Wika
92069	Office Meeting Purchase Back Orders Review 0330218 x 2, 0330263 x 1
92068	Office Meeting Purchase Back Orders Review 0330218 x 2, 0330263 x 1
103213	Office Meeting Other Are we using the correct grade grease for use with Tom Thumb resuscitators
76985	Office Meeting Sales Back Orders Review - By Customer Backorder 00000550 0380000 ORD81769
90304	Office Meeting Sales Back Orders Review - By Customer Backorder 00000600 0330263 ORD85166
92196	Office Meeting Sales Back Orders Review - By Customer Backorder 00000600 0330263 ORD85632
92122	Office Meeting Sales Back Orders Review - By Customer Backorder 00000790 0330218 ORD85630
100828	Office Meeting Sales Back Orders Review - By Customer Backorder 00000970 0330213 ORD87850
99098	Office Meeting Sales Back Orders Review - By Customer Backorder 00001310 0330212 ORD87424
82145	Office Meeting Sales Back Orders Review - By Customer Backorder 00001350 0330193 ORD82982
91318	Office Meeting Sales Back Orders Review - By Customer Backorder 00001350 0330210 ORD85437
96974	Office Meeting Sales Back Orders Review - By Customer Backorder 00001761 0330217 ORD86883
98822	Office Meeting Sales Back Orders Review - By Customer Backorder 00001761 0330217 ORD87341
96973	Office Meeting Sales Back Orders Review - By Customer Backorder 00001761 0330263 ORD86883
84814	Office Meeting Sales Back Orders Review - By Customer Backorder 00002470 0330212 ORD83711
90904	Office Meeting Sales Back Orders Review - By Customer Backorder 00002600 0380000 ORD85276
91772	Office Meeting Sales Back Orders Review - By Customer Backorder 00003580 0380000 ORD85251
103778	Office Meeting Sales Back Orders Review - By Customer Backorder 00003710 0330193 ORD88479
100933	Office Meeting Sales Back Orders Review - By Customer Backorder 00003710 0330210 ORD87878
95281	Office Meeting Sales Back Orders Review - By Customer Backorder 00003710 0330236 ORD86426
92807	Office Meeting Sales Back Orders Review - By Customer Backorder 00003785 0310030 ORD85825

Issue ID	Subject
103190	Office Meeting Sales Back Orders Review - By Customer Backorder 00003785 0310030 ORD88370
84705	Office Meeting Sales Back Orders Review - By Customer Backorder 00003785 0340000 ORD83691
85273	Office Meeting Sales Back Orders Review - By Customer Backorder 00003800 0330209 ORD83892
88388	Office Meeting Sales Back Orders Review - By Customer Backorder 00004992 0310030 ORD84717
96362	Office Meeting Sales Back Orders Review - By Customer Backorder 00004992 0380000 ORD85194
100927	Office Meeting Sales Back Orders Review - By Customer Backorder 00005260 0330193 ORD87872
82901	Office Meeting Sales Back Orders Review - By Customer Backorder 00006395 0310030 ORD83191
84035	Office Meeting Sales Back Orders Review - By Customer Backorder 00006777 0310097 ORD83534
94296	Office Meeting Sales Back Orders Review - By Customer Backorder 00006777 0310097 ORD86178
93039	Office Meeting Sales Back Orders Review - By Customer Backorder 00007291 0310030 ORD85867
96358	Office Meeting Sales Back Orders Review - By Customer Backorder 00007291 0310030 ORD86739
102890	Office Meeting Sales Back Orders Review - By Customer Backorder 00007291 0310030 ORD88316
81979	Office Meeting Sales Back Orders Review - By Customer Backorder 00007291 0330212 ORD82924
96237	Office Meeting Sales Back Orders Review - By Customer Backorder 00007356 0380000 ORD86664
94422	Office Meeting Sales Back Orders Review - By Customer Backorder 00012625 0310094 ORD86206
95473	Office Meeting Sales Back Orders Review - By Customer Backorder 00012967 0330212 ORD86498
92967	Office Meeting Other Historic specials pricing
81513	Office Meeting Back Order Report POR10994 0330216 //
81377	Office Meeting Back Order Report POR10994 0330216 //
81201	Office Meeting Back Order Report POR10994 0330216 //
83763	Office Meeting Back Order Report POR11040 0330212 //
83266	Office Meeting Back Order Report POR11040 0330212 //
88741	Office Meeting Back Order Report POR11129 0330234 //
88412	Office Meeting Back Order Report POR11129 0330234 //
91047	Office Meeting Back Order Report POR11194 0330263 //
92134	Office Meeting Back Order Report POR11225 0330218 //

Issue ID	Subject
95301	Office Meeting Back Order Report POR11281 0330236 //
97045	Office Meeting Back Order Report POR11317 0330217 //
97046	Office Meeting Back Order Report POR11317 0330263 //
97859	Office Meeting Back Order Report POR11319 0350120 //
99303	Office Meeting Back Order Report POR11356 0330217 //
99021	Office Meeting Back Order Report POR11356 0330217 //
99450	Office Meeting Back Order Report POR11365 0330193 //
103451	Office Meeting Back Order Report POR11365 0330193 29/09/2017
104098	Office Meeting Back Order Report POR11454 0330216 //
104099	Office Meeting Back Order Report POR11454 0330296 //
104653	Office Meeting Back Order Report POR11455 0330212 //
104100	Office Meeting Back Order Report POR11455 0330212 //
104575	Office Meeting Back Order Report POR11465 0330191 //
104571	Office Meeting Back Order Report POR11465 0330191 //
104569	Office Meeting Back Order Report POR11466 0330217 //
57882	Office Meeting Production Problems Precision valve screw 0330228
84611	Office Meeting VIAMED Stock Meeting Production In Production List (556)
90695	Office Meeting Sale or Returns Request Scanning Item to Sale or return
94883	Office Meeting Sale or Returns Returned Items SOR781
77441	Office Meeting Service extension Service Visit 43
103719	Office Meeting Sale or Returns SMC Northern Ireland exhibition stock - Urgent
104341	Office Meeting Other Standard to apply to Tom Thumb Infant Resuscitator
68681	Office Meeting Production TOM THUMB 0330232 Adjustable valve collar
101066	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M1 Corrective Action
101067	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M1 Effectiveness verification
101068	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M1 Initial Investigation

Issue ID	Subject
101065	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M1 Initial Investigation
101063	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M2 Corrective Action
101064	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M2 Effectiveness verification
101069	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M2 Initial Investigation
101062	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M2 Initial Investigation
101060	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M3 Corrective Action
101061	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M3 Effectiveness verification
101070	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M3 Initial Investigation
101059	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M3 Initial Investigation
101057	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M4 Corrective Action
101058	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M4 Effectiveness verification
101071	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M4 Initial Investigation
101056	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M4 Initial Investigation
101054	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M5 Corrective Action
101055	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M5 Effectiveness verification
102035	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M5 Initial Investigation
101072	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M5 Initial Investigation
101053	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M5 Initial Investigation
101051	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M6 Corrective Action
101052	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M6 Effectiveness verification
101073	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M6 Initial Investigation
101050	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M6 Initial Investigation
101048	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M7 Corrective Action
101049	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M7 Effectiveness verification
101074	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M7 Initial Investigation
101047	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M7 Initial Investigation

Issue ID	Subject
101045	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M8 Corrective Action
101046	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M8 Effectiveness verification
101075	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M8 Initial Investigation
101044	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-M8 Initial Investigation
102040	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-N1 Corrective Action
102039	Office Meeting BSI Major Non Conformances Tom Thumb 1511824-201709-N1 Initial Investigation
75534	Office Meeting Potential New products Tom Thumb new producer
83775	Office Meeting Any Other Business Tom Thumb parts cost comparisons 17-11-2016
83774	Office Meeting Any Other Business Tom Thumb parts cost comparisons 17-11-2016
89791	Office Meeting Any other business Tom Thumb service letters
89790	Office Meeting Any other business Tom Thumb service letters
89789	Office Meeting Any other business Tom Thumb service letters
100174	Office Meeting Product Feedback Negative Tom Thumb with stuck gauge
100173	Office Meeting Product Feedback Negative Tom Thumb with stuck gauge
104434	Office Meeting Repairs Review - General TT480 0401281
86420	Office Meeting Future Reviews - Waste Wee report requires some weights

Comments on Issues:

Mainly so processing and backorders

100174 VIAMED Feedback Product Feedback Negative Product Feedback Negative regarding the stuck gauge. added to risk file single one off unit.

Lots of official BSI Non conformances,
JSL still working on ticking of them one by one, we believe we have everything covered. but will not know until we get to the end.

Comments on Risks with Issues:

100174 VIAMED Feedback Product Feedback Negative Product Feedback Negative
104434 Report of unit that will not go above 10 cmh20.

Lots of official BSI Non conformances,
JSL still working on ticking of them one by one, we believe we have everything covered. but will not know

until we get to the end.
Certification risk currently.

VIAMED Sales And Marketing - Any other business

Mediprema and orders for 0330190.

Issue ID #92966

Date Created 18/Apr/2017

Issued To: Sarah Walton

Completed Status: 04 May 2017

Notes:

Added by Steve Nixon sent to Sarah Walton
Ref. Mediprema and orders for 0330190.

There is a memo on Opera (RS, dating back to July 2014) stating that the clamps should be USD \$15.00. I believe this is historic based on the price they paid for the previous version and when the exchange rate was higher. Please use USD \$15.00 for the current order.

I will look into it, but it doesn't explain why they were invoiced at \$14.14 in July 2015. Nor does it explain why there (albeit small) is a price difference between Opera and Intratsats.

18 Apr 2017 Sarah Walton
OK thank you.

Issues:92966

VIAMED Stock Meeting - Any Other Business

0330203 quotation from Wika

Issue ID #106558

Date Created 26/Oct/2017

Issued To: Derek Lamb

Completed Status: Still Outstanding

Notes:

Copy Issue Main Issue #106557

Added by Steve Nixon sent to Steve Nixon

See attached.

email to Wika:

Tomasz.Bialkowski@wika.com

Hi Tomasz

Thank you for the quote and the artwork. As discussed with John we need the artwork amended:

Change cmWG to cm H2O

At the moment we can not order any gauges as we have an ISO audit review next week and we currently have a good number of gauges in stock. Can you please also supply pricing for the replacement gauge face, I believe that the part number is 1391682.

Issues:106558

VIAMED Stock Meeting - Any Other Business

0330203 quotation from Wika

Issue ID #106557

Date Created 26/Oct/2017

Issued To: Steve Nixon

Completed Status: Still Outstanding

Linked Files

26 Oct 2017 0330203 quote - WIKA 2017-10-18

Notes:

Added by Steve Nixon sent to Steve Nixon
See attached.

email to Wika:

Tomasz.Bialkowski@wika.com

Hi Tomasz

Thank you for the quote and the artwork. As discussed with John we need the artwork amended:

Change cmWG to cm H2O

At the moment we can not order any gauges as we have an ISO audit review next week and we currently have a good number of gauges in stock. Can you please also supply pricing for the replacement gauge face, I believe that the part number is 1391682.

26 Oct 2017 Steve Nixon

Also querying the part number has changed from 611.10.063 to 9758709 and whether there is a specific reason for this?

Issues:106557

VIAMED Stock Meeting - Purchase Back Orders Review

0330218 x 2, 0330263 x 1

Issue ID #92069

Date Created 03/Apr/2017

Issued To: Katie Evans

Completed Status: 11 Apr 2017

Notes:

Copy Issue Main Issue #92068

Added by Steve Nixon sent to Jonathan Connor

Looks like we need to order some hoses for sales orders:

0330218 x 2

0330263 x 1

04 Apr 2017 Katie Evans

Issues:92069

VIAMED Stock Meeting - Purchase Back Orders Review

0330218 x 2, 0330263 x 1

Issue ID #92068

Date Created 03/Apr/2017

Issued To: Jonathan Connor

Completed Status: 11 Apr 2017

Notes:

Added by Steve Nixon sent to Jonathan Connor

Looks like we need to order some hoses for sales orders:

0330218 x 2

0330263 x 1

04 Apr 2017 Jonathan Connor

0330218 on order, 0330263 repair complete

Issues:92068

VIAMED Management Meeting - Other

Are we using the correct grade grease for use with Tom Thumb resuscitators

Issue ID #103213

Date Created 19/Sep/2017

Issued To: Derek Lamb

Completed Status: Still Outstanding

Notes:

Added by Steve Nixon sent to Derek Lamb

Would grade YNX be more suitable?

Opera: 0330220

RS: 666-4893

Fomblin Perfluoropolyether OT20-100G Grease, 100 g Tube

Fomblin Grease

Fomblin fluorinated fluid base oils from Solvay Solexis.

High temperature, high performance greases

Particularly resistant to oxidation and to chemical agents

Compatible with all types of material over a wide range of temperatures

Fomblin can be used in the presence of all organic substances which are not highly fluorinated

Grades:

Y VAC 3 - Lubrication of mechanical parts operating at high vacuum in contact with aggressive chemicals or oxygen

OT 20 - Lubrication of mechanical parts subjected to low loads

UT 18 - Lubrication of mechanical parts used in wide temperature intervals

RT 15 - Lubrication of mechanical parts requiring boundary (extreme pressure)

YNX - Particularly stable with oxygen at high pressure and for use in static operating conditions

19 Sep 2017 Derek Lamb

0310030

Issues:103213

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00000550 0380000 ORD81769

Issue ID #76985

Date Created 16/Aug/2016

Issued To: General

Completed Status: 29 Dec 2016

Stock Ref: 0380000

Opera A/c: 00000550

Order Number: ORD81769

Notes:

16 Aug 2016 Catherine Spence
Contract

Issues:76985

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00000600 0330263 ORD85166

Issue ID #90304

Date Created 02/Mar/2017

Issued To: General

Completed Status: 03 Apr 2017

Stock Ref: 0330263

Opera A/c: 00000600

Order Number: ORD85166

Notes:

02 Mar 2017 08:27:24 AM Catherine Spence
Back Order - Supplier

Issues:90304

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00000600 0330263 ORD85632

Issue ID #92196

Date Created 05/Apr/2017

Issued To: General

Completed Status: 05 Apr 2017

Stock Ref: 0330263

Opera A/c: 00000600

Order Number: ORD85632

Notes:

05 Apr 2017 07:50:09 AM Catherine Spence
Back Order - Supplier
no free stock

Issues:92196

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00000790 0330218 ORD85630

Issue ID #92122

Date Created 04/Apr/2017

Issued To: General

Completed Status: 07 Apr 2017

Stock Ref: 0330218

Opera A/c: 00000790

Order Number: ORD85630

Notes:

04 Apr 2017 08:03:29 AM Catherine Spence
Back Order - Supplier

07 Apr 2017 07:25:05 AM Catherine Spence
Shipping Fri 07 Apr 2017

Issues:92122

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00000970 0330213 ORD87850

Issue ID #100828

Date Created 16/Aug/2017

Issued To: General

Completed Status: 16 Aug 2017

Stock Ref: 0330213

Opera A/c: 00000970

Order Number: ORD87850

Notes:

16 Aug 2017 07:43:40 AM Catherine Spence
Shipping Wed 16 Aug 2017

Issues:100828

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00001310 0330212 ORD87424

Issue ID #99098

Date Created 20/Jul/2017

Issued To: General

Completed Status: 25 Jul 2017

Stock Ref: 0330212

Opera A/c: 00001310

Order Number: ORD87424

Notes:

20 Jul 2017 02:41:51 PM Katie Evans

See Attached Notes

EH emailed regarding carriage charge

20 Jul 2017 04:44:43 PM Emily Hanson

okay to go

21 Jul 2017 07:38:58 AM Catherine Spence

Shipping Fri 21 Jul 2017

24 Jul 2017 08:31:48 AM Catherine Spence

Shipping Mon 24 Jul 2017

Issues:99098

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00001350 0330193 ORD82982

Issue ID #82145

Date Created 24/Oct/2016

Issued To: General

Completed Status: 24 Oct 2016

Stock Ref: 0330193

Opera A/c: 00001350

Order Number: ORD82982

Notes:

24 Oct 2016 08:11:32 AM Catherine Spence
Shipping Mon 24 Oct 2016

Issues:82145

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00001350 0330210 ORD85437

Issue ID #91318

Date Created 21/Mar/2017

Issued To: General

Completed Status: 22 Mar 2017

Stock Ref: 0330210

Opera A/c: 00001350

Order Number: ORD85437

Notes:

21 Mar 2017 07:47:05 AM Catherine Spence
Shipping Tue 21 Mar 2017

Issues:91318

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00001761 0330217 ORD86883

Issue ID #96974

Date Created 19/Jun/2017

Issued To: General

Completed Status: 27 Jun 2017

Stock Ref: 0330217

Opera A/c: 00001761

Order Number: ORD86883

Notes:

19 Jun 2017 12:31:22 PM Sophie Lines
Aware of leadtime

20 Jun 2017 08:56:58 AM Catherine Spence
Back Order - Supplier

27 Jun 2017 07:43:54 AM Catherine Spence
Shipping Tue 27 Jun 2017

Issues:96974

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00001761 0330217 ORD87341

Issue ID #98822

Date Created 14/Jul/2017

Issued To: General

Completed Status: 27 Jul 2017

Stock Ref: 0330217

Opera A/c: 00001761

Order Number: ORD87341

Notes:

14 Jul 2017 04:51:59 PM Sophie Lines
£10.00 carriage. Emailed customer, awaiting response.

Already aware of 2-3 week lead time

17 Jul 2017 09:43:20 AM Emily Hanson
okay to go

18 Jul 2017 07:44:42 AM Catherine Spence
Back Order - Supplier

Issues:98822

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00001761 0330263 ORD86883

Issue ID #96973

Date Created 19/Jun/2017

Issued To: General

Completed Status: 27 Jun 2017

Stock Ref: 0330263

Opera A/c: 00001761

Order Number: ORD86883

Notes:

19 Jun 2017 12:31:15 PM Sophie Lines
Aware of leadime

Issues:96973

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00002470 0330212 ORD83711

Issue ID #84814

Date Created 05/Dec/2016

Issued To: General

Completed Status: 05 Dec 2016

Stock Ref: 0330212

Opera A/c: 00002470

Order Number: ORD83711

Notes:

05 Dec 2016 08:34:35 AM Catherine Spence
Shipping Mon 05 Dec 2016

Issues:84814

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00002600 0380000 ORD85276

Issue ID #90904

Date Created 13/Mar/2017

Issued To: General

Completed Status: 04 May 2017

Stock Ref: 0380000

Opera A/c: 00002600

Order Number: ORD85276

Notes:

13 Mar 2017 07:40:34 AM Catherine Spence
Shipping Mon 13 Mar 2017

Issues:90904

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00003580 0380000 ORD85251

Issue ID #91772

Date Created 28/Mar/2017

Issued To: General

Completed Status: 30 Mar 2017

Stock Ref: 0380000

Opera A/c: 00003580

Order Number: ORD85251

Notes:

28 Mar 2017 01:52:19 PM Sarah Walton

See Attached Notes

This can now be invoiced

Issues:91772

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00003710 0330193 ORD88479

Issue ID #103778

Date Created 26/Sep/2017

Issued To: General

Completed Status: 26 Sep 2017

Stock Ref: 0330193

Opera A/c: 00003710

Order Number: ORD88479

Notes:

26 Sep 2017 07:49:34 AM Catherine Spence
Shipping Tue 26 Sep 2017

Issues:103778

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00003710 0330210 ORD87878

Issue ID #100933

Date Created 17/Aug/2017

Issued To: General

Completed Status: 25 Aug 2017

Stock Ref: 0330210

Opera A/c: 00003710

Order Number: ORD87878

Notes:

17 Aug 2017 01:54:58 PM Emily Hanson
emailed about carriage.

24 Aug 2017 11:41:25 AM Emily Hanson
okay to go

Issues:100933

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00003710 0330236 ORD86426

Issue ID #95281

Date Created 23/May/2017

Issued To: General

Completed Status: 09 Jun 2017

Stock Ref: 0330236

Opera A/c: 00003710

Order Number: ORD86426

Notes:

23 May 2017 07:39:34 AM Catherine Spence
Back Order - Supplier

23 May 2017 10:47:30 AM Katie Evans
See Attached Notes
Offered part shipment

24 May 2017 07:50:48 AM Catherine Spence
Back Order - Supplier

24 May 2017 10:26:40 AM Katie Evans
Please part ship

25 May 2017 08:44:01 AM Catherine Spence
part shipment done

09 Jun 2017 07:23:54 AM Catherine Spence
Shipping Fri 09 Jun 2017

Issues:95281

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00003785 0310030 ORD85825

Issue ID #92807

Date Created 13/Apr/2017

Issued To: General

Completed Status: 13 Apr 2017

Stock Ref: 0310030

Opera A/c: 00003785

Order Number: ORD85825

Notes:

13 Apr 2017 07:41:08 AM Catherine Spence
Shipping Thu 13 Apr 2017

Issues:92807

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00003785 0310030 ORD88370

Issue ID #103190

Date Created 19/Sep/2017

Issued To: General

Completed Status: 10 Oct 2017

Stock Ref: 0310030

Opera A/c: 00003785

Order Number: ORD88370

Notes:

19 Sep 2017 07:45:27 AM Catherine Spence
Back Order - Production

29 Sep 2017 11:20:55 AM Sarah Walton
See Attached Notes
Dispatching middle of next week

02 Oct 2017 07:58:52 AM Catherine Spence
Shipping Mon 02 Oct 2017

04 Oct 2017 08:17:29 AM Catherine Spence
Back Order - Supplier
should be a special spec for customer

Issues:103190

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00003785 0340000 ORD83691

Issue ID #84705

Date Created 02/Dec/2016

Issued To: General

Completed Status: 02 Dec 2016

Stock Ref: 0340000

Opera A/c: 00003785

Order Number: ORD83691

Notes:

02 Dec 2016 08:06:07 AM Catherine Spence
Shipping Fri 02 Dec 2016

Issues:84705

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00003800 0330209 ORD83892

Issue ID #85273

Date Created 13/Dec/2016

Issued To: General

Completed Status: 13 Dec 2016

Stock Ref: 0330209

Opera A/c: 00003800

Order Number: ORD83892

Notes:

13 Dec 2016 07:33:40 AM Catherine Spence
Shipping Tue 13 Dec 2016

Issues:85273

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00004992 0310030 ORD84717

Issue ID #88388

Date Created 03/Feb/2017

Issued To: General

Completed Status: 03 Feb 2017

Stock Ref: 0310030

Opera A/c: 00004992

Order Number: ORD84717

Notes:

03 Feb 2017 08:01:53 AM Catherine Spence
Shipping Fri 03 Feb 2017

Issues:88388

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00004992 0380000 ORD85194

Issue ID #96362

Date Created 09/Jun/2017

Issued To: General

Completed Status: 03 Aug 2017

Stock Ref: 0380000

Opera A/c: 00004992

Order Number: ORD85194

Notes:

09 Jun 2017 07:34:13 AM Catherine Spence
Contract

10 Jul 2017 11:12:44 AM Steve Hardaker
Due this week. Katie to arrange with Derek and Phil and confirm with customer as per issue 98465.

20 Jul 2017 10:40:21 AM Katie Evans
Found additional units to be serviced. Requested amended PO from hospital

26 Jul 2017 01:34:08 PM Katie Evans
Service reports have been sent and receipt has been confirmed. Now waiting for PO to be amended to include 1 x extra unit. Thando Ngwenya is completing this

Issues:96362

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00005260 0330193 ORD87872

Issue ID #100927

Date Created 17/Aug/2017

Issued To: General

Completed Status: 22 Sep 2017

Stock Ref: 0330193

Opera A/c: 00005260

Order Number: ORD87872

Notes:

17 Aug 2017 12:46:19 PM Sarah Walton

See Attached Notes

This is a repair. Was turned to an order by mistake.

Issues:100927

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00006395 0310030 ORD83191

Issue ID #82901

Date Created 04/Nov/2016

Issued To: General

Completed Status: 09 Nov 2016

Stock Ref: 0310030

Opera A/c: 00006395

Order Number: ORD83191

Notes:

04 Nov 2016 02:10:02 PM Sarah Walton
See Attached Notes
Customer aware that we aim to ship next week.

07 Nov 2016 07:57:04 AM Catherine Spence
In Production

08 Nov 2016 04:37:55 PM Jonathan Connor
Shipping Wed 09 Nov 2016

Issues:82901

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00006777 0310097 ORD83534

Issue ID #84035

Date Created 22/Nov/2016

Issued To: General

Completed Status: 25 Nov 2016

Stock Ref: 0310097

Opera A/c: 00006777

Order Number: ORD83534

Notes:

22 Nov 2016 05:32:29 PM Katie Evans

See Attached Notes

Advised that we will ship by end of week as per JC

Issues:84035

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00006777 0310097 ORD86178

Issue ID #94296

Date Created 08/May/2017

Issued To: General

Completed Status: 11 May 2017

Stock Ref: 0310097

Opera A/c: 00006777

Order Number: ORD86178

Notes:

08 May 2017 08:19:01 AM Catherine Spence
Back Order - Production

08 May 2017 09:12:01 AM Katie Evans
Awaiting lead time from PC

09 May 2017 07:43:04 AM Catherine Spence
do we have a italian user manual sorted

09 May 2017 10:31:27 AM Katie Evans
Should be ready to ship tomorrow as per JC Skype

10 May 2017 07:38:02 AM Catherine Spence
In Production

11 May 2017 11:42:02 AM Catherine Spence

Issues:94296

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00007291 0310030 ORD85867

Issue ID #93039

Date Created 19/Apr/2017

Issued To: General

Completed Status: 19 Apr 2017

Stock Ref: 0310030

Opera A/c: 00007291

Order Number: ORD85867

Notes:

19 Apr 2017 07:40:59 AM Catherine Spence
Shipping Wed 19 Apr 2017

Issues:93039

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00007291 0310030 ORD86739

Issue ID #96358

Date Created 09/Jun/2017

Issued To: General

Completed Status: 13 Jun 2017

Stock Ref: 0310030

Opera A/c: 00007291

Order Number: ORD86739

Notes:

09 Jun 2017 07:32:25 AM Catherine Spence
Back Order - Production

Issues:96358

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00007291 0310030 ORD88316

Issue ID #102890

Date Created 14/Sep/2017

Issued To: General

Completed Status: 14 Sep 2017

Stock Ref: 0310030

Opera A/c: 00007291

Order Number: ORD88316

Notes:

14 Sep 2017 07:58:25 AM Catherine Spence
Shipping Thu 14 Sep 2017

Issues:102890

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00007291 0330212 ORD82924

Issue ID #81979

Date Created 20/Oct/2016

Issued To: General

Completed Status: 20 Oct 2016

Stock Ref: 0330212

Opera A/c: 00007291

Order Number: ORD82924

Notes:

20 Oct 2016 07:52:18 AM Catherine Spence
Shipping Thu 20 Oct 2016

Issues:81979

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00007356 0380000 ORD86664

Issue ID #96237

Date Created 08/Jun/2017

Issued To: General

Completed Status: 15 Jun 2017

Stock Ref: 0380000

Opera A/c: 00007356

Order Number: ORD86664

Notes:

08 Jun 2017 07:45:26 AM Catherine Spence

See Attached Notes

Ship with other orders

Issues:96237

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00012625 0310094 ORD86206

Issue ID #94422

Date Created 09/May/2017

Issued To: General

Completed Status: 12 May 2017

Stock Ref: 0310094

Opera A/c: 00012625

Order Number: ORD86206

Notes:

09 May 2017 11:56:11 AM Catherine Spence
Back Order - Production

Issues:94422

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00012967 0330212 ORD86498

Issue ID #95473

Date Created 25/May/2017

Issued To: General

Completed Status: 31 May 2017

Stock Ref: 0330212

Opera A/c: 00012967

Order Number: ORD86498

Notes:

25 May 2017 04:35:40 PM Zoey Teal
Emailed. Waiting for confirmation on quantity.

Issues:95473

VIAMED Management Meeting - Other

Historic specials pricing

Issue ID #92967

Date Created 18/Apr/2017

Issued To: Derek Lamb

Completed Status: 04 May 2017

Notes:

Added by Steve Nixon sent to Derek Lamb

For future discussion. I believe we have already discussed the need to wean off customers from historic special pricing.

For example:

Ref. Mediprema and orders for 0330190.

There is a memo on Opera (RS, dating back to July 2014) stating that the clamps should be USD \$15.00. I believe this is historic based on the price they paid for the previous version and when the exchange rate was higher.

I will try and look into it, but it doesn't explain why they were invoiced at \$14.14 in July 2015. Nor does it explain why there (albeit small) is a price difference between Opera and Intratsats.

Issues:92967

- Back Order Report

POR10994 0330216 //

Issue ID #81513

Date Created 13/Oct/2016

Issued To: Jonathan Connor

Completed Status: 13 Oct 2016

Notes:

POR10994 0330216 Estimated ship to us date changed to / /

Issues:81513

- Back Order Report

POR10994 0330216 //

Issue ID #81377

Date Created 12/Oct/2016

Issued To: Jonathan Connor

Completed Status: 12 Oct 2016

Notes:

POR10994 0330216 Estimated ship to us date changed to / /

Issues:81377

- Back Order Report

POR10994 0330216 //

Issue ID #81201

Date Created 10/Oct/2016

Issued To: Jonathan Connor

Completed Status: 10 Oct 2016

Notes:

POR10994 0330216 Estimated ship to us date changed to / /

Issues:81201

- Back Order Report

POR11040 0330212 //

Issue ID #83763

Date Created 17/Nov/2016

Issued To: Jonathan Connor

Completed Status: 17 Nov 2016

Notes:

POR11040 0330212 Estimated ship to us date changed to / /

Issues:83763

- Back Order Report

POR11040 0330212 //

Issue ID #83266

Date Created 10/Nov/2016

Issued To: Jonathan Connor

Completed Status: 11 Nov 2016

Notes:

POR11040 0330212 Estimated ship to us date changed to / /

Issues:83266

- Back Order Report

POR11129 0330234 //

Issue ID #88741

Date Created 09/Feb/2017

Issued To: Jonathan Connor

Completed Status: 09 Feb 2017

Notes:

POR11129 0330234 Estimated ship to us date changed to / /

Issues:88741

- Back Order Report

POR11129 0330234 //

Issue ID #88412

Date Created 03/Feb/2017

Issued To: Jonathan Connor

Completed Status: 03 Feb 2017

Notes:

POR11129 0330234 Estimated ship to us date changed to / /

Issues:88412

- Back Order Report

POR11194 0330263 //

Issue ID #91047

Date Created 15/Mar/2017

Issued To: Jonathan Connor

Completed Status: 15 Mar 2017

Notes:

POR11194 0330263 Estimated ship to us date changed to / /

Issues:91047

- Back Order Report

POR11225 0330218 //

Issue ID #92134

Date Created 04/Apr/2017

Issued To: Jonathan Connor

Completed Status: 05 Apr 2017

Notes:

POR11225 0330218 Estimated ship to us date changed to / /

Issues:92134

- Back Order Report

POR11281 0330236 //

Issue ID #95301

Date Created 23/May/2017

Issued To: Jonathan Connor

Completed Status: 23 May 2017

Notes:

POR11281 0330236 Estimated ship to us date changed to / /

Issues:95301

- Back Order Report

POR11317 0330217 //

Issue ID #97045

Date Created 20/Jun/2017

Issued To: Jonathan Connor

Completed Status: 20 Jun 2017

Notes:

POR11317 0330217 Estimated ship to us date changed to / /

Issues:97045

- Back Order Report

POR11317 0330263 //

Issue ID #97046

Date Created 20/Jun/2017

Issued To: Jonathan Connor

Completed Status: 20 Jun 2017

Notes:

POR11317 0330263 Estimated ship to us date changed to / /

Issues:97046

- Back Order Report

POR11319 0350120 //

Issue ID #97859

Date Created 30/Jun/2017

Issued To: Jonathan Connor

Completed Status: 30 Jun 2017

Notes:

POR11319 0350120 Estimated ship to us date changed to / /

Issues:97859

- Back Order Report

POR11356 0330217 //

Issue ID #99303

Date Created 24/Jul/2017

Issued To: Jonathan Connor

Completed Status: 26 Jul 2017

Notes:

POR11356 0330217 Estimated ship to us date changed to / /

Issues:99303

- Back Order Report

POR11356 0330217 //

Issue ID #99021

Date Created 19/Jul/2017

Issued To: Jonathan Connor

Completed Status: 20 Jul 2017

Notes:

POR11356 0330217 Estimated ship to us date changed to / /

Issues:99021

- Back Order Report

POR11365 0330193 //

Issue ID #99450

Date Created 26/Jul/2017

Issued To: Jonathan Connor

Completed Status: 27 Jul 2017

Notes:

POR11365 0330193 Estimated ship to us date changed to / /

Issues:99450

- Back Order Report

POR11365 0330193 29/09/2017

Issue ID #103451

Date Created 21/Sep/2017

Issued To: Jonathan Connor

Completed Status: 22 Sep 2017

Notes:

POR11365 0330193 Estimated ship to us date changed to 29 / 09 / 2017

Issues:103451

- Back Order Report

POR11454 0330216 //

Issue ID #104098

Date Created 29/Sep/2017

Issued To: Jonathan Connor

Completed Status: 02 Oct 2017

Notes:

POR11454 0330216 Estimated ship to us date changed to / /

Issues:104098

- Back Order Report

POR11454 0330296 //

Issue ID #104099

Date Created 29/Sep/2017

Issued To: Jonathan Connor

Completed Status: 02 Oct 2017

Notes:

POR11454 0330296 Estimated ship to us date changed to / /

Issues:104099

- Back Order Report

POR11455 0330212 //

Issue ID #104653

Date Created 05/Oct/2017

Issued To: Jonathan Connor

Completed Status: 05 Oct 2017

Notes:

POR11455 0330212 Estimated ship to us date changed to / /

Issues:104653

- Back Order Report

POR11455 0330212 //

Issue ID #104100

Date Created 29/Sep/2017

Issued To: Jonathan Connor

Completed Status: 02 Oct 2017

Notes:

POR11455 0330212 Estimated ship to us date changed to / /

Issues:104100

- Back Order Report

POR11465 0330191 //

Issue ID #104575

Date Created 04/Oct/2017

Issued To: Jonathan Connor

Completed Status: 05 Oct 2017

Notes:

POR11465 0330191 Estimated ship to us date changed to / /

Issues:104575

- Back Order Report

POR11465 0330191 //

Issue ID #104571

Date Created 04/Oct/2017

Issued To: Jonathan Connor

Completed Status: 05 Oct 2017

Notes:

POR11465 0330191 Estimated ship to us date changed to / /

Issues:104571

- Back Order Report

POR11466 0330217 //

Issue ID #104569

Date Created 04/Oct/2017

Issued To: Jonathan Connor

Completed Status: 05 Oct 2017

Notes:

POR11466 0330217 Estimated ship to us date changed to / /

Issues:104569

Production - Production Problems

Precision valve screw 0330228

Issue ID #57882

Date Created 02/Apr/2015

Issued To: Derek Lamb

Completed Status: 09 Aug 2017

Linked Files

02 Apr 2015 Precision valve

02 Apr 2015 current drawing

Notes:

Added by Philip Crossley sent to Derek Lamb

The latest batch of precision valve screws 0330228 have the screw driver slot way too narrow. The slot has always been a little tight relative to the screwdriver that fits it, all my large screwdrivers have been ground down

02 Apr 2015 Derek Lamb
current drawing - page 1

07 Apr 2015 Philip Crossley Looking at various screw drivers it looks like the slot should be 1.6mm wide since 1.6mm seems to be the slot width for both 8mm and 10mm screwdrivers

22 Apr 2015 Philip Crossley 1/32 is about 0.8mm so the slot in the diagram is about half the size it probably should be

Issues:57882

VIAMED Stock Meeting - VIAMED Stock Meeting

Production In Production List (556)

Issue ID #84611

Date Created 01/Dec/2016

Issued To: Jonathan Connor

Completed Status: 19 Dec 2016

Notes:

System Generated

Task To be Completed

List any production jobs started more 30 Days ago.

List any production jobs which QA date is more 30 Days ago.

08 Dec 2016 Jonathan Connor

PS2226100310030Jonathan Connor07/10/16Jonathan Connor07/10/16108 Nov 2016

Started and 1 item QA more than 30 days ago. Units are built but not QA. Robert does QA and his workload is very high at this time of year and very cold in TT room. Should be done in next week or so

Issues:84611

VIAMED Stock Meeting - Sale or Returns

Request Scanning Item to Sale or return

Issue ID #90695

Date Created 08/Mar/2017

Issued To: Jonathan Connor

Completed Status: 10 Mar 2017

Notes:

Added by Katie Evans sent to Jonathan Connor

Please scan to Sale or Returns Location ID34132 Stock Reference: up to 3 x 0380030 (as many as possible)

Need Phil to QA the ones with yellow gauges, need to be set with a maximum PIP of 38cmH20 as per Roger Smith`s instructions

08 Mar 2017 Jonathan Connor

Next Action Changed From Jonathan Connor To Philip Crossley Please can you sort these out for me

09 Mar 2017 Philip Crossley

Next Action Changed From Philip Crossley To Jonathan Connor 836911 SE006, 836912 SE007, 836913 SE008.

These are the 3 in my stock, will set them up to 38cmh20 and bring you them later this morning

09 Mar 2017 Jonathan Connor

836911

836912

836913

scanned to SOR

10 Mar 2017 Katie Evans

Thank you :)

Issues:90695

VIAMED Stock Meeting - Sale or Returns

Returned Items SOR781

Issue ID #94883

Date Created 16/May/2017

Issued To: Steve Hardaker

Completed Status: 17 May 2017

Notes:

Added by Jonathan Connor sent to Katie Evans

SOR ID781

Originally added by :Katie Evans

Leicester Royal Infirmary

Roger Smith

Neonatal Unit

Level 2, Kensington Building

Infirmary Square

Leicester

Leicestershire

LE1 5WW

Returned : 0380030 SE006

Returned : 0380030 SE007

Returned : 0380030 SE008

16 May 2017 Katie Evans

Next Action Changed From Katie Evans To Steve Hardaker

17 May 2017 Steve Hardaker

Complete. Services invoiced and service exchange units returned.

17 May 2017 Jonathan Connor

Thanks

Issues:94883

VIAMED Sales And Marketing - Service extension

Service Visit 43

Issue ID #77441

Date Created 23/Aug/2016

Issued To: Sarah Walton

Completed Status: 04 Nov 2016

Notes:

Added by Steve Hardaker sent to Sarah Walton

New service visit to add and arrange - Diana Princess of Wales Hospital

Sarah, please can you add a new visit to the service visits log for Diana Princess of Wales Hospital, Grimsby (a/c 1995) for order ORD81487.

This is for the 1-off upgrade of 20 resuscitation cabinets in Maternity to include air-oxygen blenders.

Phil and I visited 18/8/16, we fitted the following, completing Room 1 and Room 9:

2x 0310200 Air-oxygen blender kit,

2x 0310250 Tom Thumb conversion kit,

4x 0332057 Resuscitation cabinet rail,

Used 2x 0380000 Tom Thumb services.

I agreed today with James Wilson to ship all remaining parts to Medical Engineering in advance on Wed 31/8/16 to arrive in good time for Phil to start work on Tue 6/9/16, which is the date Phil suggested so as to fit around his current workload and holidays.

I discussed shipping with JC, who will look at 3 boxes UPS but may resort to a pallet if required. I have added notes to the back order checking.

I have confirmed the plan via email (cc'd you in) with Karen Fisk, Medical Engineering Manager who will be your primary contact for arranging the visit. You will need to contact her (or James Wilson if not available) on Monday 5th to ask if it's OK to come on Tue as Phil will be setting off Monday evening. Ideally do this early in the day as she will need to check with Maternity and advise them to keep certain rooms available.

Please can you discuss with Phil exactly how many nights he will stop over and book him some local accommodation accordingly.

I think that's everything, any questions please ask either myself or Phil. You can keep this issue open to log the progress or any issues that arise. Thanks.

23 Aug 2016 Sarah Walton

The service visit has already been added to the service log. Now added notes and will speak to JC regarding the method of shipping to be added to the ORD

05 Sep 2016 Sarah Walton

Spoken to Karen this morning (05/09/16) and everything is ok for Phil to go and service the cabinets. All 4 x boxes have arrived with Karen.

15 Sep 2016 Sarah Walton

26 Sep 2016 Steve Hardaker

I see that this has now gone yellow on the active list, however, I just realised that services stay on as a priority 9, which means it will only get invoiced if Cathy clears all the yellows with higher priorities that day.

If there are any yellows left to carry over, priority 9 services will just sit below them at the start of the next day and the same thing will happen again, waiting for all the yellows to be cleared.

If this happens, we need to ask Derek for a way of forcing them to the top of the list. I want to keep an eye on this one to see if that occurs.

27 Sep 2016 Steve Hardaker

As I thought, this yellow priority 9 is now sat below a number of yellow 3s and 4s, so if Cathy tackles the active list in order, this may get carried over again.

I have added an issue to Derek to ask if he can make yellow `ready for invoice` 9s that get carried over come to the top of the list. See issue 80041.

03 Nov 2016 Sarah Walton

04 Nov 2016 Steve Hardaker

Issues:77441

VIAMED Stock Meeting - Sale or Returns
SMC Northern Ireland exhibition stock - Urgent
Issue ID #103719
Date Created 25/Sep/2017
Issued To: Jonathan Connor
Completed Status: 29 Sep 2017

Notes:

Added by Steve Hardaker sent to Jonathan Connor
Richard Quigley at SMC in Northern Ireland has requested some demo stock to allow them to do an exhibition on Saturday 30th.

I have prepared a box of leaflets, brochures and pens, and have pulled the following items out of the ESS exhibition stock for you to send:

1x 4410520 VM-2500-S
1x 0012160 VM-2160
1x 0014750 Adult sensor
1x 0014751 Paed sensor
1x 0014835 Wrap sensor
1x 2810006 MD-300C52
1x 4430001 Flocap sample pack

Please can you also add:

1x 0310030 TT480 (demo unit is fine) complete with a Neopeep circuit with mask and reusable adapter (I have put my non-stock demo one in).

Please can these go today, sorry it's not more notice but I only got this request on Friday as I was away last week when he called.

I have created SOR817 to track it all. Thanks.

25 Sep 2017 Jonathan Connor
Done

29 Sep 2017 Steve Hardaker
Confirmed receipt and discussed at length over the phone with Richard and Karen prior to their exhibition.

Issues:103719

VIAMED Management Meeting - Other
Standard to apply to Tom Thumb Infant Resuscitator

Issue ID #104341

Date Created 02/Oct/2017

Issued To: Derek Lamb

Completed Status: Still Outstanding

Linked Files

02 Oct 2017 Neopuff Infant T-Piece Resuscitator

09 Oct 2017 Tom Thumb pressure gauge units

10 Oct 2017 1) GNW dial artwork with banded zero

10 Oct 2017 2) GNW dial artwork with banded zero & cm H2O

Notes:

Added by Steve Nixon sent to Derek Lamb

The Tom Thumb shouldn't have the ISO 60601 standard applied, as it is not Medical Electrical Equipment.

I believe that we should apply:

BS ISO 10651-5:2006 Lung ventilators for medical use. Particular requirements for basic safety and essential performance. Gas-powered emergency resuscitators

Quick rationale for this is that CEDAR referenced ISO 8382:1998 Resuscitators intended for use with humans, which has since been replaced by BS ISO 10651-5:2006

<http://www.cedar.wales.nhs.uk/sitesplus/documents/1091/05103%20Market%20survey%20infant%20warming%20and%20phototherapy.pdf>

In addition the Fisher & Paykel state that the applied standard for the Neopuff is BS ISO 10651-5:2006

ISO 10651 consists of the following parts, under the general title Lung ventilators:

Part 1: Requirements

Part 2: Particular requirements for basic safety and essential performance. Home care ventilators for ventilator-dependent patients

Part 3: Particular requirements for emergency and transport ventilators

Part 4: Particular requirements for operator-powered resuscitators

Part 5: Lung ventilators for medical use. Particular requirements for basic safety and essential performance. Gas-powered emergency resuscitators

Part 6: Lung ventilators for medical use. Particular requirements for basic safety and essential performance. Home-care ventilatory support devices

We already have a copy of BS EN ISO 10651-4:2009 Lung ventilators . Particular requirements for operator-powered resuscitators.

I suggest we purchase a copy of BS ISO 10651-5:2006

09 Oct 2017 Steve Nixon

Derek purchased and added BS ISO 10651-5:2006 to intrastats.

09 Oct 2017 Steve Nixon

The Tom Thom gauge dial has historically been labelled as cm wg (cm water gauge), which can be abbreviated to cm H2O.

However, if we applied the standard BS ISO 10651-5:2006, it states:

Numeric indications of parameters on resuscitators shall be expressed in SI units in accordance with ISO 31 (all parts) except the quantities listed in Table 2, which are not SI units but may be expressed in the indicated units.

Non-SI units of pressure that may be used on resuscitators

Name	Symbol
Millimetres of mercury	mm Hg
Centimetres of water	cm H2O
Bar	bar
Millibar	mbar

For consistency in international documents, only the symbol l is used for litre, although the symbol L is also given in ISO 1000.

NOTE: ISO 31 has now be superseded by ISO IEC 80000, and the particular edition for us to apply in this case appears to be BS EN ISO 80000-1:2013

Currently our Tom Thumb instructions for use state:

1cm wg = 1cm H2O = 0.981 mb

Suggest we edit to:

1cm wg = 1cm H2O = 0.981 mb = 0.981 hPa

We should schedule changing the artwork on the gauge dial to reflect cm H2O instead of cm WG. Ideally the SI unit to use is hPa, but the allowed and the fully backwards compatible unit is cm H2O (at 4 degrees C).

NOTE: The Fisher & Paykel Neopuff gauge is marked as cm H2O (mbar). Strictly speaking 1 cm H2O equals 0.981mb.

When we change the dial artwork, the instructions for use can be then edited to include the new artwork and to state:

1cm H2O = 1cm wg = 0.981 mb = 0.981 hPa

09 Oct 2017 Steve Nixon

Attached is Word version of Tom Thumb pressure gauge units explanation.

10 Oct 2017 Steve Nixon

See attached pressure gauge dial artwork:

- 1) GNW dial artwork with banded zero.
- 2) GNW dial artwork with banded zero and units changed from cm Wg to cm H2O.

11 Oct 2017 Derek Lamb

0310030 added for reference

Issues:104341

Production - Production

TOM THUMB 0330232 Adjustable valve collar

Issue ID #68681

Date Created 14/Mar/2016

Issued To: Derek Lamb

Completed Status: 05 Dec 2016

Notes:

Added by Philip Crossley sent to Derek Lamb

Its just an idea about slotting the collar all the way around, or maybe adding ribs around it above the threads to aid in adjusting the collar with a screwdriver through the slot in the side. The slot could also be made slightly wider if needed.

08 Aug 2016 Derek Lamb

Subject Changed From 0330232 Adjustable valve collar

Subject Changed To TOM THUMB 0330232 Adjustable valve collar

05 Dec 2016 Philip Crossleyok lets see how it does

Issues:68681

Non Conformance Issues - BSI Major Non Conformances

Tom Thumb 1511824-201709-M1 Corrective Action

Issue ID #101066

Date Created 19/Aug/2017

Issued To: Derek Lamb

Completed Status: Still Outstanding

Stock Ref: 0310030

Notes:

Added by Derek Lamb sent to Derek Lamb

31 Aug 2017 Derek Lamb

Added docid 21516 to the generic Technical file, under N 3 Quality Plan.
Explanation Technical File Risk Plans and Notifications.

Issues:101066

Non Conformance Issues - BSI Major Non Conformances

Tom Thumb 1511824-201709-M1 Effectiveness verification

Issue ID #101067

Date Created 19/Aug/2017

Issued To: Derek Lamb

Completed Status: Still Outstanding

Stock Ref: 0310030

Notes:

Added by Derek Lamb sent to Derek Lamb

Issues:101067

Non Conformance Issues - BSI Major Non Conformances

Tom Thumb 1511824-201709-M1 Initial Investigation

Issue ID #101068

Date Created 19/Aug/2017

Issued To: John Lamb

Completed Status: Still Outstanding

Stock Ref: 0310030

Notes:

Added by Derek Lamb sent to John Lamb

Linked Issue

Issues:101068

Non Conformance Issues - BSI Major Non Conformances
Tom Thumb 1511824-201709-M1 Initial Investigation

Issue ID #101065

Date Created 19/Aug/2017

Issued To: Derek Lamb

Completed Status: Still Outstanding

Stock Ref: 0310030

Linked Files

19 Aug 2017 QC 21 Non Conformance Report

Notes:

Added by Derek Lamb sent to Derek Lamb

19 Aug 2017 Derek Lamb

Created Related Issue #101066

Added by Derek Lamb sent to Derek Lamb

19 Aug 2017 Derek Lamb

Created Related Issue #101067

Added by Derek Lamb sent to Derek Lamb

19 Aug 2017 Derek Lamb

Area/process Technical Documentation Assessed

Clause Annex II, Section 3.4

Scope CE 01389

Category

Major

Statement of

nonconformance:

The solutions adopted to fulfill Annex II are incomplete.

Clause

requirements

[Annex II, Section 3.4] - The manufacturer must inform the notified body which approved the quality system of any plan for substantial changes to the quality system or the product-range covered.

Objective

evidence

No evidence has been provided in the Technical documentation despite request of a system for informing BSI of substantial changes or evaluation of such change.

19 Aug 2017 Derek Lamb

Investigation

VM3COP01 Amendment Control DOCID13956 19/05/2014 refers:

7. Informing External Bodies 8. 4.1 It is the responsibility of the person uploading a modified document to Inform any External bodies that may need to be informed of any changes. E.g. BSI / CMDCAS / GOST-R / MHRA / MDD

Roles and Responsibilities, Rolling task ID50, Triggers the Process,
No evidence of procedure currently in the Technical Files.

19 Aug 2017 Derek Lamb

Created Related Issue #101068

Added by Derek Lamb sent to John Lamb
Linked Issue

27 Aug 2017 Derek Lamb
Added Explanation Technical File Risk Plans_ID21516,

Issues:101065

Non Conformance Issues - BSI Major Non Conformances

Tom Thumb 1511824-201709-M2 Corrective Action

Issue ID #101063

Date Created 19/Aug/2017

Issued To: Derek Lamb

Completed Status: Still Outstanding

Stock Ref: 0310030

Notes:

Added by Derek Lamb sent to Derek Lamb

Issues:101063

Non Conformance Issues - BSI Major Non Conformances

Tom Thumb 1511824-201709-M2 Effectiveness verification

Issue ID #101064

Date Created 19/Aug/2017

Issued To: Derek Lamb

Completed Status: Still Outstanding

Stock Ref: 0310030

Notes:

Added by Derek Lamb sent to Derek Lamb

Issues:101064

Non Conformance Issues - BSI Major Non Conformances

Tom Thumb 1511824-201709-M2 Initial Investigation

Issue ID #101069

Date Created 19/Aug/2017

Issued To: John Lamb

Completed Status: Still Outstanding

Stock Ref: 0310030

Notes:

Added by Derek Lamb sent to John Lamb

[Link to Main Issue](#)

Issues:101069

Non Conformance Issues - BSI Major Non Conformances
Tom Thumb 1511824-201709-M2 Initial Investigation

Issue ID #101062

Date Created 19/Aug/2017

Issued To: Derek Lamb

Completed Status: Still Outstanding

Stock Ref: 0310030

Linked Files

31 Aug 2017 QC 21 Non Conformance Report 1511824-201709-M2

Notes:

Added by Derek Lamb sent to Derek Lamb

19 Aug 2017 Derek Lamb

Created Related Issue #101063

Added by Derek Lamb sent to Derek Lamb

19 Aug 2017 Derek Lamb

Created Related Issue #101064

Added by Derek Lamb sent to Derek Lamb

19 Aug 2017 Derek Lamb

Area/process Essential Requirements

Clause Annex I

Scope CE 01389

Category

Major

Statement of

nonconformance:

Solutions adopted to fulfil Annex I are incomplete.

Clause

requirements

[Annex I] - The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons

Objective

evidence

[ER 4] Lifetime is not defined in the technical documentation. There is no data in support of lifetime. There is no evidence of lifetime as part of the medical device consideration in the risk management file where lifetime based risks are explicitly stated as N/A. Individual invoices are not evidence of rationale for device lifetime, and do not represent an analysis of lifetime in evidence of selected duration. There is no evidence of lifetime as defined in ER 4.

[ER 5, 8.6] - No testing has been provided for this product. Documentation referenced by the ERC is a statement of model numbers and pictures of cardboard boxes. There is no evidence of support of claimed temperature ranges for shipment. There is no evidence provided of support for ability to meet customer need post shipment such as device testing or visual inspection. There is no evidence of storage testing or considerations in the referenced testing. No evidence to meet ER 5 has been provided.

[ER 7.2] - There is no evidence of consideration of contaminants or residues

for this device. While not provided sterile, the device in question is used in

high risk environments including infants and neonates. No evidence was found in review of the trials and validations for support of lack of contamination. No summary or expect evidence is provided in post market data for contaminants. No risk evaluation associated with contamination was provided.

[ER 7.6] - The observation by the manufacture that ingress is not applicable due to the ability to wash the device is not accepted. Ingress protection does not reference the clean ability of the device outside of use. Aspiration of liquid during use while not evaluated as part of risk is applicable to this device. No IPX rating has been defined. Evidence in support of ER 7.6 has not been provided.

[ER 8.3, 8.4, 8.5] - Device is listed in all documentation and instructions for use as non-sterile. The technical file however references a single document ID 2253 which states the unit is chromed brass, so it can be dismantled and autoclaved if required. This is in contradiction to all other provided evidence and user manuals.

The manufacturer has confirmed in the response that the device is intended to be sterilized under certain considerations. The device has incorrectly been listed as non-sterile. No evidence of sterilization validation has been provided. No Microbiology audit has been performed as required for sterile devices.

[ER 9.1] - Evidence has not been provided in the form of device testing, design inputs, system validation or structured legacy data that the device is able to be used in conjunction with other devices supplied by the manufacturer or devices used with the device such as the NeoPEEP patient circuit, flowmeter gas hose and hospital equipment. While it is recognized that function of other devices is the responsibility of those manufacturers, use in conjunction with the device under review is the responsibility of the manufacturer per ER 9.1.

[ER 12.8] - Standards Compliance testing and design verification below are not accepted. Testing provided does not contain data which supports the assertion that flow rate accuracy can be maintained. Specifically, there are no claims around accuracy made in the design input specification, and no evidence of accuracy testing provided in the technical documentation.

19 Aug 2017 Derek Lamb

ER4 :

Tom Thumb Product Life DOCID2215 19/06/2007

Individual Invoice DOCID20966 Links the Serial number of Tom Thumb VMC9070 Sold 14/03/2000

To a Current and upto date Service LOG DOCID20968 of the Same Tom thumb VMC9070

Last Serviced 10/07/2016:

Indicates the Device is Lasting 16 Years so Far.

19 Aug 2017 Derek Lamb

Created Related Issue #101069

Added by Derek Lamb sent to John Lamb

Link to Main Issue

31 Aug 2017 Derek Lamb

ER5

Testing QA, Product control outside of the technical file, covered via the QMS

Added docid 21694 Product Control Tom Thumb,

Show example of using system to show product testing for tom thumbs

Issues:101062

Non Conformance Issues - BSI Major Non Conformances
Tom Thumb 1511824-201709-M3 Corrective Action
Issue ID #101060
Date Created 19/Aug/2017
Issued To: Derek Lamb
Completed Status: Still Outstanding
Stock Ref: 0310030

Notes:

Added by Derek Lamb sent to Derek Lamb

01 Sep 2017 Derek Lamb

*Risk file reference question [25] revisited: What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device.
Oxygen used. Flagged the risk for reevaluation is now showing as unanswered in the system. will be addressed within 30 days

01 Sep 2017 Derek Lamb

Tom Thumb is a positive pressure device, no patient contamination back up the patient circuit possible, so no risk in repeated use. notes added to reference question 125

01 Sep 2017 Derek Lamb

see supporting files for other highlighted areas in the investigation

Issues:101060

Non Conformance Issues - BSI Major Non Conformances

Tom Thumb 1511824-201709-M3 Effectiveness verification

Issue ID #101061

Date Created 19/Aug/2017

Issued To: Derek Lamb

Completed Status: Still Outstanding

Stock Ref: 0310030

Notes:

Added by Derek Lamb sent to Derek Lamb

Issues:101061

Non Conformance Issues - BSI Major Non Conformances

Tom Thumb 1511824-201709-M3 Initial Investigation

Issue ID #101070

Date Created 19/Aug/2017

Issued To: John Lamb

Completed Status: Still Outstanding

Stock Ref: 0310030

Notes:

Added by Derek Lamb sent to Derek Lamb

[Link to Main Issue](#)

19 Aug 2017 Derek Lamb

Next Action Changed From Derek Lamb To John Lamb

Issues:101070

Non Conformance Issues - BSI Major Non Conformances
Tom Thumb 1511824-201709-M3 Initial Investigation
Issue ID #101059
Date Created 19/Aug/2017
Issued To: Derek Lamb
Completed Status: Still Outstanding
Stock Ref: 0310030
Linked Files
19 Aug 2017 QC 21 Non Conformance Report

Notes:

Added by Derek Lamb sent to Derek Lamb

Area/process Risk Management File

Clause Annex I ER 2

Scope CE 01389

Category

Major

Statement of

nonconformance:

The solution adopted to fulfill the essential requirement 2 is incomplete.

(Risk)

Clause

requirements

[Annex I ER 2] – “The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.”

Assessment Report.

Page 14 of 23

Objective

evidence

The risk documentation was generally not found to be acceptable and failed to follow the state of the art processes of EN ISO 14971. Specifically:

- No risk management plan was made available as part of the technical documentation. VM3COP27.11 which is referenced fails to cover the topics required by the risk management plan in accordance with ISO 14971.
- Risk is not updated using field data: Additional risk documentation has been referenced as applicable such as risk analysis document #2182. This document has not been updated since 1998
- Risks are not calculated both before and after risk controls (per 14971 section 6.4).
- An overall acceptability for each hazard is listed pre but not explicitly postmitigation (per 14971 section 6.4).
- There is no evidence that a multidisciplinary team was involved (per 14971 sections 3.3, 4.1(b)).
- The risk file explicitly states that the usability is not capable of contributing to misuse and elects to not evaluate the risk, despite the existence of user interfaces and display
- Mechanical hazards are systematically not accounted for
- Risks related to repeated use and or exposure and materials are deliberately excluded from risk analysis:
- Per ISO 14971, section 6, 7, risk control measures have not been proven to be implemented and verified.
- Per ISO 14971, section 8, the risk management plan has not been demonstrated to have been implemented. Controls are not evident as being in place for obtaining relevant production and post-production information.

19 Aug 2017 Derek Lamb

Created Related Issue #101060

Added by Derek Lamb sent to Derek Lamb

19 Aug 2017 Derek Lamb
Created Related Issue #101061
Added by Derek Lamb sent to Derek Lamb

19 Aug 2017 Derek Lamb
Symptom of a Remote BSI Audit, The risk analysis system is computerised and integrated to the QMS system.

The Start of the Risk analysis Assuming no other event such as customer complaint / Supplier return has triggered analysis, starts with the Organisation Chart and Roles and Responsibilities, Under the ISO Controller Role id 7172, there is an Automatic Issue generated Task ID 50, Task ID 50 is a reoccurring Issue once every 2 months. Task ID informs the User Current Derek Lamb to:

System Generated
Check that no Products / Designs have changed significantly to warrant informing MDD / Bsi / CMDCAS or any other related Body.

Carry out the Technical File PMS Form for Each OBL and Viamed Product
Using procedure VM3COP27.11

This trigger is not found in the Technical File as it applies to ALL technical Files so is in the QMS system.

VM3COP27.11 Performing a Technical File PMS and risk assessment
Starts by flagging the Technical Files which have not been formally reviewed for 12 Months.
Post Market Surveillance, is performed on each Due File. During the review,

The Following screen will produce all information regarding the product range e.g. stock references, suppliers, returns information, documentation updates including instruction manuals, sales, Issues system, It will also request Searches on the internet regarding clinical reports, fda / mhra reports on all similar devices on the markets Each section will have 2 input boxes it with a further action request tick box, The first section is for general comments on the section, The second section is for if any of the information presented is if and new Risks have been identified. If a risk has been identified the further Action required check box MUST be ticked.

It then proceeds how to add the Further Actions required into the Risk Management System.
While the Risk is being added to the system, options are given for if the Risk should be applied to all KNOWN files in the system.
Note: this is the risk itself not the individual analysis of the risk as applied to the current technical file.

For a complete list of topics covered See DOCID21003 as an example.
For a current fully upto date list of risks Access to the Live system is required.

Last section of Procedure VM3COP27.11
If the File is a Viamed Product : A Clinical Re-Evaluation should now be performed VM3COP27.12 Clinical Re-Evaluation Find the previous years Clinical Re-Evaluation document in the technical file, Click the Document requires amending add to the notes the re-evaluation need doing submit the new issue.

First Section of VM3COP27.12
VM3COP27.12 Clinical Evaluation Risk assessment Technical Files
*Note VM3COP27.12 should be performed by an independent person whom performed VM3COP27.11 on the product range.

19 Aug 2017 Derek Lamb
Created Related Issue #101070
Added by Derek Lamb sent to Derek Lamb

[Link to Main Issue](#)

01 Sep 2017 Derek Lamb

- No risk management plan was made available as part of the technical documentation. VM3COP27.11 which is referenced fails to cover the topics required by the risk management plan in accordance with ISO 14971.

*Added Explanation Technical File Risk Plans_ID21516

- Risk is not updated using field data: Additional risk documentation has been referenced as applicable such as risk analysis document #2182. This document has not been updated since 1998

*2182 2004 version of risk assesment.

- Risks are not calculated both before and after risk controls (per 14971 section 6.4).

- An overall acceptability for each hazard is listed pre but not explicitly postmitigation (per 14971 section 6.4).

*Noted Added Issue 102030 to system

- There is no evidence that a multidisciplinary team was involved (per 14971 sections 3.3, 4.1(b)).

*See Tom Thumb Residual Risks to Benefits Residual risks 2015_ID15756

01 Sep 2017 Derek Lamb

- Risk is not updated using field data: Additional risk documentation has been referenced as applicable such as risk analysis document #2182. This document has not been updated since 1998

* analysis of field data docid17824

summarised in Tom Thumb Post Market Surveillance _ID17690.

01 Sep 2017 Derek Lamb

- Risks related to repeated use and or exposure and materials are deliberately excluded from risk analysis:

*Risk file reference question [25] revisited:

What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device.

Oxygen used.

Flagged the risk for reevaluation is now showing as unanswered in the system. will be addressed within 30 days

Tom Thumb is a positive pressure device, no patient contamination back up the patient circuit possible, so no risk in repeated use. notes added to reference question 125

01 Sep 2017 Derek Lamb

Per ISO 14971, section 6, 7, risk control measures have not been proven to be implemented and verified.

- Per ISO 14971, section 8, the risk management plan has not been demonstrated to have been implemented. Controls are not evident as being in place for obtaining relevant production and post-production information.

Explanation Technical File Risk Plans_ID21516

VM3COP27.11 Performing a Technical File PMS and risk assessment _ID17824

Tom Thumb Post Market Surveillance _ID17690

And QMS interanl Q.A. records.

Non Conformance Issues - BSI Major Non Conformances

Tom Thumb 1511824-201709-M4 Corrective Action

Issue ID #101057

Date Created 19/Aug/2017

Issued To: Derek Lamb

Completed Status: Still Outstanding

Stock Ref: 0310030

Notes:

Added by Derek Lamb sent to Derek Lamb

Issues:101057

Non Conformance Issues - BSI Major Non Conformances

Tom Thumb 1511824-201709-M4 Effectiveness verification

Issue ID #101058

Date Created 19/Aug/2017

Issued To: Derek Lamb

Completed Status: Still Outstanding

Stock Ref: 0310030

Notes:

Added by Derek Lamb sent to Derek Lamb

Issues:101058

Non Conformance Issues - BSI Major Non Conformances

Tom Thumb 1511824-201709-M4 Initial Investigation

Issue ID #101071

Date Created 19/Aug/2017

Issued To: John Lamb

Completed Status: Still Outstanding

Stock Ref: 0310030

Notes:

Added by Derek Lamb sent to John Lamb

[Link to Main Issue](#)

Issues:101071

Non Conformance Issues - BSI Major Non Conformances
Tom Thumb 1511824-201709-M4 Initial Investigation
Issue ID #101056
Date Created 19/Aug/2017
Issued To: Derek Lamb
Completed Status: Still Outstanding
Stock Ref: 0310030
Linked Files
19 Aug 2017 QC 21 Non Conformance Report

Notes:

Added by Derek Lamb sent to Derek Lamb

19 Aug 2017 Derek Lamb
Created Related Issue #101057
Added by Derek Lamb sent to Derek Lamb

19 Aug 2017 Derek Lamb
Created Related Issue #101058
Added by Derek Lamb sent to Derek Lamb

19 Aug 2017 Derek Lamb
Area/process Pre-Clinical Data
Clause ER 1
Scope CE 01389
Category
Major
Statement of
nonconformance:
The solutions adopted to fulfil essential requirement 1 is incomplete
Clause
requirements
ER 1 The devices must be designed and manufactured in such a way that,
when used under the conditions and for the purposes intended, they will not
compromise the clinical condition
Objective
evidence
There is a systemic failure to address usability. While it is recognized that the
device has been on the market for a substantial time, compliance to essential
requirement 1 is still required. There is a failure to address multiple portions
of usability state of the art including:
- Failure to provide sufficient rationale for not applying state of the art
harmonized standard EN 62366.
- There was no evidence of a usability engineering process.
- There is no evidence of an application specification.
- Foreseeable hazards related to usability were not identified. The risk file
Assessment Report.
explicitly states that the usability is not capable of contributing to misuse and
elects to not evaluate the risk.
- There was no usability specification was available for review.
- There was no design validation was implemented on representative users
per a plan, or acceptance.
- The manufacturer has not considered EN 60601-1-6 or EN 62366, or
supplied sufficient rationale for non/partial compliance

- The manufacturer did not perform a retrospective analysis per Annex C of BS EN 62366-1: 2015 (Annex K of IEC 62366: 2015) for the legacy product.

19 Aug 2017 Derek Lamb

Created Related Issue #101071

Added by Derek Lamb sent to John Lamb

[Link to Main Issue](#)

Issues:101056

Non Conformance Issues - BSI Major Non Conformances
Tom Thumb 1511824-201709-M5 Corrective Action
Issue ID #101054
Date Created 19/Aug/2017
Issued To: Derek Lamb
Completed Status: Still Outstanding
Stock Ref: 0310030

Notes:

Added by Derek Lamb sent to Derek Lamb

01 Sep 2017 Derek Lamb

Issue102035 created to correct stack the documents in order,
*2 Extra documents 2004 version and the latest 2005 versions to stack.

Issues:101054

Non Conformance Issues - BSI Major Non Conformances

Tom Thumb 1511824-201709-M5 Effectiveness verification

Issue ID #101055

Date Created 19/Aug/2017

Issued To: Derek Lamb

Completed Status: Still Outstanding

Stock Ref: 0310030

Notes:

Added by Derek Lamb sent to Derek Lamb

Issues:101055

Non Conformance Issues - BSI Major Non Conformances

Tom Thumb 1511824-201709-M5 Initial Investigation

Issue ID #102035

Date Created 01/Sep/2017

Issued To: Derek Lamb

Completed Status: Still Outstanding

Stock Ref: 0310030

Notes:

Added by Derek Lamb sent to Derek Lamb

Design input document has not been updated since 1997, despite design changes being made as late as 2004 in accordance with the risk management file.

Several QC28 forms in error uploaded seperatley to the system instead of on top of each other,
See DOCID7461 Latest version.

Search Tom Thumb design changes and stack the documents

04 Sep 2017 Derek Lamb

Issues:102035

Non Conformance Issues - BSI Major Non Conformances
Tom Thumb 1511824-201709-M5 Initial Investigation
Issue ID #101072
Date Created 19/Aug/2017
Issued To: John Lamb
Completed Status: Still Outstanding
Stock Ref: 0310030

Notes:

Added by Derek Lamb sent to Derek Lamb
[Link to Main Issue](#)

19 Aug 2017 Derek Lamb

Next Action Changed From Derek Lamb To John Lamb

22 Aug 2017 John Lamb
Classification Rationale Doc ID 8023

Issues:101072

Non Conformance Issues - BSI Major Non Conformances
Tom Thumb 1511824-201709-M5 Initial Investigation

Issue ID #101053

Date Created 19/Aug/2017

Issued To: Derek Lamb

Completed Status: Still Outstanding

Stock Ref: 0310030

Linked Files

19 Aug 2017 QC 21 Non Conformance Report

27 Aug 2017 QC 21 Non Conformance Report - Corrected

Notes:

Added by Derek Lamb sent to Derek Lamb

Area/process Pre-Clinical Data

Clause Annex I ER 3

Scope CE 01389

Category

Major

Statement of

nonconformance:

The solutions adopted to fulfill essential requirement 3 is incomplete.

Clause

requirements

[Annex I ER 3] – “The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable...”

Objective

evidence

- Design Inputs are not uniquely or clearly identified.
- Design input document has not been updated since 1997, despite design changes being made as late as 2004 in accordance with the risk management file.
- The outputs of risk management are stated to be design inputs in the risk management but fail to be expressed in the design input file.
- While it is acknowledged that the device has been in the field for many years, there is no evidence of a design control system provided.
- No evidence of design verification, current or historical has been provided. ID2471 (Test Reports), ID 2460 (Test reports) state only “The equipment was tested against customer requirements...” Documentation identified by the manufacturer ID 8486, continues to state only general work instruction for shipment tests and makes no mention of design testing, link to risk, design inputs, outputs or acceptance criteria. No data or summary data is made available.

19 Aug 2017 Derek Lamb

Created Related Issue #101054

Added by Derek Lamb sent to Derek Lamb

19 Aug 2017 Derek Lamb

Created Related Issue #101055

Added by Derek Lamb sent to Derek Lamb

19 Aug 2017 Derek Lamb

Subject Changed From 1511824-201709-M5
Subject Changed To 1511824-201709-M5 Initial Investigation

19 Aug 2017 Derek Lamb
Created Related Issue #101072
Added by Derek Lamb sent to Derek Lamb
Link to Main Issue

27 Aug 2017 Derek Lamb
Example Files from digital QA System Added to the file.
Tom Thumb QA Procedures Example QA Report Barcode 1009081_ID21625

Tom Thumb QA Procedures Example QA Records Tom Thumb 0310030_ID21623

All units have individual Q.A. Testing records.

01 Sep 2017 Derek Lamb
Created Related Issue #102035
Added by Derek Lamb sent to Derek Lamb
Design input document has not been updated since 1997, despite design changes being made as late as 2004 in accordance with the risk management file.
Several QC28 forms in error uploaded seperatley to the system instead of on top of each other,
See DOCID7461 Latest version.

Search Tom Thumb design changes and stack the documents

01 Sep 2017 Derek Lamb
Design input document has not been updated since 1997, despite design changes being made as late as 2004 in accordance with the risk management file.
Several QC28 forms in error uploaded seperatley to the system instead of on top of each other,
See DOCID7461 Latest version.
Issue102035 created to correct stack the documents in order,
*2 Extra documents 2004 version and the latest 2005 version.

Issues:101053

Non Conformance Issues - BSI Major Non Conformances
Tom Thumb 1511824-201709-M6 Corrective Action
Issue ID #101051
Date Created 19/Aug/2017
Issued To: Derek Lamb
Completed Status: Still Outstanding
Stock Ref: 0310030

Notes:

Added by Derek Lamb sent to Derek Lamb

Issues:101051

Non Conformance Issues - BSI Major Non Conformances

Tom Thumb 1511824-201709-M6 Effectiveness verification

Issue ID #101052

Date Created 19/Aug/2017

Issued To: Derek Lamb

Completed Status: Still Outstanding

Stock Ref: 0310030

Notes:

Added by Derek Lamb sent to Derek Lamb

Issues:101052

Non Conformance Issues - BSI Major Non Conformances
Tom Thumb 1511824-201709-M6 Initial Investigation
Issue ID #101073
Date Created 19/Aug/2017
Issued To: John Lamb
Completed Status: Still Outstanding
Stock Ref: 0310030

Notes:

Added by Derek Lamb sent to John Lamb
[Link to Main Issue](#)

23 Aug 2017 John Lamb

Subject Changed From 1511824-201709-M6 Initial Investigation
Subject Changed To Tom Thumb 1511824-201709-M6 Initial Investigation EN Standards have been employed but not audited.
EN60601-2-10 relates to Nerve Stimulators
EN60601-1 relates to Electrical Instruments
COUNCIL DIRECTIVE 93/42/EEC
1993L0042 EN 11.10.2007 005.001 1
Whereas the essential requirements and other requirements set out in the Annexes to this Directive, including any reference to minimizing or reducing risk must be interpreted and applied in such a way as to take account of technology and practice existing at the time of design and of technical and economical considerations compatible with a high level of protection of health and safety;
Whereas, in accordance with the principles set out in the Council resolution of 7 May 1985 concerning a new approach to technical harmonization and standardization (2), rules regarding the design and manufacture of medical devices must be confined to the provisions required to meet the essential requirements; whereas, because they are essential, such requirements should replace the corresponding national provisions; whereas the essential requirements should be applied with discretion to take account of the technological level existing at the time of design and of technical and economic considerations compatible with a high level of protection of health and safety;

Issues:101073

Non Conformance Issues - BSI Major Non Conformances
Tom Thumb 1511824-201709-M6 Initial Investigation

Issue ID #101050

Date Created 19/Aug/2017

Issued To: Derek Lamb

Completed Status: Still Outstanding

Stock Ref: 0310030

Linked Files

19 Aug 2017 QC 21 Non Conformance Report

Notes:

Added by Derek Lamb sent to Derek Lamb

Area/process Pre-Clinical Data

Clause [Annex I ER 2]

Scope CE 01389

Category

Major

Assessment Report.

Page 16 of 23

Statement of

nonconformance:

The solution adopted to fulfil the Essential Requirement 2 is not complete.

Clause

requirements

[Annex I ER 2] - The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.

Objective

evidence

There is no evidence of compliance to claimed standards, including EN 60601-2-10, and EN 60601-1. All clauses of the standard per report ID 11655

(version 1332256919) have been listed explicitly as N/A including clearly applicable standards such as but not limited to section 7.0 and section 9.0.

There is no evidence of compliance in part or in full to the harmonized standard EN 60601-1 or a rationale for partial compliance.

19 Aug 2017 Derek Lamb

Created Related Issue #101051

Added by Derek Lamb sent to Derek Lamb

19 Aug 2017 Derek Lamb

Created Related Issue #101052

Added by Derek Lamb sent to Derek Lamb

19 Aug 2017 Derek Lamb

Created Related Issue #101073

Added by Derek Lamb sent to John Lamb

Link to Main Issue

Issues:101050

Non Conformance Issues - BSI Major Non Conformances

Tom Thumb 1511824-201709-M7 Corrective Action

Issue ID #101048

Date Created 19/Aug/2017

Issued To: Derek Lamb

Completed Status: Still Outstanding

Stock Ref: 0310030

Notes:

Added by Derek Lamb sent to Derek Lamb

Issues:101048

Non Conformance Issues - BSI Major Non Conformances

Tom Thumb 1511824-201709-M7 Effectiveness verification

Issue ID #101049

Date Created 19/Aug/2017

Issued To: Derek Lamb

Completed Status: Still Outstanding

Stock Ref: 0310030

Notes:

Added by Derek Lamb sent to Derek Lamb

Issues:101049

Non Conformance Issues - BSI Major Non Conformances
Tom Thumb 1511824-201709-M7 Initial Investigation
Issue ID #101074
Date Created 19/Aug/2017
Issued To: John Lamb
Completed Status: Still Outstanding
Stock Ref: 0310030

Notes:

Added by Derek Lamb sent to John Lamb
[Link to Main Issue](#)

23 Aug 2017 John Lamb

Subject Changed From 1511824-201709-M7 Initial Investigation
Subject Changed To Tom Thumb 1511824-201709-M7 Initial Investigation Doc ID
7887:7887:3477:3009:3008:3004:2534:2340:2338;2991
All in Section T1 Specifications of Materials
Doc ID 19538:11763:
Doc ID 2474
Risk Doc ID 2970:2182:2183:8489:21003:15756:
Biological input Lack of comment from user since circa 1998

Issues:101074

Non Conformance Issues - BSI Major Non Conformances
Tom Thumb 1511824-201709-M7 Initial Investigation

Issue ID #101047

Date Created 19/Aug/2017

Issued To: Derek Lamb

Completed Status: Still Outstanding

Stock Ref: 0310030

Linked Files

19 Aug 2017 QC 21 Non Conformance Report

Notes:

Added by Derek Lamb sent to Derek Lamb

Area/process Pre-Clinical Data

Clause ER 7.1

Scope CE 01389

Category

Major

Statement of

nonconformance:

The solutions adopted to fulfill the essential requirement 7.1 are incomplete.

Clause

requirements

ER 7.1 – “The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I on the ‘General requirements’. Particular attention must be paid to: — the choice of materials used, particularly as regards toxicity...”

Objective

evidence

Biocompatibility documentation does not fully meet requirements. Documents ID2474 and, ID7884 (No revisions provided) fail to:

- Provide a Biological Evaluation Plan or overall Biological Evaluation Report made by a qualified person
- Consider harmonized standards
- Consider duration or nature of contact
- Provided rationale for use of post market data.
- Provide evidence of any consideration of biological impact.
- Consider risk related to biological compatibility of the device.

19 Aug 2017 Derek Lamb

Created Related Issue #101048

Added by Derek Lamb sent to Derek Lamb

19 Aug 2017 Derek Lamb

Created Related Issue #101049

Added by Derek Lamb sent to Derek Lamb

19 Aug 2017 Derek Lamb

Created Related Issue #101074

Added by Derek Lamb sent to John Lamb

Link to Main Issue

Issues:101047

Non Conformance Issues - BSI Major Non Conformances
Tom Thumb 1511824-201709-M8 Corrective Action

Issue ID #101045

Date Created 19/Aug/2017

Issued To: Derek Lamb

Completed Status: Still Outstanding

Stock Ref: 0310030

Notes:

Added by Derek Lamb sent to Derek Lamb

03 Sep 2017 Derek Lamb

Controlled Document DOCID 15571 Tom Thumb Instructions for Use User Manual TT480 Requires Updating.

Needs checking against BSI Ref non conformance 1511824-201709-M8, although originally against our competitors instruction manual, its worth checking the highlighted non conformances against OUR instructions for use

Issues:101045

Non Conformance Issues - BSI Major Non Conformances

Tom Thumb 1511824-201709-M8 Effectiveness verification

Issue ID #101046

Date Created 19/Aug/2017

Issued To: Derek Lamb

Completed Status: Still Outstanding

Stock Ref: 0310030

Notes:

Added by Derek Lamb sent to Derek Lamb

Issues:101046

Non Conformance Issues - BSI Major Non Conformances

Tom Thumb 1511824-201709-M8 Initial Investigation

Issue ID #101075

Date Created 19/Aug/2017

Issued To: John Lamb

Completed Status: Still Outstanding

Stock Ref: 0310030

Notes:

Added by Derek Lamb sent to John Lamb

[Link to Main Issue](#)

23 Aug 2017 John Lamb

Subject Changed From 1511824-201709-M8 Initial Investigation

Subject Changed To Tom Thumb 1511824-201709-M8 Initial Investigation Article 17 ??

User manuals DocID 15572:15571:15570:15511:15510:15509:13307:12211:11732:8512:8506::5107

NB All have been audited before by BSI

Labels eg 11740:5922

NB All have been audited before by BSI

Issues:101075

Non Conformance Issues - BSI Major Non Conformances
Tom Thumb 1511824-201709-M8 Initial Investigation

Issue ID #101044

Date Created 19/Aug/2017

Issued To: Derek Lamb

Completed Status: Still Outstanding

Stock Ref: 0310030

Linked Files

19 Aug 2017 QC 21 Non Conformance Report

Notes:

Added by Derek Lamb sent to Derek Lamb

Non-conformance:

Ref. no 1511824-201709-M8

Area/process Information Supplied by the Manufacturer

Clause Article 17 & Annex I, ER 13

Scope CE 01389

Category

Major

Assessment Report.

Statement of

nonconformance:

The instructions for use and the labels do not meet the requirements of Article 17

The instructions for use and the labels do not meet the requirements of Essential requirement 13 of Annex I.

Clause

requirements

[Article 17] – “The CE marking of conformity, as shown in Annex XII, must appear in a visible, legible and indelible form on the device or its sterile pack, where practicable and appropriate, and on the instructions for use...”

[Annex I, ER 13] - “The label must bear the following particulars...”

Objective

evidence

- Multiple Notified Body ID numbers have been identified on active labelling: (0123) found on document ID 7Revision B.

- Precautions related to change in performance are not included

- Responses to other sections of the technical file indicate the device is intended for sterilization. Labeling and IFU do not cover sterilization methods.

- Special handling instructions as identified in the technical file and IFU are not present on the labeling.

19 Aug 2017 Derek Lamb

DOCID13654

titled

Tom Thumb Competitor Instructions for use for similar products Fisher Pake NeoPuff IFU_22_04_14

19 Aug 2017 Derek Lamb

Subject Changed From 1511824-201709-M8

Subject Changed To 1511824-201709-M8 Initial Investigation

19 Aug 2017 Derek Lamb

Created Related Issue #101045

Added by Derek Lamb sent to Derek Lamb

19 Aug 2017 Derek Lamb
Created Related Issue #101046
Added by Derek Lamb sent to Derek Lamb

19 Aug 2017 Derek Lamb
Created Related Issue #101075
Added by Derek Lamb sent to John Lamb
Link to Main Issue

27 Aug 2017 Derek Lamb
Document referred to in non conformance is a competitors instructions for use, for a competitors device with the same function as the Tom Thumb

Issues:101044

Non Conformance Issues - BSI Major Non Conformances

Tom Thumb 1511824-201709-N1 Corrective Action

Issue ID #102040

Date Created 03/Sep/2017

Issued To: Derek Lamb

Completed Status: Still Outstanding

Stock Ref: 0310030

Notes:

Added by Derek Lamb sent to Derek Lamb

Files supplied

Issues:102040

Non Conformance Issues - BSI Major Non Conformances

Tom Thumb 1511824-201709-N1 Initial Investigation

Issue ID #102039

Date Created 03/Sep/2017

Issued To: Derek Lamb

Completed Status: Still Outstanding

Stock Ref: 0310030

Notes:

Added by Derek Lamb sent to Derek Lamb

03 Sep 2017 Derek Lamb

Created Related Issue #102040

Added by Derek Lamb sent to Derek Lamb

Files supplied

Issues:102039

Projects - Potential New products

Tom Thumb new producer

Issue ID #75534

Date Created 22/Jul/2016

Issued To: Derek Lamb

Completed Status: 06 Feb 2017

Linked Files

22 Jul 2016 Quote 1

22 Jul 2016 Quote 2

22 Jul 2016 Quote 3

22 Jul 2016 Quote 4

Notes:

Added by Derek Lamb sent to Derek Lamb
see R and L quotes

24 Aug 2016 Derek Lamb
0310030

03 Feb 2017 Derek Lamb

Issues:75534

VIAMED Stock Meeting - Any Other Business
Tom Thumb parts cost comparisons 17-11-2016

Issue ID #83775

Date Created 17/Nov/2016

Issued To: Jonathan Connor

Completed Status: 26 Nov 2016

Notes:

Copy Issue Main Issue #83774

Added by Steve Nixon sent to Derek Lamb

I have been in contact with R&L, Martyn has agreed to supply us with copies of their drawings etc.

Just done a quick cost comparison check of the parts.

For the main parts:

MAJ Hi Spec/KSJ £30.85

R&L £47.11

So R&L £16.26 more expensive, but superior quality and no problems or handling/transport of parts.

For the valves:

JNK Tooling £34.30 + £42.66 = £76.96

R&L £12.90 + £23.49 = £36.39

So R&L £40.57 cheaper.

Overall saving of £24.31 per unit or £2,431.00 per batch of 100.

NOTE: I believe they have changed the size of the 3 x 0330233 screws since they found hard to source, this also affects the valve body. These screws are expensive at £2.29, but suggest leave as is, as we have overall savings. I had sourced the original screws at £0.19p each.

Also have a saving of £29.30 per unit with sourcing the pressure gauge from Gauges North West rather than Wika.

So overall savings of £5,361.00 per batch.

R&L parts prices have been added to Opera.

17 Nov 2016 Jonathan Connor

Thanks

Issues:83775

VIAMED Stock Meeting - Any Other Business
Tom Thumb parts cost comparisons 17-11-2016

Issue ID #83774

Date Created 17/Nov/2016

Issued To: Derek Lamb

Completed Status: 26 Nov 2016

Notes:

Added by Steve Nixon sent to Derek Lamb

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R&L parts prices have been added to Opera.

21 Nov 2016 Derek Lamb
thanks

Issues:83774

VIAMED Sales And Marketing - Any other business

Tom Thumb service letters

Issue ID #89791

Date Created 22/Feb/2017

Issued To: Derek Lamb

Completed Status: Still Outstanding

Notes:

Copy Issue Main Issue #89789

Added by Steve Nixon sent to Katie Evans

The following is a list of Tom Thumb models, the prime one is 0310030. NOTE: sales figures could be masking the true picture as many Tom Thumbs have been sold as part of resuscitation cabinet systems, so we should also target customers who have purchased cabinets. Some models may never have been sold and some may have been sold prior to intrastats figures...

0310027, 0310029, 0310030, 0310031, 0310032, 0310033, 0310034, 0310036, 0310072, 0310074, 0310075, 0310076, 0310080, 0310082, 0310092, 0310093, 0310094, 0310096, 0310097, 0310098, 0310099, 0310250

We should also target engineers who have purchased Tom Thumb spare parts such as the gauges (0330203, 0330193). There are also customers who have carried out Tom Thumb upgrades.

It would be prudent to not target existing service contract customers!

Katie, can you please attach 1st draft copies of proposed letter/s. You could customize the letters relating to the picture of each particular Tom Thumb.

Derek, as discussed, I know you and Michael have addressed the service manuals, procedures and reports etc. Just to make sure, can you please attach a copy of the current service reports for 0310030, 03100034, so that we can check the suitability and presentation, before we process to new customers.

Issues:89791

VIAMED Sales And Marketing - Any other business

Tom Thumb service letters

Issue ID #89790

Date Created 22/Feb/2017

Issued To: Catrin Hird

Completed Status: Still Outstanding

Notes:

Copy Issue Main Issue #89789

Added by Steve Nixon sent to Katie Evans

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Issues:89790

VIAMED Sales And Marketing - Any other business

Tom Thumb service letters

Issue ID #89789

Date Created 22/Feb/2017

Issued To: Katie Evans

Completed Status: Still Outstanding

Linked Files

06 Mar 2017 Draft - Tom Thumb Service Letter GBP End User

02 Jun 2017 TT Service TT480

02 Jun 2017 TT Service TT490

09 Aug 2017 sample service notes

Notes:

Added by Steve Nixon sent to Katie Evans

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06 Mar 2017 Katie Evans

Please find draft attached, is there any further information you would like me to include. Will locate pictures

02 Jun 2017 Katie Evans

Attached updated versions with pictures

Issues:89789

VIAMED Feedback - Product Feedback Negative

Tom Thumb with stuck gauge

Issue ID #100174

Date Created 07/Aug/2017

Issued To: Derek Lamb

Completed Status: 09 Oct 2017

Notes:

Copy Issue Main Issue #100173

Added by Steve Hardaker sent to Philip Crossley

I have just raised SRS66141 for Westmorland Hospital to return a TT480 s/n 0401365 with a stuck gauge.

Supplied 9/1/17, IN148689.

Photo evidence was provided of it stuck at 25cm H20, see attached.

Phil, this needs resolving urgently. Please see Steve N for advice when it arrives, he may want to swap the gauge with a Wika one.

CCd to Emma and Jonathan to ask that this be booked in as a priority repair, and to SN and DL who may need to create related issues to investigate further.

0310030

Issues:100174

VIAMED Feedback - Product Feedback Negative

Tom Thumb with stuck gauge

Issue ID #100173

Date Created 07/Aug/2017

Issued To: Philip Crossley

Completed Status: 19 Sep 2017

Linked Files

07 Aug 2017 TT480- sn 0401365 SRS66141 20170807

Notes:

Added by Steve Hardaker sent to Philip Crossley

I have just raised SRS66141 for Westmorland Hospital to return a TT480 s/n 0401365 with a stuck gauge.

Supplied 9/1/17, IN148689.

0310030

Photo evidence was provided of it stuck at 25cm H2O, see attached.

Phil, this needs resolving urgently. Please see Steve N for advice when it arrives, he may want to swap the gauge with a Wika one.

CCd to Emma and Jonathan to ask that this be booked in as a priority repair, and to SN and DL who may need to create related issues to investigate further.

07 Aug 2017 Philip Crossley

I don't think there are any new Wika gauges in stock

13 Sep 2017 Steve Hardaker How did you resolve this, did you use a standard (Gauges North West) gauge? If this is complete, you can close it off.

19 Sep 2017 Philip Crossley

Yeah had to fit a new GNW gauge

19 Sep 2017 Steve Hardaker

Issues:100173

VIAMED Stock Meeting - Repairs Review - General

TT480 0401281

Issue ID #104434

Date Created 03/Oct/2017

Issued To: Derek Lamb

Completed Status: Still Outstanding

Notes:

Added by Philip Crossley sent to Derek Lamb

Service Repair Sheet:65337 SRN26970 Tom Thumb 0310094 0401281 Tom Thumb (PM).

This Tom Thumb failed from new, they say it won't turn up above 10cmh2o (because the internal collar has been wound up). It didn't leave here like that

checked the QA records was qa by robert so confirm it left here ok

its a simple fix but it was replaced under warranty so we are left with a complete polemount TT480 as new

Issues:104434

VIAMED Management Meeting - Future Reviews - Waste

Wee report requires some weights

Issue ID #86420

Date Created 04/Jan/2017

Issued To: Jonathan Connor

Completed Status: Still Outstanding

Notes:

Added by Derek Lamb sent to Jonathan Connor

I need the weights and dimensions for the following part numbers to fill in viameds wee waste form.

Not urgent as I've guesstimated the figure this month but will need it in the next 2-3 months

0110290
0110380
0332022
0332023
0390015
4310013
4310014
4310015
4420971
7900290
7910210
7910211
7930125
8010005
8010010
8010015
8010021
9035004
9035021
9035033
9060026
9071036
9530025
9531020
9710040
9711610
9711902
9730037
9730063
9730087
9790002

28 Feb 2017 Jonathan Connor

Next Action Changed From Jonathan Connor To Ryan Swaine Please can you give me 1 of each of the below items, should all be Vandagraph stock

9035004
9035021
9035033
9060026
9071036
9530025
9531020
9710040

9711610
9711902
9730037
9730063
9730087
9790002

28 Feb 2017 Ryan Swaine

Next Action Changed From Ryan Swaine To Jonathan Connor Done, except for the Wallmount MixChek 9711610, as these are no longer available.

Issues:86420

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 :

Found upto date guidelines still advocating use of resuscitators and still within the limits of the tom thumb

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 FDA reports found