



VIA MED

Tom Thumb

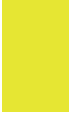
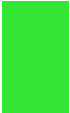
Hand held, gas powered resuscitation unit.

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

Carried out by Derek Lamb
10 / 08 / 26



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:

The Tom Thumb product range has been withdrawn from active manufacture and sale. Associated stock references remain within the system principally to support servicing, repair, spare parts and historical traceability of devices already supplied.

No evidence has been identified during this review of a new product variant, new intended use or reintroduction of the Tom Thumb to the market. Continued activity against these references is consistent with support of the established installed base.

No immediate action required. Retain associated stock references required for servicing, repair, spare parts and traceability during the legacy support period.

Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
0330210	Precision Valve	00009117	9901-40	JNK Tooling	C
0330211	Adjustable Valve	00009117	9901-18	JNK Tooling	C
0330214	O Ring Thin	00009123		RS Components Ltd	A
0390004	Leaflet - Tom Thumb Infa	00009360		Print Centre	C
0330201	TT480/490 MAIN Body Bloc	00010160		KSJ Engineering Limited	B
0330216	Screws For Clamp M5	00009123	483-9616	RS Components Ltd	A
0330030	Dovetail (male)	00009150	4505	Therapy Equipment Ltd	B
0330203	Pressure gauge for `Tom	00010395		Wika Instruments Ltd	B
0330205	Flowmeter Meter Bolt	00010160	0330205	KSJ Engineering Limited	B
0330209	Outlet 15mm	00010160		KSJ Engineering Limited	B
0330215	Clamp Spacer	00010160	9901-22	KSJ Engineering Limited	B
0330212	Gauge Seal	00009150		Therapy Equipment Ltd	B
0330218	Oxygen Hose 3m. C/W indi	00009150		Therapy Equipment Ltd	B
0320060	Flowmeter (Oxygen) 0-15	00009150	6501	Therapy Equipment Ltd	B
0330220	Fomblin OT20N Grease 10	00009123		RS Components Ltd	A
0330221	Lock Tight	00009123	514-515	RS Components Ltd	A
0330219	Right Angle For Hose	00010770	2020	Chelmer Pneumatics Ltd	B
0330201	TT480/490 MAIN Body Bloc	00010725		MAJ Hi-Spec Ltd	B
0330205	Flowmeter Meter Bolt	00010725	0330205	MAJ Hi-Spec Ltd	B
0330209	Outlet 15mm	00010725		MAJ Hi-Spec Ltd	B
0330234	Adjustable Valve Side Sc	00009117	0330234	JNK Tooling	C
0330235	Inlet Restrictor	00009117	0330235	JNK Tooling	C
0330200	TT460 MAIN Body Block	00010160	0330200	KSJ Engineering Limited	B
0330202	TT495 MAIN Body Block	00010160	0330202	KSJ Engineering Limited	B
0330204	Flowmeter (air) 0-15 Lpm	00009150	6502	Therapy Equipment Ltd	B
0330200	TT460 MAIN Body Block	00010725	0330200	MAJ Hi-Spec Ltd	B
0330202	TT495 MAIN Body Block	00010725	0330202	MAJ Hi-Spec Ltd	B
0330055	Universal clamp - 44mm h	00009150	2002	Therapy Equipment Ltd	B
0330208	Inlet 10 mm	00010160		KSJ Engineering Limited	B
0330236	Replacement Gauge Face.	00010395		Wika Instruments Ltd	B
0330207	Blanking Bolt	00009123	0330207	RS Components Ltd	A
0330208	Inlet 10 mm	00010725		MAJ Hi-Spec Ltd	B
0330800	Label - pressure control	00009930		Renlim Labels	B
0330222	Precision Valve Spring	00012028	C6409	Harlow Springs Limited	C
0330223	Adjustable Valve Spring	00012028	9968	Harlow Springs Limited	C
0330217	Oxygen hose 1m. C/W indi	00009150		Therapy Equipment Ltd	B
0330213	O Ring Thick	00009123		RS Components Ltd	A
0330207	Blanking Bolt	00010725	0330207	MAJ Hi-Spec Ltd	B
0330206	Blocking Bolt And Nut	00010160		KSJ Engineering Limited	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

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
0330216	Screws For Clamp M5	00009061	483-9616	Farnell	A
0330224	Precision Valve Body	00009117		JNK Tooling	C
0330228	Precision Valve Adjustme	00009117		JNK Tooling	C
0330227	Precision/Adjustable Val	00009117		JNK Tooling	C
0330295	Outlet 10mm do not use	00010160	0330295	KSJ Engineering Limited	B
0330300	Key Ring chain 1 inch ba	00012395	BC6	Seton	B
3210071	Single use silicone roun	00009721		Marshall Products Limite	B
3210011	NeoPEEP neonatal single	00009721		Marshall Products Limite	B
0120140	Adapter 15mm I.D. - 15m	00011844	PF 1515	Instrumentation Industri	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
0320103	Tom Thumb Rectangular Mo	00009022	PP8694	Tanda Engineering Ltd	A
0330190	Universal clamp - 44mm h	00009032		R & L Enterprises Ltd	B
0330212	Gauge Seal				B
3210011	NeoPEEP neonatal single	FL39B01			Needs Grading
0330268	Air Hose 3m. C/W indirec	00009150	ZZ HOSE 3M	Therapy Equipment Ltd	B
0330296	Blanking Bolt	00009123	367-6098	RS Components Ltd	A
0390004	Leaflet - Tom Thumb Infa	00009363		ACI Print Group Impress	B
0320221	Pole Clamp without slide	00007317	IHCPC1-SPECIAL	Inspiration Healthcare L	B
3210011	NeoPEEP neonatal single	00009602		Bunzl Healthcare	B
3210071	Single use silicone roun	00009602		Bunzl Healthcare	B
0330206	Blocking Bolt And Nut	00010725		MAJ Hi-Spec Ltd	B
0330243	Adjustable Valve Side Sc	00009073	020865070206020	Modern Screws	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
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
0330234	Adjustable Valve Side Sc	00009073	0330234	Modern Screws	B
0330191	Clamp Spacer	00009032	A4917	R & L Enterprises Ltd	B
0330242	Medirail Mounting Bracke	00009032	A5090	R & L Enterprises Ltd	B
0330185	Wing Nut Screw Black 2	00009032	3335	R & L Enterprises Ltd	B
0330263	Oxygen Hose 2m. C/W indi	00009150	ZZ HOSE 2M	Therapy Equipment Ltd	B
0330230	Adjustable Valve Screw	00009117		JNK Tooling	C
0330193	Pressure gauge: 63mm dia	00009097	74656	GNW - Gauges North West	D
0390006	Tom Thumb Instruction Ma	00009366		Warwick Printing	B
0390003	Tom Thumb Instruction Ma	00009366		Warwick Printing	B
0330209	Outlet 15mm	00009032		R & L Enterprises Ltd	B
0330208	Inlet 10 mm	00009032		R & L Enterprises Ltd	B
0330206	Blocking Bolt And Nut	00009032		R & L Enterprises Ltd	B
0330224	Precision Valve Body	00009032		R & L Enterprises Ltd	B
0330228	Precision Valve Adjustme	00009032		R & L Enterprises Ltd	B

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
0330225	Precision/Adjustable Val	00009032		R & L Enterprises Ltd	B
0330227	Precision/Adjustable Val	00009032		R & L Enterprises Ltd	B
0330229	Adjustable Valve Body	00009032		R & L Enterprises Ltd	B
0330234	Adjustable Valve Side Sc	00009032	0330234	R & L Enterprises Ltd	B
0330233	Adjustable Valve Centre	00009032		R & L Enterprises Ltd	B
0330205	Flowmeter Meter Bolt	00009032	0330205	R & L Enterprises Ltd	B
0330230	Adjustable Valve Screw	00009032		R & L Enterprises Ltd	B
0330232	Adjustable Valve Collar	00009032		R & L Enterprises Ltd	B
0330231	Adjustable Valve Interna	00009032		R & L Enterprises Ltd	B
0330201	TT480/490 MAIN Body Bloc	00009032		R & L Enterprises Ltd	B
0330217	Oxygen hose 1m. C/W indi				B
0330203	Pressure gauge for `Tom				B
3210071	Single use silicone roun	FL39B01			Needs Grading
0330218	Oxygen Hose 3m. C/W indi				B
0330220	Fomblin OT20N Grease 10				B
0330218	Oxygen Hose 3m. C/W indi	00009211		MEC Medical Limited	B
0330236	Replacement Gauge Face.				B

Comments on Suppliers:

The majority of component suppliers are recorded as no longer being active suppliers for the Tom Thumb, which is consistent with the product having been withdrawn from manufacture.

Components required for servicing the existing installed base continue to be managed through Viamed`s normal purchasing and supplier controls where required. No supplier-related trend or component issue has been identified during this review which indicates an increased product safety risk.

No safety-related action required. Continue to control any replacement components purchased for servicing through the normal approved purchasing process and ensure suitability/equivalence is established where an original component is no longer available.

Sales Information

Stock Reference	Description	2020	2021	2022	2023	2024	2025	2026
0310027	Tom Thumb Infant Resuscitator (Air).							
0310029	Tom Thumb Infant Resuscitator (Air).							
0310030	Tom Thumb Infant Resuscitator.	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.							
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.		14					
0320102	Tom Thumb Rectangular Mounting Block.							
0320103	Tom Thumb Rectangular Mo							
0330185	Wing Nut Screw Black 2							
0330190	Universal clamp - 44mm h			56	50			
0330191	Clamp Spacer			6				
0330193	Pressure gauge: 63mm dia							
0330200	TT460 MAIN Body Block							
0330201	TT480/490 MAIN Body Bloc			6				
0330202	TT495 MAIN Body Block							
0330203	Pressure gauge for `Tom	14	30	11	9			
0330204	Flowmeter (air) 0-15 Lpm							
0330205	Flowmeter Meter Bolt							
0330206	Blocking Bolt And Nut			2				
0330207	Blanking Bolt							
0330208	Inlet 10 mm	1						
0330209	Outlet 15mm			2				
0330210	Precision Valve	1	2	5	4			
0330211	Adjustable Valve	1	11	2	3			
0330212	Gauge Seal	39	89	13	18			
0330213	O Ring Thick	44	75	125	40			
0330214	O Ring Thin	182	651	170	384			

Stock Reference	Description	2020	2021	2022	2023	2024	2025	2026
0330215	Clamp Spacer							
0330216	Screws For Clamp M5			2				
0330217	Oxygen hose 1m. C/W indi			9				
0330218	Oxygen Hose 3m. C/W indi							
0330219	Right Angle For Hose							
0330220	Fomblin OT20N Grease 10			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		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.	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							
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			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	2020	2021	2022	2023	2024	2025	2026
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							
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:

The Tom Thumb has been progressively withdrawn from the market. Most variants were discontinued from 2017/2018 onwards and the product was subsequently recorded as discontinued. The records show only very limited finished-device activity thereafter, including an order for six units during 2020.

There is no indication within this review that commercial manufacture or routine sale of the Tom Thumb has recommenced. Current activity relates predominantly to legacy support, servicing and spare parts for units already in use.

Continued servicing of older devices demonstrates that a significant installed base has remained operational for considerably longer than the originally anticipated support period.

Countries Review

Country	2020	2021	2022	2023	2024	2025	2026
Belgium		[X]					
Canada							
China							
Czech Republic							
Finland							
France	[X]	[X]	[X]	[X]			
Germany							
IN India							
Italy	[X]						
Nigeria							
Portugal							
Russia	[X]						
Saudi Arabia							
Scotland	[X]	[X]	[X]				
Sri Lanka							
Switzerland							
Turkey							
UK	[X]	[X]	[X]	[X]			
UK United Kingdom			[X]				
United Kingdom							

Comments on Sales to Countries:

Comments on Sales Countries

No new sales territories or significant geographical changes have been identified since the product entered withdrawal/discontinuation. Current activity is principally support of devices previously supplied.

Further Action Required:

None.

Comments on Risks with Sales to Countries:

Sales Countries – New Risks?

No new country-specific risks identified. The product is no longer being actively introduced into new markets or territories.

Further Action Required:

None.

Returns and Q.A. Fails Review

Stock Reference	Fault	2020	2021	2022	2023	2024	2025	2026
0310030	Needs Evaluating							2
0310030	Adjusted Factory Set Valves							
0310030	Calibrated Gauge							
0310030	Converted To TT480							
0310030	Converted to TT480 and service				4	5		
0310030	Customer Declined Quotation							
0310030	Damaged Pressure Gauge							
0310030	N/a							
0310030	New				2			5
0310030	No Fault Found							
0310030	No Fault Return To Stock							
0310030	Renovated		3	13	3			
0310030	Repaired Clamp And Serviced							
0310030	Replace Gauge And Service	11	2	4	6	2	3	1
0310030	Replaced Adjustable Valve	1						
0310030	Replaced adjustable valve spring						1	
0310030	Replaced Gauge	1		1	1		1	
0310030	Replaced Gauge and Adjustable Valve							
0310030	Replaced gauge face							
0310030	Replaced Gauge Face And Service	2	1	3	1	3		
0310030	Replaced precision valve and serviced			1				
0310030	Serviced	4		15	23	5	1	
0310030	Serviced / Adjusted Factory Set Valves	5	10	2	2	58	57	30
0310030	Serviced and Upgraded	1						
0310030	Stuck Gauge							
0310030	Tested				3		1	
0310031	New				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							
0310032	Serviced							
0310032	Serviced / Adjusted Factory Set Valves							
0310032	Serviced and Upgraded							
0310032	Tested							
0310033	Replace Gauge And Service							
0310033	Serviced							
0310034	Adjusted Factory Set Valves							
0310034	Converted To TT480							

Stock Reference	Fault	2020	2021	2022	2023	2024	2025	2026
0310034	Converted to TT480 and service					1		
0310034	Damaged Pressure Gauge							
0310034	Replace Gauge And Service							
0310034	Replaced hose and service.					3	1	
0310034	Serviced	2	1					
0310034	Serviced / Adjusted Factory Set Valves		2				4	
0310034	Unchecked - Returned To Stock							
0310076	New							
0310080	Replace Gauge And Service							
0310094	Converted To TT480							
0310094	Not Delivering More Than 10cm							
0310094	Replace Gauge And Service							
0310094	Replaced Gauge Face And Service			1				
0310097	Serviced	1		1	1			
0310097	Serviced / Adjusted Factory Set Valves					1	2	
0310098	Serviced / Adjusted Factory Set Valves							
0310099	Serviced / Adjusted Factory Set Valves							
0330193	No Fault Found							
0330193	Unrepaired							
0330201	Needs Evaluating							
0330217	Unchecked - Returned To Stock							
0330218	Tested for leaks		4					
0380030	Needs Evaluating							
0380030	New		3	3				
0380030	Replaced gauge face				1			
0380030	Service exchange unit							
0380030	Serviced / Adjusted Factory Set Valves					3	3	5
0380030	Tested				3		5	
0390023	Serviced							

Comments on Returns:

Returns and service activity continue to relate predominantly to routine servicing, adjustment of factory-set valves, gauges, hoses and other serviceable components expected on ageing devices.

No adverse trend indicating a systematic product failure has been identified. Recent records also demonstrate continued return of units specifically for scheduled servicing rather than as customer complaints or reportable safety events.

The continued servicing of legacy units is considered useful post-market information and provides continuing visibility of the condition and performance of the installed base. Continue routine monitoring of service and repair codes during the remaining support period. Escalate for risk review if a new failure mode, significant increase in frequency, serious incident or recurring safety-related fault is identified.

Comments on Risks with Returns and Potential Re-work:

One new repair code, "Replaced adjustable valve spring", was identified and separately assessed. One occurrence was recorded from a total of 1,692 records (0.06%).

The spring was replaced during routine servicing and the assessment concluded that the condition

represented calibration/service adjustment rather than a new hazardous failure mode. The resulting risk was assessed as negligible/improbable and no CAPA was required.

No other new re-work or repair trend identified during this review requires amendment of the existing risk assessment.

None. Continue trending through normal PMS/service review.

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

No new design or product changes have been identified since the previous PMS review. The product has been discontinued and Viamed is not undertaking further development or manufacture of the Tom Thumb.

Current activities relate to servicing, repair and continued support of previously supplied devices and do not represent a new design or change to the intended purpose of the product.

Further Action Required:

None.

Comments on Risks with Design Changes:

No new design or product change has occurred and therefore no new change-related risk or regulatory notification requirement has been identified.

Further Action Required:

No notification required.

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:

Existing instructions for use remain applicable to the legacy Tom Thumb configurations for which Viamed continues to provide service support. No new product functionality, intended purpose or operating method has been introduced which would require amendment of the historical instructions.

No PMS or service information identified during this review indicates that the instructions introduce a new or unacceptable risk.

Further Action Required:

None. Retain controlled historical instructions for servicing and support of the relevant legacy configurations.

Comments on Risks User Instructions:

No new risks identified. Existing instructions remain appropriate for the legacy devices/configurations to which they relate.

Further Action Required:

None.

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:

Existing labels remain part of the controlled historical configuration of the devices already placed on the market. No evidence has been identified from servicing, returns or PMS which indicates that the existing labels create a new safety or usability issue.

Further Action Required:

None. Replacement labels used during servicing should continue to correspond to the original applicable device configuration and controlled records.

Comments on Risks Labels:

Risks Associated with Labels

No new labelling-related risks identified.

Further Action Required:

None.

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
218297	GBP Price List - 0310030 Tom Thumb TT480 Spare Parts	29/04/26
218295	GBP Price List - 0310034 Tom Thumb TT490-15-3 Spare Parts	29/04/26
218293	GBP Price List - 0310032 Tom Thumb TT490-15 Spare Parts	29/04/26
187074	Tom Thumb Post Market Surveillance Periodic Safety Update Repor...	02/06/25

Comments on Document Changes:

Documents added or updated since the previous review primarily concern Tom Thumb spare-parts pricing and continued post-market surveillance. These changes are administrative/support-related and do not constitute changes to the device design, intended purpose or performance.

Existing technical, servicing and risk documentation remains retained as part of the legacy technical file.

Further Action Required:

None.

Comments on Risks with Document Changes:

No new product safety risks identified as a result of the document changes.

Internal Issues Review

Number of Issues reviewed: 27

Issue ID	Subject
107694	0310030 Tom Thumb Infant Resuscitator.
359589	Blank Intrastats 2025 Barcode Showing as Vandagraph
405211	Cumberland Infirmary: 0310030
387578	File 16 Tom Thumb Risk File Updated
388639	Intelligent Control: 0330220 FOMBLIN
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
387420	Product / Design Changes, are any Post Market Surveillance reviews due (50)
377710	Product Failures New Codes Review (750)
384951	Production Statistics (551)
155166	Proposed order from STL for 0310030
369002	PVM4542 0330213 07/07/2025
369001	PVM4542 0330214 07/07/2025
392706	PVM5071 0330213 25/03/2026
392707	PVM5071 0330214 25/03/2026
379146	Queen Elizabeth Hosp: 0330203 and 0330212
385463	Queen Elizabeth Hosp: 0330203, 0330212
382652	Request Scanning Item to Sale or return
392708	Returned Items SOR973
387699	Returned Items SOR977
378693	Royal Blackburn Hosp: 0330205
359935	Sale Return SOR974 Leicester Royal Infirmary
404280	Send Service Offers (607)
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

Comments on Issues:

Issues raised since the previous review predominantly concern routine servicing, service offers, availability/pricing of spare parts, stock administration and component supply.

These issues demonstrate continuing support and monitoring of the installed Tom Thumb population. No customer complaint, serious incident, systematic failure trend or previously unidentified hazardous situation has been identified from the issues reviewed.

A new repair code relating to replacement of an adjustable valve spring was separately risk assessed and determined not to represent a new safety risk.

Comments on Risks with Issues:

None beyond continued routine monitoring.

VIAMED Stock Meeting - Stock Queries
0310030 Tom Thumb Infant Resuscitator.
Issue ID #107694
Date Created 09/Nov/2017
Issued To: Catrin Hird
Completed Status: 10 Aug 2026

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

Marketing Job Logger - Marketing Job Logger

Blank Intrastats 2025 Barcode Showing as Vandagraph

Issue ID #359589

Date Created 25/Mar/2025

Issued To: Derek Lamb

Completed Status: 10 Aug 2026

Notes:

Catrin Hird 25/03/2025 Issue Generated
Blank Intrastats 2025 Barcode Showing as Vandagraph

25 Mar 2025 Catrin Hird

Next Action Changed From To Derek Lamb Barcode 38100
Stock Ref 0310030

Showing as Vandagraph.

Showing on a few different ones, may be the stock ref which is doing it.

25 Mar 2025 Derek Lamb
seems its a historic mistag at some point

26 Mar 2025 Catrin Hird

OK
Done

Issues:359589

Projects - Projects

Cumberland Infirmary: 0310030

Issue ID #405211

Date Created 10/Aug/2026

Issued To: General

Completed Status: Still Outstanding

Notes:

emailed re 0310030 discontinued TThumb, replied these are discontinued and advised of spare parts being available and servicing

Issues:405211

VIAMED Sales And Marketing - Post Market Surveillance

File 16 Tom Thumb Risk File Updated

Issue ID #387578

Date Created 02/Feb/2026

Issued To: Derek Lamb

Completed Status: 03 Feb 2026

Stock Ref: 0390060

Notes:

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

03 Feb 2026 Derek Lamb

reviewed, no risk presented, was a service

Issues:387578

Projects - Projects

Intelligent Control: 0330220 FOMBLIN

Issue ID #388639

Date Created 11/Feb/2026

Issued To: General

Completed Status: Still Outstanding

Notes:

Requested price for 0330220 Fomblin Grease, provided current USD End User Pricing. Advised we can supply proforma if they wish to purchase.

Issues:388639

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: 10 Aug 2026

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

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: 10 Aug 2026

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: 10 Aug 2026

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

VIAMED Management Meeting - CE Files Review

Product / Design Changes, are any Post Market Surveillance reviews due (50)

Issue ID #387420

Date Created 02/Feb/2026

Issued To: Derek Lamb

Completed Status: 05 Feb 2026

Notes:

System Generated

Check that no Products / Designs have changed significantly to warrant informing MDR / Bsi or any other related Body.

First Check the Stockbox -> QA Fails Review (Slow Page) in case there are any products that have a New repair code that requires a risk assesment

Reprint the Risk Assessment Questions update the file in the index

Carry out the Technical File PMS Post Market Surveillance. Form for Each OBL and Viamed Product
Rename the file to include Periodic Safety Update Report in the title

Using procedure VM3COP27.11

then VM3COP18

for each product range required

H.S.E. implications :No health and safety implications

02 Feb 2026 Derek Lamb

Non due now,

Tom Thumb displayed a new risk to review:

[1666]0310030 Does Fault Code Replaced adjustable valve spring Type Fault present a risk

Applys

Pre Mitigation Risk level (harm)

Negligible Inconvenience or Temporary discomfort

Pre Mitigation Chance of Risk

Improbable 1 %

Reasoning if not obvious, Or factors mitigating risk or solution

Spring was replaced in a regular service, means the calibration was possibly at its limits,
no risk.

Replaced adjustable valve spring

Number Recorded 1 Total 1692 0.06 %

Post Risk level (harm)

Negligible Inconvenience found in service

Post Chance of Risk

Improbable 1 %

Issues:387420

VIAMED Management Meeting - VIAMED Management Meeting

Product Failures New Codes Review (750)

Issue ID #377710

Date Created 10/Oct/2025

Issued To: Derek Lamb

Completed Status: 16 Oct 2025

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

H.S.E. implications :No health and safety implications

10 Oct 2025 Derek Lamb

0310030 requires Cleaning! - REPLACED ADJUSTABLE VALVE SPRING
normal servicable part no capa required

Issues:377710

VIAMED Stock Meeting - VIAMED Stock Meeting
Production Statistics (551)

Issue ID #384951

Date Created 05/Jan/2026

Issued To: Derek Lamb

Completed Status: 08 Jan 2026

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 and the production procedure.
List any where the quantities dont match

2. Check QA is performed by a different person to whom productioned it

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

H.S.E. implications :No health and safety implications

05 Jan 2026 Derek Lamb

StockDescription20242025

0012167Pulse Oximeter Viamed VM 2160 SMARTsat.02

0110217Oxygen sensor R-17VAN090

0110220Oxygen sensor R-22OMS93

0110224Oxygen sensor R-33DE600563

0110225Oxygen sensor R-22DEM65

0110226Oxygen sensor R-33VAN12514

0110227Oxygen sensor R-22AEX1620

0110231Oxygen Sensor R-22DSX810

0110232Oxygen sensor R-22VAN016

0110235Oxygen sensor R33VAN-4211

0110236Oxygen sensor R-33S1 (RP)78

0110238Oxygen sensor R-22AT10564

0110239Oxygen sensor R-33VAN (RP)243132

0110241Oxygen sensor R-33VAN-23936

0110243Oxygen sensor R-22DEOX12

0110248Oxygen sensor R-9507M54

0110382Sarcostopper R-17021

0110383ERFI France R-17032

0110390Oxygen sensor STK-01150100

0121217MX300 Case Upgrade Kit Rev.1 to Rev.202

0310250Tom Thumb Conversion Kit.20

1410000Foetal Heart Simulator model V1000.5637

1430309V1000 Transducer interface cushion06

2510005Microstim DB3 Tester510

2520020Microstim DB3 - Patient Lead.92

2520021Microstim DB3 - Patient Lead.60

4410530Capnograph VM-2500-M Veterinary version.01
7910100Oxygen Analyser - VN202 MkII20
7910201Oxygen Analyser Tek-Ox Auto + Quick-Ox550
7910253Oxygen Analyser for Weld Gas - Sarco Stopper200
7910255Weld Gas Analyser-Sarco Stopper 0.00 UD0100
8000004Cable assembly for oxygen sensor 801000490187600
8000054Cable assembly for oxygen sensor 801005440520
9730215Gas Sampling DIN KIT1020

05 Jan 2026 Derek Lamb

just vandagraph sensor labels, and a few v1000, and vst cables, ntthing of concern
Done

Issues:384951

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: 10 Aug 2026

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

- Back Order Report

PVM4542 0330213 07/07/2025

Issue ID #369002

Date Created 04/Jul/2025

Issued To: Robert Connor

Completed Status: 07 Jul 2025

Notes:

PVM4542 0330213 Estimated ship to us date changed to 07 / 07 / 2025

Issues:369002

- Back Order Report

PVM4542 0330214 07/07/2025

Issue ID #369001

Date Created 04/Jul/2025

Issued To: Robert Connor

Completed Status: 07 Jul 2025

Notes:

PVM4542 0330214 Estimated ship to us date changed to 07 / 07 / 2025

Issues:369001

- Back Order Report

PVM5071 0330213 25/03/2026

Issue ID #392706

Date Created 24/Mar/2026

Issued To: Robert Connor

Completed Status: Still Outstanding

Notes:

PVM5071 0330213 Estimated ship to us date changed to 25 / 03 / 2026

24 Mar 2026 Robert Connor

Done

Issues:392706

- Back Order Report

PVM5071 0330214 25/03/2026

Issue ID #392707

Date Created 24/Mar/2026

Issued To: Robert Connor

Completed Status: Still Outstanding

Notes:

PVM5071 0330214 Estimated ship to us date changed to 25 / 03 / 2026

24 Mar 2026 Robert Connor

Done

Issues:392707

Projects - Projects

Queen Elizabeth Hosp: 0330203 and 0330212

Issue ID #379146

Date Created 27/Oct/2025

Issued To: General

Completed Status: Still Outstanding

Notes:

broken T Thumb gauge (no pressure) so asked for part numbers of 0330203 and 0330212

Issues:379146

Projects - Projects

Queen Elizabeth Hosp: 0330203, 0330212

Issue ID #385463

Date Created 08/Jan/2026

Issued To: General

Completed Status: Still Outstanding

Notes:

prices req of 0330203 and 0330212 and also glass for gauge - have asked which type of gauge

Issues:385463

VIAMED Stock Meeting - Sale or Returns

Request Scanning Item to Sale or return

Issue ID #382652

Date Created 04/Dec/2025

Issued To: Catherine Spence

Completed Status: 10 Dec 2025

Linked Files

04 Dec 2025 SOR977-N Manchester-email to start process-20251204.pdf

04 Dec 2025 T and C signed - North Manchester-20251204.pdf

10 Dec 2025 SOR977-N Manchester-MIA not signed as hard copy has been signed by SN-20251210.pdf

10 Dec 2025 SOR977-N Manchester-agreed by SN-20251210.pdf

Notes:

Added by Kate Griffiths sent to Catherine Spence

Please scan to Sale or Returns SOR977 Location ID34132

North Manchester General Hospital CID6254

Stock Reference: 0310030 x4 for service loan, requested by Timothy Holland, signed T and C received

08 Dec 2025 Catherine Spence

id: 108869

836910

836909

836911

loc 134132

Done

08 Dec 2025 Catherine Spence

sorry loc is 34132

Done

10 Dec 2025 Kate Griffiths

Back to Cathy

Done

Issues:382652

VIAMED Stock Meeting - Sale or Returns

Returned Items SOR973

Issue ID #392708

Date Created 24/Mar/2026

Issued To: Kate Griffiths

Completed Status: 30 Mar 2026

Notes:

Added by Robert Connor sent to Kate Griffiths
INFORMATION ONLY ISSUE DO NOT ADD NOTES!

SOR ID973

Originally added by :Steve Hardaker

Royal Preston Hospital

David Edmondson

Medical Engineering Dept

Sharoe Green Lane

Fulwood

Preston

PR2 9HT

Returned : 0310200 093A06B

Returned : 0380030 SE007

26 Mar 2026 Kate Griffiths

Done

30 Mar 2026 Robert Connor

Done

Issues:392708

VIAMED Stock Meeting - Sale or Returns

Returned Items SOR977

Issue ID #387699

Date Created 03/Feb/2026

Issued To: Sophie Lines

Completed Status: 04 Feb 2026

Notes:

Added by Robert Connor sent to Sophie Lines
INFORMATION ONLY ISSUE DO NOT ADD NOTES!
SOR ID977

Originally added by :Kate Griffiths
North Manchester General Hospital
Tim Holland
Clinical Engineering Dept.
Delaunays Road

Manchester
M8 5RB

Returned : 0380030 SE004
Returned : 0380030 SE005
Returned : 0380030 SE006
Returned : 0380030 SE008

04 Feb 2026 Sophie Lines

Done

04 Feb 2026 Robert Connor

Done

Issues:387699

Projects - Projects

Royal Blackburn Hosp: 0330205

Issue ID #378693

Date Created 21/Oct/2025

Issued To: General

Completed Status: Still Outstanding

Notes:

Sent in picture of broken 0330205 Flowmeter Meter Bolt. Rocket group chat advised me of part number.
Price/availability sent

Issues:378693

VIAMED Stock Meeting - Sale or Returns
Sale Return SOR974 Leicester Royal Infirmary

Issue ID #359935

Date Created 28/Mar/2025

Issued To: Steve Hardaker

Completed Status: 03 Jul 2025

Linked Files

28 Mar 2025 Director authorisation - Leicester Royal service loans

28 Mar 2025 SOR974 - Leicester Royal T&Cs 20250327

08 Apr 2025 322022.13872 Covering Letter - Leicester Royal SOR974 20250408

08 Apr 2025 MIA Agreement Delivery Note SOR974 20250408

08 Apr 2025 Checklist SOR974

Notes:

28 Mar 2025 Steve Hardaker Issue Generated from SOR

28 Mar 2025 Steve Hardaker

Next Action Changed From AUTO_SOR To Steve Hardaker Scanned SE004, 5 & 6 to SOR974.
Attached Director authorisation and signed T&Cs.

08 Apr 2025 Steve Hardaker

Next Action Changed From Steve Hardaker To Catherine Spence All paperwork attached, also printed out.
Dated for shipping on Wed 9th April, please add tracking details to this issue and close off when sent, thanks.

10 Apr 2025 Catherine Spence
1Z9W96386840215213

07 May 2025 Steve Hardaker

The services are done, just waiting for the revised PO to be invoiced.

07 May 2025 Steve Hardaker

Advised Silvia the tracking details, have issued SRS69096 For the return of 3x Tom Thumb TT480 service loan units.

09 May 2025 Steve Hardaker

Next Action Changed From Catherine Spence To Steve Hardaker Delivered 8/5/25. Awaiting return of loan units.

15 May 2025 Steve Hardaker

Followed up to ensure that they have received the 3 serviced units back and whether they have yet been able to ship the Service Loan units back to us on SRS69096. Asked for tracking details.

16 May 2025 Steve Hardaker

He took it to the post room yesterday, should be back next week.

19 May 2025 Steve Hardaker

Returned : 0380030 SE004

Returned : 0380030 SE005

Returned : 0380030 SE006

Closed off.

VIAMED Sales And Marketing - VIAMED Sales And Marketing

Send Service Offers (607)

Issue ID #404280

Date Created 30/Jul/2026

Issued To: Derek Lamb

Completed Status: Still Outstanding

Notes:

System Generated
Task To be Completed

H.S.E. implications :No health and safety implications

30 Jul 2026 Catrin Hird

Done x 3

BarcodeCompanycontactStock ReferenceLast Serviced / QA`ed DateActionLast SeenPUSH DateGet Info
1254608IN157386
Will Reappear on list :180627846129 Mar 2027
28462441052023 Jun 2026
Done
Repair/Service Apr/2026 SRS69413
29/03/2027

SaveGenerate Email <- Todo ask Catrin for text
675417North Middlesex University Hospital
Will Reappear on list :181664646127 Jul 2027
24827031020015 Oct 2025
Done
Repair/Service Sep/2025 SRS69238
27/07/2027

SaveGenerate Email <- Todo ask Catrin for text
556124
Will Reappear on list :181664646127 Jul 2027
32216031003016 Oct 2025
Done
Repair/Service Sep/2025 SRS69239
27/07/2027

SaveGenerate Email <- Todo ask Catrin for text

Derek. maybe this is a good page for a summary to add to the completion notes?

31 Jul 2026 Derek Lamb

come back to me after the holiday not sure hwat you want adding
Done

Issues:404280

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: 10 Aug 2026

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 D

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

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
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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
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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 Stock Meeting - Photography

TT480 with pole mount

Issue ID #113113

Date Created 25/Jan/2018

Issued To: Jonathan Connor

Completed Status: 10 Aug 2026

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

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: 10 Aug 2026

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)

Notes:

Catrin Hird 01/09/2015 Issue Generated

User Manual Instructions and Labels Tom thumb Artwork to Intrastats

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

01 Sep 2015 Derek Lamb

Done

Issues:62275

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 :

Current neonatal resuscitation guidance continues to recognise and recommend T-piece resuscitation technology. The Resuscitation Council UK 2025 Newborn Resuscitation Guidelines state that, where possible, a T-piece resuscitator capable of providing CPAP or positive-pressure ventilation with PEEP should be used when ventilatory support is required, particularly for preterm infants.

Current international/American neonatal resuscitation guidance similarly continues to address the use and performance of T-piece resuscitation devices.

The technology on which the Tom Thumb is based therefore remains clinically recognised and has not become inherently obsolete. This conclusion does not imply that the discontinued Tom Thumb should be treated as a current newly marketed product; rather, it supports the continued clinical validity of the fundamental T-piece resuscitation principle for the existing installed base.

No newly published information was identified indicating a specific new hazard associated with the Viamed Tom Thumb.

Review of online FDA Incident reports

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

Do any of the Results indicate outdated Technology : No

Comments on Clinical Search :

A current search did not identify an FDA MAUDE report specifically relating to the Viamed Tom Thumb Infant Resuscitator.

The FDA MAUDE database continues to provide adverse-event reporting information for medical devices, but no new Tom Thumb-specific safety signal was identified during this review.

No action required on the basis of the FDA search.