

Medical Device and Home Monitoring Solutions for Sleep Apnea Patients



Robert N. Schmidt - CEO

About Cleveland Medical Devices Inc. (CleveMed)

CleveMed has been developing innovative biomedical signal processing and instrumentation devices since 1990. It is a leader in sleep diagnostics, particularly home sleep apnea testing. Our web-based services and devices meet the American Academy of Sleep Medicine (AASM) guidelines, are easy for patients to use, streamline operations for healthcare providers, and offer cost efficient solutions for payers. The team of colleagues at CleveMed is dedicated with an average tenure of eight years and comprised of extensive expertise in engineering, business, sales and clinical sleep diagnostics.

Interview conducted by: Lynn Fosse, Senior Editor, CEOCFO Magazine

CEOCFO: Mr. Schmidt, what is the focus at CleveMed today?

Mr. Schmidt: You can think of us as Amazon.com meets health care, removing the cost of bricks and mortar from sleep testing. We are a medical device manufacturer that provides medical services and innovative home monitoring solutions for patients with sleep apnea. We produce a lower cost, high-quality sleep diagnostic solution that allows people to be diagnosed in their home rather than having to go to a facility.

CEOCFO: Why the focus on sleep?

Mr. Schmidt: We started off as a small business innovation research, SBIR, company in 1990. We were developing a number of products and started doing EEG (electroencephalogram) analysis for brain waves for various conditions, and ended up in the market of sleep because it was a place that was greatly underserved. That is the product line that we developed starting in the mid-90s.

CEOCFO: Can you test at home today?

Mr. Schmidt: Yes. Actually, no one would pay for home sleep testing until the late 2000s, just a few years ago. For the last three years, we have been tripling our sleep sales every year. We have been growing by about 12-15 percent per month in the number of sleep studies generated by our equipment and services nationwide. The way the model works is we sell our devices to primary care physicians, cardiologists, sleep specialists, dentists, nurse practitioners and other providers who can prescribe in the medical field. They then provide the device to the patient in a little kit that is the size of a sandwich bag. The patient takes it home and sleeps in their own bed. It is very simple to put it on. They put a belt around their chest, they put a ring on their finger, they put a cannula on their nose, and they sleep with it in their own bed. They bring the device back the next day, the data is uploaded to our secure web portal, it is viewed by a registered polysomnography technician and then sent to a certified sleep doctor who reads the report and signs off on it or makes recommendations that he sees fit. Then the data is sent back through us to the ordering physician. We do more than a thousand of these sleep tests per month.

CEOCFO: Is there push back from the sleep centers that make their money on doing the testing?

Mr. Schmidt: What has happened is that in the last couple of years the insurance companies have said they are not going to pay for in lab testing for simple obstructive sleep apnea. This is a way that the sleep lab can also make more money by doing these tests at home and having a model that they can then do the read, which is where they make most of their money anyway. Also, they can make sure to keep their beds full by over booking and sending some people home to do a home test where it is appropriate. The average sleep lab has about a 33 percent no show rate, so if they have six beds and two people do not show up, it is a huge cost to the lab when the beds are empty. This allows them to keep their beds full. The sleep labs are some of our best customers.

CEOCFO: In what cases might it be appropriate to test at home and when might it be inappropriate?

Mr. Schmidt: The SleepViewSM test is for obstructive sleep apnea (OSA). There are two types of apnea. One is a central apnea, where the brain stops sending signals to the lungs to keep breathing. That is not what the SleepView is used for. Our test is for obstructive apnea where there is a blockage in the air passageway, usually in the back of the throat. That area collapses during certain stages of sleep, and the person wakes up with a snort. It is a characteristic sound of this

disease. It is not the snoring, although that is indicative of obstructive sleep apnea, but it is not necessarily a diagnosis. If they stop breathing, that is a problem. The SleepView is for testing for obstructive sleep apnea. It is not appropriate for some conditions. If the person has congestive heart failure or other very serious diseases, then they should be in a lab.

CEOCFO: *What is your geographic reach today?*

Mr. Schmidt: We are selling around the world, but most of our focus has been in the US, just to be able to concentrate our resources. That has been our business focus.

CEOCFO: *How have you been getting attention from appropriate industry people and do you address the public as well?*

Mr. Schmidt: We have not been able to get to broad based direct marketing at this point. Even though we are one of the fastest growing Home Sleep Testing providers in the world right now, because of our market timing, our low cost convenient home sleep test is very well aligned with the overall paradigm shift in US healthcare aimed to improve delivery of care. We believe that as long as sleep study interpretation is done by the sleep specialist, the remaining tasks of: sleep diagnosis like identifying at-risk patients, educating patients on the procedure of using the home monitor, and data management can and should be done by the many healthcare providers who are the initial point of contact for the patients. In doing this, we believe that our business model is uniquely suited to improve delivery of care for OSA patients. One of our clients has about two million covered lives, so we are providing devices for them to be able to test their patients on a per test basis. This reduces their costs when compared to in-lab testing, and allows them to provide more convenient, faster sleep testing service to their patients.

“We have had about 12-15% per month growth rate for the last 10 quarters, along with a great sleep diagnostic product and business model that gets a lot of attention. Cutting the cost of a sleep test by 70-95%, eliminating long waits for a diagnosis, and providing a new revenue stream for physicians make patients, insurers, and doctors much happier, which drives our growth.” - Robert N. Schmidt

CEOCFO: *Do you have any statistics on how many more people will actually do the test because they can do it at home?*

Mr. Schmidt: There are about 40 million people in the US with sleep disorders. Of the people with sleep apnea and obstructive sleep apnea, various assessments have been made, but 80 to 90 percent of them have not been diagnosed. There are many millions of people out there who need this test; and the problem is that you have a disease and do not get it treated, you are losing an average of ten years of life, and it is not the last ten years. It is two or three years per decade starting in the 40s. You just age much faster. There are comorbidities with heart disease, obesity, diabetes, and all kinds of organ failures all the way through sexual dysfunction. It is very important to get sleep apnea treated as soon as possible.

CEOCFO: *You have other devices as well. Are they ancillary to the sleep apnea test?*

Mr. Schmidt: The SleepView is our product that we sell for at-home sleep apnea testing. We have another device called the Sapphire™, which is sold to sleep labs. It looks at all kinds of sleep disorders, insomnias and parasomnias, everything from sleep walking to bed wetting. We have those devices that we sell that have EEG and other sensors on the legs for restless leg syndrome or periodic limb movements. We also have another device called the SleepScout™, which is able to monitor cardiac function. The SleepScout is the next step up from the SleepView product.

CEOCFO: *What have you learned with your previous experiences, particularly with the US Army Corps of Engineers and NASA Center? What have you taken in the business side from previous ventures that is helping you guide and shape CleveMed?*

Mr. Schmidt: The first lesson I learned from my mentor is that as the president, your job is to collect checks. You have to make sure that you are keeping the money flowing and keeping people paid. That is the real focus. This then allows you to create great products that help change the world, and provide good jobs, improving peoples' lives.

CEOCFO: *Where do you manufacture?*

Mr. Schmidt: In Cleveland, Ohio. It is American made.

CEOCFO: *Does that make a difference? Do you think people pay attention?*

Mr. Schmidt: I would like to think they do. We try to create jobs in America, and we think that is important to be able to employ people locally; people who become our friends and neighbors.

CEOCFO: *What might be different a year from now for the company?*

Mr. Schmidt: We continue to grow at about 15 percent per month. We are making a big push right now to be able to take a big jump from here, if we can. Over the next few years, I would like to see us continue to expand our American market

and then go into international markets. There are a number of different steps that we can take and we just want to continue to increase our sales. The big thing about why the sales will continue to grow is because of this model and the fact that it is cheaper and easier for the patient. The primary care physician makes money. It is the only model the primary care physician can make money on sleep tests, and the insurers save money, so it is good for everybody. It is a money saver, it is more convenient, and it is a wonderful test that provides the diagnosis sooner and more conveniently for the patient.

CEOCFO: *Why is this the time for a push?*

Mr. Schmidt: Timing in the marketplace makes all the difference in the world as I mentioned before. When we started this, no one had ever heard of sleep apnea. Now, there is more awareness of the disease. What I see with health care is that you are going to see more and more people moving to the home with mobile applications, and there will be fewer and fewer visits to a doctor's office because so many of the things you will be able to do at home. With talking to the doctor over your phone or computer and going to a kiosk to visit a doctor, technology has made such huge changes in the way we can deliver health care to the patient more efficiently at a lower cost and provide better service to the patient.

CEOCFO: *What were the biggest challenges in getting the technology in place?*

Mr. Schmidt: We started off by doing wireless EEG. That was extremely difficult at the time in the 90s to be able to do very small (sub-microvolt) signals right next to a radio. We solved that technological problem, and we were the first company in the world to ever do digital wireless EEG. We developed that and we went on and did more and more EEG and then moved into sleep. Finally, we migrated into this home sleep. The first challenge is always the technology, then it is proving the technology works, then it is proving it is in the marketplace, and then finally it is growing in the market. We are in that last phase now of just growing in the market. Each one of those phases has different challenges, and this last one is time and money. The hardest parts are out of the way and they are behind us now. We have wrung out those risks, and now the issue is adding money and turning the crank.

CEOCFO: *How will you add money?*

Mr. Schmidt: We have been growing indigenously for a long time. We have one industrial partner, and we formed a nice relationship with the state of Ohio, which is helping us. We are looking at other partners as they come along. We are looking at all of those; and we have many strategic partners we are working with to be able to provide them services at a cost that allows them to save money as well. We have had about 12-15% per month growth rate for the last 10 quarters, along with a great sleep diagnostic product and business model that gets a lot of attention. Cutting the cost of a sleep test by 70-95%, eliminating long waits for a diagnosis, and providing a new revenue stream for physicians make patients, insurers, and doctors much happier, which drives our growth.

CEOCFO: *Put it all together for our readers. There are many companies to look at in medical devices and many companies to look at in the sleep area. Why CleveMed?*

Mr. Schmidt: The fact is that we are the only company in this business that allows the health care provider at the primary care level to be able to derive income from the sleep test. There are two other ways of doing a sleep test for the doctor, nurse practitioner or dentist. One is to send the patient to a sleep lab. Not only does the primary care provider not get paid for the sleep test, but they also lose their patient for all of the sleep issues. That is problematic for them. The other way is they send the patient to an independent test facility that mails the device to the patient and does the test; and that test facility does the billing. In both cases, the primary care physician makes no money from this. So we provide a way where that primary care provider can not only earn an income and significant increase to both his or her top line and bottom line, but they also keep the patient for follow up visits, and they provide better, more convenient, lower cost health care for that patient. Changing the model we think will be highly successful.

BIO: Mr. Robert N. Schmidt founded and is the Chairman and CEO of Cleveland Medical Devices, Orbital Research, NeuroWave Systems, Great Lakes NeuroTechnologies Inc., and Flocel Inc. He received his BS degree in Mechanical Engineering and his MS from Rensselaer Polytechnic Institute; his MBA from the Univ. of Utah, and his Juris Doctor (81) from Cleveland State University. He is a licensed professional engineer (Ohio, 76) and an attorney (Ohio, 81 and US Patent and Trademark Office, 82).

Mr. Schmidt supervised programs for the US military, NIH, NASA, DoEd, DoT, NSF, Exxon, Arco, and Shell. He has over 30 US patents, and has led two companies onto the Inc. 500. He is the only person to have been awarded by Michael Porter of the Harvard Business School and Inc. Magazine the "Inc. Inner City 100 Award" for the fastest growing companies 7 times in the first 7 years of the award.

Orbital Research develops and commercializes new and innovative custom-engineered solutions using our expertise in Aerodynamic Control Systems, Medical Devices and Micro Electronic Devices for various commercial and military applications. NeuroWave Systems develops innovative, state-of-the-art signal processing technologies for the next generation of brain monitors for improved and safer patient care; including the NeuroSENSE® Monitor, for anesthesia and sedation. Great Lakes NeuroTechnologies develops bioinstrumentation products, physiological monitors, and patient-centered diagnostic and therapy systems integrated with wireless, remote, and web-based applications for research and education, and movement disorders such as Parkinson's disease, telemedicine and in-home health monitoring. Flocel's dynamic in vitro blood-brain barrier (DIV-BBB) technology helps researchers in the United States and Europe conduct in vitro studies for drug discovery.

www.CleveMed.com
www.OrbitalResearch.com
www.NeuroWaveSystems.com
www.GLNeuroTech.com
www.Flocel.com



Cleveland Medical Devices Inc.
(CleveMed)
Suite 400, 4415 Euclid Avenue
Cleveland, OH 44103
216.791.6720 or 877.253.8363
www.clevemed.com