O-Two MEDICAL TECHNOLOGIES INC

CAREVent® PAR

PUBLIC ACCESS RESUSCITATOR

01CV0100

USER MANUAL

Made in Canada by
O-Two Medical Technologies Inc.

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CHAPTER 1

1.1 Introduction

The CAREvent® PAR (Public Access Resuscitator) provides trained individuals with a safe and effective means of providing artificial ventilation during cardiac arrest with the addition of voice prompts and audible signals for chest compression timing.

NOTE: The CAREvent® PAR is considered a critical device and its components considered critical components. Only those individuals trained in Cardio-Pulmonary Resuscitation should use this equipment. Thoroughly review this instruction manual before use.

NOTE: This resuscitator is intended for first response to aid a victim of sudden cardiac arrest. The ventilation rates and volumes and the compression timing signals are provided in accordance with current resuscitation guidelines.

⚠ **WARNING: Under FDA Regulations Oxygen is a drug and can only be administered by or on the order of a physician.**

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® PAR** 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 Indications for Use

The CARE*vent*® PAR (Public Access Resuscitator) is indicated for Cardio Pulmonary Resuscitation (CPR) short term ventilatory support. It is an electronically controlled, pneumatically powered resuscitator with incorporated voice instructions, compression beeps and automatic ventilations to assist CPR trained personnel for both inter- and intra-hospital and pre-hospital (EMS) settings for non-breathing adult patients.

1.4 Contraindications

The CAREvent® PAR is designed for use on adult patients over 40 Kg body weights who are in cardiac arrest. Use on smaller patients may result in activation of the pressure relief system during the ventilation phase and a warning to***"Press mask harder, tilt head more."***

1.5 Features

The CAREvent® PAR is an electronically controlled, pneumatically driven, automatic resuscitator designed for use with adult patients in cardiac arrest. The device incorporates a resuscitation guidelines compliant algorithm that provides compression prompts for closed chest compressions followed by two automatically delivered breaths. Audible and visual indicators assist the rescuer in performing CPR as well as warning the rescuer of airway obstruction or mask leakage. Additional audible and visual instructions for mask placement and head tilt as well as hand placement for chest compressions are also included.

Specifically designed for the first responder, the **CAREvent® PAR** is a unique device providing excellent ventilations along with compression timing. This device is designed for use anywhere there is a risk of cardiac arrest.

The CAREvent® PAR:

- Delivers 100% oxygen during resuscitation.
- Meets current American Heart Association/European Resuscitation Council Guidelines for CPR.
- Provides voice instructions for CPR, automatic ventilations on 100% oxygen and compression timing beeps. The timings for compressions and ventilations are set in accordance with the current resuscitation guidelines.

- Has an Airway Pressure Limiting System with Audible and Visual alarms for airway obstruction set in accordance with current standards combined with audible and visual alarms for mask leakage.

- Is designed for use by CPR trained persons for the emergency resuscitation of the patient in cardiac arrest.

- As an average mask leakage of 40% is common during resuscitation, the **CAREvent® PAR** has a tidal volume calibration set to accommodate a 40% mask leakage factor.

1.6 Performance Specifications

1.6.1 CAREvent® PAR TECHNICAL SPECIFICATIONS

Tidal Volume	700ml ± 10% (Single Setting)
Automatic Flow Rate	42 L/min ± 10%
Inspiration Time Per Breath	1 second ± 0.5 second
Expiration Time Per Breath	2 seconds ± 0.5 second
I:E Ratio	1:2 ± 20%
Compression: Ventilation Ratio	30 : 2
Body Weight	88-220 lb (40-100 kg)
Input Pressure	45 - 70 PSI
Pressure Relief	54 - 60 cmH_20
Inspiratory/Expiratory Resistance	< 6 cmH_2O @ 60 L/min
Operating Temperature	-18°C to +50°C (0°F to 122°F)
Storage Temperature	-40°C to +60°C(-40°Fto140°F)
Operating Humidity	15% to 95%
Storage Humidity	15% to 95%
Input Connection	9/16” DISS
Patient Valve Dead Space	8 ml ± 10%
Control Module Dimensions	< 9 3/4” x 7 5/8” x 3 5/16”
Weight Without Cylinder	2.7 lb (1.23 kg)

Operating Duration	~30 minutes when used with an M4 size cylinder containing 113 liters of oxygen.
Battery Type	Sealed Lead Acid 6VDC, 1.2Ah
Operating Time On Full Charge	>= 2 hours (at 25^0C ambient temperature)
Battery Monitoring	**LED**: **Off** – Battery charge too low and device is inoperable; **Yellow** - Device can work properly but the battery should be charged; **Green** - Battery full. Monitoring circuit is activated either by pressing a button or connecting the device to an external power supply.
Charging Type	Continuous Trickle Charge
Charging Time	16 - 20 Hours from full discharge
Battery Life	3 to 5 years in normal applications or more than 1000 discharge/ recharge cycles can be realized, depending on the average depth of discharge and operating/storage temperature.
Alarms	If there is a mask leakage (Airway Pressure < 8 cmH_2O ± 10%) or an airway obstruction (Airway Pressure > 40 cmH_2O ± 10%), voice warning "***Press mask harder, tilt head more***." is activated and the ventilation pictogram turns red.
Classification	PAR is classified as Internally Powered, Type BF Equipment. It is not suitable for use in the presence of a flammable anaesthetic mixture or nitrous oxide.
Electromagnetic Compatibility	PAR is classified as ISM Equipment, Class B, Group 1. It complies with IEC 60601-1-2 Electromagnetic Emissions and

	Immunity requirements.

1.6.2 CAREvent® PAR CYCLE

Repeat cycles until professional help arrives

Start up	Allows 20 seconds to apply mask to face and position the head strap
Prepare for compression	5 seconds
30 chest compressions	18 seconds
Prepare for ventilation	4 seconds
Deliver 2 breaths	1 second inspiration, 2 seconds expiration (3 seconds inserted if alarm activated)
Change over to compression	5 seconds
Change over to ventilations	4 seconds

1.6.3 CAREvent® PAR VOICE PROMPTS

Voice 0 - On first start up of PAR	***"Place mask on face. Pull strap over head to secure mask."*** ***"Press green button to begin CPR."*** Repeated at 4 seconds intervals until depressed
Voice 1 - Prepare for compression (5 sec.)	***"Place hands in centre of chest. Compress firmly in time with the tone."***
Voice 2 - Prepare for ventilation (4 sec.)	***"Press mask to face, tilt head back."***
Voice 3 - At end of 1st breath if alarm activated (5 sec.)	***"Press mask harder, tilt head more."***
Beeps - Compression Timer	30 Compression beeps. Last beep is increased in length to signify changeover to ventilations is imminent.

1.7 Safety Precautions

The CAREvent® PAR is designed to assist in the provision of cardio-pulmonary resuscitation to patients suffering from sudden cardiac arrest.

The CAREvent® PAR is intended for use by suitably trained 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] IT IS RECOMMENDED THAT AN ALTERNATIVE MEANS OF VENTILATING THE PATIENT BE AVAILABLE IN CASE OF GAS SUPPLY FAILURE.

[9] EQUIPMENT IS BATTERY POWERED ONLY.

[10] EQUIPMENT IS NOT SUITABLE FOR USE IN THE PRESENCE OF A FLAMMABLE ANAESTHETIC MIXTURE WITH AIR OR WITH OXYGEN OR NITROUS OXIDE.

[11] AVOID USING THE EQUIPMENT WHEN POTENTIAL

ELECTROMAGNETIC OR OTHER INTERFERENCE EXIST.

1.8 Electromagnetic Compatibility

The CAREvent® PAR has been tested and found to comply with IEC 60601-1-2 requirements. **The CAREvent® PAR** is intended for use in the electromagnetic environment specified below. The user of the **CAREvent® PAR** should assure that it is used in such an environment:

[1] Electromagnetic Emissions

Emission test	Compliance	Electromagnetic environment -guidance
RF emissions CISPR 11	Group 1 Class B	The **CAREvent® PAR** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment

[2] Electromagnetic Immunity

Immunity test	IEC60601 test level	Compliance level
Electrostatic discharge IEC61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air
Power frequency (50/60 Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m
Radiated RF IEC61000-4-3	10 V/m @ 80 MHz to 2.5 GHz	10 V/m

The CAREvent® PAR is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **CAREvent® PAR** as recommended below, according to the maximum output power of the communications equipment:

Rated maximum output power of transmitter **W**	Separation distance (**m**)	
	80 MHz to 800 MHz $d = 12\sqrt{P}$	800 MHz to 2.5 GHz $d = 23\sqrt{P}$
0.01	0.12	0.23
0.1	0.38	0.73
1	1.2	2.3
10	3.8	7.3
100	12	23

CHAPTER 2

PRE-USE FUNCTIONAL 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 (unless supplied with the **CAREvent® PAR**):

[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, 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 15/22mm patient connector on the resuscitator.

2.2 Testing of the Individual Features of Resuscitator

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

[1] Compression timing

[2] Ventilation delivery and timing

[3] Audible prompts and alarms

Test steps	Parameter
1. Connect PAR to oxygen source with 50 PSI output pressure and turn on the gas source.	N/A
2. The device enters “Startup” phase. The push button on the front panel shall be illuminated to green and flash once every second (1 sec On and 1 sec Off).	Yes/No
3. Within 2 seconds upon turning on oxygen source,	Yes/No

voice instructions "***Place Mask on Face. Pull Strap over Head to Secure Mask***" and "***Press Green Button to Begin CPR***" shall be played alternatively and repeatedly.	
4. After the two messages have been played for 3 times press the green button.	N/A
5. The cycle shall enter the "Prepare for Compression" phase. The green button shall turn off and the visual on the right hand side of the front panel shall be illuminated continuously.	Yes/No
6. Meanwhile, a voice message shall be played: "***Place hands in centre of chest. Compress firmly in time with the tone***".	Yes/No
7. The cycle shall enter the "Chest Compression" phase. The right side visual shall flash and audible beeps shall sound in phase with the visual flashing. The last beep shall be prolonged.	Yes/No
8. The entire "Compression" phase shall last 18 seconds. Measure the time (t3) with a stopwatch (from the beginning of the first beep and the end of the last beep).	**t3=18.0 s** **(+/- 0.5)**
9. The next is "Prepare for Ventilation". A voice "***Press mask to face. Tilt head back***" shall be played.	Yes/No
10. The cycle shall enter the "Ventilation" phase. Two ventilations shall be delivered with 1 second each and a 2 second interval between the two ventilations. Use a test lung to measure the Tidal Volume and ON time (t5) for each and the interval (t6).	**Vt=700ml** **(+/- 10%)** **t5=1.0 s** **t6=2.0 s**
11. The cycle shall go back to the "Prepare for Compression" phase.	Yes/No
12. Remove the patient circuit from the CAREvent® PAR. At the end of the first ventilation in each cycle, the left visual shall change from white to red and a warning message "***Press mask harder. Tilt head more***" shall be played.	Yes/No
13. Connect the output of the PAR to the Pressure	**P3=60.0**

Relief test fixture. The same warning message should appear as shown in step 12. Measure the maximum airway pressure during ventilation by setting the test lung volume to its minimum.	**cmH_2O** **(- 10%)**

CHAPTER 3

OPERATING PROCEDURE

3.1 Connecting the Supply Hose and Patient Circuit

The supply hose provided is attached to the oxygen inlet on the side of the resuscitator and is tightened “finger tight”.

⚠ **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 having first ensured that the head strap is located on the mask.

3.2 Use of the CAREvent® PAR during CPR

[1] If the patient is unresponsive immediately call 911.

[2] Locate the **CAREvent® PAR** (and defibrillator if available) and return to the patient.

[3] If a defibrillator is available and the patient collapse was witnessed by the rescuer, apply the defibrillator pads and follow the defibrillator instructions. If the cardiac arrest was unwitnessed, no defibrillator is available, there is a long delay before starting resuscitation efforts, “no shock” is advised by the defibrillator or after shocking the patient the defibrillator advises the rescuer to “recommence CPR”, **turn on the oxygen supply of the CAREvent® PAR and follow the voice prompts.**

[4] Continue CPR until professional help arrives.

3.3 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 patient's airway. Shake out any foreign material from the face mask.

[2] [A]ply the mask and head strap to the patient and recommence CPR following the voice prompts.

3.4 Operation in Extreme Conditions

Operation of the CAREvent® PAR in environmental conditions outside of those detailed in this manual may result in a reduction in the resuscitator's performance. In extreme cold weather a low delivered tidal volume of ventilation or a less working time of the battery may be seen. In high temperature environments the effect is not noticeable in terms of delivered ventilations but may cause excessive wear in the resuscitator components over time.

Operation of the CAREvent® PAR under supply pressures outside those detailed in this manual may result in a reduction in the resuscitator's performance. Input pressures below the minimum stated will cause the delivered tidal volume out of spec; as the pressure falls below 30 PSI, will cause the resuscitator shut down.

Input pressures higher than that recommended in this manual may result in a risk of internal component failure if the pressure exceeds three times the maximum working pressure stated.

CHAPTER 4

SERVICING

4.1 Routine Maintenance

⚠**WARNING: The CAREvent® PAR is designed to provide respiratory support and CPR instruction during Cardiac Arrest. 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 oxygen cylinder is full, the battery is charged and that the resuscitator is in working order.

Regulator working pressure and ventilator limiting pressures should be checked at least every six months, and more frequently in high use applications. Units with test parameters 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. Any malfunctioning units should be returned to the manufacturer or an Authorized Dealer. Unauthorized repairs will nullify the product 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.

4.2 Battery

4.2.1 Charging

Press the yellow button on the front panel of the unit and observe the LED to check the battery status.

Battery Status LED:	Green	Full
	Yellow	Half
	Off	Discharged

When the charging LED becomes yellow or fails to illuminate, recharge the battery by using the supplied charger.

Charging time from full discharge: 16 - 20 Hours

⚠ **WARNING: Do not use CAREvent® PAR when charging the battery.**

⚠ **WARNING: Battery is only replaceable by the manufacturer.**

4.2.2 Storage

[1] Always store the battery in a fully charged condition.
[2] If the battery is to be stored for a long period, apply a recovery top-up charge every 6 months.
[3] Store **Carevent® PAR** in a dry and cool location.
[4] Keep within ambient temperatures of -15 ^{0}C to 50 ^{0}C for both charging and discharging.

4.3 Cleaning the CAREvent® PAR and Accessories

THE RESUSCITATOR MUST BE THOROUGHLY CLEANED AFTER EACH PATIENT USE.

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

The single use patient circuits and masks should be safely discarded after each patient use and replaced with a new unit.

The cylinder should be replaced with a fresh cylinder of oxygen after each use.

The ventilator should be re-charged after each use.

The control module should be wiped clean with a mild soap solution or commonly available hard surface disinfectant. **Under no circumstances should the unit be allowed to be soaked or immersed in cleaning solutions.**

[1] Turn off the oxygen source of the **CAREvent® PAR.**

[2] Remove and discard the single use patient circuit and facemask.

[3] Remove and replace the oxygen cylinder with a fresh cylinder of oxygen.

[4] Wipe over the **CAREvent® PAR** with a soft cloth and mild soap solution or commonly available hard surface disinfectant.

[5] Dry all components thoroughly.

[6] Reassemble unit, including attaching a new patient circuit with facemask and head strap. Connect to an oxygen supply to check operation prior to packaging for emergency use.

4.4 Safe Decommissioning or Disposal of CAREvent® PAR

and Accessories

The single use patient circuits and masks should be safely discarded after each use in accordance with local state and institutional laws and procedures.

The CAREvent® PAR uses a sealed lead acid battery which may contain hazardous materials. Please follow local regulations to disposal of the battery.

The printed Circuit Boards and electronic components inside the CAREvent® PAR may also contain hazardous materials. Contact the proper agency for information on permissible methods of disposal.

CHAPTER 5

SYMBOLS AND DEFINITIONS


Start the Unit


Check Battery


Gas Output


Gas Input


Caution (Refer to Instruction Manual)

Model Number

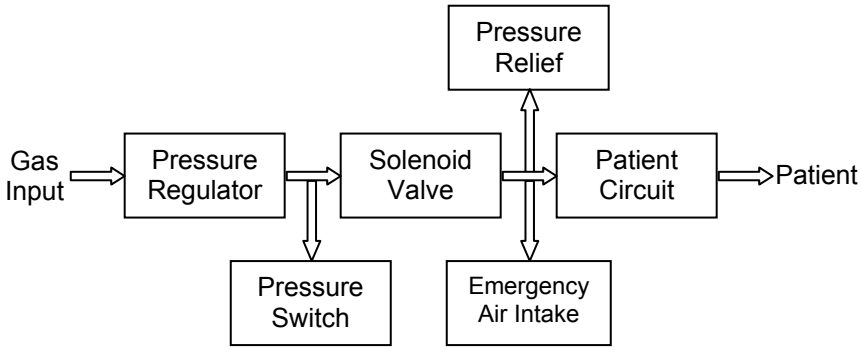
Serial Number


Manufacturer


Manufacture Date


Meet Class II equipment safety requirement


Type BF Equipment complying with IEC 60601-1



Pneumatic System Diagram

CHAPTER 6

CAREvent® PAR ACCESSORIES

01CV0101	POWER SUPPLY Input: 100-240VAC, 50-60Hz, 1A Output: 9VDC, 4.0A
01CV0102	POWER SUPPLY CORD
01CV0103	CAR CHARGER
01CV8011	**CAREvent® PAR** PATIENT CIRCUIT DISPOSIBLE
01FV4302	PVC NYLON BRAIDED 6 FT HOSE FOR SOFTPACK MOUNTED **CAREvent® PAR**
01OR8700	REGULATOR CGA 540 BRASS

MANUFACTURERS AND DISTRIBUTORS OF:

CAREvent® Range of Handheld Automatic Resuscitators
CAREvent® Range of Automatic Transport Ventilators
SMART BAG MO® Bag-Valve-Mask Resuscitators
Demand Valve Resuscitators
Equinox® 50% Nitrous Oxide / 50% Oxygen
Oxygen Demand Valves
Burn Relief® Burn Kits and Dressings
Easy Grip® Bag-Valve-Mask Resuscitators
CPR Bio-Barrier® Face Shields
Revive Aid® CPR Face Shields
Rescue Breather® CPR Pocket Ventilator
Respiratory Disposable Products
SQ® Regulators

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