

Single Use Manual Resuscitator

Product Data Sheet



PRODUCT: Single Use Manual Resuscitator**DESCRIPTION / FUNCTION**

Flexicare's Single Use Manual Resuscitator is a device used for manual ventilation of a patient by trained operators in emergency/critical situations, where short term ventilation is demanded by the patient's medical condition (e.g. inadequate or no breathing). Manual squeezing of the resuscitator bag forces air or air/oxygen mixture into the patient's lungs via a face mask or pre-positioned airway tube with a 15mm male connection. A reservoir bag is present at the distal end of the device which fills with supplementary oxygen (if using). This can be squeezed into the resuscitator for administration if required.

Flexicare's Single Use Manual Resuscitators feature a one-way duck bill valve at the patient end to deliver fresh gas to the patient, whilst preventing ingress of exhaled air and potential re-breathing. A one-way valve is also present at the distal end of the device, ensuring that upon squeezing the Resuscitator Bag, air only travels towards the patient, and upon release of a squeezed bag, fresh ambient air with/without supplementary oxygen is drawn in. Flexicare's Single Use Manual Resuscitators incorporate a pressure relief valve. This valve limits the pressure within the resuscitator and patient lungs to 60cmH₂O (Adult) or 40cmH₂O (Adult, Paediatric, Infant). One variant of Flexicare's Adult Single Use Manual Resuscitators does not feature a pressure relief valve.

Flexicare's Single Use Manual Resuscitators are comprised of disposable components including compression bag, valves, tubing and connectors. They are intended for Adult, Paediatric and Infant patients, and are to be used by CPR-trained personnel only, within hospital and/or pre-hospital environments.

PRECAUTIONS / WARNINGS

- Do not use if packaging is open or damaged.
- Ensure Resuscitation Bag is only stored in its original collapsed position.
- Regularly check the Manual Resuscitator and its accessories to ensure functionality of the equipment in line with local guidelines.
- Note: The Manual Resuscitator is supplied with the Pressure Relief Valve Open.
- The Manual Resuscitator should only be used by CPR trained personnel.
- Do not use Manual Resuscitator in noxious or hazardous atmosphere.
- Single use device only – do not sterilise.
- Do not use supplemental oxygen when an open flame is present.

- Avoid the use of or contact with oil or grease
- Switch IMMEDIATELY to mouth-to-nose or mouth-mouth ventilation in accordance with local CPR guidelines if adequate ventilation is not received with the resuscitator.
- Should the non-return valve become blocked by vomit, blood or secretions during ventilation, remove the bag and mask from the patient, while directing it at the ground and away from the patient and other people, squeezing the bag hard. Repeat until the valve is clear.

SPECIFICATIONS / KEY FEATURES

- Conical connectors are compliant with ISO 5356-1.
- 22mm male/15mm female patient end connector end conical allows for connection to an array of patient airways e.g. catheter mounts & ET Tubes.
- 30mm conical at patient end for connection of a PEEP valve.
- Self-sealing CO₂ sampling Luer port.
- MDI port for administration of aerosol drugs (not supplied) if required.
- Manometer port for attachment of a pressure indicating manometer.
- Pressure relief valve (60cmH₂O, 40cmH₂O or plain (none) for Adult, 40cmH₂O for Paediatric and Infant).
- Oxygen tubing and connectors are compliant with BE EN 13544-2.
- Integrated non-return valve – reduced risk of patient rebreathing.
- Double swivel patient end connector - resuscitator bag to be rotated fully through 360°

	Adult	Paediatric	Infant
Part Number Series	038-71-94*	038-72-94*	038-73-94*
Resuscitator Bag Volume	1.49L	0.635L	0.37L
Pressure Relief (valve in open position)	60cm H ₂ O or 40cm H ₂ O	40cm H ₂ O	40cm H ₂ O
Stroke Volume One Hand	700 ml	450ml	170ml
Stroke Volume Two Hands	850 ml	490ml	N/A
Maximum Breaths per Minute (BPM)	45 BPM	105 BPM	98 BPM
Mask Size	5	3 or 2 and 1 (round)	1 and 0 (round)
O₂ Reservoir Bag Volume	1.6L	1.6L	0.65L
O₂ Tubing Length	3.0m	3.0m	3.0m
Patient Connector (ISO 5356)	22mm Male / 15mm Female	22mm Male / 15mm Female	22mm Male / 15mm Female
Expiratory Connector (ISO 5356; ISO10651-4)	30mm Male	30mm Male	30mm Male
Operating Temperature Limits	-18°C to 50°C (-0.4°F to 140°F)	-18°C to 50°C (-0.4°F to 140°F)	-18°C to 50°C (-0.4°F to 140°F)
Storage Temperature Limits	-40°C to 60°C (-40°F to 140°F) at between 40% and 95% humidity	-40°C to 60°C (-40°F to 140°F) at between 40% and 95% humidity	-40°C to 60°C (-40°F to 140°F) at between 40% and 95% humidity
Storage Conditions	Retain in packaging in a cool dry place away from direct sunlight.	Retain in packaging in a cool dry place away from direct sunlight.	Retain in packaging in a cool dry place away from direct sunlight.

PRODUCT RANGE

Product Code	Product Description
SINGLE USE ADULT	
038-71-940	Adult Single Use Resuscitator + Pressure Relief 60cmH ₂ O+Mask Size 5
038-71-941	Adult Single Use Resuscitator + Pressure Relief 60cmH ₂ O + Mask Size 5 + Manometer
038-71-942	Adult Single Use Resuscitator + Pressure Relief 60cmH ₂ O + Mask Size 5 + Peep Valve
038-71-943	Adult Single Use Resuscitator without Pressure Relief + Mask Size 5
038-71-944	Adult Single Use Resuscitator without Pressure Relief No Strap + Mask Size 5
038-71-945	Adult Single Use Resuscitator + Pressure Relief 40cmH ₂ O + Mask Size 5
SINGLE USE PAEDIATRIC	
038-72-940	Paediatric Single Use Resuscitator + Pressure Relief 40cmH ₂ O + Mask Size 2 + Mask Size 1 Round
038-72-941	Paediatric Single Use Resuscitator + Pressure Relief 40cmH ₂ O + Mask Size 2 + Mask Size 1 Round + Manometer
038-72-942	Paediatric Single Use Resuscitator + Pressure Relief 40cmH ₂ O + Mask Size 2 + Mask Size 1 Round + Peep Valve
038-72-946	Paediatric Single Use Resuscitator + Pressure Relief 40cmH ₂ O + Mask Size 3
SINGLE USE INFANT	
038-73-940	Infant Single Use Resuscitator + Pressure Relief 40cmH ₂ O + Mask Size 1 + Mask Size 0 Round
038-73-941	Infant Single Use Resuscitator + Pressure Relief 40cmH ₂ O + Mask Size 1 + Mask Size 0 Round + Manometer
038-73-942	Infant Single Use Resuscitator + Pressure Relief 40cmH ₂ O + Mask Size 1 + Mask Size 0 Round + Peep Valve
SINGLE USE PACKS	
038-74-942	Adult, Paediatric & Infant Single Use Resuscitation Pack
SINGLE USE ACCESSORIES	
038-71-966	Single Use Manometer

MATERIALS

Component	Material
Patient End Connector (with ports)	Acrylonitrile Butadiene Styrene (ABS)
Patient End Connector	Acrylonitrile Butadiene Styrene (ABS)
Peep Valve Connector	Acrylonitrile Butadiene Styrene (ABS)

Patient End Umbrella Valve	Silicone
Patient Swivel Connector	Polycarbonate (PC)
Patient End Peep Valve Connector Cap	Polyvinyl Chloride (PVC)
MDI/Manometer Port Cap	Silicone
Pressure Relief Driver	Acrylonitrile Butadiene Styrene (ABS)
Pressure Relief Spring	Spring Steel
Pressure Relief Cover (60cmH ₂ O)	Polycarbonate (PC)
Pressure Relief Cover (40cmH ₂ O)	Polycarbonate (PC)
Bag Neck	Acrylonitrile Butadiene Styrene (ABS)
Luer Self Sealing Valve Body	Acrylonitrile Butadiene Styrene (ABS)
Patient End Connector Neck O-ring	Silicone
Single Use Bag	Thermoplastic Elastomers (TPE)
Resus Bag Strap	Silicone
Machine End Connector	Acrylonitrile Butadiene Styrene (ABS)
Machine End Bag Neck	Acrylonitrile Butadiene Styrene (ABS)
Machine End Connector O-ring	Silicone
Machine End Umbrella Valve Large	Silicone
Machine End Umbrella Valve Small	Silicone
Machine End Reservoir Bag Connector	Acrylonitrile Butadiene Styrene (ABS)
Reservoir Bag for Resuscitator	Polyvinyl Chloride (PVC) Film
Manometer End Cap	Polyvinyl Chloride (PVC)
Manometer Housing	Acrylonitrile Butadiene Styrene (ABS)
Manometer Slider	Acrylonitrile Butadiene Styrene (ABS)
Manometer Concertina Seal	Silicone
Manometer Spring	Spring Steel
Patient End Swivel Connector O-ring	Silicone
Star Lumen 3.0mm with Connector	Polyvinyl Chloride (PVC)
Pressure Relief Valve Seal	Silicone
Luer Self Sealing Valve Plunger	Silicone
NRV Plug	Acrylonitrile Butadiene Styrene (ABS)

LATEX CONTENT

Flexicare's Single Use Resuscitators do not contain natural rubber latex.

DEHP CONTENT

Flexicare's Single Use Resuscitators do not contain phthalate DEHP.

SINGLE-USE

Flexicare's Single Use Resuscitators are to be disposed of after one use. DO NOT reuse, sterilise or autoclave.

STERILITY

Flexicare's Single Use Resuscitators are supplied non-sterile.

STORAGE

Store in a cool, dry place out of direct sunlight.

SHELF LIFE

Flexicare declares a shelf life for 5 years from date of manufacture. This is based on the stability of the component devices and the raw material sourced. Expiry date is clearly marked on individual product packaging.

DISPOSAL CONSIDERATIONS

Dispose as clinical waste, in accordance with hospital policy, local guidelines and regulations.

PACKAGING MATERIALS

Primary – Polybag - Polyethylene (PE)

Secondary – Carton / Box Cardboard