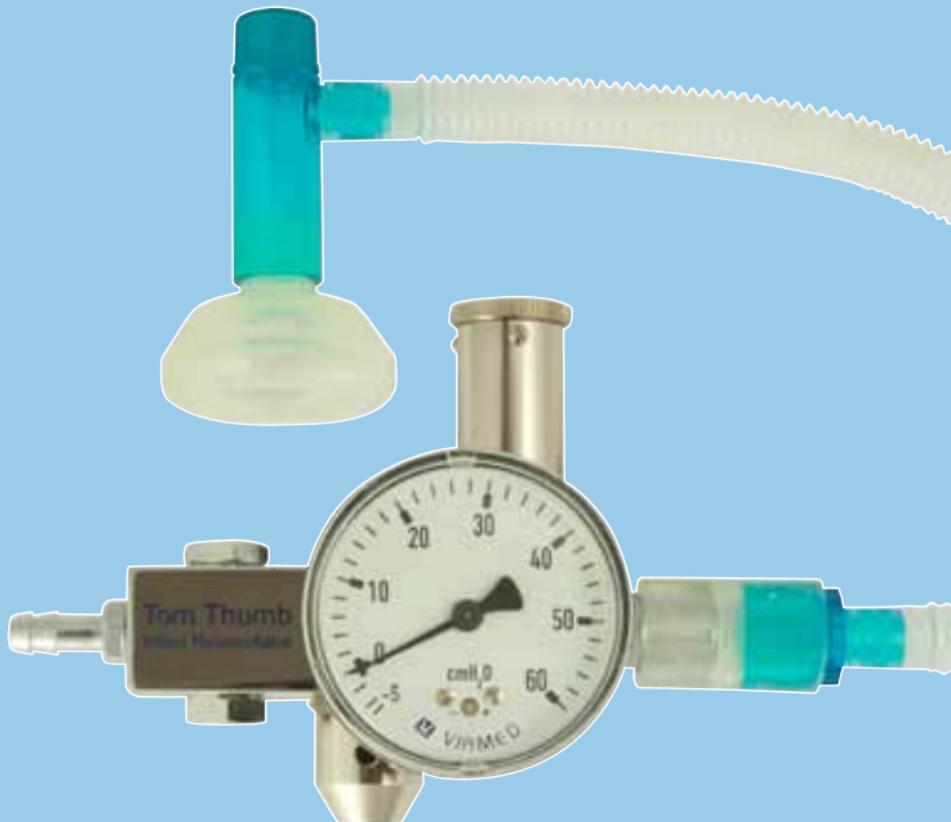


Tom Thumb

Infant T-Piece Resuscitator

Model: TT480 Series

Instructions for Use



CE 0086



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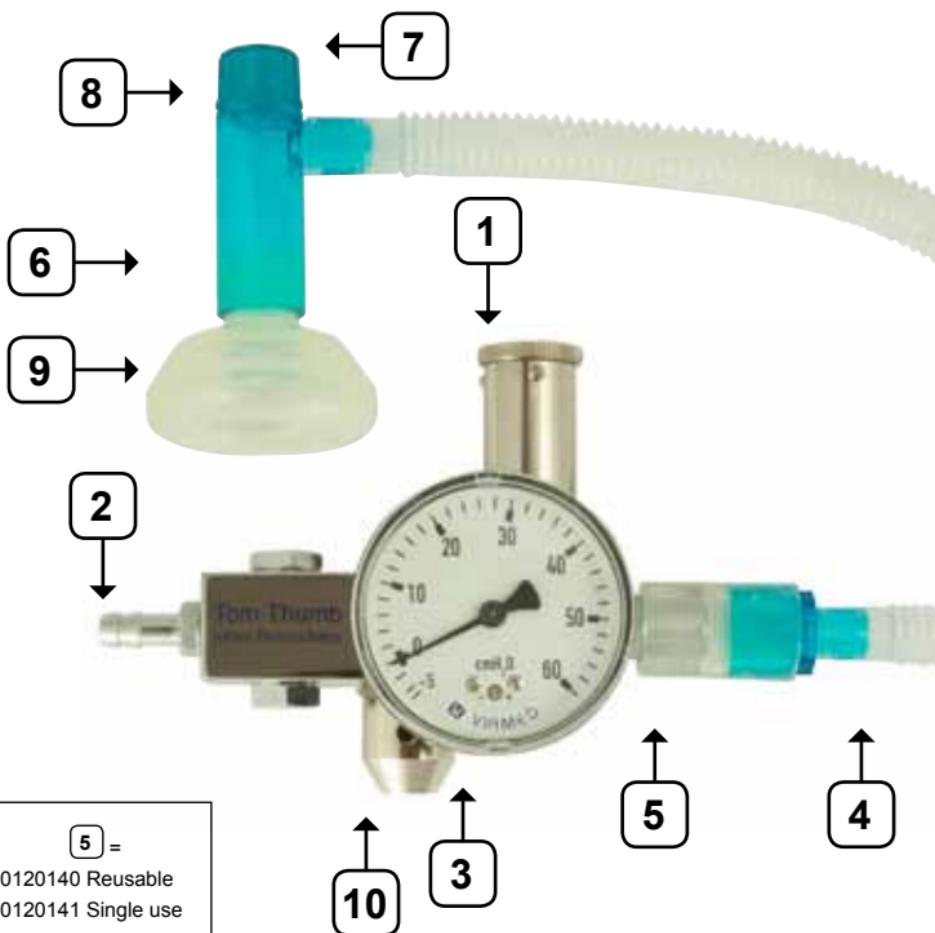
Warnings

Please read and understand the user instructions before using the Tom Thumb and its accessories.

- ⚠ For use by qualified trained personnel only.
- ⚠ To be used with regulated oxygen or air/oxygen mixtures only.
- ⚠ Recommended operating gas flow 5 - 15 lpm.
- ⚠ Use flow rates within the range of the flowmeter.
- ⚠ Adjust outlet pressure after altering the flow rate.
- ⚠ The Tom Thumb should only be used after checking that the correct pressure will be delivered to the patient.
- ⚠ The Tom Thumb should only be used with a single use NeoPEEP patient circuit.
- ⚠ An alternative means of resuscitation must be available.
- ⚠ Do not attempt to adjust the safety valve ⑩. The maximum pressure relief valve (only adjustable using a tool) is preset to 44.1 mbar \pm 1 mbar @ 10 lpm
- ⚠ No smoking or naked flames or sources of ignition should be present while the unit is in use.
- ⚠ Before performing Tom Thumb cleaning procedures, ensure all oxygen and air supplies are turned off. Explosion hazards exist in oxygen enriched environments.
- ⚠ $1\text{cm H}_2\text{O} = 1\text{cm WG} = 0.981\text{mb} = 0.981\text{ hPa}$
- ⚠ Gauge \pm 1.6% FSD

Intended Use

The Viamed Tom Thumb TT480 is an easy-to-use, compact and robust T-piece infant resuscitator. It is a manually operated, gas-powered resuscitator, which provides controlled and fatigue-free resuscitation of infants in delivery suites, nurseries and neonatal intensive care units.



Pre-use Set Up

- Adjust the external flowmeter(s) to minimum and the adjustable pressure valve control ① to minimum (fully counter clockwise).
- Connect the inlet ② to the external flowmeter(s) of the oxygen or blended oxygen/air supply.
- Check that the pressure gauge ③ reads zero (inside the black band). If not, then the Tom Thumb requires servicing.
- Connect the NeoPEEP patient circuit ④ to the Tom Thumb outlet using the adapter ⑤.
Do not apply to the patient at this stage.
- **Set the flowmeter to the required flow rate, up to the maximum of 15 lpm.**
- Occlude the patient opening of the 'T-Piece' ⑥ and the PEEP* valve outlet ⑦ to create an air tight seal.
- Turn the adjustable pressure valve control ① until the required PIP* is set, as shown by the pressure gauge ③.
- Uncover the PEEP valve outlet ⑦. Adjust the PEEP setting by adjusting the PEEP control cap ⑧ on the NeoPEEP patient circuit - until the reading on the pressure gauge ③ indicates that the correct PEEP has been achieved.
- Connect the 'T-piece' ⑥ to a suitable resuscitation mask ⑨ or to the patient's E.T. tube.
- The Tom Thumb is now ready for use.

* Note:

PIP = Peak Inspiratory Pressure

PEEP = Positive End Expiratory Pressure

Guidelines for Use During Resuscitation

1. Follow the pre-use set up procedure and set the required flow rate and outlet pressures; as defined by the hospital's protocol for resuscitation. Ensure pressures are checked prior to administering gas to the patient.
2. Apply the mask to the patient and cover the 'T-Piece' PEEP valve outlet to inflate the patient's lungs at the set flow rate and pressure.
3. Uncover the 'T-Piece' PEEP valve outlet and allow the patient's lungs to deflate.
4. Repeat steps 2 & 3 as necessary during the resuscitation of the patient (follow the hospital's protocol for resuscitation).

Cleaning and Care

Clean using a clean cloth dampened with cleaning solution approved by the hospital. The Tom Thumb is not intended to be sterilized. Do not autoclave. Do not allow moisture or foreign matter to enter the safety valve **10** or the adjustable valve **1**. Damage will occur if the Tom Thumb is subjected to severe mechanical shock or if dropped.

Servicing

The Tom Thumb should be serviced every 12 months; or if the pressure gauge does not read zero (outside of the black band) with no flow, or if the unit's accuracy is in doubt.

Viamed recommends that the gas hoses should be checked every 3 months, and replaced every 4 years as a minimum.

Specifications

Part Number	Description
0310030	Tom Thumb TT480 with Medirail mounting
0310094	Tom Thumb TT480 with pole mount
Recommended Body Weight Range	≤ 10 kg
Manometer Range	-5 to 60 cm H ₂ O
Manometer Accuracy	± 1.6% FSD
Input Connection (Barbed)	10 mm O.D.
Output Connection	15 mm O.D.
Peak Inspiratory Pressure (PIP)	@ 5 lpm maximum 40.0 mbar @ 10 lpm 42.1 ± 1 mbar, maximum 43.0 mbar @ 15 lpm maximum 45.7 mbar
Safety Valve	@ 5 lpm maximum 42.5 mbar @ 10 lpm 44.1 ± 1 mbar, maximum 45.0 mbar @ 15 lpm maximum 47.2 mbar
Recommended Gas Inlet Flow Range	5 - 15 lpm
Storage & Operating Temperature	-16°C - +60°C, no limits to atmospheric pressure
Expected Service Life	≥ 10 years with regular servicing

NeoPEEP Patient Circuit

Gas Flow Rate	1 - 15 lpm
PEEP Valve Adjustable	0 - 15 mbar
Operating Environmental Temperature	-18°C to +50°C
Storage Environmental Temperature	-40°C to +60°C

Patient Circuit Parts



Single Use Silicone Round Facemask

Part Number	Model Ref.	Size	Qty
3210073	200600D	0	Pack of 20
3210068	200550D	0.5	Pack of 20
3210074	200500D	1	Pack of 20



Single Use NeoPEEP Neonatal Resuscitation Circuit

Part Number	Model Ref.	Length	Qty
3210013	800100/BLUE	1.0m	Pack of 20
3210023	800150/BLUE	1.5m	Pack of 20



Circuit Adapters

Part Number	Model Ref.	Size	Usage	Qty
0120140	PF 1515	15mm I.D. - 15mm I.D.	Reusable	Single
0120150	PF 1515	15mm I.D. - 15mm I.D.	Reusable	Pack of 10
0120152	PF 1515	15mm I.D. - 15mm I.D.	Reusable	Pack of 50
0120141	KC 2124		Single Use	Single
0120151	KC 2124	15mm I.D./22mm O.D. - 15mm I.D./22mm O.D.	Single Use	Pack of 20
0120153	KC 2124		Single Use	Pack of 100

Warranty

Viamed warrants that the goods are free from defects of manufacture, for a period of one year from the date of shipment from Viamed.

Liability shall be limited solely to the replacement and repair of the goods and shall not include shipping costs or other incidental damages.

This warranty is null and void if any items are subjected to misuse, negligence, accident; or repairs - other than those performed by Viamed or an authorized service centre.

Disposal of Unit

The Tom Thumb infant resuscitator should be disposed of in accordance with local ordinances and regulations.

Alternatively, the Tom Thumb unit can be returned to Viamed, using the address below; if it accompanied by a decontamination certificate. You are responsible for the return packaging and carriage costs, but we will process the returned unit free of charge on your behalf.



Viamed Limited · 15 Station Road · Cross Hills
Keighley · West Yorkshire · BD20 7DT · United Kingdom
Tel: +44 (0)1535 634 542 Fax: +44 (0)1535 635 582
Email: info@viamed.co.uk Website: www.viamed.co.uk

