

# MACS<sup>®</sup> Mask CPAP System

Operators Manual

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The **MACS** CPAP delivery system is under US patent protection as part of the **pNeuton<sup>®</sup>** Ventilator (Patent # 6,591,835)

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## Table of Contents

Section 1. General Description .....	1-1
Indications for Use .....	1-1
Contraindications .....	1-2
Section 2. Warnings, Cautions, Notes .....	2-1
Warnings .....	2-1
Cautions .....	2-3
Notes .....	2-3
Medical Symbol Key .....	2-5
Section 3. Controls and Patient Safety Systems ..	3-1
Front Panel .....	3-1
Rear Panel .....	3-3
Unique Device Identifier .....	3-4
Internal Patient Safety Systems .....	3-5
Section 4. Operating Instructions .....	4-1
Device Set-up .....	4-1
Operational Verification .....	4-1
Patient Set-up.....	4-3
Oxygen Control .....	4-3
Hypobaric Operation .....	4-3
Section 5. Patient Circuit .....	5-1
Adult / Pediatric Circuit .....	5-1
Patient Connection .....	5-2
Single-Use Medical Devices/Accessories .....	5-3
Section 6. Accessories .....	6-1
Section 7. Theory of Operation .....	7-1
Pneumatic System Diagram .....	7-1
Pneumatic System Description .....	7-2
CPAP Demand Flow Breathing System .....	7-2
Oxygen Delivery System .....	7-3

Section 8. Troubleshooting .....	8-1
Section 9. Cleaning and Maintenance .....	9-1
Cleaning the Device .....	9-1
Cleaning / Disinfecting the Patient Circuit .....	9-1
Routine Maintenance .....	9-1
Factory Preventative Maintenance.....	9-1
Section 10. Specifications .....	10-1
General Description .....	10-1
System Performance .....	10-1
Environmental and Physical Characteristics ....	10-2
Power Sources .....	10-2
Section 11. Limited Warranty .....	11-1
Section 12. Index .....	12-1

## MACS Mask CPAP System

### Section 1: General Description

**MACS** is a small, lightweight Continuous Positive Airway Pressure (CPAP) system designed for use on spontaneously breathing patients who require oxygen assistance. The patient is allowed to breathe spontaneously with minimal work of breathing. The CPAP system provides expiratory positive pressure delivered non-invasively via face mask or invasively via ET tube. The delivered oxygen is adjustable between 65 and 100 percent, with oxygen as the driving source gas.

**MACS** is an all pneumatic device. Electrical power is not required for operation. **MACS** has been specifically designed for patient support by trained Emergency Medical Professionals, Respiratory Therapists, nurses and physicians, both in the prehospital and hospital environment. It may also be used at the accident scene, during intra and inter-hospital transport, in aircraft, on ambulances, and in emergency rooms.

### Indications for Use

The **MACS** CPAP System is intended for spontaneously breathing patients requiring up to 140 L/min oxygen at 65% or 100% concentrations.

The device is suitable for use in:

- Pre-hospital transport applications including accident scene, emergency rescue vehicles
- Hospital ICU transport applications including emergency, surgery, post-anesthesia / recovery
- Air transport via helicopter or fixed wing

### Contraindications

The following conditions contraindicate the use of the **MACS** CPAP System:

- Patients undergoing procedures with flammable anesthetic gasses
- Patients requiring ventilatory support with mechanical respiratory rate and tidal volume

## Section 2: Warnings, Cautions, Notes

The **MACS** Mask CPAP System is intended for use by properly trained personnel under the direct supervision of a licensed medical Physician or Practitioner only. Personnel must become thoroughly familiar with this Operators Manual prior to using the **MACS** Mask CPAP System on a patient.


As used in this manual, the following terms mean:

- Warning:** Indicates the possibility for injury to the patient or the operator
- Caution:** Indicates the possibility of damage to the device
- Note:** Places emphasis on an operating characteristic


### Warnings


This manual serves as a reference. The instructions in this manual are not intended to supercede the physician's instructions regarding the use of the **MACS** Mask CPAP System.


The operator should read and understand this entire manual before using the **MACS** system. Incorrect operation can be hazardous.


 **DO NOT** use the **MACS** system in conjunction with flammable anesthetics or in the presence of open flame. Ensure the device and all accessories are free from oil or grease.

**MACS** uses air entrained from the atmosphere. Do not use in contaminated (hazardous, explosive) atmospheres. Only compressed oxygen may be used.

 **DO NOT** use conductive (anti-static) patient breathing circuits. The only approved patient circuit for use with **MACS** CPAP are the Airon® circuits listed in Section 5 of this manual. Any other patient circuit should **NOT** be used and may lead to patient harm. The patient and equipment should be constantly monitored.


 The Airon patient circuit is a single use, disposable device. Cleaning, reprocessing and / or reuse of this device is not recommended. Reprocessing may cause a change in ventilation characteristics. The circuit and all components are sold clean and non-sterile.

 The Operational Verification tests as described in this manual (Section 4) must be performed prior to connecting a patient to the device. If the device fails any of the tests it must be removed from clinical use. **DO NOT** return the unit to clinical use until all repairs has been completed by an Airon approved repair facility and all operational verification tests are acceptable.

 The **MACS** CPAP System does not have a patient disconnect alarm. If the patient becomes disconnected from the device there will be no audible or visual alarm to indicate this condition. Always observe the patient while providing CPAP support.

## Cautions

Insure that **clean, dry** medical grade compressed air is used at all times. Compressed air that is contaminated with water or other material will damage the internal components of the ventilator.


 **DO NOT** attempt to service the unit. Service may only be performed by Airon® Corporation authorized engineers. The Preventative Maintenance program requires a general service and calibration every two years. Only original manufacturer parts and accessories should be used, and only factory trained personnel may perform Preventative Maintenance.

Any attempts to modify the hardware of this device without the express written approval of Airon Corporation will void all warranties and liabilities.

Do not immerse the **MACS** CPAP System or allow any liquid to enter the case or the inlet filter. Clean as directed in Section 9, Cleaning and Maintenance.

## Notes

In the USA, the **MACS** CPAP system is a restricted medical device intended for use by qualified medical personnel under the direction of a physician.













 The CPAP system will operate normally at altitudes up to 15,000 feet. Changes in altitude will not affect pressure provided to the patient.

Special note on the presence of latex: The components, devices, accessories, and packaging that make up the **MACS** CPAP System do not contain any dry natural rubber or natural rubber latex, which may cause allergic reactions.

Special note on the presence of di (2-ethylhexyl) phthalate (DEHP): The components, devices, accessories, and packaging that make up the **MACS** CPAP System do not contain any phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC.

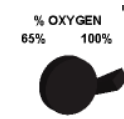
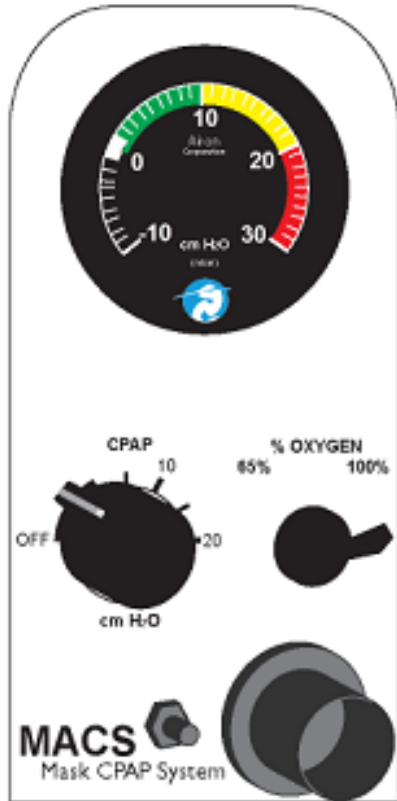
**Additional Warnings, Cautions, and Notes are located throughout this manual.**

## Airon's Medical Symbol Key

	Consult Instructions of Use
	CE Marked
	Authorized Representative in European Community
	Model (Part) Number
	Lot Number
	Do Not Reuse
	MRI Conditional (3 T)
	Manufacturer
	Manufactured Date
	Use By Date
	Keep Dry
	Temperature limitation - upper and lower temperature limits

### Section 3: Controls and Patient Safety Systems

#### Front Panel



Oxygen control, select either 100% or 65%



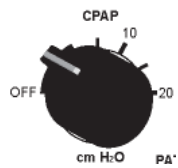
Patient Circuit connection, see section 5 for a complete description of the patient circuit and its attachment to the front panel



Expiratory Valve connection

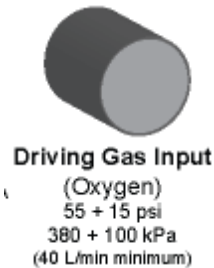
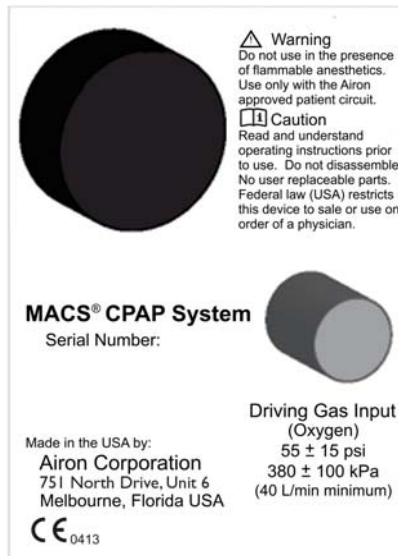


Pressure gauge, patient circuit pressure



CPAP control, calibrated, range 0 to 20 cm H<sub>2</sub>O

## Rear Panel



Driving Gas Input (oxygen), DISS connection, requires 55 ± 15 psi (380 ± 100 kPa), (40 liter/minute minimum)



Ambient Air Inlet filter

## Unique Device Identification (UDI)

Pursuant to the U.S. FDA Unique Device Identification (UDI) Rule, each device must bear a UDI code. The UDI for MACS CPAP System is located under the “Serial Number:” labeling, in plain text, on the back panel of the device. The UDI code consists of one Device Identifier (DI) and potentially four Production Identifiers (PI). Therefore, UDI = DI+PI. Production identifiers are required if the information appears on the product (box) label. The UDI on the product (box) label appears in both plain text and machine-readable format. The numbers in the parentheses indicate different parts of the UDI, as applicable to the device:

- (01) Device Identifier
- (10) Batch / Lot Number
- (11) Manufacturing / Production Date
- (17) Expiration Date
- (21) Serial Number

The format for Manufacturing / Production date and Expiration date within the UDI code is: YYMMDD

- YY = tens and units of the year (e.g. 2014 = 14)
- MM = number of the month (e.g. January = 01)
- DD = number of the day (e.g. third day = 03)
- January 03, 2014 = 140103

An example UDI for the MACS CPAP system is as follows:



(01)00853678006030(21)M0000

Device Identifier = 00853678006030

Serial Number = M0000

The Device Identifier portion of the code may be entered into AccessGUDID to obtain information about the product.  
<http://accessgudid.nlm.nih.gov/>



## Internal Patient Safety Systems

The **MACS** CPAP System has the following internal safety systems. These systems help ensure patient safety in the event of device malfunction.

### High Pressure Release

There is an internal safety pressure release valve included in the **MACS** CPAP System. This valve will automatically limit circuit pressure to approximately 42 cm H<sub>2</sub>O.

### Anti-Suffocation System

An internal safety system will allow the patient to breathe on his or her own in the event of device malfunction. At approximately 2 cm H<sub>2</sub>O negative pressure an internal valve will open allowing unimpeded ambient air to enter the patient circuit for the patient. This system is always available to the patient, irrespective of control settings.

**Note:** Always use an external oxygen monitor to ensure the desired oxygen percentage is delivered to the patient.

## Section 4: Operating Instructions

### Device Set-up

The following equipment is needed:

1. **MACS** CPAP Device with breathing circuit (See Section 5)
2. High pressure oxygen hose with pressure regulated oxygen supply
3. Test lung, (1 Liter rigid wall, Airon Part #21002)

When ready:

1. Attach breathing circuit to device following instructions in the Operators Manual.
2. Attach the test lung to the patient side of the breathing circuit.
3. With the device set up as described above, adjust the controls as follows:
  - a. Oxygen % to 65%
  - b. CPAP to 10 cm H<sub>2</sub>O.
4. Attach Oxygen Input (Driving Gas) on rear panel of the device to a high pressure oxygen source and turn on the oxygen.

NOTE: The unit will begin operation at the above settings when the oxygen is turned on.

### Operational Verification

Verification Step	Acceptable Range	Result
Expand the test lung at a rate of approximately 10 breaths per minute to simulate spontaneous breathing. Ensure that the pressure gauge returns to 10 ± 2 cm H <sub>2</sub> O after each breath.	10 ± 2 cm H <sub>2</sub> O	Pass / Fail

Switch the oxygen toggle to 100%. Expand the test lung at a rate of approximately 10 breaths per minute and ensure the pressure gauge returns to 10 ± 2 cm H <sub>2</sub> O after each breath.	10 ± 2 cm H <sub>2</sub> O	Pass / Fail
Turn the CPAP knob to the off position. Ensure the pressure gauge points inside the off range and flow stops.	Off	Pass / Fail

When the device has passed the Operational Verification procedure it is ready for clinical use. If the device fails to pass any of the following tests do not apply it to patients. Call your local distributor or Airon Corporation Customer Support at 888-448-1238. **Do not attempt to service the unit.**



**CAUTION:** Do not disassemble the **MACS** CPAP System. No internal user replaceable parts. All service must be performed by Airon Corporation or an approved service technician. Opening the device will negate the warranty. User will be responsible for all repair costs to service the unit.

## Patient Set-up

1. Set up the **MACS** CPAP System according to the set-up instructions above.
2. Attach the patient circuit with face mask to the device.
3. Set the % Oxygen control to the desired  $F_{iO_2}$ .
4. Adjust the CPAP control to the desired level. There is no adjustment for spontaneous breath trigger sensitivity as this is automatically set by the device.
5. Inform the patient of what you will be doing and apply the face mask.
6. Monitor the pressure gauge to ensure proper delivery of CPAP. Pressure should not vary more than 3 to 4 cm  $H_2O$  per breath, depending on patient effort.
7. Observe and monitor the patient and the device per your institution's standards. If using a portable oxygen gas supply, monitor the supply level to ensure there is sufficient gas to power the device. Never leave the patient unattended.

## Oxygen Control

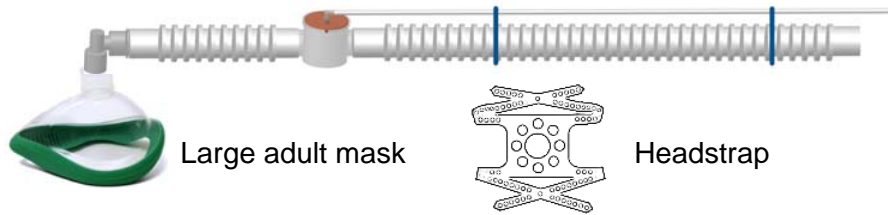
The Oxygen control sets the level of oxygen delivered to the patient. The device uses an internal venturi system which provides the 65% oxygen concentration. See Section 7 for a complete description of the Oxygen Delivery System. It is recommended that an external oxygen analyzer always be used to verify oxygen delivery.

## Hypobaric Operation

The device will operate normally at altitudes up to 15,000 feet. Changes in altitude will not affect pressure delivery to the patient. Always monitor the patient carefully using a cardiac monitor.

## Section 5: Patient Circuit

### Adult / Pediatric Circuit



The patient circuit designed for use with the **MACS** CPAP System is part number 58011; 6 ft. disposable patient circuit with disposable face mask (size Large) and headstrap. The compression volume is 1 ml per cm H<sub>2</sub>O.

Additionally, a full range of compatible patient circuits is available to meet your needs. Other patient circuits may become available in the future. All acceptable circuits will have part numbers from 58001 to 58999.

Part Number	Description
58001	6 ft. (1.8 m) disposable, box of 15
58006	6 ft. (1.8 m) disposable, with expiratory filter, box of 15
58011	6 ft. (1.8 m) disposable, with large adult mask and head strap, box of 10
58021	6 ft. (1.8 m) disposable, with expiratory filter, large adult mask and head strap, box of 10
58051	8 ft. (2.4 m) disposable, box of 15

**! WARNING:** Patient circuits other than the Airon<sup>®</sup> circuits listed above may alter the ventilator's CPAP / PEEP characteristics and / or expiratory flow resistance. They should **NOT** be used and may lead to patient harm.

**! WARNING:** Do not use air filters on the **expiratory port** of the patient circuit except those provided by Airon Corporation. Some filters may alter the ventilator's CPAP characteristics and / or expiratory flow resistance. They should **NOT** be used and may lead to patient harm.

**! CAUTION:** The **MACS** requires the use of a non-vented full-face mask for proper CPAP operation.

### Patient Connection

The patient circuit must be attached to **MACS** properly. Incorrect attachment could result in failure to provide adequate oxygen delivery.



The main breathing hose (22mm) is connected to the large connection port.



The small tubing (3mm) connects the expiratory valve to the small connection port.

**NOTE:** The Airon patient circuit is a single use, disposable device. Cleaning, reprocessing and / or reuse of this device is not recommended. The circuit and all components are sold clean and non-sterile.

## Single-Use only Medical Devices/Accessories

### How do I know if a device is Single-Use?



This symbol will be identified on the packaging and User's Manual of the device.

### What does Single-Use mean?

Do not reuse. A single-use device is used on an individual patient during a procedure, such as transport ventilation, and then discarded. It is not intended to be reprocessed and used again, even on the same patient.

### What is the concern with reused device labeled Single-Use?

The use of reprocessed devices may present serious incidents relating to the health and safety of patients and healthcare professionals. Reuse can be unsafe because of risk of:

- Cross-infection – inability to clean and decontaminate due to design, device components are not manufactured for disassembly and reassembly
- Endotoxin reaction – excessive bacterial breakdown products, which cannot be adequately removed by cleaning
- Patient injury – device failure from reprocessing or reuse because of fatigue or material alteration
- Chemical burns or sensitization – residues from chemical decontamination agents on materials that can absorb chemicals







**NOTE:** If you reuse a single-use device you may be legally liable for the safe performance of the device.

## Section 6: Accessories

Using the **MACS** CPAP System should be convenient and user-friendly for healthcare providers and patients. Accessories for the device add serviceability in clinical situations and allow the device to be adaptable to the environment of use.

	<p><b>Adult/pediatric patient circuit</b>          - Disposable, single patient use.          - 6 foot (1.8m) and 8 foot (2.4m) length</p>
	<p><b>Adult/pediatric CPAP Masks</b> -          Disposable, single patient use.          Adult Small          Adult Medium          Adult Large</p>
	<p><b>Bacterial/Viral Filter</b>          Disposable, single patient use.          Approved for use in-line and on expiratory valve.</p>
	<p><b>Test Lung</b>          A rigid wall Test Lung is ideal to test device performance and create spontaneous breaths.</p>
	<p><b>Travel Bag</b>          The Travel Bag holds the <b>MACS</b> securely and safely for transport. The clear front panel, held closed with Velcro, can be opened to make control adjustments and then closed for operation. The bag has side pouches for circuits and accessories, a bright yellow reflective stripe, hand carry strap and a shoulder strap.</p>

	<p><b>Protective Boot with Shoulder Strap</b>          The Protective Boot wraps around <b>MACS</b> to protect it from accidental falls. <b>MACS</b> can be operated while in the boot. A shoulder strap makes it very easy to carry. The Pole Mount and Bed Rail Mount brackets can be used with the Protective Boot.</p>
	<p><b>Bracket, Pole Mount</b>          The Pole Mounting Bracket allows the <b>MACS</b> to be firmly attached to a vertical pole, such as an IV pole. Poles up to 1.25" (3 cm) can be accommodated. <b>MACS</b> slide in and out of the bracket, which allows portable use.</p>
	<p><b>Bracket, Bed Rail Mount</b> The Bed Rail Mounting Bracket allows the <b>MACS</b> to be firmly attached to a horizontal tube, such as a bed rail. Tubes up to 1.25" (3 cm) can be accommodated. <b>MACS</b> slide in and out of the bracket, which allows portable use.</p>
	<p><b>Oxygen Regulator</b>          MRI compatible high pressure oxygen regulator for D / E size oxygen tanks.</p>



**High Pressure Oxygen Hose -**  
DISS Female both ends, MRI compatible. (Note: ISO color hose available)



**Oxygen Cylinder**  
**E Size**  
MRI compatible

**D Size**  
400 liter cylinder with toggle valve



**Reusable Patient Circuit**  
- Adult/pediatric patient circuit, autoclavable  
- 1.8 meters (6 ft)

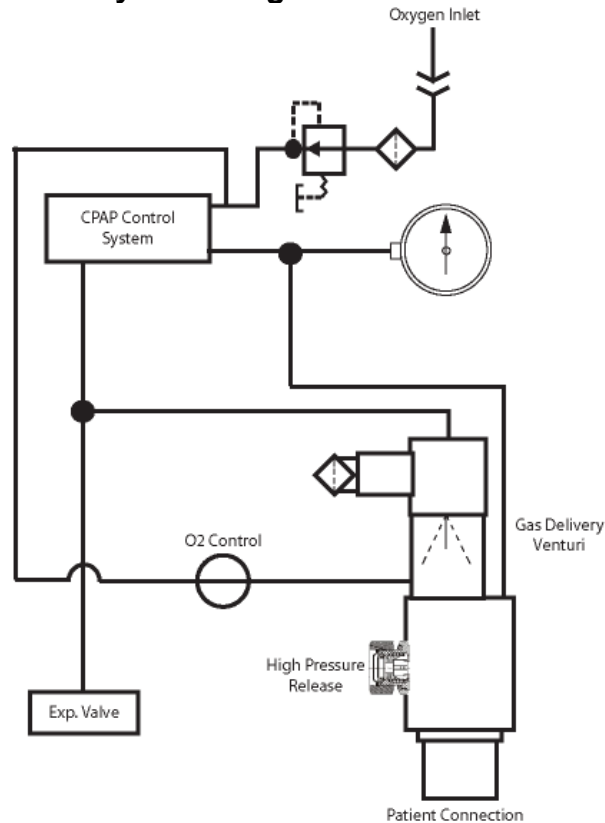
**Available for International Customers Only.**

## Section 7: Theory of Operation

**MACS** is a pneumatic device that provides Continuous Positive Airway Pressure (CPAP). It provides up to 20 cm H<sub>2</sub>O at up to 140 L/min flow for a spontaneously breathing patient. This section describes how the device operates.

Further information on the device's theory of operation, including circuit diagrams, parts lists, and calibration instructions is available from Airon Corporation to properly trained service personnel.

### Pneumatic System Diagram



### Pneumatic System Description

The major components of the pneumatic system and the control of gas flow through the device are as follows:

1. High pressure gas (oxygen) enters the device and is filtered (5 micron) and reduced to a lower working pressure (35 psi - 240 kPa).
2. The adjustable CPAP control system directs a pressure signal to the expiratory valve to generate CPAP and provides variable flow through the gas delivery venturi on demand for spontaneous breaths.
3. The oxygen control is used to increase the delivered oxygen level from 65% to 100%. When turned on, oxygen is fed into the gas delivery venturi system.

### CPAP Demand Flow Breathing System


The device's internal CPAP demand flow system provides gas for spontaneous breathing at adjustable CPAP pressures up to 20 cm H<sub>2</sub>O. This system has several key features:

1. When turned on, the system supplies a continuous flow of gas at approximately 10 L/min. This flow of gas helps to establish the desired CPAP level by balancing flow with the pressure generated on the expiratory valve by the CPAP system.
2. The continuous flow of gas also establishes the flow sensitivity to spontaneous breathing efforts. If the patient's inspiratory flow demand exceeds the continuous flow of gas, additional flow will be added to meet patient demand. There is no sensitivity adjustment to this system. The CPAP system will automatically meet the needs of the patient, with flows up to 140 L/min, by attempting to maintain the



balance between flow and pressure at the expiratory valve.

3. The CPAP control is calibrated to the dynamics of Airon Corporation disposable patient circuit (part numbers 58001 through 58999). Using this circuit will ensure proper operation and the full 0 to 20 cm H<sub>2</sub>O CPAP range.

 Using other patient circuits may affect operation and alter the device's CPAP characteristics and full CPAP range.

## Oxygen Delivery System

With the device driven by 100% oxygen as the source gas, **MACS** can be set to deliver 65% or 100% oxygen.

### Oxygen Delivery

The F<sub>I</sub>O<sub>2</sub> of this system is set by the % Oxygen control. When set for 65%, the actual oxygen percentage and baseline flow is related to the level of CPAP in use. When set for up to 10 cm H<sub>2</sub>O CPAP, the system will provide a F<sub>I</sub>O<sub>2</sub> of approximately 0.65. As the CPAP level increases to 20 cm H<sub>2</sub>O, the F<sub>I</sub>O<sub>2</sub> can be expected to increase to as high as 0.75 ± 0.10. This is due to a drop off in efficiency (stalling) of the CPAP venturi system at higher CPAP levels. Whether set for 65% or 100%, extremely high inspiratory flow demand may decrease the desired F<sub>I</sub>O<sub>2</sub>.

It is recommended that an external oxygen monitor be used at all times to measure and display the delivered oxygen concentration.

### Factors Effecting the Operating Time of Oxygen Tanks

There are several factors that affect the length of time the device will operate from a tank of oxygen. **MACS** uses very little gas for its own operation (less than 20 ml/min) and is not a major factor in oxygen tank consumption. The

major factors are:

- Volume of oxygen in the tank
- Patient's tidal volume and rate (minute volume)
- Position of the % Oxygen control
- Level of CPAP in use

Setting the % Oxygen control to 65% will decrease the amount of oxygen used from the tank, nearly doubling the time an oxygen tank lasts.

When CPAP is turned on, **MACS** uses approximately 5 L/min oxygen from the tank to provide the 10 L/min baseline flow of the system. In addition, if the % Oxygen control is set for 100%, 7 L/min more is used. The patient's own spontaneous tidal volume and rate will use additional oxygen from the tank, based upon the tidal volume of those breaths. Below are approximate operating times based on different combinations of patient tidal volume and rate, known as minute volume.

#### Approximate operating time using a full "D" size cylinder (400 liters) at 10 cm H<sub>2</sub>O CPAP

<u>Minute Volume</u>	<u>100% Oxygen</u>	<u>65% Oxygen</u>
5 L/min	44 min	65 min
10 L/min	29 min	45 min
15 L/min	22 min	35 min

#### Approximate operating time using a full "E" size cylinder (660 liters) at 10 cm H<sub>2</sub>O CPAP

<u>Minute Volume</u>	<u>100% Oxygen</u>	<u>65% Oxygen</u>
5 L/min	65 min	100 min
10 L/min	43 min	67 min
15 L/min	32 min	50 min

## Section 8: Troubleshooting

This troubleshooting guide lists common problems that may be encountered and possible solutions. If none of the corrective actions seem to work, contact Airon Corporation or your distributor.

Indication	Meaning	Corrective Action
Device does not operate – no gas flow	Missing or insufficient driving gas supply	Check gas source, 55 psi (380 kPa) at 40 L/min is required
	Patient circuit disconnection	Reconnect patient circuit
	Internal Malfunction	Send device for service
Device seems to “want” to operate, but little gas flow is available	Expiratory Valve drive line disconnected	Ensure tubing is properly connected
	Expiratory Valve is malfunctioning	Replace Patient Circuit
	Insufficient driving gas supply	Check gas source, 55 psi (380 kPa) at 40 L/min is required
	Internal Malfunction	Send device for service
Device appears to be stuck with high flow	CPAP may be turned on high	Check CPAP control
	Internal Malfunction	Send device for service
Can't get the CPAP desired	Expiratory Valve malfunctioning	Replace patient circuit with Airon part number 58011
	Using a circuit not recommended by Airon	Replace patient circuit with Airon part number 58011
	Internal malfunction	Send device for service

Indication	Meaning	Corrective Action
	Excessive “chattering” of CPAP system	Occurs when using some test lungs but will not when connected to a patient. If problem persists, send device for service
Device using too much gas	Leak at gas source	Check hoses and tank regulator for leaks
	Internal leaks	Send device for service
Oxygen concentration too low	Source gas not 100% oxygen	Ensure source gas is 100% oxygen
	High patient spontaneous ventilation	Decrease spontaneous ventilation
	Internal malfunction	Send device for service

## Section 9: Cleaning and Maintenance

### **Cleaning the Device**

- Use only mild detergent or disinfectant and water with a soft cloth.
- Do not immerse the device in water.
- Do not attempt to sterilize the device with autoclave or ethylene oxide. Severe damage to the device may occur.

### **Cleaning / Disinfecting the Patient Circuit**

The recommended Airon patient circuit is a disposable, single use device, Airon part number 58001 through 58999. This circuit must not be cleaned, disinfected or reused.

See Single-Use only Medical Device information, page 5-3.

### **Routine Maintenance**

Airon Corporation recommends that an Operational Verification Test (see Section 4) be performed with initial installation and prior to use on each patient. Institution's standards may require additional biomedical surveillance. No additional routine maintenance is required.

### **Factory Preventative Maintenance**

- A Preventative Maintenance service is required every 2 years to ensure continuous safety and reliability of the device.

- Device service includes:
  - Replacement of internal and external filters
  - Replacement of internal materials subject to wear
  - Reconditioning of the enclosure
  - Complete calibration
- This service must only be performed by Airon Corporation or an Airon approved service technician.
- Failure to perform this service may result in malfunctioning of the device.

## Section 10: Specifications

### General Description

- Pneumatically operated device provides CPAP using a demand flow system
- Equipment not suitable for use in the presence of flammable anesthetics
- Rated for continuous operation

### System Performance

- Controls
  - CPAP 0 to 20 cm H<sub>2</sub>O
  - % Oxygen 100% or 65%
- Operating Ranges
  - Internal P Limit 42 cm H<sub>2</sub>O
- Accuracy of Controls
  - CPAP  $\pm 5\%$
  - F<sub>1</sub>O<sub>2</sub>  $\pm 10\%$
- Precision - breath to breath repeatability of controls
  - CPAP  $\pm 2$  cm H<sub>2</sub>O
  - F<sub>1</sub>O<sub>2</sub>  $\pm 5\%$
- Specificity - effect of one control on another
  - CPAP  $\pm 5\%$
  - F<sub>1</sub>O<sub>2</sub>  $\pm 5\%$
- Internal Compliance 0.1 ml/cm H<sub>2</sub>O

- Device Resistance to Flow
  - Inspiratory, 60 L/min: less than 2 cm H<sub>2</sub>O
  - Expiratory, 50 L/min: less than 2 cm H<sub>2</sub>O

### Environmental and Physical Characteristics

- Hypobaric (high altitude) compatible up to 15,000 feet (4,600 meters)
- Weight: 3.0 pounds (1.35 kg)
- Size: 6.7"H x 3.7"W x 8.2"D (17.0 cm x 9.4 cm x 20.8 cm)
- Storage Temperature Range: -46 to 71 °C (-51 to 160 °F), 15 to 95 percent humidity, noncondensing
- Operating Temperature Range: -26 to 60 °C (-15 to 140 °F), 15 to 95 percent humidity, noncondensing

### Power Sources

- Driving gas requirement
  - 55 psi  $\pm$  15 psi (380 kPa  $\pm$  100 kPa)
  - 100% oxygen. Do not use the device with other types of gases.
  - The gas supply must be capable of delivering at least 40 liters per minute at 55 psi. If input pressure drops less than 40 psi due to insufficient gas flow, the device will begin to malfunction.

**NOTE:** Baseline oxygen consumption at 10 cm H<sub>2</sub>O CPAP;  
65% Oxygen: 5 L/min  
100% Oxygen: 12 L/min

## Section 11: Limited Warranty

AIRON CORPORATION, through its Official Distributor, warrants this product to be free from defects in construction, material and workmanship for a period of twelve (12) months from the date of original delivery to buyer when operated properly under conditions of normal use for which the product is intended. This twelve (12) month warranty does not extend to expendable items such as membranes, hoses, patient circuits and filters which are warranted to be free of defects only at time of original delivery.

The official AIRON CORPORATION Distributor will, at its option, either repair or replace any defective product, as above defined, which is reported to that AIRON CORPORATION Distributor within 72 hours of occurrence during the warranty period. If so instructed by the Distributor, such defective products must be returned to the official AIRON CORPORATION Distributor in the original container with freight charges prepaid. In any case, AIRON CORPORATION shall be responsible for repairs to, or replacement of, such defective product only.

### LIMITATIONS ON AND DISCLAIMER OF WARRANTIES:

AIRON CORPORATION shall be relieved of any liability under this warranty: if the product is not used in accordance with manufacturer's instructions; if attachment or incorporation of any device is made to this product without written approval; if use is made in any manner other than intended by the manufacturer; if regular periodic maintenance and service is not performed; if repairs are made by other than authorized AIRON CORPORATION service personnel; if the product has been subject to abuse, misuse, negligence or accident. Any product that has been mechanically or electronically altered without

specific written authorization from AIRON CORPORATION is also excluded from this warranty.

The warranty described in this Agreement is in lieu of all other warranties. THE PARTIES AGREE THAT THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, ARE EXCLUDED FROM THIS AGREEMENT.

Except as stated above, AIRON CORPORATION SHALL NOT BE LIABLE FOR ANY DAMAGES, CLAIMS OR LIABILITIES INCLUDING, BUT NOT LIMITED TO, PERSONAL BODILY INJURY, OR INCIDENTAL, CONSEQUENTIAL, OR SPECIAL DAMAGES.

## Section 12: Index

### A

Accessories 6-1  
Airway Connection Port 3-2  
Altitude Operation 4-3

### C

Cautions 2-3  
Circuit, Patient Breathing  
    Cleaning 9-1  
    Configuration 5-1  
    Connecting 5-2  
Cleaning 9-1  
Contraindications 1-2  
Controls  
    % Oxygen 3-2  
    CPAP 3-1  
CPAP  
    Control 3-1  
    Functional Operation 7-2

### E

Expiratory Valve  
    Connection 5-2  
    Relationship to CPAP System 7-2

### F

Front Panel 3-1

### H

Hypobaric Operation 4-3

### I

Indications For Use 1-1  
Internal Patient Safety Systems 3-5

### M

Maintenance - Device Service 9-1  
Medical Symbol Key 2-5

### N

Notes 2-3

### O

Operational Verification 4-1  
Oxygen  
    % Oxygen Control 3-2  
    Driving Gas Inlet 3-3  
    Driving Supply Requirements 10-2  
    Operational Characteristics 7-3  
    Oxygen Control, Set-up 4-3

### P

Patient Circuit  
    Cleaning 9-1  
    Configuration 5-1  
    Connecting 5-2  
Performance Verification 4-1  
CPAP  
    Control 3-1  
    Functional Operation 7-2  
    Trigger Sensitivity 7-2  
Pneumatic System 7-1  
Power Requirements - Driving Gas Supply 10-2  
Pressure - CPAP Control 3-1  
Pressure Gauge 3-1  
Principles of Operation  
    CPAP Demand Flow Breathing System 7-2  
    Oxygen Delivery System 7-3  
    Pneumatic System Diagram 7-1  
    Pneumatic System Description 7-2

### R

Rear Panel 3-3

### S

Safety Systems 3-5  
Sensitivity 7-2  
Set-up 4-1

Service, Ventilator 9-1

**Specifications**

Environmental and Physical Characteristics 10-2

General Description 10-1

Power Sources 10-2

Ventilator System Performance 10-1

**Spontaneous Breaths**

F<sub>I</sub>O<sub>2</sub> 7-3

Peak Flow 7-2

**T**

**Theory of Operation**

CPAP Demand Flow Breathing System 7-2

Oxygen Delivery System 7-3

Pneumatic System Diagram 7-1

Pneumatic System Description 7-2

**Troubleshooting 8-1**

**U**

Unique Device Identifier (UDI) 3-4

**V**

Verification, Operating 4-1

**W**

Warnings 2-1