

Focusing on Innovative Solutions and Patient Comfort, Circadiance Excites the Sleep Respiratory Industry with an International Distribution and Cutting-Edge SleepWeaver Soft Cloth Technology, Lauded by Sleep Apnea Patients and Physicians

**Healthcare
Respiratory Products**

**Circadiance
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**David Groll
CEO**

BIO: Founder and CEO, David Groll has developed, manufactured and sold medical devices for more than 20 years. He worked for Respirationics from 1986 – 1997. He was the Project Manager for the Patient Interface Group where he was responsible for the development of Respirationics CPAP masks. Subsequently, he was General Manager of Respirationics Hong Kong Ltd, where he was responsible for running the factories in Asia that manufactured Respirationics masks.

In 1997, he founded and was the CEO of Vincent Medical, a company that does contract manufacturing of medical devices in China. He sold that business in 2002. He has held senior management positions in several other medical device companies. Mr. Groll holds a Bachelor of Science Degree in Biomedical Engineering from the University of Texas at Austin and a Masters Degree in Manufacturing Systems Engineering for the University of Pittsburgh.

About Circadiance:

Circadiance develops, manufactures and markets respiratory products for people with sleep-disordered breathing or who need non-invasive ventilation.

With a keen eye on innovative solutions and patient comfort, our products have revolutionized the sleep market. Our best-selling SleepWeaver soft cloth nasal CPAP mask has been lauded by sleep apnea patients and diagnosing physicians as a key to better sleep.

With an international distribution network and cutting-edge soft cloth technology, Circadiance continues to excite the sleepy respiratory industry.

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

CEOCFO: Mr. Groll, would you tell us what your vision was when you started Circadiance and where are you today?

Mr. Groll: My background was working for one of the major CPAP manufacturers. I had gotten out of

that business for a number of years when I made the observation that the market for CPAP products had grown substantially, but the number one problem in the market remained non-compliance with CPAP therapy, due to intolerance of the hard plastic CPAP masks. I developed a more comfortable CPAP mask based on the idea of having it made of cloth.

CEOCFO: How long ago was that?

Mr. Groll: I had the idea in about 2003, and launched the company in 2006. We began marketing in 2007, and we have been growing ever since.

CEOCFO: Could you explain further how the cloth mask can do the same thing as the plastic, and why it is the best choice?

Mr. Groll: There are two principles of a cloth mask that make it a superior solution. The first one is that when the air pressure enters the mask, it inflates like a balloon and it forms to the patients' unique facial anatomy. This allows the mask to create a leak-free seal with no pressure points. The cloth material is moisture vapor breathable, which allows moisture to be taken away from the face and skin. The absence of pressure points and moisture eliminates the formation of pressure sores that accompany all hard plastic CPAP masks. This results in better patient comfort, and superior patient compliance.

CEOCFO: Would you explain to us about the cleanliness of the cloth?

Mr. Groll: It is very easy to clean. We recommend hand washing with soap and water, so people can wash it in their bathroom sink. The cleaning is

very similar to the process that is used for cleaning hard plastic CPAP masks.

CEO CFO: Would you tell us about the acceptance your product has had within the medical community?

Mr. Groll: First, the acceptance by the users is very strong. Our users are our biggest advocates, because they are the ones that have to suffer wearing a hard plastic mask all night, every night, for the rest of their lives. We have very strong emotional attachment to our products by the users. The medical community and the resellers are a bigger challenge for us. Their interests are in products that are quick and easy to use, that they are used to, and that they can get from the major manufacturers. We are dealing with all of the issues of being a challenger brand, but slowly and surely, we are winning them over.

CEO CFO: How do you reach both the medical professional and the end patient?

Mr. Groll: We use a variety of marketing channels. For the end patients, we use a lot of digital marketing and social media. By digital marketing I mean that we have a mailing list of tens of thousands of patients that we can e-mail, which we do frequently. We also post information to our social media sites which we manage and have been very popular with patients. We have a very active social media community around our products. To the professional side, we also use social media, but we rely more on more traditional marketing such as advertising in trade publications, going to trade shows, and using our own sales force to present the products and services the customers.

CEO CFO: How does the cost compare with traditional CPAP?

Mr. Groll: The cost is the same because the products are reimbursed under reimbursement codes. We have the same codes as the competitive products, which mean that the resellers who bill the insurance companies are going to make the

same money for our product versus the competitor's product.

CEO CFO: It is hard for me to imagine someone being introduced to the cloth and not preferring that over the plastic.

Mr. Groll: There is a certain paradigm that is in the market, and the paradigm is a triangular shaped piece of plastic with some type of cushion attached that gets squeezed against the patient's face. This is the way it has been done for a long time, and going way back into history it was done with oxygen masks used for air force pilots when jet engines and high altitude planes first came into being. That same paradigm evolved into medical masks, and ultimately most medical masks use the same basic design. We went back to first principles to find a better way to solve

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this problem. Throwing out everything that everyone had ever known about masks, we started from scratch and came up with the cloth CPAP mask. To the outside observer who has not lived in the existing paradigm, they could look at it and say that it is really intuitive. To the people who are used to using CPAP masks, it is what they consider non-standard technology.

CEO CFO: How do you deal with the frustration from a business level as well as a personal level of knowing that you have something better, yet it is such a challenge to achieve acceptance.

Mr. Groll: I am not frustrated. We are doing great, we are growing, and we are taking market share. We are building a customer base of very loyal and dedicated customers who love our product. They write to us and say they love the product. Our challenge is fighting against some gigantic competitors. We have to get our word out, and we have to continue to

convert the market. I tend to think of the medical market as a school of fish; if one fish changes direction, they all change direction. It happens quite suddenly and for reasons that are not always clear, so we are trying to reach that tipping point where we can rapidly change the entire market. We continue to work toward that goal.

CEO CFO: Will you be able to ramp up production rapidly, should that tipping point occur?

Mr. Groll: Yes, our business is highly scalable. We have contracted production to several large medical device contract manufacturers who have the capacity to scale up production. We work with our suppliers to develop plans for all kinds of unforeseen risks and those include what would happen if we doubled our volume or increased it tenfold. There are plans in place should that occur and we are going to continue to push toward that. Our process is not highly capital intensive, so we have the flexibility to change production output fairly quickly.

CEO CFO: Are there different models and different bells and whistles that come with the offering?

Mr. Groll: We offer three main products, and they are called SleepWeaver Advance, SleepWeaver Elan, and SleepWeaver Anew. SleepWeaver Advance is a one-size-fits-most nasal mask product. It is considered to be at the lower end of our offering, because it has fewer features. The SleepWeaver Elan is also a nasal mask, but it has multiple sizes of cushions and additional features, which the users have asked us for. Our newest product is called SleepWeaver Anew, and it is a full-face mask. It covers both the mouth and the nose. There is a segment of the population that breathes through their mouth when they fall asleep. In order to be able to satisfy all customers, we have introduced the full-face mask that has all of the advantages of our soft cloth technology and it is specifically targeted toward mouth breathers.

CEOCFO: Are you strictly in the US, is there an international component currently or will there be one?

Mr. Groll: We are a US company, and the US market is the biggest one for our products, so a majority of our sales are in the US. We do sell in about 30 countries internationally, and our international sales is growing faster than our domestic sales. We expect that trend to continue for several years, simply because it is growing off a smaller base.

CEOCFO: Where do you see the most growth?

Mr. Groll: It is across the board, and several factors driving the growth. One is that the market for CPAP products continues to grow. There are estimated to be up to 40 million people in the US that have obstructive sleep apnea, most of whom are undiagnosed today. There is a growing awareness of the serious medical consequences of untreated sleep apnea. There is also growing awareness that there are treatments for it, so more people are being diagnosed and being treated. CPAP-Continuous Positive Airway Pressure-remains the gold standard therapy,

although there are some alternatives that do not work as well or for as many people as the old-fashioned CPAP that has been around for about 30 years. CPAP is a very cost effective therapy that will work for just about everybody. The major drawback to the use of CPAP is that most people cannot tolerate wearing the hard plastic masks. We have the superior solution for the biggest problem in a growing market, and we feel that we will continue to grow by focusing on our core business. There are additional opportunities for us, and some of the most interesting are in non-invasive ventilation, which is using the same type of equipment- a positive airway pressure ventilator and a mask over the nose or both the nose and mouth- to treat other types of respiratory conditions. Very common ones would be COPD, and all kinds of acute respiratory conditions- people showing up in the emergency room after car accidents and sometimes burn victims- who could benefit from non-invasive ventilation. There is a major opportunity for us there as well. Clinically, our products have a much better side effect profile than hard

plastic masks. If a patient shows up in the hospital and the doctor wants to put them on non-invasive ventilation, they strap a hard plastic mask to them. When the patient recovers from the initial problem, they may have sores all over their face from the hard plastic face masks, which then need to be treated by a secondary treatment. Given the cost containment efforts that are going on in the hospital market these days; those side effects have to be treated at the expense of the hospital. We think that represents a very good opportunity for our technology and one that we will be pursuing in the months and years ahead.

CEOCFO: Why should people in the business and investment community pay attention to Circadiance?

Mr. Groll: In a nutshell, we have introduced an inherently superior technology to solve the biggest problem in a growing market. The biggest problem is that patients are intolerant to CPAP therapy due to not accepting hard plastic CPAP masks. We have developed a superior solution for that problem.



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