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S9

With trade show season approaching, ResMed looks to revolutionize CPAP therapy with its S9™ flow generators.

S9: All About Compliance

San Diego-based ResMed has added its considerable marketing muscle to an exciting year in sleep with the introduction of its S9™ Series of flow generators. The makers of the Swift and Mirage CPAP masks are touting the S9 as nothing less than a "radical evolution" in CPAP therapy.

The S9 Series combines sophisticated treatment technology with user-friendly controls in a new design that marks a departure from its predecessors. "Our goal in the development of the S9 was to create a system that offers more than any other device on the market—more comfort, more control and more style—so users can feel confident about incorporating it into their lifestyle, and health care providers can be confident that their patients are receiving the highest quality of sleep apnea treatment," said **Drew Terry**, senior director, product management, sleep SBU, ResMed, San Diego.

Terry says the S9 represents a new approach to patient compliance, essentially making it easier for users to accept CPAP on their own terms. "It puts them in control of the details that make the difference in their personal comfort, like EPR™ level and humidification settings," adds Terry. "It has intuitive menus and dials to make it easy to adjust. It reduces noise to a virtual whisper, so it won't disrupt a sleeping partner. And it comes in a stylish design that looks like something they want to have at their bedside."

With the S9 Series, ResMed has introduced a number of improvements, including Enhanced AutoSet™ and Easy-Breathe algorithms, and an improved Easy-Breathe motor for low noise levels. The S9 provides detailed data reporting for clinicians, and a complete S9-compatible wireless compliance management package to streamline business efficiencies. A humidification system with Climate Control intelligently adapts to the user's real-time environmental conditions to provide optimum performance and humidification delivery. An innovative SlimLine™ tube eliminates tube drag.

Ultimately, the S9 is a large part of the overall push toward greater innovation in what will surely be a huge decade for sleep medicine. Companies big and small are all angling to serve the growing market, and Terry acknowledges that competition is fierce. We asked Terry to share his thoughts on the future, the importance of compliance, and the challenges of introducing something new in an already crowded field.

What was the genesis of the S9?

We started working on this platform over three years ago, and we interviewed hundreds of people in countries all over the world with the goal of identifying challenges that prevent patients from being successful on therapy. Our objective from the start was to reduce or eliminate obstacles that prevent people from being successful CPAP users.

What did you discover during those conversations?

People expressed reservations about being connected to a machine that reminded them of a ventilator in an ICU. They didn't want to be seen as somebody who was *that* sick, and they had reservations about having the equipment visible in their home as well. When we spoke to sleep professionals, they emphasized the desire to first achieve compliance—help patients successfully use their therapy—and then to demonstrate compliance with data. We designed all the features in the machine, and all the new technology, to overcome the barriers to achieving and verifying compliance.

S9 Bedside

We have never seen a design like this. Was it a conscious effort to improve aesthetics and features?

The device looks so much different from anything else. Patients tell us it is a hugely attractive design, and something that fits in the bedroom environment. The design of the unit itself plays a critical part in overcoming the obstacle of the overly "medical" appearance of therapy equipment. It is also very travel-friendly and has all the features that you expect from ResMed carried over from the S8™ platform. Another area of

significant change is the way that the patient interfaces with the device. To program the device, change settings or view data, you have a large LCD screen with big, colorful graphics. The way that you enter information or make selections is with the knob and push buttons. The interface is designed to be familiar to patients, similar to a digital camera, mp3 player, or mobile phone/PDA device. Having an intuitive interface allows most people to set it up without any instruction. The pressure settings and other details are in large, easy-to-read fonts so that patients can use the machine without putting on glasses or turning on the light. We considered every aspect of how people interact with the device in order to make it extremely user-friendly.

What else will patients find familiar about the S9 next generation of technology?

With the previous generation of our product, we introduced Easy-Breathe technology, which included both a low-noise motor and a smooth breathing waveform. The waveform, which refers to natural and comfortable air pressure delivery, carries over from the previous generation of products. However, we have now improved the motor to be more efficient and approximately 75% quieter than most other devices on the market. We call it our enhanced Easy- Breathe motor. With enhanced Easy-Breathe, the S9 delivers a new kind of quiet.

A 75% improvement in noise reduction is significant. Explain this "new kind of quiet?"

If somebody knocks on your door and you are standing across the room, sound waves travel through the air and you hear the knock. That is called radiated noise. Now if you move to the door and press your ear against it, the sound waves travel to your ear through a solid surface, and that is called conducted noise.

Conducted noise travels via a physical connection from the source of the noise to the person who is listening. Conducted noise goes from the CPAP machine to the patient through the tube and into the mask, and the patient perceives those sound wave vibrations in a different way. Sound can actually get transmitted through the cheeks and cheekbones of the patient. Sometimes they actually hear the motor or the unit, and sometimes it feels like a different kind of pressure.

With the S9 platform, we have actually reduced the conducted noise that comes through that tube by 78%. That is an improvement over and above the S8 Series II, which was already the class leader in the area. It is a phenomenal step forward and patients really embrace it.

What has been the patient reaction to the noise reduction and ClimateLine tubing?

Recent comments include "It feels like softer air" and "It feels like less pressure," even though the pressure setting is the same. Conducted noise reduction makes that much of a difference.

The humidification system itself is another major advancement. The H5i™ humidifier with Climate Control maintains the air temperature all the way to delivery at the mask, via the ClimateLine™ heated wire tube. The system works a lot like the thermostat in your home or in some cars. You simply set the temperature and the system does the rest automatically.

It is unique from other heated wire tubes because of its sensor technology. There are four sensors that fit within the device and the humidifier. A fifth sensor can be found at the end of the tube. The five sensors send constant information back to the humidifier so that it can make adjustments to control air temperature and humidity as it is delivered to the patient.

What did you learn about humidity rates during your patient trials?

Most patients prefer a relative humidity rate of about 80%, and the amount of water in the air depends on the temperature of the air. We give the patient control of the temperature, and then Climate Control adjusts automatically to maintain relative humidity at 80%. This stays the same no matter what happens in the bedroom.

If the temperature goes way down, or if humidity levels in the bedroom change, Climate Control will maintain 80% relative humidity at the temperature that the patient sets. This is another aspect that has been very popular with our patients. It gives them another level of control and comfort.

Does S9 reduce the chance of so-called CPAP rainout?

Since the H5i always maintains 80% relative humidity, there is virtually no rainout in the system. You can eliminate any patient problems and challenges associated with rainout, and that is a benefit to health care professionals who are trying to help patients get acclimated to therapy. It is one less problem they have to work through.

What innovation does the S9 Series bring to tubing?

Since the beginning, CPAP tubing has been about the same—essentially 19 mm corrugated medical hose. It has been the same with ICU vents and early CPAPs up until today. This is the first time anybody has ever made a substantial change to the tubing, and that is important because it is a prominent part of what the patient sees, what the patient feels, and what other people see when they come into the bedroom and see this CPAP system.

We have reduced the surface area by 30%. The tubing has gone from 19 mm to 15 mm diameter. We also made it extremely flexible and lightweight, so it is easy to travel with, and does not pull on the mask and create leaks. It conforms and bends as necessary to deliver air to the patient without pulling on the mask or disturbing the patient.

ClimateLine Tubing

How have you made the unit more intelligent?

We have added intelligence in the form of a new and enhanced AutoSet™ algorithm. Enhanced AutoSet has the capability to detect central sleep apnea (CSA) using a forced oscillation technique (FOT).

FOT puts an imperceptible vibration into the airway, and then measures the response coming back. The response is evaluated to determine if the airway is open or closed, and the apnea event is then categorized as central or obstructive. By differentiating between central and obstructive apneas, AutoSet is able to adjust pressure more appropriately. If the airway is open, pressure remains static. If it is closed and the patient is having an obstructive apnea, pressure will increase until the airway reopens.

The addition of central sleep apnea detection will help health care providers to identify patients who may be having predominantly central events that may benefit from CSA therapy.

In addition to CSA detection, we've added a ramp feature to AutoSet, so patients can start therapy at a lower pressure and then gradually ramp up to their therapeutic AutoSet pressure. We have also updated the way that we record events, to now record both obstructive and central apneas. We adjusted our hypopnea detection to be more consistent with AASM 2007 guidelines, so measurements from the machine will more closely match what you see in the sleep lab.

What were the final results of patient trials?

Following our extensive market and clinical trials, we received the strongest response in the history of our patient preference trials. 95% of people that went through the trial said that they prefer the S9 to the device that they were using prior to trying the S9.

What has been the feedback from clinicians?

Some doctors have been skeptical audiences for us in the past have told us that we've hit a home run with this device. Another doctor told me that he feels sorry for the "other guys" because our machine looks so much better than the other devices on the market.

You and your competitors have stressed simplicity. Why is this such an important concept these days?

It is an important trend because everybody is being challenged to become more efficient in their business. Medicare is reducing reimbursement, so for people to maintain a good business they need to become better at what they do, and we want to provide them the tools for achieving that efficiency. Simplicity is one way of doing it. For example, when you connect the humidifier to the system, it automatically recognizes that and presents options. If the humidifier is not on, you don't get those options and patients won't be confused.

At the time of launch, we are providing an SD card which will work with any standard SD card reader, and that is a popular option. Soon after the launch, we will add both wireless and wired modem capabilities—and the same applies to the ClimateLine tube. When you connect the ClimateLine tube, you are presented with the options available for Climate Control. We have also reduced some of the options in the menu and made the selection bold and simple.

By making the setup of the machine simple and eliminating many of the problems that patients encounter, we also make our health care partners more efficient. This means that they can treat more patients more successfully.

Ultimately, it is all about efficiency, clinical effectiveness and compliance.

Drew Terry is senior director, product management, sleep SBU, for ResMed, San Diego.

For more information, visit www.s9morecomfort.com.