

SOLID SILICONE REUSABLE RESUSCITATOR

USER MANUAL



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Intended Use

The FirstCare Solid Silicone reusable resuscitator is a self-inflating manual resuscitator that is intended for patients requiring total or intermittent ventilatory support. It provides positive pressure ventilation and allows spontaneous breathing with a face mask. Ventilation is possible with or without supplemental oxygen.

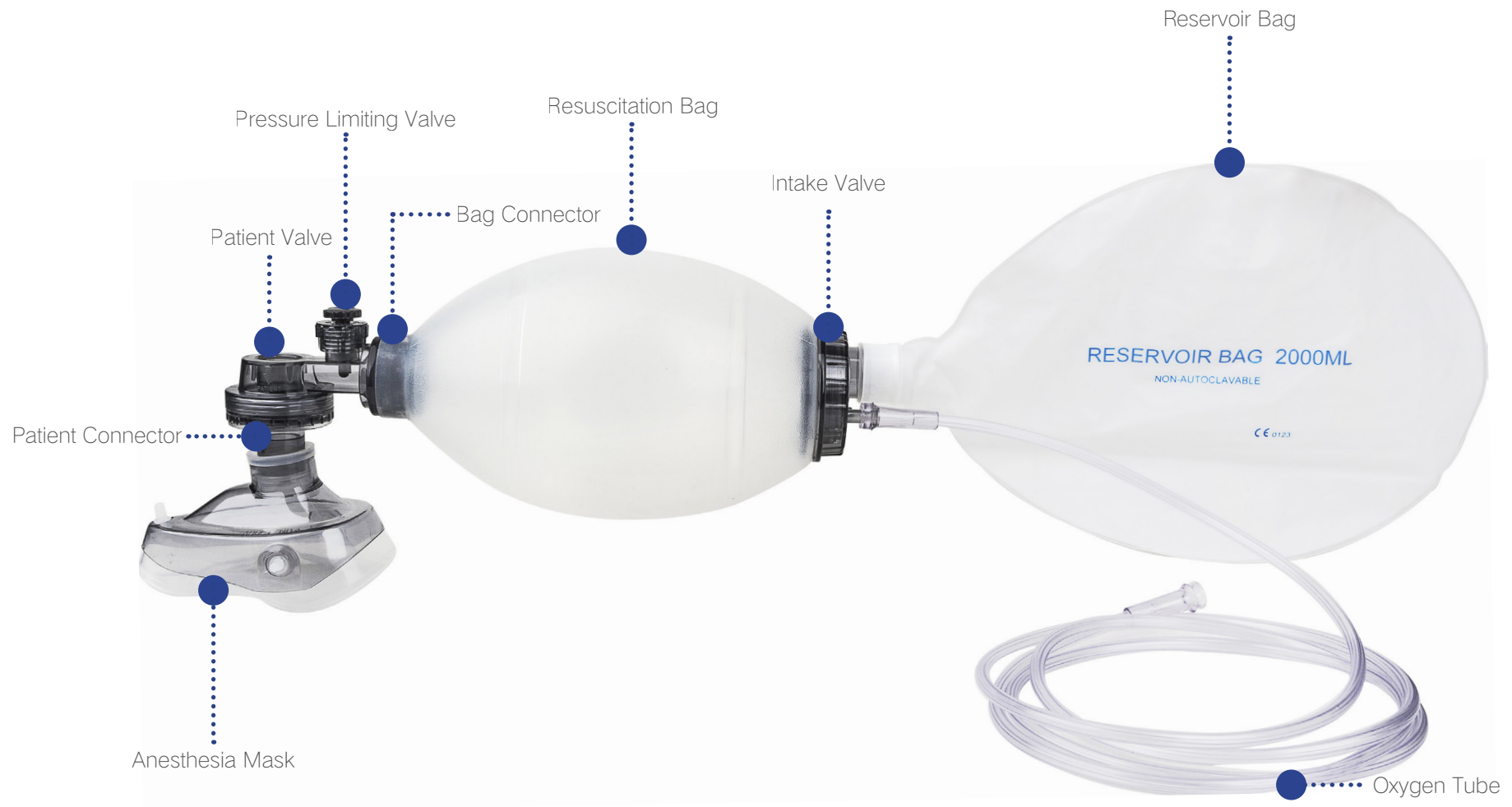
The FirstCare Solid Silicone Resuscitator is available in three sizes:

The Adult model is intended for patients over 40 kg.

The Pediatric model is intended for patients from 10 kg to 40 kg.

The Infant model is intended for patients below 10 kg.

This User Guide applies to all the above three models unless otherwise specified.



Product Overview

Part Name	Material	Remark
Anesthesia Mask	Silicone	Neonate, Infant, Pediatric
Anesthesia Mask	Silicone+PC	Adult-S, Adult-M, Adult-L
Patient Connector	PC	
Patient Valve	PC	
Pressure Limiting Valve	PC+Silicone+Steel	Infant & Pediatric: 40cmH ₂ O Adult: 60cmH ₂ O
Bag Connector	PC	
Resuscitation Bag	Solid Silicone	
Intake Valve	PC	
Reservoir Bag	EVA	
Oxygen Tube	PVC	

Assemble

The patient connector, patient valve and, pressure limiting valve, bag connector, and intake valve have already been well-assembled into PP box, please follow steps below to finish the assembly:

- ① Stretch the foldable and space-saving resuscitation bag (adult & pediatric type) to the full extend and visually check the proper valve action while squeezing the bag;
- ② Connect the anesthesia mask into patient connector via the mask outlet;

If external oxygen source like oxygen tank or cylinder is available, then:

- ③ Extend and connect the reservoir bag to the intake valve;
- ④ Extend the oxygen tube to the intake valve in one side and to the outer source in the other side. Set oxygen flow not to exceed 15 LPM or under the instruction of professionals.

Disassemble

- ① Remove the anesthesia mask from the patient connector;
- ② Unscrew the reservoir bag and oxygen tube from the intake valve;
- ③ Unscrew the patient valve and intake valve from the resuscitation bag;
- ④ Disintegrate the pressure limiting valve and patient valve connected to the patient valve;
- ⑤ Separate the lid from the patient valve;
- ⑥ The patient valve disk should not be separated from the patient connector.

Pre-use Test

Resuscitation Bag

Connect a 1.5-liter test lung to the patient connector. Squeeze and release the resuscitator several times and make sure the test lung expands and deflates visibly and accordingly. If not, check the inlet shutter and the patient valve shutter.

Pressure Limiting Valve

Close the pressure limiting valve and patient connector with a thumb while compressing the resuscitator bag firmly to check the tightness and proper valve fitting;

Open the pressure limiting valve and close the patient connector with a thumb. The pressure limiting valve should be activated and it should be possible to hear the hissing expiratory flow from the valve.

Reservoir Bag

Supply a gas flow of 3.0 L/min to oxygen tube and check if the reservoir bag fills. If not, check if it is the problems of valve shutters, torn bag or blocked oxygen tube.

Operation Instruction

- ① Open the patient's mouth and clear all the airway excretions (apply emergency aspirator if available). Tilt the head fully backwards and push the jaw upwards with neck stretched to open the airway.
- ② To assist ventilation it may be beneficial to insert an artificial airway. Be careful that it does not push the tongue back and thus obstruct the throat.

Operation Instruction

- ③ Put the mask tightly to the patient's mouth and nose with the thumb and index finger of the left hand pressed on it and the other three fingers keep the jaw upwards. Squeeze the ventilation bag properly and watch the chest expand.
- ④ Release the bag promptly and allow the chest to deflate. Repeat 12-20 times per minute or 30 times in case of infants.

Caution

- ① The resuscitators should only be used by persons who have received adequate training in the use of resuscitators.
- ② If it fails to insufflate, check the airway obstruction or the head position.
- ③ If inadequate ventilation is achieved with the resuscitator, immediately turn to mouth-to-mouth or mouth-to-nose ventilation.
- ④ The correct ventilation frequency may vary. Please follow the current ventilation frequency recommended by national or international guideline.
- ⑤ If the patient vomits during the ventilation, immediately clear the patient's airway and then squeeze the bag a few times before resuming ventilation.
- ⑥ The pressure limiting valve would open to certain extent and a hissing sound would be heard. If higher pressure is required, press and spin the button while squeezing the bag. The valve will then shut down.
- ⑦ The resuscitator (silicone mask, resuscitation bag and valves) can be autoclaved for up to 20 times only. Replace the reservoir bag and oxygen tube each time before reusing the resuscitator.

Warning

- ① Resuscitators should not be used with supplemental oxygen where smoking is permitted or when fire, flame, oil or grease is in close proximity.
- ② Resuscitators should not be used in toxic or hazardous atmospheres.
- ③ Use of non-FirstCare parts may affect safety and/or performance.
- ④ High pressure ventilation may cause lung rupture or stomach distension on certain patients.

Cleaning and Disinfection

To reduce the risk of cross-contamination, follow these instructions after each use.

Inspection

Carefully inspect all parts for signs of wear or damage. Worn or damaged components must be discarded and replaced with new components.

Washing and Rinsing

The resuscitators must be cleaned before high-level disinfection or sterilisation. They can be manually cleaned, or cleaned in an automatic washer/disinfector :

Automatic Cleaning Washer/Disinfector (applies to all parts except Reservoir Bags)
<ul style="list-style-type: none"> Place parts in wire baskets.
<ul style="list-style-type: none"> Cycle 1: 90 - 95 °C (194 - 203 °F) for more than 12 seconds.
<ul style="list-style-type: none"> Total process time: approx. 52 min.
<ul style="list-style-type: none"> Cycle 2: Use a Non-enzymatic alkaline detergent containing 2 - 5% NaOH.

Cleaning and Disinfection

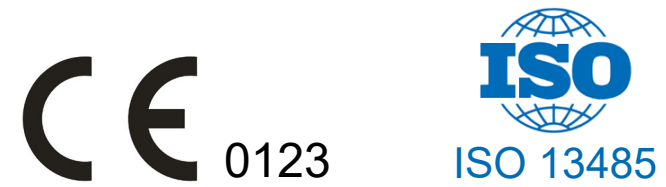
Manual Cleaning
<ul style="list-style-type: none"> Rinse parts under cold running water.
<ul style="list-style-type: none"> Submerge parts in water at 30 - 40 °C (86 - 104 °F). Ensure that all surfaces are submerged for at least 2 minutes.
<ul style="list-style-type: none"> Submerge all parts in water at 60 - 70 °C (140 - 158 °F) which contains dish washing detergent.
<ul style="list-style-type: none"> Thoroughly clean all surfaces using a brush as necessary.
<ul style="list-style-type: none"> Rinse all components in detergent-free water at 30 - 40 °C (86 - 104 °F).
<ul style="list-style-type: none"> Dry the components thoroughly. Inspect all components to confirm that they are clean and dry. If parts are worn or damaged, discard them.

Sterilization

To obtain sterilization of the resuscitator, follow method below :

Method	Process Parameters		Post-Treatment
	Temperature	Exposure time	
Steam Autoclaving (gravity-displacement)	Autoclave at 132 - 137 °C (270 - 279 °F)	15 min (+30s)	Allow parts to cool and dry
Steam Autoclaving (prevacuum-pulse)	Autoclave at 134 - 137 °C (273 - 279 °F)	3 min (+30s)	

Type	Infant	Pediatric	Adult
Patient weight	≤ 10kg	10kg-40kg	> 40kg
Stroke volume	150ml	400ml	800ml
Resuscitator volume	280ml	600ml	1650ml
Dimensions L x D	135 x 75mm	146 x 100mm	212 x 131mm
Resuscitator weight	350g	410g	600g
Pressure limiting valve	40cmH2O	40cmH2O	60cmH2O
Inspiratory resistance	< 5cmH2O (at 50L/min)		
Expiratory resistance	< 5cmH2O (at 50L/min)		
Bag reservoir volume	1600ml	1600ml	2000ml
Patient connector	ISO5356-1 : φ22/15mm		Male/Female
Recommended operating temperature	-18°C ~ +50°C		
Storage	Tested at -40°C and 60°C		

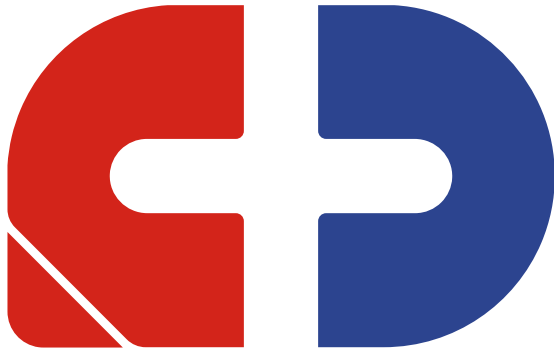


Warranty

This equipment is manufactured from the finest quality materials. Each individual part is subject to strict quality control tests to ensure exceptionally high standards.

The manufacturer warrants to the purchaser of FirstCare Resuscitators that its component parts are free from defects in material and workmanship for a period of one year from the date of purchase. The manufacturer will replace and/or repair all parts of the resuscitator at its option for one year from the date of purchase at no cost to the purchaser, upon the notification of the defects, in writing by the purchaser. All shipping costs shall be borne by the purchaser.

The manufacturer shall be liable under this warranty only if the resuscitator and its parts have been used in the normal manner described in the instruction manual.



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