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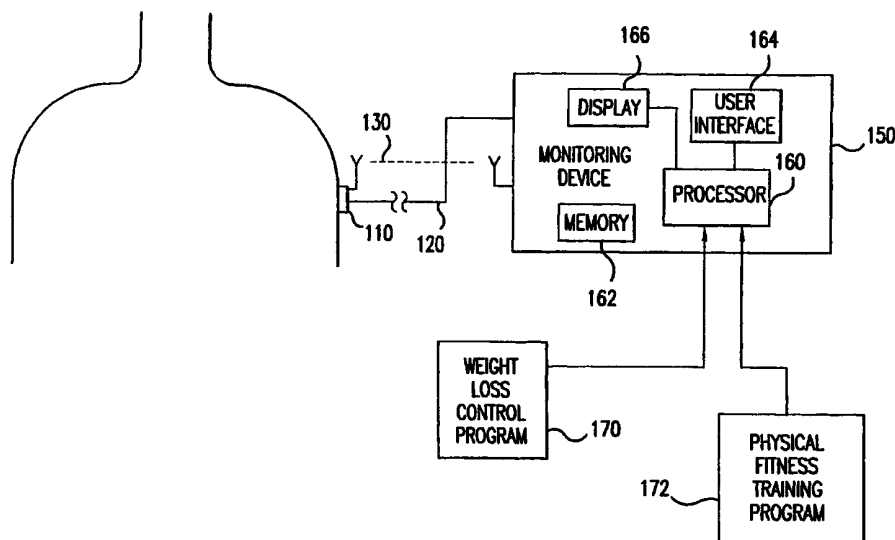
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(54) Title: SYSTEM AND METHOD FOR MONITORING GLUCOSE TO ASSIST IN WEIGHT MANAGEMENT AND FITNESS TRAINING



(57) Abstract: A system and method to manage an individual's weight by setting a maximum desired glucose level for an individual; recording glucose levels at multiple times during a day for the individual so as to obtain glucose levels after at least one meal event of the individual; and comparing post meal glucose levels with the maximum desired glucose level. A system and method are provided to assist an individual in fitness training or exercise, comprising recording glucose levels of an individual while the individual is undergoing physical exercise; comparing glucose levels during physical exercise with a threshold level; and generating an indicator when the glucose level during physical exercise is below the threshold level.



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SYSTEM AND METHOD FOR MONITORING GLUCOSE TO ASSIST IN WEIGHT MANAGEMENT AND FITNESS TRAINING

This application claims priority to U.S. Provisional Application No.
5 60/139,943, filed June 18, 1999, the entirety of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

The present invention is directed to glucose monitoring, and more particularly
10 to the use of continuous glucose measurements for personal fitness management.

Research and development efforts are being made to provide technology that makes glucose monitoring less invasive and disruptive to an individual's daily life. Some systems involve the use of implantable sensor devices, which have drawbacks such as the need for surgery to implant the sensor and the associated risks of infection.
15 Another type of system is much less invasive and involves collecting on a continual basis biological fluid from small openings made in the skin. Such a system is disclosed in co-pending PCT Application No. PCT/US99/16378, filed July 20, 1999, and entitled "System and Method for Continuous Analyte Monitoring." This type of system is proving to be more promising for use on a large scale basis.

20 The ability to automatically continuously or repeatedly monitor glucose levels of an individual over extended periods of time during an individual's normal daily routine makes it possible to monitor metabolic activity. In particular, monitoring glucose level on a continual basis provides insight into eating habits that lead to weight (gain or loss) management, and into fitness performance.

25

SUMMARY OF THE INVENTION

The present invention is directed to a system and method for using glucose measurements obtained from an individual on a continuous basis to manage an individual's weight gain or loss and exercise or fitness performance.

In accordance with one embodiment of the invention, a system and method are provided to manage an individual's weight by setting a maximum desired glucose level for an individual; recording glucose levels at multiple times during a day for the individual so as to obtain glucose levels after at least one meal event of the individual; and comparing post meal glucose levels with the maximum desired glucose level.

In accordance with another embodiment, a system and method are provided to assist an individual in fitness training or exercise, comprising recording glucose levels of an individual while the individual is undergoing physical exercise; comparing glucose levels during physical exercise with a desired level or threshold; and generating an indicator when the glucose level during physical exercise is below the threshold level.

The above and other objects and advantages of the present invention will become more readily apparent when reference is made to the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a block diagram of a system according to the present invention.

FIG. 2 is a diagram of a fluid collection and sensor device useful in connection with the present invention.

FIG. 3 is a flow chart depicting a weight management process according to an embodiment of the invention.

FIG. 4 is a flow chart depicting a fitness management process according to an embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

FIG. 1 illustrates a glucose monitoring system 100 comprising a tissue-mounted fluid collection and assay device 110 and a monitoring device 150. The fluid collection and assay device 110 is coupled to the monitoring device 150 by a wired link 120 or a wireless link 130. An example of a monitoring system suitable for

use in conjunction with the present invention is the monitoring system disclosed in the
aforementioned co-pending PCT Application No. PCT/US99/16378, the entirety of
which is incorporated herein by reference. Other examples of fluid collection and
sensor devices are disclosed in co-pending PCT Application No. PCT/US99/16226,
5 filed July 20, 1999, and entitled "System and Method for Fluid Management in a
Continuous Fluid Collection and Sensor Device," and in PCT Application No.
PCT/US00/09393, filed April 7, 2000, and entitled "Assay Device for Measuring
Characteristics of a Fluid on a Continual Basis."

With reference to FIG. 2, the fluid collection and assay device 110 is
10 positioned on the tissue proximate to one or more openings 180 made in the tissue to
collect biological fluid, such as blood or interstitial fluid. The openings in the tissue
may be made by any suitable technique and apparatus known in the art, such as
lancet, needle, micro-needle, thermal microporation, etc. An example of a thermal
microporation technique is disclosed in U.S. Patent No. 5,885,211. Vacuum may be
15 applied to the fluid collection and assay device 110 from the monitoring device 150
via a conduit 190 to draw fluid from the tissue on a periodic or continuous basis when
it is desired to make a reading. Conduit 190 may contain the wired link 120 (FIG. 1).
When biological fluid is drawn into the device 110, it contacts an assay element 112
in the fluid collection and assay device 110. The assay element 112 may be any type
20 of glucose assay element known in the art, such as an electrochemical bio-sensor,
optically read sensor, etc. Readings are made from the assay element 112 by the
monitoring device 150, either electrically via electrodes disposed in or on the assay
element 112, or optically. Further details about a fluid collection and assay device
110 are disclosed in the aforementioned PCT applications. An advantage of the
25 continuous analyte monitoring system and methods disclosed in these related
applications is the ability to extract and analyze new samples of biological fluid from
the same tissue openings over an extended period of time, such as throughout an
entire day, several days or longer.

Referring back to FIG. 1, the monitoring device 150 comprises a processor 160 suitable for performing calculations on the readings taken from the assay element in the fluid collection and assay device to derive measurements, such as glucose measurements. The processor 160 may be a microprocessor, application specific integrated circuit (ASIC), digital signal processor, or any other device capable of performing computations necessary for the processes of the present invention.

In one form, the processor 160 is a microprocessor that executes one or more programs stored in a memory 162. Memory 162 is any type of a read only memory (ROM), random access memory (RAM) or a combination thereof suitable for storing a program that contains the instructions for the processes described herein, as well as storing data obtained from measurements and other information derived from that data. One program that may be made available to the processor 160 is a weight loss control program 170 and another is a physical fitness training program 172. These programs may be based on separate instructions or derived from a common set of instructions.

The monitoring device 150 optionally includes a user interface 164 to enable input of information from a user. The user interface 164 is, for example, an alphanumeric keypad, a touch-screen user interface, voice recognition interface, handwriting recognition interface, etc. Programming of parameters into the monitoring device 150 may also be achieved via the user interface 164. A display 166 is also optionally provided to display information such as glucose levels, status information, information being input into the monitoring device by a user, and other messages or information communications from the monitoring device 150 to the user.

The human body produces glucose for nourishment of cells. When production of glucose varies, excess glucose is converted into fat for storage, or the fat is metabolized to produce glucose when glucose levels are low. It is on this principle that the present invention is based. These production mechanisms and rates can be monitored using a continuous glucose monitoring system such as the one shown in FIG. 1. Monitoring glucose levels can provide insight into foods and eating habits,

which lead to weight gain and loss, as well as to energy level and consumption rates in physical exercise.

According to one aspect of the invention, glucose levels are monitored on a continual basis to aid in the selection of nutritional consumption by providing a mechanism to monitor the results of consumption. The impact of certain foods in a particular individual can be assessed by monitoring the amount and rate of glucose produced. Guidelines can be set to achieve desired and controlled weight gain or loss. Similarly, according to another aspect of the invention, by monitoring a person during exercise, the type, rate and duration of the exercise can be assessed based on the glucose consumption and production amounts and rates. Through long term monitoring of changes in these conditions, information can be created to optimize a person's fitness endurance and performance.

Turning to FIG. 3 in conjunction with FIG. 1, a process is shown for a weight management program such as that shown at reference numeral 170 in FIG. 1. In step 200, a maximum desired glucose level is set. This level may be derived by a trained professional (such as a physician) from physical characteristics including body mass index and percentage body fat, and an individual's goals for weight loss or gain. A numeric value corresponding to this maximum level is stored in the weight management program. The storage mechanism may be via an infra-red, radio frequency, or other wireless programming technique to convey information to the monitoring device 150. Alternatively, a keypad or touch-screen is provided on the housing of the monitoring device 150 that allows user or physician access to program the monitoring device 150.

Next, in step 210, the monitoring device 100 records glucose levels at programmed times during the course of a day. For example, the monitoring device 150 will obtain and record readings 288 times a day (every 5 minutes). The number of readings taken may vary so long as readings are taken before and after every anticipated meal event for that user. In step 220, a user logs meal events into the monitoring device 150. The mechanism for logging meal events may be by actuating

a button on the monitoring device 150, triggering a command via wireless, voice or audio command, or any other action via the user interface 164. Moreover, the monitoring device 150 may be responsive to a logging event to initiate several readings at various timed intervals to be sure to obtain sufficient data around the meal event. It is particularly important to obtain sufficient readings after the meal event.

In step 230, the post meal glucose levels are compared with the maximum glucose level. When and if a post meal glucose level exceeds the maximum level, in step 240 the monitoring device 150 may generate an alert indicator that is audio, visual or any combination. In addition, the processor 160 stores an indication of the fact that the maximum level was exceeded. By keeping track of when the maximum glucose level is exceeded, the user may adjust a meal plan or eating habits in step 250. For example, the user may try eating other types of foods or combinations of foods to achieve a lower intake of simple sugars at a particular meal event. The process is repeated from step 210 for a new or modified meal. Also, the maximum glucose level may be adjusted if necessary after sufficient information is learned about the individual. Moreover, the maximum glucose level can be used as a target to achieve as part of a process to achieve weight gain for a particular user.

One method of enabling the user to keep track of the various foods eaten at each meal is through user interaction with the monitoring device 150 and additional intelligence provided in the monitoring device 150. In step 220, when a user logs a meal event, or at any other time convenient to the user, the user may enter information into the monitoring device 150 via the user interface 164 that identifies each food item ingested for a meal event. In this manner, the monitoring device 150 can track which item or items may be contributing to a high glucose reading and inform the user accordingly to assist the user in modifying food selection accordingly to prevent glucose levels from going above the maximum glucose level. This may be achieved through a program and database stored in the monitoring device 150 that is capable of identifying those food items most likely to contain high levels of simple sugars. Moreover, when a user informs the monitoring device 150 of the food items for a

particular meal, the monitoring device 150 may suggest to the user lower quantities of a particular food item if that item was one eaten by the user at that meal, or perhaps suggest other food items known to have less impact on glucose levels.

Communication of information from the monitoring device 150 to the user may be in the form of an alphanumeric message or synthesized voice message generated by the processor 160 and displayed on the display 166. This type of communication between the monitoring device 150 and the user may occur during step 250 or any other time when the user may inquire of the monitoring device 150 of eating plans or suggestions.

Referring to FIG. 4 in conjunction with FIG. 1, a process for managing fitness exercise or training will be described. In step 300, glucose levels are recorded to a user's fitness routine or exercise circuit. The monitoring system 100 shown in FIG. 1 is suitable to be worn by a user during nearly any type of physical activity. When a user is about to begin an exercise of fitness activity, a command is given to the monitoring device 150 to initiate the fitness management program so that glucose measurements are taken at appropriate time intervals during the fitness event. The number and frequency of the measurements may vary depending on the duration of the fitness event.

A threshold glucose level is computed in step 310 based on the measurements taken in step 300. The threshold is a goal or desired level and is physiologically dependent on the individual. For example, it may be 10 mg/dL below a fasting glucose level for an individual.

Once the threshold glucose level is computed, in step 320 the user begins his/her fitness routine or exercise circuit and glucose levels are recorded at appropriate time intervals during the fitness event. The monitoring device 100 compares the recorded glucose levels with the threshold level. The monitoring device 100 generates an indication when the glucose level during the fitness event is below the threshold level. The monitoring device 100 may generate (audio, visual or a combination thereof) alerts during the fitness event when the user's glucose level

drops below the threshold level. Alternatively, or in addition to the alerts, the monitoring device may generate historical data summary reports that can be viewed on a personal computer, on a display of the monitoring device itself, or sent to a printer for hard copy. The historical data summary report will indicate when (in time
5 and/or during certain exercises) during the fitness event the glucose level dropped below the threshold level. With this information, the user may modify the exercise routine in step 350 to prevent such a glucose drop. For example, the user may modify the intensity, duration and/or type of exercise in order to maintain sufficient glucose levels, thereby preventing overexertion and/or reduction of muscle mass. Moreover,
10 extended glucose monitoring can help a user determine which foods support extended level glucose periods during exercise. The user may enter information into the monitoring device that describes the type of foods ingested at a meal event. Interaction between the user and the monitoring device similar to that described above in conjunction with the weight management program may also be used in the fitness
15 management program.

The above description is intended by way of example only.

Claims:

1. A method for assisting an individual in weight management, comprising steps of:
 - setting a maximum desired glucose level for an individual;
 - recording glucose levels at multiple times during a day for the individual so as to obtain glucose levels after at least one meal event of the individual; and
 - comparing post meal glucose levels with the maximum desired glucose level.
2. The method of claim 1, and further comprising the step of generating an indicator when it is determined that a post meal glucose level exceeds the maximum glucose level.
3. The method of claim 2, and further comprising the step of generating a indicator or signal that advises the individual to alter eating habits so as to prevent glucose levels from going above the maximum glucose level.
4. The method of claim 1, and further comprising the step of receiving input from the individual indicating the occurrence of a meal event.
5. The method of claim 1, and further comprising informing the individual of a food item for a meal event that may be responsible for higher glucose levels.
6. A system for monitoring glucose levels of an individual to assist in weight management, comprising:
 - a sensor that detects glucose in biological fluid obtained from an individual;
 - a processor coupled to the sensor, the processor being operative to:
 - store data representing a maximum glucose level for an individual;

store data representing glucose levels determined from the sensor at multiple times during a day so as to obtain glucose levels after at least one meal event of the individual; and

compare post meal glucose levels with the maximum glucose level.

7. The system of claim 6, wherein the processor generates an indicator when it is determined that a post meal glucose level exceeds the maximum glucose level.

8. The system of claim 6, wherein the processor generates a signal that advises the individual to alter eating habits so as to prevent glucose levels from going above the maximum glucose level.

9. The system of claim 6, wherein the processor generates information to inform the individual of a food item for a meal event that may be responsible for higher glucose levels.

10. A method for assisting an individual in fitness training or exercise, comprising steps of:

recording glucose levels of an individual while the individual is undergoing physical exercise;

comparing glucose levels during physical exercise with a threshold level; and

generating an indicator when the glucose level during physical exercise is below the threshold level.

11. The method of claim 10, and further comprising the step of modifying physical exercise intensity, duration and or selection such that glucose levels substantially throughout the period of physical exercise are at or above the threshold level.

12. The method of claim 10, and further comprising the step of modifying eating habits to achieve glucose levels that are at or above the threshold level substantially throughout the period of physical exercise.

13. The method of claim 10, and further comprising the step of determining the threshold level based upon glucose levels recorded during physical exercise and a physiologically dependent goal.

14. A system for monitoring glucose levels of an individual to assist in fitness training or exercise, comprising:
a sensor that detects glucose in biological fluid obtained from an individual;
a processor coupled to the sensor, the processor being operative to:
store data representing glucose levels determined from the sensor during periods of physical exercise of the individual;
compare glucose levels during the physical exercise with a threshold level; and
generate an indicator when the glucose level during physical exercise is below the threshold level.

15. The system of claim 14, wherein the processor generates a signal advising the individual to modify physical exercise intensity, duration and/ or selection such that glucose levels substantially throughout the period of physical exercise are at or above the threshold level.

16. The system of claim 14, wherein the processor generates a signal advising the individual to modify eating habits to achieve glucose levels that are at or above the threshold level substantially throughout the period of physical exercise.

17. The system of claim 14, wherein the processor determines a threshold glucose level based on glucose levels recorded during physical exercise and a desired physiologically dependent goal of the individual.

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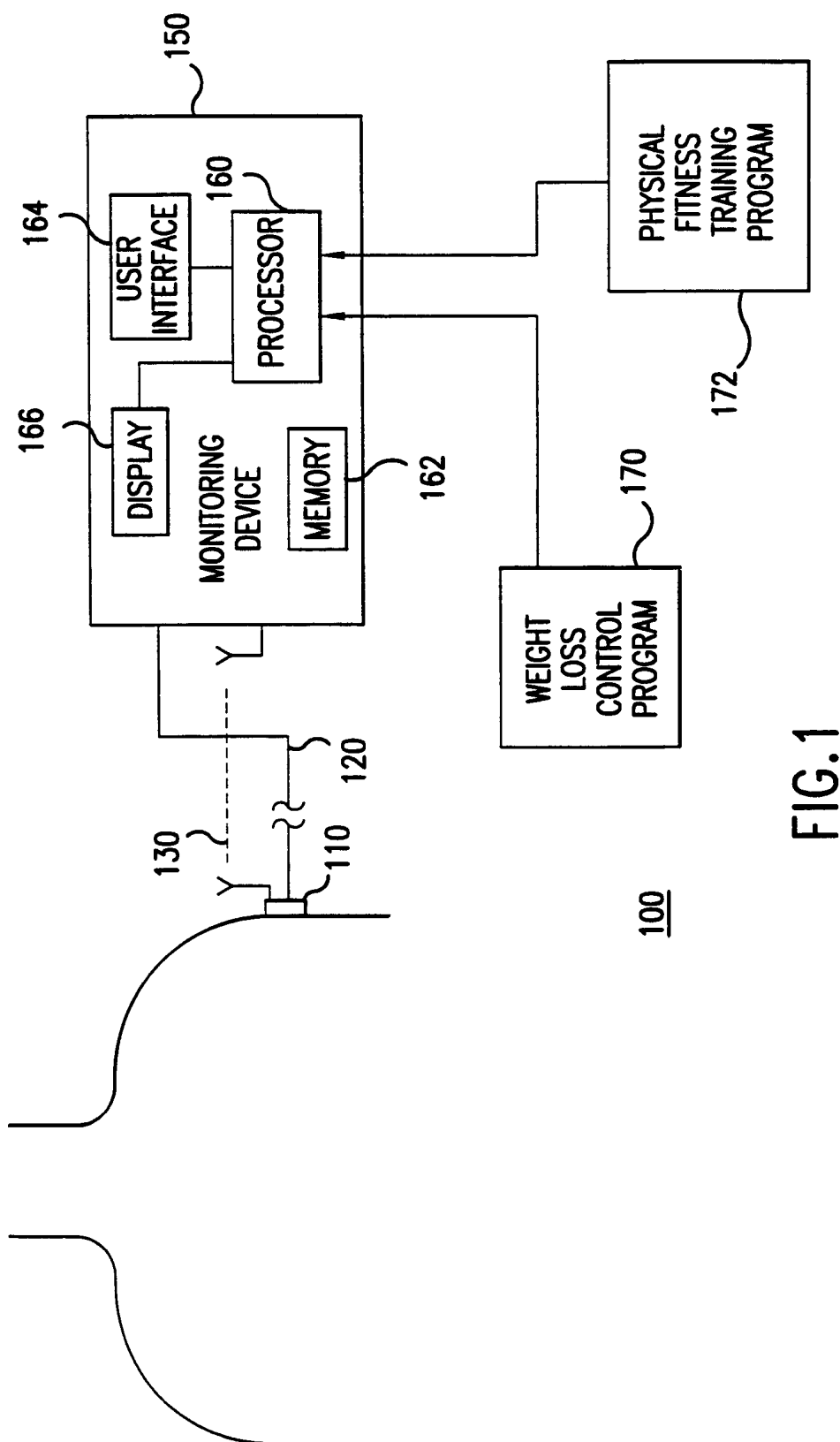


FIG.1

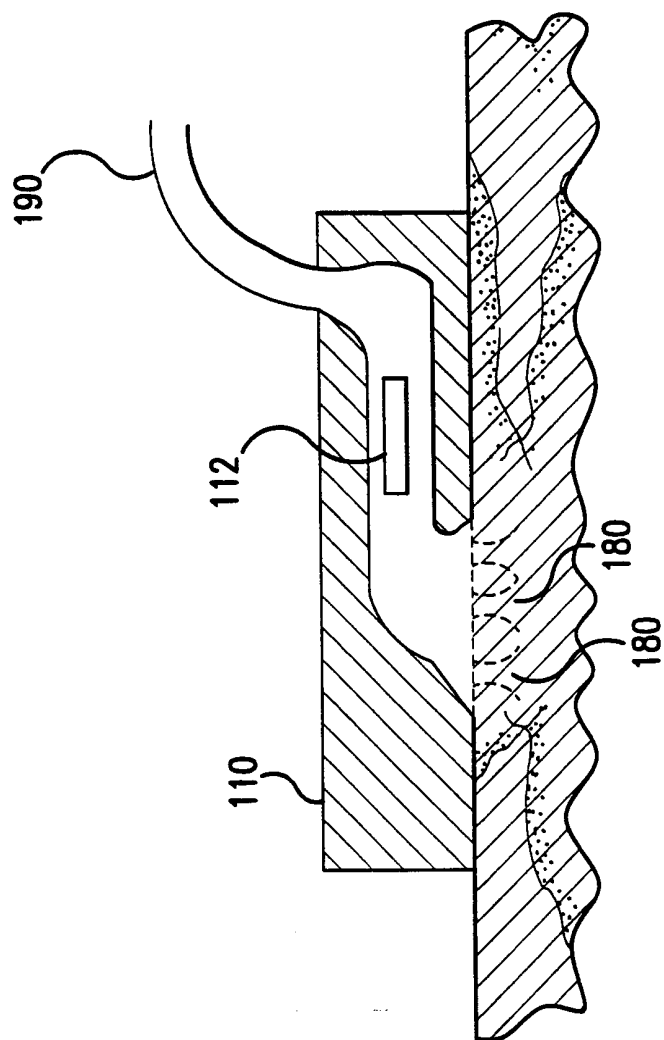


FIG.2

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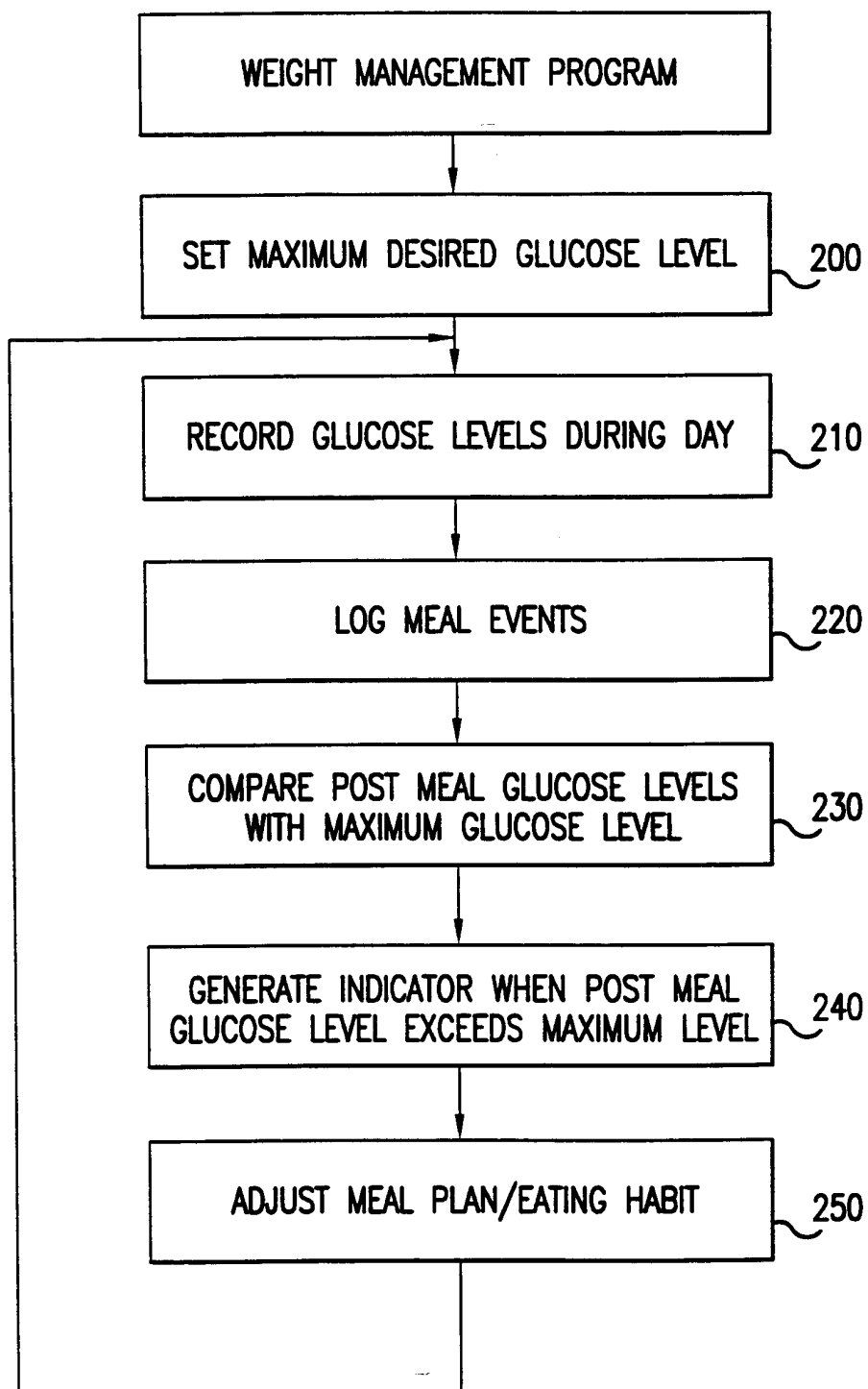


FIG.3

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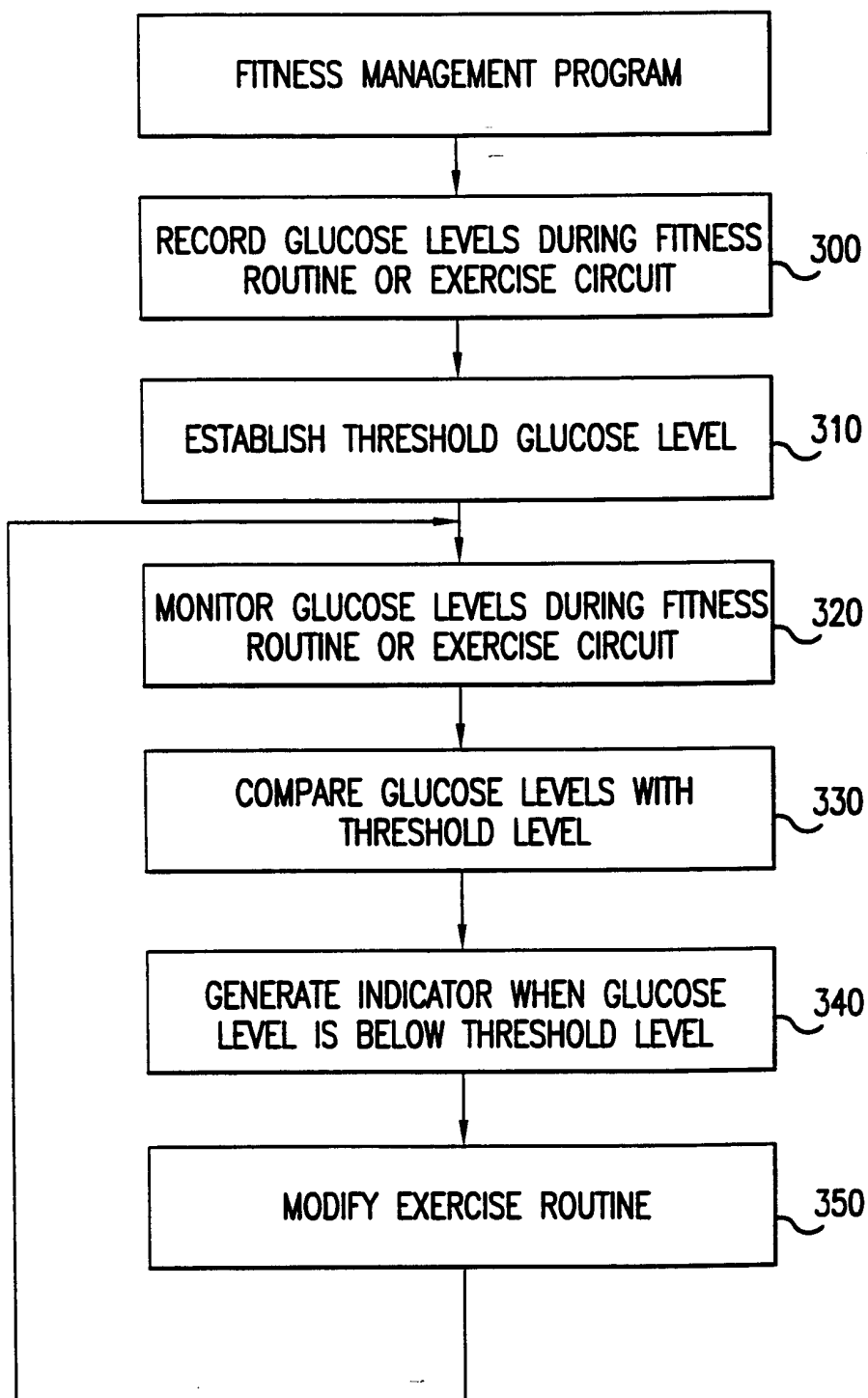


FIG.4

INTERNATIONAL SEARCH REPORT

Internat. Application No
PCT/US 00/16507

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B G06F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 4 731 726 A (ALLEN III LYLE M) 15 March 1988 (1988-03-15) column 2, line 28 - line 46 column 3, line 64 -column 4, line 32 column 9, line 12 -column 10, line 48 column 13, line 33 -column 16, line 34; tables 1-5 ---	1,6,10, 14 2-5,7-9, 11-13, 15-17
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
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- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

* & * document member of the same patent family

Date of the actual completion of the international search

28 August 2000

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04/09/2000

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 00/16507

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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