NATUS MEDICAL INC
Form 10-K
April 10, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

For the fiscal year ended December 31 2012

x **Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2012**

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	**77 0154833**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer 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)

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 x

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 x

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 x 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 x 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. x

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 x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	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 x

As of June 30, 2012, the last business day of Registrant s most recently completed second fiscal quarter, there were 30,181,324 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, 2012) was $330,919,682. 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 April 1, 2013, the registrant had 30,339,098 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 2013 Annual Meeting of Stockholders.

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NATUS MEDICAL INCORPORATED

ANNUAL REPORT ON FORM 10-K

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PART I

ITEM 1. Business

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, except as required by Federal Securities laws.

Natus®, AABR®, ABaer®, ALGO®, AOAE®, AuDX®, Balance Manager®, Balance Master®, Balance Shape®, Biliband®, Bio-logic®, Bo-JECT®, Brain Atlas®, Ceegraph®, CHAMP®, Clarity System®, Cochlea Scan®, Cool Cap®, CoolCare®, Dantec®, Ear Couplers®, Ear Muffin®, Echo Screen®, Embla US®, Embletta®, Enterprise®, EquiTest®, Fischer-Zoth®, Flexicoupler®, Gumdrop®, Halo Ear Muffin®, Hawaii Medical®, Keypoint®, Keypoint AU®, Keypoint EU®, Keypoint JP®, MASTER®, Medelec®, Medix®, MedixI.C.S.A®, Navigator®, Neatnick®, neoBLUE®, Neurocom®, Neuromax®, NeuroWorks®, Nicolet®, NicoletElite®, Oxydome®, Pocket®, REMbrandt®, REMlogic®, Sandman®, Scout®, Sleeprite®, Sleepscan®, Smart Scale®, Sonamed®, Sonara®, Sonara TEK®, Stellate Notta®, STETHODOP®, TECA®, Tootsweet®, Traveler®, Treetip®, VAC PAC®, VERSALAB®, Warmette®, Xact Trace®, Xltek® are registered trademarks of Natus Medical Incorporated and its subsidiaries. Accuscreen, Bili Lite Pad, Bili-Lite, Biomark, Circumstraint, Coherence, Deltamed, inVision, Medix MediLED, MiniMuffs, NatalCare, Neometrics and 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, incubators to control the newborn s environment, 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, Hawaii Medical and Alpine Biomed in 2009, Medix in 2010, Embla in 2011 and Nicolet in 2012.

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Product Families

We categorize our products into two product families:

Neurology Includes products for diagnostic electroencephalography (EEG), electromyography (EMG), diagnostic sleep analysis or polysomnography (PSG), intraoperative monitoring (IOM), and transcranial doppler ultrasound technology.

Newborn Care and Other Includes products for newborn care including hearing screening, brain injury, thermoregulation, jaundice management, and various disposable products, as well as products for diagnostic hearing assessment for children through adult populations, and products to diagnose and assist in treating balance and mobility disorders.

Our Product Offerings

Neurology

Our diagnostic and monitoring systems and supplies for neurology and neurophysiology markets 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, including monitoring of patients during surgery, while under sedation, in post-operative care, and in intensive care units. Our product lines consist of the following:

Electroencephalography or EEG Equipment and supplies used to monitor and visually display the electrical activity generated by nerve cells in the brain and other key physiological signals for both diagnosis and monitoring of neurological disorders in the hospital, research laboratory, clinician office and patient s home.

Electromyography or EMG Equipment and supplies used to measure electrical activity in nerves, muscles, the brain and spinal cord and includes EMG, nerve conduction and evoked potential functionality.

Polysomnography or PSG Equipment and supplies used to measure 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.

Intraoperative Monitoring or IOM Products and supplies that assist surgeons and neurophysiologists in preserving the functional integrity of a patient s nervous system during and after complex surgical procedures.

Transcranial Doppler Products that assist clinicians in evaluating the integrity of blood flow in the brain for both preventive monitoring and diagnosis as well as to assist treatment in acute conditions such as stroke and vasospasm.

Diagnostic EEG and Long-term Monitoring

Overview

We design, manufacture, and market a full line of computerized instruments and key supplies 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) as well as other physiological signals needed to support clinical findings. Routine clinical 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,

neurophysiologists and epileptologists review and interpret the results.

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Routine outpatient clinical EEG testing is performed in hospital neurology laboratories, private physician offices, and in ambulatory settings such as the patient s home, 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 monitoring of EEGs and behavior is used to determine if surgical solutions are appropriate. Patient s suffering from severe head trama and other acute conditions that may affect the brain are monitored in intensive care units. In addition, research facilities use EEG equipment to conduct research on humans and laboratory animals.

Diagnostic Electroencephalograph Monitoring Product Lines

Our EEG diagnostic monitoring product lines for neurology consist of signal amplifiers, workstations to capture and store data, and proprietary software. These products are typically used in concert, as part of an EEG system by the neurology/neurophysiology department of a hospital or clinic to assist in the diagnosis and monitoring of neurological conditions.

NeuroWorks; Ceegraph; Coherence; Harmonie; NicoletOne. 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 256 channels, and physician review stations with quantitative EEG analysis capabilities.

Stellate/Gotman Spike and Seizure; GridView; NicoletOne Trends. 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. NicoletOne Trends provides a comprehensive set of EEG analysis algorithms such as spike and seizure detection, total band power analysis, alpha-delta variability, and spectrogram. These algorithms are used to generate trends of large amounts of data to assist in the clinical evaluation and data review process.

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: Xltek, Trex, EEG32, EMU128, EMU40, Brain Monitor, Schwarzer EEG, Nicolet v32 and v44 models and Nicolet Wireless 32 and 64 channel amplifiers.

Nicolet Cortical Stimulator. This product is our proprietary device that provides cortical stimulation to the brain during functional brain mapping either before or during surgery to help the surgeon protect the eloquent parts of the brain. The device can be used as a standalone unit or with the fully integrated NicoletOne software that supports control of the device from the software, automated mapping and comprehensive report generation.

Digital Video; SmartPack; Universal Reader. 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 data compression process, and Universal Reader that is a thin-client software application installed on a physician s review station that permits fast and easy data analysis in a graphical format.

Electrodiagnostic Monitoring

Overview

Our electrodiagnostic systems include EMG, nerve conduction (NCS), and often evoked potential (brain electrical activity) functionality. EMG and NCS involve the measurement of electrical activity of muscles and

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nerves both at rest and during contraction. Measurements may or may not involve the use of stimulation depending on the required test. Measuring the electrical activity in muscles and nerves can help diagnose diseases of the peripheral nervous or musculature system. 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. EMG is also used for clinical applications of botox to relieve muscle spasm and pain. We market both the clinical system and the needles used for these procedures.

In addition to EMG and NCS functionality, many of our Electrodiagnostic systems also include Evoked Potential functionality (EP). Evoked potentials are elicited by the brain in response to a stimulus. These evoked potentials can come from the sensory pathways (such as hearing and visual) or from the motor pathways. An examination tests the integrity of these pathways including the associated area of the brain. Sophisticated amplifiers are required to recognize and average evoked potential EMG and NCS signals.

Electrodiagnostic Product Lines

Dantec Keypoint. The Dantec Keypoint EMG and EP family of products feature amplifiers, stimulators, and strong 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.

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

Nicolet EDX family. A hardware platform of amplifiers, base control units, stimulators and hand-held probes that are sold with two versions of Nicolet brand proprietary software (Viking and Synergy). These mid to high end systems have full functionality, strong signal quality, and flexibility.

Nicolet VikingSelect and Synergy Plinth. These are products for the high-end market that use proprietary Viking or Synergy hardware and software.

Nicolet VikingQuest. An EMG system for the mid-range market. The device runs on our proprietary Viking software.

Nicolet Synergy PIU. An EMG system for the low-end market focused on ease of use and portability. The PIU uses our proprietary Synergy software.

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. The Topas system can be configured as a two or four channel system and as trolley-based or portable.

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 care for 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.

Supplies. We also manufacture and market a full line of proprietary EMG needles.

Diagnostic Polysomnography Monitoring

Overview

Increasing public awareness of sleep disorders has made sleep medicine a growing specialty. Polysomnography (PSG), which involves the analysis of respiratory patterns, brain electrical activity and other

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physiological data, has proven critical for the diagnosis and treatment of sleep-related diseases such as apnea, insomnia, and narcolepsy. A full polysomnographic sleep study entails whole-night recordings of brain electrical activity, muscle movement, airflow, respiratory effort, oxygen levels, electrical activity of the heart, and other parameters. In some studies patients are fitted with treatment devices using Continuous Positive Airway Pressure technology (CPAP) during the sleep study and the proper settings for the treatment devices are determined during the latter part of the study.

Diagnostic PSG Monitoring Product Lines

We market dedicated diagnostic PSG monitoring products that can be used individually or as part of a networked system for overnight sleep studies to assist in the diagnosis of sleep disorders. Some of our EEG systems described above can also be configured to perform diagnostic PSG monitoring. 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.

Embla REMlogic, Sandman and REMbrandt; Sleepscan; SleepWorks; Coherence; Harmonie; NicoletOne. Our diagnostic PSG systems capture and store all data digitally. 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.

Proprietary Amplifiers. Our data acquisition systems incorporate recent developments in superior amplifiers for sleep analysis and are sold under brand names such as Embla and Embletta Gold, Xltek Trex and Connex, Schwarzer, and Nicolet. Our amplifiers are used in both hospitals and stand-alone clinics. 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.

Practice Management Software. Our Enterprise Practice Management Software provides a solution for institutions as well as private labs and physicians for patient scheduling, inventory control, staff scheduling, data management, business reports and billing interfaces. Enterprise may be used in conjunction with many Natus PSG products.

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. The Embla XactTrace RIP belts provide industry standard signal acquisition of respiration while its associated algorithm provides passive backup to airflow acquisition devices. This reduces the number of unattended portable studies which have to be repeated due to the loss of airflow signal.

Intraoperative Monitoring

Overview

Intraoperative monitoring (IOM) is the use of electrophysiological methods such as EEG, EMG, and evoked potentials to monitor the functional integrity of certain neural structures (i.e. nerves, spinal cord and parts of the brain) during surgery. The purpose of IOM is to reduce the risk to the patient of damage by the surgeon to the nervous system, and/or to provide functional guidance to the surgeon and anesthesiologist during surgery.

Diagnostic IOM Product Lines

Protektor. The Protector system 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.

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Nicolet Endeavor. A dedicated IOM system that offers complete flexibility in work flow and test protocols.

Nicolet EDX, Synergy Plinth, Viking Select. These systems are used in IOM applications where a smaller number of channels is sufficient. This approach is primarily followed in international markets that utilize the integrated system approach that allows for the use of the system in EMG clinical applications as well as in IOM applications.

Transcranial Doppler

Overview

Transcranial Doppler is the use of Doppler ultrasound technology to measure blood flow parameters such as velocity in key vascular structures in the brain. A Doppler probe is held against a specific location on the head and the device displays the information in both visual and auditory formats. This technology is used as preventative screening, diagnosis, and monitoring of various diseases and brain injuries such as stroke, embolism, reduced blood flow during surgery, and vasospasm.

Transcranial Doppler Products

Sonara and Sonara tek. The Sonara is an embedded system that is a self-contained unit that includes cpu, data display screen and speakers. It uses proprietary software with a touch screen menu. Sonara tek is a small portable device used with a laptop. Both models enable the uploading of images to the hospital information system.

Newborn Care and Other

Our newborn care and other products represent a comprehensive line of products that are used by physicians, nurses and medical technologists to assist in the diagnosis and treatment of common medical ailments in newborn care, and other products used in newborn through adult populations. Our principal newborn care and other product lines consist of the following:

Newborn Hearing Screening Products used to screen the hearing in the newborn.

Newborn Brain Injury Products used to diagnose the severity of brain injury, monitor the effectiveness of drug therapies, and treat brain injury.

Thermoregulation Products used to control the newborn environment including incubators and warmers.

Jaundice Management Products used to treat jaundice, the single largest cause for hospital readmission of newborns in the U.S.

Other Newborn Care Products Single use disposable products such as pacifiers, phototherapy masks, and x-ray shields, and newborn screening data management systems.

Diagnostic Hearing Assessment Products used to screen for or diagnose hearing loss, or to identify abnormalities affecting the peripheral and central auditory nervous systems in patients of all ages.

Balance and Mobility Systems to diagnose and assist in treating balance disorders in an evidence-based, multidisciplinary approach.

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

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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 Techniques

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

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 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 Ear, Nose and Throat Physician (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

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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.

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.

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. Recently it has 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.

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Newborn Brain Injury Diagnostic Products

Our newborn brain injury diagnostic products record and display parameters that the neonatologist uses to diagnose neurological disorders or brain injury in the newborn. These devices continuously monitor and record brain activity, aiding in the detection and treatment of HIE and seizures. The devices also monitor the effects of drugs and other therapies on brain activity and improve the accuracy of newborn neurological assessments. They are 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. The monitors have touch screens for easy navigation and onscreen keyboards for data entry at the bedside.

Olympic Brainz Monitor. The Olympic Brainz Monitor (OBM) is our latest generation Cerebral Function Monitor (CFM). The device can be used in single channel, two-channel or three-channel modes to continuously monitor and record brain activity. The OBM displays up to three channels of both aEEG and EEG data. Sophisticated networking, archiving and viewing functions facilitate consultation among medical professionals. Continuous impedance and corresponding EEG signals are also displayed, aiding better clinical management of the newborn.

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 amplified EEG s (aEEG), providing practitioners with the ability to monitor infants with a wider variety of neurological concerns when compared to single-channel EEG. Outside the U.S. the BRM3 is sold with an optional spike and event detection algorithm called Recognize.

Newborn Brain Injury Treatment

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 approved 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. 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.

Thermoregulation

Overview

Incubators offer a controlled, consistent microenvironment for thermoregulation and humidification within a closed system to maintain skin integrity and body temperature. This controlled microenvironment reduces noise and light, supporting developmental care while still providing access for clinical staff and family. Closed incubators are used for premature or sick babies who need a thermal and developmental environment to thrive and grow in the NICU. Transport incubators are designed to offer a controlled environment during transport either intra-hospital from one care area to another within a hospital building or inter-hospital between hospitals. Open infant warmers are the preferred device for labor and delivery rooms and NICU admission.

Thermoregulation products

Medix Incubators. Medix incubators provide high thermal performance with a double wall design. The NatalCare line of incubators includes easy to use control panels and features such as improved weighing functionality with automatic centering and an electronic tilting mechanism. The easy to clean, smooth design, and choice of options make these customizable incubators appropriate for different use environments.

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Medix Transport Incubators. Medix transport incubators are light in weight and easy to clean. They incorporate long lasting batteries and a choice of carts to meet the needs of different care environments.

Jaundice Management

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.

Jaundice Management Products

neoBLUE Product Family. This product line consists of our neoBLUE, neoBLUE Mini, neoBLUE Cozy, and neoBLUE blanket 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. Our 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.

Medix MediLED Product Family. This product line from Medix includes a full-size, free-standing LED phototherapy system and a MediLED mini light to be used on top of an incubator or attached to the Medix radiant warmer. The MediLED incorporates an array of blue and white LEDs, while the mini system utilizes blue super LEDs that provide high intensity phototherapy.

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 reproductive organs.

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

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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.

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 in patients of all ages. 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.

In the follow up evaluation of newborns diagnosed with hearing impairment, the clinician can distinguish between hearing impairments caused by mechanical or sensory dysfunction of the ear versus auditory neuropathy. Recent studies confirm the importance of making this distinction, as appropriate treatments for these impairments differ. One study showed that for patients diagnosed with auditory neuropathy, approximately 15% reported some benefit from hearing aids for language learning, while improvement in speech comprehension and language acquisition was reported in 85% of patients who received cochlear implants.

Diagnostic Hearing Assessment Product Lines

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

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: MASTER, AEP, ABaer, and Scout.