

# REMstar® Pro with C-Flex™

## Patient Preference Trials

### BACKGROUND

Obstructive Sleep Apnea (OSA) is a chronic, progressive syndrome that affects an estimated 52 million Americans or 25 percent of the adult population. (T. Young, et al., Epidemiology of Obstructive Sleep Apnea: A Population Health Perspective, Am J Respir Crit Care Med, 2002, 165:1217-1239.)

OSA occurs due to an obstruction or physiological narrowing of the upper airway in the pharynx that impedes, or reduces, inspiratory airflow (inhaling). Conventional therapy is the use of a device providing Continuous Positive Airway Pressure (CPAP), which is applied through a mask. This use of continuous pressure, when titrated properly, eliminates obstructive breathing events, including snoring. However, some patients find it difficult or impossible to comply with this treatment because of pressure sensitivity while trying to exhale against the positive pressure.

Respironics' new C-Flex is a revolutionary breakthrough in Positive Airway Pressure (PAP). A complaint of those using conventional CPAP is that they find it difficult to breathe out against the pressure. CPAP with C-Flex is designed to provide pressure relief during exhalation while maintaining effective therapy. Pressure is titrated in the same way as conventional CPAP. However, during use, the CPAP with C-Flex technology monitors the patient's airflow during exhalation and reduces expiratory pressure in response to the airflow. The relief pressure varies on a breath-to-breath basis - depending on the actual patient airflow.

### PATIENT PREFERENCE TRIALS

Two patient preference trials using the REMstar Pro with C-Flex were conducted with the aim being to assess both the patient's preference for CPAP therapy with C-Flex enabled versus conventional CPAP and the comfort and ease-of-use of the C-Flex device.

The results of both preference trials were overwhelming. In one study a remarkable **98 percent of participants** reported that they found REMstar Pro with C-Flex to be a very comfortable method of treatment. In the second study, **nine out of ten** indicated that they preferred the C-Flex device to their CPAP device.

## **STUDY ONE**

This study involved 60 individuals (30 at each of two clinical sites) who were on CPAP therapy. The mean age of Group 1 was 49 (+/- 10.2) years and that of Group 2 was 53.7 (+/- 12.5) years. Each participant had been diagnosed with OSA/H by diagnostic PSG within the past year, was on a clinically effective CPAP prescription, and had been on CPAP for at least six months with a clinically acceptable response to therapy.

All participants received a REMstar Pro with C-Flex, a user manual, a logbook and instruction on how to operate the device. Participants were instructed to use the device in the same manner that they were using CPAP for a period of 14 days, to log their usage and experience, and then return the device and log book to the clinical site.

## **STUDY ONE RESULTS SUMMARY**

Participants were asked to use a rating scale of 1 - 5 (5 being best) to answer a series of questions regarding comfort, ease of use and overall therapy comfort. The average response of all participants to all of the questions was 4.0, indicating a very strong acceptance for the therapy provided by the device with C-Flex.

## **STUDY ONE SUMMARY HIGHLIGHTS**

- 98 percent of participants indicated (with a score of 3 or higher) that CPAP with C-Flex is comfortable.
- Nearly 90 percent of all participants indicated (with a score of 4 or 5) that they believed CPAP with C-Flex was a very comfortable method of treatment.
- The overall response to the statement, "I like the availability of the different comfort settings." was 4.2. In fact, 93 percent of participants indicated they could feel a difference in the three comfort settings.

## **STUDY ONE PARTICIPANT COMMENTS**

- The machine was awesome! I want one!
- Good innovation. How do I get the upgrade?
- This is an excellent device. I would be happy to have one.
- This machine is really comfortable to use, and I was surprised when comparing it to the machine I regularly use.
- Great machine! Can I keep it?
- Much better than the machine I use now.
- Prefer the option of different settings.
- C-Flex helped me stay awake longer on less hours of sleep.
- I would like to have one. It is much quieter than my present one.
- Really liked the comfort settings. Unit was quiet and I slept well on "2."

## **STUDY TWO**

The specific aim of this study was to assess the interaction of a small group of highly experienced and compliant CPAP users with the REMstar Pro with C-Flex. Results reflect the level of the user's perception of therapy delivered by the C-Flex device as an acceptable treatment method and provide a systematic evaluation of the device features and acceptance in "real world" conditions.

The study included 10 adults between the ages of 18 and 80 (6 males and 4 females) who had been on CPAP therapy longer than six months with good compliance to therapy. Each participant received instructions on how to operate the device and complete the evaluation. They were instructed to use the device for a period of four days in the same way that they used their current equipment. At the end of the four-day trial, equipment and completed evaluation forms were returned to the clinical site.

### **STUDY TWO RESULTS SUMMARY**

Participants completed an evaluation survey using a Visual Analog Scale. The scale was calibrated from 1 to 10 in 1/2-inch increments with 10 being the best. They were asked a series of questions about REMstar Pro with C-Flex relative to size, weight, appearance, display features, noise level, ease of use, comfort, ease of sleep and how rested they felt in the morning.

Participants gave an overall rating of 8.0 in response to the question, "How would you rate the overall performance of the C-Flex device?" This indicates a very strong user perception of the overall performance and features of the device with C-Flex. The overall average response to all questions was 7.7, indicating an overall strong acceptance of the REMstar Pro with C-Flex.

### **STUDY TWO SUMMARY HIGHLIGHTS**

- Questions relative to comfort and ease of breathing, ease of falling asleep and feeling rested in the morning scored an overall response rate of 8.0.
- The overall response to the question, "How would you rate the comfort of breathing with the C-Flex device?" was 8.1.
- Overall, nine of the ten participants indicated they believed that CPAP with C-Flex was a very comfortable method of treatment and that they would choose CPAP with C-Flex over conventional CPAP therapy.

### **STUDY TWO PARTICIPANT COMMENTS**

- I really like this C-Flex device. It makes breathing easier.
- It is so quiet I don't even know it is on.
- I loved the C-Flex. Mine is quiet, but I could not believe how very quiet this is.
- It also feels more like natural breathing than forced air.
- This one so far is the "best of the best."
- I loved everything about it including the carrying case.
- Much more comfortable!
- Quieter than the CPAP that I have.
- I need one. I was very pleased with the C-Flex.



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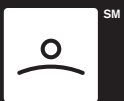
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1016941 KW 09/19/03



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