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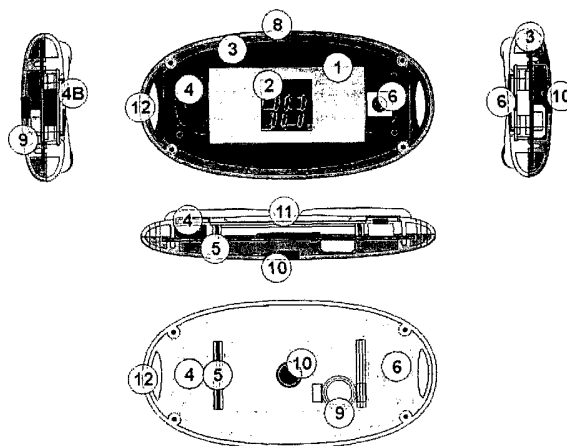
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(54) Title: CONTROL, MONITORING AND ARCHIVING PHYSIOLOGICAL PARAMETERS



(57) Abstract: Device and method of control, monitoring and archiving of human and animal physiological parameters, of small dimension, constituted by a shell (8, 8B), where the following objects are foreseen: one or more than one sensors (10) that detect the physiological parameters to which a printed electronic circuit (3) appropriate in relation to the functions to carry out and parameters to measure is destined; a battery (9) that gives the energy necessary for the device functioning; an alarm (4) of acoustic, visual or tactile type; a display or monitor (1) of functional values or values of measurement; a modulus of transmission of revealed data to other management and control devices, characterized by the fact that said device is equipped with a microprocessor (2) that contains the programming of all the functions to carry out and activate automatically or manually, according to necessities, minimum and maximum thresholds and time of alarm, limit danger thresholds and intermediate danger thresholds, times of alarm of auto-programming, in relation with the variations of basic objective and subjective parameters, that said alarm (4) is activated by the microprocessor in relation with its programming and connected to the values and parameters of measurement, the alarm can be of various acoustic type, for example, visual or of other type eventually tactile; that a stop button (6) can interrupt said alarm signal.



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CONTROL, MONITORING AND ARCHIVING PHYSIOLOGICAL PARAMETERS

Technical field of the invention

The subject of the present invention is a device and a method of control, monitoring and archiving of human and animal physiological parameters such as temperature, heartbeat frequency, blood pressure, and all other human and animal physiological parameters, invading and not, with automatic alarm system.

State of the art

The remote monitoring of physiological parameters of patients is described in the application for the international patent WO2004084720. In the mentioned document the described system consists of a device applied to the patient, devoted to the detection of physiological parameters which are transferred to an intermediate device and from the last one to the central system. The system does not have any capacity of auto-programming. The settled alarms are fixed and determined by the data set in the central system. The device carried by the patient transmits always the data to the intermediate device and the last one transmits them to the central system only if overtaking of the set threshold (event) occurs, or, if there is no connection, once the connection is re-established. The system described in WO2004084720 does not allow neither to patient nor to operators of the system of control to evaluate the increasing danger. To avoid such inconveniences the following device and method are proposed.

The device consists of:

- one or more than one sensors that detect the physiological function to which the appropriate electronic circuit is/are put in relation to the functions to carry out and parameters to measure;
- a microprocessor containing the programming of all the functions to carry out and to activate automatically, or manually, in accordance to the necessities such as, for example,

parameters to measure, minimum and maximum thresholds and times of alarm, danger thresholds and subsequent thresholds and times of alarm of auto-programming, according to the variations of basic objective and subjective parameters;

- an alarm, activated by the microprocessor according to its programming connected to the values and parameters of measurement;
- a battery that supplies the energy necessary for the device functioning.

The programming allows:

- to establish the normality values of measured parameters, the initial danger thresholds, the intermediate danger thresholds increasing or decreasing up to a maximum or minimum limit of danger threshold;
- to auto-program when the initial or intermediate danger threshold is reached, to the subsequent danger threshold up to maximum or minimum limit of danger threshold.

For example, when the temperature of a person increases the sensor detects the temperature. If the temperature goes over the initial danger threshold (i.e. exceeds the normality value of measured parameter) initial danger signal (that can be audio, visual, tactile, etc.) is produced. The initial danger signal remains active for a programmed period and turns off automatically, or remains active till the moment when a person switches off the mentioned initial danger signal. The intermediate danger signal remains active for a programmed period and turns off automatically, or remains active till the moment when a person switches off the mentioned intermediate danger signal. When the ultimate danger threshold is reached, the continuous signal of alarm is activated and will not turn off automatically, but can be switched off only with the "turn off" button.

The device may have a transmitter which sends the data to the management and control system according to one of the following ways:

- a) continuously;
- b) on request of the management and control system;
- c) at programmed intervals;

d) every time the initial, intermediate or final danger threshold is reached.

The system of control can be remote. For example, it can allow to a parent to be informed whether the temperature of a child increases or remains stationary. The management and control system can be the system of the elaboration and management of data for one or more than one persons as for example in case of a hospital, residence for old people, etc.

Moreover, the device can contain additional constructive elements:

- an alarm of various acoustic, visual or other type eventually tactile;
- a display of functional values or values of measurement;
- a modulus for transmission of detected data to other management and control devices;
 - such modulus of transmission transmits parameters subject of the measurement to an individual system of control or to a centralized system of control, where the data of more patients are directed;
 - such modulus of transmission can be used for the exact localization of a patient; by means of the modulus the direct vocal interface with the centralized control system is provided;
 - the centralized control system, managed by means of the appropriate programming software, allows to detect continuously and instantly the values of parameters subject of collecting and monitoring and to receive signals of alarm relatively to the various danger thresholds programmed manually or through auto-programming; moreover, the centralized control system permits to manage an archive of patients that constitutes a data base where all detected parameters and additional data, that, referring to the previously programmed necessities of health monitoring, will be the subject of detection, are collected;
 - the recordable and detectable data, other than those strictly connected with the physiological parameters, will be represented within the data base by the most possibly

different series that, in exemplifying way, will constitute the whole clinic-statistic card of the patient subject of monitoring:

- the software will also be able to detect the perfect localization of the patient within the supervised area or hospital;
- the data bank and the electronic program of management of the whole device will cumulate and archive data associating them with time so that it will be possible to elaborate every type of graphic or table that could reveal trends, averages, flows and tendencies of data.
- obviously every data, table or graphic can be printed, transmitted or subsequently elaborated, archived or differently treated with a common hardware on sale.
- The transmission of the data can be carried out using even contemporaneously several systems that may vary from simple radiofrequency to telephone and specific systems, up to gsm systems of transmission for data and audio, i.e. gps systems that allow the localization of the patient when the software of the own database is not able to do it, because the person subject of monitoring and able to move comes out of the closed area (hospital, nursing home or similar) that is the subject of monitoring, to more advanced technologies as by the way of example GPRS and UMTS.

The main object of the present invention is to realize a device of control of physiological parameters of a particularly small dimension; it is destined to contemporaneous monitoring of several functions allowing the automatic or manual programming of the alarm and danger thresholds.

Mentioned device consents the remote monitoring even for more than one patients contemporaneously and their localization outside and in movement through the gps system, or, in case of a still patient when it is situated within the hospital, through the device's software.

The method, besides the detection of data of monitored physiological parameters, localizes the patient and attends on the real-time registration, archiving and treatment of all data of every patient, assuring reciprocal communication, eventually even vocal, between the user and the control point. The method allows the continuity of functioning, monitoring and transmission that covers 24 hours. Other characteristics of the device subject of the present invention are:

- It can be equipped with a display that allows direct and immediate reading of detected values;
- The device, seen its small dimensions, can, if desired, be allocated inside the small band-aid or adhesive container to be put on the body;
- It can be equipped with audio that allows to system to communicate vocally the revealed values carried out (it is very useful for blinds);
- It can be integrated with a timer and a memory that allow to store more data in a time period according to the given programming or in time set in advance;
- It can be powered by a battery or through a low-tension current or by rechargeable batteries rechargeable also through magnetic induction;
- It can be equipped with a circuit of transmission that uses contemporaneously more standards or protocols necessary to various systems of communication so that more systems can be eventually used contemporaneously.

The device, therefore, keeps a parameter or parameters to monitor under control 24 hours a day; when it detects a gap from maximum or minimum values or another anomalous situation or programmed danger, it automatically produces a signal of alarm;

Obviously the minimum and/or maximum danger thresholds can be programmed manually or automatically according to the single necessities in the more different way in relation to the person and functions to monitor; in case of automatic programming all the adjustments and programming are managed in autonomous and intelligent way by a microprocessor, that is instructed by a software determining the functions to be carry out.

The product, with the use of appropriate materials, can be constructed resistant to hits, and, if desired, also unbreakable or waterproof;

Preferably, it is constructed in a very small dimension and can be allocated inside a simple band-aid;

It can be used to keep continuously both people and animals under control; moreover, the introduction in the device of a circuit of transmission allows the remote monitoring even through the use of a simple computer of medium dimensions or electronic instrumentation devoted to more patients in the same time;

Such capacity realizes the instantaneous real-time survey of data, its manipulation, treatment and therefore its subsequent archiving; it is provided the contemporaneous management of multiple and simultaneous alarms for more patients with the signal and contemporaneous immediate localization of the monitored person or of the point of alarm;

The localization is realized in accordance to the area that the device monitors through gps systems or a simple service software.

Moreover, the system allows, where it is desired, the simultaneous vocal communication between the monitored patient and the centre of control.

A non secondary scope of the present invention is the creation of a device which, for the largeness of set of parameters detected and real-time simultaneous feasible surveys, can realize a useful instrumentation to the scientific and applied research.

Functioning:

The device is applied to the body with an adhesive or with a band or with an own container of circuit; more than one sensors can be applied to the various parts of the body more suitable for to the type of survey or monitored parameters, such sensors can transmit to each other and to the system of control, therefore the detection of parameter/s to which the device is destined begins;

If the device according to the bands of programming and the original programmed instructions records a situation judged in the limits of normality, it shows on display real-time values. On the contrary, if the value reaches the risk threshold, the alarm is automatically activated;

The device when the alarm is on, besides showing on the display the revealed values, contemporaneously and automatically auto-programs itself to the higher risk threshold and remains in alarm for a period set by the internal program, and then deactivates automatically re-iterating the alarm functions to the eventual reaching to the higher threshold of risk;

In case of a drop of risk level, similarly to the former procedure, the system auto-programs to the lower threshold of alarm that could be activated or not;

If a high threshold, considered maximum, is reached, the device gives as an answer to the own auto-programming the signal of alarm which is in this specific case continuous and without end since the levels are of the extreme gravity and danger for the safety and life of the monitored patient.

Transmission of data:

The device is able to work autonomously (stand-alone) as well as transmits detected data to a remote control system which receives data and makes them available and usable in immediate way, visual and clear.

Indeed, the system is projected to activate automatically from the same remote control point all the systems of alarm and auto-programming already described previously and located at the point of the survey that consists in the sensor applied to the body;

The transmission of data and the connection between the sensor and the remote control point can occur simultaneously using all the systems of communication and transmission available for this moment and, where it is necessary, contemporaneously and simultaneously.

As for the vocal communication, possible between the monitored patient and the remote control point, it can be reciprocal;

Instead, the transmission of data can happen according to different modalities that could be activated even contemporaneously, programmed and activated manually or remotely throughout the commands offered by the remote control point; indeed, the data revealed by sensor can be transmitted:

- “Continuously” and in real time;

- “Postponed” with the transmission of “packages” of data in set intervals and according to the set timing;
- In “asynchron” modality through the messages of alarm when certain thresholds are reached;
- In “remote control” modality when reading of physiological functions parameters or loading of stored data is required by necessities of the remote control point; moreover, this modality allows the management of the detection device which is an instrumentation of telemedicine or remote intervention.

The instrumentation of detection can foresee the direct interconnection with systems of alarm of the service of the car first aid and, therefore, the immediate signal of the patient in difficulty localization transmission to the national sanitary system.

The function of subject’s localization necessary for conducting the immediate first-aid, can be performed throughout two systems according to the localization of the monitored patient:

- 1) If the subject remains in a stable position and in any case inside an inhabitant construction, the software can localize it defining inside the construction’s map the actual analytic position (department, room, bed, etc.)
- 2) If the subject moves freely, such information can be provided by the gps receiver that can be put into the instrument that making use of the same satellite system used in the traditional devices of localization and navigation provides the useful data on the person’s localization.

The device can be equipped with a system of sanitary emergency able to put immediately the person in vocal communication with the operative control point, and vice versa;

In such case the operative station can use the same channel for verifying whether the received alarm is real, or for giving at a distance the indications about the therapy to perform, as vice versa the person can communicate to the station asking any information or useful assistance.

Software:

Inside the detection device applied to the body:

allows both the manual programming of values step by step and the automatic programming named self-learning;

the values to program consist in times of alarm, maximum or minimum values of the various functions to reveal, times and intermediate thresholds of temporary alarms and thresholds of continuous alarms, parameters of frequency of the transmission of data ("continuously", "postponed", "asynchron", at the remote command, or when the maximum or minimum values are overcome);

the programming of the device can be done both at the moment of its production – programming of parameters standard and from the remote control point according to the specific necessities of single patients.

In the transmitting device for domestic use:

The device consists in two elements: the detector and the transmitter of data which is applied to the patient's body and a wireless modulus receiver which has the same programming for the model applied to the body as previously described.

In the transmitting device for professional or hospital use:

The device consists in more elements detector and transmitter singularly cabled and codified in such a way that the receiver or the remote control point recognizes and affiliate at the system ignition, generating automatically a data base assigned to every single transmitter;

Such data base contains and stores more different data useful for every single person monitored from detector/transmitter;

The software that supervises the system allows the programming of various parameters of alarm, management of simultaneous multiple masks of alarm, identification of patients and other desired things that can be useful to the management and complete elaboration of every revealed parameter, such as its printing, construction of tables and graphs.

Satellite device:

As previously, the device consists in more detectors/transmitters elements that the receiver of remote control recognize, affiliate at the system ignition assuring, as in the previous system, the complete management of data and alarms, as well as satellite localization of person and the possibility of reciprocal audio communication;

peculiarities of described system are following:

- the precise localization in the territory of the user deambulated using the satellite instrumentation;
- the possibility that the operative station can easily configure the parameters of functioning of single peripheral devices according to the person to monitor;
- the possibility to engage in it other systems of control and management that can make available the obtained data even to other applications of telemedicine.
- It can be equipped with a video and audio modulus that transmit directly the voice and imagines from the user to the remote control point and vice versa both on request of this latter and on input of the user.

Possibility of integration to mobile phone system.

The system can be easily integrated to the mobile telephony;

indeed, transforming the mobile phones into transmitter-receiver instrumentations for data revealed from small external sensors connected to them both throughout wires and other methods of transmission (bluetooth and similar), and using other functions and characteristics already existing in the mobile telephony such as simultaneous transmission of voice, images, messages and data; integrating functions already present in the mobile phone system with functions foreseen for the device and software of management of system in question.

Other characteristics and advantages of the invention will be clear from the following description of some ways of invention realization given as example without limits on figures 1, 2, 3 and 4.

Brief description of the figures

Figure 1 shows in non limitative way the various views of how the device subject of invention could appear.

Figure 2 shows various views of receiving device according to a first embodiment of the present invention.

Figure 3 shows various views of receiving device according to a second embodiment of the present invention.

Figure 4 shows non limitative figurative scheming of the GSM connection and of the GPS satellite localization with the control and management center according to the present invention.

Detailed description of the invention

In reference to the figure 1, the device subject of the present invention consists in a shell (8, 8B), where the following objects are foreseen: one or more sensors (10) that detect one or more physiological parameters to which a printed electronic circuit (3) appropriate in relation to the functions to carry out and parameters to measure is destined; a battery (9) that gives the energy necessary for the device functioning; a microprocessor (2) that contains the programming of all the functions to carry out and activate automatically or manually, according to necessities as, for example, parameters to measure, minimum and maximum thresholds and times of alarm, danger thresholds and the subsequent thresholds and times of alarm of auto-programming, in relation with the variations of basic objective and subjective parameters; an alarm (4) with alarm cover that is activated by the microprocessor in relation with its programming and connected to the values and parameters of measurement, the alarm can be of various acoustic type, for example, visual or of other type eventually tactile; a stop button (6) of said alarm signal; a display or monitor (1) of functional values or values of measurement, covered by a glass (11). Moreover, the device can be equipped with: an audio system that articulates the reached value of the physiological function; a modulus of transmission of revealed data to other devices of management and control. The device as it has a small dimension can be easily applied to the patient through a plaster or a belt that supports it throughout buttonholes (12). Otherwise it can be realized in other aesthetic form that adapts better to various parts of the body where it is applied, in relation to parameters to measure

and monitor that can contemporaneously be applied to various parts of body more suitable for a specific survey or monitoring. The aesthetic form of the device is improved with the inclusion of enterprise's logo (13).

The device of the present invention is able to work autonomously in relation to the programming of the own software as well as transmit data to a receiver shown in non limitative mode, but only as an example in the figure 2. The receiver has an integrated receiving antenna (4R), a multifunctional display (5R) through which it is possible to see the values of parameters measured by the device, a Led (6R) for verifying that the receiver works correctly, a confirmation key (8R) for received data, a modality key (9R) that allows to see different physiological parameters separately, for example, temperature, pressure, heartbeat; an alarm Led (10R) that works to signal a danger situation, an alarm loudspeaker (11R) that also signal a danger situation, shaped small feet (13R) for supporting the receiver on the surface, a hook to hook up the receiver to the belt or trousers of a person employed for control, for example a parent.

The figure 3 shows another way to realize a receiver. In a shell (30) the elements already foreseen in the embodiment described above are placed, moreover the first Led (20) is foreseen when the receiver is functioning, and the second Led (21) when the receiver signals an alarm, a turning on/off key (22), a modality key (23) and a setting up key (24), a loudspeaker (25) for alarm, an integrated antenna (29) for receiving, a clip (26) for the battery substitution, a groove (27) for inserting the hook to stick it to a belt or trousers, small feet (28) for keeping the receiver slightly raised from the supporting surface.

The figure 4 shows in a basic and simple way a figurative scheming of the GSM connection and the GPS satellite localization with the management and control center. The patients, free to continue their normal life, are equipped with a device (40) as described in the present invention which is connected to the GSM device equipped with GPS (41), that device can consist in a GSM phone equipped with a GPS modulus that through the GPS satellite (42) localizes the patient and through the GSM mobile network (43) transmit to the central system of management and control (44) the data on every single patient according to one of the following modalities: a) continuously, b) on

request of management and control system, c) at programmed intervals, d) every time the initial, intermediate or final danger threshold is reached. The central system of management and control (44) evaluates the danger level on the basis of received data and decides to send an ambulance (45) or a helicopter (46). Anyway the control point can in the same time, or, if desired, even simultaneously to the transmission of data vocally and reciprocally communicate with the patient providing him even by voice indications for the first aid, the device can also allow beyond the vocal communication, simultaneous sending of images, data and localization.

The invention, certainly, is not limited, to the representation of the figures, but can receive perfections and modifications from men skilled in the art, without going out of the patent frame.

The present invention permits numerous advantages and, particularly, allows to overcome the difficulties that could not be superated using the systems that are actually in commerce.

Claims:

1. Device of control, monitoring and archiving of human and animal physiological parameters, of small dimension, constituted by a shell (8, 8B), where the following objects are foreseen: one or more than one sensors (10) that detect the physiological parameters to which a printed electronic circuit (3) appropriate in relation to the functions to carry out and parameters to measure is destined; a battery (9) that gives the energy necessary for the device functioning; an alarm (4) of acoustic, visual or tactile type; a display or monitor (1) of functional values or values of measurement; a modulus of transmission of revealed data to other management and control devices, characterized by the fact that said device is equipped with a microprocessor (2) that contains the programming of all the functions to carry out and activate automatically or manually, according to necessities, minimum and maximum thresholds and time of alarm, limit danger thresholds and intermediate danger thresholds, times of alarm of auto-programming, in relation with the variations of basic objective and subjective parameters, that said alarm (4) is activated by the microprocessor in relation with its programming and connected to the values and parameters of measurement, the alarm can be of various acoustic type, for example, visual or of other type eventually tactile; that a stop button (6) can interrupt said alarm signal.
2. Device of control, monitoring and archiving of human and animal physiological parameters according to the claim 1 characterized by the fact that the microprocessor is programmable both originally, by the user and by the management and control system.
3. Device of control, monitoring and archiving of human and animal physiological parameters according to the claim 1 characterized by the fact that the microprocessor is programmed to allow to establish the normality values of measured parameters, of initial danger thresholds, of intermediate thresholds of increasing or decreasing danger up to the limit maximum or minimum danger threshold and to auto-programs itself, when the initial or intermediate threshold is reached, to the subsequent danger threshold up to the limit maximum or minimum threshold.

4. Device of control, monitoring and archiving of human and animal physiological parameters according to the claim 1 characterized by the fact that the device has a transmitter that sends:
 - a) the data continuously;
 - b) on request of the management and control system;
 - c) at programmed intervals;
 - d) every time the initial, intermediate or final danger threshold is reached.
5. Device of control, monitoring and archiving of human and animal physiological parameters according to claim 2 characterized by the fact that the control system is an individual system.
6. Device of control, monitoring and archiving of human and animal physiological parameters according to the claim 2 characterized by the fact that the control system centralized control system, where the data from more devices are directed.
7. Device of control, monitoring and archiving of human and animal physiological parameters according to any previous claim characterized by the fact that the transmission of the data is carried out using even contemporaneously more systems which are radiofrequency, telematic and telephone systems, gsm transmission systems for data and audio, i.e. gps systems that allow the localization of the patient.
8. Method of control, monitoring and archiving of human and animal physiological parameters that uses the device according to any previous claim characterized by the fact that the microprocessor is programmed automatically or manually for all the functions to carry out or activate according to necessities as, for example, parameters to measure, maximum or minimum threshold and time of alarm, the danger thresholds and the subsequent thresholds and times of alarm of auto-programming, in relation to the variations of parameters on objective or subjective base.
9. Method of control, monitoring and archiving of human and animal physiological parameters according to the claim 8 characterized by the fact that the device that transmits the data is situated at the exact localization of the patient, through such modulus the direct vocal communication with the centralized control system is foreseen.

10. Method of control, monitoring and archiving of human and animal physiological parameters according to the claim 9 characterized by the fact that the centralized control system, managed throughout the proper software of programming, allows the continuous and instantaneous detection of the values of parameters subject of survey and monitoring, and the reception of alarm signals relative to the various danger thresholds programmed manually or by auto-programming; moreover, the centralized control system allows to manage the archive of patients that constitutes the data base in which all revealed parameters and other data, that, in reference to previously programmed necessities of sanitary monitoring will be the subject of monitoring, are collected.
11. Method of control, monitoring and archiving of human and animal physiological parameters according to claim 9 characterized by the fact that the storable and detectable data, beyond those strictly connected to the physiological parameters, are represented in the data base by most possible different series that, will constitute the whole clinic-statistic card of the patient subject of monitoring.
12. Method of control, monitoring and archiving of human and animal physiological parameters according to claim 11 characterized by the fact that the software is also destined to the perfect localization of the patient within the monitored area or hospital construction.
13. Method of control, monitoring and archiving of human and animal physiological parameters according to claim 11 is characterized by the fact that the data bank and the electronic program of management of the whole device will cumulate and archive data associating it with time so that it will be possible to elaborate every type of graphic or table that could reveal trends, averages, flows and tendencies of data.
14. Method of control, monitoring and archiving of human and animal physiological parameters according to claim 13 characterized by the fact that every data, table or graphic can be printed, transmitted or subsequently elaborated, archived or differently treated with a common hardware on sale.

15. Method of control, monitoring and archiving of human and animal physiological parameters according to the claim 11 characterized by the fact that the transmission of the data is carried out using even contemporaneously more systems which are radiofrequency, telematic and telephone systems, gsm transmission systems for data and audio, i.e. gps systems that allow the localization of the patient.

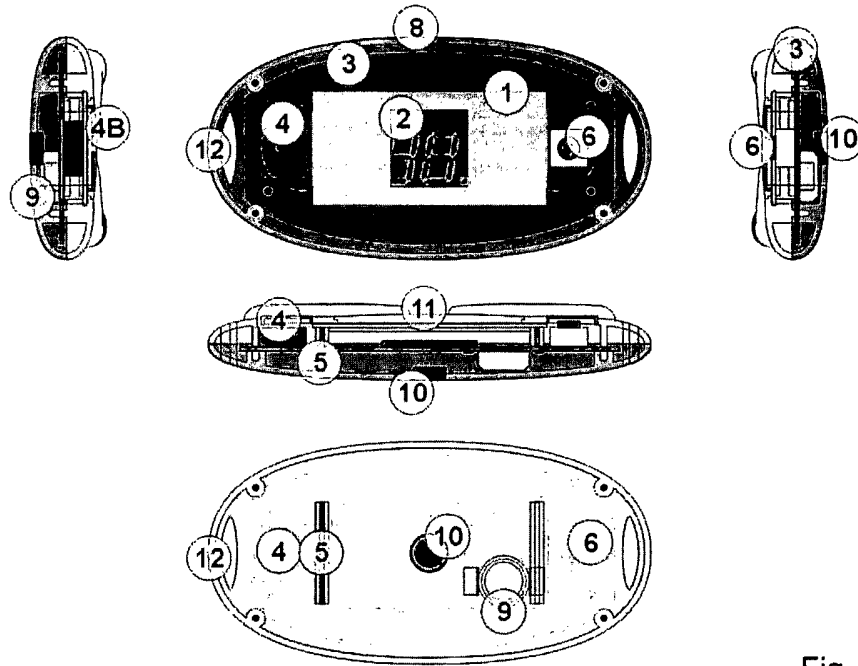
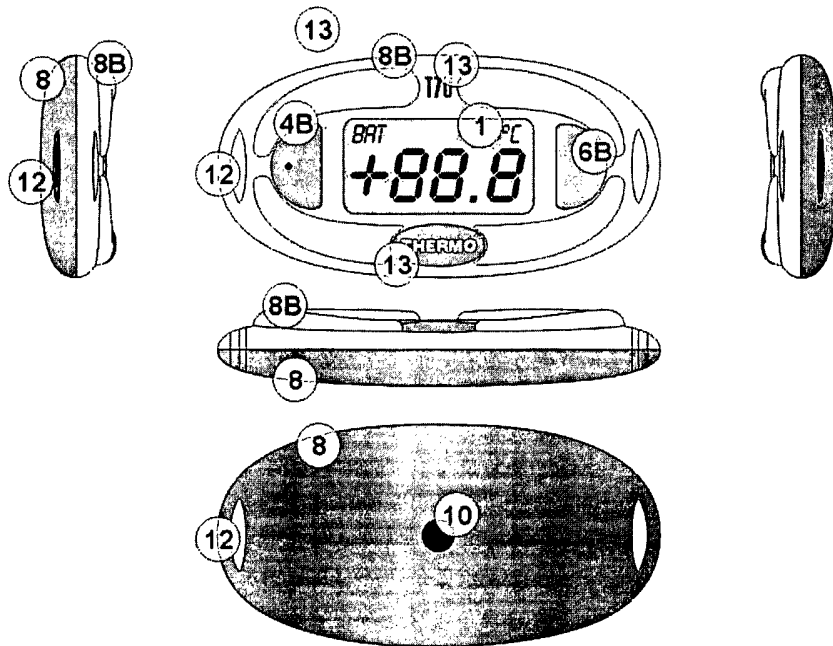
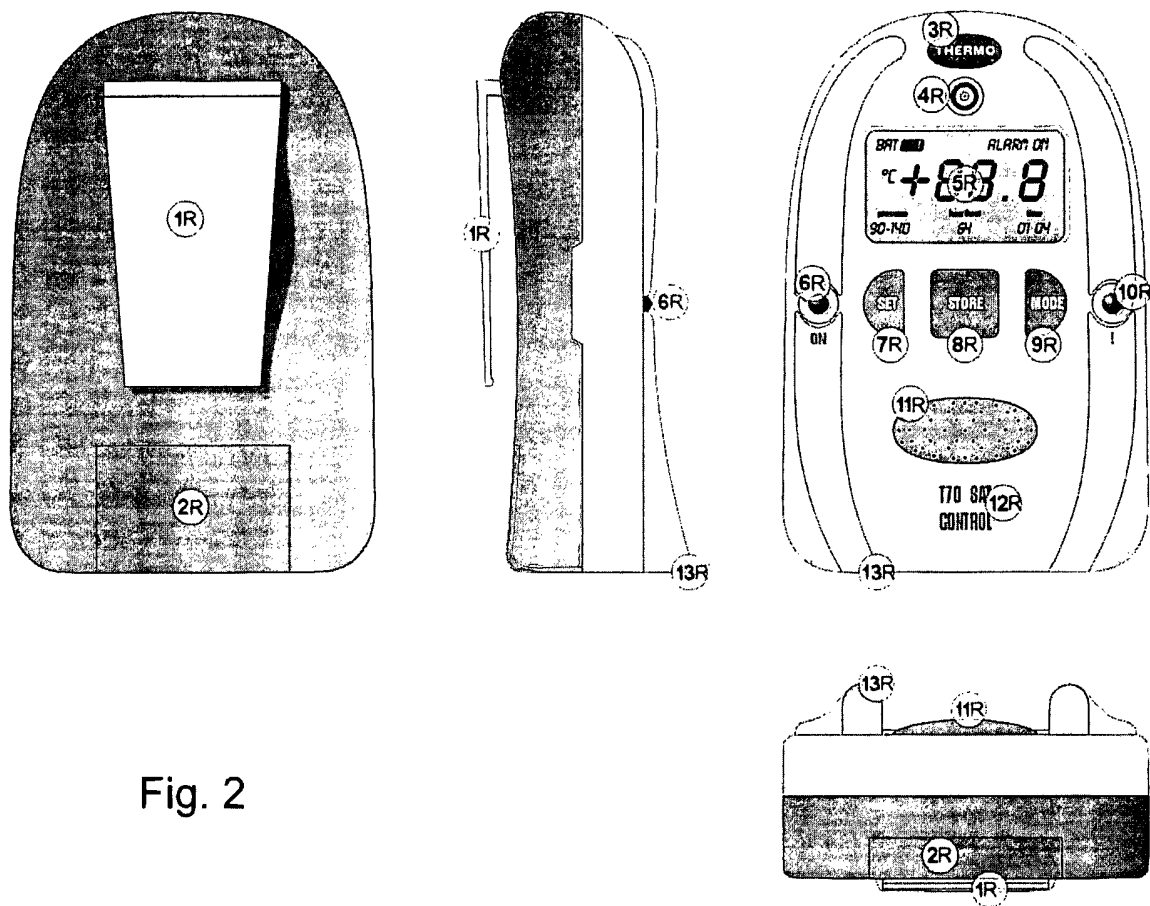


Fig. 1





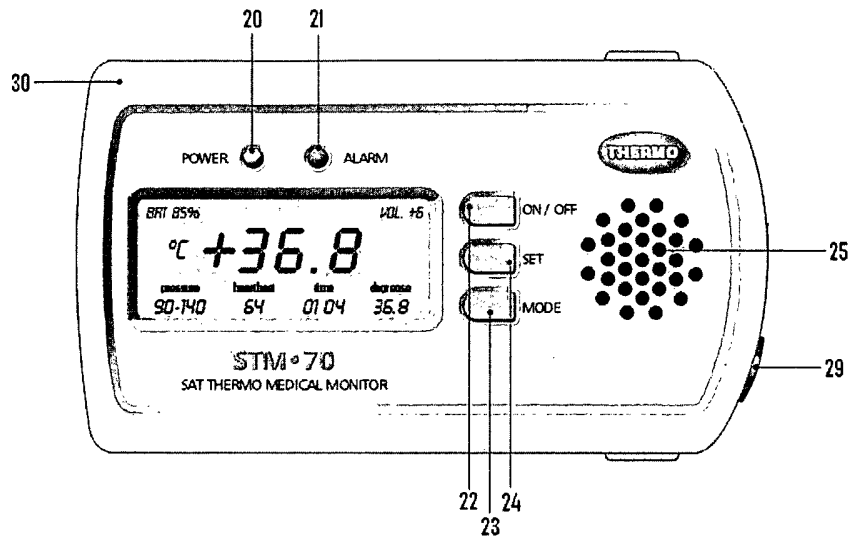
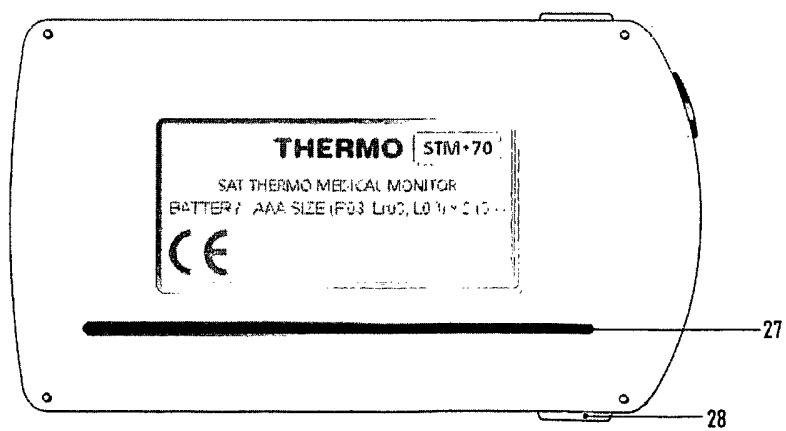
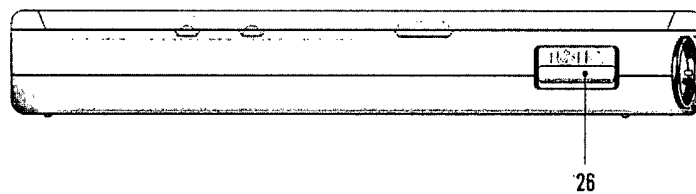
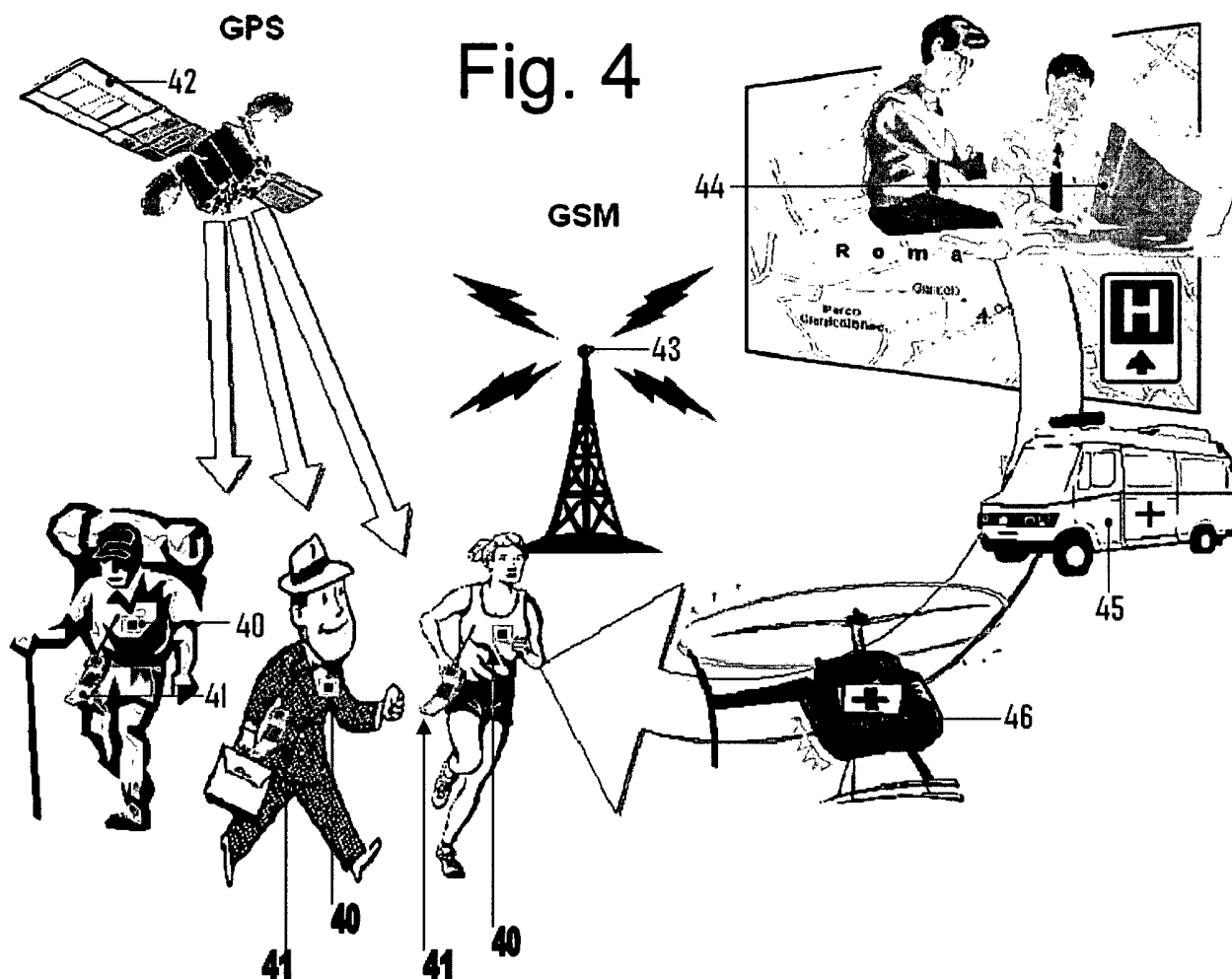


Fig. 3





INTERNATIONAL SEARCH REPORT

ational Application No

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A. CLASSIFICATION OF SUBJECT MATTER

A61B5/00

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B

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

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

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/117204 A1 (MAZAR SCOTT T ET AL) 17 June 2004 (2004-06-17) paragraphs '0001! - '0026!, '0031!, '0035!, '0040!, '0045!, '0048!, '0062! - '0068!, '0080!, '0081!, '0083!, '0086!, '0089!, '0091!, '0100! paragraphs '0101!, '0104!, '0109!, '0110! -----	1-15



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

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Date of the actual completion of the international search

24 January 2006

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2004117204 A1	17-06-2004	AU 2003301153 A1	14-07-2004
		EP 1578338 A2	28-09-2005
		WO 2004056301 A2	08-07-2004