TECHNICAL SPECIFICATION

Part Number(s):	TB5000-W **i-Puff®** Disposable Infant T-Piece Resuscitation Circuit with Adjustable PEEP Controller, Adjustable Maximum Pressure Controller, Double Swivel Elbow, Relief Blow Off Valve with Security Lock, Pressure Manometer Gauge, Universal Connector and White Flowmeter Nipple (1/4 BSP), 83"/2.1m Length Corrugated Tubing
Patient:	Up to ≤ 10kg
Manometer Accuracy:	10 cmH_2O +/- 2cmH_2O 40 cmH_2O +/- 2cmH_2O 20 cmH_2O +/- 2cmH_2O 50 cmH_2O +/- 2cmH_2O 30 cmH_2O +/- 2cmH_2O 60 cmH_2O -10 cmH_2O
Input Gas Flow Range	Max.10LPM @ 400kPa Max.10LPM @ 400kPa *WARNING: Do Not Use a Flow Rate Higher than 10LPM as it will alter the pressure*
Recommended Gas Cylinder:	Compliant to ISO 32 with Valve Compliant to ISO 10297
Oxygen Concentration:	Up to 100%
Maximum Pressure Relief:	40 cmH_2O ± 5 cmH_2O @ 10LPM
Peak Inspiratory Pressure (PIP) Range:	Up to 50 cmH_2O ± 5 cmH_2O @ 10LPM
Positive End Expiratory Pressure (PEEP) Range:	Up to 5LPM@ 5 cmH_2O Up to 8LPM@ 9 cmH_2O Up to 10LPM @ 15 cmH_2O
Tube Dimension:	10mmID
End Connector:	10mmF/15mmM (Compliant with ISO 5356-1)
Patient Connector:	22mmM/15mmF Swivel (Compliant with ISO 5356-1)
Weight:	Approx. 84grams
Dead Space:	Approx. 10.5ml
Flowmeter Nipple:	1/4 BSP (White) US 9/16 UNF (Green) M12x1.25 (Light Green)
Optional Accessories: (Available Separately)	PH-615000 Reusable Silicone Mask, Size 00 PH-615001 Reusable Silicone Mask, Size 000
Storage Temperature:	-40°C to 60°C Up to 95% Relative Humidity
Operating Temperature:	-18°C to 50°C Up to 95% Relative Humidity
Operating Time:	@8LPM 50 minutes 400L Cylinder

RWL1134 **Typical Values*

i-Puff® Disposable Infant T-Piece Resuscitation Circuit

Adjustable PEEP Controller, Adjustable Maximum Pressure Controller, Double Swivel Elbow, Relief Blow Off Valve with Security Lock, Pressure Manometer Gauge, Universal Connector and White Flowmeter Nipple (1/4 BSP), 83"/2.1m Length 10mmID Corrugated Tubing

REF **TB5000-W**

LOT **TB5000-W-0026**

QTY: **1 Piece / Pack**
20 Pieces / Box

2019-05

2023-05

Patient End
22mmM/15mmF

Gas Inlet
10mmM

83" /2.1m Length Natural/Clear Corrugated 10mmID Tubing

RESPICARE SOLUTIONS

Imported & Marketed by: Respicare Solutions
271/279, Pravin Niwas, Gr. Floor, Dr. Cawasji Hormusji Street,
Marine Lines, Mumbai - 400002.
Customer Care : 022-2200 5405 / 9820261706
Email Id: enquiry@respicare.co.in I Website: www.respicare.co.in

MRP : Rs. 2500.00
(Incl.of all taxes)

INTRODUCTION

The **i**-Puff® Infant T-Piece Resuscitation Circuit with Manometer Gauge and Blow-off Valve is a fully disposable, single use Medical Device designed to provide emergency medical gases in-line with local/institution guidelines.

The patented circuit design allows for direct connection to a British ¼ BSP or US 9/16 UNF or French M12x1.25 outlet and is capable of providing a targeted Positive End Expiratory Pressure (PEEP) whilst limiting maximum inspiratory pressure to assist in Functional Residual Capacity (FRC) and improvement in lung volume. This device is suited for use in the absence of a mechanical resuscitation device where Peak Inspiratory Pressure (PIP), PEEP and maximum pressure bleeds are controlled.

⚠ CONTRADICTIONS

- DO NOT use Peak Inspiratory Pressures above 50cmH_2O
- DO NOT use on any gas delivery system that incorporates a 'bleed' valve
- DO NOT occlude the Blow-off Safety Valve

⚠ PRECAUTIONS AND WARNINGS

- Read ALL Instructions prior to use
- DO NOT use a flow rate higher than 10LPM as it will alter the pressure
- Adjusting gas flow rates will affect PIP and PEEP
- This device is intended for first time responders to a breathing emergency only and is not designated for long-term respiratory management
- Ensure to unblock the green PEEP controller valve immediately after the inspiratory phase to allow the patient to exhale
- This device is to be used by professionals trained in Paediatric/Infant/Neonatal Resuscitation
- Refer to ILCOR/AHA/ERC guidelines to determine the suitability of different types of resuscitators for use in cardiopulmonary resuscitation
- Ensure alternative means of resuscitation is available
- Incorrect use may cause serious harm or death
- Use of 100% O_2 and/or unregulated flow rates may cause serious harm or death
- If individual packaging is damaged, DO NOT use and Discard device
- If device is damaged, contaminated (before or during resuscitation) or has come into contact with water, DO NOT use and Discard device
- Check circuit for any blockages or leaks prior to use
- Device marked Single Use. DO NOT reuse, Dispose after use
- Reuse may pose a risk of cross-contamination & danger to the patient
- DO NOT operate while smoking or in presence of open flames or flammable materials and ensure that no sources of ignition are present while the device is in use. Fire hazards are possible in oxygen enriched environments.
- The device is not to be used on unattended patients
- The Minimum Input Gas Flow Range is 5LPM @ 400kPa
- The Maximum Input Gas Flow Range is 10PM @ 400kPa
- Use regulators complaint to ISO 10524-4 or 10524-3
- If the resuscitator entrains or permits the patient to inhale gas from the atmosphere, its use in contaminated environments can be hazardous unless entrainment is prevented or appropriated filtration is provided
- Sub atmospheric pressure is present in the expiratory phase.

DISPOSABLE

- Deface and destroy by landfill or incineration in compliance with federal, state and local regulations

HANDLING AND STORAGE

- Store in a clean dry area
- DO NOT store next to chemicals
- DO NOT stack heavy items on packaging, as it can damage the device

i-Puff® Instructions for Use

TB5000-W / TB5000-G / TB5000-F

INDICATIONS/INTENDED USE

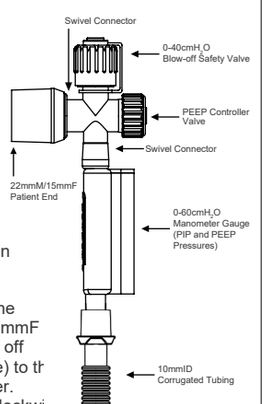
The **i**-Puff® Infant T-Piece Resuscitation Circuit with Manometer Gauge and Blow-off Valve is intended for use on infants (including neonates) weighing ≤10kg. It is capable of delivering a targeted maximum inspiratory pressure and PEEP via an appropriate facemask or airway device.

This device is designed for the clinician to set and observe the set delivery pressure of PEEP and maximum inspiratory pressure.

INSTRUCTIONS FOR USE

Section 1: Set Up

- Ensure medical gas delivery system is connected and functioning properly.
- Set desired oxygen saturation and flow rate (if applicable) according to the manufacturer/clinician's instructions.
- Connect the **i**-Puff® to the medical gas outlet by attaching the flowmeter nipple provided to a flowmeter or alternatively, connect the soft white connector directly to a flowmeter with nipple.
- Ensure the blue 22mmF outlet cap is firmly connected.
  Please Note: This cap may be removed and discarded when a test lung is used during Set Up.
- Ensure all connections are secure.
- Check/adjust maximum inspiratory pressure by occluding the green PEEP controller valve with your thumb whilst blue 22mmF end cap occludes the common gas outlet and turn the blow off valve (clockwise to increase and anti-clockwise to decrease) to th desired pressure indicated by the red line on the manometer.
- Check/adjust PEEP by turning the green PEEP controller clockwise to increase and anti-clockwise to decrease pressure as shown on manometer gauge.
  CAUTION: DO NOT occlude green PEEP valve to check PEEP.



Section 2: Resuscitation

- Remove and discard 22mmF blue outlet cap or remove test lung (if applicable).

Endotracheal Application (if applicable):

- Insert Endotrachel Tube into patient
- Attach to the patient end of the circuit.
- Resuscitate by occluding and lifting the thumb over the green PEEP controller valve at desired inspiratory expiratory rates in accordance with local/institution guidelines.

Mask Application (if applicable):

- Attach mask to the patient end of the circuit firmly with a twisting action.
- Place mask firmly over patient's nose and mouth.
- Resuscitate by occluding and lifting the thumb over the green PEEP controller valve at desired inspiratory expiratory rates in accordance with local/institution guidelines.

ACCESSORIES (Not Included)

- Mask • Endotracheal Tube or other Airways • Test Lung