



(11) **EP 1 248 555 B1**

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention
of the grant of the patent:
30.05.2012 Bulletin 2012/22

(51) Int Cl.:
G06F 19/00 ^(2011.01) **A61B 5/00** ^(2006.01)

(21) Application number: **01903011.3**

(86) International application number:
PCT/US2001/000789

(22) Date of filing: **10.01.2001**

(87) International publication number:
WO 2001/050950 (19.07.2001 Gazette 2001/29)

(54) **APPARATUS AND METHODS FOR MONITORING AND MODIFYING ANTICOAGULATION THERAPY OF REMOTELY LOCATED PATIENTS**

ANLAGE UND VERFAHREN ZUM ÜBERWACHEN UND ÄNDERN VON
ANTIKOAGULIERUNGSTHERAPIE FÜR FERNPATIENTEN

APPAREIL ET METHODES PERMETTANT DE SURVEILLER UNE THERAPIE
D'ANTICOAGULATION ET DE LA MODIFIER CHEZ DES PATIENTS ELOIGNES

(84) Designated Contracting States:
**AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU
MC NL PT SE TR**

- **ORTEL, Thomas, Lee**
Chapel Hill, NC 27514 (US)
- **MORRIS, James, J.**
Durham, NC 27707 (US)

(30) Priority: **11.01.2000 US 480432**

(43) Date of publication of application:
16.10.2002 Bulletin 2002/42

(74) Representative: **Boakes, Jason Carrington et al**
Harrison Goddard Foote
106 Micklegate
York
YO1 6JX (GB)

(73) Proprietor: **ZyCare, Inc.**
Chapel Hill, NC 27514 (US)

(56) References cited:
WO-A-98/50873 WO-A-99/03045
US-A- 4 803 625 US-A- 5 868 135
US-A- 5 933 136

(72) Inventors:

- **SURWIT, Richard, S.**
Chapel Hill, NC 27514 (US)
- **ALLEN, Lyle, M., III**
Durham, NC 27707 (US)

Note: Within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the Implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

EP 1 248 555 B1

Description**Field of the Invention**

5 **[0001]** The present invention relates generally to data processing apparatus and methods and, more particularly, to medical monitoring apparatus and systems.

Background of the Invention

10 **[0002]** Chronic disease management conventionally involves routinely monitoring patients who suffer from chronic disease to identify disease-related health problems before they become medically severe. Routine monitoring is also required in patients undergoing various forms of rehabilitation or primary prevention such as programs designed to promote healthy diet and exercise behavior. Disease management and prevention may also involve monitoring exercise and diet patterns of patients, as well as adherence to and adjustments of prescribed medicine. The management of
 15 chronic disease also often involves continuous treatment of a disease process with one or more medicines. Many of these medications have a relatively narrow therapeutic window; that is, there is a narrow range of medication dosages that provide optimal therapeutic effect without producing undesirable and potentially dangerous side effects. Other, often behavioral, factors such as illness, or changes in sleep, vitamins, diet, exercise, stress, menstrual cycles, etc. can impact the efficacy, absorption, dissipation, bioavailability and hence optimal dosing requirements of medication. Additionally,
 20 due to comorbid or co-occurring diseases or intercurrent illness, there are risks related to potential medication interactions that can also affect the efficacy dosing requirements of one or more of the medications used in treatment. Ideally, the effects of medication should be continuously monitored in order to insure that the patient is deriving maximal therapeutic benefit without suffering the effects of overmedication or from potentially dangerous interactions.

25 **[0003]** Most patient assessment of the efficacy of self-administered treatment programs such as medication regimens, rehabilitative recovery or primary prevention occurs in the offices of healthcare professionals. Unfortunately this is both time-consuming and expensive, and can only partially deal with issues related to timeliness and compliance. To overcome the disadvantages of requiring patients to visit a physician's office for assessment of their disease or condition, various health care organizations have implemented programs where case managers (*i.e.*, persons with some level of medical training) telephone patients periodically to obtain patient data and to coordinate care. Unfortunately, with often hundreds
 30 of patients per case manager, personal contact with individual patients on a daily or even regular basis may be difficult. In addition, personal contact with individual patients on a regular basis may be somewhat expensive. Accordingly, case managers using conventional management techniques may not be able to monitor, adjust or promote a patient's medication dosage or other treatment regimen as often as desirable or necessary.

35 **[0004]** Another approach used in chronic disease management involves automated voice messaging (AVM) services, wherein patients receive regular telephone calls providing various educational and motivational messages from case managers. Exemplary messages may include reminding a patient of a scheduled physician visit. Some AVM services involve one-way communication, wherein a recorded message is delivered to a patient, but no information is obtained from the patient. As a result, the medical condition of a patient may not be available unless the patient is examined in-person by a physician.

40 **[0005]** AVM services involving two-way communications may allow patients to respond to AVM telephone queries via a touch tone telephone. Information received from patients may be reviewed by a case manager (CM). The CM then may identify which patients require callbacks for gathering more detailed information, discussing problems, or providing further information. Unfortunately, AVM services involving two-way communications may require some level of human intervention to identify patients with medically severe conditions that require immediate medical attention, such as a
 45 change in warfarin or insulin dosage. Chronic disease management via AVM has another drawback in that delays may occur between the identification of a patient with a medically severe condition and actual treatment of the condition.

50 **[0006]** In order to assist the physician and CM in following a patient with chronic disease, home monitoring devices have been developed and marketed that can collect physiologic data and report this data back to the physician. Examples of such devices include home blood glucose monitors, home blood pressure monitors, home peak-flow monitors for asthma, and home coagulation time monitors for patients undergoing anticoagulation therapy. While these systems can collect physiologic data at home, they do not provide direct guidance to the patient on need changes in chronic medication dosing. They also do not provide a convenient way for physicians to use the data generated to cost-effectively manage patients.

55 **[0007]** In addition to case managers, AVMs, and home diagnostic devices, several systems have been devised that collect disease-related data at home and transmit them to a central location where the data can be analyzed by a physician or other healthcare professionals. Such systems include DiabCare (Roche Diagnostics), The Buddy System, Health Hero, and LifeChart. Some of these systems directly interface with home physiologic monitors (*e.g.*, DiabCare and LifeChart) as described above. However, all of these systems simply collect data from remotely-located patients

and present the data in summary form. They do not attempt to help the physician or health care provider prioritize patients in need of attention, recommend actions to ameliorate the patient's condition, or give information back to the patient about what he or she should do in the event the a change in the therapy regimen is indicated.

[0008] One system that has attempted to automate disease management for insulin therapy in diabetes mellitus is the Diacare® System, described in U.S. Patent No. 4,731,726. Unfortunately, the Diacare® System is narrowly focused on treating diabetic patients using insulin, and lacks many of the important features of a system that would be necessary for delivering a wide variety of interventions in a number of medical diseases or conditions such as anticoagulation therapy.

[0009] Warfarin and other anticoagulant therapies are indicated for conditions involving the increased likelihood of fibrin clot (thrombosis). These thromboses may increase the likelihood of stroke, myocardial infarctions or other cardiovascular events. Anticoagulant therapies interfere with or decrease the ability of the body to form a fibrin clot (thrombosis). Since under-medication can result in a thrombosis, and overmedication can result in potentially disastrous hemorrhagic complications, all of these therapies need to be very closely monitored. Examples of these therapies and the types of tests used to monitor them are shown in Table 1 below:

Table 1 - Anticoagulation Therapies & Tests

THERAPY	TEST
Warfarin and other vitamin K antagonists	Prothrombin (PT)
Heparin and similar glucosaminoglycans	Partial Thromboplastin Time (PTT)
	Activated Clotting Time (ACT)
	Specific heparin or low molecular weight heparin assays
Direct thrombin inhibitors (e.g., hirutin, melagatgran)	Ecarin clotting time (ECT)
	Thrombin clotting time
	PT or PTT

[0010] PT or other coagulation tests (listed in Table 1) and regular visits to the physician or clinic are needed to monitor anticoagulation therapy. Anticoagulation therapy is a highly individualized matter that should be monitored closely. Numerous factors, alone or in combination, including travel, changes in diet, environment, physical state and medication may influence response of a patient to anticoagulants. As such, anticoagulant dosage should be controlled by periodic determinations of prothrombin time (PT)/International Normalized Ratio (INR) or other suitable coagulation tests.

[0011] Coagulation tests and regular visits to the physician or clinic are typically required to effectively monitor anticoagulation therapy. Unfortunately, regular visits to a physician or clinic can be expensive and inconvenient. In addition, patients may be required to attend training prior to being allowed to self-administer medication and testing regimens. Such training may be too complex and/or cost-prohibitive for many patients.

Summary of the Invention

[0012] In view of the above discussion, it is an object of the present invention to provide apparatus and methods that allow patients to remotely self-monitor disease therapy, such as Anticoagulation or other therapies that can be optimized (*i.e.*, deliver maximum therapeutic benefit in the most cost-effective way with minimal side effects and complications by close monitoring, and that can modify medication regimens without requiring a patient to visit a healthcare provider.

[0013] It is another object of the present invention to allow health care providers to quickly and easily monitor many patients and to automatically identify patients with medical conditions that are pertinent to ongoing therapies and to organize identified medical conditions by severity.

[0014] According to a first aspect of the present invention there is provided a method for monitoring anticoagulation therapy of a patient, wherein the anticoagulation therapy includes a patient-administered medication regimen selected from the group consisting of warfarin and vitamin K antagonists, heparin and glucosaminoglycans, and direct thrombin inhibitors, and a patient-administered regimen for a coagulation test that monitors efficacy of the medication regimen, wherein the coagulation test is selected from the group consisting of prothrombin time (PT) test, partial thromboplastin time (PTT) test, activated clotting time (ACT) test, heparin assays, ecarin clotting time (ECT) test, and thrombin clotting time test, wherein a portable apparatus is configured to receive and analyse information regarding patient compliance with the patient-administered medication and coagulation test regimens, and wherein the apparatus is configured to modify the patient-administered medication and coagulation test regimens, the method comprising the following steps performed by the portable apparatus:

receiving data from a patient, wherein the patient data includes at least one of physiological data, pathophysiological data, biological data, psychological data, neuropsychological data, and behavioural data;
 assessing severity of the received patient data;
 prompting the patient to perform a patient-administered coagulation test if the received patient data are assessed to be above a threshold severity level;
 receiving coagulation test results from the patient-administered test; and
 communicating the received coagulation test results from the patient-administered test to a healthcare provider via a communications network.

[0015] According to a second aspect of the present invention there is provided a system for monitoring anticoagulation therapy of a patient, wherein the anticoagulation therapy includes a patient-administered medication regimen selected from the group consisting of warfarin and vitamin K antagonists, heparin and glucosaminoglycans, and direct thrombin inhibitors, and a patient-administered regimen for a coagulation test that monitors efficacy of the medication regimen, wherein the coagulation test is selected from the group consisting of prothrombin time (PT) test, partial thromboplastin time (PTT) test, activated clotting time (ACT) test, heparin assays, ecarin clotting time (ECT) test, and thrombin clotting time test, wherein the system comprises:

a patient apparatus, comprising:

a processor;
 a user interface in communication with the processor;

computer code executable by the processor that receives and stores data from a patient, wherein the patient data includes at least one of physiological data, pathophysiological data, biological data, physiological data, neuropsychological data, and behavioural data;
 computer code executable by the processor that assesses severity of the received patient data;
 computer code executable by the processor that prompts the patient via the user interface to perform a patient-administered coagulation test if the received patient data are assessed to be above a threshold severity level;
 computer code executable by the processor that receives and stores coagulation test results from the patient-administered coagulation test; and
 computer code executable by the processor that communicates the received coagulation test results from the patient-administered coagulation test to a healthcare provider via a communications network.

[0016] According to a third aspect of the present invention there is provided a method for monitoring disease therapy of a patient, wherein the disease is selected from the group consisting of asthma, cancer chemotherapy, depression, high blood pressure, seizure disorders, and thrombosis, wherein the disease therapy includes a patient-administered medication regimen and a patient-administered regimen for a test that monitors efficacy of the medication regimen, wherein a portable apparatus is configured to receive and analyse information regarding patient compliance with the patient-administered medication and test regimens, and wherein the portable apparatus is configured to modify the patient-administered medication and test regimens, the method comprising the following steps performed by the portable apparatus.

receiving data from a patient, wherein the patient data includes at least one of physiological data, pathophysiological data, biological data, psychological data, neuropsychological data, and behavioural data;
 assessing severity of the received patient data;
 prompting the patient to perform a patient-administered test if the received patient data are assessed to be above a threshold severity level;
 receiving test results from the patient-administered test; and
 communicating the received test results from the patient-administered test to a healthcare provider via a communications network.

[0017] According to a fourth aspect of the present invention there is provided an apparatus for monitoring disease therapy of a patient, wherein the disease is selected from the group consisting of asthma, cancer chemotherapy, depression, high blood pressure, seizure disorders, and thrombosis, wherein the disease therapy includes a patient-administered medication regimen and a patient-administered regimen for a test that monitors efficacy of the medication regimen, the apparatus comprising:

a processor;

a user interface in communication with the processor;
 computer code executable by the processor that receives and stores data from a patient, wherein the patient data includes at least one of physiological data, pathophysiological data, biological data, psychological data, neuropsychological data, and behavioural data;
 5 computer code executable by the processor that assesses severity of the received patient data;
 computer code executable by the processor that prompts the patient via the user interface to perform a patient-administered test if the received patient data are assessed to be above a threshold severity level;
 computer code executable by the processor that receives and stores test results from the patient-administered test; and
 10 computer code executable by the processor that communicates the received test results from the patient-administered test to a healthcare provider via a communications network.

Brief Description of the Drawings

15 **[0018]**

Fig. 1 schematically illustrates a system for monitoring, diagnosing and treating medical conditions of a plurality of remotely located patients according to an embodiment of the present invention.

Fig. 2 illustrates an exemplary portable patient monitor (PPM).

20 **Fig. 3** schematically illustrates operations for monitoring, diagnosing and treating medical conditions of a plurality of remotely located patients according to the present invention.

Fig. 4 schematically illustrates operations for obtaining data from a remotely located patient monitoring device.

Fig. 5 schematically illustrates operations for analyzing data to identify medical conditions of a remotely located patient.

25 **Fig. 6** schematically illustrates operations for identifying medical conditions according to aspects of the present invention.

Fig. 7 schematically illustrates operations for prioritizing identified medical conditions according to aspects of the present invention.

30 **Fig. 8** illustrates an exemplary user interface for displaying medical conditions prioritized according to medical severity.

Fig. 9 illustrates an exemplary user interface for displaying patient-specific information.

Figs. 10A-10C illustrate exemplary user interfaces for facilitating communications with a remotely located patient.

Fig. 11 illustrates an exemplary user interface for adjusting a medicine dosage algorithm stored within a patient's PPM.

35 **Fig. 12** illustrates an exemplary user interface for seeking input from other medical experts.

Fig. 13 illustrates an exemplary user interface for facilitating and tracking patient appointments with clinic personnel or other health care providers.

Fig. 14 illustrates an exemplary user interface for removing an identified medical condition from an active list.

40 **Figs. 15-19** schematically illustrate operations for monitoring anticoagulation therapy via a patient apparatus according to one embodiment, of the present invention.

Detailed Description of the Invention

45 **[0019]** The present invention now is described more fully hereinafter with reference to the accompanying drawings, in which preferred embodiments of the invention are shown. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. The present invention will now be described more fully hereinafter with reference to the accompanying drawings, in which preferred embodiments of the invention are shown. Like numbers refer to like elements throughout.

50 **[0020]** As will be appreciated by one of skill in the art, the present invention may be embodied as a method, data processing system, or computer program product. Accordingly, the present invention may take the form of an entirely hardware embodiment, an entirely software embodiment or an embodiment combining software and hardware aspects. Furthermore, the present invention may take the form of a computer program product on a computer-readable storage medium having computer-readable program code means embodied in the medium. Any suitable computer medium may be utilized including hard disks, CD-ROMs, optical storage devices, or magnetic storage devices.

55 **[0021]** The present invention is described below with reference to flowchart illustrations of methods, apparatus (systems) and computer program products according to embodiments of the invention. It will be understood that each block of the flowchart illustrations, and combinations of blocks in the flowchart illustrations, can be implemented by computer

program instructions. These computer program instructions may be loaded onto a general purpose computer, special purpose computer, or other programmable data processing apparatus to produce a machine, such that the instructions which execute on the computer or other programmable data processing apparatus create means for implementing the functions specified in the flowchart block or blocks.

[0022] These computer program instructions may also be stored in a computer-usable memory that can direct a computer or other programmable data processing apparatus to function in a particular manner, such that the instructions stored in the computer-usable memory produce an article of manufacture including instruction means which implement the function specified in the flowchart block or blocks. The computer program instructions may also be loaded onto a computer or other programmable data processing apparatus to cause a series of operational steps to be performed on the computer or other programmable apparatus to produce a computer implemented process such that the instructions which execute on the computer or other programmable apparatus provide steps for implementing the functions specified in the flowchart block or blocks.

[0023] Accordingly, blocks of the flowchart illustrations support combinations of means for performing the specified functions, combinations of steps for performing the specified functions and program instruction means for performing the specified functions. It will also be understood that each block of the flowchart illustrations, and combinations of blocks in the flowchart illustrations, can be implemented by special purpose hardware-based computer systems which perform the specified functions or steps, or combinations of special purpose hardware and computer instructions.

[0024] Computer program for implementing the present invention may be written in various object-oriented programming languages, such as Delphi and Java[®]. However, it is understood that other object oriented programming languages, such as C++ and Smalltalk, as well as conventional programming languages, such as FORTRAN or COBOL, could be utilized.

System Overview

[0025] Referring now to **Fig. 1**, a system **10** for monitoring, diagnosing, and treating medical conditions of remotely located patients with various chronic illnesses, recording to the present invention, is schematically illustrate. A plurality of remote or preferably portable patient monitors (PPMs) **12** are configured to establish communications directly with a central data processing system referred to as a Physicians Access Center server (hereinafter "PAC server") **14** via communications links **13**. It is noted that a majority of the functionality provided by a PPM as described herein for many disease applications can be achieved using remote data terminals or internet browsers, which are not necessarily portable, but which can provide personal healthcare advice via connection to a properly configured database server system that supports the features of a PPM described below.

[0026] A plurality of case manager clients (CMCs) **16** are configured to establish client-server communications with the PAC server **14** via a computer network **17**, such as the Internet or an Intranet. The term "CMC" can be considered as a synonym for professional or paraprofessional healthcare providers. It is understood that a CMC or PAC server or other apparatus configured to execute program code embodied within computer usable media, operates as means for performing the various functions and carries out the methods of the various operations of the present invention. It is also understood that the present invention may be used with various client-server communications protocols, and is not limited to specific protocols such as TCP/IP protocol.

[0027] Each of these components will be described in detail below. The present invention will be described throughout this disclosure with respect to the control of warfarin therapy for patients undergoing anticoagulation therapy. However, it is to be understood that the present invention may be utilized with a wide variety of medical therapies including, but not limited to, antiseizure therapy, cancer chemotherapy, renal failure therapy, congestive heart failure therapy, asthma therapy, high blood pressure therapy, attention deficit disorder therapy, depression therapy, and therapies for other chronic diseases and conditions.

[0028] For example a PPM may collect and use patient data to adjust medication dosage for respiratory therapy and anticoagulation therapy based on predefined physician prescriptions. The term "prescription" may include physician-prescribed algorithms for calculating medicine dosages, dosages calculated from algorithms, and fixed and contingent self-monitoring schedules for patients. An exemplary physician-prescribed medication algorithm is described in Guidelines for the Diagnosis and Management of Asthma; Expert Panel Report Two; National Institutes of Health; Heart and Lung Institute; Publication No.: 97-4051, April 1997.

[0029] Another exemplary physician-prescribed medication algorithm is described in Long-term Patient Self-management of Oral Anticoagulation; Jack E. Ansell et al.; Arch Intern Med. 1995; Vol. 155; pp. 2185-2189.

[0030] A PPM may incorporate physician-prescribed algorithms for calculating medicine dosages for various chronic illnesses. Alternatively, a PAC server may implement a medication dosage algorithm for anticoagulation therapy, based on values communicated to the PAC server by a PPM, and communicate results directly to the patient. PAC server implemented dosage algorithms may be a logical alternative to having medication dosage algorithms stored within PPMs when medication dosage changes are infrequent.

Remote or Portable Patient Monitors (PPM)

[0031] A PPM (12 in Fig. 1) serves as primary means for collecting data from a patient and as means for case managers to interface with a patient. Exemplary features of a PPM for use in accordance with the present invention are summarized below in Table 2.

Table 2

-	Small and portable so patient can carry around.
-	Data processing capabilities and built-in modem or attachable external modem.
-	Collects data from blood, breath or bodily fluids or other functions.
-	Collects patient supplied data on health status, compliance with a medical treatment or management regimen, and psychological data.
-	Allows two-way communication with PAC server.
-	Analyzes patient data collected and delivers pre-recorded or calculated responses and/or medication dosage recommendations based on physician instructions loaded in PPM.
-	Downloads patient data to PAC server at specified time intervals or in real time.
-	Receives messages, updates to physician instructions and prescription dosage parameters, dosage algorithms, fixed or contingent self-monitoring schedules, words of encouragement or other feedback from PAC server.

[0032] Patient data collected via a PPM may include physiologic or biologic data and behavioral data (e.g., assessments related to diet, exercise, stress, mental status or the presence of intercurrent illness). A PPM may also monitor patient medication intake (e.g., warfarin dosage). A PPM, depending on the chronic illness of the patient, may contain software specifically designed for a particular patient's illness. For example, a PPM for an anticoagulation therapy patient may contain physician-prescribed warfarin dosage algorithms. It is understood that other medications, well known by those of skill in the art, may be utilized in anticoagulation therapy in addition to, or in lieu of, warfarin.

[0033] A PPM designed for a patient can store various data along with other relevant self-monitoring patient data. Blood from a pricked finger may be read on a chemically treated strip via the PPM. Automated warfarin adjustment algorithms with physician-prescribed parameters can be stored within each patient's PPM for real-time analysis and adjustment of a patient's warfarin dosage. The PPM may be configured to make automatic adjustments to a patient's self-monitoring and treatment regimen based on patient-entered data as will be described below. A PPM may also contain a database to help patients evaluate the effects of new medications on their target disease or to provide other disease-specific information to patients.

[0034] With respect to medications, the term "regimen" is intended to be synonymous with a schedule for taking medication. However, it is understood that some medications are taken in different doses on different days (or other time periods). Thus, the term "regimen" also refers to dosage amounts of a medication taken according to a particular schedule. Thus, the term "modifying a medication regimen" may include changing a schedule for taking a medication and/or changing a dosage amount of a medication. With respect to tests for monitoring the efficacy of medication in disease therapy, the term "regimen" is intended to be synonymous with a schedule for taking a test. Thus, the term "modifying a test regimen" may include changing a schedule for administering a test.

[0035] Patients are responsible for recording data within their PPMs and transmitting the data to a PAC server on a regular basis. Preferably, transmission of data to a PAC server is highly automated and substantially "hands-off" for a patient. A patient preferably can plug a PPM into a standard telephone jack and, with the press of a button, establish communications with a PAC server. Each PPM may have the ability to prompt patients when data transmissions are required, and to initiate and complete data transmissions using an alarm-driven timer.

[0036] Preferably, each PPM contains a user interface for displaying text, graphics, prompts and various other information. A PPM user interface serves as the primary means of communication between the PAC server and the patient. A PPM may also be configured to notify patients of transmission schedules to the PAC server; to notify patients having emergency medical conditions to promptly seek medical attention; and to provide motivational feedback to patients based upon past performance (e.g., reward patients for keeping on schedule with data recordings and transmissions of data to a PAC server).

[0037] Referring now to Fig. 2, an exemplary PPM 20 is illustrated. The illustrated PPM 20 includes a display 22 and a keyboard 24. The PPM 20 also preferably includes the following which are not shown: internal, non-volatile data storage, internally stored medication monitoring software, and a data processor for performing various functions and for

communicating with a PAC server. Internal software (program code) may query a patient for various information via display 22. Preferably, the PPM internal software is menu-driven for ease-of-use by patients. Preferably, the menus are written in various languages including a children's version incorporating game-like features.

[0038] Preferably, all data entered within a PPM 20 is stored with date and time information and can be alarm initiated (i.e., a patient or PPM can be prompted to perform a task or function). Preferably, the PPM internal software analyzes the entered data and continuously informs the patient of his/her prescribed medication dose. The PPM internal software can calculate adjustments for a patient's medication dosage according to a physician's prescription as applied to the data entered into the PPM by the patient.

[0039] The internal software of a PPM can be configurable by a case manager via a PAC server. A case manager can make adjustments to a patient's medication dose calculations, to a patient's dosage algorithm, and to a patient's fixed or contingent self-monitoring schedules. These adjustments can be made automatically within a PPM during routine data transfer to a PAC server. In addition to providing disease therapy management, a PPM can be used to remind patients to schedule appointments for important examinations.

[0040] Preferably, a PPM contains a database of medication interaction information and is configured to allow a patient to query the database for information related to the patient's use of multiple medications. A PPM may be configured to communicate with an external database containing medication interaction information, as well. For example, a patient may query a database located within a PAC server when communications are established between the PPM and the PAC server. A PPM may also be configured to allow a patient to establish communications with other external databases, such as those residing in various legacy systems.

[0041] Other features of a PPM which are not illustrated, but which may be included, are PCMCIA slots for connecting a PPM to various peripheral devices; RJ11 connections to land line telephone systems; and infrared ports for communications with peripheral devices. Additional PPM features for diabetes patients are disclosed in U.S. Patent Number 4, 731, 726.

[0042] PPMs, according to the present invention, are not limited to land line telephone communications with a PAC server. PPMs may communicate with a PAC server using various communications technologies, without limitation. For example, a PPM may incorporate wireless communications technology for communicating with a PAC server. A PPM may also incorporate direct satellite communications technology for communicating With a PAC server.

Physician Access Center Server

[0043] Data entered into a PPM (12 of Fig. 1) by a patient is transferred to a central data processing system 14 (referred to hereinafter as a PAC server) via a telephone and modem. It is understood that a PAC server 14 may be one or more data processing devices arranged in a network. Preferably, a direct communications connection is established between a PPM 12 and a PAC server 14. Alternatively, an indirect communications connection may be established between a PPM 12 and the PAC server 14 via the Internet or other network. A communications server is preferably utilized to handle inbound and outbound communications between a PPM 12 and the PAC server 14, as would be understood by those skilled in the art of client-server communications. The term PAC server, as used herein, includes databases for storing and manipulating patient data as well as other server functions including, but not limited to web servers, application servers, e-mail servers, fax servers, AVM servers, and the like. A particularly preferred PAC server utilizes an Intel based processor running Windows NT Server 4.0 as its operating system. Preferably, a PAC server 14 is configured to handle more than 250,000 patients with at least 500 concurrent client connections. However, a PAC server 14 may be implemented using other processors and via other computing devices, including, but not limited to, mainframe computing systems and mini-computers.

[0044] A PAC server 14 analyzes and stores data transmitted from each patient PPM 12. This data is made available to authorized case managers who can access the data via a CCM 16 in TCP communication with a PAC server 14 via the Internet. In particular, a PAC server 14 identifies and prioritizes patient medical problems using the data transmitted from the patient PPMs 12. This allows case managers to focus their attention first on patients with significant medical problems.

[0045] Preferably, a PAC server 14 performs real-time analysis on data as it is being transmitted from a PPM to identify medical emergency situations that require immediate attention. If such a medical emergency is identified, a patient can be immediately notified via communications from a PAC server 14 to a PPM 12, without the intervention of a case manager. Alternatively, a case manager can be notified and the patient contacted directly via phone, e-mail, fax, or other modes of communication.

[0046] A PAC server 14 performs various other functions including allowing case managers to change the treatment program for patients, such as medication dosage, when a patient downloads data to a PAC server 14. In addition, a PAC server may include a "tickler system" for reminding case managers to verify that communications with patients have occurred and for verifying that medical conditions requiring medical attention have been resolved. A PAC server may also be configured to track patient medication supply usage automatically (e.g., warfarin, lancets, and syringes)

and this information may be used to provide just-in-time delivery of replacement medications and supplies to a patient. A PAC server may be configured to communicate with manufacturers and distributors of medical supplies utilized by patients. By monitoring patient usage of supplies, orders can be placed with manufacturers and distributors directly via a PAC server such that medical supplies can be delivered to patients.

[0047] A separate warehouse database may be added to a PAC server **14** to support complex analysis of patient data, and may also be used to review prescriptive changes made to a patient's medical regimens and medication dosages.

Case Manager Clients

[0048] As illustrated in **Fig. 1**, case managers access a PAC server **14** via a case manager client (CMC) **16** connected to the same network. The CMC **16** preferably communicates with a PAC server **14** using TCP/IP protocol over an Internet connection between the CMC and the PAC server. Data encryption may be utilized and other security methods may be implemented to transfer information between a PPM and PAC server and between a CMC and the PAC server or a PPM.

[0049] Exemplary devices which may serve as CMCs **16** for purposes of the present invention may include, but are not limited to, desktop computers and portable computing devices, such as personal digital assistants (PDAs). A CMC **16** preferably includes a central processing unit, a display, a pointing device, a keyboard, access to persistent data storage, and an Internet connection for connecting to the Internet **17**. An Internet connection may be made via a modem connected to traditional phone lines, an ISDN link, a T1 link, a T3 link, via cable television, via an ethernet network, and the like. An Internet connection may be made via a third party, such as an "Internet Service Provider" ("ISP").

[0050] An Internet connection may be made either by a direct connection of a CMC to the Internet or indirectly via another device connected to the Internet. In the latter case, a CMC is typically connected to this device via a local or wide area network (LAN or WAN). Preferably, data transfer rates between a CMC and a PAC server are equal to, or greater than, fourteen thousand four hundred baud (14,400 baud). However, lower data transfer rates may be utilized.

[0051] Preferably, a CMC **16** has an Intel® 80486 processor (or equivalent) with at least eight megabytes (8 MB) of RAM, and at least five megabytes (5 MB) of persistent computer storage for caching. Even more preferable is an Intel® Pentium® processor (or equivalent). However, it is to be understood that various processors may be utilized to carry out the present invention without being limited to those enumerated herein. Although a color display is preferable, a black and white display or standard broadcast or cable television monitor may be used. A CMC **16**, if an IBM®, or IBM-compatible personal computer, preferably utilizes either a Windows®3.1, Windows 95®, Windows NT®, Unix®, or OS/2® operating system. However, it is to be understood that a terminal not having computational capability, such as an IBM® 3270 terminal or a network computer (NC), or having limited computational capability, such as a network PC (Net PC) may be utilized in accordance with an embodiment of the present invention for accessing the Internet in a client capacity.

[0052] Herein, the term "Internet" shall incorporate the term "computer network" and "communications network" such as an "Intranet", and any references to accessing the Internet shall be understood to mean accessing a hardwired computer network as well. Herein, the terms "computer network" and "communications network" shall incorporate publicly accessible computer networks and private computer networks, and shall be understood to support modem dial-up connections.

[0053] A case manager accesses a PAC server **14** via a CMC **16** to review the medical conditions of multiple patients. Case managers preferably are able to review, via information downloaded from a PAC server **14**, all patient activity and data for their assigned patients including data transmission history, symptom reports, prescription review, analysis and adjustment. A CMC **16** allows a case manager to review patient data in various formats, including a hierarchical, problem-oriented format wherein patients with medical conditions requiring immediate attention are presented foremost. A CMC **16** may also allow a case manager to add, edit, and delete certain patient data stored in a PAC server **14**. A CMC **16** also can interface directly with each PPM **12** to provide a patient with information and to modify illness-specific software contained therein. For example, a warfarin or other anticoagulation dosage algorithm contained within the internal software of a particular patient's PPM can be modified remotely by a case manager via a CMC **16**.

System Security

[0054] Access to a system for monitoring, diagnosing, and treating medical conditions of remotely located patients with various chronic illnesses, according to the present invention, may be controlled using logon security which provides case managers and other users with certain circumscribed privileges to examine and/or edit data. These rights can limit certain users ability to examine confidential clinical health data, and may also be employed to limit the ability to edit any clinical data or make changes to specific fields in a patient's medication dosages or dosage adjustment algorithm. Similar access control may be applied to the data, at various levels, which define patients' medical conditions and their associated priorities and pre-emptive relationships.

[0055] Flexible configuration and associated security may be an element of a system for monitoring, diagnosing, and

treating medical conditions of remotely located patients, according to the present invention, that permeates many of the subsystems. Default values and classifications for many values may be provided at the system level. Default values may be modified in a hierarchical manner, and may be controlled in part by access rights of a user, to a permit uniqueness at various levels.

Operations

[0056] Referring now to Fig. 3, operations for monitoring, identifying, prioritizing and treating medical conditions of patients with chronic illnesses, according to the present invention, are schematically illustrated. Patient data are obtained by a PAC server from a PPM (Block 100). A PAC server analyzes the obtained data to identify patients with medical conditions requiring treatment or some type of medical attention (Block 200). A PAC server prioritizes the identified patient conditions according to medical severity (Block 300). A PAC server displays to a case manager (or other user), via a client in communication with the PAC server, a selectable list of patients with identified medical conditions arranged in priority order (Block 400). A PAC server provides to a case manager, via a client, options for treating each identified medical condition (Block 500). Physician-prescribed medication dosage algorithms may be implemented based on patient data obtained from a PPM (Block 600). Treatment information may be communicated directly to a patient or to a patient's PPM by a case manager via a client in communication with a central data processing system (Block 700). The operations set forth in Fig. 3 are described in detail below.

Obtaining Data From PPM

[0057] In a preferred embodiment, when a PAC server obtains patient data from a PPM (Block 100), operations schematically illustrated in Fig. 4 may be performed. Preferably, data transmitted to a PAC server is analyzed substantially simultaneously with transmission of the data for the purposes of identifying "emergency" medical conditions requiring immediate medical attention (Block 102). Preferably, this analysis is performed while communications are still established between a PAC server and a PPM transmitting the data. If emergency medical conditions are not identified (Block 104), data obtained from a PPM is stored within a PAC server database for later analysis and retrieval (Block 110).

[0058] If emergency medical conditions are identified (Block 104), instructions are downloaded to the PPM regarding what actions should be taken by the patient (Block 106). For example, the patient may be instructed to immediately take a specific medication or to immediately seek medical attention. If a medication dosage algorithm is stored in a PAC server, the PAC server may communicate a new medication dose to the PPM, or to the patient via telephone, AVM, e-mail, facsimile transmission, and the like. In addition, changes may also be made to medicine dosage algorithms stored within a PPM or within the PAC server, such that a patient's next dose of medicine is changed in response to the identified emergency medical condition. Furthermore, changes may also be made to a patient's fixed or contingent self-monitoring schedules. The next scheduled time for data transmission from the PPM to the PAC server may be set, based on an identified medical condition's severity, such that higher condition severities result in more frequently scheduled transmissions (Block 108). For example, PPMs for patients with asthma may be reprogrammed to transmit every 12 hours, while PPMs for patients with high blood pressure may be adjusted to transmit every 3 days, while patients with no identified conditions may transmit on a routine schedule such as every week. The data obtained from a PPM is then stored within a PAC server database for later analysis and retrieval (Block 110).

Analysing Patient Data to Identify Patients With Medical Conditions Requiring Medical Attention or Treatment

[0059] Referring now to Fig. 5, preferred operations for analyzing patient data transmitted from a PPM to a PAC server to identify medical conditions requiring medical attention or treatment are schematically illustrated. Initially, operations for identifying medical conditions from transmitted data (Block 202) are performed. Exemplary operations represented by Block 202 are schematically illustrated in Fig. 6, and are discussed below.

[0060] Still referring to Fig. 5, if medical conditions requiring attention are not identified from data transmitted from a PPM (Block 250), a determination is made whether there are any unresolved medical conditions for the patient requiring attention or treatment (Block 252). If there are no unresolved medical conditions, case managers may provide patients with positive feedback to reinforce their self-monitoring practices and encourage continued compliance with the treatment regimen(s) (Block 254). Additionally, patients with chronic diseases must have regularly scheduled reviews and assessments, with the latter performed predominantly in the clinic. Periodic comprehensive reviews of the patients can be performed and may utilize all available inputs, including the most recent month's PPM data. These periodic assessments may be flexibly scheduled depending upon the disease and/or disease state of individual patients. These reviews provide a structured means by which the case manager may work to optimize care for patients who otherwise are not specifically identified as having medical conditions that require treatment, but who nonetheless can benefit by feedback and further optimization of medication doses, algorithmic methods for adjusting doses, self-monitoring schedule and by coordinating

medical assessments and procedure conducted by other medical specialists.

[0061] If medical conditions are identified (Block 250) from transmitted data from a PPM, or if there are unresolved medical conditions for the patient (Block 252), a determination is made whether a medical condition requires additional patient input (Block 256). If patient input is required, the patient is notified by various methods, such as via telephone, e-mail, AVM, facsimile transmission, or via the patient's PPM (Block 258). Preferably, the present invention includes a "tickler" system for monitoring whether a patient provides required input within a specified time period (Block 260). If a patient does not provide required input within a specified time period, the present invention may prompt a case manager to re-notify a patient of required input (Block 258).

[0062] If input from a patient is not required (Block 256) or if patient input has been received (Block 260), a case manager is provided with various options for resolving one or more medical conditions. A case manager may be presented with an option to contact a patient (Block 262). If a case manager decides to contact a patient, the present invention facilitates communication via telephone, e-mail, AVM and facsimile transmission (Block 272). A case manager may be presented with an option to adjust a medicine dosage algorithm, a patient's dosage, or a patient's fixed or contingent self-monitoring schedule, either within a patient's PPM or the PAC server (Block 264). If a case manager decides to adjust a medicine dosage algorithm within a patient's PPM, the present invention facilitates this modification through a PAC server the next time communications are established between the PAC server and the patient's PPM (Block 274). A patient may be prompted to establish communications between his/her PPM and a PAC server to receive modifications made by a case manager. Alternatively, if a medicine dosage algorithm resides within a PAC server, a case manager can instruct the PAC server to adjust medicine dosage and transmit this information to the patient.

[0063] In addition, a case manager may be presented with an option to schedule a patient for a visit with a health care provider (Block 266) or with an option to seek expert medical input (Block 268). If these options are selected, the present invention facilitates scheduling a patient to visit a health care provider (Block 276) or obtaining input from a medical expert (Block 278). A case manager may decide that no action is required for a particular medical condition and may remove an identified medical condition from an active medical condition list for a particular patient after reviewing available data (Block 270).

[0064] Referring now to Fig. 6, exemplary operations performed by a PAC server for identifying medical conditions requiring medical attention or treatment are schematically illustrated. Preferably, these operations are performed by a PAC server immediately after transmission of data from a PPM to the PAC server. For any given chronic disease, there may be relationships between medical conditions that a patient may have. For example, a patient afflicted with thrombosis may exhibit two medical conditions having differing degrees of medical severity. One medical condition may have a high degree of medical severity requiring immediate attention. The other medical condition may have a much lower priority and may not require immediate medical attention. When multiple medical conditions are identified, two or more of these conditions for a given patient may represent problems of a similar type which differ only in severity (as defined by the system implementation). Conditions of lesser severity of the same type may be ignored (if identified) or may not be identified in the first place, if a condition of the same type at a higher priority has already been identified. It is presumed that identification and treatment of the most severe condition identified will obviate the needs to identify or treatment less severe conditions of the same type. Two methods are presented for achieving this aim below.

[0065] The present invention facilitates identifying and addressing medical conditions having the highest degree of medical severity first by organizing possible medical conditions for a given chronic disease into various classifications and by prioritizing medical conditions within each classification. Classification and prioritization within classes are illustrated below with respect to Table 3.

Table 3

CLASS	MEDICAL CONDITION	PRIORITY	SUB_PRIORITY
1	A	1	A
1	A	1	B
1	A	1	D
1	A	1	L
1	A	1	Q
1	B	2	A
1	B	2	D
1	B	2	F
1	B	2	M
1	B	2	Q
1	B	2	Z
1	C	3	A

(continued)

	CLASS	MEDICAL CONDITION	PRIORITY	SUB_PRIORITY
	1	C	3	B
5	1	C	3	S
	1	C	3	U
	2	D	1	A
	2	D	1	B
	2	D	1	C
10	2	D	1	F
	2	E	2	A
	2	E	2	C
	2	E	2	F
15	2	F	3	A
	2	F	3	D
	2	F	3	F
	2	F	3	Z
	3	G	1	A
20	3	G	1	B
	3	G	1	D
	3	H	2	A
	3	H	2	B
25	3	H	2	C
	3	H	2	D

[0066] The column entitled Sub_Priority presents medical conditions within each unique combination of class and medical condition (already sorted by priority with a class) in a sorted order that is defined expressly for each combination. That is, sub_priority provides a means by which the conditions in the list can be further sorted to provide additional information related to urgency. For example, problems related to late data transmissions (all within one class and assigned to have one priority) may be displayed in the order of the most overdue first. Subpriorities for each medical condition will be uniquely defined for that condition. In this example, the column labeled sub_priority may be conceived of as representing a "priority score" that can be defined for each condition. Other embodiments may utilize different methods to achieve similar means, and the process of prioritization could also be extended to additional levels as needed (*i.e.*, sub-sub-priorities). Use of a single sub_priority column will support this feature.

[0067] Using Table 3, a relationship table may be derived to determine which medical conditions have a higher degree of medical severity than other medical conditions. An exemplary relationship table is illustrated below as Table 4. Conditions may be overridden that are either 1) unrelated but of a lesser priority than those in the first column, or 2) closely related or being of the same "type" and therefore need not be identified and treated since treatment for the most severe form will obviate the need for treatment of less severe conditions of the same type.

Table 4

Medical Condition	Overrides Medical Condition
A	D and H
B	G
D	H
E	F and G

[0068] Referring back to **Fig. 6**, operations for identifying medical conditions (Block **202**) based upon Table 3 and Table 4 above are schematically illustrated. Initially a test is performed for medical condition A (Block **204**). If transmitted data from a PPM indicates that a patient has medical condition A (Block **206**), then tests for medical conditions D and H (Block **208** - Block **214**) are not performed because medical conditions D and H have lower priority than medical condition A. If transmitted data from a PPM indicates that a patient does not have medical condition A (Block **206**), a test for medical condition D is performed (Block **208**). If transmitted data from a PPM indicates that a patient has medical

condition D (Block 210), then tests for medical condition H (Block 212 - Block 214) are not performed because medical condition H has lower priority than medical condition D. If transmitted data from a PPM indicates that a patient does not have medical condition D (Block 210), a test for medical condition H is performed (Block 214).

[0069] Whether or not transmitted data from a PPM indicates that a patient has medical condition H (Block 210) or if a patient has medical condition A (Block 206), a test for medical condition B is performed (Block 216). If transmitted data from a PPM indicates that a patient has medical condition B (Block 218), then tests for medical condition H (Block 220 - Block 222) are not performed because medical condition H has lower priority than medical condition B. If transmitted data from a PPM indicates that a patient does not have medical condition B (Block 218), a test for medical condition H is performed (Block 220).

[0070] Whether or not transmitted data from a PPM indicates that a patient has medical condition H (Block 222) or if a patient has medical condition B (Block 218), a test for medical condition C is performed (Block 224). Whether or not transmitted data from a PPM indicates that a patient has medical condition C (Block 226), a test for medical condition E is performed (Block 228).

[0071] If transmitted data from a PPM indicates that a patient has medical condition E (Block 230), then tests for medical conditions F and G (Block 232 - Block 238) are not performed because medical conditions F and G have lower priority than medical condition E. If transmitted data from a PPM indicates that a patient does not have medical condition E (Block 230), a test for medical condition F is performed (Block 232). If transmitted data from a PPM indicates that a patient has medical condition F (Block 234), then tests for medical condition G (Block 236 - Block 238) are not performed because medical condition G has lower priority than medical condition F. If transmitted data from a PPM indicates that a patient does not have medical condition F (Block 234), a test for medical condition G is performed (Block 238). All medical conditions identified are then stored within a PAC server (Block 240).

[0072] It should be further noted that the definition and specification of these medical conditions and their associated priorities, and of the relationship between conditions where the treatment and identification of lower priority condition may be superseded by those of higher priority is configurable. The problem definitions may be configured in part to reflect individual patient differences by adjustment of the default physiologic or behavioral parameters which will trigger the identification of a given problems. Where default values for identification are utilized, patient parameters are inherited from the doctor, and these may in turn be inherited from other, higher levels within the system.

Prioritizing Identified Patient Medical Condition

[0073] According to a preferred embodiment of the present invention, identified patient medical conditions are prioritized based on a hierarchy of medical severity. In general, three classes of medical conditions (Class I, II and III) may be utilized. However, it is to be understood that various numbers and types of classes of medical conditions may be utilized.

[0074] Class I medical conditions are those that require immediate attention based on physiologic or behavioral data collected by a PPM. Although identified by a PAC server, many of these conditions may also be identified by a PPM and may result in prompts to the patient to transmit to a PAC server up-to-date data and to follow this up with a telephone call to the case manager or physician. While late transmissions may not necessarily require immediate action, they may be placed in the Class I category for reasons of health safety.

[0075] Class II medical conditions may be significant medical conditions, but may not require immediate medical attention or action on the part of a case manager. Class II medical conditions, if not addressed, may develop into Class I medical conditions that do require immediate attention.

[0076] Class III medical conditions are defined as suboptimal conditions in which room for patient improvement may be indicated by physiologic and/or behavioral data collected from a patient's PPM. Many Class III medical conditions may relate to poor or inconsistent compliance with a self-monitoring regimen.

[0077] Referring now to Fig. 7, operations for prioritizing identified medical conditions according to aspects of the present invention are schematically illustrated. Identified medical conditions are sorted by patient, medical condition, classification, priority and sub-priorities (Block 302). Medical conditions of lesser severity for each patient within each medical condition classification are eliminated (Block 304).

Displaying Selectable List of Patients With Identified Problems in Priority Order

[0078] After all medical conditions have been identified, a list of medical conditions for each patient is normalized to eliminate medical conditions of the same type or of lesser severity. Only the remaining medical conditions for a given patient are available for display in a larger list(s) of medical conditions identified for all patients. Fig. 8 illustrates an exemplary user interface 30 wherein a list 31 of medical conditions for a plurality of patients is displayed in priority order. In the illustrated user interface 30, the patient with the highest priority medical condition is listed first. A filter allows a user (case manager) to display various levels of detail of prioritized medical conditions. A box 32 is provided in the illustrated user interface 30 that allows a case manager to select the level of displayed detail. In the illustrated user

interface, the filter selection in box **32** allows all identified, prioritized medical conditions of all patients to be displayed.

[0079] A list of prioritized medical conditions appears when a case manager first logs into a PAC server via a CMC. The order of presentation is based on medical condition class. Within each class, medical conditions of different types are sorted by an assigned priority. Within each separate medical condition the individual cases are optionally sorted by a severity index. This feature may be defined separately for each type of medical condition, and further may reflect settings that are defined for individual patients as necessary or desirable. For example, late transmissions may be sorted by the number of days overdue, and persistent poor control might be sorted by blood pressure which is chronically elevated.

[0080] Preferably, medical conditions having the highest medical severity appear at the top of the list. Selection of a patient medical condition, such as by mouse click, results in a change of the user interface to one focused upon the selected patient, as illustrated in **Fig. 9**. In the illustrated interface user **34** of **Fig. 9**, all current medical conditions **35** for the selected patient appear on the left side **36** of the user interface **34** in a list format resembling a directory structure, and the right side **37** of the user interface contains current prescriptive and report data. The listing on the left side resembles a directory structure in form and function, whereby selection of a condition by mouse click will expand the list on the left side to reveal available treatment options for the selected condition. On the right side default screens are available in a tabbed format that can be used to modify medication dosages, parameters related to the adjustment of medication in the PPM, and the fixed and contingent self-monitoring schedule. Changes to these parameters can be directly communicated to the PPM and are summarized in documentary form in a Chart Summary Report. This report and the changed data can also be used, in part, to generate AVIM using text to speech technology that verbally summarizes new treatment instruction for the patient. Certain actions or treatment options which may appear below current medical conditions identified for this patient may cause other user windows and dialog boxes to appear, as described below.

Providing Options for Treating Identified Medical Conditions

[0081] The selection of a patient medical condition in the user interface of **Fig. 9** by mouse click may result in an expanded list of available actions that may be taken for the chosen medical condition. The actions displayed may be only those which have been associated with the specifically-defined (and "expanded") medical condition. Selection of an action for a given medical condition may provide immediate access to user interfaces where dosages or algorithmic alterations can be made (if applicable), or may provide methods for contacting patients.

Communicating Treatment Information to Patient

[0082] A variety of specific actions may be undertaken which involve or utilize a patient's PPM. These may include the adjustment of medication dosage level or the timing for administration; adjustment of the rules or algorithmic parameters which a PPM or PAC server uses to independently adjust and alter medication dosage (e.g., alteration of the target range for the physiologic function being monitoring); alteration of the patient's self-monitoring schedule; or alteration of the parameters that trigger additional or contingent self-monitoring suggestions in the PPM. In addition to these parameters, a case manager may also select and/or compose messages to be downloaded to a patient's PPM, or transmitted via telephone, AVIM, e-mail and facsimile transmission, which are designed to reinforce correct behaviors or alter maladaptive behaviors. A case manager may also compose a message asking a patient to schedule an office visit with a physician, and may also alter a PPM's transmission schedule (which may take affect following the next transmission). Special messages related to scheduling office appointments ask the patient to make an appointment with a named professional and provide his or her phone number. The PPM may query the patient on a daily basis concerning whether the appointment has been made, and then solicit the appointment date for uploading to the PAC. After the appointment date has passed, the PPM can query the patient to ascertain if the appointment was actually kept.

[0083] Preferably, screening mechanisms are provided for ensuring that treatment or information provided by a case manager is medically qualified for a particular patient before the treatment or information is communicated to a patient or to a patient's PPM.

[0084] Exemplary user interfaces **44a**, **44b**, **44c** for communicating with a patient, are illustrated in Figs. 10A-10C, respectively. In Fig. 10A, automated voice mail (AVM) messages can be selected and sent to a patient via the box 46. In addition, personal and predefined messages can be created and/or selected via boxes 48a and 48b, respectively, and transmitted directly to a patient's PPM. In Fig. 10B, various written documents can be selected and sent to a patient via the box 47. These notices can be sent via letter, fax, or e-mail, and can be personal or predefined. In **Fig. 10C**, status of communications with a patient can be monitored using various features illustrated in box **49**.

[0085] Once a change has been made in any of the above areas which utilize a patient's PPM, a case manager may optionally elevate the new dosage prescription to a high priority. In the present invention this may cause delivery of a voice message to the patient that he or she should immediately initiate communications between the patient's PPM and a PAC server in order to receive a revised treatment regimen, including, but not limited to, modified medication doses,

modified dosage algorithm(s), and modified fixed and contingent self-monitoring schedules and parameters. If a case manager elects not to elevate the revised monitoring parameters to a high priority level, the altered parameters may be loaded automatically during the next routine data transmission which is prompted by the patient's PPM according to the last transmission.

[0086] To make a newly saved prescription (e.g., modified medication doses, modified dosage algorithm(s), and modified fixed and contingent self-monitoring schedules and parameters) available to a patient, a case manager "publishes" the prescription. Publishing a prescription means that an altered prescription, which may be conveyed to a patient via a PPM, is finalized to a point where it is officially ready to be given to the patient. An exemplary user interface 54 for adjusting a patient's physician-prescribed medicine dosage (one of several options) via a patient's PPM is illustrated in **Fig. 11**. A case manager may see up to four columns of information representing four daily quadrants in which adjustments may be enabled for drugs like insulin that have a short half-life. In the case of anticoagulation therapy with warfarin, adjustments in medication are likely to be enabled once or twice per week. The adjustment parameters may appear in a quadrant in which the medication dosage being adjusted is assessed.

[0087] In cases where case managers have questions concerning a patient's medical condition or prescription, case managers may seek input from medical experts using a user interface such as that illustrated in **Fig. 12**. Expert input may be obtained at any step in the review and alteration process, and may involve referencing current patient data and unresolved medical conditions (if any) with a request for help. Expert input may be directed to a superior (e.g., a supervising case manager or the primary care physician), a specialist or to a collateral person involved in the patient's care (e.g., a dietitian, optician, neurologist, hematologist, cardiologist or podiatrist).

[0088] In the illustrated user interface 50 (**Fig. 12**), expert input may be obtained by selecting a health care giver from the box 51. Preferably, various methods of contacting a selected health care giver are available (e.g., telephone, fax, e-mail, office visit, and the like). Contacts with experts may or may not be accompanied by referenced or attached patient data available from the PAC server. Expert input can be directed to people who may not have direct access to the PAC server and be able to directly review patient data (e.g., a podiatrist), but are more typically directed to others with access to the system and are focused on the patients current medical conditions and overall treatment regimen (neurologist, hematologist, endocrinologist or primary care physician). These latter personnel may be expected to provide either advise in written or other form, or may act directly upon (and publish) the overall treatment regimen (medication dosages, dosage adjustment algorithm, or the fixed or contingent self-monitoring schedule) which may be conveyed to the Patient's PPM.

[0089] In addition to communicating with patients via a PPM, a case manager may communicate with patients in various ways, such as via telephone, e-mail, AVM and facsimile transmission. Preferably, the present invention provides pre-composed text for inclusion in text-based communications such as letters, faxes and e-mail directed to a patient. Multiple selections can be added to a letter and then edited, or the entire communication can be created manually, and delivery of the text may be done redundantly. Telephone communications may also be managed from a content screen where topic issues can be displayed and optionally highlighted for documentary reasons, and a case manager may elect to immediately make or schedule a patient call, or to schedule voice message delivery of pre-composed or personalized text. Prompting patients to make an overdue transmission of data from his/her PPM to a PAC server may be accomplished using voice message delivery of a pre-composed message. Patient contact options may also be tied to a tickler system to facilitate timely follow-up.

[0090] In addition, case managers may utilize the present invention to facilitate and track patient appointments with clinic personnel or other providers involved in health care. An exemplary user interface 56 for this purpose is illustrated in **Fig. 13**. Once a decision is made to schedule a patient appointment, a system task reminder may be generated that requires periodic follow-up until a record of a scheduled appointment time is input into a PAC server. A case manager may employ a patient's PPM to prompt the patient to make an appointment, and subsequently query the patient for the appointment date once it has been made. Other contact methods may also be employed to prompt a patient to make an appointment and subsequently to inform the case manager concerning the date (e.g., via e-mail, AVM, telephone, and facsimile transmission). A PPM may also be used to verify appointment compliance.

[0091] Preferably, the present invention also tracks appointment compliance (e.g., whether a patient kept his/her appointments). Healthcare providers can be sent communications to confirm whenever an appointment has been kept by a patient and to supply associated lab or examination data to a PAC server. To track appointment compliance with providers who cannot directly access a PAC server, a case manager may generate correspondence and associated follow-up reminders in order to obtain confirmation and associated clinical data if desired.

[0092] According to another aspect of the present invention, a blind actuarial review of changes made to the medication dosages and/or the rules utilized by a PPM to independently adjust these doses may be utilized. Statistical analysis may optionally be performed on published prescriptions that utilizes pattern analysis, multiple regression, time series and other types of analyses that compare current patient data sets to earlier data and to data of other appropriate patients. This assessment procedure is designed to screen for potential medical conditions whose probability has markedly increased as a result of the most recent prescriptive changes made to a patient's PPM-supported treatment regimen.

A secondary purpose involves alerting a case manager in situations where changes made to a prescription are unlikely to result in any significant improvement in a patient's current physiologic condition. In addition, the present invention is also designed to focus a case manager's attention on the areas of a prescription where intervention is likely to result in the greatest improvement in a patient's medical condition.

[0093] When a medical condition has been corrected, it is effectively removed from a patient's active list by use of a "Complete" button. The user interface **58** of **Fig. 14** illustrates a patient's medical condition being removed from the active list. This is graphically illustrated by the addition a check mark in front of the medical condition.

Anticoagulation Therapy

[0094] According to another embodiment of the present invention, a portable patient monitor (PPM) as described above may serve as a standalone device for monitoring and adjusting patient-administered medication and testing regimens used in therapy for various diseases. The following describes methods and apparatus for monitoring anticoagulation therapy according to various embodiments of the present invention wherein a warfarin treatment regimen and a prothrombin time (PT) test regimen are utilized. However, it is understood that therapy for other diseases may be monitored in accordance with the present invention including, but not limited to cancer, seizure disorders, depression, asthma and high blood pressure.

[0095] Anticoagulation therapy typically includes a medication (e.g., warfarin) regimen and a coagulation test regimen, such as a prothrombin time (PT) test (see, TABLE 1 above for other tests), for a patient. Hereinafter, any reference to "PT test" shall mean "coagulation test" and shall include all coagulation tests utilized in Anticoagulation therapy.

[0096] A PPM, such as the PPM 20 illustrated in Fig. 2, and described in US 6,024,699 when utilised to monitor disease therapy in accordance with this embodiment of the present invention is referred to as a CoagCare" Patient Monitor (CPM). A CPM may include all the features of a PPM described above and also includes computer code that receives and stores patient data provided by a patient. A Palm Pilot, available from 3Com Corporation, Santa Clara, California, may be provided with various program code to implement aspects of the present invention.

[0097] The term "receives" is intended to include any method of receiving data including, but not limited to, input provided via keyboard or keypad, input provided via cable connection, input provided via infrared, RF, or other wireless connection, and the like.

[0098] Exemplary patient information (data) may include physiological data, pathophysiological data, biological data, psychological, neuropsychological and behavioral data. For example, a CPM may be configured to prompt for and receive data pertaining to hemorrhagic and non-hemorrhagic conditions, signs or symptoms that a patient assesses, has experienced or is experiencing currently. A CPM also may include a medication algorithm that utilizes various patient data to modify warfarin and PT time test regimens in real time. In addition, a CPM may include computer code that communicates modified medication and PT test regimens to a patient. A CPM may also includes computer code that can communicate with a remotely located data processing system, such as a PAC server described above, and that can transmit stored patient data thereto.

[0099] A CPM may also include computer code that can prompt a patient to provide information about the patient's compliance with a warfarin regimen and with a PT test regimen during a preceding time period. A CPM also may include computer code that communicates information regarding warfarin dosage to a patient in response to determining that the patient did not comply with a warfarin regimen in a preceding time period.

[0100] Typically, a patient will interact with a CPM, such as that illustrated in **Fig. 2**, on a daily basis to assess data, signs, conditions, symptoms, behaviors and compliance with one or more prescribed medication regimens. With respect to anticoagulation therapy, a CPM contains a PT testing schedule that can be individually prescribed via the CPM. The CPM will prompt a patient to perform and store PT test results according to an individualized schedule, and to test in response to certain signs, conditions, symptoms (data as defined previously) that are evaluated by the CPM. A CPM may be configured to prompt a patient for testing which is contingent upon self-reports of alarming conditions, signs or symptoms (data) of either a supra-therapeutic and/or sub-therapeutic nature).

[0101] A CPM also may include computer code that assesses changes in patient behavior that may affect warfarin therapy on a daily (or other time period) basis. Changes in a patient's diet, medication, illness, or vitamins are flagged for potential telephone follow-up by a healthcare provider following the patient's next data transmission from the CPM to a remotely located data processing system, such as a PAC server, which was described in detail above. Patients are prompted by the CPM to indicate any warfarin or other medication dosage additions, changes, discontinuations, or omissions. Vitamin intake by a patient also can be assessed for impact to PT testing. Patients are also prompted by the CPM to identify any significant dietary changes such as eating more or less than usual, or major changes in dietary composition. Conditions that can affect warfarin therapy, such as illness, vomiting, and diarrhea, can also be assessed by the CPM.

[0102] Referring now to **Figs. 15-19**, operations for monitoring anticoagulation therapy via a remote and preferably portable patient apparatus (CPM) according to the present invention are illustrated. It is understood that the present

invention may be used for monitoring therapies for other diseases and conditions including, but not limited to, high blood pressure, depression, seizure disorders, cancer, and asthma. In the illustrated embodiment of **Figs. 15-19**, the described anticoagulation therapy includes a warfarin medication regimen and a PT test regimen. Wherever the term "warfarin" is used, it is understood that the term "medication" may be substituted therefor.

[0103] Referring initially to **Fig. 15**, a patient undergoing anticoagulation therapy logs onto his/her personal CPM (Block **1100**) according to a predefined schedule (for example, a daily schedule). If the CPM determines that information (or data) regarding the patient's warfarin and PT test regimens (or other aspects of the anticoagulation therapy) is missing or insufficient (*i.e.*, that the patient has not entered this information into the CPM during a preceding time period, or has not complied with an established warfarin regimen and/or PT test regimen) (Block **1300**), the CPM initiates a procedure for obtaining the missing patient data (Block **1350**).

[0104] It is understood that missing patient data as described herein with respect to Block **1350** and **Fig. 16** is not limited to medication and test results. Missing patient data may also include signs, conditions, symptoms, compliance with exercise regimens, confirmation of injection sites that could affect drug absorption (heparin agents), prompts to calibrate or test calibration of biological or physiological testing equipment, patient apparatus maintenance, and the like.

[0105] Referring to **Fig. 16**, a procedure for obtaining the missing patient data (Block **1350**) regarding the warfarin and PT test regimens (or other aspects of the anticoagulation therapy) is illustrated. The CPM prompts the patient to indicate whether the patient took his/her prescribed dosage of warfarin in the preceding time period of interest (Block **1351**). If the patient responds "No", the CPM prompts the patient for reasons why the patient did not take the warfarin according to the prescribed regimen and records these reasons (Block **1356**). Operations then return to Block **1353**.

[0106] With respect to Block **1356**, a check list is preferably provided via a user interface that allows a patient to indicate reasons (*e.g.*, forgot to take medication, ran out of medication, and the like). If the patient responds "Yes" (Block **1351**), the CPM obtains information from the patient about a dose(s) actually taken and updates a dose record(s) for the preceding time period of interest (Block **1352**).

[0107] The CPM then makes a determination whether a PT test was scheduled for the preceding time period of interest (Block **1353**). If the answer is "No", operations return to Block **1400** (**Fig. 15**). If the answer is "Yes", the CPM prompts the patient whether the PT test was performed (Block **1354**). If the CPM determines that the PT test was not performed the CPM prompts the patient for reasons why the PT test was not performed and records these reasons (Block **1357**). The patient may also be prompted to perform the PT test at this time (Block **1357**) and to enter the PT test results (Block **1355**). If the CPM determines that the patient did perform the PT test (Block **1354**), the CPM prompts the patient to enter the test results (Block **1355**).

[0108] A determination is then made whether other data is missing (Block **1358**). If the answer is "Yes", the missing data is entered, preferably on a prioritized basis (Block **1359**). If the answer is "No", operations then return to Block **1400** (**Fig. 15**).

[0109] Referring back to **Fig. 15**, the CPM prompts the patient as to whether the patient has experienced (or is experiencing) any supra-therapeutic signs, conditions or symptoms (collectively referred to as "data") (Block **1400**). As is well known to those of skill in the art, a supra-therapeutic sign or condition is data which indicates a patient has taken too much of a medication (over-dose). With respect to anticoagulation therapy, hemorrhagic "signs", such as bleeding, bruising, thinning blood, blood in urine or stool, severe headache, other bleeding, swollen joints, and cuts that will not stop bleeding are exemplary supra-therapeutic data. If the answer at Block **1400** is "Yes", the CPM initiates a procedure for assessing the severity of the supra-therapeutic signs and conditions (Block **1450**).

[0110] Referring to **Fig. 17**, a procedure for assessing the severity of supra-therapeutic conditions experienced by a patient (Block **1450**) is illustrated. The CPM prompts the patient to indicate supra-therapeutic conditions that the patient is either experiencing for the first time, or that have worsened (Block **1451**). A check list is preferably provided via a user interface that allows a patient to indicate the supra-therapeutic symptoms. The CPM makes a determination at Block **1452** whether the supra-therapeutic conditions indicated by the patient are severe and require immediate communication to a healthcare provider. If the answer is "Yes", information about the supra-therapeutic symptoms is communicated immediately to a healthcare provider (Block **1453**) via a communications network. The CPM may also instruct the patient to call his/her healthcare provider immediately, or to call for emergency medical attention (Block **1454**). The CPM may be configured to automatically establish voice communications with a healthcare provider or emergency medical service for the patient.

[0111] If the answer at Block **1452** is "No", the CPM determines whether information about the supra-therapeutic signs or conditions are serious enough to require communication to a healthcare provider after completing the entry or interaction with the CPM; *i.e.*, transmissions will occur as part of this interactive session, as opposed to the preset schedule (Block **1455**). If the answer at Block **1455** is "Yes", the CPM sets a flag to transmit the supra-therapeutic data to a healthcare provider's PAC system immediately following or at the conclusion of this entry or interaction with the CPM (Block **156**). If the answer at Block **1455** is "No", the CPM then prompts the patient to determine whether the patient wishes to talk with a healthcare provider about the signs, conditions or symptoms ("data" or anything else that is of concern) (Block **1457**). If the answer at Block **1457** is "No", operations are returned to Block **1500** (**Fig. 15**). If the answer

at Block **1457** is "Yes", the CPM sets a flag to transmit supra-therapeutic symptom information to a healthcare provider following entry. (Block **1458**). Operations are then returned to Block **1500** (Fig. 15).

[0112] Referring back to Fig. 15, the CPM prompts the patient as to whether the patient has undergone any behavioral or non-medication related changes (Block **1500**). For example, has the patient changed his/her diet and/or intake of vitamins and/or other medications. Behavioral and non-medication related changes include all signs, symptoms, conditions and behavior (changed or otherwise of concern) that could affect a patient's disease state, and which are not directly attributable to too much medication (supra-therapeutic) or too little medication (sub-therapeutic). According to the present invention, behavioral and non-medication related changes may be divided into those that are serious (thus requiring a call to a healthcare provider immediately) and those that bear watching. Behavioral and non-medication related changes that only bear watching may become significant if they are deemed to alter the patient's medication schedule or schedule for transmitting data to a healthcare provider.

[0113] If the answer at Block **1500** is "Yes", the CPM initiates a procedure for assessing the severity of changes in or presence of behavioral factors or other conditions that are not clearly related to supra-therapeutic or sub-therapeutic conditions (Block **1550**).

[0114] Referring to Fig. 18, a procedure for assessing the severity of changes in or presence of behavioral factors or other conditions that are not clearly related to supra-therapeutic or sub-therapeutic conditions (Block **1550**) is illustrated. The CPM prompts the patient to indicate changes in or presence of behavioral factors or other conditions that are not clearly related to supra-therapeutic or sub-therapeutic conditions (Block **1551**). A check list is preferably provided via a user interface. Exemplary check list items may include whether a patient has changed vitamins/medications, whether a patient has changed dosages of vitamins/medications, whether a patient has stopped taking vitamins/medications, whether the patient is eating more or less, and whether the patient is eating different foods.

[0115] The CPM then determines whether the information provided by the patient regarding changes in or presence of behavioral factors or other conditions that are not clearly related to supra-therapeutic or sub-therapeutic conditions requires changing (*e.g.*, accelerating) a testing regimen or an established data transmission schedule (Block **1552**). If the answer is "Yes" the patient's testing and/or data transmission schedules are modified (Block **1553**) by the CPM. Operations return to Block **1554**.

[0116] If the answer at Block **1552** is "No", the CPM determines whether the information provided by the patient regarding changes in or presence of behavioral factors or other conditions that are not clearly related to supra-therapeutic or sub-therapeutic conditions are severe enough to warrant immediate transmission to a healthcare provider (Block **1554**). If the answer is "Yes", the information provided by the patient regarding changes in or presence of behavioral factors or other conditions that are not clearly related to supra-therapeutic or sub-therapeutic conditions is immediately transmitted to a healthcare provider (Block **1555**). The CPM may then establish a call with a healthcare provider for the patient (Block **1556**).

[0117] If the answer at Block **1554** is "No", the CPM sets a flag (*i.e.*, a reminder) to send the information provided by the patient regarding changes in or presence of behavioral factors or other conditions that are not clearly related to supra-therapeutic or sub-therapeutic conditions to a healthcare provider according to a regular data transmission schedule (Block **1557**). Operations are then returned to Block **1600** (Fig. 15).

[0118] Referring back to Fig. 15, the CPM prompts the patient as to whether the patient is experiencing any sub-therapeutic symptoms, signs or conditions (Block **1600**). If the answer is "Yes", the CPM initiates a procedure for assessing the severity of sub-therapeutic conditions (Block **1650**).

[0119] Referring to Fig. 19, a procedure for assessing the severity of sub-therapeutic conditions experienced by a patient (Block **1650**) is illustrated. The CPM prompts the patient to indicate supra-therapeutic signs, conditions or symptoms that the patient is either experiencing for the first time, or that have worsened (Block **1651**). As is known to those of skill in the art, sub-therapeutic conditions related to anticoagulation therapy include non-hemorrhagic signs, symptoms or conditions ("data"), such as fever, vomiting, diarrhea, and the like. A check list is preferably provided via a user interface that allows a patient to indicate sub-therapeutic data.

[0120] The CPM then determines, based on the provided sub-therapeutic symptom information, whether the patient is at arterial risk (*i.e.*, at risk of arterial clot) (Block **1652**). If the answer is "Yes", the CPM prompts the patient to indicate whether he/she is experiencing new signs, symptoms or conditions, such as muscle weakness, slurred speech, chest pains, and blindness or other vision problems (Block **1653**). The CPM then determines, based on the provided information about new signs, symptoms or conditions (data), whether the patient is also at risk for venous conditions (Block **1654**). That is, the CPM determines whether the patient's symptoms or signs may be indicative of a heart attack or stroke. If the answer is "Yes", the CPM prompts the patient to indicate whether he/she is experiencing new venous signs or symptoms such as swollen or hot arms and/or legs, chest pain, and shortness of breath (Block **1655**).

[0121] The CPM then determines whether the patient's health data (venous and/or arterial) require immediate medical attention (Block **1656**). If the answer is "Yes", the CPM prompts the patient to call a healthcare provider or to call for other emergency medical attention (Block **1657**). A CPM may be configured to automatically establish voice communications with a healthcare provider or emergency medical service for the patient. The existence of serious arterial signs,

symptoms or conditions may cause the CPM to inhibit warfarin (and other medication) dosage recommendations until the data have been reviewed by a healthcare provider.

[0122] If at Block **1656** the CPM determines that the patient's data are such that they do not require immediate medical attention, the CPM then determines whether the data should be reviewed as soon as the CPM entry session is complete (CPM has acquired all data) but before medication is actually recommended, or whether the entry can be completed with medication recommended-but with the contents of the entry to be logged and screened immediately following the interactive CPM session (Block **1658**).

[0123] If at Block **1658** the answer is "No", the CPM prompts the patient to determine whether the patient wishes to talk with a healthcare provider about any identified or questionable signs, symptoms or conditions (Block **1659**). If the answer is "No", operations are returned to Block **1700** (Fig. 15). If the answer at Block **1659** is "Yes", the CPM sets a flag to transmit the symptom information to a healthcare provider, either now or at a future time (Block **1660**). Operations are then returned to Block **1700** (Fig. 15).

[0124] Similarly, if the CPM determines at Block **1658** that the patient's conditions is not serious enough to require immediate medical attention (i.e., the answer is "Yes"), the CPM sets a flag to transmit the symptom information to a healthcare provider, either now or at a future time (Block **1660**). Operations are then returned to Block **1700** (Fig. 15).

[0125] Referring back to Fig. 15, the CPM assesses the need for the patient to self-perform PT testing at the present time (Block **1700**). With respect to anticoagulation therapy, a CPM typically will conclude that testing should be performed if a patient has signs or symptoms of bleeding or clotting, or changes in diet or other medications, illness, vomiting, diarrhea, or if the minimum interval between tests has been exceeded. If the CPM determines that testing should be performed, the CPM prompts the patient to perform the PT test and enter the results in the CPM (Block **1750**).

[0126] If the CPM determines that testing need not be performed, the CPM assesses the need to establish a call with a healthcare provider at the present time (Block **1800**). With respect to anticoagulation therapy, a CPM typically will conclude that a call should be placed to a healthcare provider if a patient has bleeding signs or symptoms, clotting signs or symptoms, changes in diet, vitamins or other medications, as well as if the patient shows signs of illness, or has experienced vomiting and/or diarrhea. If the CPM determines that a call should be placed, the CPM is configured to initiate the call and establish voice communications and/or exchange data with the healthcare provider via a communications network (Block **1850**).

[0127] If the answer at Block **1800** is "No", the CPM assesses the need to adjust the patient's medication dosage (e.g., warfarin for anticoagulation therapy) (Block **1900**). If the CPM determines that a patient's medication dosage should be adjusted, an algorithm stored within the CPM is used to modify the medication dosage (Block **1950**). The patient is notified of the medication dosage adjustment and is prompted to administer the medication under the modified dosage (Block **1951**).

[0128] The CPM then determines whether the patient's self-testing (e.g., PT test) schedule should be adjusted based on available patient data or prior self-test results (Block **2000**). If the answer is "Yes", the patient's self-testing schedule is adjusted (Block **2050**). Operations then return to Block **2100**. If the answer at Block **2000** is "No", a determination is made whether a routine data transfer is scheduled (Block **2075**). If the answer is "Yes", patient information is transmitted to a PAC server according to schedule (Block **2100**) as described above.

[0129] As is well known to those having skill in the art, a warfarin adjusting algorithm relies on a target range for PT test results specified by a healthcare provider. At the start of therapy, the desired PT test target range and patient's current weekly and daily warfarin dosage levels are input, along with parameters that specify how changes in warfarin doses are to be calculated. In the absence of serious symptom reports, deviations in PT test results from the patient's specified target range are corrected by a change in warfarin doses, utilizing physician-prescribed adjustment parameters. Small deviations from the target PT range in previously stable patients are corrected by transient or bolus dosage adjustments. Depending upon the magnitude of the total amount of warfarin that must be added or subtracted from the weekly doses, either one- or two-day medication alterations are made. Somewhat larger deviations from the target PT range that are unaccompanied by dangerous symptom reports are corrected by the algorithm using a combination of an immediate change (positive or negative bolus) and a permanent change in the weekly basal dose.

[0130] Changed weekly doses are spread across days according to a dosing schedule that may result in the different doses being taken on even and odd days of the week. This is desirable because patients cannot be expected to have an indefinite number of different warfarin formulations (pill strengths) available, and it is possible because the half-life of the major ingredient in Warfarin that affects PT is 48 to 72 hours. A CPM transparently calculates dosage changes and divides the total weekly basal dose into a recommended daily dose informed by immediately available medications. Warfarin pills may be scored and, thus, may be cut in half if necessary. If new dosing requirements cannot be met with an available supply of warfarin, the CPM instructs the patient to transmit a request for another formulation of warfarin to be prescribed.

[0131] Computer code within a CPM may be configured to prompt a patient to place the device in a dedicated modem cradle and initiate an IP link on both a scheduled and contingent basis. A CPM can utilize secure socket layer (SSL) internet protocols for two-way communication with a data processing system of a healthcare provider or other third party.

A CPM may be uniquely identified during the communications session. Patient home-collected data are automatically uploaded and screened, and any newly available self-monitoring or prescriptive parameters are automatically downloaded to the CPM during the session. Both programmed and personalized messages can also be sent to a patient to enhance compliance with the treatment or self-care regimen.

[0132] A CPM according to the present invention may be utilized within a system utilizing a PAC server as described above. PAC server features that support remote management of insulin therapy are well suited for anticoagulation therapy with warfarin, as well as for a wide range of disease therapies. The PAC specification supports automated voice message delivery that can be used to prompt patients to make appointments, return calls or connect their CPM with a PAC server to obtain an updated warfarin management prescription.

[0133] Patient data uploaded to a PAC server (Block 2100, Fig. 15) can be screened in real-time for serious data (signs, symptoms or conditions) and individualized deviations from specified physiologic levels. Serious data (signs, symptoms or conditions), when detected, can contingently trigger paging of appropriate medical personnel on an as needed basis. Patient problems can be hierarchically prioritized by severity, and can contingently trigger software-initiated alarms for immediate review by healthcare professionals. Problems such as failure to transfer data on schedule and poor compliance with taking or recording prescribed warfarin doses can also be identified. In the absence of problems a PAC server can also schedule semi-automated periodic routine case reviews that document patient progress and can provide supportive feedback delivered using email.

[0134] The foregoing is illustrative of the present invention and is not to be construed as limiting thereof. Although a few exemplary embodiments of this invention have been described, those skilled in the art will readily appreciate that many modifications are possible in the exemplary embodiments without materially departing from the novel teachings and advantages of this invention. Accordingly, all such modifications are intended to be included within the scope of this invention as defined in the claims. Therefore, it is to be understood that the foregoing is illustrative of the present invention and is not to be construed as limited to the specific embodiments disclosed, and that modifications to the disclosed embodiments, as well as other embodiments, are intended to be included within the scope of the appended claims. The invention is defined by the following claims, with equivalents of the claims to be included therein.

Claims

1. A method for monitoring anticoagulation therapy of a patient, wherein the anticoagulation therapy includes a patient-administered medication regimen selected from the group consisting of warfarin and vitamin K antagonists, heparin and glucosaminoglycans, and direct thrombin inhibitors, and a patient-administered regimen for a coagulation test that monitors efficacy of the medication regimen, wherein the coagulation test is selected from the group consisting of prothrombin time (PT) test, partial thromboplastin time (PTT) test, activated clotting time (ACT) test, heparin assays, ecarin clotting time (ECT) test, and thrombin clotting time test, wherein a portable apparatus is configured to receive and analyse information regarding patient compliance with the patient-administered medication and coagulation test regimens, and wherein the apparatus is configured to modify the patient-administered medication and coagulation test regimens, the method comprising the following steps performed by the portable apparatus:

receiving data from a patient, wherein the patient data includes at least one of physiological data, pathophysiological data, biological data, psychological data, neuropsychological data, and behavioural data;
assessing severity of the received patient data;
prompting the patient to perform a patient-administered coagulation test if the received patient data are assessed to be above a threshold severity level;
receiving coagulation test results from the patient-administered test; and
communicating the received coagulation test results from the patient-administered test to a healthcare provider via a communications network.

2. The method according to Claim 1 further comprising the steps of:

assessing severity of the received coagulation test results from the patient-administered coagulation test;
modifying the patient-administered medication regimen if the received coagulation test results from the patient-administered coagulation test are assessed to be above a threshold severity level; and
communicating the modified patient-administered medication regimen to the patient.

3. The method according to Claim 2 further comprising the step of communicating the modified patient-administered medication regimen to a healthcare provider via a communications network.

4. The method according to Claim 2 further comprising the step of communicating the modified patient-administered medication regimen to a remotely located data processing system via a communications network.

5. The method according to Claim 1 further comprising the step of receiving from the patient information about patient compliance with the patient-administered medication and coagulation test regimens during a preceding time period.

6. The method according to Claim 1 further comprising the step of automatically communicating the received patient data to a healthcare provider via a communications network if patient data are assessed to be above a threshold severity level.

7. The method according to Claim 6 wherein the step of automatically communicating the received patient data to a healthcare provider comprises paging the healthcare provider.

8. The method according to Claim 4 further comprising the step of communicating information regarding medication dosage to the patient in response to determining, that the patient did not comply with the medication regimen in the preceding time period.

9. The method according to Claim 1 wherein the received patient data comprises at least one of information about hemorrhagic symptoms experienced by the patient and information about non-hemorrhagic symptoms experienced by the patient.

10. A system for monitoring anticoagulation therapy of a patient, wherein the anticoagulation therapy includes a patient-administered medication regimen selected from the group consisting of warfarin and vitamin K antagonists, heparin and glucosaminoglycans, and direct thrombin inhibitors, and a patient-administered regimen for a coagulation test that monitors efficacy of the medication regimen, wherein the coagulation test is selected from the group consisting of prothrombin time (PT) test, partial thromboplastin time (PTT) test, activated clotting time (ACT) test, heparin assays, ecarin clotting time (ECT) test, and thrombin clotting time test, wherein the system comprises:

a patient apparatus, comprising:

a processor;

a user interface in communication with the processor;

computer code executable by the processor that receives and stores data from a patient, wherein the patient data includes at least one of physiological data, pathophysiological data, biological data, psychological data, neuropsychological data, and behavioural data;

computer code executable by the processor that assesses severity of the received patient data;

computer code executable by the processor that prompts the patient via the user interface to perform a patient-administered coagulation test if the received patient data are assessed to be above a threshold severity level;

computer code executable by the processor that receives and stores coagulation test results from the patient-administered coagulation test; and

computer code executable by the processor that communicates the received coagulation test results from the patient-administered coagulation test to a healthcare provider via a communications network.

11. The system according to claim 10, further comprising:

a remotely located data processing system configured to communicate with and receive data from the patient apparatus, the remotely located data processing system comprising:

computer code that obtains patient data from the patient apparatus;

computer code that analyses the obtained patient data to identify medical conditions of a patient;

computer code that displays identified patient medical conditions for a patient in selectable, prioritised order according to medical severity via a remotely located client in communication with the central data processing system; and

computer code that displays treatment options for treating a selected medical condition for a patient.

12. The system according to Claim 10 wherein the patient apparatus further comprises:

computer code executable by the processor that assesses severity of the received coagulation test results from the patient-administered coagulation test;

computer code executable by the processor that modifies the patient-administered medication regimen if the received coagulation test results from the patient-administered coagulation test are assessed to be above a threshold severity level; and

computer code executable by the processor that communicates the modified patient-administered medication regimen to the patient.

13. The system according to Claim 11 further comprises computer code that communicates treatment information from the remotely located data processing system to the patient apparatus.

14. The system according to Claim 13 wherein the computer code that communicates treatment information from the remotely located data processing system to the patient apparatus comprises computer code that transmits treatment information via wireless, satellite, telephone, e-mail, AVM or facsimile transmission.

15. The system according to Claim 13 wherein the computer code that communicates treatment information from the remotely located data processing system to the patient apparatus comprises computer code that modifies the medication algorithm within the patient apparatus.

16. The system according to Claim 11 wherein the computer code that obtains patient data from the patient apparatus further comprises:

computer code that analyses data transmitted from the patient apparatus substantially simultaneously with the transmission thereof to remotely located data processing system to identify emergency medical conditions requiring immediate medical attention; and

computer code that automatically communicates treatment information to the patient apparatus for an identified emergency medical condition.

17. The system according to Claim 11 wherein the remotely located data processing systems further comprises:

computer code that monitors patient usage of medication; and

computer code that orders medication for a patient from a supplier of medication.

18. The system according to Claim 11 wherein the computer code that displays identified patient medical conditions comprises computer code that displays selected ones of the identified patient medical conditions.

19. The system according to Claim 10 wherein the patient apparatus further comprises computer code that receives information via the user interface about patient compliance with the patient-administered medication regimen and the patient-administered coagulation test regimen during a preceding time period.

20. The system according to Claim 10 wherein the patient apparatus further comprise computer code that communicates information regarding medication dosage to a patient via the user interface in response to determining that a patient did not comply with the patient-administered medication regimen in a preceding time period.

21. The system according to Claim 12' further comprising computer code executable by the processor that communicates the modified patient-administered medication regimen to a healthcare provider via a communications network.

22. The system according to Claim 12 further comprising computer code executable by the processor that communicates the modified patient-administered medication regimen to a remotely located data processing system via a communications network.

23. The system according to Claim 10 further comprising computer code executable by the processor that receives and stores information from a patient about patient compliance with the patient-administered medication and coagulation test regimens during a preceding time period.

24. The system according to Claim 10 further comprising computer code executable by the processor that automatically communicates the received patient data to a healthcare provider via a communications network if patient data are, assessed to be above a threshold severity level.

25. The system according to Claim 24 wherein the computer code that automatically communicates the received patient data to a healthcare provider comprises computer code that sends a paging signal to a healthcare provider.

26. A method for monitoring disease therapy of a patient, wherein the disease is selected from the group consisting of asthma, cancer chemotherapy, depression, high blood pressure, seizure disorders, and thrombosis, wherein the disease therapy includes a patient-administered medication regimen and a patient-administered regimen for a test that monitors efficacy of the medication regimen, wherein a portable apparatus is configured to receive and analyse information regarding patient compliance with the patient-administered medication and test regimens, and wherein the portable apparatus is configured to modify the patient-administered medication and test regimens, the method comprising the following steps performed by the portable apparatus:

receiving data from a patient, wherein the patient data includes at least one of physiological data, pathophysiological data, biological data, psychological data, neuropsychological data, and behavioural data;
 assessing severity of the received patient data;
 prompting the patient to perform a patient-administered test if the received patient data are assessed to be above a threshold severity level;
 receiving test results from the patient-administered test; and
 communicating the received test results from the patient-administered test to a healthcare provider via a communications network.

27. The method according to Claim 26 further comprising the steps of:

assessing severity of the received test results from the patient-administered test;
 modifying the patient-administered medication regimen if the received test results from the patient-administered test are assessed to be above a threshold severity level; and
 communicating the modified patient-administered medication regimen to the patient.

28. The method according to Claim 27 further comprising the step of communicating the modified patient-administered medication regimen to a healthcare provider via a communications network.

29. The method according to Claim 27 further comprising the step of communicating the modified patient-administered medication regimen to a remotely located data processing system via a communications network.

30. The method according to Claim 26 further comprising the step of receiving from the patient information about patient compliance with the patient-administered medication and test regimens during a preceding time period.

31. The method according to Claim 26 further comprising the step of automatically communicating the received patient data to a healthcare provider via a communications network if patient data are assessed to be above a threshold severity level.

32. The method according to Claim 29 further comprising the step of communicating information regarding medication dosage to the patient in response to determining that the patient did not comply with the medication regimen in the preceding time period.

33. The method according to Claim 26 wherein the received patient data further comprises at least one of information about a supra-therapeutic symptom experienced by the patient and information about a sub-therapeutic symptom experienced by the patient.

34. An apparatus for monitoring disease therapy of a patient, wherein the disease is selected from the group consisting of asthma, cancer chemotherapy, depression, high blood pressure, seizure disorders, and thrombosis, wherein the disease therapy includes a patient-administered medication regimen and a patient-administered regimen for a test that monitors efficacy of the medication regimen, the apparatus comprising:

a processor;
 a user interface in communication with the processor;
 computer code executable by the processor that receives and stores data from a patient, wherein the patient data includes at least one of physiological data, pathophysiological data, biological data, psychological data, neuropsychological data, and behavioural data;

computer code executable by the processor that assesses severity of the received patient data;
 computer code executable by the processor that prompts the patient via the user interface to perform a patient-administered test if the received patient data are assessed to be above a threshold severity level;
 computer code executable by the processor that receives and stores test results from the patient-administered test; and
 computer code executable by the processor that communicates the received test results from the patient-administered test to a healthcare provider via a communications network.

35. The apparatus according to Claim 34 further comprising:

computer code executable by the processor that assesses severity of the received test results from the patient-administered test;
 computer code executable by the processor that modifies the patient-administered medication, regimen if the received test results from the patient-administered test are assessed to be above a threshold severity level; and
 computer code executable by the processor that communicates the modified patient-administered medication regimen to the patient.

36. The apparatus according to Claim 35 further comprising computer code executable by the processor that communicates the modified patient-administered medication regimen to a healthcare provider via a communications network.

37. The apparatus according to Claim 35 further comprising computer code executable by the processor that communicates the modified patient-administered medication regimen to a remotely located data processing system via a communications network.

38. The apparatus according to Claim 34 further comprising computer code executable by the processor that receives and stores information provided by the patient about patient compliance with the patient-administered medication and test regimens during preceding time period.

39. The apparatus according to Claim 34 further comprising computer code executable by the processor that automatically communicates the received patient data to a healthcare provider via a communications network if patient data are assessed to be above a threshold severity level.

40. The apparatus according to Claim 37 further comprising computer code executable by the processor that communicates information regarding medication dosage to the patient in response to determining that the patient did not comply with the medication regimen in the preceding time period.

41. A computer program product directly loadable into the internal memory of a digital computer comprising software code portions for performing the steps of Claim 1, and any claim dependent therefrom, when said product is run on a computer.

42. A computer program product directly loadable into the internal memory of a digital computer comprising software code portions for performing the steps of Claim 26, and any claim dependent therefrom, when said product is run on a computer.

Patentansprüche

1. Verfahren zum Überwachen der Antikoagulationstherapie eines Patienten, wobei die Antikoagulationstherapie einen vom Patienten einzuhaltenden Medikamentenplan, ausgewählt aus der Gruppe bestehend aus Warfarin und Vitamin K Antagonisten, Heparin und Glukosaminoglycanen und direkten Thrombininhibitoren, und einen vom Patienten einzuhaltenden Koagulationstestplan beinhaltet, der die Wirksamkeit des Medikamentenplans überwacht, wobei der Koagulationstest ausgewählt ist aus der Gruppe bestehend aus PT-(Prothrombinzeit)-Test, PTT-(partielle Thromboplastinzeit)-Test, ACT-(aktivierte Gerinnungszeit)-Test, Heparin-Assays, ECT-(Ecaringerinnungszeit)-Test und Thrombingerinnungszeit-Test, wobei eine tragbare Vorrichtung so konfiguriert ist, dass sie Informationen über Patienten-Compliance mit den vom Patienten einzuhaltenden Medikamenten- und Koagulationstestplänen empfängt und analysiert, und wobei die Vorrichtung so konfiguriert ist, dass sie die vom Patienten einzuhaltenden Medikamenten- und Koagulationstestpläne verändert, wobei das Verfahren die folgenden von der tragbaren

Vorrichtung ausgeführten Schritte beinhaltet:

Empfangen von Daten von einem Patienten, wobei die Patientendaten physiologische Daten, pathophysiologische Daten, biologische Daten, psychologische Daten, neuropsychologische Daten und/oder Verhaltensdaten beinhalten;
 Beurteilen der Ernsthaftigkeit der empfangenen Patientendaten;
 Auffordern des Patienten, einen vom Patienten durchzuführenden Koagulationstest durchzuführen, wenn die erhaltenen Patientendaten als über einem Ernsthaftigkeitsschwellenwert liegend beurteilt werden;
 Empfangen von Koagulationstestergebnissen des vom Patienten durchzuführenden Tests; und
 Übermitteln der empfangenen Koagulationstestergebnisse des vom Patienten durchzuführenden Tests über ein Kommunikationsnetz an einen Gesundheitsdienstleister.

2. Verfahren nach Anspruch 1, das ferner die folgenden Schritte beinhaltet:

Beurteilen der Ernsthaftigkeit der empfangenen Koagulationstestergebnisse des vom Patienten durchzuführenden Koagulationstests;
 Verändern des vom Patienten einzuhaltenden Medikamentenplans, wenn die empfangenen Koagulationstestergebnisse des vom Patienten durchzuführenden Koagulationstests als über einem Ernsthaftigkeitsschwellenwert liegend beurteilt werden; und
 Übermitteln des veränderten vom Patienten einzuhaltenden Medikamentenplans an den Patienten.

3. Verfahren nach Anspruch 2, das ferner den Schritt des Übermittels des veränderten vom Patienten einzuhaltenden Medikamentenplans über ein Kommunikationsnetz an einen Gesundheitsdienstleister beinhaltet.

4. Verfahren nach Anspruch 2, das ferner den Schritt des Übermittels des veränderten vom Patienten einzuhaltenden Medikamentenplans über ein Kommunikationsnetz an ein ortsfern befindliches Datenverarbeitungssystem beinhaltet.

5. Verfahren nach Anspruch 1, das ferner den Schritt des Empfangens von Informationen von dem Patienten über Patienten-Compliance mit den vom Patienten einzuhaltenden Medikamenten- und Koagulationstestplänen während einer vorangegangenen Zeitperiode beinhaltet.

6. Verfahren nach Anspruch 1, das ferner den Schritt des automatischen Übermittels der empfangenen Patientendaten über ein Kommunikationsnetz an einen Gesundheitsdienstleister beinhaltet, wenn Patientendaten als über einem Ernsthaftigkeitsschwellenwert liegend beurteilt werden.

7. Verfahren nach Anspruch 6, wobei der Schritt des automatischen Übermittels der empfangenen Patientendaten an einen Gesundheitsdienstleister einen Funkruf an den Gesundheitsdienstleister beinhaltet.

8. Verfahren nach Anspruch 4, das ferner den Schritt des Übermittels von Informationen über Medikamentendosierung an den Patienten als Reaktion auf die Feststellung beinhaltet, dass der Patient den Medikamentenplan in der vorangegangenen Zeitperiode nicht eingehalten hat.

9. Verfahren nach Anspruch 1, wobei die empfangenen Patientendaten Informationen über vom Patienten erfahrene hämorrhagische Symptome und/oder Informationen über vom Patienten erfahrene nicht-hämorrhagische Symptome beinhalten.

10. System zum Überwachen der Antikoagulationstherapie eines Patienten, wobei die Antikoagulationstherapie einen vom Patienten einzuhaltenden Medikamentenplan, ausgewählt aus der Gruppe bestehend aus Warfarin und Vitamin K Antagonisten, Heparin und Glukosaminoglycanen und direkten Thrombininhibitoren, und einen vom Patienten einzuhaltenden Koagulationstestplan beinhaltet, der die Wirksamkeit des Medikamentenplans überwacht, wobei der Koagulationstest ausgewählt ist aus der Gruppe bestehend aus PT-(Prothrombinzeit)-Test, PTT-(partielle Thromboplastinzeit)-Test, ACT-(aktivierte Gerinnungszeit)-Test, Heparin-Assays, ECT-(Ecaringerinnungszeit)-Test und Thrombingerinnungszeit-Test, wobei das System Folgendes umfasst:

eine Patientenvorrichtung, die Folgendes umfasst:

einen Prozessor;

eine Benutzeroberfläche in Verbindung mit dem Prozessor;

Computercode, der vom Prozessor ausgeführt werden kann, der Daten von einem Patienten empfängt und speichert, wobei die Patientendaten physiologische Daten, pathophysiologische Daten, biologische Daten, psychologische Daten, neuropsychologische Daten und/oder Verhaltensdaten beinhalten;

Computercode, der vom Prozessor ausgeführt werden kann, der die Ernsthaftigkeit der empfangenen Patientendaten beurteilt;

Computercode, der vom Prozessor ausgeführt werden kann, der den Patienten über die Benutzeroberfläche auffordert, einen vom Patienten durchzuführenden Koagulationstest durchzuführen, wenn die empfangenen Patientendaten als über einem Ernsthaftigkeitsschwellenwert liegend beurteilt werden;

Computercode, der vom Prozessor ausgeführt werden kann, der Koagulationstestergebnisse des vom Patienten durchzuführenden Koagulationstests empfängt und speichert; und

Computercode, der vom Prozessor ausgeführt werden kann, der die empfangenen Koagulationstestergebnisse des vom Patienten durchzuführenden Koagulationstests über ein Kommunikationsnetz an einen Gesundheitsdienstleister übermittelt.

11. System nach Anspruch 10, das ferner Folgendes umfasst:

ein ortsfern befindliches Datenverarbeitungssystem, das so konfiguriert ist, dass es mit der Patientenvorrichtung kommuniziert und Daten von ihr empfängt, wobei das ortsfern befindliche Datenverarbeitungssystem Folgendes umfasst:

Computercode, der Patientendaten von der Patientenvorrichtung einholt;

Computercode, der die eingeholten Patientendaten analysiert, um medizinische Zustände eines Patienten zu identifizieren;

Computercode, der identifizierte medizinische Patientenzustände für einen Patienten in einer wählbaren Prioritätsfolge nach medizinischer Ernsthaftigkeit über einen ortsfern befindlichen Client anzeigt, der mit dem zentralen Datenverarbeitungssystem in Kommunikation ist; und

Computercode, der Behandlungsoptionen zum Behandeln eines gewählten medizinischen Zustands für einen Patienten anzeigt.

12. System nach Anspruch 10, wobei die Patientenvorrichtung ferner Folgendes umfasst:

Computercode, der vom Prozessor ausgeführt werden kann, der die Ernsthaftigkeit der empfangenen Koagulationstestergebnisse des vom Patienten durchzuführenden Koagulationstests beurteilt;

Computercode, der vom Prozessor ausgeführt werden kann, der den vom Patienten einzuhaltenden Medikamentenplan verändert, wenn die empfangenen Koagulationstestergebnisse des vom Patienten durchzuführenden Koagulationstests als über einem Ernsthaftigkeitsschwellenwert liegend beurteilt werden; und

Computercode, der vom Prozessor ausgeführt werden kann, der dem Patienten den veränderten vom Patienten einzuhaltenden Medikamentenplan übermittelt.

13. System nach Anspruch 11, das ferner Computercode umfasst, der Behandlungsinformationen von dem ortsfern befindlichen Datenverarbeitungssystem an die Patientenvorrichtung übermittelt.

14. System nach Anspruch 13, wobei der Computercode, der Behandlungsinformationen von dem ortsfern befindlichen Datenverarbeitungssystem an die Patientenvorrichtung übermittelt, Computercode umfasst, der Behandlungsinformationen per Funk, Satellit, Telefon, Email, AVM oder Telefax überträgt.

15. System nach Anspruch 13, wobei der Computercode, der Behandlungsinformationen von dem ortsfern befindlichen Datenverarbeitungssystem an die Patientenvorrichtung übermittelt, Computercode umfasst, der den Medikationsalgorithmus in der Patientenvorrichtung verändert.

16. System nach Anspruch 11, wobei der Computercode, der Patientendaten von der Patientenvorrichtung einholt, ferner Folgendes umfasst:

Computercode, der von der Patientenvorrichtung übertragene Daten im Wesentlichen gleichzeitig mit deren Übertragung zu dem ortsfern befindlichen Datenverarbeitungssystem analysiert, um medizinische Notfallzustände zu identifizieren, die sofortiger medizinischer Aufmerksamkeit bedürfen; und

Computercode, der automatisch Behandlungsinformationen für einen identifizierten medizinischen Notfallzustand an die Patientenvorrichtung übermittelt.

17. System nach Anspruch 11, wobei die ortsfern befindlichen Datenverarbeitungssysteme ferner Folgendes umfassen:

Computercode, der den Patientengebrauch der Medikamente überwacht; und
Computercode, der Medikamente für einen Patienten bei einem Medikamentenvertrieb bestellt.

18. System nach Anspruch 11, wobei der Computercode, der identifizierte medizinische Patientenzustände anzeigt, Computercode umfasst, der ausgewählte der identifizierten medizinischen Patientenzustände anzeigt.

19. System nach Anspruch 10, wobei die Patientenvorrichtung ferner Computercode umfasst, der Informationen über die Benutzeroberfläche über Patienten-Compliance mit dem vom Patienten einzuhaltenden Medikamentenplan und dem vom Patienten einzuhaltenden Koagulationstestplan während einer vorangegangenen Zeitperiode empfängt.

20. System nach Anspruch 10, wobei die Patientenvorrichtung ferner Computercode umfasst, der Informationen über die Medikamentendosierung über die Benutzeroberfläche an einen Patienten als Reaktion auf die Feststellung übermittelt, dass ein Patient den vom Patienten einzuhaltenden Medikamentenplan in einer vorangegangenen Zeitperiode nicht eingehalten hat.

21. System nach Anspruch 12, das ferner Computercode umfasst, der vom Prozessor ausgeführt werden kann, der den veränderten, vom Patienten einzuhaltenden Medikamentenplan über ein Kommunikationsnetz an einen Gesundheitsdienstleister übermittelt.

22. System nach Anspruch 12, das ferner Computercode umfasst, der vom Prozessor ausgeführt werden kann, der den veränderten, vom Patienten einzuhaltenden Medikamentenplan über ein Computernetz an ein ortsfern befindliches Datenverarbeitungssystem übermittelt.

23. System nach Anspruch 10, das ferner Computercode umfasst, der vom Prozessor ausgeführt werden kann, der Informationen von einem Patienten über Patienten-Compliance mit den vom Patienten einzuhaltenden Medikamenten- und Koagulationstestplänen während einer vorangegangenen Zeitperiode empfängt und speichert.

24. System nach Anspruch 10, das ferner Computercode umfasst, der vom Prozessor ausgeführt werden kann, der die empfangenen Patientendaten automatisch über ein Kommunikationsnetz an einen Gesundheitsdienstleister übermittelt, wenn Patientendaten als über einem Ernsthaftigkeitsschwellenwert liegend beurteilt werden.

25. System nach Anspruch 24, wobei der Computercode, der die empfangenen Patientendaten automatisch an einen Gesundheitsdienstleister übermittelt, Computercode umfasst, der ein Funkrufsignal an einen Gesundheitsdienstleister sendet.

26. Verfahren zur Überwachung einer Krankheitstherapie eines Patienten, wobei die Krankheit ausgewählt ist aus der Gruppe bestehend aus Asthma, Krebschemotherapie, Depression, Bluthochdruck, Anfallekrankungen und Thrombose, wobei die Krankheitstherapie einen vom Patienten einzuhaltenden Medikamentenplan und einen vom Patienten einzuhaltenden Testplan beinhaltet, der die Wirksamkeit des Medikamentenplans überwacht, wobei eine tragbare Vorrichtung zum Empfangen und Analysieren von Informationen über Patienten-Compliance mit den vom Patienten einzuhaltenden Medikamenten- und Testplänen konfiguriert ist und wobei die tragbare Vorrichtung zum Verändern der vom Patienten einzuhaltenden Medikamenten- und Testpläne konfiguriert ist, wobei das Verfahren die folgenden von der tragbaren Vorrichtung ausgeführten Schritte beinhaltet:

Empfangen von Daten von einem Patienten, wobei die Patientendaten physiologische Daten, pathophysiologische Daten, biologische Daten, psychologische Daten, neuropsychologische Daten und/oder Verhaltensdaten beinhalten;
Beurteilen der Ernsthaftigkeit der empfangenen Patientendaten;
Auffordern des Patienten, einen vom Patienten durchzuführenden Test durchzuführen, wenn die empfangenen Patientendaten als über einem Ernsthaftigkeitsschwellenwert liegend beurteilt werden;
Empfangen von Testergebnissen des vom Patienten durchzuführenden Tests; und
Übermitteln der empfangenen Testergebnisse des vom Patienten durchzuführenden Tests über ein Kommunikationsnetz an einen Gesundheitsdienstleister.

27. Verfahren nach Anspruch 26, das ferner die folgenden Schritte beinhaltet:

Beurteilen der Ernsthaftigkeit der empfangenen Testergebnisse des vom Patienten durchzuführenden Tests;
Verändern des vom Patienten einzuhaltenden Medikamentenplans, wenn die empfangenen Testergebnisse
des vom Patienten durchzuführenden Tests als über einem Ernsthaftigkeitsschwellenwert liegend beurteilt wer-
den; und
Übermitteln des veränderten, vom Patienten einzuhaltenden Medikamentenplans an den Patienten.

28. Verfahren nach Anspruch 27, das ferner den Schritt des Übermittels des veränderten, vom Patienten einzuhalten-
den Medikamentenplans über ein Kommunikationsnetz an einen Gesundheitsdienstleister beinhaltet.

29. Verfahren nach Anspruch 27, das ferner den Schritt des Übermittels des veränderten, vom Patienten einzuhalten-
den Medikamentenplans über ein Kommunikationsnetz an ein ortsfern befindliches Datenverarbeitungssystem be-
inhaltet.

30. Verfahren nach Anspruch 26, das ferner den Schritt des Empfangens von Informationen vom Patienten über die
Patienten-Compliance mit den vom Patienten einzuhaltenden Medikamenten- und Testplänen während einer vor-
angegangenen Zeitperiode beinhaltet.

31. Verfahren nach Anspruch 26, das ferner den Schritt des automatischen Übermittels der empfangenen Patienten-
daten über ein Kommunikationsnetz an einen Gesundheitsdienstleister beinhaltet, wenn Patientendaten als über
einem Ernsthaftigkeitsschwellenwert liegend beurteilt werden.

32. Verfahren nach Anspruch 29, das ferner den Schritt des Übermittels von Informationen über Medikamentendosie-
rung an den Patienten als Reaktion auf die Feststellung beinhaltet, dass der Patient den Medikamentenplan in der
vorangegangenen Zeitperiode nicht eingehalten hat.

33. Verfahren nach Anspruch 26, wobei die empfangenen Patientendaten ferner Informationen über ein vom Patienten
erfahrenes supertherapeutisches Symptom und/oder Informationen über ein vom Patienten erfahrenes subthera-
peutisches Symptom beinhalten.

34. Vorrichtung zum Überwachen der Krankheitstherapie eines Patienten, wobei die Krankheit ausgewählt ist aus der
Gruppe bestehend aus Asthma, Krebschemotherapie, Depression, Bluthochdruck, Anfallekrankungen und Throm-
bose, wobei die Krankheitstherapie einen vom Patienten einzuhaltenden Medikamentenplan und einen vom Pati-
enten einzuhaltenden Testplan beinhaltet, der die Wirksamkeit des Medikamentenplans überwacht, wobei die Vor-
richtung Folgendes umfasst:

einen Prozessor;
eine Benutzeroberfläche in Verbindung mit dem Prozessor;
Computercode, der vom Prozessor ausgeführt werden kann, der Daten von einem Patienten empfängt und
speichert, wobei die Patientendaten physiologische Daten, pathophysiologische Daten, biologische Daten, psy-
chologische Daten, neuropsychologische Daten und/oder Verhaltensdaten beinhalten;
Computercode, der vom Prozessor ausgeführt werden kann, der die Ernsthaftigkeit der empfangenen Patien-
tendaten beurteilt;
Computercode, der vom Prozessor ausgeführt werden kann, der den Patienten über die Benutzeroberfläche
auffordert, einen vom Patienten durchzuführenden Test durchzuführen, wenn die empfangenen Patientendaten
als über einem Ernsthaftigkeitsschwellenwert liegend beurteilt werden;
Computercode, der vom Prozessor ausgeführt werden kann, der Testergebnisse über den vom Patienten durch-
zuführenden Test empfängt und speichert; und
Computercode, der vom Prozessor ausgeführt werden kann, der die empfangenen Testergebnisse des vom
Patienten durchzuführenden Tests über ein Kommunikationsnetz an einen Gesundheitsleister übermittelt.

35. Vorrichtung nach Anspruch 34, die ferner Folgendes umfasst:

Computercode, der vom Prozessor ausgeführt werden kann, der die Ernsthaftigkeit der empfangenen Tester-
gebnisse des vom Patienten durchzuführenden Tests beurteilt;
Computercode, der vom Prozessor ausgeführt werden kann, der den vom Patienten einzuhaltenden Medika-
mentenplan verändert, wenn die empfangenen Testergebnisse des vom Patienten durchzuführenden Tests als

über einem Ernsthaftigkeitsschwellenwert liegend beurteilt werden; und
Computercode, der vom Prozessor ausgeführt werden kann, der den veränderten vom Patienten einzuhaltenden
Medikamentenplan an den Patienten übermittelt.

- 5 36. Vorrichtung nach Anspruch 35, die ferner Computercode umfasst, der vom Prozessor ausgeführt werden kann, der
den veränderten vom Patienten einzuhaltenden Medikamentenplan über ein Kommunikationsnetz an einen Ge-
sundheitsdienstleister übermittelt.
- 10 37. Vorrichtung nach Anspruch 35, die ferner Computercode umfasst, der vom Prozessor ausgeführt werden kann, der
den veränderten vom Patienten einzuhaltenden Medikamentenplan über ein Kommunikationsnetz an ein ortsfern
befindliches Datenverarbeitungssystem übermittelt.
- 15 38. Vorrichtung nach Anspruch 34, die ferner Computercode umfasst, der vom Prozessor ausgeführt werden kann, der
vom Patienten gegebene Informationen über Patienten-Compliance mit den vom Patienten einzuhaltenden Medi-
kamenten- und Testplänen während der vorangegangenen Zeitperiode empfängt und speichert.
- 20 39. Vorrichtung nach Anspruch 34, die ferner Computercode umfasst, der vom Prozessor ausgeführt werden kann, der
die empfangenen Patientendaten automatisch über ein Kommunikationsnetz an einen Gesundheitsdienstleister
übermittelt, wenn Patientendaten als über einem Ernsthaftigkeitsschwellenwert liegend beurteilt werden.
- 25 40. Vorrichtung nach Anspruch 37, die ferner Computercode umfasst, der vom Prozessor ausgeführt werden kann, der
Informationen über Medikamentendosierung an den Patienten als Reaktion auf die Feststellung übermittelt, dass
der Patient den Medikamentenplan in der vorangegangenen Zeitperiode nicht eingehalten hat.
- 30 41. Computerprogrammprodukt, das direkt in den internen Speicher eines digitalen Computers geladen werden kann,
umfassend Softwarecode-Teile zum Ausführen der Schritte von Anspruch 1 und den davon abhängigen Ansprüchen,
wenn das genannte Produkt auf einem Computer abgearbeitet wird.
42. Computerprogrammprodukt, das direkt in den internen Speicher eines digitalen Computers geladen werden kann,
umfassend Softwarecode-Teile zum Ausführen der Schritte von Anspruch 26 und den davon abhängigen Ansprü-
chen, wenn das genannte Produkt auf einem Computer abgearbeitet wird.

Revendications

- 35 1. Procédé pour surveiller la thérapie anticoagulante d'un patient, cette thérapie anticoagulante comprenant un régime
de médicaments administré par le patient sélectionné parmi le groupe comprenant la warfarine et les antagonistes
de la vitamine K, l'héparine et les glucosaminoglycanes, et les inhibiteurs directs de la thrombine, et un régime
administré par le patient pour un test de coagulation qui surveille l'efficacité du régime de médicaments, ce test de
40 coagulation étant sélectionné parmi le groupe comprenant le test de Quick (PT), le test de temps de thromboplastine
partielle (PTT), le test de temps de coagulation activé (ACT), les dosages d'héparine, le test de temps de coagulation
à l'écarine (ECT), le test de temps de coagulation à la thrombine, dans lequel un appareil portatif est configuré de
façon à recevoir et à analyser des informations concernant l'observance du patient des régimes de médicaments
et de test de coagulation administrés par le patient, et dans lequel l' appareil est configuré de façon à modifier les
45 régimes de médicaments et de test de coagulation administrés par le patient, ce procédé comprenant les étapes
suivantes exécutées par l'appareil portatif :

la réception de données provenant d'un patient, ces données du patient comprenant au moins un des types
de données suivants : données physiologiques, données pathophysiologiques, données biologiques, données
50 psychologiques, données neuropsychologiques, données du comportement ;
l'évaluation de la sévérité des données du patient reçues ;
l'incitation du patient à exécuter un test de coagulation administré par le patient si les données du patient reçues
sont évaluées comme étant au-dessus d'un niveau seuil de sévérité ;
la réception des résultats de test provenant du test administré par le patient ; et
55 la communication des résultats de test de coagulation reçus provenant du test administré par le patient à un
fournisseur de soins de santé via un réseau de communication.
2. Procédé selon la revendication 1, comprenant en outre les étapes consistant à :

évaluer la sévérité des résultats de test de coagulation reçus provenant du test de coagulation administré par le patient ;
 modifier le régime de médicaments administré par le patient si les résultats de test de coagulation reçus provenant du test de coagulation administré par le patient sont évalués comme étant au-dessus d'un niveau de seuil de sévérité ; et à
 communiquer au patient le régime modifié de médicaments administré par le patient.

3. Procédé selon la revendication 2, comprenant en outre l'étape consistant à communiquer le régime modifié de médicaments administré par le patient à un fournisseur de soins de santé via un réseau de communication.

4. Procédé selon la revendication 2, comprenant en outre l'étape consistant à communiquer le régime modifié de médicaments administré par le patient à un système de traitement des données situé à distance via un réseau de communication.

5. Procédé selon la revendication 1, comprenant en outre l'étape consistant à recevoir du patient des informations sur l'observance du patient des régimes de médicaments et de test de coagulation administrés par le patient pendant une période de temps précédente.

6. Procédé selon la revendication 1, comprenant en outre l'étape consistant à communiquer automatiquement les données du patient reçues à un fournisseur de soins de santé via un réseau de communication si les données du patient sont évaluées comme étant au-dessus d'un niveau seuil de sévérité.

7. Procédé selon la revendication 6, dans lequel l'étape consistant à communiquer automatiquement les données du patient reçues à un fournisseur de soins de santé comprend le téléavertissement du fournisseur de soins de santé.

8. Procédé selon la revendication 4, comprenant en outre l'étape consistant à communiquer au patient des informations concernant le dosage des médicaments en réponse à la détermination que le patient n'a pas observé le régime de médicaments pendant la période de temps précédente.

9. Procédé selon la revendication 1, dans lequel les données du patient reçues comprennent au moins soit des informations sur les symptômes hémorragiques ressentis par le patient, soit des informations sur les symptômes non hémorragiques ressentis par le patient.

10. Système pour surveiller la thérapie anticoagulante d'un patient, cette thérapie anticoagulante comprenant un régime de médicaments administré par le patient sélectionné parmi le groupe comprenant la warfarine et les antagonistes de la vitamine K, l'héparine et les glucosaminoglycanes, et les inhibiteurs directs de la thrombine, et un régime administré par le patient pour un test de coagulation qui surveille l'efficacité du régime de médicaments, ce test de coagulation étant sélectionné parmi le groupe comprenant le test de Quick (PT), le test de temps de thromboplastine partielle (PTT), le test de temps de coagulation activé (ACT), les dosages d'héparine, le test de temps de coagulation à l'écarine (ECT), le test de temps de coagulation à la thrombine, ce système comprenant :

un appareil de patient, comprenant :

un processeur ;

une interface utilisateur en communication avec ce processeur ;

un code machine exécutable par le processeur, qui reçoit et stocke les données provenant d'un patient, ces données du patient comprenant au moins un des types de données suivants : données physiologiques, données pathophysiologiques, données biologiques, données psychologiques, données neuropsychologiques, données du comportement ;

un code machine exécutable par le processeur qui évalue la sévérité des données du patient reçues ;

un code machine exécutable par le processeur qui incite le patient, via l'interface utilisateur, à exécuter un test de coagulation administré par le patient si les données du patient reçues sont évaluées comme étant au-dessus d'un niveau seuil de sévérité ;

un code machine exécutable par le processeur, qui reçoit et stocke les résultats de test de coagulation provenant du test de coagulation administré par le patient ; et

un code machine exécutable par le processeur qui communique les résultats de test de coagulation reçus provenant du test de coagulation administré par le patient à un fournisseur de soins de santé via un réseau de

communication.

11. Système selon la revendication 10, comprenant en outre :

- 5 un système de traitement des données situé à distance configuré de façon à communiquer avec l'appareil du patient et à recevoir des données de celui-ci, ce système de traitement des données situé à distance comprenant :
- 10 un code machine qui obtient les données du patient à partir de l'appareil du patient ;
un code machine qui analyse les données du patient obtenues afin d'identifier des troubles médicaux d'un patient ;
un code machine qui affiche des troubles médicaux du patient identifiés pour un patient dans un ordre de priorité sélectionnable selon la sévérité médicale via un client situé à distance en communication avec le système central de traitement des données ; et
- 15 un code machine qui affiche les options de traitement pour traiter un trouble médical sélectionné pour un patient.

12. Système selon la revendication 10, dans lequel l'appareil du patient comprend en outre :

- 20 un code machine exécutable par le processeur, qui évalue les résultats de test de coagulation provenant de l'essai de coagulation administré par le patient ;
un code machine exécutable par le processeur qui modifie le régime de médicaments administré par le patient si les résultats de test de coagulation reçus provenant du test de coagulation administré par le patient sont évalués comme étant au-dessus d'un niveau seuil de sévérité ; et
- 25 un code machine exécutable par le processeur qui communique au patient le régime modifié de médicaments administré par le patient.

13. Système selon la revendication 11, comprenant en outre un code machine qui communique à l'appareil du patient les informations de traitement provenant du système de traitement des données situé à distance.

- 30 **14. Système selon la revendication 13, dans lequel le code machine qui communique à l'appareil du patient les informations de traitement provenant du système de traitement des données situé à distance comprend un code machine qui transmet les informations de traitement par transmission sans fil, par satellite, par téléphone, par courrier électronique, par messagerie vocale automatisée ou par télécopie.**

- 35 **15. Système selon la revendication 13, dans lequel le code machine qui communique à l'appareil du patient les informations de traitement provenant du système de traitement des données situé à distance comprend un code machine qui modifie l'algorithme de médication à l'intérieur de l'appareil du patient.**

- 40 **16. Système selon la revendication 11, dans lequel le code machine qui obtient les données du patient à partir de l'appareil du patient comprend en outre ;**
un code machine qui analyse les données transmises à partir de l'appareil du patient essentiellement simultanément à la transmission de celles-ci au système de traitement des données situé à distance afin d'identifier des troubles médicaux d'urgence nécessitant des soins médicaux immédiats ; et
- 45 un code machine qui communique automatiquement les informations de traitement à l'appareil du patient pour un trouble médical d'urgence identifié.

17. Système selon la revendication 11, dans lequel le système de traitement des données situé à distance comprend en outre :

- 50 un code machine qui surveille l'emploi des médicaments par le patient ; et
un code machine qui commande des médicaments pour un patient auprès d'un fournisseur de médicaments.

- 55 **18. Système selon la revendication 11, dans lequel le code machine qui affiche les troubles médicaux du patient identifiés comprend un code machine qui affiche des troubles sélectionnés des troubles médicaux du patient identifiés.**

19. Système selon la revendication 10, dans lequel l'appareil du patient comprend en outre un code machine qui reçoit des informations via l'interface utilisateur à propos de l'observance du patient du régime de médicaments administré

par le patient et du régime de test de coagulation administré par le patient pendant une période de temps précédente.

20. Système selon la revendication 10, dans lequel l'appareil du patient comprend en outre un code machine qui communique des informations concernant le dosage des médicaments à un patient via l'interface utilisateur en réponse à la détermination qu'un patient n'a pas observé le régime de médicaments administré par le patient pendant une période de temps précédente.

21. Système selon la revendication 12, comprenant en outre un code machine exécutable par le processeur qui communique le régime modifié de médicaments administré par le patient à un fournisseur de soins de santé via un réseau de communication.

22. Système selon la revendication 12, comprenant en outre un code machine exécutable par le processeur qui communique le régime modifié de médicaments administré par le patient à un système de traitement des données situé à distance via un réseau de communication.

23. Système selon la revendication 10, comprenant en outre un code machine exécutable par le processeur qui reçoit et stocke des informations provenant d'un patient sur l'observance du patient des régimes de médicaments et de test de coagulation administrés par le patient pendant une période de temps précédente.

24. Système selon la revendication 10, comprenant un code machine exécutable par le processeur qui communique automatiquement les données du patient reçues à un fournisseur de soins de santé via un réseau de communication si les données du patient sont évaluées comme étant au-dessus d'un niveau seuil de sévérité.

25. Système selon la revendication 24, dans lequel le code machine qui communique automatiquement les données du patient reçues à un fournisseur de soins de santé comprend un code machine qui envoie un signal de téléavertissement à un fournisseur de soins de santé.

26. Procédé pour surveiller le traitement de la maladie d'un patient, cette maladie étant sélectionnée parmi le groupe comprenant l'asthme, la chimiothérapie anticancéreuse, la dépression, l'hypertension artérielle, les troubles épileptiques et la thrombose, le traitement de la maladie comprenant un régime de médicaments administré par le patient et un régime administré par le patient pour un test qui surveille l'efficacité du régime de médicaments, dans lequel un appareil portatif est configuré de façon à recevoir et à analyser des informations concernant l'observance par le patient des régimes de médicaments et de test administrés par le patient, et dans lequel l'appareil portatif est configuré de façon à modifier les régimes de médicaments et de test administrés par le patient, ce procédé comprenant les étapes suivantes exécutées par l'appareil portatif :

la réception de données provenant d'un patient, ces données du patient comprenant au moins un des types de données suivants : données physiologiques, données pathophysiologiques, données biologiques, données psychologiques, données neuropsychologiques, données du comportement ;
l'évaluation de la sévérité des données du patient reçues ;
l'incitation du patient à exécuter un test administré par le patient si les données du patient reçues sont évaluées comme étant au-dessus d'un niveau seuil de sévérité ;
la réception des résultats de test provenant du test administré par le patient ; et
la communication des résultats de test reçus provenant du test administré par le patient à un fournisseur de soins de santé via un réseau de communication.

27. Procédé selon la revendication 26, comprenant en outre les étapes consistant à:

évaluer la sévérité des résultats de test reçus provenant du test administré par le patient ;
modifier le régime de médicaments administré par le patient si les résultats de test reçus provenant du test administré par le patient sont évalués comme étant au-dessus d'un niveau seuil de sévérité ; et à
communiquer au patient le régime modifié de médicaments administré par le patient.

28. Procédé selon la revendication 27, comprenant en outre l'étape consistant à communiquer le régime modifié de médicaments administré par le patient à un fournisseur de soins de santé via un réseau de communication.

29. Procédé selon la revendication 27, comprenant en outre l'étape consistant à communiquer le régime modifié de médicaments administré par le patient à un système de traitement des données situé à distance, via un réseau de

communications.

- 5 30. Procédé selon la revendication 26, comprenant en outre l'étape consistant à recevoir du patient des informations sur l'observance du patient des régimes de médicaments et de test administrés par le patient pendant une période de temps précédente.
- 10 31. Procédé selon la revendication 26, comprenant en outre l'étape consistant à communiquer automatiquement les données du patient reçues à un fournisseur de soins de santé via un réseau de communication si les données du patient sont évaluées comme étant au-dessus d'un niveau seuil de sévérité.
- 15 32. Procédé selon la revendication 29, comprenant en outre l'étape consistant à communiquer au patient des informations concernant le dosage des médicaments en réponse à la détermination que le patient n'a pas observé le régime de médicaments pendant la période de temps précédente.
- 20 33. Procédé selon la revendication 26, dans lequel les données du patient reçues comprennent en outre au moins soit des informations sur un symptôme supra-thérapeutique ressenti par le patient, soit des informations sur un symptôme sub-thérapeutique ressenti par le patient.
- 25 34. Appareil pour surveiller le traitement de la maladie d'un patient, cette maladie étant sélectionnée parmi le groupe comprenant l'asthme, la chimiothérapie anticancéreuse, la dépression, l'hypertension artérielle, les troubles épileptiques et la thrombose, le traitement de la maladie comprenant un régime de médicaments administré par le patient et un régime administré par le patient pour un test qui surveille l'efficacité du régime de médicaments, cet appareil comprenant
un processeur ;
une interface utilisateur en communication avec ce processeur ;
un code machine exécutable par le processeur, qui reçoit et stocke les données provenant d'un patient, ces données du patient comprenant au moins un des types de données suivants : données physiologiques, données pathophysiologiques, données biologiques, données psychologiques, données neuropsychologiques, données du comportement ;
un code machine exécutable par le processeur qui évalue la sévérité des données du patient reçues ;
un code machine exécutable par le processeur qui incite le patient, via l'interface utilisateur, à exécuter un test administré par le patient si les données du patient reçues sont évaluées comme étant au-dessus d'un niveau seuil de sévérité ;
un code machine exécutable par le processeur, qui reçoit et stocke les résultats de test provenant du test administré par le patient ; et
un code machine exécutable par le processeur qui communique les résultats de test reçus provenant du test administré par le patient à un fournisseur de soins de santé via un réseau de communication.
- 35 35. Appareil selon la revendication 34, comprenant en outre :
un code machine exécutable par le processeur, qui évalue la sévérité des résultats de test reçus provenant du test administré par le patient ;
un code machine exécutable par le processeur qui modifie le régime de médicaments administré par le patient si les résultats de test reçus provenant du test administré par le patient sont évalués comme étant au-dessus d'un niveau seuil de sévérité ; et
un code machine exécutable par le processeur qui communique au patient le régime modifié de médicaments administré par le patient.
- 40 36. Appareil selon la revendication 35, comprenant en outre un code machine exécutable par le processeur qui communique le régime modifié de médicaments administré par le patient à un fournisseur de soins de santé via un réseau de communication.
- 45 37. Appareil selon la revendication 35, comprenant en outre un code machine exécutable par le processeur qui communique le régime modifié de médicaments administré par le patient à un système de traitement des données situé à distance via un réseau de communication.
- 50 38. Appareil selon la revendication 34, comprenant en outre un code machine exécutable par le processeur qui reçoit et stocke des informations fournies par le patient sur l'observance du patient des régimes de médicaments et de

test administrés par le patient pendant une période de temps précédente.

5 **39.** Appareil selon la revendication 34, comprenant en outre un code machine exécutable par le processeur qui communique automatiquement les données du patient reçues à un fournisseur de soins de santé via un réseau de communication si les données du patient sont évaluées comme étant au-dessus d'un niveau seuil de sévérité.

10 **40.** Appareil selon la revendication 37, comprenant en outre un code machine exécutable par le processeur qui communique au patient des informations concernant le dosage des médicaments en réponse à la détermination que le patient n'a pas observé le régime de médicaments pendant la période de temps précédente.

41. Produit programme informatique pouvant être chargé directement dans la mémoire interne d'un calculateur numérique comprenant des parties de code de logiciel pour exécuter les étapes de la revendication 1, et de toute revendication dépendante de celle-ci, lorsque ledit produit tourne sur un ordinateur.

15 **42.** Produit programme informatique pouvant être chargé directement dans la mémoire interne d'un calculateur numérique comprenant des parties de code de logiciel pour exécuter les étapes de la revendication 26, et de toute revendication dépendante de celle-ci, lorsque ledit produit tourne sur un ordinateur.

20

25

30

35

40

45

50

55

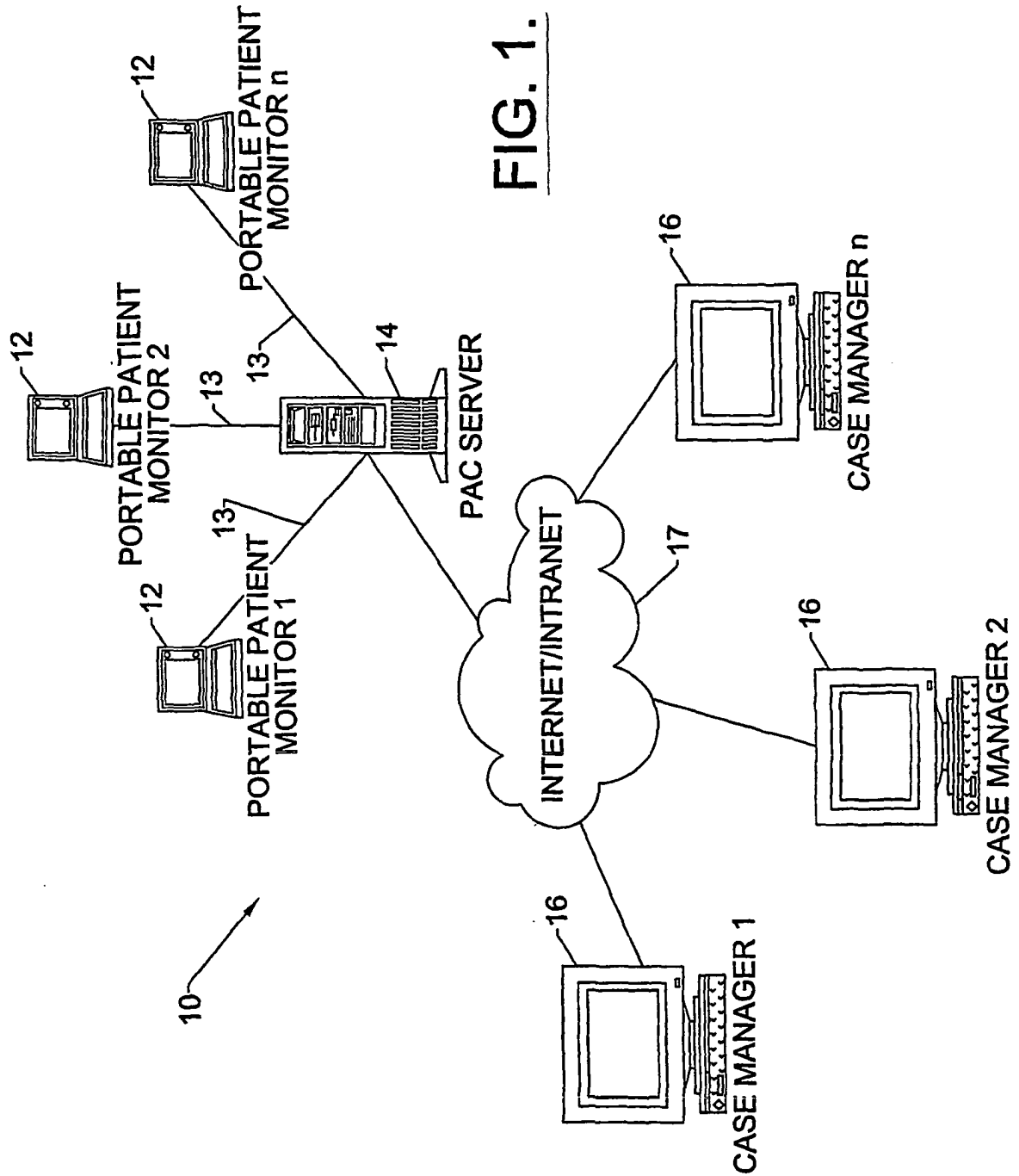


FIG. 1.

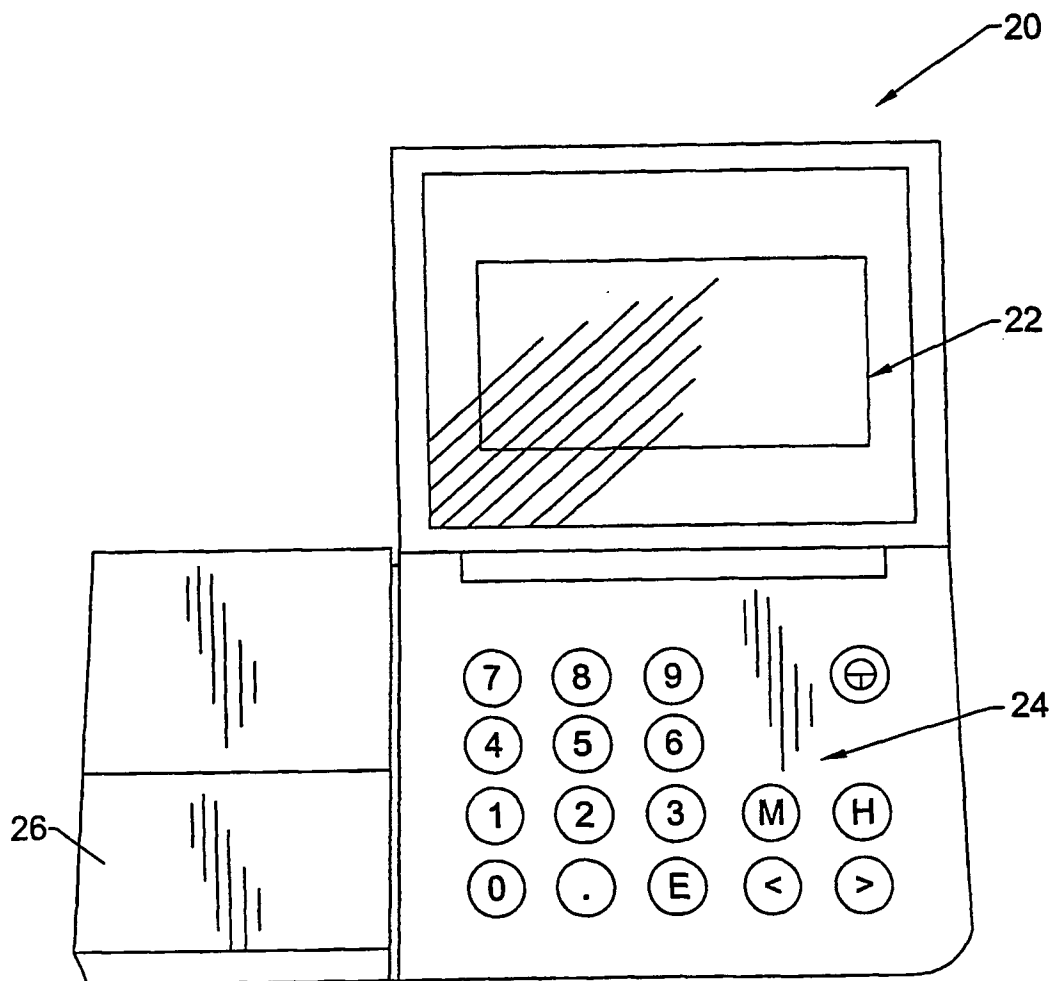


FIG. 2.

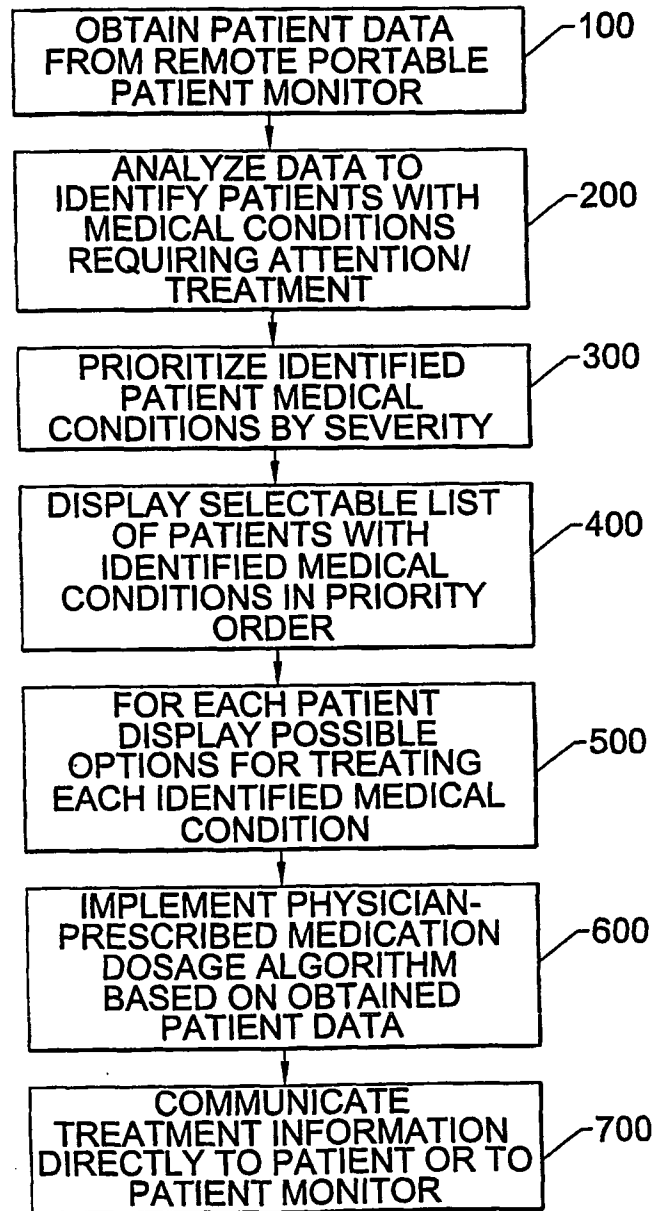
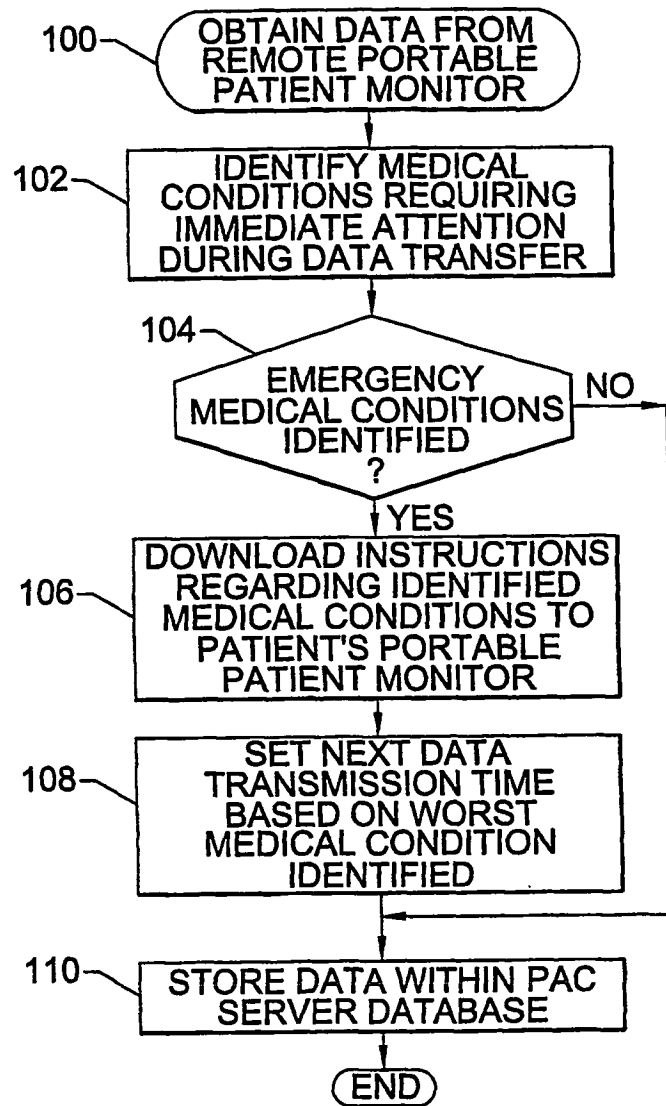


FIG. 3.

FIG. 4.

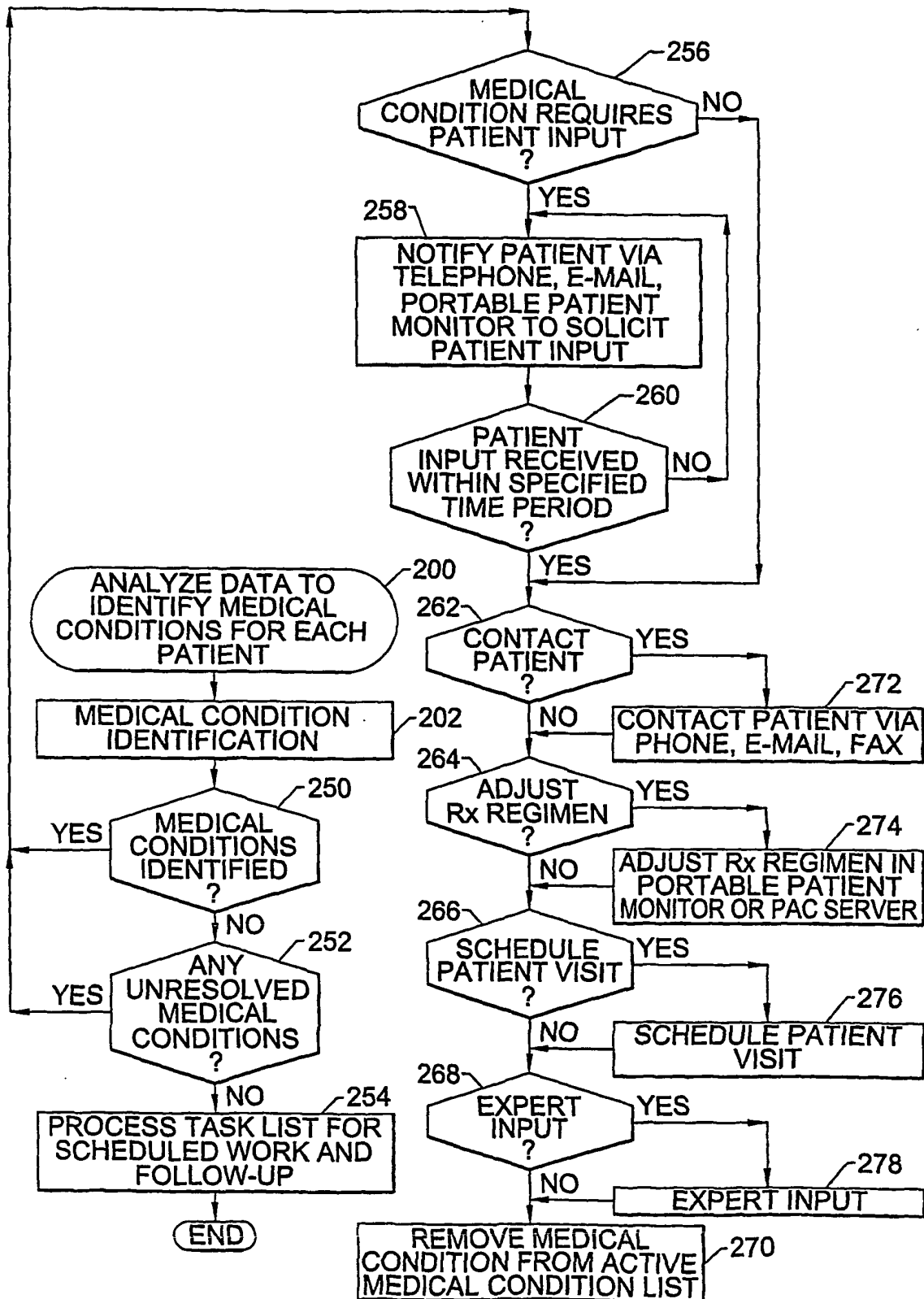


FIG. 5.

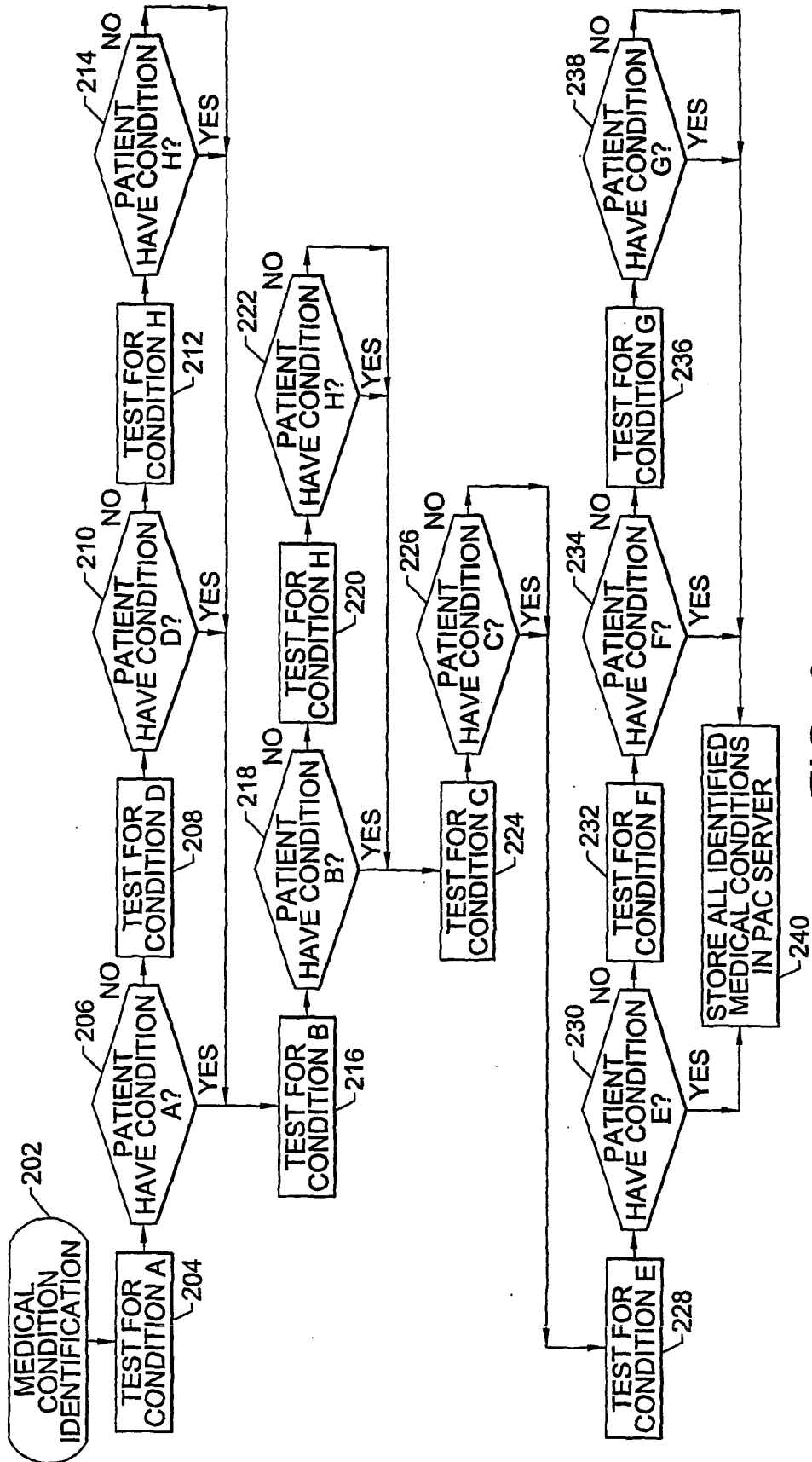


FIG. 6.

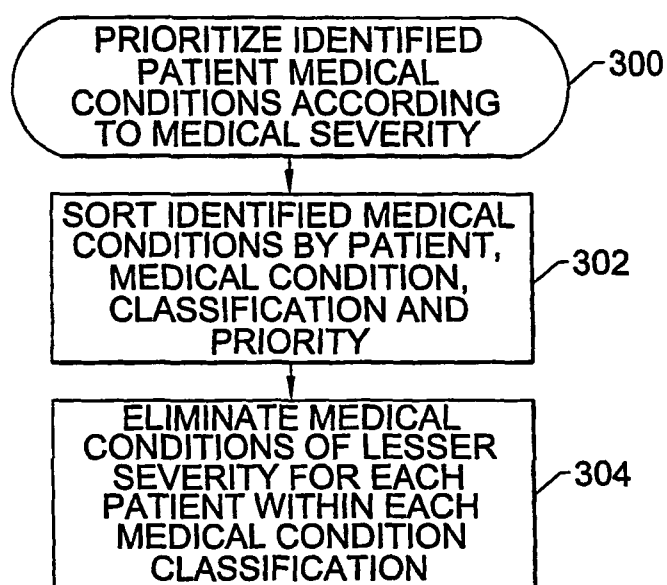


FIG. 7.

Diacare Management System
File Patients Reports Help

1 2 3
 Patients Problems Tasks Reports Search 32

Bilhome, Moe 25 yr. old Male, Type 1-5 yrs, Insulin-5yrs

Show All Problems

Priority	Actions	Last Name	First Name	M.I.	Date	Problem Description
1	0	Bilhome	Moe		01/03/1998	Assisted Hypoglycemia
2	0	Broome	Douglas		01/11/1998	HiBG s/Ketones
3	0	Smythe	Kathy	Q	02/14/1997	No Transmit - 7 days late
4	0	Guard	Randy	C	01/14/1998	Hypoglycemia
5	0	Kruger	Lonny		01/12/1998	HiBG w/o Ketones
6	0	Pole	Rusty	A	01/02/1998	Variable BG
8	0	Kruger	Lonny		01/12/1998	Periodic Review

30

31

Active List

Problem List

FIG. 8.

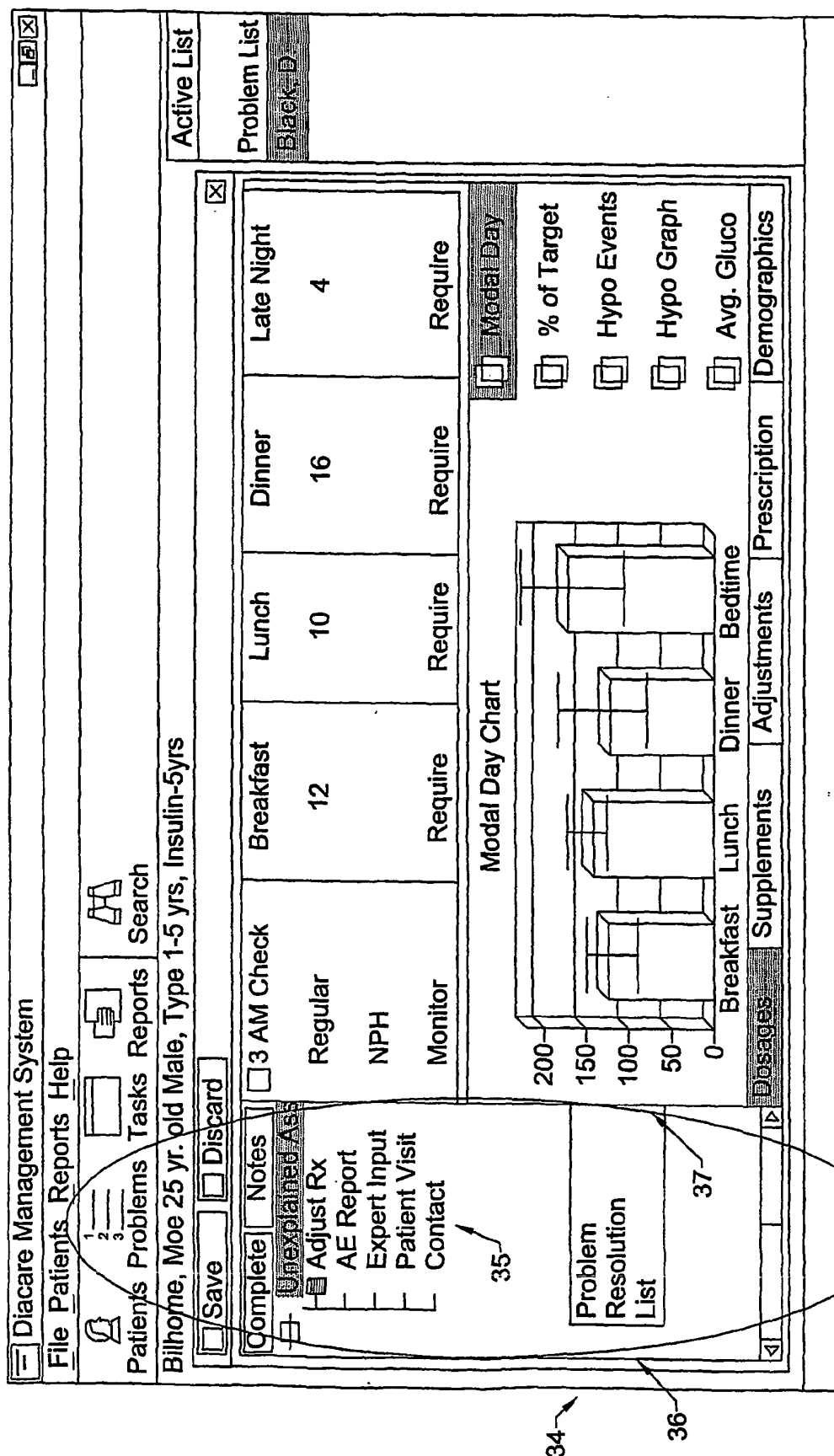


FIG. 9.

Diacare Management System	
File Patients Reports Help	
1 2 3	Search
Patients Problems Tasks Reports	
White, Doug 7 yr. old Male, Type 1-6 yrs, Insulin-6 yrs	
☐ Save ☐ Discard	☒ Complete Notes
☐ HiBG w/Ketone ☐ Adjust Rx ☐ Expert Input 03/11/199 03/11/199 ☒ Patient Visit ☐ Connect 03/10/199 03/10/199 03/12/199	Select the type(s) of communication ☒ Automated Voice Mail ~46 High BG warning Intermittent monitoring warning Test more often at lunch Transmit immediately for new prescription Special DCM Messages ☒ Personal ~48a ☐ Predifined ~48b Keep up the good work! Need to do a better job monitoring at lunch Persistent high glucoses at late night. Consider increasing exercise Please make appointment for eye exam Please stay with transmission schedule Strips and lancets have been ordered for you
Phone Call Automated Documents	

FIG. 10A.

Diacare Management System	
File Patients Reports Help	
Patients Problems Tasks Reports Search	
White, Doug 7 yr. old Male, Type 1-6 yrs, Insulin-6 yrs	
☐ Save ☐ Discard	
[Complete] Notes ☒ HiBG w/Ketone ☒ Adjust Rx ☒ Expert Input 03/11/199 03/11/199 ☒ Patient Visit ☒ Contact 03/10/199 03/10/199 03/12/199	Post ☐ Written Documents Message Type ☐ Personal Message ☒ Predefined Message Personal Predefined Messages Hypoglycemic Precautions Hi BG History Hi BG Test Ketones Variable BG Intermittent Monitoring Not Transmitting Send message in 2 hours ▾
Contact Options ☐ Send Now ☒ Send Later Send by ☒ E-Mail ☐ Fax ☒ Letter	
Active List Problem List White, D. Phone Call Automated Documents	

FIG. 10B.

Diicare Management System

File

Patients

Reports

Help

1

2

3

Search

Patients Problems

Tasks

Reports

White, Doug 7 yr. old Male, Type 1-6 yrs, Insulin-6 yrs

Save

Discard

Complete

Notes

HiBG w/Ketone

Adjust Rx

Expert Input

03/11/199

03/11/199

Patient Visit

03/10/199

03/10/199

03/12/199

49

Phone Call

Call Action

Call Now

Schedule Call

Home (919) 847-5555

Work (919) 840-5543

Phone Call

Call Now

Schedule Call

Call Action

Call Now

Schedule Call

Status

Contacted

Not Contacted

Action

Left voice mail

Msg with person

No answer

Schedule call in

2 hours

Notes

Phone Call

Automated

Documents

Active List

Problem List

White, D

FIG. 10C.

44C

	Breakfast	Lunch	Dinner	Late Night
Assesments	18u Lente @Dinner Avg. BG 120	5u Semi-Lente @Breakfast Avg. BG 100	12u Lente @Breakfast Avg. BG 130	6u Semi-Lente @Dinner Avg. BG 115
Adjustment	Enabled	Enabled	Enabled	Enabled
Increase if BG above	100	130	140	140
for Consec Days	3	3	3	3
Decrease if BG below	50	55	55	55
for Consec Days	4	2	2	2
Method	Percent ▾	Units ▾	Percent ▾	Units ▾
Amount	10%	1	5%	1

54

FIG. 11.

Diacare Management System

File Patients Reports Help

Save Discard Complete Notes

Patients Problems Tasks Reports Search

White, Doug 7 yr. old Male, Type 1-6 yrs, Insulin-6 yrs

Work (919) 787-6555 Alternate (919) 876-9431

Contact Dr. James Michell, MD, CDE Response Required

Phone Call

Call Action

Call Now Schedule Call

Status

Contacted Not Contacted

Schedule call in 2 hours

Notes

03/11/199 03/10/199 03/12/199

HiBG w/Ketone Adjust Rx Patient Visit Contact

Dr. James Michell, MD, CDE Carole Hathaway, RN Dr. David Jones, MD Alison McBeal, PA Tyron Adams, RN, CDE Dr. Dan Wesson, MD, CDE

FIG. 12.

FIG. 12.

Diacare Management System	
File Patients Reports Help	
Patients Problems Tasks Reports Search	
White, Doug 7 yr. old Male, Type 1-6 yrs, Insulin-6 yrs	
☐ Save ☐ Discard	☒ Complete ☐ Notes ☐ HiBG w/Ketone ☐ Adjust Rx ☐ Expert Input ☐ Patient Visit ☐ Contact 03/11/199 03/11/199 03/10/199 03/10/199 03/12/199
Notify Patient 2 days 4 days 1 week 2 weeks 1 month Patient needs to schedule an appointment Reason Meet with Case Manager ▾ Contact Dr. James Michell, MD, CDE ▾ Within 1 week ▾ Notes	
Meet with Dietician Meet with Educator Meet with Case Manager Meet with Provider Lab Work	Active List Problem List White, D

FIG. 13.

Diicare Management System

File

Patients

Reports

Help

1

2

3

Patients Problems

Tasks

Reports

Search

Save

Discard

Complete

Notes

HBC wike...

Insulin Doses

Supplements

Adjustments

Consult

02/03/199

Refer to

Contact

Problem Checklist

Broome, Douglas

DOB

12/16/90

SSN

111-22-3333

8521 SIX FORKS ROAD

RALEIGH

NC

27615

(919)518-0800

Work Phone

Complications

Foot Ulcers

Retinopathy

Neuropathy

Nephropathy

Hypoglycemic Unawareness

CoMorbidity Events

Stroke

Dialysis

Heart Attack

Amputation

CoMorbidity Condition

Hypertension

Coronary Artery Disease

Hyperlipidemia

Obesity (>20% ideal body weight)

Dosages

Supplements

Adjustments

Prescription

Demographics

Active List

Problem List

Broome, D

58

FIG. 14.

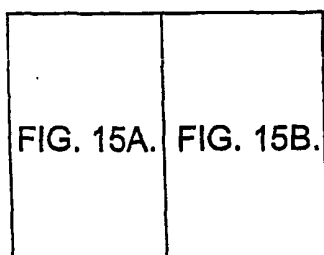
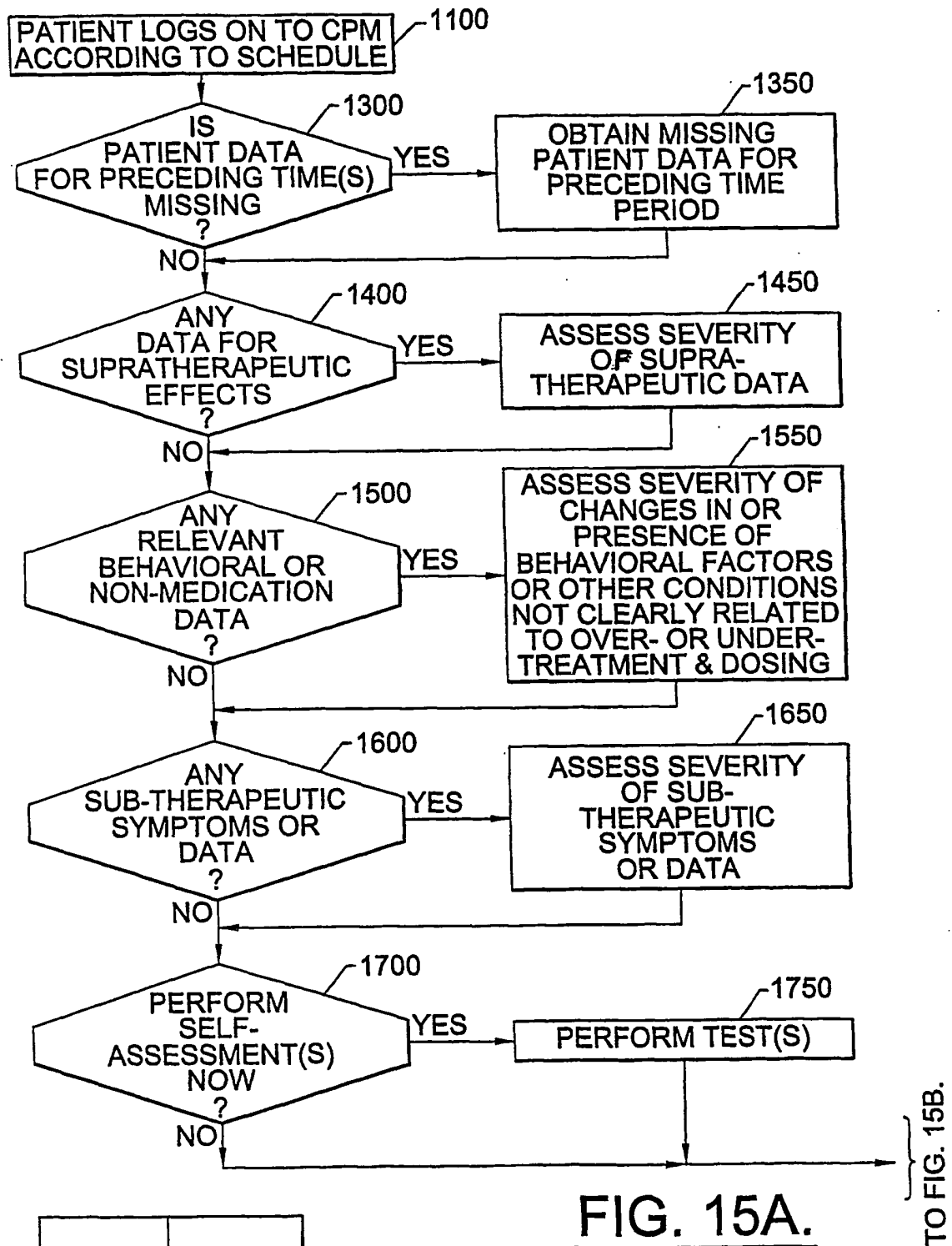
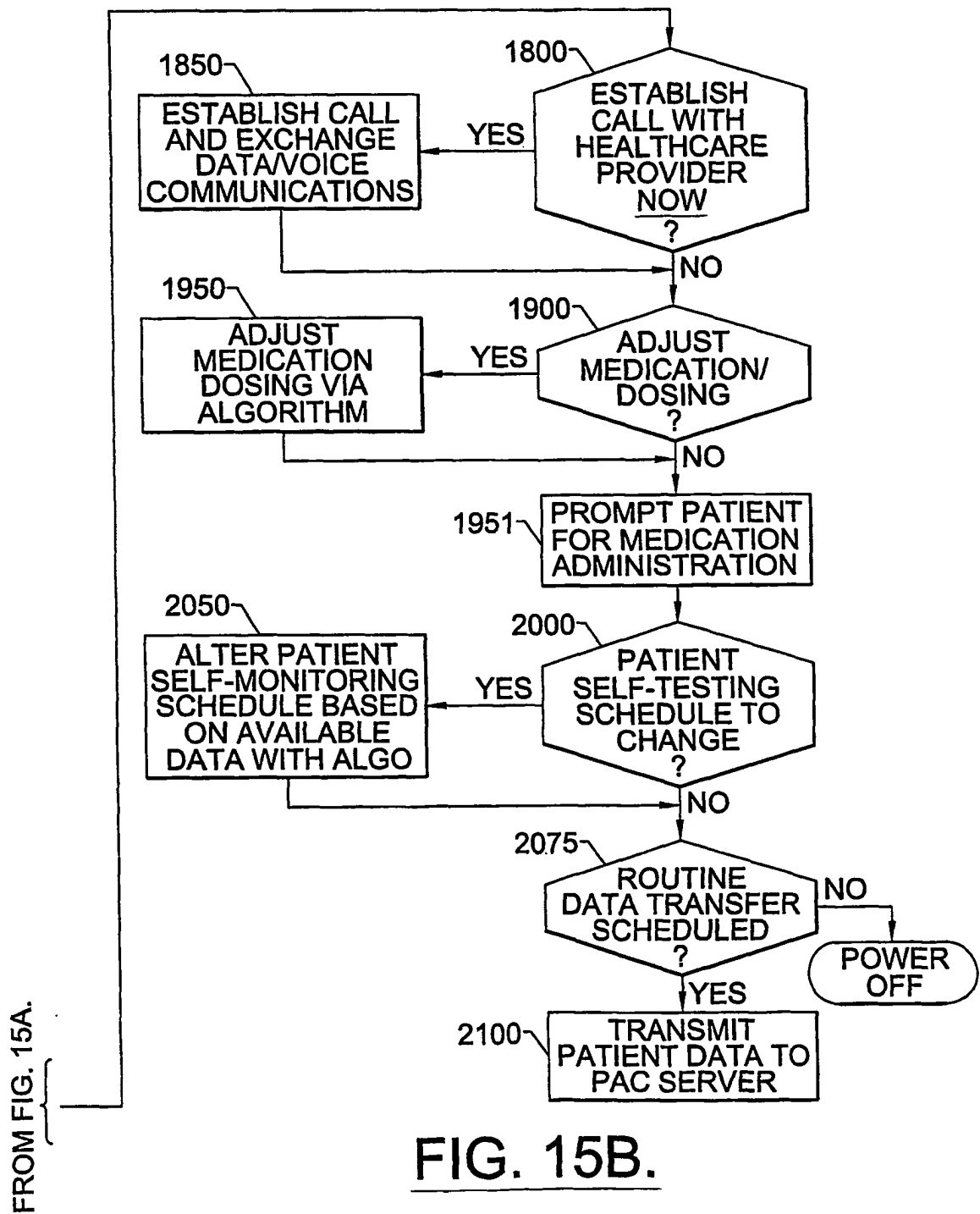


FIG. 15.



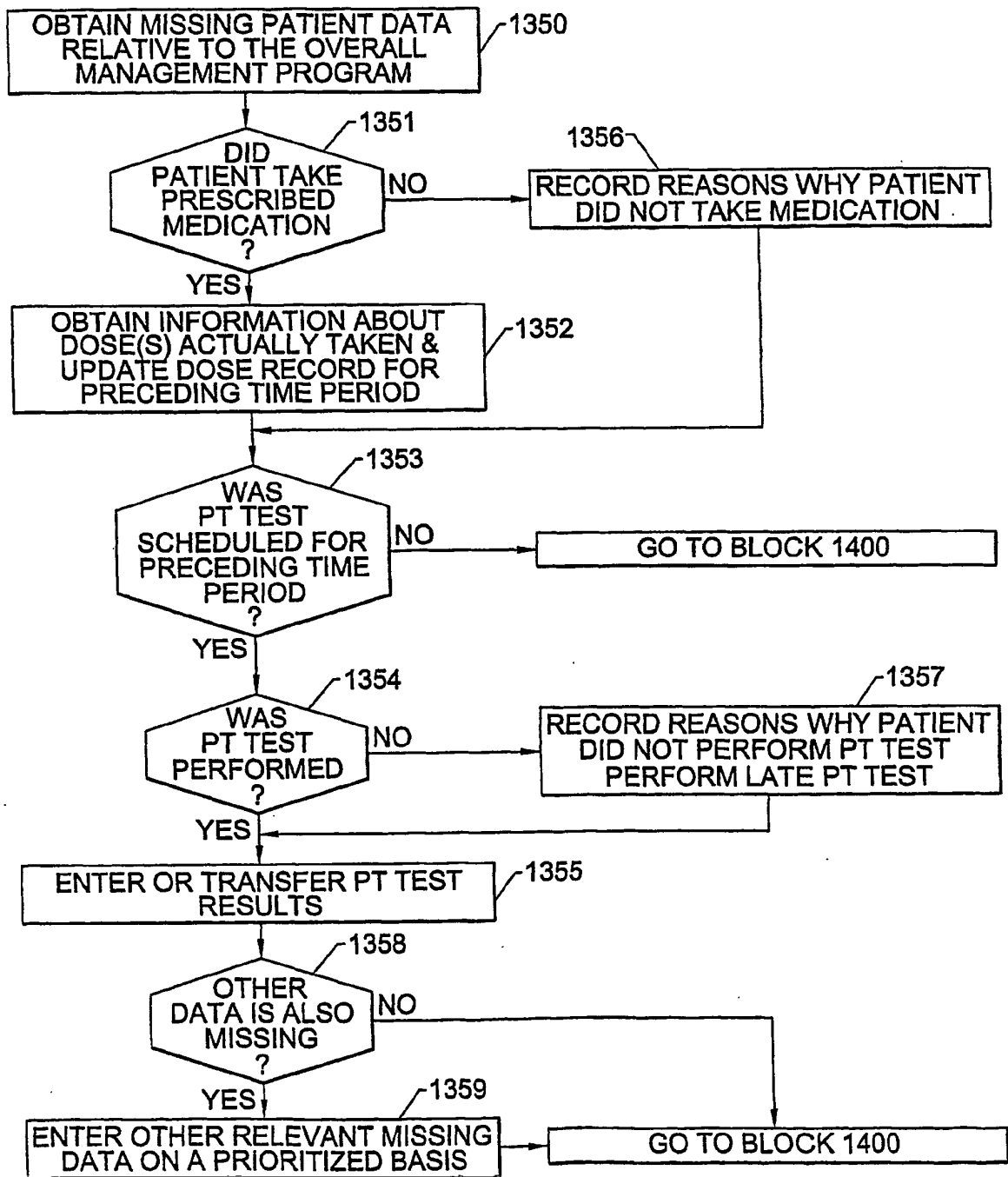


FIG. 16.

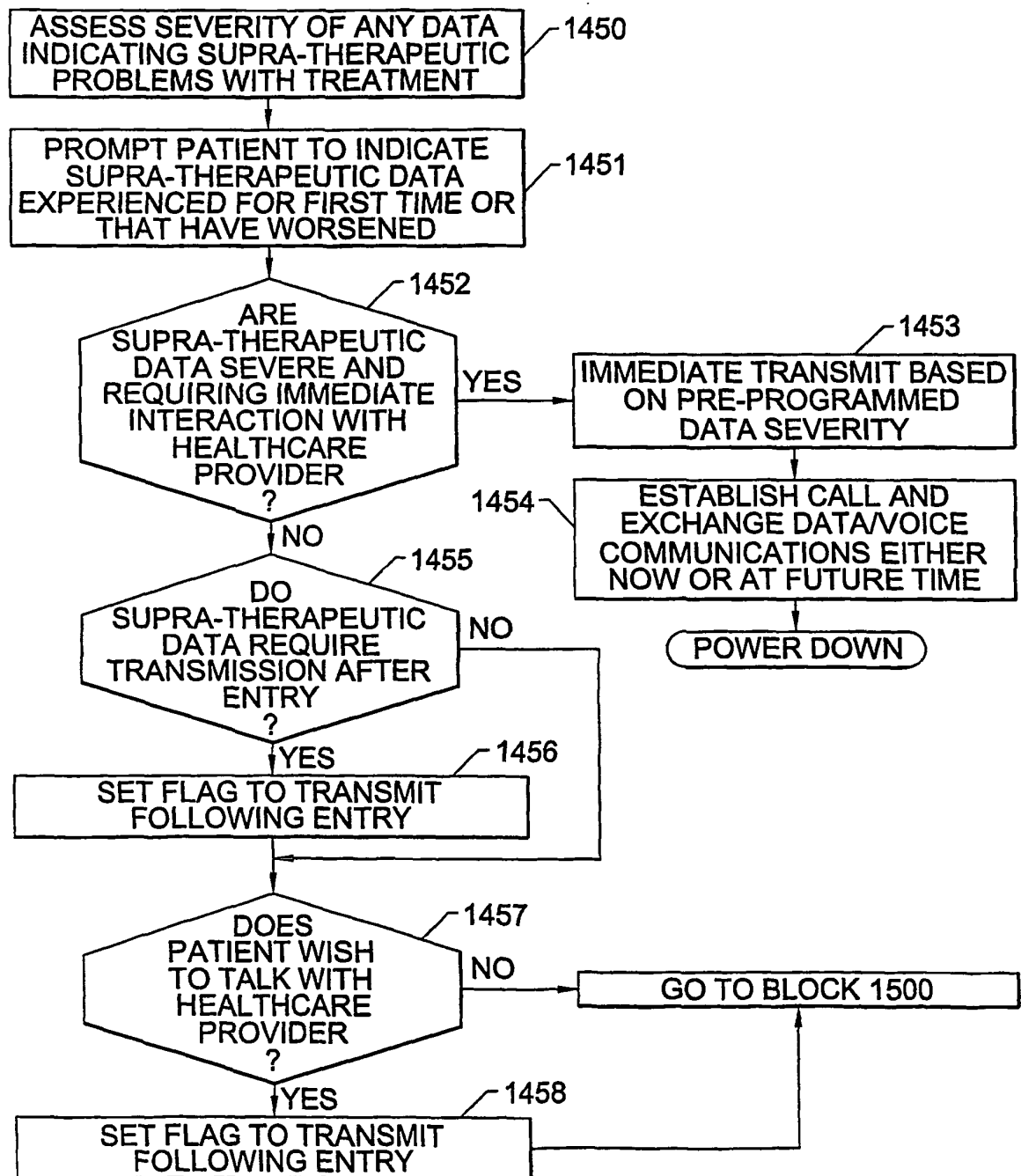


FIG. 17.

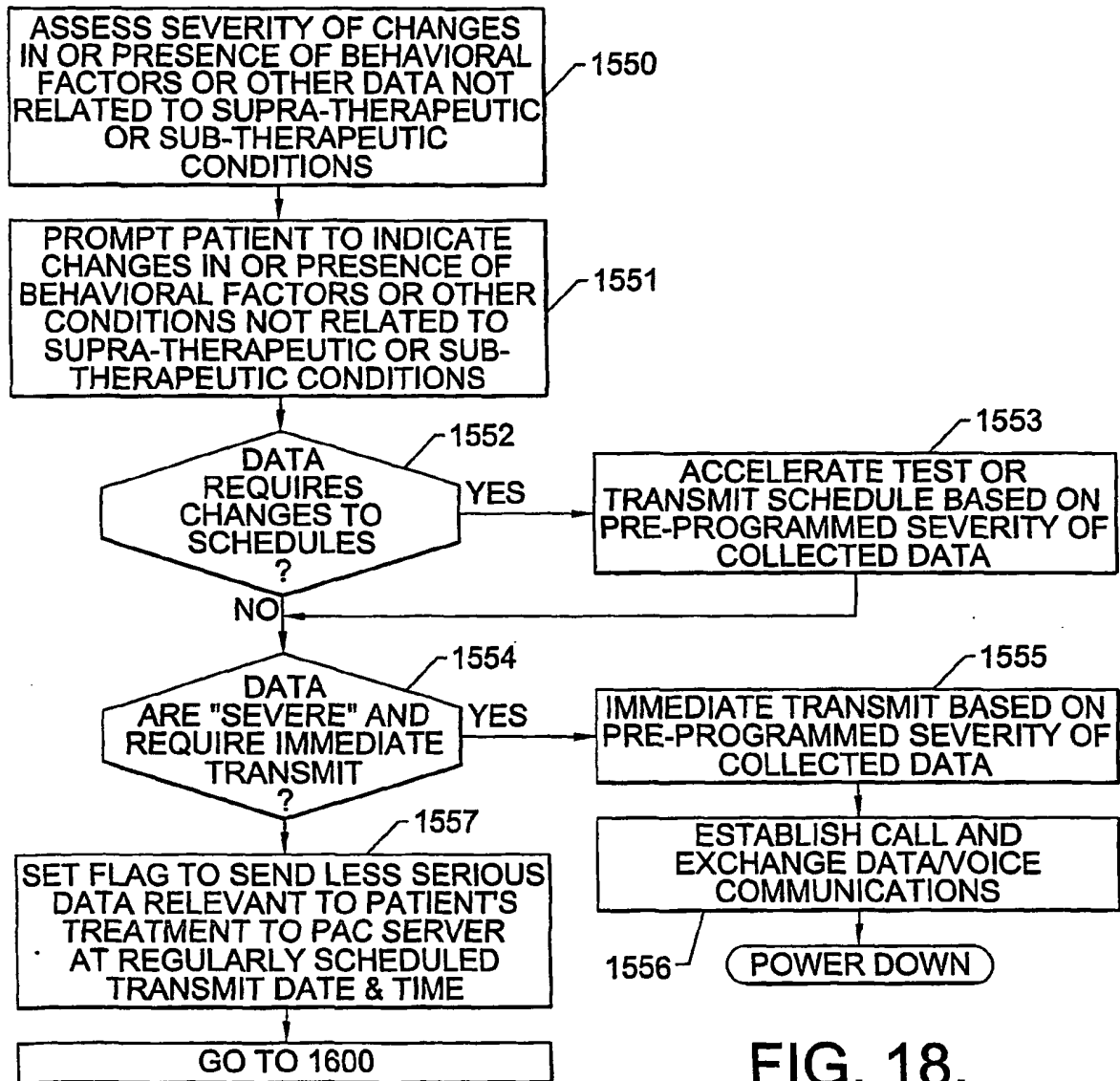
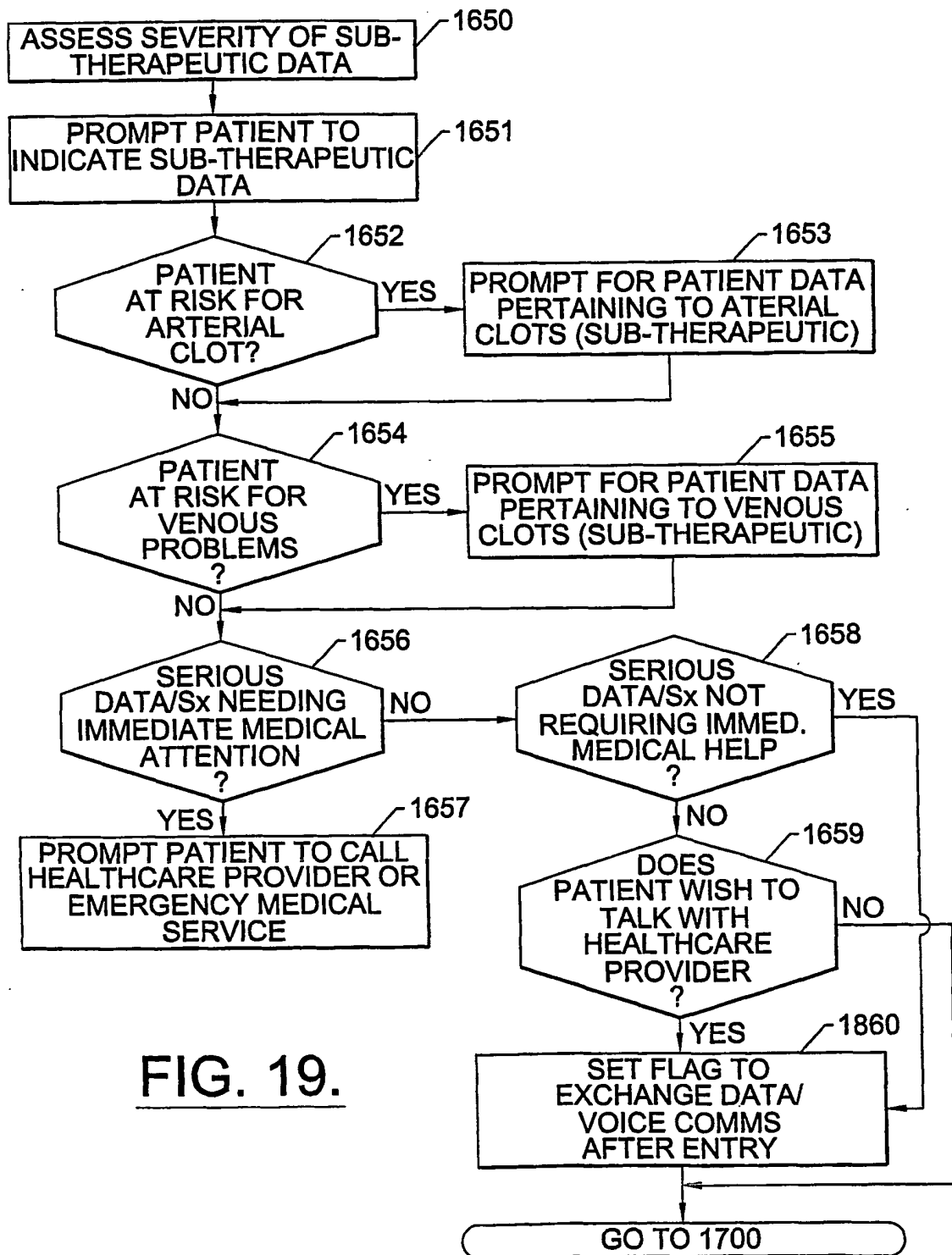


FIG. 18.



REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- US 4731726 A [0008] [0041]
- US 6024699 A [0096]

Non-patent literature cited in the description

- Guidelines for the Diagnosis and Management of Asthma; Expert Panel Report Two. National Institutes of Health, April 1997 [0028]
- **JACK E. ANSELL et al.** Long-term Patient Self-management of Oral Anticoagulation. Arch Intern Med, 1995, vol. 155, 2185-2189 [0029]

专利名称(译)	用于监测和改变远程患者的抗凝治疗的装置和方法		
公开(公告)号	EP1248555B1	公开(公告)日	2012-05-30
申请号	EP2001903011	申请日	2001-01-10
[标]申请(专利权)人(译)	ZYCARE		
申请(专利权)人(译)	ZYCARE INC.		
当前申请(专利权)人(译)	ZYCARE INC.		
[标]发明人	SURWIT RICHARD S ALLEN LYLE M III ORTEL THOMAS LEE MORRIS JAMES J		
发明人	SURWIT, RICHARD, S. ALLEN, LYLE, M., III ORTEL, THOMAS, LEE MORRIS, JAMES, J.		
IPC分类号	G06F19/00 A61B5/00 G06Q50/22 G06Q50/24 G16H10/60		
CPC分类号	A61B5/0022 G06F19/3418 G06F19/3456 G06Q50/22 G06Q50/24 G16H10/40 G16H10/60 G16H15/00 G16H40/63 G16H80/00		
优先权	09/480432 2000-01-11 US		
其他公开文献	EP1248555A2		
外部链接	Espacenet		

摘要(译)

患者装置被配置为接收和分析关于患者对抗凝药物的依从性和与抗凝治疗相关的自测凝固方案的信息。另外，患者装置被配置为从患者接收数据，包括生理数据，病理生理学数据，生物学数据，心理数据，神经心理学数据和/或行为数据。利用所接收的患者数据，患者装置可以使用装置内包含的算法来修改华法林方案。该装置可将经修改的华法林方案传达给患者和第三方，例如远程定位的医疗保健提供者。另外，该装置可以提示患者何时进行自检并且可以在需要时提示患者立即就医，或者直接联系医疗帮助。

