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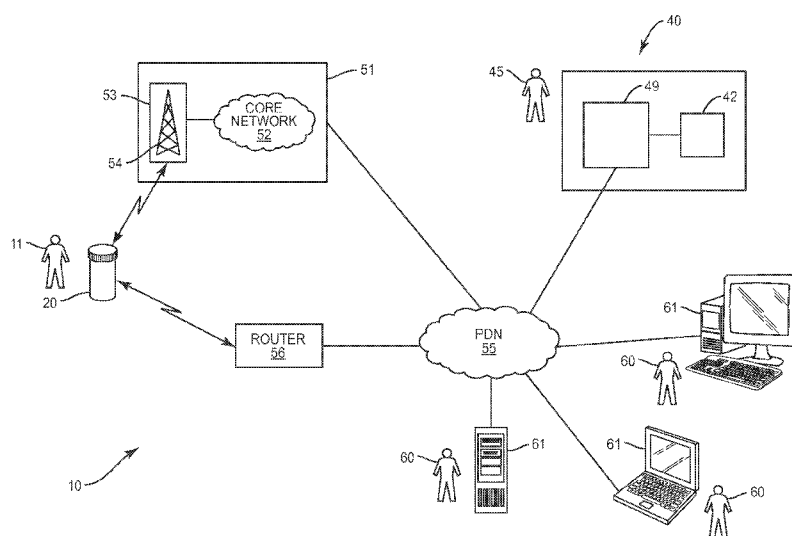


FIG. 1

(57) Abstract: Systems and methods for monitoring medication usage and adherence to one or more patients. One or more of adherence to the prescribed medication, adherence to dose times, and absolute adherence may be monitored. One or more patient entities may gain access to this information to further monitor the adherence of one or more patients.



METHODS AND SYSTEMS OF REAL-TIME MEDICATION ADHERENCE MONITORING

RELATED APPLICATIONS

5 The present application claims benefit to U.S. Application No. 61/780,483 filed on March 13, 2013, entitled "Compliance System that includes a Smart Medicine Container".

BACKGROUND

10 Medication non-adherence is a major issue in the health care industry. Numerous studies show high rates of non-adherence directly related to poor clinical outcomes, high healthcare costs, and lost productivity. In the United States, the cost of non-adherence has been estimated at \$400 billion annually, which includes \$100 billion from avoidable hospitalizations, nursing home admissions, and premature death and \$100 billion in lost drug sales. Successful treatment of chronic disease with prescription medication requires consistent
15 use of medicine as prescribed. Yet research shows that medications are not consistently used as directed. Only one out of two patients (50%) takes their medication correctly as prescribed.

 Precise and timely electronic medication adherence data collected directly from daily patient medication usage is not yet available. The current state of the art processes prescription billing and health insurance claims data to provide an estimation of medication adherence on a
20 retroactive basis. These methods, called "medication possession ratio" (MPR), and "proportion of days covered" (PDC) are not readily accessible, inaccurate, untimely and after the fact (not actionable). At best, these methods cobble together a single data point from multiple sources offering a one-dimensional snapshot of the days in between the filling and refilling of prescriptions by patients. Medication fills and refills typically last 30, 45, 60, and 90 days,
25 therefore these types of systems and methods can only provide medication adherence estimations 30-90 days after each refill. Furthermore, by processing billing and claims information this method inherently limits the access to this information to users inside the health insurance and pharmaceutical industries and is not useful to patients or caregivers. Knowing the number of days between refills does not provide any insight as to exactly when or why an
30 individual patient did not take medicine as prescribed. Current systems cannot track medication usage precisely and therefore can only supply healthcare systems and caregivers with unreliable estimations of medication adherence.

 Non-adherence to medication is not outstandingly the result of forgetfulness. Non-adherence is the result of many different factors, conditions and situations. Some reasons are
35 subjective and emotional. When patients feel better they stop taking their medicine. Other reasons are economic. Patients often split bills to extend prescriptions from 30 to 60 days reducing their costs by half. Some are also medical. Patients very often stop taking medicine when they experience side effects. Complexity of medication therapies also leads to medication

adherence failure. Many medication therapies involve six to twenty medications taken at various times of the day. These regimens are extremely complicated and difficult to track. Patients require help from caregivers to manage these regimens. Without precise knowledge of when medications are taken or not, family and caregivers are unable to help prevent non-adherence by supporting, intervening or adjusting medication therapies. Adherence to medication ultimately results in the healthcare industry's ability to communicate, analyze and act upon complex real time medication adherence information in a timely, orchestrated manner.

SUMMARY

The present application is directed to systems and methods for monitoring medication usage and adherence to one or more patients. One or more of adherence to the prescribed medication, adherence to dose times, and absolute adherence is monitored. One or more patient entities may gain access to this information to further monitor the adherence of one or more patients.

One aspect of the invention is directed to a system for monitoring usage of medication by a patient. The system includes a container with an interior space to hold the medication, one or more sensors configured to sense the medication within the interior space, a container processing circuit configured to determine a medication amount within the interior space based on readings from the one or more sensors, and a wireless communication circuit configured to transmit the medication amount over a wireless communication network. The system also includes a monitoring server located remotely from the medicine container. The monitoring server includes a communication interface configured to receive the medication amount transmitted from the container through the wireless communication network, and a memory circuit configured to store at least one of: a prescribed medication dose for the patient; and dose time periods in which the patient is to take the prescribed medication dose. The monitoring server processing circuit is configured to monitor patient medication adherence by calculating at least one of a dose time adherence as whether the medication was removed from the interior space within one of the dose time periods, and a medication adherence of whether the amount of medication taken is equal to the prescribed medication dose.

In one or more embodiments, the monitoring server processing circuit is configured to determine the amount of medication taken by the patient based on the medication amount received from the container. In one or more embodiments, the monitoring server processing circuit is configured to determine a time when the medication was removed from the interior space. In one or more embodiments, the monitoring server processing circuit is configured to calculate an absolute adherence over a time period that includes whether the taken medication was removed from the interior space within the dose time periods and whether the taken medication is equal to the prescribed medication dose. In one or more embodiments, memory circuit may store a contact address for a caregiver associated with the patient, and the

monitoring server processing circuit is configured to send a message to the contact address over the wireless communication network when the dose time adherence or the medication adherence are outside predetermined levels. In one or more embodiments, the monitoring server processing circuit is configured to calculate the medication adherence over a plurality of the dose time periods. In one or more embodiments, the monitoring server processing circuit is configured to calculate the dose time adherence over a plurality of the dose time periods. In one or more embodiments, the one or more sensors is arranged within the body. In one or more embodiments, the monitoring server processing circuit may determine a count of remaining medication left within the interior space of the container by dividing one of a mass or volume of the remaining medication by one of a mass or volume of an individual dose of the medication. In one or more embodiments, the monitoring server processing circuit may automatically transmit a refill request when the amount of the medication remaining within the interior space reaches a predetermined threshold. In one or more embodiments, the monitoring server processing circuit is configured to notify at least one of the patient and a patient entity of a negative patient medication adherence and to recheck the patient medication adherence within a predetermined time thereafter. In one or more embodiments, the container processor may calculate the taken medication for a liquid by dividing a change in volume in the medication in the interior space by a volume of a dose that is stored in a container memory circuit. In one or more embodiments, the contact information of a patient entity is stored in the memory circuit, and the monitoring server processing circuit is configured to transmit a message over the wireless communication network using the contact information upon occurrence of a triggering event related to the patient. In one or more embodiments, the monitoring server processing circuit is configured to create medication adherence data for a first display area and patient behavior data for a second display area, and to transmit the data for viewing on a remote electronic device.

Another aspect of the present invention is directed to a system for monitoring usage of medication by a patient that includes a container with an interior space to hold the medication, one or more sensors configured to sense the medication within the interior space, a container processing circuit configured to determine an amount of medication within the interior space, and a wireless communication circuit configured to transmit the amount of the medication within the interior space. A monitoring server is located remotely from the medicine container and includes a communication interface configured to receive the amount of the medication within the interior space transmitted from the container through the wireless communication network, a memory circuit configured to store at least one of: a prescribed medication dose for the patient; and dose time periods in which the patient is to take the prescribed medication dose, a monitoring server processing circuit configured to calculate taken medication based on the amount of the medication within the interior space. The monitoring server processing circuit is

further configured to monitor patient adherence in taking the medication based on the taken medication and at least one of the prescribed medication dose and the dose time periods.

In one or more embodiments, the monitoring server processing circuit is configured to calculate dose time adherence as whether the taken medication was removed from the interior space within the dose time periods. In one or more embodiments, the monitoring server processing circuit is configured to calculate medication adherence as whether the taken medication is equal to the prescribed medication dose. In one or more embodiments, the monitoring server processing circuit is configured to calculate an absolute adherence over a time period that includes whether the taken medication was removed from the interior space within the dose time periods and whether the taken medication is equal to the prescribed medication dose. In one or more embodiments, the memory circuit may store a contact address for a caregiver associated with the patient, and the monitoring server processing circuit is configured to send a message to the contact address when the dose time adherence or the medication adherence are outside predetermined levels. In one or more embodiments, the monitoring server processing circuit is configured to calculate the dose time adherence over a plurality of the dose time periods. In one or more embodiments, the one or more sensors are arranged within the body. In one or more embodiments, the monitoring server processing circuit may automatically transmit a refill request when an amount of the medication remaining within the interior space reaches a predetermined threshold. In one or more embodiments, the contact information of a patient entity is stored in the memory circuit, and the monitoring server processing circuit is configured to transmit a message over the wireless communication network to the patient entity upon occurrence of a triggering event related to the patient. In one or more embodiments, the monitoring server processing circuit is configured to create adherence data for a first display area, behavior data for a second display area, and to transmit the data for viewing on a remote electronic device. In one or more embodiments, the monitoring server processing circuit is further configured to notify at least one of the patient and a patient entity of a negative patient adherence and to recheck the patient adherence within a predetermined time thereafter. In one or more embodiments, the monitoring server processing circuit is configured to determine a time when the medication was removed from the interior space.

Another aspect of the invention is directed to a method of monitoring usage of medication by a patient that includes receiving from a medication container through a wireless communication network that includes a packet data network a taken medication which is an amount of the medication that has been removed from the container within a time period. The method includes calculating at least one or an adherence to time of whether the taken medication was removed from the container within a dose time period and an adherence to medication of whether the taken medication was equal to a prescribed medication dose. The method includes determining whether the patient is adhering to a medication schedule based on one or more of the adherence to time and the adherence to medication.

In one or more embodiments, storing the dose time period and the prescribed medication dose in a memory circuit prior to receiving the taken medication. In one or more embodiments, the method further includes transmitting a message to a remote entity when the patient is not adhering to the medication schedule. In one or more embodiments, the method further includes enrolling the patient by receiving the patient's name, contact information, and the prescribed medication dose prior to receiving the taken medication from the container. In one or more embodiments, the method further includes creating display data including adherence to medication for a first display area, creating display data for a second display area, and transmitting the display data for viewing on an electronic display of a remote computing device.

One aspect of the invention is directed to adherence to a prescribed dose. One aspect of this invention is directed to a system of monitoring usage of medication by a patient. The system includes a medication container comprising an interior space to hold the medication, one or more sensors configured to detect the medication within the interior space, a container processing circuit configured to determine an amount of the medication within the interior space based on the remaining amount of medication within the interior space, and a wireless communication circuit configured to transmit the taken medication over a wireless communication network. The system also includes a monitoring server located remotely from the medication container, the monitoring server includes a communication interface configured to receive through the wireless communication network the amount medication from the medication container, and a memory circuit configured to store a prescribed medication dose and one or more dose times in which the medication is to be taken for the patient. The monitoring server also includes a monitoring server processing circuit configured to calculate a taken medication, and an adherence to prescribed dose based on the taken medication that is removed from the container during each of the one or more dose times and the prescribed medication dose.

Another aspect of the invention directed to adherence to a prescribed dose is directed to a system of monitoring usage of medication by a patient. The system includes a medication container comprising an interior space to hold the medication, one or more sensors configured to detect an amount of the medication within the interior space, a container processing circuit configured to determine an amount of taken medication based on the remaining amount of medication within the interior space detected by the one or more sensors, and a wireless communication circuit configured to transmit the taken medication over a wireless communication network. The system also includes a monitoring server located remotely from the medication container that includes a communication interface configured to receive through the wireless communication network the taken medication from the medication container, a memory circuit configured to store a prescribed medication dose and one or more dose times in which the medication is to be taken for the patient, and a monitoring server processing circuit

configured to calculate an adherence to prescribed dose based on the taken medication that is removed from the container during each of the one or more dose times and the prescribed medication dose.

In one or more embodiments, the monitoring server processing circuit is configured to
5 determine that the patient is adherent when the taken medication is equal to the prescribed medication dose. In one or more embodiments, the monitoring server processing circuit is further configured to determine a cumulative adherence to a prescribed dose as a total amount of the medication taken over a plurality of the dose times divided by the prescribed medication dose over the plurality of dose times. In one or more embodiments, the memory circuit includes
10 contact information for an authorized entity for the patient, and wherein the monitoring server processing circuit is configured to send a message through the wireless communication network to the authorized entity when the adherence to the prescribed dose is outside a predetermined amount. In one or more embodiments, the adherence to the prescribed dose is calculated as the taken medication divided by the prescribed medication dose, and wherein the prescribed
15 medication dose is greater than 1.0 when the patient consumes an excess of the medication, and below 1.0 when the patient consumes less than the prescribed medication dose. In one or more embodiments, the container processor determines a remaining medication count within the interior space by dividing a weight of the remaining medication by a pill weight stored in a container memory. In one or more embodiments, the container processor calculates the
20 amount of medication taken as a difference between a previous medication amount remaining and a current medication amount remaining. In one or more embodiments, the container processor calculates the medication amount taken by dividing a change in an amount of weight of the medication by a known weight for each pill. In one or more embodiments, the container processor calculates the amount of medication taken for a liquid by dividing a change in volume
25 in the medication in the interior space by the volume of a dose. In one or more embodiments, the monitoring server processing circuit is configured to create display data including adherence to the prescribed dose for a first display area, and create different display data for a second display area, and to transmit the display data for viewing on an electronic display of a remote computing device.

30 Another aspect of the present invention is directed to adherence to a prescribed dose. One aspect of the invention includes a method of remotely monitoring usage of medication for a patient. The method includes receiving from a medication container a taken medication amount, the taken medication amount being received through a wireless communication network. The method includes receiving through the wireless communication network a
35 prescribed dose amount and storing the amount in a memory circuit. The method includes determining that the patient is adherent when the taken medication is equal to the prescribed dose amount.

In one or more embodiments, the method includes receiving the prescribed dose amount prior to receiving the taken medication. In one or more embodiments, the method includes transmitting a message through the wireless communication network to an address stored in the memory circuit upon determining that the patient is not adherent and the prescribed dose is different than the taken medication. In one or more embodiments, the method includes enrolling the patient by receiving the patient's name, information, and the prescribed dose amount prior to receiving the taken medication from the container. In one or more embodiments, the method includes creating display data including the adherence to the prescribe dose for a first display area, creating display data for a second display area, and transmitting the display data for viewing on an electronic display of a remote computing device.

Another aspect of the invention is directed to adherence to dose time and includes a system of monitoring medication usage by a patient. The system includes a medication container including an interior space to hold the medication, one or more sensors configured to detect the medication within the interior space, a processor configured to determine a taken medication based on sensor output from the one or more sensors, and a wireless communication circuit configured to transmit the taken medication through a wireless communication network. The system also includes a monitoring server located remotely from the medication container that includes a communication interface configured to receive the taken medication from the medication container through the wireless communication network, a memory circuit that stores a prescribed dose time period for taking the medication, and a monitoring server processing circuit configured to calculate an adherence to dose time as whether the taken medication was removed from the interior space within the prescribed dose time period.

In one or more embodiments, the monitoring server processing circuit is configured to determine that the patient is adherent when the taken medication was removed within the prescribed dose time. In one or more embodiments, the memory circuit stores prescribed dose times for multiple time periods, and the monitoring server processing circuit is configured to determine the adherence to dose time for each of the time periods. In one or more embodiments, the monitoring server processing circuit is configured to determine a cumulative adherence to dose time over the multiple time periods. In one or more embodiments, the adherence to dose time is a 1.0 when the patient takes the medication within the prescribed dose time and is 0.0 when the patient does not take the medication within the prescribed dose time. In one or more embodiments, the memory circuit stores contact information for an authorized entity of the patient, and wherein the monitoring server processing circuit is configured to transmit a message through the wireless communication network to the authorized entity when the adherence to dose time is outside a predetermined amount. In one or more embodiments, the medicine container further comprises a clock to determine a time when the medication was taken from the container. In one or more embodiments, the monitoring server

further comprises a clock to determine a time when the medication was taken from the container. In one or more embodiments, the monitoring server processing circuit is further configured to adjust the dose time period based on an input received through the wireless communication network. In one or more embodiments, the monitoring server processing circuit is configured to create display data including adherence to the dose time for a first display area, and create different display data for a second display area, and to transmit the display data for viewing on an electronic display of a remote computing device.

Another aspect of the present invention is directed to adherence to dose time and includes a system of monitoring medication usage by a patient. The system includes a medication container comprising an interior space to hold the medication, one or more sensors configured to detect the medication within the interior space, a processor configured to determine medication removal from the interior space based on sensor output from the one or more sensors, and a wireless communication circuit configured to transmit the medication removal through a wireless communication network. The system also includes a monitoring server located remotely from the medication container that includes a communication interface configured to receive the medication removal from the medication container through the wireless communication network, a memory circuit that stores a prescribed dose time period for taking the medication, and a monitoring server processing circuit configured to calculate an adherence to dose time as whether the medication removal occurred within the prescribed dose time period.

In one or more embodiments, the medicine container further comprises a clock to determine a time when the medication was taken from the container. In one or more embodiments, the monitoring server further comprises a clock to determine a time when the medication was taken from the container. In one or more embodiments, the monitoring server processing circuit is further configured to adjust the dose time period based on an input received through the wireless communication network. In one or more embodiments, the monitoring server processing circuit is configured to create display data including adherence to the dose time for a first display area, and create different display data for a second display area, and to transmit the display data for viewing on an electronic display of a remote computing device.

Another aspect of the invention is directed to adherence to dose time and includes a method of remotely monitoring usage of medication for a patient. The method includes receiving from a medication container a taken medication that has been removed from the medication container, the taken medication being received through a wireless communication network. The method includes receiving through the wireless communication network a prescribed dose time and storing the time in a memory circuit. The method includes determining that the patient is adherent when the taken medication is removed from the container within the prescribed dose time.

In one or more embodiments, the method includes receiving the prescribed dose time prior to receiving the taken medication. In one or more embodiments, the method includes transmitting a message through the wireless communication network to an address stored in the memory circuit upon determining that the patient is not adherent and the taken medication is not removed from the container within the prescribed dose time. In one or more embodiments, the method includes enrolling the patient by receiving the patient's name, information, and the prescribed dose time prior to receiving the taken medication from the container. In one or more embodiments, the method includes receiving from the medicine container a time when the medicine was removed from the container. In one or more embodiments, the method includes determining a time when the medicine was removed from the container. In one or more embodiments, the method includes after receiving the prescribed dose time, receiving an input through the wireless communication network and adjusting the prescribed dose time. In one or more embodiments, the method includes creating display data including adherence to dose time for a first display area, creating display data for a second display area, and transmitting the display data for viewing on an electronic display of a remote computing device.

Another aspect of the invention is directed to adherence to dose time and includes a method of remotely monitoring usage of medication for a patient. The method includes receiving from a medication container an indication that medication has been removed from the medication container, the indication being received through a wireless communication network. The method includes receiving through the wireless communication network a prescribed dose time and storing the time in a memory circuit. The method includes determining that the patient is adherent when the indication occurs within the prescribed dose time.

In one or more embodiments, the method includes receiving the prescribed dose time prior to receiving the taken medication. In one or more embodiments, the method includes transmitting a message through the wireless communication network to an address stored in the memory circuit upon determining that the patient is not adherent and the taken medication is not removed from the container within the prescribed dose time. In one or more embodiments, the method includes enrolling the patient by receiving the patient's name, information, and the prescribed dose time prior to receiving the taken medication from the container. In one or more embodiments, the method includes receiving from the medicine container a time when the medicine was removed from the container. In one or more embodiments, the method includes determining a time when the medicine was removed from the container. In one or more embodiments, the method includes after receiving the prescribed dose time, receiving an input through the wireless communication network and adjusting the prescribed dose time. In one or more embodiments, the method includes creating display data including adherence to dose time for a first display area, creating display data for a second display area, and transmitting the display data for viewing on an electronic display of a remote computing device.

Another aspect of the invention is directed to absolute adherence to prescription medication and includes a system of monitoring medication usage by a patient. The system includes a medication container comprising an interior space to hold the medication, one or more sensors configured to detect an amount of the medication within the interior space, a container processor, and a wireless communication circuit configured to transmit the amount of the medication remaining within the interior space. The system also includes a monitoring server located remotely from the medication container that includes a communication interface configured to receive the remaining amount of medication from the medication container through a wireless communication network, a memory circuit that stores a prescribed medication dose and a prescribed dose time, and a monitoring server processing circuit configured to calculate an amount of the medication taken based on the remaining amount of medication received from the medication container. The monitoring server processing circuit is further configured to calculate an absolute adherence score that includes whether the medication was taken within the dose time and whether the amount of the medication taken is equal to the prescribed medication dose.

In one or more embodiments, the monitoring server processing circuit is further configured to assign a first value when the amount of medication taken equals the prescribed medication dose and the medication was taken during the dose time, the monitoring server processing circuit further configured to assign a second value when the amount of medication taken does not equal the prescribed medication dose or the medication was not taken during the dose time. In one or more embodiments, the container processor is configured to determine the amount of medication taken from the interior space based on sensor output from the one or more sensors. In one or more embodiments, the memory circuit stores contact information for an authorized entity of the patient, and wherein the monitoring server processing circuit is configured to transmit a message through the wireless communication network to the authorized entity when the adherence is outside a predetermined amount. In one or more embodiments, the medicine container further comprises a clock to determine a time when the medication was taken from the container. In one or more embodiments, the monitoring server further comprises a clock to determine a time when the medication was taken from the container. In one or more embodiments, the monitoring server processing circuit is further configured to adjust the dose time period based on an input received through the wireless communication network. In one or more embodiments, the monitoring server processing circuit is configured to create display data including absolute adherence for a first display area, and create different display data for a second display area, and to transmit the display data for viewing on an electronic display of a remote computing device.

Another aspect of the invention is directed to absolute adherence to prescription medication and includes a system of monitoring patient usage of a medication. The system includes a medicine container comprising an interior space to hold the medication, one or more

sensors configured to detect medication within the interior space, a container processor configured to determine a remaining amount of medication within the interior space based on readings from the one or more sensors, and a wireless communication circuit configured to transmit the remaining amount of medication through a wireless communication network. The system also includes a monitoring server located remotely from the medicine container and configured to receive the remaining amount of medication from the medicine container through the wireless communication network. The monitoring server includes a processing circuit configured to calculate, based on the remaining amount of medication received from the medicine container, an absolute adherence to medication as to whether a correct dose of the medication was taken within a correct dose time.

In one or more embodiments, the monitoring server is further configured to calculate a medication adherence per dose time as an actual amount of the medication taken at the dose time divided by an amount of the medication prescribed to be taken at the dose time. In one or more embodiments, the monitoring server is configured to determine the absolute adherence to medication at a plurality of times during a day and to calculate a daily absolute adherence to medication. In one or more embodiments, a memory circuit is included that has contact information for an authorized entity, and wherein the monitoring server processing circuit is configured to send a message through the wireless communication network to the authorized entity when the absolute adherence to medication is outside a predetermined amount. In one or more embodiments, the medicine container further comprises a clock to determine a time when the medication was taken from the container. In one or more embodiments, the monitoring server further comprises a clock to determine a time when the medication was taken from the container. In one or more embodiments, the monitoring server processing circuit is further configured to adjust the dose time period based on an input received through the wireless communication network. In one or more embodiments, the monitoring server processing circuit is configured to create display data including absolute adherence for a first display area, and create different display data for a second display area, and to transmit the display data for viewing on an electronic display of a remote computing device.

Another aspect of the invention is directed to absolute adherence and includes a method of remotely monitoring usage of medication for a patient. The method includes receiving from a medication container an amount of medication that has been removed from the medication container, the amount of medication being received through a wireless communication network; receiving through the wireless communication network a prescribed dose time period and a prescribed medication amount and storing these in a memory circuit; determining that the patient is adherent when the medication has been removed from the medication container within the prescribed dose time period and the amount of medication is equal to the prescribed medication amount.

In one or more embodiments, the method includes receiving the prescribed dose time period and the prescribed medication amount prior to receiving the amount of medication removed from the container. In one or more embodiments, the method includes transmitting a message through the wireless communication network to an address stored in a memory circuit
5 upon determining that the patient is not adherent. In one or more embodiments, the method includes enrolling the patient by receiving the patients name, information, the prescribed medication amount and the prescribed dose time prior to receiving the taken medication from the container. In one or more embodiments, the method includes receiving from the medicine container a time when the medicine was removed from the container. In one or more
10 embodiments, the method includes determining a time when the medicine was removed from the container. In one or more embodiments, the method includes after receiving the prescribed dose time, receiving an input through the wireless communication network and adjusting the prescribed dose time. In one or more embodiments, the method includes creating display data including the absolute adherence for a first display area, creating display data for a second
15 display area, and transmitting the display data for viewing on an electronic display of a remote computing device.

Another aspect of the invention is directed to a tare system for the container. One aspect is directed to a system of monitoring patient usage of a medication that includes a medicine container with an interior space to hold the medication, a weight sensor to detect a
20 weight of the medication within the interior space, a wireless communication circuit configured to transmit the weight through a wireless communication network, and a container processor. The system also includes a monitoring server located remotely from the medication container and configured to receive the weight from the medicine container through the wireless communication network, the monitoring server configured to transmit a message to the
25 medicine container through the wireless communication network to instruct the patient to empty the interior space, and transmit a message to the medicine container through the wireless communication network to recalibrate the weight sensor to a zero.

In one or more embodiments, the container processor is configured to calculate an amount of medication removed from the interior space over a time period. In one or more
30 embodiments, the medicine container further comprises a display configured to display a message to the patient, and wherein the monitoring server is configured to transmit a message to the medicine container that causes a message to be displayed on the display indicating that the medication is to be removed from the interior space. In one or more embodiments, the medicine container further comprises a display configured to display a message to the patient,
35 and wherein the monitoring server is configured to transmit a message to the medicine container that causes a message to be displayed on the display indicating that the patient is not to perform any actions on the container during the calibration process.

Another aspect of the invention is directed to a tare system for the container. The system is configured for monitoring usage of medication by a patient and includes a container comprising an interior space to hold the medication, one or more sensors configured to detect a weight of the medication within the interior space, a container processing circuit configured to determine taken medication based on readings from the one or more sensors and a wireless communication circuit configured to transmit the taken medication over a wireless communication network. The system also includes a monitoring server located remotely from the medicine container, the monitoring server comprising: a communication interface configured to receive the taken medication transmitted from the container through the wireless communication network; a monitoring server processing circuit configured to: transmit a message to the medicine container through the wireless communication network to instruct the patient to empty the interior space; and transmit a message to the medicine container through the wireless communication network to recalibrate the weight the one or more sensors to a value indicative of a lack of the medication within the interior space.

In one or more embodiments, the medicine container further comprises a display configured to display a message to the patient, and wherein the monitoring server is configured to transmit a message to the medicine container that causes a message to be displayed on the display indicating that the medication is to be removed from the interior space. In one or more embodiments, the medicine container further comprises a display configured to display a message to the patient, and wherein the monitoring server is configured to transmit a message to the medicine container that causes a message to be displayed on the display indicating that the patient is not to perform any actions on the container during the calibration process.

Another aspect of the invention is directed to a method of calibrating a container that stores medication. The method includes transmitting a first signal over a wireless communication network to a container configured to store medication, responsive to the first signal, displaying a message on a display of the container to remove the medication from the container, transmitting a second signal over the wireless communication network to recalibrate a weight sensor to zero; receiving a confirmation from the medication container that the weight sensor has been calibrated.

The various aspects of the various embodiments is used alone or in any combination, as is desired.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic diagram of main functional elements of a medication usage monitoring system.

Figure 2 is a schematic view of a container for medication.

Figure 3 is a schematic diagram of a sensing circuit for use with a medication container.

Figure 4 is a schematic diagram of a monitoring server of Figure 1.

Figure 5 is a view of a display screen displaying information from the monitoring server. Figures 6-23 include display screen displaying information through an Analytics option. Figures 24-28 include display screens displaying information through a Bottles option. Figures 29-31 include display screens displaying information through a Messaging

5 option.

Figures 32-36 include display screens displaying information through a Monitor option. Figure 37 includes a display screen displaying information through a Patients option. Figure 38 includes a display screen displaying information through a Refill option.

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DETAILED DESCRIPTION

The present application is directed to systems and methods of tracking medication adherence for one or more patients. Patients are enrolled with the system and provided with a smart container to hold their medication and various supplements (hereinafter referred to together as medication). The smart container is configured to track medication usage and transmit the usage to a remote monitoring entity. The monitoring entity tracks medication usage for each of the enrolled patients. The entity is further able to communicate with each of the patients and their caregivers to provide various types of information relevant to their medication usage.

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Figure 1 illustrates an overview of the system 10 that provides for remote medication adherence monitoring. The system includes a monitoring server 40 that is able to track medication usage of a plurality of patients 11. Each patient 11 is assigned one or more medication containers 20 to hold their medication. Some patients 11 may be assigned a single container 20 for one or more medications, while others may include multiple different containers 20 to hold their multiple different types of medications. The container 20 is configured to track medication usage and communicate the information to the monitoring server 40 over a communication network 50. The system 10 is further configured to provide access to some or all of the usage information collected at the monitoring server 40 to authorized parties 60

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Medication Container

As illustrated in Figure 2, the system includes a medication container 20 that includes an interior space to hold medication. The container 20 may be configured to hold medications of different physical forms, including but not limited to pills, tablets, capsules, gelatin, liquid, and powder. The container 20 may also be applicable for use with various different medications to include herbal medicines and supplements. The container 20 may include various configurations, including but not limited to vials (as illustrated in Figures 1-2), bottles, and various packaging. The container 20 may also have a larger capacity that is controlled by an upstream entity, such as a care provider, pharmacist, doctor, insurer, or drug manufacturer. In

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one embodiment, the container 20 is a receptacle used at a pharmacy with a capacity to hold a relatively large amount of the given medication.

The container 20 may have a variety of different configurations for holding one or more different medications. Figure 2 includes an embodiment in which the container 20 includes a body 25 with an exterior wall 22 that forms the interior space to hold the medication. The container 20 also includes one or more outlets 21 for dispensing the medication to the patient. One or more caps 23 may be configured to extend across the outlet 21 to prevent inadvertent removal of the medication. The container 20 may be configured to hold a single type of medication, such as the vial as illustrated in Figure 2 with the interior space having a single compartment. The container 20 may also be configured with the interior space divided into two or more separate compartments to hold different types of medication, or separate doses of the same medication. The compartments may include the same or different shapes and/or sizes.

The container 20 may include a variety of different sensors 24. The sensors 24 may be combined with or separate from a processing circuit 30. One type of sensor is an orientation sensor 24 is integrated with the container 20 to determine the orientation measured as the inclination of the body 25 relative to two or more orthogonal axes against a known reference point, such as Earth, or Earth's gravity. In one embodiment, the orientation sensor 24 determines orientation relative to X, Y, and Z axes. In one embodiment, the orientation sensor 24 is an accelerometer that measures the proper acceleration of the device. The orientation of the body 25 may also be determined by various other types of orientation sensors 24. Examples include but are not limited to gyroscopes, magnetometers, analog and digital levels, and other various meters, levels, and switches.

The container 20 may include a single orientation sensor 24 that measures the orientation along one or more axes. In one embodiment, the orientation sensor 24 comprises a low-g accelerometer (e.g. +/- 2g) that measures the orientation along three separate axes. The container 20 may also include two or more accelerometers that each measures the orientation along different axes. The orientation sensor 24 may be positioned at various locations integrated with the container 20. In one embodiment, the orientation sensor 24 is positioned within the interior space formed within the walls 22. This positioning may protect the sensor 24 from external forces. The sensor 24 may also be positioned on the exterior of the body 25 or embedded within the exterior wall. In embodiments with multiple sensors 24, the sensors 24 may be positioned at the same or different locations. In one embodiment, the sensors 24 are spread around the interior space.

The one or more orientation sensors 24 are initially oriented relative to the body 25. This provides for the one or more axes of the sensor 24 to coincide with the body 25. Using the example of Figure 2, each sensor 24 may be orientated with each of its three axes aligned with axes X, Y, and Z. Alternatively, the sensors 24 may be placed in any orientation relative to the body 25. Prior to use, the sensors 24 are calibrated. One method includes placing the body 25

in a fixed position with respect to the ground and by using the measurements of the sensor 24 while in this position. The readings of the sensor 24 would then be adjusted to align with the three axes of the body 10. In one embodiment, the container 20 includes just one orientation sensor 24.

5 The container 20 may further be equipped with one or more additional sensors 24. These additional sensors detect physical characteristics regarding the medicine in the interior space, the container 20, or environmental conditions. The one or more sensors 24 may be positioned at various locations about the container 20. In one embodiment, each of the sensors 24 is positioned within the interior space. This protects the sensors 24 from being
10 dislodged or misplaced. This also places the sensors 24 in direct contact with the medication within the interior space. Alternatively, the sensors 24 may be positioned on the exterior of the body 25 or embedded within the body 25. Additionally, the sensors 24 may be positioned within the cap 23. In embodiments with multiple sensors 24, the sensors 24 may be positioned at the same or different locations. In one embodiment, the sensors 24 are spread around the interior
15 space.

 The container 20 may include multiple different sensors 24 to detect the same physical characteristic. By way of example, the container 20 may include two or more orientation sensors 24, or two or more weight sensors 24. The data from the multiple sensors detecting the same aspect may be compared to determine that the data is consistent and reliable. Disparities
20 in the sensors readings for the same physical aspect may indicate that at least one of the sensors is malfunctioning.

 One type of sensor 24 detects the weight of the medicine in the interior space. The weight sensor 24 may use load force applied to a surface. The weight sensor 24 may be configured to measure changes in electrical signals based on changes in force, torsion, or load
25 placed on a strain gauge. The weight sensor 24 may be positioned within the interior space and is acted upon by the medication. In one embodiment, the weight sensor 24 is positioned at a bottom of the interior space away from the cap 23. This positioning provides for accurate weight detection when the body 25 is placed in an upright position, such as when it is set on a shelf or counter.

30 Another sensor 24 detects the volume of the medicine within the interior space. The volume sensor 24 may include various configurations for determining the level of the medicine within the interior space. Volume sensors 24 may be particularly applicable for detecting liquid medicine, although may also have good application for medicine in pill form and powder form. The volume sensor 24 may be configured to detect displacement and/or flow of the medicine to
35 and from the interior space. The volume sensor 24 may also include ultrasonic or optical sensing components to detect a level of the medicine within the interior space. Components for sensing the volume of the medicine include but are not limited to level meters, switches, gauges, tactile sensors, float gauges, and pressure sensors and gauges.

Another sensor 24 detects the motion of the medicine in the interior space and/or the motion of the container 20. Examples of motion sensors 24 include but are not limited to: passive and active infrared sensors; optical sensors including video and camera systems; radio frequency energy sensors using radar, microwave, and tomographic motion detection; sound detection using microphone and acoustic sensors; vibration sensors with triboelectric, seismic and inertia-switch sensors; and magnetism sensors using magnetic sensor or magnetometers. Sensors 24 may also detect one or more different environmental conditions. Examples include but are not limited to temperature sensors 24 and humidity sensors 24.

The sensors 24 may take multiple measurements to obtain accuracy in determining the various physical characteristics of the medicine. In one embodiment, the weight sensor 24 takes readings at about 15-100 times sampling rate per second with a resolution potential of about 0.001 grams. In another embodiment, a volume sensor 24 takes readings at about 15-100 times sampling rate per second with a resolution potential of 0.001 millimeters. In one embodiment, averages of the sensor readings are used in the determination process. In another embodiment, readings that are outside of an expected range are discarded as being bad. These readings may be discarded with the other acceptable readings being used for the calculations. The number of discarded readings may be monitored and notification sent to a remote party in the event the number reaches a predetermined number. This may indicate that the associated sensor 24 is failing.

In containers 20 with a single compartment (e.g., Figure 2), the container 20 may include a single sensor 24 to detect the specific aspects. By way of example, the container 20 may include a single orientation sensor 24 and a single weight sensor 24. In containers 20 with multiple compartments, the container 20 may include separate sensors 24 in the different compartments to detect an aspect that is individualized to the specific compartment. In one embodiment, the container 20 includes a separate weight sensor 24 in each compartment. For aspects that are common amongst the different compartments, the container 20 may include a single sensor 24. By way of example, the container 20 may include a single orientation sensor 24 or a single temperature sensor 24.

The container 20 may include multiple different sensors 24 to detect the same characteristic at different locations and/or times. In one embodiment, the container 20 includes multiple temperature sensors 24. One sensor 24 detects a temperature of the environment for purposes of determining a correction offset as will be explained below. A second sensor 24 detects a temperature in the interior space to monitor temperature of the medicine. A third sensor 24 may detect a temperature at the location of the electrical components to monitor for overheating and possible failure.

The environmental sensors 24 may be used for a variety of different purposes. For example, a temperature sensor 24 may determine one or more temperatures to determine: a

temperature of the medication, a temperature of the exterior environment; and a temperature of the electrical components.

The containers 20 include one or more sensing circuits 30 to track medication usage.

Figure 3 illustrates a schematic view of a sensing circuit 30 that is integrated with the

5 container 20. The sensing circuit 30 may be integrated with one or more of the body 25 and the cap 23. In one or more embodiments, the entire sensing circuit 30 is integrated with the body 25. In these embodiments, one or more components of the sensing circuit 30 may be positioned within the interior space of the body 25 for protection from being damaged. In one or more embodiments, the entire sensing circuit 30 is integrated with the cap 23. In one or more
10 embodiments, components of the sensing circuit 30 are integrated with both the body 25 and the cap 23 (i.e., one or more components are integrated with the body 25 and one or more components are integrated with the cap 23).

The sensing circuit 30 includes a processing circuit 31, including, for example, one or more microprocessors, microcontrollers, Application Specific Integrated Circuits (ASICs) or the
15 like, configured with appropriate software and/or firmware to control the overall operation of the container 20 according to program instructions stored in a memory circuit 32.

The sensing circuit 30 may include one or more different sensors 24 to detect a remaining amount of medication. This may include one or more orientation sensors 24 configured to detect the orientation of the container 20 in one or more different axes X, Y, Z.
20 Other examples of sensors 24 include but are not limited a temperature sensor, motion sensor, volume sensor, and a humidity sensor. The sensors 24 may be positioned in the body 25, in the interior space, or in the attachable cap 23.

In one embodiment, the processing circuit 31 is configured to perform calculations to determine a remaining amount of medication based on one or more signals received from the
25 one or more sensors 24. In other embodiments, the processing circuit 31 is configured to cause the raw sensor readings to be transmitted to a remote location where the calculations are performed to determine a remaining amount of medication indicating the medication usage.

The sensing circuit 30 includes a computer-readable storage medium (shown as memory circuit 32), which stores instructions and/or data needed for operation. The memory
30 circuit 32 may include both volatile and non-volatile memory, for example. Memory circuit 32 may also store orientation information necessary to determine if the body 25 is in the proper orientation for accurately determining the medication.

A communication interface 33 may comprise a short-range wireless interface, such as a BLUETOOTH interface, RFID, ZIGBEE, or WIFI interface, a long range cellular phone or
35 satellite communications interface, or a wired interface, such as a serial, USB, micro USB, FIREWIRE, Lightning, or Thunderbolt interface. There may be more than one communications interface 33. An antenna 39 may be configured for transmitting and receiving wireless signals to and from remote sources (e.g. server 49).

The sensing circuit 30 may include a GPS receiver 34 or other location detector to determine location and history of locations of the container 20. A clock 35 may be associated with the processing circuit 30 that measures the various timing requirements for specific events. The clock 35 may be independent from the processing circuit 30 as illustrated in Figure 3, or
5 may be incorporated within the processing circuit 30. The clock 35 may be configured to measure the specific time during each day, as well as to measure various time periods (i.e., days, weeks, months, years, etc.) An energy storage device 36 (e.g., a battery) is provided to power the various components.

The container 20 may also include additional components that are associated with the
10 sensing circuit 30. A display 37 may be configured to display information to the user and/or medical provider. The display 37 may comprise a liquid crystal display (LCD) or an organic light emitting diode (OLED) for example. Additionally, the display 37 may use printed electronic displays, electronic paper displays, or electronic ink technology to provide a thin, flexible and durable display to enable users to view information. An input 38 may provide for a user to enter
15 applicable information. The input 38 may include a variety of formats, including but not limited to one or more buttons, touchpad, and keypad.

The container 20 may also include or control one or more alerting devices for alerting the user of specified events or conditions. The alerting devices may comprise indicator lights that illuminate or generate lighting effects, speakers, beepers, buzzers, or other sound devices; and
20 vibrators or other tactile devices. The alerting devices are controlled by the processing circuit 31 to notify the user when predetermined events or conditions occur. The alerts can be personalized and customized by the user to distinguish the alerts. In one embodiment, alerting device 31 includes an indicator light that is illuminated when the user has not taken their medication within a predetermined time period. The alerting devices may be included in the
25 display 37 to include a message for the patient.

Figure 3 includes the one or more sensors 24 included within the sensing circuit 30. Other embodiments may include one or more of the sensors as separate components that are communicatively coupled to the sensing circuit 30. The configuration of the sensing circuit 30 and the various components that are included in the sensing circuit 30 and are communicatively
30 coupled to the sensing circuit 30 may vary.

U.S. Patent Serial No. 13/827,373 entitled "Medicine Container with an Orientation Sensor" filed on March 14, 2013, discloses various medication containers that include one or more sensors and is configured to determine a remaining amount of medication within an interior space. This application is herein incorporated by reference in its entirety.

Wireless Communication Network

The communication interface 33 of the container 20 as illustrated in Figures 1 and 3 enables the container 20 to communicate with other nodes over the PDN 55. The

communication interface 33 may include a cellular interface that enables communication with a mobile communication network 51 (e.g., a WCDMA, LTE, or WiMAX network) as illustrated in Figure 1. The mobile communication network (MCN) 51 includes a core network 52 and a radio access network (RAN) 53 including one or more base stations 54. The MCN 51 may be a conventional cellular network operating according to any communication standards now known or later developed. For example, the MCN 51 may comprise a Wideband Code Division Multiple Access (WCDMA) network, a Long Term Evolution (LTE) network, or WiMAX network. The MCN 51 is further configured to access a packet data network (PDN) 55. The PDN 55 may comprise a public network such as the Internet, or a private network.

As further illustrated in Figure 1, the wireless communication interface 33 may also be able to communicate with a wireless access point 56 to access the PDN 55. In one or more embodiments, the interface 33 includes a Wireless Local Area Network (WLAN) interface that operates according to the 802.11 family of standards, which is commonly known as a WiFi interface. The communication interface 33 may further include a personal area network (PAN) interface, such as a BLUETOOTH, RFID, and ZIGBEE interface.

The container 20 may also be connected to a nearby device (not shown) through a wired interface, such as a RS 232, USB or FIREWARE interface. Such a device would be configured to access the PDN 55.

The communication interface 33 may also include a Near Field Communication (NFC) interface. Near Field Communication is a short-range wireless connectivity technology that uses magnetic field induction to permit devices to share information with each other over short distances (e.g., on the order of 4 centimeters or less). Communication between two NFC-capable devices is possible when the devices are within close physical proximity to one another, and may be initiated when the devices are actually brought into contact with each other. The distance separating two NFC-capable devices is typically anywhere between about 0 and 4 centimeters, but in some instances can be up to about 20 centimeters.

The container 20 is configured to communicate medication usage information through the PDN 55 to the monitoring server 40. The monitoring server 40 may be configured to provide a web interface 49 as illustrated in Fig. 1. The system 10 is configured for accessing information through the monitoring server 40 using a browser-based interface or an applications program interface (API). The browser-based interface may include a website through which the contents of the database 42 may be accessible. Although the website may be hosted by the server 40, it may also be hosted at another location accessible through the PDN 55. The different entities 60 may log into and access the pertinent information at various stages throughout the process. Alternatively, the different entities 60 may obtain medication usage data from the database 42 using one or more Application Programming Interfaces (APIs) through a desktop or mobile client, for example

The monitoring server 40 includes one or more processing circuits (illustrated as processing circuit 41) that may include one or more microprocessors, microcontrollers, Application Specific Integrated Circuits (ASICs), or the like, configured with appropriate software and/or firmware. A computer readable storage medium (shown as memory circuit 44) stores data and computer readable program code that configures the processing circuit 41 to implement the techniques described above. Memory circuit 44 is a non-transitory computer readable medium, and may include various memory devices such as random access memory, read-only memory, and flash memory. A communication interface 43 connects the server 40 to the PDN 55, and may be configured to communicate with the PDN 55 according to one or more 802.11 standards. The communication interface 43 may support a wired connection (e.g., Ethernet), a wireless connection, or both. The database 42 is stored in a non-transitory computer readable storage medium (e.g., an electronic, magnetic, optical, electromagnetic, or semiconductor system-based storage device). The database 42 may be local or remote relative to the monitoring server 40. Access to the web interface 49 may be restricted to one or more administrative users 45. A clock 48 may be associated with the processing circuit 41 that measures the various timing requirements for specific events. The clock 48 may be incorporated with the processing circuit 41, or may be a separate component independent from the processing circuit 41. The clock 48 may be configured to measure the specific time during each day, as well as to measure the various time periods (i.e., days, weeks, months, years, etc.).

The monitoring server 40 provides web interface 49 for accessing medication usage information. The web interface 49 may support a website through which the contents of the database 42 are accessible. In one or more embodiments the web interface 49 provides browser-based access to the contents of the database 42. The different entities 60 may login to the browser-based interface and access the pertinent medication usage information. Alternatively, the different entities 60 may obtain medication usage data from the database 42 using one or more Application Programming Interfaces (APIs) through a desktop or mobile client, for example. Also, in one or more embodiments the web interface 49 supports access to the database 42 using web services in addition to, or as an alternative to, the browser-based interface described above.

The different entities 60 may access the information at the monitoring server 40 through a variety of devices 61. The devices 61 may include laptop computers, personal computers, personal digital assistants, mobile computing/communication, tablet devices, and various other-like computing devices. The devices 61 may also include a body-worn device such as a watch or pendant configured to provide access. Each of the entities 60 uses a respective device 61 and accesses the monitoring server 40 through the PDN 55, or alternatively some other network. In one embodiment, one or more of the entities 60 may use his or her respective

device 61 to access the server 40 through a separate portal. Each entity's portal may include a secure interface through which the entity may access the information that is assigned to them.

A variety of different entities 60 may have access to some or all of the information at the monitoring server 40. This may include but is not limited to doctors, hospitals, insurance companies, drug manufacturers, pharmacies, patients, family members, patients, and caregivers. The entities 60 may access this information by accessing the server 49. In one or more embodiments, the monitoring server 40 may be configured for browser-based accessibility. The browser-based interface may support well-known browsers such as Internet Explorer and Mozilla Firefox, Safari, Chrome. Alternatively, or in conjunction with the browser-based interface, the monitoring server 40 may provide access to database 42 to requesting APIs over the PDN 55.

Monitoring Server

The monitoring sever 40 is a robust automated system that analyzes and communicates medication conditions, usage, and adherence data that are collected from the containers 20. The monitoring server 40 monitors, records, and quantifies multiple medication adherence data points providing accurate, comprehensive, and actionable information in real time. The monitoring server 40 also calculates medication usage and tracks and quantifies the effectiveness of the adherence communications between the various entities 60 and the patients 11. By monitoring, analyzing and improving medication adherence performance in real time, the entity 40 provides healthcare and pharmaceutical systems with real time cost savings and intelligence.

The various patients 11 are enrolled into the system 10 by registering with the monitoring server 40 (e.g., via the browser-based interface or with an administrator 45 (e.g., in a non-electronic fashion)). The registration may include the patient 11 providing basic information (e.g., name, age, date of birth), contact information (e.g., phone number, email address, home address). The registration also includes entry of the medication that will be taken and the applicable dose information (e.g., dose time, dose amount, tablet, capsule or liquid form, mass or volume of medication, quantity). In one or more embodiments, the registration process is completed by the patient's healthcare provider or insurance provider. These entities 60 provide the necessary information to the monitoring server 40 to begin monitoring the patient 11. The registration process may also be performed by the patient 11 themselves by accessing the monitoring server 49 through the communications network 50 and entering the necessary information. The registration may also be performed automatically by the monitoring server 40. A healthcare provider or insurance provider may give approval and access to the monitoring server 40 via APIs, so the monitoring server 40 may securely access the healthcare providers' or insurance providers' patient information for registration. The monitoring server 40 does not need to store sensitive and private patient information as long as the monitoring entity 40 has

access to the patient information, which can remain stored securely within the healthcare providers' or insurance providers' servers and computing systems. Sensitive and private information such as patient information can also be de-identified (i.e. made anonymous) and/or encrypted. Access to patient data in the database 42 can be restricted to entities that have
5 approved credentials, which can be verified through authentication (e.g., username and password).

The monitoring server 40 and system 10 are configured to track the medication adherence information from a plurality of different patients 11. Each patient 11 may be taking one or more different medications that are stored in one or more containers 20. Real-time
10 medication adherence monitoring is a major advance from the current industry standard of medication possession ratio (MPR) that sifts through prescription claims data to obtain a ratio based upon how many days a user has a prescription on hand. MPR is based on information that may be thirty to ninety days old, is not actionable, and does not capture actual patient medication adherence behavior.

The various compliance calculations performed by the system 10 may occur at one or more locations. This may include one or more calculations performed by the processing circuit 31 integrated with the container 20 and/or the processing circuit 41 of the server 40. This may include the entire processing being performed by the circuit 31 at the container 20, performed by the circuit 41 at the monitoring server 40, or calculations performed by both
20 circuits 31, 41.

Quantifying Medication Adherence per Dose

One aspect monitored by the system 10 is adherence to medication dose. A dose of medication is defined as the amount of medication to be taken by a patient. The system 10
25 quantifies adherence to dose by comparing doses taken with doses prescribed. Adherence to a prescribed dose is expressed by a ratio of the actual amount of medication taken compared to the amount of medication prescribed. This ratio quantifies adherence to dose across dose times. Dose time is defined as the prescribed time of day when a dose is to be administered. Dose times can be multiple time periods within a day such as morning, noon, afternoon,
30 evening, bedtime, or breakfast, lunch, dinner. Dose times can also be scheduled as exact times throughout the day. Dose times can also be daily, or per day, or per series of days. Quantifying dose adherence provides healthcare users with a real and actual measure of patient dosing, as well as dose adherence performance and behavior over time. Furthermore, since the system accounts for all doses taken by patients, the system can alert caregivers and patients when too
35 much, or too little medication has been taken.

As an example, a patient is prescribed a medication with a strength of 100mg per dose, taken four times daily. In oral tablet or capsule form, each tablet equals 25mg, therefore 4 tablets must be taken to equal the full 100mg dose. In liquid form, one vial or syringe containing

the medication for injection can contain one 100mg or more doses. Liquid medication can be administered by injection, intravenously, inhalation and orally. The example dose times prescribed or recommended for this medication are for morning, noon, evening and bedtime.

5 *Example 1. Quantifying Medication Adherence per Dose for Tablets*

This example demonstrates how the system quantifies the patient adherence per dose, per dose time for oral medications in tablet or capsule form.

a. Adherence to Morning Dose

- Patient takes 4 out of a prescribed 4 tablets
- 10 • Adherence to the prescribed dose at this dose time results in a ratio of 4/4, or 1.00

b. Adherence to Noon Dose

- Patient takes 3 out of a prescribed 4 tablets
- Adherence to the prescribed dose at this dose time results in a ratio of 3/4, or
- 15 0.75

c. Adherence to Evening Dose

- Patient takes 2 out of a prescribed 4 tablets
- Adherence to the prescribed dose at this dose time results in a ratio of 2/4, or
- 20 0.50

d. Adherence to Bedtime Dose

- Patient takes 0 out of a prescribed 4 tablets
- Adherence to the prescribed dose at this dose time results in a ratio of 0/4, or
- 0.00

e. Adherence to Daily Dose

- 25 • Patient takes 9 out of a prescribed 16 tablets for the day
- Average adherence and indicator of adherence performance to the prescribed doses results in a ratio of 9/16, or 0.5625 (the average of the four doses)

This example includes a prescription for four doses in a day. The same logic of the adherence monitoring is applied to various other doses (e.g., 1 dose per day, 2 doses per day, 30 etc.). Further, the ratio for determining the adherence to daily dose can be calculated in the same manner for the different variety of daily doses.

Example 2. Quantifying Medication Adherence per Dose for Liquid Medications

This example demonstrates how the system quantifies patient adherence score per 35 dose, per dose time for liquid medications.

a. Adherence to Morning Dose

- Patient takes 100mg out of a prescribed 100mg dose

- Adherence to the prescribed dose at this dose time results in a ratio of 100/100, or 1.00

b. Adherence to Noon Dose

- Patient takes 75mg out of a prescribed 100mg dose
- Adherence to the prescribed dose at this dose time results in a ratio of 75/100, or 0.75

c. Adherence to Evening Dose

- Patient takes 50mg out of a prescribed 100mg dose
- Adherence to the prescribed dose at this dose time results in a ratio of 50/100, or 0.50

d. Adherence to Bedtime Dose

- Patient takes 0mg out of a prescribed 100mg dose
- Adherence to the prescribed dose at this dose time results in a ratio of 0/100, or 0.00

e. Adherence to Daily Dose

- Patient takes 225mg out of a prescribed 400mg for the day
- Average adherence and indicator of adherence performance to the prescribed doses results in a ratio of 225/400, or 0.5625 (the average of the four doses)

Example 3. Quantifying Extra Dose

The system 10 is further configured to calculate and record if the dose taken is more than the dose prescribed. Example 3 provides an example of how the system quantifies patient extra dosing.

a. Tablet Medication Extra Dose

- Patient takes a dose of 6 tablets versus a prescribed 4 tablets
- Adherence to the prescribed dose at this dose time results in a ratio of 6/4, or 1.50
- Patient took 6 tablets, 1.5 times more than the dose prescribed

b. Liquid Medication Extra Dose

- Patient takes a dose of 150mg versus a prescribed 100mg
- Adherence to the prescribed dose at this dose time results in a ratio of 150/100, or 1.50
- Patient took 150mg, 1.5 times more than the dose prescribed

Qualifying Medication Adherence per Dose Time

The system 10 is further configured to determine adherence to medication dose time. Adherence to dosing time and frequency is critical for patients who are prescribed time sensitive medications. Dose time is defined as the prescribed time when a dose of medication is to be taken by a patient. A patient must take their medication within the prescribed dose time in order to be adherent to the dose time. The system 10 qualifies adherence to the dose time by creating a binary score of the dose taken within each dosing time. Dose times can be multiple time periods within a day such as morning, noon, afternoon, evening, bedtime, or breakfast, lunch, dinner. Dose times can also be scheduled as exact times throughout the day. Dose times can also be daily, or per day, or per series of days. The binary adherence scoring method for dose time expresses a definitive indication of dose time adherence: If a patient takes medication within a dose time then the system gives a score of 1 which indicates adherence to dose time (medication taken within a dose time). A score of 0 equals non-adherence to dose time (medication not taken within a dose time).

Example 4

A patient is prescribed a medication to be taken four times daily. The example dose times prescribed or recommended for this medication are for morning, noon, evening and bedtime. The patient takes the prescribed dose within the morning dose time; at noon, the patient takes less than the prescribed dose within the noon dose time; in the evening, the patient takes the prescribed dose after the evening dose time but before the bedtime dose time; at bedtime, the patient does not take any dose. The system qualifies the patient adherence to the prescribed medication dose time as follows:

a. Adherence to Morning Dose Time

- Patient takes a prescribed dose within the morning dose time
- Adherence to the prescribed dose time is scored 1, or YES (or Adherent)

b. Adherence to Noon Dose Time

- Patient takes a partial prescribed dose within the noon dose time
- Adherence to the prescribed dose time is scored 1, or YES (or Adherent)
- NOTE: Patient is adherent to the noon dose time, however, patient is non-adherent to the prescribed dose.

c. Adherence to Evening Dose Time

- Patient takes a prescribed dose outside the evening dose time
- Adherence to the prescribed dose time is scored 0, or NO (or Non-adherent)

d. Adherence to Bedtime Dose Time

- Patient does not take a prescribed dose within the bedtime dose time
- Adherence to the prescribed dose time is scored 0, or NO (or Non-adherent)

e. Adherence to Dose Time for the Day

- Patient is adherent 2 out of 4 dose times
- Average adherence to the prescribed doses results in a ratio of 2/4, or 0.50 (the average of the two dose times)

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Absolute Adherence to Prescription Medication Therapies

Absolute adherence to a prescribed medication therapy requires the patient 11 to take the prescribed dose at the prescribed dose time. The system 10 quantifies absolute adherence by creating a binary rating score. If a patient takes the correct dose, within the correct dose 10 time then, the absolute adherence score for this dose time is 1. If a patient does not take the correct dose (no dose, partial dose or extra dose), within the correct dose time, then the absolute adherence score for this dose time is 0, or non-adherent. This absolute adherence scoring method provides a definitive and qualitative measure of adherence to a prescribed medication therapy by totaling all scores over time. An absolute adherence score is determined 15 using the following:

RxD = Prescribed Dose

D = Dose taken

DT = Dose Time

AS = Absolute Adherence Score

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1 = Adherence

0 = Non-Adherence

If RxD = D and taken within the scheduled DT, then AS = 1

If RxD = D and taken before or after the scheduled DT, then AS = 0

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If RxD $\neq$ D and during the scheduled DT, then AS = 0

(If RxD > < D and taken within the scheduled DT, then AS = 0)

Calculating an absolute adherence rate includes the following:

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AS = Absolute Adherence Scores

DT = Dose Times (or dose days)

A = Absolute Adherence

$$A = \sum AS \div \sum DT$$

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Example 5:

Assume that the absolute adherence scores for a patient are 1, 1, 0, and 0 for four prescribed doses. The absolute adherence score for the patient over that time period is determined as follows:

$$\begin{aligned} 5 \quad A &= (AS1 + AS2 + AS3 + AS4) \div 4 \\ &= (1 + 1 + 0 + 0) \div 4 = 0.50 \\ A &= 0.50 \end{aligned}$$

$$\begin{aligned} 10 \quad A\% &= ((AS1 + AS2 + AS3 + AS4) \div 4) \times 100 \\ A\% &= 50\% \end{aligned}$$

This formula can also be expressed as a long form calculation:

$$A = \left(\frac{1}{n \cdot m} \right) \sum_{i=1}^n \sum_{j=1}^m (D \cdot T)_{i,j}$$

Where

- 15 A = absolute adherence rate
 n = total number of days the drug is given
 m = total number of doses given per day
 i = day counter (e.g., i = 1,2,3,...,n days)
 20 j = dose counter (e.g., j = 1,2,3,..., m doses per day)

$(D \cdot T)_{i,j}$ equals $D \cdot T$ for the i^{th} day and the j^{th} dose. Where $D \cdot T = 1$ when dosage and time are correct and $D \cdot T = 0$ when dosage, time or both are wrong.

- 25 Dividing the double sum by the product of n times m normalizes A so that A = 1 represents perfect adherence and A = 0 represents no adherence at all. An A = 0.5 represents an overall adherence of 50% over the entire dosage regime.

- 30 EXAMPLE: Assume drug given bid for three days. Then m = 2 and n = 3. Expanding the master equation we obtain:

$$\begin{aligned} A &= \left(\frac{1}{3 \cdot 2} \right) \sum_{i=1}^3 \sum_{j=1}^2 (D \cdot T)_{i,j} = \left(\frac{1}{6} \right) \sum_{i=1}^3 \sum_{j=1}^2 (D \cdot T)_{i,j} \\ \text{Or } A &= \left(\frac{1}{6} \right) ((D \cdot T)_{1,1} + (D \cdot T)_{1,2} + (D \cdot T)_{2,1} + (D \cdot T)_{2,2} + (D \cdot T)_{3,1} + (D \cdot T)_{3,2}) \end{aligned}$$

Day and Dose	Dose: yes (1) no (0)	Time: yes (1), no (0)	$(D \cdot T)_{i,j}$
Day 1, Dose 1	$D_{1,1} = 1$	$T_{1,1} = 1$	$(D \cdot T)_{1,1} = 1$
Day 1, Dose 2	$D_{1,2} = 0$	$T_{1,2} = 1$	$(D \cdot T)_{1,2} = 0$
Day 2, Dose 1	$D_{2,1} = 1$	$T_{2,1} = 1$	$(D \cdot T)_{2,1} = 1$
Day 2, Dose 2	$D_{2,2} = 1$	$T_{2,2} = 1$	$(D \cdot T)_{2,2} = 1$
Day 3, Dose 1	$D_{3,1} = 1$	$T_{3,1} = 0$	$(D \cdot T)_{3,1} = 0$
Day 3, Dose 2	$D_{3,2} = 0$	$T_{3,2} = 0$	$(D \cdot T)_{3,2} = 0$

$$\text{Or } A = \left(\frac{1}{6}\right)(1+0+1+1+0+0) = \frac{3}{6} = 0.5$$

That is, over the entire dosing regimen the patient's overall adherence was 50%.

Example 6

- 5 A patient is prescribed a medication to be taken four times daily. The example dose times prescribed or recommended for this medication are for morning, noon, evening and bedtime. The patient takes the prescribed dose within the morning dose time; at noon, the patient takes less than the prescribed dose at within the noon dose time; in the evening, the patient takes the prescribed dose after the evening dose time but before the bedtime dose time;
- 10 at bedtime, the patient does not take any dose.
- a. Adherence to Morning Dose Time
 - Patient takes a prescribed dose within the morning dose time
 - Adherence to the prescribed dose event is scored 1 (or Adherent)
 - b. Adherence to Noon Dose Time
 - 15 • Patient takes a partial prescribed dose within the noon dose time
 - Adherence to the prescribed dose event is scored 0 (or Non-adherent)
 - c. Adherence to Evening Dose Time
 - Patient takes a prescribed dose outside the evening dose time
 - Adherence to the prescribed dose event is scored 0 (or Non-adherent)
 - 20 d. Adherence to Bedtime Dose Time
 - Patient does not take a prescribed dose within the bedtime dose time
 - Adherence to the prescribed dose event is scored 0 (or Non-adherent)

e. Adherence Rating per Day

- Patient is adherent 1 out of 4 dose times
- Average adherence performance rate to the prescribed dose events results in a ratio of 1/4, or 0.25 (average of the four dose times)
- Absolute adherence score for the day is 25%

The adherence information is maintained at the server 41 at the managing entity 40. The information can be accessed by one or more of the entities 60 as discussed above

Alerts and Conversions

An Alert condition (hereinafter Alert) occurs when the monitoring server 40 detects that the patient 11 has failed to take the proper amount of medication at the proper time. Other Alert conditions may include but are not limited to the patient 11 has taken too much medication, the patient 11 has not taken enough medication, the patient 11 has taken medication during the proper time but not the proper amount, and the patient has taken the proper amount of medication at the wrong time. An Alert may also occur when the monitoring server 41 determines that a remaining amount of medication for the patient 11 is below a predetermined amount. This determination is based on information received from the weight sensor in the container 20.

The monitoring server 40 may be configured to contact and send a notification to the patient or other party upon determining the Alert. The monitoring server 40 may be configurable to select when and how often to contact the patient or other party. In one or more embodiments, the monitoring server 40 contacts the patient or other party at each Alert. The monitoring server 40 may also be configured to contact the patient or other party after a predetermined number of Alerts.

In the event of an Alert, the monitoring server 40 may contact one or more outside persons. For example, this may include just the patient 11 or just the physician. Other examples may include multiple outside persons being simultaneously contacted at the occurrence of an Alert (e.g., contacting both the patient 11 and the caregiver). In one or more embodiments, just the patient 11 may be contacted for a predetermined number of Alerts. Once the predetermined number is surpassed, one or more additional parties are contacted in an attempt to get them to make the patient 11 take their medication.

The monitoring server 40 is configured to provide a variety of information in the notification of an Alert. The notification may include a variety of adherence information such as dose taken, amount of pills, tablets or capsules taken, time when dose taken, difference between the actual dose taken and the dose prescribed, current pill, tablet or capsule count, current amount of medication remaining in container and/or adherence scores. Notifications may also include a history of interactions, notes, surveys, alerts, notifications, results and interventions. Notifications can also include content that can be customized and may include,

but not limited to content such as marketing messages, incentives, coupons, discounts, audio files, video files, picture and image files, barcodes, rewards, currency, points, games, and surveys.

The notification may include a variety of different contexts, such as an email, text message, or phone call (based on the patient enrollment information and preferences).

Notification may also include sending a signal that activates a light on the container 20, and/or sending a message to the container to be displayed on the container display or digital label and/or played back as an audio or voice message through the container audio and voice speakers. 37. In one or more embodiments, the notification is directly from the monitoring server 40. In other embodiments, the monitoring server 40 provides direct access to alerts and notifications via an application program interface (API). The monitoring server 40 can provide external systems and applications with adherence notifications, alerts and data in real time through APIs. External systems and applications that may use APIs include, but are not limited to healthcare electronic health records, pharmacy systems, pharmaceutical systems, care monitoring systems, hospital systems, medical and healthcare systems, insurance systems, financial systems, analytical systems, software applications, smart phone applications, mobile device applications, and wearable applications. In other embodiments, the monitoring server 40 may contact one or more of a family member, caregiver, pharmacist, physician, care manager or insurance company about the failure of the patient to adhere to their medication regimen and therapy.

An Intervention occurs when the patient 11 is contacted through the system 10 by another party to understand why the patient 11 did not take their medication correctly. This may include contact by one or more of the monitoring server 40, or other outside entity 60. The contact may be a personal visit, phone call (live or recorded message), email message, text message, etc.

The monitoring server 40 tracks the Interventions for each of the patients and their medications 11 by recording a history of all communications made to the patient by the server 40 and additional parties, by recording annotations, surveys and notes of intervention contact, by recording and transcribing phone calls placed from an electronic IP based telecommunications system. Further, the monitoring server 40 tracks medication adherence, refill and intervention conversions after the patient has been contacted as part of an Alert and/or after an Intervention.

A successful Conversion is when the patient 11 complies with an alert notification and or intervention and by performing the instructed medication adherence action within a timeframe, such as taking a dose within a dose time or refilling a prescription within a refill time frame. For example, a successful Conversion occurs when a patient 11 is monitored by the monitoring server 40 and is contacted and notified that she or he needs to take the proper amount of medication, and thereafter, takes the proper amount of the medication and the monitoring server 40 confirms the correct amount of medication taken by the container 20. A successful

Conversion can also occur when and a patient 11 is monitored by the monitoring server 40 and is contacted and notified that she or he needs to refill the medication, and thereafter, refills the medication and the monitoring server 40 confirms the correct amount of medication refilled by the container 20. The patient 11 may also be assigned a new container 20 with the refilled medication that may be delivered to or picked up by the patient 11. The monitoring server 40 can also confirm refills by tracking and confirming the receipt of the new containers 20 by the patient 11 refilled with medication. The monitoring server 40 keeps track of successful conversions as a metric of alert, notification and intervention performance.

Similar to Google AdWords, the content, frequency, timing and effectiveness of alerts, notifications and interventions can be measured and analyzed for performance. Conversions are scored and rated as a ratio of successful conversions against alerts, notifications or interventions. For example, if a particular missed dose alert, notification or intervention results in the correct dose amount taken by the patient 11, and this occurs 10 out of every 10 times then the conversion rate scores a 1.00 or 100%. In contrast, if a different missed dose alert, notification or intervention results in the correct dose amount taken by the patient 11 some of the time, and this occurs 5 out of every 10 times then the conversion rate for this missed dose alert, notification or intervention scores a 0.50 or 50%.

Display Information

The different entities 60 are able to access the patient information through the monitoring server 40. Upon accessing the monitoring server 40, each entity 60 may be required to enter a passcode to gain access to the information. Further, the information may be stored in a manner in which a particular entity 60 is able to access a limited amount of information. For example, a doctor may be able to access a first amount of information, and a caregiver may be able to access different information.

The information accessible at the monitoring server 40 is presented through a dashboard display 70 as illustrated in Figure 5. The dashboard display 70 includes a top-level navigation bar 79 that provides for the various available information. The bar 79 may include a customer title 78 such as a hospital name or an insurance company that tracks the patient information. The bar 79 also displays the top-level functionality of the monitoring server 40 that includes Monitor 180, Patients 190, Refills 200, Bottles 210, Messaging 220, and Analytics 230. The name of the specific person that is logged into the monitoring server 40 may also be displayed at the end of the bar 79.

In one or more embodiments, navigation through the dashboard display 70 occurs through movement of a cursor 71. Additional information may be displayed when the user hovers the cursor 71 over a particular point of interest. Additional information may also be displayed upon entry of an input command (e.g., mouse click). Various other methods may also be employed, including input via a keyboard, voice commands, etc.

The different information may be displayed in difference colors, patterns, formats, etc. to emphasize distinctions and provide for ease of recognition of the various information.

Analytics

The Analytics 230 function of the monitoring server 40 processes the adherence data and outputs various medication adherence performance and behavioral metrics and information for analysis. Analytics 230 provides for data visualization by displaying various aspects of the real-time medication adherence by single, multiple, grouped or many patients 11. Analytics 230 can also process, output and make available for display real-time medication adherence by organization, care provider, pharmacy, physician, medical center, medical group, insurer, pharmaceutical company, medication, dose, dose time, disease, health condition, therapy, outcome, geography, environmental, population, demographic, age, ethnicity, diet, level of fitness, income, financial and economic conditions.

Figure 5 includes one embodiment of analytics display. The Analytics display 70 includes a menu 77 that provides for displaying various adherence information. One option includes a Dashboard that displays a variety of analytical information arranged in different sections including: Adherence v. MPR 80; Behavior 90; Interventions 100; Refills 110; and Population Sample 120.

The Adherence v. MPR section 80 displays the real-time, absolute adherence measure 81 that scores each scheduled dose event in a binary format (e.g., adherent (1) or non-adherent (0)) that are accumulated since the usage of the system. The industry standard MPR 82 may also be displayed.

The Behavior section 90 displays absolute adherence and non-adherence percentages in a graph. In one embodiment, the information is presented in a ring graph, although various other types of visual graphs may be used such as a bar graph. As illustrated in Figure 6, the server 40 is configured to receive an input from the user (e.g., moving the cursor 71 over one of the percentages) to display a breakdown as well as display the overall percentage in the center of the ring graph. In the embodiment illustrated in Figure 6, the categories for non-adherence include wrong dose time, missed dose, partial dose, and extra dose.

The server 40 is further configured to receive a user input to expand the non-adherent alert categories across the entire graph. In one embodiment as illustrated in Figure 7, the input includes the cursor 71 positioned over the corresponding label 93 adjacent to the ring, or may be hovering over the non-adherent percentage 92 (in the display illustrated in Figure 6). One or more definitions of the categories may also be displayed in a space 94 on the display (not illustrated in Figure 7).

The server 40 may be configured to track a variety of different non-adherence categories such as wrong dose time, missed dose, extra dose, and partial dose as illustrated in Figures 6 and 7. Additional categories for non-adherence could also include but are not limited to cost of

medicine, financial difficulty, stretching medication supply, forgetfulness, forgot to take medicine, side effects, low medication supply no medication, patient does not believe medication is working, patient believes medication is not needed, patient believes they are cured, patient does not know how to use medication, patient taking too much of other medications, personal
5 hardship, patient needs help and support, patient too sick, patient not physically able to take medication, or other.

As illustrated in Figure 8, the server 40 is further configured to display in a separate panel 95 for each category the number of alerts and percentage, and interventions, conversions, and conversion rate for the category. An additional panel 96 may be displayed
10 listing offenders in the particular category. In one embodiment, the top offenders for the category are displayed. The system may further provide a label 97 to display an entire list of patients with at least one offense in the particular category. The server 40 may also provide for a user to input a particular name to display the patient's medication adherence run chart.

The server 40 is also configured to display the same type of information for adherent
15 behavior responsive to a user input as illustrated in Figure 9. The user is able to hover over the adherent percentage 91 with the system displaying a real-time, absolute adherence percentage within the interior of the ring.

As illustrated in Figure 10, the user is also able to move the cursor 71 over the adherent label 93 causing additional labels 98 to be displayed for the various adherent options. In the
20 embodiment of Figure 10, this includes an adherence to dose label 98 and an adherence to time label 98. The user is able to select one of the labels 98 to open a panel 96 listing the top patients adherent to dose and the top patients adherent to time. The user is further able to select one of the patients causing the system to display their medication adherence run chart.

The user may select the adherence to dose label 98 causing the ring graph to display
25 the correlating percentage as illustrated in Figure 11. A panel 96 of the best patients is also displayed, with a label 97 to provide for a complete list of the corresponding patients. The user is further able to select one of the patients with the system displaying their medication adherence run chart.

The user is further able to select an adherence to time label 98 as illustrated in
30 Figure 12. Input of this label 98 results with the system 10 displaying the correlating percentage in the ring graph. A panel 96 of the best patients is also displayed, with a label 97 to provide for a complete list of the corresponding patients. The user is further able to select one of the patients with the system displaying their medication adherence run chart.

In one or more other embodiments, the user is further able to select an adherence to
35 refill label (not illustrated). Input of this label results with the server 40 displaying the correlating percentage in the ring graph. A panel 96 of the best patients is also displayed, with a label 97 to provide for a complete list of the corresponding patients. The user is further able to select one

of the patients with the server 40 displaying their medication adherence run chart as well as medication refill graph and history.

As illustrated in Figure 13, the Interventions section 100 displays conversion information. The user may select this section to see a breakdown 101 of machine vs. human interventions and the corresponding success rate. Machine interventions include an automated call, text message, chat, instant message, iOS alert message, computer operating system alert message, social media message or post, cell phone or smart phone app alert message, tablet app alert message, Tweet, email, voice mail, signal to a home monitoring device or a medical monitoring device or from the monitoring server 40 or other non-human entity. Human interventions include contact from an actual person (e.g., caregiver, physician, pharmacist, family member).

The Refill section 110 displays information such as the number of refill alerts sent out and the number of actual refills, as well as the corresponding conversion rate. The information may also include refill ordering information such as number of refills ordered, quantity of medication, cost and price per refill, cost and price per tablet, amount of cost captured per refill conversion and number of refills remaining. This information may be displayed based on user actions, such as positioning the cursor 71 in this section 110.

As illustrated in Figure 14, the Population Sample section 120 may include information regarding the real-time adherence information for various patient groups. In one or more embodiments, this information may be displayed in a graph 121 of the adherence percentage over time for all patients, a group of the best (i.e., most-adherent) patients, and a group of the worst patients (i.e., least-adherent). The graph 121 includes chart lines 122 for each of the groups. The user may select any of the chart lines 122 to open a correlating panel 96 of the top patients in the group. The user is further able to select any of the listed patients to open their medication adherence run chart. In another embodiment, the Population Sample may also include information in graph and chart formats of adherence performance of a population against corresponding patient health conditions and medical outcomes. In yet another embodiment, the Population Sample may also include information in graph and chart formats of adherence performance of a population against medication and healthcare costs, losses and gains.

As illustrated in Figure 15, the Analytics option 230 on the main navigation bar 79 further includes a Patients Insight option in the secondary menu 77. The Patients Insight display features a real-time adherence leaderboard that includes a listing of patients 11. For each patient 11, the displayed information includes number of alerts, interventions, conversions, a possession ratio that includes MPR and percentage of the time without medication, and an adherence percentage. As illustrated in Figure 16, the display may also include various drop-down menus 201 to provide for the user to select to view additional information and to sort and filter the information.

As illustrated in Figure 17, the user can select one of the patients 11. Responsive to the selection, the server 40 displays the individual medications 202 for the patient in separate rows. For each medication the relevant adherence metrics and information is displayed comprising the combined adherence metrics and statistics of the patient.

5 As illustrated in Figure 18, the user is able to select one of the medications 202 (Sulfasalazine in the embodiment of Figure 18) to open a medication adherence run chart 203 that outputs and displays dosing behavior. The chart includes a timeline with the one or more dose time windows 205 visually illustrated. Figure 18 includes four dosing windows 205a (morning), 205b, (noon), 205c (evening), and 205d (bedtime). In one or more embodiments, the
10 dosing windows 205 are displayed in a different color than the other times during the day. The display further indicates when the patient 11 has taken the medication. This provides for a straight-forward manner to visually observe non-compliant doses that were not taken during the proper times. Further, the visual display provides for an entity 60 to observe patterns in the behavior of the patient.

15 The display further visually differentiates when the patient 11 has taken correct doses at correct times, correct doses at incorrect times, incorrect doses at incorrect times, incorrect doses at correct times, missed doses, partial doses, and extra doses. The system is configured to output and display medication adherence charting within a time period such as within a select amount of days, weeks, months, quarters or years. In one or more embodiments, the run
20 chart 203 displays as a default setting the last thirty (30) days. The embodiment of Figure 18 displays medication adherence data within two week periods (i.e., the chart 203 includes information for the last fourteen days). By scrolling or selecting points in time, the user can view stored medication adherence data. The display also includes a refill chart 204 indicating the date of refill and amount of refilled medication, the daily count of remaining medication, and
25 when refill alerts were sent. The system further provides for the user to provide an input (e.g., moving the cursor 71 over the various icons) to display detailed medication adherence information such as action that has been taken by the patient, detailed time and date, alerts and messages sent as well as interventions performed, annotations, results from patient surveys and conversion information.

30 As illustrated in Figure 18, the one or more dose time windows 205 are initially set when the patient 11 is enrolled. The length of the dose time windows 205 may vary. In the embodiment of Figure 18, the dose time windows 205 are established as two hour durations at four prescribed times.

35 As illustrated in Figure 19, the server 40 provides for adjusting one or more of the dose time windows 205 to adjust the behavior of the patient. In one embodiment, the server 40 may automatically adjust one or more of the dose time windows 205 to include the outlying non-adherent doses taken outside of the programmed dose time frame. In another embodiment, the user may edit and manually adjust one or more of the dose time windows 205 by clicking and

dragging the dose time frame window 205 to the desired time period. To facilitate the adjustment in the one or more dose time windows 205, the windows 205 are illustrated in a visually distinct manner from the outlying time periods, and from the recorded dosing information. The time windows 205 may be moved with the visual image of the time windows 205 moving relative to the dosing information to indicate an effect on whether the change may result in a more compliant patient 11.

In one embodiment, the displayed information may visually indicate a pattern of patient behavior. A doctor or caregiver may be able to note this pattern and change one or more of the time windows 205 such that the patient is more likelihood to become adherent to the dosing times. In one example, a patient may consistently take their morning dose after the prescribed time window 205. This may be caused by the patient's sleeping behavior. By moving the time window 205 to later in the day, the patient may now become more adherent. In one or more embodiments as illustrated in Figure 20, the user is able to enter an input to view an adjustment display 400. The display 400 provides for adjusting one or more aspects of the medication, including the dose times. The entity 60 enters the applicable information about the medication, including the dose amount and the frequency. For each occurrence, the entity 60 is able to select when during the day the dose is to be taken, and also the length of time in which the dose may be taken. In one or more embodiments, the ability to adjust a prescription may be limited to a physician or other authorized caregiver. This input display may not be accessible to other entities 60 (e.g., family member). Adjusting one or more of the dose time windows 205 may increase the patient's adherence as illustrated in Figure 21 (and compared with the Figure 19).

The server 40 may also provide an export option. This may be triggered by receipt of an entity input. Figure 22 illustrates one embodiment of the display in the export mode that includes the patient names displayed in a row format with the applicable events information, possession ratios, and adherence metrics. In another embodiment, the display may also include one or more additional adherence metrics such as total count of medication taken, total count of medication not taken, total count of refills, conversion rates, costs of medication taken, costs of medication not taken, cost savings, return on investment, and impact of adherence on Medicare STAR ratings. The patient medication adherence information is exported by the server 40 through input commands from the entity 60. To facilitate the exporting process, each row may further include a selection label 212 to select the one or more applicable patients. The server 40 may also include a select all label 213 for the inclusion of each of the patients on the display. A cancel label 214 provides for the user to reset their patient selections. A done label 215 provides for the user to input that the desired patients have been selected.

As illustrated in Figure 23, upon receiving an input through the done label 215, the server 40 displays a pop-up window 219 for exporting the information. The window 219 may include output options for the format of the exported data, an address to send the data (e.g., an

email address), or a link. The server 40 may also provide for connecting with other database services.

Bottles

5 The Bottles option 210 on the main navigation bar 79 provides for interacting with one or more of the containers 20. The term “bottle” is used in the various displays to indicate the medication container 20 as explained above.

 Figure 24 illustrates a display of containers 20 that are assigned to patients 11 under the care of a health care provider (e.g., this may include the patients being monitored by a particular
10 doctor, pharmacist, nurse, care manager, care provider, medical center, healthcare system or insurance company). As illustrated in Figure 24, the display includes the bottle, patient name, medication name and strength, count, and alerts. The alerts may be displayed as icons to indicate various different conditions, such as but not limited to an unknown object, pill count, signal strength, and battery level. The information may be displayed in various formats, with the
15 entity having the ability to sort the various columns as necessary. In one or more embodiments, the input is provided through a cursor 71. In one embodiment, the list is arranged in rows of bottles with the bottle having the most recent alert at the top of the list, followed by the bottle with the lowest pill count.

 A particular row may be further selected to display additional information about a
20 container 20 that is assigned to a patient 11. Figure 25 includes a display with a container icon, bottle ID, medication name and strength, start date of using the container for the indicated medication, current battery level, signal strength, temperature, and whether there is an unknown object. The information of the selected row 401 may also be displayed such that the entity 60 can determine the specific container 20 and patient 11 to which the additional information
25 applies.

 As illustrated in Figure 26, the user is also able to select a records submenu to expand a records panel 402 which provides the medication usage output information for each container 20. The amounts of medication taken, added and remaining are the result of the server 40 processing changes in weight and current weight, determined by the containers 20
30 against the medication weight, dose and fill quantity, stored or accessed by the server 40. The server 40 can determine the medication amount remaining, (e.g. pill, tablet or capsule count) equals the current weight divided by the weight per individual pill, tablet or capsule. The server 40 can determine the medication amount taken or added by calculating the difference between the previous medication amount remaining and the current medication amount
35 remaining. Medication amount taken or added can also be calculated by the server 40 by dividing the change in weight by the weight per individual pill, tablet or capsule. The weight per individual pill, tablet or capsule can also be determined by the server 40 by dividing the total fill weight of the contents of the container 20 by the fill quantity. For liquid medicines, the server 40

can determine the medicine amount taken or added by calculating the difference between the previous medicine amount remaining and the current medicine amount remaining. Liquid medicine amount taken or added can also be calculated by the system 10 by dividing the change in volume or mass by the volume or mass per dose. The server 40 determines the amount of doses remaining for liquid medicines by dividing the current volume or mass by the individual dose volume or mass. The server 40 may also monitor the accuracy of the weight calculations by comparing weight, volume, or mass measurements from the containers 20 against known medication weight, volume, or mass information stored in the server 40 or from an external database of such information. The user is able to scroll down to see the various information including the ability to navigate to previous records with a date selector 403 via click arrows or a specific date selector.

The system also provides for the entity 60 to select a container 20 that is not assigned as illustrated in Figure 27. The selected container 20 can then be assigned to a patient 11 with the applicable information being entered into the server 40. This may occur when a patient 11 is originally being enrolled, or when a new medication is being prescribed to an existing patient 11.

As illustrated in Figure 28, the Tare process includes the selection of the applicable container 20. The selection causes the display of a submenu 404 that includes a tare option 280. The entity 60 selects the tare option 280, resulting in the display of an instruction to remove the medication (if any) from the container 20. Once completed, the entity 60 selects the corresponding tare input 281. The input 281 causes the server 40 to send a command to the container 20 to recalibrate the container 20 by resetting the weight scale to a zero, (0.000) reading. The container 20 performs the task and signals the results to the server 40. The server 40 confirms the results and sets the weight as zero. During this process, the server 40 may display an instruction on the container display 37 that the tare process is in progress to ensure the patient does not perform any actions that results in an inaccurate weight determination. Once complete the server 40 displays a message on the display 37 indicating that the user should refill the container 20 with medication.

Messaging

The Messaging option 220 on the main navigation bar 79 provides for an interface to the messaging subsystem of the monitoring server 40. The Messaging system communicates with the patients 11 and/or with the entities 60. Figure 29 includes a messaging display with an inventory of messages that are programmed to be automatically sent to the assigned recipients, such as the patients 11 and/or to the entities 60. For each type of message, the display includes one or more of the format and method of sending the message, the type of message, the recipients, and the triggers that prompts the sending of the message, how many such messages were sent and the conversion rate of each message.

Message triggers cause messages to be sent to certain recipients based upon the occurrence of medication adherence conditions and/or events monitored by the monitoring server 40. Messages may be triggered by various types and ranges of conditions, such as but not limited to side effects, health, medical, nutritional, dietetic, fitness, emotional, environmental, geographical, economic, regulatory, security, safety, survey, query, prompts, algorithmic, time and date conditions. In one embodiment, a message trigger tool and manager may be used for creating, editing and managing triggers and the conditions and events for each trigger.

Messages may also be triggered and sent as a response to various conditions regarding the patient 11. Example trigger conditions can include but are not limited to admittance to the hospital, doctor visit, nurse visit, weight gain, weight loss, blood sugar change, blood pressure change, body temperature, calorie and nutritional intake, calories burned, smog and air pollution alerts, change in air quality, weather advisory and alerts, weather conditions, temperature change, humidity change, travel conditions, change in location, FDA warnings and recalls, credit score change, etc.

Figure 30 includes a list of the various types of messages (column 405), the applicable recipients 60 (column 406), the triggers (column 407), and additional recipients (column 408). The different message types include but are not limited to reminders, alerts, interventions, refills, confirmations, surveys, bottle status, incentive, marketing and promotional.

The various message types may be sent to one or more different recipients via the "Send To" option (column 406). As illustrated in Figure 30, Reminder, alert, intervention, refill, confirmation and bottle status message types may be sent to any combination of patient, family members, caregivers, care managers, care providers, nurses, physicians and pharmacist entities 60.

Each of the message types (column 405) corresponds to one or more triggering events (column 407). In one or more embodiments, an alert message may be caused by a missed dose, overdose, incorrect dose time, and a partial dose taken. An intervention message may be sent due to a missed dose, overdose, incorrect dose time, partial dose, and failed alert to the patient. A confirmation message may be triggered by a correct dose, filled bottle, and an activation. A refill message may be triggered by the detection of various days of medication remaining (e.g., 5 days, 7 days), various pills remaining (e.g., 5 pills, 7 pills), an empty container, and a refilled container. A bottle status message may be triggered by a pill count, low battery, weak signal, and unknown content. A reminder message may be triggered at the time of the dose, and a predetermined time before the dose (e.g., 5 minutes, 10 minutes).

The server 40 is further configured to add messages as illustrated in Figure 31. In one embodiment, this includes the user inputting that a message is to be entered. In one embodiment, this includes moving the cursor 71 to an "add message" prompt 282 and entering an input. This input causes a new message menu 409 to appear at the top of the message rows. The entity 60 enters the relevant information about the message from a variety of input

choices. The entity 60 also may enter the content of the message by inputting copy or by editing the default content. Furthermore, the entity 60 may input additional content and media by copying, pasting, attaching, or uploading content. In one or more embodiments as illustrated in Figure 31, the input choices are displayed in drop-down menus 410. In one or more
5 embodiments, the selection of a particular choice within one of the drop-down menus 410 will control the options in other menus. In one embodiment, when an alert message type is selected in a first drop-down menu 410, the only option for a recipient is the patient. In a similar manner, selection of an intervention message type results in the "send to" drop-down menu being limited to just the caregiver. Confirmation, refill, and bottle status messages may be sent
10 to any possible recipient.

Additional recipients may be selected through additional input options 284. These options 284 may include but are not limited to the selection of one or both of a caregiver and a pharmacy.

In one or more embodiments, one or more caregivers may be copied through input of the
15 applicable party input option 284. The message sent to the caregiver is the same message, with the prefix "Sent to [Patient Name]" with the name of the applicable patient included.

Monitor

The main navigation menu 79 includes a Monitor option 180 that provides entities 60
20 with an interface to view and manage aggregated intervention alerts processed by the monitoring server 40.

In one or more embodiments, entities 60 will typically monitor and keep track of twenty or more patients 11 each having one or more containers 20. As discussed above, the Messaging option 220 is configured to send various messages, including alert, intervention, refill,
25 confirmation and bottle status to the various entities 60 (e.g., patients, family members, caregivers, care managers, care providers, nurses, physicians and pharmacists). The Monitor option 180 aggregates the messages for each entity 60 and provides an interface to view and manage aggregated intervention alerts. Within each alert, the entity 60 can expand the message to view the relevant adherence information and content. Various displays and display
30 options provide the entity 60 with the message content, instructions, contact information, check boxes for quick survey annotations, note pad for annotations and history of intervention actions.

In one or more embodiments, a particular entity 60 is assigned to monitor multiple different patients 11. Each of the patients 11 is assigned to a particular entity 60 when enrolling, or when a new medication container 20 is assigned to them. New entities 60 may be
35 assigned existing patients 11 in a similar manner. In the various embodiments, when the entity 60 signs into the monitoring server 40, the entity 60 is able to access adherence, intervention and conversion information about their patients 11.

Figure 32 illustrates an alerts display within the Monitor option 180. In one or more embodiments, the monitor option 180 defaults to this display when an entity 60 initially logs into the server 40. The display includes a submenu navigation bar 285 for the entity 60 to view the desired information. The menu options may include viewing of alerts, conversions, non-adherent, and refill. Further, the display includes the number of occurrences of each option.

In the alert option as illustrated in Figure 32, each alert is displayed in a separate row 412. Each alert includes the date and time stamp of the trigger that caused each alert, the patient name, a condensed version of the monitoring status, and other applicable information such as the status of the alert and the time remaining for a conversion. Further, warning icons 411 may be displayed to emphasize the information to the entity 60.

The entity 60 is further able to select the other options from the submenu navigation bar 285 to view the corresponding information. The navigation bar 285 remains in each display screen to facilitate navigation through the monitor option 180.

As illustrated in Figure 32, the alerts submenu includes a condensed version of the monitoring status. This version includes just key information about the particular alert. As illustrated in Figure 33, the entity 60 is able to select a particular alert row 412 to display the full content and tools for the alert message. The row 412 with the condensed version is displayed, along with an intervention panel 287 for the selected alert. This panel 287 provides the entity 60 with additional information include the intervention history, patient contact information, family information, caregiver, care provider, care manager and pharmacy contact information, interchangeable or customizable survey of reasons for the missed dose or dosing time, and a note pad.

A call made input 286 may be selected after the entity 60 makes contact with the patient 11. This causes the server 40 to record the interaction in the history and save new inputs, information and/or changes and closes the panel 287. An entity 60 can click the call made input 286 for each call made to patients 11. The server 40 keeps count of the calls made by displaying a phone icon with the call count in the alert row. Once the information has been entered, clicking the alert row 412 closes and collapses the intervention panel 287 and saves any new inputs, information or changes. The information is saved, archived and accessible for further analysis by the server 40 and entities 60.

Entities 60 may use the Monitor option 180 to monitor real time changes in patient medication usage during intervention calls. When an entity 60 makes a missed dose phone call intervention to a patient 11 and the patient 11 takes the correct dose while on the phone with the entity 60. If the correct dose is taken by the patient 11 from the container 20, the container 20 will send the correct does amount to the server 40 and the server 40 updates the missed dose alert as a correct dose in real time so the entity 60 may easily confirm the correct dose taken while still on the phone with the patient 11. The history is also updated in real time.

In one or more embodiments, when using the intervention panel 287, phone numbers will appear as hyperlinks and the entity 60 can tap to make cellular phone calls directly when they are logged onto the server 40 through an enabled phone device 61. In another embodiment, a call patient button may be used to initiate an internet voice call from the Monitor option 180 directly to the patient 11. Voice calls may be recorded as audio files and stored for analysis and records. Voice calls may also be transcribed to provide a transcription of the voice call interventions in the history. Other embodiments may include hyperlinked contacts and/or buttons that initiate voice calls, video calls, text messages, chat, instant messages and emails directly from the Monitor option 180 to the patient 11, patient's family members, caregivers, care providers, care managers and pharmacies.

In one or more embodiments, the history section on the intervention panel 287 displays a log of messages. This displays the day and time, type of message and recipients the messages were sent to. Events logged in history are updated in real time. Each click of the call made input 286, as well as inputs from the survey check list 413, and annotations made in the note pad are also logged and related adherence events and outcomes are displayed in the history.

If a survey answer is checked, the content is preceded with "Reason"; for example if "Just forgot" was checked, the History will display: "Reason: Just forgot". If multiple surveys are checked then History displays as much content within the limitation of one row and provides a popup or rollover view to display more. If annotations are made, and no survey was checked then History displays as much content within the limitation of one row and provides a popup or rollover view to display more. If subsequent new calls are made with new annotations made as well, then the History logs and displays the newest annotation. If a survey is checked and annotations are made at the same time then history displays the survey with a note icon to click more to view annotations.

One embodiment of the conversion option 414 on the submenu navigation menu 285 is illustrated in Figure 34. Conversions are timed (missed dose and refill) alerts that have resulted in a correct dose taken or a refill within the dose or refill time limit. The conversions tab 414 displays successfully converted alerts. A converted alert displays the successful result (correct dose taken or refilled bottle for example) in place of the alert message and displays the missed dose or refill alert underneath the result greyed and crossed out (not illustrated in Figure 34). The alert warning icon is replaced with an affirmative conversion icon 415 such as a checkbox. Conversions per day are counted and displayed in the conversions tab. Total running conversions are counted and displayed in the top left conversions counter 288 as a number. Users can click the number to view the conversion rate displayed as a percentage (100%). The server 40 calculates the conversion rate by using the following calculation: $\text{Conversion Rate} = (\text{Successful Conversions} \div \text{Alerts})$. In the Intervention Panel, the History will log and display the conversion event and updates the content of the message with a correct dose confirmation

message or a refilled bottle message preceded by system inserted copy: "Successful intervention". In this display, the call made input is replaced with a close input button.

The submenu navigation bar 285 also provides for a non-adherent option 416 as illustrated in Figure 35. Non-adherent events are when patients 11 fail to take and refill their medications correctly and on time. Alerts in the adherence alerts tab that have not been successfully converted during the course of a day will be moved and displayed in the non-adherent tab. Timed alerts are moved to the non-adherent tab as soon as the dose time expires (i.e., a timer reaches 0 minutes) and the alert does not convert to a successful result.

The user may enter a particular row to obtain additional information. If no calls were made during the missed dose time or refill alert then the information in the expanded intervention panel displays "No intervention:" preceding the message content. If calls were made in attempt to convert the missed dose time or refill alert then the information in the expanded intervention panel displays "Unsuccessful intervention:" preceding the message content and the phone icon with call count.

In one or more embodiments, other alerts are moved to the non-adherent tab and archived at the end of each day at 11:59:59pm (23:59:59). The alert warning icons are replaced with a red "x" box, removed from the alerts tab and moved to the non-adherent tab.

The submenu navigation bar 285 also includes a refill option 417 as illustrated in Figure 36. Refill alerts are refill messages assigned to entities 60 in the Messaging option 180.

Refill alerts can also be displayed in the alerts tab. At the end of each day, refill alerts that have converted or become non-adherent are archived. Active refill alerts remain displayed in the refills tab until successfully converted or become non-adherent. Users have until the end of the "refill time" to successfully convert the refill alert. The "refill time" is the time period after a low pill count (refill message trigger such as "5 pills left" or "5 days left") and before the next dose time after the pill count reaches zero. A refill conversion occurs when the medication refill amount is added to the container 20 within the refill time. When a refill conversion occurs, the refill alert is removed from the refills tab 417 and is moved and displayed in the conversions tab 414. A non-adherent refill occurs when the medication refill amount is not added to the container 20 within the refill time. When refill non-adherence occurs, the refill alert is removed from the refills tab and is moved and displayed in the non-adherent tab.

The Monitor option 180 may save and archive the various alerts, alert interactions and content. In one embodiment, entities 60 can access alerts per day by using the archive navigator 289 located on the top right of the various displays. The server 40 is configured to display information from a particular date, or from a time range that may span multiple days, weeks, months, etc.

Patients

The Patients Option 190 on the main navigational bar 79 provides a summary of patients and patient information. In one or more embodiments, patient information may be stored on secure servers external to the server 40. The Patients Option 190 displays patient information by accessing external secure servers through authorized decryption and user authentication protocols. The system 10 is able to decrypt and recouple de-identified patient identities and information to their respective medication adherence data, metrics, charts and records stored on the system 10 servers 49 and databases 42.

Figure 37 illustrates a display for a new patient. In one or more embodiments, this display is displayed to just users with authorized log in credentials, such as the customer which can be a medical center, healthcare provider, nurse, pharmacist, etc. An adherence graph 419 and an adherence indicator 420 are prominently displayed, such as in the upper corner of the display. When a new patient is setup, the adherence indicator 420 is blank (e.g., "- - %") and the graph 419 includes a flat line (instead of 0%). Once the patient has been enrolled and the first scheduled dose time has passed and the server 40 determines the new score, the indicator and graph will display the application information. This initial display indicates that when a patient is first setup he/she is neither non-adherent nor adherent until their first dose time has passed.

In one or more embodiments, the information through the patients option 190 is secured through one or more security levels. The levels may include a first authorized access to allow for access to patient info. This first level requires a first security access as the information may be extremely private, sensitive and highly regulated by the federal government. A second level of access provides for accessing a limited amount of patient information. In one embodiment, the second level of access prevents access to just the medication, duration, and dose information without access to patient information. In one embodiment, the denied information will be crossed-out in the display.

During enrollment of a patient, the applicable information is inputted, such as name, cell phone, address, etc. The server 40 then assigns a patient ID.

The input screen further includes a duration input 421. The duration controls and defines the length of time the server 40 scores and charts the patient adherence. A user input may provide for a menu of options for the duration (e.g., 30 days, 60 days, ongoing, pause). A start input 423 provides for inputting the start date for the medication adherence. User input may provide for a calendar to be displayed to facilitate entry. The start input sets the day when the server 40 starts scoring and charting adherence. An end date input is further provided. In one embodiment, the duration may be set as ongoing which causes the server 40 to automatically input the end date as none. In one embodiment, input of "pause" in the duration input 421 causes the server 40 to stop the adherence scoring at that immediate dose time and date. The scoring can be restarted at which time the server 40 restarts adherence scoring immediately.

Once the patient reaches an end date, the server 40 stops calculating adherence. The running adherence score for the entirety will be displayed in the graph 419 and indicator 420.

A medication section 424 provides for input of the relevant medication data. This may include one or more of the drug name, strength, dosage form, disease, price/refill, count/refill, weight, and prescriber.

The display may include a SMS input 425. The server 40 can be set to turn off sending of text messages to this patient. This may save SMS costs.

The patient information is input while the display is at a patient information setting within input 426. The input 426 may also be set to an archive option to archive patient information. In one embodiment, the archive input deletes the patient and associated information from the input display and stores an archive of the information that includes historic data associated to the patient. This information may include one or more of medication, adherence data, run chart, monitor/alerts/intervention history, messaging, and bottle records. Archived patients can be searchable and retrieved by various information, such as patient ID number, name, drug name and organization. The containers previously used by archived patients will be made available in organization inventory for new patient and new medication use.

Refills

The Refills Option 200 on the main navigational bar 79 provides a means for tracking refill of medications for each of the patients 11. This option 200 outputs metrics based upon individual medications. In the embodiment of Figure 38, the information includes a first column 427 that includes the name brand drugs for a drug manufacturer such as Genentech. The column 427 may also include drugs monitored and compare performance.

In one embodiment, an entity 60 can provide an input at the desired medication name causing a breakdown of how the medication performed in each region and how the data rolls up to the larger region (such as the U.S. or Europe).

The server 40 further tracks start date and how long (duration) patients 11 are on each medication. The server 40 calculates and outputs average days patients 11 have possession of each medication. The server 40 also calculates and outputs the average MPR (medication possession ratio).

The server 40 tracks the total number of patients 11 that are on each medication, for each region. The server 40 further tracks the total number of tablets/pills taken by all patients 11 on each medication. The server 40 also tracks how many refills are converted, and also the monetary value of the refills converted. The server 40 also calculates and keeps a running refill conversion score per each medication. The server 40 also calculates and keeps a running average medication adherence score for each group of patients per region.

Spatially relative terms such as “under”, “below”, “lower”, “over”, “upper”, and the like, are used for ease of description to explain the positioning of one element relative to a second

element. These terms are intended to encompass different orientations of the device in addition to different orientations than those depicted in the figures. Further, terms such as “first”, “second”, and the like, are also used to describe various elements, regions, sections, etc. and are also not intended to be limiting. Like terms refer to like elements throughout the description.

5 As used herein, the terms “having”, “containing”, “including”, “comprising” and the like are open ended terms that indicate the presence of stated elements or features, but do not preclude additional elements or features. The articles “a”, “an” and “the” are intended to include the plural as well as the singular, unless the context clearly indicates otherwise.

10 The present invention may be carried out in other specific ways than those herein set forth without departing from the scope and essential characteristics of the invention. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive, and all changes coming within the meaning and equivalency range of the appended claims are intended to be embraced therein.

CLAIMS

What is claimed is:

1. A system for monitoring medication adherence by a patient, the system comprising:
a container comprising:

5 an interior space to hold the medication;
one or more sensors configured to sense the medication within the interior space;
a container processing circuit configured to determine a medication amount
within the interior space based on readings from the one or more sensors;
a wireless communication circuit configured to transmit the medication amount
10 over a wireless communication network;
a monitoring server located remotely from the medicine container, the monitoring
server comprising:
a communication interface configured to receive the medication amount
transmitted from the container through the wireless
15 communication network;
a memory circuit configured to store at least one of: a prescribed
medication dose for the patient; and dose time periods in which
the patient is to take the prescribed medication dose;
a monitoring server processing circuit configured to monitor patient
20 medication adherence by calculating at least one of a dose time adherence as
whether the medication was removed from the interior space within one of the
dose time periods, and a medication adherence of whether the amount of
medication taken is equal to the prescribed medication dose.

- 25 2. The system of claim 1, wherein the monitoring server processing circuit is configured to
determine the amount of medication taken or added by the patient based on differences in
medication amounts received from the container.

- 30 3. The system according to any preceding claim, wherein the monitoring server processing
circuit is configured to determine a time when the medication was removed from or added to the
interior space.

4. The system according to any preceding claim, wherein the monitoring server processing
circuit is configured to calculate an absolute adherence over a time period that includes whether
35 the taken medication was removed from the interior space within the dose time periods and
whether the taken medication is equal to the prescribed medication dose.

5. The system according to any preceding claim, wherein the memory circuit stores contact information for a caregiver associated with the patient, and the monitoring server processing circuit is configured to send a message to the caregiver over the wireless communication network when the dose time adherence or the medication adherence have met predetermined levels.

6. The system according to any preceding claim, wherein the monitoring server processing circuit is configured to calculate the medication adherence over a plurality of the dose time periods.

7. The system according to any preceding claim, wherein the monitoring server processing circuit is configured to calculate the medication dose and dose time adherence over a plurality of the dose time periods.

8. The system according to any preceding claim, wherein the one or more sensors are arranged within the body.

9. The system according to any preceding claim, wherein the monitoring server processing circuit determines a count of remaining medication left within the interior space of the container by dividing one of a mass or volume of the remaining medication by one of a mass or volume of an individual dose of the medication.

10. The system according to claim 9, wherein the monitoring server processing circuit automatically transmits a refill request when the amount of the medication remaining within the interior space reaches a predetermined threshold.

11. The system according to any preceding claim, wherein the monitoring server processing circuit is further configured to notify at least one of the patient and a patient entity of a negative patient medication adherence and to recheck the patient medication adherence within a predetermined time thereafter.

12. The system according to any preceding claim, wherein the container processor calculates the taken medication for a liquid by dividing a change in volume in the medication in the interior space by a volume of a dose that is stored in a container memory circuit.

13. The system according to any preceding claim, wherein contact information of at least one of the patient and a caregiver entity is stored in the memory circuit, and the monitoring server processing circuit is configured to transmit a message over the wireless communication

network using the contact information upon occurrence of a triggering event related to the patient.

14. The system according to any preceding claim, wherein the monitoring server processing circuit is configured to create medication adherence data for a first display area and patient behavior data for a second display area, and to transmit the data for viewing on a remote electronic device.

15. A system for monitoring medication adherence by a patient, the system comprising:
a container comprising:

an interior space to hold the medication;

one or more sensors configured to sense the medication within the interior space;

a container processing circuit configured to determine an amount of medication within the interior space;

a wireless communication circuit configured to transmit the amount of the medication within the interior space;

a monitoring server located remotely from the medicine container, the monitoring server comprising:

a communication interface configured to receive the amount of the medication within the interior space transmitted from the container through the wireless communication network;

a memory circuit configured to store at least one of: a prescribed medication dose for the patient; and dose time periods in which the patient is to take the prescribed medication dose;

a monitoring server processing circuit configured to calculate taken medication based on a change in the amount of the medication within the interior space;

the monitoring server processing circuit further configured to monitor patient adherence in taking the medication based on the taken medication and at least one of the prescribed medication dose and the dose time periods.

16. The system of claim 15, wherein the monitoring server processing circuit is configured to calculate dose time adherence as whether a change in the amount of medication within the interior space occurred within one of the dose time periods.

17. The system according to any preceding claim, wherein the monitoring server processing circuit is configured to calculate medication dose adherence as whether the taken medication is equal to the prescribed medication dose.

18. The system according to any preceding claim, wherein the monitoring server processing circuit is configured to calculate an absolute adherence over a time period that includes whether the taken medication was removed from the interior space within the dose time periods and whether the taken medication is equal to the prescribed medication dose.

5

19. The system according to any preceding claim, wherein the memory circuit stores a contact information for a caregiver associated with the patient, and the monitoring server processing circuit is configured to send a message to the caregiver when the dose time adherence or the medication dose adherence have met predetermined levels.

10

20. The system according to any preceding claim, wherein the monitoring server processing circuit is configured to calculate the medication dose and dose time adherence over a plurality of the dose time periods.

15

21. The system according to any preceding claim, wherein the one or more sensors are arranged within the body of the container.

22. The system according to any preceding claim, wherein the monitoring server processing circuit automatically transmits a refill request when an amount of the medication remaining within the interior space reaches a predetermined threshold.

20

23. The system according to any preceding claim, wherein contact information of the patient is stored in the memory circuit and the monitoring server processing circuit is configured to transmit a message over the wireless communication network to the patient upon occurrence of an adherence triggering event related to the patient.

25

24. The system according to any preceding claim, wherein the monitoring server processing circuit is configured to create adherence data for a first display area, behavior data for a second display area, and to transmit the data for viewing on a remote electronic device.

30

25. The system according to any preceding claim, wherein the monitoring server processing circuit is further configured to notify at least one of the patient and a patient entity of a negative patient adherence and to recheck the patient adherence within a predetermined time thereafter.

35

26. The system according to any preceding claim, wherein the monitoring server processing circuit is configured to determine a time when the medication was removed from or added to the interior space.

27. The system according to any preceding claim, wherein the monitoring server is configured to send a message to at least one of the patient and a patient entity in the event of non-adherence, and the monitoring server is further configured to score messaging conversion by dividing a number of the messages sent by a number of successful patient medication adherence.

28. A method of monitoring medication adherence by a patient comprising:
periodically receiving from a medication container through a wireless communication network that includes a packet data network an amount of medication in the container;
calculating a taken medication based on a difference between the medication amounts received in different communications from the medication container;
calculating at least one of an adherence to time of whether the taken medication was removed from the container within a dose time period and an adherence to medication of whether the taken medication was equal to a prescribed medication dose; and
determining whether the patient is adhering to a medication schedule based on one or more of the adherence to time and the adherence to medication dose.

29. The method of claim 28, further comprising storing the dose time period and the prescribed medication dose in a memory circuit prior to receiving the taken medication.

30. The method according to any preceding claim, further comprising transmitting a message to a remote entity when one of the dose time adherence and medication dose adherence have met predetermined levels.

31. The method according to any preceding claim, further comprising creating data including adherence to medication for a first display area, creating message conversion data for a second display area, and transmitting the data for viewing on an electronic display of a remote computing device.

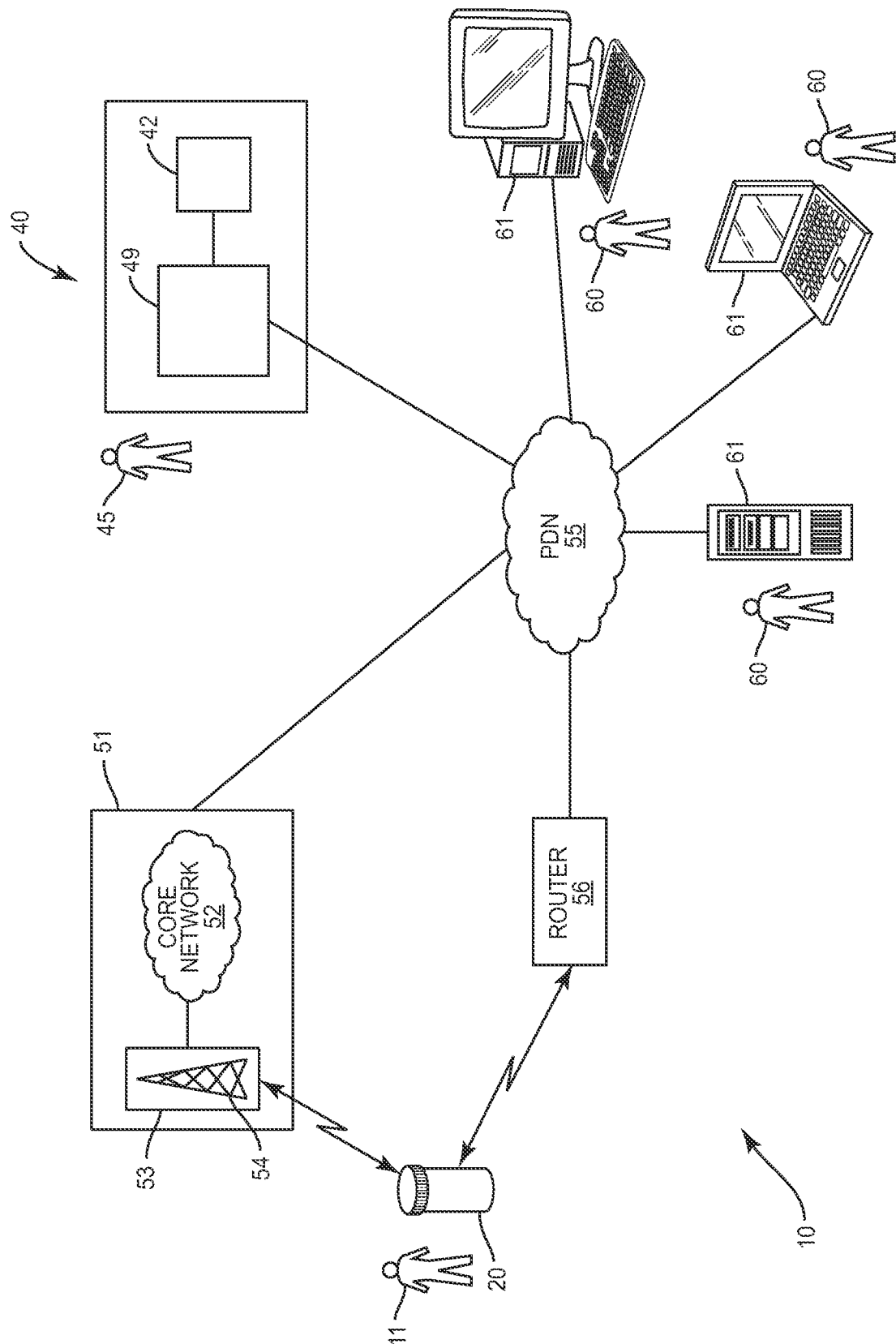


FIG. 1

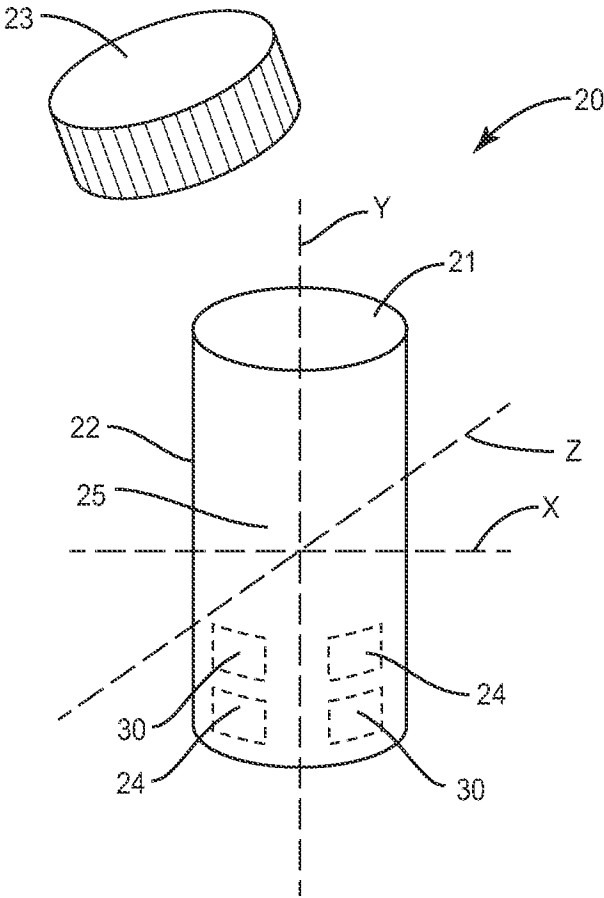
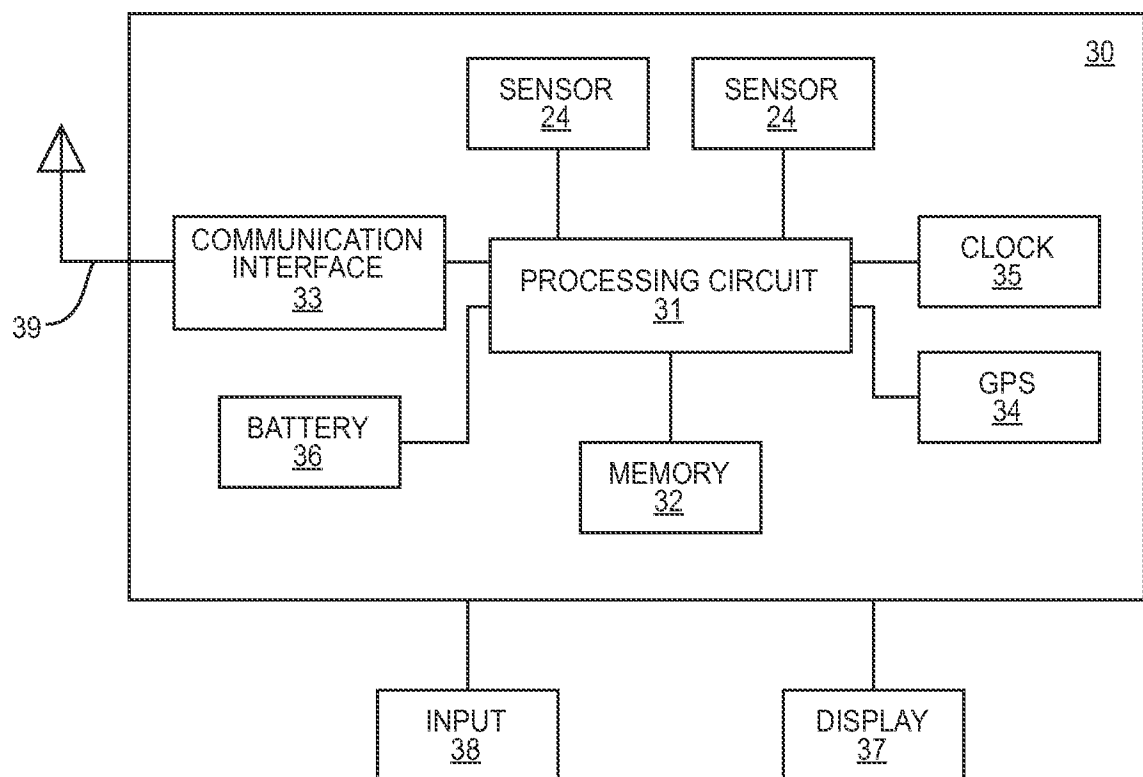
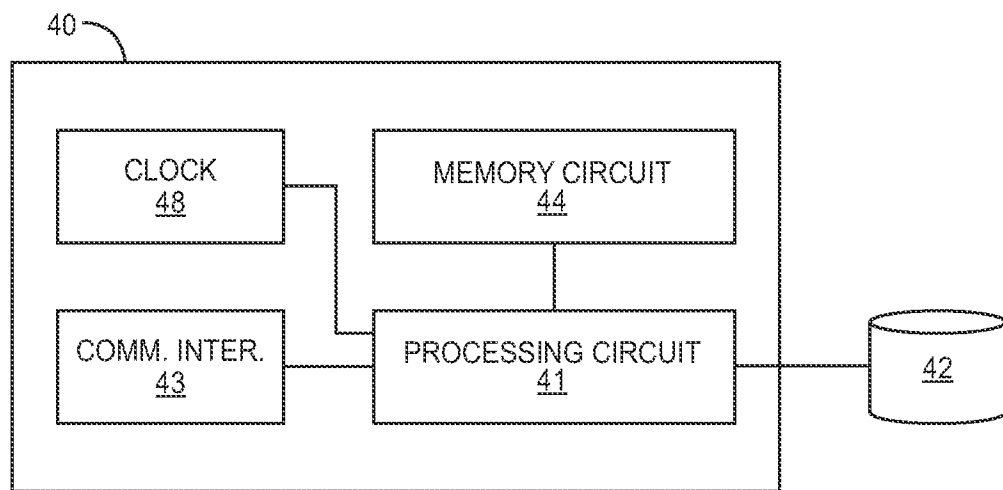


FIG. 2

**FIG. 3**

**FIG. 4**

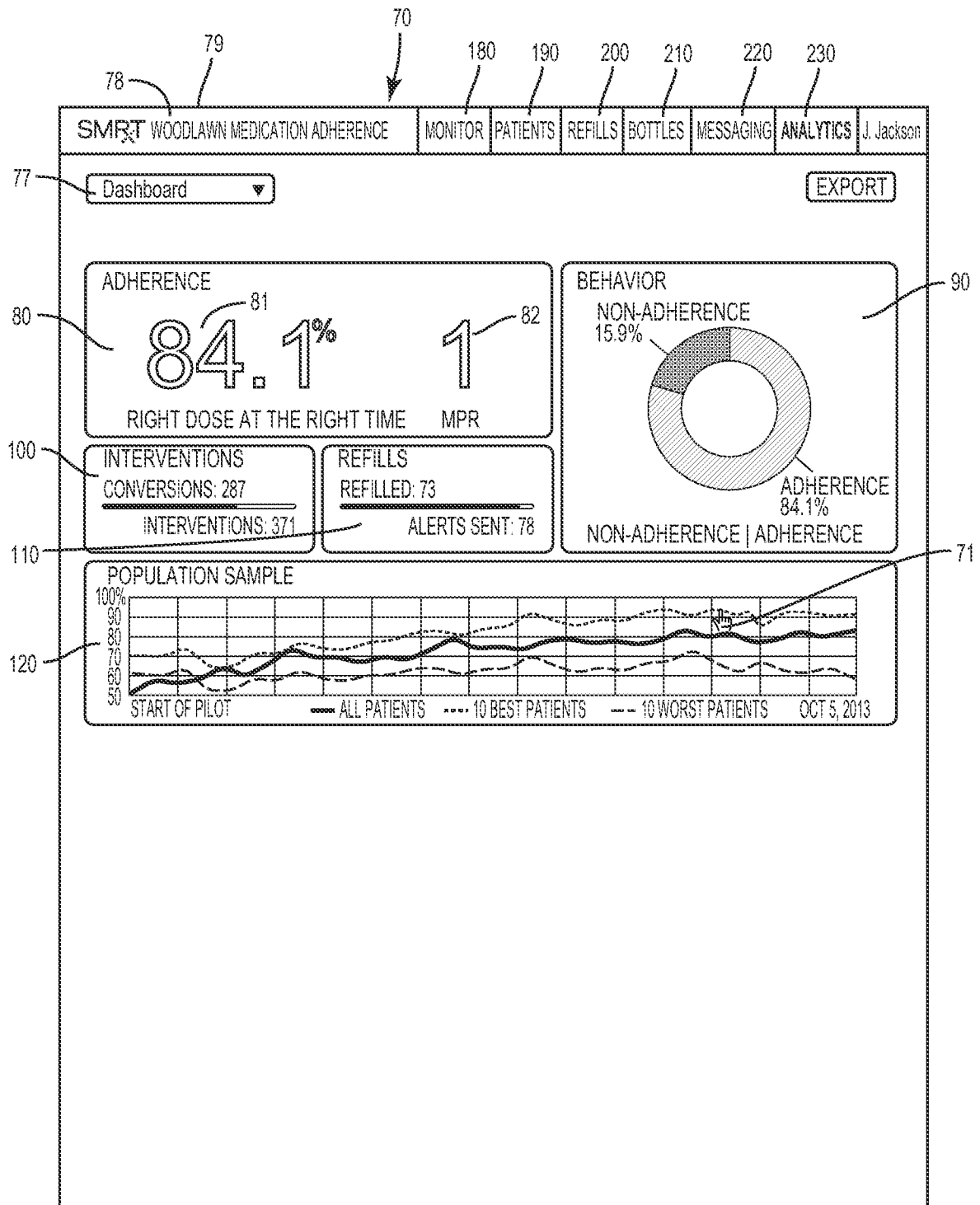


FIG. 5

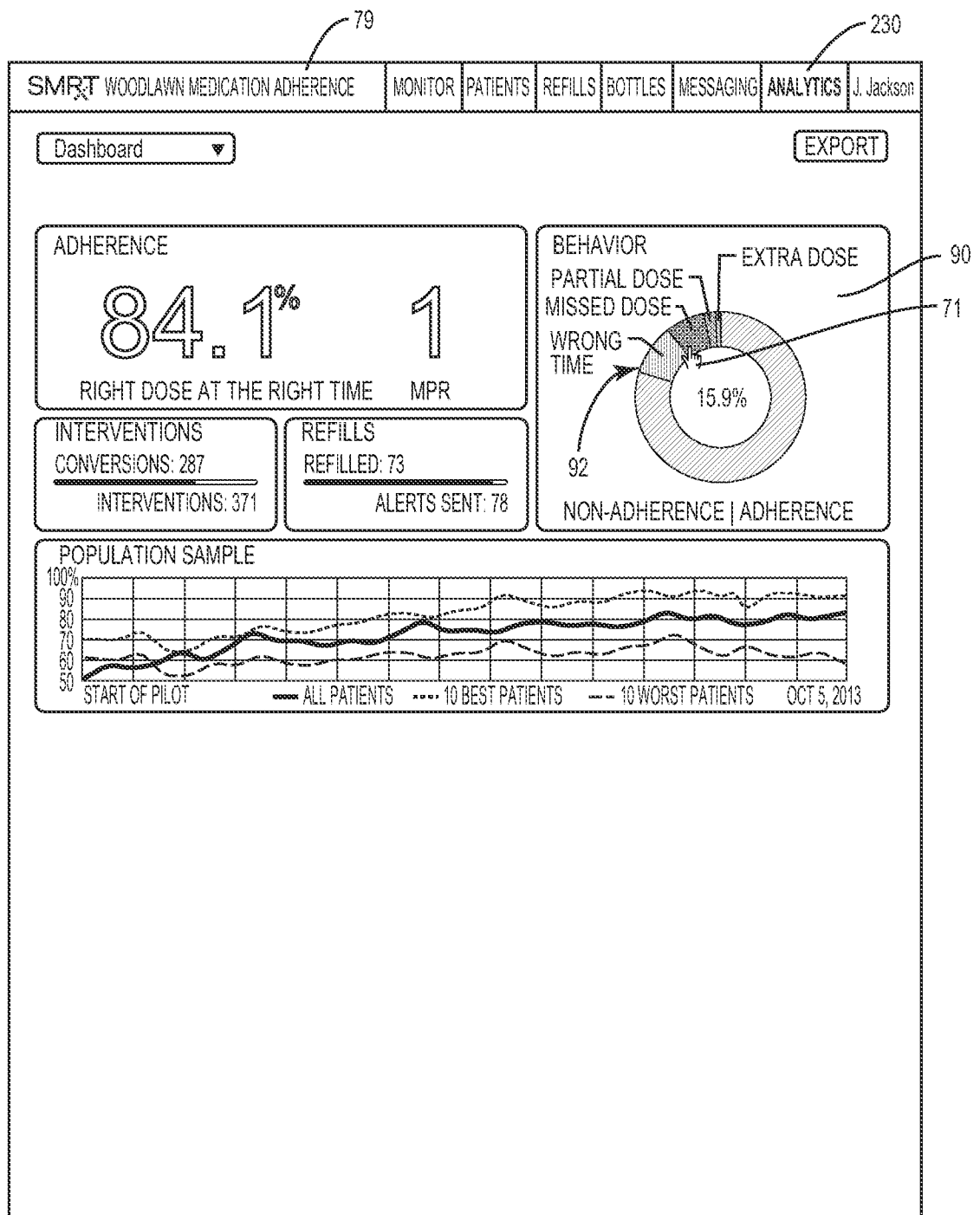


FIG. 6

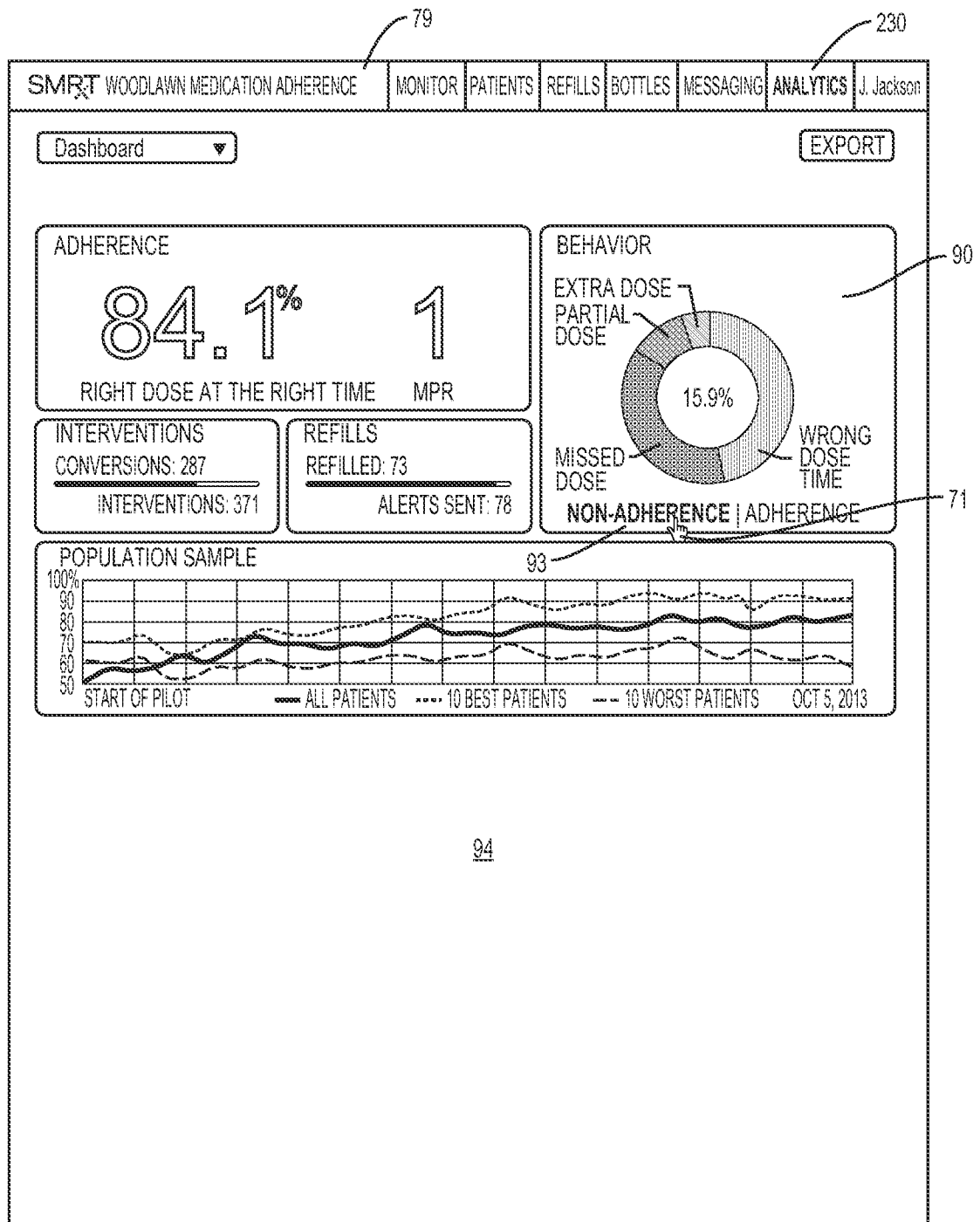


FIG. 7

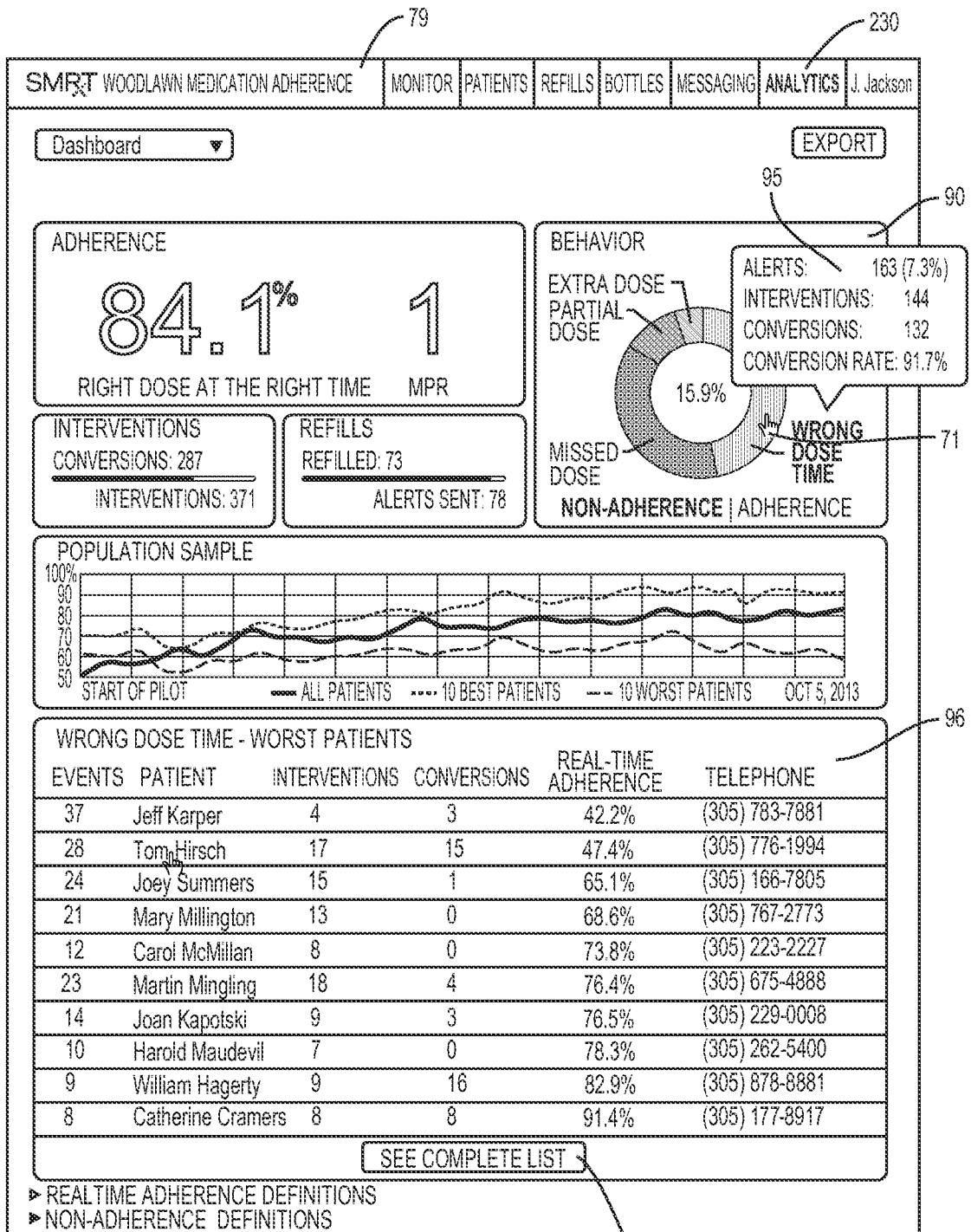


FIG. 8

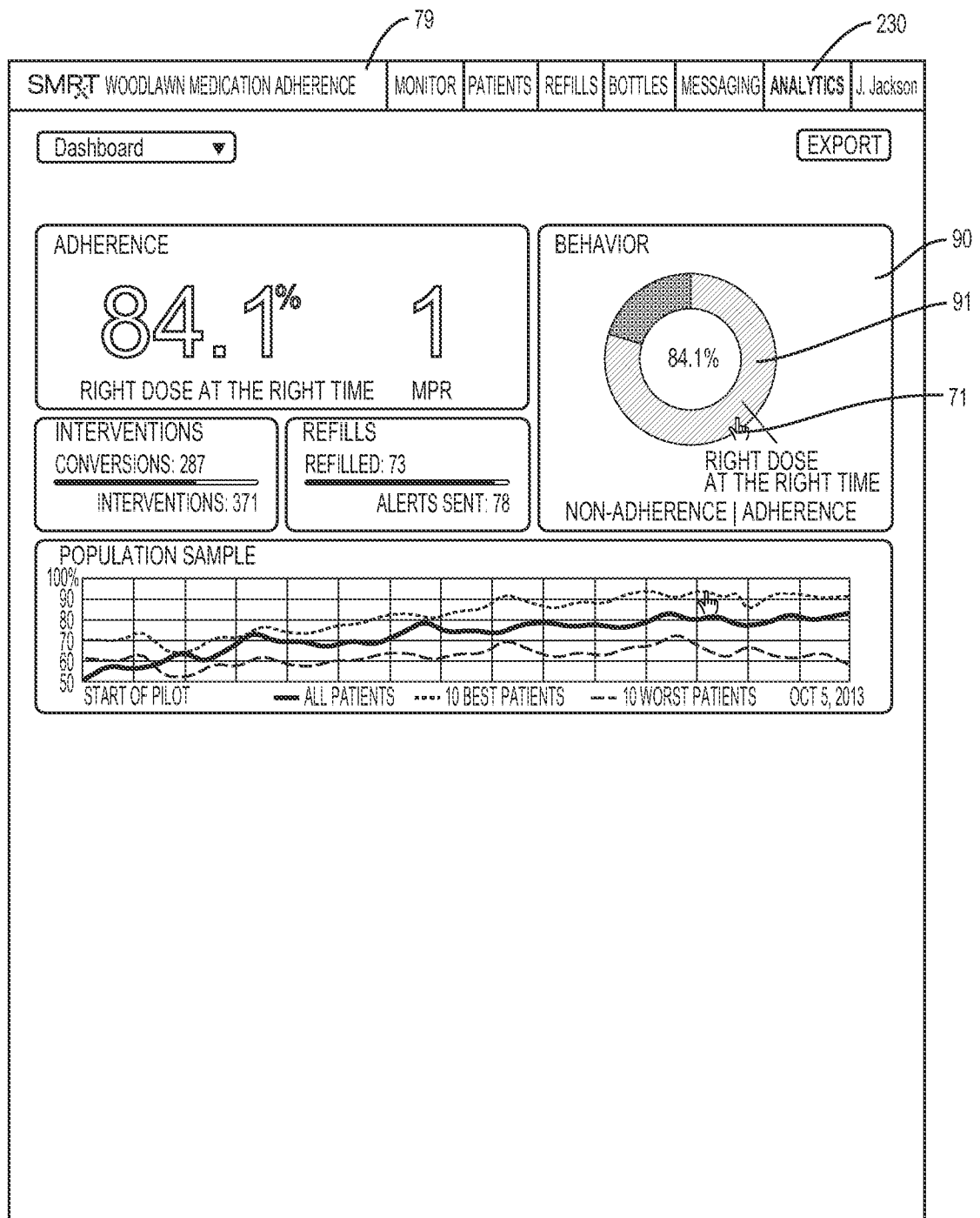


FIG. 9

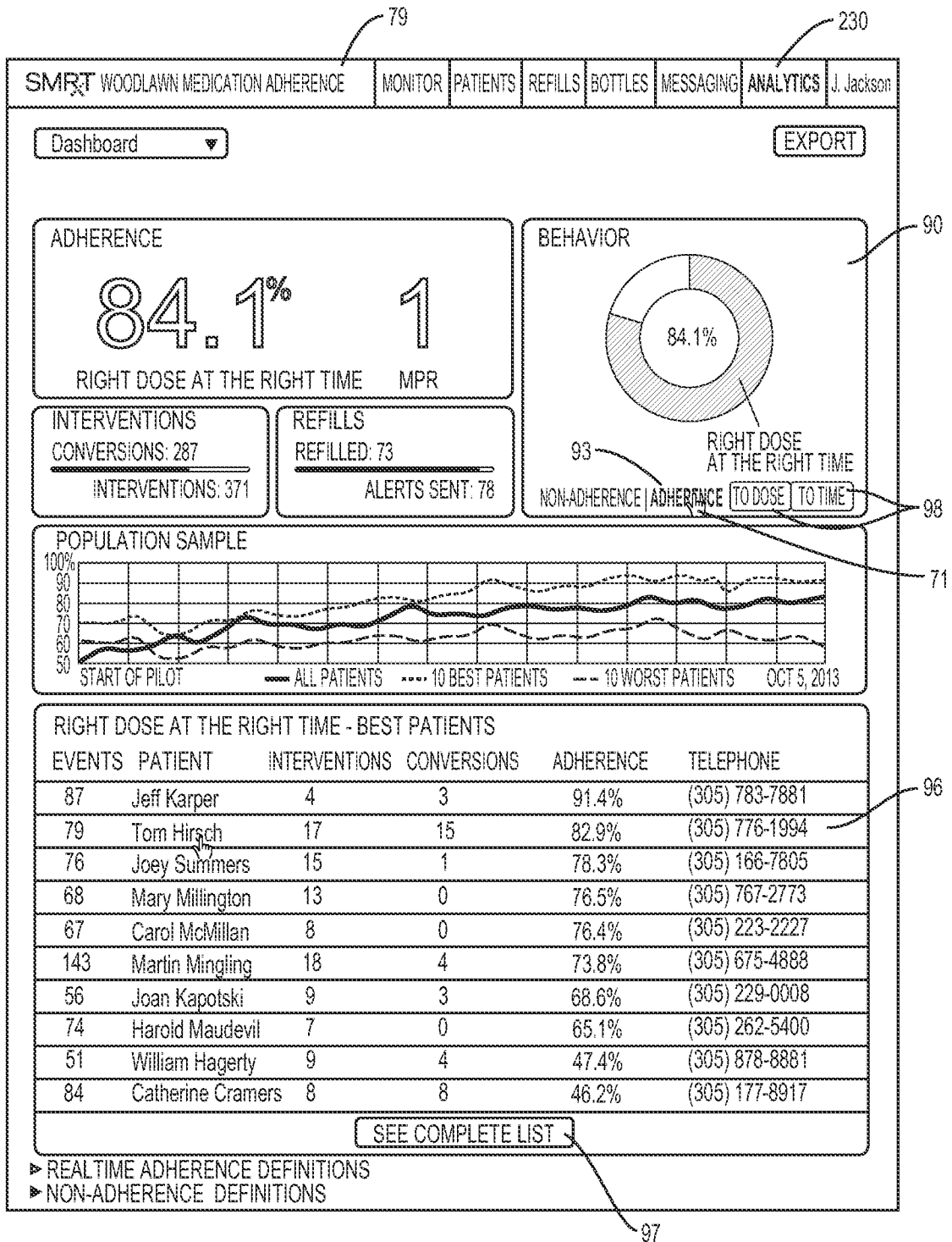


FIG. 10

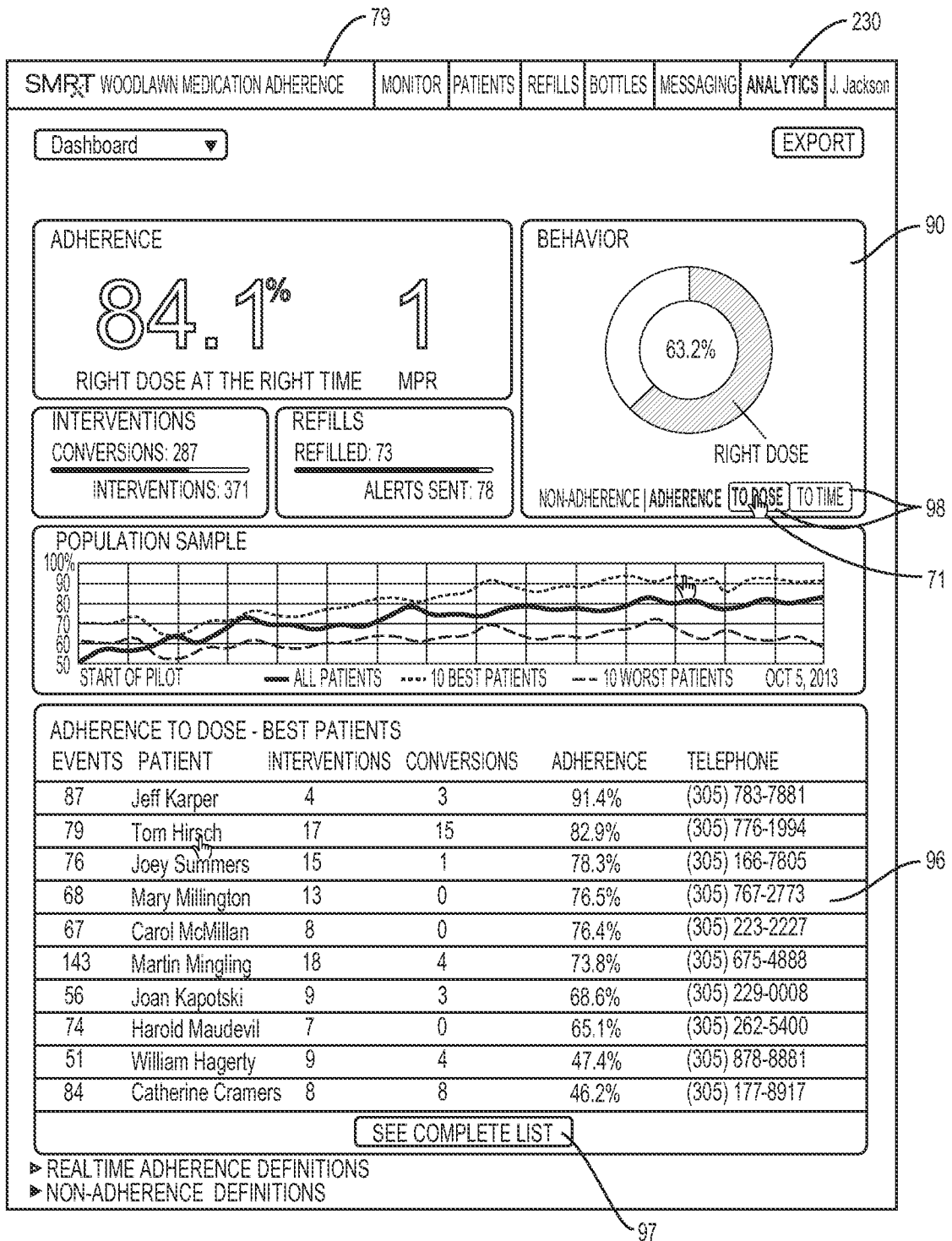


FIG. 11

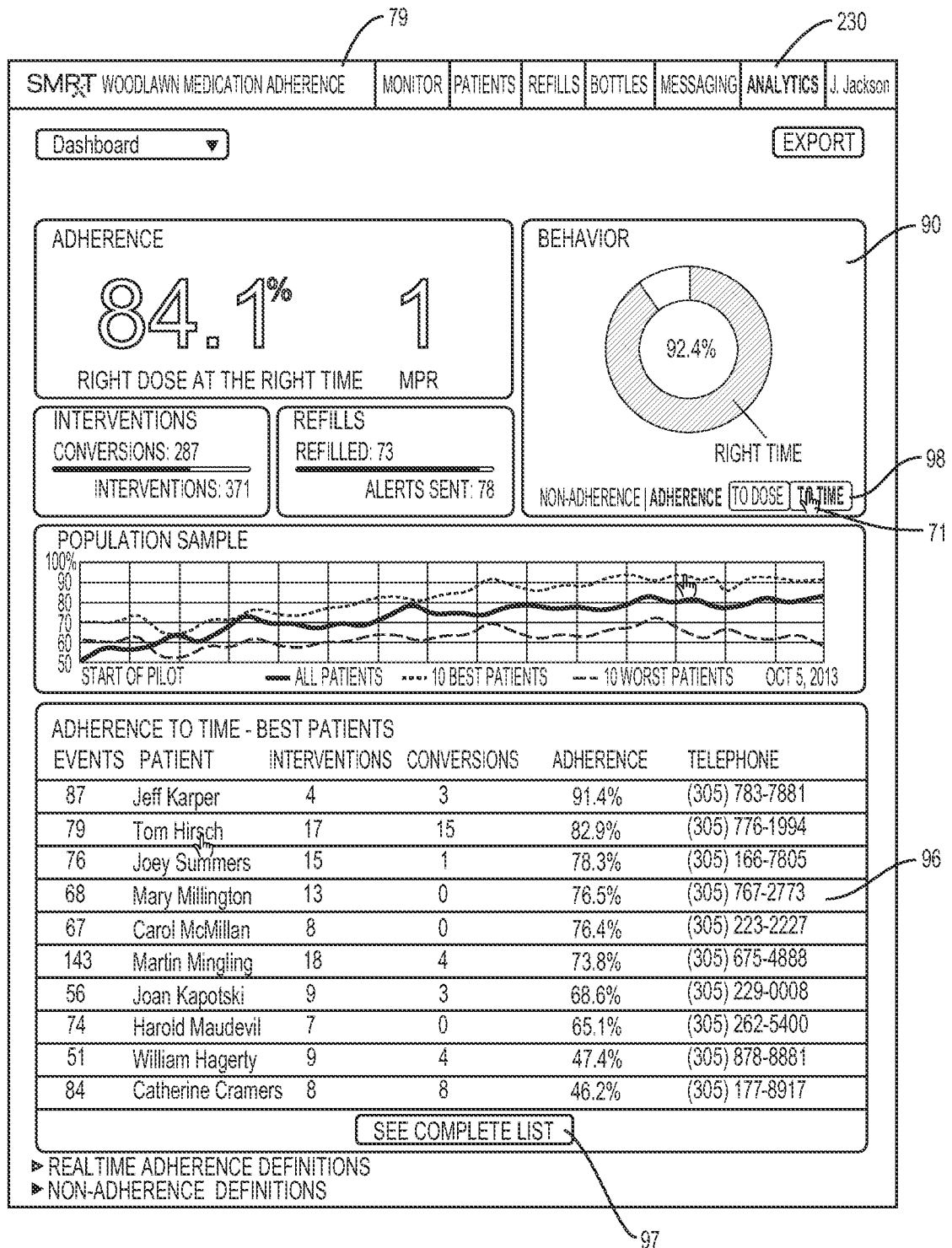


FIG. 12

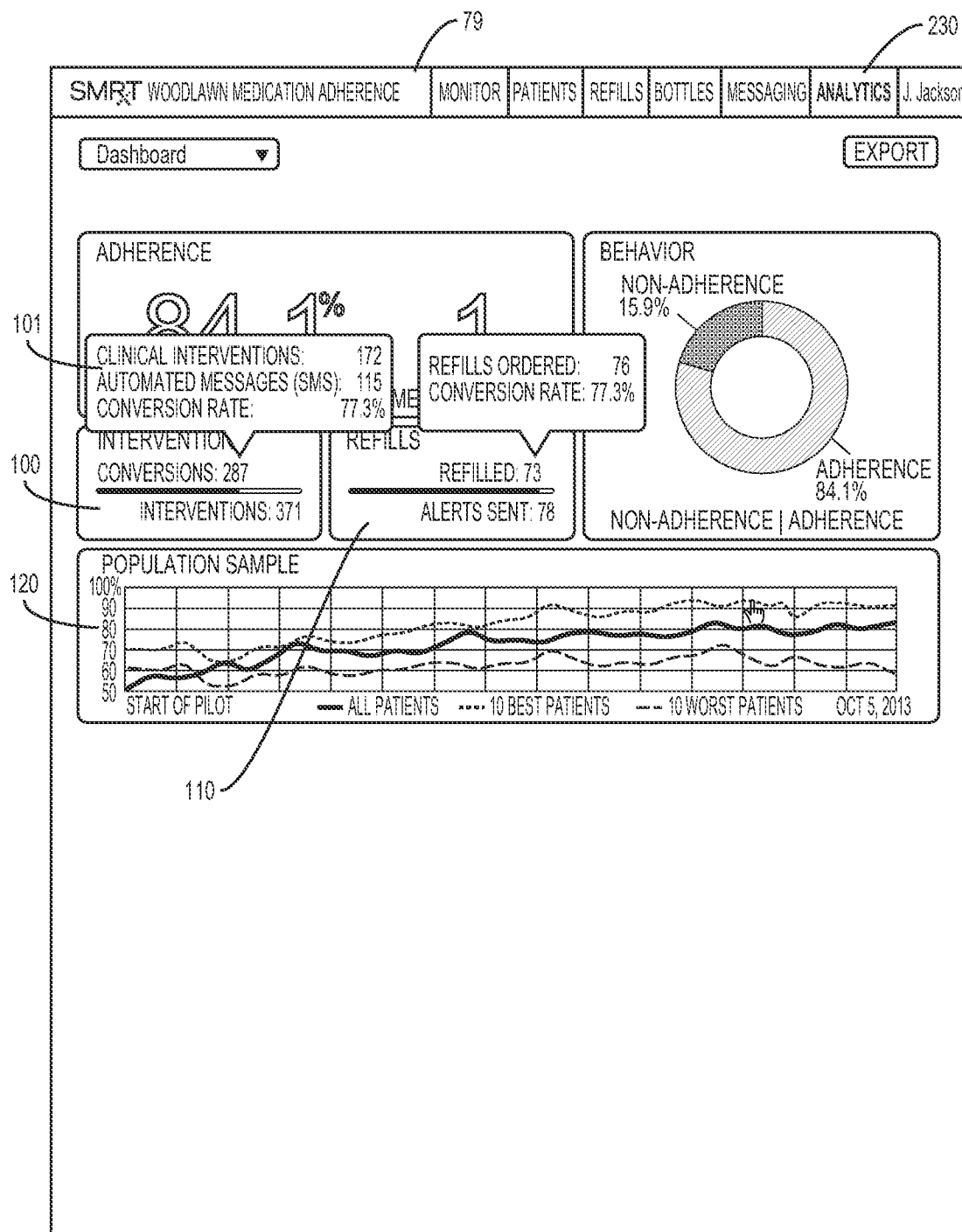


FIG. 13

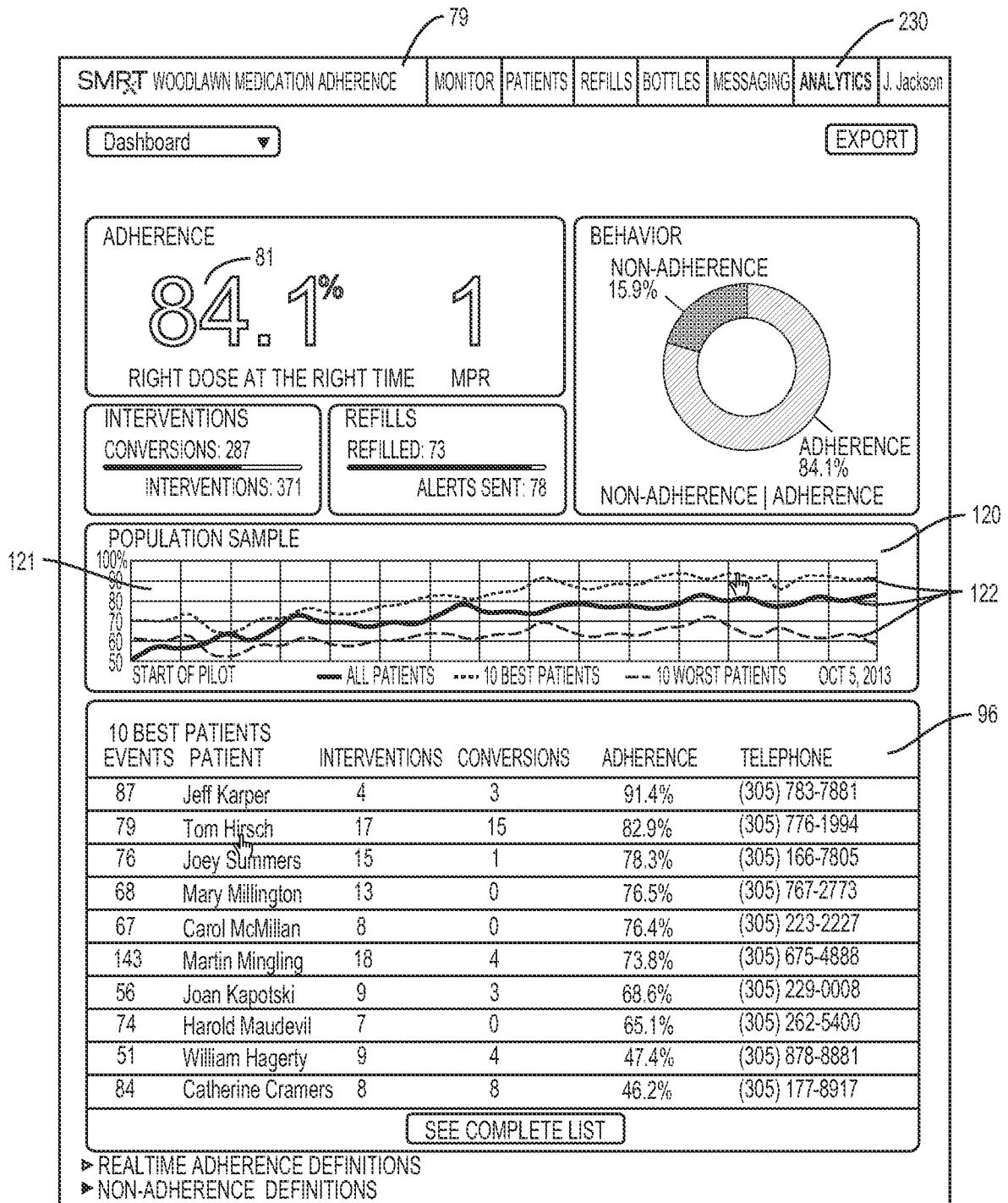


FIG. 14

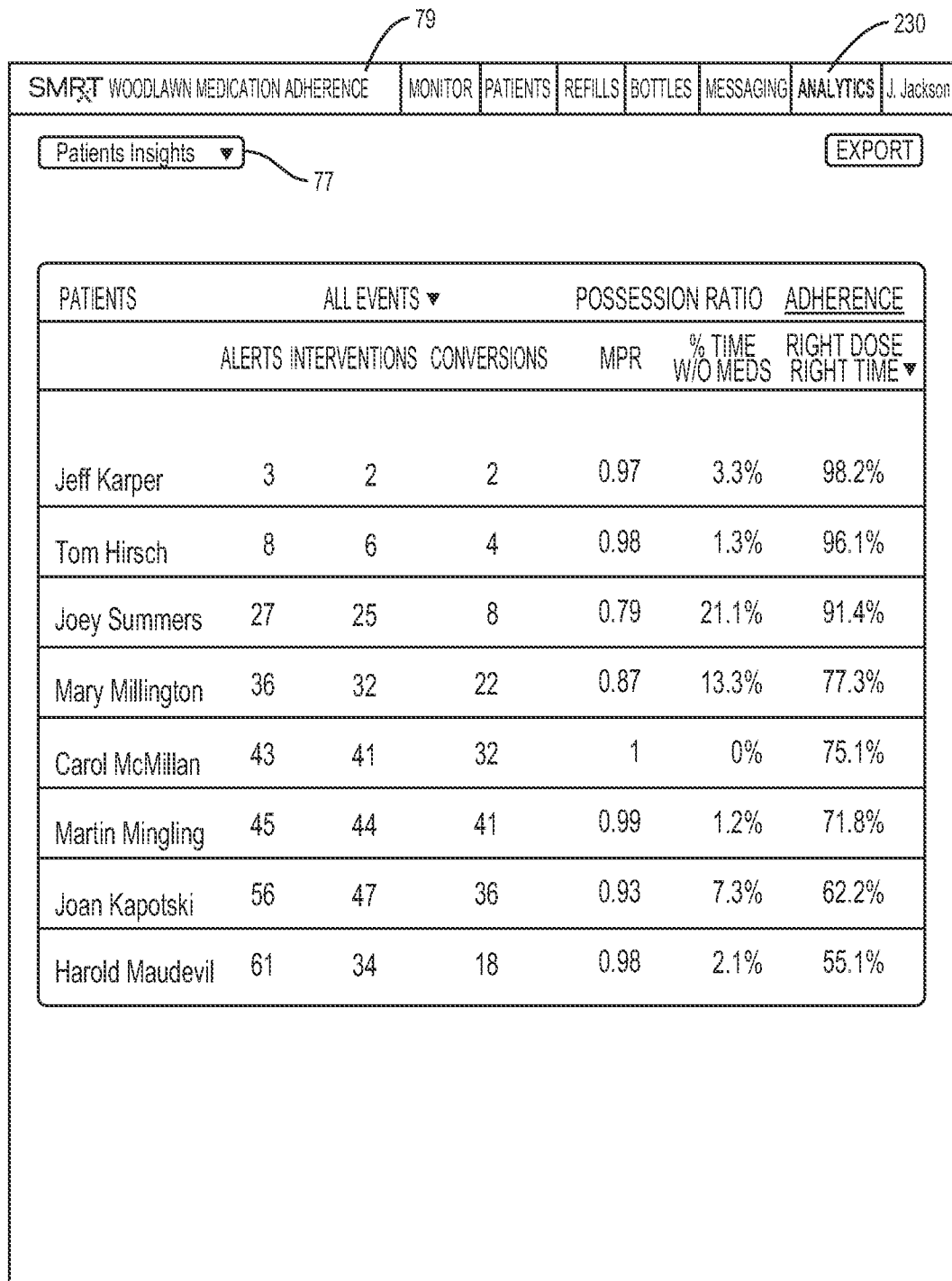


FIG. 15

79

230

SMRT WOODLAWN MEDICATION ADHERENCE

MONITOR

PATIENTS

REFILLS

BOTTLES

MESSAGING

ANALYTICS

J. Jackson

Patients Insights ▼

EXPORT

201

PATIENTS	MISSED DOSES ▼			POSSESSION RATIO		ADHERENCE
	ALL EVENTS		VERSIONS	MPR	% TIME W/O MEDS	RIGHT DOSE RIGHT TIME ▼
	MISSED DOSES					RIGHT DOSE RIGHT TIME
	INCORRECT DOSE TIMES					RIGHT DOSE, RIGHT TIME
	PARTIAL DOSES					
	EXTRA DOSES					
Jeff Karper			2	0.97	3.3	
Tom Hirsch	8	6	4	0.98	1.3%	96.1%
Joey Summers	27	25	8	0.79	21.1%	91.4%
Mary Millington	36	32	22	0.87	13.3%	77.3%
Carol McMillan	43	41	32	1	0%	75.1%
Martin Mingling	45	44	41	0.99	1.2%	71.8%
Joan Kapotski	56	47	36	0.93	7.3%	62.2%
Harold Maudevil	61	34	18	0.98	2.1%	55.1%

201

FIG. 16

79

230

SMRT WOODLAWN MEDICATION ADHERENCE

MONITOR

PATIENTS

REFILLS

BOTTLES

MESSAGING

ANALYTICS

J. Jackson

Patients Insights ▼

EXPORT

PATIENTS	MISSED DOSES ▼			POSSESSION RATIO		ADHERENCE
	ALERTS	INTERVENTIONS	CONVERSIONS	MPR	% TIME W/O MEDS	RIGHT DOSE RIGHT TIME ▼
Jeff Karper						98.2%
Tom Hirsch						96.1%
Joey Summers	27	25	9	0.99	1.1%	91.4%
Januvia 100mg	5	4	1	1	0%	98.1%
Actos 30mg	4	4	3	0.98	2.1%	82.3%
Sulfasalazine 500mg	18	17	5	0.99	1.1%	67.9%
Mary Millington						77.3%
Carol McMillan						75.1%
Martin Mingling						71.8%
Joan Kapotski						62.2%
Harold Maudevil						55.1%

202

FIG. 17

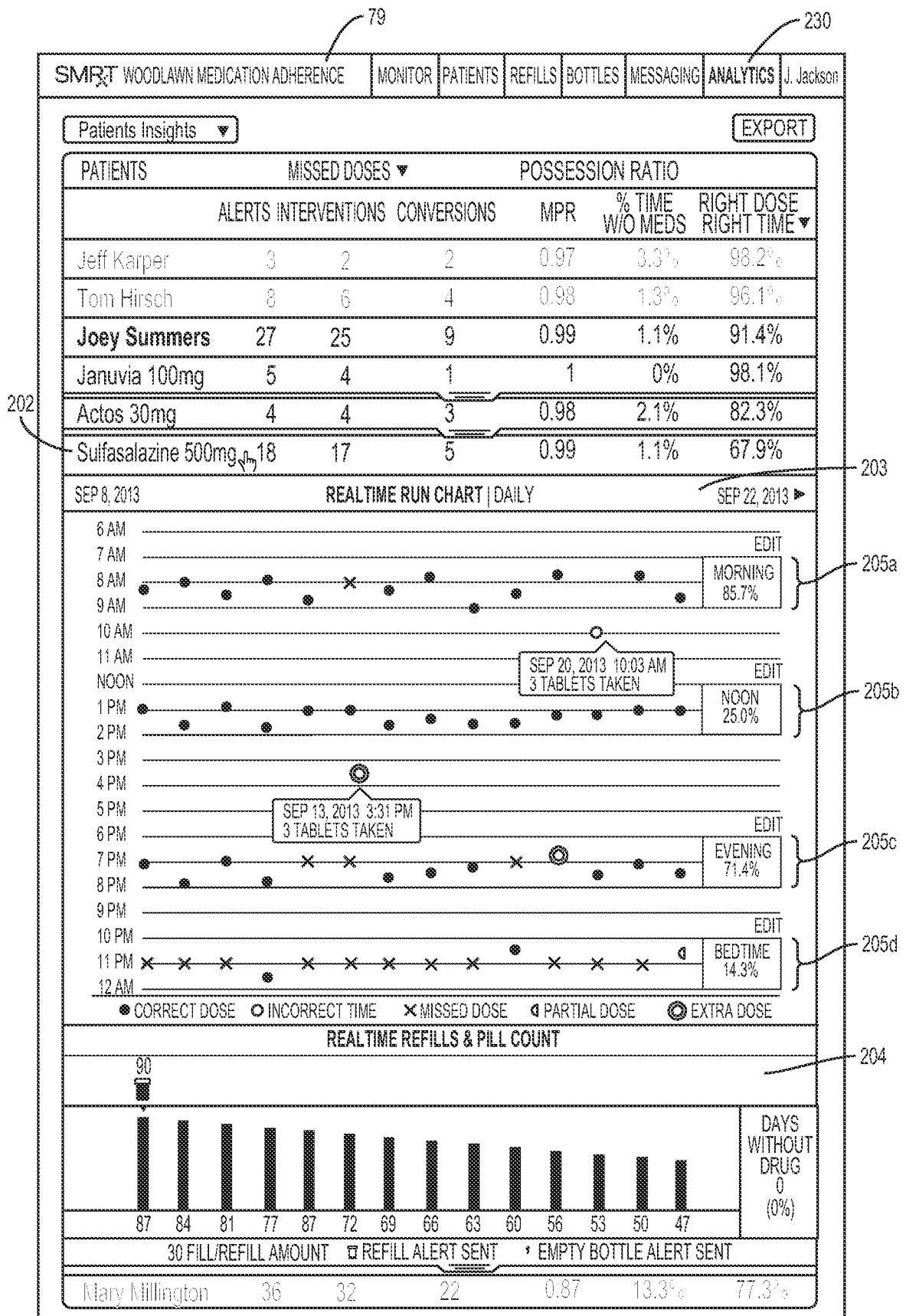


FIG. 18

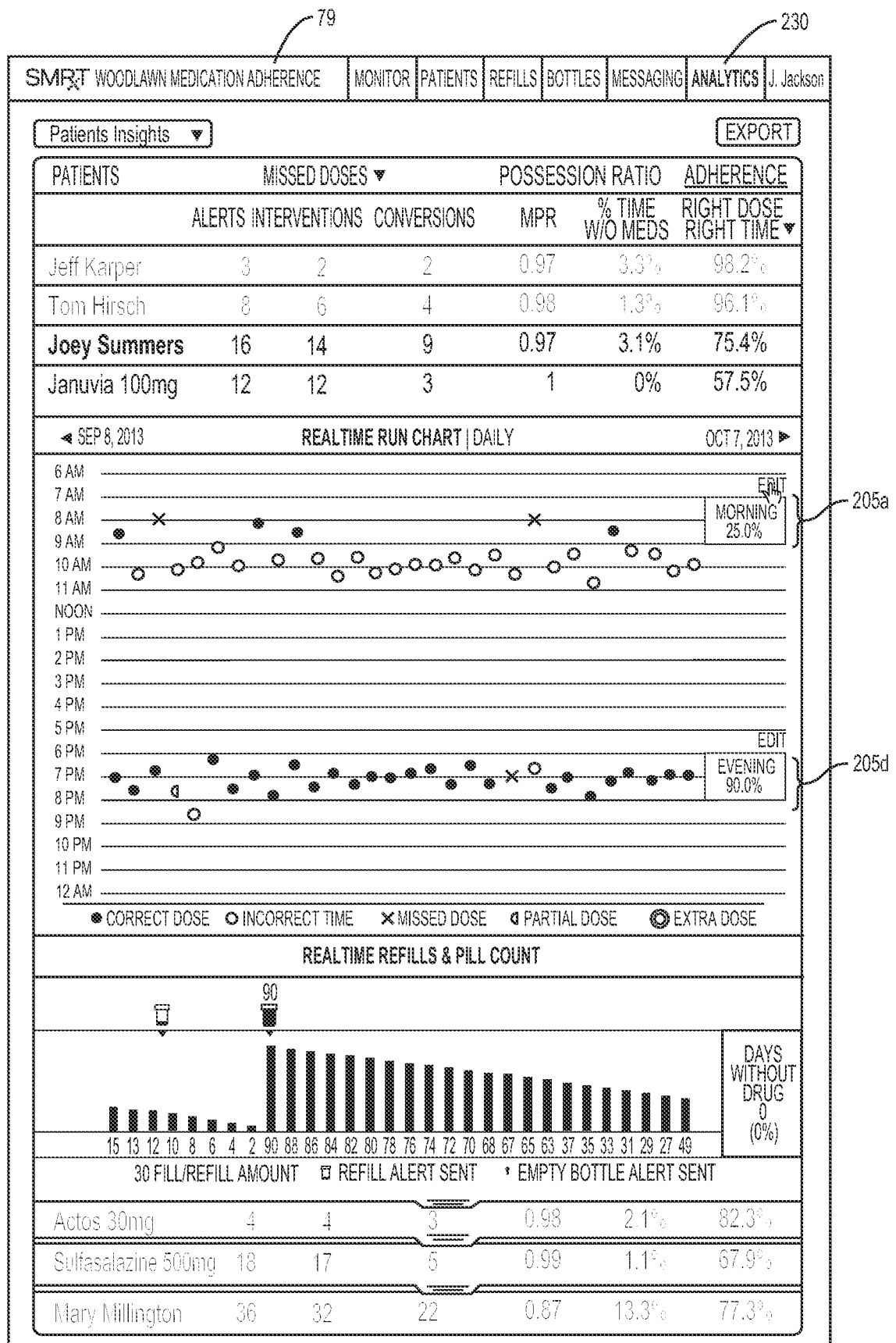


FIG. 19

SEP 8, 2013

REAL TIME RUN CHART

SEP 22, 2013

Medication 1: Januvia 80mg

DRUG NAME

Januvia

STRENGTH

80

mg

DOSAGE FORM

Tablet

DISEASE

Diabetes

PRICE/REFILL

\$918

PRICE/REFILL

30

UNIT WEIGHT

0.57

gram

DOSE

1 TABLET

FREQUENCY

TWICE A DAY

WITH FOOD

☐

HOSPITAL SETTING

☐ ?

TIME-CRITICAL

☐

MORNING

09:00 AM

11:00 AM

EVENING

6:00 PM

8:00 PM

SMRAT BOTTLE PILOT BOTTLE 1

CANCEL

SAVE

400

FIG. 20

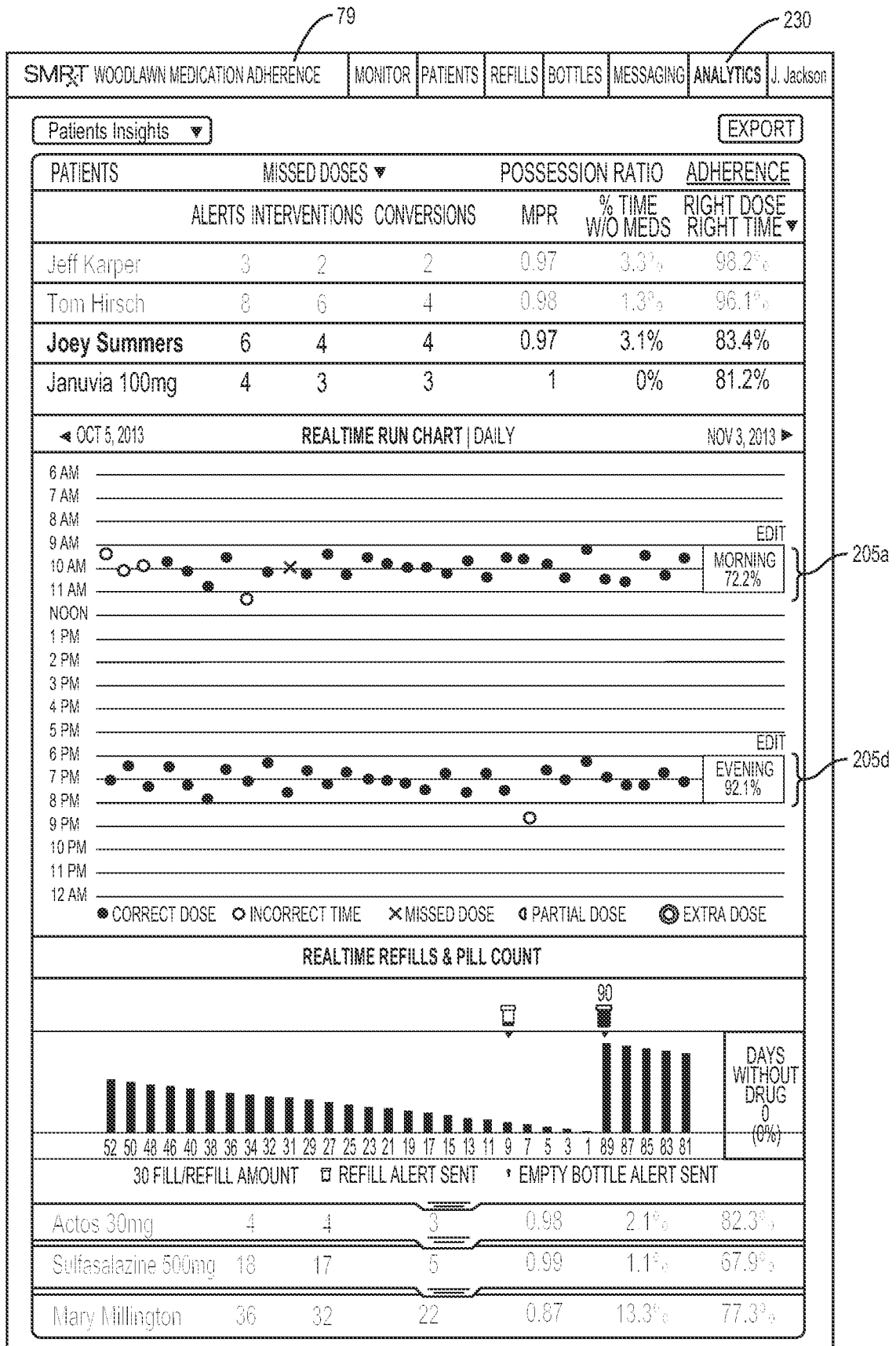


FIG. 21

79

230

SMRT WOODLAWN MEDICATION ADHERENCE

MONITOR PATIENTS REFILLS BOTTLES MESSAGING ANALYTICS J. Jackson

213 SELECT ALL

214 CANCEL

215 DONE

PATIENTS	MISSED DOSES ▼			POSSESSION RATIO		ADHERENCE
	ALERTS	INTERVENTIONS	CONVERSIONS	MPR	% TIME W/O MEDS	RIGHT DOSE RIGHT TIME ▼
☐ Jeff Karper	3	2	2	0.97	3.3%	98.2%
☐ Tom Hirsch	8	6	4	0.98	1.3%	96.1%
☒ Joey Summers	27	25	8	0.79	21.1%	91.4%
☐ Mary Millington	36	32	22	0.87	13.3%	77.3%
☐ Carol McMillan	43	41	32	1	0%	75.1%
☐ Martin Mingling	45	44	41	0.99	1.2%	71.8%
☐ Joan Kapotski	56	47	36	0.93	7.3%	62.2%
☐ Harold Maudevil	61	34	18	0.98	2.1%	55.1%

212

FIG. 22

SMART WOODLAWN MEDICATION ADHERENCE

MONITOR

PATIENTS

REFILLS

BOTTLES

MESSAGING

ANALYTICS

J. Jackson

SELECT ALL

CANCEL

DONE

PATIENTS	MISSED DOSES ▼			POSSESSION RATIO		ADHERENCE
	ALERTS	INTERVENTIONS	CONVERSIONS	MPR	% TIME W/O MEDS	RIGHT DOSE RIGHT TIME ▼
☐ Jeff Karper	3	2	2	0.97	3.3%	98.2%
☐ Tom Hirsch						96.1%
☒ Joey Summers						91.4%
☐ Mary Millington						77.3%
☐ Carol McMillan						75.1%
☐ Martin Mingling						71.8%
☐ Joan Kapotski	56	47	36	0.93	7.3%	62.2%
☐ Harold Maudevil	61	34	18	0.98	2.1%	55.1%

1. Choose export format:

CSV

TXT

XLS

2. Enter email address:

EMAIL

SHARE

or manually share the link below:

LINK

<http://bit.ly/xsd34fd>

COPY TO CLIPBOARD

DOWNLOAD

219

FIG. 23

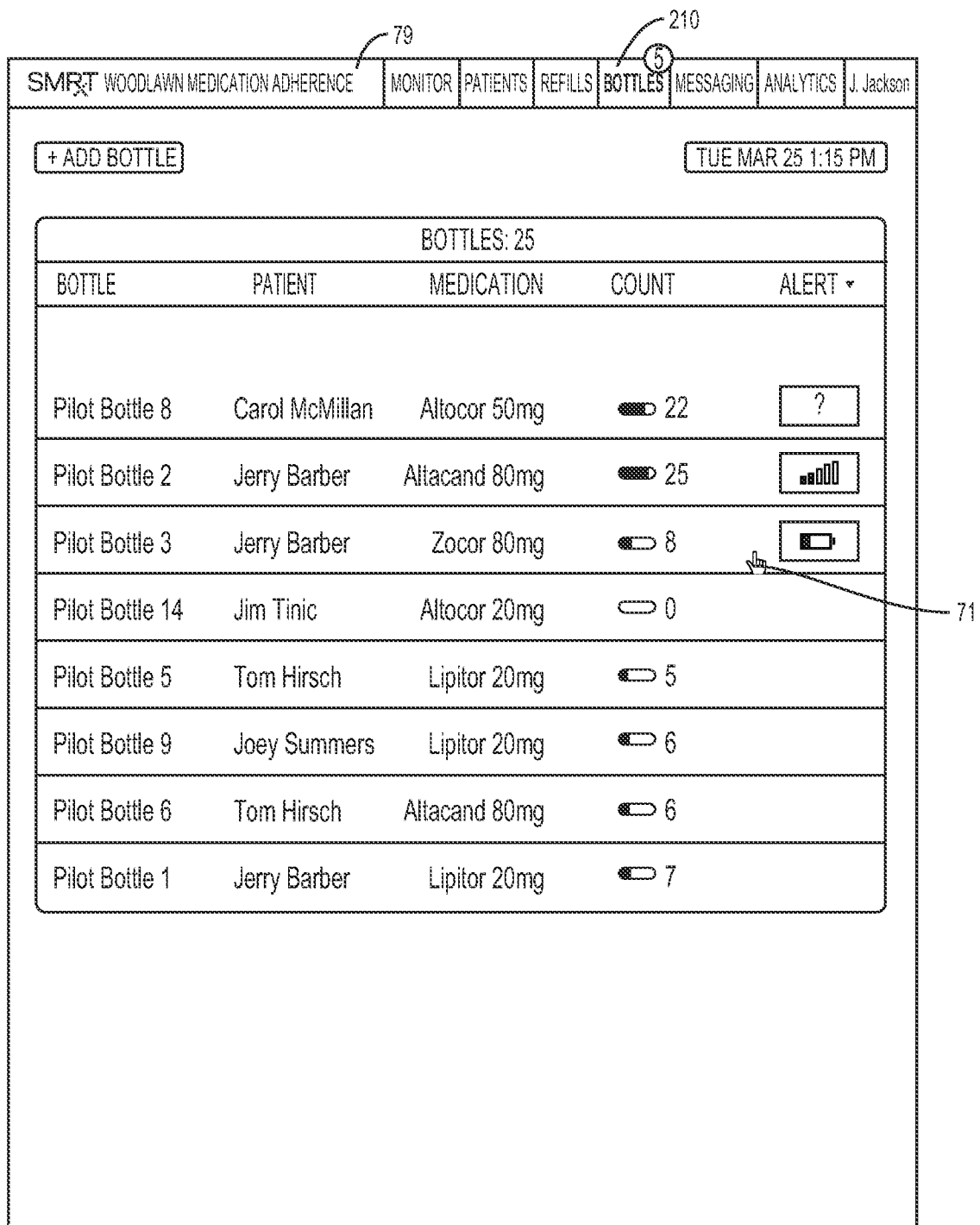


FIG. 24

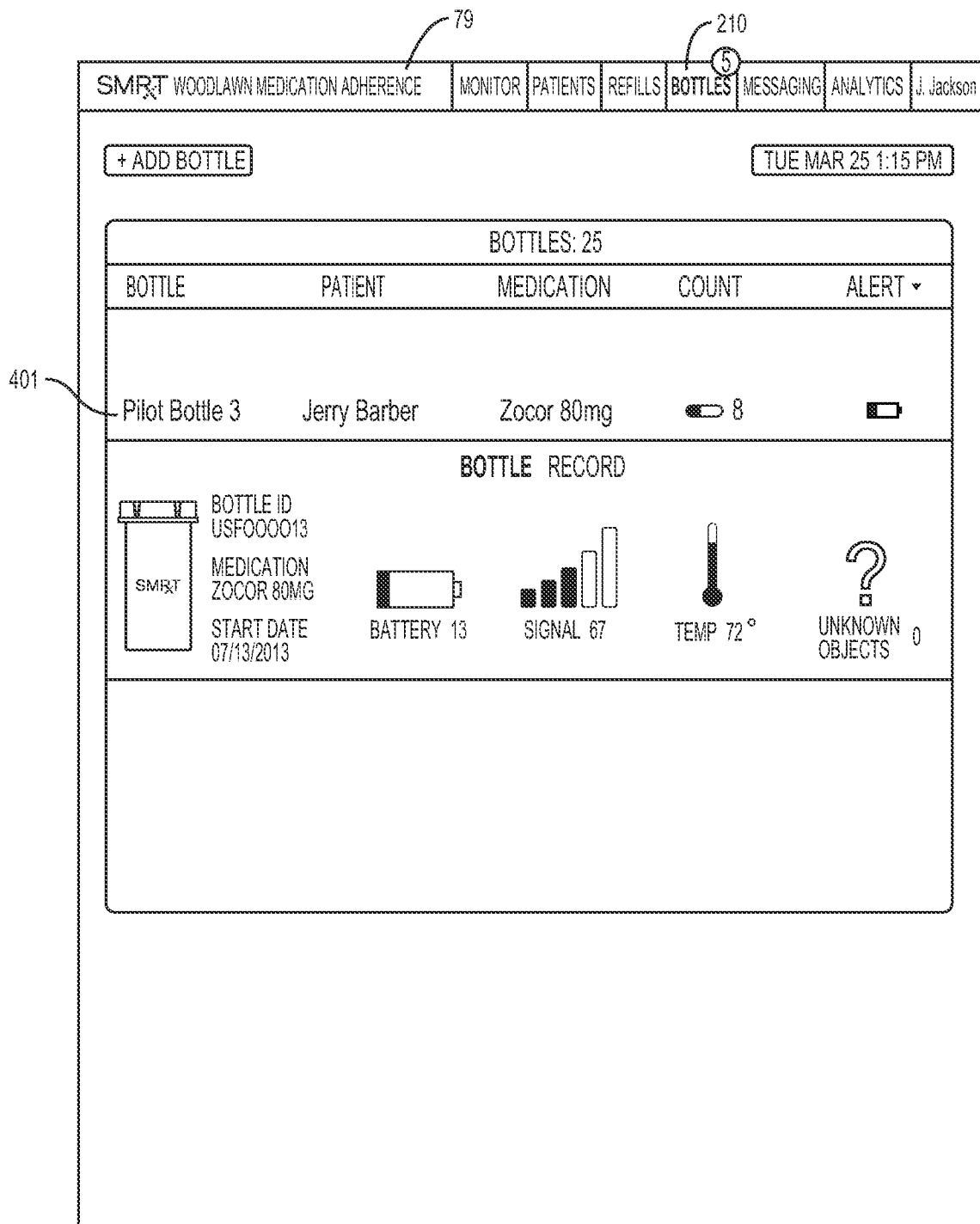


FIG. 25

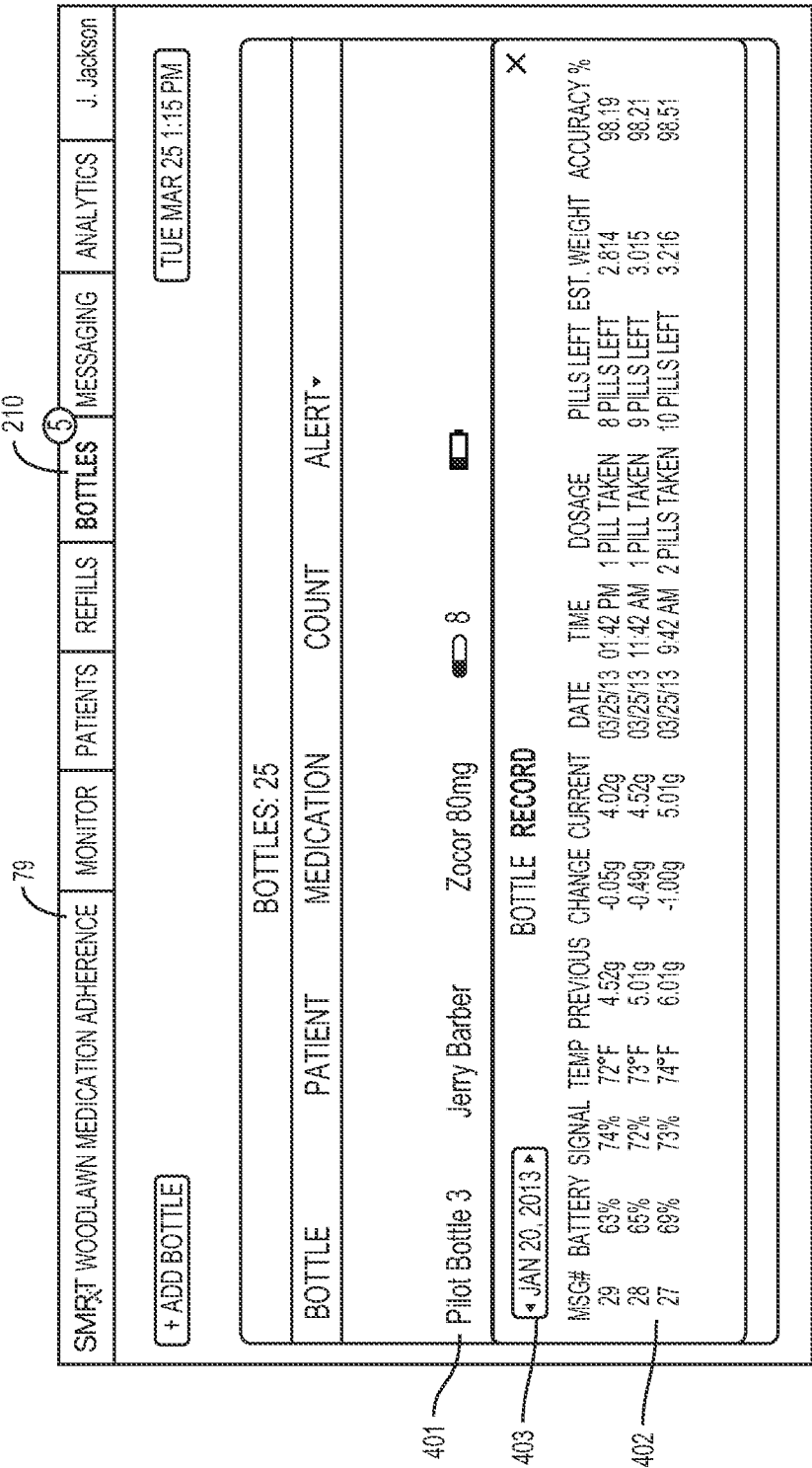


FIG. 26

79

210

5

SMRT WOODLAWN MEDICATION ADHERENCE

MONITOR PATIENTS REFILLS BOTTLES MESSAGING ANALYTICS J. Jackson

+ ADD BOTTLE

TUE MAR 25 1:15 PM

BOTTLES: 25

BOTTLE	PATIENT	MEDICATION	COUNT	ALERT ▾
Pilot Bottle 1	Carol McMillan	Altacor 50mg	 30	
Pilot Bottle 2		Not assigned		
Pilot Bottle 3		Not assigned		
Pilot Bottle 4		Not assigned		
Pilot Bottle 5		Not assigned		
Pilot Bottle 6		Not assigned		
Pilot Bottle 7		Not assigned		
Pilot Bottle 8		Not assigned		

FIG. 27

79

210

5

SMART WOODLAWN MEDICATION ADHERENCE | MONITOR | PATIENTS | REFILLS | BOTTLES | MESSAGING | ANALYTICS | J. Jackson

+ ADD BOTTLE

TUE MAR 25 1:15 PM

BOTTLES: 25

BOTTLE	PATIENT	MEDICATION	COUNT	ALERT ▾
Pilot Bottle 3	Jerry Barber	Zocor 80mg	8	

BOTTLE RECORD TARE 280

1. Remove pills from bottle, then tare bottle: TARE 281

404

FIG. 28

79

220

SMRT WOODLAWN MEDICATION ADHERENCE	MONITOR	PATIENTS	REFILLS	BOTTLES	MESSAGING	ANALYTICS	J. Jackson
------------------------------------	---------	----------	---------	---------	-----------	-----------	------------

8 MESSAGES + ADD MESSAGE

MESSAGE	FORMAT	TYPE ▼	SEND TO	TRIGGER	SENT
Missed Dose	SMS	ALERT	PATIENT	MISSED DOSE	4
Additional Dose Taken	SMS	ALERT	PATIENT	ANOTHER DOSE TAKEN	8
Parial Dose	SMS	ALERT	PATIENT	PARTIAL DOSE	2
Missed Dose	SMS	INTERVENTION	CAREGIVER	MISSED DOSE	5
Correct Dose	SMS	CONFIRMATION	PATIENT	CORRECT DOSE	5
5 Pills Left	SMS	REFILL	PHARMACY	5 PILLS LEFT	5
Empty Bottle	SMS	REFILL	CAREGIVER	EMPTY BOTTLE	3
Low Battery	SMS	BOTTLE STATUS	PATIENT	LOW BATTERY	7

FIG. 29

Type	Send to	Triggers	cc
Alert	Patient	Missed Dose Overdose Extra Dose Incorrect Dose Time Partial Dose	Caregiver Pharmacy Family All
Intervention	Caregiver	Missed Dose Overdose Extra Dose Incorrect Dose Time Partial Dose Failed Alert to Patient	Care Manager Pharmacy Physician All
Confirmation	Patient Family Caregiver Pharmacy All	Correct Dose Filled Bottle Activation	Family Caregiver Pharmacy All
Refill	Patient Family Caregiver Pharmacy All	5 days left 7 days left 10 days left 5 pills left 7 pills left 10 pills left Empty bottle Refilled bottle	Family Caregiver Pharmacy All
Bottle Status	Patient Family Caregiver All	Pill Count Low Battery Weak Signal Unknown Content	Family Caregiver Pharmacy All
Reminder	Patient	At time of Dose 5 min before Dose 10 min before Dose 15 min before Dose	Family Caregiver Pharmacy All
Surveys & Reports	Patient Family Caregiver Care Manager Pharmacy Physician Provider Insurer All	Daily Weekly Monthly Quarterly Annually	Patient Family Caregiver Care Manager Pharmacy Physician Provider Insurer All

FIG. 30

SMRT WOODLAWN MEDICATION ADHERENCE 79

MONITOR PATIENTS REFILLS BOTTLES MESSAGING 220 ANALYTICS J. Jackson

8 MESSAGES + ADD MESSAGE 282

MESSAGE	FORMAT	TYPE ▼	SEND TO	TRIGGER	SENT
Overdo	N/A	N/A	N/A	N/A	0

NAME 410 Overdo

TYPE 410 ALERT ▼

SEND TO 410 PATIENT ▼

SEND BY SMS ▼

TRIGGER MISSED DOSE ▼

REPEAT NONE ▼

MESSAGE VARIABLES

[Patient Nickname]

[Patient Name]

[Drug Name]

[Dose Time]

[Remaining Dose]

[Dose Taken Time]

[Correct Dose Taken]

[Dose Taken]

[Pills Added]

[Pills Count]

[Time Zone]

MESSAGE

You have not taken [dose] [drug name] at [dose time]. Please take [dose] [drug name] immediately.

☐ CC CAREGIVER ☐ CC PHARMACY 284

CANCEL SAVE

SAMPLE PREVIEW

You have not taken 1 Lipitor at 11:00am. Please take 1 Lipitor immediately.

Missed Dose	SMS	ALERT	PATIENT	MISSED DOSE	4
Additional Dose Taken	SMS	ALERT	PATIENT	ANOTHER DOSE TAKEN	8
Partial Dose	SMS	ALERT	PATIENT	PARTIAL DOSE	2
Missed Dose	SMS	INTERVENTION	CAREGIVER	MISSED DOSE	5
Correct Dose	SMS	CONFIRMATION	PATIENT	CORRECT DOSE	5

409

FIG. 31

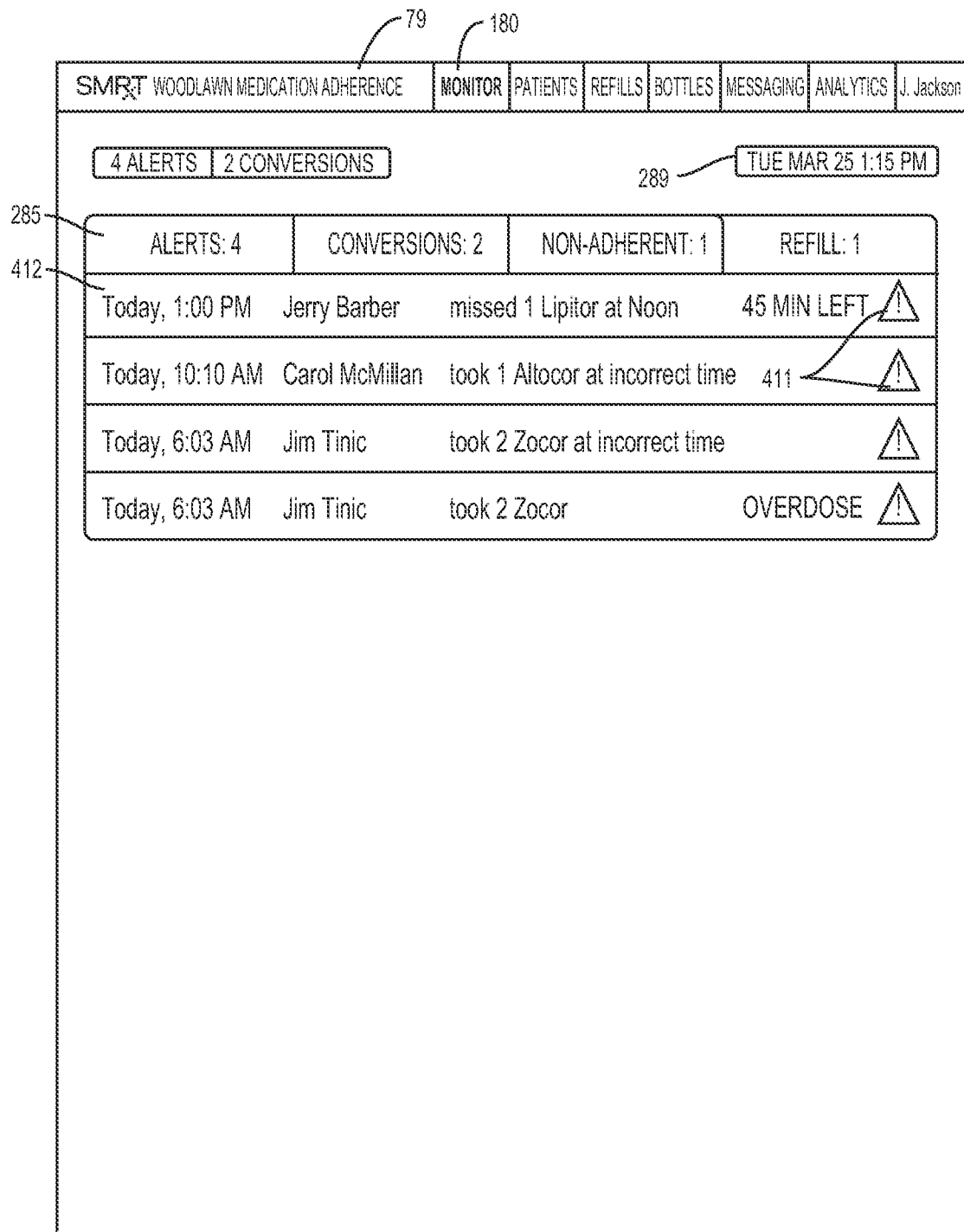


FIG. 32

79 180

SMRT WOODLAWN MEDICATION ADHERENCE				MONITOR	PATIENTS	REFILLS	BOTTLES	MESSAGING	ANALYTICS	J. Jackson
------------------------------------	--	--	--	---------	----------	---------	---------	-----------	-----------	------------

4 ALERTS

2 CONVERSIONS

TUE MAR 25 1:15 PM

ALERTS: 4

CONVERSIONS: 2

NON-ADHERENT: 1

REFILL: 1

Today, 1:00 PM
Jerry Barber
missed 1 Lipitor at Noon
23 MIN LEFT

HISTORY ▾

TODAY, 1:00 PM	MISSED DOSE	SENT TO PATIENT AND CAREGIVER JOAN MCENTYRE
TODAY, 10:45 AM	15 MIN REMINDER	SENT TO PATIENT

Jerry has missed 1 Lipitor at Noon.
Please call to make sure he takes 1 Lipitor immediately.

Jerry Barber (305) 981-1705 CALL MADE

ALL CONTACTS ▾

PATIENT ADDRESS	34 HOWARD STREET FLR 3 NEW YORK, NY 10013	
BETSY BARBER	(302) 982-1122	MOTHER
MARLIN SLACKER	(302) 454-2156	NURSE

INTERVENTION SURVEY

☐ Just forgot	☐ Cost
☐ Side effects	☐ Stretching supply
☐ Thinks drug is not working	☐ Bottle empty
☐ Thinks it's not needed	☐ Other
☐ Doesn't know how to use it	

NOTES

Today, 10:10 AM	Carol McMillan	took 1 Altacor at incorrect time	
Today, 6:03 AM	Jim Tinic	took 2 Zocor at incorrect time	
Today, 6:03 AM	Jim Tinic	took 2 Zocor	OVERDOSE

FIG. 33

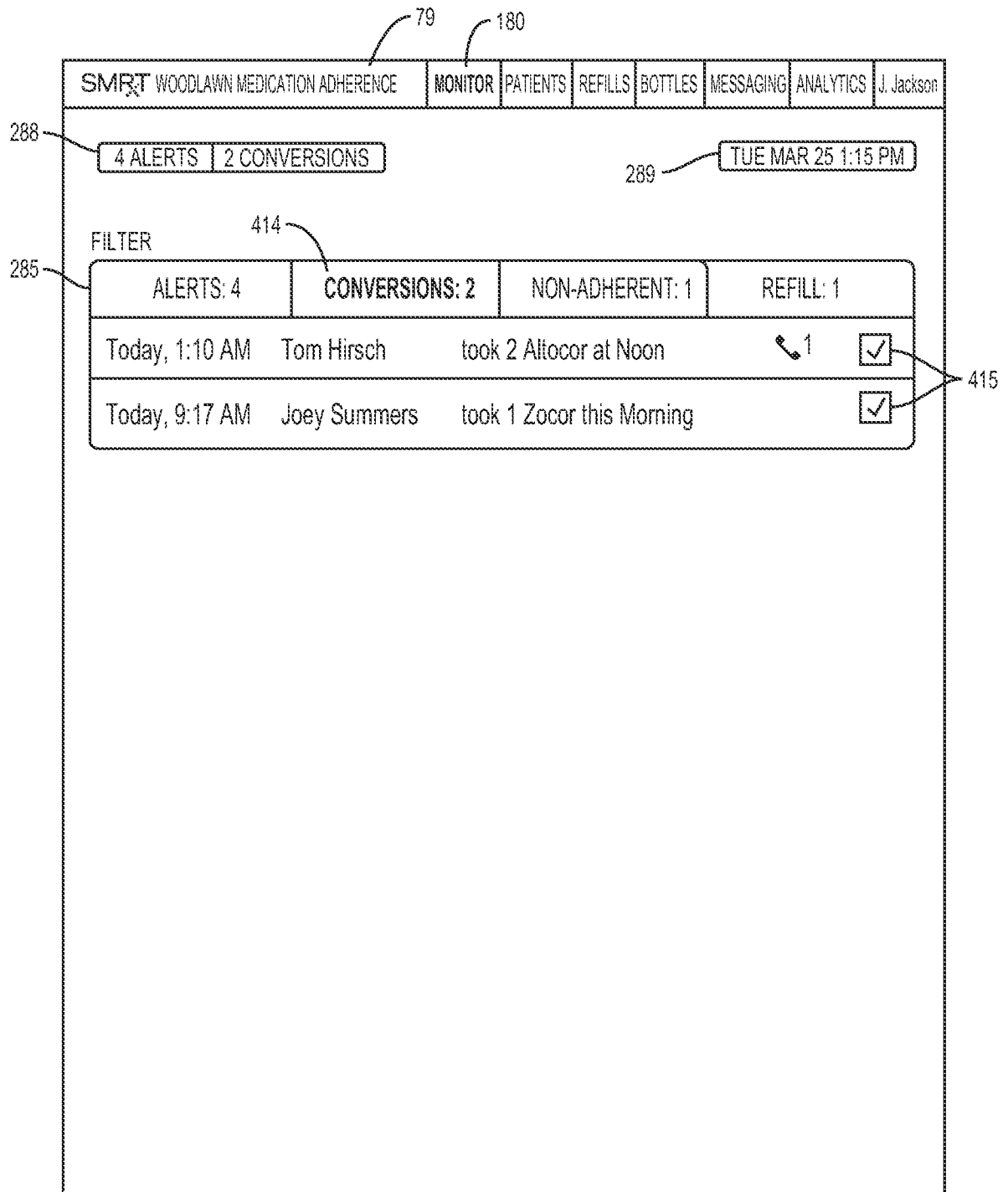


FIG. 34

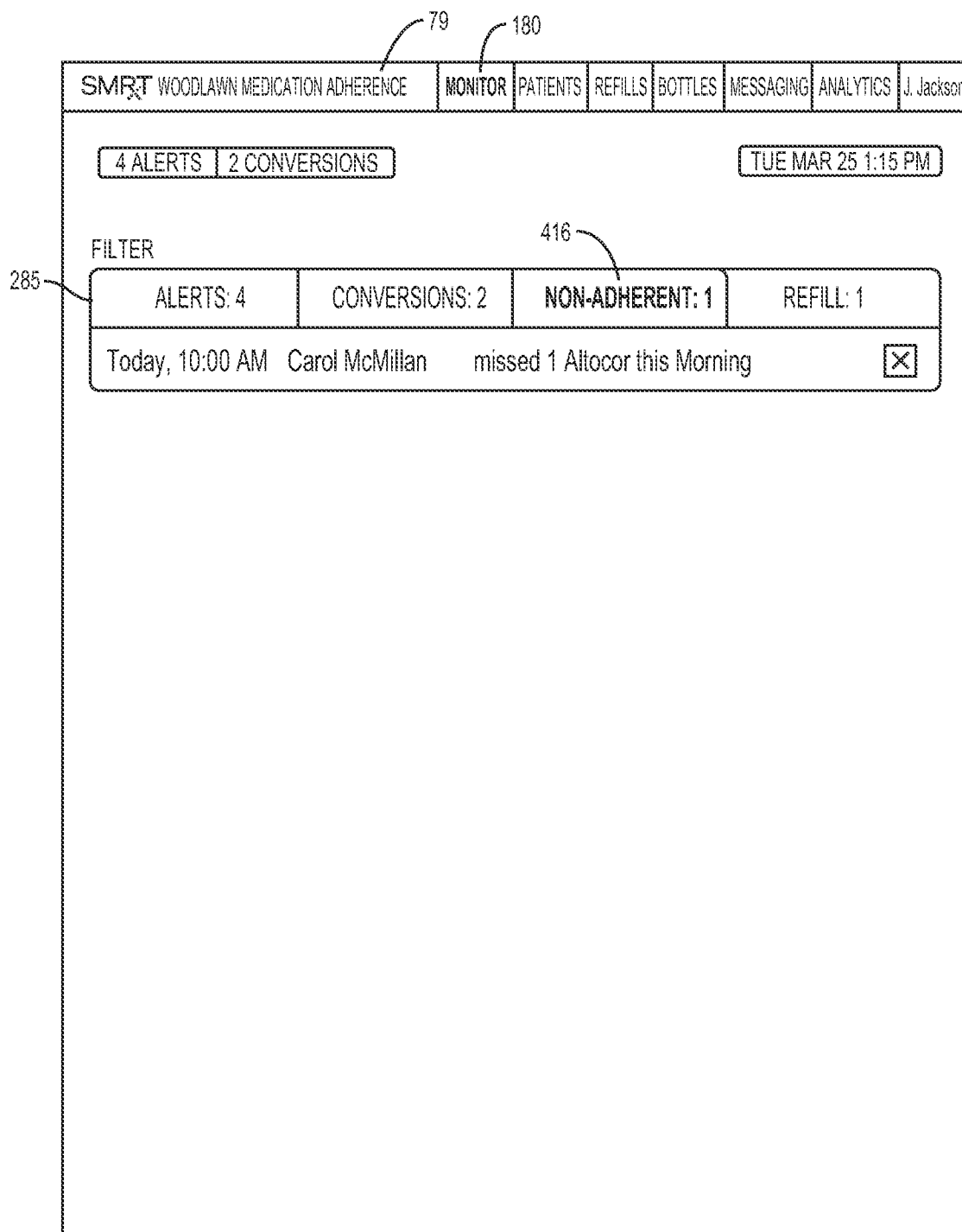


FIG. 35

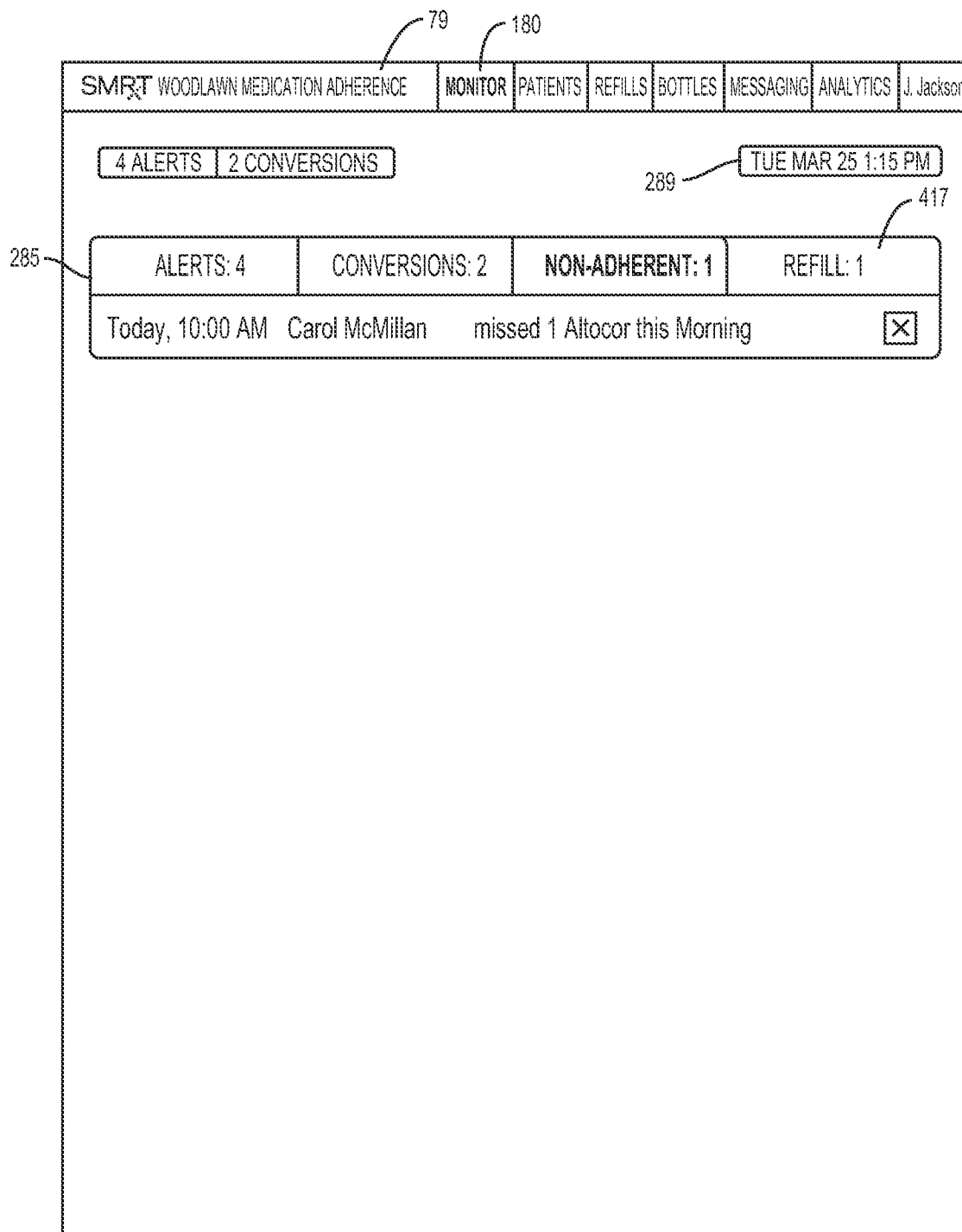


FIG. 36

SMRT WOODLAWN MEDICATION ADHERENCE

MONITOR

PATIENTS

REFILLS

BOTTLES

MESSAGING

ANALYTICS

J. Jackson

79

190

426

424

New Patient

419

420

%

426

Patient Info Archive

FIRST NAME

LAST NAME

PATIENT ID

GENDER

425

SMSON

CELL PHONE

HOME PHONE

WORK PHONE

PERSONAL EMAIL

WORK EMAIL

ADD CAREGIVER

ADD PHARMACY

CITY

STATE

ZIP CODE

TIME ZONE

Medication

421

SELECT

422

AMOUNT

423

START

END

Duration

1ST

2ND

3RD

4TH

mg

g

DRUG NAME

STRENGTH

DOSAGE FORM

DISEASE

PRICE/REFILL

COUNT/REFILL

WEIGHT

PRESCRIBER

1 tablet

None

None

None

None

None

Morning

None

None

None

06:00 AM

10:00 AM

BOTTLE A100032BD43B6

LINE 347-380-0769

Family Caregiver 1

x

FIG. 37

79

200

SMRT WOODLAWN MEDICATION ADHERENCE										J. Jackson
MONITOR				PATIENTS	REFILLS	BOTTLES	MESSAGING	ANALYTICS		
EXPORT										
MEDICATION	START	DURATION (DAYS)	POSSESSION (DAYS)	MPR	PATIENTS	TABLETS TAKEN	REFILLS CONVERTED	REFILLS \$	CONVERSION	ADHERENCE
CELLCEPT 250mg U.S.	5/1/14	200	200	1	10,000	2,000,000	63,333	\$8,866,711	95.00%	90.00%
CELLCEPT 250mg NE Region	5/1/14	200	200	1	5,000	1,000,000	31,667	\$4,433,355	99.99%	94.99%
CELLCEPT 250mg SE Region	5/1/14	200	200	1	5,000	1,000,000	31,667	\$4,433,355	90.00%	84.99%
CELLCEPT 500mg U.S.	7/31/14	100	100	1	1,000	200,000	6,333	\$866,711	90.55%	95.77%
TARCEVA 150mg U.S.	7/31/14	100	100	1	1,000	200,000	6,333	\$866,711	90.55%	95.77%
XELODA 150mg U.S.	5/1/14	200	200	1	10,000	2,000,000	63,333	\$8,866,711	92.87%	91.32%

FIG. 38

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/024788

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61K 39/395 (2014.01)

USPC - 705/2

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61K 39/395, B65D 25/00 (2014.01)

USPC - 340/309.16, 705/2

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

CPC - G06F 19/3462, G06Q 50/2, G06F 19/3 (2014.02)

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

Orbit, Google Patents, Google

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 7,928,835 B1 (JOVANOVA et al) 19 April 2011 (19.04.2011) entire document	1-3, 15-16, 28-29
(X,P)	WO 2013/127564 A1 (BEYELER et al) 06 September 2013 (06.09.2013) entire document	1-3, 15-16, 28-29
A	US 2010/0185456 A1 (KANSAL) 22 July 2010 (22.07.2010) entire document	1-3, 15-16, 28-29
A	US 2007/0016443 A1 (WACHMAN et al) 18 January 2007 (18.01.2007) entire document	1-3, 15-16, 28-29

☐ Further documents are listed in the continuation of Box C.


* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

14 July 2014

Date of mailing of the international search report

05 AUG 2014

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-3201

Authorized officer:

Blaine R. Copenheaver

PCT Helpdesk: 571-272-4300

PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2014/024788

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

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

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☒ Claims Nos.: 4-14, 17-27, 30-31
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.