CleveMed

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THE CRYSTAL MONITOR 20 & INPATIENT TESTING

Our product, Crystal Monitor 20, was developed to meet a number of important unmet clinical needs. One of the most immediate and critical ones, in my mind, is hospital inpatient testing. Research has shown that sleep disorders, especially sleep-disordered breathing (SDB), coexist with many diseases including those that require hospitalization such as cardiac and respiratory diseases. Therefore, a significant number of hospitalized inpatients with CHF, COPD, obesity, and pulmonary hypertension also have sleep apnea. Yet, inpatient care in most hospitals does not specifically diagnose or treat sleep disorders. By diagnosing SDB in the hospital room, treatment for sleep apnea can be significantly expedited. More importantly, because CPAP often improves the comorbid disease, faster sleep therapy initiation may in fact speed overall patient recovery during their hospital stay and afterwards.

WIRELESS PSG & SURGICAL PATIENTS

Another benefit of hospital inpatient sleep evaluation relates to surgical procedures. Research has shown that surgical patients with undiagnosed SDB can develop postoperative complications; therefore, by conducting a sleep study on these patients before surgery the hospital staff can better plan the perioperative care of at risk patients. The impact of sleep apnea on perioperative care is so critical that the American Society of Anesthesia has issued a new guideline for the surgical management of SDB patients, which includes pre-operative PSG when possible. Our portable and wireless PSG monitor makes such testing possible. Our product effectively expands the reach of the sleep lab by allowing attended sleep assessment in any hospital room at any time resulting in speeding treatment and potentially improving patient outcome and reducing hospital stays.

WIRELESS MEDICAL TELEMETRY STANDARD

One of our core competencies is wireless technology, which is a technology that is witnessing tremendous growth especially in hospitals. One emerging technology that may play a bigger role in the medical community, especially in hospitals, is a new wireless standard known as Wireless Medical Telemetry Standard (WMTS). This standard established by FCC and FDA in 2000 is dedicated for medical telemetry use only and was designed to eliminate any radio frequency interference from neighboring wireless devices. Like other wireless applications, larger demands for the airwaves will increase the chances of radio frequency interference between adjacent transmitters. However, unlike other industries where people will be content with reestablishing the dial tone, the medical industry cannot afford losing patient data no matter how short the interruption is. The WMTS standard was established to eliminate interference. Although the implementation of this standard has been limited to mostly critical care devices such as cardiac telemetry in the ER, the growing uses of polysomnography may indeed include the critical patient, thus requiring from us to revisit the appropriate technology for wireless PSG. CleveMed has a number of products under development that will implement WMTS technology in a number of applications including PSG.

MARKETING CAMPAIGN

We recognize the importance of increasing the awareness for our products and their new applications. Of course, like all small companies, our capabilities are limited; nonetheless, we have a great start. In addition to advertising in sleep magazines and distributing demo CD's that describe these new applications, our scientists continue to present posters and speak at regional and national sleep disorders conferences such as APSS and FOCUS. In fact, due to the new application I described earlier, we will expand our conference coverage to include other physicians, who may be interested in assessing sleep disorders in their at-risk hospitalized patients, such as cardiologists and anesthesiologists. To that end, CleveMed will be present at CHEST and AARC this fall. We are considering anesthesia meetings as well.

R&D RELATIONSHIPS

We have a number of strong collaborations in Cleveland, and other cities such as San Francisco, Baltimore, Detroit, and St. Louis. Our consultants help us during the design and validation stages of product development. We continue to strengthen this relationship. We are very fortunate to have won NIH and Ohio state funding, which helped develop products. They made it possible. This greatly minimized our R&D costs and therefore reduced our device cost. Consequently, our products are priced very competitively. We have a number of pending NIH grants to expand our technology into other sleep-related diagnoses and even into therapy. We have great relationships with excellent sleep disorders experts and many world-renowned healthcare institutions. We meet with them during the design and validation processes.

INTERNATIONAL MARKET

We are witnessing a strong interest from the international community in areas like Southeast Asia and Latin America. In fact, our first sale came from the Philippines. Sleep disorders diagnosis is relatively new in those emerging markets and the demand for compact monitors that are easier to transport between labs, quicker to hookup and run is expected to grow. We keep those markets in mind. While the interest for attended studies remains strong in those areas, there is also an interest in smaller screening devices. To that end, we are finishing the development of a new monitor called SleepScout with no wireless capability but contains onboard memory for home monitoring.