RESmart® Auto-CPAP
CLINICIAN'S MANUAL

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Indications for Use

The RESmart® APAP system is a CPAP (Continuous Positive Airway Pressure) device designed for the treatment of adult Obstructive Sleep Apnea (OSA) only. RESmart® has three treatment modes: Auto, Titrate and fixed-pressure CPAP.
The RESmart® APAP is to be used only on the instruction of a licensed health care professional. Your home care provider will make the correct pressure settings according to your health care professional's prescription.
Several accessories are available to make your OSA treatment with the RESmart® AutoCPAP system as convenient and comfortable as possible. To ensure that you receive the safe, effective therapy prescribed for you, use only BMC accessories are recommended.

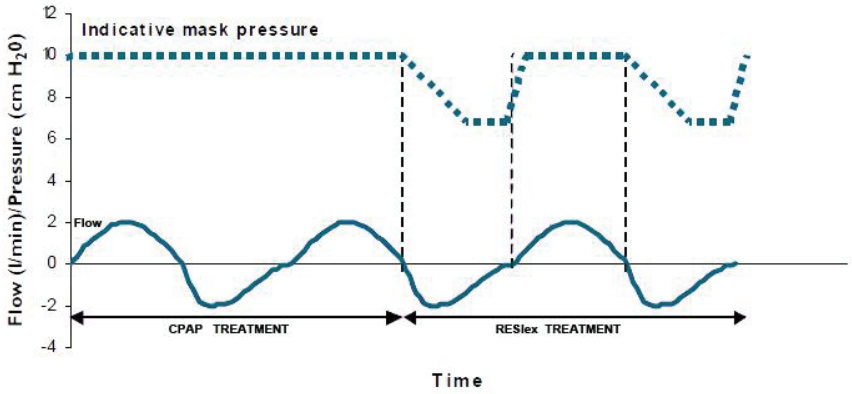
IMPORTANT! ***Read and understand the entire user manual before operating this system. If you have any questions concerning the use of this system, contact your home care provider or health care professional.***

Contraindications

The RESmart® APAP is not a life support device and may stop operating with power failure or certain fault conditions. It should not be used by patients who are dependent on continuous therapy.
Positive airway pressure therapy may be contraindicated in some patients with the following pre-existing conditions:
• Bullous Lung Disease
• Bypassed Upper Airway
• Pneumothorax
• Pathologically Low Blood Pressure
• Pneumocephalus has been reported in a patient using nasal Continuous Positive Airway Pressure. Caution should be used when prescribing CPAP for susceptible patients such as those with: cerebral spinal fluid leaks, abnormalities of the cribriform plate, prior history of head trauma, and/or pneumocephalus.
(Chest 1989; 96:1425-1426)
• The use of positive airway pressure therapy may be temporarily contraindicated if you exhibit signs of a sinus or middle ear infection.
Contact your health care professional if you have any questions concerning your therapy.

Adverse Effects

Patients should report unusual chest pain, severe headache or increased breathlessness to their prescribing physician. An acute upper respiratory tract infection may require temporary discontinuation of treatment.



Sensitivity

The speed of pressure adjustment can be modified to improve patient comfort. A lower sensitivity setting corresponds to a more gradual pressure adjustment. The higher the sensitivity setting the faster the speed of pressure adjustment. For example, at a Sensitivity setting of 5, the higher the speed of pressure adjustment (increasing or decreasing). When respirations increases rapidly and suddenly, as during waking, the treatment pressure decreases rapidly for patient comfort.

Definitions

Avg. Daily Compliance (H:M):
Average time of patient use of the device in nightly therapy
Average P95 (cmH20):
Auto pressure at or below the pressure 95-percent of that it is in use
Mean Pressure (cmH20):
The mean pressure level, in hPa, delivered within the selected range
AHI:
Apnea/Hypopnea Index (AHI), represents the average number of the apnea and hypopnea per hour for the timeframe
SNI:

CHANGING DEVICE SETTINGS

To enter the clinician's mode for the device, remove the power cord from the RESmart unit. Press and hold both the start and ramp buttons simultaneously, while reconnecting the power cord. The RESmart unit may now be programmed with therapy options.

You may step through each of the options using the + and - buttons on the device. To change a setting, press the ramp button. Confirm your setting by pressing ramp a second time.

Setting options include:

Mode: CPAP, Titrate, or Auto
Treat P: set the treament pressure
Max APAP: set the maximum treatment pressure
Ramp: Set ramp time from starting pressure to treatment pressure, in minutes. Default time is 10 minutes
Init P: set the starting ramp pressure. Default setting is 4.5 cmH20
Unit: cmH20 or hPa
Use time: Useage hours of the device
Mask test:

Important: to save settings you must advance through all setting options until you encounter the "Save?" prompt. Hit ramp to confirm settings.

The following side effects may arise during the course of therapy with the RESmart® device:

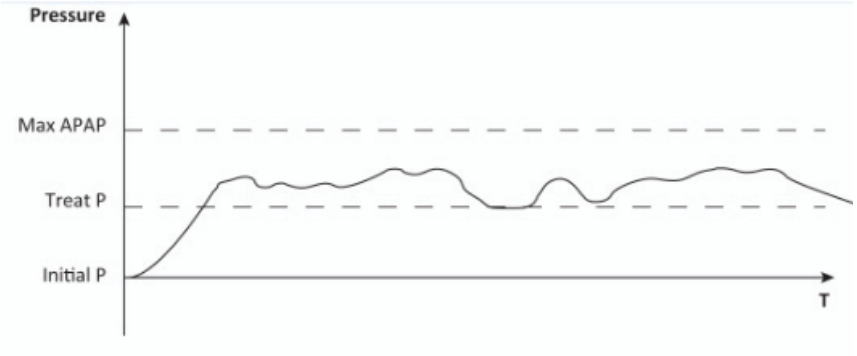
- Drying of the nose, mouth or throat
- Nosebleed
- Bloating
- Ear or sinus discomfort
- Eye irritation
- Skin rashes
- Chest discomfort.

Auto Mode

The treatment pressure required by the patient may vary through the night, and from night to night, due to changes in sleep states, body position, and airway resistance. RESmart® provides only sufficient pressure to maintain upper airway patency.

You can set the initial and maximum allowable treatment pressures. RESmart® analyzes the state of the patient's upper airway on a breath-by-breath basis and delivers pressure within the allowed range according to the degree of obstruction.

Auto Mode improves patient compliance through enhanced algorithm of Auto Mode. AutoSet algorithm auto-adjusts to maintain optimal therapy pressure. The pressure can vary from treat pressure (Treat P) to maximum treat pressure (Max APAP), which is shown as below:



RESmart® Auto Pressure adjusts treatment pressure as a function of four parameters: Apnea, Snore, Flow Limitation, and Hypopnea.

Apnea

An apnea is defined as a greater than 80% decrease in ventilation. After scores 2 apneas within 3 minutes, treatment pressure will rise. The rising speed is inverse proportion to current pressure, namely the higher current pressure the lower rising speed. Treatment pressure stops rising when normal ventilation and no snore. If ventilation keeps normal for several minutes, treatment pressure will decrease. The descending speed is direct proportion to current pressure, namely the higher current pressure the higher descending speed.

When treatment pressure approaches 10hPa(cmH_2O) during rising, not only rising speed will decrease greatly but also snore or flow limitation must be detected for increasing pressure. This is to prevent an inappropriate response to central apneas.

Snore

When a patient snores, sound is generated and the inspiratory flow/time curve is distorted by the frequency of the sound. RESmart® detects and calculates snore level breath-by-breath. When snore sound intensity exceeds 50% higher than background noise, then one snoring event is scored. Treatment pressure increases after continuing 3 snores. The rising speed is inverse proportion to current pressure, namely the higher current pressure the lower rising speed.

Snore Index (SNI), represents the mean snore count per hour.

Snore Level is index for degree of patient snoring. It is the percentage of all breathes with snoring event. For example, 20% means 20 breathe along with snoring in all 100 breathes.

Flow Limitation

Flow Limitation is the partial airway closure without snore. As the upper airway begins to collapse, the shape of the inspiratory flow/time curve changes and the central section flattens. RESmart® analyzes the curve shape of each breath and calculates the distortion. Flow Limitation usually precedes snoring and obstruction. Detection of Flow Limitation enables the device to increase the pressure before obstruction occurs, making treatment pre-emptive. This is also the important criterion for obstruction and central apnea.

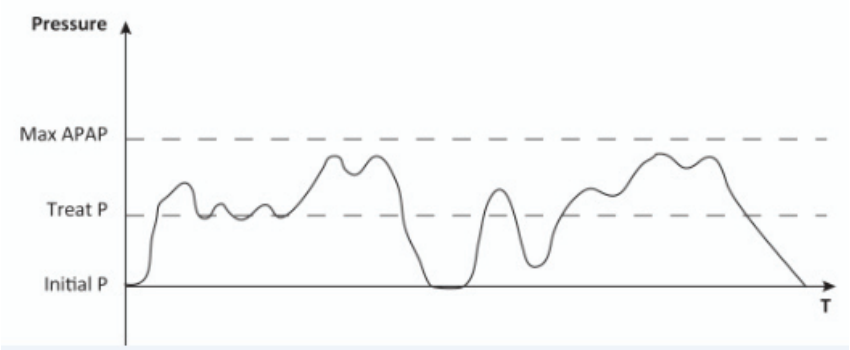
Hypopnea

A hypopnea is defined as a 60-80% decrease in ventilation. After scores 6 hypopneas within 3 minutes, treatment pressure will rise.

Titrate Mode

For the previous Auto Mode of APAP, after Ramp time, the pressure will increase from "Init P" to "Treat P". Once respiratory events appear, the treatment pressure increases; if there is no occurrence of respiratory events, the treatment pressure drops. The pressure range: the minimum is “Init P” and the maximum is “Max APAP”.

Pressure Adjustment of the Titrate Mode is shown as below:



Pressure change in Titrate Mode

When treatment pressure is rising, if current pressure is lower than Treat P, the rising speed is doubled. If current pressure is higher than Treat P, the rising speed is normal (as Auto mode). Contrarily, when treatment pressure is decreasing, if current pressure is lower than Treat P, the decreasing speed is normal. If current pressure is higher than Treat P, the decreasing speed is doubled.

Significance of Auto and Titrate Mode

The Titrate Mode is based on manual titration and its algorithm is sensitive to respiratory events. Advantages: it can decrease AHI effectively and compute the P95 pressure accurately. Disadvantages: it has large pressure range, the pressure changing is easy to cause the patient discomfort.

The APAP combines the Titrate Mode with new Auto Mode to effectively adjust the pressure for maximum comfort, with the premise of effective treatment. To get a accurate P95 pressure, Titrate Mode is applicable for the first 1-2 weeks during the use. Based on the P95 pressure, MAX APAP is determined. It is suggested to set the MAX APAP little higher(1or 2 cm H_2O) than P95 pressure. And based on the Pmean pressure, Treat P is determined. It is suggested to set the Treat P little lower(1or 2 cm H_2O) than Pmean pressure. It can improve patient's compliance with more accurate and humane pressure range.

RESlex®

In Auto mode, you can select expiratory pressure relief (RESlex®). RESlex® is designed to maintain optimal treatment pressure for the patient during inhalation and reduce the delivered mask pressure during exhalation. The desired result of RESlex is to decrease the pressure the patient must breathe out against, making the overall therapy more comfortable.

The features of RESlex® are:

- RESlex® is disabled automatically in the event of an apnoea.
- RESlex® resumes automatically when the apnoea event has passed.
- You can select a RESlex® pressure drop of 0, 1, 2 or 3 (maximum drop is 3 cm H_2O).
- Pressure drop is limited, to avoid sub-optimal treatment.
- When RESlex® is enabled, the delivered pressure will not drop below a minimum pressure of 4 cm H2O.