

COMPANY OPERATING PROCEDURE.

0310032 TT490-15 / 0310034 TT490-15 (1m & 3m hoses). 30CmH2O

VM3/COP/50.03.01

Date: 13-Jul-04.

Revision date: 7-Apr-11.

Issue: 1.

Important: Use only Fomblin grease during assembly of Tom Thumbs. Do not use or allow organic greases to enter the Tom Thumb. Ensure all parts are clean before assembly.

Equipment required. 14mm open-ended spanner, pick, isopropyl alcohol, kitchen tissue, adjustable spanner, PTFE tape, 4mm allen key.

Parts list.		
Qty.	Description.	Part No.
1	Body block	0330201
1	Diamond copper washer	0330212
1	Pressure gauge	0330203
1	Thick O ring – 3/32 section	0330213
6	Thin O ring – 1/16 section	0330214
1	Flowmeter bolt	0330205
1	Flowmeter (15 lpm)	0320060
1	Precision valve	0330210
2	Blanking bolt	0330207
1	Adjustable valve	0330211
1	15mm outlet	0330209
1	Serial no. Label	0390032 or 0390034
1	Inlet hose right angle adapter	0330219
1	Inlet hose (1m) Inlet hose (3m)	0330217 or 0330218
1	Spacer block	0330215
1	Rail Clamp	0330055
4	M4x10mm hex drive bolts	0330216
1	“Tom Thumb” label	0390015
1	Flowmeter label	0390012
1	Adjustable valve label	0390010
1	Address Label	0390016
1	Gauge Face Label	0390017
---	Fomblin grease	0330220
1	NeoPeeP Circuit	3210011
1	Reusable Silicone adaptor	0120140
1	Single Use Silicone Facemask	3210071

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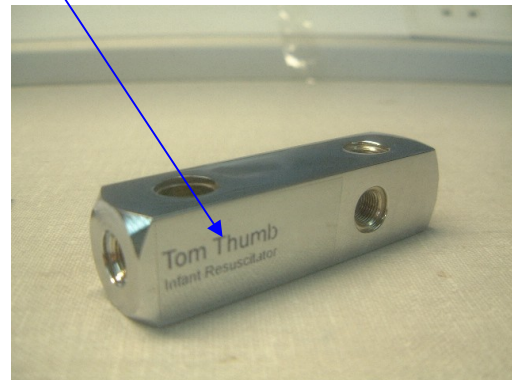
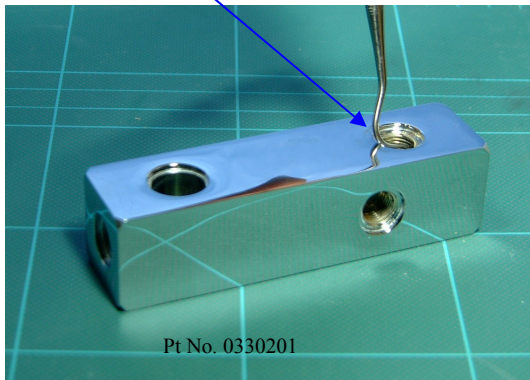
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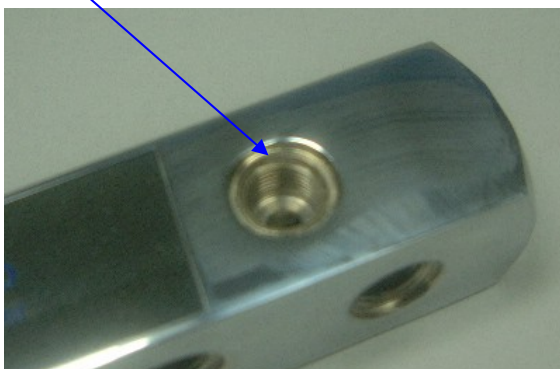
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Assembly.

1. a). Clean the body block surface thoroughly with isopropyl alcohol. Clean threads of the body block to remove residual swarf. b). Affix Tom Thumb label onto the front face of the block.



2. a). Insert diamond copper washer into the single threaded hole on the label side of body block. b). Screw in the pressure gauge in the single threaded hole on the label face of the body block; the gauge should appear straight in comparison to the block and not able to be removed without the aid of tools. Use 14mm open-ended spanner to tighten.



3. a). Push a thin O ring onto the flowmeter bolt. b). Push the flowmeter bolt / O ring from bottom to top into the left hand (non-threaded) hole.

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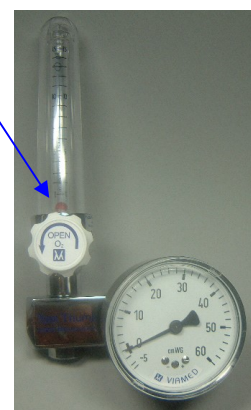
Pt No. 0330205



4. a). Push a thick O ring over the top thread of inserted flowmeter bolt. b). Remove the plastic fitting from the flowmeter and discard. Screw the flowmeter onto the inserted flowmeter bolt ensuring the flowmeter is straight in comparison to the body block. Use the adjustable spanner to tighten.

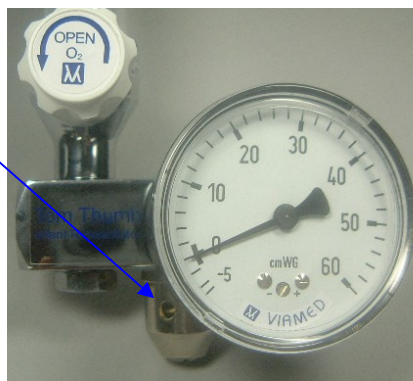


Pt No. 0320060



5. Line the thread of the precision valve with two complete layers of PTFE tape, place a thin O ring over the thread, and screw into the centre bottom threaded hole. Use adjustable spanner to tighten.

Pt No. 0330210



6. Place a thin O ring over the thread of each blanking bolt (2) and screw into threaded left side hole and remaining threaded hole on the bottom face of the body block respectively. Use the 14mm open-ended spanner to tighten.

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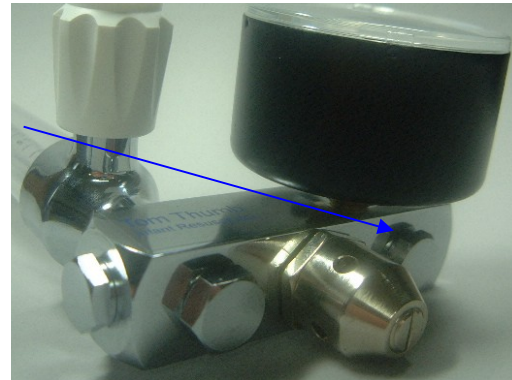
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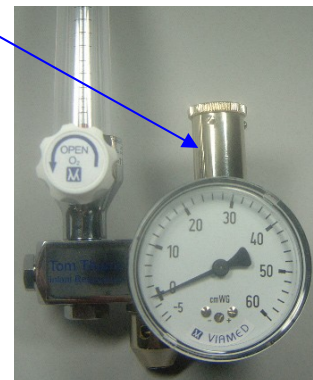
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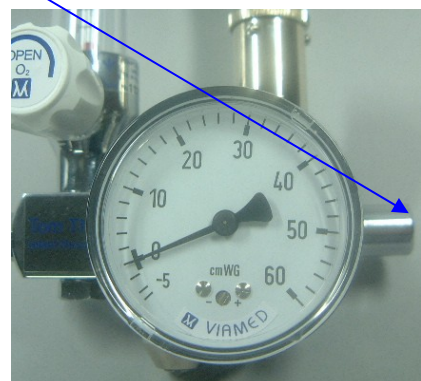
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7. Place a thin O ring over the threaded end of the adjustable valve. Screw the adjustable valve into the remaining threaded hole in the top face of the body block. Use the adjustable spanner to tighten.



8. Place a thin O ring over the threaded end of the 15mm outlet. Screw the 15mm outlet into the threaded hole in the right face of the body block. Use the adjustable spanner to tighten.



9. Affix Viamed details / serial no. Label across the Left Hand rear face of the body block.

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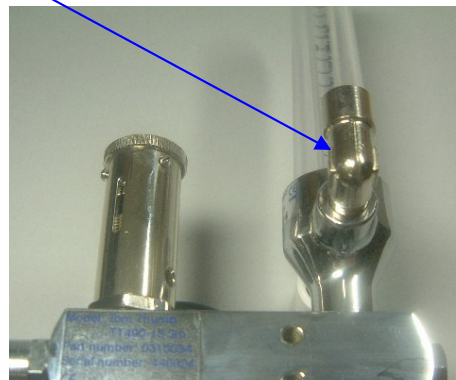
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10. Line the thread of the inlet hose right angle adapter with two complete layers of PTFE tape and screw into the rear of the flowmeter ensuring that the right angle adapter is vertical, tight and cannot be moved by hand.



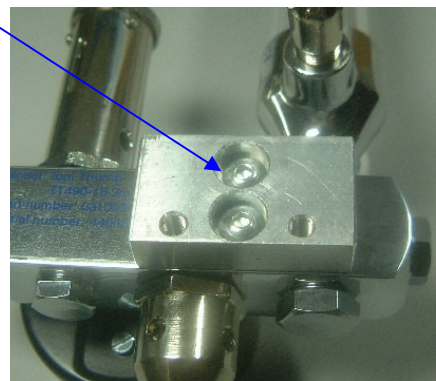
Pt No. 0330219



11. Attach the spacer block to the body block using 2x M4x10mm hex drive bolts.



Pt No's 0330215 & 0330216



12. Attach rail clamp to the spacer block using 2x M4x10mm hex drive bolts.

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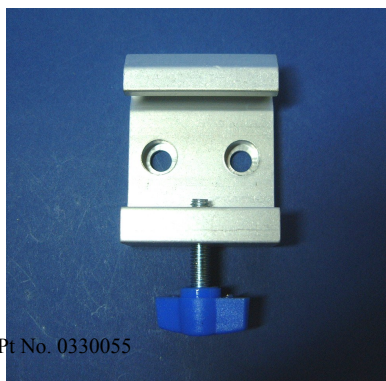
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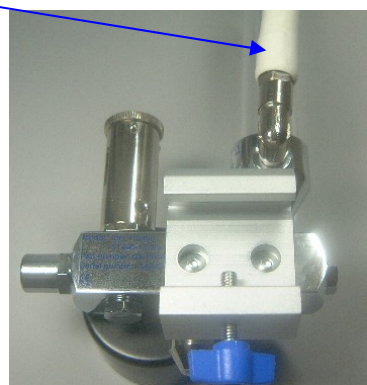
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13. Line the thread of the inlet hose with two complete layers of PTFE tape and screw into the inlet hose right angle adapter using 12mm open-ended spanner ensuring it is tight. Fit appropriate hose length; PN 0330217 have 1m hose, PN 0330218 have 3m hose.



Testing & Calibration: TT490-15.

1. Check the TT490-15 for damage i.e. scratches to plastics, poor chroming, etc.
2. Set the adjustable valve to minimum (fully counter clockwise) and the flowmeter to minimum (fully clockwise).
3. Connect the inlet hose to the oxygen supply at a pressure of 4 bar.
4. Connect the digital manometer (on 0-100.0 mbar range) with T piece adapter to the Tom Thumb outlet.
5. Set the flow meter to 15 Lpm.
6. Check all mechanical connections between parts for leaks; use Snoop fluid and check for bubbling.
7. Check for minimum pressure out: Cover the T piece adapter port. Check the TT pressure gauge is less than 8.0 cmH₂O. Check that the digital manometer reading is less than 7.8 mbar and record on the Tom Thumb Calibration / Test & QA Sheet.
8. Set up the adjustable valve: Set the adjustable valve control to maximum. Cover the holes in the precision valve and the T piece adapter port. Alter the adjustable valve collar until a reading of 23 - 27 cmH₂O is

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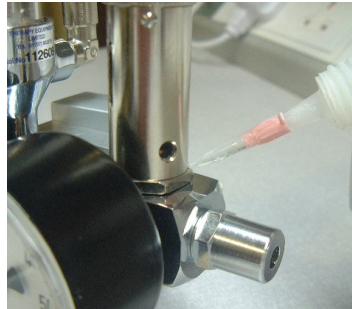
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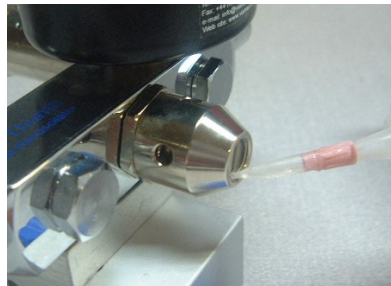
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achieved on the TT pressure gauge. Ensure a reading of 22.2 – 26.1 mbar on the digital manometer and record on the Tom Thumb Calibration / Test & QA Sheet. Slightly unscrew the adjustable valve and apply Oxygen-Compatible threadlock to the exposed threads. Retighten the adjustable valve with the adjustable spanner.



9. Check for TT pressure gauge sticking: Release and cover the T piece adapter port a number of times, ensuring that TT pressure gauge returns to 23 - 27 cmH₂O. Uncover the precision valve holes.

10. Set up the precision valve: Slightly unscrew the precision valve adjustable screw and apply Oxygen-Compatible threadlock to the exposed threads. Screw into the precision valve body until flush. Cover the holes in the adjustable valve and the T piece adapter port. Carefully adjust the precision valve screw in quarter turns to achieve a reading on the TT pressure gauge of 3.0 cmH₂O greater than the reading recorded at (8) (clockwise adjustment on precision valve screw to increase). Record the digital manometer reading on the Tom Thumb Calibration / Test & QA Sheet.



11. TT pressure gauge accuracy check: Cover the T piece adapter port and increase the flow of gas to achieve a displayed reading of 30 cmH₂O on the TT pressure gauge. Ensure a reading of $\pm 2\%$ of the Precision Valve Reading on the digital manometer and record

12. With the Flowmeter set at 15Lpm, gently shake the unit to check that the ball remains at the correct reading (not sticking), and then turn the Flowmeter and adjustable valve to minimum. Disconnect from oxygen supply and disconnect the digital manometer.

13. Clean the Tom Thumb with isopropyl alcohol and apply labels to the flowmeter adjuster, the adjustable valve and CE mark to the body block.

14. Attach the TT490-15 Instructions for Use card.

15. Ensure stock sheets are generated and submitted together with the Tom Thumb Calibration / Test & QA Sheet for QA checking.

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Quality Checks: TT490-15.

Do not carry out QA checks on Tom Thumbs until at least 1 hour after testing – this allows Oxygen-Compatible threadlock, applied during testing, to be totally dry.

1. Check the TT490-15 for damage i.e. scratches to plastics, poor chroming, etc.
2. Set the adjustable valve to minimum (fully counter clockwise) and the flowmeter to minimum (fully clockwise).
3. Connect inlet hose to oxygen supply at a pressure of 4 bar.
4. Connect the digital manometer (0 – 100.0 mbar) with T piece adapter to Tom Thumb outlet.
5. Set the flow meter to 15 Lpm.
6. Check all mechanical connections between component parts for leaks (use Snoop fluid and check for bubbling) including the T piece onto the outlet.
7. Check for minimum pressure out: Cover the T piece adapter port. Check the TT pressure gauge is less than 5.0 cmH₂O. Check that the digital manometer reading is less than 7.8mbar and record on the Tom Thumb Calibration / Test & QA Sheet.
8. Check the adjustable valve: Set the adjustable valve control to maximum. Cover the holes in the precision valve and the T piece adapter port. Ensure a reading of 23 - 27 cmH₂O on the TT pressure gauge. Check for a reading of 22.2 – 26.1 mbar on the digital manometer and record on the Tom Thumb Calibration / Test & QA Sheet.
9. Check for TT pressure gauge sticking: Release and cover the T piece adapter port a number of times, ensuring that TT pressure gauge returns to 23 - 27 cmH₂O. Uncover the precision valve holes.
10. Check the precision valve: Cover the holes in the adjustable valve and the T piece adapter port. Ensure a reading on the TT pressure gauge of 3.0 cmH₂O greater than the reading recorded at (8). Record the digital manometer reading on the Tom Thumb Calibration / Test & QA Sheet.
11. TT pressure gauge accuracy check: Cover the T piece adapter port and increase the flow of gas to achieve a displayed reading of 30 cmH₂O on the TT pressure gauge. Ensure a reading of $\pm 2\%$ of the Precision Valve Reading on the digital manometer and record
12. With the Flowmeter set at 5Lpm, gently shake the unit to check that the ball remains at the correct reading (not sticking), and then turn the Flowmeter and adjustable valve to minimum. Disconnect from oxygen supply and disconnect the digital manometer.
13. Clean the Tom Thumb with isopropyl alcohol.
14. Ensure the appropriate labels have been fitted, and the “TT 490-15 - Instructions for Use” card is attached. Complete stock sheets and file. Ensure the unit is booked onto the computerised stock system.

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Complete Tom Thumb TT490-15



Packaging.

Wrap thoroughly in bubble packaging.

Add One Patient Circuit (if required)

Pack appropriately for despatch by insured post, courier or company delivery.