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(71) Applicant(s):

Drager Medical AG & Co. KG
(Incorporated in the Federal Republic of Germany)
Moislinger Allee 53-55, D-23558 Lübeck,
Federal Republic of Germany

(72) Inventor(s):

Hans-Ullrich Hansmann

(74) Agent and/or Address for Service:

Graham Watt & Co LLP, Patent & Trade Mark Attorneys
St Botolph's House, 7-9 St Botolph's Road,
SEVENOAKS, Kent, TN13 3AJ,
United Kingdom

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(56) Documents Cited:

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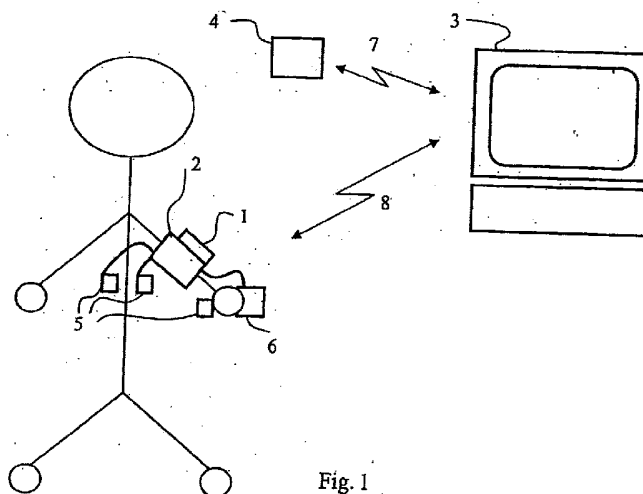
(58) Field of Search:

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(54) Abstract Title: **Automated method for adapting the settings of a patient monitor**

(57) An automated method is proposed for setting a patient monitor 1 for the detection of a patient's vital parameters measured by means of patient sensors 2,5,6 in dependence on the current patient situation, whereby a statistical evaluation for several up to all measurement data of at least one of the measured vital parameters is carried out in a computing unit from the measured values of the vital parameters and the settings of the patient monitor 1 are adapted in dependence on the statistical evaluation carried out, whereby the adaptation of the settings relates to at least the vital parameters to be measured, and the measurement frequency, together with the data quality and/or properties of the data transmission.



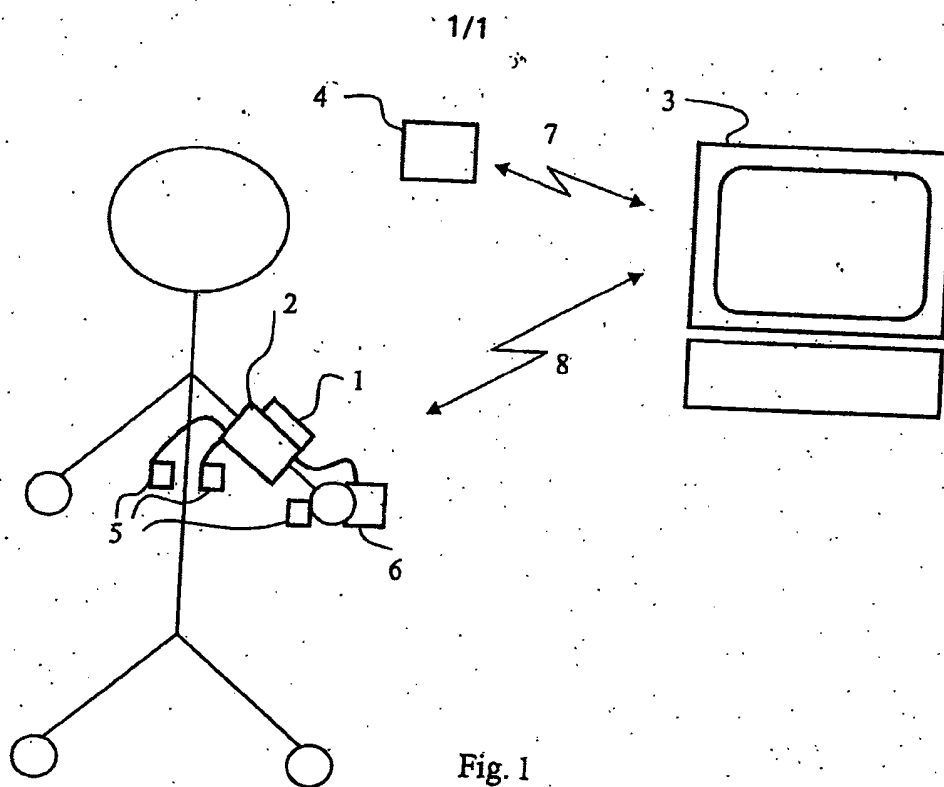


Fig. 1

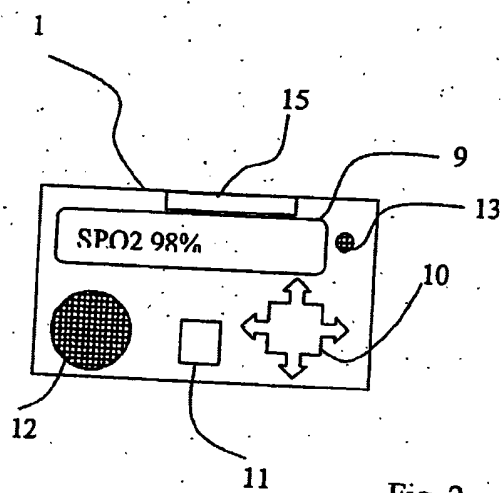


Fig. 2

Method for setting a patient monitor

The invention relates to a method for setting a patient monitor for the detection of a patient's vital parameters measured by means of patient sensors in dependence on the current patient situation.

Within the clinical monitoring of intensive care wards, it is common to provide patients with a monitoring system. Various vital parameters are usually measured continuously or at least very frequently. Examples of measured vital parameters are ECGs, temperature, oxygen saturation, respiratory rate, heart rate, non-invasive blood pressure, pulse transit time.

A similar monitoring system is sometimes used outside intensive care wards or a system with telemetric patient data transmission is used.

Outside clinics, in the outpatient sphere of patient care, simple sensors with GSM (cell phone/mobile) transmission are sometimes used.

All these patient monitors transmit either continuously as in the intensive care wards or at a fixed measurement and transmission rate (telemetry) or at the user's individual request as an event recorder.

This kind of monitoring, which is known in principle, is described for example in DE 103 45 171 A1, DE 198 49 607 C1 and DE 693 08 322 T2.

All the known patient monitoring systems have a fixed setting of the measured vital parameters including measurement quality, transmission rate and limiting values. An adaptation to changed ambient/situational conditions can take place solely by manual intervention. Situations thus arise in which too few or unsuitable measurement data of

crisis-prone patients are available or patients are unnecessarily encumbered, the transmission network is unnecessarily loaded and/or the service life of the energy storage unit is unnecessarily shortened in the case of mobile patient monitoring systems.

The present invention is as claimed in the claims.

Embodiments of the invention provide an automated method for setting a patient monitor for the detection of a patient's vital parameters measured by means of patient sensors.

An essential advantage of the method according to the present invention is that the restriction of the patient due to monitoring of vital parameters is reduced to the essential requirements adapted in each case. Furthermore, the amount of data to be transmitted is reduced and the energy requirement is lowered by the method, which is geared to the current patient status. The patient-relevant assessment criteria can be adapted by the assessed patient status and, if appropriate, ensure more stable alarm conditioning.

No additional staff is required on account of the automation of the method.

The measurement of the patient data takes place with a monitoring system. This system may comprise many individual patient monitors with patient sensors, also referred to as patient units, and one or more central stations. The patient monitors are preferably designed as small, portable monitors, which transmit data wireless or via a fixed infrastructure depending on the patient's mobility into the hospital network or "TeleHealthCare" system. The "Dräger Infinity" monitors, for example, are designed in a similar fashion.

The receiving central station may report back information and settings to the individual patient monitors. There is the possibility of bi-directional communication of a data-systems nature, but optionally also the possibility of audio and video transmission.

A meaningful and necessary data acquisition profile is calculated for each individual patient inside the central station, i.e. rules are established as to the conditions under which the

time-slot pattern for a request for the measurement of a parameter is to take place. The quality of a vital parameter measurement with regard to resolution, averaging interval or derivation number (ECG) can also be varied. The band width can extend from a continuous detection and transmission of vital parameters online to the replacement of measurements by direct communication with the patient by means of display, loudspeaker, microphone and keyboard stroke.

These rules are based on an assessment of the patient by the medical staff and especially by the doctor and can be varied on the basis of the observation of a trend or a statistical evaluation of the vital parameter history. The change in the rules within a risk group can be calculated by the observation of a trend in respect of measurement value variance and basic value.

The range of the measurement rates can extend from continuous to infrequent individual measurements. Individual measurements that lie within the expectation window can, if appropriate, be evaluated and stored solely locally, without a data transmission being activated. In addition, there is the possibility of carrying out the measurements as a reaction to an individual request from the central station or the patient.

There may be installed in a central station or in a patient monitor a control mechanism, which allows the medical staff to vary the settings for the monitoring of the patient status within absolute and individual limits. The limits for the settings of the patient monitor as well as the limits for the measured values that lead to a change in the settings can be varied.

The limits, like the individual limiting values of a conventional patient monitor, are fixed for individual vital parameters. Within these limits, restricting limits can also be set by the medical staff, depending on the patient's risk group, illness pattern and other individual reasons. For this purpose, a set of settings can be filed which can be used as a reference value when carrying out the settings for new patients.

The rules that are employed for the assessment are based on methods that are already used in other technical spheres:

In quality assurance for incoming goods, for example, a high proportion of the batches of new products are usually statistically evaluated and measured. On the basis of the statistical distribution of the measured values (middle and width of the Gaussian distribution curve) and the rising number of properties conforming to expectations, the proportion of parts to be qualified within a batch is reduced.

In communications technology, it is usual to install control mechanisms and to operate a counter unit with each transmission unit. Faulty transmissions are usually counted negatively with a larger value and transmissions conforming to expectations are counted positively with a smaller value.

The two methods are used in order to enable automatic adaptation from the medical standpoint. The statistical evaluation of a blood pressure course produces a uniform course in the case of unremarkable patients and could lead to a more infrequent measurement in the case of a constant mean value and small scatter range. On the other hand, there can also be a rapid reaction when a deviation is ascertained and the frequency of the measurements can be increased in order to detect the course reliably and to detect in good time possible rapid gradients in the course. A reduction in the measurement frequency may take place only after a preset number of "good" measured values, whilst "poor" measured values lead more quickly to an increase in the measurement frequency.

The rules that are used for the method can also be based on relationships between various vital parameters. A change in a vital parameter may require a more frequent measurement of another vital parameter in order to obtain a medically adequate picture of the patient.

A frequent quarter hourly measurement of blood pressure can be reduced in its frequency in the case of a low standard deviation and mean value in the expectation window and possibly be replaced by a simpler measuring procedure, such as pulse wave propagation

time, with a limited informative value. On the other hand, an ascertained raised blood pressure may also lead to a more frequent ECG signal transmission.

The request for a measurement to be carried out can also be generated directly from the central station. This allows the medical staff to ascertain the current status.

Apart from the measured vital parameters, other information can also be transmitted via the patient units.

This may include drug dose (for example "high-level user"), certain background information (such as for example movement artifacts due to rehabilitation measures, walking), stressful situations (patient) or a direct audio or video communication. Further additional measured values such as acceleration, location and ambient temperature may be helpful for a specific assessment or also be used for a plausibility test.

On the basis of localisation information, for example by means of RFID technology, which is transmitted at certain central passageways to the mobile patient units and to the central station, a localisation can take place at least zonally even with an interruption in communications.

The number of measurements carried out and their quality are adapted by the present method to the level required for medical safety. The burdens on the patient are thus duly adapted to the current individual situation. The medical reliability of the monitoring also remains intact during changed patient circumstances, without measurements having to be carried out unnecessarily frequently.

The adapted measuring method leads to the following advantages:

a) The energy requirement of the patient unit, i.e. the patient monitor, with individual measurement rates can, depending on the current patient situation and patient risk group, be drastically reduced compared to a steady, global measurement rate conforming to a standard. Mobile patients, whose independence and mobility are a decisive factor for

recovery, can move for much longer independent of the charging station with the same battery or storage-battery capacity or alternatively can be equipped with smaller, lighter energy storage units.

b) The quantity of measurement data that is to be transmitted can be compressed into a high information content with a suitable design of the request-rule mechanism. This enables a reduction in transmission times and thus a reduction in energy consumption and utilisation of the transmission network.

c) The additional information that is available concerning the patient enables a specific evaluation of the data with regard to an assessment of his medical risk. Thus, a mobile patient may be subjected to physical strain which increases his pulse for a short time. A temporary shifting of the alarm limits can ensure in the case of established physical activity that an unnecessary alarm is not triggered. The reliability of the assessment of the patient's status is increased and the alarm criteria are stabilised.

d) The localisation of the area in which a patient is spending time assists with the speed at which possible help can be rendered. The additional information may also be useful in the case of a short-term change of arrangements within the medical service provider, i.e. hospital or TeleHealthCare system. The changed situation can be used to communicate the new arrangement to the patient in good time.

e) The localisation can be used, when certain areas are entered, to adapt the settings of the patient monitor to the circumstances in the area. This includes, for example, leaving a building or entering a certain therapy area with certain applications and associated physical strains, change of position or temperatures. A time-limited switching-off of the patient unit for washrooms or similar can also be arranged.

f) The two-way communication facility expands the patient unit to include a direct response in both directions. Information such as changed diagnosis appointments can be entered in a calendar using data systems technology. Audio and video transmissions can however also be used in order to conduct a report of short duration or a personal adjustment. A

flexible information system can arise in connection with the localisation of the area where time is being spent.

g) As a result of the two-way communication facility, there is the possibility of giving the patient tips. These tips can be used to communicate certain behavioural guidelines in the case of faulty measurements. Mention may be made here, for example, of the avoidance of movement artifacts during a measurement or the notification of specific measurements such as an NIBP (non-invasive blood pressure) measurement with a pressure cuff.

h) If the measurement for individual patients represents an unreasonable burden, the measurement can also be replaced by the patient occasionally reporting back directly. Especially in the case of mobile patients, the desired freedom of movement can thus be achieved by the fact that the patient can sign off for a specified period for a walk or for visits. In this period, the expected measured values are replaced by the answering of targeted questions via his patient unit in a time sequence.

i) The central unit or alternatively the patient monitor can request a measurement. The performance of the measurement, however, only takes place after a trigger event by the patient.

An exemplary embodiment will be explained below with the aid of the figures.

In the figures:

Figure 1 shows a patient monitoring system for the patient,

Figure 2 shows the patient monitor in detail.

Mobile patient monitor 1 with a plurality of patient sensors for the represented patient is in a communication connection with a central station 3. Patient monitor 1 is also referred to as a patient unit.

Patient monitor 1 is equipped for the measurement of the vital parameters ECG (three electrodes 5 for two derivations), an oscillatory blood pressure measurement NIBP by means of an upper arm cuff 2 and an oxygen saturation measurement SPO2 by means of finger clip 6.

Patient monitor 1 is operated from a storage battery with, for example, four hours' operating time and transmits its data by means of GSM cellphone/mobile systems 8.

In this arrangement, it is sensible for reasons of capacity to reduce the measurement frequency, as long as this involves an acceptable loss of information.

The ECG measurement in real time requires a high data rate, with which it is necessary to maintain the data connection during the whole operating time (transmitting operation). This means a short service life of the energy storage unit ($< 4h$) and loads the transmission capacity of the transmitting/receiving systems.

The operation of the oxygen saturation sensor system does not require a high data rate, but it does call for a high power input for the operation of the infrared diodes.

Upper arm cuff 2, which has to be pumped up for each new measured value, requires the energy for the pumping for each individual procedure and represents a considerable restriction for the patient, since each measurement requires a rest phase and a certain position. Furthermore, the pressure sensation is unpleasant for the patient and can lead to nerve damage in the case of very frequent measurement.

Patient monitor 1 receives from the doctor administering treatment an individual setting for each individual parameter, which matches the patient's risk group and his specific illness history.

Patient monitor 1 is initialised for example as follows:

Vital parameter	Measurement rate	Transmission
ECG	Every 5 min: store 10 s signal	Every 10 min: 10 s signal 2 derivations
NIBP	Every 15 min: 1 measurement cycle	Every 30 min: dia. + sys. value
SPO2	Every 2 min: 20s measurement	Every 10 min: 5 values + mean value

The limiting values for the SPO2 measurement stand at 96%. If smaller values are ascertained, spontaneous control measurements take place. The patient receives a message so that, on the basis of his reaction (acknowledgement), conclusions can be drawn regarding the reliability of the measurement results. An increase in the measurement rate for all 3 parameters follows.

Vital parameter	Measurement rate	Transmission
ECG	Continuous	Every 1 min: 10 s signal 2 derivations
NIBP	Every 2 min: 1 measurement cycle	Every 2 min: dia. + sys. value
SPO2	Continuous	Every 1 min: 20 values + mean value

If unstable values are then measured or if the values lie outside, a direct visit by a medical member of staff takes place. If an SPO2 value of 94% is measured, the value is confirmed by an additional control measurement and a visit is prompted.

If no striking values, but on the contrary stable and expected ones are ascertained, the setting is changed after 2 hours as follows:

Vital parameter	Measurement rate	Transmission
ECG	Every 5 min: store 10 s signal	Every 10 min: 10s signal 1 derivation
NIBP	Every 30 min: 1 measurement cycle	Every 30 min: dia. + sys. Value
SPO2	Every 5 min: 20s measurement	Every 10 min: 2 mean values

After further, stable and expected values, the setting is changed in a comparable manner. Subsequently, the measurement rates can be reduced after two days to an extent such that upper arm cuff 2 can be taken off and only two measurements per day should take place.

Vital parameter	Measurement rate	Transmission
ECG	None	None
NIBP	2 per day	2 per day: dia. + sys. value + heart rate
SPO2	None	None

An additional movement sensor 11 on patient monitor 1, figure 2, can recognise sleep phases with the aid of the movement profile and place the NIBP measurement outside these sleep phases, as long as this is consistent with the time intervals.

If the patient senses uncertainty or suspects a cardiac event, he can at any time carry out an additional measurement cycle and return the setting back to the preceding one. In addition, there is the possibility of making contact directly with the nursing staff. A display 9, a loudspeaker 12, a microphone 13 and a multifunctional knob 10 serve for this purpose.

Both units, i.e. central station 3 and patient monitor 1, store the current settings. Central station 3 is the master for possible changes.

In this way, continuous monitoring of vital patient parameters is ensured and the patient is gradually unburdened according to his state of health.

In the raised setting, the patient must change the storage battery at the latest every four hours, or connect patient monitor 1 for 0.5 h to a charging station. In the last setting, the storage battery lasts for two days' operation.

Inside the clinical area, detectors 4, which can detect the proximity of patient monitor 1 with the aid of an RFID (transponder) 15, are located at strategic points such as passageways. This information is transmitted via central station 3 to patient monitor 1, as indicated by double arrow 7.

If an information package cannot be transmitted, the loss of information can be detected at central station 3, since the expected information does not arrive in the time window. Patient monitor 1 works, until restoration of the transmission, by using the storage of the set values in its internal memory.

The evaluation of the measurement data of the vital parameters preferably takes place in the computing unit of patient monitor 1 or alternatively in central station 3.

CLAIMS

- 1. A method for setting a patient monitor for the detection of a patient's vital parameters measured by means of one or more patient sensors, wherein**
 - a) a statistical evaluation of some or all measurement data of at least one of the measured vital parameters is carried out in a computing unit from the measured values of the vital parameters and**
 - b) the settings of the patient monitor are adapted in dependence on the statistical evaluation carried out, whereby the adaptation of the settings relates to at least the vital parameters to be measured and the measurement frequency together with the data quality and/or properties of the data transmission.**
- 2. The method according to claim 1, in which the statistical evaluation comprises the formation of a sliding average value with trend evaluation and gradient monitoring.**
- 3. The method according to claim 1 or 2, in which the statistical evaluation for various vital parameters calculates separate trends for different time windows.**
- 4. The method according to any one of the preceding claims, in which an evaluation of the measured values takes place in dependence on a preset therapy target, so that measured values of vital parameters which, after comparison with stored values, point to a deterioration in the patient's condition, are weighted more heavily than measured values which indicate an improvement in the patient's condition.**
- 5. The method according to any one of the preceding claims, in which the adaptation of the settings takes place according to rules which have been previously stored, whereby the rules in particular comprise the adaptation rate and the limits for a change in the settings as well as the warning and alarm limits.**

6. The method according to any one of the preceding claims, in which selected evaluations or the totality of the statistical evaluations are taken into account for the adaptation of the settings.
7. The method according to any one of the preceding claims, in which additional information is involved in the statistical evaluation of the measurement data, in particular patient data and/or current patient status data including the patient's position and the patient's movement.
8. The method according to any one of the preceding claims, in which the verification of the measured values takes place via the patient monitor by means of a speech connection.
9. The method according to any one of claims 1, 7 or 8, in which the patient monitor receives additional patient information by means of a movement sensor with an acceleration and/or positional measurement.
10. The method according to any one of the preceding claims, in which additional actual information on the patient monitor including the charge state of its energy storage unit is sent to a central station.
11. The method according to any one of the preceding claims, in which the measured vital parameters comprise one or more of the following:
ECG derivations, heart rate, temperature, oxygen saturation, respiratory rate, pulse transit time, patient position, patient movement.
12. The method according to any one of the preceding claims, in which statistical values derived from the measured values of the vital parameters are used for the statistical evaluation.
13. The method according to any one of the preceding claims, in which the adapted settings of the patient monitor relate to the frequency of measurements, the data quality of

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the measured values, the resolution of the measured values, the measurement sequence, the data transmission and/or the performance of the measurements.

14. A method for setting a patient monitor substantially as hereinbefore described iwth reference to the accompanying drawings.

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Application No: GB0706037.9

Examiner: Mrs Saskia Jonkhart

Claims searched: 1-14

Date of search: 29 June 2007

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
X	1-14	US 2004/0017300 A (KOTZIN ET AL.), see abstract
X,P	1-14	WO 2006/109072 A (HIDALGO), see page 34, line 26 - page 35, line 30
X,P	1-14	WO 2006/070895 A (MEDICAL ELECTRONIC SCIENCE INSTITUTE), see abstract
X	1-14	US 5924979 A (SWEDLOW ET AL.), see abstract
X,P	1-14	WO 2006/104844 A (MEDTRONIC), see claim 10
X	1-14	EP 1070479 A (ALTEC), see paragraph 30
X	1-14	JP 2001252250 A (DENSO), see PAJ-abstract

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^X :

Worldwide search of patent documents classified in the following areas of the IPC

A61B; G06F

The following online and other databases have been used in the preparation of this search report

16

WPI, EPODOC

International Classification:

Subclass	Subgroup	Valid From
A61B	0005/00	01/01/2006