

## The Heart of the Matter: with Home Sleep Testing

The Somté Home Sleep Testing (HST) Device by Compumedics addresses the Technological Challenges of Home Studies while its Sophisticated ECG Capabilities help set the Device Apart from its Peers.

When engineers from Australia-based Compumedics developed the Somté, they knew cardiology was likely to play a growing role within sleep medicine. With this in mind, they developed a Holter-type sleep system that earned a 2006 Frost & Sullivan award for Technology Leadership.

Since that time, interest in sleep disorders and home sleep testing has exploded from all sectors of medicine. Combining home sleep diagnostics with the optional capability for Holter ECG monitoring and pulse transit time results, is one way to recognize this new reality. Most other HST units do not have the option, because they don't record electrocardiography (ECG) signals.

**Jeff Kuznia, Vice-President of North American Sales and Marketing for Compumedics**, says the unit's ability to record reliable data means that the equipment fits well into the Type 3 recorder market. Holter ECG monitoring exists as a stand-alone product, but the software development required to combine it with sleep makes it difficult for other companies to make a similar device.

Compumedics' involvement in the Sleep-Heart Health Study sparked the original Holter idea, and there are no regrets—but still some work to do. "Most cardiologists are aware of the connection between sleep disordered breathing and cardiovascular disease. However I do not believe that many have firsthand experience with managing sleep disorders, and may not appreciate the impact that sleep disorders have on cardiovascular disease, but also the effect of treating Sleep Disordered Breathing 'SDB' when it comes to managing many patients who suffer from complex hypertension or cardiac arrhythmias."

### HOME TESTING: WHAT'S DRIVING THE MARKET?

*Sleep Diagnosis & Therapy* spoke with Kuznia about a wide-ranging discussion on the future of home sleep testing. Topics such as reimbursement and clinical efficacy are driving the market, but what shape will these changes make, and how will new discoveries alter diagnostic testing?



Somté unit

### ARE RESEARCHERS CLOSER TO DETERMINING A FIRM LINK BETWEEN SDB AND CARDIOVASCULAR PROBLEMS?

Data is out there, but from a scientific standpoint, the issue is still one of determining causality. There definitely is clear interaction between these processes, and a lot of people with cardiovascular disease have OSA or develop CSA. However, the evidence is inconclusive in showing SDB actually leads to cardiovascular disease. If you have cardiovascular disease, chances are increased that you have SDB, which should be treated. In many patients, treating SDB improves the status of their cardiovascular disease, or improves the ability to manage that disease, but what caused the other has not been determined. With respect to "hard science" this question may be viewed as rhetorical as hopefully either diagnosis warrants treatment.

### THERE IS A LOT OF COMPETITION IN HOME TESTING. WHAT MAKES THE SOMTE STAND OUT?

One of the advantages of the Somté is it has some flexibility and capabilities that a lot of the other products don't have that are in that class. It is one of the few units that has a built-in display that allows the technician to verify the quality of the recording prior to sending the patient away, avoiding a wasted recording night. It's easy for the patient to set it up in most cases, the Somté uses the best methods of measuring respiratory data, with built-in RIP technology. It's also one of the few units that provide additional inputs to record limb movement.

You've got the ability to look at body position with the Somté if you so desire, and you can add in these high frequency channels. There are two of them, and the original concept was they would be used for ECG, but when we released the product we made it flexible enough so they could be used for a channel of EEG or EMG, and we've got people that are looking at this and saying this would be a very good thing to monitor Bruxism for instance.

An operational advantage of the system is that you can pre-configure the unit for the recording. The patient can put it on themselves, and does not have to interact with the unit because it will turn on automatically, record the data, and then turn off. A lot of the people that send the units out to patients will pre-program the unit to turn on at night and shut off in the morning. All patients have to do is hook themselves up, and they do not have to worry about touching the unit and turning it on and off. So in some cases patients may come to the sleep clinic or the physician's office, get wired up, and then they can test to make sure that everything looks good before they go home.

### WHAT ARE PATIENTS SAYING ABOUT THE PRODUCT?

It's small, lightweight, and it's easy to wear. Some of the units out there for home studies are still fairly large and bulky. There is a comfort factor to this that comes into play, and I think we've addressed that effectively.

## IS THE BATTLE FOR CLINICAL ACCEPTANCE OF HOME SLEEP TESTING OVER?

The vast majority of sleep professionals believe that home sleep testing is valid and appropriate in certain populations, and that it can be done reliably. There are concerns still amongst some that if everybody was evaluated with a home sleep test that we would be missing other factors and other issues involved with their symptoms, such as co-existing sleep disorders. That being said, if you go to your primary care physician complaining of stomach pain and are treated and he/she missed the fact that you had an ear infection, does this constitute "bad medicine"? It is one of these things where there are still questions in the mind of the marketplace that would only be answered when home sleep testing is done in larger numbers.

If more people are doing home sleep testing, and have a larger volume of experience, the general consensus of the marketplace may shift because they would might experience more success, or they would be able to determine when it would not be successful and be able to more clearly state which set of patients need to be done in the lab.

## DO YOU BELIEVE THE POTENTIAL OF THE HOME SLEEP MARKET IS A REALITY?

We have been telling ourselves for the last 20-plus years that the number of people in the population with undiagnosed sleep disorders is large. If we are claiming that 80% of the people with sleep disorders are currently not diagnosed and treated, than there is this population of people not being cared for in our health care system. The thought was that if we had more home sleep testing being done, we would reach more patients with sleep disordered breathing and treat them, and that would be a cost effective way of managing this particular part of the health care challenge.

We don't have a good handle on whether that is true or not. The economics are driven from the reimbursement end, whether it is Medicare or other third party payers. They look at the growth of sleep diagnostics and the cost of ongoing treatment, and are concerned at the cost and not necessarily the benefit. Anytime a diagnostic procedure or a treatment procedure has rapid growth, it puts a spotlight on it and payors look and say we maybe need to manage this more aggressively.

The issue is that if, or maybe when, reimbursement drops in the clinical lab, will it necessarily push people to doing more sleep studies in the home? This is unclear because the reimbursement at the home level is also relatively low, and so, from a business operations standpoint, to provide home sleep testing services in a manner that you can more than cover your costs is still a challenge for a lot of practitioners.

### **Somté Software Package Includes:**

- full waveform review;
- automatic respiratory event detection and statistics (central apnea, obstructive apnea, mixed apnea, hypopnea, SpO<sub>2</sub> desaturation events and artifacts);
- oximetry analysis;
- full manual event editing capabilities (deletion, reclassification, marking new);
- event searching;
- ability to view patient information; and
- comprehensive report generation with user definable template
- full disclosure printing
- Optional ECG Analysis with arrhythmia detection, classification, heart rate variability and ST-Segment measurements and statistics.

## WHERE DO YOU SEE HOME SLEEP TESTING IN THE FUTURE?

There is definitely a role for home sleep testing in the whole milieu of sleep medicine, and clearly there are a lot of people, including physicians, insurers, and patients, that are very strong advocates for that approach. The concern in the minds of many sleep professionals is that sleep medicine and managing patients with obstructive sleep apnea is not within the general training of most internal medicine physicians and most family practitioners. You are going to have family practitioners and internists with no sleep medicine training, caring for patients who may require more complex management than just prescribing a CPAP pressure. That is precisely the reason that sleep centers should be looking at expanding into it [home testing] because it keeps the profession in the sleep home testing market.

## CAN HOME SLEEP TESTING EXPAND INTO OTHER AREAS SUCH AS THE REALM OF TRUCKING?

I think you can expand trucking industry to transportation in general. The airline industry is definitely another example and here you've got other complicating issues. You've got shift work compounded with potentially a pilot that may have OSA. Clearly anything involving hazardous waste material or in the broad category of transportation is certainly a legitimate testing population.

It is still unclear what role home sleep testing plays in that arena. For instance, the truck drivers: one of the concerns is that if you would give a recorder to a truck driver and say, "put this on and bring it back in the morning after you have slept all night," is that the truck driver is going to take that unit home and place it on his kid and not necessarily on himself. This is one situation where it may need to be a monitored study, since you need to verify whom the recording was actually done on.

One other population is those patients who are already diagnosed, that are already on treatment but have not been reevaluated for a while. Once a patient is diagnosed with sleep apnea and we have put them on treatment, we often don't know how effective the treatment is long term, or if it needs to be adjusted. This has been one of the issues with tracking compliance in the usage of CPAP over time; in many cases those patients are not retested to see if their treatment is still valid, or if it is effective from an objective standpoint. Home sleep testing is an ideal way to do cost-effective follow-up.

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