

ENFANT[®] PEDIATRIC VEP VISION TESTING SYSTEM

2010 Fact Sheet

Enfant[®] Technology



The Enfant[®] Pediatric VEP Vision Testing System is a non-invasive, child-friendly medical device that tests for visual deficits, including amblyopia, optic nerve disorders, and refractive errors, in **pre-verbal children, ages six months and older**. The Enfant[®] system is the first and only pediatric vision test of its kind.

According to the American Academy of Pediatrics (AAP), vision disorders are the fourth most common disability among children in the United States. Although vision assessment beginning at birth has been endorsed by major pediatric and ophthalmologic medical associations, recent studies estimate that only 21% of all preschool children are screened for vision problems and only 14% receive a comprehensive vision exam.

The Enfant[®] uses technology called Visual Evoked Potential (VEP), which evaluates the child's response to an external stimulus along the entire visual pathway from the lens of the eye to the visual cortex of the brain. By using VEP, the Enfant[®] is able to identify vision deficits that a physician might not otherwise detect during more conventional, subjective eye exams, such as eye charts. The Enfant[®] system allows testing of much younger children, since it does not require a response from the patient.

The Enfant[®] Pediatric VEP Vision Testing System:

- Utilizes clinically proven, FDA cleared technology
- Delivers a 97% sensitivity in detecting visual deficits where and when they exist
- Provides immediate, on-site test results in simple, pass/fail format
- Requires no dilation or sedation for maximum patient safety
- Features child-friendly animated characters and graphics accompanied by music
- Can be completed in five to seven minutes, contributing to a more than 90% test completion rate
- Is currently utilized by more than 350 pediatric practices, and is easily incorporated into a child's regular well care visit
- Stimulates the vision system with a specific pattern to elicit electrical signals to the visual cortex of the brain
- Uses objective, statistical analysis to assess the child's neurological response to the stimuli, and compares the two eyes to determine if asymmetries are present
- If asymmetries are present, the patient is referred to an eye care specialist for further evaluation

About Diopsys, Inc.

Diopsys, Inc. is a medical instrumentation company dedicated to delivering high-quality, cost-effective preventative health care. The company specializes in the development and marketing of patient-friendly, non-invasive diagnostic vision testing equipment utilizing Evoked Potential technology. Diopsys has developed and markets the patented **Enfant[®] Pediatric VEP Vision Testing System**, a device for children as young as six months of age, and the **Diopsys[™] NOVA-DT** and **Diopsys[™] NOVA-TR VEP Vision Testing Systems** utilized by ophthalmologists and optometrists for the detection, diagnosis and treatment of vision disorders.

SIDEBAR: EYE-OPENING FACTS ABOUT AMBLYOPIA



More commonly referred to as “lazy eye,” **amblyopia** is decreased vision of a child that results when one (or both eyes) sends a blurry image to the brain, inhibiting development of the vision system. Typically occurring in early childhood, the brain “favors” one eye while the other eye is underused. As a result, the visual pathway does not develop properly, and the child experiences poor vision, and, potentially, blindness in the affected eye. While amblyopia is not currently preventable, it can be treated successfully with early intervention.

Here are some additional amblyopia facts:

- According to the U.S. Preventive Services Task Force, amblyopia is the most common cause of vision problems in children; it is estimated that four out of every 100 children (4 %) under age six have amblyopia.
- Children can develop amblyopia at any time from birth.
- An estimated 200,000 children are born each year with visual deficits like amblyopia, reports the Journal of American Association for Pediatric Ophthalmology and Strabismus.
- Amblyopia often results from either a misalignment of a child's eyes, such as crossed eyes (which are noticeable to the parent or doctor), or a difference in image-processing quality between the two eyes. One eye focuses better than the other (which is not easily detected by a parent and difficult to diagnose in a traditional pediatric exam).
- A child with amblyopia may not know that he or she is using only one eye, because they don't know what “normal” vision is and can't tell the difference, or are too young to verbalize the difference.
- Amblyopia usually affects only one eye, but it may occur in both eyes.
- Some children with amblyopia may have an eye that wanders or does not move in sync with the other eye, which may be noticeable. But in many cases, a child with amblyopia does not exhibit these obvious symptoms.
- Prevent Blindness America says that only one in five (21 %) children in the U.S. have their vision screened before kindergarten, with only 14 percent receiving a comprehensive eye exam.
- It's important to detect and treat amblyopia when a child is young because the first few years of life are critical for eyesight development; for most children, the brain's vision system is almost fully developed by age eight, making vision deficits more difficult to improve after this age.
- Amblyopia is commonly treated by patching or covering the strong eye for a period of time so that the weak eye is forced to work, encouraging proper development of that eye's visual pathway.
- According to the American Academy of Pediatrics (AAP), vision disorders are the fourth most common disability among children in the United States.
- The Children's Eye Foundation estimates that 4.5 million adults are legally blind or visually incapacitated in at least one eye due to amblyopia that was left untreated.

For more information on amblyopia, children's vision and the importance of early vision testing, visit www.KidsAmblyopiaTesting.com.