NorthEast Monitoring, Inc.

advancing Holter technology™

DR180+
3-CH Holter
Recorder

✦

DR200/HE
Holter Recorder

✦

Holter LX
Analysis Software

✦

OxyHolter
Recorder

✦

LX Sleep Software

✦

12-Lead Recorder

✦

DR200/E
Event Recorder

✦

LX Event Software

✦

Industry-leading
3-year warranty

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NorthEast Monitoring obtains FDA approval for LX Sleep home sleep test for assessing OSA

(Summary)
NorthEast Monitoring, Inc. (Maynard, MA) announced that it has obtained FDA approval for LX Sleep®, a software product that diagnoses OSA from data collected during a simple, overnight, unattended, at-home, sleep test. The equipment consists of NorthEast's flagship OxyHolter® (oximetry plus Holter) product and the recently approved LX Sleep® software. NorthEast will sell and market the product worldwide through its extensive line-up of Channel Partners as well as through new OEM relationships with other partners.

(Body)
Maynard, MA (OPENPRESS) February 6, 2009
NorthEast Monitoring, Inc. (Maynard, MA) announced that it has obtained FDA approval for LX Sleep®, a software product that calculates an AHI number used to diagnose OSA from data collected during a simple, overnight, unattended, at-home, sleep test. The equipment consists of NorthEast's flagship OxyHolter® (oximetry plus Holter) product and the recently approved LX Sleep® software. NorthEast will sell and market the product worldwide through its extensive line-up of Channel Partners as well as through new OEM relationships with other partners.

The unification in one ambulatory unit of data related to the analysis of OSA / SDB (obstructive sleep apnea / sleep disordered breathing) and cardiovascular disease represents a confluence of technology that has become a very "hot" topic among sleep professionals and cardiologists. The links between OSA / SDB and cardiovascular disease will become increasingly important over the next few years. According to Dr.. Leslie W. Miller, MD, FACC, Professor and Chief of Integrated Cardiology programs, Washington Hospital Center (DC) and Georgetown University Hospital and School of Medicine, "It is very clear when you start getting into the moderate range of heart failure that untreated, sleep disordered breathing has a potentially significant impact on symptoms and potentially mortality." Miller says, "I think that this is a field that is just going to take off—the links between heart failure and cardiovascular disease and sleep disordered breathing."

The new HST (home sleep test) product is based on well-proven, existing technology with the addition of a new, accurate, signal processing algorithm to determine the AHI (Apnea Hypopnea Index). The OxyHolter® has been in production and approved for other uses by the FDA since January 2001. Mark Hubelbank, PhD, President and founder of NorthEast noted, "Our engineering team has been producing Holter equipment for more than 35 years. The OxyHolter® is an extension of that Holter technology and is already a very mature, reliable product. It has long been used for simple multi-day and/or overnight ambulatory oximetry (SpO2) measurements. Up to now, the principle use has been to provide an accurate way to assess the need for LTOT (long term oxygen therapy) throughout the range of a patient's normal activities. Adding the new signal processing algorithms to analyze the five streams / channels of data to determine OSA (obstructive sleep apnea) was a natural extension of this technology."

NorthEast partnered with another company, BiancaMed Ltd., of Dublin, Ireland, to license and integrate this signal processing technology as an optional component to NorthEast's flagship software Holter LX Analysis®. Scott R. Winick, Director of Sales & Marketing at NorthEast commented, "We've come a long way from the old "Holter for Windows" product that we created many years ago. We've consistently added value to our products to create today's Holter LX Analysis® software for our large installed base. Today it is the convenience of an at-home sleep test. Tomorrow it is the convenience of Unicode compatible languages, color reports, 6 minute walk assessments and a host of other value-based, medical procedures built on top of these core devices and software."
The OxyHolter® and LX Sleep® combination has undergone extensive testing during its development.

One of the independent researchers who worked extensively with this product, Dr. Jordan Stern, stated, "The combined Holter-Oximeter represents a new, easy to use, and reliable device for the home diagnosis of obstructive sleep apnea." He concludes, "…ninety seven percent (97%) of the tests administered provided usable data and a complete sleep report. All patients tolerated wearing the device at home with little discomfort."

Conor Heneghan, PhD, of BiancaMed (Dublin, Ireland), is one of the developers of the algorithm on which LX Sleep® software is based. He points out, "By analyzing the combined data with our new software, you will get an accurate estimate of the AHI, the prime diagnostic tool used when evaluating a person for OSAS by way of a polysomnography." Heneghan continues, "The OxyHolter® device has been tested in the laboratory and compared to PSG and the numbers correlate very, very strongly." In his study, the OxyHolter® plus the prototype LX Sleep® software were used to record and evaluate ECG and SpO2 in patients simultaneously undergoing PSG. The OxyHolter® / LX Sleep® system classified all 60 subjects correctly, including one with central apneas. The correlation between AHI by the two techniques was 0.95 ($p<0.001$).

Winick of NorthEast described how this technology fits the burgeoning need for sleep analysis and accurate detection of OSA. "New technology is one element of LX Sleep®. We've done the research to verify how well it works. Patient compliance is an entirely different matter." He explained, "When you compare the ease-of-use of this new system in an at-home sleep test with the intrusiveness of virtually every other method for quantifying OSA, you are looking at a clear winner." This technology makes diagnosis of OSA available to a wider range of medical professionals. NorthEast expects that the more patient-oriented PSG (sleep) labs will use this to inexpensively assess patients with OSA and free-up beds to concentrate on more complex sleep disorders and titration to fulfill their mission. Winick says, "Savvy labs are beginning realize that OxyHolter® and LX Sleep® represent the confluence of economic forces and good medicine."

New users with no NorthEast products would need a DR180+ Holter, an OxyHolter® cable and LX Sleep®. For existing NorthEast customers with a DR180+ Holter and/or any level of Holter LX Analysis software, LX Sleep® and an OxyHolter® cable can be added as simple options. LX Sleep® runs on the same Holter database structure as is used with all of NorthEast's Holter products (DR200/HE, DR180+). LX Sleep® analysis software utilizes five (5) channels of data recorded by the OxyHolter®, including SpO2, to provide an extraordinarily accurate assessment of OSA. Several studies have been completed and papers presented that compare concurrent, full PSG (polysomnography) results to unattended, overnight multi-parameter sleep studies done with ECG only and with OxyHolter® (ECG + SpO2). The data shows that OxyHolter® dramatically improves the correlation with the baseline PSG studies.

LX Sleep® uses the two direct ECG channels, SpO2 data plus other derived parameters to compute the AHI (Apnea Hypoxia Index). The algorithm is based on pattern recognition of SDB (sleep disturbed breathing) patterns in the ECG, impedance measurements to determine respiratory effort, SpO2 to determine efficiency or saturation and beat/pulse information. Cross-checking data on these channels allows artifact rejection. The data is organized into epochs and filtered by a number of classifiers to produce the proper AHI data. The product is available now. The new FDA approval is specifically for the LX Sleep® analysis software. The other constituent parts had already been approved and are known as Holter LX Analysis®, OxyHolter® and an earlier version of LX Sleep® utilizing only ECG signals (no SpO2).

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(Keywords)
Holter, OxyHolter, Holter LX Analysis, sleep apnea, obstructive sleep apnea , OSA, psg, sleep lab, DR200, DR180+, ECG, ENT, Cardiology, SDB, sleep disordered breathing