NATUS MEDICAL INC
Form 10-K
March 16, 2006
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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, 2005**

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: None

Securities Registered Pursuant to Section 12(g) of the Act: Common Stock, $0.001 par value

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 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 x Non-accelerated Filer ¨

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, 2005, the last business day of Registrant s most recently completed second fiscal quarter there were 17,261,048 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 National Market on June 30, 2005) was approximately $148,758,000. 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 1, 2006, there were 17,864,201 shares of Registrant s common stock, $0.001 par value, issued and 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 2006 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 following: 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 expectations regarding growth in international sales, our marketing, technology enhancement, and product development strategies, our intention to enter into agreements with group purchasing organizations, our intention to introduce new products and extend existing product lines, our intention to seek strategic partners, our belief that we bring products to market efficiently, development of technologies into successful products, our estimate of the length of time for patents to issue, identity of our competition and factors for competition, our compliance with regulatory requirements and laws, and our plan to seek approval to sell our products in additional countries.

Forward-looking statements are not guarantees of future performance and are subject to substantial risks and uncertainties that could cause the actual results predicted in the forward-looking statements as well as our future financial condition and results of operations to differ materially from our historical results or currently anticipated results. Investors should carefully review the information contained under the caption Risk Factors contained in Management s Discussion and Analysis of Financial Condition and Results of Operations, for a description of risks and uncertainties. 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®, AOAE®, ALGO®, Cochlea-Scan®, Echo-Screen®, Ear Couplers®, Flexicoupler®, MiniMuffs® and neoBLUE® are registered trademarks of Natus Medical Incorporated. EchoLink™, Neometrics™, and Accuscreen™ are non-registered trademarks of Natus. Solutions for Newborn Care℠ is a non-registered service mark of Natus. Bio-logic®, AuDX®, ABaer®, Ceegraph®, MASTER®, Navigator®, Sleepscan®, and Traveler® are registered trademarks of Bio-logic Systems Corp. CHAMP and Smartpack are non-registered trademarks of Bio-logic.

Overview

Natus is a leading provider of healthcare products used for screening, detection, treatment, monitoring and tracking of common medical ailments such as hearing impairment, neurological dysfunction, epilepsy, sleep disorders, newborn jaundice and newborn metabolic testing. We design our products to deliver accurate results in a rapid and reliable manner. In addition, our products address guidelines for standard medical practices as adopted by various medical-industry associations such as the American Academy of Pediatrics (AAP) and the Joint Committee on Infant Hearing (JCIH).

We have received clearance from the Food and Drug Administration to market the following product lines. Our ALGO Newborn Hearing Screener (ALGO screener) is a product line for hearing screening in newborns. Our Echo-Screen OAE screener is a product line that can be used either for hearing screening in newborns or to monitor the hearing in young children and adults. These two product lines consist of medical devices and single-use disposable supplies. Our line of neoBLUE LED Phototherapy devices (neoBLUE phototherapy devices) are medical devices and our Biliband Eye Protectors are single-patient disposable supplies for the treatment of newborn jaundice. Our lines of neonatal

oxygen delivery hoods and heat shields are designed to provide a stable environment of oxygen and humidity for newborns with special needs. Our MiniMuffs neonatal

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noise attenuators are disposable earmuffs designed to decrease noise exposure for babies in neonatal intensive care units or other noisy environments.

Our ALGO screening products use our clinically validated Automated Auditory Brainstem Response (AABR) technology to enable simple, noninvasive and accurate screening for hearing impairment in newborns. The ALGO screener delivers sound stimuli to a newborn s ears and analyzes the resulting brain wave responses to automatically produce a Pass or Refer result. The procedure can be performed within hours after birth. In addition, ALGO screening products meet AAP and JCIH guidelines without requiring a trained clinician to conduct the screening or interpret the results.

Our Echo-Screen screening products use Automated Otoacoustic Emissions (AOAE) technology, which can be used both to test the hearing in newborns and to perform hearing monitoring in young children and adults. The Echo-Screen products deliver sound stimuli into the ear and then measure the response of the outer hair cells of the cochlea using a highly sensitive external microphone. The Echo-Screen device analyzes the response of the hair cells and utilizes binomial statistics to deliver a Pass or Refer result. Like our ALGO products, the Echo-Screen device does not require a trained clinician to conduct the screening or interpret the results.

Our neoBLUE phototherapy devices are designed for use in the treatment of newborn jaundice. Phototherapy is the standard of care treatment for newborn jaundice and consists of exposing the skin of a patient to a light source to accelerate the elimination of bilirubin from the body. Our neoBLUE phototherapy devices are based on Light Emitting Diode, or LED, technology and generate a narrow spectrum of blue light that is most effective in converting bilirubin to a form that is easily excreted by the body. Compared to other available light sources, we believe our neoBLUE phototherapy devices have the advantages of emitting less ultraviolet and infrared light, sustaining longer bulb life, and generating less heat. In October 2005 we received Federal Drug Administration (FDA) 510(k) clearance to market our newest phototherapy device, the neoBLUE Cozy, which provides a light source from below the patient. We expect to begin selling the neoBLUE Cozy during the first quarter of 2006. Our Biliband Eye Protector is a
single-patient use product that is used when a newborn is undergoing phototherapy.

Our Neometrics suite of newborn screening data management products consists of proprietary software that collects, tracks, manages and reports newborn screening data to regional government health labs 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. Recently some states have begun using tandem mass spectrometry in their newborn metabolic screening programs, which has greatly increased the number of treatable disorders that can be detected.

Our Oxydome, Oxypod, Oxy-Igloo, and Foldadome are neonatal oxygen delivery hoods, and our Igloo is a neonatal heatshield. These products are designed to provide a stable environment of oxygen and humidity for newborns with special needs in neonatal units and nurseries. These products, and our Biliband Eye Protector, are licensed from Australia-based Nascor Pty Ltd.

We were incorporated in California in May 1987 and reincorporated in Delaware in August 2000. Our principal executive offices are located at 1501 Industrial Road, San Carlos, California 94070 and our telephone number at that location is (650) 802-0400. Our website is *www.natus.com*. The contents of our website are not incorporated by reference in this Annual Report on Form 10-K. We make our Annual Report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports, available on our website as soon as reasonably practicable after we electronically file them with the Securities and Exchange Commission.

On January 5, 2006, we acquired Bio-logic Systems Corp. (Bio-logic) pursuant to an Agreement and Plan of Merger dated as of October 16, 2005. Pursuant to the terms of the merger agreement, each outstanding share of Bio-logic common stock was converted into the right to receive $8.77 in cash. Each outstanding option to

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acquire Bio-logic common stock was cancelled, with the holder of the option receiving, for each share covered by the option, an amount equal to the excess (if any) of $8.77 over the exercise price per share of the option. The total aggregate payment by the Company to the former stockholders and option holders of Bio-logic was approximately $68.8 million, exclusive of direct costs associated with the acquisition. In their Form 10-K for the year ended February 28, 2005 filed with the Securities and Exchange Commission, Bio-logic reported revenue of $30.5 million and net income of $1.9 million.

The discussion that follows provides an overview of the business of Natus prior to the acquisition of Bio-logic. The discussion has been supplemented with information regarding the impact of the acquisition of Bio-logic on the business of Natus. Unless noted, the information and other disclosures presented herein refer to Natus prior to the acquisition and thus exclude related information pertaining to Bio-logic.

Our Products

Our proprietary products are designed, manufactured and packaged into product families that offer what we believe is superior quality and clinical performance at a competitive value for our customers. We currently sell our products into over 80 countries, through several distribution channels including: our direct sales force and distributor network in the United States (U.S.), our distributor network outside of the United States; and via several private label partnership agreements with such companies as Fisher & Paykel Healthcare, GN Otometrics, and Welch Allyn.

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 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 who had risk factors for hearing impairment, including a family history of hearing impairment, infection prior to birth, low birth weight, skull or facial anomalies, or bacterial meningitis. 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. Babies identified as hearing impaired at birth will typically begin therapy immediately and can learn and progress at a rate comparable to children with normal hearing, regardless of the severity of hearing loss. However, 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 and who received treatment early had significantly better language skills and vocabularies than those children whose hearing loss was detected later.

Newborn Hearing Screening in the United States

Newborn hearing screening has been performed in the U.S. since 1964. However, until 1993 when the National Institutes of Health and, in 1994, the Joint Committee on Infant Hearing endorsed universal newborn hearing screening, screening had generally been limited to babies with risk factors for hearing impairment. In recent years, clinical evidence in support of early detection for hearing impairment, combined with the introduction of new screening technology, has increased support for universal newborn hearing screening programs. The combined clinical benefit and cost savings encouraged additional highly populated states to adopt

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mandates for universal newborn hearing screening as early as 1997. We estimate that today approximately 90 to 95% of the children born in the U.S. are being tested for hearing impairment prior to discharge from the hospital. In 1999, the American Academy of Pediatrics Task Force on Newborn and Infant Hearing published guidelines for universal newborn hearing screening programs. These guidelines are intended to establish the standard of care and provide that:

- At least 95% of all newborns should be screened;
- The screening method used must have the ability to detect all infants with a hearing impairment of at least 35 decibels, normal hearing level (dB nHL), a common audiological unit to measure hearing, in the better ear;
- The screening method should not refer more than 4% of all children tested for further evaluation;
- No more than 3% of children with normal hearing who are screened should receive results that indicate they have a hearing impairment, a screening error known as a false positive or false refer result; and
- No child whose hearing is impaired should receive a normal result, a screening error known as a false negative or false pass result.

Because positive results are referred to an audiologist or physician 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 trauma for parents.

In order to meet the guidelines set forth by the American Academy of Pediatrics, a screening method must focus on two parameters: sensitivity and specificity. Sensitivity is the capacity to detect the disease or disorder in those infants with the disease or disorder. A sensitivity of 100% indicates that no newborn with a hearing impairment receive results indicating the absence of a hearing impairment. Specificity is the capacity to detect those infants without the disease or disorder. A specificity of 100% indicates that no normal-hearing newborn receive results indicating the presence of a hearing impairment.

Newborn Hearing Screening Techniques

Traditional methods of screening for hearing impairment include subjective behavioral tests and more expensive objective diagnostic processes. We believe widespread acceptance of screening newborns for hearing impairment requires a relatively inexpensive screening method that produces sensitive, specific, and reliable results. The two traditional technologies used to screen newborns and infants for hearing impairment are auditory brainstem response and otoacoustic emissions.

In addition, guidelines published in 2000 by the Joint Commission on Infant Hearing (JCIH) address the need for surveillance hearing screening of infants and children. The JCIH recommends that ongoing audiologic and medical monitoring and surveillance should be administered to those infants at risk for delayed or late-onset hearing loss.

Auditory brainstem response (ABR). Auditory brainstem response technology is the most accurate and comprehensive method for diagnosing hearing impairment in adults and infants. Auditory brainstem response technology uses sensors placed on the head to measure the response of the brain and auditory nerves to sounds delivered through earphones. Hearing impairment is evaluated by monitoring the brain s response to varying frequency and volume of sounds. Trained clinicians must operate the auditory brainstem response screening equipment, and the screening results must be interpreted by an audiologist or trained physician. Non-automated auditory brainstem response technology is primarily used to assess the degree of hearing impairment in adults and children and is not widely used for newborn screening due to the high cost, lengthy procedure time, and unavailability of trained specialists in many neonatal nurseries. Enhanced auditory brainstem response devices automate portions of the screening process, such as providing pre-determined parameter menus, to make these devices easier to use or the results easier to interpret. The user has discretion to set some or all of the screening

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parameters and, as a result, many enhanced auditory brainstem response devices require substantial user training. A physician, audiologist, or other trained specialist may also be required to review a pass or refer result because these products permit discretion in setting screening parameters.

Otoacoustic emissions (OAE). Otoacoustic emissions screening is a method of detecting hearing impairment in adults and children, by measuring the function of the cochlea. Otoacoustic emissions are sounds created by the active biomechanical processes within the sensory cells of normal ears. Since otoacoustic emissions are present in normal ears, an absence of otoacoustic emissions is a sign of irregular function of these sensory cells, which could be an indicator for hearing impairment. Otoacoustic emissions screening uses a probe placed in the ear to deliver auditory stimuli and measures the response of the sensory cells with a sensitive microphone. However, otoacoustic emissions screening does not evaluate the function of the entire hearing pathway because it does not assess the neural pathways. Therefore, otoacoustic emissions technology can fail to detect hearing disorders affecting the neural pathways, such as auditory neuropathy. Different studies have found that as many as 15% of hearing impaired children have normal inner and middle ear function, and are hearing impaired because of disorders of the neural pathways. There are several different types of OAE technologies, however, the two most commonly used for hearing screening are transient evoked otoacoustic emissions (TEOAE), and distortion product otoacoustic emissions (DPOAE).

Natus ALGO Newborn Hearing Screening Product Line

In order to address the limitations of traditional ABR screening techniques, our ALGO screening product family utilizes proprietary Natus AABR Technology to provide accurate, non-invasive and automated hearing screening for newborns. The ALGO screener, like traditional ABR devices, utilizes a number of sensors placed on the newborn s head to measure the response of the brain and auditory nerves to sounds delivered through specially designed earphones. However, unlike traditional ABR devices, our ALGO screener does not require a trained clinician to conduct the screening or an audiologist or physician to interpret the results. The ALGO screener uses our proprietary signal detection algorithms to perform the screening and draw a conclusion as to whether a baby needs to be referred to an audiologist for further clinical evaluation.

ALGO Newborn Hearing Screening Products

Our ALGO hearing screening product family utilizes proprietary signal detection technology to provide accurate and non-invasive hearing screening for newborns. Our ALGO screening product family utilizes automated auditory brainstem response technology to provide accurate and non-invasive hearing screening for newborns. The ALGO screener delivers thousands of soft clicking sounds to the newborn s ears through sound cables and disposable earphones connected to the instrument. Each click elicits a series of identifiable brain waves, which are detected by disposable sensors placed on the baby s forehead, shoulder, and nape of the neck. This methodology will detect hearing loss at 35 dB nHL or higher. The ALGO screener automatically extracts the infant s brainwave responses resulting from the clicks and differentiates them from other brain activity resulting from muscle activity, ambient sounds, or other stimuli affecting the brain. These brainwave responses are then compared to a template based on the brainwave responses of infants with normal hearing. The ALGO screener issues a Pass result when it collects sufficient data to establish that the baby s responses are consistent with the responses of a normal hearing child to a 99.96% level of statistical confidence. If a determination cannot be reached after 15,000 sweeps, the ALGO screener issues a Refer result, indicating that the infant should be referred for more detailed clinical evaluation, including repeating the hearing screening by an audiologist or other specialist. Once the result of the second hearing screening is available, if the result is still a Refer , the specialist will conduct additional tests to determine the type and severity of the hearing impairment. We believe that our ALGO newborn hearing screening products, which use automated auditory brainstem response technology, provide the following benefits:

Accuracy and objectivity. Our AABR technology has the highest documented specificity and sensitivity for newborn hearing screening devices not requiring a trained audiologist. The documented sensitivity of the

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ALGO system exceeds 99%, while the specificity is greater than 96%. Our test produces an objective Pass or Refer result, which does not require further interpretation by a specialist. Our Refer result provides an indication that the baby s brainwave response is not consistent with a normal hearing child, but does not quantify the severity of the possible hearing impairment.

Compliant with standard of care guidelines; Easy to use. Our ALGO screener meets the requirements and recommendations of the American Academy of Pediatrics and the Joint Commission on Infant Hearing for universal newborn hearing screening for low refer rates, minimizing parental anxiety and the cost of re-screening. In addition, our test does not require an audiologist or physician to conduct the screening or interpret the results.

Immediate crib-side results. Our screening tests can be conducted within hours after birth. Middle ear fluid and ear canal debris, which are often still present in the first 12 to 24 hours of after birth, do not significantly impact the ALGO s ability to obtain test results. ALGO hearing screenings can be performed and results are most often obtained prior to discharge from the hospital.

The ALGO newborn hearing screening product line was first introduced in 1985. We acquired the ALGO product line in 1987, and we have since introduced seven new versions of the ALGO screener using the same AABR technology. We currently market the ALGO 3 and our latest hearing screening product, the handheld ALGO 3i screener.

ALGO 3i Newborn Hearing Screener. In June 2003, we introduced the handheld ALGO 3i hearing screener. The ALGO 3i utilizes our proprietary AABR technology and operates similarly to our ALGO 3 without some of the ALGO 3 features (cart, storage drawers, large display screen), while adding a multiple-language user interface. The ALGO 3i product targets the need primarily in foreign markets for a handheld device that provides patient data storage and wireless data-transfer capabilities.

ALGO 3 Newborn Hearing Screener. In October 2001, we introduced the ALGO 3 newborn hearing screener. The ALGO 3 screener incorporates our proprietary AABR technology interfaced with a laptop computer and operating system software. This system uses our proprietary software to conduct simultaneous screening of both ears and conducts tests at 35 dB nHL. The ALGO 3 screener utilizes our proprietary software to automatically store results from every test, which facilitates prompt follow-up and tracking of patient results. Users can print daily, weekly, or monthly reports, create backup files, and integrate screening results into statewide databases.

Natus Echo-Screen Hearing Screening and Monitoring Product Line

Otoacoustic emissions are an objective measure of the function of the cochlea. OAE technologies record and analyze echoes generated by the hair cells of the inner ear through sound cables and disposable ear probes. There are several different types of OAE technologies, however, the two most common used for hearing screening are: transient evoked otoacoustic emissions and distortion product otoacoustic emissions, which are described below.

Transient Evoked Otoacoustic Emissions. Transient Evoked OAE tests measure the echoes recorded after a brief stimuli over a range of frequencies. TEOAE technology tests several parts of the cochlea individually and simultaneously.

Distortion Product Otoacoustic Emissions. Distortion Product OAE tests are those echoes recorded after continuous and more intense stimuli are introduced at specific frequencies which test one part of the cochlea at a time.

To address the needs of hearing screening programs requiring a low cost device for the surveillance screening of newborns, infants, and children, we provide the Echo-Screen hearing screening product line. Unlike our AABR technology, which is designed to screen newborns prior to six months of age, the Echo-Screen device

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uses OAE technology, which makes it suitable for screening a wider range of patients, including newborns, infants and children. OAE technology is unable to detect hearing disorders affecting the neural pathways, such as auditory neuropathy. Nonetheless, our Echo-Screen product provides the following benefits in specific markets:

Economical devices and single-use supplies. The Echo-Screen line of devices and the single-use disposable supplies used with them are sold at lower price points than our ALGO hearing screening devices and disposable supplies. In international markets, many countries are in the early stages of establishing universal newborn hearing screening programs and the costs associated with implementing these programs can be significant. Economic considerations often dictate that OAE technology is the best solution for a hearing-screening program.

Effective for multiple patient populations. After about six months of age, a child s brain response to auditory stimuli changes. Because of these changes in response, our AABR technology is no longer as effective in identifying hearing impairment. Otoacoustic emissions technology is effective in identifying hearing impairment in newborns, children, and adults. Guidelines published by the Joint Commission on Infant Hearing establish that all children at risk of hearing impairment be monitored for possible hearing loss through age three.

Multiple technologies in one device. The Echo-Screen line of products can be configured with any combination of up to three hearing screening technologies in one handheld device. These technologies are: (1) Transient evoked otoacoustic emissions, (2) Distortion product otoacoustic emissions, and (3) Automated auditory brainstem response. Both TEOAE and DPOAE technologies can be complementary as they test the cochlea in different ways. TEOAE testing can be more valuable when used for screening purposes while DPOAE testing will be more valuable when evaluating hearing impairment at specific frequencies.

The Echo-Screen product line, based on clinically validated automated otoacoustic emissions technology (AOAE) delivers clicks or tone bursts to the patient s ear canal via a probe which is inserted within the ear canal. The patient s cochlea generates sound waves in response to these clicks or tone bursts. The ear probe, which contains a very sensitive microphone, then measures and records the sound wave responses of the patient s cochlea. The Echo-Screen device analyzes the patient s response and automatically provides a pass or refer result.

Hearing Screening Supply Products

ALGO Screening Supply Kits. For infection control, accuracy, and ease of use, our ALGO screening devices are designed so that each newborn hearing test conducted with the ALGO screener is carried out with screening supplies designed specifically for use with our AABR technology. Natus offers a variety of packaging options that include single-use earphones, which we call Ear Couplers or Flexicouplers, and electrodes, which we call Jelly Tab sensors. All of our screening supplies are alcohol and latex-free, and our adhesives are specially formulated for use on the sensitive skin of newborns.

Echo-Screen Supply Products. For infection control, accuracy, and ease of use, our Echo-Screen devices are designed so that each hearing test conducted with the Echo-Screen screener is carried out with screening supplies designed specifically for use with our AOAE and AABR technology. Natus offers a variety of screening supply options that include single-use probe tips in a variety of sizes and single-use earphones. We also offer disposable electrodes for use with the AABR screening software.

MiniMuffs Neonatal Noise Attenuators. Our MiniMuffs, which are not designed for hearing screening, are disposable earmuffs designed to decrease noise exposure for babies in neonatal intensive care units. The MiniMuffs fit securely over a baby s ear and reduce sound levels by at least seven decibels, representing a reduction of sound pressure of more than 50%. Our MiniMuffs product is sold worldwide and meets health care infection control standards through its single-use design.

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Jaundice Management

Overview

Babies are generally born with a quantity of red blood cells necessary for fetal life but in excess of their needs as newborns. The body, in a normal process known as hemolysis, breaks down excess red blood cells. Two byproducts of hemolysis are a yellow pigment called bilirubin and a proportional amount of carbon monoxide. Abnormal rates of hemolysis cause abnormal levels of bilirubin and carbon monoxide. An abnormal rate of hemolysis may also be an indicator of a number of other disorders including anemia, infection, and some genetic disorders.

High amounts of bilirubin in the body can cause a condition known as jaundice, with characteristic yellowing of the skin and eyes. The high level of bilirubin can result either from too much bilirubin being produced by hemolysis or from the body s failure to excrete the bilirubin. Extremely high levels of bilirubin, or hyperbilirubinemia, are toxic and may cause irreversible brain damage and potentially result in death.

The American Academy of Pediatrics Committee on Fetus and Newborns 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.

Depending on its cause, jaundice can be treated by helping the newborn to excrete the bilirubin or to reduce bilirubin production. In early stages, jaundice can be treated with phototherapy, hydration, and frequent feedings. Dangerous or toxic levels of bilirubin are treated by blood exchange transfusion, which is a high-risk procedure for newborns. The standard of care treatment for severe jaundice is phototherapy. During phototherapy, the patient is exposed to a light source, which converts the bilirubin to a form that is more easily excreted by the body. The optimal color of light to cause this conversion is in the blue range at a wavelength of approximately 450 nanometers. Most phototherapy lights use either fluorescent or halogen light sources. While these other light sources produce light that is effective in converting bilirubin, they also produce light outside the optimal color range that may include harmful ultraviolet and/or infrared light. Ultraviolet light can cause skin damage similar to that resulting from overexposure to the sun. In addition, fluorescent, and, in particular, halogen light sources generate heat energy, which can result in dehydration of the newborn.

Jaundice Management Products

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 AAP guidelines and meet the needs of our customers related to the treatment of newborn jaundice:

neoBLUE Phototherapy Device. In October 2002, we introduced our neoBLUE phototherapy device as a crib-side unit used for the treatment of jaundice. The device utilizes Light Emitting Diode, or LED, technology to generate a narrow spectrum of blue light that, we believe, is optimal for the conversion of bilirubin, and produces a negligible amount of both ultraviolet and infrared light. These LEDs emit a high-intensity band of blue light, which is clinically proven to be most effective in the breakdown of bilirubin. Because the neoBLUE phototherapy device emits significantly less ultraviolet light and heat than conventional phototherapy devices, it may reduce the risk of skin damage and dehydration for

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infants undergoing treatment. Also, the utilization of this light may result in a more rapid reduction of bilirubin levels in newborns and potentially reduce the treatment time associated with phototherapy.

neoBLUE Mini Phototherapy Device. In September 2004, we introduced our neoBLUE Mini phototherapy device. Designed as a smaller counterpart to our existing overhead neoBLUE phototherapy device, the neoBLUE mini system offers clinicians a more compact and portable alternative to other brands of phototherapy devices currently on the market. The neoBLUE mini device s adjustable arm with pole mount facilitates attachment to a variety of patient care apparatuses such as incubators and radiant warmers, which are often used during phototherapy treatment.

neoBLUE Cozy Phototherapy Device. In October 2005, we received FDA 510(k) clearance for the newest extension of our neoBLUE line of LED Phototherapy lights. The neoBLUE Cozy, with its streamlined, oval design conforms to the shape of the baby and provides a light source from underneath the patient. The light source exposes the full length of the baby from head to toe, covering a larger surface area than standard phototherapy blankets, pads, or beds. We will begin marketing the neoBLUE Cozy in the first quarter of 2006.

Biliband Eye Protector. In October 2003, we began selling the Biliband Eye Protector, a single-patient use supply product designed to block light from reaching the eyes of newborns undergoing phototherapy treatment. Test results from an independent study demonstrate that the Biliband blocks more light than other leading brands of phototherapy eye shields. Moreover, unlike other phototherapy shields that may not stay in place very well, the Biliband s unique Y-shaped design allows it to conform to various head shapes and remain in place.

Newborn Metabolic Screening

Overview

The goal of newborn metabolic screening is the early identification of conditions for which early and timely interventions can lead to the elimination or reduction of associated early mortality or lifelong disability. Each year, approximately four million babies in the U.S. participate in state-mandated newborn screening programs. Utilizing dried blood spot specimens collected at the birthing site and mailed to state-specific or regional laboratories, these screening programs are generally regarded as successful and cost-effective. The efficiency of these programs depends on the integration of sample collection, laboratory testing, follow-up, diagnosis, timely treatment, and tracking of outcomes.

Currently, newborn metabolic screening programs are run by state public health agencies. Notably, the array of screening tests performed by each state varies and changes periodically. As many as ten or more treatable disorders can be detected through the use of reagent based screening technology. Recently some states have begun using tandem mass spectrometry in their newborn metabolic screening programs. Through the use of tandem mass spectrometry, more than 40 disorders of body chemistry can be detected in the analysis of a single blood specimen.

These rapid advances in screening are providing an increasing ability to develop effective treatments for a wider range of metabolic disorders. The availability of accurate demographic and other information is a key component in the identification of at-risk infants and the timely application of these treatments. Testing for a broader range of metabolic disorders in newborns has created the need for more efficient and complex data management. New federal and state initiatives, focusing on the security of medical information, are coupled with a desire to increase the utility of newborn metabolic screening data. Key to this utility is the integration of public health data into a central repository.

Data Management Products

Our Neometrics newborn screening data management products consist of an integrated suite of software modules that collect and analyze demographic data and test results associated with the newborn screening

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process. The suite of products assists laboratory personnel in quickly and accurately identifying infants with possible life-threatening disorders and to relay this information to appropriate medical personnel. With protocols customized to the specific rules and regulations of each state, the applications then assist in the management of patient follow-up and treatment. The key to the effectiveness of these applications is their ability to meet the specific requirements of high-volume, state-based newborn screening laboratories. The modular-based system utilizes an advanced database engine and is highly configurable. In addition, the latest designs of the modules utilize a standard and familiar graphical user interface format for ease of customer use. Comprehensive help systems and well-planned modules contain advanced look-up and retrieval features which provide rapid access to an individual patient record and all associated results. The primary modules are:

Metabolic Screening Database System (MSDS). MSDS is the core database module in a system that provides the newborn screening laboratory with a tool for the processing of laboratory test results and demographic data. The module is configured in a client-server system utilizing a state-of-the-art database engine. Sub-modules of MSDS provide for look-up and retrieval of specimen information, comprehensive on-line help systems, flexible reporting, and extensive data exporting capabilities.

Case Management System (CMS). Follow-up of presumptive cases is a time-consuming and laborious effort. The CMS module helps to automate the entire process by organizing daily workflow for follow-up staff according to their specific requirements. Linked to MSDS, the case management system uses a library of preprogrammed actions to highlight time-critical tasks. Many of these tasks, such as the generation of letters to parents and physicians, can occur automatically.

Voice Response System (VRS). The voice response system provides on-demand spoken test results over a touch-tone phone to physicians and other authorized personnel. This module reduces the workload of lab staff by eliminating or reducing requests for newborn screening results.

Tandem Mass Spectrometry Testing Upgrade. Many customers have already invested in this next generation of newborn metabolic screening technology known as tandem mass spectrometry (MS/MS) in order to test each newborn for up to 40 or more disorders. Our MS/MS upgrade allows users to easily incorporate increasing numbers of metabolic screening tests and present the data and results in a useful manner.

Automated Newborn Screening Data Transfer Utility (iNSIST). This software utility automatically transfers data from state laboratories to the National Newborn Screening Information System (NNSIS) at the University of Texas, which acts as a data collection facility and clearing house for the Centers for Disease Control (CDC). The iNSIST application can interface with Neometrics MSDS and CMS applications as well as other data management systems

Lead Follow-Up. This software provides the case management team with the ability to track lab specimens by geographic location and provide one to many analysis. An example of this would be to determine if lead exposure is caused at a school. Geographic tracking is critical when monitoring exposure to lead, as effective follow up and remediation must not only address the needs of the patient, but also the source of the exposure.

Thermoregulation

Overview

A full-term baby normally loses large amounts of heat and water vapor through the skin because of its relatively large amount of body surface area relative to its body weight. Newborns also sustain increased evaporative water loss due to the immaturity of the outer skin layers, resulting in a reduced ability to retain body water. In pre-term babies, this water loss is more exaggerated and can contribute to a high degree of body water loss. As the water passes through the newborn s skin and evaporates from the skin surface, it contributes to a loss of body heat. This heat

loss can be problematic, especially for premature babies, since newborns are limited in their ability to generate and conserve body heat.

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Heat shields provide a microenvironment for the newborn in order to control water loss and heat loss. Heat shields also allow for the creation of a high-humidity environment for the premature newborn. This humidified atmosphere decreases evaporative water loss from the newborn, and thereby reduces associated heat loss.

Thermoregulation Products

We sell the following products to meet the needs of newborn thermoregulation; they are used in neonatal units, nurseries, and postnatal wards in hospitals and clinics as well as in emergency transport vehicles:

Igloo. A high quality, integrated heat shield made of clear, medical-grade polycarbonate and acrylic materials. It has multiple uses in neonatal units, nurseries, and postnatal wards, and can be used during phototherapy, as an oxygen hood for large babies, and also within incubators under heat sources.

Oxy-Igloo. A half-cylinder clear plastic oxygen hood with a soft, disposable silicon flap that can be hand-cut to fit around larger, full-term babies.

Foldadome. A foldable, self-erecting oxygen hood that can be stored flat for service in emergency vehicles or intensive care units where storage facilities may be limited.

Pulmonary Function

Overview

Prior to delivery, the fetus depends on the placenta to provide the normal gas exchange functions of ventilation, the removal of carbon dioxide, and respiration, the oxygenation of blood. At delivery, the newborn loses the placental support and is then required to initiate breathing so that its lungs can support these necessary gas exchange functions. This transition requires that the lungs expand and fill with air while eliminating the amniotic fluid previously contained in the lungs. Some newborns have difficulty clearing the fluid from their lungs and thus require assistance with normal gas exchange. These newborns usually have some form of respiratory distress that compromises the ability of their lungs to eliminate carbon monoxide or absorb oxygen. These newborns typically have difficulty breathing, which may appear as rapid breathing, grunting with breathing efforts, or cyanosis, a blueness due to lack of oxygen. In particular, pre-term babies often suffer from immature lung development whereby their lungs are stiff and difficult to inflate. These pre-term babies often need to work harder in order to breathe, and they may still not be able to absorb adequate amounts of oxygen. Some pre-term or full-term babies will require supplemental oxygen due to other disease processes such as infection, or aspiration of substances that cause lung irritation.

Oxygen hoods are able to provide a microenvironment where high concentrations of oxygen are desired, well above what can be achieved with nasal prongs. When used in conjunction with an oxygen analyzer, oxygen hoods can deliver precise oxygen concentrations from 21% (room air) to nearly 100%.

Pulmonary Function Products

Our line of oxygen hood products stay in position over the newborn and are designed to provide optimal gas flow, unobstructed viewing, and access to the newborn. These products are made of clear, medical-grade polycarbonate, plastic, and acrylic materials. They are easy to clean and disinfect, stackable, and do not interfere with airflow when used inside an incubator. Natus sells the following oxygen hood products:

Oxydome I and II. Heatbox products for oxygen therapy made from a single piece of unbreakable, molded thermoplastic. The domes have no corners for ease of cleaning.

Oxypod I and II. Similar to the Oxydome with the same footprint and a slightly larger interior volume.

Bio-logic Product Lines

Through our acquisition of Bio-logic in January 2006, we have now extended our product offerings beyond those targeted solely for the care of newborns. In particular, we now have product offerings in three distinct new

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markets: diagnostic hearing assessment by audiologists and Ear, Nose and Throat (ENT) physicians, EEG monitoring for neurology, and computerized polysomnography used to detect sleep disorders. Bio-logic also markets a product line that is similar to our hearing screening products. These four product lines are described below.

Diagnostic Hearing Assessment by Audiologists and ENT Physicians

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 otoacoustic emission. In 2004, Bio-logic added an enhancement to their hearing products line that facilitate testing of functional speech intelligibility in noise (HINT Pro).

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 auditory brainstem response (ABR) test. This test, which records brain waves that correspond to responses from the inner ear and brain stem, is used to screen for and define hearing loss characteristics, particularly for patients who cannot reliably verbally respond to standard behavioral tests of hearing. 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.

Our diagnostic hearing assessment product line consists of the Navigator Pro system, which is augmented by discrete software applications that are marketed as enhancements to the system.

Navigator Pro. The Navigator Pro EP System is a PC-based, configurable device that utilizes Evoked Potentials for use in the recording and display of human physiological data, for auditory screening purposes, and to assist in determining possible auditory and hearing-related disorders. Auditory stimuli are presented to the patient s ear through an earphone or headphones, and the corresponding auditory brainstem responses from the patient are recorded using EEG electrodes placed on the scalp. The Navigator Pro EP 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 software to upgrade the system with a combination of OAE and ABR screening as well as additional diagnostic functions as described below.

Stacked ABR. A modification of the standard ABR measure, developed to improve the sensitivity of ABR as a screening tool for auditory nervous system abnormalities. Currently, patients suspected of having an acoustic tumor, for example, are routinely referred for expensive Magnetic Resonance Imaging (MRI) tests because a less expensive screening method that has acceptable sensitivity to the presence of small tumors is not available. Based on the research and clinical data collected to date, stacked ABR holds significant promise as a viable, sensitive screening tool for auditory nervous system abnormalities, such as small acoustic tumors.

CHAMP. The Cochlear Hydrops Assessment Masking Procedure module is licensed from House Ear Institute and incorporated into our Navigator Pro product. CHAMP assists in the evaluation of cochlear hydrops, a fluid imbalance condition in the inner ear often associated with Meniere s disease. CHAMP is a modified ABR test that uses unique acoustic stimuli and response measures to elicit a response pattern characteristic of cochlear hydrops.

M.A.S.T.E.R. The M.A.S.T.E.R. technology, which Bio-logic introduced in 2003, defines the magnitude of hearing loss at specific frequencies, and is suitable in situations where patients cannot

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actively participate in the testing process. M.A.S.T.E.R allows both ears to be tested simultaneously and with multiple frequencies to define hearing loss characteristics quickly. This product incorporates computer-assisted interpretation features to meet the expanding needs of hearing health care givers who are involved in the follow-up of patients referred with the suspicion of hearing loss.

EEG Monitoring for Neurology

We design, manufacture and market a full line of computerized instruments (electroencephalographs or EEGs) used to help diagnose the presence of seizure disorders, look for causes of confusion, and evaluate head injuries, tumors, infections, degenerative diseases, and metabolic disturbances that affect the brain. This type of testing is also done to confirm 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.

Routine outpatient EEG testing is performed both in private physicians offices and hospital EEG 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 EEG and behavior is used to determine if surgical solutions are appropriate.

Our diagnostic EEG monitoring product line for neurology consists of our Ceegraph VISION computer workstation, the Netlink EEG amplifier, the Netlink LTM, and the Netlink Traveler. These devices 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.

Ceegraph VISION. The Ceegraph VISION line of computerized EEG systems includes 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 powerful physician review stations with advanced quantitative EEG analysis capabilities.

Netlink EEG. A proprietary amplifier that interfaces the patient and computer and incorporates recent advances in amplifier and ergonomic design. Recent innovations in electronics technology and advanced internet-protocol data transmission enable Netlink EEG to provide recordings of up to 32 channels of digital data using Ethernet communication. Its custom cart allows the instrument to be moved easily and adjusted to the configuration needed.

Netlink LTM. Designed for use in long-term epilepsy monitoring applications allowing laboratories to place amplifiers and recording PCs anywhere in the facility using Ethernet data transmission, eliminating commonly encountered connectivity and associated data quality issues. We also offer two automated spike and seizure detection software options that assist in the identification of clinical events indicative of epilepsy: Stellate and Persyst. Stellate Systems patented algorithms include newborn seizure, seizure onset, and state-dependent seizure detection. Persyst s Reveal is a neural network algorithm that detects spikes and seizures in adults and children.

Netlink Traveler. A solid-state, battery-operated ambulatory recorder for seizure monitoring that records continuous information from up to 32 channels and saves data on removable flash card media. Data can immediately be reviewed and analyzed using Ceegraph VISION and automatic spike and seizure programs.

A digital video option, which provides synchronized video recording of a patient s behavior while recording electrical activity from the brain, is available for Ceegraph VISION systems utilizing Netlink EEG and LTM amplifiers, and for Ceegraph XL. SmartPack, a patented software option available with the Ceegraph line, is an innovative data compression process that reduces the size of data files by as much as 60%. Data compression is performed in real-time with no loss of information. Universal Reader is a physician s review station that permits fast and easy data analysis in a graphical format using Ceegraph software.

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Computerized Polysomnography (Diagnostic Sleep Analysis)

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. We offer a broad range of products for the contemporary sleep laboratory, including fully configured laboratory systems, portable systems, and ambulatory recorders for home monitoring. Our Sleepscan systems provide flexible report generation capabilities, expert analysis modules, and many advanced features.

Our diagnostic EEG monitoring product line for polysomnography consists of our Sleepscan VISION computer workstation and the Sleepscan Netlink headbox, which are typically used together as a system for overnight sleep studies to assist in the diagnosis of several sleep disorders.

Sleepscan VISION. A sleep study entails whole-night recordings of brain electrical activity, muscle movement, airflow, respiratory effort, oxygen levels, electrocardiogram (EKG), and other parameters. These recordings result in over 1,000 pages of data that must be reviewed, analyzed, scored by a specialist, and summarized in a report typically a costly and time-consuming process. Our Sleepscan system stores all of this information digitally and provides time-saving features and software for acquiring and analyzing data. Its flexibility enables the user to specify rules and personal preferences to be used during analysis. Once these rules and preferences are set, the system rapidly performs the analysis, summarizing the results graphically and incorporating them into a readily available detailed report. The user has the ability to verify the analysis, manually override sections as needed, modify parameters, and then re-analyze the data. The Sleepscan VISION s customized analysis includes color-coded sleep stages, flow loop analysis, and other important features. Sleepscan Netlink systems, available in both desktop or laptop versions, include 40-channel recording capability and a built-in oximeter, a device that measures the oxygen content in the blood.