

Instructions for Use

SafeT T-Piece Resuscitator



Indications for Use: The SafeT T-Piece Resuscitator is a gas-powered emergency resuscitator intended to provide emergency respiratory support by means of a face mask or a tube inserted into a patient's airway. It is intended for use with neonates and infants weighing less than 10 kg (22 lb).

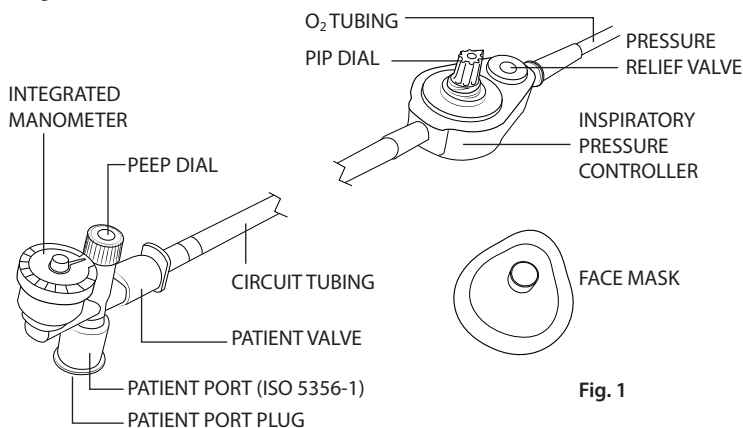


Fig. 1

SafeT Components & Accessories: Each SafeT Resuscitator comes with the following (Fig. 1):

- Patient valve with variable positive end-expiratory pressure (PEEP) dial, and integrated manometer to monitor pressure
- Adjustable inspiratory pressure (PIP) controller, 0-40 cm H₂O
- 40 cm H₂O pressure relief valve
- 7' oxygen tubing with red universal oxygen connector (Fits-All)
- 10 mm circuit tubing – approximate length 18"
- Patient port plug
- Face mask options (15 mm OD conical connector - ISO 5356-1):

MASK SIZE	DESCRIPTION	MASK SIZE	DESCRIPTION
X-Small Neonate	Anatomical Shape	Neonate	Round Shape
Small Neonate	Anatomical Shape	Infant	Round Shape
Small Infant	Anatomical Shape		
Infant	Anatomical Shape		

- Endotracheal tube* range (15 mm OD conical connector - ISO 5356-1):

TUBE ID (mm)	TUBE OD (mm)	TUBE ID (mm)	TUBE OD (mm)
2.0	2.9	3.5	4.8
2.5	3.4	4.0	5.4
3.0	4.2	4.5	6.2

* Endotracheal tubes are not available as a kit option. The SafeT T-Piece patient port will accept any 15 mm OD ISO 5356-1 compliant neonate/infant endotracheal tube.

WARNINGS

- ⚠ MR Unsafe.
- ⚠ Incorrect operation of this device can be hazardous.
- ⚠ SafeT T-Piece Resuscitator is capable of delivering high oxygen concentrations. DANGER – Use near open flames or sparks may result in combustion. Oil, grease, and other potentially flammable substances should not be used on the resuscitator or any parts of the resuscitator system.
- ⚠ Users should uncover the PEEP dial hole as soon as the peak inspiratory pressure (PIP) is delivered; failure to do so will result in an extended inspiratory time which could prevent adequate expiration.
- ⚠ DO NOT leave patient unattended when device is in use.
- ⚠ The recommended gas flow range is from 5-15 LPM; DO NOT EXCEED 15 LPM.
- ⚠ NEVER DELAY resuscitation. In the event a SafeT T-Piece Resuscitator is not immediately available, cannot be used effectively, or an adequate flow rate cannot be provided, follow department protocol or AHA guidelines for other accepted resuscitation procedures.
- ⚠ To be used only by personnel who have been trained in infant/neonatal resuscitation.
- ⚠ This device should only be used after verification that correct ventilatory pressures will be delivered to the patient.

CAUTIONS

- ⚠ Federal law restricts this device to sale by or on order of a physician.
- ⚠ Oxygen concentration should be monitored at all times using an oxygen analyzer.
- ⚠ Adjusting the flow rate on the flow meter will affect PIP and PEEP, so re-adjustment of PIP and PEEP may be necessary when flow has changed.
- ⚠ DO NOT attempt to disinfect any part of the SafeT T-Piece Resuscitator.
- ⚠ Reuse of this device may pose a risk of cross-contamination and the device may not perform as intended.

General Information

1. The SafeT T-Piece Resuscitator contains a variable PEEP dial along with an integrated manometer on the patient valve.
2. The adjustable PIP dial on the inspiratory pressure controller will allow the user to adjust the PIP pressure from 0 to 40 cm H₂O of pressure.
3. The pressure relief valve on the inspiratory pressure controller is a safety feature that limits the PIP from exceeding 40 cm H₂O of pressure.

4. The O₂ tubing is supplied with a red universal connector (Fits-All) so that the user can easily identify the tubing is connected to the appropriate gas source. The universal connector will allow connection to the flowmeter whether a nut/nipple connector is present or absent.
5. Use of the patient port plug is optional. It may be loose in package; reinsert into patient port to assist with PIP/PEEP set-up. Plug must be removed following set-up to allow for mask or tube connection to patient port.

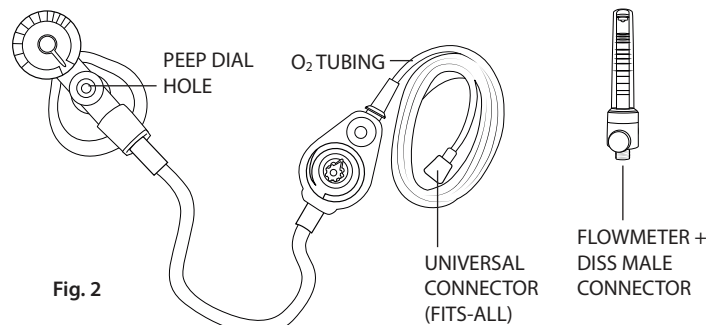


Fig. 2

Pre-Use Check

1. Connect the inspiratory pressure controller with the O₂ tubing provided to the gas source via the red universal connector (Fig. 2). If the nut/nipple connector is missing from the flowmeter, push the universal connector straight on to the DISS male connector. Screwing on the universal connector is not necessary.
2. Make sure the circuit tubing is securely connected to the patient valve.
3. Adjust the flow on the flowmeter between 5 and 15 LPM. 10 LPM is the most common flow used and is the recommended starting point.
4. Set the PIP by occluding the patient port with the patient port plug (Fig. 3) and PEEP dial hole with thumb or finger (Fig. 4). NOTE: Use of the plug is optional; occlusion may also be achieved by blocking the patient port opening with thumb or finger. Adjust the PIP dial with the opposite hand to achieve the desired PIP as indicated on the integrated manometer. Adjust the PIP dial (Lo - Hi) *clockwise* to increase PIP and *counter clockwise* to decrease PIP.
5. To set PEEP, uncover the PEEP dial hole, and while occluding the patient port, adjust the variable PEEP dial to obtain the desired pressure value as indicated on the integrated manometer. To adjust PEEP, turn the PEEP dial *clockwise* to increase PEEP and *counter clockwise* to decrease PEEP.

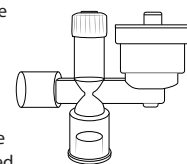


Fig. 3



Fig. 4

Directions for Use

1. After pressures have been verified, remove and discard the patient port plug and connect patient port to face mask (Fig. 5) and place over patient's mouth and nose, or connect patient port directly to an endotracheal tube.
2. Ventilate patient by placing and removing thumb (or finger) over the PEEP dial hole (Fig. 5) to allow inspiration and expiration achieving the desired PIP, PEEP, and respiratory rate. Monitor patient and continue ventilation as needed.
3. To administer continuous positive airway pressure (CPAP), set pressure using the PEEP dial (turn *clockwise* to increase pressure and *counter clockwise* to decrease pressure). Refer to the yellow PEEP range sticker on the side of the inspiratory pressure controller to assure the appropriate flow is being used to obtain the desired CPAP level. To deliver CPAP, the PEEP dial hole will need to remain open or uncovered. Connect the SafeT to the mask or airway accessory. If using a mask, make sure there is a proper seal to obtain the desired CPAP level. If PIP has not been set prior to CPAP being used, make sure a safe PIP is set using the integrated pressure manometer. PIP should be at least 5 cm H₂O pressure above the CPAP setting. NOTE: If PIP was set previously, that same PIP will be delivered if the PEEP hole is occluded.
4. Discard the device following use.

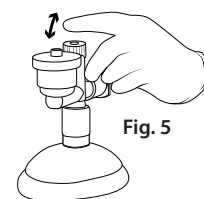


Fig. 5

Clearing Instructions

1. Inspect the resuscitator for vomitus/obstructive matter.
2. To remove vomitus, disconnect resuscitator from patient.
3. Tap patient valve several times while intermittently covering the PEEP dial hole to clear vomitus from patient port.
4. Re-test resuscitator for proper function.
5. If resuscitator does not function properly, discard and continue resuscitation with a new device.
6. Do not attempt to disinfect any part of the resuscitator.

Performance Specifications

Patient Body Mass Range	Less than 10 kg (22 lb)
Device Mass	160 g
External Dimensions	Fits through 300 mm x 600 mm rectangular opening (ISO 10651-5 - 6.4.1)
Delivery Pressure Range	0 to 40 cm H ₂ O
Expiratory Resistance	0.8 cm H ₂ O @ minimum PEEP setting of 6 LPM
Inspiratory Resistance	1.2 cm H ₂ O @ minimum PEEP setting of 6 LPM
Input Flow Range	5-15 LPM
Maximum Achievable Pressure	40 +/- 5 cm H ₂ O
Peak Inspiratory Pressure (PIP) Range	0 to 40 cm H ₂ O
Positive End Expiratory Pressure (PEEP) Range	1 to 3 cm H ₂ O @ 5 LPM 2 to 7 cm H ₂ O @ 8 LPM 4 to 12 cm H ₂ O @ 10 LPM 9 to 23 cm H ₂ O @ 15 LPM
Manometer Accuracy	+/- 3 cm H ₂ O for 0-15 cm H ₂ O / +/- 5 cm for > 15 cm H ₂ O
Dead Space	3.07 mL
Operation Time (Full E Cylinder - 660 Liters)	47 minutes @ 15 LPM
Storage Temperature Range	-40°C to 60°C, up to 95% RH
Operating Temperature Range	-18°C to 50°C, up to 95% RH
Patient Port	ISO 5356-1 - 15 mm taper female
Universal Connector (Fits-All)	Mates with DISS standard oxygen fittings