

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

MACS[®] Mask CPAP System

Operators Manual

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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 breath 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.

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 and face mask for use with **MACS** CPAP system are Airon part numbers 58001 through 58060. The patient and equipment should be constantly monitored.

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 have 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.

The **MACS** CPAP System is not intended for use under hyperbaric pressure conditions. If used in these conditions peak flow delivery will significantly decrease. Careful patient monitoring of tidal volume with a hyperbaric compatible external spirometer is mandatory.

To reduce the risk of infection, a bacteria filter may be used at the patient breathing circuit connection to the CPAP system. This will help to prevent patient (or device) contamination. Never clean or sterilize disposable bacteria filters.

Cautions

DO NOT attempt service procedures other than the routine maintenance specified in this Manual. 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.

Patient circuits other than the **MACS** circuit (Airon part numbers 58001 through 58060) may alter the CPAP characteristics and / or expiratory flow resistance. They should **NOT** be used.

Do not immerse the **MACS** CPAP System or allow any liquid to enter the case or the inlet filter. Clean as directed in Section 8, 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.

During the transport of patients it is recommended that an alternate source of ventilation be available in the event of driving gas supply failure or device malfunction.

The CPAP system will operate normally at altitudes up to 15,000 feet. Changes in altitude will not affect pressure settings. Always monitor the patient carefully using a cardiac monitor and an external spirometer if possible.

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

Indications for Use

The **MACS** CPAP System is intended for spontaneously breathing patients requiring up to 140 l/m 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

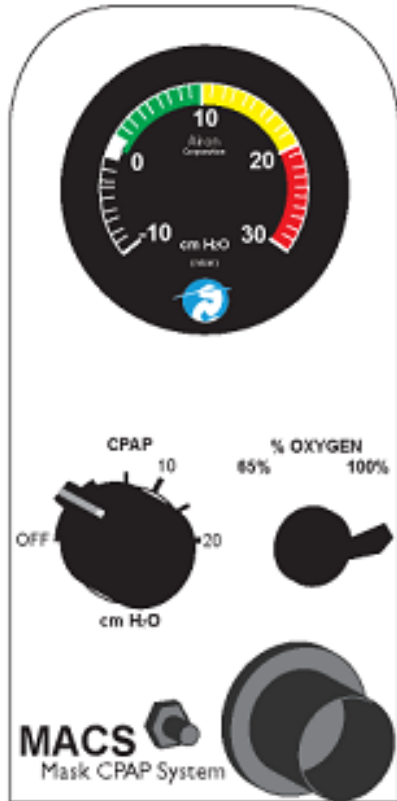
Contraindications

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

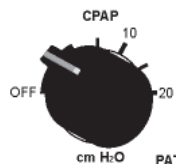
- Patients undergoing procedures with flammable anesthetic gasses
- Patients undergoing hyperbaric treatment

Section 3: Controls and Patient Safety Systems

Front Panel



Pressure gauge, patient circuit pressure



CPAP control, calibrated, range 0 to 20 cm H₂O

% OXYGEN
65% 100%



Oxygen control, select either 100% or 65%

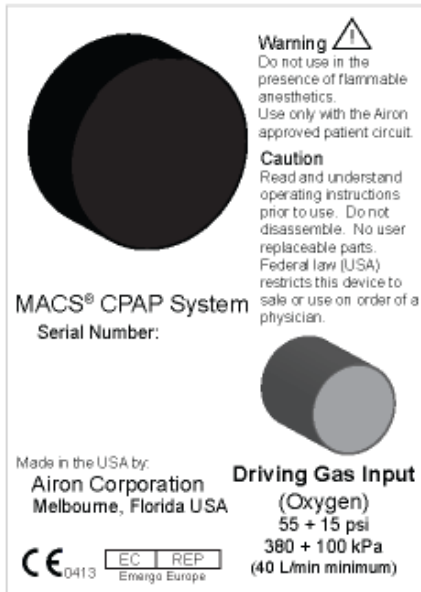


Patient Circuit connection, see section 5 for a complete description of the patient circuit and its attachment to the front panel



Expiratory Valve connection

Rear Panel



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



Ambient Air Inlet filter



When this symbol appears on the device it means "Refer to documentation for information"

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 H₂O.

Anti-Suffocation System

An internal safety system will allow the patient to breathe on their own in the event of device malfunction. At approximately 2 cm H₂O 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

1. Attach patient circuit to device (see Section 5 for a description of the patient circuit). Ensure that the tubes are connected to the proper fittings on the front panel.
2. Attach Driving Gas Input (Oxygen), located on rear panel, to an appropriate oxygen supply using a high pressure hose.
3. Turn on the oxygen supply.
4. The device will immediately begin operation at its current settings.

Note: To turn off the device, set the CPAP level to zero, disconnect the oxygen supply hose from the source or turn off the oxygen cylinder.

Operational Verification

1. With the device set-up as described above, remove the face mask and attach a test lung (1 liter, rigid sidewall style suggested) to the patient side of the patient circuit. Set the controls as follows:
 - a. Oxygen % to 65%
 - b. CPAP to 10 cm H₂O.
2. 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 H₂O after each breath.
3. 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 H₂O after each breath.

Patient Set-up

1. Set up the **MACS** CPAP System according to the setup instructions above.
2. Attach the patient circuit to the device.
3. Set the % Oxygen control to the desired F_IO₂.
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 H₂O per breath, depending on patient effort.
7. Observe and monitor the patient and the device per your institution's standards. If using a portable gas supply, monitor the supply level to ensure there is sufficient gas to power the device. Never leave the patient unattended.

Oxygen Control

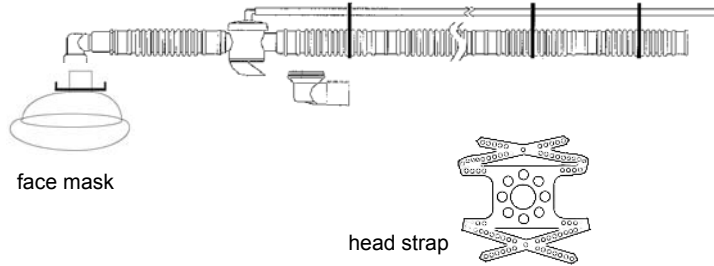
The device uses an internal venturi system which provides the oxygen concentration delivered to the patient. See Section 6 for a complete description of this system. It is recommended that an external oxygen analyzer always be used to verify oxygen delivery.

Hypobaric Operation

The device will operate normally at altitudes up to 15,000 feet. Changes in altitude will not affect pressure settings. Always monitor the patient carefully using a cardiac monitor and an external spirometer if possible.

Section 5: Patient Circuit

Pediatric / Adult Circuit



The patient circuit designed for use with **MACS** system is a disposable adult patient circuit with large mask, Airon part number 58011. Its compression volume is 1 ml per cm H₂O. This patient circuit is intended to be a single use, disposable device. Cleaning, reprocessing and / or reuse of this circuit is not recommended. A pediatric / adult patient circuit without mask is Airon part number 58001. This circuit can be used with a non-vented anesthesia mask for mask CPAP or directly connected to the patient with an endotracheal tube or other artificial airway.

WARNING: Patient circuits other than the Airon circuit may alter the CPAP characteristics and / or expiratory flow resistance. They should **NOT** be used.

Note: The breathing circuit and all of its components are sold clean and non-sterile.

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.

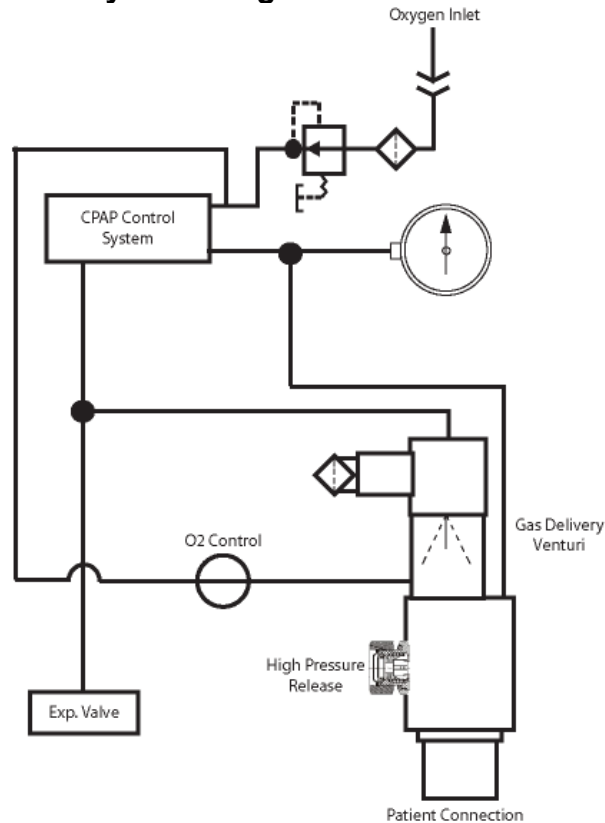
It is suggested that a high efficiency respiratory filter (99.9% retention of all particles > 0.5 micron with minimal airflow resistance, for example Pall # BB50T, Hudson # 1605 or equivalent) be used between the large connection port and the large breathing hose. This will protect the patient and the device from contamination.

Section 6: Theory of Operation

MACS is a pneumatic device that provides Continuous Positive Airway Pressure (CPAP). It provides up to 20 cm H₂O at up to 140 l/m 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 (6 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 H₂O. 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.

- The CPAP control is calibrated to the dynamics of Airon Corporation disposable patient circuit (part numbers 58001 through 58060). Using this circuit will ensure proper operation and the full 0 to 20 cm H₂O CPAP range. Using other patient circuits may effect operation and not allow for the full CPAP range.

- 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.

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_IO₂ 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 H₂O CPAP, the system will provide a F_IO₂ of approximately 0.65. As the CPAP level rises to 20 cm H₂O, the F_IO₂ 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_IO₂.

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

Approximate operating time using a full "D" size cylinder (400 liters) at 10 cm H₂O CPAP

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

Approximate operating time using a full "E" size cylinder (660 liters) at 10 cm H₂O CPAP

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

Section 7: 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 Technical Services at 1-888-448-1238 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 (38 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 (38 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 8: 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 patient circuit is a disposable, single use device, Airon part number 58001 through 58060. This circuit must not be cleaned, disinfected or reused.

Routine Maintenance

The **MACS** does not require routine maintenance by the user. A simple check of the accuracy of the device is suggested every 6 months. This can be performed by using calibrated pressure and oxygen measuring devices. Follow the Operation Verification Procedure (OVP) in section 4 of this manual. In addition to the OVP procedure do the following:

- Use a calibrated pressure measuring device to ensure that 10 cm H₂O CPAP is being generated (± 2 cm H₂O). Attach a T fitting with measurement tube / analyzer between the patient circuit output of the MACS and the patient circuit for this measurement.
- Use a calibrated oxygen measuring device to ensure that 65% and 100% oxygen ($\pm 10\%$) is being delivered when set for the 2 oxygen settings.
 - The oxygen level is measured by first replacing the patient circuit exhalation valve output cover with the spare elbow connector included in each Airon patient

circuit.

- Attach a T fitting with the oxygen analyzer probe to the output of the elbow connector.
- Attach a 6 inch reservoir hose past the T fitting to ensure accurate measurements. Ensure that the analyzer T fitting and reservoir do not obstruct flow from the expiratory valve.
- Generate breaths as described in the OVP for at least 1 minute or until the measured oxygen level stabilizes. The oxygen level should read between 55% and 75% at the 65% setting, and greater than 90% at the 100% setting.

Always follow the manufacturers instructions for the calibration and use of pressure and oxygen measuring devices.

Device Service

- A Preventative Maintenance service is recommended every 2 years by an Airon Corporation approved service technician.
- 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 approved service technician.
- Failure to perform this service may result in malfunctioning of the device.

Section 9: Specifications

General Description

- Pneumatically operated device provides CPAP using a demand flow system
- IEC 601 Classification
 - Class I/Internally Powered Equipment
 - Type B Equipment
 - Drip Proof Equipment IPX4
 - Equipment not suitable for use in the presence of flammable anesthetics
 - Continuous Operation

System Performance

- Controls
 - CPAP from 0 to 20 cm H₂O
 - % Oxygen 100% or 65%
- Operating Ranges
 - Internal P Limit 42 cm H₂O
- Accuracy of Controls
 - CPAP \pm 5%
 - F_IO₂, \pm 10%
- Precision - breath to breath repeatability of controls
 - CPAP \pm 2 cm H₂O
 - F_IO₂ \pm 5%
- Specificity - effect of one control on another
 - CPAP \pm 5%
 - F_IO₂ \pm 5%
- Internal Compliance 0.1 ml/cm H₂O
- Device Resistance to Flow
 - Inspiratory, 60 l/min: 2 cm H₂O//sec
 - Expiratory, 50 l/min: 2 cm H₂O//sec

CAUTION: Use of a non-Airon patient circuit may increase flow resistance, increase patient work of breathing, or alter accuracy of operation and is therefore not recommended.

Environmental and Physical Characteristics

- Hypobaric (high altitude) compatible up to 15,000 feet (5,000 meters)
- Weight: 3 pounds (1.35 kg)
- Size: 3.5" W x 8" D x 6.75" H (9 cm x 20 cm x 17 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 below 40 psi due to insufficient gas flow, the device will begin to malfunction.

- NOTE:** Baseline gas consumption at 10 cm H₂O CPAP
- 65% Oxygen: 5 l/min
 - 100% Oxygen: 12 l/min

Section 10: 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.

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