

NATUS MEDICAL INC
Form 10-K
March 15, 2010
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x **Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2009**

OR

.. **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the transition period from _____ to _____.**

Commission file number: 000 33001

NATUS MEDICAL INCORPORATED

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of

77 0154833
(I.R.S. Employer

incorporation or organization)

Identification Number)

1501 Industrial Road, San Carlos, California 94070

(Address of principal executive offices, including zip code)

(650) 802 0400

(Registrant's telephone number, including area code)

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Securities Registered Pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	The NASDAQ Stock Market LLC (Nasdaq Global Select Market)

Securities Registered Pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of the Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

As of June 30, 2009, the last business day of Registrant's most recently completed second fiscal quarter, there were 28,323,029 shares of Registrant's common stock outstanding, and the aggregate market value of such shares held by non-affiliates of Registrant (based upon the closing sale price of such shares on the Nasdaq Global Select Market on June 30, 2009) was \$260,973,950. Shares of Registrant's common stock held by each executive officer and director and by each entity that owns 5% or more of Registrant's outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

On March 8, 2010, the registrant had 28,417,196 shares of its common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The Registrant has incorporated by reference, into Part III of this Form 10-K, portions of its Proxy Statement for the 2010 Annual Meeting of Stockholders.

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NATUS MEDICAL INCORPORATED

ANNUAL REPORT ON FORM 10-K

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This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 about Natus Medical Incorporated (Natus, we, us, or our Company). These statements include, among other things, statements concerning our expectations, beliefs, plans, intentions, future operations, financial condition and prospects, and business strategies. The words may, will, continue, estimate, project, intend, believe, expect, anticipate, and other similar expressions generally identify forward-looking statements. Forward-looking statements in this Item 1 include, but are not limited to, statements regarding the effectiveness and advantages of our products, factors relating to demand for and economic advantages of our products, our plan to develop and acquire additional technologies, products or businesses, our marketing, technology enhancement, and product development strategies, and our ability to complete all of our backlog orders.

Forward-looking statements are not guarantees of future performance and are subject to substantial risks and uncertainties that could cause the actual results to differ materially from those that we predicted in the forward-looking statements. Investors should carefully review the information contained under the caption Risk Factors contained in Item 1A for a description of risks and uncertainties that could cause actual results to differ from those that we predicted. All forward-looking statements are based on information available to us on the date hereof, and we assume no obligation to update forward-looking statements.

Natus®, AABR®, ABAer®, ALGO®, AOAE®, AuDX®, Balance Manager®, Balance Master®, Biliband®, Bio-logic®, Ceegraph®, CHAMP®, Cochlea-Scan®, Cool-Cap®, Ear Couplers®, Echo-Screen®, EquiTest®, Fischer-Zoth®, Flexicoupler®, Gundrop®, Keypoint®, Keypoint AU®, Keypoint EU®, and Keypoint JP®, MASTER®, Navigator®, Neatnick®, neoBLUE®, Neuromax®, NeuroWorks®, Oxydome®, Sleeprite®, Sleepscan®, Smart Scale®, Tootsweer®, Traveler®, Warmette® and VAC-PAC® are registered trademarks of Natus Medical Incorporated and its subsidiaries. Accuscreen®, Bili-Lite Pad®, Bili-Lite®, Biomark®, Circumstraint®, Coherence®, Deltamed®, inVision®, MiniMuffs®, Neometrics®, Smartpack® are non-registered trademarks of Natus and its subsidiaries. Solutions for Newborn CareSM is a non-registered service mark of Natus.

Overview

Natus is a leading provider of healthcare products used for the screening, detection, treatment, monitoring and tracking of common medical ailments in newborn care, hearing impairment, neurological dysfunction, epilepsy, sleep disorders, and balance and mobility disorders. Product offerings include computerized neurodiagnostic systems for audiology, neurology, polysomnography, and neonatology, as well as newborn care products such as hearing screening systems, phototherapy devices for the treatment of newborn jaundice, head-cooling products for the treatment of brain injury in newborns, and software systems for managing and tracking disorders and diseases for public health laboratories.

We have completed a number of acquisitions since 2003, consisting of either the purchase of a company, substantially all of the assets of a company, or individual products or product lines. Our significant acquisitions are as follows: Neometrics in 2003; Fischer-Zoth in 2004; Bio-logic, Deltamed, and Olympic in 2006; Xltek in 2007; Sonamed, Schwarzer Neurology, and Neurocom in 2008; and Hawaii Medical and Alpine Biomed in 2009.

Product Families

We categorize our products into the following product families:

Hearing Includes products for newborn hearing screening and diagnostic hearing assessment.

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Monitoring Systems for Neurology Includes products for diagnostic electroencephalography (EEG), diagnostic sleep analysis, or polysomnography (PSG), electromyography (EMG), intra-operative monitoring (IOM), newborn brain monitoring, and assessment of balance and mobility disorders.

Newborn Care Includes products for the treatment of brain injury and jaundice in newborns.

Our principal product offerings within these product families are presented in the table on the following page.

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Our Product Offerings

Hearing

Newborn Hearing Screening

Overview

Hearing impairment is the most common treatable chronic disorder in newborns, affecting as many as five babies out of every 1,000 newborns. It is estimated that 20,000 hearing-impaired babies are born in the United States (U.S.) every year, and as many as 60,000 more in the rest of the developed world. Until the introduction of universal newborn hearing screening programs, screening was generally performed only on those newborns that had identifiable risk factors for hearing impairment. However, screening only those newborns with risk factors for hearing impairment overlooks approximately half of newborns with some level of hearing impairment.

Early identification of hearing impairment and early intervention has been shown to improve language development significantly. Undetected hearing impairment often results in the failure to learn, process spoken language, and speak. If hearing impairment is not detected prior to discharge from the hospital it is often not detected until the child is 18 months of age or older. A 1997 study conducted at the University of Colorado, Boulder evaluated the impact of hearing impairment on language and speech. All of the children evaluated in the study were born with a hearing impairment but differed by the age at which the hearing impairment was detected. The study concluded that those children whose hearing loss was detected early and who received appropriate treatment had significantly better language skills and vocabularies than those children whose hearing loss was detected later.

Newborn Hearing Screening in the United States

We estimate that today approximately 95% of the children born in the U.S. are being screened for hearing impairment prior to discharge from the hospital. In 1994, the American Academy of Pediatrics Task Force on Newborn and Infant Hearing first published specific guidelines for universal newborn hearing screening programs. In 2000 and 2007, the Joint Committee on Infant Hearing (JCIH) Position Statements outlined principles, guidelines, and benchmarks for early hearing detection and intervention programs. These principles and guidelines are considered the standard of care today. Because positive results are referred to an audiologist or an Ear, Nose and Throat physician (ENT) for additional testing and evaluation, limiting the number of refers stemming from false positive results reduces the cost of a newborn screening program. In addition, false positive results can cause unnecessary emotional distress for parents.

The 2007 JCIH Position Statement updated and expanded the definition of targeted hearing loss and recommended a specific protocol for babies admitted to the Neonatal Intensive Care Unit (NICU) for more than 5 days. Additionally, the document expressed increased awareness, not only of the need for diagnostic audiology evaluation for children diagnosed with hearing impairment at birth, but also for surveillance and hearing screening for children at risk of delayed onset and progressive hearing impairment during the first three years of life.

Newborn Hearing Screening Techniques

The two traditional technologies used to screen newborns and infants for hearing impairment are auditory brainstem response and OAE s.

Auditory brainstem response (ABR). ABR technology is the most accurate and comprehensive method for screening and diagnosing hearing impairment. ABR technology is based on detecting the brain s electric impulses resulting from a specific auditory stimulus. ABR screening devices, used for newborn hearing screening, detect and analyze the brainwave response resulting from audible click stimuli presented to the

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infant's ears. Automated Auditory Brainstem Response (AABR) devices were developed to automatically analyze the ABR waveform resulting from the auditory stimuli with computerized detection algorithms and statistical analysis. These devices can be used by any level of hospital personnel with a minimal amount of training and will deliver a clinically valid and accurate screen. The detection algorithms indicate a PASS or REFER result that requires no interpretation, thereby reducing staffing requirements, test times, and total hearing screening program costs. A REFER test result indicates that the patient should be referred to an Audiologist or ENT for further diagnostic evaluation.

Otoacoustic emission (OAE). OAEs are sounds created by the active biomechanical processes within the sensory cells of the cochlea. They occur both spontaneously and in response to acoustic stimuli. OAE screening uses a probe placed in the ear canal to deliver auditory stimuli and to measure the response of the sensory cells with a sensitive microphone. OAE screening devices have technology that allows them to discriminate between randomly occurring OAEs, OAEs created by interfering room noise present in the test environment, and the OAEs that are a response to specific test stimuli. Automated OAE screening devices are capable of filtering non-specific OAEs in order to detect and analyze the OAEs that lead to an accurate screen of the infant's hearing. While a PASS test result indicates a proper functioning cochlea, a REFER test result indicates that the OAEs are absent or small compared to normal data. A REFER test result indicates that the patient should be referred to an Audiologist or ENT for further diagnostic evaluation. OAE technology is unable to detect hearing disorders affecting the neural pathways, such as auditory neuropathy. Estimates of the incidence rate of auditory neuropathy among hearing impaired newborns vary widely, but are thought to be in the range of 5% to 15%.

Newborn Hearing Screening Product Lines

Our newborn hearing screening product lines consist of the ALGO, ABaer, AuDX, and Echo-Screen newborn hearing screeners. These hearing screening products utilize proprietary signal detection technologies to provide accurate and non-invasive hearing screening for newborns and are designed to detect hearing loss at 35 dB nHL or higher. Each of these devices is designed to generate a PASS or REFER result.

ALGO 5 and 3i Newborn Hearing Screeners. These AABR devices deliver thousands of soft audible clicks to the newborn's ears through sound cables and disposable earphones connected to the instrument. Each click elicits an identifiable brain wave, which is detected by disposable electrodes placed on the head of the child and analyzed by the screening device. These devices use our proprietary AABR signal detection algorithm.

ABaer Newborn Hearing Screener. The ABaer, which is a PC-based newborn hearing screening device, offers a combination of AABR, OAE, and diagnostic ABR technologies in one system. The automatic ABR technology utilizes our patented Point Optimized Variance Ratio (POVR) signal detection algorithm developed by the House Ear Institute. Like our ALGO newborn hearing screeners, this device delivers thousands of soft audible clicks to the newborn's ears through sound cables and disposable earphones. Each click elicits an identifiable brain wave, which is detected by disposable electrodes placed on the head of the child and analyzed by the screening device. The ABaer OAE software is the same technology used in our AuDX product and the diagnostic ABR software is the same technology used in our Navigator diagnostic hearing assessment product.

AuDX and Echo-Screen. Our AuDX product is a hand-held OAE screening device that can be used for newborn hearing screening, as well as for patients of all ages, from children through adults. Our Echo-Screen product is a hand-held combination AABR and OAE device for newborn screening that can also be used for children through adults in OAE only mode. These devices record and analyze OAEs generated by the cochlea through sound cables and disposable ear probes inserted into the patient's ear canal. OAE technology is unable to detect hearing disorders affecting the neural pathways, such as auditory neuropathy.

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Hearing Screening Supply Products

For infection control, accuracy, and ease of use, the supply products used with our newborn hearing screening devices are designed as single-use, disposable products. Each screening supply product is designed for a specific hearing screening technology.

ABR Screening Supply Kits. Each ABR screen is carried out with single-use earphones and electrodes, which are alcohol and latex-free. The adhesives used in these supply products are specially formulated for use on the sensitive skin of newborns. To meet the needs of our customers we offer a variety of packaging options.

OAE Supply Products. Each OAE screen is carried out with single-use ear tips that are supplied in a variety of sizes and packaging options.

Diagnostic Hearing Assessment

Overview

We design and manufacture a variety of products used to screen for or diagnose hearing loss, or to identify abnormalities affecting the peripheral and central auditory nervous systems. The technology used in most of these systems is either electrodiagnostic in nature or measures a response from the cochlea known as an OAE.

Electrodiagnostic systems record electrical activity generated in the central nervous system. An electrodiagnostic testing device delivers acoustic stimuli to the ears while electrodes placed on the scalp record the brain's electrical response. The most common auditory test performed with electrodiagnostic equipment is the ABR test. This test, which records brainwaves that correspond to responses from the inner ear and brainstem, is used to screen for and define hearing loss characteristics, particularly for patients who cannot reliably respond to standard behavioral tests of hearing, either verbally or through motor response. A technician with minimal training can operate an instrument that performs an automated ABR screening test. More advanced ABR testing techniques that either define the nature of the hearing loss or that screen for other auditory abnormalities such as an acoustic tumor, require the expertise of a trained clinician, usually an audiologist or an ENT physician, an understanding of the technology being used, and the ability to interpret complex waveforms that represent the brain's electrical activity.

Diagnostic Hearing Assessment Product Lines

Our diagnostic hearing assessment products consist of the Navigator Pro system, the Scout Sport portable diagnostic device, the HINT PRO, the AuDX PRO and the Cochlea-Scan.

Navigator PRO. Our Navigator PRO for hearing assessment consists of a base system that is augmented by discrete software applications that are marketed as enhancements to the system. The Navigator Pro System is a PC-based, configurable device that utilizes evoked potentials, which are electrical signals recorded from the central nervous system that appear in response to repetitive stimuli, such as a clicking noise. The evoked potentials are used to record and display human physiological data associated with auditory and hearing-related disorders. The Navigator Pro System can be used for patients of all ages, from children to adults, including infants and geriatric patients. The device can be configured with additional proprietary software programs for various applications. These additional software programs include: CHAMP, MASTER, AEP, VEMP, BioMAP, ABAer and Scout.

Scout SPORT. The Scout SPORT is a PC-based OAE system. The ultra portable Scout Sport can be carried from one computer to another to test in different locations. For office-based environments, the Scout Sport can be used with a dedicated notebook computer to create an independent portable system.

HINT PRO. Our Hearing in Noise Test (HINT) application uses test sentences, procedures, and headphone norms developed by the House Ear Institute. The system features computerized

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administration, scoring, report generation, and data storage. The HINT measures the patient's ability to recognize and repeat short sentences presented in quiet or in noise. The speech and noise sources can be spatially separated to measure binaural directional hearing and spatial unmasking. The patient's sentence recognition threshold is measured in quiet and in three noise conditions.

AuDX PRO. The AuDX Pro is a hand-held OAE screening device with a large color display that can be used for patients of all ages. The AuDX records and analyzes OAEs generated by the cochlea through sound cables and disposable ear probes inserted into the patient's ear canal. A REFER test result indicates that the patient should be referred to an Audiologist or ENT for further diagnostic evaluation.

Cochlea-Scan. The Cochlea-scan is an easy to use handheld device to assess hearing loss. It utilizes Distortion Product OAE technology, which allows the user to quantify hearing loss using physiologic measures instead of relying upon a patient's behavioral response.

Diagnostic Hearing Supply Products

For infection control, accuracy, and ease of use, most supply products used with our diagnostic hearing devices and systems are designed as single-use, disposable products. Each screening supply product is designed for a specific diagnostic hearing technology, and is similar in nature to our previously described OAE supply products for use in newborn hearing screening.

Monitoring Systems for Neurology

Our monitoring systems for Neurology represent a comprehensive line of products that are used by physicians, nurses and medical technologists to assist in the diagnosis and monitoring of neurological disorders of the central and peripheral nervous system, and as an aid in monitoring patients during surgery, while under sedation, or in post-operative care. Our product lines consist of the following:

Electroencephalography or EEG Equipment that monitors and visually displays the electrical activity generated by nerve cells in the brain for both diagnosis and monitoring of neurological disorders in the hospital, laboratory, office or patient's home;

Polysomnography or PSG Equipment that measures a variety of respiratory and neurological functions to assist in the diagnosis and monitoring of sleep disorders, such as snoring and obstructive sleep apnea, a condition that causes a person to stop breathing intermittently during sleep;

Electromyography or EMG Equipment that measures electrical activity in nerves, muscles, and the spinal cord; and

Intra-operative Monitoring or IOM Products that assist surgeons in preserving the functional integrity of a patient's nervous system during and after complex surgical procedures.

Diagnostic EEG Monitoring

Overview

We design, manufacture, and market a full line of computerized instruments used to help diagnose the presence of seizure disorders and epilepsy, look for causes of confusion, evaluate head injuries, tumors, infections, degenerative diseases, and metabolic disturbances that affect the brain, and assist in surgical planning. This type of testing is also done to diagnose brain death in comatose patients. These systems and instruments work by detecting, amplifying, and recording the brain's electrical impulses (EEGs). Routine EEG recording is done by placing electrodes on a patient's scalp over various areas of the brain to record and detect patterns of activity and specific types of electrical events. EEG technologists perform the tests, and neurologists review and interpret the results.

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Routine outpatient EEG testing is performed both in private physicians' offices and hospital neurology laboratories, providing physicians with a clinical assessment of a patient's condition. For patients with seizures that do not respond to conventional therapeutic approaches, long-term inpatient testing of EEGs and behavior is used to determine if surgical solutions are appropriate.

Diagnostic Electroencephalograph (EEG) Monitoring Product Lines

Our diagnostic EEG monitoring product lines for neurology consist of devices operating with our proprietary software, augmented by signal amplifiers. These products are typically used in concert, as part of an EEG system by the neurology department of a hospital to assist in the diagnosis of assorted neurological conditions.

NeuroWorks; Ceegraph VISION; Coherence; Harmonie. Our computerized EEG Systems include a broad range of products, from software licenses and ambulatory monitoring systems to advanced laboratory systems with multiple capabilities for EEG, ICU monitoring, long-term epilepsy monitoring of up to 128 channels, and physician review stations with quantitative EEG analysis capabilities.

Stellate/Gotman Spike and Seizure; GridView. Our proprietary Spike and Seizure detection algorithm detects, summarizes, and reports EEG events that save health care professionals time by increasing the speed and accuracy of interpretation. GridView is a tool that allows the clinician to correlate EEG patterns with electrode contacts on a 3D view of the patient brain using magnetic resonance (MR) or computed tomography (CT) images, thus enabling the visualization and annotation of the brain surface and internal structures involved in the diagnosis of epilepsy.

Proprietary Signal Amplifiers. Our proprietary signal amplifiers function as the interface between the patient and the computer, and are also known as the headbox. The headbox connects electrodes attached to the patient's head to our EEG monitoring systems. Our proprietary headbox products are sold for a wide variety of applications under the following brand names: Bio-logic Netlink and Netlink Traveler, Xltek Trex, EEG32, EMU128, EMU40, Brain Monitor and Schwarzer epas. Recent innovations in electronics technology and advanced internet-protocol data transmission enable certain of our amplifiers to record and transmit up to 32 channels of digital data using Ethernet communication.

Several additional options are available to enhance our EEG products, including: a digital video option, which provides synchronized video recording of a patient's behavior while recording electrical activity from the brain; our patented SmartPack software option, which is an innovative data compression process that reduces the size of data files by as much as 60%, and our Universal Reader which is a physician's review station that permits fast and easy data analysis in a graphical format.

Diagnostic PSG Monitoring

Overview

Increasing public awareness of sleep disorders has made sleep medicine a rapidly growing specialty. The analysis of respiratory patterns, brain electrical activity and other physiological data has proven critical for the diagnosis and treatment of sleep-related diseases such as apnea, insomnia, and narcolepsy. A sleep study entails whole-night recordings of brain electrical activity, muscle movement, airflow, respiratory effort, oxygen levels, electrical activity of the heart (ECG or EKG), and other parameters. These recordings typically result in over 1,000 pages of data that are reviewed, analyzed, and scored by a technician, and summarized in a report for the physician. We market configured laboratory systems, portable systems, and ambulatory recorders for home monitoring.

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Diagnostic PSG Monitoring Product Lines

Our diagnostic PSG monitoring products can be used individually or as part of a networked system for overnight sleep studies to assist in the diagnosis of sleep disorders. These products include software licenses, ambulatory monitoring systems, and laboratory systems that combine multiple capabilities, including EEG monitoring, physician review stations, and quantitative EEG analysis capabilities.

Sleepscan VISION; SleepWorks; Coherence and Harmonie. Our diagnostic PSG systems capture and store all data digitally and provide time-saving features and software for acquiring and analyzing the data. The systems enable users to specify rules and personal preferences to be used during analysis, summarizing the results graphically and incorporating them in detailed reports. Software packages include customized analysis, tools and interfaces with third party equipment.

Proprietary Amplifiers. Our data acquisition systems incorporate recent developments in superior amplifiers for sleep analysis. Sold under the brand names Xltek Trex and Connex, Bio-logic Netlink and Netlink Traveler, Schwarzer epas duo 44 and comlab PSG, our amplifiers are used in stand-alone clinics and hospital settings. In addition to exceptional signal quality, headboxes include various tools such as built-in oximeters, and controls to allow the user to start and stop a study or perform electrode impedance testing either at the patient's bedside or from the monitoring room.

We also market a broad line of disposable products and accessories for the PSG laboratory. The Airflow Pressure Transducer uses pressure changes as an indicator of patient airflow levels, as contrasted to other monitoring devices that use temperature to indicate these levels. This product detects shallow breathing in situations where temperature related transducers might remain substantially unchanged. This method has been documented in industry publications to produce the signature waveform used in identifying a respiratory disorder known as Upper Airway Resistance Syndrome.

DiagnosticEMG Monitoring

Overview

An electromyogram measures the electrical activity of muscles both at rest and during contraction. Measuring the electrical activity in muscles and nerves can help diagnose diseases that damage muscle tissue or nerves. An electromyogram is done to determine if there is any disease present that damages muscle tissue, nerves, or the junctions between nerve and muscle (neuromuscular junctions). An electromyogram can also be used to diagnose the cause of weakness, paralysis, and muscle twitching and is also used as a primary diagnosis for carpal tunnel syndrome, which is the most frequently encountered peripheral compressive neuropathy.

Diagnostic EMG Product Lines

Xltek NeuroMax. A dedicated EMG device focused entirely on signal quality and clinical efficiency. The device gathers neurophysiological data that is saved to a fully customizable report, allowing physicians to take care of patients with the most informed advice.

Xltek XCalibur. An EMG system that uses advanced circuit design and digital signal processing to deliver clean signals, making the process of acquiring patient data reliable and quick. The system provides enhanced data acquisition, reporting, and review capabilities.

Schwarzer Topas. The topas system offers a wide range of sophisticated EMG and evoked potential (EP) examination protocols, as well as an attractive and functional design. Topas can be configured as a two or four channel system, as trolley-based or portable version, depending on the needs of the hospital or private practice.

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Dantec Keypoint. The Dantec Keypoint EMG and EP family of products feature superior amplifiers, stimulators, and outstanding signal quality. The Keypoint is used for advanced neurodiagnostic applications such as single fiber EMG, visual and auditory evoked potentials, and in routine nerve conduction studies. The Keypoint system is also available in a portable laptop configuration.

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Dantec Clavis. The Dantec Clavis is a hand-held EMG and current stimulation (STIM) device that provides muscle and nerve localization information to assist with botulinum toxin injections (i.e. Botox). In conjunction with the Bo-ject hypodermic needle and electrodes, it delivers a precise dose of the agent.

IOM

Overview

Intra-operative monitoring is the use of electrophysiological methods such as EMG and EEG to monitor the functional integrity of neural structures (brain, nerves, spinal cord) during surgery. The most common applications are in neurosurgery such as spinal surgery, some brain surgeries, ENT procedures, and peripheral nerve surgery. IOM is used to localize neural structures and test the function of these structures for early detection of intra-operative injury, allowing for immediate corrective measures.

Intra-operative Monitoring Products

Protector. The protector is an IOM system that provides medical professionals with all information necessary to make immediate and critical surgical decisions. The system combines flexibility with multi-modality allowing full coverage of IOM techniques.

Balance and Mobility

Overview

Balance disorders impact a large percentage of the population in all age ranges from children to adults. Common complaints include dizziness, vertigo, or an inability to walk or drive a vehicle, which can all lead to the curtailment of daily life activities. These symptoms are exacerbated in elderly patients and can result in falls, orthopedic injuries, and sometimes death.

Balance problems are difficult to diagnose and treat because they can be caused by a combination of diseases or movement dysfunctions. Healthcare professionals who take a traditional clinical approach to the examination and treatment of balance problems typically explore one component of the balance system at a time. This approach often requires patients to consult multiple specialists, leading to patient dissatisfaction and increased health care costs, frequently without achieving an optimal outcome.

We believe the most effective strategy for diagnosing and treating balance disorders is an evidence-based, multidisciplinary approach applying a broad range of patient information. Our Balance Manager systems are designed to facilitate the assessment and management of complex balance problems in the context of the total patient to support this process. These systems are used in a broad spectrum of medical disciplines including otolaryngology, neurology, psychiatry, orthopedics/sports medicine, geriatrics, and physical rehabilitation.

Balance and Mobility Products

Our principal balance and mobility products are sold under the Neurocom brand:

EquiTest. Proprietary protocols in the EquiTest family of devices objectively quantify and differentiate among sensory, motor, and central adaptive impairments to balance control. This approach is commonly referred to as computerized dynamic posturography (CDP). CDP is complementary to clinical tests designed to localize and categorize pathological mechanisms of balance disorders in that it can identify and differentiate the functional impairments associated with the identified disorders.

Balance Master. A family of devices providing objective assessment and retraining of the sensory and voluntary motor control of balance. With visual biofeedback on either a stable or dynamic support

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surface and in a stable or dynamic visual environment, the clinician can both assess and retrain patients performing tasks ranging from essential daily living activities through high-level athletic skills. The objective data captured by the device supports the design of effective treatment and/or training programs focused on the specific sensory and motor components underlying a patient's functional limitations.

inVision. Our inVision device incorporates a set of proprietary diagnostic tests that quantify a patient's ability to maintain visual acuity and stable gaze while actively moving the head. The objective information enables the clinician to assess the patient's ability to live and move safely in a dynamic world and to participate in daily-life functions such as driving, walking through a grocery store, or actively engaging in family activities.

Newborn Care

Newborn Care Products

We manufacture a wide variety of products used in the medical care of newborns. These product lines include products to diagnose and treat newborn brain injury, as well as phototherapy lights to treat newborn jaundice. We also sell a variety of newborn care products to meet the needs of clinicians in the nursery and NICU.

Newborn Brain Injury

Overview

For many years, newborn infants admitted to the NICU of a hospital have routinely been monitored for heart activity, temperature, respiration, oxygen saturation, and blood pressure. Only recently has it also been considered important to monitor brain activity using continuous EEG. A cerebral function monitor, utilizing amplitude-integrated EEGs (aEEGs), is a device for monitoring background neurological activity.

Neurological Assessment and Treatment Options

Early diagnosis of brain injury in newborns, when combined with early intervention, has been shown to reduce the severity of these brain injuries and in some cases, save the patient's life. These brain injuries, which can occur in as many as three out of every 1,000 newborns, are caused by conditions such as hypoxic ischemic encephalopathy (HIE), subclinical seizures, or neurological disorders. Diagnosing these conditions shortly after birth is imperative, as patients who undergo therapy within six hours after birth show a greater potential for improved outcomes. We believe that diagnoses utilizing aEEG technology can have a marked and positive impact upon the outcomes of some newborns suffering from brain injury.

Newborn Brain Injury Product Line

Olympic CFM-6000 System. The Cerebral Function Monitor (CFM) allows the Neonatologist to diagnose neurological disorders or brain injury in the newborn. The device continuously monitors and records brain activity, aiding in the detection and treatment of HIE and seizures. The device also monitors the effects of drugs and other therapies on brain activity and improves the accuracy of newborn neurological assessments. The Olympic CFM-6000 helps determine the need for further neurological examination or transport to a tertiary-care center. The CFM is used with electrodes attached to the head of the newborn to acquire an EEG signal that is then filtered, compressed, and displayed graphically on the device or as a hardcopy printout.

Brainz BRM3. The Brainz BRM3 is a bedside monitor that collects and measures electrical activity from both the right and left hemispheres of the brain. The monitor presents a simplified 2-channel EEG display, along with the option to view three channels of time-compressed, aEEG. The BRM3 has the ability to collect EEG and aEEG data from both hemispheres of the brain providing practitioners with the ability to monitor infants with a

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wider variety of neurological concerns when compared to single channel EEG. For ease of use at the bedside, the BRM3 has a touch screen for easy navigation and an onscreen keyboard for quick data entry. The straightforward set up and compact design of the BRM3 makes it an ideal tool for clinicians to initiate neurological monitoring and aEEG trending.

Olympic Cool-Cap System. The Olympic Cool-Cap is the only FDA approved device for the treatment of moderate to moderately-severe HIE. A four-year clinical trial for the Cool-Cap was completed in 2003, and the FDA gave approval for the product in December 2006. The clinical trial validated the benefit of selective head cooling as a means of reducing the temperature of the brain to diminish the severity of brain injury resulting from HIE in newborns. The device conforms to the clinical trial protocol and is designed to assist the clinician in safely administering treatment, thereby preventing or significantly reducing the severity of neurological injury associated with HIE.

Newborn Brain Injury Supply Products. In addition to disposable electrodes used to perform each EEG test using the CFM-6000 and the BRM3, the Olympic Cool-Cap brain cooling system uses a single-patient, disposable, cooling cap to continuously circulate sterile water to the patient during the 72-hour treatment period.

Jaundice Management Products

Overview

The American Academy of Pediatrics estimates that each year 60% of the approximately four million newborns in the U.S. become jaundiced. According to the Journal of the American Medical Association, neonatal jaundice is the single largest cause for hospital readmission of newborns in the U.S., and accounts for 50% of readmissions. Because of the serious consequences of hyperbilirubinemia, the American Academy of Pediatrics recommends that all newborns be closely monitored for jaundice and has called for the physician to determine the presence or absence of an abnormal rate of hemolysis to establish the appropriate treatment for the newborn.

In 2004, the American Academy of Pediatrics issued new guidelines for the treatment of jaundice in newborns. The guidelines recommend phototherapy as the standard of care for the treatment of hyperbilirubinemia in infants born at 35 weeks or more of gestation. The guidelines further highlight the need for intense phototherapy, and specifically recommend the use of the blue light treatment incorporated into our neoBLUE products.

We currently offer the following products that meet guidelines of the American Academy of Pediatrics for the treatment of newborn jaundice:

neoBLUE Product Family. This product line consists of our neoBLUE, neoBLUE Mini, and neoBLUE Cozy devices, which utilize light emitting diodes (LEDs) to generate a high-intensity, narrow spectrum of blue light that is clinically proven to be most effective in the treatment of newborn jaundice. The neoBLUE phototherapy devices emit significantly less ultraviolet light and heat than conventional phototherapy devices, reducing the risk of skin damage and dehydration for infants undergoing treatment. Because of the high intensity of these lights, the treatment time associated with phototherapy is reduced.

Bili-Lite Product Family. These devices utilize fluorescent light bulbs for the treatment of hyperbilirubinemia. The Bili-Bassinet provides intensive phototherapy from both under and over the baby for maximum surface area coverage. The Bili-Lite pad is a product designed for both hospital and home-based phototherapy.

Table of Contents**Other Newborn Care Product Lines**

Medical Devices. These products include devices such as: photometers, radiometers, patient warming lamps, neonatal heatshields, pediatric scales, blanket warming cabinets, exam lights, oxygen hoods, restraining boards, and our newborn circumstraint.

Hawaii Medical Products. These single-use disposable products are sold into the NICU and nursery in hospitals. The Hawaii Medical line includes Gumdrop pacifiers, TootSweet sucrose solution and NeatNick heel lancets, among a range of positioning devices, electrodes and other newborn care products.

Disposable Supplies. These products include other disposable supplies such as: neonatal noise attenuators, phototherapy eye masks and x-ray shields for newborn gonads.

Newborn Screening Data Management Product Line. Our suite of newborn screening data management products consists of proprietary software that collects, tracks, manages and reports newborn screening data to regional government health laboratories and national disease control centers. While all states have laws and/or regulations requiring newborn screening for metabolic disorders, the laws and regulations vary widely in the extent of screening required. Some states use tandem mass spectrometry in their newborn metabolic screening programs, which increases the number of treatable disorders that can be detected. Revenue from installation and upgrades of our newborn screening data management systems is classified as devices and systems revenue, and revenue from maintenance contracts on the systems is classified as supplies and services revenue.

Segment and Geographic Information

We operate in one reportable segment in which we provide healthcare products used for the screening, detection, treatment, monitoring and tracking of common medical ailments in newborn care, hearing impairment, neurological dysfunction, epilepsy, sleep disorders, and balance and mobility disorders.

Our end-user customer base includes hospitals, clinics, laboratories, physicians, nurses, audiologists, and governmental agencies. Most of our international sales are to distributors, who in turn, resell our products to end users or sub-distributors.

Information regarding our sales and long-lived assets in the U.S. and in countries outside the U.S. is contained in *Note 16 Segment, Customer and Geographic Information* of our consolidated financial statements included in this report and is incorporated in this section by this reference.

Revenue by Product Family and Product Category

For the years ended December 31, 2009, 2008 and 2007, revenue from our four product families as a percent of total revenue was approximately as follows:

	Year Ended December 31,		
	2009	2008	2007
Hearing	40%	41%	53%
Monitoring Systems for Neurology	39%	34%	14%
Newborn Care	16%	19%	28%
Other	5%	6%	5%
Total	100%	100%	100%

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We also look at revenue as either being generated from sales of Devices and Systems, which are generally non-recurring, or related Supplies and Services, which are generally recurring. The products that are attributable to these categories are described above. Revenue from Devices and Systems, and Supplies and Services, as a percent of total revenue for the years ending December 31, 2009, 2008 and 2007 is as follows:

	Year Ended December 31,		
	2009	2008	2007
Devices and Systems	58%	63%	62%
Supplies and Services	40%	35%	37%
Other	2%	2%	1%
Total	100%	100%	100%

In 2009, 2008 and 2007, sales to no single end-user customer comprised more than 10% of our revenue, and revenue from services was less than 10% of our revenue.

Backlog

As of December 31, 2009, our backlog was approximately \$8.9 million, compared to \$2.1 million at December 31, 2008 and \$4.4 million at December 31, 2007. We anticipate that we will complete all of the backlog orders by the fourth quarter of 2010.

Marketing and Sales**Marketing**

Our marketing strategy differentiates our products by their level of quality, performance, and customer benefit. We educate customers and potential customers worldwide about our products through several traditional methods, including, but not limited to:

Trade conference exhibits;

Direct presentations to healthcare professionals;

Publications in professional journals and trade magazines;

The Internet via our website, *www.natus.com*;

Print and direct mail advertising campaigns; and

Sponsorship of and participation in clinical education seminars.

Educational efforts directed at government agencies, physicians, and clinicians about the benefits of universal screening in terms of patie