

# 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

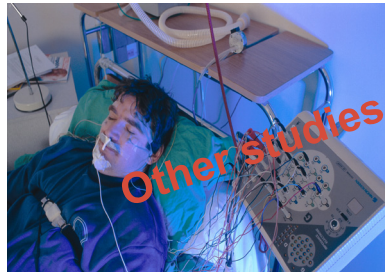


Integrated, add-on software to Holter LX® Analysis



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)**

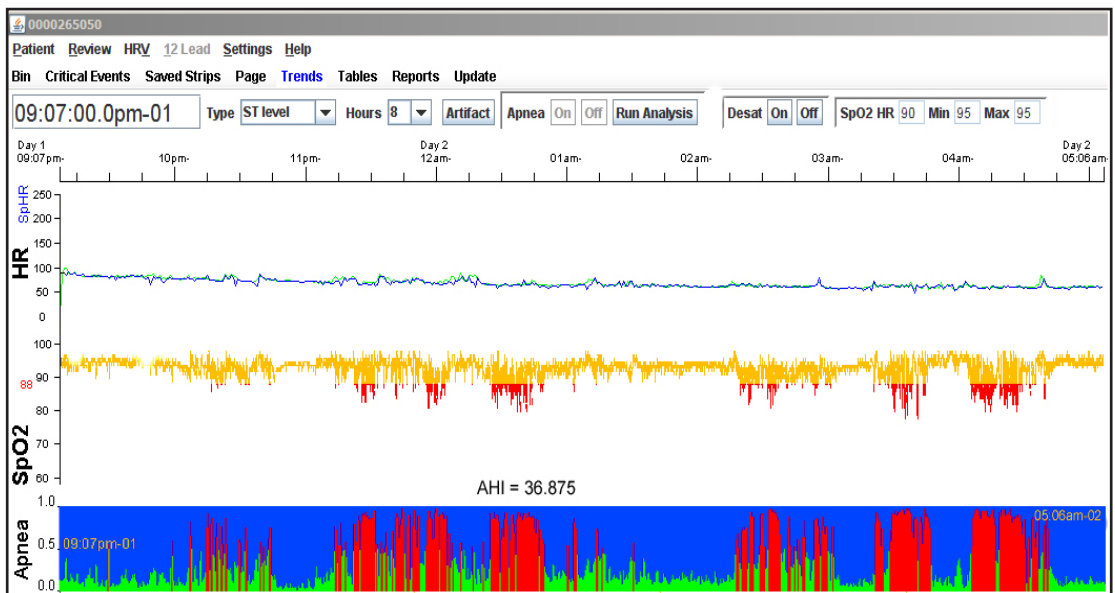
This convenient HST (Home Sleep Test) device provides a conforming methodology for multi-parameter, overnight, unattended sleep study that is described in CMA's NCD (National Coverage Decision) CAG-00093R2. LX® Sleep software applies proprietary algorithms to data collected by NorthEast's OxyHolter to 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 SpO2 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<sup>®</sup> Sleep Software

## ◆ OxyHolter plus LX<sup>®</sup> 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<sub>2</sub> 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<sup>®</sup> 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<sub>2</sub> 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<sup>®</sup> Analysis

*Add LX<sup>®</sup> Sleep to Holter LX<sup>®</sup> Analysis for the best in graphical display and report generation of ECG, SpO<sub>2</sub>, 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.*

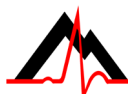
### **Distributed by:**

FDA 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.

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## Benefits

- ◆ Single unit for SpO<sub>2</sub>, ECG and Airflow
- ◆ 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<sub>2</sub> 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<sub>2</sub>, ECG and Airflow data
- ◆ Meets Type III with OxyHolter/A cable

## Availability

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