USER MANUAL

o_two controlled™ ventilation

CAREvent® ATV+
01CV6000

CAREvent® MRI
01CV7000

CAREvent® ATV+ & MRI

01CV6000 01CV7000

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1. Introduction

1.1. Warnings

The CAREvent® ATV+ and MRI are intended for use by suitably trained and qualified personnel.

The following precautions should always be observed:

1. Read this manual prior to attempting to use the ventilator.
2. When the unit is in use, do not smoke or use near open flame either during use or when changing the cylinder.
3. When not in use, always turn off the gas supply.
4. Never allow oil or grease to come into contact with any part of the cylinder, regulator or ventilator.
5. This device is not designed for use with heated humidifiers.
6. This resuscitator is not recommended for use on neonates and pregnant or nuring women.
7. Do not disassemble any part of the ventilator except where described in this manual as any unauthorized disassembly will invalidate the warranty.
8. After use, always ensure that all components are cleaned in accordance with the instructions provided in this manual. (See section 4)
9. Always use the check list to ensure that all components are reassembled correctly and ready for use.
10. It is recommended that an alternative means of ventilating the patient be available in case of gas supply failure.
11. During use, the patient should not be left unattended.
12. The use of this device in areas where the ambient air may be hazardous or explosive should be avoided as entrainment of ambient air during the use of the air mix mode will permit the patient to inhale atmospheric gas.
13. Only the CAREvent® MRI unit may be used in a magnetic resonance imaging department.
14. Only patient circuits supplied by O-two Medical should be used, as the use of other circuits may adversely affect the output performance of the ATV.

15. 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.

16. The use of this device in carring case of any type may, when used in the 60% air mix mode, result in an increase in oxygen concentration. If the air mix mode is to be used it is recommended that the ventilator be placed in its normal operating orientation and that the air intake on the rear of the ventilator is not obstructed.

1.2. Intended Use

The CAREvent® ATV+ and MRI are pneumatically powered, time cycled, intermittent, positive pressure automatic transport ventilator used to provide resuscitation and/or ventilatory support to a widerange of patients (from above 5 kg (11 lbs.) and higher) during transport.

They are designed to be used by suitably trained medical personnel in the pre-hospital, intra-hospital, inter-hospital, and air ambulance settings.

In addition, CAREvent® MRI is suitable for use in 1.5 - 3.0 Tesla MRI medical imaging suite environments, where ventilatory support may also be required during an MRI imaging procedure.

The ventilator is suitable for use in:

- Pulmonary resuscitation during respiratory and/or cardiac arrest.
- Short term ventilatory support in the pre-hospital, intra-hospital, inter-hospital, and air ambulance transport of non-breathing patients.
- In addition, CAREvent® MRI only is suitable for use in 1.5 - 3.0 Tesla MRI medical imaging suite environments, where ventilatory support may also be required during an MRI imaging procedure.

1.3. Terms and Definitions

Airway Resistance:	Pressure drop across the airway per unit flow.
ATV:	Automatic Transport Ventilator
CMV:	Controlled Mandatory Ventilation.
CPAP:	A positive pressure applied to the lungs during all ventilation phases (Continuous Positive Airway Pressure).
Demand Valve:	A valve that delivers gas to the patient at a flowrate equivalent to that demanded by the patient's inspiratory effort.
Expiratory Phase:	The time period from the end of the inspiratory flow to the end of the expiratory flow.
Expiratory Time (Te):	Duration of the expiratory phase.
Frequency (f):	The number of breaths in one minute (also expressed as BPM).
Inspiratory Flow:	The flow delivered to the patient by the ventilator during the inspiratory phase.
Inspiratory Phase:	The interval from the start of the inspiratory flow to the start of the expiratory phase.
Inspiratory Time (Ti):	Duration of the inspiratory phase.
Lung Compliance:	Volume added per unit pressure increase when gas is added to a human or artificial lung.
Maximum Patient Inflation Pressure:	The maximum airway pressure delivered by the ventilator to the patient.
Minute Volume (Vm):	The total volume of gas delivered to the patient in one minute.
PHT **DEHP**	The material used in this device contains "DEHP".
Oxygen Concentration:	The oxygen content of the inspired gases expressed as a percentage.
Proximal Airway Pressure:	The airway pressure measured at the patient valve.
Patient Valve:	The valve which directs the flow of gas into the lungs and out of the expiratory port to atmosphere during expiration.

PEEP Valve:	A device which, when attached to the expiratory port of the patient valve, holds a positive pressure in the patients airway at the end of the expiratory phase. (Positive End Expiratory Pressure)
Pressure Relief Valve:	Valve which limits the maximum lung inflation pressure by venting excess gas to atmosphere.
Tidal Volume (Vt):	Volume of gas delivered to the patient during each inspiratory phase.
G05® :	Guidelines 2005 compliance. Complies with the requirements of the ERC and AHA for 30:2 compression : ventilation ratio.

1.4. General Information

The CAREvent® ATV+ and MRI are designed for use in the prehospital, intrahospital, interhospital and air ambulance settings.

Designed to be used by suitably trained personnel, the various modes of operation of the device support the resuscitation and transportation of a wide range of patients (from infants to adults) who require ventilatory support. The features and controls offered by the device comply with the various International Standards for Transport Ventilators.

The G05® models have been manufactured to comply with the latest Guidelines 2005 for CPR and ECC from the European Resuscitation Council and the American Heart Association.

1.5. CAREvent® MRI

The CAREvent® MRI has been designed to meet the requirements of ventilation within the MRI environment. The CAREvent® MRI has been tested in a 1.5 Tesla MRI environment (unshielded magnet - spatial gradient of <23Mt/m/sec and a slew rate of 120 T/m/sec at an RF transmitter power of 2000 watts) and a 3.0 Tesla MRI environment (unshielded magnet - spatial gradient of < 40Mt/m/sec and a slew rate of 150 T/m/sec at an RF transmitter power of 8000 watts) during a head phanton spectroscopy test scan with the device located no less than 12 inches from the magnet aperture which would be its normal use position during clinical use.

In addition, the CAREvent® MRI model can be attached to the CAREvent® MRI mounting plate or attachment to a cart or wall/medirail mounting bracket.

1.6. Device Description

The CAREvent® ATV+ and MRI consist of a ruggedly constructed, portable control module, input hose and optional single use (or reusable where available) patient circuit. The ergonomically designed control groupings facilitate the selection and setting of the breathing parameters. The colour groupings provided on the controls adds to this ease of use concept.

The unique pneumatic alarm for low input pressure improves the level of safety for the patient by warning the operator of any problems of insufflcient or failed gas supply.

The air mix capability of the ventilator improves the operating time on bottled oxygen for long duration transports. The extremely low drive gas consumption ensures full utilization of the cylinder contents.

Controls

The controls provided are as follows:

- Ventilation Frequency
- Pressure Relief (Proximal Airway Pressure)
- Minute Volume
- Delivered Oxygen Concentration (%)
- Manual Ventilation
- Manual/AUTO Selector
- CPAP/PEEP Control
- BSI Alarm Silence Button

Visual Indicators

- Proximal Airway Pressure Gauge (cmH_2O)
- Gas Supply Status Indicator
- BSI Alarm Indicator

Connections

Connections are provided on the side of the ventilator for the Oxygen Input and the Gas Output.

1.7. Principles of Operation

The CAREvent® ATV+ and MRI are time-cycled, Intermittent Positive Pressure devices providing a range of frequencies of ventilation and Minute Volume settings to provide a comprehensive range of delivered tidal volumes and ventilation rates. The design of the micro-pneumatic circuitry in the

Automatic Transport Ventilator maintains a consistent I:E ratio of 1:2 across the Minute Volume/frequency combinations to optimise the exchange of gases in the alveoli. This helps avoid the risk of inconsistent ventilations and protracted expiratory times that may cause additional physiological acidosis or short inspiratory times that may not allow for complete alveolar filling or may generate high airway pressures.

Note: The design of these ventilators does not incorporate a negative pressure phase during either automatic or manual ventilation.

1.8. Modes of Operation

Automatic Ventilation Mode

In the automatic mode (selected by turning the Manual/AUTO Selector on the ventilator control panel to AUTO) the ventilator will supply the patient with positive pressure ventilations of a frequency and minute volume as selected using the Ventilation Frequency and Minute Volume Selectors on the front panel. The I:E ratio is maintained at a constant 1:2 to ensure that good gas exchange takes place in the lung.

Manual Ventilation Mode

In the AUTO mode, when the Manual Override Button is depressed, the ventilator will cease automatic cycling and will deliver a constant flowrate equivalent to that selected on the flowrate selector for as long as the button is depressed. Releasing the button will allow the ventilator to recycle into an automatic ventilation mode following a delay period of approximately 20 seconds. This delay allows the operator sufficient time to provide chest compressions or initiate a further manual breath should they so wish. If the Manual Override Button is depressed for too long the patient is protected from high airway pressure by the Pressure Relief system.

Note: During the provision of chest compressions during mask Ventilated CPR, the BSI alarm may activate if the mask seal is not maintained or if there is insufficient positive intra-pulmonary pressure created during the compression phrase to disable the alarm. Under these circumstances the BSI alarm acts as a warning of the impending recommencement of automatic cycling.

In the Manual mode, depressing the Manual override button will allow the operator to manually ventilate the patient at a flowrate equivalent to the Minute Volume selected.

Demand Breathing
During automatic ventilation, the Demand Breathing mode will allow the patient to commence spontaneous breathing through the ventilator while causing the automatic cycling to cease. As with the Manual Override, there is an increase in the expiratory time before the next automatic breath is delivered to allow the patient to continue demand breathing. This system ensures that the patient receives a sufficient minute volume should their inspiratory efforts be erratic. Demand Breathing is available to the patient in both the inspiratory and expiratory phases of the ventilation cycle.

In the Manual mode the patient can demand breathe at their own rate and volume.

Note: It is important to constantly observe the patient's respirations to ensure that adequate perfusion is occurring.

Note: Small children may not be able to demand at a sufficient flowrate to disable the automatic cycling.

Note: If used in conjunction with external chest compressions the Auto Circuit Shut Off function may be actuated should the depth of compression create sufficient tidal volume on chest re-coil. Under these circumstances a manual breath may be delivered (if deemed necessary) between sets of compressions.

Adjustable Pressure Relief
This control allows the operator to vary the maximum delivered airway pressure. This is achieved by diverting the excess delivered volume to atmosphere should the set airway pressure be reached.

Air Mix Mode
To conserve oxygen during long transports or when a patient's respiratory condition demands an oxygen concentration of less than 100%, the air mix mode can be selected. This reduces the oxygen concentration to 60%. In this mode the ventilator entrains

ambient air into the system and automatically reduces the oxygen flow to maintain a consistent tidal volume. By using this mode the operating time on the cylinder supply is significantly increased.

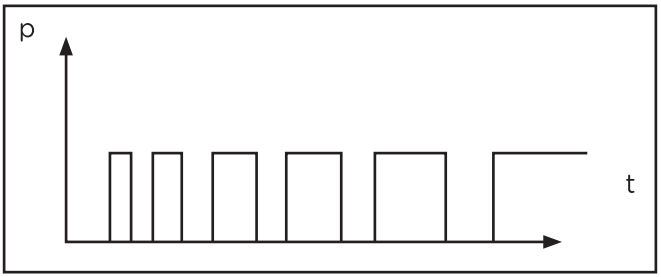
Note: Due to the design of the micro-pneumatic circuit, increasing pulmonary resistance has little effect on the delivered tidal volume or respiratory rate. Research has shown that decreasing pulmonary compliance in the infant Minute Volume settings may give a minimal increase in the delivered oxygen concentration when used in the Air Mix mode.

Emergency Air Intake System for Gas Supply Failure
In accordance with the International Standards for this type of device, the ventilator is equipped with a failsafe Emergency Air Intake circuit which allows the spontaneously breathing patient to draw ambient air through the circuit should the gas supply fail.

1.9. Alarms and Gauges

The alarm systems in the Automatic Transport Ventilator provide an audible indication of any inconsistencies in the patients breathing and warn of a loss of driving pressure from the gas supply. The alarms function as follows:

Low Input Pressure Alarm - Gas Supply
A low frequency oscillating alarm occurs when the gas supply reaches the minimum safe operating pressure. (See also Gas Supply Status indicator).

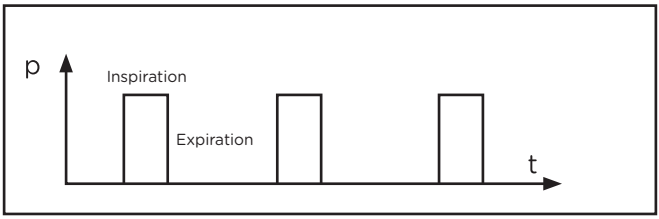


p = Audible Pulsed Tone t = Time

Fig. 1 - Graphic illustration of the audible alarm signal

⚠ WARNING ⚠
When this alarm sounds, immediately change the gas supply.

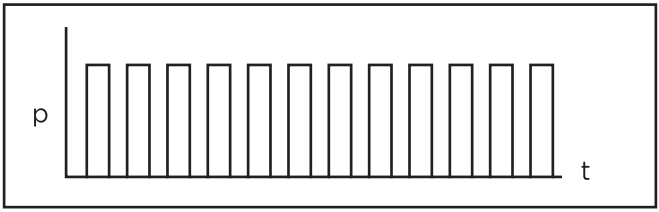
Airway Over Pressure Alarm – Pressure Relief
Continuous tone of a low pitch during the inspiratory phase of the ventilation that indicates that the maximum airway pressure selected has been reached.



p = Audible Pulsed Tone t = Time

Fig. 2 - Graphic illustration of the Pressure Relief audible alarm signal

Breathing System Integrity (BSI) Alarm
Pulsed tone of a high pitch which activates if the patient circuit becomes disconnected or the airway pressure achieved does not reach 10 cmH_2O. Alarm can be silenced for 15 seconds by depression of the BSI Alarm Mute Button (See also BSI Visual Indicator).



p = Audible Pulsed Tone t = Time

Fig. 3 - Graphic illustration of the BSI audible alarm signal

Gas Supply Status Indicator
Located on the front panel, this visual indicator will show green when gas is supplied to the ventilator. Used in conjunction with the Low input pressure alarm, this indicator provides an additional reference for the operator as to the ventilators gas supply status.

BSI Alarm Visual Indicator
Located on the front panel above the airway pressure gauge, this visual indicator will flash red in time with the BSI Audible Alarm when the patient circuit is disconnected or insufficient airway pressure is being produced.

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.

1.10. Accessories

Supply Hose
The supply hose is a standard armoured oxygen hose with a 9/16 DISS threaded connection for the ventilator.

Single Use and Reusable Patient Circuits
The Single Use Deluxe Transport Ventilation Circuits and Deluxe Reusable Patient Circuits are comprised of a patient valve housing and 22 mm tubing. The expiratory port is configured to accept either 30 or 19 mm PEEP valves. The 22 mm corrugated tubing is easily attached to the patient circuit output connector on the side of the ventilator. (fig 5.)

Note:
1. The choice of using either a Single Use or Reusable circuit is at the discretion of the user. Only patient circuits supplied by O-Two Medical Technologies Inc. should be used.
2. The use of a Bacterial/Viral filter is recommended to reduce the potential for cross infection and contamination of the reusable patient circuit. If used, the Bacterial/Viral filter must be used on a single patient basis.
3. The use of a Bacterial/Viral Filter in conjunction with a reusable patient circuit does not guarantee that the patient circuit will remain free of contamination.
4. The use of a bacterial/viral Filter on any of the CAREvent® circuits will increase inspiratory resistance and if used on the distal side of the patient valve will increase deadspace.

Note: Careful consideration should be given to the use of a reusable patient circuit on more than one patient. Single use circuits are not designed for use on more than one patient and must be discarded after each use. The manufacturer recommends that circuits are used on a per patient basis and reusable circuits should be cleaned and single use circuits discarded, after each use.

Note: The patient valve assembly is flow direction sensitive. Ensure that the patientcircuit is attached to the ventilator correctly.

1.11. Control Adjustment

The ventilator is equipped with a number of selectors depending on the model. Each selector is actuated by the following method (Fig 4).

Note: All selector positions are as viewed from the front of the ventilator.

1. **Ventilation Frequency (BPM):** Located on the top right hand side of the control panel. Rotary control with an anti-clockwise rotation from low to high.
2. **Minute Volume (Litres):** Located on the bottom right hand side of the control panel. Rotary control with a clockwise rotation from high to low.
3. **Pressure Relief (Maximum Delivered Airway Pressure (cmH_2O):** Located on the top of the control panel slightly left of center. Rotary control with a clockwise rotation from low to high.
4. **Delivered O_2 Concentration(%):** Located on the bottom left hand side of the control panel. Rotary control with a clockwise rotation from low to high.
5. **Manual Ventilation:** Located on the lower center section of the control panel activated by depression of the button.
6. **Manual/Auto Selector:** Located on the front panel of the ventilator. Rotary control with a clockwise rotation from Manual to Auto.
7. **CPAP/PEEP Control:** Located on the front panel of the ventilator. Rotary control with a clockwise rotation from 0 - 20 cmH_2O.
8. **BSI Alarm Mute Button:** Located on the front panel of the ventilator above the pressure gauge. Activated by depression of the button.

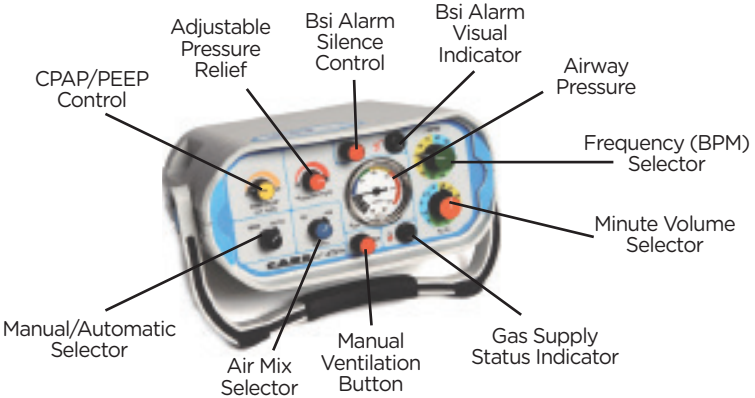


Fig. 4 - Front Panel Layout for ATV+ and MRI models

1.12. Technical Data

(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/-15%)

Minute Volume Range:	2 - 14 L/min
Frequency Range:	8 - 40 BPM
I:e Ratio:	1:2
Input Pressure:	45 - 87 PSI (3 - 6 Bar)
Automatic Flowrate:	6 - 42 L/min
Manual Flowrate:	6 - 42 L/min
Manual Overide Delay Time:	17 - 23 sec
Demand Breathing Flowrate:	>100 L/min @ -6 cmH_20 (hPa)
Demand Breathing Triggering Pressure:	-2 cmH_20 max
Auto Shut Off Delay Time:	5 - 8 sec
CPAP/PEEP:	0 - 20 cmH_20
Oxygen Concentration:	60 or 100 %
Inspiratory/Expiratory Resistance:	< 6 cmH_20 (hPa) @ 60 L/min
Operating Temperature:	-18°C to + 50°C / 0°F to +122°F
Storage Temperature:	- 40°C to + 60°C / - 40°F to + 140°F
Gas Supply Status Indicator:	Provides a visual Indication of gas Supply status.
Pressure Relief Range:	20 - 60 cmH_20 19.6 TO 58.8 mBar

Low Input Pressure Alarm:		Audible pulsed alarm to indicate input pressure is dropping below the minimum requirement. Cannot be switched off.
Airway Pressure Alarm:		Audible alarm to indicate that the selected peak airway pressure has been reached.
BSI Alarm:		Audible high frequency pulsed alarm indicating that the patient circuit is disconnected or insufficient ventilation pressure (<10 cmH_2O) has been attained
Pressure Gauge Accuracy:		± 2% Full Scale
Input Connection:		9/16" DISS
Patient Connection:		15 / 22 mm
Dimensions:		9.27 X 7.6 X 4.4 INCHES 236 X 194 X 112 MM
Weight:		2.84 Kg Approx for ATV+ 3.0 Kg Approx for MRI
Patient Valve Dead Space:		8 ml
Cylinder Duration (Aluminum "D" size cylinder containing 415 Litres of oxygen.):		
On 100% Setting:	(a) 2 Litre Mv	207 minutes
	(b) 14 Litre Mv	30 minutes
On 60% Setting:	(a) 2 Litre Mv	345 minutes
	(b) 14 Litre Mv	50 minutes

MRI Test Condition Parameters:
The CAREvent® MRI has been tested in a 1.5 Tesla MRI environment (unshielded magnet - spatial gradient of < 23Mt/m/sec and a slew rate of 120 T/m/sec at an RF transmitter power of 2000 watts) and a 3.0 Tesla MRI environment (unshielded magnet - spatial gradient of < 40Mt/m/sec and a slew rate of 150 T/m/sec at an RF transmitter power of 8000 watts) during a head phanton spectroscopy test scan with the device located no less than 12 inches from the magnet aperture which would be its normal use position during clinical use.

Note: When tested as indicated above, the spectroscopy traces were not affected in any way by the CAREvent® MRI ventilator, and the CAREvent® MRI ventilator functioned to specification.

1.13. Warranty

WARRANTY

The CAREvent® ATV+ and MRI are 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 Automatic Transport Ventilator 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 Automatic Transport Ventilator 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 and confirmation of said defect by the manufacturer. All shipping costs shall be borne by the purchaser. The manufacturer shall be liable under this warranty only if the Automatic Transport Ventilator 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.

Note: THIS DEVICE MUST BE SERVICED BY AN O-TWO MEDICAL AUTHORIZED SERVICE CENTER.

2. Preparation for use

2.1. Component List

Having unpacked the ventilator from its shipping carton, use the following list to ensure that all components have been received:

1. Operating Manual
2. Ventilator
3. Supply Hose.
4. Single Use or Reusable Patient Circuit with Patient Valve
5. Calibrated Test Lung

Note: If any components are missing from the shipping carton, immediately call the supplier quoting the packing slip number, your original purchase order number and the description of the item which is missing.

2.2. Connection of Hoses

The supply hose provided is attached to the input connection on the side of the ventilator “finger tight” (fig 5).

⚠ WARNING ⚠

Using a wrench or excessive force in tightening the supply hose may damage the seal or the thread of the connection.

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

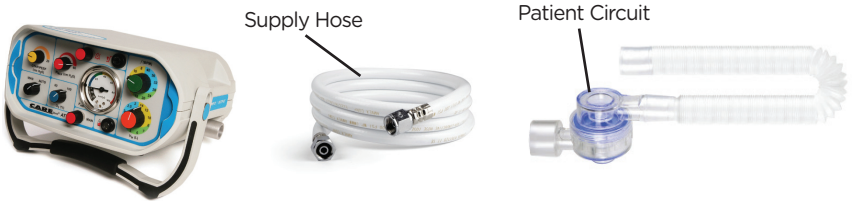


Fig 5. - Connecting the Supply hose and Patient Circuit.

2.3. Pre-use Functional Checks

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 100 L/min at no less than 40.6 PSI (2.8 Bar). Calibrated Test Lung (supplied with ventilator)

Having connected the supply hose to the regulator, ensure that the ventilator Manual/AUTO Selector is in the Manual position and turn on the oxygen supply. Using a mild soap solution, spray the input connection to the ventilator 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 Patient Circuit. Using the selectors on the front panel, select a frequency of ventilation and a flowrate. Turn the Manual/AUTO Control to the Auto position and the ventilator will commence cycling.

Testing of the Individual Features of the Ventilator.
The following features can be individually tested during the pre-use Functional Check:

1. Airway Over Pressure Alarm, Pressure Gauge Function and Pressure Relief Adjustment Function
2. Low Input Pressure Alarm
3. Frequency Adjustment
4. Flow Adjustment
5. Air Mix
6. Manual Ventilation
7. Demand Valve Function and Automatic Circuit Shut Off
8. CPAP/PEEP Control
9. BSI Alarm

1. Airway Over Pressure Alarm, Pressure Gauge Function and Pressure Relief Adjustment Function
With the ventilator connected to the 60 PSI source, set the ventilator cycling at 12 BPM with a Minute Volume control setting of 14 L. Set the adjustable Airway Pressure Control to 20 cmH_2O. Remove the Test Lung from the Patient Connector and occlude the Patient Connector outlet. This will cause the Airway Over Pressure Alarm to activate and a continuous tone will be heard during the inspiratory cycle of the ventilator.

To confirm the pressure relief setting, observe the needle on the Airway Pressure Gauge during the inspiratory cycle and ensure that the needle reaches the 20 cmH_2O mark. Now turn the Adjustable Airway Pressure Selector to the 60 cmH_2O position. Repeat the test and observe that the needle reaches the 60 cmH_2O mark.

2. Low Input Pressure Alarm

Note: To fully test this function it is necessary to have a supply regulator with an adjustable output pressure. (Not supplied) Checking of the alarm can be undertaken by simply slowly closing the cylinder valve.

With the adjustable outlet pressure regulator set with an outlet pressure of 60 PSI, set the ventilator cycling at 12 BPM with a Minute Volume control setting of 14 L.

As the ventilator cycles, gradually reduce the outlet pressure of the regulator until you hear the Low Input Pressure Alarm activate. This will be a slow, mid pitched, pulsed tone. Continue to decrease the regulator outlet pressure and the tone will gradually slow in frequency until it becomes a continuous tone. This indicates that the drive gas is now exhausted to the point where the ventilator will no longer function correctly.

3. Frequency Adjustment
With the ventilator connected to the 60 PSI source, set the ventilator cycling at 8 BPM with a Minute Volume control setting of 6 L. Connect the Test Lung to the Patient Connector and turn the ventilator Manual/Auto Selector to the Auto position.

After every 5 breaths rotate the frequency control counter clockwise to the next setting and observe the increasing frequency of ventilation in the Test Lung. Repeat for every setting. If required, a stopwatch may be used to check the frequency in each setting.

4. Minute Volume Adjustment
With the ventilator connected to the 60 PSI source, set the ventilator cycling at 18 BPM with a Minute Volume control setting of 2 L. Connect the Test Lung to the Patient Connector and turn the ventilator Manual/Auto Selector to the Auto position.

After every 5 breaths rotate the Minute Volume control counter clockwise to the next setting and observe the increasing expansion of the Test Lung. Repeat for every setting. The increasing expansion of the lung indicates an increase in the delivered tidal volume, as the frequency remains constant so the delivered Minute Volume (tidal volume x frequency) will increase with each increase in flowrate.

Note: When testing the lower Minute Volume settings using the test lung provided, there may be insufficient volume delivered with each breath to attain an airway pressure that will cause the BSI Alarm to be shut off. Under these circumstances simply depress the BSI Mute Button to silence the alarm.

5. Airmix

Note: To fully test this function a calibrated 0 - 100% oxygen monitor is required (not supplied).

With the ventilator connected to the 60 PSI medical oxygen source, set the frequency control to 8 BPM and the Minute Volume Selector set at 14 L, attach the oxygen monitor to the outlet of the patient connector. Turn the Air Mix control to the 100% setting and verify that the oxygen concentration, using the oxygen monitor, is 100%.

Now turn the Air Mix control to the 60% setting and again verify (using the oxygen monitor) that the oxygen concentration is in the range of 54 to 66%.

6. Manual Ventilation

With the ventilator connected to the 60 PSI source turn the Manual/AUTO Selector to the AUTO position. Set the frequency control to 14 BPM and the Minute Volume Selector to the 6 L position. Allow the ventilator to cycle automatically for 5 breaths.

Depress the Manual Ventilation Button located on the front of the ventilator. Hold the button in and gas will flow to the test lung for as long as the button is depressed.

Release the button and the automatic cycling will restart with a delay of approximately 20 seconds.

7. Demand Valve Function and Automatic Circuit Shut Off

With the ventilator connected to the 60 PSI source, set the ventilator cycling at 12 BPM with a Minute Volume control setting of 14 L. Turn the Manual / AUTO Selector to AUTO and with the ventilator cycling, apply a vacuum to the patient connector equivalent to a flowrate of 30 L/min for a minimum of 1 second. The demand valve will provide a flowrate equivalent to that demanded and the automatic cycling will cease.

Remove the vacuum from the patient connector and check for the automatic cycling restart after a delay of 5-8 seconds.

Note: The vacuum source can be as simple as a 500 ml calibration syringe.

8. BSI Alarm

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 and the Minute Volume Selector to the 6 L position. Turn the ventilator to AUTO and allow it to cycle for 5 breaths. Remove the test lung and time the delay until the BSI alarm sounds. Depress the silence button and time the delay until the alarm re-starts.

9. CPAP/PEEP Control

With the Patient Circuit attached to the ventilator attach a test lung to the 15/22 mm adapter. Set the frequency control to 20 BPM and the Minute Volume Select or to the 2 L 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.

3. Operating Instructions

3.1. Setting of the Ventilation Parameters

The setting of the ventilation parameters is dependent upon the patient's size, condition and the clinical parameters required to be provided to the patient by the operator. The controls should be set according to the established protocols to which the operators perform their tasks.

3.2. Frequency/Minute Volume Chart (Fig.6)

Infant (3.33-20 kgs) | Child/Teen (11.3-67 kgs) | Adult (40-180 kgs)

FREQUENCY OF VENTILATION (BPM)

MINUTE VOLUME (LITRES)

	40	36	32	28	24	20	18	16	14	12	10	8
2.0	.050	.056	.063	.071	.08	.10	.11	.13	.14	.17	.20	.25
2.5	.063	.069	.078	.089	.10	.13	.14	.16	.18	.21	.25	.31
3.0	.075	.083	.094	.107	.13	.15	.17	.19	.21	.25	.30	.38
3.5	.088	.097	.109	.125	.15	.18	.19	.22	.25	.29	.35	.44
4.0	.100	.110	.130	.14	.17	.20	.22	.25	.29	.33	.40	.50
5.0	.13	.14	.16	.18	.21	.25	.28	.31	.36	.42	.50	.63
6.0	.15	.17	.19	.21	.25	.30	.33	.38	.43	.50	.60	.75
7.0	.18	.19	.22	.25	.29	.35	.39	.44	.50	.58	.70	.88
8.0	.20	.22	.25	.29	.33	.40	.44	.50	.57	.67	.80	1.0
10	.25	.28	.31	.36	.42	.50	.56	.63	.71	.83	1.0	1.3
12	.30	.33	.38	.43	.50	.60	.67	.75	.86	1.0	1.2	1.5
14	.35	.39	.44	.50	.58	.70	.78	.88	1.0	1.2	1.4	1.8

TIDAL VOLUMES (LITRES)

Recommended bodyweight range: 5 Kg to 180 Kg (@ 10ml/Kg)

This chart gives an easy reference to the delivered tidal volumes provided by the different combinations of frequency of respiration and minute volume.

3.3. Operation in Extreme Conditions

Operation of the ventilator in environmental conditions outside of those detailed in this manual may result in a reduction in the ventilator's performance. In extreme cold weather a slowing down of the frequency of ventilation may be seen with a corresponding increase in the delivered tidal volume. In high temperature environments the effect is not noticeable in terms of delivered ventilations but may cause excessive wear in the ventilator components over time.

Operation of the ventilator under supply pressures outside those detailed in this manual may result in a reduction in the ventilator's performance. Input pressures below the minimum stated will cause the low input pressure alarm to function and will, as the pressure falls to the point where the alarm is constant, cause the ventilator to cease cycling.

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.

4. After Use Cleaning and Testing

4.1. Dismantling and Cleaning

After use turn off the ventilator and disconnect the supply hose from the gas supply. Disconnect the patient circuit from the gas outlet on the side of the ventialtor and either (a) discard the circuit if it is designed for single use or (b) process the reusable circuit following your normal protocols. Disinfect using a legally marketed, commercially available, hard surface disinfectant solution which is compatible with the materials in accordance to local protocols.The ventilator can then be cleaned using a mild soap solution and warm water and a soft nail brush to remove ingrained contamination.

⚠ WARNING ⚠

Do not immerse the ventilator in any solutions. Do not use chlorine based cleaning agents. If the ventilator is accidentally submerged in any liquid it should be shaken to remove as much of the liquid as possible and then the ventilator should be returned to the manufacturer for factory service.

4.1.1. Changing the Air Intake Filter

To change the air intake filter, undo the locking screw on the filter cover, which is located on the rear panel of the unit. Remove the old filter and discard following local protocols. Replace the filter with a new one ensuring that the filter is properly located and then reattach the cover, screwing the cover on finger tight.

Note: It is recommended that the air intake filter is changed after each use of the ventilator using the 60% air/oxygen mix mode to avoid using a partially occluded or contaminated filter for the next patient.

Fig. 7 - Rear Panel Layout

4.2. After Use and Monthly Checking

- **After Use**

After each use the ventilator should be cycled to confirm function. The selectors should be rotated through all positions and all alarm functions should be checked to ensure function (see section 2.3).

5. Preventive Servicing

- **Monthly Checking**

Every month (or more frequently if local protocols dictate) the ventilator should be put through a checking procedure to ensure full function of all features. The checking protocol detailed in section 2.3 “Pre-use Functional Check” should be followed for this purpose.

- **Annual**

It is recommended that the ventilator is returned to a service centre (authorized by the manufacturer to undertake service and repair of this device) for an Annual Preventative Maintenance inspection (more frequently in high use areas). The inspection will incorporate

a full diagnostic test of all parameters. When complete, a certificate of compliance will be issued to cover the device for the next service period.

This maintenance inspection, providing it is carried out by an authorized service centre, will not affect the product warranty.

- **Full Service**

Level II Service
The device shall be returned to the manufacturer or a service center authorized by the manufacturer for annual Level II Service every year.

Manufacturer Full Service
The device shall be returned to O-Two Medical Technologies for Manufacturer Full Service every 5 years.

	DESCRIPTION	PROCEDURE	CRITERIA	SCHEDULE	BY
Monthly	Function Check	User Manual Chapter 2.3	Within specification	Monthly	User
Annual	Level II Service	Service Manual	Meet product specifications	Every year	Manufacturer/ Service Center
Every 5 years	Full Service	Service Manual	Meet product specifications	Every 5 years	Manufacturer

6. Troubleshooting Chart

Note: If any of the remedies do not resolve the problem you are experiencing please contact your nearest Approved Service Centre.

Symptom	Probable Cause	Remedy
Ventilator does not function in any mode	Gas supply exhausted	Replace cylinder
	Gas supply not turned on fully	Open cylinder valve
	Supply hose not connected	Connect supply hose to regulator outlet
	Gas pressure regulator faulty	Replace pressure regulator
	Gas supply hose kinked or cut	Replace supply hose
Ventilator does not function in automatic mode	Manual/AUTO switch in the Manual position.	Switch to AUTO
	Internally clogged orifice in the Frequency or Minute Volume controls	Switch selector knobs to a different position
	Other control knobs may be incorrectly positioned	Check all selector knob positions
Insufficient ventilations	Incorrect control setting selection	Check selector positions
	Other control knobs may be incorrectly positioned	Check selector positions
	Internal blockage in Minute Volume Control	Switch to another Minute Volume setting
	Pressure relief setting too low	Check selector position
Low Input Pressure Alarm sounds intermittently or continuously	Gas supply low	Change Cylinder
	Cylinder valve not fully opened	Open Valve fully
	Gas supply hose kinked or cut	Replace supply hose
	Gas supply regulator faulty	Replace pressure regulator
Automatic circuit shut-off not activating on demand breathing	Poor patient circuit integrity/ loose connections or faulty patient valve	Check all circuit connections and hose for tears/holes
	Poor facemask seal	Re-position facemask
Breathing System Integrity Alarm Sounds	Patient circuit has become disconnected	Re-connect circuit
	Tidal volume being delivered is too low	Adjust ventilator settings

Symptom	Probable Cause	Remedy
Demand flowrate low or not functioning	Supply pressure too low (Low Input Pressure Alarm will sound)	Faulty gas supply regulator
	Gas supply cylinder low or empty.	Replace cylinder
	Regulator output insufficient	Replace regulator
	Cylinder valve not fully open	Open valve fully
	Brand of circuit used may be entraining room air through expiratory port	Use only O-Two approved circuits
Airway Pressure Alarm	Incorrectly selected airway pressure	Select a higher pressure
	Airway obstructed	Correct the obstruction
	Selected Minute Volume too high/Frequency of ventilation too slow	Change the settings selected

7. CAREvent® Accessories

ORDER Nº	PART
01CV8015	CAREvent® Deluxe Single Use Transport Ventilation Circuit with PEEP Port
01CV8016-CS	O-Two CAREvent® MRI Ventilation Circuit with PEEP Port and 10 Foot Hose
17MP7010	Single Use PEEP Valve
17MP7327-Cs	Air Intake Filter for CAREvent® ATV+ & MRI
01CV7025	CAREvent® MRI Mounting Bracket
01CV7026	CAREvent® MRI Stand and Mounting Bracket
01CV7030	CAREvent® ATV+ & MRI Ambulance Mounting Bracket

Your Representative is:

O-TWO MEDICAL TECHNOLOGIES INC.

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For your nearest Authorized O-Two Distributor
In North America call Toll Free 1-800-387-3405

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