



# 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  
04 / 12 / 18



# VIA MED

-  Stock References Review
-  Supplier Review
-  Sales Review
-  Countries Review
-  Returns Review
-  Design Changes Review
-  User Instructions Review
-  Labels Review
-  Document Updates Review
-  Internal Issues Review
-  Clinical / FDA Incidents online search

# 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 M5
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:

# 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	B
0330185	Wing Nut Screw Black 2	00009032	3335	R & L Enterprises Ltd	B
0330190	Universal clamp - 44mm h	00009032	A4916	R & L Enterprises Ltd	B
0330191	Clamp Spacer	00009032	A4917	R & L Enterprises Ltd	B
0330201	TT480/490 MAIN Body Bloc	00009032	0330201	R & L Enterprises Ltd	B
0330205	Flowmeter Meter Bolt	00009032	0330205	R & L Enterprises Ltd	B
0330206	Blocking Bolt And Nut	00009032	0330206	R & L Enterprises Ltd	B
0330208	Inlet 10 mm	00009032	0330208	R & L Enterprises Ltd	B
0330209	Outlet 15mm	00009032	0330209	R & L Enterprises Ltd	B
0330224	Precision Valve Body	00009032	0330224	R & L Enterprises Ltd	B
0330225	Precision/Adjustable Val	00009032	0330225	R & L Enterprises Ltd	B
0330227	Precision/Adjustable Val	00009032	0330227	R & L Enterprises Ltd	B
0330228	Precision Valve Adjustme	00009032	0330228	R & L Enterprises Ltd	B
0330229	Adjustable Valve Body	00009032	0330229	R & L Enterprises Ltd	B
0330230	Adjustable Valve Screw	00009032	0330230	R & L Enterprises Ltd	B
0330231	Adjustable Valve Interna	00009032	0330231	R & L Enterprises Ltd	B
0330232	Adjustable Valve Collar	00009032	0330232	R & L Enterprises Ltd	B
0330233	Adjustable Valve Centre	00009032	0330233	R & L Enterprises Ltd	B
0330234	Adjustable Valve Side Sc	00009032	0330234	R & L Enterprises Ltd	B
0330242	Medirail Mounting Bracke	00009032	A5090	R & L Enterprises Ltd	B
0330216	Screws For Clamp M5	00009061	483-9616	Farnell	B
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	B
0330213	O Ring Thick	00009123	129-050	RS Components Ltd	B
0330214	O Ring Thin	00009123	129-044	RS Components Ltd	B
0330216	Screws For Clamp M5	00009123	483-9616	RS Components Ltd	B
0330220	Fomblin OT20 Grease 100	00009123	666-4893	RS Components Ltd	B
0330221	Lock Tight	00009123	514-515	RS Components Ltd	B
0330296	Blanking Bolt	00009123	367-6098	RS Components Ltd	B
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	A
0350121	Packing box for Tom Thum	00009353	RPT17B	Rajapack Ltd	A
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	40415422	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	B
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:

gnw and maj no longer used,  
harlow springs used for the first time in years, however its for a simple spring, will do supplier review after  
this post market



# Sales Information

Stock Reference	Description	2012	2013	2014	2015	2016	2017	2018
0310027	Tom Thumb Infant Resuscitator (Air).							
0310029	Tom Thumb Infant Resuscitator (Air).							
0310030	Tom Thumb Infant Resuscitator.	259	94	129	67	48	52	58
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).		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.							
0310094	Tom Thumb Infant Resuscitator.		9		6	1	1	
0310096	Tom Thumb Oxygen Vent with Pole Mount		1					
0310097	Tom Thumb Infant Resuscitator (TG).		5	7	18	18	1	6
0310098	Tom Thumb Oxygen Flow.							
0310099	Tom Thumb Oxygen Vent.		1	1				
0310250	Tom Thumb Conversion Kit.	6	6	28	3	33		1
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	1
0330193	Pressure gauge: 63mm dia				18	22	17	13
0330200	TT460 MAIN Body Block							
0330201	TT480/490 MAIN Body Bloc						1	
0330202	TT495 MAIN Body Block		1					
0330203	Pressure gauge for `Tom	10	21	9		1		1
0330204	Flowmeter (air) 0-15 Lpm							
0330205	Flowmeter Meter Bolt							
0330206	Blocking Bolt And Nut	12	10					2
0330207	Blanking Bolt							
0330208	Inlet 10 mm	12	10		5			1
0330209	Outlet 15mm				15	7	5	2
0330210	Precision Valve		3	2	3	3	8	4
0330211	Adjustable Valve	2	3	3	5	7	7	
0330212	Gauge Seal	40	28	28	69	55	81	110
0330213	O Ring Thick	8	34	193	90	95	92	98
0330214	O Ring Thin	48	227	137	534	541	674	564

Stock Reference	Description	2012	2013	2014	2015	2016	2017	2018
0330215	Clamp Spacer							
0330216	Screws For Clamp M5						2	
0330217	Oxygen hose 1m. C/W indi		6	6	2	4	16	3
0330218	Oxygen Hose 3m. C/W indi	2	7	17	12		3	2
0330219	Right Angle For Hose							
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		4
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.	5	13	13	24	8	19	3
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	5
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						4	
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	2012	2013	2014	2015	2016	2017	2018
0380030	Tom Thumb Infant Resuscitator.							
0390003	Tom Thumb Instruction Ma							
0390004	Leaflet - Tom Thumb Infa		50		10			
0390005	Tom Thumb Training Manual							
0390006	Tom Thumb Instruction Ma			20				
0390007	Tom Thumb Instruction Ma							
0390008	Tom Thumb Serial Number Label							
0390009	`Tom Thumb` Label							
0390011	Tom Thumb CE Label							
0390015	Tom Thumb label					5		2
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 in limited qtys

# Countries Review

Country	2012	2013	2014	2015	2016	2017	2018
B Belgium	[X]	[X]				[X]	[X]
BRA Brazil							
C China			[X]				
CAN Canada							
CZ Czech Republic			[X]	[X]			
F France	[X]	[X]	[X]	[X]	[X]	[X]	[X]
FI Finland							[X]
HK Hong Kong							
IN India		[X]					
IT Italy					[X]	[X]	[X]
MA Malaysia							
NE Netherlands			[X]	[X]			
NG Nigera			[X]				
NI Northern Ireland							
P Poland							[X]
PA Pakistan				[X]			
PO Portugal					[X]		
RU Russia	[X]	[X]	[X]		[X]	[X]	[X]
SAU Saudi Arabia	[X]	[X]					
SC Scotland		[X]	[X]		[X]	[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 problems in supplying countries

Comments on Risks with Sales to Countries:

# Returns and Q.A. Fails Review

Stock Reference	Fault	2012	2013	2014	2015	2016	2017	2018
0310030	Needs Evaluating						1	
0310030	Adjusted Factory Set Valves		3			1	2	1
0310030	Calibrated Gauge				1			
0310030	Converted To TT480	1						1
0310030	Customer Declined Quotation					2		
0310030	Damaged Pressure Gauge			1	1		2	1
0310030	N/a							
0310030	New		1		2			
0310030	No Fault Found					2		1
0310030	No Fault Return To Stock							
0310030	Repaired Clamp And Serviced					1		
0310030	Replace Gauge And Service			1	1	4	3	2
0310030	Replaced gauge face							1
0310030	Replaced Gauge Face And Service					1		
0310030	Serviced					1	10	14
0310030	Serviced / Adjusted Factory Set Valves	3	11	11	10	12	3	7
0310030	Stuck Gauge						1	1
0310030	Tested				1	1	1	1
0310031	Serviced					2		
0310032	Adjusted Factory Set Valves							
0310032	Calibrated Gauge							
0310032	Converted To TT480	1						
0310032	Damaged Pressure Gauge							
0310032	New							
0310032	Replaced Gauge Face And Service						2	
0310032	Serviced						1	3
0310032	Serviced / Adjusted Factory Set Valves		1				1	
0310032	Serviced and Upgraded						4	
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	Serviced		1				1	
0310034	Serviced / Adjusted Factory Set Valves	1	2		5		2	
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	
0310094	Replace Gauge And Service						1	

Stock Reference	Fault	2012	2013	2014	2015	2016	2017	2018
0310094	Replaced Gauge Face And Service						1	
0310097	Serviced						1	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	No Fault Found							1
0330193	Unrepaired							2
0330201	Needs Evaluating				10			
0330217	Unchecked - Returned To Stock			8				
0380030	Needs Evaluating					3		
0380030	Service exchange unit							3
0390023	Serviced							

Comments on Returns:

normal returns and services, no cause for concern

Comments on Risks with Returns and Potential Re-work:

normal returns and services, no cause for concern

# 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

# 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 changes

Comments on Risks User Instructions:

no changes



# 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
17722	0330193 Pressure gauge: 63mm dial -5 to +60 cmWG (1416 / 1437)	19/10/16
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
7658	0310030 TT480 labelling modification 140211	14/02/11
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:

no changes

Comments on Risks Labels:

no changes

# Documentation Updates / Changes

Document ID	Description	Date Added/Updated
27474	VM3COP02.02 Viamed Company Responsibility's organisation chart s...	20/09/18
27256	Tom Thumb VM3COP Procedures Rework of Tom Thumbs	04/09/18
27092	Tom Thumb Literature reviews Resuscitation Guidelines 2000	29/08/18
27040	Tom Thumb Service Manual Parts required for Annual Service of TT...	20/08/18
26802	Tom Thumb Training Information Pressure Pipes World Wide	27/07/18
26720	Tom Thumb Literature reviews Tom Thumb Papers	19/07/18
26487	Tom Thumb Manufacturing route	15/06/18
26301	Tom Thumb Legal Actions and Litigation reports Shrewsbury	04/06/18
26245	Tom Thumb QA Procedures QA Records	30/05/18
25973	Tom Thumb Leakage and Liquid damage ingress	23/04/18
25814	Tom Thumb Description of Device Variants discontinued	09/04/18
25770	Tom Thumb Promotional Leaflets - Master Art work Gauge Wika	06/04/18
25768	Tom Thumb Classification rationale	06/04/18
25758	Tom Thumb Leakage and Liquid damage Ingress Tom Thumb	05/04/18
25744	Tom Thumb Legal Actions and Litigation reports Sunderland Royal ...	03/04/18
25742	Tom Thumb Legal Actions and Litigation reports	03/04/18
25596	Tom Thumb Test and Design Reports GNW Gauge Fault Reports	13/03/18
25530	Tom Thumb Manufacturing route Current Suppliers 2017-2018	06/03/18
25360	VM3COP50.13 Quality Control Tom Thumb	20/02/18
25356	VM3COP50.14 Calibration / Test Sheet Blank Tom Thumbs	20/02/18
25282	Tom Thumb Description of Accessories (8)	13/02/18
24820	Tom Thumb Tooling List Tom Thumb valve collar insertion tool - 0...	04/01/18
24672	Tom Thumb Flammability and Fire Risks	18/12/17
24623	Tom Thumb Product usability Misuse	11/12/17
24197	Tom Thumb Clinical Trials Reports Reviews and Post Market Survei...	27/11/17
24149	Tom Thumb Packaging Trials and validation Tom Thumb Background N...	23/11/17
24117	Tom Thumb Leakage and Liquid damage Ingress statistics	22/11/17
24101	Tom Thumb Leakage and Liquid damage TOM Thumb Ingress Issue 1085...	22/11/17
23922	Tom Thumb Clinical Trials Reports Reviews and Post Market Survei...	14/11/17
23912	Tom Thumb Clinical Trials Research JSL Tom Thumb Clinical Papers...	14/11/17
23908	Tom Thumb Residual Risks Estimation of Frequency of Use of Tom T...	14/11/17
23904	Tom Thumb Clinical Trials Reports Reviews and Post Market Survei...	14/11/17
23900	Tom Thumb Pre-Clinical Trials Data Tom Thumb summation annex X 1...	14/11/17
23896	Tom Thumb Residual Risks Foreseeable Misuse of Product Tom Thumb	14/11/17
23878	Oxygen Tents/Hoods Tanda Design Input Device Design Theory Oxy...	13/11/17
23874	Tom Thumb Purchase specifications Wika 6111.10 gauge Tom Thumb S...	13/11/17
23855	Tom Thumb Specifications 2017	10/11/17
23849	Tom Thumb Essential requirements	10/11/17
23843	Tom Thumb Risk analysis reports Risk assessment	10/11/17
23831	Tom Thumb Risk analysis reports Risk analysis 2017	09/11/17
23811	Tom Thumb Clinical Trials Reports Reviews and Post Market Survei...	09/11/17
23809	Tom Thumb Clinical Trials Reports Reviews and Post Market Survei...	09/11/17

Document ID	Description	Date Added/Updated
23803	Tom Thumb Product Changes Discontinuation of Products in the ran...	08/11/17
23705	BRI Documentation 2005 10mm adapter Report	02/11/17
23703	BRI Documentation 2005	02/11/17
23511	Tom Thumb Specifications Wika quote gauge cmH2o	27/10/17
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 expec...	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
22488	Tom Thumb Specifications of Materials Nitrile O rings	10/10/17
22482	Tom Thumb Post Market Surveillance	10/10/17

#### Comments on Document Changes:

technical documentation, has been brought in from old paper system, or further explanation documents added to the system due to technical audit last year

#### Comments on Risks with Document Changes:

no risks

# Internal Issues Review

Number of Issues reviewed: 147

Issue ID	Subject
107694	Office Meeting Stock Queries 0310030 Tom Thumb Infant Resuscitator.
107693	Office Meeting Stock Queries 0310030 Tom Thumb Infant Resuscitator.
108582	Office Meeting Other 0310030 Tom Thumb IP rating
108581	Office Meeting Other 0310030 Tom Thumb IP rating
123755	Office Meeting Any Other Business 0310030 Tom Thumb stock review.
123754	Office Meeting Any Other Business 0310030 Tom Thumb stock review.
123753	Office Meeting Any Other Business 0310030 Tom Thumb stock review.
115942	Office Meeting Other 0330203 Quotation and specifications March 2018
106558	Office Meeting Any Other Business 0330203 quotation from Wika
106557	Office Meeting Any Other Business 0330203 quotation from Wika
60091	Office Meeting Purchase Order Requirements 0330222 Precision valve spring
123564	Office Meeting Sales Back Orders Review - By Product Active list shortages update notes
123563	Office Meeting Sales Back Orders Review - By Product Active list shortages update notes
123562	Office Meeting Sales Back Orders Review - By Product Active list shortages update notes
123561	Office Meeting Sales Back Orders Review - By Product Active list shortages update notes
123560	Office Meeting Sales Back Orders Review - By Product Active list shortages update notes
112412	Office Meeting Production Apgar Timer brackets - 0320201
118441	Office Meeting Sales Back Orders Review - By Customer Backorder 00000149 0330212 ORD91731
133415	Office Meeting Sales Back Orders Review - By Customer Backorder 00000620 0330209 ORD95431
126880	Office Meeting Sales Back Orders Review - By Customer Backorder 00000690 0330033 ORD93771
132278	Office Meeting Sales Back Orders Review - By Customer Backorder 00000780 0330212 ORD95059
132279	Office Meeting Sales Back Orders Review - By Customer Backorder 00000780 0330213 ORD95059
132280	Office Meeting Sales Back Orders Review - By Customer Backorder 00000780 0330214 ORD95059
110371	Office Meeting Sales Back Orders Review - By Customer Backorder 00001040 0330210 ORD89880

Issue ID	Subject
107572	Office Meeting Sales Back Orders Review - By Customer Backorder 00001310 0310030 ORD89219
120729	Office Meeting Sales Back Orders Review - By Customer Backorder 00001350 0330206 ORD92309
113795	Office Meeting Sales Back Orders Review - By Customer Backorder 00002130 0330212 ORD90566
122973	Office Meeting Sales Back Orders Review - By Customer Backorder 00002500 0330263 ORD92545
114592	Office Meeting Sales Back Orders Review - By Customer Backorder 00002600 0380000 ORD90040
107160	Office Meeting Sales Back Orders Review - By Customer Backorder 00002662 0310030 ORD89131
110810	Office Meeting Sales Back Orders Review - By Customer Backorder 00002950 0330212 ORD90012
120177	Office Meeting Sales Back Orders Review - By Customer Backorder 00003710 0330193 ORD92122
132814	Office Meeting Sales Back Orders Review - By Customer Backorder 00003785 0310030 ORD95268
115076	Office Meeting Sales Back Orders Review - By Customer Backorder 00003960 0330213 ORD90905
129041	Office Meeting Sales Back Orders Review - By Customer Backorder 00004260 0340000 ORD94288
132915	Office Meeting Sales Back Orders Review - By Customer Backorder 00004560 0330212 ORD95303
109312	Office Meeting Sales Back Orders Review - By Customer Backorder 00004900 0330212 ORD89574
126088	Office Meeting Sales Back Orders Review - By Customer Backorder 00004992 0380000 ORD93539
124786	Office Meeting Sales Back Orders Review - By Customer Backorder 00005143 0330193 ORD88533
131711	Office Meeting Sales Back Orders Review - By Customer Backorder 00006070 0310030 ORD94567
120872	Office Meeting Sales Back Orders Review - By Customer Backorder 00006070 0330193 ORD92335
124483	Office Meeting Sales Back Orders Review - By Customer Backorder 00006679 0310097 ORD93140
119656	Office Meeting Sales Back Orders Review - By Customer Backorder 00006777 0310097 ORD92018
126613	Office Meeting Sales Back Orders Review - By Customer Backorder 00007273 0310030 ORD93731
109701	Office Meeting Sales Back Orders Review - By Customer Backorder 00007291 0310030 ORD89669
111261	Office Meeting Sales Back Orders Review - By Customer Backorder 00007291 0310030 ORD90085
116444	Office Meeting Sales Back Orders Review - By Customer Backorder 00007291 0310030 ORD91245
123709	Office Meeting Sales Back Orders Review - By Customer Backorder 00007291 0310030 ORD92992
133066	Office Meeting Sales Back Orders Review - By Customer Backorder 00007291 0310030 ORD95362
121715	Office Meeting Sales Back Orders Review - By Customer Backorder 00007291 0330193 ORD92499

Issue ID	Subject
133280	Office Meeting Post Market Surveillance File 16 Tom Thumb Risk File Updated
107515	Office Meeting Post Market Surveillance File 16 Tom Thumb Risk File Updated
124085	Office Meeting Stock Queries IN157418 0330263 stock query Allocations
108577	Office Meeting Marketing Job Logger Leaflet Tom Thumb Leaflet Amend 3rd Checking Stage
114403	Office Meeting Marketing Job Logger Leaflet Update Infant Resus Cabinet Leaflet Leaflet Designed
59171	Office Meeting Information for Intrastats and L Drive Parts required for annual service of Tom Thumbs
125584	Office Meeting Marketing Job Logger Photos/Images Tom Thumb for Cabinet Obtain Samples
106822	Office Meeting Back Order Report POR11498 0330217 //
106823	Office Meeting Back Order Report POR11498 0330218 //
107517	Office Meeting Back Order Report POR11508 0330217 //
115360	Office Meeting Back Order Report POR11588 0330242 //
115358	Office Meeting Back Order Report POR11588 0330242 //
112709	Office Meeting Back Order Report POR11588 0330242 //
114205	Office Meeting Back Order Report POR11613 0330217 //
114184	Office Meeting Back Order Report POR11613 0330217 //
113807	Office Meeting Back Order Report POR11613 0330217 //
115189	Office Meeting Back Order Report POR11628 0390015 //
114554	Office Meeting Back Order Report POR11628 0390015 //
116158	Office Meeting Back Order Report POR11654 0330203 //
116152	Office Meeting Back Order Report POR11654 0330203 //
116031	Office Meeting Back Order Report POR11655 0330214 //
108584	Office Meeting Intrastats Price List Weightings - Tom Thumb
132350	Office Meeting VIAMED Management Meeting Product Failures New Codes Review (750)
119115	Office Meeting VIAMED Management Meeting Product Failures New Codes Review (750)
125521	Office Meeting VIAMED Stock Meeting Production Statistics (551)
120200	Office Meeting Sale or Returns Request Scanning Item to Sale or return

Issue ID	Subject
107169	Office Meeting Sale or Returns Returned Items SOR519
117331	Office Meeting Sale or Returns Returned Items SOR756
123539	Office Meeting Sale or Returns Returned Items SOR854
131615	Office Meeting Intrastats Servicable Items Page
124534	Office Meeting Intrastats Serviceable Items: Clear
107033	Office Meeting VIAMED Management Meeting Software Validation In Production List (762)
104341	Office Meeting Other Standard to apply to Tom Thumb Infant Resuscitator
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
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

Issue ID	Subject
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
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
109967	Office Meeting Other Tom Thumb design change body block 0330201
108575	Office Meeting Marketing Job Logger Tom Thumb Leaflet Amend
107596	Office Meeting Other Tom Thumb Review 8 th November 2017
107595	Office Meeting Other Tom Thumb Review 8 th November 2017
107613	Office Meeting Sales Tom Thumb Review 8th November 2017 - Discontinued Variants
107612	Office Meeting Sales Tom Thumb Review 8th November 2017 - Discontinued Variants
107611	Office Meeting Sales Tom Thumb Review 8th November 2017 - Discontinued Variants
107610	Office Meeting Sales Tom Thumb Review 8th November 2017 - Discontinued Variants
107609	Office Meeting Sales Tom Thumb Review 8th November 2017 - Discontinued Variants
107608	Office Meeting Sales Tom Thumb Review 8th November 2017 - Discontinued Variants



Issue ID	Subject
107607	Office Meeting Sales Tom Thumb Review 8th November 2017 - Discontinued Variants
107606	Office Meeting Sales Tom Thumb Review 8th November 2017 - Discontinued Variants
107605	Office Meeting Sales Tom Thumb Review 8th November 2017 - Discontinued Variants
107604	Office Meeting Sales Tom Thumb Review 8th November 2017 - Discontinued Variants
107603	Office Meeting Sales Tom Thumb Review 8th November 2017 - Discontinued Variants
107602	Office Meeting Sales Tom Thumb Review 8th November 2017 - Discontinued Variants
107601	Office Meeting Sales Tom Thumb Review 8th November 2017 - Discontinued Variants
107600	Office Meeting Sales Tom Thumb Review 8th November 2017 - Discontinued Variants
107599	Office Meeting Sales Tom Thumb Review 8th November 2017 - Discontinued Variants
109225	Office Meeting Sales Tom Thumb Review 8th November 2017 - Discontinued Variants - Price list
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
110794	Office Meeting Purchase Order Requirements Tom Thumb valve collar insertion tool - 0360011
123903	Office Meeting Product Feedback Positive TT-480 0310097 fitted to Inspiration/Inditherm LifeStart
104434	Office Meeting Repairs Review - General TT480 0401281
113113	Office Meeting Photography TT480 with pole mount
121614	Office Meeting Web Site Updates Web Site Question ID 1200
86420	Office Meeting Future Reviews - Waste Wee report requires some weights

Comments on Issues:

mainly order processing issues,

plus all the BSI non conformances, which were raised due to remote audit

Comments on Risks with Issues:

no risks found in the issues system

---

VIAMED Stock Meeting - Stock Queries  
**0310030 Tom Thumb Infant Resuscitator.**  
Issue ID #107694  
Date Created 09/Nov/2017  
Issued To: Catrin Hird  
Completed Status: 22 Nov 2017

---

Notes:

Copy Issue Main Issue #107693  
Added by Derek Lamb sent to Steve Nixon  
Design input specifications with mbar as test numbers.

worst case i.e. we set the values to the maximums as per the QA

Adjustable Value @ 10lpm 42.1 +/- 1 mbar  
Setting on Test unit 43.0

Precision Value @ 10lpm Maximum 44.1 mbar +/- 1  
Setting on the Test unit 45.0

At 5 Lpm

Adjustable 40.0  
Precision Valve 42.5

At 10 Lpm

Adjustable 43.0  
Precision Valve 45.0

At 15 Lpm

Adjustable 45.7  
Precision Valve 47.2

---

20 Nov 2017 Catrin Hird  
Do we have the recommended body weight range also?

---

20 Nov 2017 Catrin Hird

Urgent Flag Changed To On Also Gas Inlet flow range and operating time (400 litre cylinder) plus any additional notes to add to the specification screen. Thanks

---

20 Nov 2017 Catrin Hird  
Added to marketing job 829 and issue reference 108587.

If you know the answer to the above 2 questions let me know otherwise I have included in issue to SN.

---

21 Nov 2017 Catrin Hird  
Artwork in job 829, Sn to review and signed off for printing when suitable.

---

Issues:107694

---

VIAMED Stock Meeting - Stock Queries

**0310030 Tom Thumb Infant Resuscitator.**

Issue ID #107693

Date Created 09/Nov/2017

Issued To: Steve Nixon

Completed Status: 07 Mar 2018

---

Notes:

Added by Derek Lamb sent to Steve Nixon

Design input specifications with mbar as test numbers.

worst case i.e. we set the values to the maximums as per the QA

Adjustable Value @ 10lpm 42.1 +/- 1 mbar

Setting on Test unit 43.0

Precision Value @ 10lpm Maximum 44.1 mbar +/- 1

Setting on the Test unit 45.0

At 5 Lpm

Adjustable 40.0

Precision Valve 42.5

At 10 Lpm

Adjustable 43.0

Precision Valve 45.0

At 15 Lpm

Adjustable 45.7

Precision Valve 47.2

---

07 Mar 2018 Derek Lamb

---

Issues:107693

---

VIAMED Management Meeting - Other

**0310030 Tom Thumb IP rating**

Issue ID #108582

Date Created 20/Nov/2017

Issued To: Derek Lamb

Completed Status: 04 Dec 2017

---

Notes:

Copy Issue Main Issue #108581

Added by Steve Nixon sent to John Lamb

For further discussion.

It appears that the minimum requirement is IPX4. No need to test for foreign objects, I assume it is because due to the nature of the device that there will be openings.

ISO 10651:

8.2.10 Indication of protection against water ingress The resuscitator shall be marked with a symbol, using the letters IP followed by the designations described in IEC 60529, according to the degree of protection provided by the enclosure with respect to harmful ingress of particulate matter and water. See also 6.3.2. The minimum requirement of this part of ISO 10651 is IPX4. Check compliance by inspection.

6.3.2 Splash proof The resuscitator shall be splash proof, classified as IPX4 in IEC 60529. During and after the test specified in IEC 60529, the resuscitator, under the least favourable working conditions but in accordance with the accompanying documents, shall continue to function within the tolerances indicated for normal use and shall not cause a safety hazard. Check compliance by inspection and by application of the requirements of IEC 60529.

---

22 Nov 2017 Derek Lamb

ISO 10651-5 does not apply  
as per its scope:

ISO 10651-5:2006 specifies the basic safety and essential performance requirements for gas-powered emergency resuscitators intended for use with humans by first responders. This equipment is intended for emergency field use and is intended to be continuously operator attended in normal use.

No Electronic Components,

---

22 Nov 2017 Derek Lamb

comparison to main market leader. fisher paykel neo puff resusitare unit. also does not have an IPX rating.

---

22 Nov 2017 Derek Lamb

added issue to the technical files

---

Issues:108582

---

VIAMED Management Meeting - Other

**0310030 Tom Thumb IP rating**

Issue ID #108581

Date Created 20/Nov/2017

Issued To: John Lamb

Completed Status: 10 Apr 2018

---

**Notes:**

Added by Steve Nixon sent to John Lamb  
For further discussion.

It appears that the minimum requirement is IPX4. No need to test for foreign objects, I assume it is because due to the nature of the device that there will be openings.

ISO 10651:

8.2.10 Indication of protection against water ingress The resuscitator shall be marked with a symbol, using the letters IP followed by the designations described in IEC 60529, according to the degree of protection provided by the enclosure with respect to harmful ingress of particulate matter and water. See also 6.3.2. The minimum requirement of this part of ISO 10651 is IPX4. Check compliance by inspection.

6.3.2 Splash proof The resuscitator shall be splash proof, classified as IPX4 in IEC 60529. During and after the test specified in IEC 60529, the resuscitator, under the least favourable working conditions but in accordance with the accompanying documents, shall continue to function within the tolerances indicated for normal use and shall not cause a safety hazard. Check compliance by inspection and by application of the requirements of IEC 60529.

---

09 Apr 2018 John Lamb

---

Issues:108581

---

VIAMED Stock Meeting - Any Other Business

**0310030 Tom Thumb stock review.**

Issue ID #123755

Date Created 10/Jul/2018

Issued To: Philip Crossley

Completed Status: 18 Sep 2018

---

Notes:

Copy Issue Main Issue #123753

Added by Steve Nixon sent to Derek Lamb

Tom Thumb stock review.

Can the following be checked please. Do the demo ones have WIKA gauge?

1 x 126715 What is this, sales or demo stock

1 x 324432 Demo stock?

1 x 324434 Demo stock?

1 x 34096 Sales stock

2 x 34100 Being booked in? Where are these from?

1 x 34121 Sales stock

10 x 34237 In production

1 x 34243 I don't have this.

1 x 34281 Scanned to Keith, where is this now?

---

31 Aug 2018 Philip Crossley

---

Issues:123755

---

VIAMED Stock Meeting - Any Other Business

**0310030 Tom Thumb stock review.**

Issue ID #123754

Date Created 10/Jul/2018

Issued To: Catherine Spence

Completed Status: Still Outstanding

---

Notes:

Copy Issue Main Issue #123753

Added by Steve Nixon sent to Derek Lamb

Tom Thumb stock review.

Can the following be checked please. Do the demo ones have WIKA gauge?

1 x 126715 What is this, sales or demo stock

1 x 324432 Demo stock?

1 x 324434 Demo stock?

1 x 34096 Sales stock

2 x 34100 Being booked in? Where are these from?

1 x 34121 Sales stock

10 x 34237 In production

1 x 34243 I don't have this.

1 x 34281 Scanned to Keith, where is this now?

---

04 Sep 2018 Catherine Spence

Has this been sorted, as there are no notes.

---

Issues:123754

---

VIAMED Stock Meeting - Any Other Business

**0310030 Tom Thumb stock review.**

Issue ID #123753

Date Created 10/Jul/2018

Issued To: Derek Lamb

Completed Status: 03 Aug 2018

---

Notes:

Added by Steve Nixon sent to Derek Lamb

Tom Thumb stock review.

Can the following be checked please. Do the demo ones have WIKA gauge?

1 x 126715 What is this, sales or demo stock

1 x 324432 Demo stock?

1 x 324434 Demo stock?

1 x 34096 Sales stock

2 x 34100 Being booked in? Where are these from?

1 x 34121 Sales stock

10 x 34237 In production

1 x 34243 I don't have this.

1 x 34281 Scanned to Keith, where is this now?

---

03 Aug 2018 Derek Lamb

---

Issues:123753



---

VIAMED Management Meeting - Other  
**0330203 Quotation and specifications March 2018**

Issue ID #115942

Date Created 09/Mar/2018

Issued To: Derek Lamb

Completed Status: 10 Apr 2018

Linked Files

09 Mar 2018 Quotation QUO00070274

09 Mar 2018 40415422 gauge artwork

09 Mar 2018 611.10 DS\_PM0601\_en\_co\_3841 datasheet

09 Mar 2018 OI\_PressureGauges\_en\_6345 instructions

09 Mar 2018 Certificate 9001\_IQNet\_WIKA\_en

---

**Notes:**

Added by Steve Nixon sent to Steve Nixon  
26/10/17

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.

---

09 Mar 2018 Steve Nixon  
30 October 2017

Hello Steve

Please find our artwork for your approval attached please advise if approved.

As the dial layout is changed now the new part number is 40415422, and this is unique part number which you should use when ordering..

611.10.063 is just a model of the gauge.

Hope the ISO audit this week will be successful.

Could you advise any dates for next requirements?

Attached please find the re-vised quote with new part number and window as a replacement.

Weve arranged better price for window considered that youll looking to place your gauge requirements with us as well.

Hope youll find it well.

Waiting for hearing from you.

Kind Regards

Tomasz Bialkowski

Internal Sales Engineer

Industrial Instrumentation Division

---

09 Mar 2018 Steve Nixon  
Thanks Tomasz

Should there be a small spacing between cm and H2O ?

---

09 Mar 2018 Steve Nixon  
09 Mar 2018

Hi Tomasz

I've tried returning your call, but your phone is engaged.

So, from your voice mail, the gauge design hasn't changed, it is still the same quality standard/materials/design and is still being produced in Switzerland?

Can you please supply a current copy of the datasheet for the gauge that ours is based upon. Also can you please supply a copy of your ISO certificates, i.e. ISO 9001.

I'll process an order for an initial 100 gauges. There's no need for a sample if they are the same as we previously purchased (apart from the small artwork change cm WG to cm H2O)

Regards

Steve

---

09 Mar 2018 Steve Nixon  
Hi Steve

Yes, I confirm as advised on the phone that nothings changed apart the units as you mentioned..

Please find current copy of data sheet for standard model 611.10 and our ISO9001 attached.

For any further documents related to this product please go to:

[https://www.wika.co.uk/611\\_10\\_631\\_10\\_en\\_co.WIKA](https://www.wika.co.uk/611_10_631_10_en_co.WIKA)

where you'll find further info under Tabs Approvals or Documents.

When ordering please refer to quote QUO00070274(for both - gauges and windows)

Thanks in advance for your order and bearing with us for future business.

Hope to hear from you soon.

Kind Regards

Tomasz Bialkowski

Internal Sales Engineer

Industrial Instrumentation Division

WIKA Instruments Ltd

RH1 3LG, Redhill/England

United Kingdom

Phone +44 (0) 1737 / 646-740

Fax +44 (0) 1737 / 646-736

Tomasz.Bialkowski@wika.com

---

09 Mar 2018 Steve Nixon

Next Action Changed From Steve Nixon To Derek Lamb Derek, see the attached files for the Tom Thumb technical files

---

06 Apr 2018 Derek Lamb

files in intrastats not sure why issue not showing as such, but they are in

---

Issues:115942

---

VIAMED Stock Meeting - Any Other Business

**0330203 quotation from Wika**

Issue ID #106558

Date Created 26/Oct/2017

Issued To: Derek Lamb

Completed Status: 14 Nov 2017

---

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.

---

31 Oct 2017 Derek Lamb

thanks

---

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 Order Requirements

**0330222 Precision valve spring**

Issue ID #60091

Date Created 29/Jun/2015

Issued To: Derek Lamb

Completed Status: 24 Oct 2018

Linked Files

29 Jun 2015 spring

29 Jun 2015 Valve seat + adjusting screw

---

Notes:

Added by Philip Crossley sent to Derek Lamb

The precision valve springs seem a little short at around 12mm. When the valve is set at around 45 mbar it leaves almost no adjustment left on the screw before it comes into contact with the valve seat.

A 15mm spring makes the precision valve far easier to adjust with a few turns of the screw spare.

---

16 Aug 2018 Derek Lamb

we are finally being quoted for new springs,

..

have got a quote,

can I have a rough estimate of number of springs of both type we have remaining,

in light of shuttleworth going out of business, we going to have to relook at tom thumb requirements

---

16 Aug 2018 Philip Crossley Roughly 178 of 0330222 and 56 of 0330223

---

24 Oct 2018 Philip Crossley Tried a new spring in a precision valve and it looks good

---

Issues:60091

---

VIAMED Stock Meeting - Sales Back Orders Review - By Product

**Active list shortages update notes**

Issue ID #123564

Date Created 06/Jul/2018

Issued To: Zoey Teal

Completed Status: 06 Jul 2018

---

Notes:

Copy Issue Main Issue #123561

Added by Steve Nixon sent to Catherine Spence

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

4420552

Checking with Bluepoint whether this has been discontinued and replaced by 4421513 (which also need ordering, will do Monday).

4420525

One order still unresolved. I have added order memo for Sarah to try and resolve.

0121217 Upgrade Kit

Production order has been raised.

B-66024

Checking/confirming with Teledyne whether discontinued.

0110001

Production order raised

0014770

I'll order (25) more on Monday, need 13 for current orders

0330263 Upon checking actual looks like we do need to order 2, I'll do this Monday.

---

Issues:123564

---

VIAMED Stock Meeting - Sales Back Orders Review - By Product

**Active list shortages update notes**

Issue ID #123563

Date Created 06/Jul/2018

Issued To: Sarah Walton

Completed Status: 10 Jul 2018

---

Notes:

Copy Issue Main Issue #123561

Added by Steve Nixon sent to Catherine Spence

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

4420552

Checking with Bluepoint whether this has been discontinued and replaced by 4421513 (which also need ordering, will do Monday).

4420525

One order still unresolved. I have added order memo for Sarah to try and resolve.

0121217 Upgrade Kit

Production order has been raised.

B-66024

Checking/confirming with Teledyne whether discontinued.

0110001

Production order raised

0014770

I'll order (25) more on Monday, need 13 for current orders

0330263 Upon checking actual looks like we do need to order 2, I'll do this Monday.

---

Issues:123563



---

VIAMED Stock Meeting - Sales Back Orders Review - By Product

**Active list shortages update notes**

Issue ID #123562

Date Created 06/Jul/2018

Issued To: Derek Lamb

Completed Status: 06 Jul 2018

---

Notes:

Copy Issue Main Issue #123561

Added by Steve Nixon sent to Catherine Spence

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

4420552

Checking with Bluepoint whether this has been discontinued and replaced by 4421513 (which also need ordering, will do Monday).

4420525

One order still unresolved. I have added order memo for Sarah to try and resolve.

0121217 Upgrade Kit

Production order has been raised.

B-66024

Checking/confirming with Teledyne whether discontinued.

0110001

Production order raised

0014770

I'll order (25) more on Monday, need 13 for current orders

0330263 Upon checking actual looks like we do need to order 2, I'll do this Monday.

---

Issues:123562

---

VIAMED Stock Meeting - Sales Back Orders Review - By Product

**Active list shortages update notes**

Issue ID #123561

Date Created 06/Jul/2018

Issued To: Catherine Spence

Completed Status: 07 Aug 2018

---

Notes:

Added by Steve Nixon sent to Catherine Spence  
INFORMATION ONLY ISSUE DO NOT ADD NOTES!

4420552

Checking with Bluepoint whether this has been discontinued and replaced by 4421513 (which also need ordering, will do Monday).

4420525

One order still unresolved. I have added order memo for Sarah to try and resolve.

0121217 Upgrade Kit

Production order has been raised.

B-66024

Checking/confirming with Teledyne whether discontinued.

0110001

Production order raised

0014770

I'll order (25) more on Monday, need 13 for current orders

0330263 Upon checking actual looks like we do need to order 2, I'll do this Monday.

---

Issues:123561

---

VIAMED Stock Meeting - Sales Back Orders Review - By Product

**Active list shortages update notes**

Issue ID #123560

Date Created 06/Jul/2018

Issued To: Catherine Spence

Completed Status: 10 Jul 2018

---

Notes:

Added by Steve Nixon sent to Catherine Spence  
INFORMATION ONLY ISSUE DO NOT ADD NOTES!

4420552

Checking with Bluepoint whether this has been discontinued and replaced by 4421513 (which also need ordering, will do Monday).

4420525

One order still unresolved. I have added order memo for Sarah to try and resolve.

0121217 Upgrade Kit

Production order has been raised.

B-66024

Checking/confirming with Teledyne whether discontinued.

0110001

Production order raised

0014770

I'll order (25) more on Monday, need 13 for current orders

0330263 Upon checking actual looks like we do need to order 2, I'll do this Monday.

---

Issues:123560

---

Production - Production

**Apgar Timer brackets - 0320201**

Issue ID #112412

Date Created 16/Jan/2018

Issued To: Jonathan Connor

Completed Status: 17 Jan 2018

---

**Notes:**

Added by Steve Hardaker sent to Jonathan Connor

We need to start a production job for more Apgar timer brackets, we will have just 3 left after the next order for 4 cabinets goes out.

It looks like the sub-components may need re-stocking, we are showing 0 stock of the mounting plate 0330242. Thanks.

---

17 Jan 2018 Jonathan Connor  
Done, thanks

---

17 Jan 2018 Steve Hardaker

---

Issues:112412

---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00000149 0330212 ORD91731**

Issue ID #118441

Date Created 18/Apr/2018

Issued To: General

Completed Status: 18 Apr 2018

Stock Ref: 0330212

Opera A/c: 00000149

Order Number: ORD91731

---

Notes:

18 Apr 2018 07:43:14 AM Catherine Spence  
Shipping Wed 18 Apr 2018

---

Issues:118441

---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00000620 0330209 ORD95431**

Issue ID #133415

Date Created 03/Dec/2018

Issued To: General

Completed Status: 03 Dec 2018

Stock Ref: 0330209

Opera A/c: 00000620

Order Number: ORD95431

---

Notes:

03 Dec 2018 08:12:13 AM Catherine Spence  
Shipping Mon 03 Dec 2018

---

Issues:133415

---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00000690 0330033 ORD93771**

Issue ID #126880

Date Created 28/Aug/2018

Issued To: General

Completed Status: 05 Oct 2018

Stock Ref: 0330033

Opera A/c: 00000690

Order Number: ORD93771

---

Notes:

28 Aug 2018 11:30:05 AM Kate Griffiths

See Attached Notes

Emailed customer re carriage charge and is it ok to part ship? Warehouse request done for 0330218. KG 28.8.18

30 Aug 2018 01:55:34 PM Kate Griffiths

Siobhan Hughes will contact her end user and get back to us. KG 30.8.18

30 Aug 2018 04:15:02 PM Kate Griffiths

Siobhan Hughes will contact her end user and get back to us. KG 30.8.18

31 Aug 2018 10:17:18 AM Kate Griffiths

Please do not part ship. OK with carriage charge. KG 31.8.18

27 Sep 2018 07:35:00 AM Catherine Spence

Shipping Thu 27 Sep 2018

27 Sep 2018 10:47:01 AM Steve Hardaker

See Attached Notes

Spoke to John Hyland in MEMO as Cathy advised these hoses are dated 2016. They can't accept them as this would force an earlier replacement date next time. Cathy will request a supplier PO for new ones. Dont part ship.

28 Sep 2018 07:37:28 AM Catherine Spence

Back Order - Supplier

---

Issues:126880

---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00000780 0330212 ORD95059**

Issue ID #132278

Date Created 15/Nov/2018

Issued To: General

Completed Status: 21 Nov 2018

Stock Ref: 0330212

Opera A/c: 00000780

Order Number: ORD95059

---

Notes:

15 Nov 2018 11:54:09 AM Steve Hardaker

See Phil, we have these but may not be individually barcoded.

---

Issues:132278



---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00000780 0330213 ORD95059**

Issue ID #132279

Date Created 15/Nov/2018

Issued To: General

Completed Status: 21 Nov 2018

Stock Ref: 0330213

Opera A/c: 00000780

Order Number: ORD95059

---

Notes:

15 Nov 2018 11:54:52 AM Steve Hardaker

See Phil, we have these but may not be individually barcoded.

---

Issues:132279

---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00000780 0330214 ORD95059**

Issue ID #132280

Date Created 15/Nov/2018

Issued To: General

Completed Status: 21 Nov 2018

Stock Ref: 0330214

Opera A/c: 00000780

Order Number: ORD95059

---

Notes:

15 Nov 2018 11:55:00 AM Steve Hardaker

See Phil, we have these but may not be individually barcoded.

---

Issues:132280

---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00001040 0330210 ORD89880**

Issue ID #110371

Date Created 14/Dec/2017

Issued To: General

Completed Status: 15 Dec 2017

Stock Ref: 0330210

Opera A/c: 00001040

Order Number: ORD89880

---

Notes:

14 Dec 2017 09:12:09 AM Catherine Spence  
Shipping Thu 14 Dec 2017

---

Issues:110371

---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00001310 0310030 ORD89219**

Issue ID #107572

Date Created 08/Nov/2017

Issued To: General

Completed Status: 08 Nov 2017

Stock Ref: 0310030

Opera A/c: 00001310

Order Number: ORD89219

---

Notes:

08 Nov 2017 08:19:31 AM Catherine Spence  
Shipping Wed 08 Nov 2017

---

Issues:107572

---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00001350 0330206 ORD92309**

Issue ID #120729

Date Created 23/May/2018

Issued To: General

Completed Status: 23 May 2018

Stock Ref: 0330206

Opera A/c: 00001350

Order Number: ORD92309

---

Notes:

23 May 2018 07:43:42 AM Catherine Spence  
Shipping Wed 23 May 2018

---

Issues:120729

---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00002130 0330212 ORD90566**

Issue ID #113795

Date Created 05/Feb/2018

Issued To: General

Completed Status: 05 Feb 2018

Stock Ref: 0330212

Opera A/c: 00002130

Order Number: ORD90566

---

Notes:

05 Feb 2018 07:52:12 AM Catherine Spence  
Shipping Mon 05 Feb 2018

---

Issues:113795

---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00002500 0330263 ORD92545**

Issue ID #122973

Date Created 27/Jun/2018

Issued To: General

Completed Status: 18 Jul 2018

Stock Ref: 0330263

Opera A/c: 00002500

Order Number: ORD92545

---

Notes:

27 Jun 2018 09:41:51 AM Zoey Teal  
See Attached Notes

---

Issues:122973

---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00002600 0380000 ORD90040**

Issue ID #114592

Date Created 15/Feb/2018

Issued To: General

Completed Status: 08 Jun 2018

Stock Ref: 0380000

Opera A/c: 00002600

Order Number: ORD90040

---

Notes:

15 Feb 2018 05:51:56 PM Steve Hardaker  
Sent SOR T&Cs but Roger Smith is on leave until 19/2/18.

14 May 2018 02:18:40 PM Steve Hardaker  
See Attached Notes  
Chased T&Cs repeatedly, finally received back Fri 11/5/18. Added issue 120200 to Cathy to scan 3 service exchange TT480 Tom Thumbs to SOR and asked Phil to check the calibration.

---

Issues:114592



---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00002662 0310030 ORD89131**

Issue ID #107160

Date Created 02/Nov/2017

Issued To: General

Completed Status: 02 Nov 2017

Stock Ref: 0310030

Opera A/c: 00002662

Order Number: ORD89131

---

Notes:

02 Nov 2017 08:15:16 AM Catherine Spence  
Shipping Thu 02 Nov 2017

---

Issues:107160

---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00002950 0330212 ORD90012**

Issue ID #110810

Date Created 21/Dec/2017

Issued To: General

Completed Status: 18 Jan 2018

Stock Ref: 0330212

Opera A/c: 00002950

Order Number: ORD90012

---

Notes:

21 Dec 2017 03:48:22 PM Willow Merryweather

See Attached Notes

Awaiting confirmation of invoice address. 21.12.17 WM

08 Jan 2018 08:24:22 AM Zoey Teal

Invoice address confirmed.

10 Jan 2018 12:03:39 PM Willow Merryweather

Should be ready to ship within the next couple of weeks. 10.01.18 WM

---

Issues:110810

---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00003710 0330193 ORD92122**

Issue ID #120177

Date Created 14/May/2018

Issued To: General

Completed Status: 14 May 2018

Stock Ref: 0330193

Opera A/c: 00003710

Order Number: ORD92122

---

Notes:

14 May 2018 08:54:06 AM Catherine Spence  
Shipping Mon 14 May 2018

---

Issues:120177

---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00003785 0310030 ORD95268**

Issue ID #132814

Date Created 23/Nov/2018

Issued To: General

Completed Status: 26 Nov 2018

Stock Ref: 0310030

Opera A/c: 00003785

Order Number: ORD95268

---

Notes:

23 Nov 2018 08:59:25 AM Catherine Spence  
Back Order - Production

---

Issues:132814

---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00003960 0330213 ORD90905**

Issue ID #115076

Date Created 23/Feb/2018

Issued To: General

Completed Status: 27 Jun 2018

Stock Ref: 0330213

Opera A/c: 00003960

Order Number: ORD90905

---

Notes:

23 Feb 2018 08:14:24 AM Catherine Spence  
Shipping Fri 23 Feb 2018

23 Feb 2018 08:14:47 AM Catherine Spence  
See Attached Notes

26 Feb 2018 08:14:41 AM Catherine Spence  
part number 0330129 is out of stock

---

Issues:115076

---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00004260 0340000 ORD94288**

Issue ID #129041

Date Created 27/Sep/2018

Issued To: General

Completed Status: 28 Sep 2018

Stock Ref: 0340000

Opera A/c: 00004260

Order Number: ORD94288

---

Notes:

27 Sep 2018 12:32:27 PM Sarah Walton

See Attached Notes

Waiting for engineer notes to be changed

---

Issues:129041

---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00004560 0330212 ORD95303**

Issue ID #132915

Date Created 26/Nov/2018

Issued To: General

Completed Status: 04 Dec 2018

Stock Ref: 0330212

Opera A/c: 00004560

Order Number: ORD95303

---

Notes:

26 Nov 2018 08:48:16 AM Catherine Spence  
Shipping Mon 26 Nov 2018

---

Issues:132915

---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00004900 0330212 ORD89574**

Issue ID #109312

Date Created 29/Nov/2017

Issued To: General

Completed Status: 30 Nov 2017

Stock Ref: 0330212

Opera A/c: 00004900

Order Number: ORD89574

---

Notes:

29 Nov 2017 07:58:15 AM Catherine Spence  
Shipping Wed 29 Nov 2017

---

Issues:109312



---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00004992 0380000 ORD93539**

Issue ID #126088

Date Created 15/Aug/2018

Issued To: Catherine Spence

Completed Status: 10 Sep 2018

Stock Ref: 0380000

Opera A/c: 00004992

Order Number: ORD93539

---

Notes:

15 Aug 2018 10:09:05 AM Sarah Walton

See Attached Notes

This is with DL and SN to sort out who is going to do the service visit.

06 Sep 2018 04:17:19 PM Sarah Walton

This can now be invoiced as the service has been completed.

---

10 Sep 2018 Catherine Spence

Done

---

Issues:126088

---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00005143 0330193 ORD88533**

Issue ID #124786

Date Created 26/Jul/2018

Issued To: General

Completed Status: 27 Jul 2018

Stock Ref: 0330193

Opera A/c: 00005143

Order Number: ORD88533

---

Notes:

26 Jul 2018 04:53:17 PM Catherine Spence

See Attached Notes

DO NOT SHIP. Error in system, DL and HL working on it

---

Issues:124786

---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00006070 0310030 ORD94567**

Issue ID #131711

Date Created 07/Nov/2018

Issued To: General

Completed Status: 26 Nov 2018

Stock Ref: 0310030

Opera A/c: 00006070

Order Number: ORD94567

---

Notes:

07 Nov 2018 08:12:06 AM Catherine Spence

See Attached Notes

Still waiting on customer to see if we can ship the tom thumb

13 Nov 2018 09:50:40 AM Sarah Walton

Please do not ship this until the customer has confirmed that they do want it. I have followed up again and they are still waiting to hear from their customer.

20 Nov 2018 04:12:47 PM Sarah Walton

Customer is happy for us to proceed with the remainder of the order.

---

Issues:131711

---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00006070 0330193 ORD92335**

Issue ID #120872

Date Created 24/May/2018

Issued To: General

Completed Status: 24 May 2018

Stock Ref: 0330193

Opera A/c: 00006070

Order Number: ORD92335

---

Notes:

24 May 2018 09:05:57 AM Catherine Spence  
Shipping Thu 24 May 2018

---

Issues:120872

---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00006679 0310097 ORD93140**

Issue ID #124483

Date Created 23/Jul/2018

Issued To: General

Completed Status: 06 Aug 2018

Stock Ref: 0310097

Opera A/c: 00006679

Order Number: ORD93140

---

Notes:

23 Jul 2018 08:51:28 AM Catherine Spence  
In Production

---

Issues:124483

---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00006777 0310097 ORD92018**

Issue ID #119656

Date Created 04/May/2018

Issued To: General

Completed Status: 01 Jun 2018

Stock Ref: 0310097

Opera A/c: 00006777

Order Number: ORD92018

---

Notes:

04 May 2018 08:58:52 AM Catherine Spence  
Back Order - Production

---

Issues:119656

---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00007273 0310030 ORD93731**

Issue ID #126613

Date Created 23/Aug/2018

Issued To: General

Completed Status: 12 Sep 2018

Stock Ref: 0310030

Opera A/c: 00007273

Order Number: ORD93731

---

Notes:

23 Aug 2018 08:03:19 AM Catherine Spence  
Back Order - Production

---

Issues:126613

---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00007291 0310030 ORD89669**

Issue ID #109701

Date Created 05/Dec/2017

Issued To: General

Completed Status: 13 Dec 2017

Stock Ref: 0310030

Opera A/c: 00007291

Order Number: ORD89669

---

Notes:

05 Dec 2017 08:56:25 AM Catherine Spence  
Back Order - Production

05 Dec 2017 04:43:16 PM Sarah Walton  
See Attached Notes  
Advising customer of the lead time once JC has got back to me. Customer aware of this.

12 Dec 2017 08:39:30 AM Sarah Walton  
Chased last week a couple of times with JC and RC. Customer chasing, so asked CG to sort for me.

12 Dec 2017 08:54:51 AM Catherine Spence  
Still being produced, rc is going to qa some units today to cover this order, aim to ship today/tomorrow

---

Issues:109701



---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00007291 0310030 ORD90085**

Issue ID #111261

Date Created 02/Jan/2018

Issued To: General

Completed Status: 10 Jan 2018

Stock Ref: 0310030

Opera A/c: 00007291

Order Number: ORD90085

---

Notes:

02 Jan 2018 09:16:10 AM Catherine Spence  
Back Order - Production

08 Jan 2018 09:08:10 AM Sarah Walton  
See Attached Notes  
Asked JC for a lead time so that I can update the customer.

10 Jan 2018 08:01:56 AM Catherine Spence  
Shipping Wed 10 Jan 2018

---

Issues:111261

---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00007291 0310030 ORD91245**

Issue ID #116444

Date Created 19/Mar/2018

Issued To: General

Completed Status: 20 Mar 2018

Stock Ref: 0310030

Opera A/c: 00007291

Order Number: ORD91245

---

Notes:

19 Mar 2018 07:58:11 AM Catherine Spence  
Shipping Mon 19 Mar 2018

---

Issues:116444

---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00007291 0310030 ORD92992**

Issue ID #123709

Date Created 10/Jul/2018

Issued To: General

Completed Status: 12 Jul 2018

Stock Ref: 0310030

Opera A/c: 00007291

Order Number: ORD92992

---

Notes:

10 Jul 2018 07:47:54 AM Catherine Spence  
In Production

12 Jul 2018 09:22:23 AM Catherine Spence  
Shipping Thu 12 Jul 2018

---

Issues:123709

---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00007291 0310030 ORD95362**

Issue ID #133066

Date Created 28/Nov/2018

Issued To: General

Completed Status: 29 Nov 2018

Stock Ref: 0310030

Opera A/c: 00007291

Order Number: ORD95362

---

Notes:

28 Nov 2018 08:46:31 AM Catherine Spence  
Back Order - Production

---

Issues:133066

---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00007291 0330193 ORD92499**

Issue ID #121715

Date Created 05/Jun/2018

Issued To: General

Completed Status: 05 Jun 2018

Stock Ref: 0330193

Opera A/c: 00007291

Order Number: ORD92499

---

Notes:

05 Jun 2018 07:46:33 AM Catherine Spence  
Shipping Tue 05 Jun 2018

---

Issues:121715

---

VIAMED Sales And Marketing - Post Market Surveillance

**File 16 Tom Thumb Risk File Updated**

Issue ID #133280

Date Created 30/Nov/2018

Issued To: Derek Lamb

Completed Status: 03 Dec 2018

Stock Ref: 0390060

---

**Notes:**

Risk file has changed, VM3COP27.12 Needs reviewing for 16 Tom Thumb as the Risk assesment has changed

---

30 Nov 2018 Derek Lamb

no review needed, add risk as repair system, due to us not using returned guages from supplier marked as no fault found,  
we simply opted not to reuse them.

---

Issues:133280

---

VIAMED Sales And Marketing - Post Market Surveillance

**File 16 Tom Thumb Risk File Updated**

Issue ID #107515

Date Created 07/Nov/2017

Issued To: Derek Lamb

Completed Status: 10 Nov 2017

Stock Ref: 0390060

---

**Notes:**

Risk file has changed, VM3COP27.12 Needs reviewing for 16 Tom Thumb as the Risk assesment has changed

---

09 Nov 2017 Derek Lamb

under going more changes, no point in updating risk benfits

---

Issues:107515

---

VIAMED Stock Meeting - Stock Queries

**IN157418 0330263 stock query Allocations**

Issue ID #124085

Date Created 16/Jul/2018

Issued To: Catherine Spence

Completed Status: 26 Jul 2018

---

Notes:

Added by Helen Lamb sent to Catherine Spence

IN157418 0330263 (reciepts) Sent To Leeds General Infirmary

Raise Issue

Opera Invoice Notes

1/8th tailpipe. S/N:108566-70

Viamed Order Number ORD92545

Serial numbers say we sent 5 but order for 3 can you check please

---

18 Jul 2018 Catherine Spence

will do

looked at this customer ordered five and we shipped five

---

Issues:124085



---

Marketing Job Logger - Marketing Job Logger

**Leaflet Tom Thumb Leaflet Amend 3rd Checking Stage**

Issue ID #108577

Date Created 20/Nov/2017

Issued To: Steve Nixon

Completed Status: Still Outstanding

Linked Files

20 Nov 2017 Tom Thumb Leaflet 2017-11-20

20 Nov 2017 Tom Thumb Leaflet 2017-11-20

20 Nov 2017 Tom Thumb Leaflet 2017-11-20 AMENDED

21 Nov 2017 Tom Thumb Leaflet 2017-11-21

---

**Notes:**

Catrin Hird 20/11/2017 Issue Generated  
Leaflet Tom Thumb Leaflet Amend 3rd Checking Stage

---

20 Nov 2017 Catrin Hird

Next Action Changed From To Steve Nixon Please find attached revised artwork for Tom Thumb Leaflet removing relevant products.

Hard copy with proof sheet on SN desk.

---

20 Nov 2017 Catrin Hird

Updated reference to Configuration One on reverse of leaflet. Reattached.

---

21 Nov 2017 Catrin Hird

Revisions received, amended and provided back with fresh proof sheet.

Price list on issue 107601.

---

12 Mar 2018 Catrin Hird

0310094 to be added  
Cabinet Tom Thumb (new part)

Cabinet Variant requires new image

Notes require clarification from 25/01/18 meeting above

---

Issues:108577

---

Marketing Job Logger - Marketing Job Logger

**Leaflet Update Infant Resus Cabinet Leaflet Leaflet Designed**

Issue ID #114403

Date Created 13/Feb/2018

Issued To: Steve Hardaker

Completed Status: 06 Nov 2018

---

**Notes:**

Catrin Hird 13/02/2018 Issue Generated  
Leaflet Update Infant Resus Cabinet Leaflet Leaflet Designed

---

13 Feb 2018 Catrin Hird

Next Action Changed From To Steve Hardaker  
Priority Changed From 5 To 0 Hi,

I have been asked to amend the current infant resus cabinet leaflet so that it lists the individual parts that can be purchased...

As standard I've got:

Cabinet 0330105  
Tom Thumb 0310030  
Low suction controllers; oxytitre 0310140?  
Therapy 7725 0310048 or 0310050  
Cereatherm 0310302  
Blender 0310200

But if we are offering a pick and mix sort of option then are there a large number of parts we can include?

Blenders - including precision or you happy to stick with Tom Thumb?

I guess we should also be including Apgar, AX300, Liners?

I think we have gone to look at this years ago but not sure where we got to.

---

15 Feb 2018 Steve Hardaker

Low suction controllers; oxytitre 0310140?  
- This is not a standard unit, was used as a problem solver for 1 customer with no piped vacuum, offer 0310035 S714R with 3m hose instead.

Therapy 7725 0310048 or 0310050 - go with 0310050 which has a 3m hose but state shorter hoses available upon request.

Blenders - stick with Inspiration for now, I will discuss Precision Medical ones if the customer wants an alternative.

You can include the part numbers of the other main items, such as Apgar timer, Vacsax jars, liners, bed, mattress etc but leave off the AX300: we will offer it as a custom-requirement if it comes up but only 1 customer ever had them and took them all out again immediately.

The complete parts list can be found in the user instructions, you don't want to add absolutely everything as it goes down to spare parts, but the part numbers for the main items are all in there. Note: the version on L is out of date, the latest (v11.0) is attached to Issue 70173 for SN to upload.

---

16 Feb 2018 Catrin Hird  
Fab thanks

---

19 Feb 2018 Steve Hardaker

---

Issues:114403

---

Intrastats - Information for Intrastats and L Drive

**Parts required for annual service of Tom Thumbs**

Issue ID #59171

Date Created 22/May/2015

Issued To: Derek Lamb

Completed Status: 29 Aug 2018

Linked Files

22 May 2015 Parts required for Annual Service of TT480 and TT490 v1.0.pdf

22 May 2015 Parts required for Annual Service of TT480 and TT490 Tom Thumb v1.0.doc

22 May 2015 Parts required for Annual Service of TT480 and TT490 v1.0.pdf (USE THIS ONE! Theres a

06 Aug 2015 Parts required for Annual Service of TT480 and TT490 Tom Thumb v1.1.pdf

20 Aug 2018 Parts Required for Annual Service of TT480 and TT490 Tom Thumb v1.2.pdf

20 Aug 2018 Parts Required for Annual Service of TT480 and TT490 Tom Thumb v1.2.doc

---

Notes:

Added by Steve Hardaker sent to Derek Lamb

I often get asked what parts are required for annual service of Tom Thumbs, so I have put together a summary.

Can you review it and, if nothing to add, upload it to ISO index then forward it to Steve N for upload to L drive? Thanks.

Note: I have referred to the spare parts price lists rather than put the prices in here (so we dont have to keep updating it) but there is currently only a TT480 spare parts price list, not a TT490. This is currently on an open issue #53370.

---

22 May 2015 Derek Lamb

Next Action Changed From Derek Lamb To Steve Nixon

---

26 May 2015 Steve Nixon

To tie everything together please add the parts numbers of the Tom Thumbs:

0310030 TT480

0310032 TT490-15

0310034 TT490-15-3

Do we need to emphasise the 2nd and 3rd from bottom notes

Do we need to add a note regarding fittings ,i.e. state the standard, other variants such as... also available.

When updated I will add to L drive.

---

06 Aug 2015 Steve Hardaker

Amended as per above and attached to this issue. see PDF document entitled:

Parts required for Annual Service of TT480 and TT490 Tom Thumb v1.1.pdf

---

16 Feb 2016 Steve Nixon

Priority Changed From 5 To 4

---

26 Jul 2018 Steve HardakerPlease can you add the most recent version (v1.1) to L drive. Catrin did a

mailing this month and we are getting asked for this. Thanks.

See also issue #118478 regarding the latest copies of the service manuals, which also need adding to L.

---

20 Aug 2018 Steve Nixon  
Added to L drive, will also link to Intrastats

---

20 Aug 2018 Steve Hardaker Sorry Steve, I just notice when reviewing the uploaded doc there was a typo - T480 instead of TT480.  
Please see amended version 1.2 in both Word and PDF.

---

24 Aug 2018 Steve Nixon  
Thanks

---

29 Aug 2018 Steve Hardaker

Next Action Changed From Steve Nixon To Derek Lamb Checked L drive and corrected document (v1.2) is now present.

Derek, the ISO Index filename for file 27040 (20th August 18) incorrectly states version 1.1 but the doc itself is version 1.2, please can you amend.

---

29 Aug 2018 Derek Lamb  
done

---

29 Aug 2018 Steve Hardaker

---

Issues:59171

---

Marketing Job Logger - Marketing Job Logger

**Photos/Images Tom Thumb for Cabinet Obtain Samples**

Issue ID #125584

Date Created 06/Aug/2018

Issued To: Catherine Spence

Completed Status: Still Outstanding

---

Notes:

Catrin Hird 06/08/2018 Issue Generated  
Photos/Images Tom Thumb for Cabinet Obtain Samples

---

06 Aug 2018 Catrin Hird

Next Action Changed From To Catherine Spence  
Priority Changed From 5 To 0 Hi

Trying to tidy up my issues, I still require a Tom Thumb for Cabinet with a WIKA gauge 0310095 for photography. Thanks

I also require the pole clamp version 0310094 also with Wika gauge.

---

07 Aug 2018 Catherine Spence  
i think we have a tom thumb in stock with the wika gauge, but i dont have the clamp

---

07 Aug 2018 Catrin Hird  
I believe the 2 types of tom thumb as different, the cabinet version is different from the pole clamp version.  
Do we have the clamps in stock or does SN need to order?

---

Issues:125584

---

- Back Order Report

**POR11498 0330217 //**

Issue ID #106822

Date Created 30/Oct/2017

Issued To: Jonathan Connor

Completed Status: 30 Oct 2017

---

Notes:

POR11498 0330217 Estimated ship to us date changed to / /

---

Issues:106822

---

- Back Order Report

**POR11498 0330218 //**

Issue ID #106823

Date Created 30/Oct/2017

Issued To: Jonathan Connor

Completed Status: 30 Oct 2017

---

Notes:

POR11498 0330218 Estimated ship to us date changed to / /

---

Issues:106823



---

- Back Order Report

**POR11508 0330217 //**

Issue ID #107517

Date Created 07/Nov/2017

Issued To: Jonathan Connor

Completed Status: 07 Nov 2017

---

Notes:

POR11508 0330217 Estimated ship to us date changed to / /

---

Issues:107517

---

- Back Order Report

**POR11588 0330242 //**

Issue ID #115360

Date Created 28/Feb/2018

Issued To: Jonathan Connor

Completed Status: 01 Mar 2018

---

Notes:

POR11588 0330242 Estimated ship to us date changed to / /

---

Issues:115360

---

- Back Order Report

**POR11588 0330242 //**

Issue ID #115358

Date Created 28/Feb/2018

Issued To: Jonathan Connor

Completed Status: 01 Mar 2018

---

Notes:

POR11588 0330242 Estimated ship to us date changed to / /

---

Issues:115358

---

- Back Order Report

**POR11588 0330242 //**

Issue ID #112709

Date Created 19/Jan/2018

Issued To: Jonathan Connor

Completed Status: 19 Jan 2018

---

Notes:

POR11588 0330242 Estimated ship to us date changed to / /

---

Issues:112709

---

- Back Order Report

**POR11613 0330217 //**

Issue ID #114205

Date Created 09/Feb/2018

Issued To: Jonathan Connor

Completed Status: 12 Feb 2018

---

Notes:

POR11613 0330217 Estimated ship to us date changed to / /

---

Issues:114205

---

- Back Order Report

**POR11613 0330217 //**

Issue ID #114184

Date Created 09/Feb/2018

Issued To: Jonathan Connor

Completed Status: 12 Feb 2018

---

Notes:

POR11613 0330217 Estimated ship to us date changed to / /

---

Issues:114184

---

- Back Order Report

**POR11613 0330217 //**

Issue ID #113807

Date Created 05/Feb/2018

Issued To: Jonathan Connor

Completed Status: 05 Feb 2018

---

Notes:

POR11613 0330217 Estimated ship to us date changed to / /

---

Issues:113807

---

- Back Order Report

**POR11628 0390015 //**

Issue ID #115189

Date Created 26/Feb/2018

Issued To: Jonathan Connor

Completed Status: 26 Feb 2018

---

Notes:

POR11628 0390015 Estimated ship to us date changed to / /

---

Issues:115189



---

- Back Order Report

**POR11628 0390015 //**

Issue ID #114554

Date Created 15/Feb/2018

Issued To: Jonathan Connor

Completed Status: 15 Feb 2018

---

Notes:

POR11628 0390015 Estimated ship to us date changed to / /

---

Issues:114554

---

- Back Order Report

**POR11654 0330203 //**

Issue ID #116158

Date Created 14/Mar/2018

Issued To: Jonathan Connor

Completed Status: 15 Mar 2018

---

Notes:

POR11654 0330203 Estimated ship to us date changed to / /

---

Issues:116158

---

- Back Order Report

**POR11654 0330203 //**

Issue ID #116152

Date Created 14/Mar/2018

Issued To: Jonathan Connor

Completed Status: 14 Mar 2018

---

Notes:

POR11654 0330203 Estimated ship to us date changed to / /

---

Issues:116152

---

- Back Order Report

**POR11655 0330214 //**

Issue ID #116031

Date Created 12/Mar/2018

Issued To: Jonathan Connor

Completed Status: 12 Mar 2018

---

Notes:

POR11655 0330214 Estimated ship to us date changed to / /

---

Issues:116031

---

Intrastats - Intrastats

**Price List Weightings - Tom Thumb**

Issue ID #108584

Date Created 20/Nov/2017

Issued To: Derek Lamb

Completed Status: 27 Nov 2017

---

**Notes:**

Added by Catrin Hird sent to Derek Lamb

Just trying to generate a price list using Intrastats for the Tom Thumb. I've added weightings to some products to try and make it the same as the previous price list but they don't seem to be working....

Stock group Tom Thumb Price List 2017-11-20

First 3 showing as 0120141 0120141 0310030, should be ordered 0310030 at the top (weighted as 5) then 0120140 and 0120141 (weighted as 1).

---

23 Nov 2017 Derek Lamb

you need to come see me at my desk I cannot remember how i did this

---

27 Nov 2017 Catrin Hird

Now working, DL to remove weights number from price list.

---

27 Nov 2017 Derek Lamb

done

---

27 Nov 2017 Catrin Hird

thanks

---

Issues:108584

---

VIAMED Management Meeting - VIAMED Management Meeting

**Product Failures New Codes Review (750)**

Issue ID #132350

Date Created 16/Nov/2018

Issued To: Derek Lamb

Completed Status: 16 Nov 2018

---

Notes:

System Generated  
Task To be Completed

Review Intrastats Page:

Returns-> Repair codes Clean up

If New Faults have entered the system,

Review the Stock Repairs and apply a clean code and tag Fault / user or No Fault.

Complete all Stock References until the list is empty

---

16 Nov 2018 Derek Lamb  
0012160 requires Cleaning!  
TFT Upgrade  
0012161 requires Cleaning!  
PCB Fault  
0111263 requires Cleaning!  
LCD Fault  
0310030 requires Cleaning!  
Replaced gauge face  
4420594 requires Cleaning!  
power unit upgrade?  
7910100 requires Cleaning!  
connector fault.

no cap require general failure

---

Issues:132350

---

VIAMED Management Meeting - VIAMED Management Meeting

**Product Failures New Codes Review (750)**

Issue ID #119115

Date Created 27/Apr/2018

Issued To: Derek Lamb

Completed Status: 03 May 2018

---

Notes:

System Generated  
Task To be Completed

Review Intrastats Page:

Returns-> Repair codes Clean up

If New Faults have entered the system,

Review the Stock Repairs and apply a clean code and tag Fault / user or No Fault.

Complete all Stock References until the list is empty

---

27 Apr 2018 Derek Lamb  
Created Related Issue #119205  
Added by Derek Lamb sent to Steve Nixon  
0110122 requires Cleaning!

has been flagged up for review due to the 130 continental sensors.

Need to determine if we need a corrective action plan as per ISO,

---

27 Apr 2018 Derek Lamb

0012160 requires Cleaning!  
Usb fault no need for cap  
0110122 requires Cleaning!  
Followup Issue 119205  
0330193 requires Cleaning!  
No Fault Found  
4410520 requires Cleaning!  
Repeat of existing - on off button failure  
8010023 requires Cleaning!  
No Fault Found

---

Issues:119115

---

VIAMED Stock Meeting - VIAMED Stock Meeting

**Production Statistics (551)**

Issue ID #125521

Date Created 06/Aug/2018

Issued To: Derek Lamb

Completed Status: 09 Aug 2018

---

Notes:

System Generated

Task To be Completed

Review recent 30-40 Days completed Production runs,

Check the last 3 Completed runs.

1. Check the pick parts (Audit Button) against the previous builds pick parts.

List any where the quantities dont match

List production jobs any where Days to complete are greater than 30 Days.

---

06 Aug 2018 Derek Lamb

Checked

0320201 APGAR mounting bracket Rev2 Previous 3 builds

0310097 Tom Thumb TT480 (TG) Previous 3 builds

0110232 Oxygen Sensor R-22VAN Previous 3 builds

Only tom thumbs in the build list over 30 days to complete

---

Issues:125521



---

VIAMED Stock Meeting - Sale or Returns

**Request Scanning Item to Sale or return**

Issue ID #120200

Date Created 14/May/2018

Issued To: Catherine Spence

Completed Status: 06 Jun 2018

---

**Notes:**

Added by Steve Hardaker sent to Catherine Spence

Please scan to Sale or Returns Location ID34132 Stock Reference:

3x 0310030 Tom Thumb TT480 for use as Service Exchange units for Leicester Royal Infirmary. These are to allow them to send back their 3 units for service on ORD90040.

I have asked Phil to test them and check the calibration first, if you let me know when scanned, I will complete the SOR paperwork, thanks.

---

15 May 2018 Catherine Spence

id: 836913

836912

836911

---

16 May 2018 Steve Hardaker

SOR854 - paperwork complete and passed to office this morning for checking.

Please can you advise me of the tracking number when shipping and I will email the customer, thanks.

---

18 May 2018 Catherine Spence

scanned into sale and return

1Z9W9638DK67495178

---

06 Jun 2018 Steve Hardaker

Urgent Flag Changed To Off Sent. The customer Tom Thumbs have been received on SRS66547.

---

Issues:120200

---

VIAMED Stock Meeting - Sale or Returns

**Returned Items SOR519**

Issue ID #107169

Date Created 02/Nov/2017

Issued To: Steve Hardaker

Completed Status: 28 Nov 2017

---

**Notes:**

Added by Catherine Spence sent to Steve Hardaker

SOR ID519

Originally added by :Steve Hardaker

Liverpool Women's NHS Foundation Trust

Dave Cordon

Medical Engineering

Crown Street

Liverpool

L8 7SS

Returned : 0310030 040315

Sold on ORD89131

Sold on ORD89131

---

02 Nov 2017 Steve Hardaker

---

28 Nov 2017 Catherine Spence

---

Issues:107169

---

VIAMED Stock Meeting - Sale or Returns

**Returned Items SOR756**

Issue ID #117331

Date Created 03/Apr/2018

Issued To: Ryan Swaine

Completed Status: 03 Aug 2018

---

Notes:

Added by Emma Clark sent to Ryan Swaine

SOR ID756

Originally added by :Ryan Swaine

Mediq Suomi Oy

Juha Leppasalo

Luomanportti 3

Espoo

02200

Returned : 0310030 0401324

sold on ord914585

Returned : 0310100 00855

Returned : 3210071 Tracking896198\_68

---

03 Apr 2018 Ryan Swaine

---

Issues:117331

---

VIAMED Stock Meeting - Sale or Returns

**Returned Items SOR854**

Issue ID #123539

Date Created 06/Jul/2018

Issued To: Steve Hardaker

Completed Status: 24 Jul 2018

---

**Notes:**

Added by Catherine Spence sent to Steve Hardaker

SOR ID854

Originally added by :Steve Hardaker

Leicester Royal Infirmary

Roger Smith

Neonatal Unit

Level 2, Kensington Building

Infirmary Square

Leicester

LE1 5WW

Returned : 0380030 SE006

Received back and has gone to engineer for testing and returning to our service stock

Returned : 0380030 SE007

Returned : 0380030 SE008

---

06 Jul 2018 Steve Hardaker

Noted, thanks.

---

24 Jul 2018 Catherine Spence

---

Issues:123539

---

Intrastats - Intrastats

## **Servicable Items Page**

Issue ID #131615

Date Created 06/Nov/2018

Issued To: Derek Lamb

Completed Status: 28 Nov 2018

---

### Notes:

Added by Catrin Hird sent to Derek Lamb  
Showing 4410520 for all listed.

Sunderland Royal has been sent (its for a TT480) but I have left it on the list for you to see. Please mark as sent when you have sorted.

Thanks

---

06 Nov 2018 Derek Lamb  
fix that bug, added the service list lookup, needs another look

---

06 Nov 2018 Catrin Hird  
This list has gone big again, its showing ones from Feb?

History list is just a long list of numbers?

---

07 Nov 2018 Catrin Hird Also pulling out the wrong date, front screen says 1st Dec 2017, invoice says 4th Jan 2018? IN154642

---

08 Nov 2018 Derek Lamb  
you can clear off the service visit items for now  
will deal with them later.  
I'm going to have to come back to the service page, just too many little other things going on atm

---

09 Nov 2018 Catrin Hird  
365495WSPS888  
031003406 Nov 2017  
Error unable to Match to Company  
Service Visits item

removed in error as item not in use please rectify

---

09 Nov 2018 Catrin Hird  
Please can you also start the auto issues regarding servicing to come to me as I think as we are changing the system it would be best for me to complete them for the forecessale (I was anyway as Gail having to focus on office work). Thanks

---

09 Nov 2018 Derek Lamb  
do you know the task id for the issue?

---

09 Nov 2018 Catrin Hird  
Not old ones I don't think

---

12 Nov 2018 Derek Lamb  
only issue I can find is the service visit ones..

---

13 Nov 2018 Catrin Hird

Urgent Flag Changed To On The list is not working correctly, the dates which are being brought up are

incorrect. Please can you review. It would seem that maybe a different date is being shown, maybe when booked in? List currently showing capnograph requiring to be sent but weren't invoiced until March/April this year.

---

14 Nov 2018 Derek Lamb  
example reference for me to follow please

---

14 Nov 2018 Derek Lamb  
added the date invoiced to the (i) lookup button,

very possible qa / service dates are well in advance of the Invoice date,  
not sure how to get around this yet, so will take another look in a couple weeks

---

14 Nov 2018 Catrin Hird Hmm, that's going to get complicated then as we need to see them firstly 11 months after they are invoiced. Then after that when they were last QA'd. I'll leave the ones on the list that aren't required yet. Maybe we could add a notes field on this so we can put it needs completing at another date.

---

27 Nov 2018 Derek Lamb  
think it's fixed and behaving now

---

28 Nov 2018 Catrin Hird  
Amazing, working fine now thanks

---

Issues:131615

---

Intrastats - Intrastats

**Serviceable Items: Clear**

Issue ID #124534

Date Created 23/Jul/2018

Issued To: Derek Lamb

Completed Status: 24 Jul 2018

---

**Notes:**

Added by Catrin Hird sent to Derek Lamb

Please can you clear the list of Serviceable items. I have contacted all UK unique customers for:

0310002

0310097

0310030

0310031

0310032

0310034

1410000

From tomorrow we are then able to contact the customers which come up on the list.

Will these be by date or will they get notice of the service period running out?

---

24 Jul 2018 Derek Lamb

cleared the list,

currently its looking just at new sales a year ago, and or srs returns a year ago,

I can change it to 11 months i guess for early warning of a service due

---

24 Jul 2018 Catrin Hird

Perfect thanks

---

Issues:124534

---

VIAMED Management Meeting - VIAMED Management Meeting

**Software Validation In Production List (762)**

Issue ID #107033

Date Created 01/Nov/2017

Issued To: Derek Lamb

Completed Status: 02 Nov 2017

---

Notes:

System Generated

\*\*\* AUDIT \*\*\* Enure the Task is being Completed

---

01 Nov 2017 Derek Lamb

first audit here so physically checked lists,

3 on list all found ok,

not extra production jobs found

JobQuantityStock RefCreated byCreated OnStarted byStarted OnProduction ByQ.A. RecordsQA

DateMEMO (hover)

PS2438100310030Jonathan Connor28/09/17Jonathan Connor28/09/17Philip Crossley423 Oct 2017Memo

PS24493008000004Jonathan Connor17/10/17Jonathan Connor17/10/17Michael Green

PS245051410000Jonathan Connor18/10/17Jonathan Connor18/10/17Philip Crossley526 Oct 2017

---

Issues:107033



---

VIAMED Management Meeting - Other

**Standard to apply to Tom Thumb Infant Resuscitator**

Issue ID #104341

Date Created 02/Oct/2017

Issued To: Catrin Hird

Completed Status: 25 Jan 2018

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 H<sub>2</sub>O.

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 H <sub>2</sub> O
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 H<sub>2</sub>O = 0.981 mb

Suggest we edit to:

1cm wg = 1cm H<sub>2</sub>O = 0.981 mb = 0.981 hPa

We should schedule changing the artwork on the gauge dial to reflect cm H<sub>2</sub>O instead of cm WG. Ideally the SI unit to use is hPa, but the allowed and the fully backwards compatible unit is cm H<sub>2</sub>O (at 4 degrees C).

NOTE: The Fisher & Paykel Neopuff gauge is marked as cm H<sub>2</sub>O (mbar). Strictly speaking 1 cm H<sub>2</sub>O 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 H<sub>2</sub>O = 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 H<sub>2</sub>O.

---

11 Oct 2017 Derek Lamb

0310030 added for reference

---

07 Nov 2017 Steve Nixon

Next Action Changed From Derek Lamb To Catrin Hird As discussed, see note above 9th October.

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

1cm H<sub>2</sub>O = 1cm wg = 0.981 mb = 0.981 hPa

---

20 Nov 2017 Catrin Hird

Updated as discussed, copy of issue from DL regarding lpm to update spec.

Updated user manual, copy provided to SN for review. Added to marketing jobs list #829, against issue 108587.

---

Issues:104341

---

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: 30 Oct 2017  
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: 30 Oct 2017

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: 30 Oct 2017

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: 30 Oct 2017

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: 30 Oct 2017

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: 30 Oct 2017

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: 30 Oct 2017

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: 30 Oct 2017

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: 30 Oct 2017  
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: 30 Oct 2017

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: 30 Oct 2017

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: 30 Oct 2017

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: 30 Oct 2017

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: 30 Oct 2017

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: 30 Oct 2017

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: 30 Oct 2017

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: 30 Oct 2017  
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: 30 Oct 2017

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: 30 Oct 2017

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: 30 Oct 2017  
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: 30 Oct 2017

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: 30 Oct 2017

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: 30 Oct 2017

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: 30 Oct 2017  
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: 30 Oct 2017

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: 30 Oct 2017

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: 30 Oct 2017

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: 30 Oct 2017  
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: 30 Oct 2017

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: 30 Oct 2017

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: 30 Oct 2017

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: 30 Oct 2017

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: 30 Oct 2017

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: 30 Oct 2017

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: 30 Oct 2017  
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

---

VIAMED Management Meeting - Other

**Tom Thumb design change body block 0330201**

Issue ID #109967

Date Created 07/Dec/2017

Issued To: John Lamb

Completed Status: 10 Apr 2018

Linked Files

07 Dec 2017 Tom Thumb design change QC28 B, 2017-12-07

08 Dec 2017 Tom Thumb design change QC28 B, 2017-12-08

08 Dec 2017 Tom Thumb design change QC28 B, 2017-12-08 Word ver

---

Notes:

Added by Steve Nixon sent to Derek Lamb

See attached QC28 B

---

07 Dec 2017 Derek Lamb

Next Action Changed From Derek Lamb To John Lamb 0310030 added for reference

---

08 Dec 2017 Steve Nixon

See attached up dated version.

---

08 Dec 2017 Steve Nixon

VM3COP50.10 requires updating

---

09 Apr 2018 John Lamb

---

Issues:109967

---

Marketing Job Logger - Marketing Job Logger

**Tom Thumb Leaflet Amend**

Issue ID #108575

Date Created 20/Nov/2017

Issued To: 38

Completed Status: Still Outstanding

---

Notes:

Remove all variants apart from 0310030

---

06 Aug 2018 Catrin Hird

does it require 0310094+0310095?

---

Issues:108575



---

VIAMED Management Meeting - Other

**Tom Thumb Review 8 th November 2017**

Issue ID #107596

Date Created 08/Nov/2017

Issued To: John Lamb

Completed Status: 14 Nov 2017

---

**Notes:**

Copy Issue Main Issue #107595

Added by Steve Nixon sent to Derek Lamb

As discussed as of today we will discontinue non relevant Tom Thumb devices, either due to non blended gas, special or low/no sales. See attached list.

Retain & continue:

0310030 TT-480

Required for general sales and for use with resuscitation cabinets

0310094 TT-480 with pole mount

Continue, but monitor - low sales to date.

---

Issues:107596

---

VIAMED Management Meeting - Other

**Tom Thumb Review 8 th November 2017**

Issue ID #107595

Date Created 08/Nov/2017

Issued To: Derek Lamb

Completed Status: 14 Nov 2017

Linked Files

08 Nov 2017 Tom Thumb Review 8th November 2017

08 Nov 2017 Tom Thumb Review 8th November 2017 pdf

---

**Notes:**

Added by Steve Nixon sent to Derek Lamb

As discussed as of today we will discontinue non relevant Tom Thumb devices, either due to non blended gas, special or low/no sales. See attached list.

Retain & continue:

0310030 TT-480

Required for general sales and for use with resuscitation cabinets

0310094 TT-480 with pole mount

Continue, but monitor - low sales to date.

---

Issues:107595

---

VIAMED Sales And Marketing - Sales

**Tom Thumb Review 8th November 2017 - Discontinued Variants**

Issue ID #107613

Date Created 08/Nov/2017

Issued To: Zoey Teal

Completed Status: 04 Dec 2017

---

**Notes:**

Copy Issue Main Issue #107599

Added by Steve Nixon sent to Derek Lamb

As of today we will discontinuing non relevant Tom Thumb (Infant T-piece Resuscitator) devices, either due to using non blended gas, specials or low/no sales. See attached list for further details.

Variants retained & continued:

0310030 TT-480

Required for general sales and for use with resuscitation cabinets

0310094 TT-480 with pole mount

Continue, but monitor - low sales to date.

Catrin, please edit price lists, leaflet, catalogues & web site accordingly, i.e. just retain 0310030 TT-480

Once reviewed and appraised, may add 0310094.

---

29 Nov 2017 Zoey Teal

Noted

---

Issues:107613

---

VIAMED Sales And Marketing - Sales

**Tom Thumb Review 8th November 2017 - Discontinued Variants**

Issue ID #107612

Date Created 08/Nov/2017

Issued To: Steve Hardaker

Completed Status: 04 Dec 2017

---

**Notes:**

Copy Issue Main Issue #107599

Added by Steve Nixon sent to Derek Lamb

As of today we will discontinuing non relevant Tom Thumb (Infant T-piece Resuscitator) devices, either due to using non blended gas, specials or low/no sales. See attached list for further details.

Variants retained & continued:

0310030 TT-480

Required for general sales and for use with resuscitation cabinets

0310094 TT-480 with pole mount

Continue, but monitor - low sales to date.

Catrin, please edit price lists, leaflet, catalogues & web site accordingly, i.e. just retain 0310030 TT-480

Once reviewed and appraised, may add 0310094.

---

08 Nov 2017 Steve Hardaker

Noted.

---

Issues:107612

---

VIAMED Sales And Marketing - Sales

**Tom Thumb Review 8th November 2017 - Discontinued Variants**

Issue ID #107611

Date Created 08/Nov/2017

Issued To: Sophie Lines

Completed Status: 04 Dec 2017

---

**Notes:**

Copy Issue Main Issue #107599

Added by Steve Nixon sent to Derek Lamb

As of today we will discontinuing non relevant Tom Thumb (Infant T-piece Resuscitator) devices, either due to using non blended gas, specials or low/no sales. See attached list for further details.

Variants retained & continued:

0310030 TT-480

Required for general sales and for use with resuscitation cabinets

0310094 TT-480 with pole mount

Continue, but monitor - low sales to date.

Catrin, please edit price lists, leaflet, catalogues & web site accordingly, i.e. just retain 0310030 TT-480

Once reviewed and appraised, may add 0310094.

---

13 Nov 2017 Sophie Lines

Noted

---

Issues:107611

---

VIAMED Sales And Marketing - Sales

**Tom Thumb Review 8th November 2017 - Discontinued Variants**

Issue ID #107610

Date Created 08/Nov/2017

Issued To: Sarah Walton

Completed Status: 04 Dec 2017

---

**Notes:**

Copy Issue Main Issue #107599

Added by Steve Nixon sent to Derek Lamb

As of today we will discontinuing non relevant Tom Thumb (Infant T-piece Resuscitator) devices, either due to using non blended gas, specials or low/no sales. See attached list for further details.

Variants retained & continued:

0310030 TT-480

Required for general sales and for use with resuscitation cabinets

0310094 TT-480 with pole mount

Continue, but monitor - low sales to date.

Catrin, please edit price lists, leaflet, catalogues & web site accordingly, i.e. just retain 0310030 TT-480

Once reviewed and appraised, may add 0310094.

---

10 Nov 2017 Sarah Walton

Noted

---

Issues:107610

---

VIAMED Sales And Marketing - Sales

**Tom Thumb Review 8th November 2017 - Discontinued Variants**

Issue ID #107609

Date Created 08/Nov/2017

Issued To: Ryan Swaine

Completed Status: 04 Dec 2017

---

**Notes:**

Copy Issue Main Issue #107599

Added by Steve Nixon sent to Derek Lamb

As of today we will discontinuing non relevant Tom Thumb (Infant T-piece Resuscitator) devices, either due to using non blended gas, specials or low/no sales. See attached list for further details.

Variants retained & continued:

0310030 TT-480

Required for general sales and for use with resuscitation cabinets

0310094 TT-480 with pole mount

Continue, but monitor - low sales to date.

Catrin, please edit price lists, leaflet, catalogues & web site accordingly, i.e. just retain 0310030 TT-480

Once reviewed and appraised, may add 0310094.

---

21 Nov 2017 Ryan Swaine

Correspondence with regards to the TT with top gauge for our customer in Italy:

Ryan Swaine &#060;ryan.swaine@viamed.co.uk&#062;

9 Nov (12 days ago)

Hi Domenico

I have just spoken with one of our directors, he has agreed that we can wait until the 21st.

You will have to send the PO to me or CC me in, as my colleagues in our sales office will reject it.

Best regards

Ryan

Ryan Swaine

International Sales Manager

VIAMED

www.viamed.co.uk

Email: ryan.swaine@viamed.co.uk

Office: +44 (0) 1535 634542

Fax: +44 (0) 1535 635582

Mobile: +44 (0) 7803 907117

On 9 November 2017 at 11:26, &#060;domenico@ingrande.it&#062; wrote:

Hi Ryan,

I have a meeting on november 20th with Inspiration, please, can you wait until 21?

Thank you in advace

Domenico

---

23 Nov 2017 Ryan Swaine

---

Issues:107609



---

VIAMED Sales And Marketing - Sales

**Tom Thumb Review 8th November 2017 - Discontinued Variants**

Issue ID #107608

Date Created 08/Nov/2017

Issued To: Robert Connor

Completed Status: 04 Dec 2017

---

**Notes:**

Copy Issue Main Issue #107599

Added by Steve Nixon sent to Derek Lamb

As of today we will discontinuing non relevant Tom Thumb (Infant T-piece Resuscitator) devices, either due to using non blended gas, specials or low/no sales. See attached list for further details.

Variants retained & continued:

0310030 TT-480

Required for general sales and for use with resuscitation cabinets

0310094 TT-480 with pole mount

Continue, but monitor - low sales to date.

Catrin, please edit price lists, leaflet, catalogues & web site accordingly, i.e. just retain 0310030 TT-480

Once reviewed and appraised, may add 0310094.

---

08 Nov 2017 Robert Connor

Noted, thanks

---

Issues:107608

---

VIAMED Sales And Marketing - Sales

**Tom Thumb Review 8th November 2017 - Discontinued Variants**

Issue ID #107607

Date Created 08/Nov/2017

Issued To: Robert Bonser

Completed Status: 15 Jan 2018

---

**Notes:**

Copy Issue Main Issue #107599

Added by Steve Nixon sent to Derek Lamb

As of today we will discontinuing non relevant Tom Thumb (Infant T-piece Resuscitator) devices, either due to using non blended gas, specials or low/no sales. See attached list for further details.

Variants retained & continued:

0310030 TT-480

Required for general sales and for use with resuscitation cabinets

0310094 TT-480 with pole mount

Continue, but monitor - low sales to date.

Catrin, please edit price lists, leaflet, catalogues & web site accordingly, i.e. just retain 0310030 TT-480

Once reviewed and appraised, may add 0310094.

---

10 Jan 2018 Robert Bonser  
read it.

---

Issues:107607

---

VIAMED Sales And Marketing - Sales

**Tom Thumb Review 8th November 2017 - Discontinued Variants**

Issue ID #107606

Date Created 08/Nov/2017

Issued To: Philip Crossley

Completed Status: 04 Dec 2017

---

**Notes:**

Copy Issue Main Issue #107599

Added by Steve Nixon sent to Derek Lamb

As of today we will discontinuing non relevant Tom Thumb (Infant T-piece Resuscitator) devices, either due to using non blended gas, specials or low/no sales. See attached list for further details.

Variants retained & continued:

0310030 TT-480

Required for general sales and for use with resuscitation cabinets

0310094 TT-480 with pole mount

Continue, but monitor - low sales to date.

Catrin, please edit price lists, leaflet, catalogues & web site accordingly, i.e. just retain 0310030 TT-480

Once reviewed and appraised, may add 0310094.

---

14 Nov 2017 Philip Crossley

ok

---

Issues:107606

---

VIAMED Sales And Marketing - Sales

**Tom Thumb Review 8th November 2017 - Discontinued Variants**

Issue ID #107605

Date Created 08/Nov/2017

Issued To: Katie Evans

Completed Status: 04 Dec 2017

---

**Notes:**

Copy Issue Main Issue #107599

Added by Steve Nixon sent to Derek Lamb

As of today we will discontinuing non relevant Tom Thumb (Infant T-piece Resuscitator) devices, either due to using non blended gas, specials or low/no sales. See attached list for further details.

Variants retained & continued:

0310030 TT-480

Required for general sales and for use with resuscitation cabinets

0310094 TT-480 with pole mount

Continue, but monitor - low sales to date.

Catrin, please edit price lists, leaflet, catalogues & web site accordingly, i.e. just retain 0310030 TT-480

Once reviewed and appraised, may add 0310094.

---

15 Nov 2017 Katie Evans

Noted, thank you

---

Issues:107605

---

VIAMED Sales And Marketing - Sales

**Tom Thumb Review 8th November 2017 - Discontinued Variants**

Issue ID #107604

Date Created 08/Nov/2017

Issued To: Jonathan Connor

Completed Status: 04 Dec 2017

---

**Notes:**

Copy Issue Main Issue #107599

Added by Steve Nixon sent to Derek Lamb

As of today we will discontinuing non relevant Tom Thumb (Infant T-piece Resuscitator) devices, either due to using non blended gas, specials or low/no sales. See attached list for further details.

Variants retained & continued:

0310030 TT-480

Required for general sales and for use with resuscitation cabinets

0310094 TT-480 with pole mount

Continue, but monitor - low sales to date.

Catrin, please edit price lists, leaflet, catalogues & web site accordingly, i.e. just retain 0310030 TT-480

Once reviewed and appraised, may add 0310094.

---

22 Nov 2017 Jonathan Connor

ok thanks

---

Issues:107604

---

VIAMED Sales And Marketing - Sales

**Tom Thumb Review 8th November 2017 - Discontinued Variants**

Issue ID #107603

Date Created 08/Nov/2017

Issued To: John Lamb

Completed Status: 10 Apr 2018

---

**Notes:**

Copy Issue Main Issue #107599

Added by Steve Nixon sent to Derek Lamb

As of today we will discontinuing non relevant Tom Thumb (Infant T-piece Resuscitator) devices, either due to using non blended gas, specials or low/no sales. See attached list for further details.

Variants retained & continued:

0310030 TT-480

Required for general sales and for use with resuscitation cabinets

0310094 TT-480 with pole mount

Continue, but monitor - low sales to date.

Catrin, please edit price lists, leaflet, catalogues & web site accordingly, i.e. just retain 0310030 TT-480

Once reviewed and appraised, may add 0310094.

---

09 Nov 2017 John Lamb

Does this take into account models for midwives

---

09 Apr 2018 John Lamb

---

Issues:107603

---

VIAMED Sales And Marketing - Sales

**Tom Thumb Review 8th November 2017 - Discontinued Variants**

Issue ID #107602

Date Created 08/Nov/2017

Issued To: Emily Hanson

Completed Status: 15 Jan 2018

---

**Notes:**

Copy Issue Main Issue #107599

Added by Steve Nixon sent to Derek Lamb

As of today we will discontinuing non relevant Tom Thumb (Infant T-piece Resuscitator) devices, either due to using non blended gas, specials or low/no sales. See attached list for further details.

Variants retained & continued:

0310030 TT-480

Required for general sales and for use with resuscitation cabinets

0310094 TT-480 with pole mount

Continue, but monitor - low sales to date.

Catrin, please edit price lists, leaflet, catalogues & web site accordingly, i.e. just retain 0310030 TT-480

Once reviewed and appraised, may add 0310094.

---

29 Dec 2017 Emily Hanson

---

29 Dec 2017 Emily Hanson

---

Issues:107602

---

VIAMED Sales And Marketing - Sales

**Tom Thumb Review 8th November 2017 - Discontinued Variants**

Issue ID #107601

Date Created 08/Nov/2017

Issued To: Catrin Hird

Completed Status: 04 Dec 2017

Linked Files

20 Nov 2017 Infant Resuscitation Catalogue 2017-11-20

20 Nov 2017 Tom Thumb Price List 2017-11-20 DRAFT WEIGHTINGS ISSUE OUTSTANDING WITH DL

21 Nov 2017 Tom Thumb Price List 2017-11-21 DRAFT WEIGHTINGS ISSUE OUTSTANDING WITH DL

21 Nov 2017 Tom Thumb GBP Price List 2017-11-21

21 Nov 2017 Tom Thumb GBP Price List 2017-11-21 b

21 Nov 2017 Infant Resuscitation Catalogue 2017-11-21

21 Nov 2017 Infant Resuscitation Catalogue 2017-11-21 b

---

**Notes:**

Copy Issue Main Issue #107599

Added by Steve Nixon sent to Derek Lamb

As of today we will discontinuing non relevant Tom Thumb (Infant T-piece Resuscitator) devices, either due to using non blended gas, specials or low/no sales. See attached list for further details.

Variants retained & continued:

0310030 TT-480

Required for general sales and for use with resuscitation cabinets

0310094 TT-480 with pole mount

Continue, but monitor - low sales to date.

Catrin, please edit price lists, leaflet, catalogues & web site accordingly, i.e. just retain 0310030 TT-480

Once reviewed and appraised, may add 0310094.

---

20 Nov 2017 Catrin Hird

All variants of Tom thumb apart from 0310030, removed from website.

Infant Resus Catalogue - removed tom thumb variants and updated image - still needs work regarding acrylics being removed - attached current artwork for review by SN - i.e. page 9 has some white space left - would you like further information regarding specifications to be included (even though we are trying to steer away from that in catalogues)?!?

Amended pages 14/15 regarding "also available" pages.

Hard copy provided to SN with proofing sheet.

Price List

9901-22 shown on price list - is 0330191 correct replacement part? Have updated price list to generate from Intrastats - issue with DL regarding weightings not working (108584) but attached for reference.

The following prices as required to update other price list (if required)... Hard copy provided to SN with proofing sheet.

0310030 0005 International End User USD

0330191 0002 UK Distributor

0330191 0004 International Distributor Euros

0330191 0006 International Distributor USD

3210011 0003 International End User Euros

3210011 0005 International End User USD

3210013 0003 International End User Euros



3210013 0005 International End User USD  
3210067 0002 UK Distributor  
3210067 0003 International End User Euros  
3210067 0005 International End User USD  
3210067 0006 International Distributor USD  
3210068 0002 UK Distributor  
3210068 0003 International End User Euros  
3210068 0004 International Distributor Euros  
3210068 0005 International End User USD  
3210068 0006 International Distributor USD  
3210069 0002 UK Distributor  
3210069 0003 International End User Euros  
3210069 0004 International Distributor Euros  
3210069 0005 International End User USD  
3210069 0006 International Distributor USD  
3210070 0003 International End User Euros  
3210070 0005 International End User USD  
3210071 0003 International End User Euros  
3210071 0005 International End User USD  
3210073 0003 International End User Euros  
3210073 0005 International End User USD  
3210074 0003 International End User Euros  
3210074 0005 International End User USD  
3210076 0003 International End User Euros  
3210076 0005 International End User USD  
3210077 0003 International End User Euros  
3210077 0005 International End User USD

---

21 Nov 2017 Catrin Hird

9901-22/0330191 removed from price list as requested.

Incorrect part numbers given for silicone adapters, should have been 0120150 (instead of 0120149),  
0120152 (instead of 0120159).

Updated prices required list...

0120151 0003 International End User Euros  
0120151 0005 International End User USD  
0120153 0002 UK Distributor  
0120153 0003 International End User Euros  
0120153 0004 International Distributor Euros  
0120153 0005 International End User USD  
0310030 0005 International End User USD  
3210013 0003 International End User Euros  
3210013 0005 International End User USD  
3210023 0003 International End User Euros  
3210023 0005 International End User USD  
3210067 0002 UK Distributor  
3210067 0003 International End User Euros  
3210067 0005 International End User USD  
3210067 0006 International Distributor USD  
3210068 0002 UK Distributor  
3210068 0003 International End User Euros  
3210068 0004 International Distributor Euros  
3210068 0005 International End User USD  
3210068 0006 International Distributor USD  
3210069 0002 UK Distributor  
3210069 0003 International End User Euros  
3210069 0004 International Distributor Euros  
3210069 0005 International End User USD  
3210069 0006 International Distributor USD  
3210070 0003 International End User Euros  
3210070 0005 International End User USD  
3210071 0003 International End User Euros

3210071 0005 International End User USD  
3210073 0003 International End User Euros  
3210073 0005 International End User USD  
3210074 0003 International End User Euros  
3210074 0005 International End User USD  
3210076 0003 International End User Euros  
3210076 0005 International End User USD  
3210077 0003 International End User Euros  
3210077 0005 International End User USD

---

21 Nov 2017 Catrin Hird

Next Action Changed From Catrin Hird To Katie Evans Please review price list for correct descriptions.

Hard copy provided and saved in Z Checking, proof sheet provided.

---

21 Nov 2017 Catrin Hird  
Updated and reattached.

---

21 Nov 2017 Catrin Hird  
SN - Infant Resus catalogue provided to you for checking with proof sheet.

---

27 Nov 2017 Catrin Hird  
Price list updated (still waiting for product weighing coding to be updated by DL #108584. Hard copy with proof sheet with KE.

---

28 Nov 2017 Catrin Hird  
Created Related Issue #109225  
Added by Catrin Hird sent to Steve Nixon  
Price list updated and sent to SN for review with proof sheet. Pricing missing as follows:

0120151 0003 International End User Euros  
0120151 0005 International End User USD  
0120153 0002 UK Distributor  
0120153 0003 International End User Euros  
0120153 0004 International Distributor Euros  
0120153 0005 International End User USD  
0310030 0005 International End User USD  
3210013 0003 International End User Euros  
3210013 0005 International End User USD  
3210023 0003 International End User Euros  
3210023 0005 International End User USD  
3210067 0002 UK Distributor  
3210067 0003 International End User Euros  
3210067 0005 International End User USD  
3210067 0006 International Distributor USD  
3210068 0002 UK Distributor  
3210068 0003 International End User Euros  
3210068 0004 International Distributor Euros  
3210068 0005 International End User USD  
3210068 0006 International Distributor USD  
3210069 0002 UK Distributor  
3210069 0003 International End User Euros  
3210069 0004 International Distributor Euros  
3210069 0005 International End User USD  
3210069 0006 International Distributor USD  
3210070 0003 International End User Euros  
3210070 0005 International End User USD  
3210071 0003 International End User Euros  
3210071 0005 International End User USD  
3210073 0003 International End User Euros  
3210073 0005 International End User USD  
3210074 0003 International End User Euros  
3210074 0005 International End User USD

3210076 0003 International End User Euros  
3210076 0005 International End User USD  
3210077 0003 International End User Euros  
3210077 0005 International End User USD

Also saved in: Z:Information for LibraryIn Checking with SN

---

28 Nov 2017 Catrin Hird

Next Action Changed From Katie Evans To Catrin Hird See related issue.

---

28 Nov 2017 Catrin Hird  
see related issue

---

Issues:107601

---

VIAMED Sales And Marketing - Sales

**Tom Thumb Review 8th November 2017 - Discontinued Variants**

Issue ID #107600

Date Created 08/Nov/2017

Issued To: Catherine Spence

Completed Status: 13 Feb 2018

---

**Notes:**

Copy Issue Main Issue #107599

Added by Steve Nixon sent to Derek Lamb

As of today we will discontinuing non relevant Tom Thumb (Infant T-piece Resuscitator) devices, either due to using non blended gas, specials or low/no sales. See attached list for further details.

Variants retained & continued:

0310030 TT-480

Required for general sales and for use with resuscitation cabinets

0310094 TT-480 with pole mount

Continue, but monitor - low sales to date.

Catrin, please edit price lists, leaflet, catalogues & web site accordingly, i.e. just retain 0310030 TT-480

Once reviewed and appraised, may add 0310094.

---

01 Feb 2018 Catherine Spence  
noted

---

Issues:107600

---

VIAMED Sales And Marketing - Sales

**Tom Thumb Review 8th November 2017 - Discontinued Variants**

Issue ID #107599

Date Created 08/Nov/2017

Issued To: Derek Lamb

Completed Status: 04 Dec 2017

Linked Files

08 Nov 2017 Tom Thumb Review 8th November 2017 v1.1

---

**Notes:**

Added by Steve Nixon sent to Derek Lamb

As of today we will discontinuing non relevant Tom Thumb (Infant T-piece Resuscitator) devices, either due to using non blended gas, specials or low/no sales. See attached list for further details.

Variants retained & continued:

0310030 TT-480

Required for general sales and for use with resuscitation cabinets

0310094 TT-480 with pole mount

Continue, but monitor - low sales to date.

Catrin, please edit price lists, leaflet, catalogues & web site accordingly, i.e. just retain 0310030 TT-480

Once reviewed and appraised, may add 0310094.

---

08 Nov 2017 Derek Lamb

thanks

---

Issues:107599

---

VIAMED Sales And Marketing - Sales

**Tom Thumb Review 8th November 2017 - Discontinued Variants - Price list**

Issue ID #109225

Date Created 28/Nov/2017

Issued To: Steve Nixon

Completed Status: 10 May 2018

Linked Files

28 Nov 2017 Tom Thumb GBP Price List 2017-11-28

26 Mar 2018 Tom Thumb GBP Price List 2018-03-26 Including 0310095

26 Mar 2018 Tom Thumb GBP Distributor Price List 2018-03-26 Including 0310095

---

**Notes:**

Added by Catrin Hird sent to Steve Nixon

Price list updated and sent to SN for review with proof sheet. Pricing missing as follows:

0120151 0003 International End User Euros  
0120151 0005 International End User USD  
0120153 0002 UK Distributor  
0120153 0003 International End User Euros  
0120153 0004 International Distributor Euros  
0120153 0005 International End User USD  
0310030 0005 International End User USD  
3210013 0003 International End User Euros  
3210013 0005 International End User USD  
3210023 0003 International End User Euros  
3210023 0005 International End User USD  
3210067 0002 UK Distributor  
3210067 0003 International End User Euros  
3210067 0005 International End User USD  
3210067 0006 International Distributor USD  
3210068 0002 UK Distributor  
3210068 0003 International End User Euros  
3210068 0004 International Distributor Euros  
3210068 0005 International End User USD  
3210068 0006 International Distributor USD  
3210069 0002 UK Distributor  
3210069 0003 International End User Euros  
3210069 0004 International Distributor Euros  
3210069 0005 International End User USD  
3210069 0006 International Distributor USD  
3210070 0003 International End User Euros  
3210070 0005 International End User USD  
3210071 0003 International End User Euros  
3210071 0005 International End User USD  
3210073 0003 International End User Euros  
3210073 0005 International End User USD  
3210074 0003 International End User Euros  
3210074 0005 International End User USD  
3210076 0003 International End User Euros  
3210076 0005 International End User USD  
3210077 0003 International End User Euros  
3210077 0005 International End User USD

Also saved in: Z:Information for LibraryIn Checking with SN

---

29 Jan 2018 Catrin Hird

GBP price list generated and printed for sign off with proof sheet and provided to SN.

Saved in Z:Information for LibraryIn Checking with SN.

The following prices are still missing so I am unable to produce other currency price lists.

0120153 0005 International End User USD  
3210067 0002 UK Distributor  
3210067 0006 International Distributor USD  
3210068 0002 UK Distributor  
3210068 0004 International Distributor Euros  
3210068 0006 International Distributor USD  
3210069 0002 UK Distributor  
3210069 0004 International Distributor Euros  
3210069 0006 International Distributor USD

---

26 Mar 2018 Catrin Hird

Updated price list for GBP tom thumb, following prices still not included:

0310095 0003 International End User Euros  
0310095 0004 International Distributor Euros  
0310095 0005 International End User USD  
0310095 0006 International Distributor USD

GBP End user and Distributor Price Lists saved in Z:Information for LibraryIn Checking with SNTom Thumb Price Lists

USD and Euro saved in Z:Information for LibraryIn Checking with SNTom Thumb Price Lists  
0310095 Price Missing, incase you are wanting to use with 0310095

Hard copies of GBP provided with proof sheet, notes from this issue also noted on proof sheet.

---

10 Apr 2018 Catrin Hird

Price lists updated to include 0310094, Price lists saved in Z:Information for LibraryIn Checking with SNTom Thumb Price Lists

Hard copy and proof sheet provided to SN.

---

03 May 2018 Catrin Hird

SN approved price list verbally. He will add to L.

---

10 May 2018 Catrin Hird

Done

---

Issues:109225

---

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: 31 Jan 2018

---

**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.

---

25 Jan 2018 Derek Lamb

---

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: 04 Dec 2017

---

**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.

---

31 Oct 2017 Catrin Hird

This has been dealt with by KE

---

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: 31 Jan 2018

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

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, 0310034, so that we can check the suitability and presentation, before we process to new customers.

---

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

---

27 Dec 2017 Katie Evans

---

Issues:89789

---

VIAMED Stock Meeting - Purchase Order Requirements

**Tom Thumb valve collar insertion tool - 0360011**

Issue ID #110794

Date Created 21/Dec/2017

Issued To: Derek Lamb

Completed Status: 04 Jan 2018

Linked Files

21 Dec 2017 Quotation - R&L ref 3807 20171221

21 Dec 2017 Valve collar insertion tool

03 Jan 2018 0360011 - A101787 - Tom Thumb Valve Collar Insertion Tool 20180104.pdf

---

**Notes:**

Added by Steve Hardaker sent to Steve Nixon

Steve, I gave Martyn at R&L one of our Tom Thumb valve collar insertion tools to allow them to manufacture more. He has come back with a quotation for £17.00 for a quantity of 5 (see attached) and will provide a technical drawing upon purchase.

Please can you add to Opera and place a purchase order 5, Homerton Hospital want to order 3. Thanks.

---

21 Dec 2017 Steve Hardaker

For clarity: £17.00 EACH based on a quantity of 5.

---

02 Jan 2018 Steve Hardaker Please can you advise a part number and selling price, I now have a second hospital wanting to buy one, thanks.

---

03 Jan 2018 Steve Hardaker

Next Action Changed From Steve Nixon To Derek Lamb

Subject Changed From Tom Thumb valve collar insertion tool

Subject Changed To Tom Thumb valve collar insertion tool - 0360011 SN provided part number 0360011 @ £25.00+VAT UK end user.

I have obtained a technical drawing from Martyn Garner at R&L Enterprises Ltd (see attached). They have given it part number A10187.

Derek, please could you upload it to the ISO document index.

We will need to review if any other documents are required at this stage. I will look into the technical files to see which requirements may apply and can use this as a starter project to get me into building the files and working with those pages in Intrastats.

If there is anything that immediately comes to mind, please let me know, thanks.

---

04 Jan 2018 Derek Lamb

added to tech file

0310030 added for reference

---

04 Jan 2018 Steve Hardaker

Thanks. Found where Derek added it in the tech file, under Tooling.

---

Issues:110794

---

VIAMED Feedback - Product Feedback Positive

**TT-480 0310097 fitted to Inspiration/Inditherm LifeStart**

Issue ID #123903

Date Created 12/Jul/2018

Issued To: Ryan Swaine

Completed Status: 13 Jul 2018

Linked Files

12 Jul 2018 LifeStart

---

Notes:

Added by Ryan Swaine sent to Ryan Swaine

TT-480 0310097 fitted to Inspiration/Inditherm LifeStart

---

12 Jul 2018 Ryan Swaine

---

13 Jul 2018 Ryan Swaine

---

Issues:123903

---

VIAMED Stock Meeting - Repairs Review - General

**TT480 0401281**

Issue ID #104434

Date Created 03/Oct/2017

Issued To: Derek Lamb

Completed Status: 27 Oct 2017

---

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

---

27 Oct 2017 Philip CrossleyAs new, parts being broken down, cleaned and returned to stock. O rings are being thrown away. Serial number

---

27 Oct 2017 Philip Crossley

---

Issues:104434

---

VIAMED Stock Meeting - Photography

**TT480 with pole mount**

Issue ID #113113

Date Created 25/Jan/2018

Issued To: Jonathan Connor

Completed Status: 23 Apr 2018

---

Notes:

Added by Catrin Hird sent to Catrin Hird

---

25 Jan 2018 Catrin Hird

Next Action Changed From Catrin Hird To Jonathan Connor Please can I have a TT480 with pole clamp 0310094 for photography.

Thanky

---

19 Feb 2018 Catrin Hird

Header Changed From 332 VIAMED Stock Stock Queries To VIAMED Sales And Marketing Photography

---

Issues:113113

---

Non Conforming Stock Transfers. (QC19) - Web Site Updates

**Web Site Question ID 1200**

Issue ID #121614

Date Created 04/Jun/2018

Issued To: Ryan Swaine

Completed Status: 04 Jun 2018

---

**Notes:**

Web Site Question ID 1200

03/06/18

mnayeemuddin@alfaisaliah.com

Information Request to Viamed Limited at the <https://www.viamed.co.uk/uk/ WebSite>

Nayeemuddin Mohammed

Al- Faisaliah Medical Systems

Customer support and Spare parts

mnayeemuddin@alfaisaliah.com

Saudi Arabia

Type: Pricing

Hello,

We are from Alfaisaliah Medical Systems in Saudi Arabia.

We have one request from our VIP customer to supply the Tom Thumb infant resuscitator ( Model : TT-480), part number : 0310030. We are to find the in locally but we donâ€™t find the distributor in Saudi Arabia.

if you have any local distributor in Saudi Arabia, kindly share the contact details to get the quotation to submit our customer.

If you donâ€™t have any local distributor in Saudi Arabia, kindly arrange to send us the quotation for 15 Qty from direct purchasing from you.

Waiting for your reply

Kind Regards

Nayeemuddin

Alfaisaliah Medical Systems

Saudi Arabia

Mobile: 00966-508956251

Email; mnayeemuddin@alfaisaliah. com

Request further Information on

Medical Tom Thumb Infant Resuscitators

---

04 Jun 2018 Kate Griffiths

Next Action Changed From Kate Griffiths To Steve Hardaker Hi Steve, website question re Tom Thumb. Thank you.

---

04 Jun 2018 Steve Hardaker

Next Action Changed From Steve Hardaker To Ryan Swaine

---

04 Jun 2018 Ryan Swaine

Done, thank you.

---

04 Jun 2018 Kate Griffiths  
done

---

Issues:121614



---

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: 14 Nov 2017

---

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 :

limited results

## 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 :