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O-Two MEDICAL TECHNOLOGIES INC
"Innovation in Resuscitation"

CAREVent® ALS+

AUTOMATIC AND MANUALLY TRIGGERED RESUSCITATOR

USER MANUAL

G2K ☐ G05 ☐ CPAP ☐

Made in Canada by
O-Two Medical Technologies Inc.
17MP9658 - Rev K Sept. 2008

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CHAPTER 1

1.1 Introduction

The CAREvent® ALS+ Resuscitator provides trained individuals with a safe and effective means of maintaining artificial ventilation during respiratory arrest for patients with body mass specified in (fig 2) of section 2.4.

The CAREvent® ALS+ 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 or breathing air supply 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.

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.

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+ 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 the other rights that may vary according to local regulations.

THE RESUSCITATOR MUST BE THOROUGHLY CLEANED AFTER EACH PATIENT USE.

1. Operate CAREvent® ALS+ to blow out any contaminant from the face mask.

2. Ensure CAREvent® ALS+ is disconnected from the gas supply source.

3. Remove the Single Use Transport Ventilation Circuit (a) from the resuscitator (Fig. 3).

   If you are using the Deluxe ReusableTransport Ventilation Circuit , disassemble the patient valve being careful to ensure that the diaphram (a) is retained (Fig. 4) .

NOTE: Single Use Transport Ventilation Circuits should be safely disposed of after each patient use.

4. Wash all reusable cicuit components thoroughly in a mild soap solution and disinfect as required.

5. The CAREvent® ALS+ housing (b) can be wiped over with a soft cloth and mild soap solution (Fig 3).

6. Dry all components thoroughly.

7. Reassemble unit and replace the Single Use Transport Ventilation Circuit or suitably cleaned and disinfected re-usable circuit. Connect to a breathing air or oxygen supply to check operation prior to packaging for emergency use.

4. CAREvent® ALS+ Accessories

01CV8015	Single Use Transport Ventilation Circuit with PEEP Port (patient valve dead space 8 ml)
01CV8020	Deluxe ReusableTransportVentilation Circuit with PEEP Port (patient valve dead space 8 ml)
17MP7010	Single Use PEEP Valve

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 an authorized repair centre.

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. Units with test pressures outside of the ranges listed in the product specifications should not be used. The product is **not** designed for field disassembly or service outside that indicated in this manual. Factory inspection, Service and Certification are recommended every 24 months.

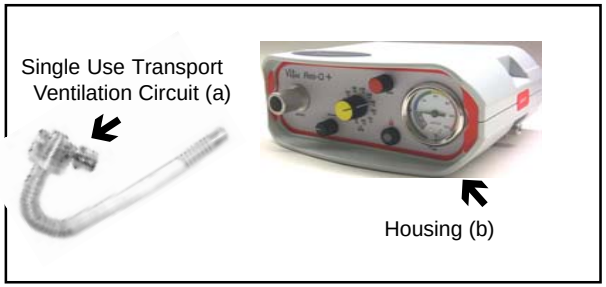
WARNING: Any malfunctioning units should be returned to the manufacturer or an Authorised Dealer. Unauthorised repairs will nullify the product warranty.

3.2 Cleaning the CAREvent® ALS+ and Accessories

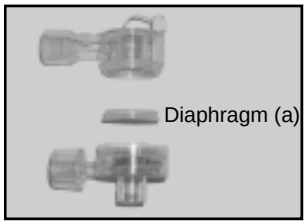
Routine cleaning of the CAREvent® ALS+ should be undertaken to maintain the equipment in a clean condition.

Face masks, and Deluxe ReusableTransport Ventilation Circuit with PEEP Port can all be cleaned using a mild soap solution and disinfected using a legally marketed commercially available disinfectant, suitable for the application.

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 for cleaning Fig 3.



Disassembly of Re-Usable Patient Valve (Fig 4)

1.3 Features

The CAREvent® ALS+ 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. The resuscitator also 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 resuscitator will automatically restart cycling in the setting selected.

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

The CAREvent® ALS+ Resuscitator:

- Delivers 100% oxygen during resuscitation (when attached to an oxygen source).
- Meets American Heart Association and European Resuscitation Guidelines for Resuscitation 2000 or 2005 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.
- 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 selector switch for **MAN**ual or **AUTO**matic ventilation.
- Has a Manually Actuated, Automatic Ventilation Override Button (Manual Button).
- Has a twelve position selector providing twelve, 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 a **MAN** 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.
- Has an Airway Pressure Gauge for monitoring the patient's airway pressure.
- Is equipped with a visual Gas Supply Status Indicator to show that the gas supply is turned on and adequate.
- Has an audible Low Input Pressure Alarm to warn of low cylinder contents or poor input pressure regulation.

1.4 Performance Specifications

(All specifications are subject to a tolerance of +/- 10% except the I:E Ratio and CPAP which are subject to a tolerance of +/- 20%, Manual delay +/- 15% and Maximum Airway Pressure +0/-15%).

TIDAL VOLUME:	*G05/CPAP*.....	100 - 650 ml
	G2K.....	200 - 1350 ml
BREATHS PER MINUTE:		20 - 10 BPM
I:E RATIO:		Fixed 1 : 2
AUTOMATIC FLOW RATE:	*G05/CPAP*.....	6.0 - 19.5 L/min
	G2K.....	12.0 - 40.5 L/min
MANUAL FLOW RATE:		As per automatic setting
MANUAL OVERIDE DELAY TIME:	*G05/CPAP*.....	17 ~ 23 Sec
	G2K.....	9 - 11 Sec
DEMAND BREATHING FLOWRATE:		>100 L/min
DEMAND BREATHING TRIGGERING PRESSURE:		-2.0 cmH_20 (-2.0 mBar)
AUTO SHUT OFF DELAY TIME:		5 - 8 Sec
INPUT PRESSURE:		45 - 70 PSI (3.0 - 5.0 Bar)
MAXIMUM AIRWAY PRESSURE:		60 cmH_20 (58.8 mBar)
EXPIRATORY/INSPIRATORY RESISTANCE		< +/- 6.0 cmH_20 (+/- 5.9 mBar)
OPERATING TEMPERATURE:		-18 to + 50°C (0 to +122°F)
STORAGE TEMPERATURE:		- 40 to + 60°C (- 40 to + 140°F)
CPAP (CPAP model only)		0 - 20 cmH_20 (0 - 19.6 mBar)
INPUT CONNECTION:		9/16" DISS
PATIENT CONNECTION:		15 / 22 mm
WEIGHT:		1.5 Kg (3.3 lb) Approx
SIZE:		8.7" x 6.7" x 3.6" 225 x 170 x 92 mm
CYLINDER DURATION:		
(a) 20 BPM / 100ml V_T		207 minutes
(b) 10 BPM / 650ml V_T		63 minutes

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

3. Replace the Single Use Transport Ventilation Circuit and operate the manual button or automatically cycle the resuscitator for a few breaths to ensure correct function.

4. Restart resuscitation as previously indicated.

WARNING: When using the Single Use Transport Ventilation Circuit vomitus or contamination may be forced past the diaphragm and contaminate the bio-filter. This may necessitate the use of a new single use circuit.

2.6 Demand Breathing and Automatic Circuit Shut Off

Should the patient commence spotaneous breathing 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 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).

2.7 CPAP/PEEP Control (CPAP model only)

With the Patient Circuit attached to the ventilator attach a test lung to the 15/22 mm adapter. Set the frequency control to 10 BPM / Tidal Volume Selector to the 650 ml position. Turn the ventilator to AUTO and allow it to cycle for 5 breaths. Slowly open the CPAP/PEEP control and monitor the gauge. As the control is rotated the baseline pressure should increase.

2.8 Airway Pressure Gauge

Located on the front panel of the ventilator, this gauge provides the operator with a visual indication of the airway pressure being reached during the ventilation cycle.

CHAPTER 3
SERVICING

3.1 Routine Maintenance

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

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 patients 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	7	8	9	10	11	12
Tidal Volume Vt (ml)		100	150	200	250	300	350	400	450	500	550	600	650
	*	*200*	*250*	*300*	*350*	*400*	*500*	*600*	*700*	*800*	*900*	*1100*	*1350*
Frequency (BPM)		20	20	20	20	10	10	10	10	10	10	10	10
	*	*20*	*20*	*18*	*18*	*18*	*15*	*15*	*12*	*12*	*12*	*10*	*10*
Minute Volume Vm		2.0	3.0	4.0	5.0	3.0	3.5	4.0	4.5	5.0	5.5	6.0	6.5
(ltrs)	*	*4.0*	*5.0*	*5.4*	*6.3*	*7.2*	*7.5*	*9.0*	*8.4*	*9.6*	*10.8*	*11.0*	*13.5*
Automatic flowrate		6.0	9.0	12.0	15.0	9.0	10.5	12.0	13.5	15.0	16.5	18.0	19.5
(L/min)	*	*12.0*	*15.0*	*16.2*	*18.9*	*21.6*	*22.5*	*27.0*	*25.2*	*28.8*	*32.4*	*33.0*	*40.5*
Body Weight (kg) min.		13	19	26	32	39	45	51	58	64	71	77	84
(6-7 ml/kg) max.		18	28	37	46	55	64	73	83	92	101	110	119

* G2K Model

Automatic Adjustable Setting Selections (fig 2)

2.5 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 patients 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 Single Use Transport Ventilation Circuit of foreign material.

2. If depressing the manual button repeatedly or automatically cycling the resuscitator does not clear the foreign material from the Single Use Transport Ventilation Circuit, turn the selector to the MAN position and remove the Single Use Transport Ventilation Circuit.

1.5 Safety Precautions

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

The CAREvent® ALS+ 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. BREATHING SYSTEM FILTER IS NESSARY TO PREVENT CROSS-CONTAMINATION OF PARTS OF THE RESUSCITATOR, CAN NOT BE DISASSEMBLED FOR CLEANING AND DISINFECTION.

6. AFTER USE, ALWAYS ENSURE THAT ALL COMPONENTS ARE CLEANED IN ACCORDANCE WITH THE INSTRUCTIONS PROVIDED IN THIS MANUAL.

7. ENSURE THAT ALL COMPONENTS ARE REASSEMBLED CORRECTLY AND THAT ALL ITEMS ARE REPLACED IN THE CARRYING CASE.

8. AFTER USE, ALWAYS ENSURE THAT A FULL AIR OR OXYGEN CYLINDER IS ATTACHED BEFORE RETURNING THE UNIT TO ITS NORMAL STORAGE POSITION.

9. ENSURE THAT A NEW SEALING WASHER IS USED EVERY TIME YOU ATTACH THE REGULATOR TO THE CYLINDER.

10. IT IS RECOMMENDED THAT AN ALTERNATIVE MEANS OF VENTILATING THE PATIENT BE AVAILABLE IN CASE OF GAS SUPPLY FAILURE.

1.6 Symbols

Oxygen Supply Pressure

$\frac{Vt}{BPM}$

Vt: Tidal Volume (ml)

BPM: Breathe Per Minute

CHAPTER 2
OPERATING PROCEDURE

2.1 Pressure relief check up.

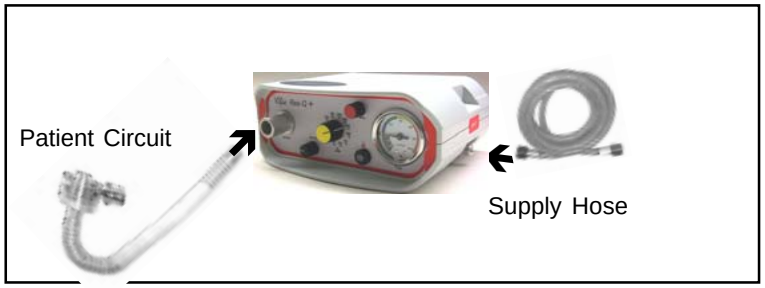
Using Test Lung provided in the kit, test blow off (pressure relief) valve for function by attaching patient connector to bag, and allowing the resuscitator to cycle. The blow off will trigger and an audible alarm will sound. Check gauge for reading and record the results.

2.2 Connecting the supply hose and patient circuit.

The supply hose provided is attached to the oxygen inlet on the side of the control module and is tightened "finger tight".

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

The patient circuit is attached to the gas outlet on the front left hand side of the control module by simply pushing the 22mm taper over the outlet.



Connecting the supply hose (fig 1)

2.3 Manual Ventilation and Cardiac Compressions.

The CAREvent® ALS+ resuscitator has a Manually Actuated, Automatic Ventilation Override Button (Manual Button) to assist in the timing of ventilations in conjunction with external cardiac compressions. This button works in either the Automatic or Manual modes. In the MAN mode the ventilator does not cycle automatically and depressing the manual button provides a flowrate equvalent to the setting on the automatic setting selector

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 patient's 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 either the MAN or AUTO mode and 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 blow off valve operates, reposition the patient's head and adjust your hand position to obtain an effective mask to face 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.

2. 4 Automatic Ventilation.

1. If you have been ventilating manually simply release the manual button and after a short pause 17-23 seconds (G05 and CPAP models) and 9-11 seconds (G2K 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.

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.