

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
29 November 2001 (29.11.2001)

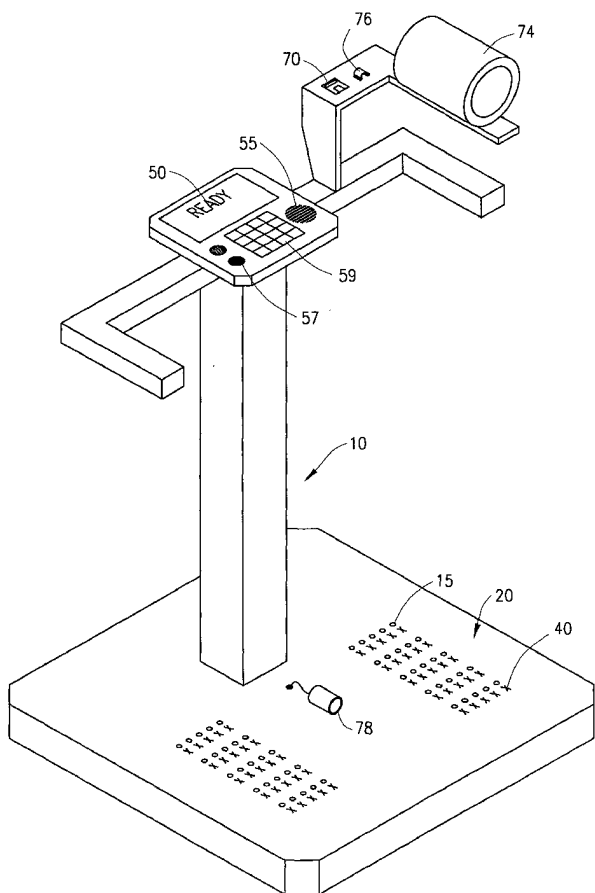
PCT

(10) International Publication Number
WO 01/89367 A2

- (51) International Patent Classification⁷: **A61B** (US). **CONSTANTINIDES, George, P.**; 1118 Oak Path, San Antonio, TX 78258 (US). **LANCTOT, Dan, R.**; 10260 White Bonnet, San Antonio, TX 78240 (US). **ZAMORANO, Ruben, G.**; 8907 Mansfield, San Antonio, TX 78251 (US).
- (21) International Application Number: PCT/US01/17063
- (22) International Filing Date: 25 May 2001 (25.05.2001)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
09/578,948 25 May 2000 (25.05.2000) US
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- (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.
- (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European

[Continued on next page]

(54) Title: HUMAN FOOT MONITORING SYSTEM



(57) Abstract: An apparatus and method for monitoring items of vital health information including temperature of the plantar aspects of the foot of the human, body weight, blood pressure, pulse rate, blood glucose level and blood oxygen level. The apparatus includes a platform on which the user stands. Included on the platform are a set of heat sensitive signal generating devices. The temperature at predetermined locations on the plantar aspects of the human foot are determined by the signals obtained from the individual heat sensitive, signal generating probes. Other items of vital health information may be obtained by other sensors on the apparatus.



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patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

- *without international search report and to be republished upon receipt of that report*

HUMAN FOOT MONITORING SYSTEM**FIELD**

The present invention pertains to a monitoring
5 apparatus; more particularly, the present invention
pertains to an apparatus and method for monitoring the
temperatures on the plantar aspects of a human foot as well
as other vital information indicative of the health of a
human being.

10 BACKGROUND

Many conditions which have a negative impact on the
health of a human being are preceded by small changes in
measurable parameters such as temperature, weight, or blood
pressure. For example, a significant weight gain may be
15 indicative of fluid retention. And fluid retention and/or
an increase in blood pressure may be predictive of severe
heart problems such as congestive heart failure (CHF).

Afflictions of the lower extremities can also be
predicted by a change in the temperatures on the bottom of
20 the feet. In the United States alone, it is estimated that
up to 16,000,000 people suffer from diabetes and
approximately 60-70% of these diabetics will develop foot-
related medical problems sometime during their lifetime.
Of all diabetes-related hospitalizations, 20% of these
25 hospitalizations are for foot-related complications. The
number of hospitalizations can be reduced if medical
personnel are forewarned of significant changes in the
temperatures on the bottom of the feet. For example, it is
well known that skin temperatures on the bottom of a
30 person's feet will increase before ulceration. In
addition, 30% of CHF patients also have diabetes.

Foot problems are particularly problematic for
diabetics because diabetics often lose sensation in their
feet. This loss of sensation to the feet often leads to
35 ulceration. This coupled with a decrease in blood flow

leads to faulty healing and infections, which eventually lead to amputation of the diabetic's foot. The foot problems typically associated with the disease of diabetes often cause immense pain and suffering. Such pain and suffering significantly diminishes the quality of life for a diabetic and for the family members. In addition, these foot problems substantially increase the diabetic's health care cost. Ulcers often develop on the sole of the foot at sites of moderate or high pressure. Injury to these areas is not detected or felt by diabetics because of nerve damage. When pressure areas are exposed to repetitive injury, the areas cannot be seen or felt, but it can be measured as a change in temperature at the site of injury. Temperatures can then be used to alert patients to impending ulceration before tissue is damaged enough to necrose and ulcerate. Therefore, there is a need in the art for a device which facilitates the monitoring of foot temperatures that provides an early warning of any significant temperature differences between the two feet. Such foot temperature monitoring may provide an early indication to ulceration, infection, fracture, and even amputation.

In yet another area, changes in blood pressure at various locations on the human body may be indicative of reduced blood flow. Such reduced blood flow may lead to significant reduction in the health of the affected body part.

In yet still another area, changes in blood chemistry, such as blood sugar level, may be indicative of nascent problems which are not yet symptomatic.

Thus, there is a significant need to develop a device to facilitate the monitoring of other vital health information to include weight and blood pressure. Such monitoring of other vital information may provide an early indication of conditions which can lead to future health

problems. For instance, patients with congestive heart failure often have sudden changes in their health status that can signal impending exacerbations of heart disease. Sudden weight gain is one of these warning signs. It can go unrecognized by the patient, but if detected early it can trigger action by health care professionals. Early treatment can prevent hospitalization, advanced heart complications, and death.

SUMMARY

The present invention facilitates the monitoring of vital health information to include the temperature on the bottoms of a person's feet, body weight, and blood pressure. This monitoring of vital health information is accomplished by an apparatus which is built around a system for monitoring the temperature at different locations on the plantar aspects of the foot of a human being, particularly a diabetic.

In the preferred embodiment of the invention, a platform includes an array of force or pressure sensors. The output of the array of force or pressure sensors provides an indication of the position of a person's feet on the platform. The platform also includes a set of heat sensitive, signal generating probes. Once the force or pressure sensors have provided an indication of the position of the person's feet on the platform, the heat sensitive signal generating probes that are in direct contact with the patient's feet are activated. These heat sensitive, signal generating probes sense the temperature at predetermined locations on the plantar aspects of both the left foot and the right foot. The activation of the temperature sensing probes results in the production of an electrical signal that is representative of the temperatures on each of the patient's feet. If there is a significant difference between the temperatures on the left foot and the right foot, an alarm signal can be provided to

the user. The electrical signals can also be displayed to the user as a temperature reading, stored for future use, or sent to a central monitoring facility.

In the preferred embodiment, the output of the force or pressure sensors is also used to monitor the patient's weight. If desired, a blood pressure cuff and pulse monitor may also be used. The blood pressure cuff may be placed at heart level on the user's arm or an additional cuff may be placed around the user's ankle or the user's toe.

Once other vital health information has been sensed, that information may be compared to previously sensed vital health information. For example, a comparison of a patient's weight to prior readings may reveal a weight gain predictive of congestive heart failure. Similarly, significant differences in blood pressure readings may be predictive of future cardiovascular problems.

All of the sensed vital health information may be displayed to the user or transmitted by telephone or other commonly used wireless communication systems to a central facility where medical professionals can determine if the sensed conditions are predictive of future medical problems. If desired, the apparatus itself may produce alarms of particularly dangerous conditions. For example, if the difference in the temperatures sensed on the bottom of the left foot and the bottom of the right foot or if the patient's blood pressure is above a certain level, an audible signal or a visual message can be displayed.

BRIEF DESCRIPTION OF THE FIGURES

A better understanding of the apparatus and method for monitoring the temperature on the plantar aspects of a human foot and other vital health information may be had by reference to the drawings, wherein:

Figure 1 is a perspective view of the preferred embodiment of the present invention;

Figure 2 is a perspective view of the platform which is used to measure the temperatures on the plantar aspects of the user's feet; and

Figure 3 is a schematic diagram of the interrelationship of the main components of the present invention.

DESCRIPTION OF THE EMBODIMENTS

As may be seen in Figure 1, the preferred embodiment of the apparatus 10 for monitoring vital health information to include the temperature of the plantar aspects of the human foot, body weight, and blood pressure is designed for use either in the patient's home or in health care facilities. It is expected that the patients who would receive the greatest benefit from the apparatus are diabetics who are at high risk for developing medical complications on their lower extremities, particularly their feet, and patients with congestive heart failure.

The preferred embodiment of the present invention 10 allows the patient to obtain a quick scan of the temperatures on the plantar aspects of both feet, body weight, and blood pressure. In a less expensive embodiment 110 as shown in Figure 2, the capabilities to monitor either body weight or blood pressure are eliminated.

The quick scan of foot temperatures allows the monitoring of differences in temperatures between the left foot and the right foot or the monitoring of foot temperatures at different locations on the patient's foot over time. Variations in foot temperatures often signal conditions which are predictive of inflammation or ulceration, or Charcot foot, and which conditions, if left untreated, may lead to eventual amputation of an entire lower extremity.

As shown in Figure 1 and Figure 2, the apparatus of the present invention 10, 110 is not unlike a commonly used bathroom scale for determining body weight. Specifically,

the user is instructed to first step on the platform 20. In the embodiment shown in Figure 1 an array of pressure sensitive transducers 15 in the platform 20 detect the position of the user's foot by locating those portions of the foot which bear the weight of the body such as the heel and ball of the foot. Once the force signals provide an indication of foot position, the temperatures at preselected sites on the bottom or plantar aspects of both feet are measured. The device 10 will alert the user if there is an abnormally high temperature gradient between the corresponding aspects of the contralateral feet. The presence of such a significant temperature gradient may be indicative of a pathologic inflammation or possible tissue damage at that location on the user's foot. Such inflammation or tissue damage might be an indicator of a predisposition to further tissue breakdown in the foot and/or significant morbidity which, if left untreated, may lead to an ulcer, amputation or, in extreme cases, death.

As shown in Figure 1 and Figure 2, the apparatus of the present invention 10, 110 is built around a platform assembly 20 that is placed on a hard surface (not shown). Two pads or foot guides 130 may be used to guide the placement of the patient's feet. These foot guides 30 assure that the patient places his feet reproducibly and accurately on the platform assembly 20. Each foot guide 130 assures proper registration of the patient's foot with respect to a set of commonly available temperature sensing transducers 140. For patients with unusually shaped or deformed feet, custom made foot guides may be used.

In the preferred embodiment shown in Figure 1 pressure sensitive transducers 15 determine the location of the user's feet on the platform 20. This location information is then used to activate temperature sensing transducers 40 at predetermined locations.

The temperature sensing transducers 40, which provide an electrical signal representative of a temperature level, are disbursed on top of the platform assembly 20. These electrical signals are then displayed as either Fahrenheit or Celsius temperature readings to the user.

If desired a liquid crystal display 50, 150 can either show the actual temperature values measured by one or more temperature sensitive transducers 40, 140 and/or alert the user that a difference in temperature may exist between two sensor sites. Alternatively, the temperature readings or warnings about possibly dangerous temperature differences may be conveyed audibly to the user through one or more speakers 55, 155.

It has also been found that the utility of the apparatus 10 for monitoring the temperature of the plantar aspects of the human foot can be expanded to measure other vital health information through the use of a variety of different enhancements. Specifically, the apparatus of the present invention 10, 110 can easily be modified to also measure the weight of the patient. The measurement of weight is important because fluctuations in weight may be significant to patients with exacerbations of congestive heart failure. Such sudden weight change usually signifies water retention throughout the body. The need to monitor fluctuations in weight is particularly important for diabetics who are prone to suffer from congestive heart failure (CHF). Thus, it is desirable for diabetics that the foot temperature variations and body weight changes be quantified and displayed on a daily basis. Selection of the health information displayed is facilitated by the use of easily accessible buttons 57 or a keypad 59 as shown in Figure 1.

If desired, body weight may be measured with the apparatus 10, 110 using a force or pressure transducer 15 in the same way that force or pressure transducers are used

in standard bathroom scales. The liquid crystal display 50, 150 may be used for the display of body weight.

It has also been found that the preferred embodiment of the apparatus 10 of the present invention may be further enhanced by the addition of still other medical condition monitoring systems well known to those of ordinary skill in the art. Such other medical condition monitoring systems may measure blood glucose levels with a finger pin stick system 70, or some other non-invasive system, an arm blood pressure cuff and pulse counter 74, or a red light and light sensor clipped on the end of a finger to measure blood oxygen 76. Present technology enables the measurement of blood glucose levels and blood oxygen using a variety of techniques including lasers, infrared percutaneous readings or assessment of blood glucose levels using the patient's saliva or standard fingersticks and strips. Blood pressure may even be measured at foot level with an ankle cuff or toe cuff 78.

Once the vital health information has been obtained by the apparatus 10 of the present invention, it may be stored internally where it can be compared with prior data to inform the user of noticeable trends in changes of weight or temperature and, if necessary, provide an alarm signal. Alternatively, the information may be sent to a central computer using a standard telephone system 80, the internet, cell phone, or other wireless communication means. The central computer 100 monitors the measurements of vital health information taken by the device 10, 110 and thereby allows such measurements to be taken much more frequently by patients in the comfort of their own home.

The schematic diagram of Figure 3 shows how the various components of the device of the present invention are interconnected.

OPERATION

The present invention may be utilized if the patient is either lying down, sitting, or standing up. The key aspect of the present invention is to ensure that the bottom of the patient's feet are properly registered with respect to the array of temperature sensitive transducers 40 located in the platform assembly 20. Alternatively, foot temperatures could be measured by non-contact means such as infra-red probes or by the use of thermal imaging techniques.

In the low cost embodiment shown in Figure 2, the proper registration of each foot with respect to the array of probes may be accomplished by the use of simple guides 125 which surround the array of temperature sensitive transducers 140. These simple guides may be pre-located by medical personnel for an individual patient and preferably include a heel plate and a side plate against which the patient may rest his/her foot.

If it is necessary to measure the temperature variations in a person's foot while the person is in a hospital bed or in an ambulance, portable pads which contain the temperature sensitive transducers may be strapped into proper position on the user's foot. In yet another alternative embodiment, the temperature sensitive transducers may actually be placed in a pad which is insertable into a shoe. Connections from temperature sensitive transducers 40 would then lead to a plug-in connection on the patient's shoe, a sock, or any footwear. The data sent by the temperature sensitive transducers could then be sent from the shoe by merely plugging in a connector at a convenient location on the shoe--which connector is connected to individual temperature sensitive transducers. The foot temperature data could be sent to a central monitoring facility 100 using a modem, cellular, or conventional techniques.

In yet another embodiment the data collected by the apparatus 10, 110 will include an indication of the date and time the temperature readings were taken. This data may be stored at the device 10, 110 itself or transmitted
5 to a remote location by wire or wireless means where it may be stored and later analyzed.

If the data is transmitted to a database at a remote location, it would then be possible for a health care professional to monitor the data and determine if a
10 significant change has occurred in the contralateral temperatures of a user's lower extremities, the user's weight, or the user's blood pressure.

The apparatus and method of the present invention may also provide the foundation for a method of operating a
15 health information monitoring business. Specifically, the sensed vital health information could be sent to a data storage facility and compared with past data or predetermined levels of vital health information. If this comparison yields an indication of a condition which is
20 predictive of future health problems, a health care professional may call the patient and recommend a consultation or treatment which may cure a nascent condition before limb or life-threatening symptoms are experienced. Such a vital health information monitoring
25 system could be required for use by designated employees of an employer to reduce lost time maladies. Further, such a vital health information monitoring system could also be required for use by life or health insurance companies to provide a basis for reassessing the risk that the insurance
30 company will have to pay for the health care costs associated with an illness or malady or the face amount of a life insurance policy on the death of the insured. Such risk reassessment could be used to tailor premium rates to the health of individual insureds.

It will be understood by those of ordinary skill in the art that while the apparatus and method of the present invention has been described with respect to its preferred embodiment, those of ordinary skill in the art will understand the numerous other embodiments of this invention which may be possible without departing from the foregoing teachings. Such other embodiments shall be included within the scope and meaning of the appended claims.

CLAIMS

What is claimed is:

- 1 1. An apparatus for monitoring the temperature of
2 the plantar aspects of the foot of a human being, said
3 device comprising:
4 a platform;
5 an array of force sensitive devices for
6 determining the location of the left foot on the platform;
7 an array of force sensitive devices for
8 determining the location of the right foot on the platform;
9 a set of temperature sensitive, signal generating
10 devices activated by the determined locations of the human
11 being's feet on the platform;
12 means for converting said signals generated by
13 said temperature sensitive devices into an output expressed
14 in terms of temperature.
- 1 2. The apparatus as defined in Claim 1 further
2 including means for generating a warning if a temperature
3 beyond a predetermined level as between two or more of said
4 temperature sensitive devices is sensed.
- 1 3. The apparatus as defined in Claim 1 wherein said
2 output of sensed temperatures is a visual output.
- 1 4. The apparatus as defined in Claim 3 wherein said
2 visual output is a liquid crystal display.
- 1 5. The apparatus as defined in Claim 1 wherein said
2 output of sensed temperatures is an audio output.
- 1 6. The apparatus as defined in Claim 1 further
2 including means for sensing and displaying the weight of
3 the human being.

1 7. The apparatus as defined in Claim 1 further
2 including means for sensing and displaying the blood
3 pressure of the human being.

1 8. The apparatus as defined in Claim 1 further
2 including means for sensing and displaying the pulse rate
3 of the human being.

1 9. The apparatus as defined in Claim 1 further
2 including means for sensing and displaying the blood
3 glucose levels of the human being.

1 10. The apparatus as defined in Claim 1 further
2 including means for sensing and displaying the blood oxygen
3 levels of the human being.

1 11. The apparatus as defined in Claim 1 further
2 including a modem for transmitting the sensed foot
3 temperatures to a remote location.

1 12. The apparatus as defined in Claim 7 further
2 including means for transmitting the sensed blood pressure
3 to a remote location.

1 13. The apparatus as defined in Claim 8 further
2 including means for transmitting the sensed pulse rate to a
3 remote location.

1 14. The apparatus as defined in Claim 9 further
2 including means for transmitting the sensed blood glucose
3 level to a remote location.

1 15. The apparatus as defined in Claim 10 further
2 including means for transmitting the sensed blood oxygen
3 level to a remote location.

1 16. A system for monitoring the temperatures of the
2 plantar aspects of the feet of a plurality of patients,
3 said system comprising:

4 a plurality of individual foot temperature
5 measuring devices, each of said plurality of individual
6 foot temperature measuring devices including:

7 a platform;

8 a means for determining the location of the left
9 foot on the platform;

10 a means for determining the placement of the
11 right foot on the platform;

12 a set of heat sensitive, signal generating probes
13 constructed and arranged on said platform to sense the heat
14 levels at predetermined locations on both the left foot and
15 the right foot of the human being;

16 means for converting said signals generated by
17 said heat sensitive probes into an output expressed in
18 terms of temperature;

19 means for sending said signals to a remote
20 location;

21 means for storing and analyzing said signals at
22 said remote location;

23 whereby the temperatures of the feet of a
24 plurality of human beings may be monitored at said remote
25 location.

1 17. The system as defined in Claim 16 wherein said
2 means for sending said signals to a remote location is a
3 telephone modem.

1 18. The system as defined in Claim 16 further
2 including means for generating a warning if a temperature
3 beyond a predetermined level as between two or more of said
4 probes is sensed.

1 19. The system as defined in Claim 16 further
2 including a visual display of sensed temperatures.

1 20. The system as defined in Claim 18 further
2 including means for generation of an audio warning.

1 21. The system as defined in Claim 16 further
2 including means for sensing and displaying the weight of
3 the human being.

1 22. The system as defined in Claim 16 further
2 including means for sensing and displaying the blood
3 pressure of the human being.

1 23. The system as defined in Claim 16 further
2 including means for sensing and displaying the pulse rate
3 of the human being.

1 24. The system as defined in Claim 16 further
2 including means for sensing and displaying the blood
3 glucose levels of the human being.

1 25. The system as defined in Claim 16 further
2 including means for sensing and displaying the blood oxygen
3 levels of the human being.

1 26. The system as defined in Claims 16, 21, 22, 23,
2 24 and 25 further including means for storing the sensed
3 information along with the date and time when the
4 information was sensed.

1 27. A health monitoring system comprising:
2 a left footpad and a right footpad;
3 each of said left footpad and said right footpad
4 including:

5 a plurality of individual temperature sensors
6 located at predetermined locations on said left footpad and
7 said right footpad;

8 at least one guide for repeated registration of
9 the physical position of said temperatures in said footpad
10 with respect to the plantar aspects of a foot;

11 whereby the temperature predetermined locations
12 on the plantar aspects of the feet of a human being may be
13 repeatedly measured.

1 28. The health monitoring system as defined in Claim
2 28 further including means for securing said left foot pad
3 and said right foot pad to the feet of the patient.

1 29. The health monitoring system as defined in Claim
2 28 wherein said left foot pad and said right foot pad are
3 tailored to fit an individual patient.

1 30. A method for monitoring the temperature at
2 predetermined locations on the feet of a human being, said
3 method comprising the steps of:

4 placing a plurality of temperature sensors at
5 predetermined locations in a pad;

6 placing said pad against the bottom of the foot
7 of a patient so that said temperature sensors are
8 repeatedly in contact with the same locations on the
9 plantar aspects of the patient's foot.

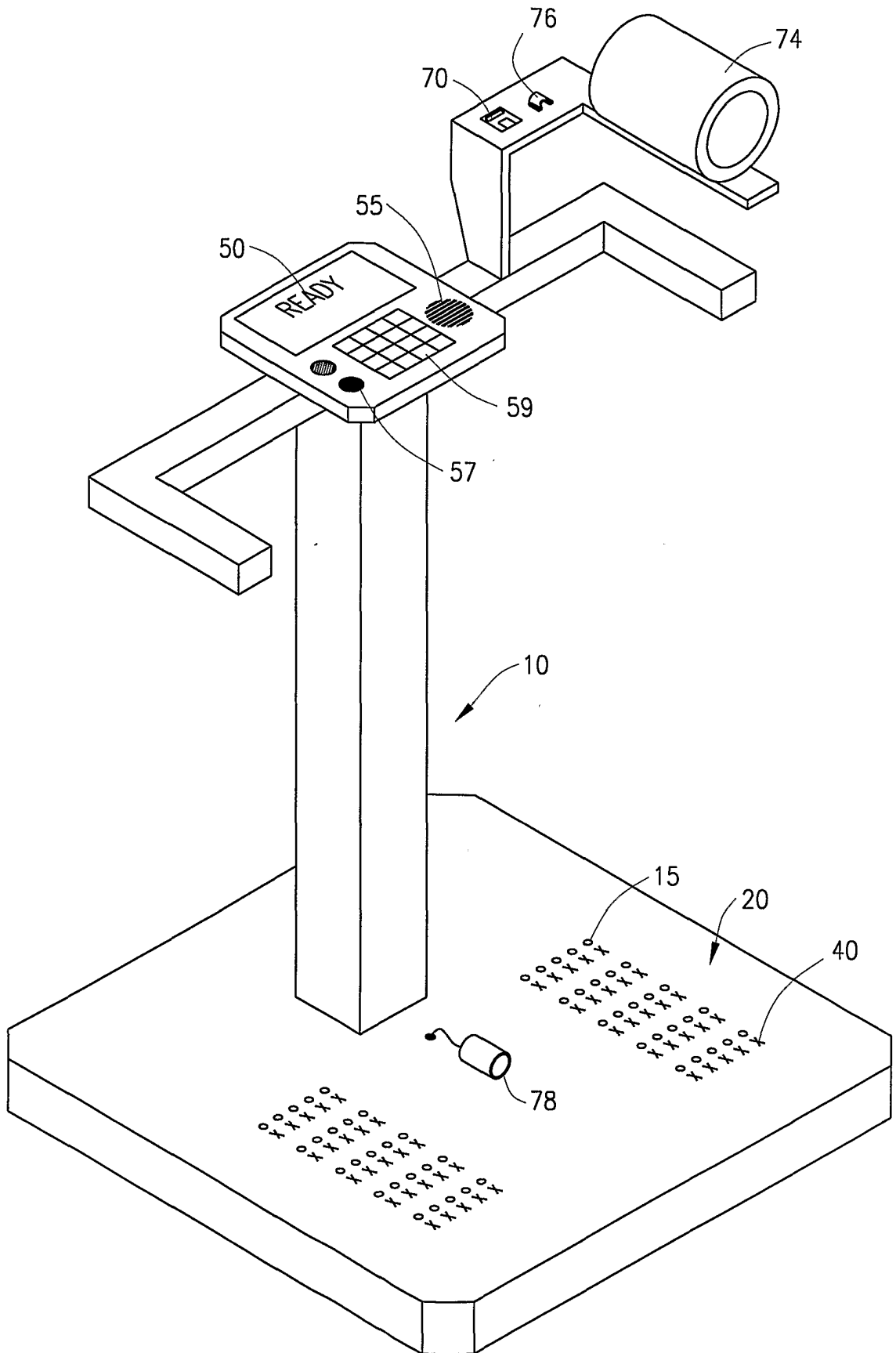
1 31. A method of monitoring the health of an employed
2 human being comprising the steps of:

3 a) repeatedly sensing at least one of the
4 following items of health information:

- 5 i) temperatures on the bottom of the feet
6 ii) body weight
7 iii) blood pressure

- 8 iv) pulse rate
9 v) blood glucose level
10 vi) blood oxygen level;
11 b) transmitting said at least one item of
12 health information to the employer;
13 c) comparing said at least one items of health
14 information to other like items of health information
15 sensed on prior occasions;
16 d) alerting the employed human being of a
17 potential health problem.

- 1 32. A method of monitoring the health of an insured
2 human being comprising the steps of:
3 a) repeatedly sensing at least one of the
4 following items of health information:
5 i) temperatures on the bottom of the feet
6 ii) body weight
7 iii) blood pressure
8 iv) pulse rate
9 v) blood glucose level
10 vi) blood oxygen level;
11 b) transmitting said at least one item of
12 health information to the employer;
13 c) comparing said at least one items of health
14 information to other like items of health information
15 sensed on prior occasions;
16 d) re-evaluating the insurance risk of the
17 insured human being based on the sensed health information.



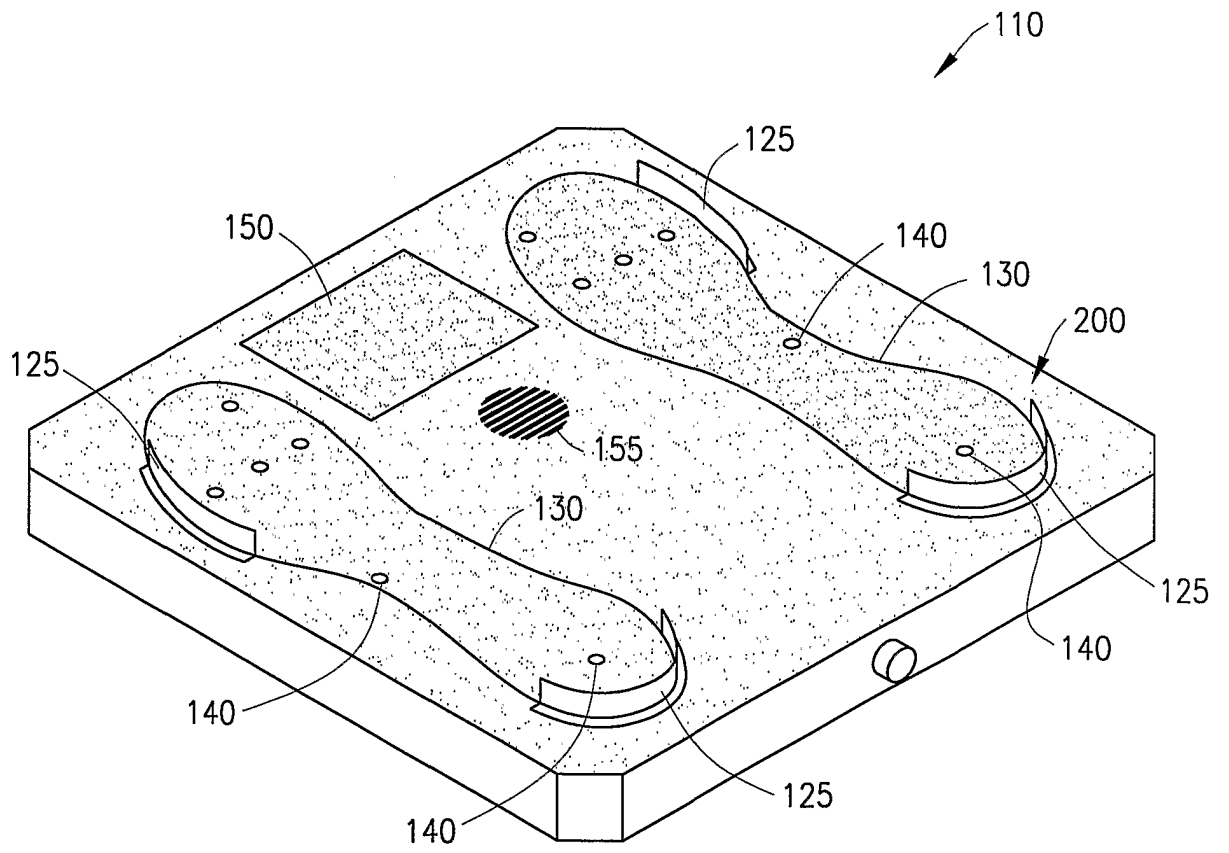


FIG. 2

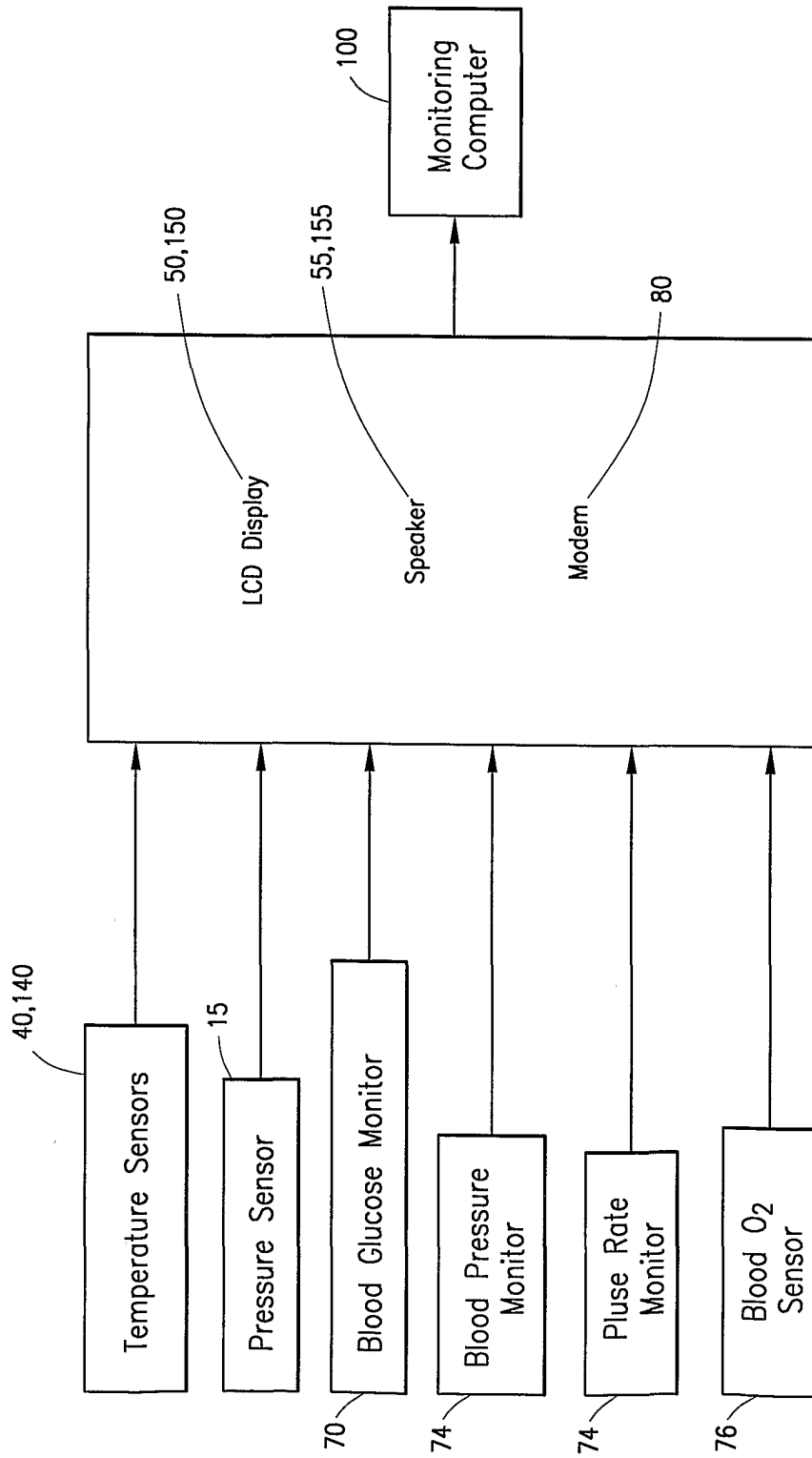


FIG. 3

专利名称(译)	人体足部监测系统		
公开(公告)号	EP1289410A2	公开(公告)日	2003-03-12
申请号	EP2001939488	申请日	2001-05-25
[标]申请(专利权)人(译)	萨利克斯医疗设备公司		
申请(专利权)人(译)	SALIX MEDICAL , INC.		
当前申请(专利权)人(译)	SAVE医疗 , INC.		
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IPC分类号	A61B5/00 A61B5/01 A61B5/022 A61B5/024		
CPC分类号	A61B5/015 A61B5/022 A61B5/024 A61B5/145 A61B5/14532 Y10S128/903 Y10S128/904		
代理机构(译)	UEXKÜLL & STOLBERG		
优先权	09/578948 2000-05-25 US		
其他公开文献	EP1289410A4		
外部链接	Espacenet		

摘要(译)

一种用于监测重要健康信息项的装置和方法，包括人体足底的体温，体重（15），血压（78），脉搏率（74），血糖水平（70）和血液的温度氧气水平（76）。装置（10）包括用户站在其上的平台（20）。平台（20）上包括一组热敏信号发生装置（40）。人脚的足底方面的预定位置处的温度由从各个热敏信号产生探针（40）获得的信号确定。其他重要健康信息项可以由设备上的其他传感器获得。