

Advancing the Science of Sleep Medicine

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THE MOST ADVANCED SENSOR – PVDF

We have the intellectual capacity that our founder, Peter Stasz, a brilliant electrical engineer and experienced inventor, brings to Dymedix. It was his ability to couple signal processing technology with the piezo film to create the most advanced sensor. Piezo film technology is used in many sophisticated applications including Navy sonar arrays, dual chamber rate responsive pacemakers, seismic accelerometers and it is the sensor in the Welch Allyn stethoscope.

Piezo film generates its own electrical energy. A very small amount of electrical energy is enough to make this film ideal for measuring temperature variance and pressure variance because it has both piezo and pyro electric properties. In addition, the signal processing capabilities of polyvinylidene fluoride film or PVDF allows us to be compatible with every single PSG in the market. Others have tried, but they could not come up with the filtration to get that particular sense of physiological change whether it is movement, pressure or temperature. The whole patent portfolio of Dymedix is based on our PVDF sensor and the signal processing required to display the appropriate clinical waveform. This allowed us to enter the market with the most advanced sensor technology available to sleep labs. Our competitors have tried to get PVDF film to work but have been unable to do so.

UNIQUE, INNOVATIVE AND DIFFERENT SENSING TECHNOLOGY

We have a very unique and different sensing technology. It measures thermal, pressure, noise and movement and does it quicker than anything else because it is linear and works in real time so we can get an accurate fast signal to the PSG where others have a timing delay. The response time of PVDF film is an incredibly fast five thousandths of a second. Dymedix has nine issued patents for our technology as it relates to the sleep industry along with another seven new patents pending. Behind these, we have another ten concepts in development. The technology is unique and innovative. We do not produce “me too” products. Ours are an improvement on what is currently available, and the corporate vision of Dymedix is to help “advance the science of sleep”. If we cannot come up with a better technology, we do not develop it. We have constructed a broad patent portfolio that surrounds our technology, which we intend to protect at all costs.

TWO NEW PREMIERE PRODUCTS IN OUR PORTFOLIO

In our core business we have all of the data capture devices that are used during clinical sleep studies. We also now have the capabilities to provide custom disposable patient kits for Levels 1, 2, 3 and 4 home testing. We design our products to be 100% in compliance with, or surpass the current AASM standards.

Two of our premiere products that are getting great traction in the marketplace are the Apollo™ dual airflow sensor and our Perfect Fit™ respiratory effort belt.

The Apollo product has two individual sensors to measure pressure and temperature signals. What it does best is plot two very key physiological functions, and it does it without a cannula. Most people who are around sleep labs understand how burdensome a cannula is to fit on the patient, keeping it in place, and basically all the issues that go along with patient comfort. The objective is to have the patient lie down, be comfortable and get a good night's sleep so it can be measured. Unfortunately inserting a sensor up a person's nose is quite uncomfortable, especially for pediatrics, and can very easily dislodge with any kind of movement. There is a preference and an opening in the market for an alternative to cannulas.

Perfect Fit respiratory effort belts provide an alternative to RIP that is more economical and solves problems associated with piezo ceramic belts. Perfect Fit also provides greater patient comfort at a tremendous cost savings, better reliability and greater ease of use for sleep disorder center staff.

DETERMINING UNMET MARKET NEEDS

These two new products were a result of Dymedix conducted market research to identify and define significant unmet needs within sleep medicine. Both sleep doctors and lab technicians were surveyed to identify areas that Dymedix could add value to clinical outcomes and greater efficiencies during a sleep study. Three opportunities became apparent from the outcomes of this research.

- Expand the pediatric line of sensors.
- A respiratory effort belt that is durable, accurate and comfortable.
- Get the cannula out of the nose.

We have introduced advanced solutions for all three unmet needs. Our pediatric line was expanded in the summer of 2007. We launched our new respiratory effort belt at the end of 2007 and added a SUM channel in Q2, 2008. We then introduced our cannula free Apollo™ airflow sensor in September of 2008, which combines both pressure and thermal signals to detect hypopneas and apneas. Our market research has identified additional unmet market needs and we are actively developing more advanced solutions.

SUPPORTING THE SAFETY, EFFICACY AND BENEFIT OF OUR PRODUCTS WITH CLINICAL SCIENCE

All Dymedix products have FDA 510K clearance that satisfies all safety and efficacy issues. We have over 25 clinical

publications and white papers from Board Certified Sleep Medicine Physicians, RPSGT's and our R&D group. A clinical study published in CHEST (Berry et al, 2005)¹ concluded that our HDAR (PVDF) sensor compared favorably with pneumotach. Another study published in Sleep Diagnosis and Therapy (Orr et al, 2006)² shows a favorable clinical comparison of PVDF to esophageal balloons.

We have two clinical trials ongoing at Case Western Reserve University School of Medicine. The first study compares our Perfect Fit respiratory effort belt with respiratory inductive plethysmography (RIP) that is currently recommended by the AASM. The second is based on a 3-year study of 1,200 patients, which compared our PVDF airflow sensor to air pressure transducer technology. 150 patients from this cohort will be double blind scored with an equal distribution of mild, moderate and severe OSA. The outcomes from this study will prove once and for all, the similarities and/or differences between our PVDF film technology and nasal prong pressure.

Two other studies that are in progress are being directed by Dr. Richard Berry, University of Florida Health Science Center based in Gainesville Florida who is working on a comprehensive study on our Apollo airflow sensor and a second study on our respiratory effort belts.

THE PERFECT-FIT EFFORT BELT – UNLIKE ANY IN THE MARKET

Our Perfect Fit belts were developed in response to an unmet market need. Our market research in 2006 told us that customers were not at all happy with any belt on the market. We developed customer required specifications and worked with United Sleep Medicine and Johns Hopkins to design and test these new belts. The Perfect Fit belts were introduced in the fourth quarter of 2007 and a SUM channel was added in the second quarter, 2008. Ironically, one of the roadblocks has come from the new standards published by the American Academy of Sleep Medicine "AASM".

The AASM published new standards for the scoring of sleep and associated events in early 2008. These standards address rules, terminology and technical specifications to help establish a more comprehensive system of standardized metrics. We support their efforts and their commitment to advance the science. Unknowingly and unintentionally however, they have created a barrier for innovative companies like Dymedix who bring new technologies to the market to improve clinical outcomes. As an example, there are two recommendations within this new scoring manual that have created challenges to our ability to market our products. First is the specific reference to respiratory inductance plethysmography as the recommended method for measuring respiratory effort. The second is section 3.4 published in the *Journal of Clinical Sleep Medicine* (Redline et al, 2007)³. Both of these have restrained our ability to conduct trade.

OVERCOMING CHALLENGES

Our effort belt technology utilizes the capacitance element of impedance not the inductance element of impedance that is specified by the AASM standards. Impedance consists of three electrical principles: resistance, capacitance and inductance. Our impedance technology however, is not the same

as what was referenced in many of the published literature that refers to respiratory impedance plethysmography. The impedance technology in these publications utilize two electrodes that pass a current through the body to measure breathing as referenced in Sleep Diagnosis and Therapy (Cardozo 2007)⁴. Our effort belt technology is unlike any in the market. PVDF film generates pencil sharp waveforms for better effort measurements. Unfortunately, certain elements in the market are making it difficult for customers to experience the quality signal, durability, patient comfort and economic advantages of our new technology for fear of implications to their accreditation status.

The second involves a gross misperception about our piezo film technology and has been greatly accentuated by section 3.4 *Journal of Clinical Sleep Medicine* (Redline et al, 2007)³. This section specifically states that all piezo electric and strain gauge sensors are not recommended for measuring respiratory effort. We believe this section was intended to refer to piezo crystal and ceramic sensors that have not had a good track record in accurately measuring effort. By casting such a broad scope on piezo electric technology certain elements in the market have mistakenly attached piezo film to this category when we are not even similar to the crystal and ceramic technologies. This is like inferring that apple pies are the same as pizza pies. Certain market elements are also claiming that our belt sensor technology is a strain gauge, which is completely untrue. More specific definitions of piezo electric and strain gauge technologies by the AASM would clarify these misperceptions in the market.

We are encouraging the AASM to come up with a way to allow new technology, from all companies, to be evaluated fairly and accurately until the evidence based, peer reviewed process can be completed. We have also suggested that an engineering expertise be coupled with the Rand/UCLA "Consensus" process described in the standards manual. This could have eliminated the misperceptions about the differences in piezo electric and strain gauge technologies.

The current standards make it challenging for innovative companies with new technology to conduct business in sleep medicine and they could impact R&D investment decisions. The current position of, "meets or doesn't meet standards" effectively restrains new technology from being marketed for 12-14 months in order to comply with these new standards. I am not aware of any other medical specialty that restrains new technology like this.

UNDERSTANDING AND BEING UNDERSTOOD BY THE MARKET

By far, our biggest challenge has been getting the industry to understand that PVDF is not a traditional thermal or pressure sensor. Our piezo film technology is completely different than thermistor and thermocouple sensors. We know that our technology can deliver the same results as the nasal prong pressure sensors with the added benefits of nasal and oral airflow detection in the same sensor, without cannula.

Our customers really like our products. However, the Dymedix technology has been a blessing as well as a curse. As a result, we have been typecast with piezo crystal and piezo ceramic, although our technology is based on dif-

ferent electrical principles. We are also different from traditional piezo crystal and piezo ceramic sensors that are used in the non square root versions of air pressure transducers and our film is not a strain gauge. We have had to address some misconceptions in the market but we are close to clarifying these misconceptions with evidence based, peer reviewed data.

HOW OUR PRODUCTS AFFECT PATIENT CARE

There are several ways that our products directly affect patient care. Apart from our reusable sensors that utilize PVDF technology, we are the only company that has a full line of completely disposable sensors. Infection control and Joint Commission inspections are important in hospital-owned and affiliated segments and we are seeing an accelerated rate of conversion from reusable to disposable in these settings.

Within our disposable line we have developed disposable custom patient kits for home testing. Another benefit to the patient is we do not have a cannula on our airflow sensors, which is especially beneficial for our broad line of pediatric products which are all disposable. We also offer our effort belts in both reusable and disposable models along with a disposable pediatric version, which nobody else offers.

The signal from our sensors is filtered through our Electronic Filtration Module™ (EFM™) to produce the most clinically appropriate waveform so the patient is accurately diagnosed to receive the proper therapy prescription. Sleep medicine reimbursements vary from state to state and payer to payer. Our sensors will produce the appropriate clinical waveforms to ensure reimbursement without jeopardizing accurate diagnosis. The independent labs and regional-national sleep lab chains need economical and durable supplies to meet their operating objectives while still providing high-quality outcomes. We believe we offer the best technology for this segment of the market.

Lastly, all of our sensors offer convenience and ease of use to the lab technicians. Cleaning and sanitizing our reusable sensors are much easier and faster than the traditional thermal and pressure products. Our disposable line offers the ultimate combination of accuracy for better outcomes and convenience to make life easier in sleep labs.

PRODUCT DEVELOPMENT AND LISTENING TO OUR CUSTOMERS

We do not develop new products or modify existing products without customer and patient involvement. Dymedix has a technical advisory board, which was formed two years ago, and meets several times a year to test new ideas and concepts with people who use our products every day. As an example, our Perfect Fit respiratory effort belt was co-developed and market tested at John Hopkins University in Baltimore, MD. All new and current technology is driven by customer-defined specifications.

PRODUCTS THAT EQUIP SLEEP LABS TO COMPETE

The comfort of our sensors with no cannula, the quality of our effort belts and the upcoming launch of our wireless

technology to the market, we believe, will all have a significant impact on a lab's ability to compete for referring physician's patients. Also, as the home testing market develops we believe we are well positioned with our custom disposable patient kits and a new wireless, web based diagnostic technology from Europe that will allow for real time remote monitoring from sleep centers.

THE FUTURE FOR DYMEDIX AND SLEEP MEDICINE

Our mission statement is to develop and market technology that helps advance the science of sleep medicine. This is one of our strategic filters, which every new idea must pass. Everything Dymedix has developed in the past three years or products that we are currently in the process of developing must pass these strategic filters or we will not move forward with it.

We also view 2008 as a landmark year for sleep medicine. There are several significant reasons for this:

- New AASM scoring standards.
- CMS recommendation to approve Home Sleep Testing for reimbursement.
- Published literature about sleep disorders has quadrupled in the past 10 years.
- The acute co-morbidities that are now directly related to sleep apnea.

In response to and in an effort to address the co-morbidities associated with sleep disorders, Dymedix entered into a 5-year Master Research Agreement with the Mayo Clinic in Rochester, MN. This global clinical partnership with Mayo will focus on co-developing new technologies to address these acute co-morbidities relating to sleep disorders. Mayo is a unique example of cross medical specialties collaborating. This is a great opportunity for Dymedix to work with the different sub specialties to address the co-morbidities linked to sleep disorders with the end point of helping to advance the science of sleep medicine. Along with companies such as G.E., Siemens and Philips Healthcare, Dymedix is part of a prestigious group of companies that has this Master Research Agreement with the Mayo.

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