Daniel Merfeld
Steven Rauch
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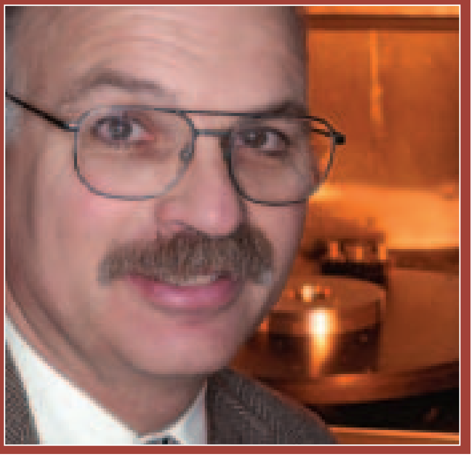

Balance Prosthesis

Patent No. 6,546,291 B2, Issued April 8, 2003

Over 90 million Americans will seek medical attention for dizziness, a malfunction of the inner ear, at least once in their lifetime. Relying on the low weight and excellent performance available in Draper Microelectromechanical System (MEMS) inertial instruments, we developed and successfully tested a prototype vestibular prosthesis. Balance-impaired patients who were unable to stand unaided stood with the prosthesis. Multiple-axes tilt modules are now being tested at three sites.

The inner ear vestibular organs, which detect linear and angular accelerations, vision, and proprioception (forces sensed by ankles or finger touch) are the sensors that work with the brain to effect balance. If one of these inputs is lost, the body can usually compensate after an adjustment period of days or weeks; thus, a vestibular prosthesis would be useful for people recovering from inner ablative surgery and for those with temporary dizziness. The elderly, in whom multiple sensor functions are often impaired and for whom falling is a leading cause of injury and death, would benefit.

The patent describes a vestibular prosthesis that consists of MEMS inertial instruments, a computer, and a stimulator. Usually mounted to the torso, the instruments detect the subject's angular rate and acceleration plus gravity. The digital processor separates gravity from acceleration by spectral content and combines the accelerometer and gyroscope signals so that modestly performing instruments can perform the balance function with suitable accuracy. Much of the patent deals with these unique algorithms.

There are several means to convey the vertical information to the patient. The patient's inner ear nerves can be stimulated by electrical impulses, much in the manner of a cochlear implant. Thus far, our testing has employed invasive, externally-worn vibrators that are located circumferentially about the torso. The prosthesis can also be used with other navigational sources, such as GPS, to further assist in position location and orientation.

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Merfeld et al.

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(54) **BALANCE PROSTHESIS**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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(65) **Prior Publication Data**

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Related U.S. Application Data

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(51) **Int. Cl.**[7] **A61N 1/08**
(52) **U.S. Cl.** **607/62**
(58) **Field of Search** 607/48, 49, 62; 600/595

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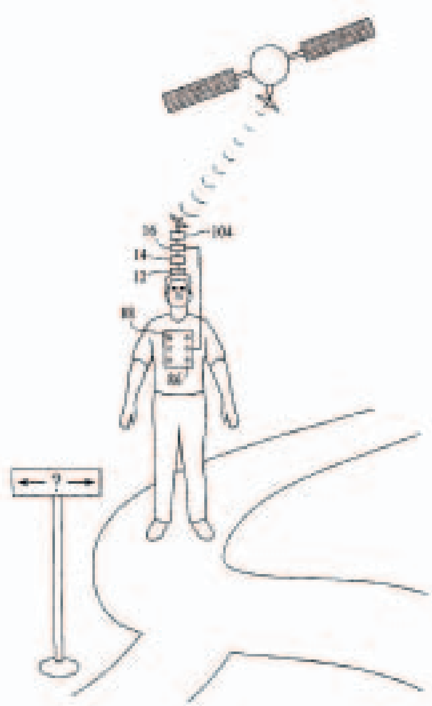
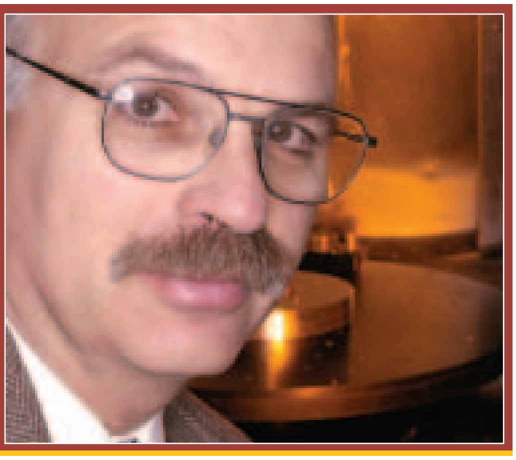
(57) **ABSTRACT**

A wearable balance prosthesis provides a information indicative of a wearer's spatial orientation. The balance prosthesis includes an motion sensing system to be worn by the wearer and a signal processor in communication with the motion sensing system. The signal processor provides an orientation signal to an encoder. The encoder generates a feedback signal on the basis of the estimate of the spatial orientation provides that signal to a stimulator coupled to the wearer's nervous system.

17 Claims, 11 Drawing Sheets





BIOGRAPHIES

DANIEL MERFELD is an Associate Professor of Otology and Laryngology at Harvard Medical School and in the joint Harvard-MIT Whitaker College of Health Sciences Technology. He is the Founder and Director of the Jenks Vestibular Physiology Laboratory at the Massachusetts Eye and Ear Infirmary. Dr. Merfeld was honored in 1995 as the Biomedical Engineering Society's Whitaker Young Investigator. He received a BS in Mechanical Engineering from the University of Wisconsin, Madison, an MS in Mechanical and Aerospace Engineering from Princeton University, and a PhD in Biomedical Engineering from MIT.

STEVEN RAUCH is an Associate Professor of Otology and Laryngology at Harvard Medical School and member of the Otology Service of the Massachusetts Eye and Ear Infirmary. He also serves as Associate Medical Director of the Jenks Vestibular Diagnostic Laboratory. Dr. Rauch divides his time between clinical practice of otology and sponsored research into disorders of hearing and balance, including autoimmune inner ear disease, sudden deafness, and Meniere's disease. His research has been continuously supported by the National Institutes of Health (NIH) for 18 years. He has served on the Equilibrium Committee of the American Academy of Otolaryngology – Head and Neck Surgery and on numerous editorial boards. He did his General Surgery internship and residency at University of Massachusetts Medical Center and his Otolaryngology Residency at Massachusetts Eye and Ear Infirmary, where he has been a faculty member since 1984. Dr. Rauch received a BA cum laude in Biology from Amherst College and an MD from University of Cincinnati Medical School.

CONRAD WALL, III is an Associate Professor of Otology and Laryngology at Harvard Medical School and in the joint Harvard-MIT Whitaker College of Health Sciences Technology. He is the Founder and Director of the Jenks Vestibular Diagnostic Laboratory at the Massachusetts Eye and Ear Infirmary where he also participates in sponsored research. He is Project Lead and Associate Team lead in the Neurovestibular Adaptation Team of NASA's National Space Biomedical Research Institute, and Project Lead of the Balance Project at the Infirmary's Neural Prosthesis Research Center. Dr. Wall chairs the working group in charge of the ANSI standard on the vestibular function test battery. He received BS and MS degrees in Physics from Tulane University and a PhD in Bioengineering from Carnegie-Mellon University.

MARC WEINBERG is Laboratory Technical Staff in the Hardware Design and Development Directorate at Draper. He is responsible for the design and testing of a wide range of micromechanical gyroscopes, accelerometers, hydrophones, microphones, angular displacement sensors, chemical sensors, and biomedical devices. He holds 21 patents with 11 additional in application. He was given Draper's Best Patent Award (three times), Best Publication Award (twice), and a Distinguished Performance Award for his work on the tuning-fork gyro, the first silicon micromechanical gyroscope to demonstrate resolution better than 100 deg/h in 60 Hz, and other MEMS work. He has been an ASME member since 1973. He received BS, MS, and PhD degrees from MIT in Mechanical Engineering.