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 510(k) for Atrial Fibrillation detection in DR200 Series

(Summary)
NorthEast Monitoring has obtained approval from the FDA to sell its DR200 Series devices with automatic atrial fibrillation (AFIB) detection.

(Body)
Maynard, MA: March 11, 2008 – NorthEast Monitoring has obtained approval from the FDA to sell its DR200 Series devices with automatic atrial fibrillation (AFIB) detection. Until now, the stand-alone DR200 series "Tel-a-heart" Event Recorders and the DR200/HE Combination Holter and Event recorders were sold only in the user activated (DR200/E) configuration for the Event Recorder. Now, with automatic AFIB detection, the unit continuously "watches" the patient's ECG data and automatically identifies and records events the patient might have missed. In addition, the DR200 units will record Events that the patient self-identifies by pressing the Event button. This auto-plus-manual mode gives an enhanced picture of the patient's cardiac situation.

Although the 510(k) approval for the use of the algorithm in the DR200 Series is new, the proprietary NorthEast algorithm itself has been in use for years inside NorthEast's Holter LX Analysis software. LX Analysis software helps medical staff quickly review Holter ECG data. It automatically identifies and categorizes many cardiac issues from the ECG data, among them atrial fibrillation. The algorithm was ported forward to the DR200 Series Event Recorder and verified to be effective as part of the recent submission to the FDA. The algorithm was extensively tested against the standard ECG database known as the MIT-BIH Arrhythmia Database, in which there are known examples of cardiac anomalies, among them atrial fibrillation, that must be accurately detected without showing a propensity for indicating false positives – both important criteria in qualifying AFIB software. In the 510(k) submission, the DR200 automatic AFIB detection system accurately detected and confirmed the incidences of atrial fibrillation, with a low incidence of false positives, in the MIT-BIH Arrhythmia Database. In preliminary in-house testing, the DR200 series was shown to have a much lower false positive rate than competitive units already in the US market and approved for such use.

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(Keywords)
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