

# Sample Invention Report

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## I. Source Document

This sample is constructed from an actual patent application. Because we cannot show real invention reports that have been prepared for BML customers we because of the limitations of confidentiality we have chosen to construct this example taken from an actual patent. This document is intended to be complimentary to our material describing how an invention report is prepared and what materials go in each section.

**United States Patent 6,520,921 “Method for determining attention deficit hyperactivity disorder (ADHD) medication dosage and for monitoring the effects of (ADHD) medication”**

We have extracted sections from the above patent and edited them to show how they might look in an invention report. A comparison with the actual patent will show that the main differences are that the invention report is does not use legal language and is formatted for easy reading, as opposed to patent office practice.

## II. Abstract

A method for determining the appropriate dosage of a medication to treat Attention Deficit Hyperactivity Disorder (ADHD) in an individual who has ADHD which includes:1) sampling the peripheral skin temperature of a human subject during a predetermined time interval when the subject is in an inactive state to provide sampled peripheral skin temperature data; 2) analyzing the sampled peripheral skin temperature data for a pre-selected parameter to determine whether the pre-selected parameter has a value indicative of ADHD; and 3) determining the proper dosage of a medication to treat ADHD based upon the determined value of the pre-selected parameter.

## III. Phantom Claims

1. A method for determining the appropriate dosage of a medication to treat Attention Deficit Hyperactivity Disorder (ADHD) in an individual who has ADHD comprising:

- Sampling the peripheral skin temperature of a human subject during a predetermined time interval when the subject is in an inactive state to provide sampled peripheral skin temperature data;
- Analyzing the sampled peripheral skin temperature data for a pre-selected parameter to determine whether the pre-selected parameter has a value which indicates ADHD; and

- Determining the proper dosage of a medication to treat ADHD based upon the determined value of the pre-selected parameter.
2. The method of claim 1 wherein the analytical approach includes:
- dividing the sampled data into windows of subsets of data;
  - processing the subset data for each window with a Fast Fourier Transform (FFT) algorithm to produce FFT data having magnitude values;
  - calculating a magnitude range value for each window; and
  - aggregating the magnitude range values to produce an aggregate value; and
  - comparing the produced value with a previously determined threshold value to determine the proper dosage.

.....Additional phantom claims follow

## **IV. Background of the Invention**

ADHD is the most common neurobehavioral disorder of childhood as well as among the most prevalent health conditions affecting school-aged children. Between 4% and 12% of school age children (several millions) are affected. \$3 billion is spent annually on behalf of students with ADHD. Moreover, in the general population, 9.2% of males and 2.9% of females are found to have behavior consistent with ADHD. Upwards of 10 million adults may be affected.

ADHD is a difficult disorder to diagnose. The core symptoms of ADHD in children include inattention, hyperactivity, and impulsivity. ADHD children may experience significant functional problems, such as school difficulties, academic under achievement, poor relationships with family and peers, and low self-esteem. Adults with ADHD often have a history of losing jobs, impulsive actions, substance abuse, and broken marriages. ADHD often goes undiagnosed if not caught at an early age and affects many adults who may not be aware of the condition. ADHD has many look-alike causes (family situations, motivations) and co-morbid conditions (depression, anxiety, and learning disabilities) are common.

Diagnosis of ADHD involves a process of elimination using written and verbal assessment instruments. However, there is no one objective, independently validated test for ADHD. Various objective techniques have been proposed but have not yet attained widespread acceptance. These include:

- The eye problem called convergence insufficiency was found to be three times more common in children with ADHD than in other children by University of California, San Diego researchers.
- Infrared tracking to measure difficult-to-detect movements of children during attention tests combined with functional MRI imaging of the brain were used by psychiatrists at McLean Hospital in Belmont, Mass. to diagnose ADHD in a small group of children (Nature Medicine, Vol. 6, No. 4, April 2000, Pages 470-473).
- Techniques based on EEG biofeedback for the diagnoses and treatment of ADHD are described by Lubar (Biofeedback and Self-Regulation, Vol. 16, No. 3, 1991, Pages 201-225).
- In US 6,097,980; Monastra et al, discloses a quantitative electroencephalographic process assessing ADHD.
- Several patents by Brown: disclose the use of video game for the diagnosis and treatment of ADHD including: US 5,913,310, US 5,918,603 and U.S. 5,940,801.....

## V. Description of the Invention

According to the invention, it has been found that a signature of ADHD is hidden in fluctuation of the temperature of the skin as measured at the extremities such as at a fingertip. In general, as an individual's stress level increases the peripheral vasculature constricts and often the person's blood pressure increases. As the blood vessels in the body constrict, blood flow is restricted.

This is most easily monitored in the extremities such as the fingers, because the blood vessels in the extremities are small and very responsive to Sympathetic Nervous System (SNS) innervations. A direct result of decreased blood flow to the blood vessels in the extremities is a decrease in the peripheral temperature of the extremities. Conversely, as an individual's stress level decreases and relaxation occurs, the blood vessels expand, allowing blood to flow in a less restricted manner. As the blood flow to the vessels in the extremities increases the peripheral temperature of the extremities increases.

It is suspected that when a subject with ADHD is subjected to sensory deprivation such as being made to look at a blank screen or an obscured image for a period of time in an inactive state, the lack of stimulation increases and there tends to be a shift in the subject's physiologic reactivity indicative of an increase in their stress level.

As their stress level increases their blood vessels contract and the peripheral temperature of their extremities decreases. Biofeedback practitioners have long used measurement of hand temperature to help subjects manage their physiology by controlling blood flow to the extremities. The literature reports that reduced blood flow to the brain is frequently found in patients with ADHD....

As shown in FIG. 1, a subject 10 is sitting on a chair 12 at a table 13 watching a screen 14. The screen 14 is used to block any visual stimulus from disturbing the subject 10. The subject 10 is wearing a set of earphones 20. The earphones 20 can be connected to a sound-generating device not shown.

The earphones 20 can be used to block out ambient noise or to produce a white noise intended to reduce or eliminate the audio stimulus from the environment during the test.

The subject is at rest in an inactive state.

The fingertip 16 of subject 10 is inserted into an analyzer module **A1**, where the skin temperature is measured via a sensor 22 (shown in FIG. 2). In another embodiment of the present invention, which is not shown, the subject can wear a pair of translucent glasses, goggles or eye mask. The glasses or goggles are used to block any visual stimulus from the subject.

## VI. Figures

The figure below is (Fig 1) taken from the patent. BML will use figures you supply and will convert them to standard patent format as shown below. We can also draft figures for you from sketches.

Note that we have replaced the callout #18 from the patent with the letter A1. We mark all figures with codes in this fashion. Patent figures are required to be numbered sequentially starting at the first figure. Since we don't know which figures will be used in the ultimate application and in what order, we use the nomenclature A1,A2,A3... B1,B2,B3 where A and B refer to a specific figure. When the figures are finally placed it is a simple matter to replace all the textual callouts and have them still apply to the correct item on the correct figure.

