



31/Jul/2013

Post market Surveillance and Risk Assessment Re-evaluation

Tom Thumb
Viamed Product
Post market Surveillance
Risk Assessment
Stock References Review
Supplier Review
Sales Review
Country Sales Review
Stock Returns Review
Design Changes Review
User Manuals Review
Labels Review
Document Updates Review
Internal Issues Review
Clinical Information Review
FDA Incidents Review
Carried out by Derek Lamb on 31 / 07 / 13

Stock References Reviewed

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.
0310098	Tom Thumb Oxygen Flow.
0310099	Tom Thumb Oxygen Vent.
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
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	Diamond Copper Washer
0330213	O Ring Thick
0330214	O Ring Thin
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 Grease
0330221	Lock Tight

Stock Reference	Description
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 Adjustable Screw
0330229	Adjustable Valve Body
0330230	Adjustable Valve Screw
0330231	Adjustable Valve Internal Stop
0330232	Adjustable Valve Collar
0330233	Adjustable Valve Center Screw
0330234	Adjustable Valve Side Screw
0330235	Inlet Restrictor
0330236	Replacement Gauge Face.
0330241	TT480/490 MAIN Body Block
0330242	Medirail Mounting Plate
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

Comments on Stock references review:

Added some component part numbers,

Supplier Information on Main and Component Parts

Stock Reference	Description	Supplier A/C	Supplier Name	Rating
0320221	Pole Clamp without slide bracket.	00007317	Inspiration Healthcare Limited	B
0320103	Tom Thumb Rectangular Mounting Block.	00009022	Tanda Engineering Ltd	A
0330185	Wing Nut Screw Black 25mm Thread	00009032	R & L Enterprises Ltd	B
0330190	Universal clamp - 44mm horizontal	00009032	R & L Enterprises Ltd	B
0330191	Clamp Spacer	00009032	R & L Enterprises Ltd	B
0330242	Medirail Mounting Plate	00009032	R & L Enterprises Ltd	B
0330216	Screws For Clamp	00009061	Farnell	A
0330234	Adjustable Valve Side Screw	00009073	Modern Screws	B
0330243	Adjustable Valve Side Screw. Bag 100	00009073	Modern Screws	B
0330210	Precision Valve	00009117	JNK Tooling	b
0330211	Adjustable Valve	00009117	JNK Tooling	b
0330224	Precision Valve Body	00009117	JNK Tooling	b
0330227	Precision/Adjustable Valve Seat	00009117	JNK Tooling	b
0330228	Precision Valve Adjustable Screw	00009117	JNK Tooling	b
0330234	Adjustable Valve Side Screw	00009117	JNK Tooling	b
0330235	Inlet Restrictor	00009117	JNK Tooling	b
0330207	Blanking Bolt	00009123	RS Components Ltd	B
0330213	O Ring Thick	00009123	RS Components Ltd	B
0330214	O Ring Thin	00009123	RS Components Ltd	B
0330216	Screws For Clamp	00009123	RS Components Ltd	B
0330220	Fomblin Grease	00009123	RS Components Ltd	B
0330221	Lock Tight	00009123	RS Components Ltd	B
0330296	Blanking Bolt	00009123	RS Components Ltd	B
0320060	Flowmeter (Oxygen) 0-15 Lpm.	00009150	Therapy Equipment Ltd	A
0330030	Dovetail (male)	00009150	Therapy Equipment Ltd	A
0330055	Universal clamp - 44mm horizontal	00009150	Therapy Equipment Ltd	A
0330204	Flowmeter (air) 0-15 Lpm	00009150	Therapy Equipment Ltd	A
0330212	Diamond Copper Washer	00009150	Therapy Equipment Ltd	A
0330217	Oxygen hose 1m. C/W indirect probe &	00009150	Therapy Equipment Ltd	A
0330218	Oxygen Hose 3m. C/W indirect probe &	00009150	Therapy Equipment Ltd	A
0330250	Oxygen hose 1.5m. C/W DIN fitting:	00009150	Therapy Equipment Ltd	A
0330251	Oxygen hose 3.0m. C/W DIN fitting:	00009150	Therapy Equipment Ltd	A
0330268	Air Hose 3m. C/W indirect probe &	00009150	Therapy Equipment Ltd	A
3210011	NeoPEEP neonatal single patient use	00009602	Bunzl Healthcare	C
3210071	Single use silicone round facemask	00009602	Bunzl Healthcare	C
3210011	NeoPEEP neonatal single patient use	00009721	Marshall Products Limited	B
3210071	Single use silicone round facemask	00009721	Marshall Products Limited	B
0330200	TT460 MAIN Body Block	00010160	KSJ Engineering Limited	B
0330201	TT480/490 MAIN Body Block	00010160	KSJ Engineering Limited	B
0330202	TT495 MAIN Body Block	00010160	KSJ Engineering Limited	B
0330205	Flowmeter Meter Bolt	00010160	KSJ Engineering Limited	B
0330206	Blocking Bolt And Nut	00010160	KSJ Engineering Limited	B
0330208	Inlet 10 mm	00010160	KSJ Engineering Limited	B
0330209	Outlet 15mm	00010160	KSJ Engineering Limited	B
0330215	Clamp Spacer	00010160	KSJ Engineering Limited	B
0330241	TT480/490 MAIN Body Block	00010160	KSJ Engineering Limited	B

Stock Reference	Description	Supplier A/C	Supplier Name	Rating
0330246	Blocking Bolt And Nut	00010160	KSJ Engineering Limited	B
0330248	Inlet 10 mm	00010160	KSJ Engineering Limited	B
0330249	Outlet 15mm	00010160	KSJ Engineering Limited	B
0330295	Outlet 10mm do not use	00010160	KSJ Engineering Limited	B
0330203	Pressure gauge for `Tom Thumb` Infant	00010395	Wika Instruments Ltd	B
0330236	Replacement Gauge Face.	00010395	Wika Instruments Ltd	B
0330200	TT460 MAIN Body Block	00010725	MAJ Hi-Spec Ltd	B
0330201	TT480/490 MAIN Body Block	00010725	MAJ Hi-Spec Ltd	B
0330202	TT495 MAIN Body Block	00010725	MAJ Hi-Spec Ltd	B
0330205	Flowmeter Meter Bolt	00010725	MAJ Hi-Spec Ltd	B
0330206	Blocking Bolt And Nut	00010725	MAJ Hi-Spec Ltd	B
0330207	Blanking Bolt	00010725	MAJ Hi-Spec Ltd	B
0330208	Inlet 10 mm	00010725	MAJ Hi-Spec Ltd	B
0330209	Outlet 15mm	00010725	MAJ Hi-Spec Ltd	B
0330219	Right Angle For Hose	00010770	Chelmer Pneumatics Ltd	B
0120140	Adapter 15mm I.D. - 15mm I.D	00011844	Instrumentation Industries Inc	B
0330222	Precision Valve Spring	00012028	Harlow Springs Limited	B
0330223	Adjustable Valve Spring	00012028	Harlow Springs Limited	B
0330300	Key Ring chain 1 inch ball	00012395	Seton	B

Comments on Suppliers:

All suppliers ratings ok,

Sales Information

Stock Reference	Description	2007	2008	2009	2010	2011	2012	2013
0310027	Tom Thumb Infant Resuscitator (Air).							
0310029	Tom Thumb Infant Resuscitator (Air).							
0310030	Tom Thumb Infant Resuscitator.	33	102	58	80	121	259	35
0310031	Tom Thumb Infant Resuscitator (Oxygen).							
0310032	Tom Thumb Infant Resuscitator (Oxygen).	2			6			1
0310033	Tom Thumb Infant Resuscitator (Oxygen).							
0310034	Tom Thumb Infant Resuscitator (Oxygen).	1		4		1		
0310072	Tom Thumb Infant Resuscitator.		11					
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).		2					
0310093	Tom Thumb Infant Resuscitator.					2		
0310094	Tom Thumb Infant Resuscitator.					4		9
0310098	Tom Thumb Oxygen Flow.							
0310099	Tom Thumb Oxygen Vent.			5				
0320102	Tom Thumb Rectangular Mounting Block.							
0320103	Tom Thumb Rectangular Mounting Block.		1					
0330185	Wing Nut Screw Black 25mm Thread							
0330190	Universal clamp - 44mm horizontal							
0330191	Clamp Spacer							
0330200	TT460 MAIN Body Block							
0330201	TT480/490 MAIN Body Block	1				1		
0330202	TT495 MAIN Body Block							1
0330203	Pressure gauge for `Tom Thumb` Infant	19	17	30	20	13	10	14
0330204	Flowmeter (air) 0-15 Lpm							
0330205	Flowmeter Meter Bolt							
0330206	Blocking Bolt And Nut					16	12	
0330207	Blanking Bolt							
0330208	Inlet 10 mm					46	12	
0330209	Outlet 15mm		5					
0330210	Precision Valve	1		2	2	4		3
0330211	Adjustable Valve	4	1		2	1	2	3
0330212	Diamond Copper Washer	19	34	29	55	31	40	23
0330213	O Ring Thick	52	14	40	13	77	8	24
0330214	O Ring Thin	142	163	235	135	358	48	160
0330215	Clamp Spacer		4	1				
0330216	Screws For Clamp		28		4			
0330217	Oxygen hose 1m. C/W indirect probe &			8	2			6
0330218	Oxygen Hose 3m. C/W indirect probe &	12	6	28	13	15	2	7
0330219	Right Angle For Hose				1	2		
0330220	Fomblin Grease							
0330221	Lock Tight							
0330222	Precision Valve Spring						1	

Stock Reference	Description	2007	2008	2009	2010	2011	2012	2013
0330223	Adjustable Valve Spring						2	
0330224	Precision Valve Body							
0330225	Precision/Adjustable Valve Seating	5						
0330227	Precision/Adjustable Valve Seat				1		2	1
0330228	Precision Valve Adjustable Screw							
0330229	Adjustable Valve Body	1						1
0330230	Adjustable Valve Screw							
0330231	Adjustable Valve Internal Stop							
0330232	Adjustable Valve Collar							
0330233	Adjustable Valve Center Screw							
0330234	Adjustable Valve Side Screw							
0330235	Inlet Restrictor	4			5			
0330236	Replacement Gauge Face.	20	5	9	17	6	5	11
0330241	TT480/490 MAIN Body Block							
0330242	Medirail Mounting Plate							
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 &							1
0330268	Air Hose 3m. C/W indirect probe &							
0330291	Inlet 10mm Thumbelina Inlet							
0330292	Outlet 15mm Thumbelina							
0330295	Outlet 10mm do not use			2				
0330296	Blanking Bolt							
0330297	Clamp Spacer - dove tailed.				5			
0330300	Key Ring chain 1 inch ball							

Comments on Sales Information:

Sales way down on last year, however some of the bigger customers have orders coming through.

New Countries

Country	2007	2008	2009	2010	2011	2012	2013
B Belgium		[X]	[X]			[X]	[X]
BRA Brazil	[X]						
CAN Canada			[X]				
F France	[X]	[X]	[X]	[X]	[X]	[X]	[X]
IN India							[X]
IT Italy				[X]			
MA Malaysia			[X]				
NE Netherlands							
RU Russia			[X]	[X]	[X]	[X]	
SAU Saudi Arabia						[X]	[X]
SWI Switzerland			[X]				
T Turkey			[X]			[X]	
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]

Comments on Sales to Countries:

Expecting a Russia order any time, and Mediprima,
new country India added,

Comments on Risks with Sales to Countries:

no risks identified

Returns Information

Stock Reference	Fault	2007	2008	2009	2010	2011	2012	2013
0310030	Adjusted factory set valves							3
0310030	Converted to TT480		1				1	
0310030	Damaged Pressure Gauge	1	2	4	2			
0310030	n/a							
0310030	No Fault Return to Stock							
0310030	Serviced		2	3				
0310030	Serviced / adjusted factory set valves			2	1		3	7
0310030	Tested			1				
0310032	Adjusted factory set valves				1			
0310032	Calibrated Gauge			1				
0310032	Converted to TT480						1	
0310032	Damaged Pressure Gauge				1			
0310032	Serviced		1					
0310032	Serviced / adjusted factory set valves			1	2			1
0310032	Tested			1				1
0310033	Serviced	1						
0310034	Adjusted factory set valves			2				
0310034	Damaged Pressure Gauge		1					
0310034	Serviced	1						1
0310034	Serviced / adjusted factory set valves				2	1	1	
0310094	Converted to TT480							9

Comments on Returns:

Most returns are services,
no problems identified.

Comments on Risks with Returns and Potential Re-work:

no risks identified with returns

Design Changes / Product Changes

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

No design changes have occurred

Comments on Risks with Design Changes:

no risk identified.

User Instructions

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
12212	Tom Thumb Instructions for Use User Manual TT480	30/11/12
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
8503	Tom Thumb Instructions for Use / User Manual TT490-15	06/07/11
5107	Instructions For Use Tom Thumb TT480	23/02/09

Comments on User Instructions:

instructions updated to include flow-meter accuracy as per BSI visit 2012

Comments on Risks User Instructions:

no risks identified

Labels

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
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
2204	Tom Thumb Labels Tomb Thumb Infant Resuscitator	19/06/07

Comments on Labels:

Comments on Risks Labels:

no risks identified with labels

Documentation Updates / Changes

Comments on Document Changes:

Document changes listed in previous sections, added documents on expected life.

Comments on Risks with Document Changes:

no risks identified,

Review of Issues

Number of Issues reviewed: 24

Issue ID	Subject
43326	0310093 Tom Thumb
42776	Parts required to modify a TT490 Tom Thumb to deliver air (May13)
38387	JSC - Quotation for Carriage
38386	JSC - Quotation for Carriage
42436	Returned Items SOR478
41478	Returned Items SOR543
41131	Returned Items SOR549
40683	Returned Items SOR539
39977	Request Scanning Item to Sale or return
42600	0330190 & 0330191 drawings
41290	7900000 Production procedure update
28097	Tom Thumb with a pole clamp
42381	Declarations of Conformity required
42380	Declarations of Conformity required
43723	Remove p/n 3210011
37072	Tom Thumb stock location discrepancy
39338	JSC - Germany
39337	JSC - Germany
34970	Capnograph battery failure
34839	Potential order from Eden Medical
44436	0330190 0330191 JSC Serceinstrument
42523	0330190 0330191 JSC Serceinstrument
42522	0330190 for Mediprema?
32978	Lost Customers - Infant Resus and Blenders

Comments on Issues:

no problems found in the Issues system,

Comments on Risks with Issues:

no risks identified

Review of online clinical reports

Do any of the Results indicate a Risk / Problem : No

Do any of the Results indicate outdated Technology : No

Comments on Clinical Search :

Review of online FDA Incident reports

Do any of the Results indicate a Risk / Problem : No

Do any of the Results indicate outdated Technology : No

Comments on Clinical Search :