



# 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  
13 / 04 / 23



# VIA MED

-  Stock References Review
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# Stock References Review

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

Stock Reference	Description
0330215	Clamp Spacer
0330216	Screws For Clamp M5
0330217	Oxygen hose 1m. C/W indirect probe &
0330218	Oxygen Hose 3m. C/W indirect probe &
0330219	Right Angle For Hose
0330220	Fomblin OT20N 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:

no changes

# Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
0330203	Pressure gauge for `Tom				Needs Grading
0330212	Gauge Seal				Needs Grading
0330217	Oxygen hose 1m. C/W indi				Needs Grading
0320221	Pole Clamp without slide	00007317	IHCP1-SPECIAL	Inspiration Healthcare L	B
0320103	Tom Thumb Rectangular Mo	00009022	PP8694	Tanda Engineering Ltd	B
0330185	Wing Nut Screw Black 2	00009032	3335	R & L Enterprises Ltd	A
0330190	Universal clamp - 44mm h	00009032		R & L Enterprises Ltd	A
0330191	Clamp Spacer	00009032	A4917	R & L Enterprises Ltd	A
0330201	TT480/490 MAIN Body Bloc	00009032	0330201	R & L Enterprises Ltd	A
0330205	Flowmeter Meter Bolt	00009032	0330205	R & L Enterprises Ltd	A
0330206	Blocking Bolt And Nut	00009032		R & L Enterprises Ltd	A
0330208	Inlet 10 mm	00009032		R & L Enterprises Ltd	A
0330209	Outlet 15mm	00009032		R & L Enterprises Ltd	A
0330224	Precision Valve Body	00009032		R & L Enterprises Ltd	A
0330225	Precision/Adjustable Val	00009032		R & L Enterprises Ltd	A
0330227	Precision/Adjustable Val	00009032		R & L Enterprises Ltd	A
0330228	Precision Valve Adjustme	00009032		R & L Enterprises Ltd	A
0330229	Adjustable Valve Body	00009032		R & L Enterprises Ltd	A
0330230	Adjustable Valve Screw	00009032		R & L Enterprises Ltd	A
0330231	Adjustable Valve Interna	00009032		R & L Enterprises Ltd	A
0330232	Adjustable Valve Collar	00009032		R & L Enterprises Ltd	A
0330233	Adjustable Valve Centre	00009032		R & L Enterprises Ltd	A
0330234	Adjustable Valve Side Sc	00009032	0330234	R & L Enterprises Ltd	A
0330242	Medirail Mounting Bracke	00009032	A5090	R & L Enterprises Ltd	A
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	D
0330210	Precision Valve	00009117	9901-40	JNK Tooling	C
0330211	Adjustable Valve	00009117	9901-18	JNK Tooling	C
0330224	Precision Valve Body	00009117		JNK Tooling	C
0330227	Precision/Adjustable Val	00009117		JNK Tooling	C
0330228	Precision Valve Adjustme	00009117		JNK Tooling	C
0330230	Adjustable Valve Screw	00009117		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		RS Components Ltd	B
0330214	O Ring Thin	00009123		RS Components Ltd	B
0330216	Screws For Clamp M5	00009123	483-9616	RS Components Ltd	B
0330220	Fomblin OT20N Grease 10	00009123		RS Components Ltd	B
0330221	Lock Tight	00009123	514-515	RS Components Ltd	B

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
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
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		Therapy Equipment Ltd	B
0330217	Oxygen hose 1m. C/W indi	00009150		Therapy Equipment Ltd	B
0330218	Oxygen Hose 3m. C/W indi	00009150	ZZ HOSE 3M	Therapy Equipment Ltd	B
0330250	Oxygen hose 1.5m. C/W DI	00009150		Therapy Equipment Ltd	B
0330251	Oxygen hose 3.0m. C/W DI	00009150		Therapy Equipment Ltd	B
0330263	Oxygen Hose 2m. C/W indi	00009150	ZZ HOSE 2M	Therapy Equipment Ltd	B
0330268	Air Hose 3m. C/W indirec	00009150	ZZ HOSE 3M	Therapy Equipment Ltd	B
0390006	Tom Thumb Instruction Ma	00009345		Duffield Printers	A
0390007	Tom Thumb Instruction Ma	00009345		Duffield Printers	A
0350120	Packing box for Tom Thum	00009353	RPT10B	Rajapack Ltd	B
0350121	Packing box for Tom Thum	00009353	RPT17B	Rajapack Ltd	B
0390004	Leaflet - Tom Thumb Infa	00009360		Print Centre	C
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		Bunzl Healthcare	B
3210071	Single use silicone roun	00009602		Bunzl Healthcare	B
3210011	NeoPEEP neonatal single	00009721		Marshall Products Limite	B
3210071	Single use silicone roun	00009721		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		KSJ Engineering Limited	B
0330208	Inlet 10 mm	00010160		KSJ Engineering Limited	B
0330209	Outlet 15mm	00010160		KSJ Engineering Limited	B
0330215	Clamp Spacer	00010160	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		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

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
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		MAJ Hi-Spec Ltd	B
0330207	Blanking Bolt	00010725	0330207	MAJ Hi-Spec Ltd	B
0330208	Inlet 10 mm	00010725		MAJ Hi-Spec Ltd	B
0330209	Outlet 15mm	00010725		MAJ Hi-Spec Ltd	B
0330219	Right Angle For Hose	00010770	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	C
0330223	Adjustable Valve Spring	00012028	9968	Harlow Springs Limited	C
0330300	Key Ring chain 1 inch ba	00012395	BC6	Seton	B
3210011	NeoPEEP neonatal single	FL39B01			Needs Grading
3210071	Single use silicone roun	FL39B01			Needs Grading

Comments on Suppliers:

only for spare parts, no new units being built



# Sales Information

Stock Reference	Description	2017	2018	2019	2020	2021	2022	2023
0310027	Tom Thumb Infant Resuscitator (Air).							
0310029	Tom Thumb Infant Resuscitator (Air).							
0310030	Tom Thumb Infant Resuscitator.	52	58	109	6			
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.	1						
0310096	Tom Thumb Oxygen Vent with Pole Mount							
0310097	Tom Thumb Infant Resuscitator (TG).	1	6					
0310098	Tom Thumb Oxygen Flow.							
0310099	Tom Thumb Oxygen Vent.							
0310250	Tom Thumb Conversion Kit.		1	1		14		
0320102	Tom Thumb Rectangular Mounting Block.							
0320103	Tom Thumb Rectangular Mo							
0330185	Wing Nut Screw Black 2							
0330190	Universal clamp - 44mm h	43		100			56	50
0330191	Clamp Spacer	1	1				6	
0330193	Pressure gauge: 63mm dia	17	13	2				
0330200	TT460 MAIN Body Block							
0330201	TT480/490 MAIN Body Bloc	1					6	
0330202	TT495 MAIN Body Block							
0330203	Pressure gauge for `Tom		1	24	14	30	11	9
0330204	Flowmeter (air) 0-15 Lpm							
0330205	Flowmeter Meter Bolt							
0330206	Blocking Bolt And Nut		2				2	
0330207	Blanking Bolt							
0330208	Inlet 10 mm		1		1			
0330209	Outlet 15mm	5	2	15			2	
0330210	Precision Valve	8	5	4	1	2	5	4
0330211	Adjustable Valve	7		13	1	11	2	3
0330212	Gauge Seal	81	140	69	39	89	13	18
0330213	O Ring Thick	92	148	77	44	75	125	40
0330214	O Ring Thin	674	644	979	182	651	170	384

Stock Reference	Description	2017	2018	2019	2020	2021	2022	2023
0330215	Clamp Spacer							
0330216	Screws For Clamp M5	2					2	
0330217	Oxygen hose 1m. C/W indi	16	3	5			9	
0330218	Oxygen Hose 3m. C/W indi	3	2	7				
0330219	Right Angle For Hose			10				
0330220	Fomblin OT20N Grease 10			1			2	
0330221	Lock Tight							
0330222	Precision Valve Spring							
0330223	Adjustable Valve Spring				6			
0330224	Precision Valve Body							
0330225	Precision/Adjustable Val							
0330227	Precision/Adjustable Val		9			2		
0330228	Precision Valve Adjustme							
0330229	Adjustable Valve Body							
0330230	Adjustable Valve Screw							
0330231	Adjustable Valve Interna							
0330232	Adjustable Valve Collar							
0330233	Adjustable Valve Centre							
0330234	Adjustable Valve Side Sc							
0330235	Inlet Restrictor							
0330236	Replacement Gauge Face.	19	3	6	1	6	4	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	2	5	2				
0330268	Air Hose 3m. C/W indirec							
0330291	Inlet 10mm Thumbelina Inlet							
0330292	Outlet 15mm Thumbelina							
0330295	Outlet 10mm do not use							
0330296	Blanking Bolt	4					2	
0330297	Clamp Spacer - dove tailed.							
0330300	Key Ring chain 1 inch ba							
0330800	Label - pressure control							
0340000	Labour - Tom Thumb infant resuscitator.				1		1	
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				8	24	15	9

Stock Reference	Description	2017	2018	2019	2020	2021	2022	2023
0380030	Tom Thumb Infant Resuscitator.							
0390003	Tom Thumb Instruction Ma							
0390004	Leaflet - Tom Thumb Infa							
0390005	Tom Thumb Training Manual							
0390006	Tom Thumb Instruction Ma							
0390007	Tom Thumb Instruction Ma							
0390008	Tom Thumb Serial Number Label							
0390009	`Tom Thumb` Label							
0390011	Tom Thumb CE Label							
0390015	Tom Thumb label		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:

only spares being sold, no new units going out

# Countries Review

Country	2017	2018	2019	2020	2021	2022	2023
Belgium	[X]	[X]			[X]		
Canada							
China			[X]				
Czech Republic							
Finland		[X]					
France	[X]	[X]	[X]	[X]	[X]	[X]	[X]
Germany	[X]	[X]	[X]				
IN India							
Italy	[X]	[X]		[X]			
Nigeria							
Portugal							
Russia				[X]			
Saudi Arabia							
Scotland	[X]	[X]	[X]	[X]	[X]	[X]	
Sri Lanka							
Switzerland							
Turkey							
UK	[X]	[X]	[X]	[X]	[X]	[X]	[X]
UK United Kingdom	[X]		[X]			[X]	
United Kingdom		[X]	[X]				

Comments on Sales to Countries:

no issues with countrys only selling spares

Comments on Risks with Sales to Countries:

# Returns and Q.A. Fails Review

Stock Reference	Fault	2017	2018	2019	2020	2021	2022	2023
0310030	Needs Evaluating	1						
0310030	Adjusted Factory Set Valves	2	1	2				
0310030	Calibrated Gauge							
0310030	Converted To TT480		1	2				
0310030	Converted to TT480 and service							3
0310030	Customer Declined Quotation							
0310030	Damaged Pressure Gauge	2	1	1				
0310030	N/a							
0310030	New							
0310030	No Fault Found		2	2				
0310030	No Fault Return To Stock							
0310030	Renovated					3	13	3
0310030	Repaired Clamp And Serviced							
0310030	Replace Gauge And Service	3	2	2	11	2	4	2
0310030	Replaced Adjustable Valve			1	1			
0310030	Replaced Gauge			2	1		1	
0310030	Replaced Gauge and Adjustable Valve			2				
0310030	Replaced gauge face		1	1				
0310030	Replaced Gauge Face And Service			1	2	1	3	
0310030	Replaced precision valve and serviced						1	
0310030	Serviced	10	14	3	4		15	1
0310030	Serviced / Adjusted Factory Set Valves	3	7	15	5	10	2	
0310030	Serviced and Upgraded				1			
0310030	Stuck Gauge	1	1					
0310030	Tested	1	1					
0310031	Serviced							
0310032	Adjusted Factory Set Valves							
0310032	Calibrated Gauge							
0310032	Converted To TT480							
0310032	Damaged Pressure Gauge							
0310032	New							
0310032	Replaced Gauge Face And Service	2		1				
0310032	Serviced	1	3	1				
0310032	Serviced / Adjusted Factory Set Valves	1						
0310032	Serviced and Upgraded	4						
0310032	Tested							
0310033	Replace Gauge And Service							
0310033	Serviced							
0310034	Adjusted Factory Set Valves							
0310034	Converted To TT480							
0310034	Damaged Pressure Gauge							
0310034	Replace Gauge And Service			1				

Stock Reference	Fault	2017	2018	2019	2020	2021	2022	2023
0310034	Serviced	1			2	1		
0310034	Serviced / Adjusted Factory Set Valves	2		2		2		
0310034	Unchecked - Returned To Stock							
0310076	New							
0310080	Replace Gauge And Service							
0310094	Converted To TT480							
0310094	Not Delivering More Than 10cm	1						
0310094	Replace Gauge And Service	1						
0310094	Replaced Gauge Face And Service	1					1	
0310097	Serviced	1	1		1		1	
0310097	Serviced / Adjusted Factory Set Valves	1		1				
0310098	Serviced / Adjusted Factory Set Valves							
0310099	Serviced / Adjusted Factory Set Valves							
0330193	No Fault Found		1					
0330193	Unrepaired		2					
0330201	Needs Evaluating							
0330217	Unchecked - Returned To Stock							
0330218	Tested for leaks					4		
0380030	Needs Evaluating			1				
0380030	New					3	3	
0380030	Service exchange unit		3					
0380030	Tested			3				
0390023	Serviced							

Comments on Returns:

no issues , just serving, no new units out for past few years

Comments on Risks with Returns and Potential Re-work:

# Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

no changes

Comments on Risks with Design Changes:

# 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:

Comments on Risks User Instructions:



# Labels Review

## Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
28357	Tom Thumb Labels Original labels as at Dec 2018	07/12/18
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
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 Valve 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:

# Documentation Updates / Changes

Document ID	Description	Date Added/Updated
86604	Tom Thumb Post Market Surveillance Periodic Safety Update Repor...	05/04/22

Comments on Document Changes:

Comments on Risks with Document Changes:

# Internal Issues Review

Number of Issues reviewed: 15

Issue ID	Subject
107694	0310030 Tom Thumb Infant Resuscitator.
281230	0310250 Tom Thumb conversion kits
281229	0310250 Tom Thumb conversion kits
281228	0310250 Tom Thumb conversion kits
108577	Leaflet Tom Thumb Leaflet Amend 3rd Checking Stage
114403	Leaflet Update Infant Resus Cabinet Leaflet Leaflet Designed
125584	Photos/Images Tom Thumb for Cabinet Obtain Samples
167665	Proposed order from STL for 0310030
155166	Proposed order from STL for 0310030
259402	PVM2508 0330213 06/05/2022
288448	PVM2983 0330203 08/06/2023
107601	Tom Thumb Review 8th November 2017 - Discontinued Variants
113113	TT480 with pole mount
62275	User Manual Instructions and Labels Tom thumb Artwork to Intrastats
291217	Watch List Update 03 Apr 2023

Comments on Issues:

nothing of concern in the issue system,  
no new units made/sold for last few years

Comments on Risks with Issues:

---

VIAMED Stock Meeting - Stock Queries  
**0310030 Tom Thumb Infant Resuscitator.**  
Issue ID #107694  
Date Created 09/Nov/2017  
Issued To: Catrin Hird  
Completed Status: 13 Apr 2023

---

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 - Any Other Business

**0310250 Tom Thumb conversion kits**

Issue ID #281230

Date Created 20/Dec/2022

Issued To: Robert Connor

Completed Status: Still Outstanding

---

Notes:

Copy Issue Main Issue #281228

Added by Steve Nixon sent to Catherine Spence

Looks like we have an order, do we need to make more kits up now?

---

21 Dec 2022 Robert Connor

The one showing up in stock appears to be a stocktake mis-scan, I`m moving it to a removal location.

As for the 9 needed, I will create some barcodes for Phil to use in servicing and multibarcoding the parts to them.

---

06 Mar 2023 Robert Connor

---

Issues:281230

---

VIAMED Stock Meeting - Any Other Business

**0310250 Tom Thumb conversion kits**

Issue ID #281229

Date Created 20/Dec/2022

Issued To: Philip Crossley

Completed Status: Still Outstanding

---

Notes:

Copy Issue Main Issue #281228

Added by Steve Nixon sent to Catherine Spence

Looks like we have an order, do we need to make more kits up now?

---

21 Dec 2022 Philip Crossley

I had a quick look at the order and it looks like they are sending in 9 TT490s for conversion and service by me. So the kits don't need to be made up, I just need the parts if that helps.

I also noticed it says we have 1 in stock but I can't actually find it.

---

30 Jan 2023 Philip Crossley

---

Issues:281229

---

VIAMED Stock Meeting - Any Other Business

**0310250 Tom Thumb conversion kits**

Issue ID #281228

Date Created 20/Dec/2022

Issued To: Catherine Spence

Completed Status: 23 Jan 2023

---

Notes:

Added by Steve Nixon sent to Catherine Spence

Looks like we have an order, do we need to make more kits up now?

---

22 Dec 2022 Catherine Spence

---

Issues:281228

---

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: 13 Apr 2023

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

---

26 Mar 2019 Steve Nixon

Product discontinued.

---

Issues:108577



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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: 13 Apr 2023

---

**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

---

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: 13 Apr 2023

---

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?

---

11 Dec 2018 Catrin Hird  
Cabinet has been discontinued therefore no images of the tom thumb for cabinet to be taken.

---

11 Dec 2018 Catrin Hird  
Cabinet has been discontinued therefore no images of the tom thumb for cabinet to be taken.

---

Issues:125584

---

Marketing Job Logger - Marketing Job Logger

**Proposed order from STL for 0310030**

Issue ID #167665

Date Created 04/Mar/2020

Issued To: 2

Completed Status: 07 Mar 2023

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Notes:

Issue 155166

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Issues:167665

---

VIAMED Sales And Marketing - Sales Viamed Medical Export

**Proposed order from STL for 0310030**

Issue ID #155166

Date Created 25/Sep/2019

Issued To: Derek Lamb

Completed Status: 13 Apr 2023

---

Notes:

Copy Issue Main Issue #155165

Added by Steve Nixon sent to Ryan Swaine

Proposed order from STL for 0310030

Can you please confirm quantity (35) and timescale required.

Derek: If we have sufficient notes on Intrastats/Opera we could use the same part number. If so, we can use the existing labels, the CE mark is in an ideal position to be cut off.

or

We can generate a new part number to make it absolutely clear in terms of traceability.

Ryan have you registered the existing part number or would we be free to change it.

---

27 Sep 2019 Derek Lamb

see 155165

---

10 Feb 2020 Steve Nixon

I believe that they have ordered 6.

Suggest that you add link to sales projects. The main part to keep an eye on is the gauge, which we order from WIKA. They have been accepting orders for 50 rather than 100.

---

04 Mar 2020 Derek Lamb

job 1096

---

Issues:155166

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- Back Order Report

**PVM2508 0330213 06/05/2022**

Issue ID #259402

Date Created 06/May/2022

Issued To: Robert Connor

Completed Status: 09 May 2022

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Notes:

PVM2508 0330213 Estimated ship to us date changed to 06 / 05 / 2022

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Issues:259402

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- Back Order Report

**PVM2983 0330203 08/06/2023**

Issue ID #288448

Date Created 03/Mar/2023

Issued To: Robert Connor

Completed Status: 06 Mar 2023

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Notes:

PVM2983 0330203 Estimated ship to us date changed to 08 / 06 / 2023

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Issues:288448

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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: 13 Apr 2023

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

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**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

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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

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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.

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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.

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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

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28 Nov 2017 Catrin Hird

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

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28 Nov 2017 Catrin Hird  
see related issue

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Issues:107601

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VIAMED Stock Meeting - Photography

**TT480 with pole mount**

Issue ID #113113

Date Created 25/Jan/2018

Issued To: Jonathan Connor

Completed Status: 13 Apr 2023

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Notes:

Added by Catrin Hird sent to Catrin Hird

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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

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Issues:113113

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Marketing Job Logger - Marketing Job Logger

**User Manual Instructions and Labels Tom thumb Artwork to Intrastats**

Issue ID #62275

Date Created 01/Sep/2015

Issued To: Derek Lamb

Completed Status: 13 Apr 2023

Linked Files

01 Sep 2015 Tom Thumb TT490 Instructions for Use (high)

01 Sep 2015 Tom Thumb TT480 Instructions for Use (high)

01 Sep 2015 Tom Thumb TT480TG Instructions for Use (high)

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**Notes:**

Catrin Hird 01/09/2015 Issue Generated

User Manual Instructions and Labels Tom thumb Artwork to Intrastats

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01 Sep 2015 Catrin Hird

Next Action Changed From To Derek Lamb Please add attached to intrastats, print and email versions in Z for L

0310027

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01 Sep 2015 Derek Lamb

Done

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Issues:62275

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Auto Heading Watch Lists - Auto Heading Watch Lists

**Watch List Update 03 Apr 2023**

Issue ID #291217

Date Created 03/Apr/2023

Issued To: Catherine Spence

Completed Status: 11 Apr 2023

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Notes:

SupplierOrder Docid115224 31 Mar 2023 PVM2991 Supplier Invoice PVM2991 -  
Expandable\_Alert\_2001\_i\_20230330230002\_334711 (1).pdf Supplier Reference 370816

SupplierOrder PVM2991 Status has been updated by Steve Nixon

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Issues:291217

# 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 :

## 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 :