NorthEast Monitoring, Inc.

advancing Holter technology™

LX® Sleep Software

OxyHolter plus LX® Sleep exceeds accuracy of ECG-only analysis

✦

90+% sensitivity and specificity for OSA in preliminary studies

✦

Less than 1/3rd the cost of a full PSG study

✦

Epoch-driven analysis, pattern recognition and classifiers provide AHI (Apnea Hypopnea Index)

✦

Improve per bed revenue in sleep labs

✦

The first step to relieve symptoms of OSA

✦

Integrated, add-on software to Holter LX® Analysis

✦

Industry-leading 3-year warranty

Where would you rather sleep?

Let LX® Sleep be the answer to your dreams with in-home, overnight, unattended, multi-parameter, sleep study for detection of OSA (Obstructive Sleep Apnea)

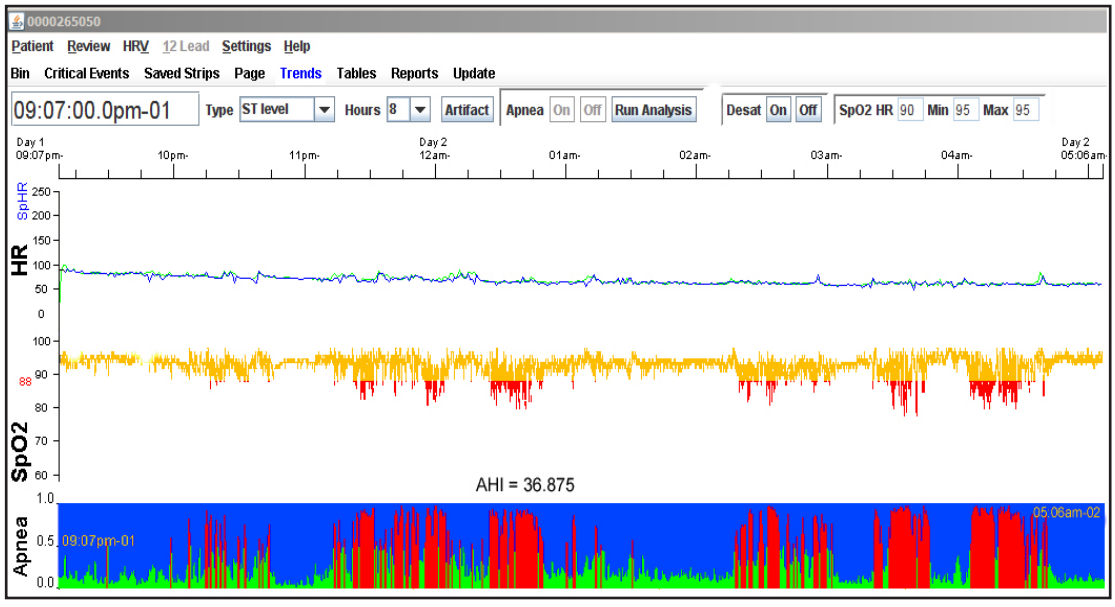
This convenient HST (Home Sleep Test) device provides a conforming methodology for multi-parameter, overnight, unattended sleep study that is described in CMA's NCD (National Coverage Decision) CAG-00093R2. LX® Sleep software applies proprietary algorithms to data collected by NorthEast's OxyHolter to provide a simple alternative to the PSG sleep lab experience to accurately identify OSA (Obstructive Sleep Apnea).

LX® Sleep defines epochs of normal versus SDB (Sleep Disordered Breathing). Then it performs pattern recognition on ECG and SpO_2 signals; and applies a linear discriminant analysis and an age-based classifier to derive an AHI (Apnea Hypopnea Index). An AHI < 5 represents no clinically significant apnea; 5 ≤ AHI < 15 represents mild apnea; AHI ≥ 15 represents moderate-to-severe apnea.*

Current users of Holter LX® Analysis and/or the tried-and-true DR180 Series can easily add the LX® Sleep software option and either an OxyHolter or OxyHolter/A (with airflow) cable, thereby creating the most accurate, easy-to-use OSA detection system on the market today.

*As per Decision Memo for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (CAG-00093R2); March 13, 2008.

Sleep Apnea Screen for Ambulatory Holter/Oximetry



LX® Sleep Software

✦OxyHolter plus LX® Sleep exceeds accuracy of ECG-only analysis

Earlier systems from other vendors only utilized the ECG signal to assess OSA. Combined analysis of ECG and SpO_2 yields better correlation with simultaneously collected, full PSG study data. HST method yields more accurate results with a reduced "white coat effect" by sleeping at home rather than in an unfamiliar, lab environment.

✦90+% sensitivity and specificity for OSA in preliminary studies

In the many preliminary studies that compared the diagnostic accuracy for OSA using simultaneously collected data from full PSG studies to data collected with OxyHolter and analyzed with LX® Sleep, results showed from 90 - 100% specificity / sensitivity.

✦Less than 1/3rd the cost of a full PSG study

Full PSG (sleep lab) studies require enormous facility, staff and equipment resources. Compare that with the simplicity of an at-home study with a single unit recorder for ECG, SpO_2 and derived respiratory signals. For detecting OSA, which accounts for the overwhelming percentage of sleep studies, LX Sleep is the economical alternative.

✦Epoch-driven analysis, pattern recognition and classifiers provide AHI (Apnea Hypopnea Index)

Data intervals called epochs are defined. Direct measurements on the ECG signals are made and EDR (ECG-Derived Respiratory) signals are developed. Pattern recognition and a set of age-dependent classifiers are used to develop the AHI.

✦Improve per bed revenue in sleep labs

Sleep labs can be filled with higher reimbursement, CPAP titration procedures rather than preliminary OSA detection procedures.

✦The first step to relieve symptoms of OSA

Detection is the first step. After that, your medical professional can recommend any of a variety of remedies – from passive sleep aids, to CPAP arrangements, and perhaps corrective surgery.

✦Integrated add-on software to Holter LX® Analysis

Add LX®Sleep to Holter LX®Analysis for the best in graphical display and report generation of ECG, SpO_2, AHI,airflow and a number of other parameters.

✦ Industry-leading 3-year warranty

Includes Hotline support and software updates during the Warranty period. eMSA (extended Maintenance and Service Agreement) available.

Distributed by:

Benefits

- ✦Single unit for SpO_2, ECG and Airlflow
- ✦AHI gives accurate probability of OSA
- ✦Improve outcome for Pillar (palatal implant) surgery
- ✦Improve revenue per bed with higher percentage of CPAP titration procedures
- ✦Achieve higher patient compliance by using HST (Home Sleep Test) procedure
- ✦Lower cost than PSG lab
- ✦Appropriate for most OSA patients

Key Features

- ✦Unique algorithm combines ECG and SpO_2 for accurate AHI calculation
- ✦Convenient in-home, multi-parameter sleep study
- ✦Fewer wires/probes means easy to connect
- ✦Non-volatile data storage - fewer repeat studies
- ✦Displays combine graphical SpO_2, ECG and Airflow data
- ✦Meets Type III with OxyHolter/A cable

Availability

- ✦Easy add-on to Holter LX® Analysis software
- ✦Works with OxyHolter (DR180 Series with OxyHolter or OxyHolter/A cable)
- ✦Free updates with 3-year Warranty and/or 2-year eMSA

510(k)K081861

Indications For Use: This device is intended for use on adult patients to determine the need for clinical diagnosis and evaluation by polysomnography based on the patient's score.

NB: In the U.S.A., Federal Law restricts devices to sale by or on the order of a physician. For in vitro diagnostic use. Not intended to replace real-time telemetry monitoring for patients suspected of having life-threatening arrhythmias.

January 2015

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ISO 13485:2003 CERTIFICATION Intertek

CE 0413