

PuffinLT™

Infant Resuscitator

Technical Manual

Puffin Lite™ Infant Resuscitator

Technical Manual

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2797

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SECTION 1: GENERAL INFORMATION

INTRODUCTION

This manual describes features and operations specific to the Puffin Lite™ Infant Resuscitator. The resuscitation system provides the basic equipment required for pulmonary resuscitation of neonatal infants. Pulmonary resuscitation includes practices necessary to establish a clear airway and provide oxygen or air/oxygen mixtures and/or manual ventilation to the neonatal infant. These are clinical practices that represent the established standard of care according to International Liaison Committee on Resuscitation (ILCOR). Resuscitation may be required whenever an infant fails to establish effective, adequate breathing patterns necessary to meet tissue oxygen demands and/or to rid the body of carbon dioxide.

INTENDED USE

The intended use for the Puffin Lite™ Infant Resuscitator is to provide the basic equipment required for pulmonary resuscitation of neonatal infants. Pulmonary resuscitation includes practices necessary to establish a clear airway and provide oxygen or air/oxygen mixtures and/or manual ventilation to the neonatal infant.

WARNING: **For medical professionals only. U.S. Federal law restricts this device to sale by, or on order of, a licensed medical practitioner.**

SECTION 1: GENERAL INFORMATION

SAFETY SUMMARY

The Puffin Lite™ Infant Resuscitator is intended for use only by qualified clinicians, under the direction of a qualified physician. All personnel operating the system should be thoroughly familiar with operating instructions, warnings, and cautions contained in this manual.

The resuscitator should be verified according to the procedures in this manual before putting into operation. If the unit fails any portion of the checkout procedure, it must be removed from service and repaired.

IMPORTANT SAFETY CONSIDERATIONS

Safety concerns or additional pertinent information will be displayed using warnings, cautions, and notes, having the following significance:

WARNING: Alerts to potential serious injury, adverse event, or safety hazard.

CAUTION: Alerts to the possibility of minor injury or damage to the equipment.

NOTE: *Provides additional information to clarify a point in the manual.*

The principal **WARNING** and **CAUTION** notices to be observed in use of this device are brought together here for emphasis.

SECTION 1: GENERAL INFORMATION

WARNINGS

- **MONITOR PATIENT OXYGEN LEVELS:** Patient oxygen levels should be monitored during resuscitation.
- **OBSERVE BEST PRACTICE:** The instructions in this manual in no way supersede established medical procedures or staff preference concerning patient care.
- **USE OF OXYGEN INCREASES FIRE DANGER:** Spark-producing auxiliary equipment should not be placed near the resuscitator.
- Incorrect operation can be hazardous.
- Do not use on unattended patient.
- Alternate means of ventilation should be available.
- For medical professionals only: U.S. Federal law restricts this device to sale by, or on order of, a licensed medical practitioner.
- The resuscitator should only be used by clinicians trained in neonatal resuscitation.
- The resuscitator must be mounted securely prior to use.
- The T-Piece resuscitator is not intended for use of oxygen delivery other than resuscitation.
- Do not operate the resuscitator during a supply pressure alarm. The resuscitator may not supply accurate fraction of inspired oxygen (FiO₂) during this alarm.
- Do not operate the resuscitator in an MRI environment.
- The pre-use checkout procedures must be completed before putting the resuscitator into operation. If the resuscitator fails the checkout procedure, the resuscitator must be removed from service.
- The T-Piece circuit is single use only. Cleaning and reusing may damage the circuit and expose the patient to risk of infection.
- The T-piece gas outlet is not intended for use with self-inflating or flow-control manual resuscitators.
- Before use of the T-Piece System, set Flow, PIP, and PEEP parameters to check circuit integrity.

SECTION 1: GENERAL INFORMATION

- Always check that the T-piece circuit and connection is clean and unobstructed before patient use.
- Patient flow rates above 10 L/M require the operator to override the flow rate stop. Flow rates above 10 L/M may cause an increase in PEEP beyond desired levels and should be closely monitored by the operator.
- Using positive end expiratory pressure (PEEP) may present a hazard. Always use the airway pressure manometer to verify PEEP.
- When a manual resuscitator is connected to the AUX gas outlet, always use an independent manometer.
- The auxiliary flow meter is not designed for use with a Nasal Cannula, NCPAP, or Oxygen Hood.
- As with all medical equipment, carefully route tubing to reduce the possibility of patient entanglement or strangulation.
- Take caution when mounting above patient level.
- Oil or grease should not be used on the resuscitator or any parts of the resuscitator set.

CAUTIONS

- Oxygen concentration should be verified via an oxygen analyzer.
- Close the tank valves prior to disconnecting the tank input hoses from the device.
- Open tank valves slowly to avoid damaging the device.
- Turn medical gas switch off when the resuscitator is not in use to avoid inadvertently draining the tanks to low or empty.
- Leaving medical gas switch in the "ON" position when not in use may unnecessarily bleed (waste) gas.
- Use only International Biomedical T-Piece Circuits with the Puffin Lite™ Infant Resuscitator.
- Clean, dry sources of medical grade oxygen and air, regulated to the input requirements, must be used or malfunction can result.








NOTES

- Air always means medical air.

SECTION 1: GENERAL INFORMATION

SYMBOLS

The following symbols appear in the resuscitator documentation and labels.

	Consult Instructions For Use
	“ON” Medical Gas
	“OFF” Medical Gas
	Date of Manufacture
	General Warning, Caution, Risk of Danger
	Variability for Rotating Movement
PIP	Peak Inspiratory Pressure
EXT	External Gas Source
	Gas Input

SECTION 1: GENERAL INFORMATION

ABBREVIATIONS

ABBREVIATION	DEFINITION
cmH ₂ O	Unit of pressure, centimeters of water
FiO ₂	Fraction of inspired oxygen
mmHg	Unit of pressure, millimeters of mercury
NICU	Neonatal Intensive Care Unit
PEEP	Positive End Expiratory Pressure
PIP	Peak Inspiratory Pressure
L/min	Liters per minute
ILCOR	International Liaison Committee on Resuscitation
AUX	Auxiliary
NCPAP	Nasal Continuous Positive Airway Pressure

SECTION 2: OPERATING INSTRUCTIONS

SINGLE USE ONLY

Items designated as single use are designed in a way that reuse may affect accuracy, system performance, or risk of cross-contamination.

SYSTEM DESCRIPTION

The Puffin Lite™ Infant Resuscitator is a gas powered emergency resuscitation system. It is designed to be used inside the hospital by trained medical professionals to provide precise FIO₂ delivery and manual ventilation as established by resuscitation guidelines to neonates and infants weighing less than 10 kg (22 lb).¹ The expected life of the Puffin Lite™ Infant Resuscitator is 8 years when properly maintained.

The resuscitation system includes:

- Air/Oxygen Blender
- T-Piece Resuscitator
- Airway Pressure Manometer
- Peak Inspiratory Pressure (PIP) Control
- Positive End Expiratory Pressure (PEEP) Control

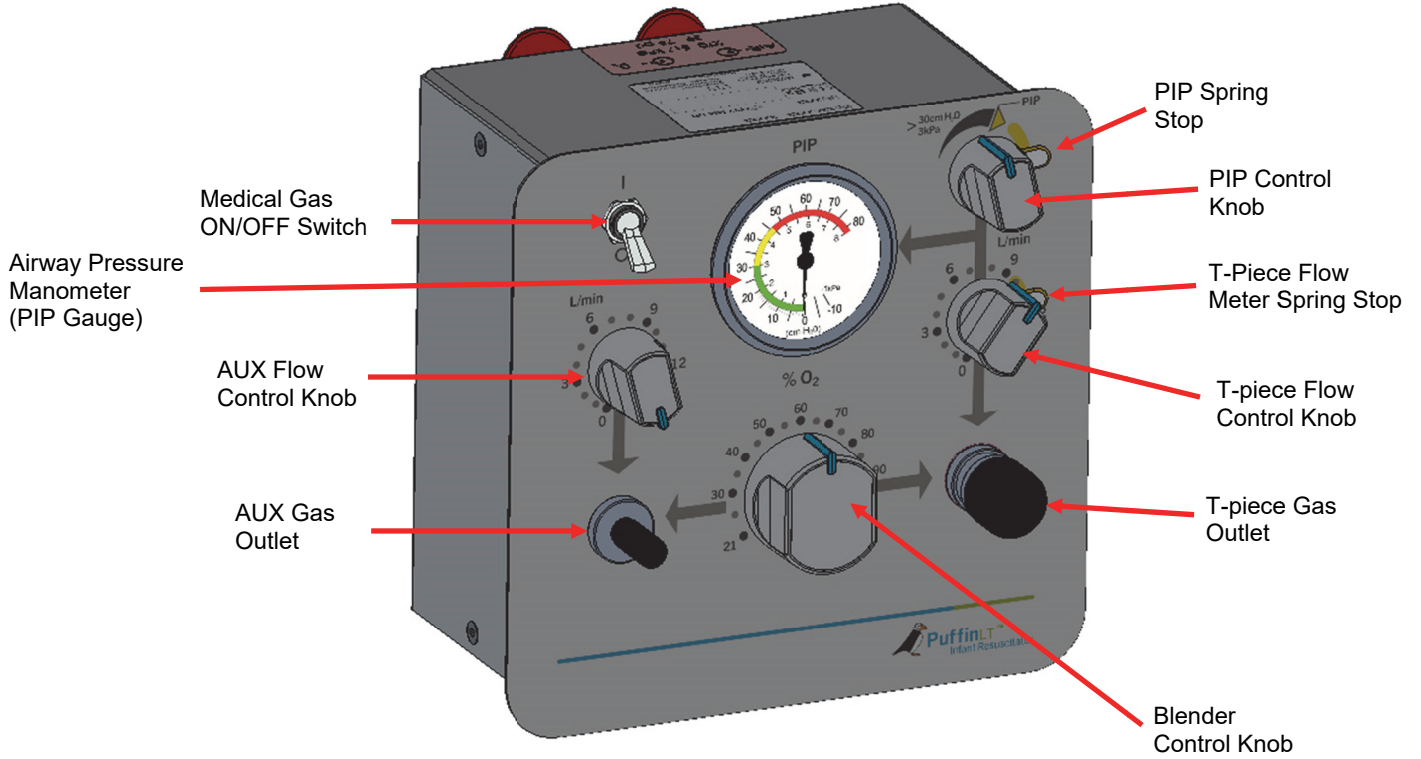
WARNING: **The Resuscitator should only be used by clinicians trained in neonatal resuscitation.**

¹ American Academy of Pediatrics/American Heart Association: Textbook of Neonatal Resuscitation (NRP) (6th ed.) Elk Grove Village, IL, 2010, American Academy of Pediatrics

SECTION 2: OPERATING INSTRUCTIONS

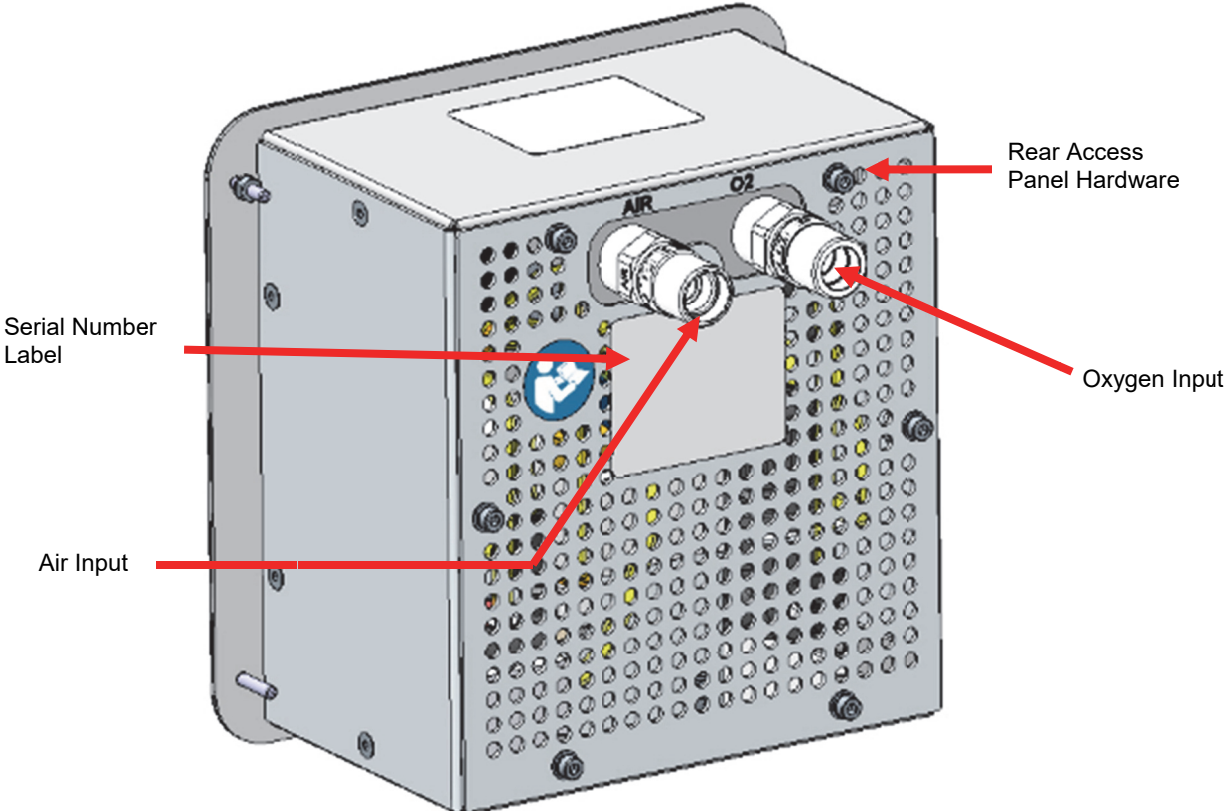
RESUSCITATION SYSTEM CONTROLS AND CONNECTIONS

Figure 2 - 1 Front View



SECTION 2: OPERATING INSTRUCTIONS

Figure 2 - 2 Rear View



SECTION 2: OPERATING INSTRUCTIONS

AIR/OXYGEN RESUSCITATION MODULE

PIP Control

The Peak Inspiratory Pressure (PIP) control knob regulates the maximum pressures that can be achieved when using the T-piece circuit.

A standard pressure range from 0 - 30 cm H₂O can be selected.

Pressures exceeding 30 cm H₂O to a maximum of 45 cm H₂O may be selected by activating the PIP Override mechanism.

T-Piece Flow Meter

The T-piece flow meter regulates blended medical gas to the T-piece circuit.

A standard flow range from 0-10 L/min can be selected.

Flows exceeding 10 L/min up to a maximum of 15 L/min can be selected by activating the T-piece flow meter override mechanism.

Auxiliary Flow Meter

The auxiliary flow meter regulates blended medical gas to the auxiliary gas outlet. Auxiliary outlet is designed for free flowing oxygen (Blow-By) or a manual resuscitator (Bag & Mask) meeting the requirements of ISO 10651-4 or ISO 5356-1.

WARNING: **When a manual resuscitator is connected to the AUX gas outlet, always use an independent manometer.**

The Auxiliary flow meter is not designed for use with a Nasal Cannula, NCPAP, or Oxygen Hood.

Take caution when mounting above patient level.

Blender

The blender regulates FiO₂ from 21% to 100% oxygen from both gas outlets.

Supply Pressure Alarm

A pneumatic alarm will sound from the air/oxygen blender when there is a loss of pressure in either the supplied air or oxygen. Adjusting the air and oxygen supply pressures to be equal will resolve the alarm.

WARNING: **Do not operate the resuscitator during a supply pressure alarm. The resuscitator may not supply accurate fraction of inspired oxygen (FiO₂) during this alarm.**

SECTION 2: OPERATING INSTRUCTIONS

Airway Pressure Manometer

The airway pressure manometer displays the pressures during a respiratory cycle when using the T-piece resuscitator. Both PIP and PEEP can be observed on the airway pressure manometer. Pressures between -10 to 80 cm H₂O can be observed.

ACCESSORIES

Part Number	Description
738-1699	Patient T-Piece Circuit (10/case)
738-1700	Patient T-Piece Circuit (single)

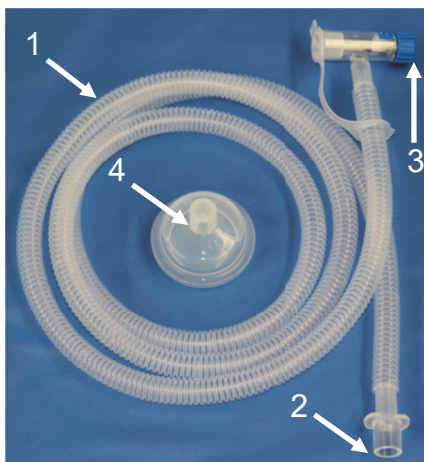


Figure 2 - 3 T-Piece Circuit

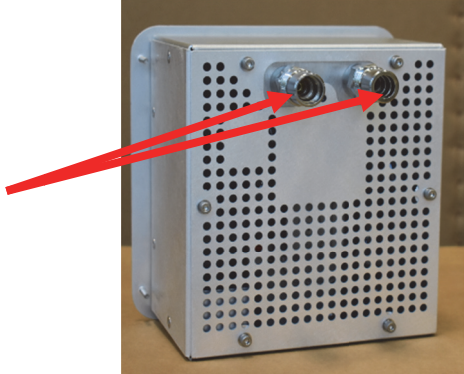
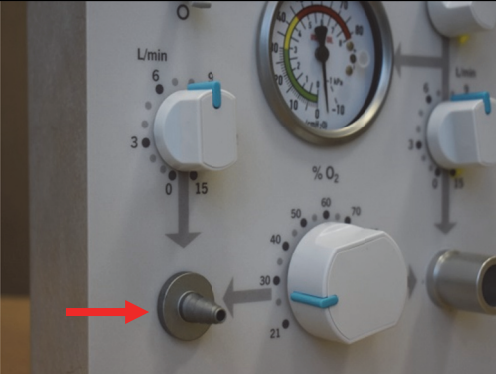


The T-piece circuit consists of (1) 5 ft. (1.2 m) length of tubing, (2) 15 mm male connector, (3) PEEP control knob, and (4) #1 mask.

SECTION 2: OPERATING INSTRUCTIONS


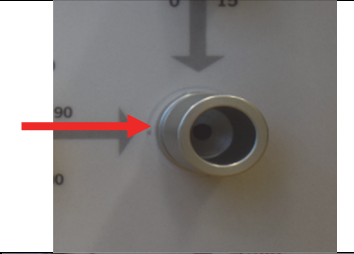
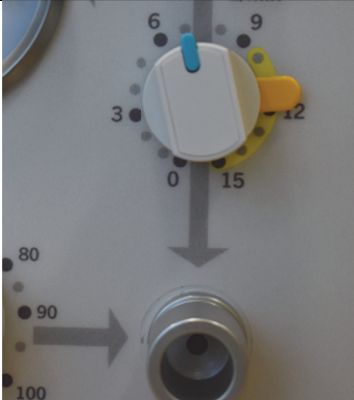
1.1. PRE-USE CHECK AND SET-UP OF T-PIECE RESUSCITATOR

- WARNING:** The checkout procedures must be completed before putting the resuscitator into operation. If the resuscitator fails the checkout procedure, the resuscitator must be removed from service.
- WARNING:** **USE OF OXYGEN INCREASES FIRE DANGER:** Spark-producing auxiliary equipment should not be placed near the resuscitator.
- WARNING:** The T-Piece circuit is single use only. Cleaning and reusing may damage the circuit and expose the patient to risk of infection.
- WARNING:** The T-Piece resuscitator is not intended for use of oxygen delivery other than resuscitation.
- WARNING:** Before use of the T-Piece System, set Flow, PIP and PEEP parameters to check circuit integrity.
- WARNING:** Using positive end expiratory pressure (PEEP) may present a hazard. Always use the airway pressure manometer to verify PEEP.
- CAUTION:** Use only International Biomedical T-Piece circuits with the Puffin Lite™ Infant Resuscitator.
- CAUTION:** Clean, dry sources of medical grade oxygen and air, regulated to the input requirements, must be used or malfunction can result.
- CAUTION:** Close the tank valves prior to disconnecting the tank input hoses from the device.
- CAUTION:** Open tank valves slowly to avoid damaging the device.


SECTION 2: OPERATING INSTRUCTIONS

Description	Step	Illustration
Connect the resuscitator to an Air/O ₂ Gas source.	1	
Connect bag system or oxygen tubing to the AUX gas outlet.	2	
Rotate AUX outlet flow control knob to 10 L/min.	3	
Toggle Medical Gas Switch to the "ON" position and check to ensure the bag or oxygen tubing is receiving flow.	4	

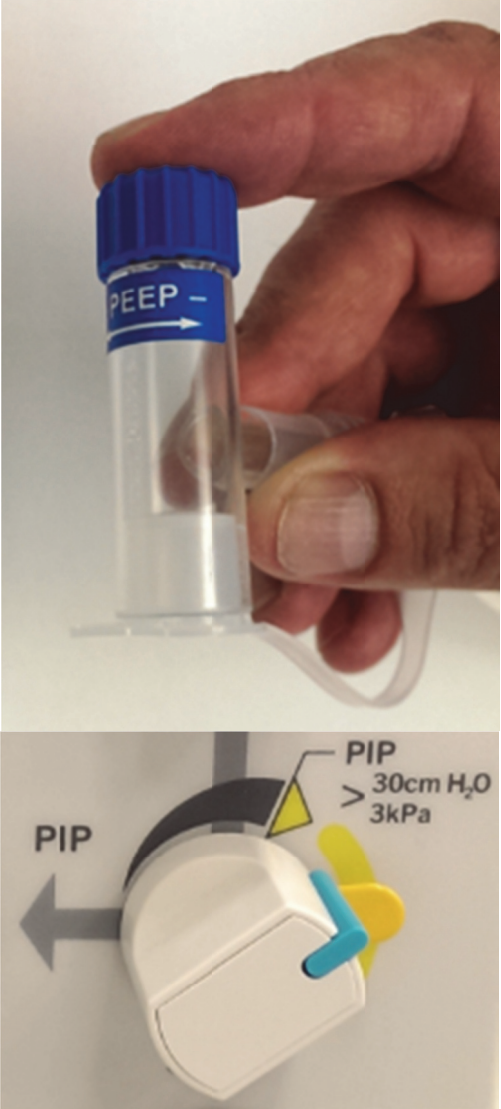
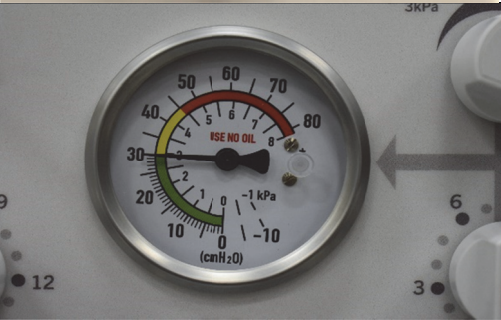
SECTION 2: OPERATING INSTRUCTIONS

Description	Step	Illustration
Rotate AUX outlet flow control knob to 0 L/min.	5	 A close-up photograph of a white flow control knob on a grey panel. The knob is marked with 'L/min' and has numerical values 0, 3, 6, 9, 12, and 15. The knob is rotated so that the blue indicator points to the '0' mark. A grey arrow points downwards from the knob. To the right, a portion of a circular scale with markings at 20 and 30 is visible.
Connect the T-Piece circuit to the T-Piece gas outlet.	6	 A close-up photograph of a metal gas outlet on a grey panel. A red arrow points horizontally from the left towards the outlet. Above the outlet, a portion of a circular scale with markings at 80 and 90 is visible.
Turn the T-Piece flow meter control knob for a flow of 7 L/min.	7	 A close-up photograph of a white flow control knob on a grey panel. The knob is marked with 'L/min' and has numerical values 0, 3, 6, 9, 12, and 15. The knob is rotated so that the blue indicator points to the '7' mark. A yellow arrow points to the right from the knob. Below the knob, a portion of a circular scale with markings at 80, 90, and 100 is visible.



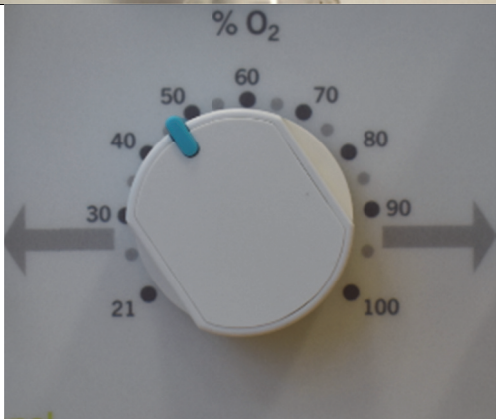
SECTION 2: OPERATING INSTRUCTIONS

Description	Step	Illustration
<p>Occlude the T-Piece Outlet with plug attached to the T-Piece circuit.</p>	8	 A close-up photograph showing a person's hand holding a clear plastic T-piece circuit. The circuit has a blue cap on top with the word 'PEEP' and a right-pointing arrow printed on it. The circuit is connected to a clear plastic tube. The background is a plain, light-colored surface.

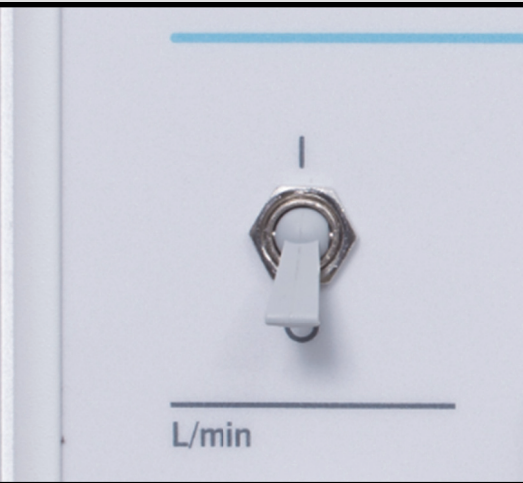
SECTION 2: OPERATING INSTRUCTIONS

Description	Step	Illustration
<p>Occlude PEEP knob orifice with thumb or index finger and adjust PIP control knob to the pressure override mechanism.</p>	<p>9</p>	
<p>Verify airway pressure manometer reads 30 cmH₂O ± 4 cmH₂O.</p>	<p>10</p>	

SECTION 2: OPERATING INSTRUCTIONS

Description	Step	Illustration
Set PIP for desired pressure as indicated on the manometer	11	
Release thumb or index finger from PEEP knob hole and adjust variable PEEP knob for desired end expiratory pressure as indicated on the manometer.	12	
Adjust blender control knob for desired FiO ₂ .	13	

SECTION 2: OPERATING INSTRUCTIONS

Description	Step	Illustration
Toggle Medical Gas Switch to the "OFF" position until ready for use.	14	

SECTION 2: OPERATING INSTRUCTIONS

1.2. T-PIECE INSTRUCTIONS FOR USE

WARNING: The T-Piece gas outlet is not intended for use with self-inflating or flow control manual resuscitators.

WARNING: Always check that the T-piece circuit and connection is clean and unobstructed before patient use.



WARNING: As with all medical equipment, carefully route tubing to reduce the possibility of patient entanglement or strangulation.

WARNING: **OBSERVE BEST PRACTICE:** The instructions in this manual in no way supersede established medical procedures or staff preference concerning patient care.



CAUTION: Oxygen concentration should be verified via an oxygen analyzer per hospital policies.

CAUTION: Leaving medical gas switch in the “ON” position when not in use may unnecessarily bleed (waste) gas.

SECTION 2: OPERATING INSTRUCTIONS

Description	Step	Illustration
Toggle Medical Gas Switch to the "ON" position.	1	
Connect patient circuit to mask and place over mouth and nose, or connect patient circuit to laryngeal airway or endotracheal tube.	2	

SECTION 2: OPERATING INSTRUCTIONS

Description	Step	Illustration
<p>Resuscitate by alternating between occluding and releasing thumb or index finger from the orifice in PEEP knob on the circuit. This will allow for inspiration and expiration.</p>	<p>3</p>	 <p>The top photograph shows a hand with the thumb occluding the blue PEEP knob. The bottom photograph shows the hand with the thumb released, allowing air to flow through the knob.</p>
<p>To administer free-flow oxygen with a T-Piece circuit, set flow and FiO₂ according to hospital policy. Hold mask near patient's face.</p>	<p>4</p>	 <p>The photograph shows a hand holding a clear plastic T-piece mask with a blue PEEP knob, positioned near the baby mask on the patient's face.</p>

SECTION 3: MAINTENANCE AND CLEANING

Warranty repair and service should be performed by an International Biomedical Service Representative or at the International Biomedical manufacturing and service center. To contact an International Biomedical service representative, call International Biomedical.

Do not use malfunctioning equipment, including equipment that does not pass the checkout procedure. Non-warranty repairs may be performed by an International Biomedical service representative. After service, follow the checkout procedure prior to returning the unit to service.

WARNING: **Oil or grease should not be used on the resuscitator or any parts of the resuscitator set.**

MAINTENANCE SCHEDULE

The resuscitator should be sent to International Biomedical every two years for maintenance.

At a minimum, an annual functional check of the Infant Resuscitator is required. If any portion of the functional check does not pass, the Infant Resuscitator should be removed from service for proper maintenance and calibration. See Appendix A for the recommended annual functional check.

FREQUENCY	DETAILS
After each use:	<ul style="list-style-type: none">• Clean and disinfect the resuscitator as required.• Replace the single-use patient circuit and mask.

CLEANING INSTRUCTIONS

After each patient use, follow the hospital's infection control procedures for surface disinfection. Wipe down the surfaces of the resuscitator with a soft cloth dampened with a disinfectant-detergent solution. Always follow the cleaning solution manufacturer's direction for use. Dry all surfaces with a soft cloth to remove any cleaner residue. Do not spray cleaner into the ports and outlets.

SECTION 4: TECHNICAL SPECIFICATIONS

Operating Specifications	
Recommended Patient Weight Range	<ul style="list-style-type: none"> • 22 lbs (10 kg) Maximum Weight
Gas Supply Characteristics	<ul style="list-style-type: none"> • Air & Oxygen • Input Pressure: 39-75 psi (270-517 kPa) • Gas Supply Minimum Flow Rating: 70 L/min
Adjustable PIP	<ul style="list-style-type: none"> • Max PIP: 45 ± 5 cmH₂O • Override: $> 30 \pm 4$ cmH₂O • Flow Capacity: 15 L/min
Adjustable PEEP Range	<ul style="list-style-type: none"> • @ 5 L/min to approximately 2 cmH₂O • @ 8 L/min to approximately 5 cmH₂O • @ 10 L/min to approximately 8 cmH₂O • @ 15 L/min to approximately 20 cmH₂O
Flow Meters	<ul style="list-style-type: none"> • Flow Range: 0-15 L/min • Flow Accuracy: <ul style="list-style-type: none"> < 5 L/min $\pm .5$ L/min 5-10 L/min ± 1.5 L/min >10-15 L/min ± 2.0 L/min
Air/O ₂ Blender	<ul style="list-style-type: none"> • Range: 21 to 100% • Accuracy: $\pm 5\%$ of full scale
Airway Pressure Manometer	<ul style="list-style-type: none"> • Range: -10 - 80 cmH₂O • Accuracy: $\pm 5\%$ of full scale
Approximate Operating Time*	<ul style="list-style-type: none"> • @ 5 L/min 204 min • @ 10 L/min 102 min • @ 15 L/min 68 min <p>*E Cylinders (680 L @ 2200 psi) 60% FIO₂</p>
Environmental Specifications	
Operating Temperature	18 to 41° C
Storage Temperature Range	-25 to 60° C
Operating Humidity	5-95% (non-condensing)
Storage Humidity	5-95% (non-condensing)
Storage Pressure	70-106 kPa
Physical Characteristics	
Depth	4.5 in (114 mm)
Height	8.1 in (206 mm)
Width	8.3 in (211 mm)
Weight	7.216 lbs (3.28 kg)
Patient Connection	15/22 mm ID/OD, Auxiliary Barb
Inspiratory Resistance of T-Piece Circuit	-0.3 cmH ₂ O at minimum PEEP setting at 6 L/min
Expiratory Resistance of T-Piece Circuit	0.3 cmH ₂ O at minimum PEEP setting at 6 L/min
Dead Space of T-Piece Circuit	< 5 mL
Dead Space of the resuscitator w/Accessories	43 mL

SECTION 5: WARRANTY

Unless otherwise specified, International Biomedical warrants all products of its manufacture at the time of shipment to be free from defects of material and workmanship for a period of twelve months from the date of shipment when owned by the original purchaser. Any product which is believed to be defective, if returned within twelve months after date of shipment by the Company with freight prepaid and found by the Company's inspection to be defective within the terms of this warranty, will be repaired or replaced free of charge and shipped, freight prepaid, to any point in the United States. If inspection by the Company of any such product does not disclose any defect within the terms of this warranty, the Company's regular charges for repairs or replacement and freight shall apply. All consumable and disposable products are guaranteed to be free from defects upon shipment only.

This warranty specifically excludes and replaces all other express and implied warranties. The Company shall have no liability under any warranty in any amount greater than the Company receives for the sale of the product involved. The use and manner of use of the Company's products shall be the responsibility of the purchaser and the purchaser covenants and agrees to indemnify and save harmless the Company in respect to any loss and damage that may arise through the use by the purchaser, or others, of any of the Company's products.

This warranty is rendered void and International Biomedical cannot be held liable for conditions resultant therefrom if:

1. Damage to the unit is incurred as a result of mishandling.
2. The customer fails to maintain the unit in a proper manner.
3. The customer uses any parts, accessories, or fittings not specified or sold by International Biomedical.
4. Sale or Service is performed by a non-certified service / dealer agency or any other unauthorized agency.

All shipping claims must be made within 30 days from date of shipment from International Biomedical; otherwise factory will not be liable for claims of missing items. Any item ordered in error and returned to the factory for credit, will be subject to a minimum restocking charge of 15%. Requests for returning items must be made within 30 days of factory shipment date.

International Biomedical will accept no returned goods without a Returned Goods Authorization number (RGA) obtained from Customer Service Department.

SECTION 6: SYSTEM DOCUMENTATION

EUROPEAN REGULATORY AFFAIRS REPRESENTATIVE

The authorized regulatory affairs representative in Europe for the incubator is:

Emergo Europe
Prinsessegracht 20
2514 AP
The Hague, The Netherlands

PARTS AND ACCESSORIES

For general assistance or for parts and accessories, contact:

International Biomedical
8206 Cross Park Drive
Austin, TX 78754
512-873-0033
www.int-bio.com

Appendix A: Puffin Lite™ Infant Resuscitator Annual Functional Check

Procedure:	Check
1. Verify the airway pressure manometer is at 0 cmH ₂ O ± 2 cmH ₂ O	
2. Connect an air and oxygen hose to the external inputs and pressurize the Resuscitator.	
Auxiliary Flow Check:	
1. Turn the Medical Gas On/Off switch to the “ON” position	
2. Turn the Auxiliary flow meter control knob to 7 L/min and verify gas is flowing out of the auxiliary gas outlet.	
3. Turn the Auxiliary flow meter control knob to 0 L/min and verify no gas is flowing out of the auxiliary gas outlet.	
T-Piece Pressure & Flow Check:	
1. Connect a T-Piece circuit to the T-Piece gas outlet.	
2. Turn the T-Piece flow meter control knob to 7 L/min and set the PIP control knob to the stop.	
3. Occlude the Patient port and PEEP orifice on the T-Piece circuit.	
4. Verify the PIP pressure on the Airway manometer is 30 cmH ₂ O ± 4 cmH ₂ O.	
5. Only occlude the PEEP orifice of the T-Piece circuit and verify gas is flowing out of the T-Piece patient port.	
6. Turn the T-Piece flow meter control knob to 0 L/min and verify no gas is flowing out of the T-Piece gas outlet.	
7. Turn the Medical Gas On/Off switch to the “OFF” position and disconnect the air and oxygen hoses.	

Infant Resuscitator System Functional Check:

PASS

FAIL

Name: _____

Date: _____

Title: _____