The RESmart® APAP is to be used only on the instruction of a licensed health care professional. The device offers three treatment modes: Auto, Titrate and fixed-pressure CPAP. It is designed for the treatment of adult Obstructive Sleep Apnea (OSA) only. RESmart® has been shown to improve sleep quality, reduce the number of apneas and hypopneas, and increase the use of continuous treatment in patients.

Indications for Use:

Positive airway pressure therapy may be contraindicated in some patients with the following pre-existing conditions:

- Bullous Lung Disease
- Pneumothorax
- Bypassed Upper Airway
- Pneumocephalus
- Pathologically Low Blood Pressure
- Several accessories are available to make your OSA treatment with the RESmart® as convenient and comfortable as possible. To ensure that you receive the safe, effective therapy prescribed for you, use only BMC accessories.

Contraindications:

- 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.
- Several studies have shown that OSA patients who are treated with continuous therapy may exhibit some respiratory symptoms, such as a cough or increased breathlessness, which are unrelated to their OSA. In such cases, it is important to contact your prescribing physician. An acute upper respiratory tract infection may require temporary discontinuation of treatment.

Adverse Effects:

Patients should report unusual chest pain, severe headache or increased breathlessness to their prescribing physician. However, in some cases, these symptoms may be due to other medical conditions and may not be related to the positive airway pressure therapy.

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.
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:
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:

![Pressure Graph](image)

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(-cmH2O) 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:

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**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 H2O).
- 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.