

A background image showing a medical data visualization on a grid. It includes a large white waveform on the right side, a smaller waveform on the left, and a bar chart at the bottom left. The overall color scheme is blue and white.

**BI-LEVEL RESCUE PROGRAM:
Improving Sleep Therapy Patient Comfort and Compliance**

Part of the
LASTING IMPRESSIONSSM
Therapy Assurance Program

Bi-level Rescue Program: Improving Sleep Therapy Patient Comfort and Compliance

Introduction

The Resironics Bi-level Rescue Program is intended to help patients continue their PAP therapy when they are not able to tolerate, or do not perceive a response to, standard treatment. A bi-level device provides comfort features that will increase the likelihood that these patients will be compliant with their therapy. Such patients may be identified in the lab or home setting.

In a lab setting, there are three reasons for transitioning a patient from CPAP to a bi-level management protocol:

1. Patient is not able to fall asleep on CPAP therapy
2. Patient is non-tolerant of CPAP therapy
3. A pre-determined pressure threshold has been reached (13 cm H₂O) or a patient-specific threshold has been reached

In the home setting, if a patient has been identified as non-tolerant or non-responsive to CPAP therapy and interventions have not increased usage, it is time to consider bi-level therapy.

The benefit of bi-level therapy is that it allows the patient to maintain airway stability at a lower mean airway pressure, which is more comfortable because it mimics the sine wave of normal breathing. Bi-level therapy allows the expiratory pressure to be reduced enough to lessen the additional work of exhaling against a high CPAP pressure while simultaneously avoiding any recurrence of obstruction during the onset of inspiration.

Bi-level positive airway pressure uses two individually set pressures. The lower pressure overcomes the physiologic dynamics trying to close the airway during the expiratory phase of the breathing cycle. The higher pressure maintains airway patency during the inspiratory phase of the breathing cycle when negative pressure is being exerted on an already compromised airway. These pressures are titrated separately during a therapeutic study. In bi-level positive pressure therapy, the inspiratory positive airway pressure (IPAP) has been shown to be equal to the CPAP pressure. The expiratory positive airway pressure (EPAP) that is set lower than IPAP holds the airway open and prevents airway instability during the expiratory phase. The patient exhales against a lower pressure which decreases the mean airway pressure.

Bi-level Therapy Use in OSA

Bi-level therapy can be used as an alternative for patients who do not tolerate CPAP during the lab titration or at home. Bi-level therapy may also be used for hypoventilation patients or those who require a back-up rate. Bi-level therapy may result in the perception of more comfortable breathing while receiving positive airway pressure.

There are 2 types of bi-level therapies available:

- **Basic Bi-level** – stabilizes the airway with a baseline expiratory pressure set to prevent airway occlusion (EPAP) and an inspiratory positive airway pressure set to prevent hypopneas and snoring (IPAP).
- **Auto Bi-level** – makes subtle changes in pressure based on instances of flow limitation at inhalation by measuring the roundness, flatness, peak and shape of each breath. It then assesses the impact of these changes on the patient's breathing patterns. It can also determine how much of a response is necessary to eliminate events and deliver appropriate pressure.

Bi-Flex®—provides basic or auto bi-level therapy with flex technology enabled. Bi-Flex is a comfort setting that softens pressure delivery on inspiration and reduces pressure on transition to expiration. It offers varying degrees of pressure relief at the beginning of the expiratory phase and returns to the prescribed EPAP level prior to the end of the expiratory phase. The amount of pressure relief varies breath to breath, but is more comfortable as it mimics the sine wave of normal breathing.

It is important to note that with proper documentation which validates that the patient is not able to tolerate CPAP therapy, both types of bi-level therapy (basic and auto) are reimbursable by insurance.

Bi-level Rescue Study Results

A study by Reeves-Hoche determined that while there was no significant difference in compliance among CPAP users and bi-level users at one year, there was a greater compliance rate in the bi-level group when the difference between IPAP and EPAP was greater than 6 cm H₂O. There was also a much greater drop-out rate in the CPAP group versus the bi-level group.¹

Another study by Szumstein showed that bi-level therapy is an effective salvage therapy for about 50% of patients who do not tolerate and/or respond to CPAP.² An additional multi-center study by Gay showed that at 30 days, 45% of patients used bi-level therapy with Bi-Flex more than 4 hours per night compared to 33% of those on CPAP. And at 90 days, 54% of bi-level patients used their therapy more than 4 hours per night compared to 32% of those on CPAP. The study concluded that patients having difficulty using CPAP may benefit from bi-level therapy with Bi-Flex after conventional rescue protocols have failed.³

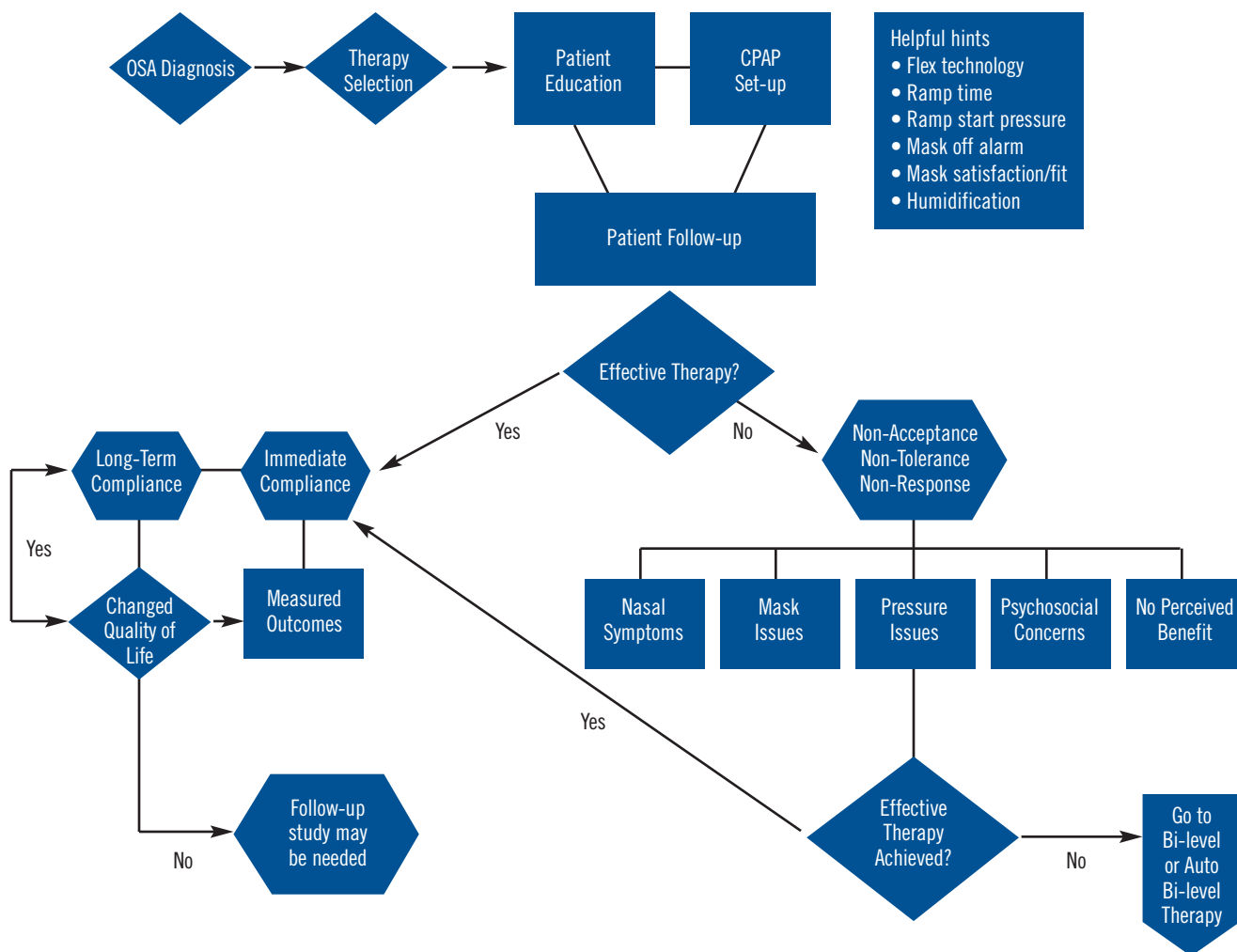
Timely Implementation of Bi-level as a Rescue Strategy

The majority of patients who are diagnosed in the sleep lab with OSA (80%) will be set up on CPAP. The initiation of CPAP in the lab is critical for primary and secondary acceptance. Patient education on the goals of therapy, interface selection, acclimatization period and interventions to cope with questions, anxiety, and initial side effects are critical. The patient's initial experience can affect long-term acceptance.

From the very start, a few patients will have problems with pressure tolerance or will be placed on high levels of pressure during their sleep study and switched to bi-level therapy before leaving the lab. Other patients are sent home on CPAP but eventually have difficulty tolerating or responding to it. The problems they experience are addressed with traditional methods including hints for troubleshooting, new masks, and use of humidifiers. If these traditional methods do not work, these patients are often lost to PAP therapy. An alternative to having a patient drop out of therapy is placing them on a BiPAP® or BiPAP® Auto bi-level device.

The following diagram shows the PAP clinical pathway. If effective therapy is not achieved with CPAP, re-start the pathway using bi-level. If effective therapy is still not achieved, implement the pathway using Auto Bi-level.

Clinical Pathway



A study by Weaver showed that skipping CPAP for two or more nights within the first week of treatment signals potential for non-adherence and emphasizes the need for close follow-up during this period of time.⁴ Kribbs found that more than half of the patients she studied (54%) could be considered inconsistent users.⁵ The effectiveness of CPAP is in question when used inconsistently. Nineteen to thirty-seven percent of patients abandon treatment. **The first week to month of home therapy appears to be the most critical phase for intervention and securing long-term compliance.** It is imperative to quickly identify and document causes of non-tolerance and non-response in order to convert appropriate patients to bi-level therapy. Documentation must include interventions which have been tried as well as patient response/non-response to those interventions. An “Intervention Utilization Worksheet” is a valuable tool to use in comprehensively documenting the methods tried and failed in order to change the patient’s therapy to bi-level and receive reimbursement for that change. If conventional methods to rescue CPAP therapy patients have failed, changing the patients’ therapy to bi-level is indicated.

Compliance Monitoring

Tools which can be used for monitoring compliance include:

- An “Intervention Utilization Worksheet” which documents problems, attempted interventions and results.

This is an example of a section of the worksheet used for patient complaints of pressure or airflow issues.

Pressure/Airflow Related Symptoms	Corrective Action
<input type="checkbox"/> Chest discomfort	<input type="checkbox"/> Ramp
<input type="checkbox"/> Aerophagia	<input type="checkbox"/> BiPAP
<input type="checkbox"/> Smothering sensation	<input type="checkbox"/> Comfort settings (i.e., C-Flex or Bi-Flex)
<input type="checkbox"/> Difficulty exhaling	<input type="checkbox"/> Auto-PAP
<input type="checkbox"/> Difficulty initiating or maintaining sleep	<input type="checkbox"/> Mask change
<input type="checkbox"/> Sinus discomfort	

This is an example of a worksheet section used for complaints of nasal issues.

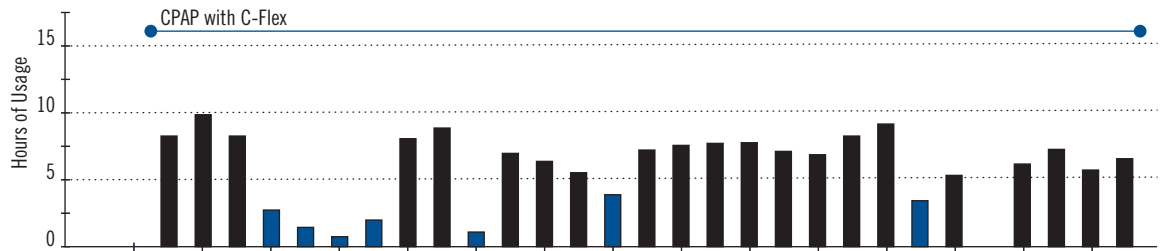
Symptoms Related to the Nasal Route	Corrective Action
<input type="checkbox"/> Rhinorrhea	<input type="checkbox"/> Chin strap for oral dryness
<input type="checkbox"/> Nasal congestion	<input type="checkbox"/> Ramp pressure
<input type="checkbox"/> Nasal or oral dryness	<input type="checkbox"/> Heated humidifier
<input type="checkbox"/> Nasal bleeding	<input type="checkbox"/> Pass-over humidifier
<input type="checkbox"/> Pressure too high, sinus distress	<input type="checkbox"/> Auto-PAP
	<input type="checkbox"/> BiPAP
	<input type="checkbox"/> Nasal spray
	<input type="checkbox"/> Topical nasal steroid preparation

This is an example of a worksheet section used for complaints of psychosocial issues.

Problems Related to Psychosocial Symptoms	Corrective Action
_____ Noise	_____ Assess travel needs
_____ Cumbersome	_____ Intensify patient/spouse education
_____ Inconvenient	_____ Recommend AWAKE group
_____ Appearance	_____ Attendance by patient and spouse
_____ Anxiety	_____ Motivational enhancement
_____ Spousal intolerance	

Most of the above corrective approaches are intuitive to clinicians working with OSA patients. Motivational enhancement, however, is a new approach that incorporates theories of how people change behavior with the known consequences of not using PAP therapy. Perhaps the most important part of motivational enhancement is the approach that the clinician takes with the patient. Motivational enhancement is a non-directive therapy. This does not mean that the clinician fails to interact with the patient or provide information. It simply means that the clinician attempts to be aware of where the patient stands with treatment and does not try to force change. Forcing change is almost always ineffective. For example, a patient is not confronted with poor compliance, but is asked what might stand in the way of meeting their treatment goals. Then, effort is placed into trying to find evidence of the patient coming close to treatment goals and pointing out the benefits of simply trying rather than giving up with treatment altogether. Goals are sometimes changed to reflect something more attainable by the patient. Once these goals are met, more effective long-term goals can be established. Objective compliance is crucial to this process. Compliance is reviewed and used to highlight previous successful nights of therapy in an attempt to build patient confidence.

Compliance Information 9/1/2003 – 10/1/2003



- Encore® Pro SmartCard® records objective usage and device performance information, FOSQ scores by date, and ability to perform a one-time prescription change.

Blue bars show nights when therapy was used less than 4 hours. Blank areas are nights when therapy was not used at all.*

It is important to remember that compliance measured by phone interviews or questionnaires conducted with patients may not be as reliable as objective SmartCard data. Self-reports of CPAP use by patients has been documented as being significantly over-reported.⁵

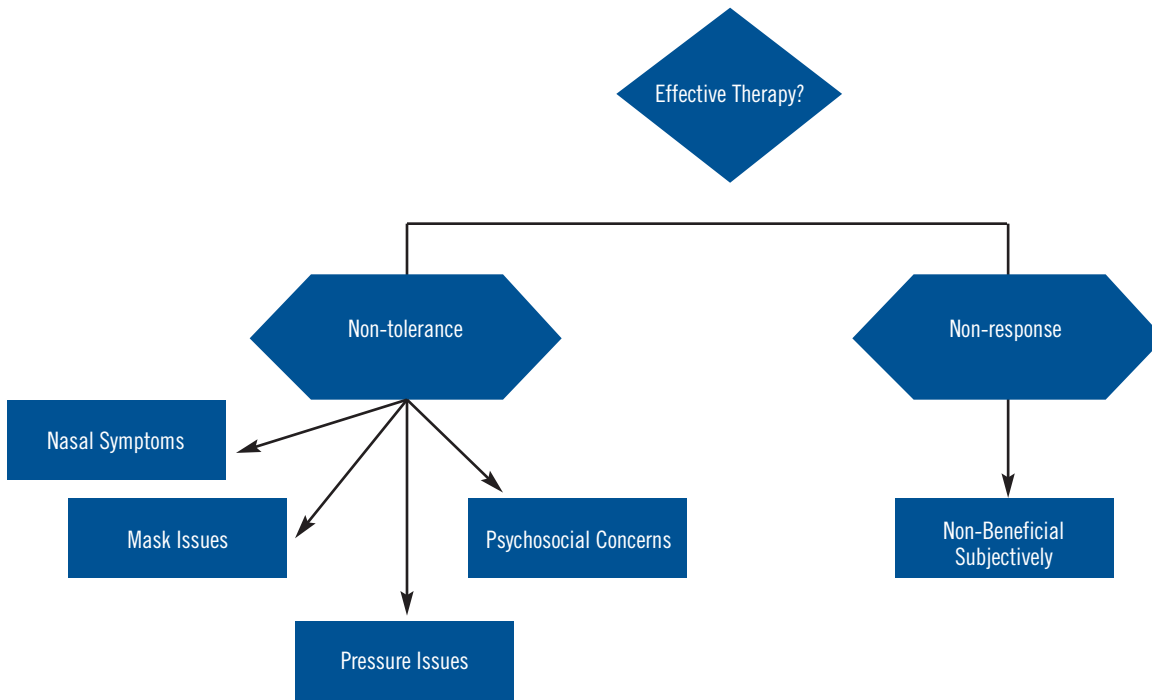
Non-tolerance refers to problems that are mask, nasal route, pressure/airflow or psychosocial in nature. Inconsistent users can be identified in the first week of therapy using Encore Data Management Software to review compliance. **Non-response** is when a patient feels no benefit to using therapy. This may be uncovered when reviewing the FOSQ with Encore software. The patient's usage may be consistent with that of a compliant patient, but the FOSQ score shows no benefit. Changing to bi-level may be an effective alternative for long-term compliance and increased quality of life.

Patients who are non-responsive to CPAP in the lab setting may present with symptoms such as: failure to fall asleep in the lab, inability to breathe out against pressure, and refusal to sleep on CPAP therapy.

Patients who are non-tolerant in the home or lab may present with symptoms such as: difficulty exhaling or falling asleep using pressure, using ramp excessively, fragmented usage patterns (many nocturnal awakenings), an underlying ventilation problem, significant aerophagia, and feeling a smothering sensation.

Patients who are non-tolerant in the home may present with symptoms such as: no quality-of-life improvement, no perceived benefit from therapy, and persistent OSA symptoms. Using objective methods of documentation such as the Encore compliance reports, subjective patient comments and the FOSQ will support the documented need for the patient to be changed to bi-level therapy.

*Colors in actual Encore reports will vary.



Bi-level Rescue — System Options and Implementation

There are three reasons for transitioning a patient from CPAP to the bi-level management protocol in the **lab** setting:

1. Patient is not able to fall asleep on CPAP therapy
2. Patient is non-tolerant of CPAP therapy
3. A pre-determined pressure threshold has been reached (13 cm H₂O) or a patient specific threshold has been reached

In the **home** setting, if a patient has been identified as non-tolerant or non-responsive to CPAP therapy and interventions have not increased usage, it is time to consider bi-level therapy.

At this point a prescription needs to be obtained from the physician for the bi-level device (Bi-level or Auto Bi-level) as well as the IPAP and EPAP settings of the device.

How Will the IPAP and EPAP Pressure Settings be Determined?

There are four ways to establish a BiPAP prescription:

1. Auto bi-level titration may be used to establish the IPAP and EPAP pressures.

A study by Wylie et al. showed that the Auto bi-level device treats OSA as effectively as manually titrated, conventional bi-level PAP therapy.⁶ A second study by Strollo et al. also showed that Auto bi-level effectively controlled OSA and there was no tendency to overventilate⁷. A suggested implementation protocol for bi-level therapy with BiPAP Auto is to:

- Set the EPAP similar to Auto CPAP devices
 - If CPAP is < 10 cm H₂O, start EPAP at 4 cm H₂O
 - If CPAP is > 10 cm H₂O, start EPAP at 6 cm H₂O
- Delta at Max
 - 8 cm H₂O

2. Bi-level titration is done during the initial sleep study so that settings are known, or a second sleep study is performed.

If the lab routinely does bi-level titrations, the homecare provider simply calls to get the IPAP and EPAP pressure settings documented from the study and calls the physician for the order. If bi-level titration was not performed in the lab as part of the lab's usual protocol, and the patient needs IPAP and EPAP settings, an option is to repeat the PSG study to determine these levels. This can be expensive, as insurance may not cover a second study and the patient may also have to wait a long time to be rescheduled, which could negatively impact the patient's future compliance with PAP therapy.

3. Analyze the sleep study to determine appropriate bi-level settings.

- Set the IPAP at the prescribed CPAP pressure
 - Set the EPAP at the level of CPAP that eliminated the last apnea recorded
- These levels may be determined by reviewing the PSG flow sheet or event log of the study.

4. Use empirical values for the IPAP and EPAP settings.

The pressures may be set by the physician based on general knowledge using the patient's current CPAP pressure setting.

- The IPAP setting can be set at or 2 cm above the current CPAP setting
- The EPAP setting might then be set either at 2 or 4 cm below the CPAP setting

Follow-up

With any of the above methods for setting bi-level pressures, the outcome is critical. You must communicate back to the physician. You have been successful in determining pressure levels and rescuing the patient to continue PAP therapy if you can demonstrate that the patient now:

- Tolerates the therapy
- Perceives a subjective benefit
- Has an increased quality of life
- And is compliant with therapy, using objective and subjective methods

Bibliography

1. Reeves-Hoche, MK., Hudgel, DW., Meck, R., Witteman, R., Ross, A., Zwillich, CW. *Continuous Versus Bilevel Positive Airway Pressure for Obstructive Sleep Apnea.* Am. J. Respir. Crit. Care Med., Vol 151, No. 2, Feb 1995, 443-449.
2. Szumstein, S., Atwood, CW., Strollo, PJ., Sanders, MH. *Is Bi-level Positive Airway Pressure an Effective Salvage Therapy for Obstructive Sleep Apnea Patients who Fail CPAP Therapy?* ATS Abstract 1999.
3. Gay, PC., Ballard, R., Strollo, PJ. *Randomized Multi-Center Trial to Improve Compliance in Non-Adherent OSA Patients using CPAP vs. Novel Bi-level Positive Airway Pressure.* Sleep Abstract 2005; 28:A210.
4. Weaver, TE., Kribbs, NB., Pack, AI., Kline, LR., Chugh, DK., Maislin, G., Smith, PL., Schwartz, AR., Schubert NM., Gillen, KA., Dinges, DF. *Night to Night Variability in CPAP use Over the First Three Months of Treatment.*
5. Kribbs, NB., Pack, AI., Kline, LR., Smith, PL., Schwartz, AR., Schubert, NM., Redline, S., Henry, JN., Getsy, JE., Dinges, DF. *Objective Measurements of Patterns of Nasal CPAP use by Patients with Obstructive Sleep Apnea.* Am. Rev. Respir. Dis. 1993; 147: 887-895.
6. Wylie, P., Grover, S. *A Multi-Center Randomized Controlled Trial of the First Automatically Titrating Bilevel Positive Airway Pressure Device During Polysomnography.* Sleep, Vol. 29, Abstract Suppl. #0578, 2006.
7. Strollo, PJ., Drumheller O., Rogers S., Peterson J., Givelber, R., Atwood, CW. *A Preliminary Assessment of Automatically Titrated Bilevel Positive Airway Pressure: Is There a Ventilatory Effect?* Sleep., Vol. 29, Abstract Suppl. #0617, 2006.

THIS PAGE INTENTIONALLY LEFT BLANK



Customer Service: 1-800-345-6443 or 724-387-4000

Respironics Europe: +33-(0)1-55-60-19-80

Respironics Asia Pacific: +852-3194-2280

www.respironics.com

Respironics, BiPAP, Bi-Flex, Encore and SmartCard are registered trademarks, and Lasting Impressions is a service mark of Respironics, Inc. and its affiliates.

©2006 Respironics, Inc. and its affiliates. All rights reserved.

Hoech KW 9/22/06 4100789 PN 1038429

Post-Test

This monograph has been approved for 1.0 hour of APT and AARC Category I credits. A certificate of course completion will be mailed to you within 90 days upon receipt of a completed post-test that meets the 90 percent scoring standard. Mail your completed post-test to:

Medical Education
Respironics Sleep and Home Respiratory
1740 Golden Mile Highway
Monroeville, PA 15146

If you have any questions regarding this material, call 1-800-553-5781, voice mailbox 5355.

Please PRINT legibly.

Name _____ Birth Date _____

Credentials _____ APT # _____ AARC # _____

Job Title _____

Sleep Lab Name _____

Sleep Lab Address (number and street) _____

City/Town _____

State/Province _____ ZIP/Postal Code _____

Sleep Lab Phone Number _____

Sleep Lab Fax Number _____

E-mail _____

Bi-level Rescue Program Post-Test

Use blue or black ink to complete each of the following questions:

1. The benefit of bi-level therapy is that it allows the patient to maintain airway stability at a lower mean airway pressure, which is more comfortable because it mimics the sine wave of normal breathing. True___ False___
2. There is no reason to transition a patient from CPAP to bi-level in a sleep lab setting. True___ False___
3. Two types of bi-level therapy devices which are available are _____ and _____.
4. A patient who skips CPAP use for two or more nights within the first week of treatment signals potential for non-adherence and emphasizes the need for close follow-up during this period of time. True___ False___
5. It is important to record documentation of causes of non-tolerance and non-adherence to CPAP therapy as well as interventions tried for patients who are non-adherent and non-responsive to CPAP prior to requesting a prescription for bi-level. True___ False___
6. The only way to determine a bi-level setting for a CPAP patient is to repeat the sleep study. True___ False___
7. If a patient does not tolerate basic bi-level therapy, auto bi-level therapy should be tried. True___ False___
8. Self-report of CPAP use by the patient is usually as accurate as recorded Encore SmartCard data. True___ False___
9. Once a patient has been switched to bi-level therapy, the patient no longer needs follow-up. True___ False___
10. Without appropriate documentation, a switch from CPAP to bi-level may not be reimbursed by insurance. True___ False___
11. It is not important to assess a new patient's adaptation to CPAP within the first week of use. You should allow use for two to three weeks before calling the patient. True___ False___

Evaluation Form

Course Sponsor: Respironics, Inc.

Course Title: Bi-level Rescue Program: Improving Sleep Therapy Patient Comfort and Compliance

Part 1: Teaching Effectiveness of the Monograph

Rate the teaching effectiveness of the monograph using the scale below:

1=Poor 2=Fair 3=Good 4=Excellent 5=Superior

Organization of monograph_____

Content of the monograph_____

Part 2: Achievement of Educational Objectives

Rate the degree to which you believe you achieved the educational objectives for each section of the monograph by placing a check mark in the appropriate space corresponding to each.

I achieved this activity’s educational objectives:

	Strongly Agree	Agree	Disagree	Strongly Disagree
Identify the benefits of bi-level therapy				
Identify the PAP Clinical Pathway steps required to achieve effective therapy				
Identify reasons for transitioning a patient from CPAP to bi-level therapy				
Importance of early intervention in securing long-term patient compliance to therapy				
Importance of documentation in validating patient is unable to tolerate CPAP therapy and requires bi-level therapy				
Identify bi-level system options, implementation, and follow-up procedures				

Part 3: Program Integrity

Indicate your agreement with the following statement by checking the appropriate response:

The content of this monograph was presented without bias with respect to any commercial product.

Strongly Agree_____ Agree_____ Disagree_____ Strongly Disagree_____

Comments: _____

PLACE FIRST CLASS
POSTAGE HERE
The post office will
not deliver mail
without postage.

**Medical Education
Respironics Sleep and Home Respiratory
1740 Golden Mile Highway
Monroeville, PA 15146**

FOLD HERE

SEAL HERE