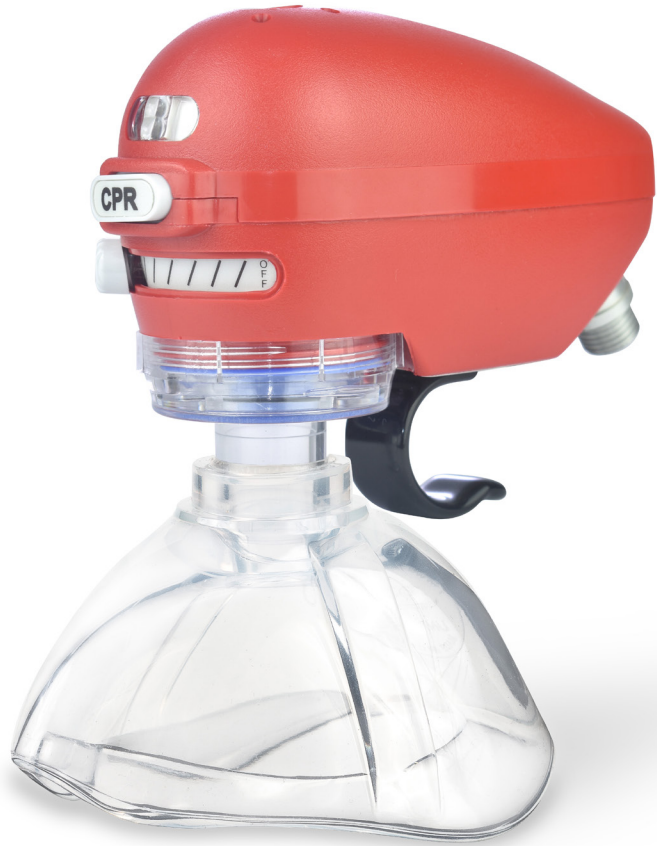
USER MANUAL

o_two controlled™ ventilation



CAREvent® ALS

AUTOMATIC AND MANUALLY TRIGGERED RESUSCITATOR

01CV3000

Part Number: 17MP9656 - REV 16 Feb, 2021

TABLE OF CONTENTS

1. THE CAREvent® ALS Handheld Automatic and Manually Triggered Resuscitator

1.1. Introduction

The CAREvent® ALS Handheld Resuscitator provides trained individuals with a safe and effective means of providing artificial ventilation during respiratory and/or cardiac arrest.

The CAREvent® ALS Handheld Resuscitator is lightweight, portable, and extremely durable. Designed for the demands of the emergency medical and rescue environment, they can be operated anywhere an oxygen cylinder or piped wall outlet is present.

Note: An Automatic and Manually Triggered Resuscitator is considered a critical device, and its components considered critical components. Only those individuals trained in Cardio-Pulmonary Resuscitation and the operation of oxygen-powered ventilators should use this equipment. Thoroughly review this instruction manual before use.

INTENDED USE:
The CAREvent CA resuscitator is intended for use in pulmonary resuscitation during respiratory and/or cardiac arrest, and to provide short term ventilatory support for both intra-hospital and inter-hospital of non-breathing patients.

Note: This resuscitator is intended for first response to a breathing emergency only and that patients must be transferred to a transport and emergency ventilator as equipment becomes available.

⚠ WARNING ⚠

Resuscitator used in contaminated environments can be hazardous unless entrainment is prevented or appropriate filtration is provided.

⚠ WARNING ⚠

This resuscitator is not recommended for use on neonates and pregnant or nursing women.

PHT DEHP The material used in this device contains “DEHP”.

1.2. 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 the CAREvent® ALS Handheld Resuscitator that its component parts are free from defects in material and workmanship for a period of two years from the date of purchase. The manufacturer will replace and/or repair all parts of the resuscitator at its option for two years 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 and serviced in the normal manner described in the instruction manual. There are no other expressed or implied warranties. This warranty gives no specific legal rights. You may also have other rights that may vary according to local regulations.

1.3. Features

The CAREvent® ALS Handheld Resuscitator is a pneumatically powered, time/volume cycled ventilatory resuscitator with the added feature of a Manually Actuated, Automatic Ventilation Override Button (Manual Button) to allow the operator to control the ventilations manually at a rate and volume they desire.

In addition the CAREvent® ALS allows the breathing patient to “Demand Breathe” on 100% oxygen while their inspiratory efforts causes the automatic cycling to cease. Should they stop breathing, the ventilator will automatically restart cycling in the setting selected.

The “pneumatic logic circuit” can be run on either approved, compressed, breathing air or medical oxygen. The unit is self contained and only requires its attachment to a regulated oxygen or air supply (as specified) for immediate use.

The CAREvent® ALS Handheld Resuscitator:

- Delivers 100% oxygen during resuscitation (when attached to an oxygen source).
- Meets American Heart Association/J.A.M.A. recommendations for C.P.R.
- Provides physiologically normal respiratory rates and volumes.
- Has an Audible Airway Pressure Limiting System set in accordance with the recommendations of the American Heart Association/ JAMA.
- Is lightweight and extremely durable.
- Is designed for emergency resuscitation and pre-hospital care / patient transport and for resuscitation and inter-departmental transport in the hospital environment where the potential patient use is with children and adults.
- Has a Manually Actuated, Automatic Ventilation Override Button (Manual Button).
- Has a seven position selector providing six, preset, automatic settings for a range of patient sizes from children to adults with tidal volumes and frequencies of ventilation in line with established guidelines for the range of patient sizes indicated and an OFF position to allow the ventilator to be left in a “standby mode” with the oxygen supply turned on.
- Provides “Demand Breathing” with automatic cycling shut off and re-start.

1.4. Performance Specifications

(All specifications are subject to a tolerance of +/- 10% except the I:E Ratio which is subject to a tolerance of +/- 20% and Maximum Airway Pressure +0/-10%)

Tidal Volume	150 - 600 ml
Breaths per Minute	20 – 10
I:E Ratio	1 : 2
Automatic Flow Rate	9.0 - 18.0 L/min
Manual Flow Rate	As per automatic setting
Manual Overide Delay Time	17 - 23 Sec
Demand Breathing Flowrate	0 - 120 L/min
Demand Breathing Triggering Pressure	-2.0 cmH_20 / -2.0 mBar
Inspiratory Resistance	-6.0 cmH_20 / -5.9 mBar
Expiratory Resistance	6.0 cmH_20 / 5.9 mBar
Auto Shut Off Delay Time	5 - 8 Sec
Input Pressure	45 - 87 PSI (3.0 - 6.0 Bar)
Maximum Airway Pressure	60 cmH_20 / 58.8 mBar
Operating Temperature	-18°C - + 50°C / 0°F - +122°F
Storage Temperature	-40°C - +60°C / -40°F - +140°F
Input Connection	9/16" DISS
Patient Connection	15 / 22 mm
Weight	16 OZ (0.45 Kg)(ALS) 14 OZ (0.40 Kg)(BLS)
Size	140 x 63 x 73 mm / 5.5" x 2.5" x 2.9"
Cylinder Duration: CAREvent® ALS	31 ~ 103 minutes*
Cylinder Duration: CAREvent® BLS	69 ~ 138 minutes*

* (Based on an Aluminum "D" size cylinder containing 415 Litres of oxygen.)

1.5. Safety Precautions

The CAREvent® ALS Handheld Resuscitator is designed to provide emergency ventilatory support to patients suffering from respiratory and/or cardiac arrest.

The CAREvent® ALS Handheld Resuscitator is intended for use by suitably trained and qualified personnel. The following precautions should always be observed:

1. Do not leave the patient unattended.
2. When not in use, always turn off the cylinder.
3. Never allow oil or grease to come into contact with any part of the cylinder, regulator or resuscitator.
4. Do not disassemble any part of the resuscitator except where described in this manual, as any unauthorized disassembly will invalidate the warranty.
5. After use, always ensure that all components are cleaned in accordance with the instructions provided in this manual.
6. Ensure that all components are reassembled correctly and that all items are replaced in the carrying case.
7. After use, always ensure that a full air or oxygen cylinder is attached before returning the unit to its normal storage position.
8. Ensure that a new sealing washer is used every time you attach the regulator to the cylinder.
9. It is recommended that an alternative means of ventilating the patient be available in case of gas supply failure.

2. Pre Use Function Check

2.1. Set Up

Along with the contents of the shipping cartons you will require the following items to enable you to undertake the pre-use functional check:

1. Full oxygen cylinder
2. Oxygen regulator with a 60 PSI 9/16 DISS outlet. The regulator must be able to output a minimum of 120 L/min at no less than 45 PSI (3.1 Bar).

Having connected the supply hose to the regulator, ensure that the Setting Selector is in the OFF position and turn on the oxygen supply. Using a mild soap solution, spray the input connection to the resuscitator to check for leaks. If any leak is present, tighten the connection and re-test.

Once no leaks are found, connect the Test Lung to the 15/22 mm patient connector on the resuscitator. Using the Sliding Setting Selector , select the first automatic setting.

2.2. Testing of the Individual Features of the Ventilator.

The following features can be individually tested during the pre-use Functional Check:

1. Maximum Airway Pressure and Audible Alarm
2. Frequency/Tidal Volume Adjustment
3. Manual Ventilation
4. Demand Valve Function and Automatic Circuit Shut Off

3. Operating Procedure

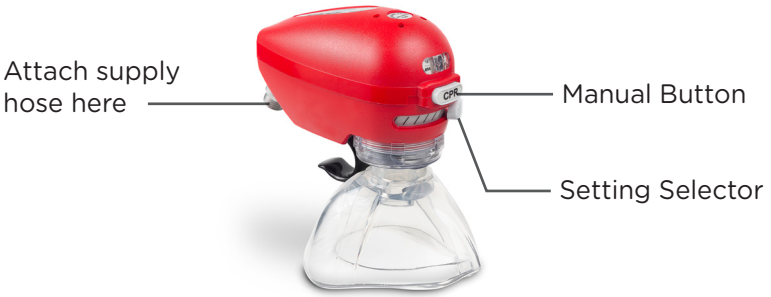
3.1. Connecting the Supply Hose and Patient Circuit

The supply hose provided is attached to the oxygen inlet on the rear of the resuscitator and is tightened “finger tight” (fig 1).

⚠ WARNING ⚠

The use of excessive force in tightening the supply hose may damage the seal and /or thread.

The facemask is attached to the patient connection port by simply pushing the mask onto the 22mm taper.



Connecting the supply hose (fig 1)

3.2. Manual Ventilation and Cardiac Compressions.

The CAREvent® ALS Handheld Resuscitator has a Manually Actuated, Automatic Ventilation Override button (Manual Button) to assist in the timing of ventilations in conjunction with external cardiac compressions.

By using the Manual Button, the operation of the ventilator can be easily timed with the chest compressions so as to avoid the potential problem of the aspiration of stomach contents due to gastric distension which may occur if overlap of chest compression and inflation occurs. (It has been shown in some studies that, in patients that are intubated, this overlap of compression and inflation may increase cardiac output without the danger of gastric distension.) The flowrate provided is equivalent to the setting on the automatic setting selector providing flowrates equivalent to the size of patient being ventilated, thereby reducing airway pressures and the risk of aspiration of stomach contents still further.

1. If no respiratory effort is observed, position yourself above the patient's head and apply the face mask over the patients mouth and nose. The thumb and index fingers are used to hold the mask to the face while the remaining three fingers of each hand are placed along the angle of the jaw. A tilt action is used to hyperextend the neck and move the jaw forward. This helps displace the tongue away from the back of the throat and maintains an open airway.
2. Select the tidal volume/frequency of ventilation for the size of patient being resuscitated. Depress the manual button and observe the rise of the patient's chest. Release the button when chest rise is adequate.
3. If the patient's chest does not rise or gas escapes around the mask or the pateint valve(A) (Fig.3) operates, reposition the patients head and adjust your hand position to obtain an effective mask seal and an open airway.
4. Monitor the patient's skin, nailbed and lip colour.
5. If mask indicates signs of vomitus, remove immediately and clear the airway. Restart ventilation immediately after clearing airway.
6. Continue ventilation at an appropriate rate until relieved or until spontaneous breathing returns.

3.3. Automatic Ventilation

1. If you have been ventilating manually simply release the manual button and after a short pause (5 - 8 seconds) (17-23 seconds in the G05 model), the ventilator will commence automatic cycling at the rate and volume selected. If you are commencing automatic ventilation immediately, rotate the setting selector to the setting appropriate for the size of patient being ventilated and the ventilator will commence automatic cycling (fig 1).

2. Closely observe the patient's chest movements. If there is any leak from around the mask or any obstruction in the patients airway (blow off valve will operate) reposition patients head and adjust mask and hand position to ensure a good airway and mask to face seal.

3. Should repositioning the mask and adjusting hand/neck position not resolve the situation adjust the automatic selector control to establish the correct tidal volume. This is accomplished by moving the control toward the child setting if the blow off valve operates or towards the adult setting if chest rise is insufficient. This can be done by simply using your thumb to slide the control without removing your hand from the mask.

⚠ WARNING ⚠

Automatic ventilation of the patient who is intubated or whose mask is held in place with the optional head harness system, does not mean that the patient is safe to be left unattended and constant observation of the patient's pulse and chest movement must be continued.

⚠ WARNING ⚠

The use of gas pressure regulators that do not maintain a minimum output pressure and flowrate in line with the requirements of the specification may cause the device to fail resulting in the patient not being ventilated.

Control Position	1	2	3	4	5	6
Tidal Volume V_t (ml)	150	200	300	400	500	600
Frequency (BPM	20	20	10	10	10	10
Minute Volume Vm (ltrs)	3.0	4.0	3.0	4.0	5.0	6.0
Automatic Flow Rate (L/min)	9.0	12.0	9.0	12.0	15.0	18.0
Body Weight (kg) min.	21	28	42	57	71	85

Automatic Adjustable Setting Selections (fig 2)

3.4. Action to be taken if patient vomits during resuscitation

Should the patient vomit into the mask during resuscitation the following steps should be followed to clear the foreign material:

1. Remove the mask from the patient's face and clear any foreign material from the patients airway. Depress the manual button or allow the resuscitator to cycle automatically for a few breaths to clear the mask and valve of foreign material.
2. If depressing the manual button repeatedly or automatically cycling the resuscitator does not clear the foreign material from the patient valve,either disconnect the resuscitator from the gas supply or turn the selector to the OFF position, remove the facemask and unscrew patient valve swivel housing (a) from the resuscitator body being careful to ensure that the diaphragm (b) is retained (Fig.3).
3. Shake out any foreign material from the resuscitator, diaphragm, face mask and patient valve swivel housing.
4. Rotate the selector to the appropriate position and either operate the manual button to blow out any contaminant or cycle automatically for a few breaths.
5. Re-assemble diaphragm, patient valve and face mask and operate the manual button or automatically cycle the resuscitator for a few breaths to ensure correct function.
6. Restart resuscitation as previously indicated.

Note: When using the single use patient valve, vomitus may be forced past the diaphragm and contaminate the bio- filter. This may necessitate the use of a new single use valve.

3.5. Demand Breathing and Automatic Circuit Shut Off

Should the patient commence spotaneous breathing at a flowrate of greater than 30 lpm for more than 1 second the CAREvent® ALS will sense the patient's inspiratory effort and will stop cycling automatically allowing the patient to "Demand Breathe" at their own rate and volume on 100% oxygen (if connected to an oxygen supply). If they cease spontaneous breathing the ventilator will recommense automatic cycling after a delay of 5 - 8 seconds (depending on the depth of the patients previous respiration) without intervention by the rescuer.

Note: The use of a Transport Ventilator Circuit with the CAREvent® ALS will increase Demand Valve Triggering Pressure due to the secondary patient valve. The use of the Transport ventilator Circuit does not increase the patient valve deadspace.

4. Servicing

4.1. Routine Maintenance

⚠ WARNING ⚠

The CAREvent® ALS Automatic Rescue Resuscitator is designed to provide respiratory support in emergency situations. Failure to follow the maintenance and inspection routines properly could result in incorrect operation of the resuscitator.

To ensure proper operation of the resuscitator regular inspection and checking of the resuscitator and accessories for correct function should be undertaken by a responsible member of staff on a routine basis. This check is to ensure that all of the accessories and resuscitator components are present, the air or oxygen cylinder is full and that the resuscitator is in working order.

Regulator working pressure, suction (if equipped), and ventilator limiting pressures should be checked at least every six months, and more frequently in high use applications.

Level I Preventative Maintenance should be performed annually and a Level II Factory Preventative Maintenance Service should be performed every 2 years.

The product is not designed for field disassembly or service outside that indicated in this manual. Any malfunctioning units should be returned to the manufacturer or an Authorised Dealer. Unauthorised repairs will nullify the product's warranty.

Note: Units with test parameters outside of their ranges listed in the product specifications, should not be used. Any units not meeting performance criteria should be returned to the Manufacturer or an authorized repair centre.

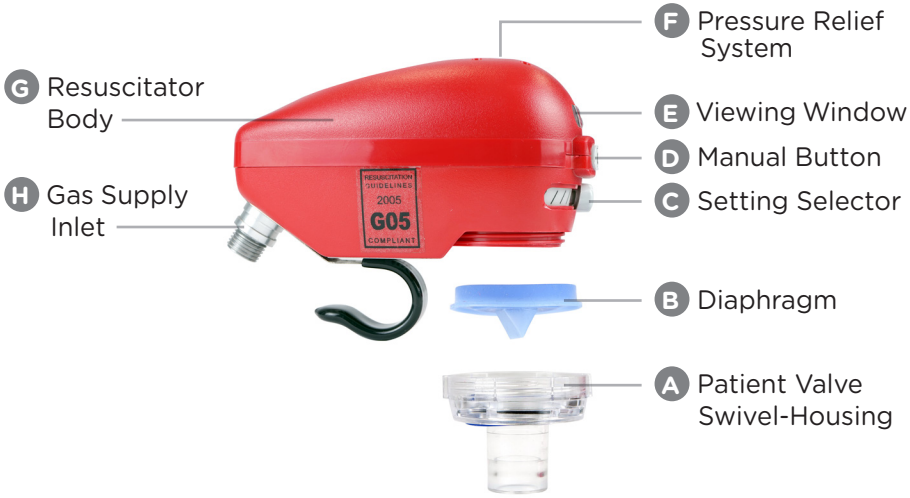
	DESCRIPTION	PROCEDURE	CRITERIA	SCHEDULE	BY
PM	Visual Inspection	User Manual Chapter 4.1 Monthly Checking	Device in work order, gas tanks are full, no missing item	Month	User
PM	Function Check	Regulator work pressure limiting pressure	Within specification	Every 6 months	User
PM	Level I	Service Manual	Within specification	Every year	User
Servicing	Level II Service	Service Manual	Meet product specifications	Every 2 years	Manufacturer/ Service Center

4.2. Cleaning the CAREvent® ALS Resuscitator and Accessories

Routine cleaning of the equipment should be undertaken to maintain the equipment in a clean condition.

Reusable patient valve swivel housing and diaphram can be cleaned using a mild soap solution and disinfected using a legally marketed commercially available disinfectant, suitable for the application. Single use patient valves and masks should be discarded after each patient use and replaced with a new unit.

All other components should be wiped clean with a mild soap solution. Under no circumstances should the complete unit be allowed to be soaked or immersed in cleaning solutions.



Disassembly of the resuscitator (fig 3.)

The Resuscitator must be thoroughly cleaned after each patient use.

1. Operate CAREvent® ALS Handheld Resuscitator to blow out any contaminant from the patient valve.
2. Ensure CAREvent® ALS Handheld Resuscitator is disconnected from the gas supply source.
3. Remove the patient valve swivel housing (a) from the body of the resuscitator (c), being careful to ensure that the diaphram (b) is retained (fig 3).
4. Remove the facemask from the resuscitator (after removing the mask retaining insert (if supplied) using the extraction tool).
5. Shake out any foreign material.
6. Wash all components thoroughly in a mild soap solution and disinfect as required.
7. The resuscitator can be wiped over with a soft cloth and mild soap solution.
8. Dry all components thoroughly.
9. Reassemble unit, connect to an air or oxygen supply to check operation prior to packaging for emergency use.

Note: If a single use patient circuit is used, safely dispose of after use.

5. CAREvent® ALS Handheld Resuscitator Accessories

ORDER N⁰	PART
17MP9039	Reusable Patient Valve Swivel Housing
01PV1121	Reusable diaphragm (duckbill style)
01CV8015-Cs	O-Two Deluxe Disposable Ventilation Circuit with PEEP Port
17MP1535-Cs	Anti-Entrainment Ring
01FG6500	Mask Retaining Insert
01FG6501	Mask Insert Extraction Tool
01FG6502	Head Harness System
01CV8010-Cs	Single Use Transport Ventilation Circuit

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