

**(12) STANDARD PATENT**  
**(19) AUSTRALIAN PATENT OFFICE**

(11) Application No. **AU 2010302270 B2**

(54) Title  
**Continuous non-interfering health monitoring and alert system**

(51) International Patent Classification(s)  
**A61B 5/00** (2006.01)

(21) Application No: **2010302270**

(22) Date of Filing: **2010.09.20**

(87) WIPO No: **WO11/039745**

(30) Priority Data

(31) Number  
**61/246,990**

(32) Date  
**2009.09.30**

(33) Country  
**US**

(43) Publication Date: **2011.04.07**

(44) Accepted Journal Date: **2014.11.27**

(71) Applicant(s)  
**HEALTHWATCH LTD.**

(72) Inventor(s)  
**Romem, Yoram**

(74) Agent / Attorney  
**Adam Law Patent & Trade Mark Attorney, 26 Glengariff Drive, FLOREAT, WA, 6014**

(56) Related Art  
**US 2004/0158194**  
**US 2006/0286960**  
**US 2009/0131759**

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
7 April 2011 (07.04.2011)

(10) International Publication Number  
**WO 2011/039745 A4**

(51) International Patent Classification:  
*A61B 5/00* (2006.01)

(21) International Application Number:  
PCT/IL2010/000774

(22) International Filing Date:  
20 September 2010 (20.09.2010)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
61/246,990 30 September 2009 (30.09.2009) US

(71) Applicant (for all designated States except US):  
**HEALTHWATCH LTD.** [IL/IL]; 34 Hazeitim Street,  
46307 Herzeliya (IL).

(72) Inventor; and

(75) Inventor/Applicant (for US only): **ROMEM, Yoram**  
[IL/IL]; 34 Hazeitim Street, 46307 Herzeliya (IL).

(81) Designated States (unless otherwise indicated, for every  
kind of national protection available): AE, AG, AL, AM,  
AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ,  
CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO,

DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,  
HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP,  
KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD,  
ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI,  
NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD,  
SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR,  
TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every  
kind of regional protection available): ARIPO (BW, GH,  
GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG,  
ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ,  
TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK,  
EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU,  
LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK,  
SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ,  
GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

— with amended claims (Art. 19(1))

Date of publication of the amended claims: 26 May 2011

(54) Title: CONTINUOUS NON-INTERFERING HEALTH MONITORING AND ALERT SYSTEM

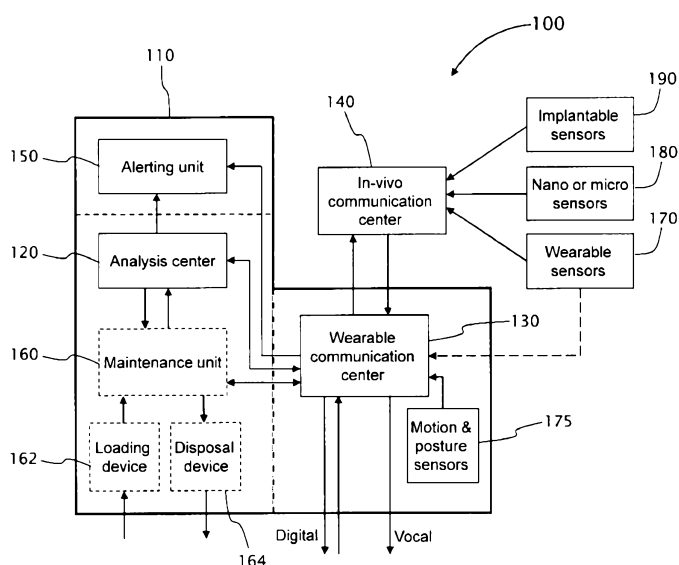


Fig. 1

(57) Abstract: A seamless and preferably substantially continuous health monitoring system, designed for use by a healthy living being but also suitable for non-healthy living being, the system including a control module, a communication unit and one or more sensors. The sensors can be in-vivo nano-sensors, micro-sensors, subcutaneous, wearable or implanted sensors. The control unit includes an analysis subsystem having a processing unit and an alerting unit. Each of the sensors is configured to detect a predetermined physiological or chemical parameter of the living being. The communication unit is facilitated to transmit the detected parameters to the analysis subsystem. The processor analyzes the detected parameters to thereby determine if the health state of the monitored living being is abnormal. When at least one detected parameter or the health state is determined to be abnormal, the alerting unit is operatively activated to alert a predetermined alert receiving entity.

# CONTINUOUS NON-INTERFERING HEALTH MONITORING AND ALERT SYSTEM

## CROSS REFERENCE TO RELATED APPLICATIONS

5           This application claims the benefit under 35 USC 119(e) from US provisional application 61/246,990 filed September 30<sup>th</sup>, 2009, the disclosure of which is included herein by reference.

## FIELD OF THE INVENTION

10           In preferred forms, the present invention relates to real-time health monitoring systems and more particularly, to a real-time health monitoring system, carried in-vivo or ex-vivo by a living-being being monitored, such that the system does not interfere with the everyday life of the monitored living being. Furthermore, in some preferred forms, the system of the present invention issues an alert upon detecting a potentially health  
15   hazardous situation.

## BACKGROUND OF THE INVENTION AND PRIOR ART

          Various prior art systems can monitor health parameters of a person after the  
20   person has been hospitalized or detected as being in some health danger and therefore needs special monitoring attention. Prior art systems and methods require the monitored person to make some adjustments to his/her normal life style: going to a laboratory, wearing a special monitoring device, or undergoing routine or non-routine checkups. However, before being detected as being in danger, the person is considered to be a healthy  
25   person. As such, no disturbances to his/her normal life style are usually acceptable: the person expects to live without any materials and/or devices attached to his/her body or to allow any disruption to daily activities. The problem is that people (or any other living being), considered to be healthy, are not monitored and that leads to frequent situations, in which a person suddenly suffers from a fatal or significant medical problem event that  
30   causes a major change in his/her normal life, sometimes for the rest of his/her life. Early detection of such significant medical problems may prevent (or minimize) such events.

          There is, therefore, a need and it would be advantageous to have a health monitoring system, implantable into and/or wearable by a living being to be monitored,

wherein the system does not interfere with the everyday life of the monitored living being and issues an alert upon detecting a potentially health hazardous situation or a tendency to develop such situation. This "early warning" system is the subject of the current invention.

5 In a common method to reduce fatal/major health risks, a person undergoes annual health checkups to determine his/her health status. However, these checkups do not provide any assurance that a short time after the checkup, the health situation of the checked person will not deteriorate, nor do such checkups cover a significant percentage of health hazards that may cause a significant life style change for the person. It should be  
10 noted that in most populations, people do not conduct routine health checkups and therefore these populations are more exposed to health hazardous situations.

There is a need, therefore, that the health monitoring system will continuously check the well being of a person (or any other living being) that is considered healthy, covering a significant range of health hazards that might cause a significant life style  
15 change/limitation, and provide an alert as early as possible – all this with no significant limitation to the normal life style of the person bearing the system. Preferably, with no limitation, no special routine action required of the monitored living being in order to get the alert, no special surgery should be needed for the system nor should limiting wearable devices be needed, as the system's major goal is to let the person continue his/her normal  
20 life until a potentially dangerous health situation occurs or starts to develop. Naturally, such a system may also be used by a sick person, detecting potential deterioration situations or new problems.

The term "continuous monitoring", as used herein with conjunction with a health monitoring system, refers to a health monitoring system, facilitated to monitor a living  
25 being substantially continuous, day and night, when the monitored living being is awake or asleep, and active in substantially all common activities of such living being.

The term "seamless", as used herein with conjunction with a wearable or implantable device, refers to a device that when worn by a person, the device puts no significant limitation to the normal life style of that person. Preferably, with no limitation,  
30 the in-vivo sensors insertion process does not require surgery or painful injection, but rather can be inserted by a laser-based insertion technique, an injection by micro-needles or by nano-needles, by swallowing pills or capsules, by transdermal patches, transmembrane receptors, using RF-based techniques or other nano sensors insertion

means known in the art. Furthermore, no activity is required from the monitored person in order to be able to be alerted when needed.

Prior art monitoring systems are not seamless, but rather interfere with the life style of the system wearer or require some special active actions by the wearer in order to get an alert. Prior art systems are not capable of detecting chemical parameters, for example in the blood or other internal systems (which require in-vivo sensors or methods to extract body fluids or organs). Furthermore, prior art systems are usually not adaptive to the specific person's dynamic health state, and do not algorithmically integrate between chemical and physical inputs to generate a reliable personal local alert. For example, US patent 6840904, given to Jason Goldberg, provides a portable device that receives data provided by one or more wearable sensors and displays statistical data related to the sensor data or otherwise related to the person. The system further includes a remote computer. Figure 2 of US patent 6840904, illustrates a portable medical monitoring device and sensors coupled to the device, wherein the portable device is mounted on the person's wrist and is wirely connected to a sensor mounted on the person's finger.

The term "nano sensor", as used herein, refers to a device that is constructed using molecular manufacturing techniques, also referred to as nano-technology.

The terms "nano technology based sensor" and "nano sensor" are used herein interchangeably.

The term "abnormal", as used herein with conjunction with health related parameters, refers to a parameter value or one or more ranges of values which are defined as health hazardous and require attention. For example, the normal blood pressure of an adult person is in the range 80-120 mm Hg. Typically, a blood pressure of 130 mm Hg would not be considered hazardous. However, if a person has a stable blood pressure around  $85 \pm 10$ , and suddenly it goes to  $125 \pm 10$ , this may be considered as an abnormal case. The threshold value from which the high blood pressure parameter is considered as health hazardous may vary and can be set personally and optionally, dynamically updated, either manually or automatically, by an adaptation algorithm. Once the high blood pressure parameter, in the above example, is set, any value out of the set threshold value will then be considered as abnormal for that person.

It would be further advantageous for the health monitoring system to have an algorithm that combines several parameters in the decision whether an abnormal situation occurs. Referring to the hereabove blood pressure example, when the blood pressure is

proximal to the threshold value and another parameter, such as arrhythmia, is proximal to its abnormal state, the combination of both may suffice to trigger an alert.

It is to be recognised that any discussion in the present specification is intended to explain the context of the present invention. It is not to be taken as an admission that the material discussed formed part of the prior art base or relevant general knowledge in any particular country or region.

In the present specification, the presence of particular features does not preclude the existence of further features. The words 'comprising' 'including' and 'having' are to be construed in an inclusive rather than an exclusive sense.

10

#### BRIEF SUMMARY OF THE INVENTION

According to preferred embodiments herein described there is provided a seamless health monitoring and alerting system, configured for use by a healthy living being, comprising:

- 15           a)       a control module including:
- i)       an analysis subsystem having a processing unit; and
- ii)       an alerting unit;
- b)       a communication unit; and
- c)       one or more sensors,

20           wherein each of said one or more sensors is configured to detect a predetermined physiological or chemical parameter of said living being;

              wherein said communication unit is facilitated to receive said detected parameters from each of said one or more sensors and transmit said detected parameters to said analysis subsystem;

25           wherein said processor of said analysis subsystem of said control module analyzes said detected parameters to thereby determine if one or more of said detected parameters or a combination of said detected parameters is abnormal;

              wherein, when at least one of said detected parameters is determined to be abnormal, said alerting unit is operatively activated by said processing unit to alert said living being carrying the health monitoring system and optionally, one or more

30

predetermined alert receiving entities; and

wherein, when said alerting unit is activated to alert said living being, carrying the health monitoring system, the health monitoring and alert system is fully independent of any remote entity.

5 Preferably said living being is a human-being, wherein said human-being is either healthy or non-healthy.

10 Preferably said analysis subsystem includes a memory for storing at least a portion of said detected parameters; wherein said stored detected parameters are used for trends analysis, for adaptation analysis, for abnormality prediction analysis, and for enabling data extraction for further external analysis; and wherein said analysis subsystem analyzes said trends to detect abnormal trends in said detected parameters or a combination thereof, and wherein, when at least one of said trends is determined to be abnormal, said alerting unit is operatively activated to alert one or more predetermined alert receiving entities.

15 Preferably said health monitoring system is facilitated to operate substantially continuously.

Preferably the boundary definition of said parameter abnormality of said physiological or chemical parameter is personally adaptive.

Preferably the boundary definition of said parameter abnormality is dynamically adaptable to the changes over time of the normal state of said living being.

20 Preferably said processing unit of said analysis subsystem analyzes and determines the correlation between two or more of said detected parameters, thereby creating correlated parameters.

25 Preferably said detected correlated parameters are determined to be abnormal, said alerting unit is operatively activated by said processing unit to alert said living being and optionally, one or more predetermined alert receiving entities.

Preferably the system is facilitated to provide said alert with no operative action being performed by said living being during health monitoring.

Preferably said sensor is a wearable sensor.

30 Preferably said communication unit includes one or more communication subunits, and wherein each of said sensors is coupled with one or more of said communication subunits.

Preferably said sensor is an in-vivo sensor. Said in-vivo sensor may be nano-sensor, and wherein said nano-sensor is delivered to an in-vivo target location, via blood vessels.

Preferably said in-vivo sensor is delivered to a subcutaneous location.

5 Said in-vivo sensor may be an implanted sensor. The sensor may be implanted during a non-related surgery. Said in-vivo sensor may be a nano-sensor or a micro-sensor.

10 Said in-vivo sensor may be delivered to an in-vivo target location, in a non-painful laser-based insertion, RF-based technology, by swallowing pills or capsules, by transdermal delivery patches, by injection using micro-needles or by nano-needles. Said in-vivo sensor may be delivered to an in-vivo target location, using targeted-liposome delivery techniques. Said in-vivo sensor may be delivered to an in-vivo target location, using nanotube delivery techniques. Preferably said in-vivo sensor requires no internal power source.

15 Preferably said communication unit includes one or more communication subunits, and wherein each of said sensors is coupled with one or more of said communication subunits.

20 Preferably said communication unit or said communication subunit are configured to transmit a signal to said in-vivo sensor and to receive a modulated echo of said transmitted signal, returned from said in-vivo sensor, and wherein said modulated echo carries the information sensed by said in-vivo sensor.

Preferably said control module is selected from the group consisting of a wearable module, an in-vivo module and a mobile device.

Preferably said wearable control unit is a wearable device selected from the group including a wrist watch, a patch, an earring, a necklace, a bracelet and an armlet.

25 Preferably said wearable control unit is a wearable device attached to or integrated into a mobile electronic device, a wheel chair or a personal device carried regularly by said living being.

Preferably said mobile electronic device is a cellular phone, a PDA, a wearable indicator or a mobile PC.

30 Preferably said control module is disposed in the oral cavity of said living being, thereby being an oral control unit.



Preferably said oral control unit is disposed inside one or more natural or artificial teeth of said living being.

Preferably said oral control unit further comprises: iii) an internal power source; and iv) a maintenance unit, wherein said maintenance unit facilitates external maintenance activities of said oral control unit.

Preferably the internal power source is rechargeable by normal operational motion of said oral control unit inside the oral cavity.

Preferably said external maintenance activities are selected from a group of maintenance activities including updating said processing unit, downloading data, setup and update of parameters, insert a new or a replacement nano sensor, loading test analysis elements, unloading disposal waste, recharging internal power source, and perform diagnostic processes of selected members of the health monitoring system.

Preferably said oral control unit further comprises: v) an oral test unit having at least one oral sensor; and vi) at least one oral sampler,

wherein said maintenance unit preferably includes a storage for test analysis elements and a storage for waste resulting from tests analysis;

wherein said at least one oral sampler collects oral material selected from the group of orally disposed materials including oral fluids, breath and blood;

wherein said oral test unit is operatively activated to engage one or more of said analysis elements with said one or more oral materials, thereby producing a testable material;

wherein said at least one oral sensor is configured to sense said testable material and create tested data; and

wherein said maintenance unit transfers said tested data to said analysis subsystem of said control module.

Preferably said one or more test analysis elements are reagents, wherein said reagents are part of said at least one oral sensor.

Preferably wherein said maintenance unit includes storage for nano sensors and/or reagents, and wherein said maintenance unit is facilitated to deliver said nano sensor and/or reagent on demand or by a predetermined time interval.

Preferably said maintenance unit further includes a loading service channel for

loading said storage for test analysis elements from an external source, wherein said loading service channel is sealingly closed during normal operation;

5 Preferably said maintenance unit further includes a disposing service channel for disposing accumulated waste from said storage for waste to an external location, wherein said disposing service channel is sealingly closed during normal operation.

Preferably said sensor is a digital acoustic sensor facilitated to sense bodily acoustic data.

Preferably said bodily acoustic data includes heart beat, lung and breathing sounds.

10 Preferably said sensor is selected from the group of physical sensors including an electric sensor, an optical sensor, an acceleration sensor, a pressure based sensor, a conductivity sensor and a humidity sensor.

Preferably said physical sensors sense bodily-movements related data.

Preferably the definition of said parameter abnormality depends also on said bodily-movements related data.

15 Preferably said bodily-movements related data is processed by a motion-posture detection unit.

Preferably said physical sensors sense bodily-posture related data.

Preferably the definition of said parameter abnormality depends also on said bodily-posture related data.

20 Preferably said bodily-posture related data are processed by a motion-posture detection unit.

Preferably wherein said bodily-movements related data and said bodily-posture related data are processed by a motion-posture detection unit.

25 Preferably wherein said control module further comprises an internal power source.

Preferably, wherein said internal power source is a micro-battery or a nano-battery.

According to preferred embodiments herein described there is provided a method for monitoring the health status of a living being, comprising the steps of:

30 a) providing a seamless health monitoring and alerting system, configured for use by the healthy living being, the system including:

- i) a control module having:
    - (A) an analysis subsystem having a processing unit; and
    - (B) an alerting unit;
  - ii) a communication unit; and
  - 5 iii) one or more sensors;
- b) sensing at least one designated health related parameter by said one or more sensors, thereby generating sensed data;
- c) transmitting said sensed data to said communication center;
- d) transmitting said sensed data to said analysis center;
- 10 e) analyzing said sensed data;
- f) determining if said sensed data is abnormal; and
- g) upon determining that said sensed data is abnormal,
- i) selecting a proper alert type;
- ii) transmitting said selected alert type(s) to said alerting unit; and
- 15 iii) activating said alerting unit by said processing unit, to thereby alert said living being carrying the health monitoring system and optionally, one or more predetermined alert receiving entities.

Preferably the method includes the steps of:

- 20 h) analyzing said sensed data by said processing unit, thereby generating analyzed sensed data;
- i) determining if said sensed analyzed data is abnormal;
- j) upon determining that said analyzed sensed data is abnormal,
  - i) selecting a proper alert type;
  - ii) transmitting said selected alert type(s) to said alerting unit; and
  - 25 iii) activating said alerting unit.

Preferably said control module includes an oral control unit, disposed in the oral cavity of said living being.

Preferably said oral control unit further includes a maintenance unit, wherein said

seamless health monitoring system further includes an oral test unit having at least one oral sensor, and at least one oral sampler, and wherein the method further includes the steps of:

- h) collecting selected oral materials from said oral cavity of the living being;
- 5 i) transferring said oral materials to said test unit;
- j) transferring test analysis elements from an optional storage for test analysis elements or from external sources, to said test unit;
- k) engaging said analysis elements with said oral materials, thereby producing a testable material;
- 10 l) sensing said testable material by said at least one oral sensor, thereby creating sensed data; and
- m) proceeding with step (d) of the method.

Preferably said health monitoring system further includes a waste disposal storage, and wherein the method further includes the step of:

- 15 n) disposing waste materials resulted from said engaging said analysis elements with said oral materials.

Preferably, in the method, wherein said health monitoring system is facilitated to operate substantially continuously.

Preferably the method further includes the steps of:

- 20 h) analyzing said sensed data by said processing unit, thereby generating trend analyzed data;
- i) determining if said trend analyzed data is analyzed to predict a future abnormal health state;
- j) upon predicting a future abnormal health state,
- 25 i) selecting a proper alert type;
- ii) transmitting said selected alert type(s) to said alerting unit; and
- activating said alerting unit.

The principal intentions of a number of variations of the present invention include providing systems for monitoring multiple aspects of the health of a living being and to

issue an alert upon detecting a potentially health hazardous situation. Variations are directed towards systems designed to be used by healthy living being and thereby, which do not interfere with the everyday life of the monitored living beings. It should be noted that in the variation, the system does not require any operative activity by the living being  
5 (or from anyone else) in order to provide the alert when needed. It should be noted that the system is not limited for use by healthy living beings and can be also used by non-healthy living beings. Furthermore, since a healthy living being may object to a surgical procedure or to a painful injection, there is an optional transport (delivery) method, preferably non-surgical injectionless intake and transport, and maintenance provisions for  
10 the in-vivo components of the system.

According to the a number of variations, there is provided a seamless and preferably substantially continuous health monitoring system, designed for use by a healthy living being but also suitable for non-healthy living being. The system includes a control module, a communication unit and one or more sensors and preferably motion-  
15 posture detectors. The control unit includes an analysis subsystem having a processing unit, preferably memory and an alerting unit.

In the variations, each of the one or more sensors is configured to detect a predetermined physiological or chemical parameter (including of parameters of internal systems such as the blood vessels, kidneys, lung, etc.) of the monitored living being,  
20 preferably a person. The communication unit is facilitated to receive the detected parameters from each of the one or more sensors and transmit the detected parameters to the analysis subsystem. The processor of the analysis subsystem of the control module analyzes the detected parameters to thereby determine if one or more detected parameters or a combination of the detected parameters are abnormal, preferably in conjunction with  
25 the determined motion-posture state of the monitored living being. When at least one of the detected parameters is determined to be abnormal, or the combination of various parameters (which may not individually be abnormal) constitutes an abnormal situation, alerting unit is operatively activated to alert one or more predetermined alert receiving entities.

Preferably, the processor has an optional adaptation algorithm that determines the "normal state" of the individual living being, so that the thresholds and other parameters' characteristics are individually set. Furthermore, the adaptation mechanism is substantially continuously active, so that the dynamic nature of the human state is taken into account in the adaptation process. Furthermore, the processor can determine the ergometric parameters and physical status of the monitored living being (standing, lying down, extreme activity etc.), using motion-posture detectors controlled by the system control unit.

Preferably, the analysis subsystem includes a memory for storing at least a portion of the detected parameters. The stored detected parameters are used for trends analysis, for adaptation analysis and for enabling data extraction for further external analysis. The analysis subsystem analyzes the trends to detect abnormal trends in the detected parameters or a combination thereof, and wherein, when at least one of the trends is determined to be abnormal, the alerting unit is operatively activated to alert one or more predetermined alert receiving entities.

In variations of the present invention, the definition of the abnormality of the physiological or chemical parameter may be personally adaptive. In variations of the present invention, the definition of the abnormality is dynamically adaptable per the changing state over time of the living being and optionally, the motion-posture status.

Optionally, the processing unit of the analysis subsystem analyzes and determines the correlation between the detected parameters of two or more of the detected, thereby creating correlated parameters. When the detected correlated parameters are determined to be abnormal, the alerting unit is operatively activated to alert one or more predetermined alert receiving entities. Preferably, the system is facilitated to provide the alert with no operative action performed by the living being during health monitoring.

The control module can be a wearable module or an in-vivo module.

The sensor can be a wearable sensor or an implanted/in-vivo sensor.

The sensor can be delivered to an in-vivo target location, via blood vessels, via the digestive system or via the respiration system. In variations of the present invention, the sensor is delivered to a subcutaneous location. Optionally, the sensor is implanted during a non related surgery.

The communication unit includes one or more communication subunits, wherein each sensor is coupled with one or more of the communication subunits.

5 In variations of the present invention, the sensor is a nano-sensor or a micro-sensor. Preferably, the sensor is delivered to an in-vivo target location, in a non-painful procedure such as laser-based insertion, RF-based technology, by swallowing pills or capsules, by trans-dermal delivery patches or by injection using micro-needles or nano-needles.

10 In variations of the present invention, the sensor is delivered to an in-vivo target location, using targeted-liposome delivery techniques. In other variations of the present invention, the sensor is delivered to an in-vivo target location, using nanotube delivery techniques.

15 Optionally, the sensor requires no internal power source. Optionally, the communication unit or a communication subunit are configured to transmit a signal to the nano sensor and to receive a modulated echo of the transmitted signal, returned from the nano sensor, and wherein the modulated echo carries the information sensed by the nano sensor.

20 The wearable control unit is optionally a wearable device selected from the group including a wrist watch, a patch, an earring, a necklace, a bracelet and an armlet. In variations of the present invention, the wearable control unit is a wearable device attached to or integrated into a mobile electronic device, or a wheel chair or a personal device carried regularly by the living being. The mobile electronic device can be a cellular phone, a PDA, a wearable indicator or a mobile PC.

25 In variations of the present invention, the control module includes an oral control unit, disposed in the oral cavity of the living being. The oral control unit can be disposed inside one or more natural or artificial teeth of the living being.

30 The oral control unit may further include an internal power source and a maintenance unit, wherein the maintenance unit facilitates external maintenance activities of the oral control unit. The external maintenance activities are selected from a group of maintenance activities including updating the processing unit, setting up and update of parameters, downloading data, inserting a new or a replacement nano sensor, recharging internal power source, and performing diagnostic processes of selected members of the health monitoring system.

Preferably, the maintenance unit includes storage for nano sensors, and wherein the maintenance unit is facilitated to deliver the nano sensor on demand or by a predetermined time interval.

5        Optionally, the oral control unit further includes an oral test unit having at least one oral sensor and at least one oral sampler. The maintenance unit preferably includes storage for test analysis elements and storage for waste resulting from tests analysis. The at least one oral sampler collects oral material selected from the group of orally disposed materials including oral fluids, breath and blood. The oral test unit is operatively activated to engage one or more of the analysis elements with the one or more oral materials, thereby  
10        producing a testable material. The at least one oral sensor is configured to sense the testable material and create tested data. The maintenance unit transfers the tested data to the analysis subsystem of the control module. Preferably, the one or more test analysis elements are reagents, wherein the reagents are part of the oral sensor.

15        In variations of the present invention, the maintenance unit further includes a loading service channel for loading the storage for test analysis elements from an external source, wherein the loading service channel is sealingly closed during normal operation. Preferably, a loading device operatively loads test analysis elements through the loading service channel to the storage for test analysis elements. Preferably, the maintenance unit further includes a disposing service channel for disposing accumulated waste from the  
20        storage for waste to an external location, wherein the disposing service channel is sealingly closed during normal operation, wherein preferably, a disposal collecting device operatively removes waste from the storage for waste through the disposing service channel. The above mentioned loading and disposal are optionally made by a dental professional.

25        In variations of the present invention, the sensor is a digital acoustic sensor facilitated to sense bodily acoustic data, wherein the bodily acoustic data includes heart beat, lung and breathing sounds.

30        In variations of the present invention, the sensor is selected from the group of physical sensors including an electric sensor, an optical sensor, an acceleration sensor (usually an accelerometer for each of the three dimensions), a pressure based sensor, a conductivity sensor and a humidity sensor.

Optionally, the physical sensors sense bodily movement related data, wherein the definition of the abnormality depends also on the bodily movement related data.



Optionally, the physical sensors sense bodily posture related data, wherein the definition of the abnormality depends also on the bodily posture related data.

Optionally, the movement related data and the bodily posture related data are processed by a motion-posture detection unit.

5 Typically, the control module further includes an internal power source. Preferably, in in-vivo control units, the internal power source is a micro-battery or a nano-battery.

10 There may be provided a method for monitoring the health status of a living being. The method includes a step of providing a seamless health monitoring system, which system includes a control module including a control module having an analysis subsystem having a processing unit, and an alerting unit. The control module further includes communication unit and one or more sensors.

15 The method further includes a step of sensing designated health related parameter by the one or more sensors, thereby generating sensed data, transmitting the sensed data to the communication center, transmitting the sensed data to the analysis center, analyzing the sensed data, and determining if the sensed data is abnormal. Upon determining that the sensed data is abnormal, the method proceeds with selecting a proper alert type, transmitting the selected alert type(s) to the alerting unit, and activating the alerting unit.

20 In variations of the present invention, the method further includes the steps of analyzing the sensed data by the processing unit, thereby generating analyzed sensed data, and determining whether the analyzed sensed data is abnormal. Upon determining that the analyzed sensed data is abnormal, the method proceeds with selecting a proper alert type, transmitting the selected alert type(s) to the alerting unit, and activating the alerting unit.

25 In variations of the present invention, the control module includes an oral control unit, disposed in the oral cavity of the living being, wherein the oral control unit further includes a maintenance unit, wherein the seamless health monitoring system further includes an oral test unit having at least one oral sensor, and at least one oral sampler, and wherein the method further includes the steps of collecting selected oral materials from the oral cavity of the living being, transferring the oral materials to the test unit, 30 transferring test analysis elements from an optional storage for test analysis elements or from external sources to the test unit, engaging the analysis elements with the oral materials, thereby producing a testable material, sensing the testable material by the at

least one oral sensor, thereby creating sensed data, and proceeding with step of transmitting the sensed data to the analysis center.

In variations of the present invention, the seamless health monitoring system further includes a waste disposal storage, and wherein the method further includes the step of disposing waste materials resulted from the engagement of the analysis elements with the oral materials.

#### BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will become fully understood from the detailed description given herein below and the accompanying drawings, which are given by way of illustration and example only and thus not limitative of the present invention:

FIG. 1 is a schematic block diagram of a health monitoring and alert system, according to embodiments of the present invention, having a wearable control unit;

FIG. 2a illustrates, by way of example, an elongated nanotube for delivering nano technology based sensors, according to embodiments of the present invention;

FIG. 2b illustrates, by way of example, a spherical nanotube for delivering nano technology based sensors, according to embodiments of the present invention;

FIG. 3 illustrates, by way of example, a liposome for delivering nano technology based sensors, according to embodiments of the present invention;

FIG. 4 is a schematic block diagram of a health monitoring and alert system, according to embodiments of the present invention, having an oral control unit;

FIG. 5 is a schematic illustration of a health monitoring and alert system, as shown in Figure 4, whereas the oral device is implanted in a tooth;

FIG. 6 illustrates the main components of a health monitoring and alert system, according to embodiments of the present invention, as disposed on a human being;

FIG. 7 is a schematic flow diagram that outlines the steps of monitoring the health status of a living being, performed for example on the system shown in Figure 1 or 2, and the steps of activating an alerting unit upon detecting a potentially health hazardous situation; and

FIG. 8 is a schematic flow diagram that outlines a cycle of monitoring the health status of a living being.

## DETAILED DESCRIPTION OF THE INVENTION

The principal intentions of a number of variations of the present invention include providing systems for monitoring multiple aspects of the health of a living being and to  
5 issue an alert upon detecting a potentially health hazardous situation. Variations are directed towards systems designed to be used by healthy living being and thereby, do not interfere with the everyday life of the monitored living beings and do not require any operative action from the monitored living being in order to provide the alert when needed. It should be noted that the system is not limited for use by healthy living beings and can  
10 be also used by non-healthy living beings. Furthermore, since a healthy living being may object to a surgical procedure or to a painful injection, there are optional non-surgical injectionless transport and maintenance provisions for the in-vivo components of the system.

15 Embodiments of the present invention will now be described with reference to the accompanying drawings. Systems may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided, so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. Unless otherwise defined,  
20 all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. The methods and examples provided herein are illustrative only and not intended to be limiting.

Reference now made to the drawings. Figure 1 is a schematic block diagram of a  
25 seamless and preferably continuous health monitoring and alert system **100**, according to embodiments of the present invention, having a wearable control unit **110**. System **100** further includes one or more sensors selected from the group consisting of nano or micro sensors **180**, implantable sensors **190** and wearable sensors **170**. Wearable control unit **110** includes an analysis center **120**, a communication center **130**, an alerting unit **150** and  
30 optionally, a maintenance unit **160**. System **100** may further include an in-vivo or ex-vivo communication center **140**.

Analysis center **120** receives health status data from all the sensors (**170, 180, 190**), through communication center **130** and optionally, through in-vivo communication center **140**. Optionally, analysis center **120** receives posture orientation and bodily motion data  
35 from motion and posture sensors **175**, such as accelerometer based sensors and orientation

sensors. Motion and posture sensors **175** may sense, for example, movement related data enabling the system determine instantaneous body states such as running, jumping, exerting physical force, etc. Motion and posture sensors **175** may further sense, for example, posture orientation such as standing, lying, sitting, etc. In variations of the present invention, the sensed bodily movement related data and sensed bodily posture related data are processed by a separate motion-posture detection unit (not shown).

Analysis center **120** includes a processing unit that analyzes the health status data received from the sensors (**170, 180, 190**), and thereby determines if a health hazardous situation occurs. The processing unit may further calculate values, compare thresholds, trends, averages etc, and may provide the calculated data to an external recipient. Preferably, analysis center **120** further includes memory for storing data for calculations, comparisons to past measurements, determining trends, calibration, determining sensors reliability, further remote analysis at external places and for future use (for example, for use in physical exercise consulting).

In variations of the present invention, the definition of the abnormality of the physiological or chemical parameter is personally adaptive, wherein the “normal” health state of a particular monitored living being is personally set. In variations of the present invention, the definition of the abnormality is dynamically adaptable per the changing state over time of the living being.

Upon detecting abnormal health related parameters, or an abnormal state determined as a result from an analysis of combined inputs acquired from different sensors, or from a trends analysis, analysis center **120** sends alert information to alerting unit **150**. Optionally or additionally, analysis center **120** sends alert information to communication center **130** that sends alert information to a predetermined external recipient. Optionally, the processing unit of analysis center **120** analyzes and determines the correlation between the detected parameters of two or more of the detected, thereby creating correlated parameters. When the detected correlated parameters are determined to be abnormal, the alerting unit is operatively activated to alert one or more predetermined alert receiving entities.

Alerting unit **150** is activated by analysis center **120**. Alerting unit **150** may have various alerting types, such as the following non limiting examples: vocal, visual and digital signals designated for various target recipients (typically, via communication center **130**). In variations of the present invention, alerting unit **150** is a separate unit and not integrated into wearable control unit **110**.

Communication center **130** receives input data from the sensors (**170, 180, 190**) and optionally from motion and posture sensors **175**, and transfers the data to analysis center **120**. Communication center **130** receives alerts requests from alerting unit **150** and communicates the alerts to various predetermined external devices such as, with no limitations, a cellular phone, a PDA, a computer, wearable indicator, etc. Communication center **130** may also receive maintenance requests from maintenance unit **160** and transmit the maintenance requests to various predetermined external remote devices. Communication center **130** may also receive requests for additional data information, such as sensed data, from an external source and transfer the requests to analysis center **120**, which in turn can activate and/or interrogate the appropriate sensor (**170, 180, 190**). Communication center **130** may also receive maintenance/setup data information from an external source and transfer the maintenance/setup data information to maintenance unit **160**. In variations of the present invention, communication center **130** is a separate unit and not integrated into wearable control unit **110**.

System **100** uses one or more sensors to detect a potentially health hazardous situation when occurs. The sensors types are selected from the group consisting of nano sensors and/or micro-sensors **180**, implantable sensors **190** and wearable sensors **170**.

Implantable sensors **190** can be any implantable sensing device facilitated to sense in-vivo events, gathering data and send indications. It should be noted that in the context of the present invention, which prefers not to use surgery procedures, if the monitored living being undergoes a surgery anyhow, it is possible to add implantable sensor/s without violating the above preference. For example, US patent 5411535, given to Tadashi Fujii et al., provides a cardiac pacemaker improved to reduce the weight and size and to unburden the wearer of the pacemaker, while ensuring safe wireless transmission of signals. The cardiac pacemaker includes a main body having at least two electrodes for detecting cardio-information, a control section for performing a control by outputting pulses on the basis of the cardio-information, and a transmitting section for modulating the pulses and transmitting the modulated pulses. The pacemaker also has pacing electrode portion having a receiving section for receiving the transmitted pulses and stimulating electrodes activated by the pulses output from the receiving section.

Wearable sensors **170** can be any wearable device, having means for sensing ex-vivo and in-vivo events, gathering data and transmit data to analysis center **120**. Wearable sensors **170** are optional, as wearable sensors **170** must not interfere in the life style of the

human or animal wearing wearable sensors **170**. For example, US patent 6413223 given to Boo-ho Yang et al., provides a device for noninvasive, continuous monitoring of arterial blood pressure for advanced cardiovascular diagnoses.

Nano sensors **180** are constructed using molecular manufacturing techniques, also referred to as nano technology. Nano (or micro) sensors **180** can be a chemical sensor operating in the blood system, digestive system, kidneys sub-system or any other biological system. Nano (or micro) sensors **180** can be a pathogen detector, tissue chemical imbalance detector, cancerous cells detector, etc. in variations of the present invention, sensors **180** are encapsulated in nano-capsules and nano-spheres, mainly for transporting, targeting and increase survivability. The nano sensors **180** are used continuously to detect and measure needed parameters such as HDL/LDL cholesterol, Hemoglobin, Hematocrit, Triglyceride, glucose, HbA1c, Bilirubin, Creatinine, PSA, CEA, Calcium Cerum, CPK, Lymphocytes, Monocytes, Basophils, Neutrophils, Eosinophils, Myelocytes, Blood pressure, Heart beat (pulse), Blood count, Body temperature, Oxygen saturation, Sweat, Conductivity etc. The nano sensors **180** are continuously available for transmitting the sensed data (usually by responding to an interrogation pulse) either directly to communication center **130** or indirectly, via in-vivo communication center **140**.

A nano sensor **180** can be inserted by a laser-based insertion technique, an injection by micro-needles or by nano-needles (which does not yield a painful experience by the person as a regular injection does, thus maintaining the preferred objective of "injectionless goal", in the context of painful injections), by swallowing pills or capsules, by transdermal patches, transmembrane receptors, using RF-based techniques or other nano sensors insertion means known in the art. Some of the above techniques are usually used for different purposes (for example, TransPharma's RF-MicroChannels® for drug delivery are created within milliseconds, with no resulting skin trauma or pain. Alma Lasers' cosmetics treatments with the Pixel® CO2, laser light passes through the patented Pixel® micro optics lens array to penetrate the skin with tiny thermal channels), however, the current embodiment is using similar techniques for sensors intake.

Reference is made to Figures 2a and 2b, which illustrate by way of example, nanotubes **192** adapted to deliver nano sensors **180c** and **180d**, according to embodiments of the present invention. Figures 2a illustrates a portion of an elongated nanotube **192a** and Figures 2b illustrates a portion of a spherical nanotube **192b**. Nanotubes **192** are used to deliver an active matter such as nano or micro sensors **180c** and **180d** to target organs

through the skin. Optionally, Nano-needles are used to penetrate cells for carbon nanotubes **192** sensor delivery (for example, UK-based researchers from the School of Pharmacy, University of London, found that they were able to enter a variety of cell types, including human cancer cells). Optionally, health monitoring and alert system **100** uses this technique for sensor delivery. By piercing plasma membranes and heading straight to the cytoplasm, the functionalized carbon nanotube encounters fewer biological barriers and delivers the sensor more directly. The nanotubes also offer a structural advantage being extremely thin but very long, thereby offering a large surface area on which to graft the required sensor. This technique facilitates regulation of the amount of sensors loaded onto the nanotube.

It should be noted that often nano sensors **182** undergo a chemical reaction upon sensing a designated parameter. Such nano sensors **182** include an active region, often referred to the “reagent”, which reagent undergoes a chemical reaction upon sensing a designated matter. Therefore, such a deformed nano sensor **182** needs to be replaced. Carbon nanotubes **192** are facilitated to deliver a multiplicity of nano sensors **182** to thereby create a reservoir of nano sensors **182**.

Figure 3 illustrates, by way of example, a liposome **182** adapted to deliver nano sensors **180a** and **180b**, according to embodiments of the present invention. Liposome **182** is used to deliver an active matter such as nano or micro sensors **180a** and **180b** to target organs via the blood system, using homing peptide **188**.

Liposome **182** encapsulates/entraps the one or more nano/micro sensors **180** inside a region **183** of aqueous solution enclosed, by a hydrophobic membrane **186**, which can be dissolved into the cell membrane. Sensors **180a** and **180b** include an external layer **181a** and **181b** respectively, which external layer is lipid-soluble, configured to fuse with a lipid bilayer **184** of liposome **182** and other bilayers, such as the cell membrane, passing through the lipids and thereby delivering nano sensors **180**. For example, item **189** is shown passing through lipid bilayer **184**.

Nano sensors **180** are used to monitor a target organ or any other in-vivo biological target. For example, in-vivo transportation can be performed by carbon nanotubes (CNTs), which are extremely narrow, hollow cylinders made of carbon atoms (may include Titanium dioxide for enhanced Osseointegration or other means). Optionally, health monitoring and alert system **100** uses time-resolved Raman spectroscopy to monitor and detect nano sensors **180** moving through the blood circulation system.

Nano sensors **180** are positioned at a designated target location by various

transport and targeting methods, for example, through the blood, homing peptide **188** (see Figure 3) or any other biological species attached as a ligand to the liposome in order to enable binding via a specific expression on the targeted delivery site of nano sensor **180**. The targeting ligand can be a monoclonal antibody (making an immunoliposome or membrane recognition and adhesion molecules), a vitamin or specific an antigen, thus creating a "targeted liposome" acting as vehicles or carriers. Therefore, a targeted liposome can target nearly any cell type in a living body. It should be noted that liposome **182** is typically protected from the host body immune system by a protective layer **189**. It should also be noted that using nano-tubes **192** rather than liposomes **182**, facilitates leveraging the durability characteristics, which enables extending the interval periods between sensors' replacements.

Nano sensor **180** is kept at a target designated location/site, for example, by adhesion or adsorption. An alert is generated and transmitted to analysis center **120** when nano sensor **180** is dispatched from the target designated location/site. Biomarkers are adhered to the surface of the liposome (when used as the vehicle) which delivers it to the target. They are controlled by a diffusion (mobility) mechanism, as explained hereinbelow, and monitored by the analysis center **120**.

Nano sensor **180** can sense a location shift, for example by associated biomarkers, comparing the current location with the original stable location. The location shift (which is typically a mobility change indication) is transmitted to analysis center **120**. For example, transmission is embodied using pulsed gradient spin echo NMR techniques. The pulsed gradient spin echo NMR technique for such alert requires either dual components for each nano sensor **180** (one acting as a location indicator and the second is the nano sensor itself), or the assessment of the nano sensors **180** self mobility from the self diffusion coefficient. The mobility corresponds to the relaxation effect that determines the diffusivity of the molecule. Several nano sensors **180** can use the same biomarker as a "mobility reference".

Nano sensor **180** can transmit the sensed data either as 1/0 states or as scaled values or by other conventional transmission methods. Typically, the process of transmission has two phases: firstly, communication center **130** sends an interrogation/inquiry pulse to a specific nano sensor **180**; then, the specific nano sensor **180** acts as an electric capacitor and responds with the same pulse modulated by the "sensed data" the specific nano sensor **180** contains; the response is received by communication center **130**, which communication center **130** sends to analysis center **120** for decoding. Typically, the same



transmission method provides alerts for a location shift of the nano sensor **180**, discussed hereabove.

Analysis center **120** receives indications regarding the location of nano sensor **180** and determines whether an alert should be issued, a location-correction is needed or whether a certain nano sensor **180** stopped functioning (typically, both require a sensor replacement procedure. It should be noted that typically, a replacement of a nano sensor is a simple delivery of a new nano sensor, wherein when using nanotubes **192**, the old nano tube **192** is withdrawn). Accordingly, analysis center **120** indicates to alerting unit **150** the alert type needed.

In variations of the present invention, the sensor (**170, 175, 180, 190**) is a digital acoustic sensor facilitated to sense bodily acoustic data, wherein the bodily acoustic data includes heart beat, lung and breathing sounds.

In variations of the present invention, the sensor (**170, 175, 180, 190**) is selected from the group of physical sensors including an electric sensor, an optical sensor, an acceleration sensor (usually an accelerometer for each of the three dimensions), a pressure based sensor, a conductivity sensor and a humidity sensor.

It should be noted that to minimize the living being's inconvenience and limitations, wearable control unit **110** can be worn as a wrist watch, a patch, an earring, a necklace, a bracelet, an armlet, etc. Optionally, wearable control unit **110** can be customized per wearer's preferences, for non-interference in his/her daily life. Maintenance unit **160** is used mainly to setup and update various parameters of health monitoring and alert system **100**, facilitating data extraction from the memory and to perform self-testing of various sub-systems of health monitoring and alert system **100**. Wearable control unit **110** may be attached to or integrated into a mobile electronic device or a wheel chair or other devices that are continuously situated proximal to the living being.

It should be further noted that communication center **130** and optional in-vivo communication center **140** can be used together, sharing the communication tasks in any configuration. Typically, a wearable sensor **170** communicates with communication center **130**, residing in wearable control unit **110**.

It should be further noted that some of the processing tasks can be performed at a remote monitoring center. The communication center **130** can optionally send the data to

any remote processor, which can further process the information, compare the obtained data to corresponding data obtained from other monitored people, make statistics-based decisions and other decision-making issues to improve alerts (for example by detecting suspicious trends that did not trigger the automatic alert but a physician may want to further check the person) and providing information for assisting the treatment of the living being once getting to a treating facility.

In variations of the present invention, a portion of the health monitoring and alert system is disposed orally, into one or more teeth. Reference is now made to Figure 4, which is a schematic block diagram of a health monitoring and alert system **200**, having an oral control unit **210**. Generally, health monitoring and alert system **200** operates similarly to health monitoring and alert system **100**, except for a few adaptations. Health monitoring and alert system **200** does not need to be worn by the monitored living being, and therefore does not interfere with the everyday life of the monitored living being. Furthermore, health monitoring and alert system **200** has direct contact with some in-vivo entities of the monitored living being, such as saliva and exhalation.

Analysis center **220** includes a processing unit that analyzes the health status data received from the sensors (**170**, **175**, **180**, **190**), and thereby determines if a health hazardous situation occurs. The processing unit may further calculate values, compare thresholds, perform comparisons to past measurements, determine trends, determine sensors reliability, perform calibrations, compute averages, create adaptive normal states references etc, and may provide the calculated data to an external recipient. Preferably, analysis center **220** further includes memory for storing data for calculations and for future use (for example, when calculating trends).

Reference is also made to Figure 5, which is a schematic illustration of health monitoring and alert system **200**, whereas oral control unit **210** is disposed inside one or more natural or artificial teeth **20**. System **200** further includes one or more sensors selected from the group consisting of nano and/or micro sensors **180**, implantable sensors **190** and wearable sensors **170**. Oral control unit **210** includes an analysis center **220**, a communication center **230**, an alerting unit **250**, preferably a maintenance unit **260** and optionally, a test unit **240**. Analysis center **220** and communication center **230** are generally similar to respective units **120** and **130** of health monitoring and alert system **100**.

Test unit **240** resides in oral control unit **210** and serves as a small laboratory to

perform chemical tests. Test unit **240** is operatively coupled with one or more oral samplers **242**, configured to collect oral material selected from the group of orally disposed materials including oral fluids such as saliva, blood and other available oral materials like breath. Test unit **240** receives the samples of materials from sampler **242**,  
5 as well as analysis elements (lab materials), needed for specific tests, directly from a loading device **262** (via service channel **266**, see Figures 4 and 3), or indirectly from test analysis elements storage **263** of maintenance unit **260**. Test unit **240** is operatively activated to engage the one or more of reagents with the one or more sampled oral materials, thereby producing a testable material. The reagent is typically part of an oral  
10 sensor **244**, configured to sense the testable material and create test results. Sometimes, oral sensor **244** needs to be replaced upon detection of a target sensed matter, which chemically reacts with the reagent, but usually, only the reagent is replaced by the next one from the reservoir.

Test unit **240** reports the test results to analysis center **220** for further analysis. The  
15 disposal from the tests is returned by test unit **240** either directly to a disposal collecting device **264** (via service channel **268**, see Figure 3), or indirectly to a waste storage **265** of maintenance unit **260**.

Maintenance unit **260** (and optionally, maintenance unit **160** of health monitoring and alert system **100**) has various functions in maintaining the orderly operation of health  
20 monitoring and alert system **200**. Maintenance unit **260** is configured to:

- a) add needed chemical reagents for testing unit **240**;
- b) insert a new (or a replacement of) nano/micro sensor **180**;
- c) re-charge power source **270** of oral control unit **210**;
- d) dispose of waste material through disposal collecting device **264**;
- 25 e) setup and update various parameters of health monitoring and alert system **200**;
- f) perform diagnostic processes of selected members of health monitoring and alert system **200**; and
- g) download stored data.

30 It should be noted that typically, oral control unit **210** is installed inside an artificial tooth **20** by a dentist. In case of a need for replacement or maintenance, it is done by a dental treatment. Preferably, oral control unit **210** includes disposal unit **262** for disposing of chemical waste through a special gate in channel **268**, which gate opens only during

maintenance.

It should also be noted that the fact that the transmission of nano sensors **180** is "passive" (i.e. just returning inquiry pulses from communication center **130**) enables system **100** to get the required power from oral control unit **210** or wearable control unit **110** only.

It should be further noted that oral control unit **210** is typically powered by micro-batteries or nano-batteries. Optionally, the shelf-life of the batteries can be increased by nano-particles coated on the surface of the electrode. Part of the recharging method is performed by the normal operational motion of the oral control unit **210**. For example, regular daily food chewing and/or daily teeth brushing can cause the batteries to recharge. Typically, the wearable control unit **110** is also powered by micro-batteries. However, the recharging of the batteries is performed by regular movement, and only the replacement of a battery of the oral control unit requires a dentist visit. A special alert is sent by the maintenance unit when a battery is about to require replacement.

Reference is also made to Figure 6, which illustrates, by way of example, the main components of a health monitoring and alert system (**100, 200**), according to embodiments of the present invention, as disposed on a human being **30**. With no limitation, wearable control unit **110** is shown being implemented as a wrist watch and alternatively, oral control unit **210** is embodied in a tooth. Wearable sensor **170** is also shown being implemented as a wrist watch. Nano sensors **180** are disposed at various locations in the blood system, the lymphatic system, the digestive system, the urinary system etc. – per the specific configuration of the individual health monitoring and alert system. Implantable sensors **190** are shown monitoring the hearty and the lungs. When a potentially health hazardous situation occurs, an alert is activated as well as an alert message is sent to an external receiving device **600** such as a mobile phone (or any device with communication). Optionally, the recipient of the alert message returns an acknowledge message, for example, in the form of an SMS message. Upon receiving the acknowledge message, the control unit (**110, 210**) deactivated the alert (to be resent after an interval per the configuration of the system). Other configurations might include another living being and/or living beings and/or a multiple of remote monitoring centers.

In variations of the present invention, the control unit (**110, 210**) is facilitated to communicate with other implantable devices that maybe implanted in the living being, for example a pacemaker.

Optionally, the health monitoring and alert system (**100, 200**) includes sensors for detecting the characteristics of the physical activities of the living being, for example, acceleration sensors, pressure sensors, orientation sensors, etc.

5 An aspect of the present invention includes providing a method for monitoring the health status of a living being and issuing an alert upon detecting a potentially health hazardous situation.

Reference is made to Figure 7, which is a schematic flow diagram **300** that outlines the steps of monitoring the health status of a living being, performed for example on system **100** or **200**, and the steps of activating an alerting unit (**150** or **250**, respectively) upon detecting a potentially health hazardous situation. Method **300** includes the following steps:

**Step 310:** sensing designated health related parameter, thereby generating sensed data.

Each sensor<sub>i</sub> (**170, 180** or **190**) senses the parameter that sensor<sub>i</sub> is designed to measure, and thereby generating sensed data. For example, sensor<sub>i</sub> is a nano sensor  
15 **180** designed to measure the level of Triglycerides in the blood. Hence, in this example, the sensed data is the measured level of Triglycerides in the blood.

**Step 320:** transmitting the sensed data to the communication center (**130, 140** or **230**).

The sensed data is transmitted to communication center (**130, 140** or **230**). To continue the example, the measured level of Triglycerides in the blood is  
20 transmitted to communication center (**130, 140** or **230**).

**Step 330:** transmitting the sensed data to the analysis center (**120** or **220**).

The sensed data is transmitted to the analysis center (**120** or **220**). To continue the example, the measured level of Triglycerides in the blood is transmitted to the analysis center (**120** or **220**).

25 **Step 335:** transmitting carrier's motion and posture data to the analysis center (**120** or **220**).

Optionally, the sensed motion and posture data is transmitted to the analysis center (**120** or **220**). For example, movement related data can be running jumping, exerting physical force, etc.; posture orientation can be standing, lying, sitting, etc.  
30 it should be noted that the motion and posture data is used as input to the analysis algorithm for the determination of the appropriate thresholds to determine an

abnormal state.

**Step 340:** analyzing the sensed data.

The sensed data is analyzed by the processing unit of the analysis center (**120** or **220**). To continue the example, the level of Triglycerides in the blood is analyzed.

5 For example, the processing unit calculates:

IF {Triglycerides level} < 10 mg/dl;

AND sufficient time elapsed since last identical state identified;

THEN send an alert type  $j$  to the alert unit (**150** or **250**);

ELSE

10 IF {Triglycerides level} > 250 mg/dl;

AND sufficient time elapsed since last identical state identified;

THEN send an alert type  $k$  to the alert unit (**150** or **250**).

**Step 350:** determining if the sensed data is abnormal.

If the sensed data is within the normal range, go to step **310**.

15 It should be noted that a preliminary step of determining the "normal range" ("normal range" being non-abnormal range) for a specific individual (function of parameters like age, family history, life style etc.) and a specific ergometric state (such as standing, lying, extreme effort, etc.) is optionally performed. Optionally, the parameters and coefficients are remotely set up and/or controlled.

20 **Step 360:** selecting a proper alert type.

It has been determined that the sensed data is abnormal. To continue the example, an alert type  $j$  or  $k$  is set.

**Step 370:** transmitting the selected alert type(s) to the alerting unit (**150** or **250**).

The selected alert type is transmitted to the alerting unit (**150** or **250**).

25 **Step 380:** activating the alerting unit (**150** or **250**).

Alert unit (**150** or **250**) is activated with the selected alert type. To continue the example, the alert type activating a vocal 'beep' and sending an SMS message to a predetermined phone number.

Go to step **310**.

(end of steps details of process **300**)

Optionally, method **300** further includes the steps of: sending an acknowledge message by the recipient of the alert message, for example, in the form of an SMS message; and upon receiving the acknowledge message, the control unit (**110**, **210**) deactivates the alert.

Reference is now made to Figure 8, which is a schematic flow diagram that outlines a cycle **400** of monitoring the health status of a living being, according to variations of the present invention. Cycle **400** begins in virtual step **402** and proceeds in the following steps:

**Step 410:** sensing designated health related parameter, thereby generating sensed data.

Each sensor<sub>*i*</sub> senses the parameter that a sensor<sub>*i*</sub> is designed to measure, and thereby generating sensed data  $X_i$ .

**Step 420:** determine ergometric state.

The ergometric state of the monitored living being is determined, that is the motion state and the bodily orientation of the monitored living being.

**Step 430:** perform data analysis using adaptation algorithm.

Analysis center **120** activates an adaptation algorithm to compute the following:

**Step 432:** determine the current adaptive normal state

Determine the current normal state of the monitored living being, adjusted to a variety of personal parameters of the monitored living being. The History of measurements of the monitored living being is obtained from database **482**.

**Step 434:** determine the current dynamic interval.

Determine the current dynamic interval of the monitored living being, forming the envelope in which the health state of the monitored living being is considered normal and out of which the health state of the monitored living being is considered abnormal. The History of measurements of the monitored living being is obtained from database **482**.

**Step 440:** determine the deviation of the measured value  $X_i$  from normal state.

The deviation  $\Delta i$  of the measured value  $X_i$  from normal state is determined.

**Step 450:** determine the deviation of a group of measured values, from normal state.

The deviation  $F\{\Delta i\}$  a group of measured values from normal state is determined.

**Step 460:** perform trend analysis.

5 A trend analysis performed to compute the deviation a trend from normal state.

**Step 470:** determining if the sensed data or trend is abnormal.

If the sensed data or trend is determined to be abnormal, go to step **490**.

**Step 480:** store data.

Store all sensed data and computed data in Database **482**.

10 Go to step **402**.

**Step 490:** activate alert.

The sensed data or trend is determined to be abnormal and therefore, the alerting unit (**150** or **250**) is activated.

Go to step **402**.

15 (end of steps details of cycle **400**)

It should be noted that health monitoring and alert system (**100, 200**) is designed to detect one or more potentially health hazardous situations.

20 Preferably, health monitoring and alert system (100, 200) complies with to the IEEE 802.15 standard (currently under planning) and FCC Medical Body Area Network (MBAN) systems (currently under planning).

25 It should be further noted that the monitoring of the health condition is done continuously. Alerts are generated immediately as a dangerous situation is detected. The user does not have to perform any activity action in order to get the alert. For the sake of clarity, activity may be required at installation time, but not during monitoring.

It should be further noted that alerts can be issued to the monitored being and/or to an external entity, such as an emergency center, a close relative, etc. The alert can be transmitted to a computer, a telephone and/or any other communication device.

30 It should be further noted that the health monitoring and alert system can optionally send the data to any remote processor, which can further process the information, compare



it to many other monitored people, make statistics-based decisions and other decision-making methods to improve alerts and providing information for the treatment of the living being once getting to a treating facility.

- 5           The invention being thus described in terms of embodiments and examples, it will be obvious that the same may be varied in many ways. Such variations are not to be regarded as a departure from the spirit and scope of the invention, and all such modifications as would be obvious to one skilled in the art are intended to be included within the scope of the following claims.

## THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A seamless health monitoring and alerting system, configured for use by a healthy living being, comprising:

- a) a control module including:
  - i) an analysis subsystem having a processing unit; and
  - ii) an alerting unit;
- b) a communication unit; and
- c) one or more sensors,

wherein each of said one or more sensors is configured to detect a predetermined physiological or chemical parameter of said living being;

wherein said communication unit is facilitated to receive said detected parameters from each of said one or more sensors and transmit said detected parameters to said analysis subsystem;

wherein said processor of said analysis subsystem of said control module analyzes said detected parameters to thereby determine if one or more of said detected parameters or a combination of said detected parameters is abnormal;

wherein, when at least one of said detected parameters is determined to be abnormal, said alerting unit is operatively activated by said processing unit to alert said living being carrying the health monitoring system and optionally, one or more predetermined alert receiving entities; and

wherein, when said alerting unit is activated to alert said living being, carrying the health monitoring system, the health monitoring and alert system is fully independent of any remote entity.

2. The health monitoring system as in claim 1, wherein said living being is a human-being, wherein said human-being is either healthy or non-healthy.

3. The health monitoring system as in claim 1 or 2, wherein said analysis subsystem includes a memory for storing at least a portion of said detected parameters; wherein said stored detected parameters are used for trends analysis, for adaptation analysis, for abnormality prediction analysis, and for enabling data extraction for further external analysis; and wherein said analysis subsystem analyzes said trends to detect abnormal trends in said detected parameters or a combination thereof, and

wherein, when at least one of said trends is determined to be abnormal, said alerting unit is operatively activated to alert one or more predetermined alert receiving entities.

4. The health monitoring system as in claim 1, 2 or 3, wherein said health monitoring system is facilitated to operate substantially continuously.

5. The health monitoring system as in any one of claims 1 to 4, wherein the boundary definition of said parameter abnormality of said physiological or chemical parameter is personally adaptive.

6. The health monitoring system as in any one of claims 1 to 5, wherein the boundary definition of said parameter abnormality is dynamically adaptable to the changes over time of the normal state of said living being.

7. The health monitoring system as in any one of claims 1 to 6 wherein said processing unit of said analysis subsystem analyzes and determines the correlation between two or more of said detected parameters, thereby creating correlated parameters.

8. The health monitoring system as in claim 7, wherein when said detected correlated parameters are determined to be abnormal, said alerting unit is operatively activated by said processing unit to alert said living being and optionally, one or more predetermined alert receiving entities.

9. The health monitoring system as in claim 7 or 8, wherein the system is facilitated to provide said alert with no operative action being performed by said living being during health monitoring.

10. The health monitoring system as in any one of claims 1 to 9, wherein said sensor is a wearable sensor.

11. The health monitoring system as in claim 10 wherein said communication unit includes one or more communication subunits, and wherein each of said sensors is coupled with one or more of said communication subunits.

12. The health monitoring system as in any one of claims 1 to 9, wherein said sensor is an in-vivo sensor.
13. The health monitoring system as in claim 12, wherein said in-vivo sensor is a nano-sensor, and wherein said nano-sensor is delivered to an in-vivo target location, via blood vessels.
14. The health monitoring system as in claim 12, wherein said in-vivo sensor is delivered to a subcutaneous location.
15. The health monitoring system as in claim 12, wherein said in-vivo sensor is an implanted sensor.
16. The health monitoring system as in claim 12 or 15, wherein said sensor is implanted during a non-related surgery.
17. The health monitoring system as in claim 12, wherein said in-vivo sensor is a nano-sensor or a micro-sensor.
18. The health monitoring system as in claim 17, wherein said in-vivo sensor is delivered to an in-vivo target location, in a non-painful laser-based insertion, RF-based technology, by swallowing pills or capsules, by trans-dermal delivery patches, by injection using micro-needles or by nano-needles.
19. The health monitoring system as in claim 17, wherein said in-vivo sensor is delivered to an in-vivo target location, using targeted-liposome delivery techniques.
20. The health monitoring system as in claim 17, wherein said in-vivo sensor is delivered to an in-vivo target location, using nanotube delivery techniques.
21. The health monitoring system as in claim 17, wherein said in-vivo sensor requires no internal power source.

22. The health monitoring system as in any one of claims 12 to 21, wherein said communication unit includes one or more communication subunits, and wherein each of said sensors is coupled with one or more of said communication subunits.

23. The health monitoring system as in any one of claims 12 to 22, wherein said communication unit or said communication subunit are configured to transmit a signal to said in-vivo sensor and to receive a modulated echo of said transmitted signal, returned from said in-vivo sensor, and wherein said modulated echo carries the information sensed by said in-vivo sensor.

24. The health monitoring system as in any one of claims 1 to 9, wherein said control module is selected from the group consisting of a wearable module, an in-vivo module and a mobile device.

25. The health monitoring system as in claim 24, wherein said wearable control unit is a wearable device selected from the group including a wrist watch, a patch, an earring, a necklace, a bracelet and an armlet.

26. The health monitoring system as in claim 24, wherein said wearable control unit is a wearable device attached to or integrated into a mobile electronic device, a wheel chair or a personal device carried regularly by said living being.

27. The health monitoring system as in claim 26, wherein said mobile electronic device is a cellular phone, a PDA, a wearable indicator or a mobile PC.

28. The health monitoring system as in any one of claims 1 to 27, wherein said control module is disposed in the oral cavity of said living being, thereby being an oral control unit.

29. The health monitoring system as in claim 28, wherein said oral control unit is disposed inside one or more natural or artificial teeth of said living being.

30. The health monitoring system as in claim 28 or 29, wherein said oral control unit further comprises:

- iii) an internal power source; and
- iv) a maintenance unit,

wherein said maintenance unit facilitates external maintenance activities of said oral control unit.

31. The health monitoring system of claim 30, wherein said internal power source is rechargeable by normal operational motion of said oral control unit inside the oral cavity.

32. The health monitoring system as in claim 30 or 31, wherein said external maintenance activities are selected from a group of maintenance activities including updating said processing unit, downloading data, setup and update of parameters, insert a new or a replacement nano sensor, loading test analysis elements, unloading disposal waste, recharging internal power source, and perform diagnostic processes of selected members of the health monitoring system.

33. The health monitoring system as in any one of claims 30 to 32, wherein said oral control unit further comprises:

- v) an oral test unit having at least one oral sensor; and
- vi) at least one oral sampler,

wherein said maintenance unit preferably includes a storage for test analysis elements and a storage for waste resulting from tests analysis;

wherein said at least one oral sampler collects oral material selected from the group of orally disposed materials including oral fluids, breath and blood;

wherein said oral test unit is operatively activated to engage one or more of said analysis elements with said one or more oral materials, thereby producing a testable material;

wherein said at least one oral sensor is configured to sense said testable material and create tested data; and

wherein said maintenance unit transfers said tested data to said analysis subsystem of said control module.

34. The health monitoring system as in claim 33, wherein said one or more test analysis elements are reagents, wherein said reagents are part of said at least one oral sensor.

35. The health monitoring system as in any one of claims 30 to 34 wherein said maintenance unit includes storage for nano sensors and/or reagents, and wherein said maintenance unit is facilitated to deliver said nano sensor and/or reagent on demand or by a predetermined time interval.

36. The health monitoring system as in any one of claims 30 to 35, wherein said maintenance unit further includes a loading service channel for loading said storage for test analysis elements from an external source, wherein said loading service channel is sealingly closed during normal operation.

37. The health monitoring system as in any one of claims 30 to 36, wherein said maintenance unit further includes a disposing service channel for disposing accumulated waste from said storage for waste to an external location, wherein said disposing service channel is sealingly closed during normal operation;

38. The health monitoring system as in any one of claims 1 to 37, wherein said sensor is a digital acoustic sensor facilitated to sense bodily acoustic data.

39. The health monitoring system as in claim 38, wherein said bodily acoustic data includes heart beat, lung and breathing sounds.

40. The health monitoring system as in claim 1, wherein said sensor is selected from the group of physical sensors including an electric sensor, an optical sensor, an acceleration sensor, a pressure based sensor, a conductivity sensor and a humidity sensor.

41. The health monitoring system as in claim 40, wherein said physical sensors sense bodily-movements related data.

42. The health monitoring system as in claim 41, wherein the definition of said parameter abnormality depends also on said bodily-movements related data.

43. The health monitoring system as in claim 41 or 42, wherein said bodily-movements related data is processed by a motion-posture detection unit.

44. The health monitoring system as in claim 40 wherein said physical sensors sense bodily-posture related data.

45. The health monitoring system as in 44, wherein the definition of said parameter abnormality depends also on said bodily-posture related data.

46. The health monitoring system as in claims 44 or 45, wherein said bodily-posture related data are processed by a motion-posture detection unit.

47. The health monitoring system as in claims 43 and 46, wherein said bodily movements related data and said bodily-posture related data are processed by a motion-posture detection unit.

48. The health monitoring system as in any one of claims 1 to 47, wherein said control module further comprises an internal power source.

49. The health monitoring system as in claim 48, wherein said internal power source is a micro-battery or a nano-battery.

50. A method for monitoring the health status of a living being, comprising the steps of:

a) providing a seamless health monitoring and alerting system, configured for use by the healthy living being, the system including:

i) a control module having:

(A) an analysis subsystem having a processing unit; and

(B) an alerting unit;

ii) a communication unit; and

iii) one or more sensors;



- b) sensing at least one designated health related parameter by said one or more sensors, thereby generating sensed data;
- c) transmitting said sensed data to said communication center;
- d) transmitting said sensed data to said analysis center;
- e) analyzing said sensed data;
- f) determining if said sensed data is abnormal; and
- g) upon determining that said sensed data is abnormal,
  - i) selecting a proper alert type;
  - ii) transmitting said selected alert type(s) to said alerting unit; and
  - iii) activating said alerting unit by said processing unit, to thereby alert said living being carrying the health monitoring system and optionally, one or more predetermined alert receiving entities.

51. The method as in claim 50 further including the steps of:

- h) analyzing said sensed data by said processing unit, thereby generating analyzed sensed data;
- i) determining if said sensed analyzed data is abnormal;
- j) upon determining that said analyzed sensed data is abnormal,
  - i) selecting a proper alert type;
  - ii) transmitting said selected alert type(s) to said alerting unit; and
  - iii) activating said alerting unit.

52. The method as in claim 50 or 51, wherein said control module includes an oral control unit, disposed in the oral cavity of said living being.

53. The method as in claim 52, wherein said oral control unit further includes a maintenance unit, wherein said seamless health monitoring system further includes an oral test unit having at least one oral sensor, and at least one oral sampler, and wherein the method further includes the steps of:

- h) collecting selected oral materials from said oral cavity of the living being;
- i) transferring said oral materials to said test unit;
- j) transferring test analysis elements from an optional storage for test analysis elements or from external sources, to said test unit;

- k) engaging said analysis elements with said oral materials, thereby producing a testable material;
- l) sensing said testable material by said at least one oral sensor, thereby creating sensed data; and
- m) proceeding with step (d) of the method.

54. The method as in any one of claims 50 to 53, wherein said health monitoring system further includes a waste disposal storage, and wherein the method further includes the step of:

- n) disposing waste materials resulted from said engaging said analysis elements with said oral materials.

55. The method as in any one of claims 50 to 54, wherein said health monitoring system is facilitated to operate substantially continuously.

56. The method as in claim 50 further including the steps of:

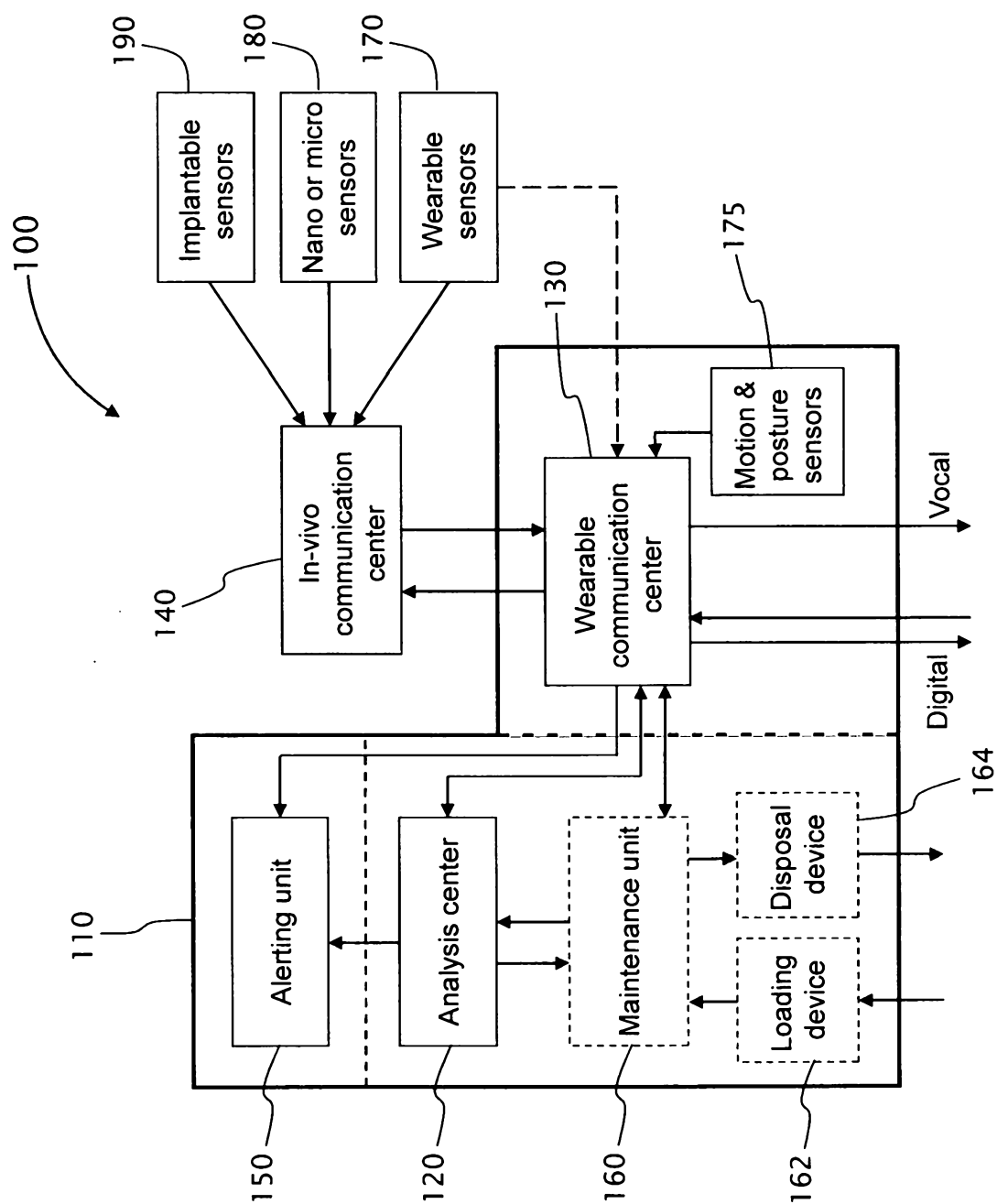
- h) analyzing said sensed data by said processing unit, thereby generating trend analyzed data;
- i) determining if said trend analyzed data is analyzed to predict a future abnormal health state;
- j) upon predicting a future abnormal health state,
  - i) selecting a proper alert type;
  - ii) transmitting said selected alert type(s) to said alerting unit; and activating said alerting unit.

57. A seamless health monitoring and alerting system, configured for use by a healthy living being, substantially as herein described with reference to the accompanying  
5 drawings.

58. A seamless health monitoring and alerting system, configured for use by a healthy living being, as in claim 1, substantially as herein described with reference to the accompanying drawings.

59. A method for monitoring the health status of a living being, substantially as herein described with reference to the accompanying drawings.

60. A method for monitoring the health status of a living being, as in claim 50,  
5 substantially as herein described with reference to the accompanying drawings.

*Fig. 1*

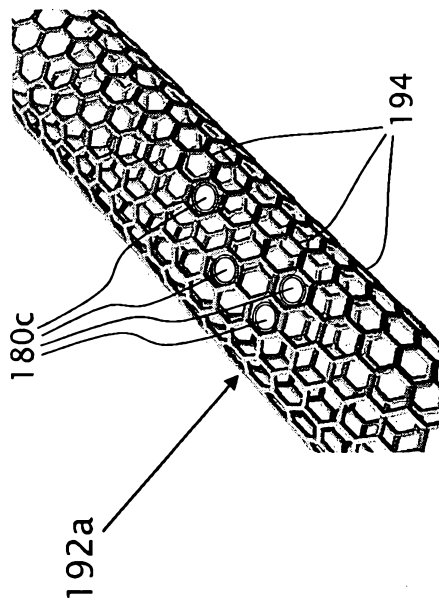


Fig. 2a

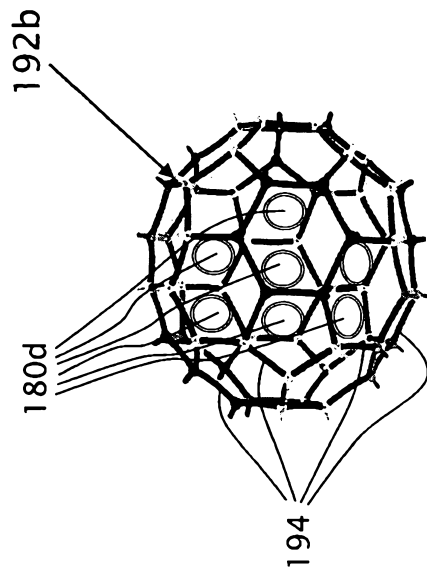


Fig. 2b

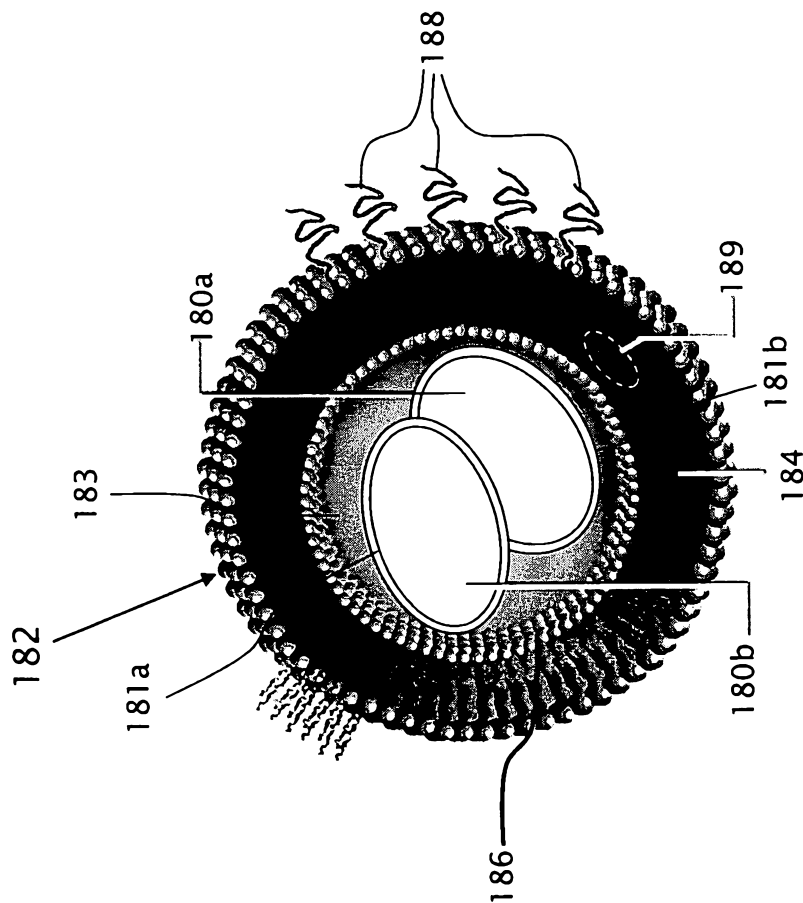


Fig. 3

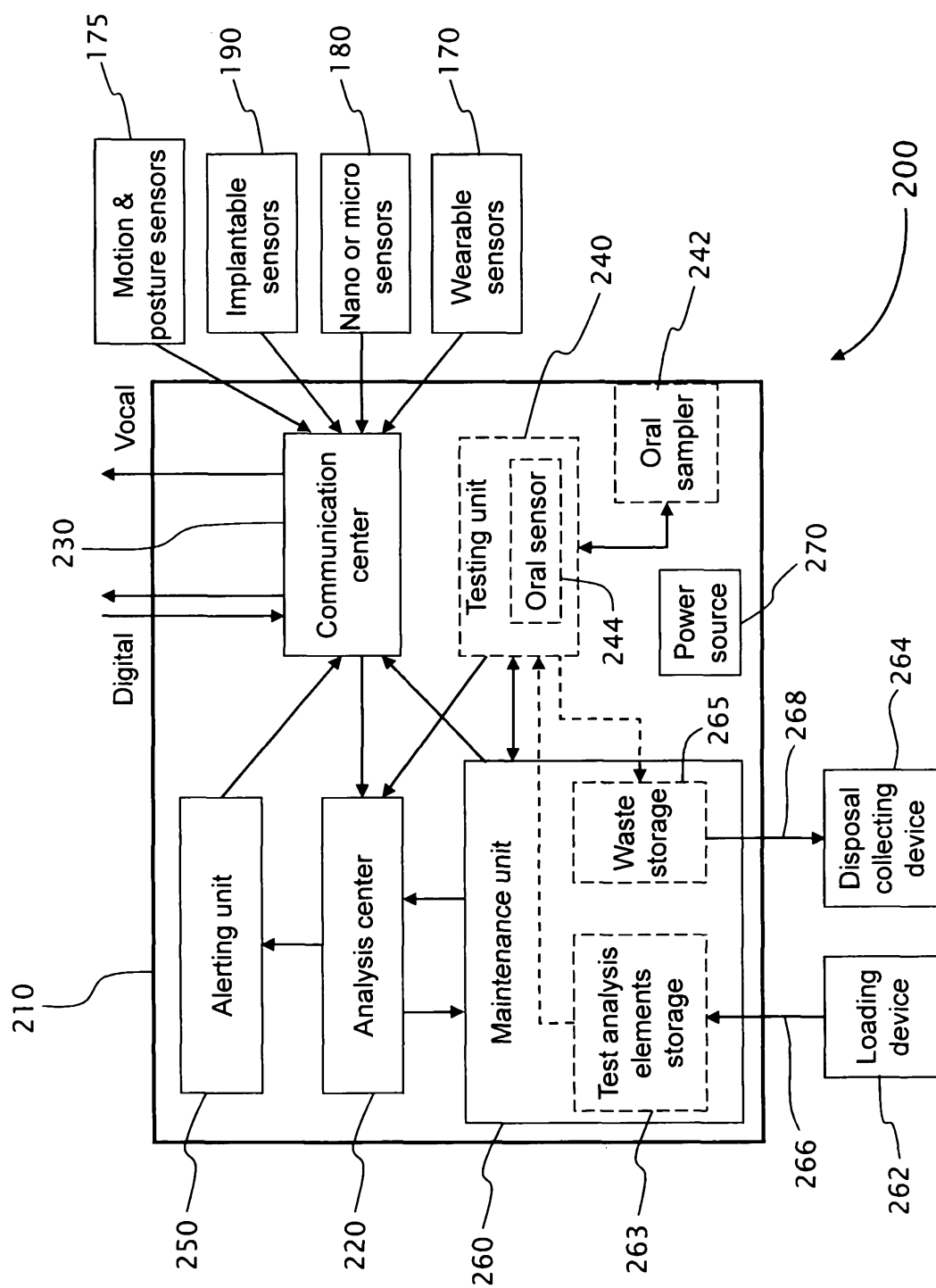
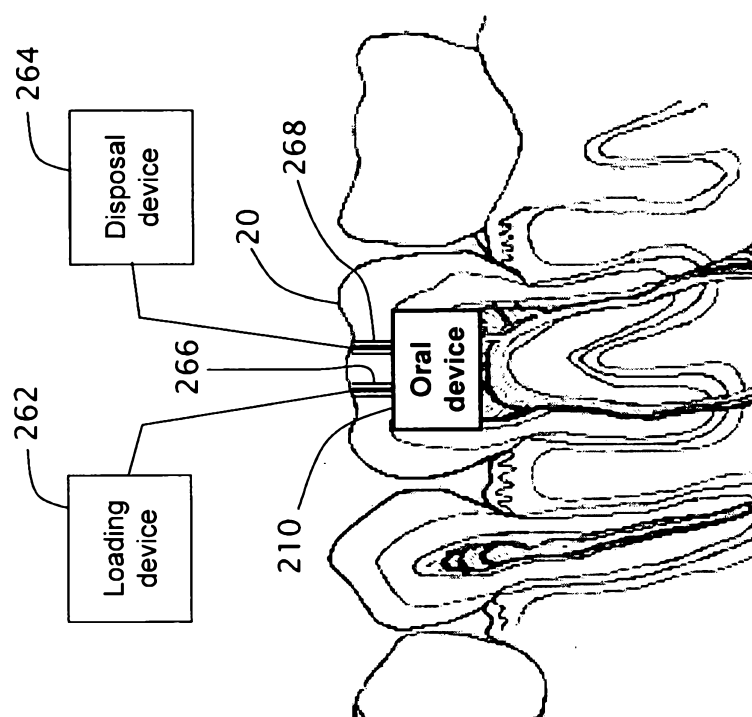
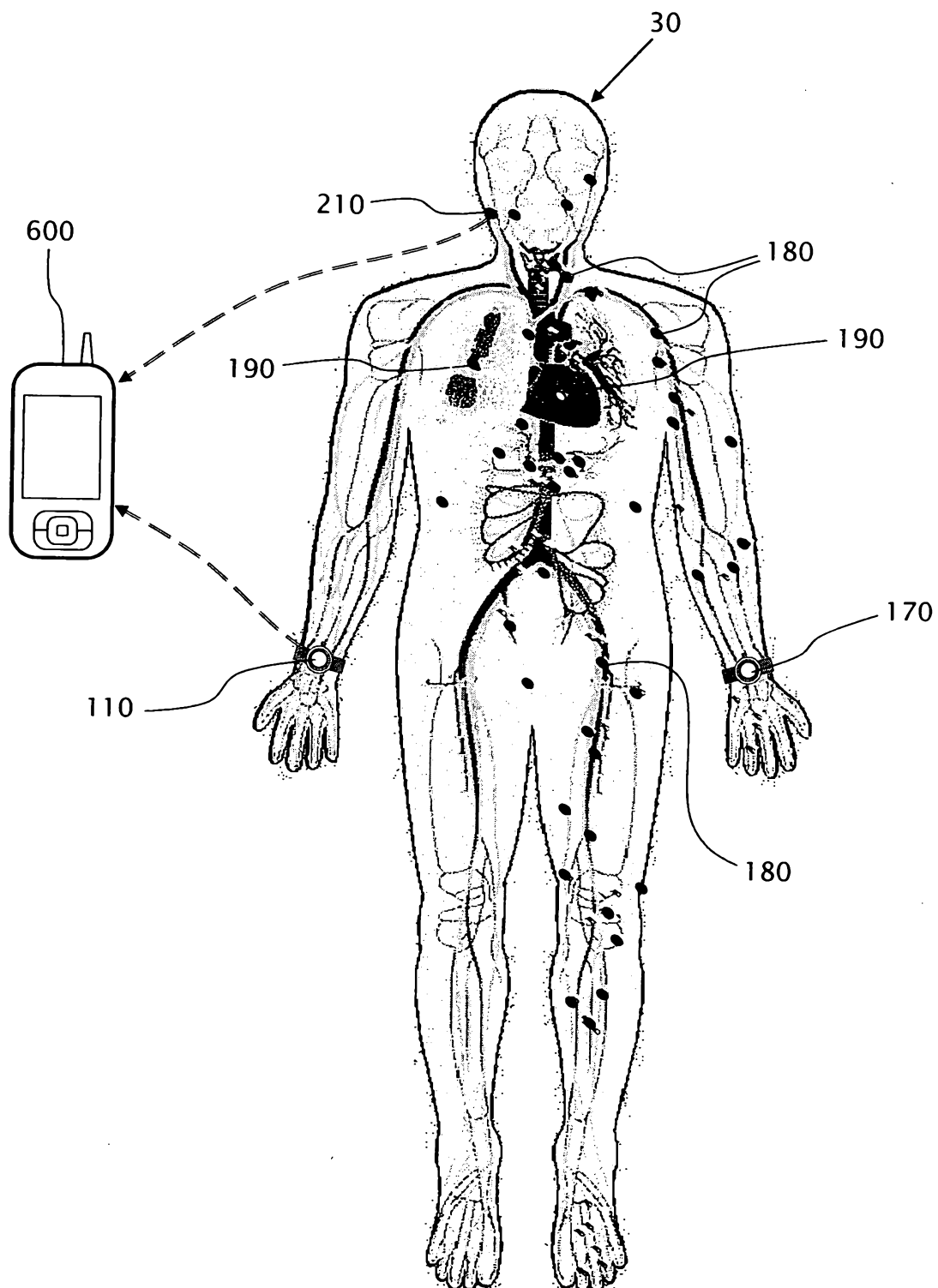


Fig. 4



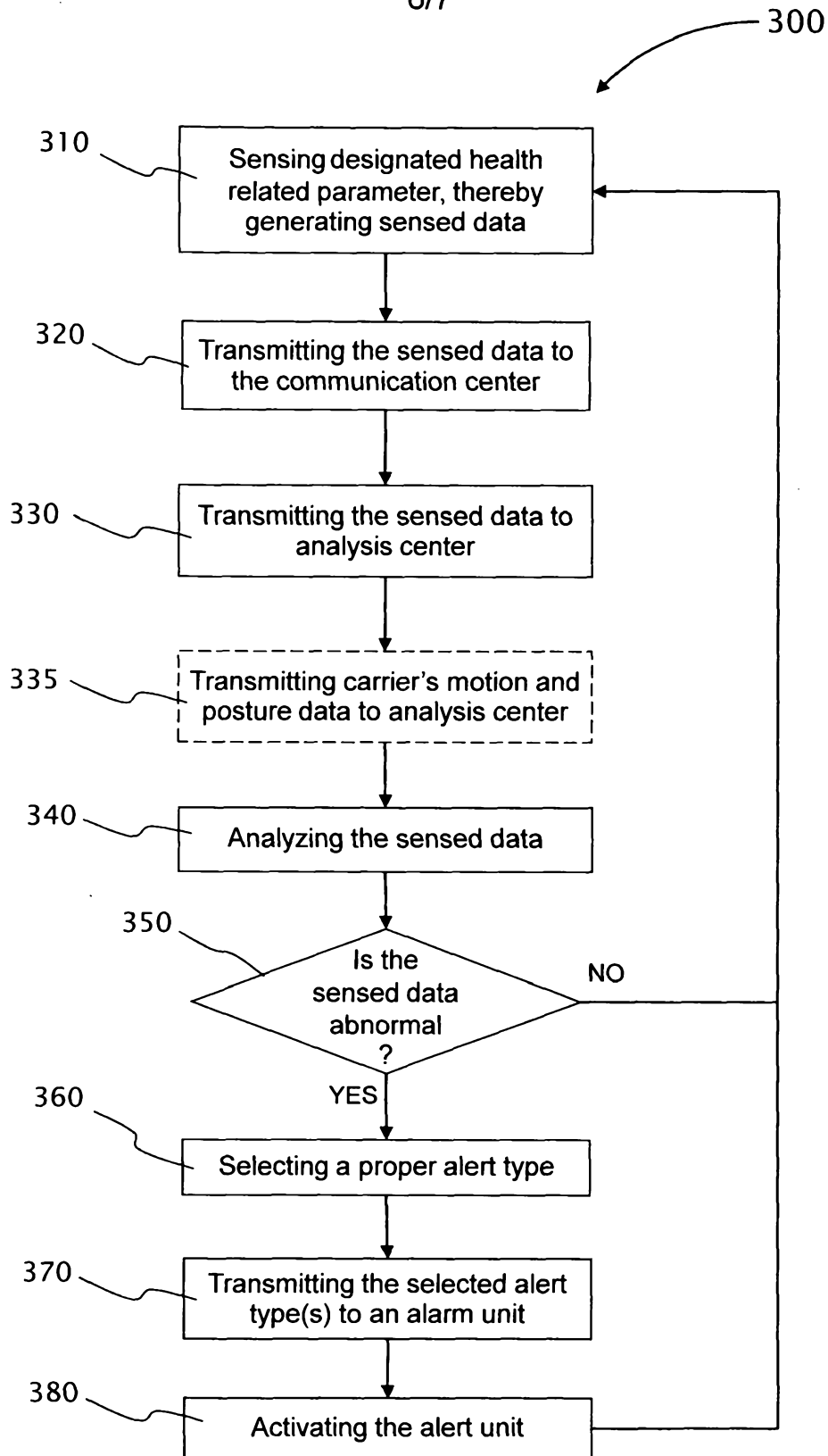
**Fig. 5**

5/7

*Fig. 6*



6/7

*Fig. 7*

7/7

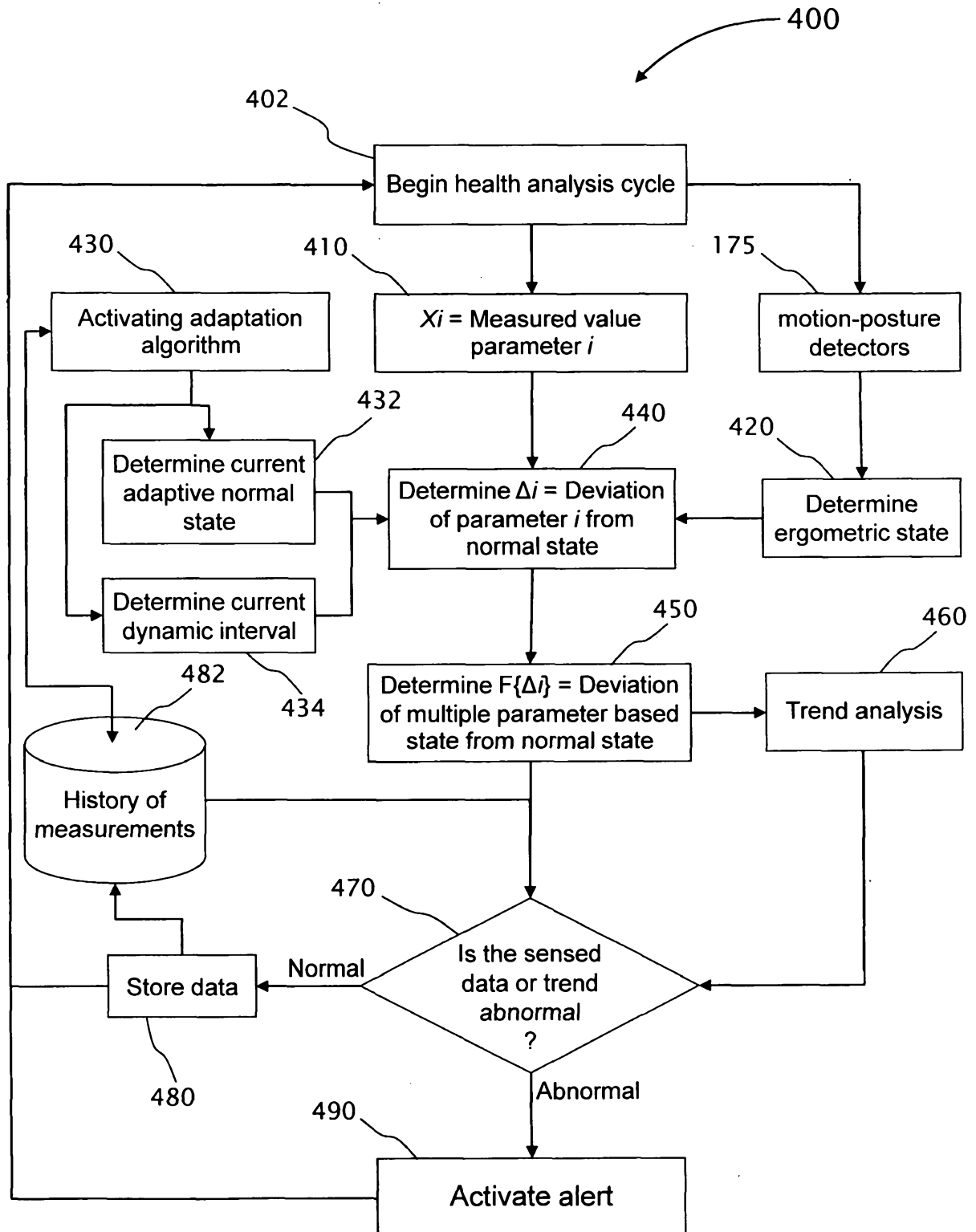


Fig. 8