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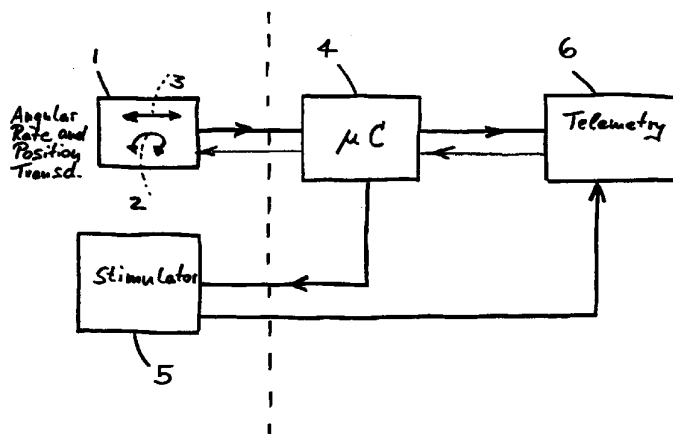
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(54) **Balance prosthesis apparatus and method**

(57) A balance prosthesis apparatus comprises transducers (1) for detecting and measuring the upper body movements, and means for providing information on the changes in the amplitudes and frequency of

these movements over time to the subject using either vibro-tactile, auditory, visual or direct electrical stimulation to the subject.

Fig.1



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Description

This invention concerns a prosthetic apparatus and method which would augment the balance signals normally used by the brain to control the body in a stable position and prevent a fall.

Quantitative information on the efficacy of the human sense of balance can at present be obtained for medical purposes using eye movements or postural responses of the limbs measured electrophysiologically to determine if a response is outside of limits expected for individuals with a normal balance function. In the case when an individual has eye movements or postural responses outside normal limits then medication is given to that individual to reduce the action of peripheral senses on the brain or the individual takes part in a course of physical therapy over several weeks with the objective of training the brain to deal with a reduced sense of balance when trying to maintain the body upright and preventing a fall. However, these techniques do not fully meet the requirements of the clinician for a technique which would immediately augment the balance signals used by the brain. Difficulties arise with the presently available techniques mentioned above because the first kind, medication, can also reduce the capability of the brain to process balance information from the peripheral senses (vestibular, proprioceptive and visual) and because the second kind requires a long training period over more than two months. These difficulties are most evident when the subject is older than 65 years of age and likely to have a falling tendency, and when it would be advisable for a central monitoring station or a relative of the subject to know if the subject was in danger of falling.

In the field of hearing which is physiologically related to that of balance two types of prosthesis exist to augment the sense of hearing. The first kind involves augmenting the sound waves in the external ear canal so that these have greater excursions when they reach the inner ear to be transduced into electrical signals reaching the brain. The second kind involves direct electrical stimulation to the inner ear. For the sense of balance for which sensory signals from different neurophysiological systems, including a major input from the vestibular system of the inner ear, are combined by the brain to yield a unitary sense of balance no prosthetic device exists.

Therefore it is the object of the present invention to provide a prosthetic device which does not reduce the capability of the brain to process balance information from the peripheral senses (vestibular, proprioceptive and visual) and which requires no long training period over more than two months and therewith improves the current situation.

This object is solved with an apparatus according to the characterizing part of claim 1 and a method according to the characterizing part of claim 10. Preferred embodiments of the apparatus and the method of the invention are defined in the respective dependent

claims.

The invention has arisen from two findings, both contrary to present understanding. The first finding is that the unitary sense of balance computed by the human brain is directed towards monitoring the upper body with a minimum angular velocity within a cone of angular stability. Once this cone of stability is exceeded with an excessive angular velocity, normal individuals will respond by correcting the trunk's position within 200 msecs. The second finding concerns the relationships between angular and linear accelerations of the head sensed by the vestibular system in the inner ear, and angular and linear accelerations of the trunk during balance disturbances. These two findings are utilised in the current invention to develop the method and apparatus for a balance prosthesis.

Accordingly, in a more general form thereof, the present invention provides a method and an apparatus for a balance prosthesis comprising a means for measuring the angular position and rate of the trunk, a means for comparing the current angular position and rate of the trunk to known safe limits, means for providing the information measured via any of four different sensory modalities and its relation to the safety limits to the subject, and means for providing the aforementioned measured information, safety limits and the functional status of the apparatus used to provide this information to the subject to any monitoring station interested in knowing the subject's state of balance.

In order that this invention may be better understood, the same will now be described by way of example with reference to the accompanying figure 1 which schematically illustrates one form of the invention as developed so far.

The illustrated form of the invention is of the more particular form mentioned above and comprises an angular rate and position transducer 1 worn by the subject on his/ her upper body firmly attached to the chest or lower neck. This transducer measures the angular rate and position in pitch (fore-aft), roll (side-to-side) and, if necessary, in the yaw direction (turning about the vertical axis) as illustrated by the arrow 2. The technique used to measure the angular rate or position of the subject's trunk with respect to the earth's coordinates is not specific for the invention. The angular position, rate, or acceleration could be measured and then integrated or differentiated respectively to yield angular rate and position. In another form of the transducer linear acceleration transducers can be used as illustrated by the arrow 3. In this latter form pairs of linear acceleration transducers can be used to generate angular acceleration measurements. In a further form the transducer 1 can be firmly attached to the head either by placing it in an ear mould in the external ear canal or it can be attached to a pair of spectacles. The angular rate and position signals from the head-mounted transducer would then be transformed to trunk rate and position in a microprocessor 4 or other equivalent electronics using algorithms that relate the angular rate

and position of the head to those of the trunk during balance perturbations.

The processor 4 carries a detector and transformer stages. As indicated above the detector stages examine angular velocity and position signals separately for rotations in pitch, yaw and roll planes and detect if either a rotation angle or velocity exceeds safety limits previously set in the processor 4. On the basis of the development of the invention so far it can be expected that the safety limits for backwards pitching will be 3 deg and 30 deg/sec and for forwards pitching 6 deg and 100 deg/sec. The detailed form of the safety limits in each of the rotation planes appear to vary uniquely between individual patients requiring a test of the patients balance capability to build into the processor 4 rather than relying on a standard set of safety limits.

The transformer stage converts the angular rate and position signals from the transducer 1 as appropriate for the mode of stimulation (visual, vibrotactile, aural or electrical) used by the wearable stimulator 5. In the current form of the invention for vibro-tactile stimulation three vibrators are used to convey a sense of rotation in one direction. Two vibrators operate at 250 Hz, each conveying, for example, a sense of forwards and backwards sway with a modulation of the frequency of vibration corresponding to the velocity of sway and the amplitude of vibration corresponding to the angle of sway. The third vibrator in this form of the invention is used to signal the fact that sway has exceeded the limits of safety.

In another development of the invention the position and angular rate of the trunk is displayed to the subject in a head-mounted visual see-through display. In this form of the invention exceeding the safety limits is conveyed to the subject using repetitive changes in intensity of the display.

In a further development of the invention the position and angular rate of the trunk is transformed into a varying auditory signal the subject hears. In this form of the invention exceeding the safety limits or a sense of motion of the trunk or head is conveyed to the subject using the emission of sound.

In a still further development of the invention the position and angular rate of the trunk is transformed into a varying electrical signal directly stimulating the vestibular nerve and sensed as a change in an angular and/or linear position of the head. In this form of the invention exceeding the safety limits is conveyed to the subject using direct electrical stimulation of the vestibular nerve of the subject in his/her inner ear, therefore control signals for such direct electrical stimulation are transmitted transcutaneously to an implantable device directly connected via electrodes to the close proximity of the vestibular nerve or to the nerve itself and the pulse rate and duty cycle of the electrical stimulation at the electrodes vary according to the amplitudes and frequencies produced while measuring the movements of the upper body.

In a simple form of the apparatus, only the trans-

ducer and stimulator are worn by the subject as indicated by the dashed vertical line in figure 1. The signals from the transducer 1 and control signals to the stimulator 5 can be transmitted telemetrically to an external processor 4. Furthermore, the external processor can monitor telemetrically the status of the transducer 1 and/or stimulator 5. In a more sophisticated apparatus the processor 4 can also be worn by the subject. In an even more sophisticated device signals from the processor 4 and from the stimulator 5 can be passed telemetrically to and from a central monitoring station 6 which can control the state of instability of the wearer and whether the wearer is receiving adequate warning that he/she is in danger of falling.

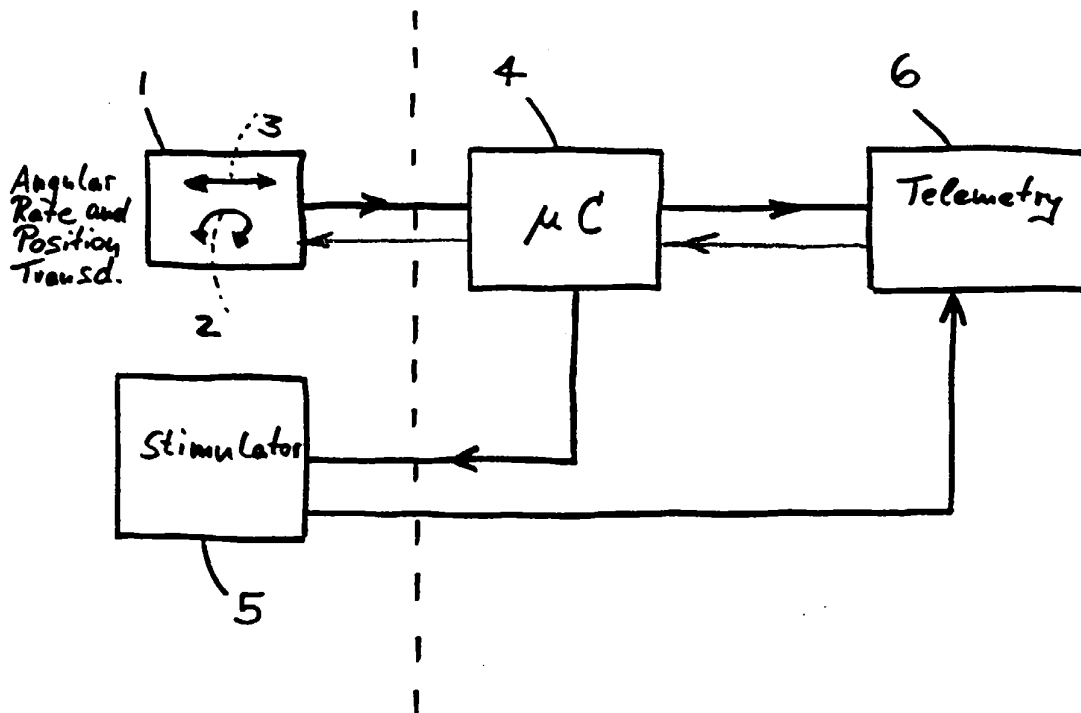
Turning lastly to the question of practical application of the invention: it is clear from the above discussion that the invention finds its primary application in augmenting the sense of balance of the elderly and others prone to fall, thereby helping to prevent a fall. Another application of the invention is to monitor the safety of a large number of patients who are in danger of falling as well as providing a record of how and when a patient in a home for the elderly actually fell. A third application is directly related to the individual limits of safety for impeding a fall of the subject. Modifications of these safety limits over time provides a way to test the efficacy of medication on balance function.

Claims

1. Balance prosthesis apparatus **characterised by** means for detecting and measuring the upper body movements, and means for providing information on the changes in the amplitudes and frequency of these movements over time to the subject using either vibro-tactile, auditory, visual or direct electrical stimulation to the subject.
2. Apparatus according to claim 1 **characterised in that** said detecting and measuring means includes motion measuring systems whose primary mode of operation is a measurement of linear or angular changes in the position or velocity or acceleration of the trunk or head of the subject.
3. Apparatus according to claim 2 **characterised by** angular velocity transducers mounted on the trunk of the subject and capable of measuring angular velocities at least in the range 0 to 1000 deg/sec from 0 Hz up to a frequency of 100 Hz.
4. Apparatus according to anyone of claims 1 to 3, **characterized in that** the information gathered by said detecting and measuring means is transformed to a varying vibro-tactile signal the subjects feels by the means for providing information to the subject consisting of one or more vibro-tactile devices placed on the skin of the subject either on the chest or on the back of the neck, or on the upper

- legs and capable of transmitting a sense of motion of the trunk or head to the subject using vibration.
5. Apparatus according to anyone of claims 1 to 3, **characterized in that** the information gathered by said detecting and measuring means is transformed to a varying auditory signal the subject hears by the means for providing information to the subject consisting of an aural probe for insertion in the external canal of the subject's ear and said probe is capable of emitting sound conveying a sense of motion of the trunk or head to the subject.
 6. Apparatus according to anyone of claims 1 to 3, **characterized in that** the information gathered by said detecting and measuring means is transformed to a visual signal the subject sees by the means for providing information to the subject consisting of a see-through head-mounted display in which the subject sees a visual display of the position or velocity of the trunk or head with either the left or right eye or both eyes and thereby visually senses motion of the trunk or head.
 7. Apparatus according to anyone of claims 1 to 3, **characterized in that** the information gathered by said detecting and measuring means is transformed to a varying electrical signal directly stimulating the vestibular nerve and sensed as a change in an angular and/or linear position of the head by the means for providing information to the subject consisting of a means for direct electrical stimulation of the vestibular nerve of the subject in his/her inner ear, wherein control signals for such direct electrical stimulation are transmitted transcutaneously to an implantable device directly connected via electrodes to the close proximity of the vestibular nerve or to the nerve itself, and the pulse rate and duty cycle of the electrical stimulation at the electrodes vary according to the amplitudes and frequencies measured by said detecting and measuring means.
 8. Apparatus according to anyone of claims 1 to 7, **characterized by** a processor in which a set of safety rules is determined for each axis of turning of the body (pitch, roll and yaw) consisting of limits of angular velocity and angular position separate for each axis in the positive and negative direction which the trunk and/or head must not exceed if a fall is to be avoided.
 9. Apparatus according to claim 8, **characterized by** transmitting means which transmit the status of the trunk and/or head movements when exceeding said safety rules and the status of said means for providing information to the subject or to a central monitoring station telemetrically.
 10. Balance prosthesis method **characterised by** providing information on the changes in the amplitudes and frequency of movements of the upper body over time to the subject using either vibro-tactile, auditory, visual or direct electrical stimulation to the subject, thereby inducing a reduction in upper body movements to be within safe limits.
 11. Method according to claim 10, **characterised in that** said movements of the upper body are primary measured as linear or angular changes in the position or velocity or acceleration of the trunk or head of the subject.
 12. Method according to claim 11, **characterised by** measuring angular velocities at least in the range 0 to 1000 deg/sec from 0 Hz up to a frequency of 100 Hz.
 13. Method according to anyone of claims 10 to 12, **characterized in that** the information about the movements of the upper body is transformed to a) a varying vibro-tactile signal the subjects feels, or b) a varying auditory signal the subject hears, or c) a visual signal the subject sees, or d) a varying electrical signal directly stimulating the vestibular nerve and sensed as a change in an angular and/or linear position of the head.
 14. Method according to claim 13, **characterized in that** for said direct electrical stimulation of the vestibular nerve of the subject in his/her inner ear control signals for such direct electrical stimulation are transmitted transcutaneously to an implantable device directly connected via electrodes to the close proximity of the vestibular nerve or to the nerve itself, and the pulse rate and duty cycle of the electrical stimulation at the electrodes vary according to the amplitudes and frequencies produced while measuring the movements of the upper body.
 15. Method according to anyone of claims 10 to 14, **characterized in that** a set of safety rules is determined for each axis of turning of the body (pitch, roll and yaw) consisting of limits of angular velocity and angular position separate for each axis in the positive and negative direction which the trunk and/or head must not exceed if a fall is to be avoided.
 16. Method according to claim 15, **characterized in that** the status of the trunk and/or head movements exceeding said safety rules and the status of the transformation of the information about the movements of the upper body are transmitted to a central monitoring station telemetrically.

Fig.1





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EUROPEAN SEARCH REPORT

Application Number
EP 96 10 4356

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	US-A-4 092 633 (FLETCHER JAMES C ADMINISTRATOR ET AL) 30 May 1978 * the whole document * ---	1,2,5, 10,11,13	A61B5/00 A61N1/36
A	US-A-5 469 861 (PISCOPO MARK F ET AL) 28 November 1995 * the whole document * ---	1,2,4, 8-11,13, 15,16	
A	WO-A-88 04909 (NEUROCOM INT INC) 14 July 1988 * abstract; claim 1; figures * ---	1,2,7, 10,11,14	
A	DE-A-34 16 873 (SCHEUNEMANN RUEDIGER DIPL ING) 14 November 1985 * the whole document * ---	1,2,7, 10,11,14	
A	US-A-5 361 788 (R.H. SEITZ) 8 November 1994 * column 1, line 48 - column 2, line 16 * ---	1,10	
A	US-A-5 281 957 (SCHOOLMAN ARNOLD) 25 January 1994 * abstract; figures * -----	6	TECHNICAL FIELDS SEARCHED (Int.Cl.6) A61B A61N
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 10 July 1996	Examiner Ferrigno, A
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

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