METHOD AND APPARATUS FOR MONITORING PATIENTS

A system and method are described that include a microprocessor based entity receiving prescriptions from many different patients. A schedule is generated for each prescription and at an appropriate time a reminder is sent to each patient to take his drug. The system can also be used to monitor diabetic patients. The diabetic patients are provided with blood sugar testers that are used to check the sugar level of the patients at home. The blood sugar data from the testers is automatically transmitted to a data bank that collects the data for each day from a plurality of patients and presents the data to the physician as required. Patients may also be provided with A1c testers that measure and transmit to the data bank A1c data collected monthly.
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METHOD AND APPARATUS FOR MONITORING PATIENTS

Background of the Invention

a. Field of Invention

This invention pertains to a method and apparatus for monitoring whether patients are taking their prescribed medicines from a remote location. Apparatus is further described for allowing a patient to determine his blood sugar level and to send this information to a remote location. This invention further pertains to a method and apparatus for monitoring diabetic patients who are treated with insulin and/or other drugs. In the present invention, the results of the tests are automatically recorded, uploaded to a data base and shared with health care providers.

b. Background of the Invention

Patients suffering various kinds of illnesses and other health-related issues are frequently prescribed medication that should be taken at regular intervals. These intervals may range from several hours to several days. Very often, patients have to take different medications at different times, with some of the medications being taken orally, while other may have to be injected or otherwise introduced or applied. Failure to take some or all of this medication can have serious consequences to the patient's health. However, it is believed that in fact many patients do not take their medication as required. This is especially frequent with elder patients who may forget or may get confused as to what medication they are required to take and/or when. At other times, elderly patients may take a medication inadvertently more often than required.

Various devices have been tried in the past to solve this problem. For example, drug containers are available that have several
compartments with some indication or label indicating when the contents of each compartment are to be taken. Other devices include electronic timers that announce to the patients when a medication needs to be taken.

However all these devices proved to be ineffective and too complicated.

In addition, diabetes is a major disease that affects many patients throughout the world. The disease pertains to the lack of a patient's body to either manufacture adequate supply and/or fails to utilize insulin in it metabolism. At present there is no cure for the disease but it can be manage thus allowing a patient a better quality of life. This management includes testing the blood sugar of the patient one or more times a day and taking insulin and/or other drugs. (The term "taking" is used herein generically to any act of administering a drug to a patient, including administration of the drug by taking the drug orally, by injection, etc., and administering the drug by the patient or another person). Often both the testing and the administering are done by the patient himself.

The patient then visits his physician at somewhat regular intervals and gives the physician a list of the days on which his blood sugar was measured, the data obtained and the amount of medicine that the patient took. The physician then analyzes this data and modifies the amount of insulin/drugs that the patient has to take in the future based on this analysis.

While somewhat successful, this process is not very desirable since it is relies too much on the patient. The patient first must remember to measure the blood sugar level, which is already a daunting process since it involves taking a sharp object pricking the patient's finger or other member and then applying a drop of blood on a strip. Next, the strip is inserted into a glucose meter. Next, the glucose meter is read and the data is recorded together with the date (and, optionally, the time of day) for each reading. These are already difficult tasks to be performed routinely, especially in elder patients—a large number of the diabetic population.

Moreover, recently some reports have estimated that the data
obtained this way is wrong 70% of the time and, in order to correct this problem a secondary test has been suggested as well. This second test involves having a patient go every three months to a lab or other similar facility and have a separate blood test done to determine their HbA1c level. The results of the test are transmitted to the physician who then compares them to the data obtained from the glucose meter by the patient to determine how to modify the administration of insulin/drugs for the patient. In other words, the insulin management process is becoming more and more complicated.

SUMMARY OF THE INVENTION

In one embodiment of the invention, a microprocessor-based device is provided to perform, a method of monitoring drug intake by a patient. The method includes the steps of: receiving a prescription for a drug for a particular patient indicating a time for the taking of the drug by the patient; generating by said device a time schedule of the dates and times when the patient is to take the medicine; generating at the appropriate time a message to the patient indicating that the drug should be taken by the patient; and sending said message to the patient.

In another embodiment of the present invention, a system is provided wherein data is collected from a patient, such as a glucose meter at the patient site is obtained and automatically uploaded to a data base. A master monitor reviews the data and collates it for the physician as needed. For example, the physician may obtain the data on a daily, weekly, monthly basis and/or during a visit by the patient. Optionally the HbA1c level in the blood is also measured at regular intervals (preferably monthly) at the patient site and data is also uploaded, stored in the data base, and reviewed by the physician to confirm the data from the glucose meter. The central monitor can also be configured to monitor the data from each patient on a regular basis and to alert the physician and/or others if abnormal glucose levels are detected.

The system and method has several advantages, as discussed below.
All patients will have mandatory monthly HbA1c testing at home. This provides a much more accurate picture of what is happening with the patient without requiring the patient to go to a separate lab.

In one embodiment, the communication channel used to collect the data is also used to (a) remind each patient to test his blood; and (b) take his medicine if no indicated. Each patient will be contacted as a reminder to complete this portion of the testing. The patient may also be asked to provide not only the test data but to confirm that he has taken his medicine (and/or has given himself on injection). This process has the added benefit of providing information to the master monitor and/or another service indicative of how much drugs the patient has, and, if necessary, to alert the physician, drug store, etc., that the patient is about to run out of a certain drug.

BRIEF DESCRIPTION OF THE FIGURES

Fig. 1 shows a block diagram of a system incorporating the present invention;

Fig. 2 shows a block diagram of a patient monitor apparatus used in the system of Fig. 1;

Fig. 3 shows a flow chart illustrating a patient registration stage;

Fig. 4 shows a flow chart of the operation of the patient monitor;

Fig. 5 shows a block diagram of a system configured in accordance with this invention for diabetes testing;

Fig. 5A shows a diagrammatic view of a device used to test a blood sample for two different criteria;

Fig. 6 shows a flow chart illustrating the operation of the system of Fig. 5; and

Fig. 7 shows a more proactive method for operating the system of
DESCRIPTION OF THE INVENTION

The present invention provides a simple and yet effective means of overcoming the problems described above. Several embodiments are described that not only remind the patient from a remote location at the right time to take a drug but, at least in some of the embodiments, provide a positive indication that the reminder has been received and acknowledged by the patient. These features alone and in combination, insure that patients receive proper care for their ailment.

In the following embodiments, it is assumed that a patient has been dispensed one or more medications and that he has been issued proper instructions on when and how to take the medications. The same information is simultaneously provided to a remote agent, e.g., an agent that is located outside the patient’s home. This agent is an automated apparatus that, in one embodiment, automatically contacts the patient at a designated date and time related to when the patient needs to take the medication.

More particularly, as shown in Fig. 1, in a system 10 in accordance with this invention, a health care provider such as a hospital 12, a doctor 14, or other health care professional or entity 16 provides a prescription for a patient. This prescription is either transmitted directly to a drug store A (or other similar dispensing entity) 18 or is given to a patient who then presents it to the drug store A 18. This information is also sent to a patient monitor apparatus 20 by any one of the prescription suppliers, or by some other entity, such as a health insurance company. The insurance company receives the information from the drug store 18 or by other means.

Referring to Fig. 2, the patient monitor apparatus (or patient monitor, for short) 20 includes a microprocessor 30, a transceiver or other data communication device 32 and a data bank 34. The data bank 34 is used to store all information relevant to various patients 22 in the system 10, including the information related to a particular prescription for one of the patients. As part of
the step of collecting the information, as shown in Fig. 3, the patient registers and provides his critical information related to his health, as well as one more communications channels by which he can, or prefers to be reached. It should be noted that, except for the last part, all the other information is already required under various applicable laws by the drug store. Moreover, all the entities described, including the patient monitor 20 is arranged and configured to maintain this patient information secret and safe, again, in accordance with the applicable laws.

The patient 22 then receives the medication and relevant instructions from the respective health care provider 12, 14, 16 and/or the drug store 18, including when to take the medication, how often, and any other special instructions, such as whether to take the medication before or after a meal, and/or whether the medication should be taken certain foods or liquids, etc.

The instructions to the patient are also transmitted to the patient monitor 20 by the health care provider and/or the drug store 18. The patient monitor 20 stores all this information and also establishes a schedule for prescription, including the medication and the special instructions specific to each patient 20.

Once the schedule is established, the patient monitor 20 operates as shown in the flow chart of Fig. 4. That is, at a prescribed date and time, for example, the patient monitor 20 sends an automated alert message to the patient 22. The mode of transmission and the form of the alert message is dependent on the patient's preferences, his location, his devices, etc. Possible modes of transmission could over a standard land-line telephone line, in which case the alert message typically consists of a voice mail indicating what medicine should
be taken, when and any special instructions. Of course, preferably the message is sent to patient 20 at least a couple of minutes before the medicine is to be taken. Alternatively, the voice alert message could be sent to a cellular telephone, a pager, a VOIP device or other audible devices.

In another embodiment of the invention, the alert message is sent by the patient monitor 20 as a text message to a cell phone, an e-mail address, a beeper, a pager, etc.

In the simplest embodiment, the alert message goes out to the patient, and a record is made by the microprocessor 30 that the message was sent. The record of all messages are kept and presented to any authorized entity when requested.

In a more complex embodiment, the patient monitor 20 is configured to determine whether the alert message was actually received by determining either that the alert message was delivered to a live person or that it was recorded by an answering machine. For example, when a verbal message is sent to the patient 20, the patient may be requested to confirm that he has received the instructions by saying "YES", by pressing the number "1" on his telephone, etc. If no confirmation is received within a predetermined time, then alert message is resent. The alert message can be resent in this manner several times. After N such tries, if confirmation is still not received then an appropriate record is stored for the patient 22. In addition, or alternatively, a separate message is sent to an appropriate entity (a health care provider (e.g., 12, 14) or a
designated relative) to indicate that the alert message could not be delivered. A similar process is performed if a text message is sent to the patient 22.

In another embodiment, instead of, or in addition to confirmation, the patient monitor 20 is also configured to receive an actual acknowledgement from the patient either that he has received the alert message, or that he has actually taken the medication. For example, either in the original message, or in a follow up message, the patient is asked to say "YES" or push the number "1" if he has taken the medicine, and say "NO' or push the number "2" if he has not taken the medicine. The same process can be used to obtain an acknowledgement to a text message. Again, if such a positive acknowledgement is expected, the patient monitor waits for a predetermined time for it, and if it is not received, the alert message is resent. If no acknowledgement is received, a record of this event is made and an appropriate alert message is sent to the appropriate entities, e.g. the health care provider and/or a relative. As previously indicated, the acknowledgment can be initiated by the patient by merely pushing a button on his land line or cell phone when he receives the alert message, or by sending a separate message to the patient monitor using any convenient channel.

Returning to the system of Fig. 1, the patient monitor can be made an integral part of any of the entities generating the prescription, the drug store, or some other entity providing other services for any of the parties discussed. Moreover, the system can be easily implemented even if the patient goes to several different drug stores, such as drug store B. If a given patient is prescribed several medications, the alert message can cover all them, or alternatively, several alert messages can be sent to the same patient as required.

The information recorded from the patient can be made available to the doctor, the hospital, the drug store, the insurance company, to insure that the patient is taking his medicine or for various medical studies. Moreover, the patient monitor is further adapted to aggregate the data in the data bank 34 and generate various reports that do not include the actual patient identification, such
as how many patients were prescribed drug X in a given month, how many patients actually took drug X in that month, how many patients obtained their drugs from drug store A, how many patients obtained their drugs from drug store B and so forth.

Another type of report may indicate information about which health care provider or how many health care providers prescribed a drug Y as opposed to a similar drug Z, how often was a patient instructed to take a drug, etc.

Another type of report may be include a cost analysis based on what various drug stores charged for either a specific drug, or a specific type of drug.

Another aspect of the invention is now described in conjunction with Figs. 5-7. Starting with Fig. 5, a system 510 constructed in accordance with this invention includes several elements. Some of the elements are at a patient site while others are at one or more remote locations that are interconnected by the Internet, a private communication, network and could be cloud-based.

At the patient site, there is provided a glucose tester that is similar to testers available from various sources in that it is able to accept a blood sample from the patient, either directly, or via a strip provided for this purpose. The glucose tester determines the current sugar concentration in the blood of the patient. Once this determination is made, the resulting number as well as the current date and time are stored in a data memory 514. There is further provided a modem 516 that is connected to the data memory to transmit the data recorded therein to a remote location. The modem 516 includes a USB port, a jack for a land-line telephone, a port for a cell phone connection and/or any other similar port that can be used to establish data communication with the remote location.

In addition, there is also provided a A1C tester 518. This tester 518 also receives a blood sample and determines the HbA1c level therein. Testers of this sort are presently available, for example, from Bayer, however, they merely provide a reading and do not transmit it anywhere. Instead the results are recorded manually. In the present invention, the recording from the A1c tester are also recorded in the same data memory 514 or a separate data memory and are
then transmitted by modem 516 as well.

The arrangement shown and discussed so far on Fig. 5 can be implemented in a number of different configuration. In one configuration, two separate independent testers are provided, each performing its own test, data storage and modem. In another embodiment, two physically separate testers are provided that share a data memory and/or modem. In yet another embodiment, the testers 512, 518, the data memory 514 or memories and the modem 516 or modems are disposed in a single hand held unit.

In any event, the system further includes a master monitor 520 that is connected to a central data bank 522. The central data bank receives information and stores from the modem 516 via a communication channel 524, as well as similar information from other patients. The master monitor 520 sets up what information is to receive in order to establish an effective diabetes management process for each patient. As part of this process, the master monitor exchange information with several physicians, or other health care providers and/or pharmacies and hospitals, all commonly indicated in Fig. 5 by numeral 526. In addition, the master controller 520 can also provide a reminder service 528 to its patients, and if necessary, activate an emergency service 530.

Fig. 5A shows a somewhat diagrammatic representation of a device 40 used to collect data. The device includes two ports or other means 42, 44 for receiving respectively a sample of blood for testing sugar level and A1c, respectively. Once the samples are provided at the respective ports, a respective button 46, 48 is activated to indicate to the device 40 that samples are ready to be tested. The device 40 further includes several communication ports 50, 52, 54 that may be, respectively, a USB port, an Ethernet port, a phone jack/wireless access port, etc.

Once the device 40 completes its test, the result together with other information, such as the type of test, the date and the time, are shown on a screen 56, typically an LCD screen. The result is also stored in the data memory 14. The patient then activates a button 58 requesting that the information be sent to a remote location. Alternatively, the data can be sent automatically.

Device 40 is also provided with several indication lights 60, 62, 64.
Light 60 may be used to alert the patient that it is time for a test an/or the administration of a drug. Light 62 may be used to indicate to the patient that the data has been correctly received and stored, or that the data seems to be wrong and the test should be repeated. Light 64 may be used for other indication, such as a reminder or a request that he should visit his physician or other health care provider, or that his medicine is about to run out and should obtain a new supply.

In another embodiment of the invention, the patient is provided with two devices. One device is similar to the device of Fig. 5A but only takes daily measurements, stores them and transmits them as described above. A second device is used to make the A1c test, for example, monthly. Once this measurement is made, the patient enters the results manually into the first device which then transmits it together with any other data it may have collected.

One mode of operation is now described for the system in conjunction with the flow chart of Fig. 6. In step 100 a patient registers with the system and at least some of the following information is collected. This can be done in various forms, such as having the patient fill in a form manually or electronically:

a. Name
b. Address
c. Telephone
d. E-Mail
e. Medications
f. Name of physician
g. Physician Telephone
h. Physician Address
i. Physician E-Mail
j. Escalation Notification 1
k. Escalation Notification 2
l. Escalation Notification 3
m. Any kind of authorization needed for HIPA
n. Any kind of authorization for billing insurance or Medicare/Medicaid Patients and any consent form to collect demographic information.
o. Any information for supplies and prescription from the physician in order to bill for these supplies.

p. Supply order form. Based on the amount of times the pt is testing would give the system the amount of supplies needed per month. An area on the pt form should have choices such as:

- ___ I test twice daily
- ___ I test once daily
- ___ I test once weekly

In step 110, information not received from the patient is obtained from another source, such as the physician. This information may include the amount of drugs required for the patient, etc.

In step 120, the physician or other competent authority sets up a monitoring schedule and several levels of alarm levels for various events as defined above for j, k and l.

At the end of step 130, the central monitor 520 has only the information required for effective diabetic management process of the patient, including when the patient should receive insulin/drugs, how much he needs in a month, 3 months, etc., how often he should perform each test, including sugar tests and A1C tests (as discussed above, the sugar level typically are tested from 1 to 3 times a day, the A1c test is typically performed once a month). The management process also defines (as set by or suggested by the physician) what are the normal sugar levels, under what conditions should physicians and/or others, such as an alternate care giver, a relative or other responsible person, or, in extreme cases, an emergency service should be notified. All this information is stored in the data bank 22 and the system is now ready for operation.

In a basic mode of operation, shown in Fig. 6, starting in step 130, data is collected from each patient device, stored in the data bank 522 and analyzed. In step 140 a determination is made if the data is within certain ranges as previously defined for each patient. If the data is within range, data collection continues in step 130. If the data exceeds a certain range or meets some other
criteria, as initially defined, an alarm condition is established and data collection is
continued for the other patients. Depending on preset thresholds, when an
abnormal sugar level is indicated, notifications are sent automatically to the
patient's physician an alternate giver, family member, emergency services, etc.

Moreover, while not shown in the flow chart, authorized personnel,
including a patient's primary physician, is issued a password to allow the physician
to access the patient's records at any time. For example, the physician can access
the records just before, or during a standard (e.g., monthly visit), or when receiving
an emergency message.

The data collection of step 130 can be implemented in various ways. For example, data can be collected asynchronously, whenever the analysis of a
blood sample has been completed. Preferably, after the data is transmitted, the
data bank and/or monitor analyzes the data to check if it is correct and then sends
an acknowledgement that either turns on one of the indicator lights or activates a
message on the screen 56 indicating that the test has been successful.

In another embodiment, the test data is stored in the memory, and the
data bank poles all the data memory of the serviced patients and collects the data
sequentially.

Of course, the system can be operated in another mode as well. For example, as shown in one embodiment depicted in Fig. 7, the process may start in
step 200 by sending a reminder to the patient to take his medicine. This step may
be implemented by either activating a light on the device (as discussed above in
relation to Fig. 1C) or by other means. For example, the patient may receive an oral
or text message on a land-line telephone, cell phone, e-mail, text message, etc.

In step 210, the monitor looks for an acknowledgement from the
patient that he has taken the medicine or at least has received the reminder. If no
acknowledgement is received, an appropriate alert is sent to the physicians,
relatives or others in step 220.

If acknowledgement is received then in step 230 the monitor checks
when was the last time the patient received a supply of drugs and whether that
supply is getting low, the patient, or the drug store are alerted (steps 240, 250).
Next in step 260 the patient is sent a reminder that he needs to test his blood sugar
level. If this reminder is acknowledged (step 270, for example by pressing an appropriate button on device 40), then in step 290 the results are stored and then analyzed as previously discussed. If the reminder for a blood test is not acknowledged, an alert is sent to the physicians and/or others (step 280). The sequence of steps in Fig. 7 are only exemplary and other sequences may be implemented as well. For example, determining how much drugs the patient should have can be made independently of the reminders. Moreover, the reminder to check for blood sugar may be before sending the reminder to administer drugs.

Obviously numerous modifications can be made to this invention without departing from its scope as defined in the appended claims.
We claim:

1. A method for monitoring at least health related parameter of a patient comprising the steps of:

- Generating a reminder to the patient regarding said condition;
- Collecting information related to the patient in the patient's home;
- Transmitting said information automatically to a central location;
- Comparing said information at said central location with preselected threshold; and
- generating an alert automatically for a health care provider if said information exceeds certain limits as compared to said threshold.

2. In a microprocessor-based device, the method of monitoring drug intake by a patient comprising the steps of:

- receiving a prescription for a drug for a particular patient indicating a time for the taking of the drug by the patient;
- generating by said device a time schedule of the dates and times when the patient is to take the medicine;
- generating at the appropriate time a message to the patient indicating that the drug should be taken by the patient; and
- sending said message to the patient.

3. The method of claim 2 wherein prescription is received automatically from a drug store.

4. The method of claim 3 wherein said message is transmitted over a telephone.
5. The method of claim 2 further comprising the step of receiving a return signal from the patient.

6. The method of claim 5 wherein said return signal includes information indicating that the patient has received said message.

7. The method of claim 6 wherein said return signal includes information indicating that the patient has taken the drug.

8. The method of claim 6 wherein said return signal indicates that the patient has not acknowledged receiving said message.

9. The method of claim 2 further comprising recording data indicating that said message was sent.

10. The method of claim 5 further comprising recording data indicating that said message was sent and information from said return signal.

11. The method of claim 6 further comprising generating another message to a third party providing information regarding said message.

12. An automated apparatus for monitoring of drug intake of patients based on prescription comprising: a data communication device receiving a prescription for a drug for a particular patient, said prescription including frequency information indicating when the drug is to be taken by the patient;

a microprocessor receiving said prescription and being
configured to generate a schedule based on said prescription, said schedule defining the times when reminder messages must be sent to the patient, said microprocessor further being configured to generate said reminder messages at predetermined times as determined by said schedule; and

a data base used by the microprocessor for recording events related to said prescription and said reminder messages.

13. The automated apparatus of claim 12 wherein said reminder message is sent by a land line.

14. The automated apparatus of claim 12 wherein said reminder message is sent to a cell phone.

15. The automated apparatus of claim 12 wherein said microprocessor is further configured to receive response messages in response to said reminder messages.

16. The automated apparatus of claim 12 wherein said response message indicate at least one of several events, including an acknowledgement that said reminder message has been received, and an acknowledgement that the drug has been taken by the patient.

17. The automated apparatus of claim 16 wherein said reminder and said response messages are stored in said data base.

18. The automated apparatus of claim 12 wherein said microprocessor is configured several prescriptions for several patients and to generate respective reminder messages to said patients.
19. The automated apparatus of claim 18 wherein said microprocessor is further configured to compile information related to various drugs defined by said prescriptions and store said information in said data base.

20. A system for treating diabetes in a patient comprising:
a glucose tester configured to receive a patient blood sample, measure the blood sugar and transmit blood sugar data electronically indicative of said blood sugar;
a data bank receiving and storing said blood sugar data; and
a master monitor coupled to said data bank and generating a reminder transmitted electronically to said patient to use said glucose tester.

21. The system of claim 20 wherein said master monitor is configured to analyze said blood sugar data from said patient and to generate a blood sugar alert based on a set of predetermined rules.

22. The system of claim 20 wherein said master monitor is configured to generate a schedule for said reminders based on patient information.

23. The system of claim 20 wherein said master monitor is configured to determine a drug supply of said patient and to generate a drug supply alert when said drug supply falls below a threshold.

24. The system of claim 20 further comprising an A1c tester for testing a patient's A1c level.

25. The system of claim 20 wherein said master monitor is configured to generate a first reminder to the patient to test the blood sugar and a second reminder to test the A1c level.

26. The system of claim 20 wherein said sugar blood tester and A1c tester are disposed in a single hand-held device.

27. A method of diabetes managing in patients having at least a blood sugar tester comprising the steps of:
transmitting a reminder to said patients to test their blood sugar level using said testers;

RECTIFIED SHEET (RULE 91)
collecting blood sugar data from said patients; and
generating an alert when said blood sugar data from at least one of
said patients meets a predetermined criteria.

28. The method of claim 27 wherein said reminder is sent to said
patients based on a schedule determined by each patient's physician.

29. The method of claim 27 wherein said reminder is sent at least
daily.

30. The method of claim 27 wherein at least some patients also
have an A1c tester further comprising sending to patients a separate reminder to
test their A1c in their blood.

31. The method of claim 20 wherein said separate reminder is
transmitted monthly.

32. The method of claim 31 further comprising receiving separate
data indicating some patients' A1c level in their blood.

33. The method of claim 31 wherein all data for each patient is
presented to a physician.

34. The method of claim 33 further comprising determining a level
of drug required by each patient based on data from said testers.

35. The method of claim 34 further comprising calculating the
amount of drugs used by at least some patients and generating a drug alert when
the amount left for some patients is below a threshold.
FIG. 1
REGISTER PATIENT, DOCTOR, PHARMACY, EMERGENCY CONTACT 100

OBTAIN PARAMETERS 110

SET UP MONITORING SCHEDULE 120

COLLECT DATA FROM PATIENT 130

DATA WITHIN RANGE 140

NO

GENERATE ALARM 150
REGISTRATION PROCESS

PATIENT GETS MEDICINE AND INSTRUCTIONS

INFO TRANSMITTED TO PATIENT MONITOR

PATIENT MONITOR STORES INFORMATION AND ESTABLISHES SCHEDULE FOR PATIENTS

SEND ALERT TO A PATIENT

RECEIVE CONFIRMATION OF ALERT

WAIT FOR ACKNOWLEDGEMENT

REPEAT

USE ALT. ROUTES (ALTERNATIVE)

SEND ALARM

RECORD EVENT

FIG. 4

FIG. 3
REGISTER PATIENT, DOCTOR, PHARMACY, EMERGENCY CONTACT 100

OBTAIN PARAMETERS 110

SET UP MONITORING SCHEDULE 120

COLLECT DATA FROM PATIENT 130

DATA WITHIN RANGE 140

NO

GENERATE ALARM 150

FIG. 6
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION

O.F. SUBJECT MATTER

IPC(8) - GO6Q 50/00 (201 1.01)

USPC - 705/3

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC (8) - GO6Q 50/00 (201 1.01)
USPC - 705/3

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

USPC -705/1, 3, 7.12, 7.13; 600/300, 301 ; 700/1, 90 (See Keywords Below)

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

Pub WEST (USPT, PGPR, JPAB, EPAB), Google Scholar Search terms: Monitor, tracing, tracking, supervising, health, patient, generate, create, populate, trigger, alert, notify, send, transmit, reminder, measure, read, conduct, test, condition, parameter, patient, glucose, blood sugar, pressure, collect, gather, transmit, send, deliver, aggregate, cons

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category*</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
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<td>US 2004/0249250 A1 (MCGEE et al.), 09 December 2004 (09.12.2004), entire document, especially Abstract; para [0010], [0025], [0028]-[0029], [0031], [0039], [0042]-[0043], [0073]</td>
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Further documents are listed in the continuation of Box C.

* Special categories of cited documents:
  "A" document defining the general state of the art which is not considered to be of particular relevance
  "E" earlier application or patent but published on or after the international filing date
  "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
  "O" document referring to an oral disclosure, use, exhibition or other means
  "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is considered to be combined with one or more other such documents, such combination being obvious to a person skilled in the art
"A" document member of the same patent family

Date of the actual completion of the international search: 27 November 201 1 (27.1 1.201 1)
Date of mailing of the international search report: 06 DEC 2011

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Authorized officer: Lee W. Young

Form PCT/ISA/210 (second sheet) (July 2009)
INTERNATIONAL SEARCH REPORT  

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [ ] Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:

2. [ ] Claims Nos.: because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1, in order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group 1: Claims directed to a method for monitoring at least health related parameter of a patient comprising the steps of:
- Generating a reminder to the patient regarding said condition;
- Collecting information related to the patient in the patient’s home;
- Transmitting said information automatically to a central location;
- Comparing said information at said central location with preselected threshold; and
- Generating an alert automatically for a health care provider if said information exceeds certain limits as compared to said threshold.

(See Supplemental Page)

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

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Remark on Protest [ ] The additional search fees were accompanied by the applicant’s protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant’s protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (July 2Q09)
Continuation of: BOX III
Observations where unity of invention is lacking

Group II: Claims 2-19 directed to a microprocessor-based device and automated apparatus for monitoring drug intake by a patient comprising the steps of: receiving a prescription for a drug for a particular patient indicating a time for the taking of the drug by the patient; generating by said device a time schedule of the dates and times when the patient is to take the medicine; generating at the appropriate time a message to the patient indicating that the drug should be taken by the patient; and sending said message to the patient.

Group III: Claims 20-35 directed to a system and method for treating diabetes in a patient comprising: a glucose tester configured to receive a patient blood sample, measure the blood sugar and transmit blood sugar data electronically indicative of said blood sugar; a data bank receiving and storing said blood sugar data; and a master monitor coupled to said data bank and generating a reminder transmitted electronically to said patient to use said glucose tester.

The inventions listed as Groups I - III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I does not recite monitoring drug intake by a patient comprising the steps of receiving a prescription for a drug for a particular patient indicating a time for the taking of the drug by the patient and generating by said device a time schedule of the dates and times when the patient is to take the medicine as recited by Group II; or treating diabetes in a patient comprising a glucose tester configured to receive a patient blood sample, measure the blood sugar and transmit blood sugar data electronically indicative of said blood sugar as recited by Group III.

Group II does not recite the method for monitoring at least health related parameter of a patient comprising the steps of collecting information related to the patient in the patient's home; transmitting said information automatically to a central location; and comparing said information at said central location with preselected threshold as recited by Group I; or treating diabetes in a patient comprising a glucose tester configured to receive a patient blood sample, measure the blood sugar and transmit blood sugar data electronically indicative of said blood sugar as recited by Group III.

Group III does not recite for monitoring at least health related parameter of a patient comprising the steps of collecting information related to the patient in the patient's home; transmitting said information automatically to a central location; and comparing said information at said central location with preselected threshold as recited by Group I; or treating diabetes in a patient comprising a glucose tester configured to receive a patient blood sample, measure the blood sugar and transmit blood sugar data electronically indicative of said blood sugar as recited by Group III.

Groups I-III share generating an alert while Groups II and III teach a schedule. However, this shared technical feature is well known and does not represent a contribution over the prior art of US 7,765,114 B2 to Frick (27 July 2010), which discloses an alert schedule and generating an alert (Claim 1). As the above alert and schedule was known at the time, as evidenced by the teaching of Frick, this cannot be considered a special technical feature that would otherwise unify the groups.

Groups I-III therefore lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.