

RemedyTM Renew

CPAP Sleep Therapy

Patient Manual



AIRSEP[®]

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Introduction

Remedy™ Renew is a ventilation assistance device intended for use in the treatment of obstructive sleep apnea (OSA) in adults.

Remedy Renew supplies pressurized air through a nasal mask to the patient during sleep, maintaining Continuous Positive Airway Pressure (CPAP). Continuous positive pressure acts as a physical “pressure splint” that prevents the airway from collapsing during sleep. The device maintains a constant pressure during inhalation and exhalation.

Remedy Renew is primarily intended for use in the home while sleeping. It can also be used while away from home since it is relatively small and easy to set up and operate.

Remedy Renew's pressure range (3 to 18 cm of water) allows your physician to choose a pressure setting that will work best for you. In addition, the device is equipped with a Delay function for greater comfort.

Obstructive Sleep Apnea

AirSep's Remedy Renew is used in the treatment of obstructive sleep apnea (OSA) in adults. OSA usually occurs in middle-aged persons who may be overweight. Their soft palate, tongue, and uvula tend to lose muscle tone, with the uvula becoming enlarged and the airway collapsing during sleep. This is what causes a halt in breathing, leading to insufficient ventilation and fragmented sleep. The result is tiredness, daytime sleepiness, hypoxia, hypertension, and an increased risk of heart failure. An individual suffering from OSA often exhibits the following symptoms: continual fatigue, difficulty in focusing on the job, high accident rates, and diminished social life. Various studies show that 2–10% of the population suffer from OSA.

Additional Information

Contact the addresses listed below for more information on sleep disorders:

American Sleep Apnea Association

1424 K St. NW
Suite 302
Washington, DC 20005
(202) 293-3650
www.sleepapnea.org

National Sleep Foundation

1522 K St. NW
Suite 500
Washington, DC 20005
(202) 347-3471
www.sleepfoundation.org

Warnings, Cautions, and Notes

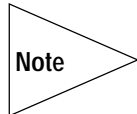
As you read the manual, pay special attention to the warning, caution, and note messages. They identify safety guidelines and other important information as follows:



Provides information that can prevent severe bodily injury or death.



Provides information that can prevent minor bodily injury or property damage.



Provides information important enough to emphasize or repeat.

Label Symbol Definitions



Type BF equipment.



Attention, consult patient manual.



Class II equipment.

Warning

Messages

Federal law restricts this device to sale by or on the order of a physician.

This manual serves only as a reference. Follow all instructions given by your physician.

Use Remedy Renew only with an AirSep-approved patient circuit. An AirSep-approved patient circuit consists of a noninvasive patient interface (such as a nasal mask) with a continuous leak exhalation port.

The continuous leak exhalation ports are designed to exhaust carbon dioxide from the patient circuit. Continuous flow is required for safe operation. **DO NOT BLOCK OR OTHERWISE TRY TO SEAL THE OPENING (FOR CONTINUOUS LEAK EXHALATION) ON THE MASK.**

Use this device only with masks (and connectors) recommended by AirSep, your physician, or respiratory therapist. The mask should not be used unless the device is turned on and operating properly.

Remedy Renew is intended for use with special masks (or connectors) that contain leak exhalation port(s) to allow a continuous flow of air from the mask. With the device turned on and operating properly, new air from the device flushes the exhaled air out through the leak port. When the device is not in operation, adequate fresh air is not provided through the mask, and exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can lead to suffocation. This warning applies to most CPAP devices.

All patient settings must be determined via appropriate diagnostic testing and monitoring.

Setting adjustments should be performed by your health care professional **ONLY**.

To avoid electrical shock, disconnect the Remedy Renew unit before you clean it.

To avoid electrical shock, disconnect the electrical supply before changing the fuse.

For continued protection against risk of fire, replace the fuse only with those of the same type and rating.

If you suspect that the Remedy Renew unit is functioning incorrectly, discontinue use and contact your Equipment Provider.

Repairs and adjustments must be performed only by authorized personnel, fully acquainted with this equipment. Service done by unqualified personnel or installation of unauthorized parts could cause personal injury, void the product warranty, and/or result in costly repairs. Contact your Equipment Provider if the unit fails to meet performance specifications.

Caution Messages

Disinfectant residues left on any parts of the patient circuit can shorten their useful life and irritate your skin. Rinse all items thoroughly after disinfection.

When transporting or storing the Remedy Renew unit, take precautions to avoid exposure to temperature extremes. If exposure to such temperatures occurs, allow the unit to reach room temperature before you turn it on.

Confirm correct rating of fuses before operating unit.

Position the unit only on its base for proper operation.

Caution Messages

The air flow for breathing produced by this device can be as much as 9°F (5°C) higher than the temperature of the room. Exercise caution if the room temperature is warmer than 90°F (32°C).

Note Messages

Use only patient tubing with a smooth inner lumen and a nominal diameter of 22 mm. The overall length of the tubing must not exceed 12 feet (365.7 cm).

Product Warranty

AirSep Corporation warrants the Remedy Renew CPAP sleep therapy device to be free from defects in parts for two years (or, as specified in the invoice provided) from the date of delivery to the original purchaser, under normal use and operation. AirSep Corporation's obligations under this warranty are limited to the repair or replacement of any such item of equipment (or part thereof) shown to be defective or, at AirSep Corporation's option, to refunding the purchase price of any such defective item of equipment.

Each item of equipment for which a warranty claim is asserted shall, at the request of AirSep Corporation, be returned on a prepaid basis with proof of purchase date to the AirSep Factory at the expense of the purchaser. The purchaser will be responsible for return freight charges. Replacement parts shall be warranted as stated above for the unexpired portion of the original two-year warranty. This warranty does not extend to any items or parts subjected to misuse, accident, improper maintenance, or application, or which have been repaired or altered outside of the AirSep Corporation Factory without the express prior written authorization of AirSep Corporation.

THE FOREGOING WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, IN FACT OR IN LAW, INCLUDING WITHOUT LIMITATION THE WARRANTY OF MERCHANTABILITY OR THE WARRANTY OF FITNESS FOR PARTICULAR PURPOSE. IT IS EXPRESSLY UNDERSTOOD THAT PURCHASER'S SOLE AND EXCLUSIVE RECOURSE FOR DEFECT IN PARTS IS LIMITED TO ENFORCEMENT OF AIRSEP CORPORATION'S OBLIGATION AS SET FORTH ABOVE, AND AIRSEP CORPORATION SHALL NOT BE LIABLE TO PURCHASER OR OTHERS FOR LOSS OF USE OF THE EQUIPMENT OR FOR OTHER SPECIAL, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES.

Specifications

Mode of Operation:	CPAP Delivers pressure at a constant level
Pressure Range:	3–18 cm H ₂ O
Delay:	20 minutes to reach full pressure setting
Weight:	4.75 lbs (2.16 kg)
Dimensions:	13.5 x 8.5 x 6.25 in. (34 x 22 x 16 cm)
Electrical Requirements:	Model AP007-1 120 VAC, 60 Hz Model AP007-2 220–240 VAC, 50 Hz Model AP007-3 100 VAC, 50–60 Hz
Fuses:	For 120V or 100V operation: T1A, 250V For 220-240V operation: T500 mA, 250V
Power Consumption:	35 W maximum
Air Filter:	2-part foam/polypropylene
Operating Temperature:	50–100°F (10–38°C)
Storage Temperature:	20–120°F (-7–49°C)

Principle of Operation

Remedy Renew operates in a Continuous Positive Airway Pressure (CPAP) mode, where the pressure setpoint is fixed and the same pressure is applied during inhalation and exhalation.

Delay Function

The Delay function, when activated, lowers the initial pressure to the lowest available level (3 cm H₂O) and then gradually raises it over 20 minutes until pressure reaches the preset level. The Remedy Renew unit must be running before the Delay function can be activated.

Control Panel

Your Remedy Renew unit is easy to use with a simple one-switch operation to allow you to set the unit to on or off, or to delay the preset pressure. This OFF/ON/DELAY switch is located on the back of the unit.

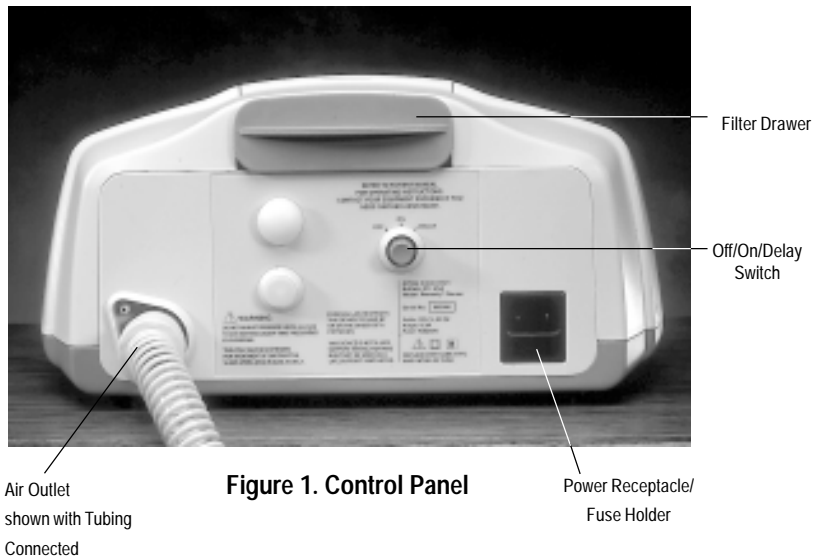





Figure 1. Control Panel

Back Panel

Item	Description
OFF/ON/DELAY	Enables you to turn on the unit, turn off the unit, or set the unit to delay to gradually increase to the prescribed pressure.
 <p>Power Receptacle/ Fuse Holder</p>	<p>Provides the connection for the power cord.</p> <p>The fuse holder provides the housing for two fuses (one spare).</p> <p>Use ONLY T1 A 250V fuse for 120 or 100 VAC.</p> <p>Use ONLY T500 mA 250V fuse for 220–240 VAC.</p>
 <p>Air Outlet</p> <p>Optional:</p>  <p>Hour Meter</p>	<p>Accepts 22 mm patient tubing.</p> <p>An optional LCD hour meter displays the actual operating time of the unit.</p>

Remedy Renew Set-Up and Use

1. Connect one end of the connection tubing to the air outlet port located on the back of your unit. (See Figure 2.)



Figure 2. Tubing Connection to Air Outlet Port

2. Connect the other end of the connection tubing to the nasal mask.
3. Confirm that the OFF/ON/DELAY switch is set to the OFF position.



Figure 3. Power Cord Connection to Inlet



Figure 4. Connection to Electrical Outlet

4. Connect the electrical cord into the power inlet on the back of the unit. (See Figure 3.)
5. Connect the unit's electrical cord into a standard electrical outlet. (See Figure 4.)
6. Set the OFF/ON/DELAY switch on the back of your unit to ON.

Remedy Renew Set-Up and Use

7. Put on and adjust your mask system on your face until you reach your desired comfort level.
8. Make sure that little or no air can leak from your mask, and adjust as necessary. Refer to the mask and headgear manufacturers' instructions for proper placement and adjustment of your mask and headgear (and chin strap, if desired.)

Figures 5 and 6 show a typical mask/strap headgear and mask/mesh net headgear setup for a Remedy Renew patient. Notice that when lying in bed, the patient tubing should extend to your side (or directly above the headboard on your bed) to prevent it from becoming entangled in bed coverings or clothing.



Figure 5. Proper Setup of Mask/Strap Headgear



Figure 6. Proper Setup of Mask/Mesh Net Headgear

9. **Optional:** Set the OFF/ON/DELAY switch further to the right to *DELAY* if you desire the Delay function and it is prescribed by your health care professional.
10. To turn off your unit, set the OFF/ON/DELAY switch to *OFF*.

Maintenance

Check with your Equipment Provider at least on a yearly basis so that operating pressures and performance can be tested. You do not need to test the unit yourself or perform any maintenance on the inside of your unit. You can perform three simple external procedures to maintain your unit.

Cleaning the Unit

Caution

Do not clean the Remedy Renew unit or any of its operating parts with alcohol or cleaning solutions that contain alcohol. Do not clean the unit by steam autoclave or gas sterilization methods, or hardening/deforming of the parts of the unit can result and impair its function.

1. Disconnect the power cord from the electrical outlet.
2. Wipe the exterior of the Remedy Renew unit with a cloth dampened slightly with water and mild dish detergent.
3. Allow the unit to dry before you reconnect the plug into the electrical outlet.

Replacing the Filter

Maintenance on the Remedy Renew unit is simple. You must perform just a **monthly replacement** of the *white air inlet filter* and a **weekly washing** of the *gray foam filter* located in the filter drawer on the back of the unit.

Caution

Failure to replace a dirty filter can cause higher than recommended operating temperatures, which can reduce flow and limit output pressure.

1. Disconnect the power cord from the electrical outlet.
2. Locate the gray filter drawer on the back of the unit, and pull outward to remove it. (See Figure 7.)
3. Remove and discard the white disposable filter.
4. Wash the gray foam filter with a mild dish detergent, and rinse it thoroughly.



Figure 7. Removal of Filter Drawer

5. Allow the gray foam filter to air dry before you return it to the unit.
6. Insert a new white disposable filter into the drawer.
7. Replace the gray foam filter into the drawer.
8. Reconnect the power cord to the electrical outlet.

Replacing the Fuses

1. Use a screwdriver to remove the fuse holder, which is located below the power inlet on the back of the unit. (See Figure 8.)
2. Pull the fuse holder completely out from the back of the unit. (See Figure 9.)



Figure 8. Removal of Fuse Holder



Figure 9. Replacement of Fuse

3. Replace the blown fuse with another fuse of the same type and rating. (See Figure 10.)
4. Insert the new fuse into the unit.

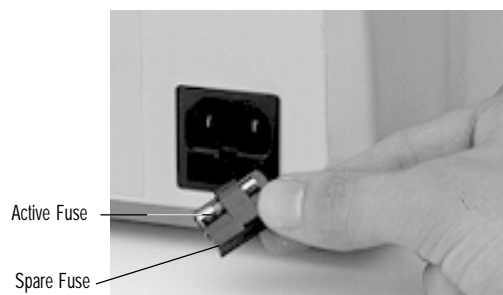


Figure 10. Housing for Fuses

Accessories

Selecting a Mask

To maximize your comfort level, your Equipment Provider has selected a mask that is well-fitted to your face and ensures your safety and maneuverability.

As an option, AirSep offers masks in various sizes.

If you do not become accustomed to the mask after a short period of time, contact your Equipment Provider for alternative setups.

Optional Carrying Case for Travel

Remedy Renew is light weight and easy to transport from place to place for overnight travel or lengthier stays. At just 4.75 lb (2.16 kg), the unit fits comfortably in its optional carrying case, along with the power cord, mask, headgear, tubing, and patient manual.

Figure 11 shows the optional carrying case, which may be provided with the Remedy Renew unit.



Figure 11. Carrying Case for Remedy Renew and Accessories

Note

Messages

If you live or will travel to areas of high elevation (above approximately 2,000 ft [610m]), consult your Equipment Provider on any necessary pressure adjustments to your Remedy Renew unit.

Troubleshooting

The troubleshooting chart below lists the most common problems that can occur when you use your Remedy Renew unit. If the following solutions do not correct your problem, contact your Equipment Provider for further assistance.

Problem	Probable Cause	Solution
Unit does not turn on.	Power cord not firmly connected to the unit or the wall outlet.	Make sure that the power cord is plugged into the unit and the electrical outlet.
	Unit not connected to a “live” electrical outlet.	Make sure that the unit is plugged into a “live” outlet. Test same outlet with a working item such as a lamp.
	Unit fuse blown.	Replace the fuse. If the replacement fuse blows out, contact your Equipment Provider.
Unit stops then starts up.	Power cord not secure at the unit’s receptacle or power outlet.	Make sure the power cord is completely connected at the unit’s receptacle and power outlet.
For any other problem that occurs.		Consult your Equipment Provider for assistance.

Notes

Notes

Notes



You're not the only one with sleep apnea, and when you join the ASAA, you're no longer alone. You belong to an organization with thousands of others across America affected by sleep apnea. As a member, you receive an annual subscription to the bi-monthly ASAA newsletter **WAKE-UP CALL, The Wellness Letter for Snoring and Apnea**, with useful articles such as "Sleep Apnea and Anesthesia," "Understanding a Sleep Study," and the "Ask the Doctor" column. The only sleep apnea wellness newsletter published in America, **WAKE-UP CALL**, gives you information on current developments in the field of sleep medicine and on social and legal issues people with sleep apnea face.

In addition, you receive a medical-alert identification bracelet or necklace to help ensure that you receive appropriate treatment for your sleep apnea during a medical emergency. You are also invited to participate in the ASAA A.W.A.K.E. Network with approximately 200 mutual-help groups throughout the country. (A.W.A.K.E. stands for "Alert, Well, And Keeping Energetic," characteristics that are uncommon in people with untreated sleep apnea.) An advocate for people with sleep apnea, the ASAA can also provide you with a better understanding of this disorder and the benefits of treatment.

Join today and help to build a strong organization — for you and others like you.

The American Sleep Apnea Association is dedicated to reducing injury, disability, and death from sleep apnea and to enhancing the well-being of those affected by this common disorder. The ASAA promotes education and awareness, the ASAA A.W.A.K.E. Network of voluntary mutual support groups, research, and continuous improvement of care.



Yes, I want to join the American Sleep Apnea Association!

Enclosed are my annual dues of:

- \$25 Member* \$50 Friend \$100 Contributor \$250 Investor
 \$500 Patron \$750 Benefactor \$1000 Sponsor
 Other: \$ _____.

Members who join at the Contributor level and above will be recognized in the Annual Report unless they request otherwise.

Please send me my medical alert (*check one*): Bracelet Necklace

*For members whose mailing address is outside of the United States, minimum dues are \$50; payment must be made in U.S. dollars.

Please let me know if there is an A.W.A.K.E. group near me.

I am undecided, but please send me a sample newsletter.

Name _____

Address _____

City _____ State _____ Zip _____

Phone _____
HOME WORK

Your membership dues are tax-deductible to the extent allowed by law.

Please cut out this form and mail it with your check made payable to the American Sleep Apnea Association to the address below.

The American Sleep Apnea Association
1424 K Street NW, Suite 302
Washington, DC 20005
Tel: (202) 293-3650
Fax: (202) 293-3656
website: www.sleepapnea.org

Thank you for your support!

The American Sleep Apnea Association is a non-profit 501(c)(3) organization.

AirSep Corporation is pleased to support the American Sleep Apnea Association as a Contributor in the ASAA Industry Roundtable. Members of the Industry Roundtable are, in descending order of support, Sponsors, Benefactors, Patrons, Investors, and Contributors.

As a non-profit organization, the American Sleep Apnea Association does not endorse any company or products.



For service on your Remedy™ Renew Sleep Therapy
System, contact:



Manufactured by
AirSep Corporation
401 Creekside Drive
Buffalo, NY 14228-2085 USA