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(54) SMART APPARATUS FOR GAIT MONITORING AND FALL PREVENTION

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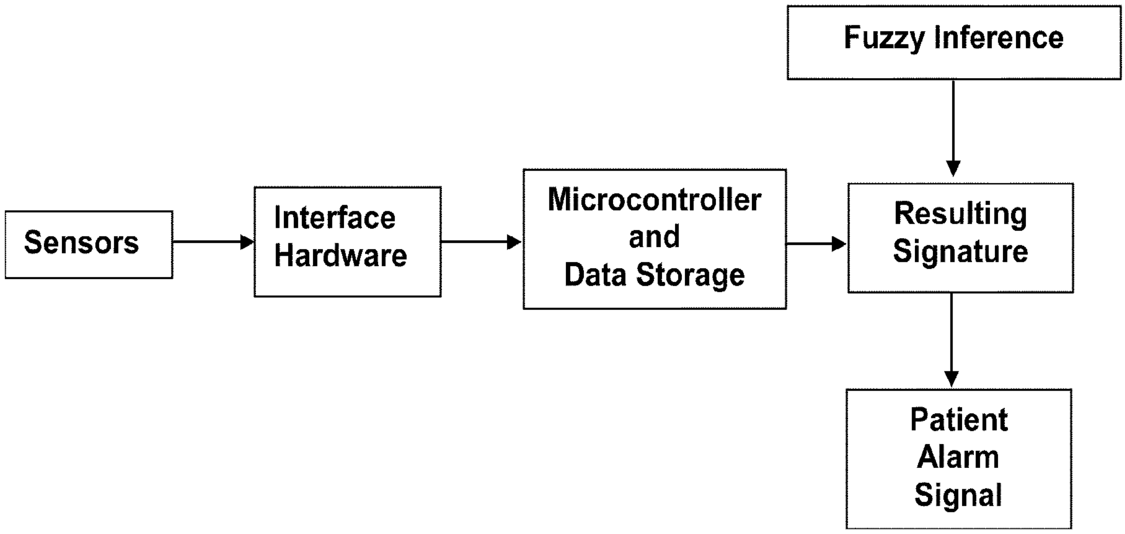
(57) ABSTRACT

Provided is a system for monitoring gait. More particularly, the system comprises: one or more pressure sensors; an algorithm which compares the data from the pressure sensor(s) to a stability profile, and provides a feedback value; means for communicating the feedback value; and a power source. Also provided is a method for gait analysis comprising: collecting signals from one or more pressure sensors located in pressure proximity to a foot, generating a test profile; comparing the test profile to a stability profile; generating a feedback signal; and communicating the feedback signal. The system may also comprise one or more accelerometers.



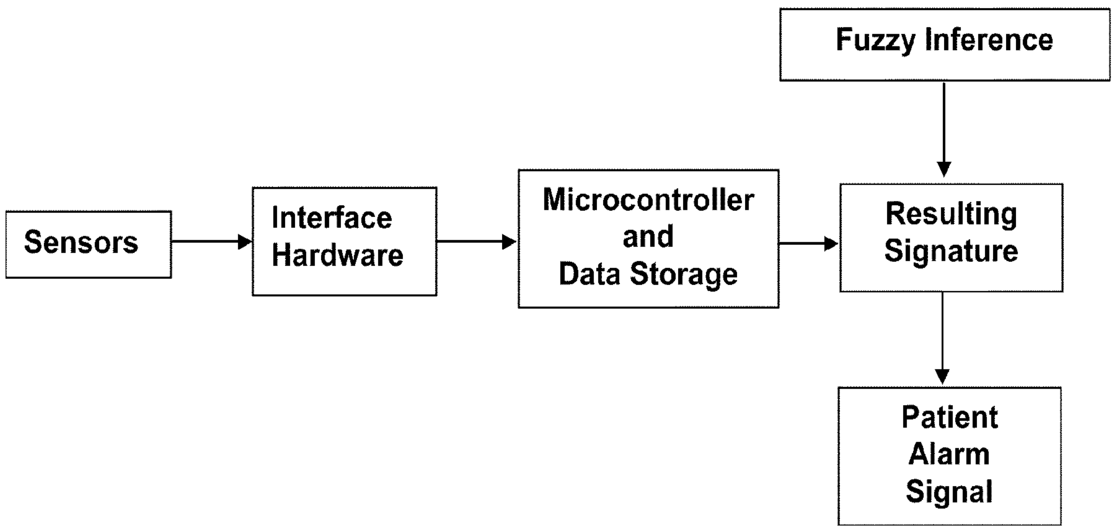

Fuzzy Inference
Sensors
Interface Hardware
Microcontroller and Data Storage
Resulting Signature
Patient Alarm Signal

FIGURE 1

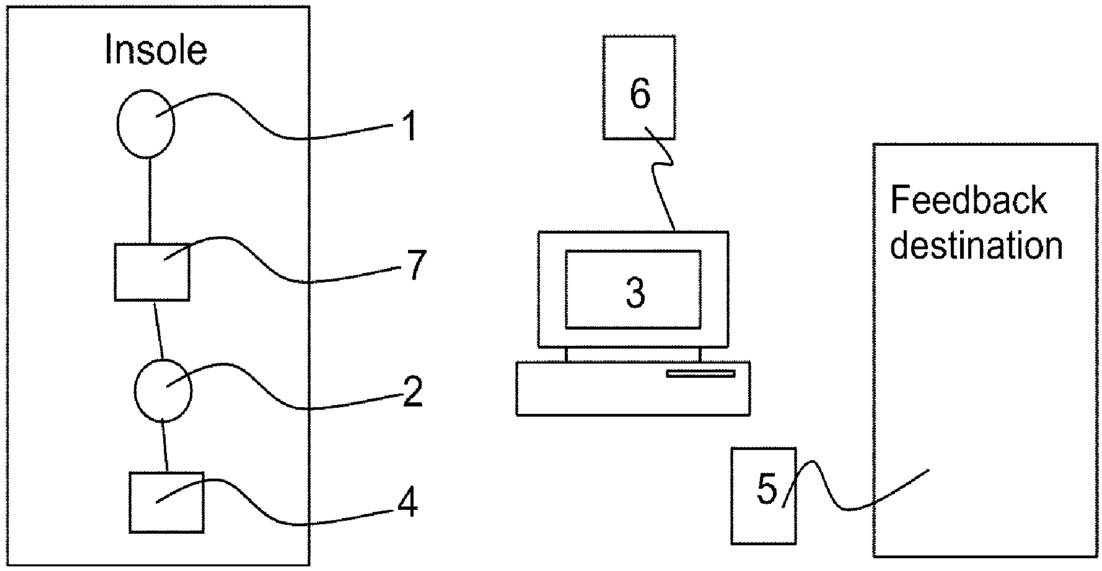


FIGURE 2

FIGURE 3

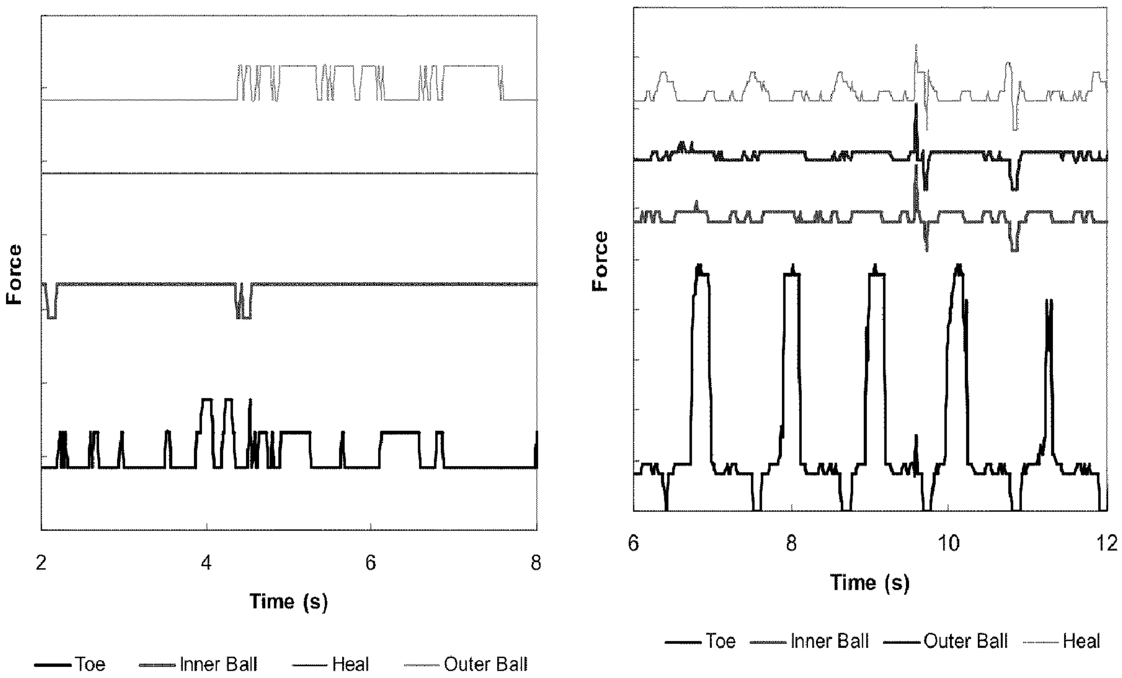
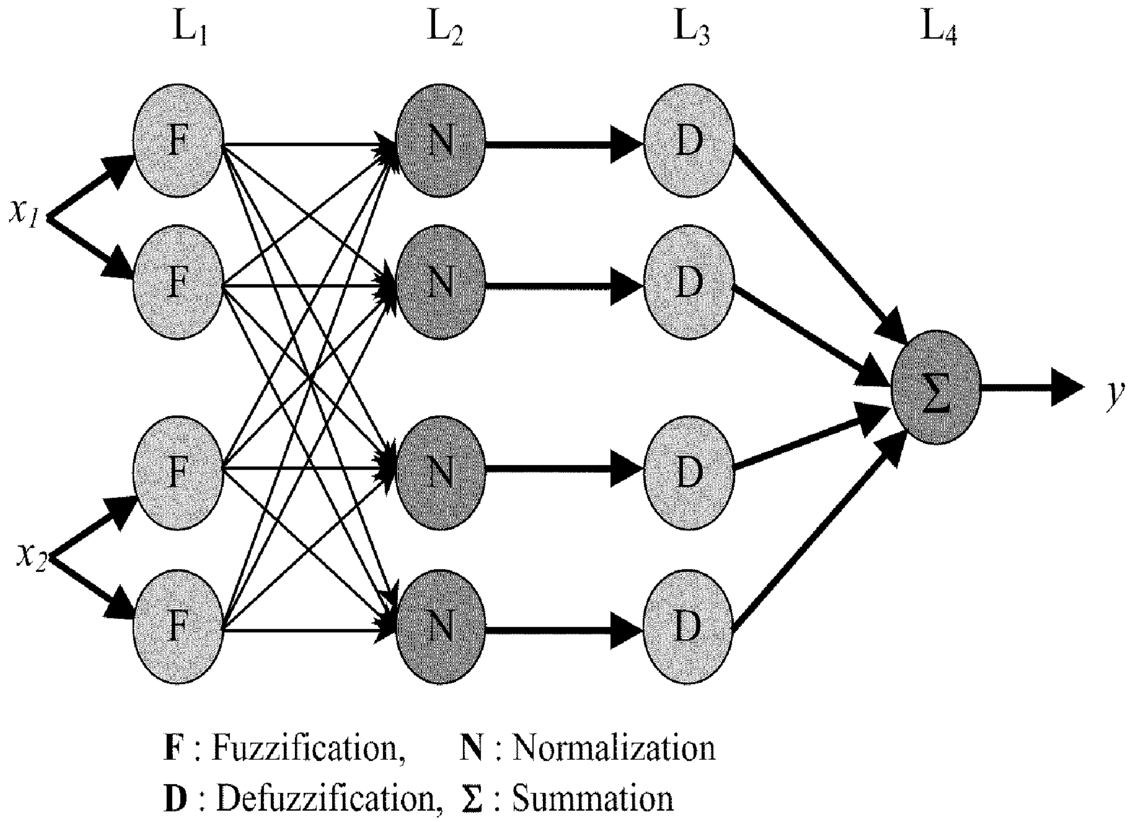

Force
2
4
6
8
Time (s)
Toe
Inner Ball
Heal
Outer Ball
Force
6
8
10
12
Time (s)
Toe
Inner Ball
Outer Ball
Heal

FIGURE 4



L_1
L_2
L_3
L_4
x_1
x_2
F
F
F
F
N
N
N
N
D
D
D
D
Σ
y
F : Fuzzification, **N** : Normalization
D : Defuzzification, **Σ** : Summation

FIGURE 5

SMART APPARATUS FOR GAIT MONITORING AND FALL PREVENTION

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. patent application Ser. No. 11/556,858, filed Nov. 6, 2006, which is hereby incorporated by reference to the extent not inconsistent with the disclosure herewith.

BACKGROUND OF THE INVENTION

[0002] Between 2011 and 2030 the demographics of the United States will dramatically change as the baby boomers retire. The percentage of people over age 65 will shift from 12% to 20% nationwide [Federal Interagency Forum on Aging Related Statistics, Key Indicators of Well-Being]. Coupled with this rising population is the knowledge that the greatest reduction in quality of life and highest percentage of health care costs are associated with individuals older than 85 years of age. Since 1950, the development of early detection and assistive technologies has improved the quality of life and life expectancy for seniors in the United States. Examples include: hip replacement numbers have risen well beyond 250,000 and the average age of death for men and women of all races has risen by 4.2 years or 5% [National Vital Statistics, 2002]. Further improvements must concentrate on accelerating these advances as well as reducing the associated costs. New sensors and computer technologies place these goals within reach.

[0003] 21^{st} century advances in the care of the elderly will utilize embedded technology within a care delivery and prevention plan. Consequently, the technology must assist the patient with evaluating and building on their own strengths, while decreasing the time and labor commitments of caregivers. Data collection must be held to a minimum to maintain sensitivity while monitors/sensors used for data collection need to be small, non-intrusive, and affordable.

[0004] Diminished stability in older adults poses a serious health risk resulting from fall events. Approximately 28% of people between 70-79 years of age, 47% of people between 80-90 years of age and 65% of people between 90-99 years of age die from injuries related to falling [National Safety Council, 2000]. More than one-third of adults over 65 years of age report at least one fall per year, and more than 10% of these falls lead to serious injury. In 1994, fall related medical expenses in the aging population exceeded $20 billion, and this is anticipated to reach $32 billion by 2020. The prevention of falls in the aging population has become a leading health issue in America.

[0005] Skin, bone and muscle injuries do not completely account for the decline in mobility observed after a fall. More than 70% of women and 26% of men over the age of 60 who have experienced a fall report a fear of falling that leads to a significant increase in balance or gait disorders. Following a fall, these individuals reduce their activity out of fear, further increasing their risk of a fall and hampering their rate of recovery, as one day in bed translates into 7 to 14 new days of physical therapy to regain the same degree of mobility. Recent studies indicate that older adults who fell during a given 12-month period were 50% more likely to die compared to cohorts who did not fall regardless if the fall event resulted in injury or not.

[0006] Diminished balance is frequently a multi-factorial result of aging (e.g. visual, auditory and tactile sensory deficits, reduced reaction times and muscular strength, and progressive alteration in sense of joint-position), disease (e.g. acute illness, hypertension, stroke, arthritis, etc.), medications and/or environmental factors (e.g., lighting, slippery surfaces, obstacles, etc.). General models for balance suggest that when balance is perturbed, a person controls his/her center of mass by repositioning the center of pressure. While environmental factors typically initiate the perturbation in balance, it is the reduction in strength, cognition and sensory input that yield insufficient compensations that result in falls.

[0007] Many current interventions focus solely on strength or balance issues inherent to the multifaceted problem of falling. Traditional programs include exercise programs, adoption of assistive walking tools, and/or protection such as hip protectors. Proprioceptive physical exercises (e.g. yoga or soft gymnastics) has demonstrated the largest benefit to postural control, followed by bioenergetic activities such as jogging or cycling; while little improvement appears in subjects simply participating in a walking program. Walking aids such as canes and walkers increase patient confidence and reduce fall frequency, but the devices are frequently undesirable to patients due to personal preference or environmental limitations. While fall protection devices appear to reduce fall related fractures under certain circumstances, they do not address patient fears or mortality rates associated with non-injured fallers.

[0008] There have been some attempts to monitor physical characteristics that may be related to falls. US application 2003/0009308 describes gyro sensors and force-sensitive resistors mounted in an insole to measure acceleration and rotation of the insole. This device is reported to determine the cadence and ankle power of the user, which may be useful to diagnose disorders in which ankle-push off is reduced. U.S. Pat. No. 5,357,696 describes a force-concentrating system which directs all forces in a shoe to a central point. This total force is compared to a desired amount of force and a notification is communicated to the user if the total force is higher or lower than desired. This device is reported to be useful in recuperation following an injury or surgery. U.S. Pat. No. 5,678,448 describes a multiplicity of force sensors covering the entire area of the user's foot. An alarm sounds when a force is greater than a predetermined threshold force. U.S. Pat. No. 5,408,873 describes measuring the compressive force exerted by a foot using an insole having a plurality of layers of dielectric material. U.S. Pat. No. 6,033,370 describes a capacitive force sensor having a plurality of layers of dielectric and conductive materials. U.S. Pat. No. 5,323,650 describes a force sensor for use in a shoe, where sensors are arranged in a pattern that covers the entire area of the foot. U.S. Pat. No. 5,566,479 describes a shoe or insole having a cutout region where a force sensing resistor is placed. When the pressure on the force sensing resistor exceeds a threshold value, an alarm sounds.

[0009] The reported systems do not prevent falls or allow the elderly or injured to build muscle strength and coordination. There is a need for such a system. In addition, there is a need for a system that can detect changes in walking gait speed and cycle to predict illnesses, for example.

BRIEF SUMMARY OF THE INVENTION

[0010] Provided is a system for monitoring gait. More particularly, the system comprises: one or more sensors; means for capturing the data from the sensor(s); means for generating a feedback value from a comparison of the data from the sensor(s) and a stability profile; and means for communicating the feedback value. The means for generating a feedback value can comprise an algorithm. The system can also comprise a power source. Also provided is a system for monitoring gait comprising: a plurality of sensors which generate a signal; a circuit means electrically connected to the plurality of sensors whereby said signal is collected; a transmission means to transmit the signals; a power source electrically connected to said plurality of sensors, circuit means, and transmission means; software that receives the transmitted signal and compares the transmitted signal to a stability profile and generates a feedback signal; and a feedback means which transmits the feedback signal. Also provided is a method for gait analysis comprising: collecting signals from one or more sensors, generating a test profile; comparing the test profile to a stability profile; generating a feedback signal; and communicating the feedback signal.

[0011] In the embodiments described herein, the sensors comprise one or more pressure sensors and optionally, one or more accelerometers. Accelerometers provide additional information about gait speed, stride length, and gait timing. Accelerometers are an optional component of the embodiments described herein.

[0012] Accelerometers may also be used as a redundancy to check the data received from the pressure sensors. In particular embodiments, one, two, three or more accelerometers may be used

[0013] In one embodiment, the sensor(s) are located in a shoe, shoe insole, or sock. As used herein, "shoe" indicates a device which at least partially encloses the foot. A shoe may contain attachment devices known in the art such as velcro, laces, or elastic, or other attachment devices known in the art or may be attached to the foot by the use of tape, for example medical tape. As used herein, "shoe insole" indicates a structure that may be placed in a shoe, such as a conventional insole known in the art. A shoe insole may also be placed on the foot and attached using any suitable means, such as the use of tape, string, or elastic bands. The use of a separate insole without a shoe may be useful if the patient is unable to be fitted with shoes.

[0014] The pressure sensors may be any suitable pressure sensor, as known in the art. One suitable example is the FlexiForce, obtained by Teskan, South Boston, Mass. There are other pressure sensors that are useful in the invention. A combination of pressure sensors may be used. In one embodiment, there is a plurality of pressure sensors. In one embodiment, the pressure sensors are located in pressure communication with different parts of the foot. The different parts of the foot may include one or more of: big toe pad, heel, under one or more metatarsals, inner ball, outer ball, outside edge. The pressure sensors may be different sizes, depending on the location or other factors, as known in the art. There may be as many or as few pressure sensors as desired to obtain the desired sensitivity of measurement, as balanced by cost, durability and other factors as known in the art. In different embodiments, there are one, two, three, four, five, six, seven, eight, nine or ten pressure sensors. In one embodiment, there are more than ten pressure sensors. In one embodiment, there are less than ten pressure sensors. In one embodiment, there are less than five pressure sensors. In one embodiment, there are five or fewer pressure sensors. In one embodiment, there are more than two pressure sensors. All individual values and ranges are intended to be included to the extent as if they were individually listed. In one embodiment, the pressure sensors do not cover a substantial portion of the user's foot. In one embodiment, the pressure sensors are not arranged in an array.

[0015] Suitable accelerometers and the use thereof is known to one of ordinary skill in the art without undue experimentation.

[0016] The system can be powered by any suitable energy source. The power source can be one or more of: kinetic energy (energy generated by the user walking); and alternating or direct current, including one or more batteries which may be rechargeable or non-rechargeable. In one embodiment, there is a combination of energy sources used. Different portions of the system can be powered in different ways. For example, the portions of the system that are present in the shoe, shoe insole or sock may be powered by kinetic energy, while the other portions of the system are powered by alternating current. Alternatively, the portions of the system that are present in the shoe, shoe insole or sock may be powered by batteries. In a portable system, it is desired that no parts of the system require wall current.

[0017] In one embodiment, the means for communicating the feedback value is selected from the group consisting of: visual indication, tactile indication, audible indication and combinations thereof. Visual indication can include different colored lights which correspond to various feedback conditions. For example: green can be used to indicate the situation is safe, yellow can be used to indicate the situation requires caution, and red can be used to indicate the situation is unsafe and the behavior should be stopped. These lights may be present in any suitable reporting device. For example, the lights may be incorporated in eyeglasses which the user may wear. The lights may be incorporated in a hand-held device or a device worn around the neck. The lights may be incorporated in a wall-mounted system, for example, in a physician's office or patient room. Audible indication can include different tones and/or volumes of tones to correspond to various feedback conditions. Tactile indication can include a physical sensation presented to the user if a particular feedback condition is present. For example, a system that presents a signal such as a tapping motion can be incorporated in a band worn on a body part such as the wrist or arm, and the system can be designed to send a signal when an unsafe condition is present.

[0018] The invention is useful for any animal or person that applies pressure to one or more feet. The invention is useful for mammals. The invention is useful for humans. The invention is also useful for animals, including horses, cows or dogs, where the alteration in gait can be used as an early determiner of illness or injury.

[0019] The system can be used in different ways. For example, the system can be used to prevent falls. In this example, the pressure sensors generate a profile of the center of mass of the individual ("test profile"). This profile is compared to an ideal center of mass profile "stability profile" using an algorithm such as a Neuro-Fuzzy decision-making system which uses a learning algorithm to determine its rules by processing data samples. An inference engine that integrates advantages of a neural network and fuzzy logic is incorporated in this system.

[0020] This neuro-fuzzy inference engine has five layers, in one embodiment, and can be used for any number of inputs and outputs (MIMO). It employs the gradient descent method and the least square estimation (LSE) algorithms to train the network. FIG. 5 shows the architecture of the inference engine.

[0021] Layer 1: (Fuzzification layer) Each node generates a membership degree of a linguistic value. The k^{th} node in this layer performs the following operation:

$$O_k^1 = \mu_{A_{ij}}(x_i) = \frac{1}{1+\left(\frac{x_i - a_{ij}}{b_{ij}}\right)^2} \tag{8}$$

[0022] Layer 2: (Multiplication Layer) Each node calculates the firing strength of each rule by using multiplication operation.

$$O_k^2 = \prod_i O_{ij}^1(x_i) \quad (1 \le k \le 4) \tag{9}$$

[0023] Layer 3: (Normalization layer) The number of nodes in this layer is the same as the first layer, where the output of layer two is determined according to:

$$O_k^3 = \frac{O_k^2}{\sum_k O_k^2} \quad (1 \le k \le 4) \tag{10}$$

[0024] Layer 4: (Defuzzification layer) The number of nodes in this layer is equal to the number of nodes in layer one times the number of outputs. The defuzzified value for the

$$y_k = \left\{\begin{matrix} c_k - d_k\sqrt{\frac{1}{O_k^3} - 1} & \text{if } k = \text{odd} \\ c_k + d_k\sqrt{\frac{1}{O_k^3} - 1} & \text{if } k = \text{even} \end{matrix}\right\} \quad (1 \le k \le 4) \tag{11}$$

where $\{c_k, d_k\}$ are consequent parameters and are used to adjust the shape of the membership function of the consequent part. Then, the output of this layer becomes:

$$\begin{aligned} O_k^4 &= O_k^3 \cdot y_k \\ &= \left\{\begin{matrix} O_k^3 \cdot \left(c_k - d_k\sqrt{\frac{1}{O_k^3} - 1}\right) & \text{if } k = \text{odd} \\ O_k^3 \cdot \left(c_k + d_k\sqrt{\frac{1}{O_k^3} - 1}\right) & \text{if } k = \text{even} \end{matrix}\right\} (1 \le k \le 4) \end{aligned} \tag{12}$$

[0025] Layer 5:(Summation layer) Here, the number of nodes is equal to the number of outputs. There is only one connection between each node in layer three and a node in the output layer:

$$O_1^5 = \sum_k O_k^4 \quad (1 \le k \le 4) \tag{13}$$

[0026] In the training process, the engine tries to find the minimizing error function between target value and the network output. For a given training data set with P entries, the error function is defined as:

$$E = \sum_{p=1}^{P} E_p = \frac{1}{2}\sum_{p=1}^{P}(T_p - O_{1,p}^5)^2, \quad (1 \le p \le P). \tag{14}$$

[0027] There are several key attributes of this neuro-fuzzy inference engine that adapt it well for the present invention:

[0028] (a) it uses a combination of a fuzzy inference engine and an adaptive neural network

[0029] (b) it uses fuzzy reasoning for both fuzzification and defuzzification, that is, the membership functions are half of a bell-shape function called monotonic nonlinear functions

[0030] (c) it can be applicable to Multi-input and Multi-output (MIMO) system

[0031] (d) it uses associated hybrid learning algorithm to tune the parameters of membership functions: Feedforward Process; Least Square Estimation; Backward Process; Gradient Descent method

[0032] (e) it uses an optimal learning rate that is updated after each learning process

[0033] (f) it has the least number of coefficient to learn, has a fast convergence rate, and is therefore suitable for real-time applications.

[0034] This inference engine can be used in modeling and mapping of uncertain systems whose mathematical representation (e.g. differential equations) is not available to predict its future behavior. It integrates the best features of a fuzzy system (fuzzy reasoning) and neural networks (learning). Neuro-fuzzy inference technique provides a means for the fuzzy modeling to learn information about a data set, which will compute and generate the membership function parameters, so that the associated fuzzy inference system can track the given input and output pattern. Its learning method works similarly to that of neural networks. This network can be used to find out system parameters and unknown factors through the training process, which means it achieves the goal of system identification.

[0035] The algorithm provides a feedback value. The feedback value can be used in many different ways. In one embodiment, the feedback can be communicated to the user. In one example of this embodiment, the user is notified if the test profile is within the stability profile parameters or outside the stability profile parameters. The notification can be visual, audio and/or vibratory feedback, as described elsewhere herein. The user is altered if his behavior is "safe" (little risk of falling) or unsafe (high risk of falling). The user can thus continue his behavior without concern for falling if the behavior is safe, or change his behavior in response to the notification. The system can also be used to detect changes in walking gait speed and cycle that are predictors of illnesses or measures of reactions to changes in a patient's drug regimen, for example, by using accelerometers. The system detects changes in gait speed and cycle and provides feedback to either the user or a care-giver, for example. "On-demand" physical therapy can be performed using the system. In this aspect of the invention, the user can build stability and coordination by correlating how changes in movement change the feedback. The feedback and/or data from the pressure sensor

(s) may be stored on electronic media for future use. This can be useful for medical professionals to review and monitor a patient's activity for use in a physical therapy protocol, for example. There are other uses of the invention which will become apparent upon review of the disclosure herein. These uses are intended to be encompassed here.

BRIEF DESCRIPTION OF THE FIGURES

[0036] FIG. **1** shows a block diagram of one embodiment of the invention.

[0037] FIG. **2** shows a flow chart showing one embodiment of the system (not to scale). **1** is one or more force/pressure and accelerator sensors. **2** is a controller. **3** is software. **4** is a circuit. **5** is the feedback. **6** is a receiver/transmitter. **7** is a power source. Although the insole, microcontroller, and output feedback are shown separately in FIG. **2**, all components could be present on the same apparatus, such as the insole.

[0038] FIG. **3** shows one example of the system incorporated in a shoe.

[0039] FIG. **4** shows real-time data collected wirelessly from insole sensor system: (i) postural sway when balancing on a single foot, (ii) force data from a single foot during normal walking.

[0040] FIG. **5** shows an architecture of the inference engine.

DETAILED DESCRIPTION OF THE INVENTION

[0041] The following description contains non-limiting examples which are intended to further illustrate some embodiments of the invention.

[0042] This invention augments the patient's diminished natural sensory feedback system, and provides information to the patient on their current stability situation such as stable [green], therapeutic [yellow] and danger [red] zones. Stability information allows individuals to assess their own performance and regain confidence in their ability to remain upright after a perturbation. By intentionally moving oneself into the therapeutic zone of instability, a patient can use this system to perform their own strength and coordination building physical therapy. Embedding this technology into existing physical therapy programs monitored and designed by rehabilitation specialists, patients gain access to individualized, interactive physical therapy programs on-demand, 24 hours a day, thus extending the period of active therapy and reducing the time to acquire (or reacquire) improved stability. Physicians also gain access to data on daily balance control and conditioning. Artificial intelligence (neuro-fuzzy logic) provides for automated stability zone narrowing or widening as the patient abilities change with time. Such a device is also useful to evaluate the effects of a new therapy (such as a new medication or a change in dose) on patient stability. This is useful, for example, when a potentially destabilizing (centrally active) medication is added to an existing regimen.

[0043] It is known that a healthy, stress-free work environment improves productivity through improved concentration. Illness, whether mental or physical, can decrease our action functions, particularly those controlled by our sensory system. This decrease in function may be very subtle in young adults who can divide and refocus their attention efficiently, but the elderly, especially those individuals with borderline or dependent functionality confined to an assisted living or nursing home environment, for example, may exhibit a dramatic decline in motor function during illness or stress. Gait is regulated by the basal ganglia using information provided by the prefrontal and/or frontal cortices. Therefore, although walking is a previously learned motor program, older adults experience a reduced walking speed while performing a dual cognitive task, such as talking. Because illness (or other stressors such as new medications) can impair executive functions, the onset of a physical illness in older adults may first become detectable as a subtle change in gait speed or timing cycle. Fried (1991) suggested that an unperceived decline in physical function precedes clinically observable declines. This "preclinical disability" arises because daily function must decrease dramatically before older individuals will recognize a problem through self-evaluation and seek medical help. Therefore, longitudinal gait variability can be used as an early warning indicator for caregivers to detect illnesses earlier, especially in those individuals who have difficulty articulating their health state. Caregivers might also gain faster feedback on drug interactions and therapeutic performance before a patient's condition declines.

[0044] FIG. **1** shows a block diagram of one embodiment of the system. The information from sensors is transmitted through interface hardware to a microcontroller which may also contain data storage. The sensor information is converted into a resulting signature. A fuzzy inference is made on the signature, and based on the inference, a signal is generated. This signal can be an alarm for the patient, as shown in FIG. **1**, or can be a signal transmitted to a doctor or caregiver, for example, or other examples as described herein.

[0045] FIG. **2** illustrates a more detailed example of the system. In this example, the system comprises force/pressure sensors (**1**) (such as FlexiForce, Teskan), an integrated microcontroller/radio transmission and receiver communication system (**2**) (such as MICA2Adot Mote) and data collection software (**3**) (such as LabView). The compact sensors (four in one example) were placed in the insole pad of a shoe. The thin, flexible sensors measures force on various points on the foot (heel, toe, outer ball, inner ball). The signal is conditioned by a circuit (**4**) and prepared for evaluation and storage by a microcontroller system (**2**). Here all the algorithm calculations and stability alarm programming is stored and operated. Self learning algorithms are utilized to minimize the amount of on board stored data and provide the appropriate electrical stimulus to an audio/visual/wearable feedback system (**5**). The system transmits the packets of data for long term storage to a base station (laptop) (**6**) via a radio link. Measurement data can to down loaded via a directional antenna on the base station. The CC1000 radio (**2**) operates in the 900 MHz ISM band utilizing a Spread Spectrum Frequency Hopping scheme. This scheme divides the band into a series of sub-bands that the radio "hops" through an algorithmic manner. Only the radios communicating with each other know the "hopping" sequence. Thus interference can be avoided by hopping to different frequencies within the bank, and the system can operate within a multi radio (e.g., multi-patient) network. Small, replaceable batteries (**7**) power the insole unit, with unit lifetimes estimated to be 25 hours at full power. However, the insole sensor system goes to sleep when not in range of the base station or when the patient is not in motion, extending unit life times to weeks. As an additional feature to this invention, a piezo-based power generation can be used that converts the kinetic energy from the walking into electric power to make the system independent of any batteries. Data received at the base computer is decoded and stored for future use. Alarms are provided within the system when the algorithm detects a pending illness. As opposed to traditional gait collection systems, the insole device is designed to be convenient to use in environments outside of the lab as the small size and wireless module of the insole is user friendly and helps avoid distraction and maintain minimum interference with natural gait.

[0046] Once the data is received from sensors, an artificial intelligence algorithm (fuzzy interference) will be activated to analyze and develop a signature about the state of walking stability of the patient. If this signature falls within a stable region, then a GREEN light LED is turned on, or a certain frequency audio is activated. If the signature is outside of the stability region, then a RED light LED is turned on, or a different frequency audio is activated. In case that the signature falls within the fuzzy bands of stability/instability, then a YELLOW light LED is turned on, or a third alarm audio frequency would be activated.

[0047] A device incorporating the system has been made and tested. FIG. **3** shows one example of a shoe containing the system described here. FIG. **4** shows exemplary data obtained from the example shoe. The plots in FIG. **4** show force versus time data for sensors measuring forces beneath the toe (bottom line), inner ball (second line from bottom), heel (third line from bottom) and outer ball (top line) as the subject balanced on a single foot (left plot) and normally walked (right plot). A wireless sneaker with embedded sensors and electronics has also been developed.

[0048] Although the description herein contains many specificities, these should not be construed as limiting the scope of the invention, but as merely providing illustrations of some of the embodiments of the invention. Thus, additional embodiments are within the scope of the invention and within the following claims. All references cited herein are hereby incorporated by reference to the extent that there is no inconsistency with the disclosure of this specification. Some references provided herein are incorporated by reference herein to provide details concerning additional methods of analysis and additional uses of the invention.

[0049] When a Markush group or other grouping is used herein, all individual members of the group and all combinations and subcombinations possible of the group are intended to be individually included in the disclosure. Every combination of components described or exemplified can be used to practice the invention, unless otherwise stated. One of ordinary skill in the art will appreciate that methods, device elements, and components other than those specifically exemplified can be employed in the practice of the invention without resort to undue experimentation. All art-known functional equivalents, of any such methods, device elements, and components are intended to be included in this invention. Whenever a range is given in the specification, all intermediate ranges and subranges, as well as all individual values included in the ranges given are intended to be included in the disclosure.

[0050] As used herein, "comprising" is synonymous with "including," "containing," or "characterized by," and is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. As used herein, "consisting of" excludes any element, step, or ingredient not specified in the claim element. As used herein, "consisting essentially of" does not exclude materials or steps that do not materially affect the basic and novel characteristics of the claim. Any recitation herein of the term "comprising", particularly in a description of elements of a device, is understood to encompass those methods consisting essentially of and consisting of the recited components or elements. The invention illustratively described herein suitably may be practiced in the absence of any element or elements, limitation or limitations which is not specifically disclosed herein.

[0051] The terms and expressions which have been employed are used as terms of description and not of limitation, and there is no intention in the use of such terms and expressions of excluding any equivalents of the features shown and described or portions thereof, but it is recognized that various modifications are possible within the scope of the invention claimed. Thus, it should be understood that although the present invention has been specifically disclosed by preferred embodiments and optional features, modification and variation of the concepts herein disclosed may be resorted to by those skilled in the art, and that such modifications and variations are considered to be within the scope of this invention as defined by the appended claims.

[0052] In general the terms and phrases used herein have their art-recognized meaning, which can be found by reference to standard texts, journal references and contexts known to those skilled in the art. The definitions are provided to clarify their specific use in the context of the invention.

We claim:

1. A system for monitoring gait comprising:

(a) a pressure sensor;

(b) neuro-fuzzy inference algorithm which computes and generates monotonic nonlinear membership function parameters and provides a feedback value;

(c) means for communicating the feedback value; and

(d) a power source.

2. The system of claim **1**, wherein the means for communicating the feedback value is selected from the group consisting of: visual indication, tactile indication, audible indication and combinations thereof.

3. The system of claim **1**, further comprising one or more accelerometers.

4. The system of claim **1**, wherein the pressure sensor is located in a shoe, shoe insole, or sock.

5. The system of claim **1**, further comprising a plurality of pressure sensors.

6. The system of claim **1**, comprising pressure sensors at different parts of the foot.

7. The system of claim **1**, comprising less than 10 pressure sensors.

8. The system of claim **1**, comprising more than 2 pressure sensors.

9. The system of claim **1**, wherein the power source is kinetic energy.

10. The system of claim **1**, wherein the power source is alternating or direct current.

11. The system of claim **1**, wherein the power source is one or more batteries.

12. A system for monitoring gait comprising: (a) a plurality of sensors which generate a signal; (b) a circuit means electrically connected to the plurality of sensors whereby said signal is collected; (c) a transmission means to transmit the signal; (d) a power source electrically connected to said plurality of sensors, circuit means, and transmission means; (e) a computer memory storing an executable program for receiving the transmitted signal and using neuro-fuzzy inference logic to compute and generate monotonic nonlinear membership function parameters from the transmitted signal and generating a feedback signal; (f) a feedback means which transmits the feedback signal.

13. The system of claim **12**, wherein the sensors comprise a plurality of pressure sensors and optionally one or more accelerometers.

14. The system of claim **12**, wherein the feedback means is selected from the group consisting of: visual indication, tactile indication, audible indication and combinations thereof.

15. The system of claim **12**, wherein the sensors are located in a shoe, shoe insole, or sock.

16. The system of claim **12**, wherein the pressure sensors are located at different parts of the foot.

17. The system of claim **12**, comprising less than 10 pressure sensors.

18. The system of claim **12**, comprising more than 2 pressure sensors.

19. The system of claim **12**, wherein the power source is kinetic energy.

20. The system of claim **12**, wherein the power source is alternating or direct current.

21. The system of claim **12**, wherein the power source is one or more batteries.

22. A method for gait analysis comprising: collecting signals from one or more sensors; using a neuro-fuzzy inference algorithm to compute and generate monotonic nonlinear membership function parameters; generating a feedback signal; communicating the feedback signal.

23. The method of claim **22**, wherein the sensors comprise a plurality of pressure sensors located in pressure proximity to a patient's foot and optionally one or more accelerometers.

24. The method of claim **22**, wherein the comparing step is performed by fuzzy logic.

25. The method of claim **22**, wherein the communicating step is one or more of: visual, tactile, and audible.

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(54) Apparatus for telemetering interaction forces between the foot and the ground in a subject walking

(57) An apparatus for measuring, in a walking subject, the vertical component (F_b) of the resultant of the forces of interaction between foot and ground and the co-ordinates of its point of application (frequently also referred to as centre of pressure) in a reference system integral with the foot comprises at least one insole (S) sensitive to the forces, which is inserted into a shoe, and a very light mobile unit (P,T) to be attached to the belt and which performs at least one pre-processing of the signals emitted by the sensitive insole and their teletransmission via radio to a processing unit (R,PC), which performs the final processing and shows the information.

The sensitive insole (S) preferably consists of a matrix of force sensors of resistive type comprising 64 sensors.

Taking into account the signals emitted by the sensors of the sensitive insole (S), the pre-processing unit (P) yields, instant by instant, the vertical component (F_b) of the resultant of the forces of interaction between foot and ground and the co-ordinates of its point of application.

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Description

State of the art.

Both at a research level and at a commercial one various sensitive insoles have been proposed, which comprise a number of sensors and must be inserted in a shoe for measuring the distribution of the forces under the foot.

Such sensors are sensitive only to the vertical component of the force and, consequently, since the area taken by the sensors is known, they actually measure the pressure locally exchanged between the foot and the ground, and are therefore usually referred to as pressure sensors.

Sensitive insoles always consist of a discrete set of sensors, whose number may vary from a few sensors (e.g., 16) positioned at points corresponding to characteristic points of the foot sole up to as many as a thousand of sensors positioned and arranged according to a matrix.

The most usually used technology (because it is the least expensive one) produces sensors of resistive type in which the electric resistance is a decreasing function of the pressure; just to provide examples, the following may be cited:

- a sensitive insole with sensors spaced 5 mm apart (produced by the firm Tekscan Inc.), which is sold as an accessory (with a life limited to a few dozen measurements) of a complete measuring system which involves a cable connection with the subject;
- a sensitive insole (produced by the firm InterInk, involved only in the sale of sensors) consisting of a mylar film where 64 sensors are laid out, arranged according to a not altogether regular matrix.

Finally, a sensor produced by the firm Interlink and proposed for realising push-button panels of special type is cited, which is suitable for measuring the magnitude and the position of a force in a plane. As expressly stated by the firm Interlink itself, this sensor cannot, however, be adapted and/or used for the production of sensitive insoles to be inserted in shoes.

One form of presentation of the information of these devices consists simply of the image of the foot sole with superimposed thereon the responses of the individual sensors coded according to an arbitrary colours scale.

It is possible to show both the successive instantaneous responses recorded at regular time intervals (with a lower limit of about 10 msec) and the maximum values measured by the individual transducers for the entire period in which the foot is pressing down. In any case, this type of presentation, which is a qualitative one, must be combined with numerical information if more precise evaluations are needed, such as those necessary for comparing results of different kinds of therapy and for following the effects thereof over time.

A very effective synthesis of this type of information is obtained by representing on the foot sole the succession of the points of application of the resultant force of reaction of the entire foot associated, if possible, to the values of the vertical component of said force: due to the slight inclination of the resultant force of reaction with respect to the vertical, said values practically coincide with those of the resultant force of reaction. This result is obtained by processing (at each sampling instant) the responses of all the sensors taking into account their position in the matrix. This operation calls for a certain computation power and is therefore normally carried out off-line at the end of the data acquisition step.

The sensitive insoles currently available allow the measurement of the distribution of the forces under the foot sole during the entire phase in which the foot is pressing against the ground, but the acquisition of the responses of all the sensors is, however, not compatible with the limited capacity of a telemetering channel, particularly if the aim is to keep costs down. It is therefore advantageous to pre-process the information to be transmitted by means of an electronic circuit which, once it has received the responses of all the sensors of the sensitive insole, supplies instant by instant a limited amount of information to be transmitted to the microprocessor.

In the device to which the present invention refers, a pre-processing unit calculates the vertical component of the resultant of the forces of interaction between the foot and the ground, thus allowing an on-line monitoring via radiotelemetering.

In this case, in fact, only three quantities need to be transmitted for each foot (the vertical component of the resultant force and the co-ordinates of its point of application) and a low-capacity and low-cost transmission channel is therefore suitable for this purpose.

In fact, a transmission rate of the transmission channel of about 4800 bits/sec with a sampling frequency of 100 Hz and an 8-bit analog-to-digital converter are adequate.

The acquisition of the responses of all the sensors would instead involve a data flow that would prove hard to handle for a radiotelemetering channel unless the number of sensors is very low.

As an alternative to radiotelemetering, a cable connection or the storage on a local storage means would limit the duration of the observation times to a few minutes.

The displacement of the centre of pressure during the time in which the foot is exerting pressure is sufficiently representative of the complexity of the foot-ground interaction and of its possible pathological alteration.

Summary of invention

The present invention refers to an apparatus for measuring the vertical component of the resultant force of the foot-ground interaction and of the coordinates (in a reference system integral with the foot) of its point of application, comprising at least one sensitive insole (to be inserted in a shoe) equipped with a number of force sensors of resistive type and a pre-processing unit associated to the at least one sensitive insole.

The force sensors of resistive type are arranged in a matrix addressable by rows and columns, where one end of each row, respectively of each column of the matrix is connected to a generator supplying a voltage whose intensity is proportional to the co-ordinate of the row, respectively of the column in the aforesaid reference system, and the co-ordinates of the point of application of the vertical component of the resultant force are correlated to the voltage measured at the other ends of the rows, respectively of the columns, connected together in parallel. The vertical component of the resultant force is correlated to the intensity of the current supplied by a voltage generator connected to one end of the rows (or of the columns) of the matrix, connected together in parallel, when the other ends of the rows (or of the columns) of the matrix are connected to ground.

The pre-processing unit comprises at least one logical unit and switching means activated by the logical unit and suitable for connecting the voltage generators to one end of the rows, respectively of the columns, and for connecting the other ends of the rows, respectively of the columns of the matrix to a scanning unit (in turn connected to the logical unit via an analog-to-digital converter), respectively to ground.

List of figures

The invention will now be described in greater detail with reference to a non-limiting embodiment shown in the attached figures, where:

- Figure 1 shows a schematic representation of an apparatus according to the invention;
- Figures from 2 to 5 show schematic circuit diagrams and a graph suitable for illustrating the working of an apparatus according to the invention;
- Figure 6 shows a schematic representation of the equivalent circuit of a sensitive insole S and a block diagram of the pre-processing unit P associated to it;
- Figure 7 shows a simplified flowchart to better illustrate the working of the logical unit 4 of Figure 6.

Detailed description

Figure 1 shows a schematic representation of an apparatus according to the invention. In Figure 1 there are shown two sensitive insoles S, the preprocessing units P associated to each sensitive insole S and the transceiver apparatus (T, R) which connects via radio the pre-processing units P to the processing unit PC, if present.

The sensitive insoles S and the associated pre-processing units P will be described in greater detail with reference to the following figures. The transceiver apparatus (T, R) and the processing unit PC (which could be omitted if no further processing of the data pre-processed by the units P is required) will not be described herein since they are known and anyway outside the present invention.

Figure 2 shows a schematic circuit diagram used for calculating a co-ordinate (conventionally the vertical one, x) of the point of application of the resultant force.

The sensitive insole S is represented by a number of resistors, whose resistance is a function of the local pressure, arranged in a matrix addressable by rows and columns.

Each row of the matrix is supplied by a generator supplying a voltage V_i that is proportional to the co-ordinate x of the row in a reference system integral with the foot. In a preferred embodiment, these voltage generators V_i are realised by means of a voltage generator connected to a resistance divider consisting of resistors whose values are sufficiently low that the equivalent impedance of the generators is negligible with respect to the minimum value of resistance resulting from the parallel of all the sensors connected to one row, assuming that they are simultaneously subject to the maximum pressure.

Figure 3 shows the equivalent circuit of the diagram of Figure 2, where the conductance g_i is the sum of the conductance of the sensors belonging to the i-th row of the matrix.

The output voltage V_x can be calculated as follows:

Given:

$$g_i = \beta \cdot F_i \text{ (the conductance of the i-th row is proportional to the force acting on the entire row)}, \quad 1)$$

$$V_I = \alpha \cdot x_i \text{ (the voltage applied to the i-th row is proportional to its co-ordinate in the above-mentioned reference system)}, \quad 2)$$

by imposing the equilibrium of the currents at the node A we obtain

$$\sum_{i=1}^{n}(V_i - V_x) \cdot g_i = 0 \qquad V_x = \frac{\sum_{i=1}^{n} V_i \cdot g_i}{\sum_{i=1}^{n} g_i}, \quad 3)$$

whence, by substituting Equations (1) and (2) in Equations (3), we obtain

$$V_x = \frac{\sum_{i=1}^{n} \alpha \cdot x_i \cdot \beta \cdot F_i}{\sum_{i=1}^{n} \beta \cdot F_i} = \alpha \cdot x_b \quad 4)$$

From the above formula it is clear that the co-ordinate x_b of the point of application of the vertical component of the resultant force is correlated to the voltage V_x; in particular, if the conductance of the sensors is linearly proportional to the pressures and therefore to the vertical components of the forces acting on the sensors, the co-ordinate x_b of the point of application of the vertical component of the resultant force is proportional to the voltage V_x.

If the above procedure is repeated exchanging the rows of the matrix of sensors with the columns of said matrix, a voltage V_y representing the co-ordinate y_b of the point of application of the vertical component of the resultant force is calculated.

Figure 4 shows a typical response of a resistive pressure sensor to a pressure cycle whose amplitude and duration are similar to those that may be encountered during walking. It is immediately found that, within the precision limits of these sensors (which are usually affected by large non-linearity and hysteresis), their conductance approximates a linear behaviour, especially in the ascending part of the cycle.

It may then be concluded that the voltages V_x and V_y represent, with an approximation which is acceptable for the specific application, the co-ordinates of the point of application of the vertical component of the resultant force.

A source of error comes from the presence of static loads (which are different from zero even in the resting situation) due mainly to the deformation stresses that the sensitive insole S undergoes as a result of its insertion in the shoe, or to the appearance of a known term in the relation that links the conductance of a sensor to the force acting on the sensor.

In this case, the conductance of the i-th row is $g_i = \beta \cdot F_i + g_{i0}$.

Given the particular working of the sensitive insole S, said local stresses at rest (and/or said known term) give rise to an overall effect that can be represented by a pre-loading force F_0 applied in a point of co-ordinates (x_0, y_0): this is equivalent to a linear transformation of the reference system, which can be easily amended by applying the inverse transformation.

Combining the pre-loading force F_0 with the force F_b to be measured, we obtain

$$x_r = \frac{F_b \cdot x_b + F_0 \cdot x_0}{F_b + F_0} \quad 5)$$

where x_r is the co-ordinate of application of the resultant force, and x_b is the co-ordinate of the point of application of the force F_b ; the resultant force F_r is

$$F_r = F_b + F_0. \quad 6)$$

Deriving F_b from Equation (6) and substituting in Equation (5), we obtain

$$x_r=\frac{(F_r - F_0)\bullet x_b + F_0 \bullet x_0}{F_r}=x_b\bullet\left(1-\frac{F_0}{F_r}\right) + x_0\bullet\frac{F_0}{F_r}$$

whence

$$x_b = \frac{x_r - x_0 \bullet \frac{F_0}{F_r}}{1 - \frac{F_0}{F_r}}$$

Applying the translation of co-ordinates $X=x\text{-}x_0$ we have

$$X_b + x_0 = \frac{X_r + x_0 - x_0 \bullet \frac{F_0}{F_r}}{1 - \frac{F_0}{F_r}} = \frac{X_r + x_0 \bullet \left(1 - \frac{F_0}{F_r}\right)}{1 - \frac{F_0}{F_r}} = \frac{X_r}{1 - \frac{F_0}{F_r}} + x_0$$

whence, given

$$\lambda = \frac{1}{1 - \frac{F_0}{F_r}} = 1 + \frac{F_0}{F_b}$$

,finally we obtain

$$X_b=\lambda\bullet X_r \qquad 7)$$

If we set the origin of the reference system in the point (x_O , y_O) where the pre-loading force F_O is applied, the co-ordinate x_b of the point of application of the force F_b is obtained simply by applying the corrective factor λ to the measured value.

It is moreover necessary to pay attention to the fact that the factor λ diverges for $F_b << F_0$: in other words, it may be said that, for small forces, X_r is strongly attracted by the origin x_O, and hence there is a large corrective factor required to re-establish the correct position.

In order to prevent an amplification at the same time of the inevitable errors of measurement and of quantization included in X_r, it is necessary to limit the application of Equation (7) to the cases where $F_b \geq F_O$, which are markedly prevalent and more significant in practical applications.

The measurement of the vertical component (F_b) of the resultant force is obtained by measuring the current I which flows to ground in the schematic circuit diagram of Figure 5, where the generator which supplies the voltage V_f is, preferably, different from the voltage generator to which (in a preferred embodiment of the invention) is connected a resistance divider for supplying each row, respectively each column of the matrix with a voltage proportional to the co-ordinate (x) of the row, respectively to the co-ordinate (y) of the column of the matrix.

In fact, if the conductance of the i-th row of sensors is indicated by g_i, we have

$$I=V_f\bullet\sum_{i=1}^{n}g_i=V_f\bullet\beta\bullet\sum_{i=1}^{n}F_i$$

The vertical component F_b of the resultant force is thus correlated to the intensity of the current supplied by the voltage generator V_r connected to one end of the rows of the matrix (which are connected in parallel together), when the other ends of the rows of the matrix are connected to ground. In particular, if the conductance of the sensors is linearly proportional to the pressure, and hence to the vertical component of the force acting on each sensor, the vertical component F_b of the resultant force is proportional to the intensity of the current supplied by the voltage generator V_f.

Obviously, the principle continues to hold good if the rows are exchanged with the columns.

Preferably, but not necessarily, the vertical component F_b of the resultant force and the co-ordinates (X_b, Y_b) of its point of application determined via the schematic circuit diagrams of Figures 3 and 5 are further corrected to take into account the pre-loading forces.

Figure 6 shows a schematic representation of the equivalent circuit of a sensitive insole S (represented by the corresponding matrix of sensors) and the block diagram of the pre-processing unit P associated to it, which comprises at least a logical unit 4 and switching means T (represented in Figure 6 by the MOS transistors T1-T6, which act as switches) activated by the logical unit 4 and suitable for connecting the voltage generators V_{cc} (not explicitly shown in Figure 6) to one end of the resistance divider associated to the rows, respectively to the columns of the matrix, for connecting the voltage generator V_f (not explicitly shown in Figure 6) to one end of the rows, respectively of the columns of the matrix, and for connecting the other ends of the rows and of the columns to the scanning unit 2 (connected to the logical unit 4 via the analog-to-digital converter 3), respectively to ground.

The circuits (schematically shown by the schematic circuit diagrams of Figures 3 and 5) used to measure the co-ordinates (x_b, y_b) of the centre of application of the resultant force, respectively the vertical component (F_b) of the force itself, are realised one at a time by the logical unit 4 (in a cyclical sequence whose frequency is corresponding to the wanted sampling frequency) by activating the switching means T (the MOS transistors T1-T6) according to the "activation matrix" shown in Figure 6 and loaded in tabular form into the memory of the logical unit 4. The logical unit 4 moreover acquires, through the scanning unit 2 and the analog-to-digital converter 3, the signals representing the co-ordinates (x_b, y_b) of the centre of application of the resultant force, respectively the vertical component (F_b) of the force itself, and sends them in serial form to the transmitter T.

The operational amplifier 1, connected in inverting configuration, measures and converts into a voltage the current I which flows to ground, and supplies the voltage V_f, in accordance with the schematic circuit diagram of Figure 5.

The operational amplifier 1, the scanning unit 2 and the analog-to-digital converter 3 will not be further described because they are known. The working of the logical unit 4 will be better described with reference to the flowchart of Figure 7.

Preferably, the pre-processing unit P is held in a self-supplied container, built in such a way that it can be worn by the subject, and teletransmits via radio the pre-processed digital data to the processing unit PC.

Figure 7 shows a simplified flowchart which better illustrates the working of a logical unit 4, which carries out in order at least the following functional steps:

- when switched on or restarted (RESET; phase 70), after a preset and preliminary checking phase (INIZ; phase 71) the logical unit 4 enters a wait cycle (ATT; 72) which is periodically interrupted by the Int_0 routine (phases 700-711), activated (phase 700) by a timer (not explicitly shown because it is known) programmed to generate interrupts with a preset frequency F;
- after activation of the Int_0 routine (phase 700), the logical unit 4 resets the timer (RT; phase 701) before verifying (phase 702) the state of a counter (T_{xl}), which can assume 4 states, where the 0-state is associated to the transmission of a start-of-cycle synchronism character (SYNC) and the states 1-3 are associated to the acquisition from the sensitive insole S of the vertical component of the resultant force and of the co-ordinates of its point of application;
- if the counter T_{xl} is in the 0-state, the logical unit 4 causes the transmission of the start-of-cycle synchronism character (SYNC; phase 703) before incrementing by one step the counter T_{xl} (phase 704) and ending the Int_0 routine (END; phase 705);
- if the counter T_{xl} is in a state other than the 0-state, the logical unit 4 drives the scanning unit 2 (US; phase 706) to acquire from the sensitive insole S the information (the vertical component of the resultant force or one of the co-ordinates of its point of application) associated to the state of the counter T_{xl} ; activates (MOS; phase 707), according to the "activation matrix" shown in Figure 6 and loaded in tabular form into its memory, the MOS transistors T1-T6 which make up the switching means T and activates (A/D; phase 708) the analog-to-digital converter 3.

In a preferred embodiment of the pre-processing unit P, the frequency F is equal to 7 • F_1 (where F_1 is the total sampling frequency for a system including one sensitive insole S) and the logical unit 4 carries out the further functional steps of:

- carry out (CV, phase 709) at least the correction due to the pre-loading force on the digital datum present on the output of the analog-to-digital converter 3;
- modify the digital datum present on the output of the analog-to-digital converter 3 if its digital value corresponds to the start-of-cycle synchronism character (SYNC);

- after the above correction phase (CV; phase 709), deactivate (MOFF; phase 711) the switching means T to reduce the power consumption of the pre-processing unit P;
- start (TD; phase 710) the teletransmission of the pre-processed digital data to the processing unit PC (if present) via the transmitter T;
- activate an universal asynchronous receiver-transmitter (UART), not described herein because it is known, which automatically completes the teletransmission of the pre-processed digital data to the processing unit PC (if present) via the transmitter T during the wait cycle (ATT; 72) of the logical unit 4.

To allow the study of the time relations between the applications of the soles of the two foots on the ground, an apparatus according to the invention may comprise two sensitive insoles S whose responses are acquired by a single pre-processing unit P: said apparatus differs from the previously described one by the fact that:

- the timer generates the interrupts, activating the Int_0 routine, with a frequency F equal to 7 • F_2, where F_2 is the total sampling frequency for a system including two insoles;
- the counter T_{xl} can assume 7 states, where the 0-state is associated to the transmission of the start-of-cycle synchronism character (SYNC), states 1-3 are associated to the acquisition of the vertical component of the resultant force and of the co-ordinates of its point of application from a sensitive insole S, and states 4-7 are associated to their acquisition from the other sensitive insole S;
- the logical unit 4 drives in order the switching means T relative to one, respectively to the other sensitive insole S and drives the scanning unit 2 to acquire in order the vertical component of the resultant force and the co-ordinates of its point of application from one, respectively from the other sensitive insole S.

Also in the embodiment of an apparatus according to the invention suitable for managing two sensitive insoles S, the logical unit 4 carries out the correction phase (CV; phase 709), modifies (if necessary) the digital datum present on the output of the analog-to-digital converter 3, starts (TD; phase 710) the teletransmission of the pre-processed digital data to the processing unit PC (if present) via the transmitter T and activates the universal asynchronous receiver-transmitter (UART).

In a possible embodiment of the invention, the sensitive insole S and at least a part of the pre-processing unit P are built into a shoe to create a measuring apparatus which is practically imperceptible by the foot of the subject.

Without departing from the scope of the invention, it is possible for a skilled person to make to the apparatus object of the present invention all modifications and improvements suggested by the ordinary experience and by the natural evolution of techniques.

Claims

1. Apparatus for measuring the vertical component (F_b) of the resultant force of the foot-ground interaction and of the co-ordinates ($x_{b'}$, y_b) of the point of application of the vertical component (F_b) of the resultant force in a reference system integral with the foot, characterised in that it comprises at least one sensitive insole (S), to be inserted in a shoe, equipped with a number of force sensors of resistive type, and a pre-processing unit (P) associated to the at least one sensitive insole (S); in that the force sensors of resistive type belonging to the sensitive insole (S) are arranged in a matrix addressable by rows and columns; in that one end of each row of the matrix is connected to a generator, which supplies a voltage whose intensity is proportional to the co-ordinate (x) of said row in the aforesaid reference system, the co-ordinate ($x_{b'}$) of the point of application of the vertical component (F_b) of the resultant force being correlated to the voltage measured at the other ends of the rows of the matrix connected together in parallel; in that one end of each column of the matrix is connected to a generator, which supplies a voltage whose intensity is proportional to the co-ordinate (y) of said column in the aforesaid reference system, the co-ordinate ($y_{b'}$) of the point of application of the vertical component (F_b) of the resultant force being correlated to the voltage measured at the other ends of the columns of the matrix connected together in parallel; and in that the vertical component (F_b) of the resultant force is correlated to the intensity of the current supplied by a voltage generator (V_f) connected to one end of the rows (of the columns) of the matrix, connected together in parallel, when the other ends of the rows (of the columns) of the matrix are connected to ground;

   apparatus further characterised in that the pre-processing unit (P) comprises at least one logical unit (4) and switching means (T) activated by the logical unit (4) and suitable for connecting the aforesaid voltage generators to one end of the rows, respectively of the columns of the matrix and for connecting the other ends of the rows, respectively of the columns of the matrix to a scanning unit (2), in turn connected to the logical unit (4) via an analog-to-digital converter (3), respectively to ground.

2. Apparatus according to Claim 1, characterised in that the pre-processing unit (P) teletransmits the pre-processed digital data to a processing unit (PC).

3. Apparatus according to Claim 1, characterised in that the generators supplying a voltage whose intensity is proportional to the co-ordinate (x) of the row of the matrix of sensors to which each of them is connected are realised by means of a voltage generator and of a resistance divider connected to the voltage generator.

4. Apparatus according to Claim 1, characterised in that the generators supplying a voltage whose intensity is proportional to the co-ordinate (y) of the column of the matrix of sensors to which each of them is connected are realised by means of a voltage generator and of a resistance divider connected to the voltage generator.

5. Apparatus according to Claim 1, where the conductance of the force sensors of resistive type is linearly proportional to the pressure, characterised in that the co-ordinates (x_b, respectively y_b) of the point of application of the vertical component (F_b) of the resultant force are proportional to the voltage measured at an end of the rows of the matrix connected together in parallel, respectively at the end of the columns of the matrix connected together in parallel, when the other end of each row, respectively of each column of the matrix is connected to a generator supplying a voltage whose intensity is proportional to the co-ordinate (x, respectively y) of the row, respectively of the column of the matrix to which said voltage generator is connected; and in that the vertical component (F_b) of the resultant force is proportional to the intensity of the current supplied by the voltage generator (V_f) connected to one end of the rows (of the columns) of the matrix, connected together in parallel, when the other ends of the rows (of the columns) of the matrix are connected to ground.

6. Apparatus according to Claim 1, characterised in that the current supplied by the voltage generator (V_f) when the rows (the columns) of the matrix are connected to ground is converted into a voltage by an operational amplifier (1), belonging to the pre-processing unit (P), connected in inverting configuration.

7. Apparatus according to Claim 2, characterised in that the pre-processing unit (P) is held in a self-supplied container, built in such a way that it can be worn by the subject, and in that the pre-processed digital data are teletransmitted to the processing unit (PC).

8. Apparatus according to Claim 1, characterised in that the vertical component (F_b) of the resultant force and the co-ordinates (x_b, y_b) of its point of application are corrected to take into account the pre-loading force.

9. Apparatus according to Claim 1, characterised in that the logical unit (4) belonging to the pre-processing unit (P) carries out in order at least the following functional steps:

- when switched on or restarted, after a preset and preliminary checking phase (INIZ), the logical unit (4) enters a wait cycle (ATT) which is periodically interrupted by a routine (Int_0) activated by a timer generating interrupts with a preset frequency (F);
- after activation of the routine (Int_0), the logical unit (4) resets the timer before verifying the state of a counter (T_{xl}), which assumes at least 4 states, where the 0-state is associated to the transmission of a start-of-cycle synchronism character (SYNC) and the other states are associated to the acquisition of the vertical component (F_b) of the resultant force and of the co-ordinates (x_b, y_b) of its point of application from the at least one sensitive insole (S);
- if the counter (T_{xl}) is in the 0-state, the logical unit (4) causes the transmission of the start-of-cycle synchronism character (SYNC) before incrementing by one step the counter (T_{xl}) and ending the routine (Int_0);
- if the counter (T_{xl}) is in a state other than the 0-state, the logical unit (4) drives the scanning unit (2) to acquire from the at least one sensitive insole (S) the information associated to the state of the counter (T_{xl}), activates the switching means (T) and activates the analog-to-digital converter (3).

10. Apparatus according to Claims 8 and 9, characterised in that the logical unit (4) further carries out the correction due to the pre-loading force on the digital datum present on the output of the analog-to-digital converter (3).

11. Apparatus according to Claim 9, characterised in that the logical unit (4) further modify the digital datum present on the output of the analog-to-digital converter (3) if the digital value of said digital datum corresponds to the start-of-cycle synchronism character (SYNC).

12. Apparatus according to Claim 10 or to Claim 11, characterised in that, after the correction of the digital datum

present on the output of the analog-to-digital converter (3), the logical unit (4) deactivates the switching means (T).

13. Apparatus according to Claims 2 and 9, characterised in that, after activating the analog-to-digital converter (3), the logical unit (4) starts the teletransmission of the pre-processed digital data to the processing unit (PC).

14. Apparatus according to Claim 13, characterised in that the logical unit (4) further activates an universal asynchronous receiver-transmitter (UART) which completes the teletransmission of the pre-processed digital data to the processing unit (PC) during the wait cycle (ATT) of the logical unit (4).

15. Apparatus according to Claim 9, characterised in that the preset frequency (F) is equal to 7 • F_1, where F_1 is the total sampling frequency for a system including one sensitive insole (S).

16. Apparatus according to Claim 1, characterised in that the vertical component of the resultant force (F_b) and the co-ordinates (x_b, y_b) of its point of application are acquired from two sensitive insoles (S), one for each foot.

17. Apparatus according to Claim 16, characterised in that the vertical component (F_b) of the resultant force and of the co-ordinates (x_b, y_b) of its point of application are acquired from both sensitive soles (S) by a single pre-processing unit (P).

18. Apparatus according to Claims 9 and 17, characterised in that:

- the timer generates the interruptions, activating the routine (Int_0), with a frequency (F) equal to 7 • F_2, where F_2 is the total sampling frequency for a system including two sensitive insoles (S);
- the counter (T_{xl}) assumes 7 states, where the 0-state is associated to the transmission of the start-of-cycle synchronism character (SYNC), the states 1-3 are associated to the acquisition of the vertical component (F_b) of the resultant force and of the co-ordinates (x_b, y_b) of its point of application from a sensitive insole (S), and the states 4-7 are associated to the acquisition of the vertical component (F_b) of the resultant force and of the co-ordinates (x_b, y_b) of its point of application from the other sensitive insole (S);
- the logical unit (4) drives in order the switching means (T) relative to one, respectively to the other sensitive insole (S) and drives the scanning unit (2) to acquire in order the vertical component (F_b) of the resultant force and the co-ordinates (x_b, y_b) of its point of application from one, respectively from the other sensitive insole (S).

19. Apparatus according to Claims 8 and 18, characterised in that the logical unit (4) further carries out the correction due to the pre-loading force on the digital datum present on the output of the analog-to-digital converter (3).

20. Apparatus according to Claim 19, characterised in that the logical unit (4) further modify the digital datum present on the output of the analog-to-digital converter (3) if the digital value of said digital datum corresponds the start-of-cycle synchronism character (SYNC).

21. Apparatus according to Claim 19 or Claim 20, characterised in that, after the correction of the digital datum present on the output of the analog-to-digital converter (3), the logical unit (4) deactivates the switching means (T).

22. Apparatus according to Claim 2 and 18, characterised in that, after activating the analog-to-digital converter (3), the logical unit (4) starts the teletransmission of the pre-processed digital data to the processing unit (PC).

23. Apparatus according to Claim 22, characterised in that the logical unit (4) activates an universal asynchronous receiver-transmitter (UART) which completes the teletransmission of the pre-processed digital data to the processing unit (PC) during the wait cycle (ATT) of the logical unit (4).

24. Apparatus according to Claim 1, characterised in that the sensitive insole (S) and at least part of the pre-processing unit (P) are built into the shoe.

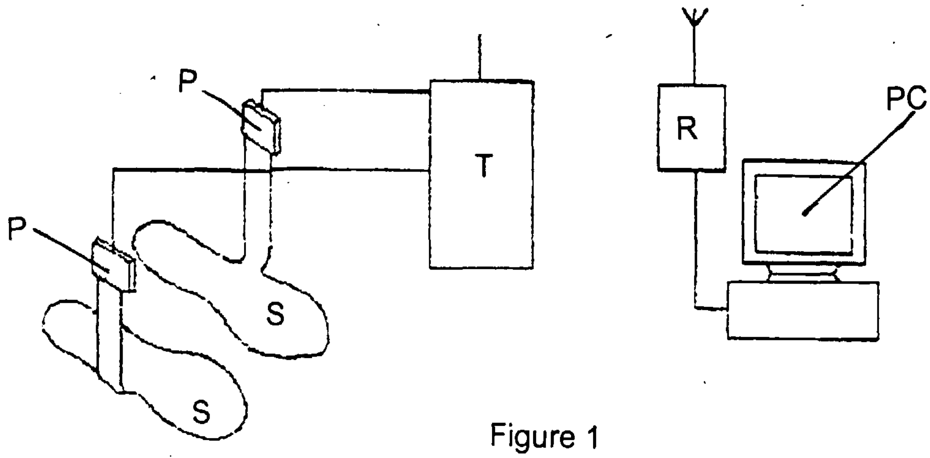
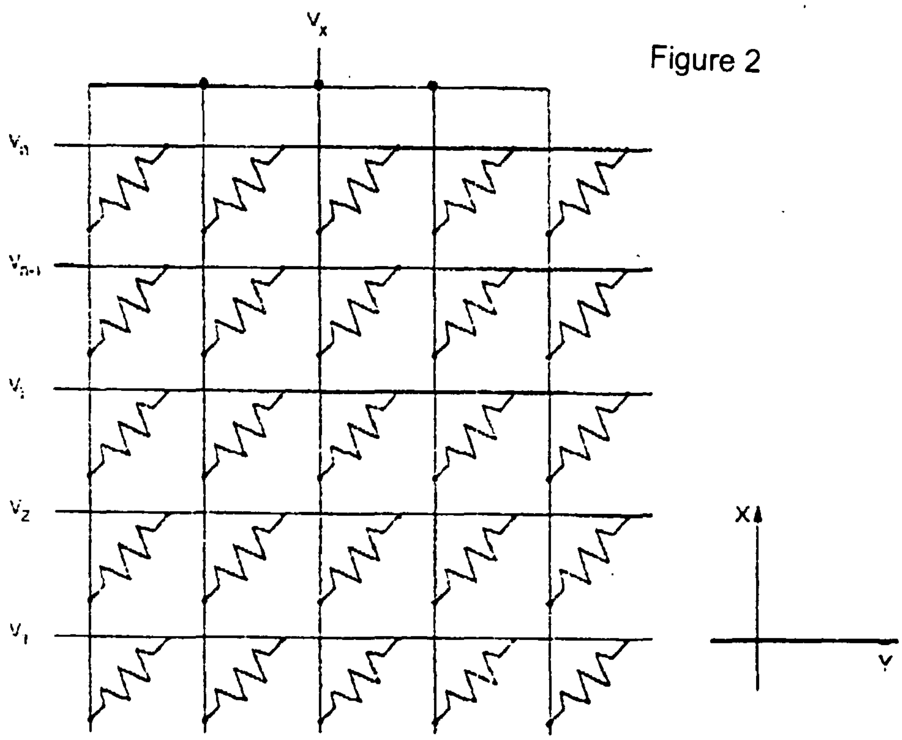


Figure 1

Figure 2



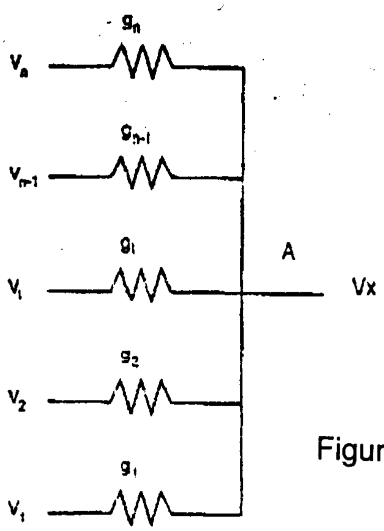


Figure 3

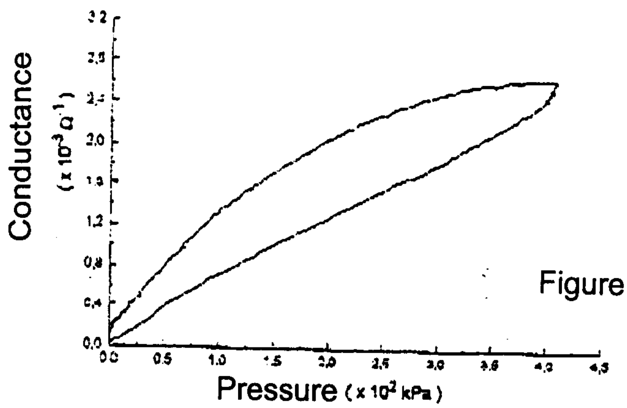
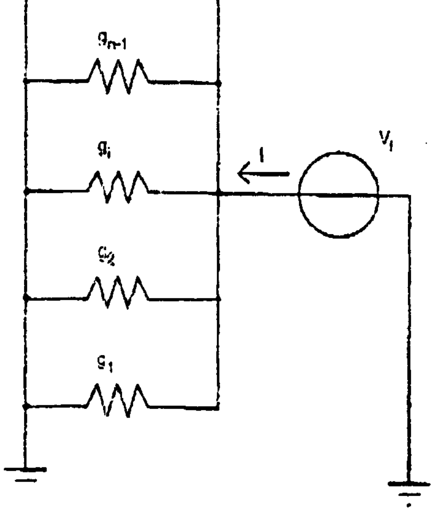


Figure 4

Figure 5



	T1	T2	T3	T4	T5	T6
x	OFF	OFF	OFF	ON	ON	OFF
y	ON	OFF	ON	OFF	OFF	OFF
F	OFF	ON	ON	OFF	OFF	ON

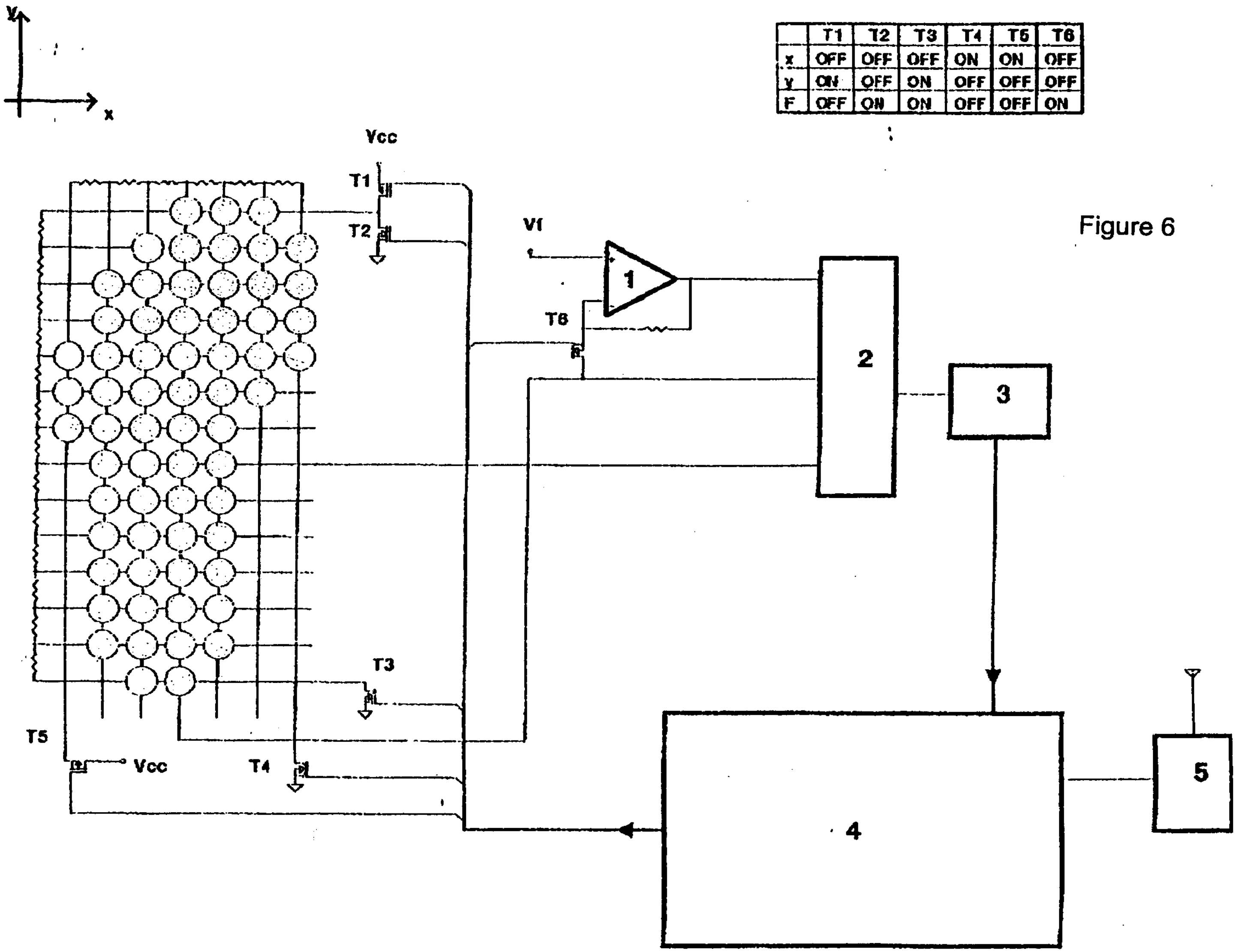


Figure 6

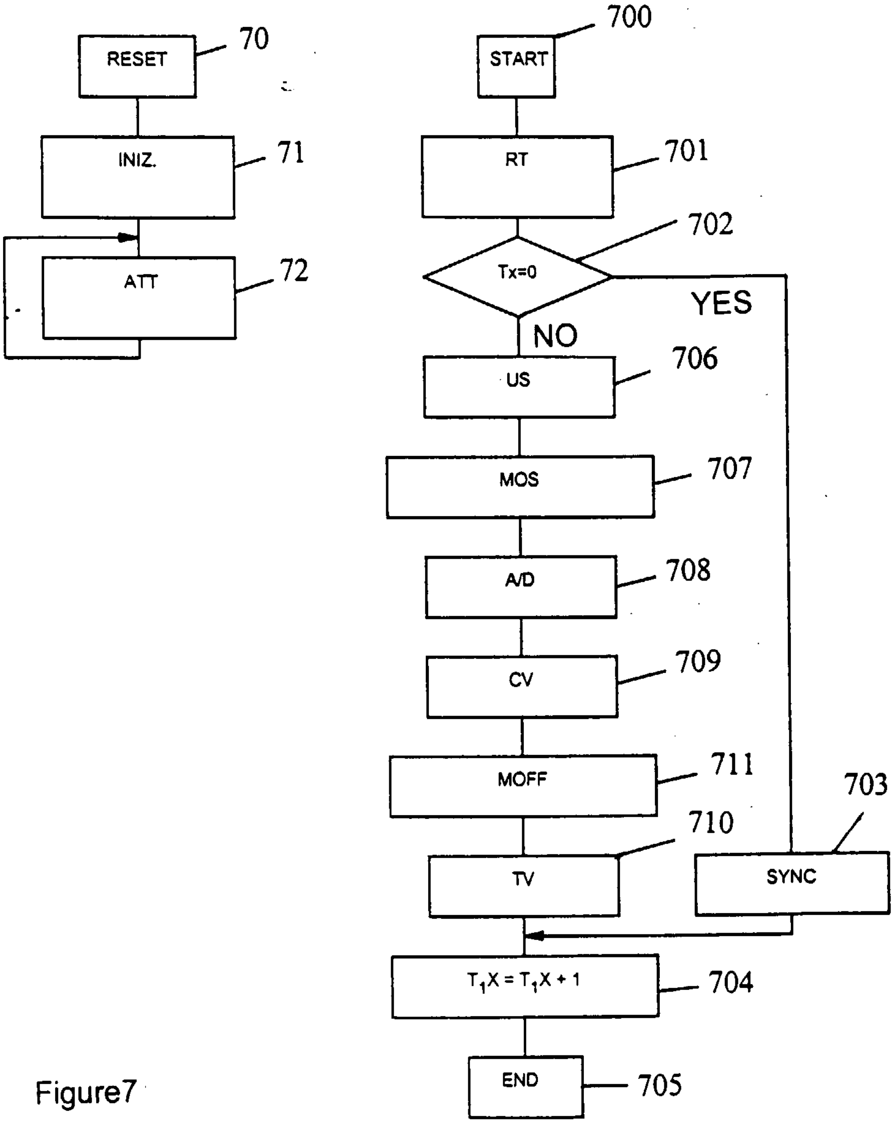

RESET
70
INIZ.
71
ATT
72
START
700
RT
701
Tx=0
702
YES
NO
US
706
MOS
707
A/D
708
CV
709
MOFF
711
710
TV
703
SYNC
T1X = T1X + 1
704
END
705

Figure7

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 97 12 1153

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)
A	C. ALVARADO ET AL: "TELEMETRY SYSTEM FOR CONTINUOUS MEASUREMENT OF VERTICAL FOOT FORCES DURING WALKING" PROCEEDINGS OF THE INSTRUMENTATION AND MEASUREMENT TECHNOLOGY CONFERENCE, WALTHAM, MA., APR. 23 - 26, 1995, 23 April 1995, INSTITUTE OF ELECTRICAL AND ELECTRONICS ENGINEERS, pages 581-583, XP000534919 * the whole document *	1,2,5, 16,17,24	A61B5/103 G01L1/20
A	US 5 323 650 A (G. FULLEN ET AL) * column 4, line 55 - line 65 *	1,5-8	
A	* column 6, line 67 - column 7, line 19 *	10,24	
A	WO 87 01574 A (ISTITUTO SUPERIORE DI SANITA) * page 5, line 21 - page 6, line 27 *	1,5,6, 9-11	
A	EP 0 172 784 A (CYBERTRONICS LTD) * page 1, line 1 - line 13 * * page 10, line 14 - page 12, line 31 *	1,5,6	
			TECHNICAL FIELDS SEARCHED (Int.Cl.6)
			A61B G01L

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	25 March 1998	Geffen, N

CATEGORY OF CITED DOCUMENTS

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