

PHYSIOLOGICAL AND ENVIRONMENTAL MONITORING  
SYSTEMS, ASSESSMENTS, AND METHODS

RELATED APPLICATION

This application claims the benefit of and priority to U.S.  
Provisional Patent Application No. 60/905,761, filed March 8, 2007, U.S.  
Provisional Patent Application No. 60/876,128, filed December 21, 2006, and  
5 U.S. Provisional Patent Application No. 60/875,606, filed December 19, 2006,  
the disclosures of which are incorporated herein by reference as if set forth in  
their entireties.

FIELD OF THE INVENTION

10 The present invention relates generally to health and, more  
particularly, to health monitoring.

BACKGROUND

There is growing market demand for personal health and  
15 environmental monitors, for example, for gauging overall health and metabolism  
during exercise, athletic training, dieting, and physical therapy. However,  
traditional health monitors and environmental monitors may be bulky, rigid, and  
uncomfortable – generally not suitable for use during daily physical activity.  
There is also growing interest in generating and comparing health and  
20 environmental exposure statistics of the general public and particular  
demographic groups. For example, collective statistics enable the healthcare  
industry and medical community to direct healthcare resources to where they are  
most highly valued. However, methods of collecting these statistics may be  
expensive and laborious, often utilizing human-based recording/analysis steps at  
25 multiple sites.

# EXHIBIT 2113

## SUMMARY

In view of the above discussion, systems and methods for monitoring various physiological and environmental factors, as well as systems and methods for using this information for a plurality of useful purposes, are provided. According to some embodiments of the present invention, real-time, noninvasive health and environmental monitors include a plurality of compact sensors integrated within small, low-profile devices. Physiological and environmental data is collected and wirelessly transmitted into a wireless network, where the data is stored and/or processed. This information is then used to support a variety of useful methods, such as clinical trials, marketing studies, biofeedback, entertainment, and others.

Though the methods herein may apply broadly to a variety of form factors for a monitoring apparatus, in some embodiments of the invention an earpiece functions as a physiological monitor, an environmental monitor, and a wireless personal communicator. Because the ear region is located next to a variety of "hot spots" for physiological and environmental sensing – including the tympanic membrane, the carotid artery, the paranasal sinus, etc. – in some cases an earpiece monitor takes preference over other form factors. The earpiece can take advantage of commercially available open-architecture, ad hoc, wireless paradigms, such as Bluetooth®, Wi-Fi, or ZigBee. In some embodiments, a small, compact earpiece contains at least one microphone and one speaker, and is configured to transmit information wirelessly to a recording device such as, for example, a cell phone, a personal digital assistant (PDA), and/or a computer. The earpiece contains a plurality of sensors for monitoring personal health and environmental exposure. Health and environmental information, sensed by the sensors is transmitted wirelessly, in real-time, to a recording device, capable of processing and organizing the data into meaningful displays, such as charts. In some embodiments, an earpiece user can monitor health and environmental exposure data in real-time, and may also access records of collected data throughout the day, week, month, etc., by observing charts and data through an audio-visual display.

Each physiological sensor is configured to detect and/or measure one or more of the following types of physiological information: heart rate, pulse rate, breathing rate, blood flow, heartbeat signatures, cardio-pulmonary health,

organ health, metabolism, electrolyte type and/or concentration, physical activity, caloric intake, caloric metabolism, blood metabolite levels or ratios, blood pH level, physical and/or psychological stress levels and/or stress level indicators, drug dosage and/or dosimetry, physiological drug reactions, drug chemistry, biochemistry, position and/or balance, body strain, neurological functioning, brain activity, brain waves, blood pressure, cranial pressure, hydration level, auscultatory information, auscultatory signals associated with pregnancy, physiological response to infection, skin and/or core body temperature, eye muscle movement, blood volume, inhaled and/or exhaled breath volume, physical exertion, exhaled breath physical and/or chemical composition, the presence and/or identity and/or concentration of viruses and/or bacteria, foreign matter in the body, internal toxins, heavy metals in the body, anxiety, fertility, ovulation, sex hormones, psychological mood, sleep patterns, hunger and/or thirst, hormone type and/or concentration, cholesterol, lipids, blood panel, bone density, organ and/or body weight, reflex response, sexual arousal, mental and/or physical alertness, sleepiness, auscultatory information, response to external stimuli, swallowing volume, swallowing rate, sickness, voice characteristics, voice tone, voice pitch, voice volume, vital signs, head tilt, allergic reactions, inflammation response, auto-immune response, mutagenic response, DNA, proteins, protein levels in the blood, water content of the blood, pheromones, internal body sounds, digestive system functioning, cellular regeneration response, healing response, stem cell regeneration response, and/or other physiological information.

Each environmental sensor is configured to detect and/or measure one or more of the following types of environmental information: climate, humidity, temperature, pressure, barometric pressure, soot density, airborne particle density, airborne particle size, airborne particle shape, airborne particle identity, volatile organic chemicals (VOCs), hydrocarbons, polycyclic aromatic hydrocarbons (PAHs), carcinogens, toxins, electromagnetic energy, optical radiation, X-rays, gamma rays, microwave radiation, terahertz radiation, ultraviolet radiation, infrared radiation, radio waves, atomic energy alpha particles, atomic energy beta-particles, gravity, light intensity, light frequency, light flicker, light phase, ozone, carbon monoxide, carbon dioxide, nitrous oxide, sulfides, airborne pollution, foreign material in the air, viruses, bacteria,

signatures from chemical weapons, wind, air turbulence, sound and/or acoustical energy, ultrasonic energy, noise pollution, human voices, animal sounds, diseases expelled from others, exhaled breath and/or breath constituents of others, toxins from others, pheromones from others, industrial and/or transportation sounds, allergens, animal hair, pollen, exhaust from engines, vapors and/or fumes, fuel, signatures for mineral deposits and/or oil deposits, snow, rain, thermal energy, hot surfaces, hot gases, solar energy, hail, ice, vibrations, traffic, the number of people in a vicinity of the person, coughing and/or sneezing sounds from people in the vicinity of the person, loudness and/or pitch from those speaking in the vicinity of the person, and/or other environmental information.

In some embodiments, the signal processor is configured to process signals produced by the physiological and environmental sensors into signals that can be heard and/or viewed by the person wearing the apparatus. In some embodiments, the signal processor is configured to selectively extract environmental effects from signals produced by a physiological sensor and/or selectively extract physiological effects from signals produced by an environmental sensor.

A monitoring system, according to some embodiments of the present invention, may be configured to detect damage to a portion of the body of the person wearing the apparatus, and may be configured to alert the person when such damage is detected. For example, when a person is exposed to sound above a certain level that may be potentially damaging, the person is notified by the apparatus to move away from the noise source. As another example, the person may be alerted upon damage to the tympanic membrane due to loud external noises.

Information from the health and environmental monitoring system may be used to support a clinical trial and/or study, marketing study, dieting plan, health study, wellness plan and/or study, sickness and/or disease study, environmental exposure study, weather study, traffic study, behavioral and/or psychosocial study, genetic study, a health and/or wellness advisory, and an environmental advisory. The monitoring system may be used to support interpersonal relationships between individuals or groups of individuals. The monitoring system may be used to support targeted advertisements, links,

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