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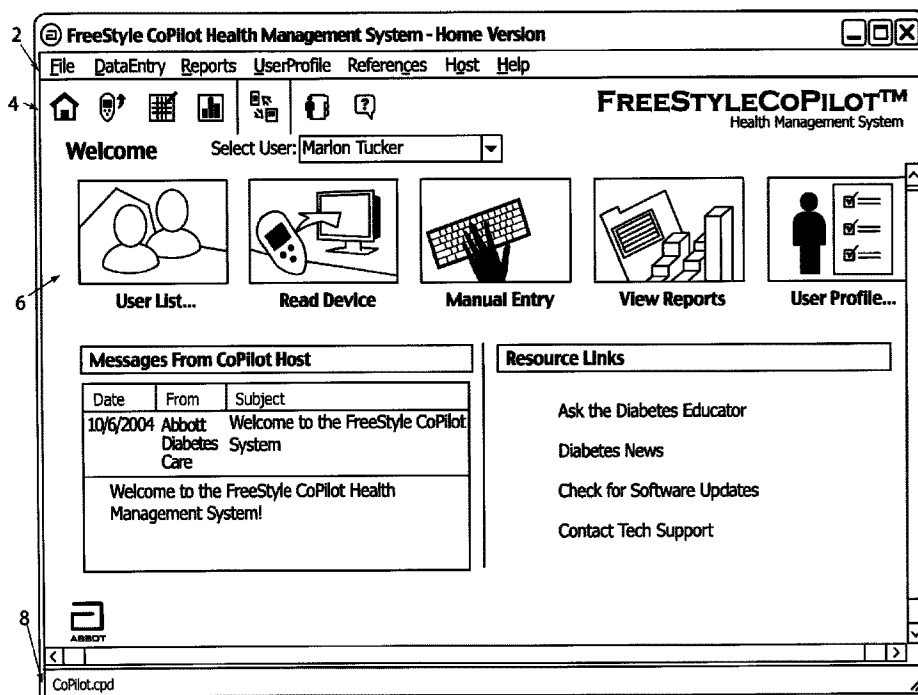
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(54) **Titre :** ARCHITECTURE HOTE-CLIENT DE SOINS POUR LE DIABETE ET SYSTEMES DE GESTION DE DONNEES

(54) **Titre :** DIABETES CARE HOST-CLIENT ARCHITECTURE AND DATA MANAGEMENT SYSTEM



(57) **Abrégé/Abstract:**

A host-client data sharing system manages diabetes care data. A host database, preferably web or internet based, is implemented for storing diabetes care data relating to multiple diabetics. A client or local database stores the diabetes care data relating to multiple diabetics on a personal appliance such as a PC, or a portable or handheld microprocessor-based computing device. The host database uses multiple servers for handling client interactions with the system.

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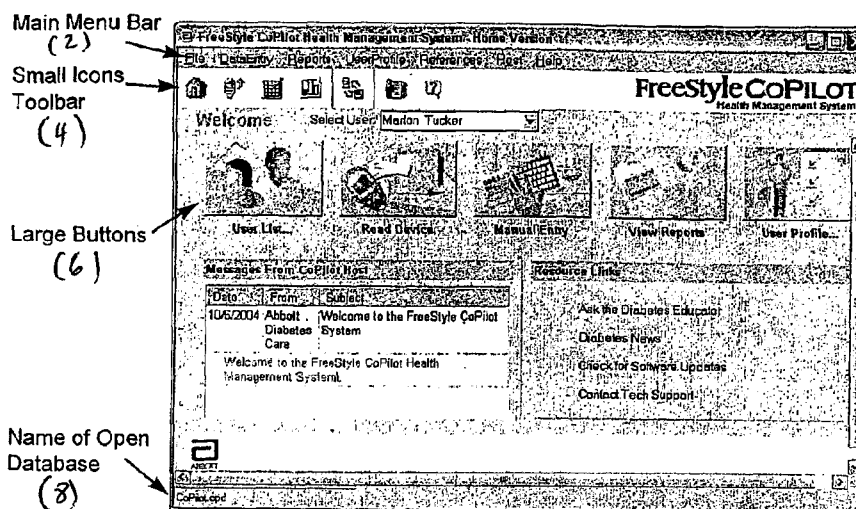
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(54) Title: DIABETES CARE HOST-CLIENT ARCHITECTURE AND DATA MANAGEMENT SYSTEM



Home Page

(57) **Abstract:** A host-client data sharing system manages diabetes care data. A host database, preferably web or internet based, is implemented for storing diabetes care data relating to multiple diabetics. A client or local database stores the diabetes care data relating to multiple diabetics on a personal appliance such as a PC, or a portable or handheld microprocessor-based computing device. The host database uses multiple servers for handling client interactions with the system.

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DIABETES CARE HOST-CLIENT ARCHITECTURE AND DATA MANAGEMENT SYSTEM

FIELD OF THE INVENTION

The invention relates to diabetes care data management, and particularly to a host-client architecture for communicating, managing and analyzing the data and for generating versatile reports.

SUMMARY OF THE INVENTION

The invention provides a host-client data sharing system for managing diabetes care data. a host database, preferably web or internet based, is implemented for storing diabetes care data relating to multiple diabetics. A client or local database stores the diabetes care data relating to multiple diabetics on a personal appliance such as a PC, or a portable or handheld microprocessor-based computing device. The host database uses multiple servers for handling client interactions with the system. A host based data warehouse component is used for storing, searching and/or analyzing, customer information and health data stored on the host database for the population of multiple diabetics using the Host. The host-based data warehouse component applies security mechanisms to protect access to the data stored on the host server. The data mining terminal runs an analytical data processing application and has access to the data warehouse.

A browser-accessible or client-resident graphics rendering component provides a graphical user interface (GUI) that includes a patient selection component permitting uploading data to or calling data from, the database, or both, relating to a particular

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diabetic of the multiple diabetics. The GUI further includes diabetes care device and health care professional (HCP) selection components, and report configuration components for generating customized reports of selected diabetics, HCPs, data ranges, data types or categories and other criteria.

Population analysis reporting or generation of reports on a population of multiple diabetics is permitted with the report generation component. These reports are allowed to base the data analysis on multiple selection criteria. These data elements may be applied in a selected combination and may use a selected number of selection criteria, such as patient profile information, demographic information, selected data event types, a range of values for a given selection criteria, dates, or other data filters or elements. The report may then be ordered using a selected column or field in the resulting report. Multiple Filter/search criteria may be stored together or individually, and then selectively applied and turned off in the resulting display. A pattern recognition component for the resulting display uses the GUI (color or other highlighting) to draw the user's attention to determining whether patterns of interest exist within the data and for indicating any recognized patterns.

Diabetes related health information may be overlaid in a particular form of report. In a weekly Pump Report, a combination of insulin data (which may be derived from an insulin pump) is provided in a weekly format summarizing each day in a one week period where the GUI is divided left to right by day with vertical demarcation, and containing data analysis statistics that include insulin information, glucose information and/or carbohydrate information, among other data types described herein, summarized in each day's column. In a daily combination report, a combination of Glucose, insulin and/or carbohydrate data, or other data type, may be provided in an hourly format summarizing one full day, where the GUI is divided left to right by hour with vertical demarcation, and containing data analysis statistics that include insulin information, glucose information and carbohydrate information summarized into each hour's column. For each report, whether it be monthly, weekly, daily or another selected temporal duration, the report may include graphical charts or pictures or text-based analytical information, or a combination of these. The statistics and analytical information shown can be adjusted for pump users and non pump users depending on the insulin data type.

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The system provides an ability to tracking a large number of health and demographic elements on a same report. These may include glucose, insulin, meals, exercise, state of health, medication, medical exam, lab result, ketones, or combinations thereof. These elements may be displayed in a graphical or text based (charts) or in a tabular form. Reports may be filtered, grouped or sorted by any of the fields associated with these events. Multiple criteria may be applied to a single patient's data or multiple patients' data.

The system provides a data sharing feature including a synchronization architecture by which a diabetic client may share data useful in management of the diabetic condition with selected health care professionals. This architecture may be implemented through an Internet-based synchronizing server. The system can handle incrementally added or modified data that is synchronized to the internet-based server. This features saves having to copy a full database each time a synchronization operation is requested. A security process assures that data is shared only as authorized by the original user and is accepted by the sharing health care professional.

The system provides for storing packets of new or modified data on the Internet-based synchronizing server. The system of stored packets of new or modified data can be organized into a database for meaningful viewing and analysis of the contained data. A diabetic client may maintain data useful in management of the diabetic condition in two or more physically separate locations and/or computers and by which this data may be synchronized to be identical on the multiple locations and/or computers.

Data protection is provided by which a diabetic client may store back-up copies of data useful in management of the diabetic condition in a remote, protected internet server location.

Local area networking provides a mechanism by which multiple client computers may store and retrieve data useful in management of diabetes from a single server database in a local area networking environment.

Synchronizing internet computer scalability is provided for distributing stored synchronizing diabetes management data across multiple server computers in order to scale the capacity of the system. A client database is also synchronized within the system. Traffic to the multiple servers is managed for storing synchronizing diabetes

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management data that balances the load more or less equally among the various multiple available servers.

A host email system permits the host to send email messages notifying host users of upgrades, or other health or product information or upgrades. A user may also upload from a compatible device and immediately or subsequently print out any or all of the available reports (or specific multiple reports) in a desired date range (date ranges apply specifically to each report) with any personal printing preferences specified. In one embodiment, a user profile may be created first, while selection of report generation and printing preferences may be manually applied or automatically selected based on past history or other default criteria.

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Figure 43. Glucose Targets Mode Drop-Down Box

Figure 44. Pre/Post Meal Mode with Hypo/Hyper Checked (left);
All Time Periods Mode (right)

Figure 45. Hypo/Hyper Values Check Box

Figure 46. Glucose Unit of Measure Drop-Down Box

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Figure 52. Patient List Screen

Figure 53. Patient List Screen

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Figure 153. Invite HCP to Share Data Screen

Figure 154. Enter Host HCP Account Number Screen

Figure 155. Assign Access Level Screen

Figure 156. Process Complete Screen

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Figure 181. File Browser: Restore Log

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Figure 187. Customer Service Contact Information Screen

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

A system in accordance with a preferred embodiment is referred to as the FreeStyle CoPilot™ Health Management System (also referred to as the FreeStyle CoPilot System or the System), and is a personal computer (PC or portable or handheld appliance)-based software application that permits people with diabetes, their healthcare team, and caregivers to upload data preferably from FreeStyle™ and Precision Xtra™ blood glucose monitoring systems (and generally to several other

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commercially available blood glucose meters and insulin pumps) into the FreeStyle CoPilot application.

The FreeStyle CoPilot System provides graphs and other software tools for people with diabetes and their healthcare professionals (HCPs) to help evaluate and analyze glucose readings, carbohydrate intake, insulin dosage, and other diabetes-related factors uploaded from devices or manually entered into the System. The System can help identify trends that can be used to educate persons with diabetes to improve their glucose control.

Common terms that have additional special meanings within the FreeStyle CoPilot System are capitalized to distinguish their special usage (for example, **Diary** as opposed to a written diary). System-specific screen, control, commands, and function names (for example, **Home** page, the **Apply** button) are also capitalized throughout. The specific usages of these terms within the system of the preferred embodiment is intended to be added to their ordinary meanings and usages to enlarge the scopes of these terms in the context of the invention, and not to limit them.

The FreeStyle CoPilot Health Management System provides an accessory to a blood glucose monitoring system such as the FreeStyle and Precision Xtra blood glucose monitoring systems and other commercially available blood glucose meters and insulin pumps. The FreeStyle CoPilot Health Management System may be used in home and clinical settings to upload data from these devices to a patient's or healthcare professional's computer where the data may be saved, displayed in a number of formats, printed, or exported to an authorized user. The FreeStyle CoPilot System is an aid to people with diabetes and healthcare professionals in the review, analysis, and evaluation of historical blood glucose test results, insulin dosages, and carbohydrate intake data to support an effective diabetes management program. The System may be used in home and healthcare professional settings to manage diabetes factors, such as insulin dosage, carbohydrate intake, and exercise.

There are two primary users contemplated for the System: home users (people with diabetes or their caregivers), and HCP users (healthcare professionals). A home version of the software for a person with diabetes or the caregiver of a person with diabetes may permit recording information for them such as glucose, insulin, meals, exercise and/or other data types described herein. A HCP version of the software is for

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managing health data provided to a HCP by one or more patients with diabetes. HCP can mean an individual healthcare professional (such as physician, nurse educator, or other diabetes healthcare team member), a group or entity (such as a clinic), or even case managers, medical directors, and other managed care professionals, if authorized by the person with diabetes. The System may be used to monitor the health status of the patients they manage.

The System is a personal computer (PC) or personal computing appliance software application that enables users to upload, store, and/or analyze glucose readings and other important information for diabetes management. This information can be used by people with diabetes, their healthcare professionals (HCPs), and caregivers.

After installing the System on a PC or PC appliance, glucose data can be uploaded or copied from a compatible glucose meter, or data can typed in from a keyboard, or imported from a file. One can maintain a record of his or her glucose, carbohydrates, insulin, exercise, state of health, doctor visits, medications, blood ketones, and/or laboratory results. One may enter as much or as little information as desired.

The System analyzes the data and displays it in simple, clear reports (graphs and tables). The reports can be viewed on the computer screen or on the display of the computing appliance or they can be printed out (black-and-white or color). One can also automatically print one or more reports that are selected to be printed or displayed each data is uploaded from a particular device.

The System further allows permits data sharing securely over the Internet with selected HCPs. The System further promotes teamwork for effective diabetes health management. The System encourages people with diabetes to stick to lifestyle recommendations and medication plans. It can help them and their HCPs to identify trends in health or care.

The System preferably utilizes a personal computing desktop, portable or handheld appliance with 400 megahertz (MHz) or higher processor clock speed recommended. The system preferably includes either an internet connection or a compact disc (CD-ROM) drive or other digital storage device interface. Random access memory (RAM) of 64 megabytes (MB) or more is recommended, while available hard

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disk space of 30 MB is used for running the program. Microsoft® Windows 98 SE, 2000, NT, ME, or XP operating systems are preferred. A monitor with 1024 x 768 or higher resolution is preferred. A standard keyboard and mouse are also preferred, or other input device that may be utilized with a particular personal computing appliance.

A few optional accessories that can be useful in combination with the System include a serial port, available 9-pin EIA-232 (also known as RS-232 or V.24) or appropriate adapter for a universal serial bus (USB) for glucose meter connection, a Windows-compatible printer for printing copies of reports, a Windows-compatible fax software and drivers for faxing reports, an email application for e-mailing reports, data cables for uploading from compatible devices, and a HotSync® cradle for uploading data from a PDA-type diabetes management system.

The System is preferably available as a download from a web site such as the FreeStyle CoPilot website (www.freestylecopilot.com), and/or on a CD purchased through a website or customer care center.

Using the System, a diabetic or HCP can read (upload) or export data from devices such as glucose meters and insulin pumps. These devices can be connected to the System by serial port or USB.

GRAPHICAL USER INTERFACE

Display screens of the System preferably have a consistently similar look and structure. Common screen icons are preferably organized on a **Home** page, such as that illustrated in Figure 1, with the main user activities highlighted. The screen shot illustrated at Figure 1 includes a main menu bar 2, a small icons bar 4, large buttons 6, and name of open database 8.

Tabs on the main menu bar 2 enable access to program activities. The small icons 4 and large buttons 6 represent a subset of the program activities including commonly used activities. Clicking on a tab of the main menu bar 2, a small icon 4, or a large button 6 opens a corresponding screen. The **Home** page is described in more detail below with reference to Figure 9.

The System can as a stand-alone product operated by itself on a user's PC and can serve as a self-management tool for the collection and analysis of diabetes-related

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data. The System can also be used by HCPs in an office or clinic. The System can also operate in a LAN environment. In this case, a central database is preferably installed on the LAN server, wherein each computer in the network can access and review this central database.

For users who want to communicate and share data remotely, the System has a Host server on the internet that acts as a processing, storage, and routing center for the files of users who choose to use these communication and data access capabilities. A user may choose to synchronize with the Host via internet access from a PC or other capable desktop, portable or handheld appliance (hereinafter simply referred to as PC). The communication can occur between people with diabetes and their HCPs or among HCPs.

Users (Home and HCP) can share data by synchronizing. Synchronization allows each user to update and match the data they track. The process includes sending data from a PC to a Host server. The Host server acts as the central database for the System. When a user synchronizes the client System with the Host server, diabetes data, notes, comments, new entries, and edits entered into the client System are mirrored on the Host server and client PC. Each party sharing data preferably synchronizes regularly with the Host server to stay current.

The System software can be installed by downloading the program from the Internet, or installing the program from a CD or other digital storage device. Figure 2 illustrates a screen shot of an application installation screen.

Figure 3 illustrates an installation destination screen. A user may install the System on a selected device. If installing the program on a local area network (LAN), synchronizing with a network administrator is preferred. At a select program manager group screen, such as that illustrated at Figure 4, a suggested program manager group 10 or another selected from a scroll-down list 12, may be selected. A start installation screen such as that illustrated at Figure 5 permits the software to be installed. If the installation is successful in fully installing the System, a final setup screen then displays, such as that illustrated at Figure 6. A System icon will now appear on the PC desktop, and System program and user guides are added to the PC's Programs list.

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Figure 7 illustrates location of Start Button 14 (PC Desktop) and Programs List 16 within Windows™. The system program files and guides menu options 18 can be accessed this way.

A User Profile can now be set up, as described in more detail below. Setting up a User Profile allows a diabetic to take full advantage of advantageous features of the System. The process begins with an initial user set up screen, such as that illustrated at Figure 8, if this is the first time a user is running the program. The user may select Home User 20 if he or she is a person with diabetes, or Health Care Professional 22 if he or she is a HCP. Personal identification information including a password is then input in a user identification section 24. After filling in the **Initial User Setup** information, this screen is not utilized again, and instead a home page, such as that illustrated at Figure 9, will display when the System program is run.

HOME PAGE

From the Home page, a diabetic or HCP can access multiple advantageous features of the System, either by clicking a small icon 4 or a large button 6, or by selecting a tab on the main menu bar 2.

A select user field 24 is illustrated in Figure 9. The name of the active user is displayed in the Select User field 24. The select user field 24 includes a drop-down list of multiple persons each having a User Profile in the System. Referring to Figure 10, in a HCP version, there is a Select HCP field 26 and a Select Patient field 28.

The small icons 4 provide access to program functions. From left to right in Figure 9, preferred small icons 4 include: a go to home page icon, a read data from a meter icon, a manually enter data icon, a view reports icon, a synchronize with host icon, and edit current user's profile or edit current patient's profile icon, and a show context help icon.

The Large Buttons 6 provide quick access to main program functions. From left to right in Figure 9, preferred large icons 6 include: a User List or patient list icon a Read Device icon, a Manual Entry icon, a View Reports icon, and a User Profile or Patient Profile icon.

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When the client is synchronized with the Host computer via the Internet, messages are preferably sent from the Host that may include information about data sharing, healthcare management, and updates to the System.

A Resource Links section provides options to take a user directly to resources available as the System website. These may include Ask the Diabetes Educator, Diabetes News, Check for Software Updates and Contact Tech Support. Contact tech support is preferably an email support option that, upon clicking, will result in a pop-up window either informing the user that a "local mail client" is not available or will supply the user with the e-mail address for Customer Service/Tech Support.

A Turning On Password Protection option is for users desiring to protect their data (and their privacy) by requiring the entry of a User ID and Password each time they start the System or each time they select a different user in the Select User field (Home version) or the Select HCP field (HCP version). To turn on password protection, on the Home page, a user may select System Settings from the File drop-down box (see Figure 11). If System Settings is grayed out, then a user does not have the User Rights to turn on password protection. If a user does have User Rights, then the System Settings screen displays (see Figure 12). When the box to Require User Logon is checked, then password protection is turned on and the first screen will be a Logon to System screen (see Figure 13). This screen will also display when changing users in the Select User field (Home version) or in the Select HCP field (HCP version). The home page will appear upon typing in or otherwise inserting a User ID and Password.

For a home user to take advantage of many features of the program, a user should set up a Home User Profile. This allows the user and HCP, if selected, to enter data and create reports to monitor trends in the health or care of the diabetic user.

Figure 14 illustrates a home page having a UserProfile tab on the main menu bar 2 selected and expanded. The User Profile button of the large icon bar 6 may also be clicked. Either way, User Profile may be now selected from the drop-down box 30 or other menu expansion architecture.

A Profile For screen is illustrated in Figure 15. In the screen display of Figure 15, the User Information tab 32 is selected. A user may provide whatever information that he or she wishes to, except that fields marked with an asterisk (*) or double-asterisk (**) will be required fields. Information can be added by selecting items from drop-down

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boxes or by typing in words and numbers. A Health Profile tab is illustrated at Figure 16. When a Condition column arrow is clicked, a drop-down box is displayed such as that illustrated at Figure 17. The user can select any of the conditions listed that apply to him or her, or type in a new condition that will be added to the list.

A screen shot such as that illustrated at Figure 18 will appear when the arrow on a Date Diagnosed column is clicked. The screen shot of Figure 18 is preferably a basic calendar. The arrows may be used to select the date this condition was diagnosed.

Figure 19 illustrates a Data Entry Preferences screen that can be used to save time in manually entering data by setting up Data Entry Preferences. For example, if a user regularly takes a certain type of insulin at a particular dose, the user can enter it here. The same is true for regular exercise routines and other medications the user may take. Information entered here will then be automatically listed when manual entries are made. To enter your preferences, the user selects a Data Entry Preferences tab and fills in Exercise Preferences (type, duration, intensity); Insulin Preferences (insulin name, dosage, type); and/or Medication Preferences (medication name, dosage, number of pills). Each column heading preferably has a drop-down box. A user can select one of the listed entries or type in a new entry that will be added to the list.

A user may select a **Glucose Targets** tab to enter target glucose ranges. If these are not known, the HCP can be contacted to help manage glucose levels. The target ranges that are set are displayed on a graph on the screen illustrated at Figure 20, as well as in many other reports that can be generated by the System. The ranges may be displayed in signal colors for easy viewing.

A graph can be viewed preferably in at least three modes. A desired mode may be selected from a Mode drop-down box 40, such as that illustrated at Figure 21. Standard, Pre/Post Meal and All Time Periods modes may be selected. In Standard mode, glucose target ranges set apply to all glucose readings, regardless of when the glucose reading is taken. For example, target ranges will be the same for pre-meal readings as for post-meal readings or bedtime readings. In Pre/Post Meal mode, glucose target ranges set for pre-meal readings can be different from the target ranges for post-meal readings. In All Time Periods mode, glucose target ranges set can be different for each time period listed, for example, Pre-Bkfst, Post-Bkfst, Pre-Lunch, Post-

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Lunch, Pre-Dinner, Post-Dinner, Bed, and Sleep. Figure 22 illustrates Ore/Post Meal Mode with Hypo/Hyper checked (left) and All Time Periods Mode (right).

Glucose targets may be set in all three modes to take advantage of different reports the System can create. A table of the reports that use glucose targets and the modes they use is provided further below. The glucose targets mode selected here will become the default and will display in the reports that use glucose targets. To change the mode, a different Mode can be selected by returning to the Glucose Targets screen illustrated at Figure 21.

Clicking on up/down arrows for High and Low sets glucose targets. To automatically restore Glucose Target Ranges to the ranges shown in Figure 20 (the defaults), a Restore Default Glucose Target Ranges button 42 can be clicked. Clicking Restore Default Glucose Target Ranges 42 preferably automatically also restores the mode to Standard Mode and unchecks a Use Hypo/Hyper Values box 44 illustrated at Figure 23. Checking the Use Hypo/Hyper Values box 44 activates Very Low and Very High data fields 46 and 48. Clicking on up/down arrows for Very Low 46 and Very High 48 changes these values.

To customize Time Periods to a normal daily schedule, a user can click on up/down arrows next to a time period (for example, Pre-Bkfst, Post-Bkfst, Sleep, etc.) to change the time. To automatically restore all Time Periods to the times shown here as defaults, a user can click Restore Default Time Periods in the box illustrated at Figure 24. The System will generally not allow a user to enter a normal daily schedule that exceeds 24 hours. If a user tries, he or she will receive an error message illustrated at Figure 25, and the time periods will be readjusted to equal 24 hours. As user can select a Glucose Unit of Measure from the drop-down box illustrated at Figure 26. The default is mg/dL; and another choice is mmol/L.

An option tab may be selected, and an options screen will appear such as that illustrated at Figure 27. Under Program Options, boxes may be checked for the options a user wishes to use. A user may also select Data Entry and Report Options, and can select the options that apply to his or her diabetes management. This simplifies use, entry, and viewing of data/events.

By selecting Rights 52 at the lower left of the Options screen illustrated at Figure 27, a User Rights screen displays as illustrated at Figure 28. A user may choose to

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control access for additional profiles that he or she may create. By checking the Edit Data box 54 allows the user to edit data/events and delete user accounts. For example, many households might have only one person using the System, but some households may have more than one.

HOME USER: MANAGING A USER PROFILE

A user profile may be changed or updated. A user selects the tab he or she wants (e.g., User Information, Health Profile, etc.) and changes or adds information.

A User Profile may also be added by selecting Add User from a File drop-down box on the Home Page. Figure 29 illustrates a File Drop-Down Box for Adding a User.

A user may also remove a User Profile at a User List screen such as that illustrated at Figure 30. If a user tries to delete his or her own user profile, the System will display an error message such as that illustrated at Figure 31.

User rights may also be assigned. From the UserProfile drop-down box on the main menu bar 2 of the Home Page, User List may be selected as illustrated at Figure 32. The User List screen displays (see Figure 30). User rights may be changed by first highlighting the name of the user whose rights are to be changed. The User Rights screen will appear such as illustrated at Figure 33, and rights can be selected or de-selected by checking or unchecking appropriate boxes. The Edit Data box 54 allows the user to edit data/events and/or delete user accounts.

A HCP Profile may also be added. A user can create as many HCP profiles as is desired. This is often a good way to store names, addresses, and other information about doctors, clinics, etc. The HCPs added here will not have access to the user's System data unless the user invites them to share your data (described below). Figure 34 illustrates a drop down box for adding a HCP. The Profile for screen displays as illustrated at Figure 35. A user may select a description of the HCP from the HCP Type drop-down box illustrated at Figure 36. If there is no selection for the one desired, then a user may type in a description.

A HCP Profile may be edited. From the UserProfile drop-down box illustrated at Figure 37, which is accessible from the main menu bar 2 of the Home Page, HCP List is selected and the HCP list screen appears (see Figure 38). The name of the HCP User is then highlighted. By selecting Edit HCP Profile from the File menu on the HCP List

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screen, or clicking a representative icon, the Profile for screen for the HCP user displays, and edits can be made on the screen.

A HCP Profile can be removed. From the UserProfile drop-down box on the main menu bar (see Figure 37), a user can choose HCP List. By highlighting the name of the HCP User on the HCP List screen, and selecting Remove HCP from the File menu on the HCP List screen, the HCP can be removed. The System will ask the user to confirm.

HCP USER: SETTING UP A USER PROFILE

With a User ID and password, a user can use the System. But to take greater advantage of the System, a user may also set up a HCP Profile. This will allow a HCP user to view (and sometimes edit) data and reports to monitor trends in the patient's health or care. Figure 39 illustrates a HCP Home Page. On the Home page, a user may select HCP Profile from the UserProfile drop-down box 64 on the main menu bar 62. The HCP Profile for screen displays with the User Information tab selected as illustrated at Figure 41. Information is filled in here. Information may be added by selecting items from drop-down boxes or by keying in words and numbers. If a desired HCP type is not found in the HCP Type drop-down box, a description can be entered at the keyboard.

GLUCOSE TARGETS

The Glucose Targets tab 66 can be selected from the HCP profile for screen illustrated at Figure 42 to customize glucose target ranges. The glucose targets set here will apply to the reports viewed for the persons with diabetes the HCP user manages via the System. A HCP user may view the graph in three modes as illustrated in Figure 43 by selecting the desired mode from the Mode drop-down box. The standard, Pre/Post Meal and All Time Periods modes were described above and not repeated here. In addition, setting target glucose ranges were described above and the descriptions of Figures 44, 45 and 46 are similar to those described above and thus not repeated here. Figures 47-48 illustrate an Options tab and User Rights screen also similar to described above for diabetic users and not repeated here. In addition, managing a HCP profile is similar to managing a diabetic user profile, and that description is not repeated here with reference to Figures 49-54.

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A user may set an Authorization Level (, e.g., None, Read Only, Full, Owner) for the HCP by checking the desired level as illustrated at Figure 55. Adding, Editing and Removing HCP profiles are similar to those described above and not repeated here with reference to Figures 55-57. However, if a HCP is to be removed, and if local patients are assigned to this HCP, the System then will prompt the user to reassign the patients to another HCP on the local computer as illustrated at Figure 58. User rights may be assigned similar to above at a User Rights screen as illustrated at Figure 59.

DATA ENTRY

There are three ways to enter events (data) into the System in accordance with a preferred embodiment: upload from a device, manually enter data (e.g., from a keyboard, and import an existing file or database. The System can upload data from supported glucose monitoring devices (meters), such as FreeStyle Meter, Precision Xtra Meter, FreeStyle Flash Meter, FreeStyle Tracker System, and glucose meters of companies other than Abbott Diabetes Care™, as well as insulin pumps. At least the following data (event types) may be automatically uploaded to the System when uploading from a device: glucose readings, state of health, insulin doses, lab results, carbohydrates, medical exams, exercise, ketones (blood), medications and notes. Data previously uploaded from a device will not be overwritten when uploading again from that same device. Only the new data will be uploaded to your file. Meter functions, displays, and printed output assume a single glucose calibration type, either plasma or whole blood. When uploading glucose data from a device, the System does not differentiate between devices that are whole-blood or plasma calibrated. The System merely uploads the data with no calculations made. Because there are slight differences between the two calibrations, a user should not mix data from devices that use different calibration references. Uploading data into a user's account occurs if the device contains only that person's data. The System is preferably designed not to upload a specific portion of data from a device if data is intermixed with data from another person.

CONNECTING A DEVICE TO A COMPUTER

Before uploading, the device is connected to an available COM port on a PC or other computing appliance using an approved data cable for that device. A exemplary

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cable connection is illustrated at Figure 60. To set up the device to the computing device, on the Home page, the user whose data is being uploaded from the device is selected, from the select user menu illustrated at the Home page of Figure 61. Next, Data Entry 72 is selected on the main menu bar 2, as illustrated at Figure 62; and then Device Setup 74 is chosen from the drop-down list.

A Device Setup screen appears as illustrated at Figure 63.. Under Select Options 76, the device is selected from the Meter Type drop-down list 78. The communications port (COM1, COM2, etc.) is selected from the Available Ports drop-down list 80. The System stores Meter Type and Available Ports settings during Device Setup. The user will not have to select them the next time he or she uploads data from this meter as long as he or she connects the device to the same communications port. By clicking Test at the bottom of the Device Setup screen illustrated at Figure 63, the device details are displayed in the Details box 84, and the System is ready to upload data from the meter. An illustration of the meter and details are preferably displayed as illustrated at Figure 64.

UPLOADING DATA FROM A DEVICE

Once the device is connected to the computer and the device is set up, data may be uploaded to the System. On the home page the user whose data is being uploaded from the device is selected. As illustrated at Figure 65, from DataEntry on the main menu bar; Read Device 86 is selected from the drop-down list. When a device has been detected but cannot be identified as belonging to a specific user, the System will prompt the user to assign the device to an existing user or to add a new user as illustrated at Figure 66. The data from the device is then automatically uploaded to the PC. A progress bar indicates when the upload is complete. A summary of the upload then displays in a pop-up window as illustrated at Figure 67.

A device upload may be undone. That is, the data from the most recent device upload may be undone as long as no data has been manually since the device upload and another user has not been selected. DataEntry is selected on the main menu bar of the Home page; then Undo Last Upload 88 is chosen from the drop-down menu illustrated at Figure 68. The System will then automatically undo the last upload.

Uploading from a PDA-based system such as the FreeStyle Tracker System may be handled somewhat differently than uploads from other devices as follows. The PDA-

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based system is connected to the PC. DataEntry is selected from the main menu bar, and Read Tracker 90 or other PDA-based product is selected from the drop-down list as illustrated at Figure 69. If the device is detected, the System prompts to HotSync 92 as illustrated at Figure 70. As HotSync takes place, the HotSync Progress screen displays as illustrated at Figure 71.

When HotSync completes, options may be selected for upload from the FreeStyle Tracker of other PDA-based device such as Event Data, Glucose Targets, Time Periods and Preferences, as illustrated at Figure 70. Event Data will be generally automatically uploaded from the FreeStyle Tracker System. Glucose Targets may be selected to upload and overwrite the Glucose Targets data with data from the FreeStyle Tracker System. Time Periods may be selected to reset Time Periods data according to data from the FreeStyle Tracker System. Preferences may be selected to overwrite Preference Settings with settings from the FreeStyle Tracker System. Set as Default may be selected if a user wants to save these options as the defaults. If prompted to assign the device to a current user or to a new user, as illustrated at Figure 72, then OK should be clicked after making a choice, keeping in mind that more than one device may be associated with a same user.

As data from the FreeStyle Tracker System is uploaded, the System displays the Profile Updated message illustrated at Figure 73 if Preferences were checked on the Read Tracker screen of Figure 70. When the upload is done, an Upload Summary screen displays (see Figure 74). It shows a list of the type and number of events uploaded.

MANUAL DATA ENTRY

The System allows data to be added, edited, deleted, and recovered manually, e.g., from a keyboard. When manually recorded events are deleted, they are omitted from views and reports but are preferably not removed from your database. A complete list of a user's events (whether entered manually, uploaded, or imported) may be viewed by clicking on Reports 94 and selecting Diary List 96 as illustrated at Figure 75.

Manually recordable events include the following categories: glucose readings, glucose control readings, insulin doses, meals (carbohydrates in grams, e.g.), exercise sessions, state of health/health conditions, medication doses, medical exams, lab results, ketone readings, or ketone control readings, or combinations thereof.

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Figure 76 illustrates a glucose reading data entry screen. If the date and time of the glucose reading are different from the current date and time, the Date, Time, and Time Period fields 98 at the top of the Glucose Reading screen should be adjusted using drop-down boxes and up/down arrows. The value of the manual glucose reading should be entered in the Glucose Value field 100. In the Sample Site field 102, the site may be selected from which the reading was taken (finger, forearm, etc.). In the Hours Since Last Meal field 104, the time of the last meal should be entered. A calibration code may be entered from the glucose monitor into the Calibration Code field 106. The control reading box 108 should be checked if this is a Control Solution reading from your glucose monitor. To add another event, the icon at the top of the Data Entry screen should be selected that applies, e.g., Insulin, Meal, Exercise, Health, Meds, Exam, Lab, Ketones, or Note.

RECORDING AN INSULIN DOSE

The insulin data screen illustrated at Figure 77 will display when the insulin icon 110 is clicked on the Data Entry screen. An icon may be clicked at the Home page to get to the data entry screen as already described. The Date, Time, and Time Period fields can be set using the up/down arrows for the time of the injection that is being recorded. The field 112 directly under the Insulin Name header is for selecting the brand of insulin from the drop-down box. If the name of the insulin is not listed, it can be typed in. Dosage (Units) and injection type also are entered. Injection types generally include bolus, injection, meal, correction, combination, dual wave, and square wave.

RECORDING A MEAL

A meal may be recorded by selecting the Meal icon from the Data Entry screen to reveal a Meal data entry screen as illustrated at Figure 78. Date, Time, and Meal fields may be adjusted for the meal being entered. Drop-down boxes may be used to describe the meal. The drop-down box displays a very extensive list of foods to choose from. If what was eaten is not listed, it may be typed in. Serving size and carbohydrates per serving should be entered with it. The number of servings should be selected, after which the grams of carbohydrates per serving and total carbs are automatically displayed.

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One meal may include more than one item (beverage, entree, fruit, etc.). To select several items to describe one meal, a food is selected in the Food Item list as well as the number of servings eaten. The Carbs and Total Carbs automatically display. The cursor is placed in the Total Carbs field to the right of the carbs displayed there. Then, another item is selected and so on. As items are added, the total carbs for the meal are shown as illustrated at Figure 79. Other activities may be recorded including Exercise Activity (Figure 80), State of Health (Figure 81), a Medication event (Figure 82), a Medical Exam (Figure 83), a Lab Test Result (Figure 84), a Ketone Reading (Figures 85 and 86) and notes (Figure 87).

To make manual data entry faster and easier, a user can modify several of the drop-down lists by adding new entries or by hiding entries he or she does not use. The following lists may be modified.

- | | |
|------------------|---------------|
| • Exercise Types | • Test Types |
| • Food Items | • Medications |
| • Insulin Names | • Exam Types |

A list may be customized by selecting Customize Data Entry Lists 114 from the DataEntry drop-down box as illustrated at Figure 88. The desired list is selected from the Select List to Customize drop-down list 116 illustrated at Figure 89. Figures 90-95 illustrate different lists from the above table that may be customized.

IMPORTING A DATABASE

Some databases can be imported directly into the System. Databases from certain programs may be automatically detected by the System as long as the software for the programs that created them is installed on the user's PC. These programs are referred to as supported databases. To import a database, DataEntry 118 is selected on the main menu bar 2 of the Home page; and then Import 120 is selected from the drop-down box. From the Import drop-down box 122, the name of the device to upload the database from is selected as illustrated at Figure 96. If the database is detected, the System will simply ask the user to confirm the import operation. If the database is not detected, the file browser opens as illustrated at Figure 97. The user then browses to the directory where the file is located, selects the file type in the Files of Type window 124, and if the file is located in that directory, it will be displayed and can be opened. Figure 98 illustrates an Import Drop-Down Box for Activating FreeStyle CoPilot I Data,

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and Figure 99 illustrates an Import Drop-Down List for Importing Events From a File. Figure 100 illustrates a File Browser Window for selecting a file type for automatic import according to file type.

EXPORTING DATA

Exporting data is similar to archiving data (see below), except that exported data is not removed from the System's database. To export data, a user selects Reports 126 on the main menu bar; then chooses Diary List 128 from the drop-down box, as illustrated at Figure 101. The Diary List displays, which is a log of the events that have been entered. The date may be adjusted to include the data desired to be exported, as illustrated at Figure 102. A user selects Export from the File menu on the Home page. When file browser opens, a user can browse to the directory where the file is to be saved as illustrated at Figure 103.

REPORTS

With the FreeStyle CoPilot System, data entered manually or uploaded from a device can be displayed on the screen in a variety of ways. Statistical and other calculations are automatically performed on the data, and the results are put into tables and graphs. A report is one or a set of these tables and/or graphs designed to present information helpful for health management. A reports window is illustrated at Figure 104 as a Glucose Modal Day Report (Default Report).

A report can be customized to a user's preferences. Many variables can be adjusted in real time as the report is studied. Data preferably cannot be changed in reports except the Diary List. Corrections or additions can be made by accessing the Data Entry screen for the event. The changes display immediately on any affected report.

Once opened, a report remains open until it is closed by the user. Any number of reports can be open at the same time; while preferably only one is visible. Each open report shows as a tab at the top of the screen. Open reports apply an active date range, data filter options, and display features. In a preferred embodiment, changing these settings in one report changes them for one or more other open reports.

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OPENING A REPORT

To call up a default report from the Home page, the View Reports large button is clicked. The user may select a default report and date range interval. To open another report, a name may be selected from a drop-down box under Reports on the main menu bar as illustrated at Figure 105. The first report remains open but hidden, except for its tab (see Figure 106). The new report displays with the same date range, active data filters, and display features. To redisplay a report, the user clicks its tab. To close an active report, the user clicks the Close Report icon on the Reports toolbar.

NAVIGATING A REPORT

The reports screens offer numerous tools for navigation, including tools for setting the date range, interactive data elements, and signal colors that help users interpret reports at a glance. Displaying the legend will help a user understand the report.

The data range may be adjusted to include any date and any date interval (see Figure 107). To view entries over a date range ending on the current date (up to and including today's data), a user may select an interval of interest (for example, Last 2 Weeks, Current Month, etc.) from an Interval drop-down box on the Reports toolbar.

To move back in time in increments equal to the currently displayed date interval, the user clicks the Previous arrow (For example, if a 2-week date range is currently displayed, the user clicks the Previous arrow to display additional 2-week intervals). To move forward in time, the user may click the Next arrow. To select a specific date range (with beginning and ending dates specified), the user clicks or otherwise chooses the respective dates from the drop-down calendars.

DATA ELEMENTS

The reports preferably have interactive data elements that link to related or more complete information. These elements can include data points on a graph, regions on a chart, and/or cells in a table. A pointer becomes the hand icon when it is hovering over an interactive data element. For example, by hovering the pointer over a triangle (glucose reading data element), a user can display the value, date, and time of the reading in a pop-up bubble. To go to the Glucose Reading event in the Diary List, the

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user can double-click the triangle. For example, carbohydrate events are represented by peach-colored circles; the size of each circle is proportional to the carbohydrate value. Insulin data is represented by dark green and dark red bars. Glucose readings are represented by circles (manual entries) or triangles (uploaded entries), which can be linked by a solid or dotted line.

Glucose readings are separated into target ranges, which are represented on graphs and tables either in signal colors or in distinctive patterns for black-and-white printing. A user can choose to display data in three ranges (High, Within, and Low) or five ranges (Very High, High, Within, Low, and Very Low). These choices can be changed at any time on the Miscellaneous tab of the Report Configuration form (see Figure 111) by checking or unchecking the Show Hypo/Hyper box. Each target range is associated with a distinctive signal color: Very High (turquoise), High (purple), Within (green), Low (peachy-gold), and Very Low (pink). If a user selects to display glucose data in three ranges (the Show Hypo/Hyper box is not checked), Very High readings display as High readings (purple) and Very Low readings display as Low readings (peachy-gold).

Reports may be printed (using a Print drop down box such as that illustrated at Figure 108) and sent using standardized printing and email or fax architectures. A user may print one copy of each of his or her favorite reports on a default printer by clicking Print Favorite Reports. To save the open report in the Adobe Acrobat (PDF) file format, a user can click Save as PDF file. A user can select this option if the E-Mail Report to option (below) does not automatically create a *.pdf file. A user can select this option if there is a printing problem and then the report may be printed from Adobe Acrobat. To email a report as an attachment, a user can click E-Mail Report to, and the report will be attached to the e-mail message as a *.pdf file. (The user does not have to Save as PDF file before selecting E-Mail Report to). The E-Mail Report option is designed to automatically access a user's e-mail account and open a new e-mail message screen. The report is automatically attached to the message as a *.pdf file. If the e-mail account is not detected automatically, the user may e-mail the report manually.

Reports can be personalized to a user's preferences by making choices for Report Options on the Profile for screen and by activating data filters and display features on the Report Configuration screen. Figure 109 illustrates a User Profile Screen with Options Tab Active. Report options include default report type, default

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report data range, include statistics summary with each report printout, Print Favorite Reports After Device Upload, and Favorite Reports.

Data filters are tools for selecting the types of data a user wants to include in a report. A user selects the data filters desired by clicking a Report Configuration icon on the Reports toolbar and choosing items from the Event Types, Time Periods, and Week Days sections on the Data Filter tab (see Figure 110). Data filters and display features (see below) preferably apply to all reports except the HCP Group Analysis Report. Changing data filter or display settings in a report changes them for other open reports. Not all filters are configurable in all reports. Several data filters can be applied together. For example, a user could uncheck Exercise events in the Event Types filter and check only Tuesday and Friday in the Week Days filter.

Some display features are configured on the Miscellaneous tab of the Report Configuration screen, as illustrated at Figure 111. These include options to display time periods, show hypo/hyper, show glucose targets, show hidden data, show text on graphs in daily combination report, show legend and color. Figure 112 illustrates a black-and-white display having distinctive patterns (screen detail).

GLUCOSE TARGET MODES

The following is a table of reports that use glucose targets and the modes they use.

Reports: Glucose Target Modes Used

<u>Report</u>	<u>Home Version Glucose Target Mode</u>	<u>HCP Version Glucose Target Mode</u>
Diary List	User's choice	HCP's choice
Glucose Modal Day	User's choice	HCP's choice
Glucose Line	Standard Mode	Standard Mode
Glucose Average	Standard Mode	Standard Mode
Glucose Histogram	Standard Mode	Standard Mode
Glucose Pie	User's choice	HCP's choice
Logbook	User's choice	HCP's choice
Lab & Exam Record	Not applicable	Not applicable
Statistics	User's choice	HCP's choice

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<u>Report</u>	<u>Home Version Glucose Target Mode</u>	<u>HCP Version Glucose Target Mode</u>
Daily Combination View	User's choice	HCP's choice
Weekly Pump View	Standard Mode	Standard Mode
HCP Group Analysis	Not applicable	Standard Mode

DEFINITION OF A DAY

Depending on the report, a day (24 hours) is calculated from midnight to midnight or pre-breakfast to pre-breakfast. The various reports define a day as follows:

REPORTS: DEFINITION OF A DAY

<u>Report</u>	<u>Definition of a Day</u>
Diary List	Midnight to Midnight
Glucose Modal Day	Pre-breakfast to Pre-breakfast
Glucose Line	Midnight to Midnight
Glucose Average	Pre-breakfast to Pre-breakfast
Glucose Histogram	Midnight to Midnight
Glucose Pie - Total Pie	Pre-breakfast to Pre-breakfast
Logbook	Pre-breakfast to Pre-breakfast
Lab & Exam Record	Midnight to Midnight
Statistics	Pre-breakfast to Pre-breakfast
Daily Combination View	Midnight to Midnight
Weekly Pump View	Midnight to Midnight
HCP Group Analysis	Midnight to Midnight

DESCRIPTIONS OF REPORTS

The Diary List is a table of data entries made over the specified date range. Each row corresponds to one event. Figure 113 illustrates a Diary List. A day (24 hours) is defined as midnight to midnight. The glucose target mode is user's choice. Columns are for data categories. The Value column displays the value in units appropriate to the event type. For Glucose Reading events, the Value cell is shaded with the signal color for the glucose target range. To call up the original Data Entry screen for a specific event, the user can double-click any cell in the row. Data that was entered manually can be edited. Uploads from devices cannot be edited.

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To Hide an event, a user can click any cell in the row, then right-click, and then Click Hide Data on the pop-up menu (see Figure 114). To Un-Hide the event, the user can click on the Reports toolbar. On the Miscellaneous tab screen, the user can check the box to Show Hidden Data. The Diary List now displays with a Hidden column (far left). Hidden entries display in this column. The user can Right-click the hidden entry and select Un-Hide Data. The event is no longer hidden.

A user can customize columns in the Diary List by changing the order of events in a column, adding and removing columns, and resizing columns. To change the order of the events in the Diary List, the user can click any of the following column heads:

Hidden	Hidden entries display at the top. Click to display hidden entries at the bottom.
Type	Events are grouped by Event Type. Click to reverse the order.
Date	Events display in ascending order (earliest date at the top) or descending order (latest date at the top). Click to reverse the order.
Time	The events display in chronological order. Click to group entries by time of day.
Time Period	Time periods are arranged in chronological order. Click to list the time periods in alphabetical order.
Value	Click to change the order.
Description	Events are displayed in ascending alphabetical order. Click to reverse the order.
Other Info	Click to reverse the order.
Comment	Events with Comments display in ascending alphabetical order. Events with no comments display first. Click to reverse the order.

To remove a column from the report, the user can drag-and-drop the column head cell off the table. To add a column to the report, right-click anywhere on the table to call up the pop-up window (see Figure 114). Select Customize Columns. The

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Customization list displays (see Figure 115). From the list, select the column head you want to add. Then drag-and-drop it to the preferred position in the column-head row. Two green arrows display to help you position the column. To move columns left or right in the table, the user can drag-and-drop the column-head cell to the preferred position in the column head row. To adjust the width of any column, the user can use the sizing tool that becomes active when hovering the pointer over the right margin of the column-head cell.

GLUCOSE MODAL DAY REPORT

The Glucose Modal Day Report shows the daily pattern of glucose levels over the specified date range. A dotted line linking the readings for a specific date can be displayed or hidden. Figure 116 illustrates a Glucose Modal Day Report (Dotted Line Linking Readings for 4/3/2004). The horizontal axis is a 24-hour timeline. All readings for all dates display on the same timeline. The vertical axis plots the glucose level. A day (24 hours) is defined as pre-breakfast to pre-breakfast. The glucose target mode is user's choice. Each data element represents one glucose reading. For the date, time, and value of the reading, the pointer can be hovered over the triangle. HI/LO indicates a reading outside the working range of the meter. A list of all days in the date range displays to the right of the graph. To link all the readings for a single day with a dotted line, the user can click the date of interest in the list of all days in the date range (Figure 116). All the data elements for that date change color and enlarge, and a dotted line is drawn linking them. By clicking on it, a triangle data element in the line can be cancelled.

To zoom in on (magnify) an area of the graph, a user can place the mouse in the upper left of the graph, press and hold the left mouse button, and drag to the lower right corner of the graph. The user can repeat this action to further magnify the area of interest. To return the graph to its original state, the user can place the mouse in the lower right of the graph, press and hold the left mouse button, and drag to the upper left corner. To go to the Glucose Reading entry in the Diary List, the user can double-click the data element.

GLUCOSE LINE REPORT

The Glucose Line Report is useful for seeing trends in glucose levels. It plots each glucose reading over the specified date range. Figure 117 illustrates a Glucose

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Line Report (Show Line Is Activated). The horizontal axis is a timeline of the entire date range. The vertical axis plots the glucose level. A day (24 hours) is defined as midnight to midnight. The glucose target mode is Standard. Each data element represents one reading; a solid line connecting them can be displayed or hidden. To hide the line, point to any data element, then right-click. A user can click Show/Hide Line on the pop-up menu (see Figure 118). For the date, time, and value of the glucose reading, the pointer can be hovered over the data element. To zoom in on (magnify) an area of the graph, the user can place the mouse in the upper left of the graph, press and hold the left mouse button, and drag to the lower right corner of the graph. The user can repeat this action to further magnify the area of interest. To return the graph to its original state, the user can place the mouse in the lower right of the graph, press and hold the left mouse button, and drag to the upper left corner. To go to the event data in the Diary List, the user can double-click the data element.

GLUCOSE AVERAGE REPORT

The Glucose Average Report may help identify times of the day that may need more testing or improved control. The report separates glucose readings over the specified date range into pre-meal (cream-colored bars) and post-meal (blue bars) groupings and averages the values for each group. For convenience, there are two graphs. One shows pre-meal and post-meal glucose averages over the date range by meal. The other shows overall pre-meal and post-meal averages by day over the date range. Figures 119-120 illustrate Glucose Average Reports by meal and by day, respectively. The horizontal axis is a timeline showing the time periods (pre-meal and post-meal) and the average for all meals. The vertical axis plots the glucose level. Each bar shows the average value of all glucose readings over the date range for the specific time period (for example, the average value of all pre-breakfast readings). A day (24 hours) is defined as pre-breakfast to pre-breakfast. A user can Double-click any bar to call up the Diary List entries for these events.

GLUCOSE HISTOGRAM REPORT

The Glucose Histogram Report separates glucose readings over the specified date range into the default target ranges and displays the data as a histogram (bar

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chart) with its bar height proportional to the number of readings in each glucose target range. Figure 121 illustrates a Glucose Histogram Report. The horizontal axis shows the default glucose target ranges (not the user-defined glucose target ranges). The vertical axis plots the glucose level. A day (24 hours) is defined as midnight to midnight. The color of the bar corresponds to the signal color for the glucose target range. The height of the bar is proportional to the number of readings in that range; that is, the bar for a range in which there are 20 readings is twice as high as the bar for a range with 10 readings. The percentage of readings in the range is shown at the top of the bar. The user can double-click the bar to call up the Diary List entries that make up that bar.

GLUCOSE PIE CHART

The Glucose Pie Chart separates glucose readings over the date range into the default glucose target ranges and averages the values within each range. These averages are displayed in a series of pie charts. Each segment (wedge) displays in the signal color of its glucose target range. Figure 122 illustrates a Glucose Pie Chart Report: Total Readings Pie Chart, and Figure 123 illustrates a Glucose Pie Chart Report: Ten Summary Pie Charts. A maximum of 10 individual pie charts (2 rows of 5) and 1 total pie chart summarizing the glucose readings for all configured time periods over the date range are displayed. A day (24 hours) is defined as pre-breakfast to pre-breakfast on Total Readings pie chart (see Figure 122). The glucose target mode is user's choice. A user can double-click a wedge on any of the pie charts to call up the Diary List entries that make up that wedge.

LOGBOOK REPORT

The Logbook Report is a table of glucose, carbohydrate, and insulin values associated with each time period over the specified date range. Figure 124 illustrates a Logbook Report. Insulin, carbohydrate, and pre-meal, post-meal, bedtime, and sleep glucose reading values are displayed in columns under each time period (Breakfast, Lunch, Dinner, Bed and Sleep) for each day over the date range. A day (24 hours) is defined as pre-breakfast to pre-breakfast. The glucose target mode is user's choice. To call up the entry in the Diary List, a user can double-click any cell in the row.

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LAB AND EXAM RECORD REPORT

The Lab and Exam Record Report is a table of data from all Medical Exam and Lab Test Result data entry screens over the specified date range. Figures 125-127 illustrate Lab & Exam Record Reports: Lab Record, Exam Record, and A1C History, respectively. The screen shows a table of lab test data on the top (Figure 125) and the exam data below (Figure 126). Each event is shown in one row. Below the table is a graph showing A1C test results for the current year and the previous year (Figure 127). A day (24 hours) is defined as midnight to midnight. A user can double-click any cell in a row to go to the Diary List entry for the event. The user can double-click any bar on the graph to go to the Diary List entry for the A1C test event.

STATISTICS REPORT

The Statistics Report provides an overview of glucose, carbohydrate, and insulin data (including insulin pump data) over the date range and displays it in a series of tables. A user can attach the Statistics Report to any other report by default. Figure 128 illustrates a Statistics Report: Glucose Statistics. A day (24 hours) is defined as pre-breakfast to pre-breakfast. The glucose target mode is user's choice. A user can double-click any cell to see the entries from the Diary List that are included in the data set for a particular statistical calculation.

GLUCOSE STATISTICS

The Glucose Statistics table (see Figure 128) shows data regarding the number of readings per day, the values of the highest and lowest readings in each time period, and the results of some automatic calculations (averages and standard deviation) within and across time periods.

# Readings	By Time Period: Reports the number of readings recorded during the Time Period specified for each day of the selected Date Range. Total/Summary: Reports the number of readings recorded during the selected Date Range.
# Days w/ Readings	By Time Period: Reports the number of days within the selected Date Range where one or more readings are recorded during the

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specified Time Period.

Total/Summary: Reports the number of days within the selected Date Range where one or more readings are recorded.

Avg Readings /
Day

By Time Period: Reports the number of readings recorded during the Time Period specified for each day of the selected Date Range divided by the number of days in the selected Date Range regardless of whether a glucose reading was recorded or not.

Total/Summary: Reports the number of readings recorded during the selected Date Range divided by the number of days in the selected Date Range regardless of whether a glucose reading was recorded or not.

Highest

By Time Period: Reports the highest reading recorded during the Time Period specified within the selected Date Range.

Total/Summary: Reports the highest reading recorded during the selected Date Range.

Lowest

By Time Period: Reports the lowest reading recorded during the Time Period specified within the selected Date Range.

Total/Summary: Reports the lowest reading recorded during the selected Date Range.

Average

By Time Period: Reports the sum of the readings recorded during the selected Date Range that fall within the specified Time Period divided by the number of readings recorded during the selected Date Range that fall within the specified Time Period.

Total/Summary: Reports the sum of the readings recorded during the selected Date Range divided by the number of readings recorded during the selected Date Range.

Standard
Deviation

By Time Period: Reports the mean* of the readings recorded during the Time Period specified within the selected Date Range.

Total/Summary: Reports the mean* of the readings recorded during the selected Date Range.

Note: N/A is displayed where fewer than three readings are recorded.

Above %

By Time Period: Reports the number of readings recorded above

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the patient's defined normal glucose limits during the Time Period specified within the selected Date Range divided by the total number of readings recorded during the Time Period specified within the selected Date Range.**

Total/Summary: Reports the total number of readings recorded above the patient's defined normal glucose limits during the selected Date Range divided by the total number of readings recorded during the selected Date Range.**

Within %

By Time Period: Reports the number of readings recorded within the patient's defined normal glucose limits during the Time Period specified within the selected Date Range divided by the total number of readings recorded during the Time Period specified within the selected Date Range.

Total/Summary: Reports the total number of readings recorded within the patient's defined normal glucose limits during the selected Date Range divided by the total number of readings recorded during the selected Date Range.

Below %

By Time Period: Reports the number of readings recorded below the patient's defined normal glucose limits during the Time Period specified within the selected Date Range divided by the total number of readings recorded during the Time Period specified within the selected Date Range.**

Total/Summary: Reports the total number of readings recorded below the patient's defined normal glucose limits during the selected Date Range divided by the total number of readings recorded during the selected Date Range.**

Very High %

By Time Period: Reports the number of readings recorded as hyper events during the Time Period specified within the selected Date Range divided by the total number of readings recorded during the Time Period specified within the selected Date Range.***

Total/Summary: Reports the total number of readings recorded as hyper events during the selected Date Range divided by the total number of readings recorded during the selected Date Range.***

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- High %** By Time Period: Reports the number of readings recorded above the patient's defined normal glucose limits and below the limits of a hyper event during the Time Period specified within the selected Date Range divided by the total number of readings recorded during the Time Period specified within the selected Date Range.***
Total/Summary: Reports the total number of readings recorded above the patient's defined normal glucose limits and below the limits of a hyper event during the selected Date Range divided by the total number of readings recorded during the selected Date Range.***
- Low %** By Time Period: Reports the number of readings recorded below the patient's defined normal glucose limits and above the limits of a hypo event during the Time Period specified within the selected Date Range divided by the total number of readings recorded during the Time Period specified within the selected Date Range.***
Total/Summary: Reports the total number of readings recorded below the patient's defined normal glucose limits and above the limits of a hypo event during the selected Date Range divided by the total number of readings recorded during the selected Date Range.***
- Very Low %** By Time Period: Reports the number of readings recorded as hypo events during the Time Period specified within the selected Date Range divided by the total number of readings recorded during the Time Period specified within the selected Date Range.***
Total/Summary: Reports the total number of readings recorded as hypo events during the selected Date Range divided by the total number of readings recorded during the selected Date Range.***

* The mean of the recorded readings is related to the patient's average glucose level. For example, a small number (less than half the average) indicates that most of the glucose readings during the day are close to the average value and that the patient is maintaining glucose levels near that value. A large number (more than half the average) indicates that many glucose levels during the day vary considerably from the average and that the patient is not maintaining glucose levels near the average value.

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** Available when three target zones are being reported: Show Hypo/Hyper not selected. *** Available when five target zones are being reported: Show Hypo/Hyper selected.

INSULIN STATISTICS

The Insulin Statistics table (see Figure 129) shows average insulin dosages over the date range (calculated from insulin data). Figure 129 illustrates a Statistics Report: Insulin and Carbs Statistics Tables.

Avg per Day (insulin name)	By Time Period: Reports the sum of the units of Insulin delivered during the Time Period specified for the selected Date Range divided by the number of days in the selected Date Range where that particular type of Insulin was recorded during that Time Period. Total/Summary: Reports the sum of the units of Insulin delivered during the selected Date Range divided by the number of days in the selected Date Range where that particular type of Insulin was recorded.
	Note: Separate entries exist for each type of Insulin recorded.
Avg Total Insulin per Day	By Time Period: Reports the sum of the units of all Insulin delivered during the Time Period specified for the selected Date Range divided by the number of days in the selected Date Range where any type of Insulin was recorded during that Time Period. Total/Summary: Reports the sum of the units of all Insulin delivered during the selected Date Range divided by the number of days in the selected Date Range where any type of Insulin was recorded.

These entries are calculated using all types of insulin recorded.

PUMP STATISTICS

If the insulin is administered by pump, the table (Figure 129) will say Pump Statistics (instead of Insulin Statistics) and display the following information:

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Avg General Bolus per Day	By Time Period: Reports the sum of all Meal Bolus* Insulin recorded during the specified Time Period for the selected Date Range divided by the number of days in the selected Date Range where Meal Bolus* Insulin entries were recorded during that Time Period. Total/Summary: Reports the sum of all Meal Bolus* Insulin recorded during the selected Date Range divided by the number of days in the selected Date Range where Meal Bolus* Insulin entries were recorded.
Avg Correction Bolus per Day	By Time Period: Reports the sum of all Correction Bolus Insulin recorded during the specified Time Period for the selected Date Range divided by the number of days in the selected Date Range where Correction Bolus Insulin entries were recorded during that Time Period. Total/Summary: Reports the sum of all Correction Bolus Insulin recorded during the selected Date Range divided by the number of days in the selected Date Range where Correction Bolus Insulin entries were recorded.
Total Avg Bolus per Day	By Time Period: Reports the sum of all Meal and Correction Bolus Insulin entries recorded during the specified Time Period for the selected Date Range divided by the number of days in the selected Date Range where Meal and Correction Bolus Insulin entries were recorded during that Time Period. Total/Summary: Reports the sum of all Meal and Correction Bolus Insulin entries recorded during the selected Date Range divided by the number of days in the selected Date Range where Meal and Correction Bolus Insulin entries were recorded.
Avg Basal per Day	By Time Period: Reports the sum of the Basal Insulin delivered during the Time Period specified for the selected Date Range divided by the number of days in the selected Date Range where Basal Insulin was recorded for that Time Period. Total/Summary: Reports the sum of the Basal Insulin delivered during the selected Date Range divided by the number of days in

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the selected Date Range where Basal Insulin was recorded.

Avg Total Insulin per Day By Time Period: Reports the sum of the Total Bolus and Basal Insulin doses delivered during the Time Period specified for the selected Date Range divided by the number of days in the selected Date Range where Insulin entries were recorded for that Time Period.

Total/Summary: Reports the sum of the Total Bolus and Basal Insulin doses delivered during the selected Date Range divided by the number of days in the selected Date Range where Insulin entries were recorded.

* Meal Bolus is defined as the sum of all insulin entries (from pump uploads and manual entries) of the following injection types: Injection, Bolus, Meal Bolus, Combination Bolus, Dual Wave Bolus, and Square Wave Bolus.

CARBOHYDRATE STATISTICS

The Carbs Statistics table (see Figure 129) shows average carbohydrates over the date range (calculated from carbohydrates data).

Average per Day Carbs By Time Period: Reports the sum of the meal Carbohydrate intake for the Time Period specified during the selected Date Range divided by the number of days within the selected Date Range where meal Carbohydrate entries were recorded during the Time Period specified.

Total/Summary: Reports the sum of the meal Carbohydrate intake during the selected Date Range divided by the number of days within the selected Date Range where meal Carbohydrate entries were recorded.

DAILY COMBINATION VIEW REPORT

The Daily Combination View Report summarizes glucose, carbohydrate, and insulin data (including pump data) for a *single* day and displays it in both graphic and table formats. To select the day for the data you want to see, a user can use the date field on the right (see Figure 130). Also, the user can set the date field on the left to the

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same date. Figure 130 illustrates a Date Field for Selecting Date. Figure 131 illustrates a Daily Combination View Report: Glucose Line and Carbohydrates Graphs.

GLUCOSE LINE GRAPH

This graph (see Figure 131) plots glucose readings by hour of day. The horizontal axis is a 24-hour timeline. The vertical axis plots the glucose level. Each data element represents one reading. The user can Hover the cursor over the data element to see the glucose value, date, and time of that reading. The user can double-click a data element to view this entry in the Diary List. To display or hide the solid line connecting the data elements, the user can right-click a data element, then select Toggle Glucose Line from the pop-up list.

CARBOHYDRATES GRAPH

This graph (see Figure 131) plots carbohydrate events by hour of day. The carbohydrate data element represents one carbohydrate event. The size of the circle is proportional to the carbohydrate value. Its position along the horizontal axis corresponds to the time (hour) of the meal. The user can double-click an icon to view this entry in the Diary List.

INSULIN SUMMARY

Figure 132 illustrates a Daily Combination View Report: Insulin Summary and Data Table. This graph (Figure 132) plots insulin events by hour of day. The horizontal axis is a 24-hour timeline. The vertical axis is units of insulin. Basal insulin data (light green shaded area) can be uploaded to the System. Each dark green bar represents one meal bolus insulin event. Its position along the horizontal axis corresponds to the time (hour) of the insulin event. Its height correlates with dosage. A user can double-click to view this entry in the Diary List. Each red bar represents one correction bolus insulin event. Its position along the horizontal axis corresponds to the time (hour) of the insulin event. Its height correlates with dosage. A user can double-click to view this entry in the Diary List. A meal bolus may be an extended, square wave, or combination bolus. The scale is indicated on the left.

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DATA TABLE

This table (see Figure 132) tracks glucose, carbohydrates, and insulin values hourly. Each column represents 1 hour. Each event type is one row. Each event is one cell. The value associated with the event displays in the cell. A user can double-click the cell to view this event in the Diary List.

WEEKLY PUMP VIEW REPORT

The Weekly Pump View Report shows the components of insulin doses for each day in a seven-day period in bar graph (Figure 134) and pie chart (Figure 135) formats. To select the week (7 days) for the data a user wants to view, using the date field on the right (see Figure 133), the user can select the last date in the week the user wants to see (8/3/2004, for example). The user can set the date field on the left to the first day of that week (7/28/2004, for example). Figure 133 illustrates a Date Field for Selecting a Date. Figures 134-135 illustrates Weekly Pump View Reports: Bar Graph and Pie Charts and Glucose Statistics Table, respectively. A Glucose Statistics table (see Figure 135) summarizes the glucose readings for the week displayed.

HCP GROUP ANALYSIS REPORT

The HCP Group Analysis Report is available to HCP users only. This report is a user-configurable view of all FreeStyle CoPilot System data for all patients of the HCP. The HCP can display data for any patient he/she manages. This includes all device data uploaded at the clinic during a patient visit, all data entered manually at the clinic, and all data imported into the HCP's database through information sharing (see Chapter 7, Host). This report facilitates viewing and comparing of data for all patients of the HCP or clinic. Figure 136 illustrates a HCP Group Analysis Report. By default, the report displays with column heads for Patient ID, Last Name, First Name, and for a number of event-related data fields. Data for each patient displays in one row. Each glucose value displays in a cell shaded the signal color of its target range. The glucose target mode is Standard. A day (24 hours) is defined as midnight to midnight.

A user can customize the columns in the HCP Group Analysis Report by changing the order of events in a column, adding and removing columns, and resizing columns. To save the custom changes, the user can click Customize (bottom right of

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screen). The Filter Builder screen displays (see Figure 139). The user can then select Save As, enter a filename, and click Save.

To reverse the order of items in any column, the user can click on the column heading, then click on the little arrow that appears to the right of the heading. The user can do the same to change the order back to its original sequence. To remove a column from the report, the user can drag-and-drop the column head cell off the table. To add a column to the report, the user can right-click anywhere on the table to call up a pop-up window (see Figure 137), and select Customize Columns. The Customization list displays (see Figure 138). From the list, the user can select the column head you want to add. Then the user can drag-and-drop it to the preferred position in the column-head row. Two green arrows display to help the user position the column. Figure 138 illustrates a Customization List. To move columns left or right in the table, the user can drag-and-drop the column-head cell to the preferred position in the column head row. To adjust the width of any column, the user can use the sizing tool that becomes active when he or she hovers the pointer over the right margin of the column-head cell.

DATA FILTER

For any column-head in the table, a user can configure a data filter using the selection list. To display the selection list for any column, the user can click the down-arrow at the right. To display data for all patients, with any or no entry in the corresponding data field, the user can click All. To customize the data filter, the user can click Customize, and complete the dialog box. Figure 139 illustrates a Filter Builder Screen. To display data for any patient with a particular value in the corresponding data field, the user can click the value of interest. To save the data filter changes, the user can click Customize (bottom right of screen). The Filter Builder screen displays (see Figure 139). The user can select Save As, enter a filename, and click Save.

INSULIN MANAGEMENT TOOLS

The System of the preferred embodiment incorporates insulin management tools to make health management easier for Home and HCP users. The System provides additional insulin management tools to support the Home User's healthcare. An Insulin Adjustment Table is used to determine insulin dose adjustment based on a user's

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current blood glucose level. All values entered in this table should be determined by the HCP. A Prescribed Plan table is used to store and review healthcare guidelines established by the HCP. Figure 140 illustrates a References Drop-Down Box.

INSULIN ADJUSTMENT TABLE

The HCP first sets up the values in this table (see Figure 141). Insulin adjustment may not be necessary for every Home user. The Glucose Start Value (mg/dL) in the table is the blood glucose level at which the insulin dose should be increased. Beginning with this value, consecutive blood glucose ranges are provided for each increase in insulin. These ranges are determined by the value entered as the patient's Insulin Sensitivity. The Insulin Dosage Amount is the amount of insulin above the patient's normal dose that should be taken when the patient's blood glucose level falls within the range specified. The Insulin Adjustment Table is provided as a convenient reference, and entries made in this table are generally not used by other application features.

DEFINING INSULIN ADJUSTMENT

On the Home page, a user can select References on the main menu bar (see Figure 140). A user can select Insulin Adjustment Table from the drop-down list, and the Insulin Adjustment Table displays. Figure 141 illustrates an Insulin Adjustment Table. The user can set the Glucose Start Value (mg/dL) to the value determined by his or her HCP. The Glucose Start Value is used to set the lowest glucose value on the Insulin Adjustment Table and indicates when to start adjusting the insulin dose. The user can set the value of Insulin Sensitivity to the value determined by your HCP. The Insulin Sensitivity value is used to set the increase in value between each of the consecutive blood glucose ranges displayed.

PRESCRIBED PLAN

The Prescribed Plan is a table Home users can use to store and review guidelines from their HCP for Insulin type, dosage, and time of day, insulin sensitivity, medication type, dosage, and time of day, carbohydrates for each individual meal time, and/or ratio of amount of insulin per grams of carbohydrate. Figure 142 illustrates a

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Prescribed Plan. Data for each of these items can be individually entered for breakfast, lunch, dinner, bedtime, and a snack. Comments can also be added. Once the Prescribed Plan is entered, a user can view the plan by returning to this screen. A user can also print it out by clicking Print at the bottom of the screen.

DEFINING A PRESCRIBED PLAN

On the Home page, a user can select References on the main menu bar (see Figure 140). The user can select Prescribed Plan from the drop-down list. The Prescribed Plan screen (see Figure 142) then displays. The user can select an entry type from the Type drop-down list: Insulin or Medication. The user can select Insulin to record an insulin type and dose for each meal field. The user can select Medication to record a medication type and dose for each meal field where it is taken. The user can enter the name of the Insulin or the Medication and the dosage in the Item field. The user can select Ratio to record the optimum meal-based insulin-to-carbohydrate ratio. The user can select Carbohydrates to record the optimum carbohydrate intake. The user can enter the desired number of grams of carbohydrate for each meal field. The user can select Sensitivity and enter the Insulin Sensitivity factor his or her HCP calculated for the user. The user can enter any comments in the Comments field (optional). By clicking OK, the plan is saved and the Prescribed Plan window closes. (Or, to clear all data entered into the plan, the user can click Reset.)

INSULIN SENSITIVITY

Individuals with low insulin sensitivity usually need a higher insulin dose to lower their glucose levels to acceptable levels than people with higher insulin sensitivity. The user's insulin sensitivity is determined by his or her HCP. The insulin-to-carbohydrate ratio is used to determine how much insulin to administer per grams of carbohydrates eaten. A user's insulin-to-carbohydrate ratio is determined by his or her HCP.

HOST

The Host System of the preferred embodiment resides on an Internet server. The Host database stores data that has been synchronized with the System data on a user's PC. Data stored on the Host can be shared with other users. A Home user can choose

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to share your data with his or her HCP or several HCPs. HCP users can share data with other HCPs. In either case, the user "invites" the other party to share data. The user sets up a Host Account if he or she wishes to use the Host's capabilities. A Host Account defines access, privileges, and functions associated with a particular user.

SYNCHRONIZATION

Synchronization is the process whereby the System application on a user's PC connects to the Internet and transmits data and other information between the user's program and the Host server. Synchronization matches and updates the data between the System application installed on the user's computer and the Host System. Following synchronization, new and modified data is reflected in both the local System database and the database on the Host server.

HOST ACCOUNT SETUP

The first time a user synchronizes with the Host, the Synchronize window opens. The user can follow the steps on the screen, a Host account will be created and a confirmation e-mail will be sent to the user. The user can verify his or her Host account number by looking on the User Profile screen. If a user selects an item from the **Host** drop-down menu, the System will try to open an Internet connection automatically. If the Internet connection cannot be opened this way, it can be opened manually before selecting items on the **Host** menu.

The user can click the Synchronize icon or select Host on the main menu bar and choose Synchronize from the drop-down box (Home version) or Synchronize Current HCP (HCP version).

Figure 143 illustrates a Home User: Host Drop-Down Box (left), and HCP User: Host Drop-Down Box (right). The End-User Agreement Screen will display. The user can review the End-User Agreement (see Figure 144), and click Next to continue.

Figure 144 illustrates a First Time Synchronization Screen. The user proceeds through the setup process on the screen. A password is established and a Host Account number is assigned to the user (which now appears on his or her user Profile screen).

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Figure 145 illustrates a Host Account Number. The System then synchronizes the user's account, and a summary of the synchronized data automatically displays.

Figure 146 illustrates a Synchronization Summary Screen. A confirmation message is sent to the user from the Host and to the user's e-mail address. Figure 147 illustrates a Confirmation Message From the Host

SYNCHRONIZING WITH THE HOST

If the user has previously logged in and set up an account, he or she can synchronize with the Host as follows. The user can click the icon or select Host on the main menu bar and choose Synchronize from the drop-down box (Home version) or Synchronize Current HCP (HCP version) (see Figure 143). The System then automatically synchronizes the user's local and Host accounts (including all event and profile data). A summary of the synchronized data automatically displays (see Figure 146).

SYNCHRONIZE ALL (HOME VERSION)

In a single household, there may be more than one person with diabetes that manages their diabetes using the System. For convenience, a Home user may synchronize the data for all the Home users using the System in the household with a single click of the mouse. The user can select **Host** on the main menu bar and choose **Synchronize All** from the Home user **Host** drop-down box (see Figure 143). The System displays a list of all the Home users on your PC. Synchronization starts automatically. A blue progress bar indicates when synchronization is complete for each Home user's data.

SYNCHRONIZE ALL HCP USERS (HCP VERSION)

In a clinic, for example, there may be several HCPs using the same System. For convenience, a HCP may synchronize the patient data for all the HCPs using the System with a single click of the mouse. The user can select **Host** on the main menu bar and choose **Synchronize All HCPs** from the drop-down box (see Figure 143). The System displays a list of all the HCPs on your local system and the patients they

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manage. Synchronization starts automatically. A blue progress bar indicates when synchronization is complete for each HCP's and patient's data.

INVITATION TO SHARE DATA

Once the user (Home or HCP) sets up a Host Account, he or she can authorize one or more HCPs to have access to the data. To do this, the user can initiate an "invitation" to the HCP to share data via the Host. This notifies the Host that the user will allow the selected HCP to view (and in some cases, edit) their data.

There are several ways to invite an HCP to share data. The HCP may have a Host Account: Once a user is logged in to the Host, he or she can search for the HCP using the HCP's State/Province or Host Account number. The HCP may not have a Host Account: In this case, the HCP's e-mail address is discovered and used. If the HCP fails to accept or decline the invitation within 30 days, the invitation to share data expires. A user then can send another invitation to the same HCP after 30 days.

INVITATION TO SHARE DATA: HCP HAS A HOST ACCOUNT

From the Host menu on the main menu bar, the user can choose Invite to Share Data. Figure 148 illustrates an Invite to Share Data (Home User Screen, left; HCP User Screen, right). An Internet connection to the Host server will be opened and the screen illustrated at Figure 149 will display. The user can select the appropriate option. If the user does not know the HCP's Host Account number, he or she can select Search Host HCP database to find an HCP from the list of existing accounts, and then click next. On the next screen, the user can select the state/province where the HCP is located.

Figure 150 illustrates a Find HCP from Existing Accounts Screen. The user can then click Search. HCPs from the selected state with a Host Account will be displayed. The user can then highlight the HCP he or she wants and click Next. The screen for selecting Access Level displays.

Figure 151 illustrates an Assign Access Level Screen. The user can select Read-Only Access or Full Access (Read and Enter Data), and then click Submit. The Host then displays the Process Complete screen and sends an invitation to share data to the HCP.

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Figure 152 illustrates a Process Complete Screen. If you know the HCP's Host Account Number, he or she can select enter the Host HCP Account Number provided by the HCP.

Figure 153 illustrates an Invite HCP to Share Data Screen. The user can click Next. On the next screen, the user enters the Host HCP Account Number.

Figure 154 illustrates an Enter Host HCP Account Number Screen. The user can click Search. The HCP is displayed as the search result. If this is the HCP the user is looking for, the user can click Next. The screen for selecting Access Level displays. The user can select Read-Only Access or Full Access (Read and Enter Data), and click Submit.

Figure 155 illustrates an Assign Access Level Screen. The Host then displays the Process Complete screen and sends an invitation to share data to the HCP. Figure 156 illustrates a Process Complete Screen

ACCEPTING AN INVITATION FROM THE HOST TO SHARE DATA: HCPS ONLY

If a patient user issues an invitation to share their data with a user, the user will see a message in the Messages From CoPilot Host window as illustrated at Figure 157. If the user fails to accept or decline the invitation within 30 days, the invitation to share data expires. The user can double-click the message header to display the invitation to share data. Figure 158 illustrates an Invitation to Share Data (from Host). To accept the invitation, a user can click Accept Invitation (bottom of screen). The Host will then synchronize with the user's system, and the patient's data will be uploaded to Host computer. A summary of the synchronized data then automatically displays. The user can then click Close to exit. At this point, the user has successfully accepted the invitation and received the patient's data.

INVITATION TO SHARE DATA: HCP DOES NOT HAVE A HOST ACCOUNT

If the HCP does not have a Host Account, a user can send an e-mail invitation to the HCP to share data if the HCP's Internet address (example: jsloane@aol.com) is known. From the Host menu on the main menu bar, the user can choose Invite to Share Data. An Internet connection to the Host server will open and the screen illustrated at Figure 159 will display. The user can select send an e-mail invitation to an HCP who does not have an existing account, and click next. When the next screen

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opens, the user can enter the Name and E-mail Address of the HCP he or she wishes to invite.

Figure 160 illustrates an E-mail Invitation to HCP with No Host Account. The screen for selecting Access Level displays. The user can select Read-Only Access or Full Access (Read and Enter Data), and click Submit.

Figure 161 illustrates an Assign Access Level screen. When the user clicks next, the Host then displays the Process Complete screen. Figure 162 illustrates a process Complete Screen. The Host will send the HCP an e-mail inviting him/her to have access to the data. The message instructs the HCP to download the Management System, install the software and set up a user profile, and synchronize with the Host and set up a Host Account. The user then makes note of the Invitation Code included near the end of the e-mail. The Host will notify the user when the HCP has accepted the invitation to share data. If the user does not receive this message within a reasonable period of time, the HCP should be contacted directly.

ACCEPTING AN E-MAIL INVITATION TO SHARE DATA (HCPS ONLY)

When a user receives an e-mail invitation to share data, the message will instruct the user to download the Health Management System from the Internet (e.g., by just clicking on the hyperlink in blue), install the software and set up a user profile, and synchronize with the Host and set up a Host Account. The user then makes note of the Invitation Code included near the end of the e-mail (see Figure 164). Figure 163 illustrates an E-mail Invitation to Register and Share Data. An invitation code may look like that illustrated in Figure 164.

After the user has downloaded and installed the software, he or she can set up a user profile and register with the Host. From the Host drop-down box on the main menu bar, the user can choose Accept E-Mail Invitation. Figure 165 illustrates a HCP: Host Drop-Down List. The System connects to the Host server and the screen illustrated at Figure 166 displays. The user can enter the Invitation Code in the box provided and click Next. The Host then synchronizes with the user's System, and the patient's data is downloaded. A summary of the synchronized data then automatically displays. A synchronization screen is illustrated at Figure 167.

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MANAGING SHARED DATA: HOME USER

A user can limit, expand, or deny an HCP access to his or her data on the Host using a Manage Shared Data function.

DEFINING OR CHANGING HCP ACCESS TO DATA

From the Host drop-down box (see Figure 168) on the main menu bar, the user can choose Manage my shared data. The next screen shows a list of each authorized HCP along with the level of access granted to them. Figure 169 illustrates a Manage My Shared Data Screen. The user can highlight the HCP whose access he or she wishes to change and choose to Grant NO Access which removes all access to your data by the listed HCP, Grant Read-Only Access, which restricts the HCP to viewing your data, or Grant Full Access, which allows the HCP to view and edit the data, including event data, glucose targets, the user's prescribed plan, etc. The user can click Close to exit, and the Host sends a message to the HCP about the changed access level.

MANAGING SHARED DATA: HCP USER

A HCP user can view a list of the patients with whom he or she shares data. The HCP user can also unsubscribe patients, which means the HCP user will no longer have access to their data. From the Host drop-down box (see Figure 170) on the main menu bar, the HCP user can choose Manage data being shared with me (see Figure 171). The next screen shows a list of the patients who share data with the HCP user. The HCP user can then highlight the patient that he or she wants to unsubscribe. Then, the HCP user can click the Unsubscribe button (lower left of screen). The Access Level for this patient will change to NONE. The Host will send a message confirming the changed Access Level. The next time the patient or the HCP who assigned the patient to synchronize with the Host, the Access Level on their Manage My Shared Data screen will be NONE. Figure 172 illustrates a Changed Access Level Message.

DATABASE MANAGEMENT

To ensure that information remains accurate, the System provides the user with the capability to perform database maintenance. The **Database Maintenance** feature

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includes the ability to, archive data, backup data and restore data from the last backup. More than one database can be created and maintained by the System application. The last database selected will be opened by each successive execution of the software until another database is selected by the user.

ARCHIVING DATA

When a user chooses to archive data, the data being archived will be removed from the System database. The user can restore the data by importing it. On the Home page, the user can select Database Maintenance from the File drop-down box (see Figure 173). The user can select the Archive option from the menu. A window will open, allowing the user to specify a date. The user can select the last date of the data to be included in the archive, and click OK. Figure 174 illustrates an Archive Event Data Screen. A file browser will open. The user can browse to the directory where the file is to be saved. The user should make sure XML file (*.xml) is displayed in the Save as Type window. Figure 175 illustrates a File Browser Window: Save Archive Data. The user can enter the name of the file in the File Name window and click Save. The file is saved as an .xml file in the directory specified.

VIEWING ARCHIVED DATA

The user can close or minimize the system application. The user opens the file browser and browses to the folder where he or she saved the archived *.xml file. Figure 176 illustrates a File Browser: Location of Archived Data File (*.xml). To open an *.xml file, a Web browser (for example, Internet Explorer, Netscape, etc.) is used that is installed on your PC. The user can highlight the archive file and click Open.

RESTORING ARCHIVED DATA

Archived data can be reloaded into the System as follows. On the Home page, a user can select Import from the DataEntry drop-down box (see Figure 177). The user can choose Import Events from File from the Import submenu. A file browser opens. The user can browse to the directory where the file is located. The user can select the file type (*.xml or *.tab) in the Files of Type window. The user can Highlight the file and

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click Open. Importing will automatically begin. The Importing progress screen (see Figure 178) displays the progress of the import procedure. The Importing screen closes when data import is finished.

BACKING UP THE DATABASE

A backup of the database is performed automatically each time the user exits (closes) the application. The user can also create a backup of his or her database at any time and save it in any directory. The user can Backup the database as follows. On the Home page, the user can select Database Maintenance from the File drop-down box (see Figure 173). The user can choose Backup from the Database Maintenance submenu. A file browser opens. The user can browse to the directory where he or she wants the file to be located. Figure 179 illustrates a File Browser: Select Backup Location. The user makes sure that the words System (or other designated name such as FreeStyle CoPilot) Backup File are displayed in the Save as Type window. The user can then enter the name of the file in the File Name window and click Save.

RESTORING A BACKED UP DATABASE

The System database is automatically restored if a system integrity check fails. A user can also restore a database whenever desired, as follows. On the Home page, the user can select Database Maintenance from the File drop-down box (see Figure 173). The user can choose Restore from the Database Maintenance submenu. A file browser opens. The user can browse to the directory where the database was saved. The checks to make sure the words System or FreeStyle CoPilot Backup are displayed in the File of Type window. The user enters the name of the file in the File Name window and clicks Open. The Restore Log then displays as illustrated at Figure 180, showing the restored transactions.

VIEWING THE RESTORE LOG

The user can view the Restore Log at any time, as follows. The user can close or minimize the System application. The user can open the file browser and find the Health Management System folder. This is the folder where the application was

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installed. Figure 181 illustrates a File Browser: Restore Log. The user can highlight the file named Restore log and click Open to view the log.

HELP

For answers to questions about how to do something within the System, a user can consult the User's Guide or take advantage of the System's built-in onscreen Help. The user can access Help from any screen in the System that displays the main menu bar. The user can get context-sensitive Help on most screens. For example, if the user is viewing the Diary List and has a question, he or she can click WY. The Help screen will automatically open to the Help text that describes the Diary List.

ACCESSING ON-SCREEN HELP

On the Home page, a user can click an icon, or select Help on the main menu bar and then select Contents from the drop-down list (see Figure 182). Figure 183 illustrates a Help Screen that would then display.

HELP SCREEN

Help text is displayed in the large window on the Help screen. The Contents, Index, and Search tabs at the left offer three ways to find the Help topic the user is looking for. When the user selects a topic, the Help text appears in the large window on the right. Some text may contain links to more detailed information about a topic. These links appear as blue text followed by three dots (for example, Local Home User Account . . .). If it is a link, the cursor will change from an arrow to a hand when passed over the link. The user can click the link to see the additional text. Green text may be underlined and in italics. If it is a link, the cursor will change from an arrow to a hand when passed over the link. The user can click the link to see the additional text.

HELP SCREEN ICONS

The user can click to hide the column with the Contents, Index, and Search tabs from displaying on screen. The user can click to show the column with the Contents,

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Index, and Search tabs. The user can click to see the previous page in the Help text. The user can click to see the next page in the Help text, and can click to print the Help page being viewed.

CONTENTS TAB

Contents is the first tab displayed when the user opens the Help screen (see Figure 183). This is the table of contents for the Help file. The Help information is arranged by topic here. The user can double-click on a topic listed (for example, Getting Started) and subsections will display. Some of the subsections have further subsections.

INDEX TAB

The user can click on the Index tab to display an alphabetical list of all topics covered in the Help file. The user can select a topic from the list and double-click. The text displays in the big window (see Figure 183). Figure 184 illustrates a Help: Index Tab. Alternatively, a user can type a keyword into the Type in the keyword to find: field. Then click the icon at the bottom of the screen. A list of Help topics matching the keyword displays. The user can select a topic and double-click. The text displays in the big window.

SEARCH TAB

The user can click on the Search tab if he or she wants to use keywords to find Help text. Figure 185 illustrates a Help: Search Tab. To search, The user can type a keyword into the Type in the keyword to find: field. Then click the icon. A list of topics related to your keyword displays in the Select Topic to Display window. The user can select a topic and double-click (or select a topic and click the icon. The text displays in the large window. The user can also contact Technical Support and Service (see Figure 186 which illustrates a Help Drop-Down Box). A Customer Service Contact Information screen displays (see Figure 187). The screen shows the ways a user can get help if he or she has questions about using the System, such as On-Line Help, E-Mail Customer Service, and Customer Service Hotline. Figure 187 illustrates a Customer Service Contact Information Screen.

The present invention is not limited to the embodiments described above herein, which may be amended or modified without departing from the scope of

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the present invention as set forth in the appended claims, and structural and functional equivalents thereof.

In methods that may be performed according to preferred embodiments herein and that may have been described above and/or claimed below, the operations have been described in selected typographical sequences. However, the sequences have been selected and so ordered for typographical convenience and are not intended to imply any particular order for performing the operations.

In addition, the following references, in addition to the summary of the invention section, disclose alternative embodiments:

United States patents no. 5,307,263, 5,899,855, 6,186,145, 5,918,603, 5,913,310, 5,678,571, 5,822,715, 5,956,501, 6,167,362, 6,233,301, 6,379,301, 5,997,476, 6,101,478, 6,168,563, 6,248,065, 6,368,273, 6,381,577, 5,897,493, 5,933,136, 6,151,586, 5,960,403, 6,330,426, 5,951,300, 6,375,469, 6,240,393, 6,270,455, and 6,161,095;

United States published applications no. 2001/0011224, 2003/0163351, and 2003/0069753;

United States patent applications nos. 60/577,064 and 10/112,671; and

Internet web sites: www.freestylecopilot.com, www.abbottdiabetescare.com, www.lifescan.com/care, www.bddiabetes.com, www.roche-diagnostics.com, www.healthhero.com, and www.minimed.com.

What is claimed is:

1. A host-client system for managing diabetes care data, comprising:
 - a client terminal comprising:
 - electronics adapted to receive data from a glucose monitoring device, and
 - a communication interface adapted to provide access over a computer network to a host; and
 - the host comprising:
 - a database for storing diabetes care data relating to a plurality of diabetics;
 - one or more processors; and
 - memory operably coupled to the one or more processors, wherein the memory includes instructions stored therein that, when executed by the one or more processors, cause the one or more processors to:
 - provide a browser-accessible or client-resident graphics rendering component for providing a graphical user interface (GUI) that includes:
 - a report generation component for generating a report illustrating a plurality of types of overlayed diabetes related health information periodically obtained over a selected temporal duration, wherein the report generation component permits generating of reports based on selected data and presenting an integrated text and graphical information display screen, and
 - a security component adapted to enable a patient to authorize or revoke access to one or more health care professionals (HCPs) to have access to diabetes care data relating to the patient, wherein the security component is adapted to prompt the patient for an HCP number of the HCP to authorize access;
 - prompt a user to assign the glucose monitoring device to an existing user or a new user, when the glucose monitoring device is detected but not identified as belonging to a specific user;
 - upload data from the glucose monitoring device;
 - perform statistical and other calculations on the uploaded data to place results of the statistical and other calculations on the uploaded data in tables and graphs; and
 - display the results in a reports window.

2. The system of claim 1, wherein the diabetes related health information comprises insulin dosage data and glucose data.

3. The system of claim 2, wherein the diabetes related health information further comprises data relating to carbohydrate intake, exercise, state of health, medication, medical examination, lab results or ketones, or combinations thereof.

4. The system of any one of claims 1 to 3, wherein the report illustrates data of the plurality of diabetics.

5. The system of any one of claims 1 to 4, wherein the report comprises insulin dosage data and is adjusted depending on whether the data was derived from an insulin pump.

6. The system of any one of claims 1 to 5, wherein the report comprises an integration of text and graphical information.

7. The system of any one of claims 1 to 6, further comprising the glucose monitoring device connected to the client terminal, and wherein the glucose monitoring device is configured to upload blood glucose data to the client terminal.

8. The system of any one of claims 1 to 7, wherein the GUI further comprises a glucose monitoring device selection component permitting uploading or reviewing of data, or both, from a particular glucose monitoring device model of a plurality of glucose monitoring device models.

9. A system for managing diabetes care data, comprising:
a client terminal comprising:
 electronics adapted to receive data from a glucose measurement device;
and
 a communication interface adapted to provide access over a computer network to a host; and
the host, comprising:

a database for storing diabetes care data relating to a plurality of diabetics;
one or more servers accessible over the computer network for handling
client interactions with the system;
one or more processors; and
memory operably coupled to the one or more processors, wherein the
memory includes instructions stored therein that, when executed by the one or
more processors, cause the one or more processors to provide a browser-
accessible or client-resident graphics rendering component adapted to provide a
graphical user interface (GUI) that includes:

a report generation component configured to generate reports
based on selected data and to present an integrated text and graphical
information display screen; and

a security component adapted to enable a patient to authorize a
health care professional (HCP) to have access to diabetes care data
relating to the patient, wherein the security component is adapted to
prompt the HCP to enter an invitation code provided by the patient, and
wherein the invitation code is configured to expire if not accepted within a
predetermined amount of time.

10. The system of claim 9, further comprising the glucose measurement device,
wherein the glucose measurement device is connectable to the client terminal and
configured to upload glucose data to the client terminal for transmission to and storage
within the database.

11. The system of claim 9 or 10, wherein the GUI further comprises a device selection
component permitting uploading or reviewing of data, or both, from a particular device
model of a plurality of device models.

12. The system of any one of claims 9 to 11, wherein the GUI further comprises a
plurality of user interactive data elements in a first window, wherein the integrated text
and graphical information display screen comprises graphical information comprising at
least one of a graph, a chart, and a table, wherein the interactive data elements are linked
to a subset of diabetes care data selected from the group comprising glucose reading
events, carbohydrate events, and insulin events.

13. The system of claim 12, wherein the system is configured such that a selection of at least one of the interactive data elements causes a second window that is smaller than the first window to open on top of the first window and contains information from the selected subset of diabetes care data.

14. The system of any one of claims 9 to 13, wherein the memory includes instructions stored therein that, when executed by the one or more processors, causes the one or more processors to generate the invitation code in response to an input from the patient.

15. The system of claim 14, wherein the input from the patient comprises a selection of an access level for the HCP.

16. A system for managing diabetes care data, comprising:
a database for storing diabetes care data relating to a plurality of diabetics;
one or more servers accessible over a computer network for handling client interactions with the system;
one or more processors; and
memory operably coupled to the one or more processors, wherein the memory includes instructions stored therein that, when executed by the one or more processors, cause the one or more processors to provide a browser-accessible or client-resident graphics rendering component adapted to provide a graphical user interface (GUI) that includes:
a report generation component configured to generate reports based on selected data and to present an integrated text and graphical information display screen; and
a security component adapted to enable a patient to authorize a health care professional (HCP) to have access to diabetes care data relating to the patient, wherein the security component is adapted to prompt the HCP to enter an invitation code provided by the patient, and wherein the invitation code is configured to expire if not accepted within a predetermined amount of time.

17. The system of claim 16, further comprising a glucose measurement device, wherein the glucose measurement device is connectable to the client terminal and configured to upload glucose data to the client terminal for transmission to and storage within the database.
18. The system of claim 16 or 17, wherein the GUI further comprises a device selection component permitting uploading or reviewing of data, or both, from a particular device model of a plurality of device models.
19. The system of any one of claims 16 to 18, wherein the GUI further comprises a plurality of user interactive data elements in a first window, wherein the integrated text and graphical information display screen comprises graphical information comprising at least one of a graph, a chart, and a table, wherein the interactive data elements are linked to a subset of diabetes care data selected from the group comprising glucose reading events, carbohydrate events, and insulin events.
20. The system of claim 19, wherein the system is configured such that a selection of at least one of the interactive data elements causes a second window that is smaller than the first window to open on top of the first window and contains information from the selected subset of diabetes care data.
21. The system of any one of claims 16 to 20, wherein the memory includes instructions stored therein that, when executed by the one or more processors, causes the one or more processors to generate the invitation code in response to an input from the patient.
22. The system of claim 21, wherein the input from the patient comprises a selection of an access level for the HCP.
23. A system for managing diabetes care data, comprising:
 - a host configured to receive data associated with glucose levels from a plurality of client devices, the host comprising:
 - a database for storing the received data associated with glucose levels;

one or more servers accessible over a computer network for handling client interactions with the system;

one or more processors; and

memory operably coupled to the one or more processors, wherein the memory includes instructions stored therein that, when executed by the one or more processors, cause the one or more processors to interact with graphical user interfaces (GUIs) on the plurality of client devices, each of the GUIs including:

- a report generation component configured to generate a set of reports based on selected data associated with glucose levels, wherein the set of reports includes:
 - a plurality of data elements configured in a daily pattern of glucose levels for a plurality of time periods; and
 - a glucose histogram associated with at least three predetermined glucose ranges, wherein the glucose histogram comprises one or more bars, wherein a length of each of the one or more bars corresponds with a percentage of time in which the glucose levels were within one of the at least three predetermined glucose ranges during a specified time period; and
 - a security component adapted to enable a patient to authorize a health care professional (HCP) to have access to diabetes care data relating to the patient, wherein the security component is adapted to prompt the HCP to enter manually, with an input of a computing device, an invitation code provided by the patient, and wherein the invitation code is configured to expire if not accepted within a predetermined amount of time.

24. The system of claim 23, wherein each of the GUIs further comprises a device selection component permitting reviewing of data from a particular device model of a plurality of device models.

25. The system of claim 23 or 24, wherein the set of reports further includes a table displaying statistics corresponding to the glucose levels, wherein the table displaying statistics further includes a displayed average carbohydrate intake per day.

26. The system of claim 25, wherein the table displaying statistics corresponds to a one month period of time.
27. A system for managing diabetes care data, the system comprising:
one or more servers configured to receive, over a computer network, data associated with glucose levels from a plurality of client devices, the one or more servers comprising:
a database for storing the received data associated with the glucose levels;
one or more processors; and
memory coupled with the one or more processors, the memory storing instructions that, when executed by the one or more processors, cause the one or more processors to interact with graphical user interfaces (GUIs) on the plurality of client devices, wherein the GUIs include:
a report generation component configured to generate a set of reports based on the received data associated with the glucose levels, the set of reports comprising:
a plurality of data elements configured in a daily pattern of glucose levels for a plurality of time periods; and
a glucose histogram associated with at least three predetermined glucose ranges, wherein the glucose histogram comprises one or more graphical elements, and wherein a dimension of each graphical element corresponds with a percentage of time in which the glucose levels were within one of the at least three predetermined glucose ranges; and
a security component configured to generate an invitation code to enable a patient to authorize a health care professional (HCP) to have access to diabetes care data relating to the patient, wherein the invitation code is configured to expire after a predetermined amount of time, and wherein the invitation code is configured to be entered manually by an HCP to access the patient's diabetes care data.
28. The system of claim 27, wherein the glucose histogram is based on the received data associated with the glucose levels for a predetermined time period.

29. The system of claim 28, wherein the predetermined time period comprises a one month period of time.

30. The system of any one of claims 27 to 29, wherein the plurality of client devices comprises a plurality of portable handheld computing devices.

31. The system of any one of claims 27 to 30, wherein each of the GUIs further comprises a device selection component permitting reviewing of data from a particular device model of a plurality of device models.

32. The system of any one of claims 27 to 31, wherein the set of reports further comprises a table displaying statistics corresponding to the received data associated with the glucose levels, wherein the table displaying statistics comprises: a number of glucose readings statistic, a highest glucose reading statistic, a lowest glucose reading statistic, an average glucose reading statistic, a standard deviation statistic, a percentage of glucose readings within range statistic, a percentage of glucose readings above a predetermined high glucose threshold, a percentage of glucose readings below a predetermined low glucose threshold, and a percentage of glucose readings below a predetermined very low glucose threshold.

33. The system of claim 32, wherein the table displaying statistics corresponds to a customizable date range.

34. The system of claim 32 or 33, wherein the table displaying statistics further comprises insulin statistics or carbohydrate statistics.

35. A system for managing diabetes care data, comprising:
a database for storing diabetes care data relating to a plurality of diabetics;
one or more processors; and
memory operably coupled to the one or more processors, wherein the memory includes instructions stored therein that, when executed by the one or more processors, cause the one or more processors to:
provide a browser-accessible or client-resident graphics
rendering component for providing a graphical user interface (GUI) that
includes:

a report generation component permitting generating of reports based on the diabetes care data relating to the plurality of diabetics, data analysis utilizing a plurality of selection criteria, or application of a user-selected number and combination of categories of data elements, and

a security component adapted to enable a patient to authorize or revoke access to one or more health care professionals (HCPs) to have access to diabetes care data relating to the patient, wherein the security component is adapted to prompt the patient for an HCP number of the HCP to authorize access;

prompt a user to assign a glucose monitoring device to an existing user or a new user, when the glucose monitoring device is detected but not identified as belonging to a specific user;

upload data from the glucose monitoring device;

perform statistical and other calculations on the uploaded data to place results of the statistical and other calculations on the uploaded data in tables and graphs; and

display the results in a reports window.

36. The system of claim 35, further comprising the glucose monitoring device connected to a client terminal, and wherein the glucose monitoring device is configured to upload blood glucose data to the client terminal.

37. The system of claim 35 or 36, wherein the GUI further comprises a glucose monitoring device selection component permitting uploading or reviewing of data, or both, from a particular glucose monitoring device model of a plurality of glucose monitoring device models.

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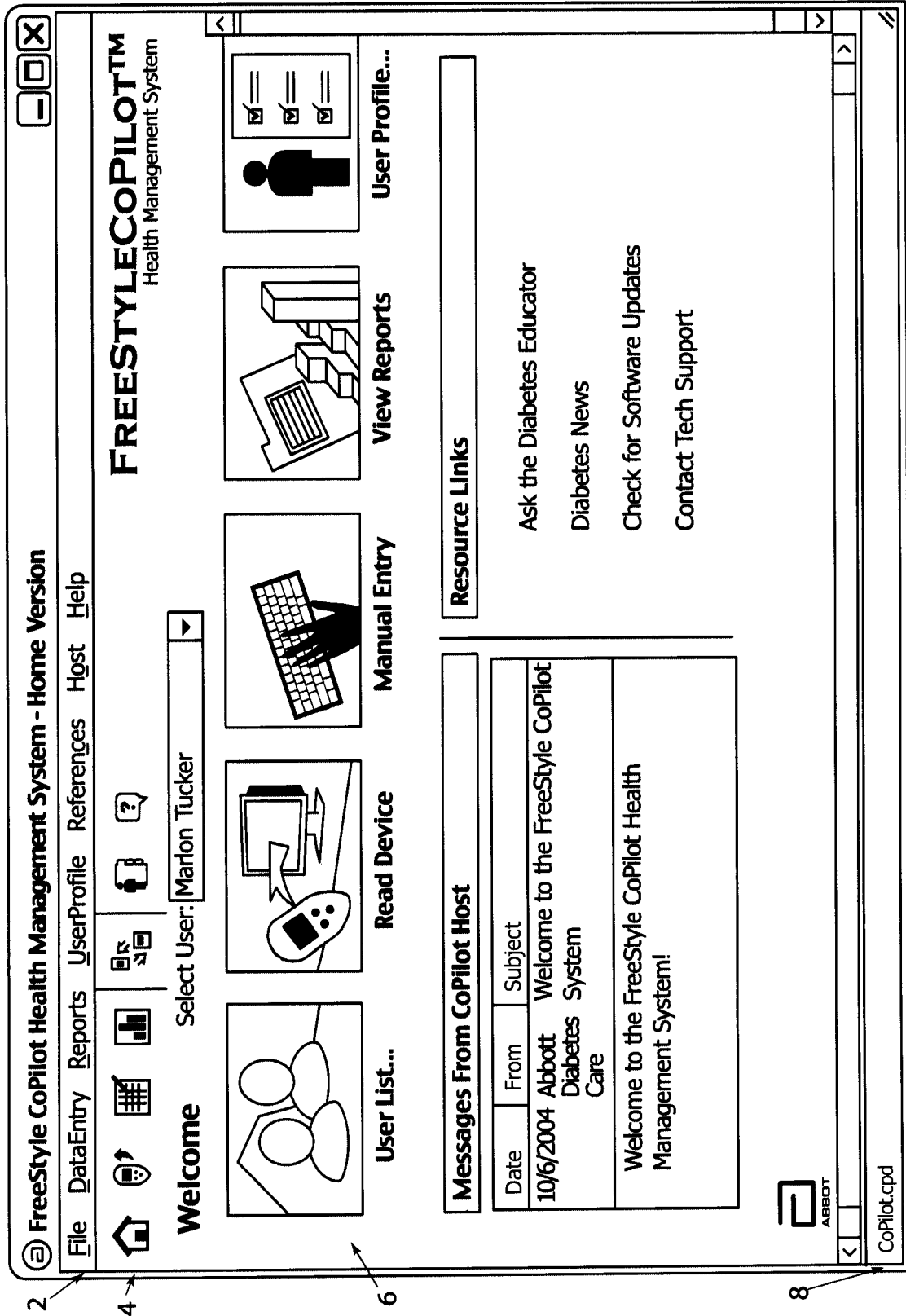


FIG. 1

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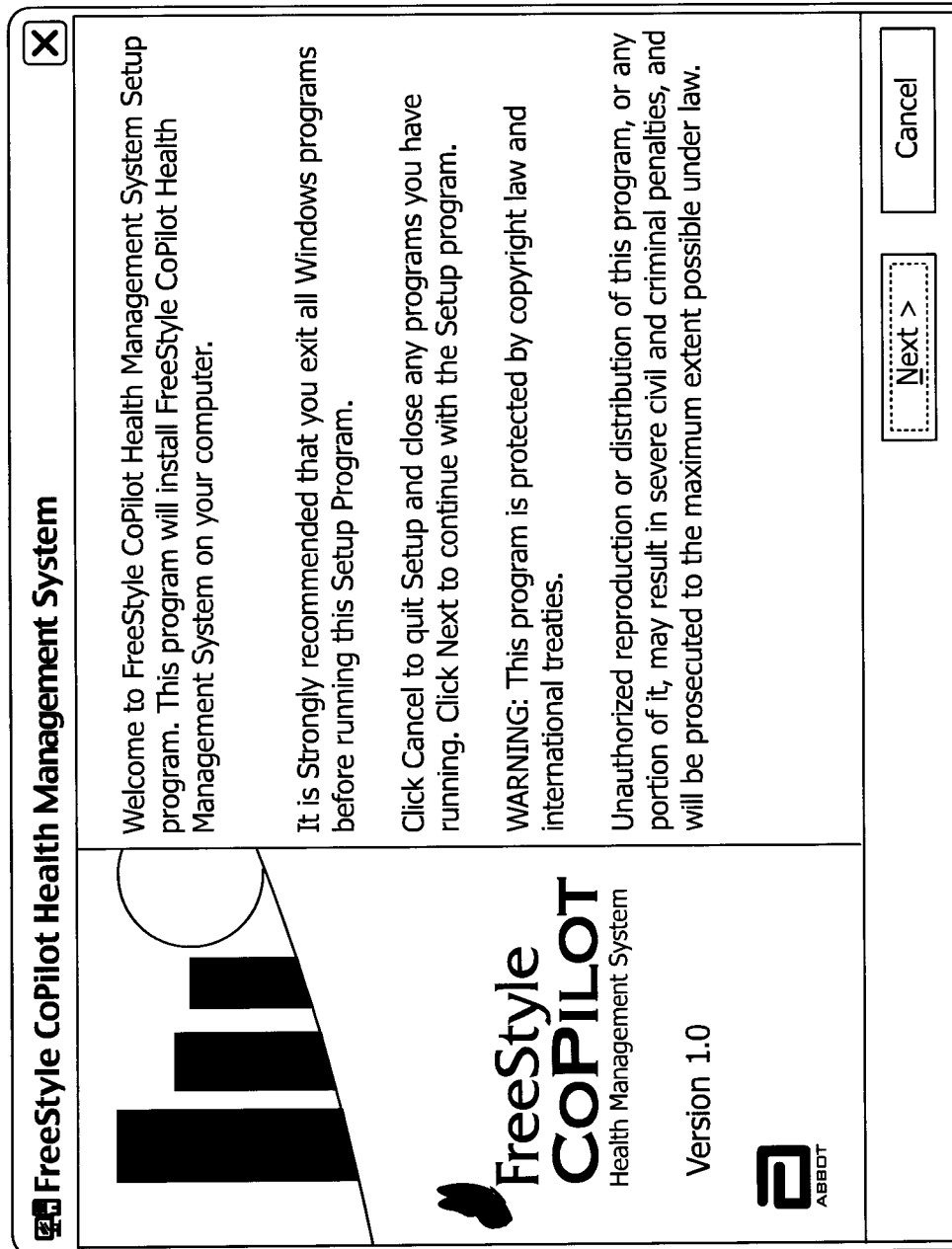


FIG. 2

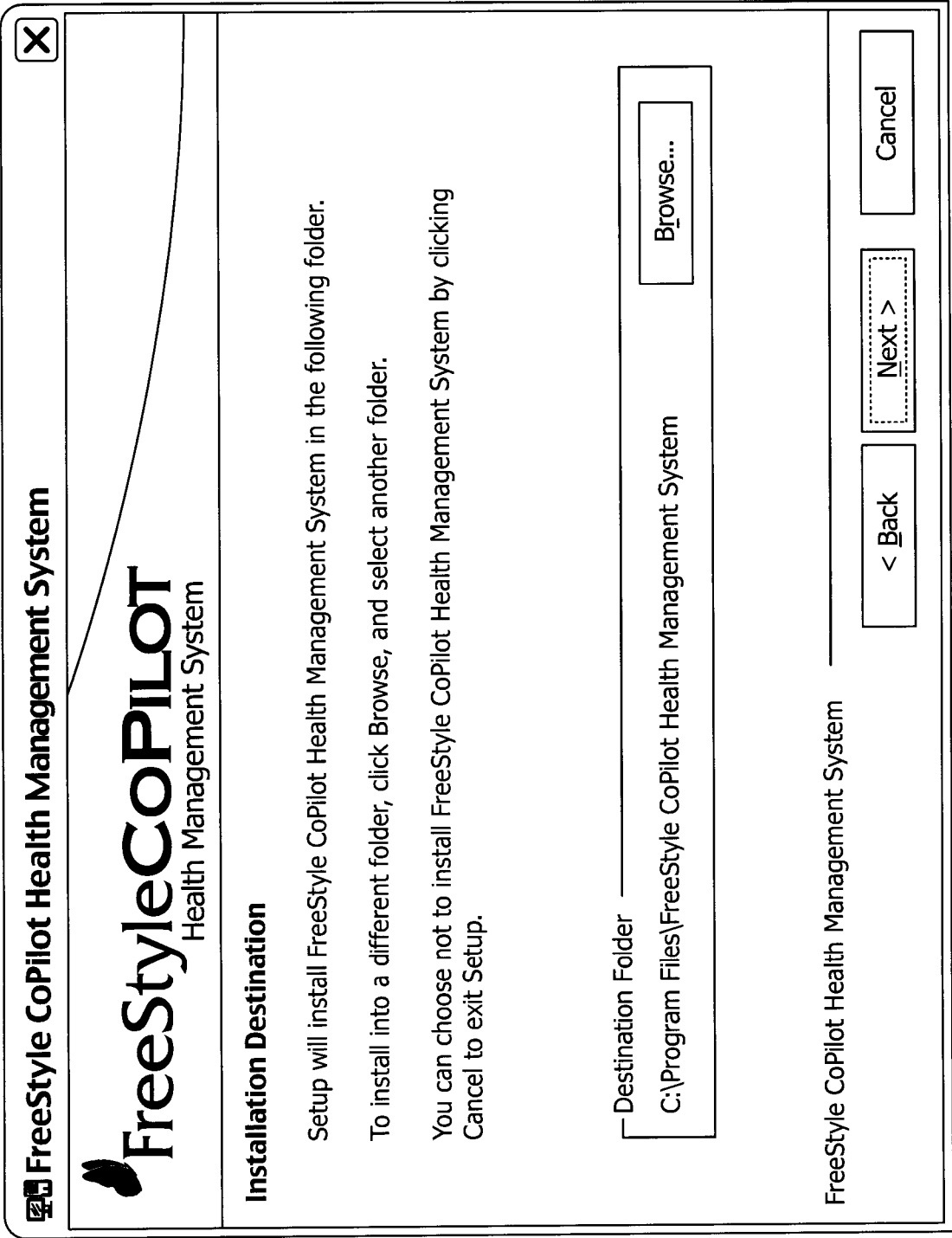


FIG. 3

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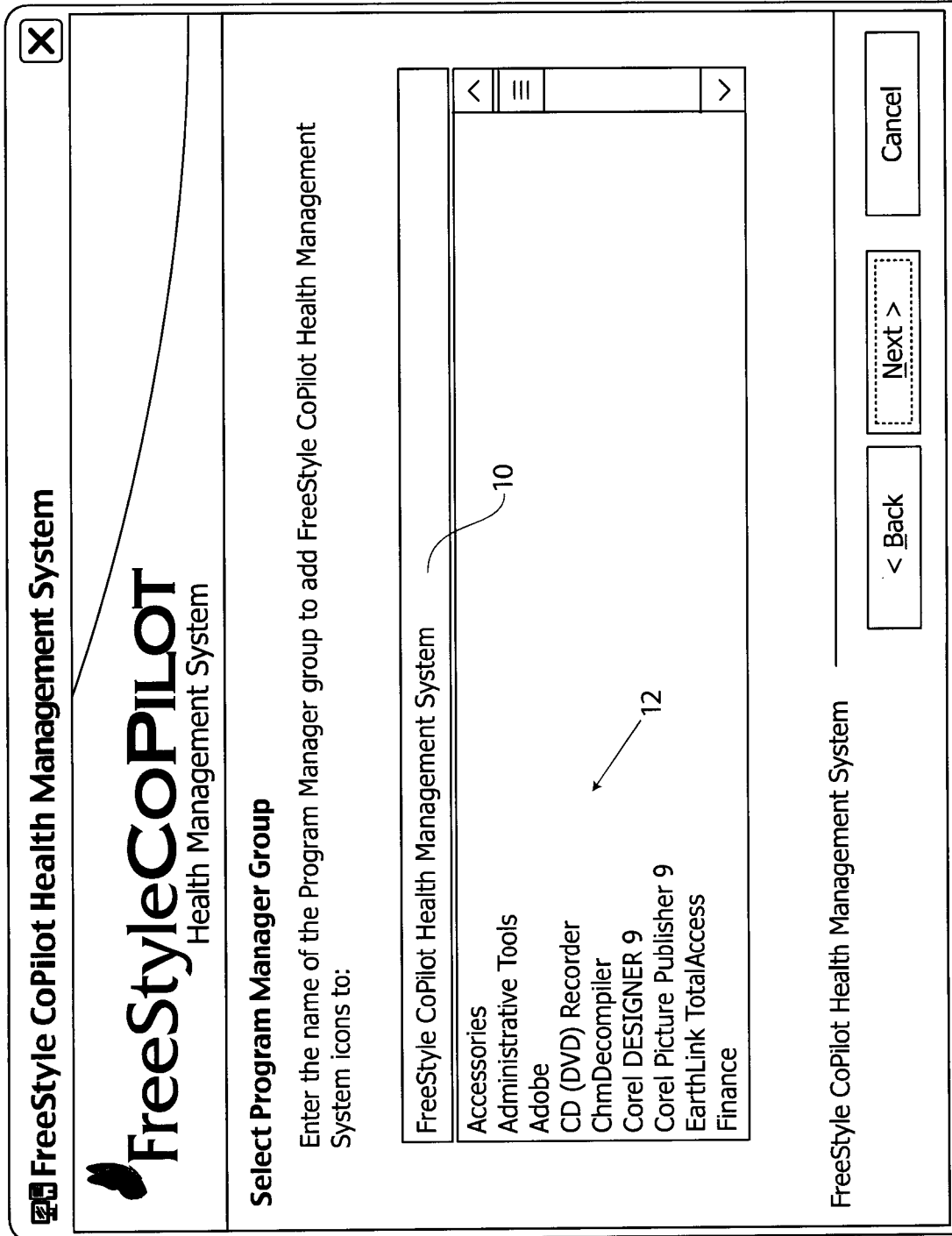


FIG. 4

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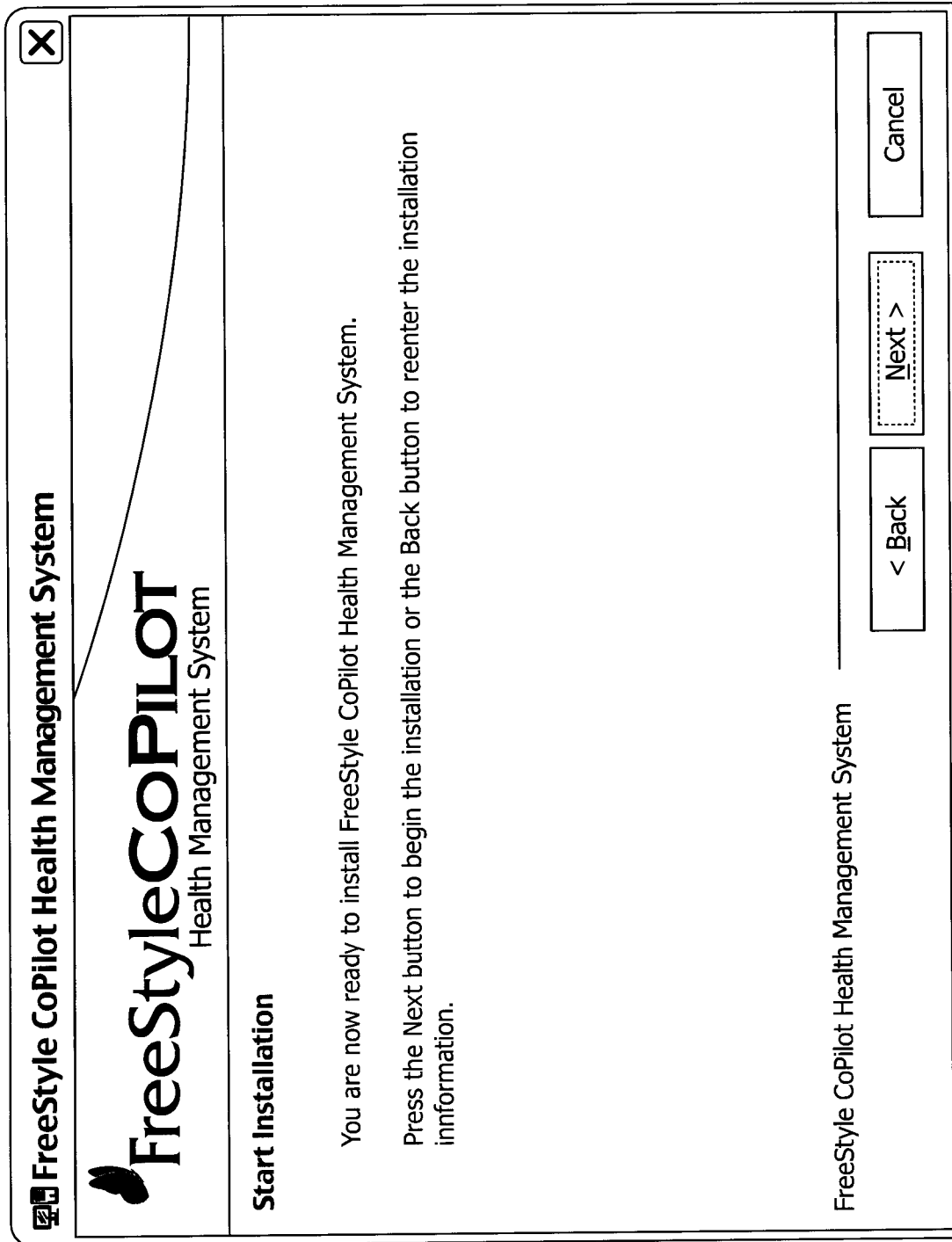


FIG. 5

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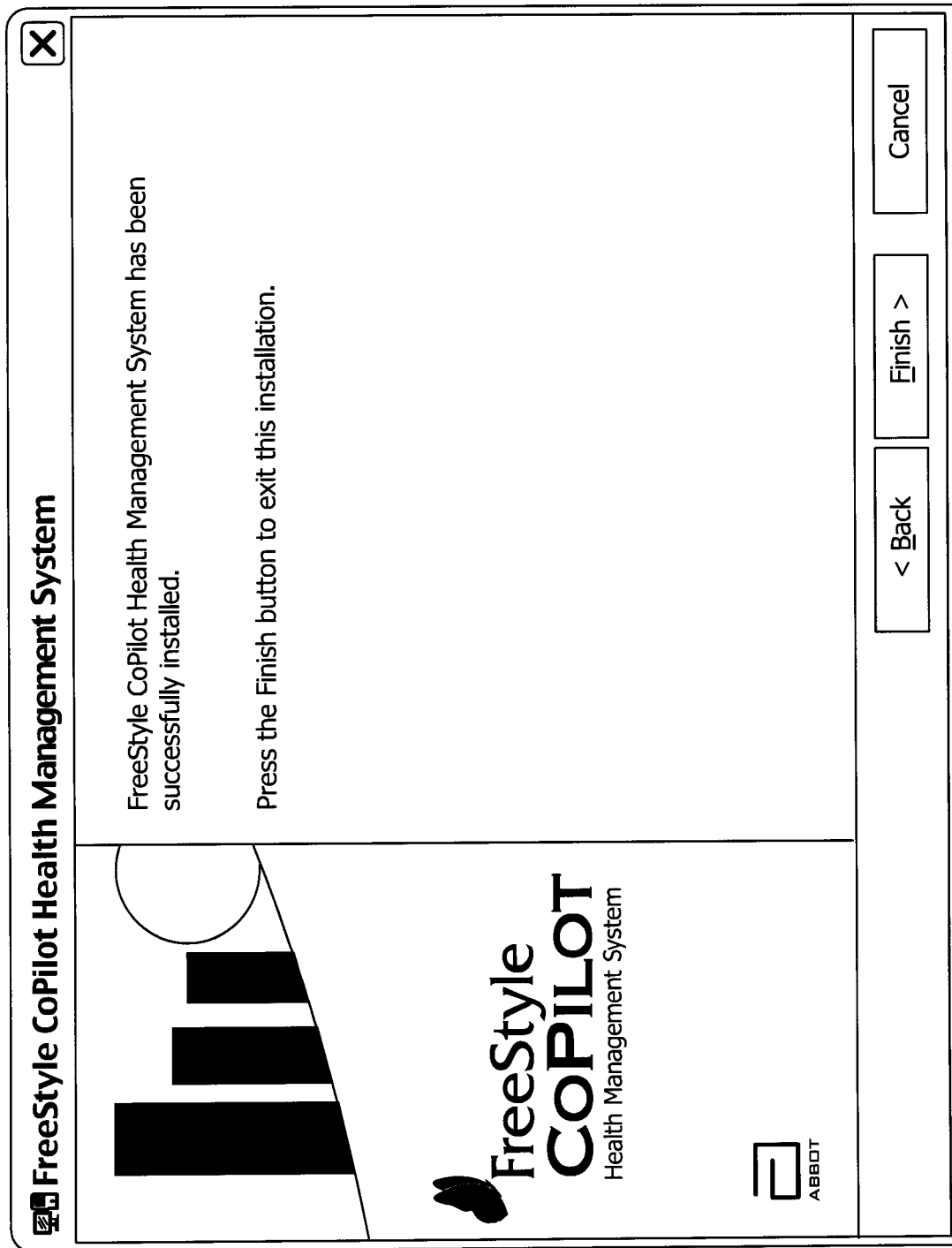


FIG. 6

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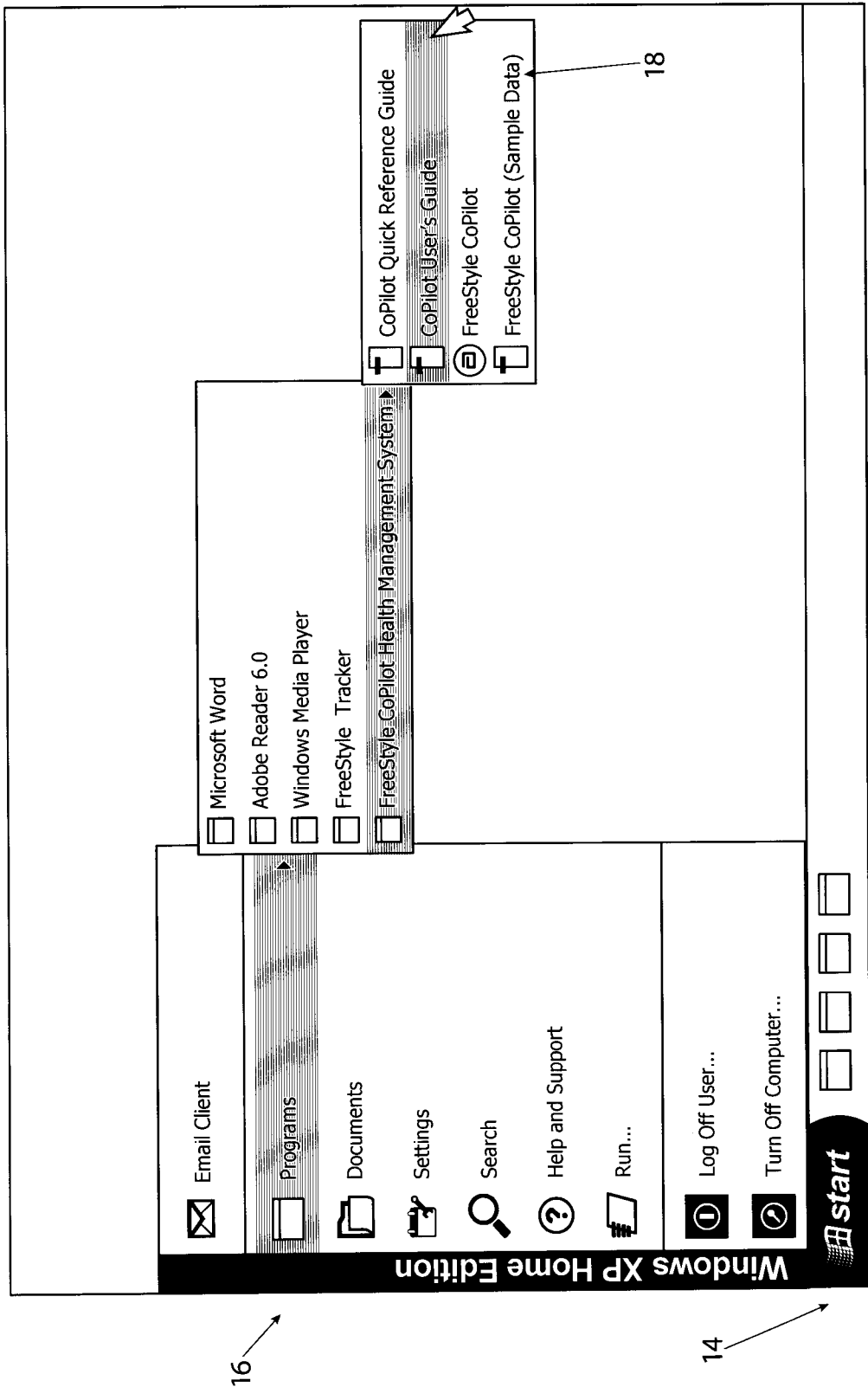
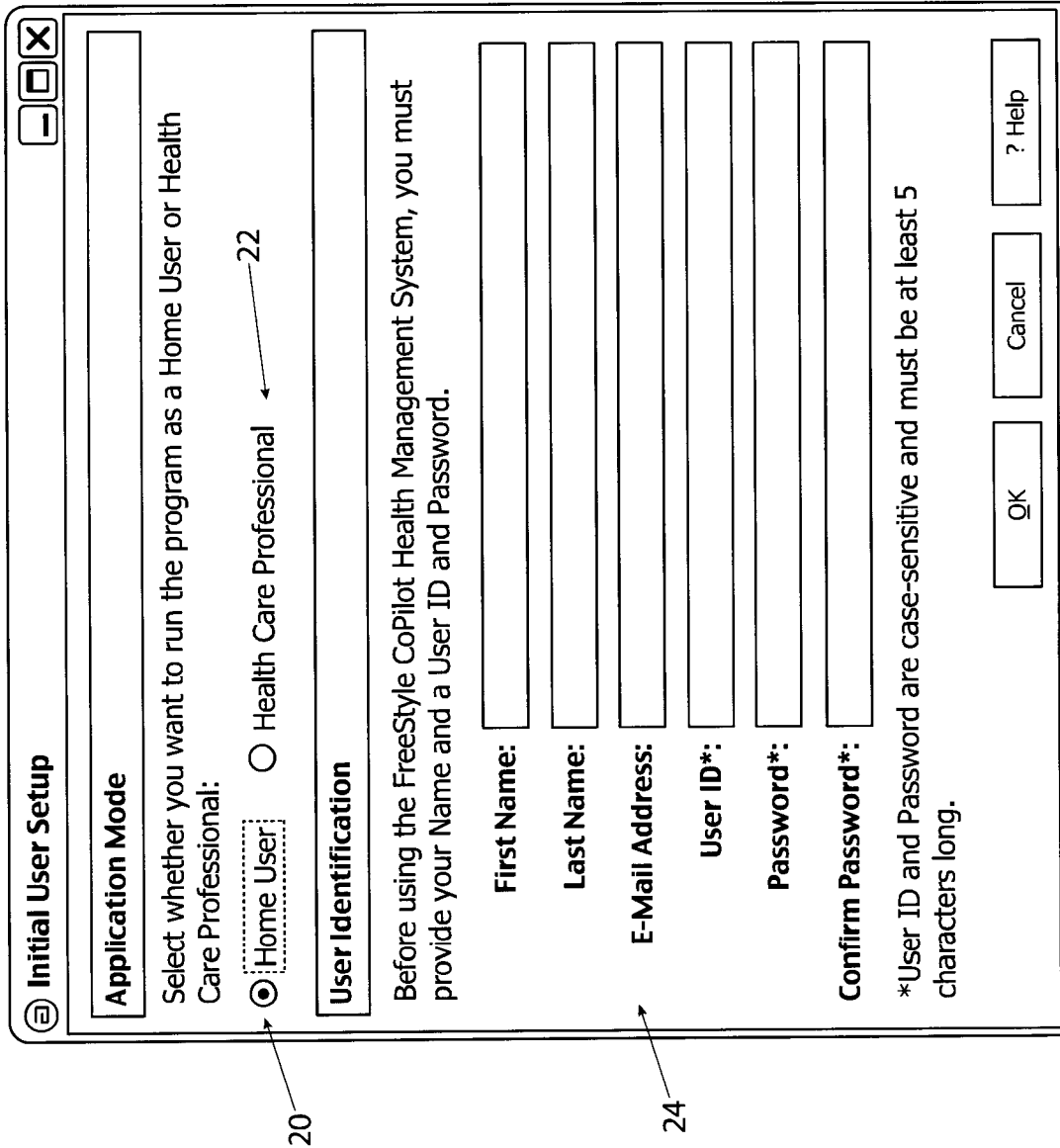


FIG. 7

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The dialog box is titled "Initial User Setup" and contains two main sections: "Application Mode" and "User Identification".

Application Mode: This section asks the user to select whether they want to run the program as a Home User or Health Care Professional. The "Home User" option is selected, indicated by a radio button and a dashed box labeled 20. The "Health Care Professional" option is unselected, indicated by a radio button and a label 22.

User Identification: This section contains a message: "Before using the FreeStyle CoPilot Health Management System, you must provide your Name and a User ID and Password." Below this message are five text input fields: "First Name:", "Last Name:", "E-Mail Address:", "User ID*:", and "Password*:". The "E-Mail Address:" label is pointed to by a line labeled 24. Below these fields is a "Confirm Password*:" field.

Buttons: At the bottom right of the dialog box are three buttons: "OK", "Cancel", and "? Help".

Footnote: A note at the bottom states: "*User ID and Password are case-sensitive and must be at least 5 characters long."

FIG. 8

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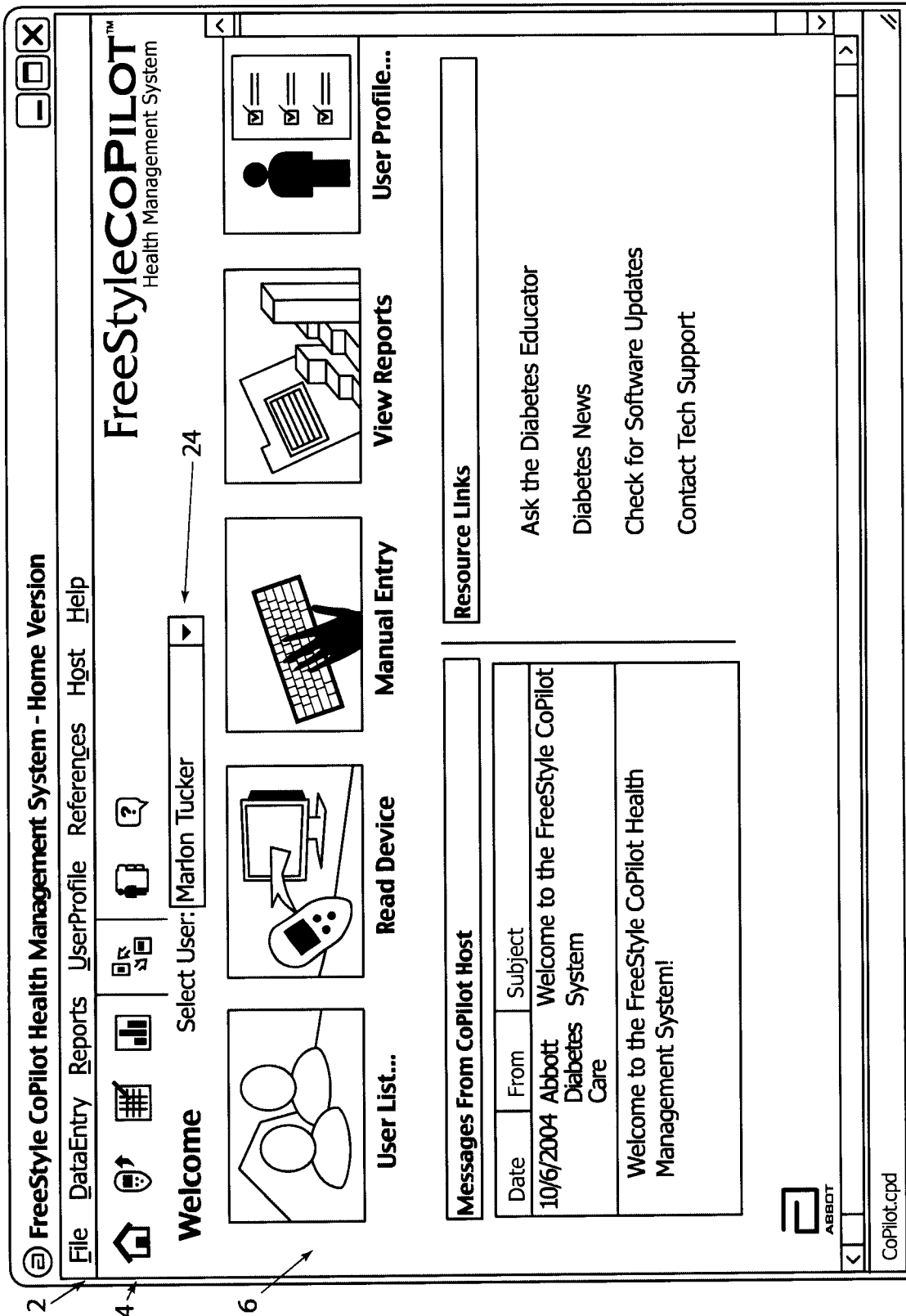


FIG. 9

Select HCP:

Dr. Katherine Lange

Select Patient:

Alberto Rose

FIG. 10

File	DataEntry	Reports	Use
	Home	Ctrl+H	
	Export		
	Add User...		
	Add HCP...		
	Print		
	Print Preview...		
	Page Setup...		
	Print Favorite Reports		
	Save as PDF...		
	System Settings...		
	Database Maintenance		
	Exit	Alt+F4	

FIG. 11

System Settings

X

File

Security

Require User Logon ☐

Database Options

Local ☒ Remote ☐

Test

Server Name

Local

Database Name

C:\Program Files\Freestyle CoPilot Health Ma

Browse

Host

Server URL

http://nucleus.ashvinsgroup.com/nucleus/NUCLEUS.dll

OK

Cancel

Apply

? Help

FIG. 12

Logon to System

Enter your user name and password to logon to the system:

User ID*:

Password*:

*User IDs and Passwords are case sensitive

OK

Quit

Forgot your password?

FIG. 13

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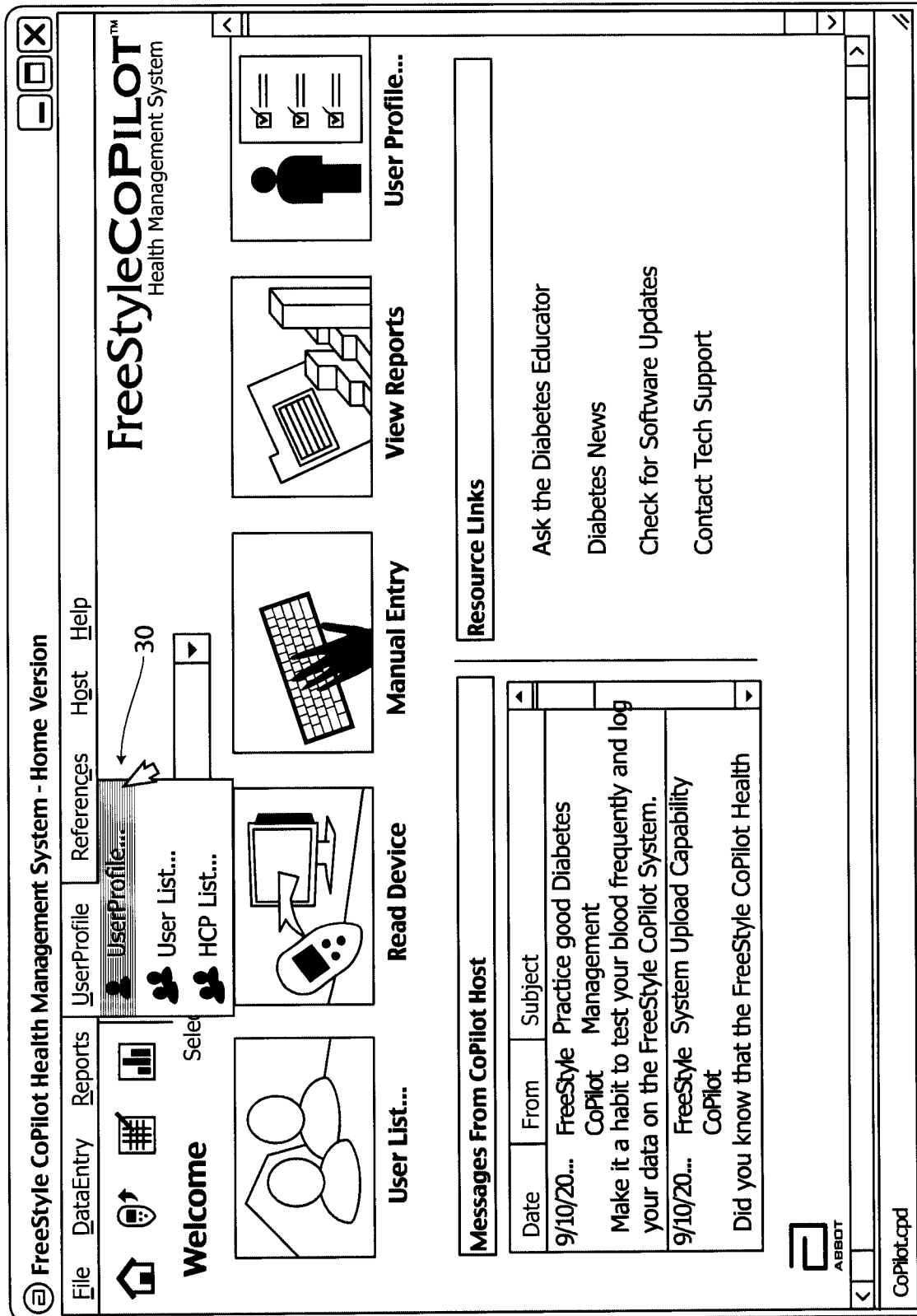


FIG. 14

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Profile for: Marlon Tucker

File Edit Help

User Information Health Profile Data Entry Preferences Glucose Targets Options

Contact Information

User ID* mtucker Host Account

Title

First* Marlon MI Last* Tucker

Address 1

Address 2

Address 3

City State/Province

Country Zip/Postal Code

E-Mail** mtucker@anynet.net

Phone Type Phone Number

Click here to add a new Phone

***Denotes a required field / **Required to Synchronize**

Assign Password

Password* *****

Confirm Password*

Insurance Providers

Provider Name

Click here to add a new Insurance Provider

Custom User Information

Custom 1

Custom 2

Custom 3

Custom 4

Custom 5

Rights...

OK Cancel Apply ? Help

FIG. 15

ⓐ Profile for: Marlon Tucker

File

Edit

Help

User Information

Health Profile

Data Entry Preferences

Glucose Targets

Options

General

Date Of Birth

Diabetes Type

Year Diagnosed

Height

Weight

Male ☐ Female ☐

Other Conditions

Condition	Date Diagnosed	Comment
Click here to add a new Condition		

Rights...

OK

Cancel

Apply

? Help

FIG. 16

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Condition	
Cardiovascular Disease (CVD)	▼
Cardiovascular Disease (CVD)	▲
Hyperlipidemia	
Hypertension	
Nephropathy	
Neuropathy	
Obesity	
Peripheral Arterial Disease (PAD)	
Retinopathy	▼

FIG. 17

Date Diagnosed	
	▼
◀ September ▶ 2004 ▶	
S	M T W T F S
	1 2 3 4
5 6 7 8 9	10 11
12 13 14 15 16 17 18	
19 20 21 22 23 24 25	
26 27 28 29 30	
Today Clear	

FIG. 18

FIG. 19

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Profile for: Marlon Tucker

File

Edit

Help

User Information

Health Profile

Data Entry Preferences

Glucose Targets

Options

Glucose Target Ranges

Mode

Standard

Restore Default Glucose Target Ranges

300

250

200

150

100

50

0

Glucose (mg/dL)

High

Low

180

80

All

Use Hypo/Hyper Values

Very Low

60

Very High

60

Glucose Unit of Measure

mg/dL

Time Periods

Pre-Bkfst

05:01 AM

to 7:00 AM

Post-Bkfst

07:01 AM

to 10:00 AM

Pre-Lunch

10:01 AM

to 12:00 PM

Post-Lunch

12:01 PM

to 03:00 PM

Pre-Dinner

03:01 PM

to 06:00 PM

Post-Dinner

06:01 PM

to 09:00 PM

Bed

09:01 PM

to 11:30 PM

Sleep

11:31 PM

to 05:00 AM

Restore Default Time Periods

Rights...

OK

Cancel

Apply

? Help

FIG. 20

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File Edit Help

User Information | Health Profile | Data Entry Preferences | Glucose Targets | Options |

Glucose Target Ranges

Mode

Pre/Post Meal

Standard

Pre/Post Meal

All Time Periods

Restore Default Glucose Target Ranges

300

250

200

150

100

50

0

Glucose (mg/dL)

High

Low

180

80

All

Pre-Meal

Use Hypo/Hyper Values

☐

Very Low

60

Very High

250

Post-Meal

180

80

All

Post-Meal

Glucose Unit of Measure

mg/dL

FIG. 21

User Information | Health Profile | Data Entry Preferences | Glucose Targets | Options |

Glucose Target Ranges

Mode

Pre/Post Meal

Restore Default Glucose Target Ranges

300

250

200

150

100

50

0

Glucose (mg/dL)

High

Low

180

80

All

Pre-Meal

180

80

All

Post-Meal

Use Hypo/Hyper Values

☒

Very Low

60

Very High

250

Glucose Unit of Measure

mg/dL

FIG. 22A

FIG. 22B

22/157

44 46 48

Use Hypo/Hyper Values ☒ **Very Low** 60 **Very High** 250

Glucose Unit of Measure

FIG. 23

23/157

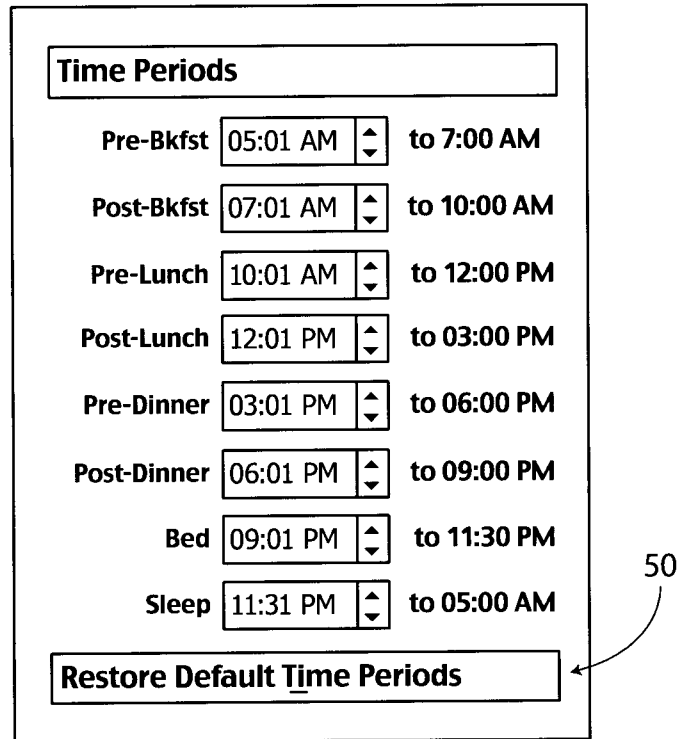


FIG. 24 is a screenshot of a 'Time Periods' configuration window. The window has a title bar 'Time Periods'. Inside, there are eight rows of time period settings, each with a label, a time input field, and a 'to' time. The labels are: Pre-Bkfst, Post-Bkfst, Pre-Lunch, Post-Lunch, Pre-Dinner, Post-Dinner, Bed, and Sleep. The time input fields are: 05:01 AM, 07:01 AM, 10:01 AM, 12:01 PM, 03:01 PM, 06:01 PM, 09:01 PM, and 11:31 PM. The 'to' times are: 7:00 AM, 10:00 AM, 12:00 PM, 03:00 PM, 06:00 PM, 09:00 PM, 11:30 PM, and 05:00 AM. At the bottom of the window is a button labeled 'Restore Default Time Periods'. A curved arrow labeled '50' points to this button.

Time Period	Start Time	End Time
Pre-Bkfst	05:01 AM	to 7:00 AM
Post-Bkfst	07:01 AM	to 10:00 AM
Pre-Lunch	10:01 AM	to 12:00 PM
Post-Lunch	12:01 PM	to 03:00 PM
Pre-Dinner	03:01 PM	to 06:00 PM
Post-Dinner	06:01 PM	to 09:00 PM
Bed	09:01 PM	to 11:30 PM
Sleep	11:31 PM	to 05:00 AM

Restore Default Time Periods

FIG. 24

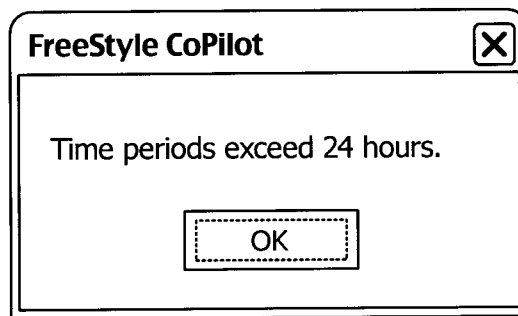


FIG. 25 is a screenshot of a 'FreeStyle CoPilot' error dialog box. The dialog has a title bar 'FreeStyle CoPilot' with a close button (X). The main text inside the dialog reads: 'Time periods exceed 24 hours.' Below the text is an 'OK' button.

FreeStyle CoPilot

Time periods exceed 24 hours.

OK

FIG. 25

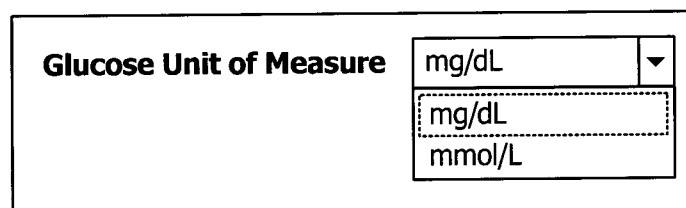


FIG. 26 is a screenshot of a 'Glucose Unit of Measure' selection window. The window has a title bar 'Glucose Unit of Measure'. Inside, there is a dropdown menu showing 'mg/dL' as the selected unit. Below the dropdown menu are two buttons: 'mg/dL' and 'mmol/L'.

Glucose Unit of Measure

mg/dL

mg/dL

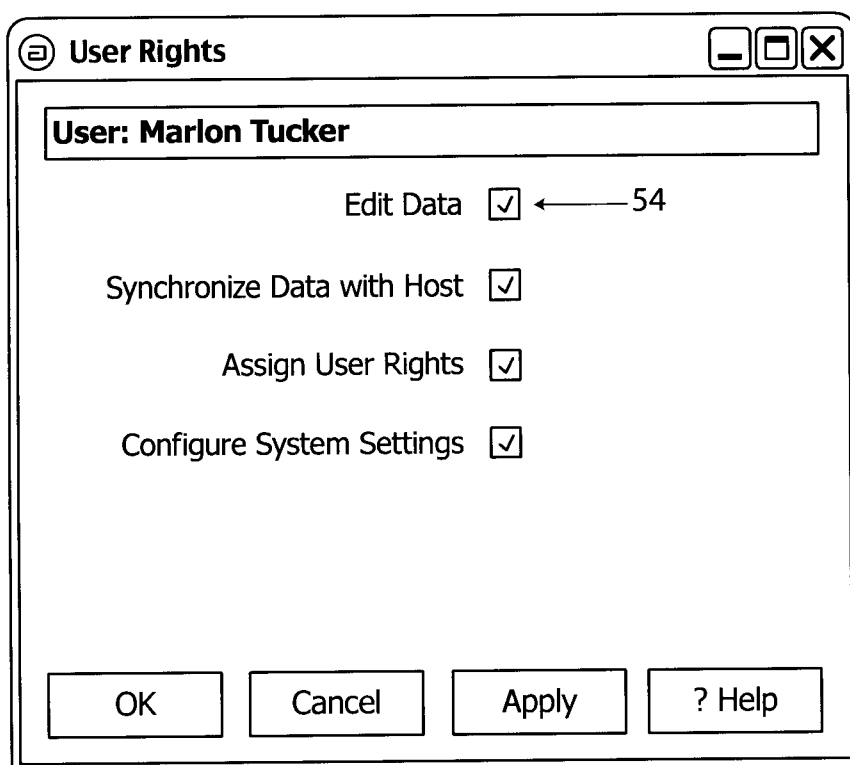
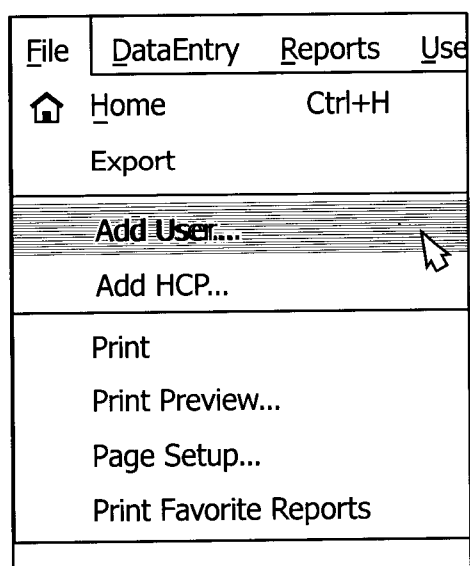
mmol/L

FIG. 26

52

FIG. 27

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**FIG. 28****FIG. 29**

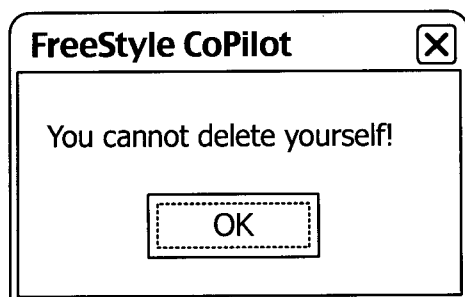
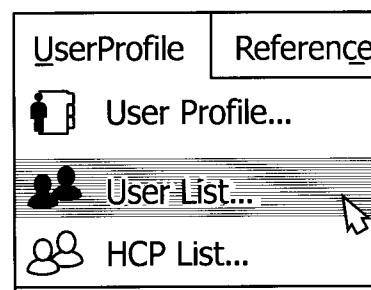
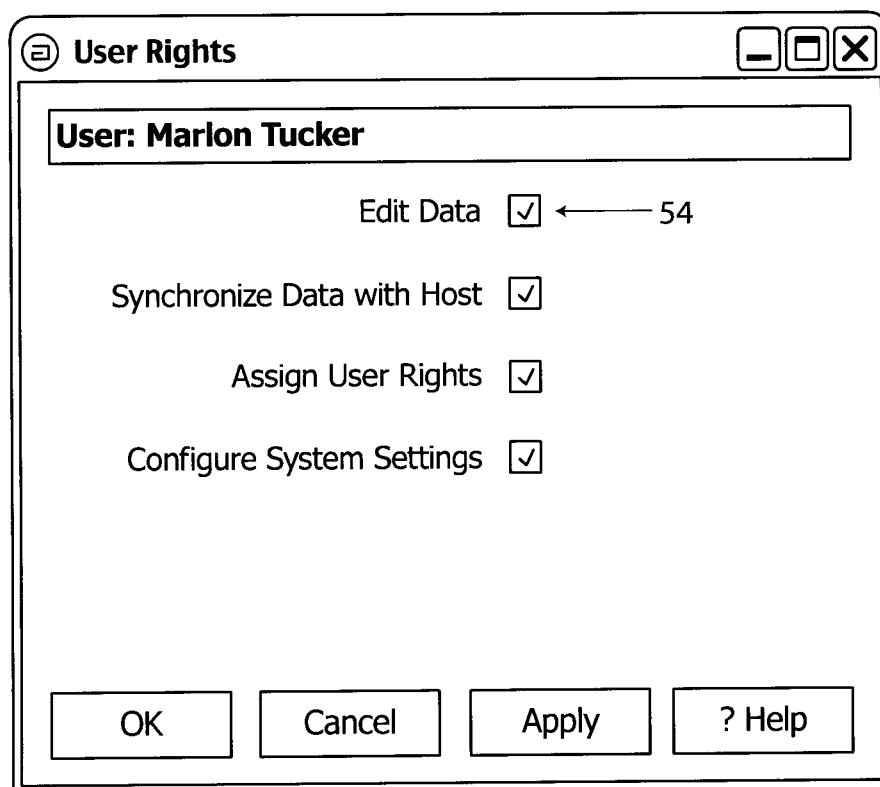
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Profile for: Marlon Tucker			
File			
Last	First	MI	ID
Administrator		System Admin	
Tucker	Marlon		mtucker
Tucker	Linda	ltucker	

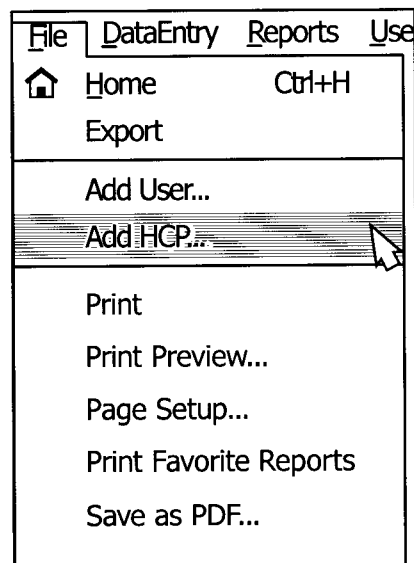
OK ? Help

FIG. 30

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**FIG. 31****FIG. 32****FIG. 33**

28/157

**FIG. 34**

29/157

X

Profile for:

File Edit Help

Contact Information

HCP ID*

Host Account

Title

HCP Type

First

MI

Last*

Facility**

Address 1

Address 2

Address 3

City

State/Province

Country

Zip/Postal Code

Email

Phone

Type

Phone Number

Click here to add a new Phone

No data to display

*Denotes a required field / ** Required to Synchronize

OK

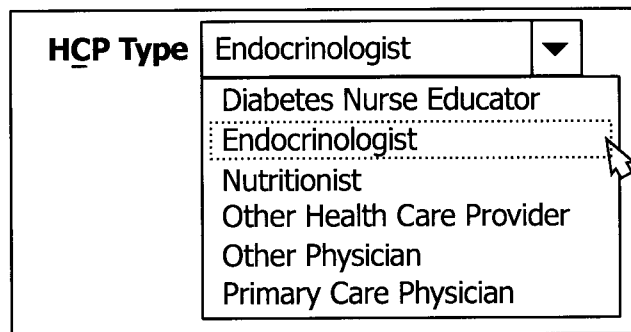
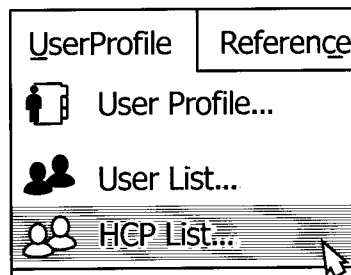
Cancel

Apply

? Help

FIG. 35

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**FIG. 36****FIG. 37**

ⓧ

HCP List

File

+







Last

First

MI

ID

Sloane

Jeremy

jsloane

OK

? Help

FIG. 38

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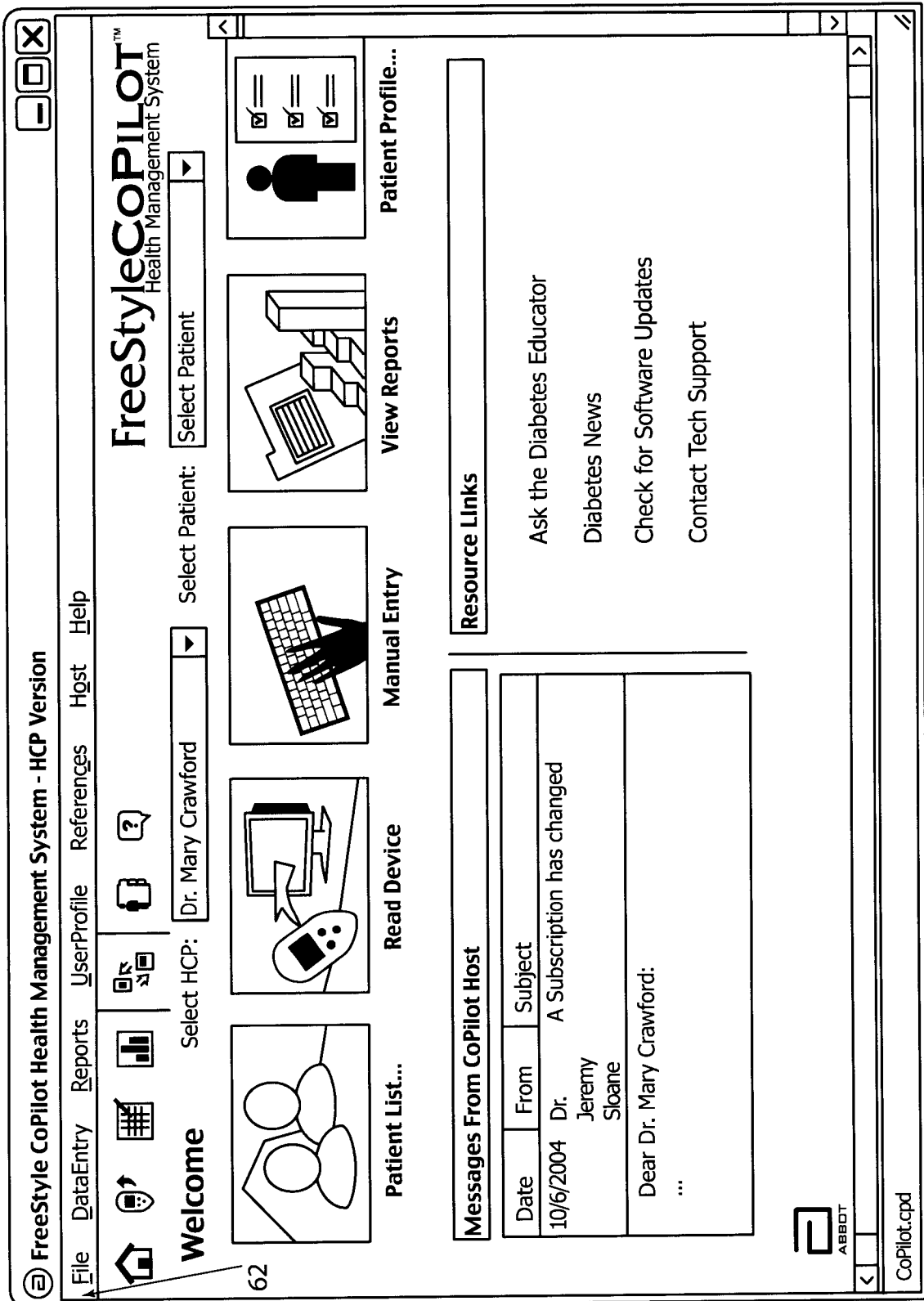
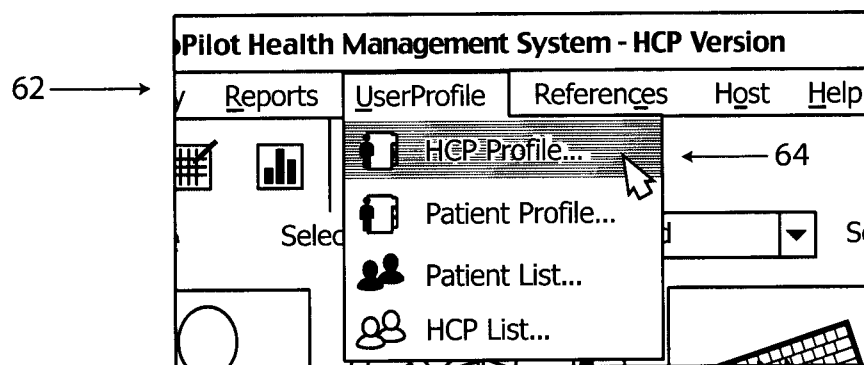


FIG. 39

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**FIG. 40**

✕

Profile for: Dr. Jeremy Sloane

File

Edit

Help

User Information

Glucose Targets

Options

Contact Information

User ID*

jsloane

Host Account

Title

Dr.

HCP Type

First

Jeremy

MI

Last*

Sloane

Facility**

Gotham Diabetes Center

Address 1

100 Main Street

Address 2

Address 3

City

Anywhere

State/Province

AK

Country

USA

Zip/Postal Code

Email

jsloane@anynet.net

Phone

Type

Phone Number

Click here to add a new Phone

No data to display

*Denotes a required field / ** Required to Synchronize

Rights...

OK

Cancel

Apply

? Help

Assign Password

Password*

Confirm Password*

FIG. 41

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66

⊞ HCP Profile for: Dr.Jeremy Sloane

File

Edit

Help

User Information

Glucose Targets

Options

Glucose Target Ranges

Mode

Standard

Restore Default Glucose Target Ranges

300

250

200

150

100

50

0

Glucose (mg/dL)

High

Low

180

80

All

Use Hypo/Hyper Values

Very Low

60

Very High

250

Glucose Unit of Measure

mg/dL

Rights...

OK

Cancel

Apply

? Help

FIG. 42

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Ⓜ HCP Profile for: Dr.Jeremy Sloane

File Edit Help

User Information | **Glucose Targets** | Options

Glucose Target Ranges

Mode

Standard

Standard

Pre/Post Meal

All Time Periods

Restore Default Glucose Target Ranges

300

250

200

150

100

50

0

High

Low

180

80

All

Use Hypo/Hyper Values

☐

Very Low

60

Very High

250

Glucose Unit of Measure

mg/dL

Rights...

OK

Cancel

Apply

? Help

FIG.43

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Glucose Target Ranges	
Mode	Pre/Post Meal ▼
Restore Default Glucose Target Ranges	
Glucose (mg/dL)	300
	250
	200
	150
	100
	50
	0
	0
High	180 ▼
Low	80 ▼
All Pre-Meal	
High	180 ▼
Low	80 ▼
All Post-Meal	
Use Hypo/Hyper Values ☒ Very Low 60 ▼ Very High 250 ▼	
Glucose Unit of Measure mg/dL ▼	

Glucose Target Ranges	
Mode	All Time Periods ▼
Restore Default Glucose Target Ranges	
Glucose (mg/dL)	300
	250
	200
	150
	100
	50
	0
	0
High	180 ▼
Low	80 ▼
Pre-Bkfst	
High	180 ▼
Low	80 ▼
Post-Bkfst	
High	180 ▼
Low	80 ▼
Pre-Lunch	
High	180 ▼
Low	80 ▼
Post-Lunch	
High	180 ▼
Low	80 ▼
Pre-Dinner	
High	180 ▼
Low	80 ▼
Post-Dinner	
High	180 ▼
Low	80 ▼
Bed	
High	180 ▼
Low	80 ▼
Sleep	
Use Hypo/Hyper Values ☐ Very Low 60 ▼ Very High 250 ▼	
Glucose Unit of Measure mg/dL ▼	

FIG. 44

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Use Hypo/Hyper Values	☒	Very Low	60	↑	↓	Very High	250	↑	↓
Glucose Unit of Measure							mg/dL	▼	

FIG. 45

Glucose Unit of Measure	mg/dL	▼
mg/dL mmol/L		

FIG. 46

FIG. 47

FIG. 47

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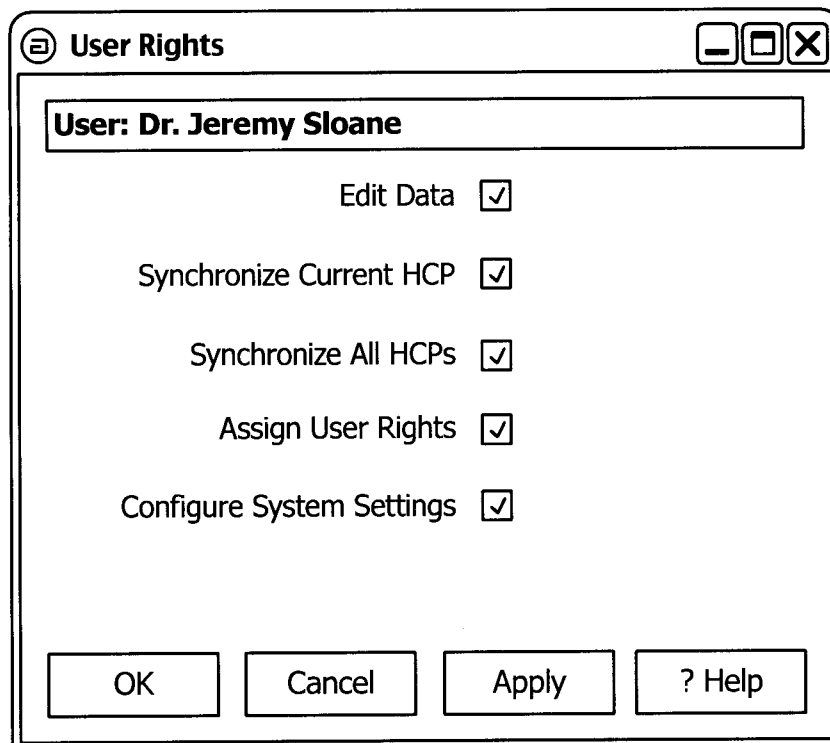


FIG. 48

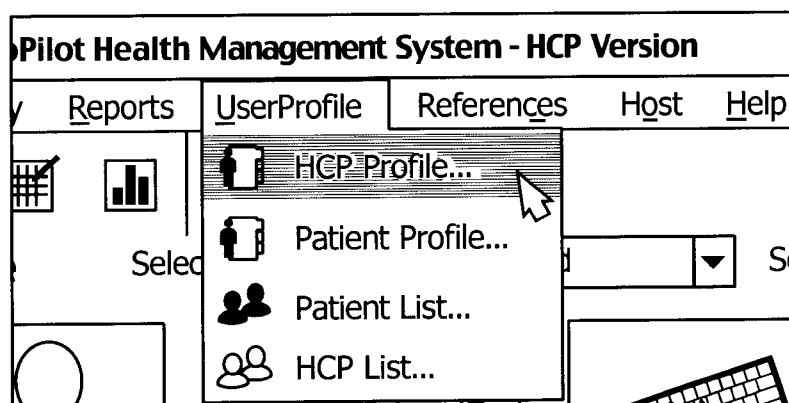


FIG. 49

⌵

⊞

Patient List

✕

File

+







Last	First	MI	ID	Type
Doe	John		AOF7eGX4KQASOPPPRK8z	
Tucker	Marlon		mtucker	

OK

? Help

FIG. 50

FIG. 51

ⓧ

Patient List

File

+







Last	First	MI	ID	Type
Doe	John		AOF7eGX4KQASOPPPRK8z	
Tucker	Marlon		mtucker	

OK

? Help

FIG. 52

⌵

Patient List

✕

File

+







Last

First

MI

ID

Doe

John

ACF7eGX4KQASOPPPRK8z

Tucker

Marlon

mtucker

OK

? Help

FIG. 53

FIG. 54

Last	First	MI	ID	Authorization Level		
Tucker	Marlon		mtucker	☐ None	☐ Read Only	☒ Full
				☐ Owner		

FIG. 55

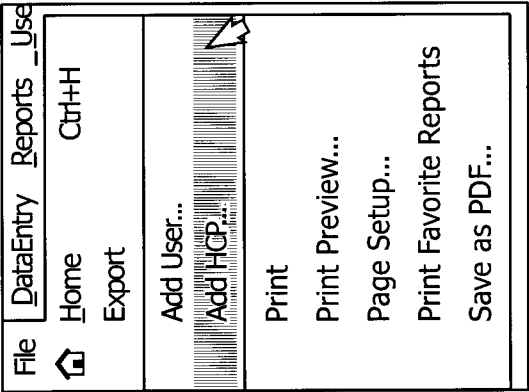


FIG. 56

⊞ HCP List

✕

File

+







Last	First	MI	ID
Administrator	System		Admin
Andrews	David		dandrews
Crawford	Mary		mcrawford
Meyer	Samuel		smeyer
Sloane	Jeremy		jsloane
Thatcher	Rhonda		rthatcher

OK

? Help

FIG. 57

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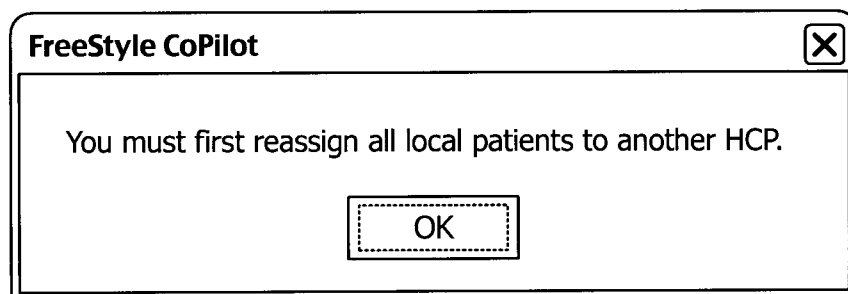
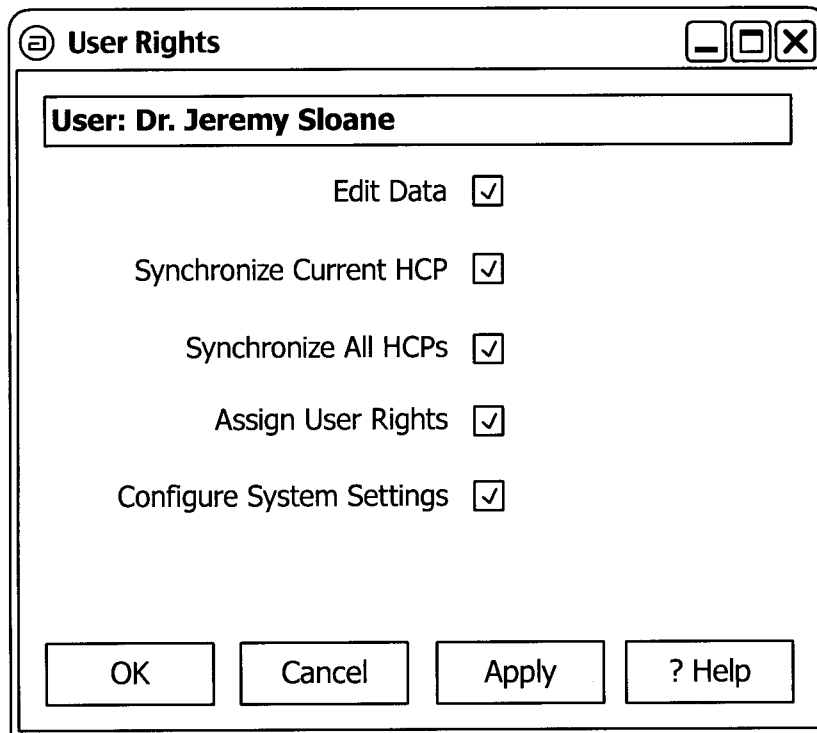
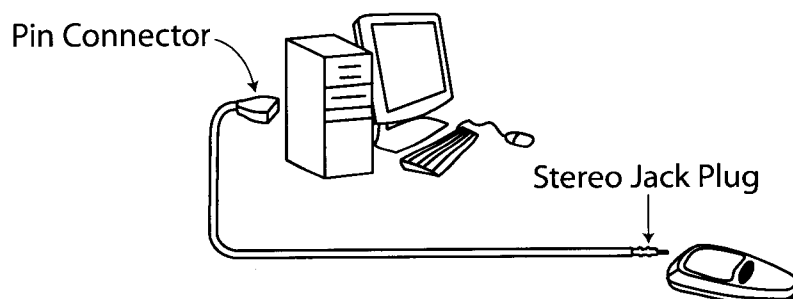


FIG. 58

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**FIG. 59****Cable Setup Diagram****FIG. 60**

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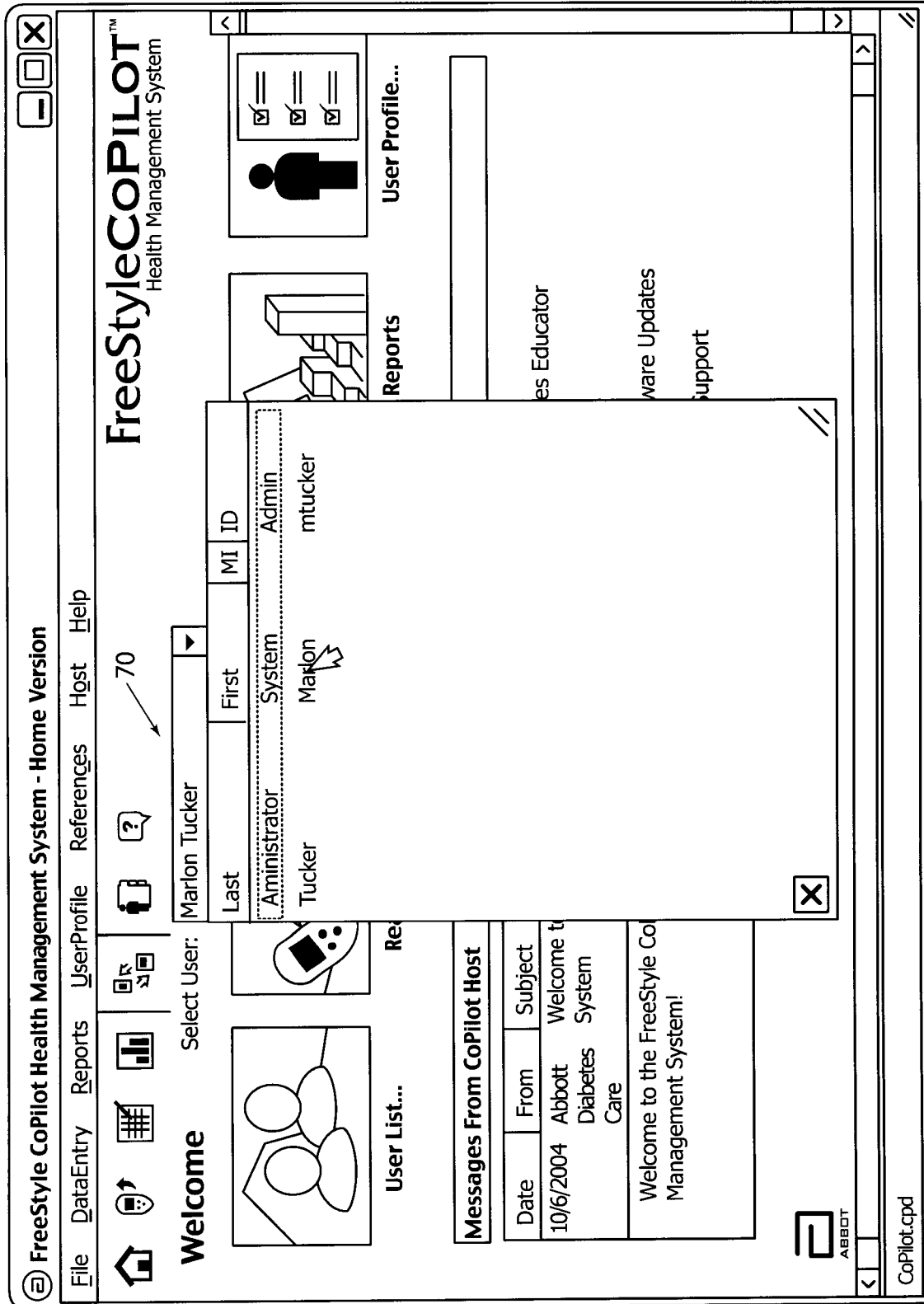


FIG. 61

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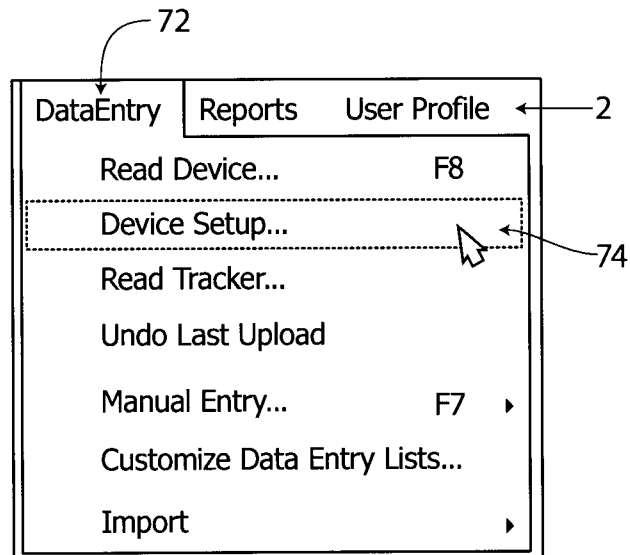


FIG. 62

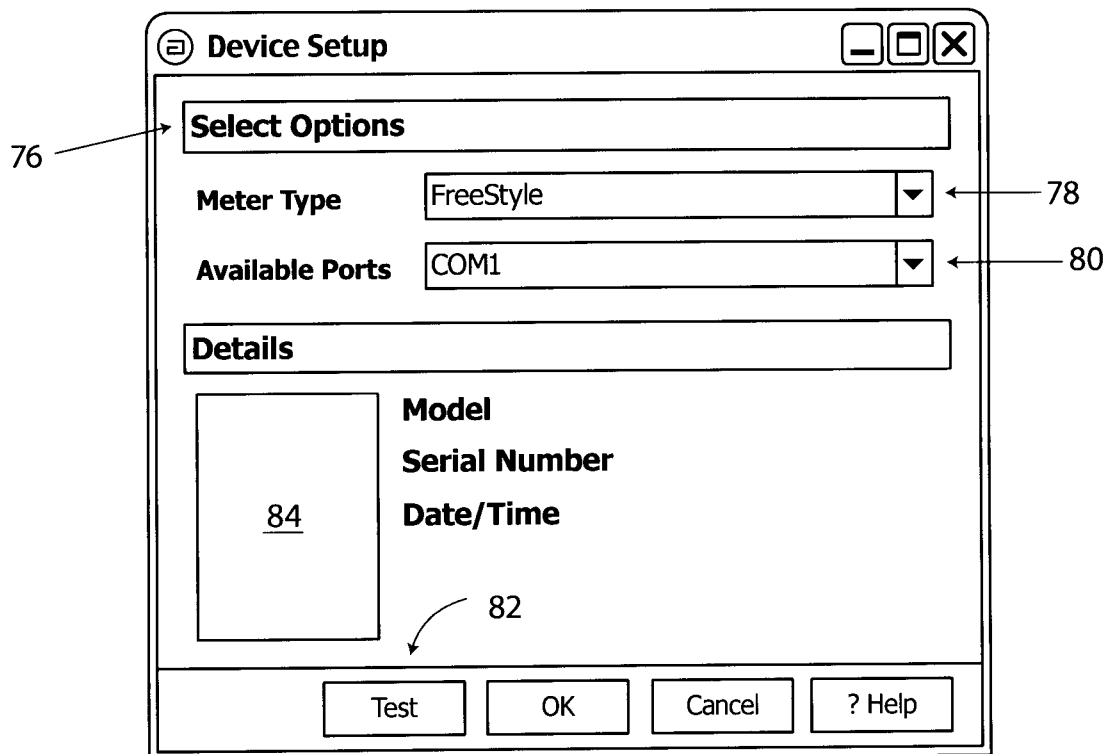


FIG. 63

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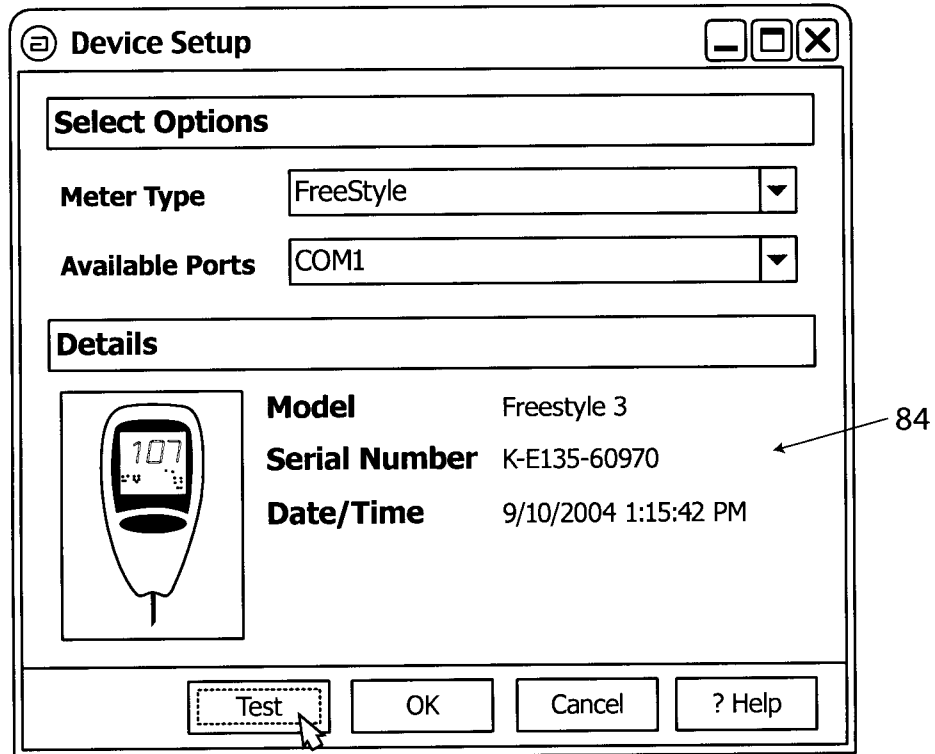


FIG. 64

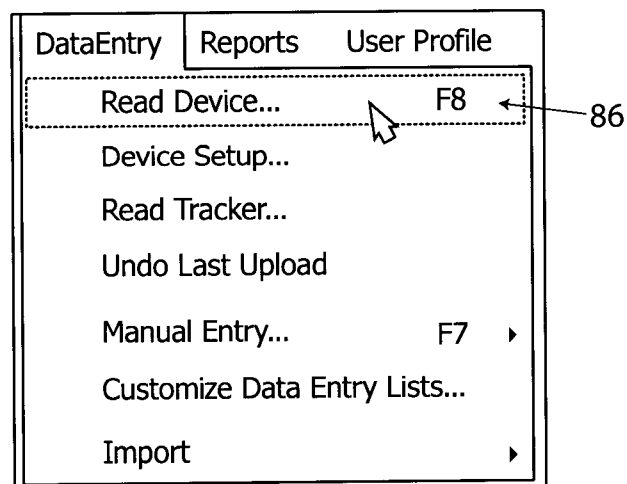


FIG. 65

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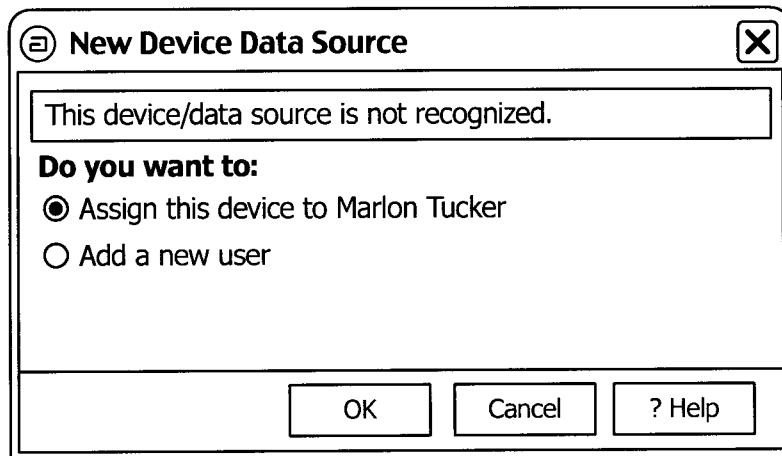


FIG. 66

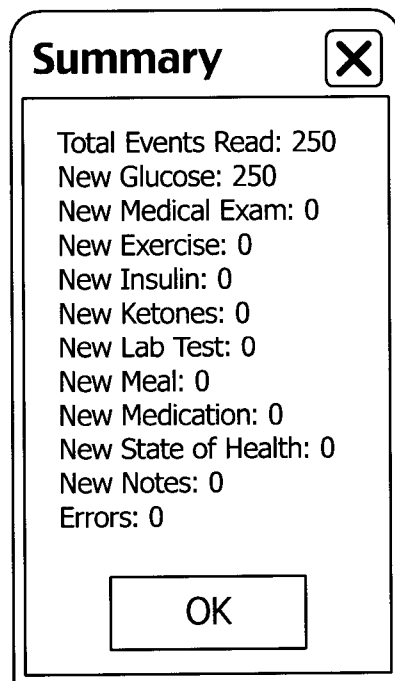
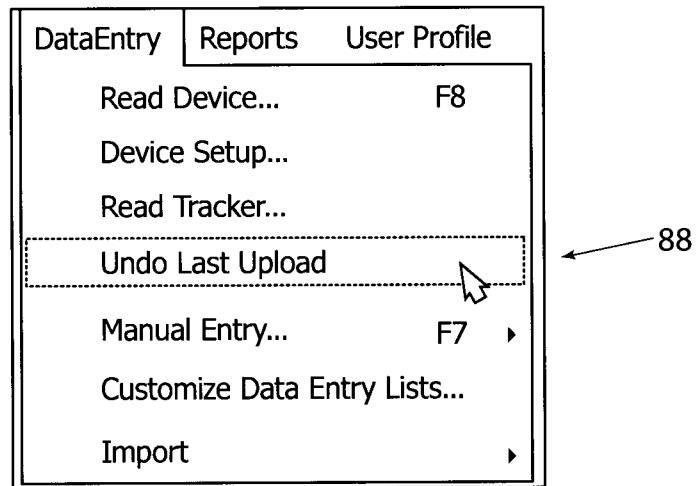
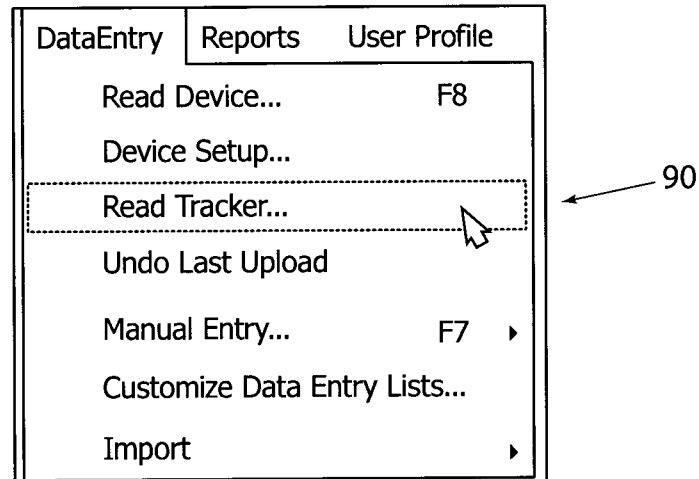


FIG. 67

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**FIG. 68****FIG. 69**

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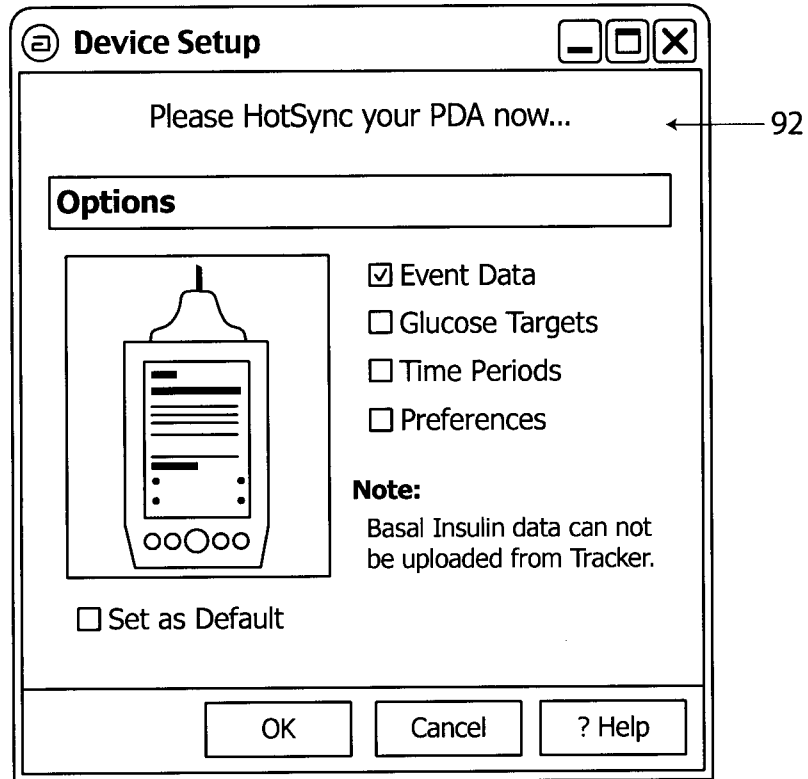


FIG. 70

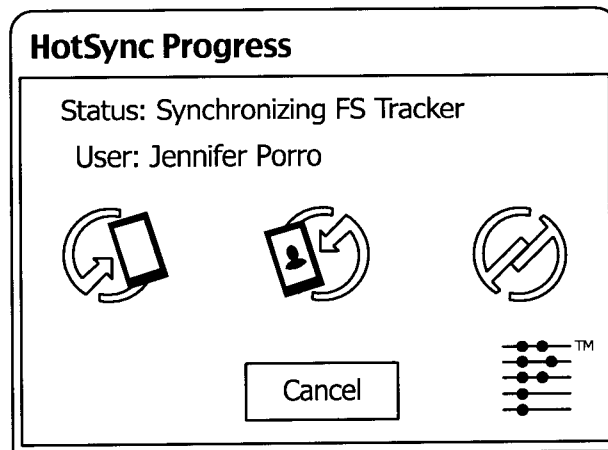


FIG. 71

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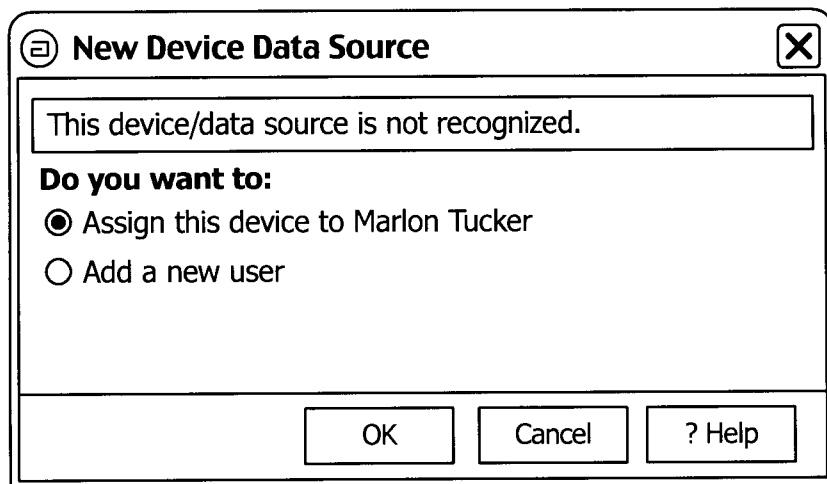


FIG. 72

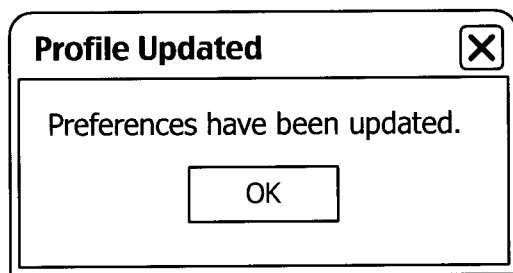


FIG. 73

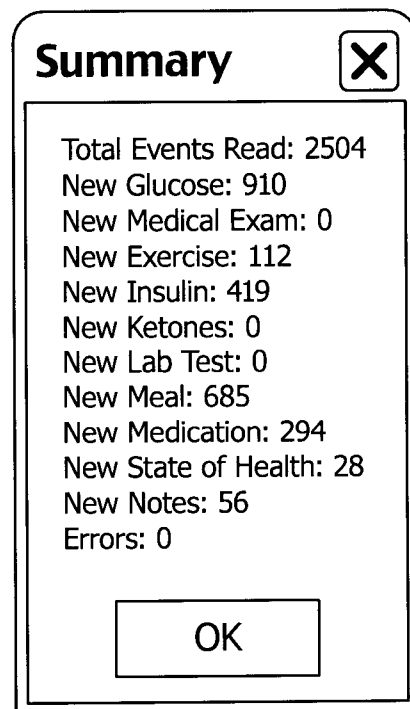
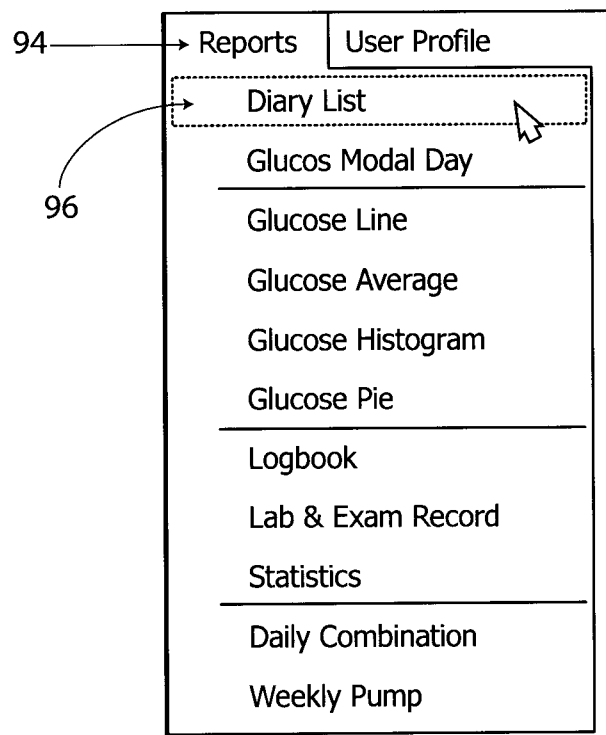


FIG. 74

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**FIG. 75**

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Data Entry [Min] [Max] [Close]

Menu

G [G] [K] [A]

Glucose Reading

Date [9/10/2004] Time [2:26 PM] Time Period [Post-Lunch] 98

Glucose Value (mg/dL) [] ← 100

Sample Site [] ← 102

Hours Since Last Meal [] ← 104

Calibration Code [] ← 106

Control Reading ☐ ← 108

Data Source Manual

Comment

[OK] [Cancel] [Apply] [Help]

FIG. 76

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Data Entry

Menu

Bolus Insulin

Date: 9/10/2004 Time: 11:47 AM Meal: Pre-Lunch

	Insulin Name	Dosage (Units)	Injection Type
☒	Humalog	1.00	Bolus

☒ Check the check box to include an entry

Comment

OK Cancel ? Help

110

112

98

FIG. 77

Data Entry

Menu

G K

Meal

Date Time Meal

Food Item	Svgs	Carbs (g)	Total Carbs (g)
Click here to add a new meal item			

Use Only Favorite Foods ☐

Comment

OK Cancel Apply ? Help

FIG. 78

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Data Entry

Menu

G        **K** 

 **Meal**

Date Time Meal

Food Item	Svgs	Carbs (g)	Total Carbs (g)
Milk, 1/2% (1 cup)	1	11	11
8" white cake with whip cream (Chuck E. Cheese) (1 slice)	1	26	26
Albacore tuna sandwich, light, small (Schlotzsky's) (1 serving)	1	50	50
			76.00

Use Only Favorite Foods ☐

Comment

OK Cancel Apply ? Help

FIG. 79

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Data Entry

Menu

G        **K** 

 **Exercise**

Date Time Time Period

☒	Type	Duration	Intensity
Click here to add a new row			
☒	Aerobics	0:30	Low

Check the check box to include an entry ☒

Comment

FIG. 80

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Data Entry

Menu

G        **K** 

 **State of Health**

Date Time

State of Health

Comment

Stress
Infection
Tired
Stress
Fever
Flu
Allergy
Dizzy
Menstruation/Period

OK Cancel Apply ? Help

FIG. 81

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Data Entry

Menu

G        **K** 

 **Medication**

Date Time Time Period

☒	Medication	Dosage	# of Pills
Click here to add a new row			
☒	Prandin 2 mg		1

Check the check box to include an entry ☒

Comment

FIG. 82

65/157

Data Entry

Menu

G        **K** 

 **Medical Exam**

Date

Exam Type

Examined By

Comment

FIG. 83

66/157

Data Entry

Menu

G        **K** 

 **Lab Test Result**

Date

Test Type

Result Value

Units

Reference Range

Comment

A1C
ALT
AST
BP
BUN (Blood Urea Nitrogen)
Cholesterol HDL
Cholesterol LDL
Cholesterol Total

FIG. 84

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Data Entry [Minimize] [Maximize] [Close]

Menu

G **K**

Ketones (Blood)

Date Time Time Period

Value (mmol/L)

Sample Site

Calibration Code

Control Reading ☐

Data Source |

Comment

FIG. 85

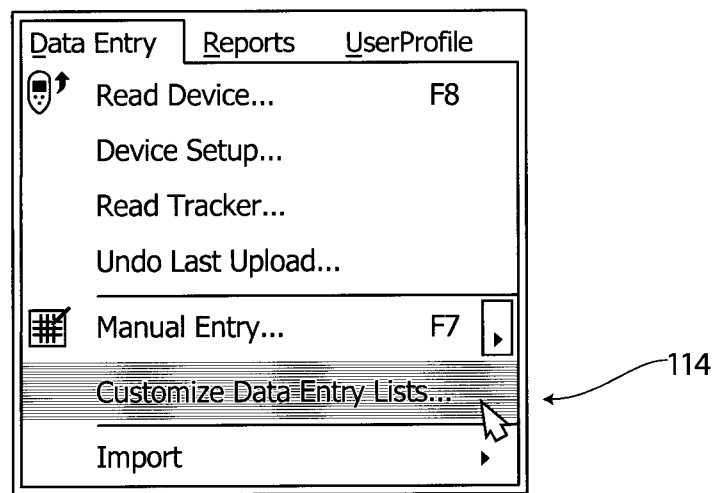
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<u>S</u>ample Site	
<u>C</u>alibration Code	Abdomen
<u>C</u>ontrol Reading	Finger
<u>D</u>ata Source	Hand
<u>C</u>omment	Upper Arm
	Calf
	Forearm
	Thigh
	Venipuncture

FIG. 86

FIG. 87

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**FIG. 88**

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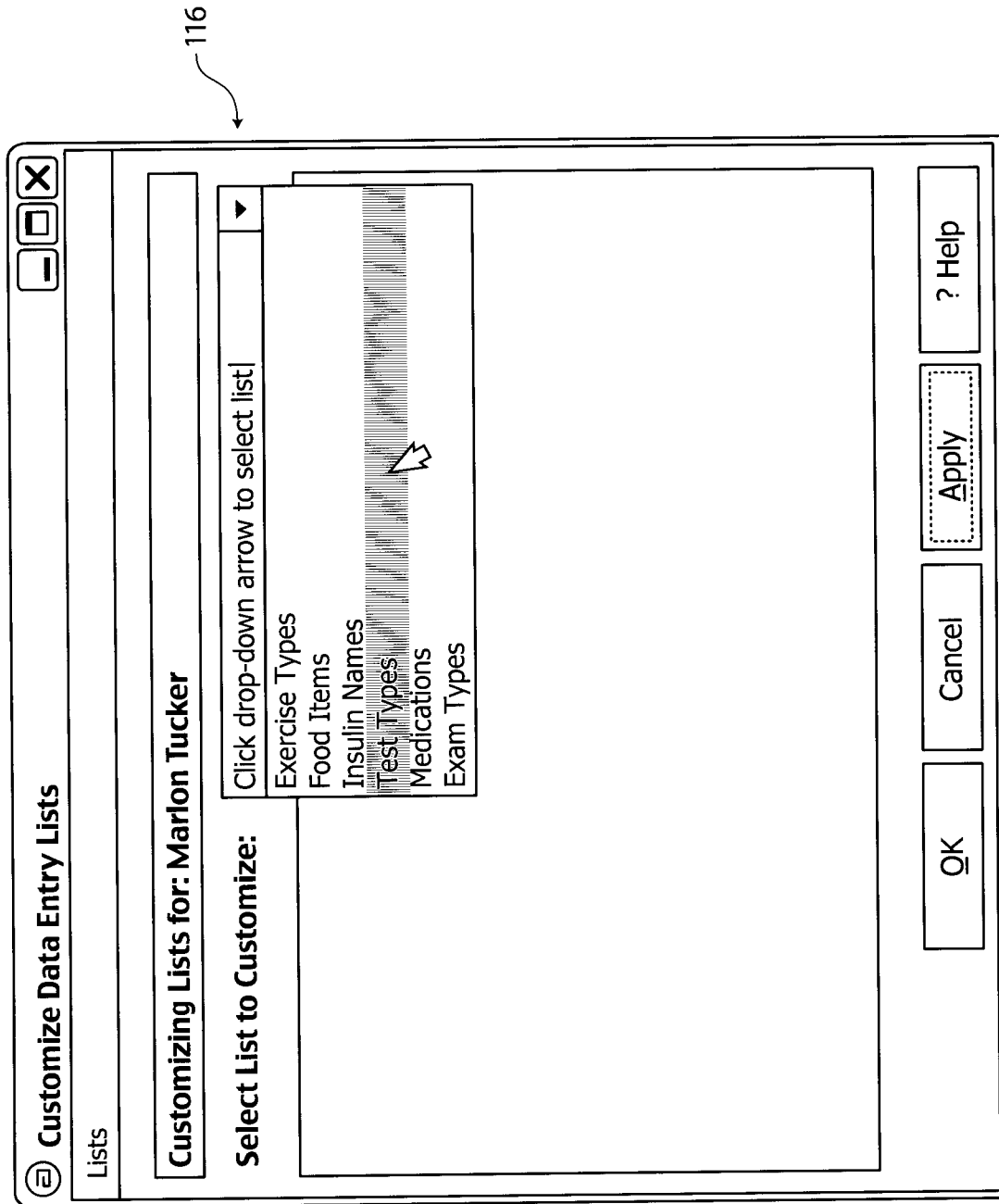


FIG. 89

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Customize Data Entry Lists

Lists

Customizing Lists for: Marlon Tucker

Select List to Customize: Exercise Types

Item	Hide
Click here to add a new row	
 Aerobics	☐
 Bike	☐
 Jog	☐
 Other	☐
 Pilates	☐
 Run	☐
 Step Class	☐
 Swim	☐
 Walk	☐
 Weights	☐

OK Cancel Apply ? Help

FIG. 90

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Customize Data Entry Lists

Lists

Customizing Lists for: Marlon Tucker

Select List to Customize: Food Items

	Item	Svg Size	Carbs (g)	Hide	Fav
Click here to add a new row					
	Beef steak with onions, Puerto Rican Style (mixture)(Biftec encebollado)	1 cup	7	☐	☐
	Beef stew, canned entree	8 oz	10	☐	☐
	Beef stroganoff (Healthy Choice)	1 meal (11 oz)	40	☐	☐
	Beef stroganoff (Lean Cuisine)	1 meal (14 oz)	44	☐	☐
	Beef tallow	1 tsp	0	☐	☐
	Beef tamale, Trader Joe's	1	26	☒	☒
	Beef tasso	1 oz	0	☐	☐
	Beef tenderloin, lean, broiled	1 oz	0	☐	☐
	Beef teriyaki (Healthy Choice)	1 meal (10 oz)	48	☐	☐
	Beef teriyaki and rice (Stouffer's Lean Cuisine)	0.5 package (24 oz)	50	☐	☐
	Beef tips portabello (Healthy Choice)	1 meal (11 oz)	34	☐	☐
	Beef tongue	1 oz	0	☐	☐
	Beef vegetable soup, Mexican style (Sopa / caldo de Res)	1 cup	11	☐	☐
	Beef, chipped, dried	1 oz	0	☐	☐
	Beef chuck pot roast cooked	1 oz	0	☐	☐

OK Cancel Apply ? Help

FIG. 91

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Customize Data Entry Lists

Lists

Customizing Lists for: Marlon Tucker

Select List to Customize:

	Item	Hide
Click here to add a new row		
	50/50	☐
	70/30	☐
	75/25	☐
	Glargine	☐
	Humalog	☐
	Humalog Mix 75/25	☐
	Lantus	☐
	Lente	☐
	Novolog	☐
	Novolog Mix 70/30	☐

OK Cancel **Apply** ? Help

FIG. 92

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Customize Data Entry Lists

Lists

Customizing Lists for: Marlon Tucker

Select List to Customize: Test Types

	Item	Hide
Click here to add a new row		
	Ketones (Blood)	☐
	Ketones (Urinary)	☐
	LDH	☐
	Microalbumin	☐
	Proteinuria	☐
	PSA	☐
	Pulse	☐
	Serum theophylline level	☐
	T4	☐
	T4 (free)	☐

OK Cancel Apply ? Help

FIG. 93

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Customize Data Entry Lists

Lists

Customizing Lists for: Marlon Tucker

Select List to Customize: Medications

	Item	Hide
Click here to add a new row		
	Capoten	☐
	Crestor	☐
	Glipizide	☐
	Glucophage	☐
	Glucophage XR	☐
	Glucotrol	☐
	Glucotrol XL	☐
	Glucovance	☐
	Glyburide 5 mg	☐
	Glypase	☐

OK Cancel Apply ? Help

FIG. 94

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Customize Data Entry Lists

Lists

Customizing Lists for: Marlon Tucker

Select List to Customize: Exam Types

	Item	Hide
Click here to add a new row		
	Cardiologist	☐
	Educator	☐
	Endocrinologist	☐
	Exercise Consultant	☐
	Eye	☐
	Family Planning	☐
	Foot	☐
	Kidney specialist	☐
	Nutritionist	☐
	Other Physician	☐

OK Cancel Apply ? Help

FIG. 95

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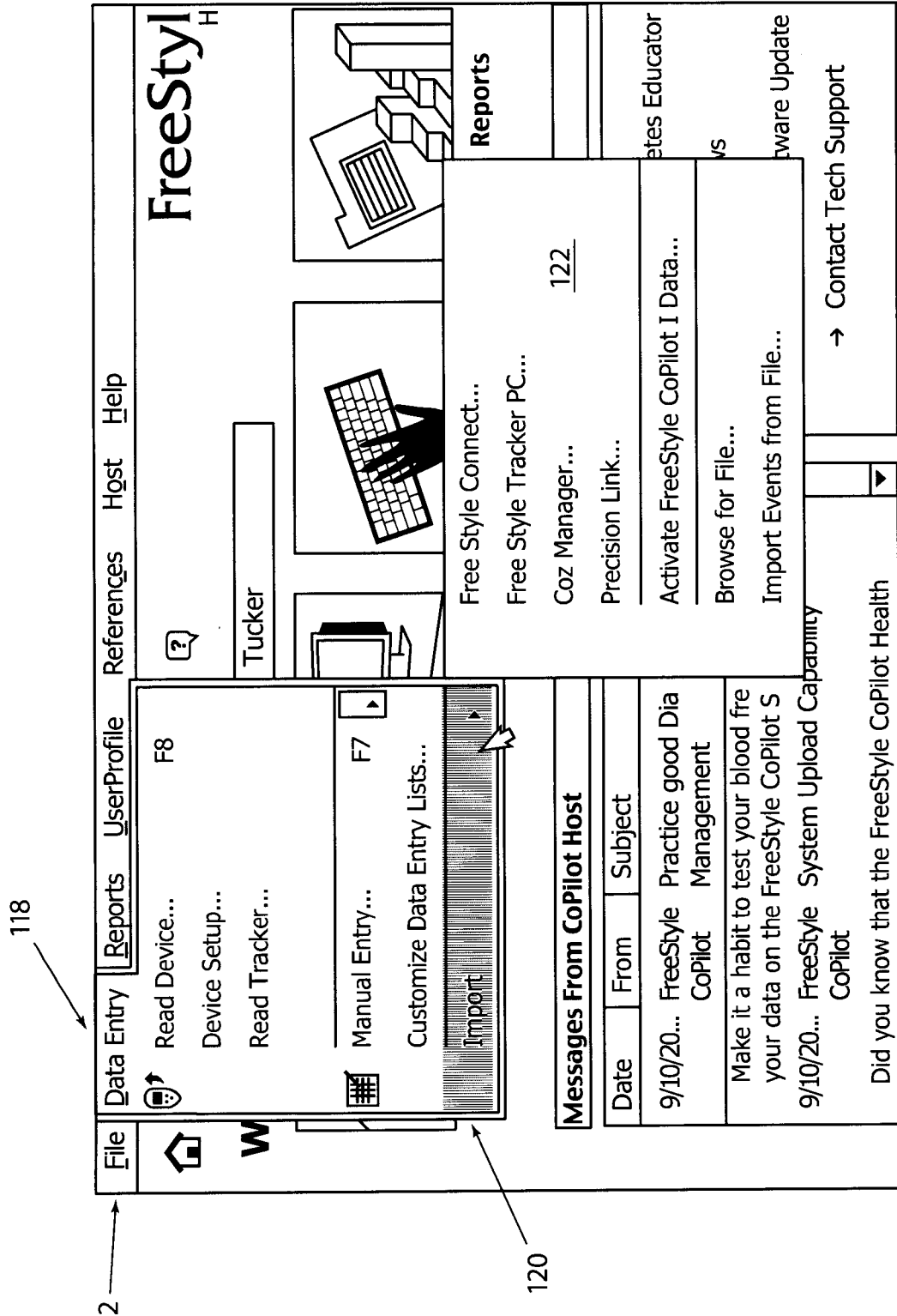


FIG. 96

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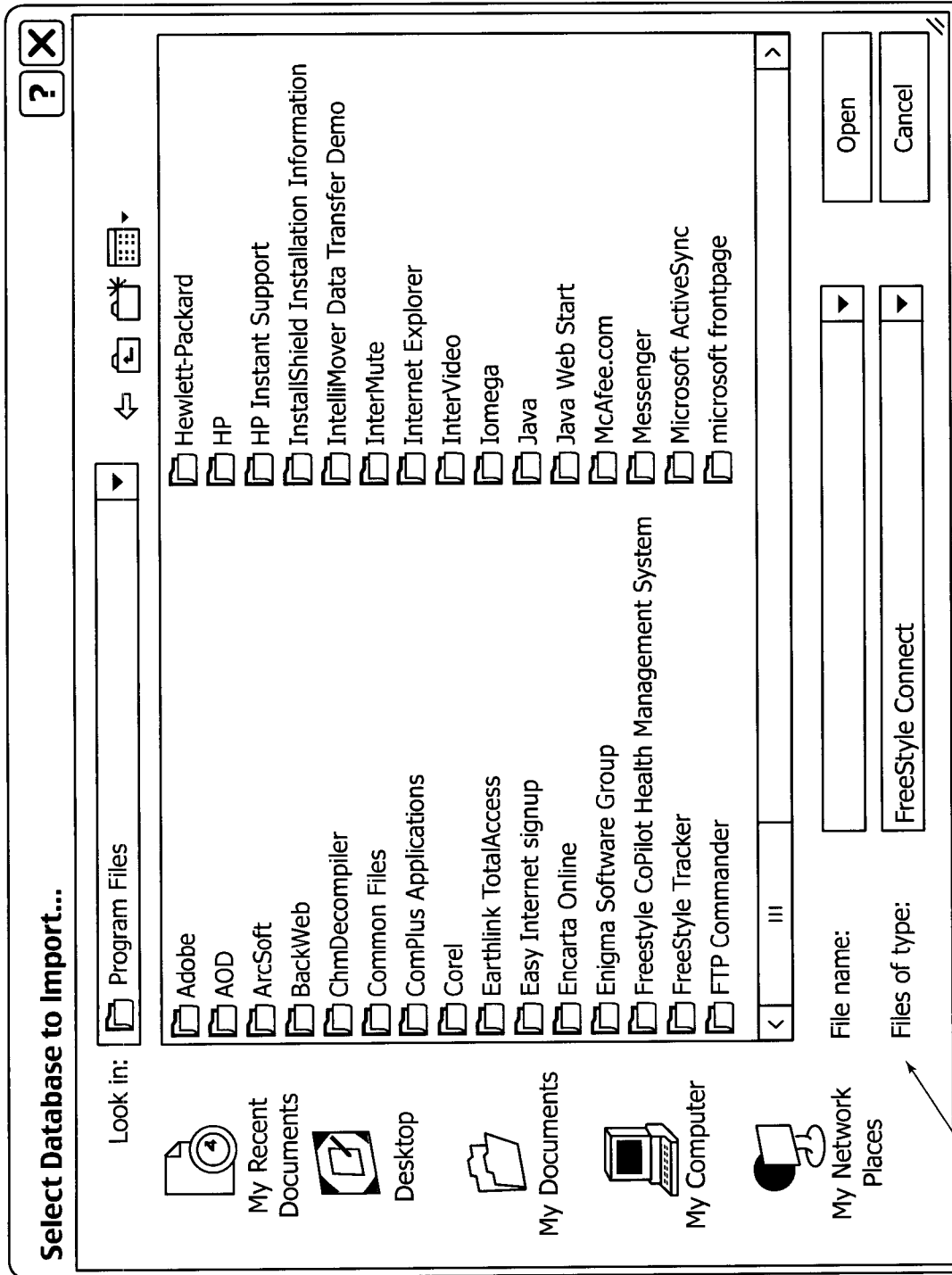
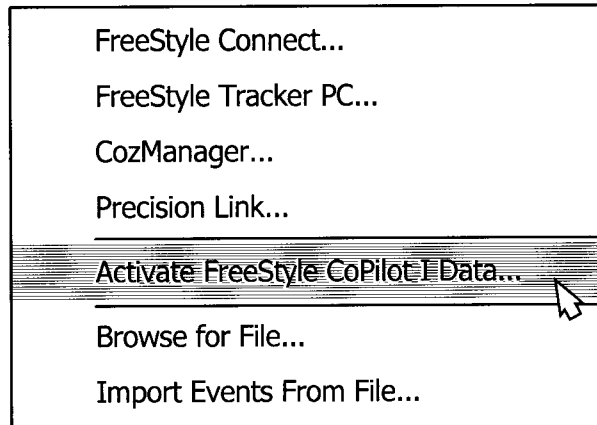
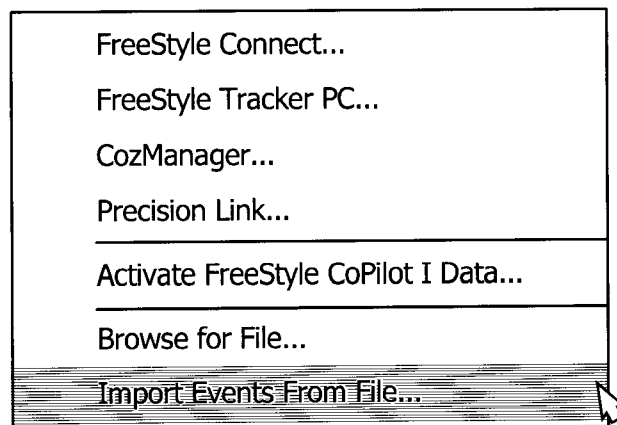
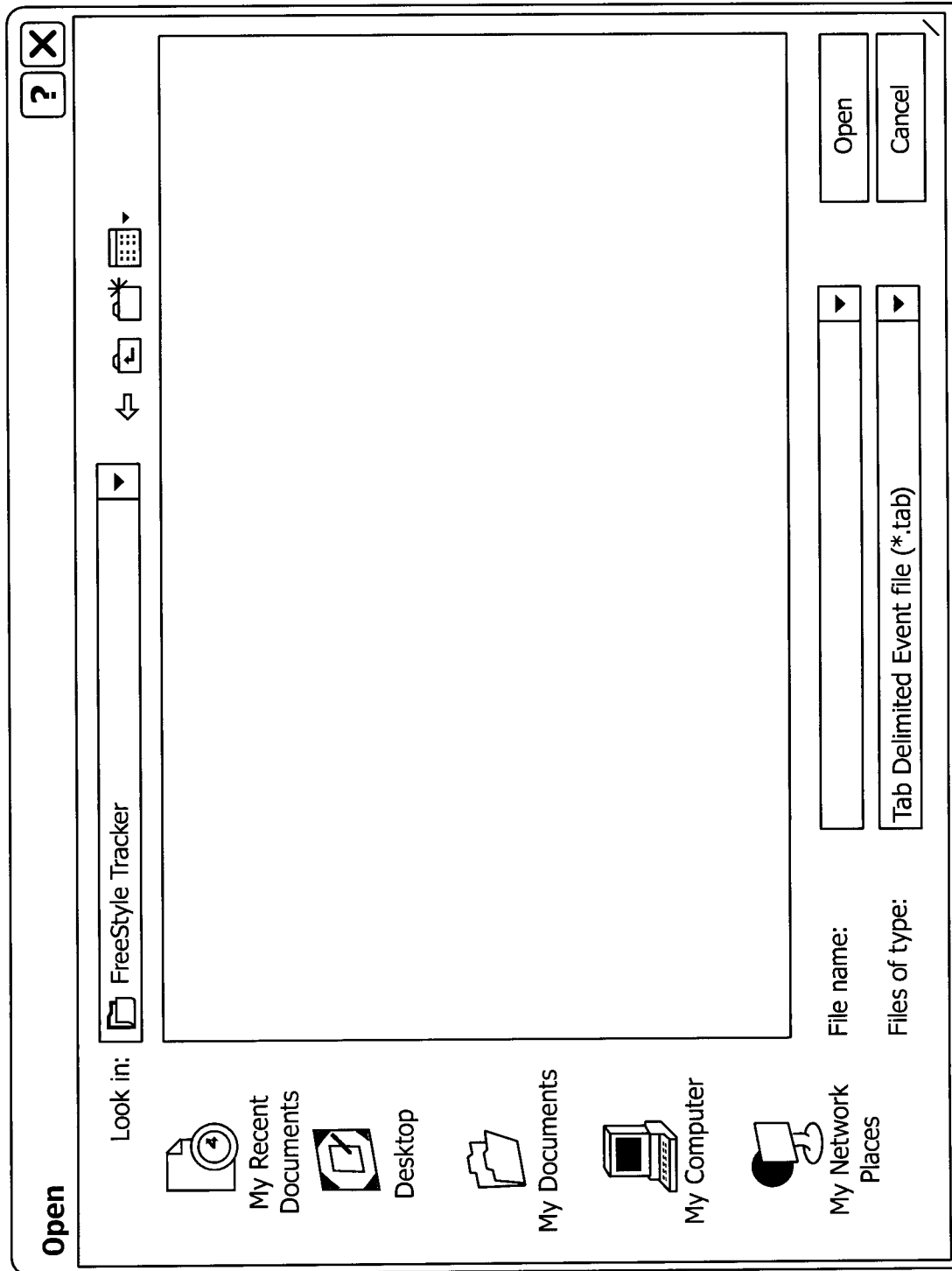


FIG. 97

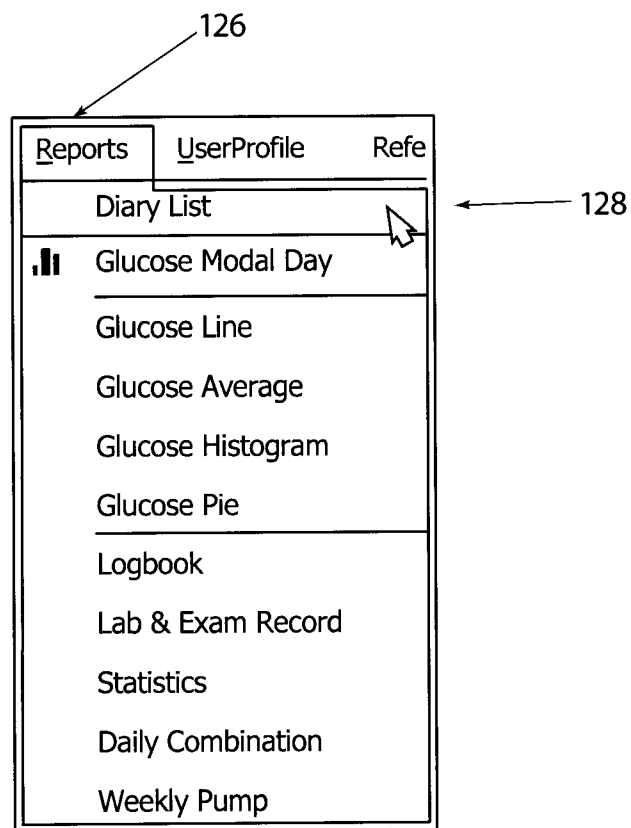
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**FIG. 98****FIG. 99**

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**FIG. 100**

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**FIG. 101**

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FreeStyle CoPilot
Health Management System

File DataEntry Reports UserProfile References Host Help

Select User: Marlon Tucker

Custom Dates 5/5/2004 7/4/2004 July 2004

Type	Date	Time	Time Period	Other Info	Comment
	5/17/2004	11:09 PM	Snack		
	5/17/2004	11:08 PM	Bed		
	5/17/2004	07:08 PM	Post-Dinner		
	5/17/2004	06:08 PM	Dinner	45 grams	
	5/17/2004	06:08 PM	Post-Dinner	169 (mg/dL)	
	5/17/2004	02:26 PM	Post-Lunch	2	
	5/17/2004	02:07 PM	Lunch	40 grams	
					Late lunch after church

CoPilot.cpd

FIG. 102

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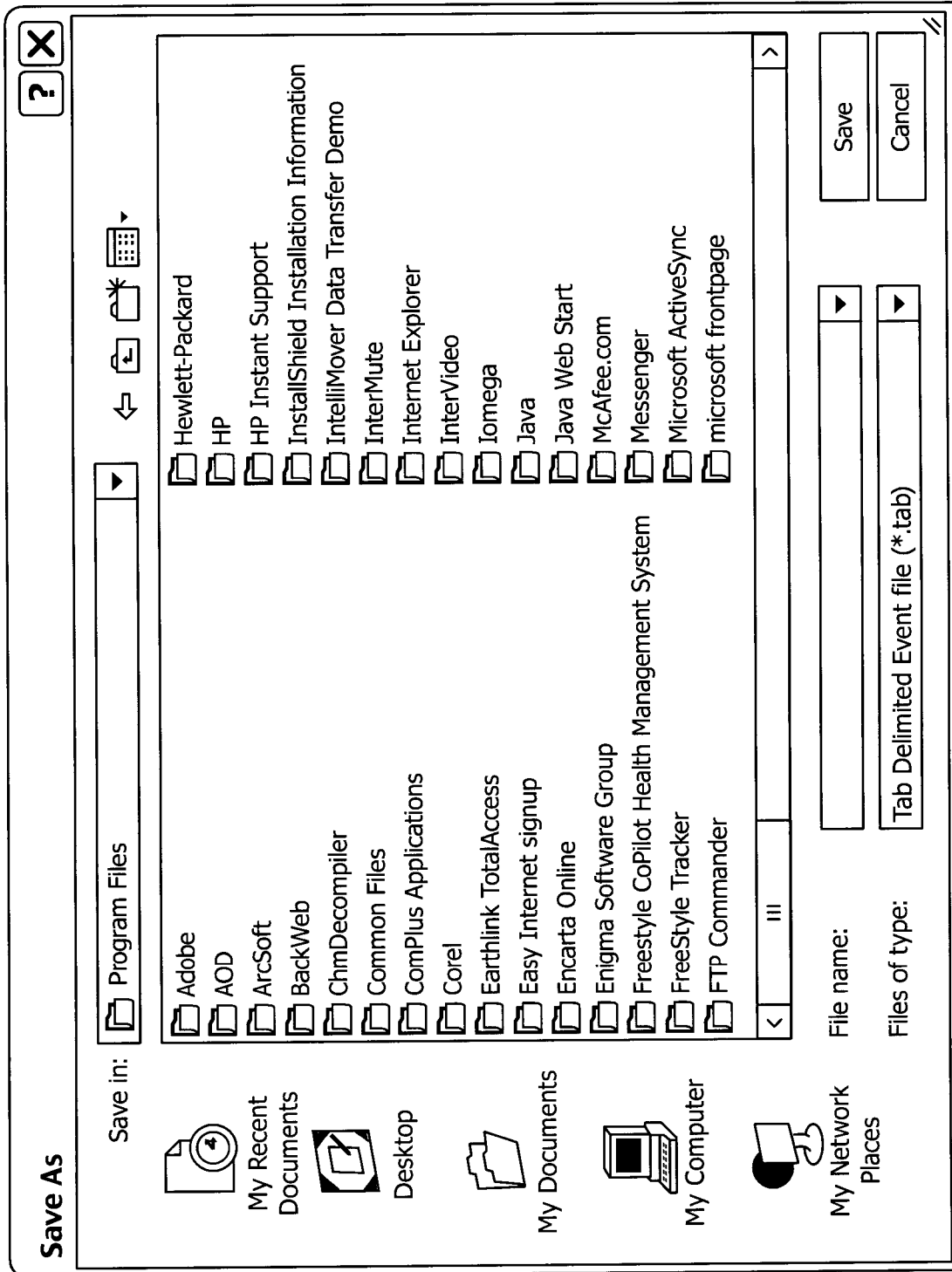


FIG. 103

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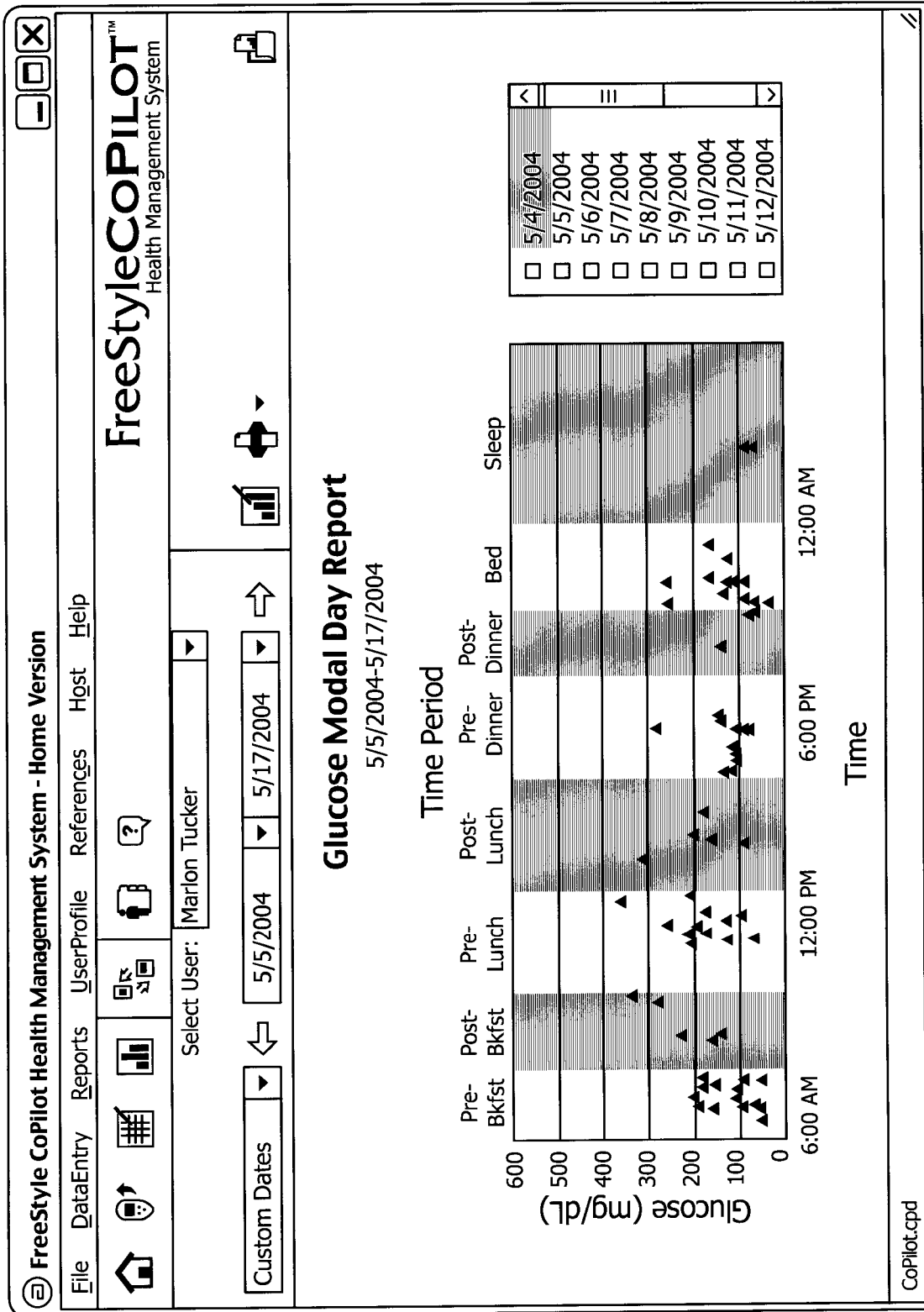


FIG. 104

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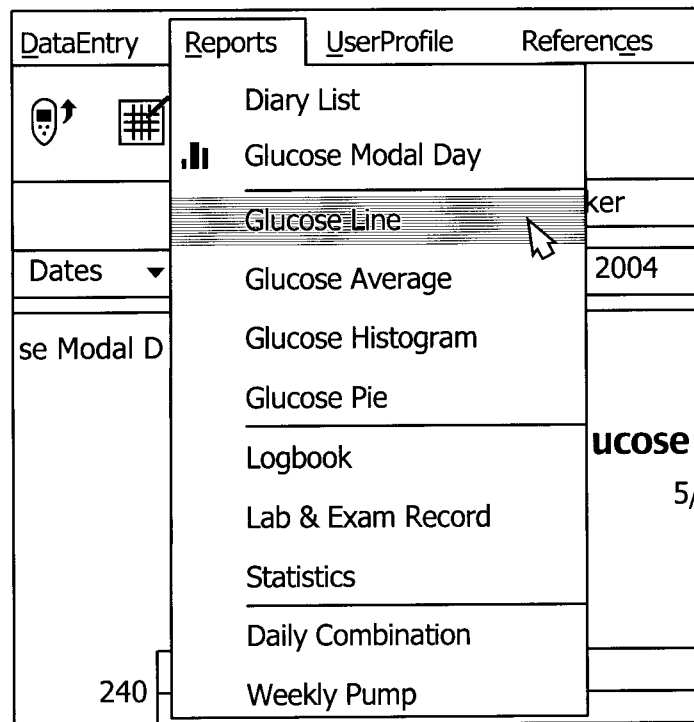


FIG. 105

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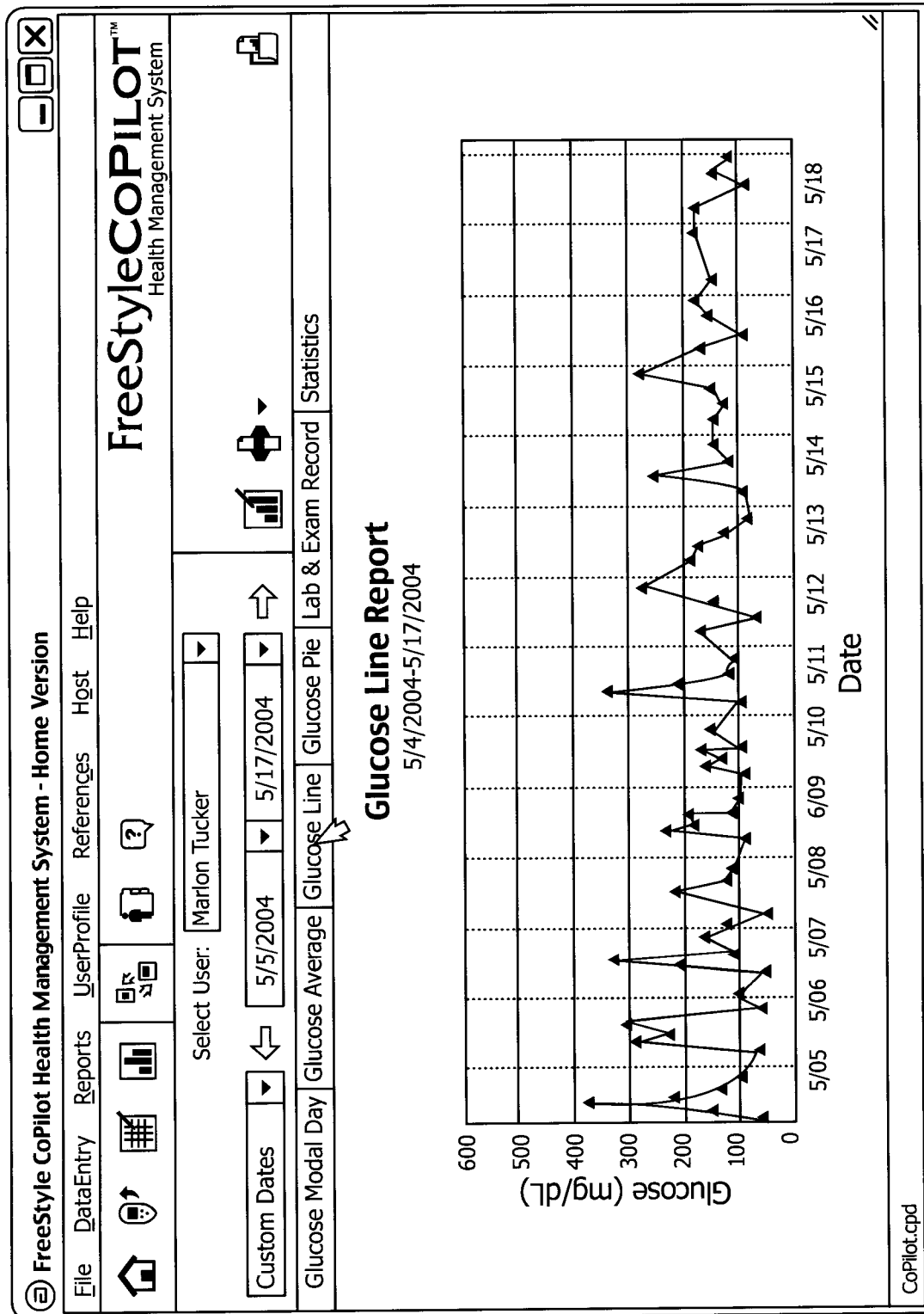


FIG. 106

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Custom Dates ▼		←	5/17/2004 ▼	5/17/2004 ▼	→
Glucose Modal Day	Glucose	◀ May ▶ ◀ 2004 ▶ S M T W T F S 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 Today		Glucose Pie	La
600		Pre-Bkfst	P	e Modal D 4/2004-5/17/	
				Period Pre- Post- Dinner Dinne	

FIG. 107

	▼
	Print... Page Setup... Print Preview... Print Favorite Reports Save as PDF file... E-Mail Report To...

FIG. 108

FIG. 109

FIG. 109

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Ⓜ Report Configuration

Data Filter

Miscellaneous

Event Types

☒ Glucose

☒ Insulin

☒ Carbohydrates

☒ Exercise

☒ Medications

☒ State of Health

☒ Lab Results

☒ Exams

☒ Ketones

☒ Notes

Time Periods

☒ Pre-Breakfast

☒ Post-Breakfast

☒ Pre-Lunch

☒ Post-Lunch

☒ Pre-Dinner

☒ Post-Dinner

☒ Bed

☒ Sleep

Week Days

☒ Sunday

☒ Monday

☒ Tuesday

☒ Wednesday

☒ Thursday

☒ Friday

☒ Saturday

Reset

OK

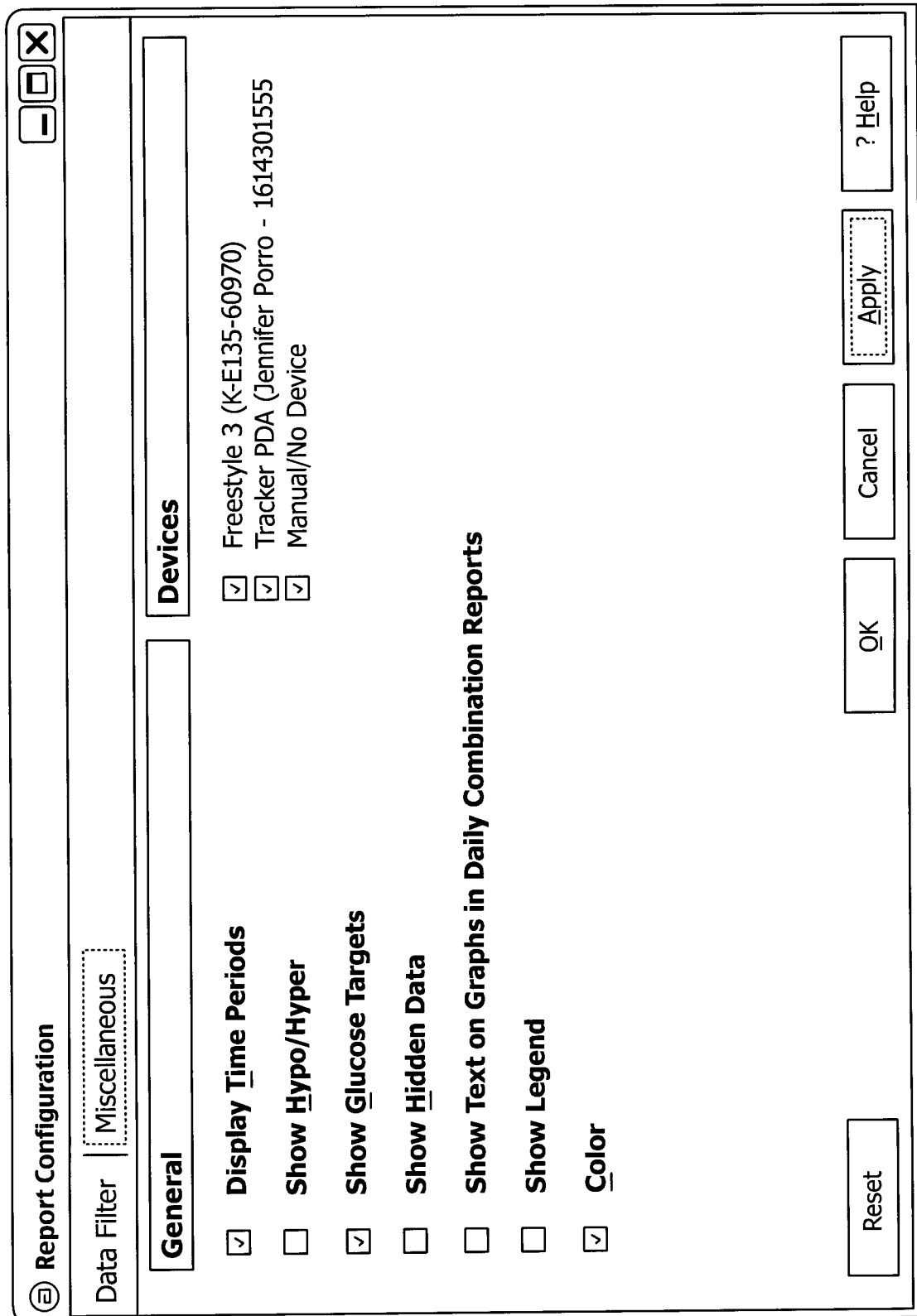
Cancel

Apply

? Help

FIG. 110

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The image shows a 'Report Configuration' dialog box with a title bar containing minimize, maximize, and close buttons. The dialog has a tabbed interface with 'Data Filter' and 'Miscellaneous' tabs. The 'Miscellaneous' tab is active, showing a 'General' section with a list of configuration options. Each option consists of a checkbox and a label. The options are: 'Display Time Periods' (checked), 'Show Hypo/Hyper' (unchecked), 'Show Glucose Targets' (checked), 'Show Hidden Data' (unchecked), 'Show Text on Graphs in Daily Combination Reports' (unchecked), 'Show Legend' (unchecked), and 'Color' (checked). To the right of these options is a 'Devices' section with a list of three devices, each with a checked checkbox: 'Freestyle 3 (K-E135-60970)', 'Tracker PDA (Jennifer Porro - 1614301555)', and 'Manual/No Device'. At the bottom of the dialog are four buttons: 'Reset', 'OK', 'Cancel', and '? Help'.

Report Configuration

Data Filter | Miscellaneous

General

☒ Display Time Periods

☐ Show Hypo/Hyper

☒ Show Glucose Targets

☐ Show Hidden Data

☐ Show Text on Graphs in Daily Combination Reports

☐ Show Legend

☒ Color

Devices

☒ Freestyle 3 (K-E135-60970)

☒ Tracker PDA (Jennifer Porro - 1614301555)

☒ Manual/No Device

Reset OK Cancel ? Help

FIG. 111



FIG. 112

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FreeStyle CoPilot Health Management System - Home Version

File DataEntry Reports UserProfile References Host Help

FreeStyleCOPILOT
Health Management System

Select User: Marlon Tucker

Custom Dates: 5/5/2004 7/4/2004

Glucose Modal Day Glucose Average Glucose Line Glucose Pie Lab & Exam Record Statistics Diary List

Diary List

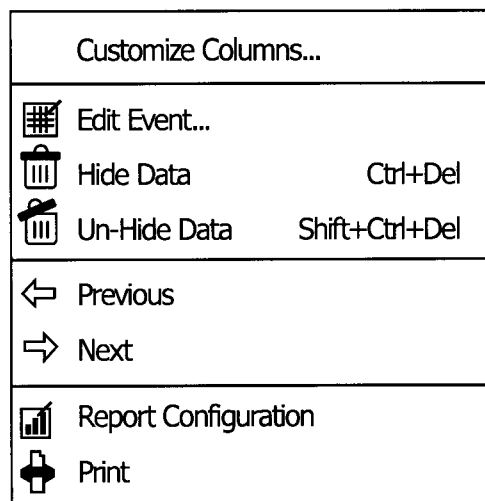
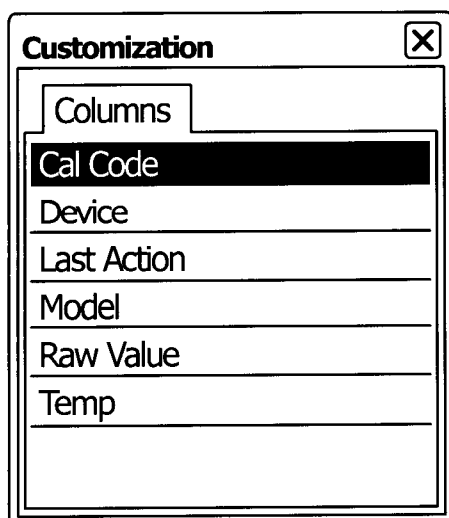
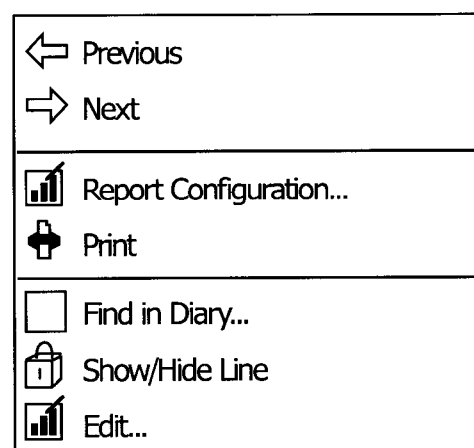
5/4/2004-5/1/2004

Type	Date	Time	Time Period	Value	Description	Other Info	Comment
	5/17/2004	11:09 PM	Snack	15 grams	1 Svg (15 g) - N/A		
	5/17/2004	11:08 PM	Bed	142 (mg/dL)			
	5/17/2004	07:08 PM	Post-Dinner	2	Prandin Dosage:		
	5/17/2004	06:08 PM	Dinner	45 grams	1 Svg (45 g) - N/A		
	5/17/2004	06:08 PM	Post-Dinner	169 (mg/dL)			
	5/17/2004	02:26 PM	Post-Lunch	2	Prandin Dosage:		
	5/17/2004	02:07 PM	Lunch	40 grams	1 Svg (40 g) - N/A		Late lunch after church

CoPilot.cpd

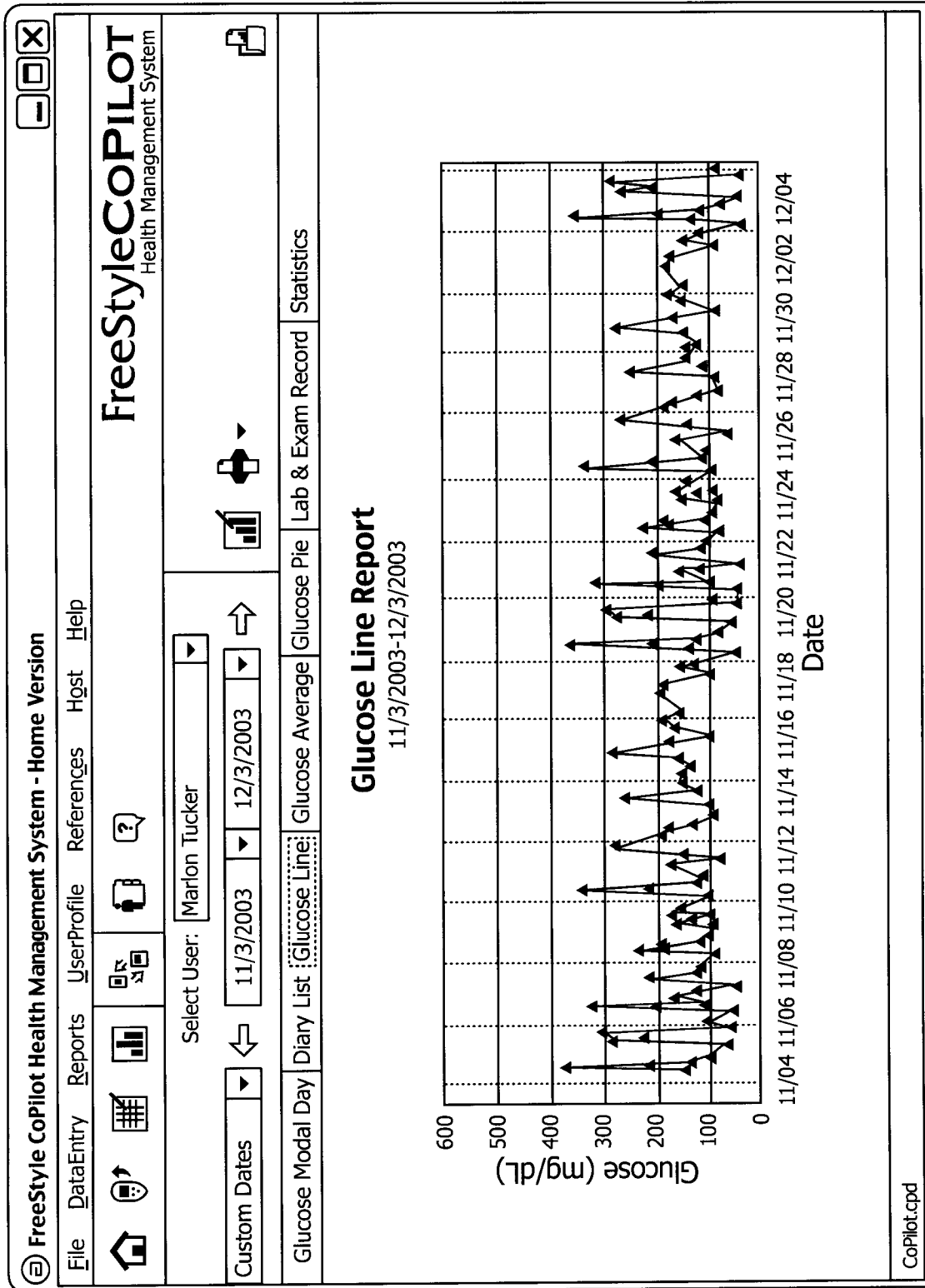
FIG. 113

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**FIG. 114****FIG. 115****FIG. 118**



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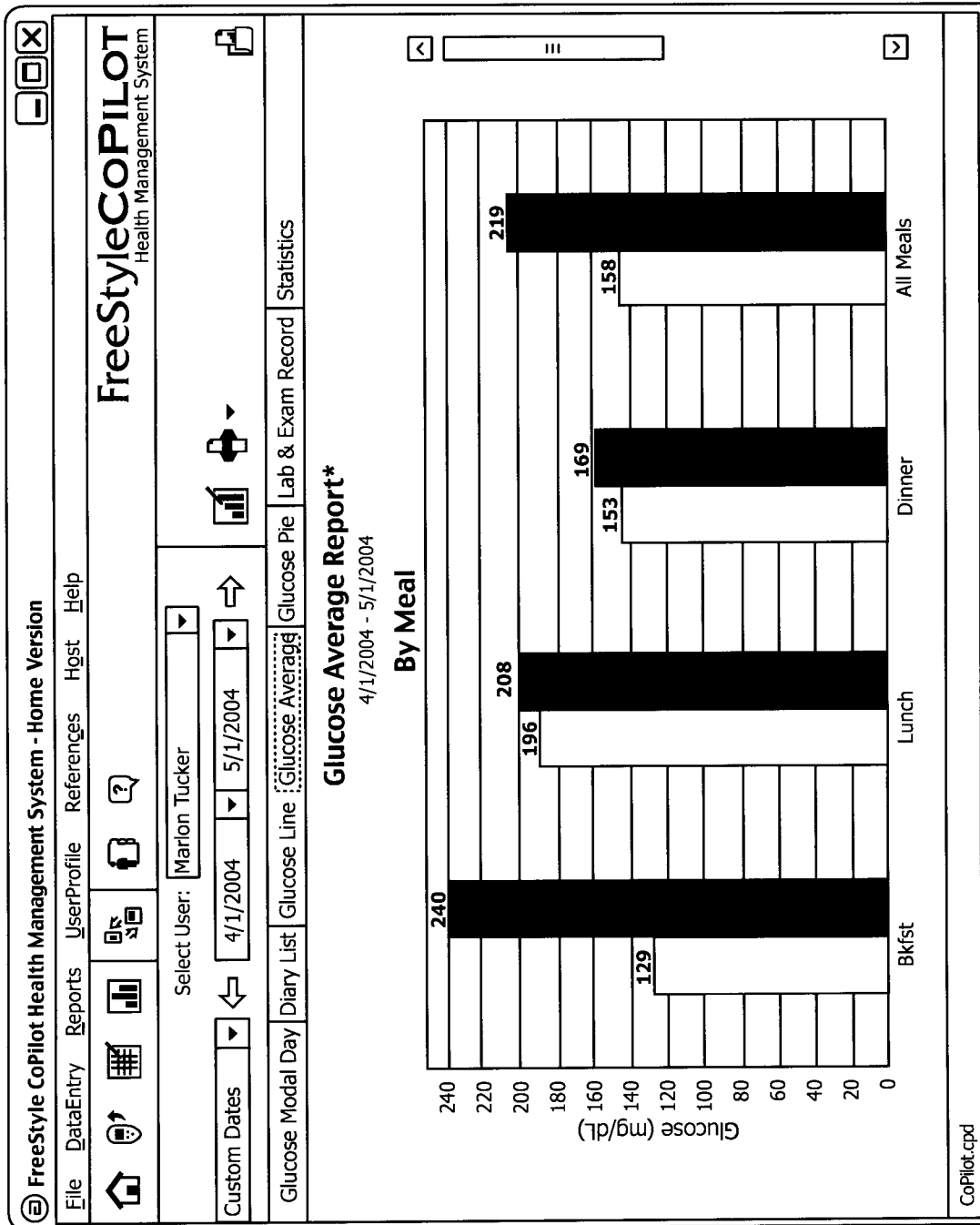


FIG. 119

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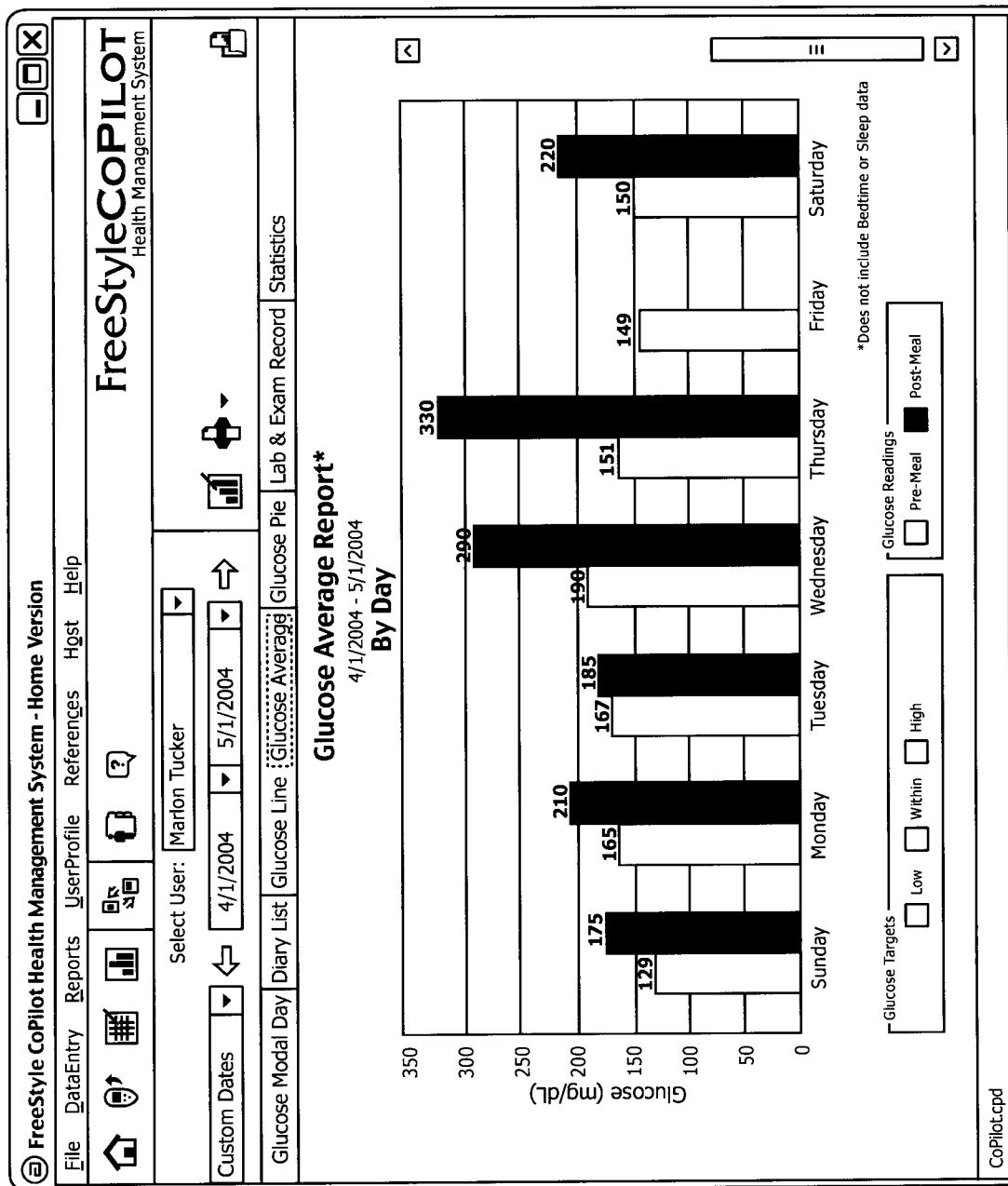


FIG. 120

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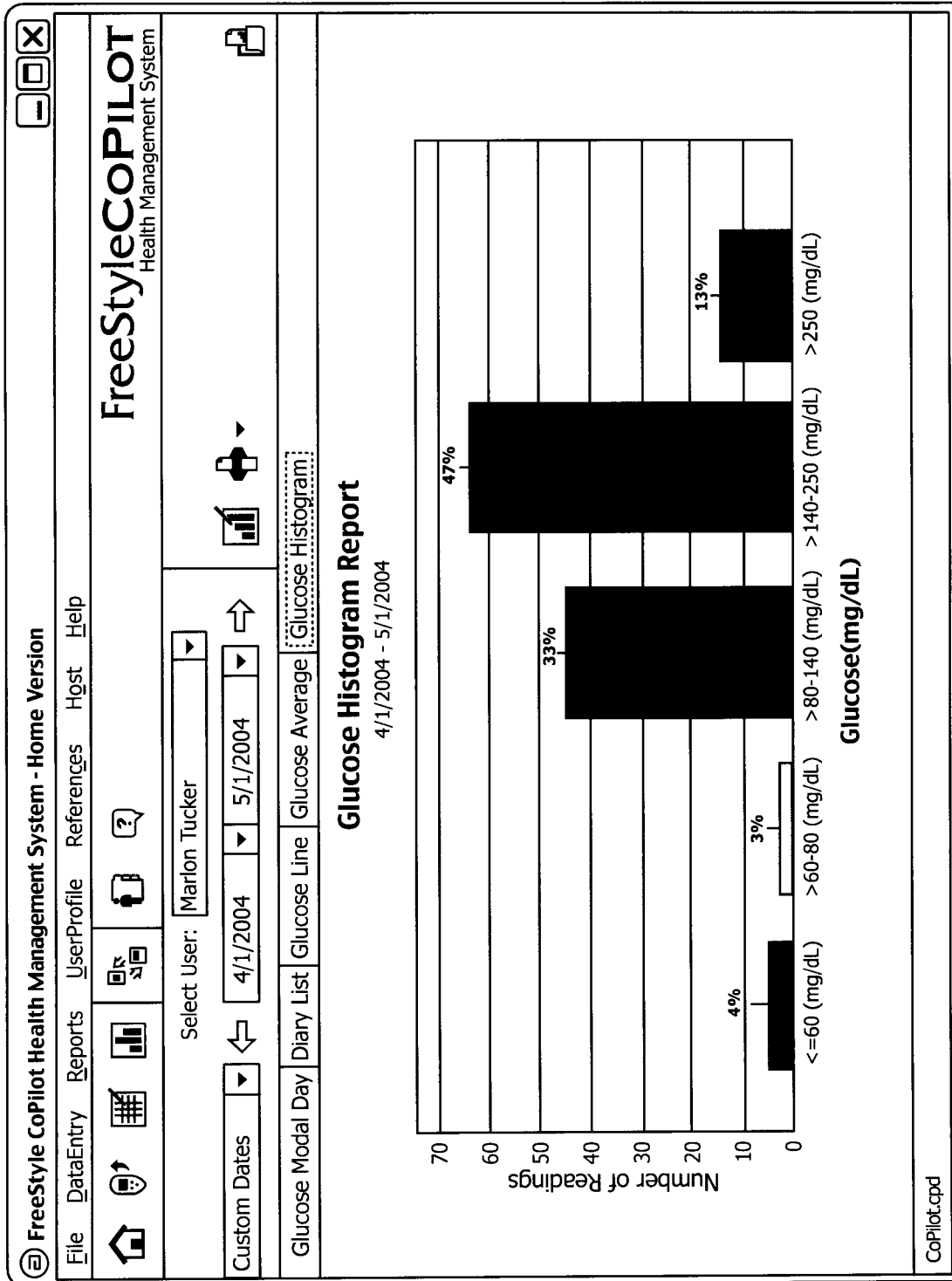
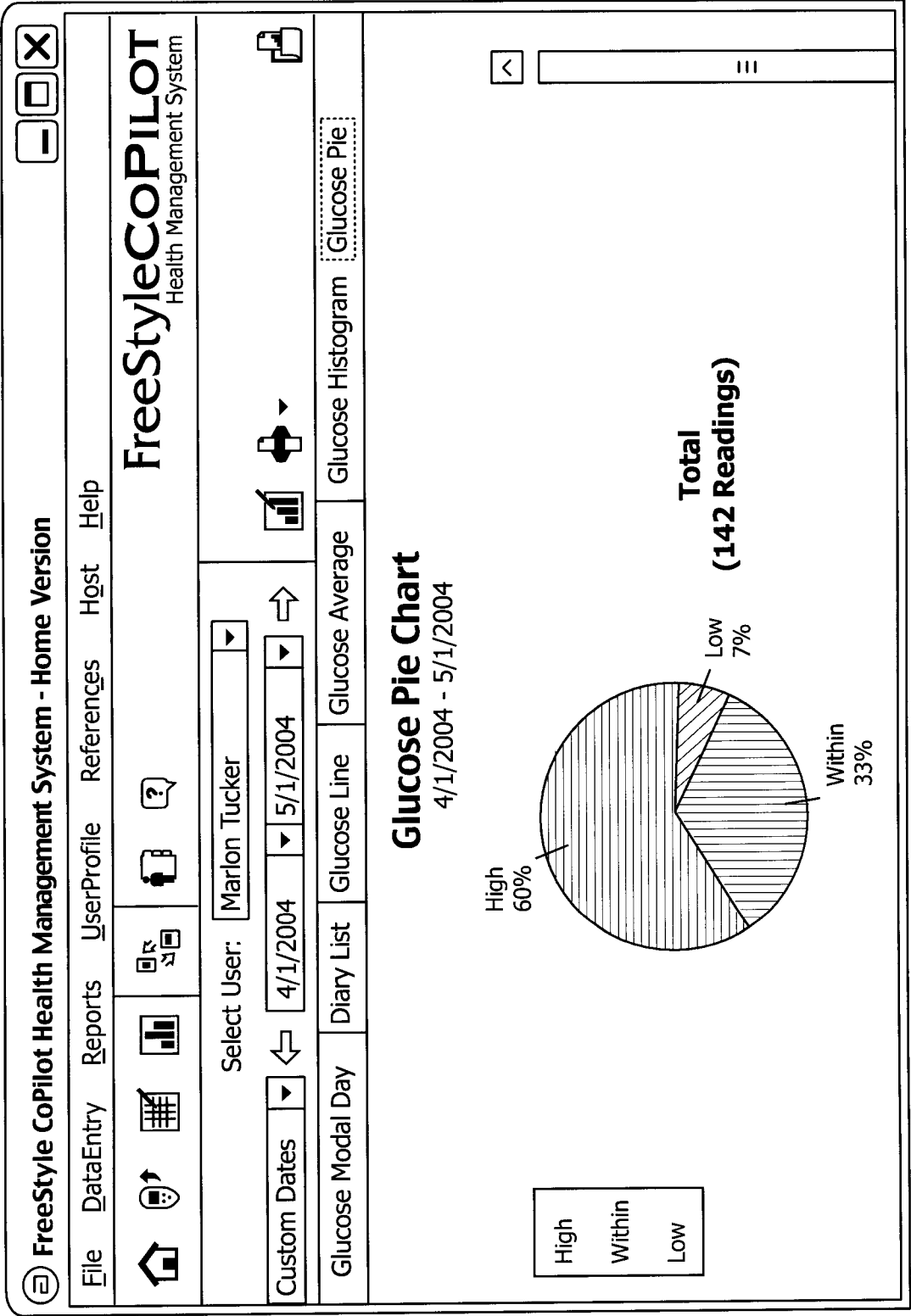
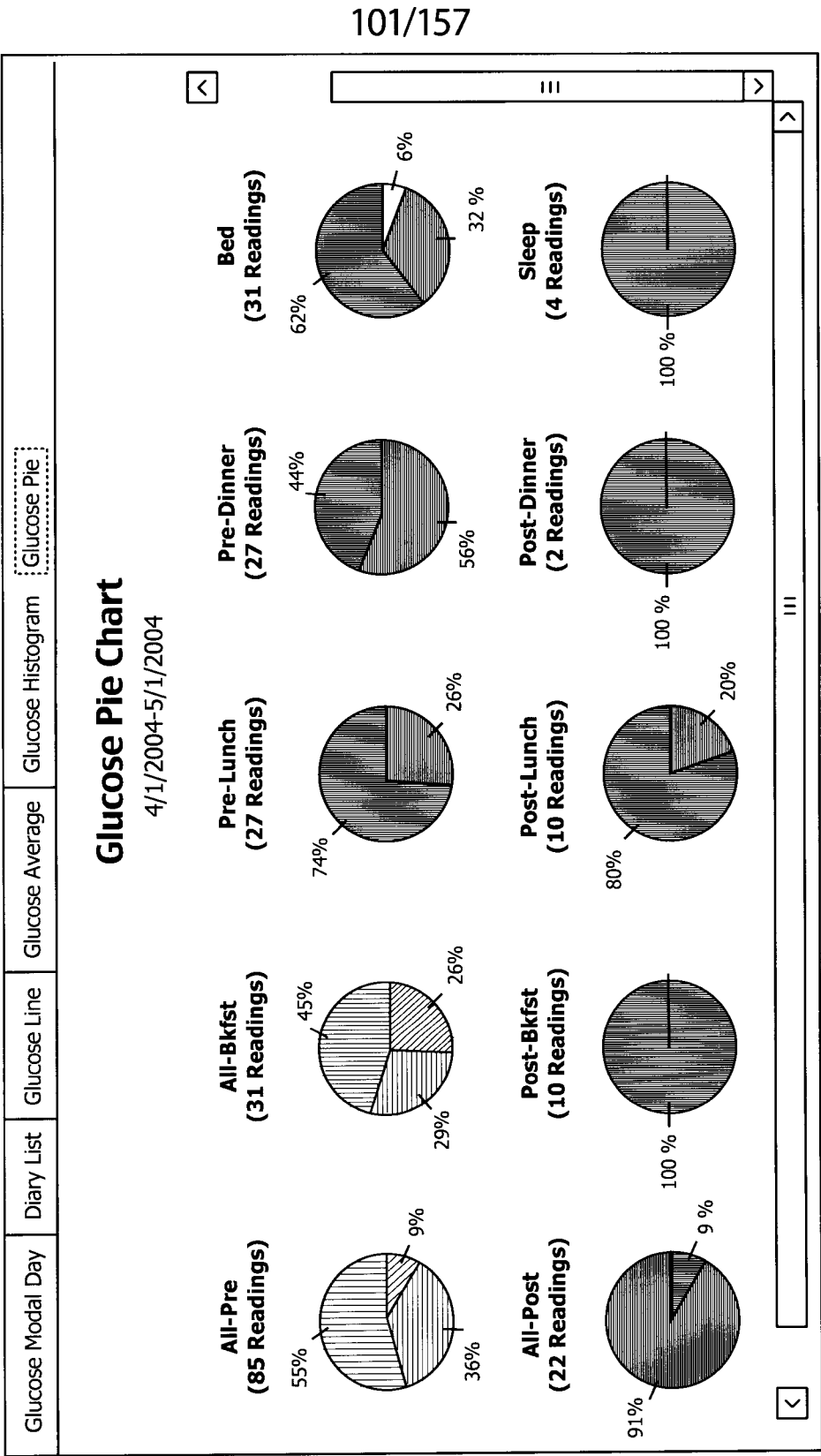


FIG. 121





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FreeStyle CoPilot Health Management System - Home Version

File

DataEntry

Reports

UserProfile

References

Host

Help

Health Management System

Select User:

Marlon Tucker

Custom Dates

4/1/2004

5/1/2004

Glucose Modal Day

Diary List

Glucose Line

Glucose Average

Glucose Histogram

Glucose Pie

Logbook

Logbook Report

4/1/2004-5/1/2004

Date	Breakfast			Lunch				
	Units/Type	(g)	G Pre (mg/dL)	G Post (mg/dL)	Units/Type	(g)	G Pre (mg/dL)	G Post (mg/dL)
5/1/2004			188				112	
4/30/2004		35	161			50	144	
4/29/2004		50	110			35	271	
4/28/2004	Dr. Appt ate bf at 11am	30	201			45	188	
4/27/2004	Small BF	50	183			45	82	
4/26/2004	5.00(H)		110	350	5.00(H)	60	220	
4/25/2004	5.00(H)	46	100	170	3.00(H)	60	140	180
4/24/2004	4.00(H)	40	98	240	4.00(H)	55	190	200

CoPilot.cpd

FIG. 124

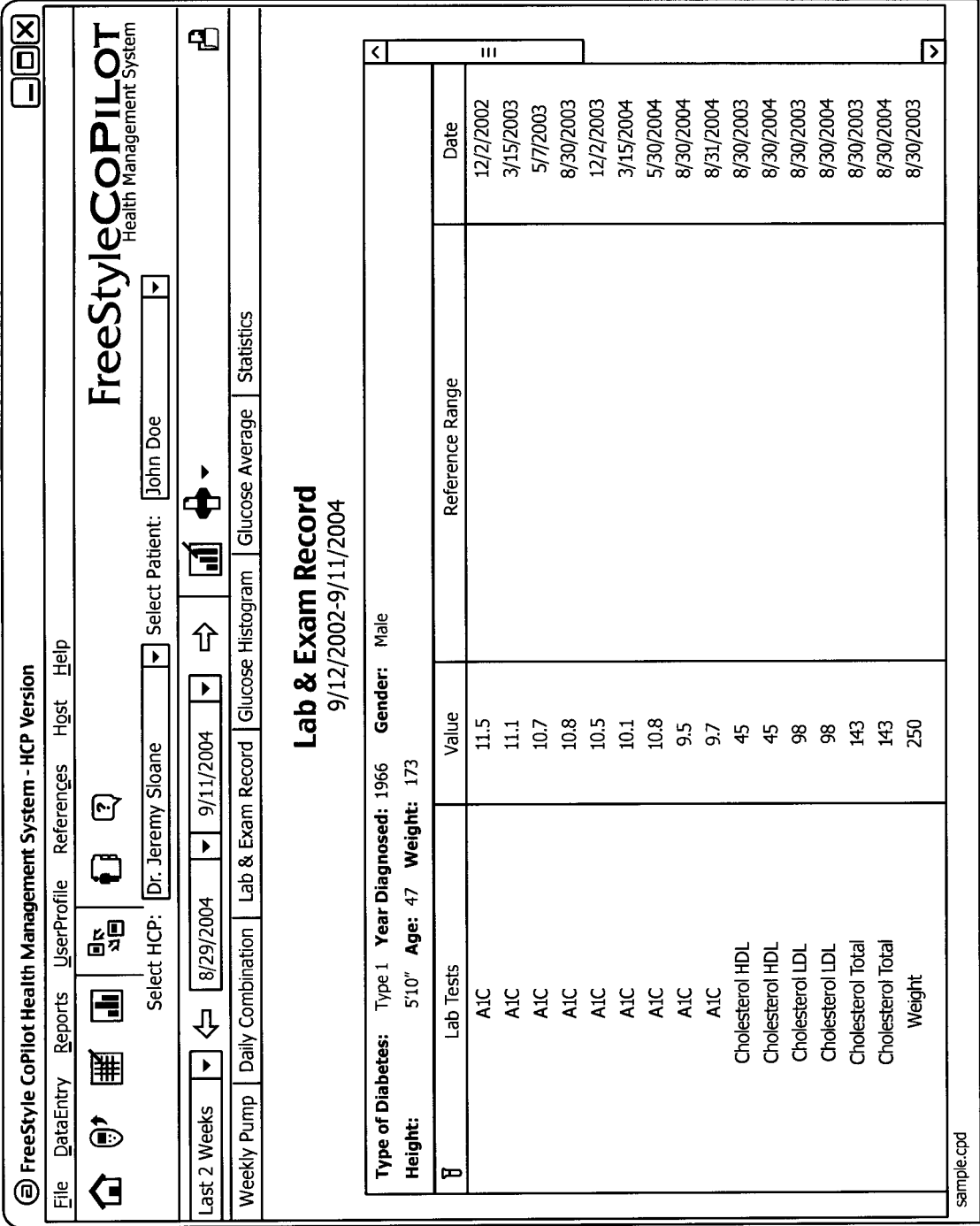


FIG. 125

FIG. 126

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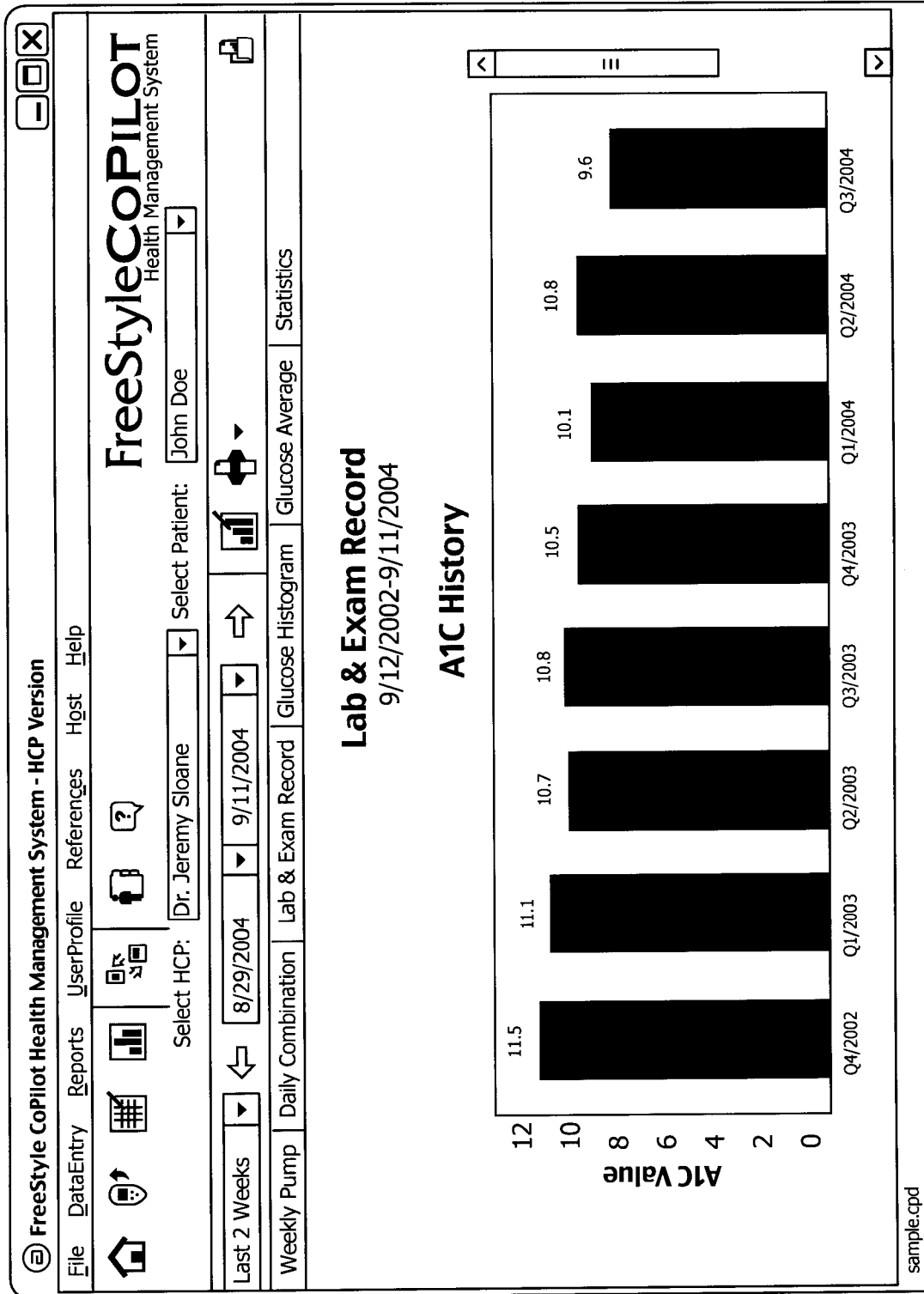


FIG.127

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FreeStyle CoPilot Health Management System - Home Version

File

DataEntry

Reports

UserProfile

References

Host

Help

FreeStyleCOPILOT

Health Management System

Custom Dates

4/1/2004

5/1/2004

Select User:

Marlon Tucker

Diary List

Glucose Modal Day

Glucose Line

Glucose Average

Glucose Histogram

Glucose Pie

Logbook

Lab & Exam Record

Statistics

Statistics Report

4/1/2004-5/1/2004

	Breakfast		Lunch		Dinner		Bed & Sleep		
G Glucose Statistics (mg/dL)	Pre	Post	Pre	Post	Pre	Post	Bed	Sleep	Total/Summary
#Readings	31	10	27	10	27	2	31	4	142
#Days w/Readings	31	10	27	10	27	2	31	4	31
Avg. # Readings/day	10	0.3	0.9	0.3	0.9	0.1	1.0	0.1	4.6
Highest	201	350	380	330	310	169	297	130	380
Lowest	55	150	82	112	105	169	65	110	55
Average	129	240	196	208	153	169	166	120	168
Standard Deviation	52	74	75	71	49	N/A	67	10	70
Above %	29	60	63	60	7	0	32	0	35
Within%	45	40	37	40	93	100	62	100	58
Below%	26	0	0	0	0	0	6	0	7

CoPilot.cpd

FIG. 128

FreeStyle CoPilot Health Management System - Home Version

File

DataEntry

Reports

UserProfile

References

Host

Help

FreeStyleCoPILOT™

Health Management System

Custom

Dates

4/1/2004

5/1/2004

Marlon Tucker

Glucose Line

Glucose Average

Glucose Histogram

Glucose Pie

Logbook

Lab & Exam Record

Statistics

Diary List

Glucose Modal Day

Glucose Line

Glucose Average

Glucose Histogram

Glucose Pie

Logbook

Lab & Exam Record

Statistics

Statistics Report

4/1/2004 - 5/1/2004

Insulin Statistics (Units)		Breakfast		Lunch		Dinner		Bed & Sleep		Total/Summary
		Pre	Post	Pre	Post	Pre	Post	Bed	Sleep	
Avg./day. Glargine								14.43		14.43
Avg./day. Humalog		4.29	4.43	4.43		8.86		1.00		5.43
Avg./day. Total Insulin		4.29	4.43	4.43		8.86		11.44		7.53

Carbs Statistics (Grams)		Breakfast		Lunch		Dinner		Bed & Sleep		Total/Summary
Avg./day. Carbohydrates		41.2		49.1		66.6		16.3		164.4

CoPilot.cpd

FIG. 129

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Custom Dates ▼	←	8/3/2004 ▼	8/3/2004 ▼	→
----------------	---	------------	------------	---

FIG. 130

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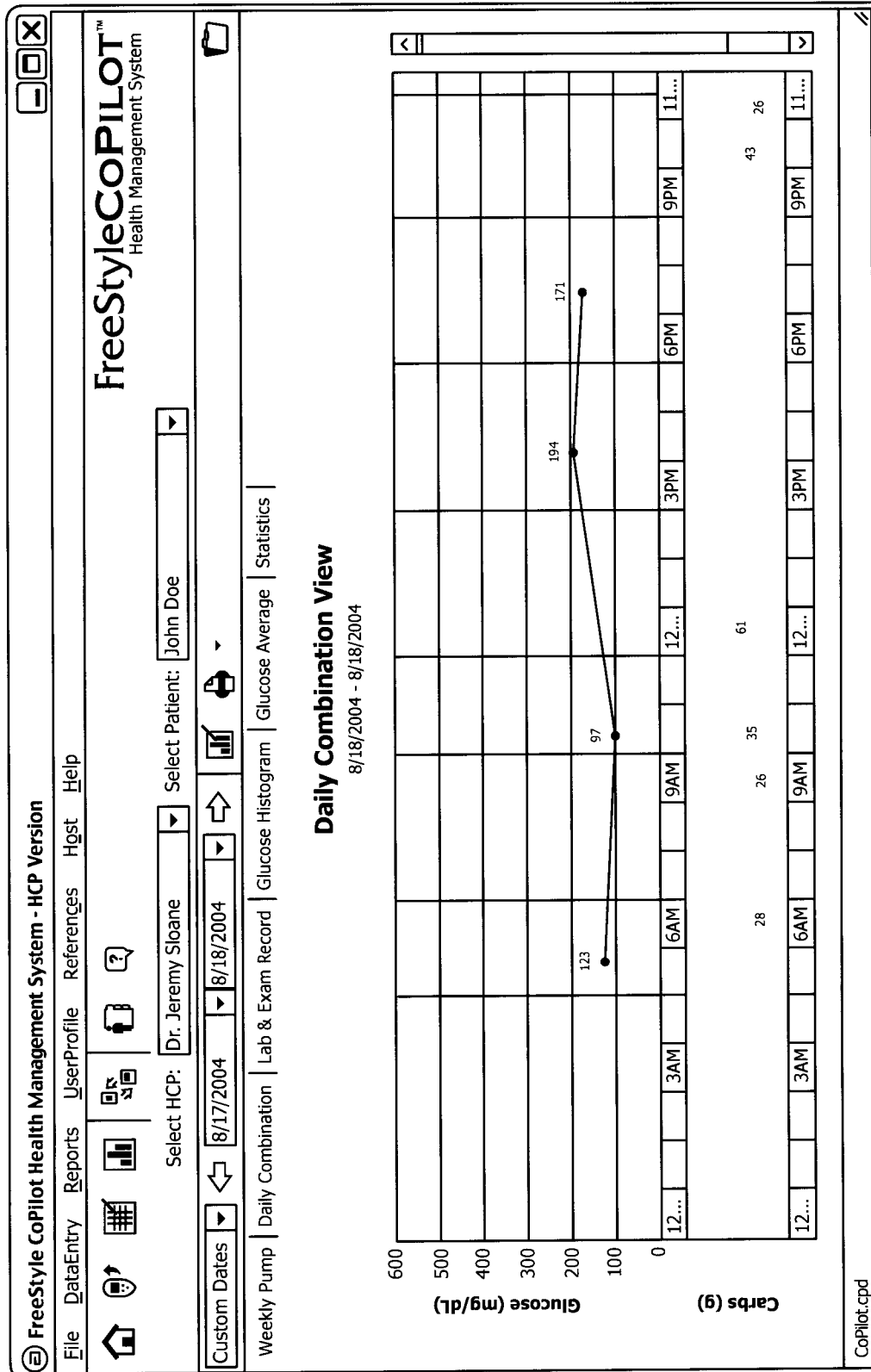


FIG. 131



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Custom Dates ▼	←	7/8/2004 ▼	8/3/2004 ▼	→
----------------	---	------------	------------	---

FIG. 133

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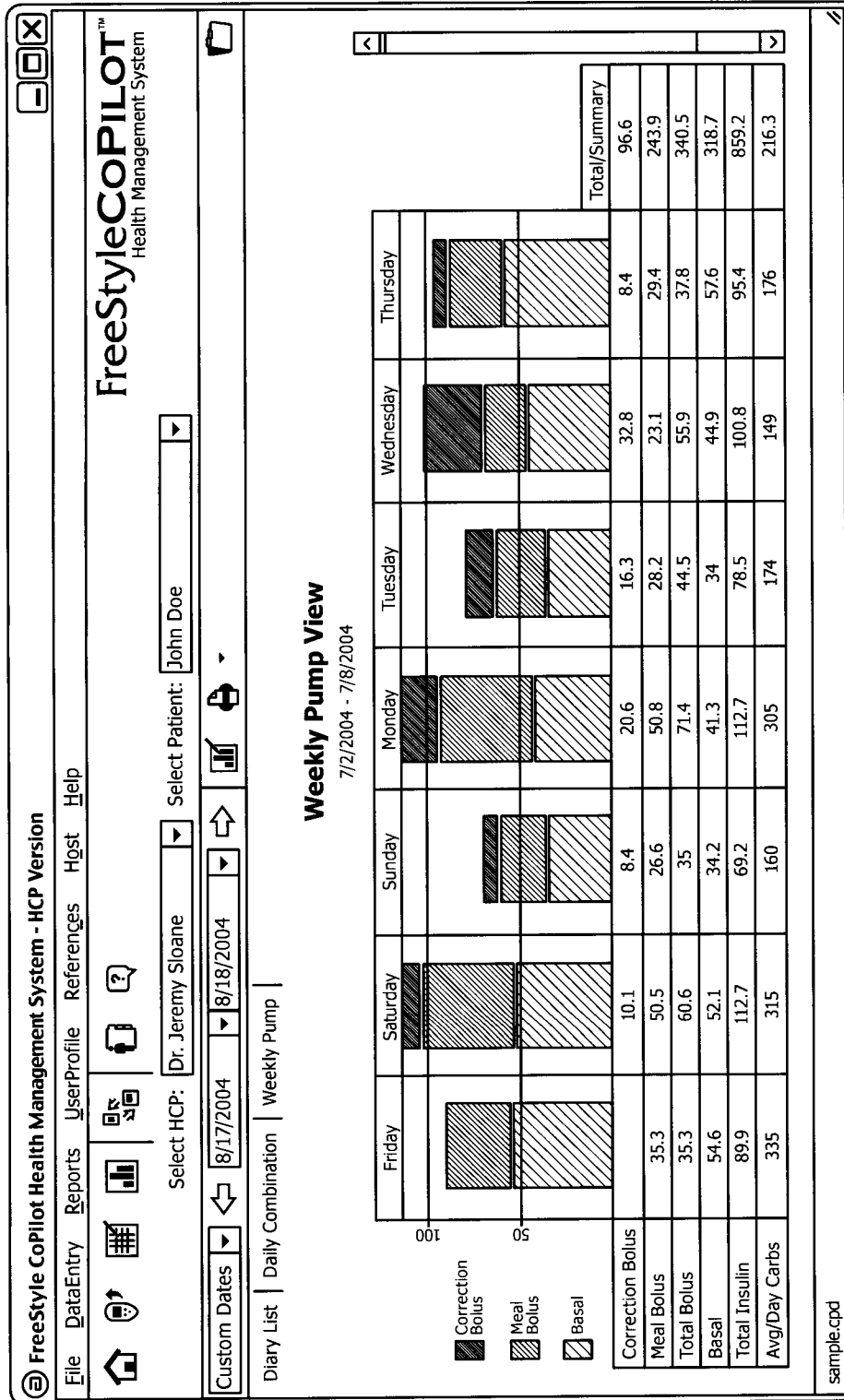


FIG. 134

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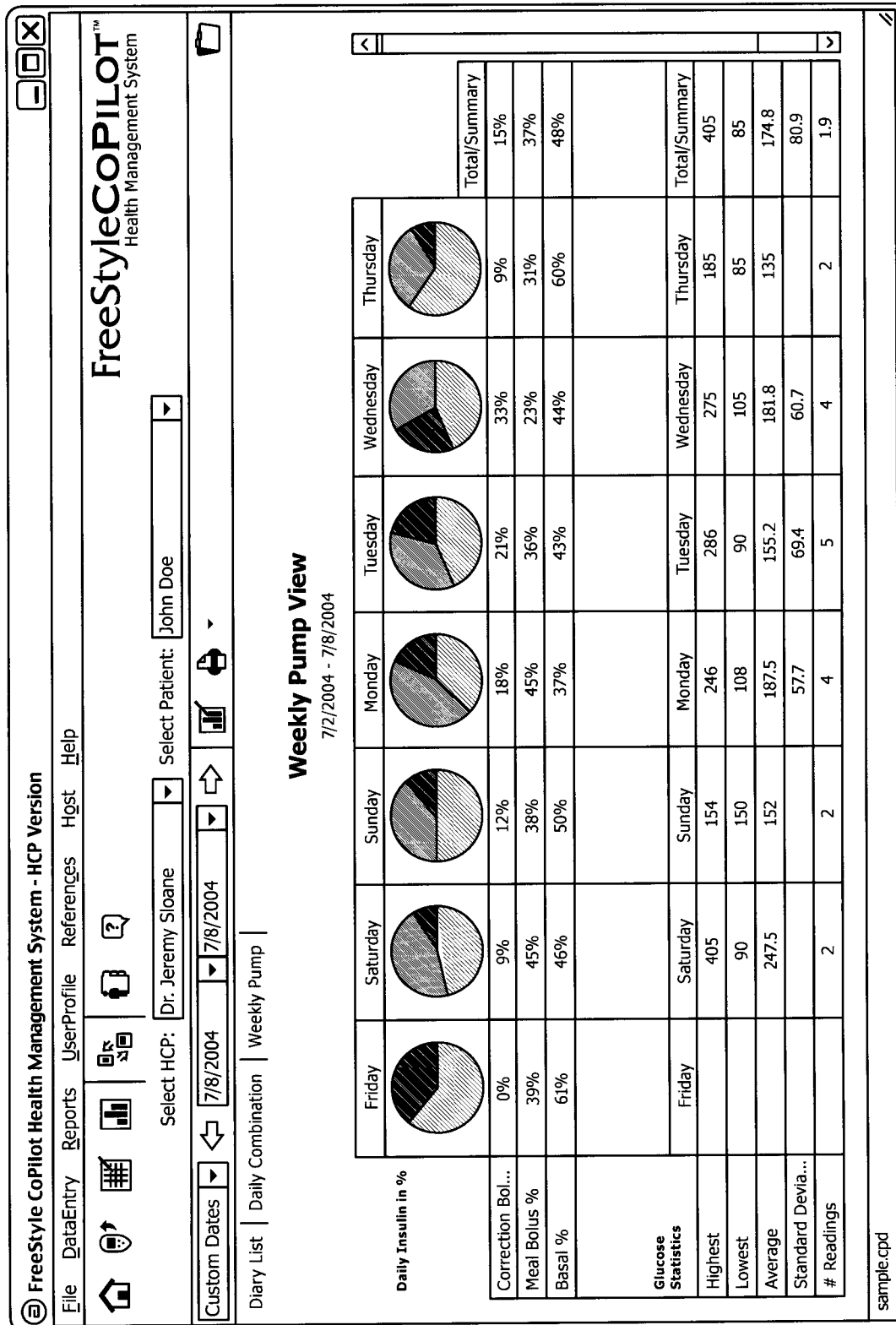


FIG. 135

FIG. 136

FIG. 136

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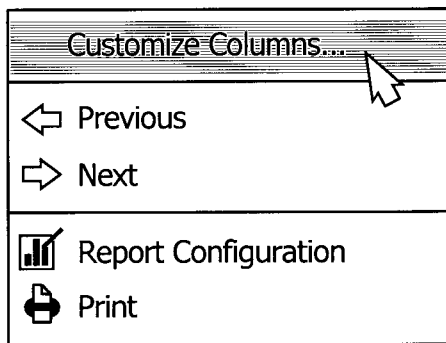


FIG. 137

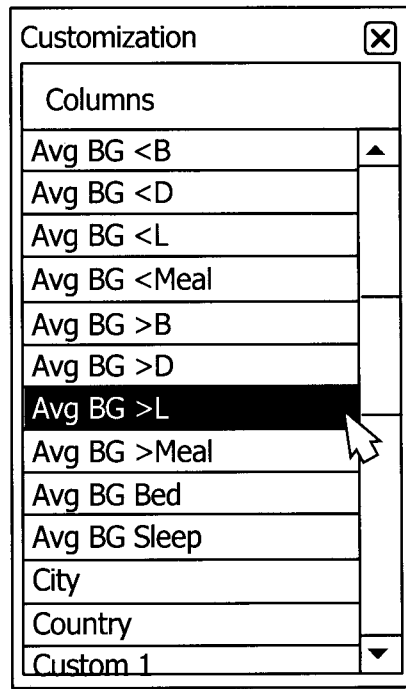


FIG. 138

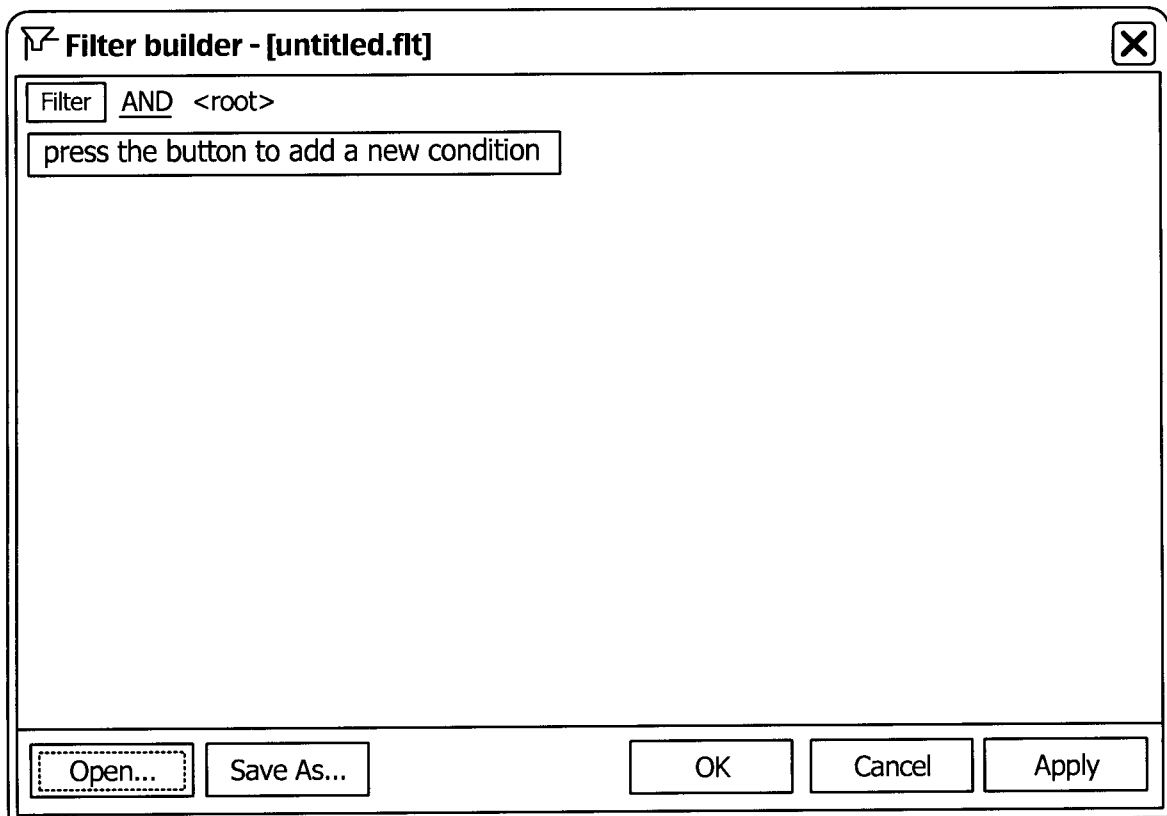


FIG. 139

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Health Management System - Home Version

[Reports](#)
[UserProfile](#)
[References](#)
[Host](#)
[Help](#)





Insulin Adjustment Table... F5
 Prescribed Plan... F6

Select User: ▼

FreeStyle Hea

FIG. 140

Insulin Adjustment Table

Insulin Sensitivity ▼

Glucose Start Value (mg/dL) ▼

Low Glucose Value	High Glucose Value	Insulin Dosage Amount
150	200	1
201	251	2
252	302	3
303	353	4
354	404	5
405	455	6
456	506	7
507	557	8

FIG. 141

Prescribed Plan

Prescribed Plan for: Marlon Tucker

Type	Item	Bkfst	Lunch	Dinner	Bed	Snack
Click here to add a new row						
Ratio						
Sensitivity						
Carbohydrates (grams)						

Comments

Print

Reset

OK

Cancel

Apply

? Help

FIG. 142

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Host	Help
 Synchronize	F9
Synchronize All	Ctrl+F9
Invite to Share Data...	
Manage my shared data...	

Host	Help
 Synchronize Current HCP	F9
Synchronize All HCPs	Ctrl+F9
Invite to Share Data...	
Accept E-mail Invitations...	
Manage my shared data...	
Manage data being shared with me...	

FIG. 143

FIG. 144

FIG. 144

Ⓜ

Profile for: Dr. Samuel Meyer, Endocrinologist

X

FileEditHelp

User InformationGlucose TargetsOptions

Contact Information

User ID*smeyerHost Account

TitleDr.HCP TypeEndocrinologist.

First*SamuelMILast*Meyer

Address 1Gotham Diabetes Center

Address 2100 Main Street

Address 3

CityAnyplaceState/ProvinceCA

CountryUSAZip/Postal Code

E-Mail**smeyer@anynet.net

PhoneTypePhone Number

Click here to add a new Phone

Assign Password

Password******

Confirm Password*

*Denotes a required field / **Required to Synchronize

Rights...

OKCancelApply? Help

FIG. 145

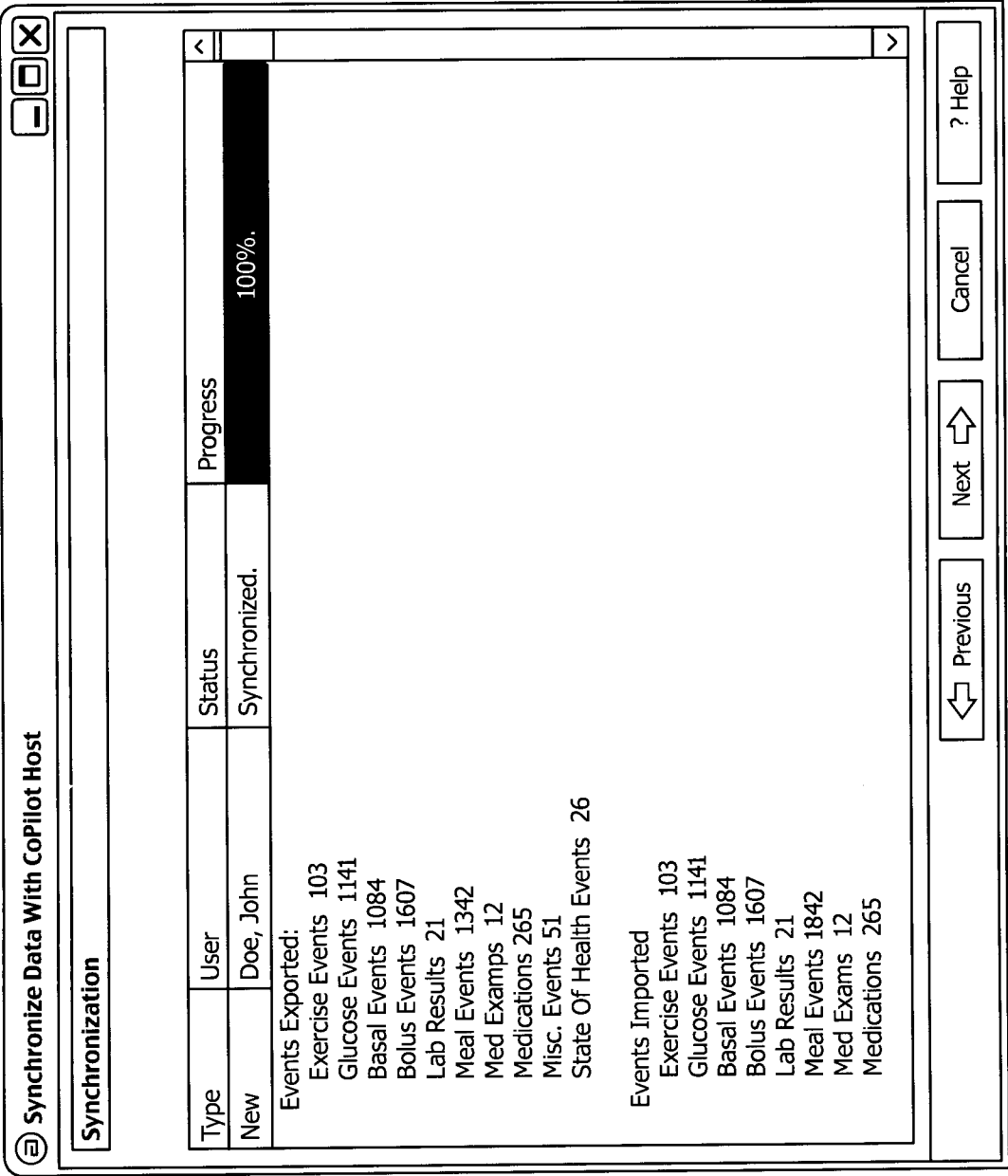


FIG. 146

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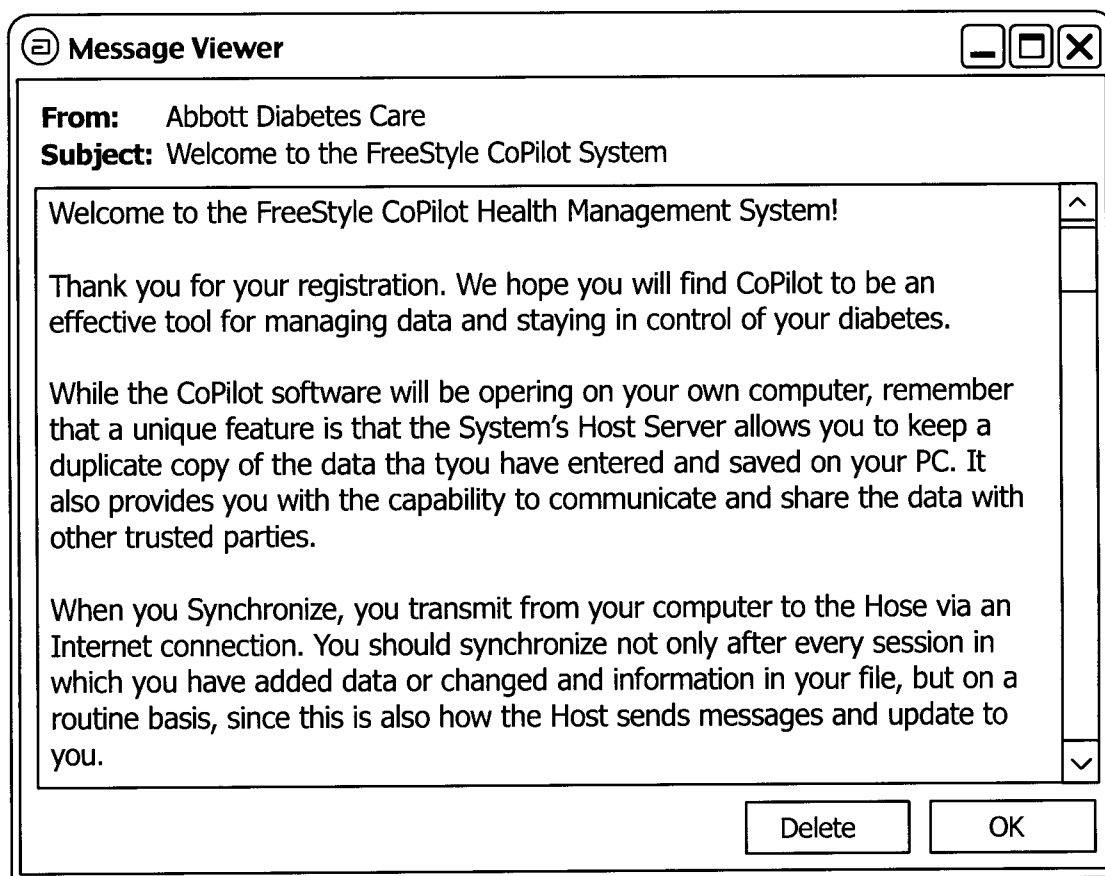


FIG. 147

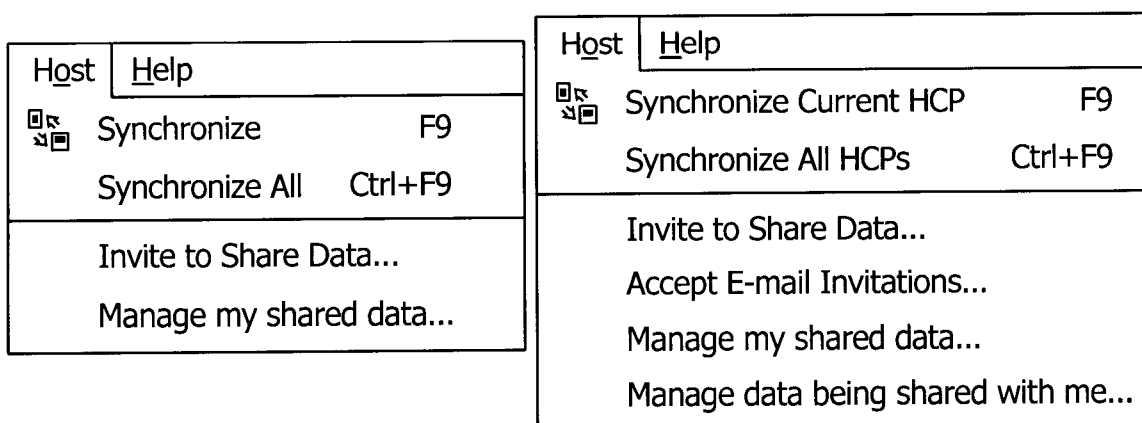


FIG. 148

Invite HCP to Share Data

Step 1: Invite to Share Data

This feature assists you in inviting an HCP to access your data. After you specify the HCP to whom you wish to grant this access, they will be sent an invitation message identifying you and giving instructions on how to accept the invitation, if they choose to do so.

Select the appropriate option below and click NEXT.

☒

 Search Host HCP Database to find an HCP from the list of existing accounts

☐

 Enter the Host HCP Account Number given to you by your HCP

☐

 Send an email invitation to an HCP who does not have an existing account

Previous

Next

Cancel

? Help

FIG. 149

Invite HCP to Share Data

Step 2: Find an HCP from the list of existing accounts

Indicate the location of your HCP and click SEARCH. Then select the desired HCP on the list. Click NEXT to continue.

CA

Search

HCP Name

Facility

Address

Previous

Next

Cancel

Help

FIG. 150

Invite HCP to Share Data

Step 3: Assign Access Level for selected HCP

Specify the Access Level that you wish to assign
(You may change this level at any time)

☒ Read Only Access

☐ Full Access (Read and Enter Data)

After assigning and Access Level, click SUBMIT. A message will be sent to the HCP advising them of your wish that they have access to your data.

You will be notified by a message on your Main Menu screen when the HCP has accepted your invitation. Be sure to Synchronize regularly to the Host Server to keep current with your messages.

Note: If you receive no messages confirming acceptance by the HCP within a reasonable period of time, you should follow-up with the HCP yourself as the system will not generate repeat invitation messages.

Previous

Submit

Cancel

? Help

FIG. 151

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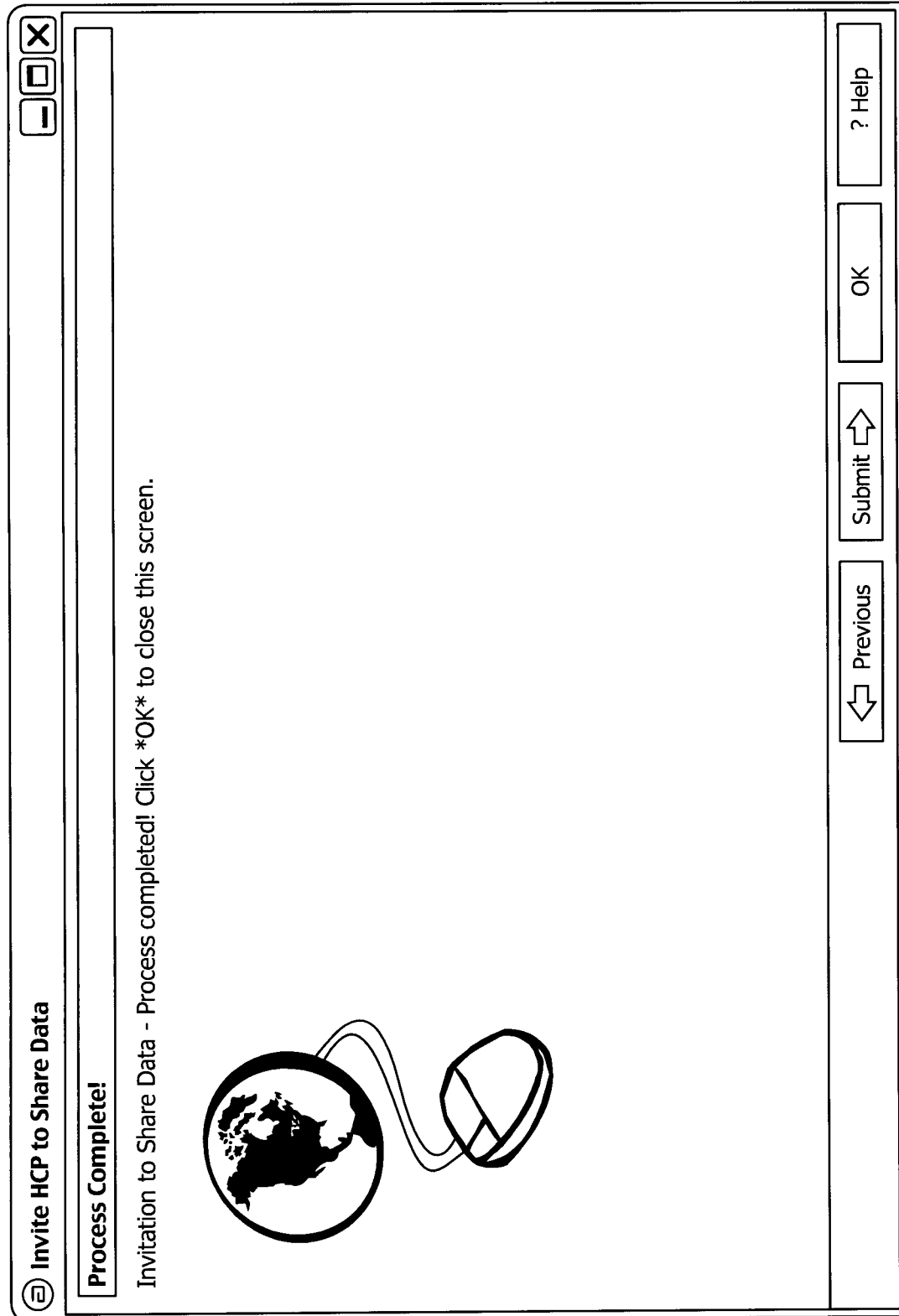


FIG. 152

Invite HCP to Share Data

Step 1: Invite to Share Data

This feature assists you in inviting an HCP to access your data. After you specify the HCP to whom you wish to grant this access, they will be sent an invitation message identifying you and giving instructions on how to accept the invitation, if they choose to do so.

Select the appropriate option below and click NEXT.

☐

Search Host HCP Database to find an HCP from the list of existing accounts

☒

Enter the Host HCP Account Number given to you by your HCP

☐

Send an email invitation to an HCP who does not have an existing account

Previous

Next

Cancel

? Help

FIG. 153

Invite HCP to Share Data

Step 2: Enter the Host HCP Account Number

Enter the Host Account Number and click SEARCH. The database will then be searched and the desired HCP will be listed. Click NEXT to continue.

HCP Account#

Search

Verify result then click [Next] to continue

Search Result

123694

Dr. Jeremy Sloane

Previous

Next

Cancel

? Help

FIG. 154

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Invite HCP to Share Data

Step 3: Assign Access Level for selected HCP

Specify the Access Level that you wish to assign
(You may change this level at any time)

☐ Read Only Access

☒ Full Access (Read and Enter Data)

After assigning and Access Level, click SUBMIT. A message will be sent to the HCP advising them of your wish that they have access to your data.

You will be notified by a message on your Main Menu screen when the HCP has accepted your invitation. Be sure to Synchronize regularly to the Host Server to keep current with your messages.

Note: If you receive no messages confirming acceptance by the HCP within a reasonable period of time, you should follow-up with the HCP yourself as the system will not generate repeat invitation messages.

Previous

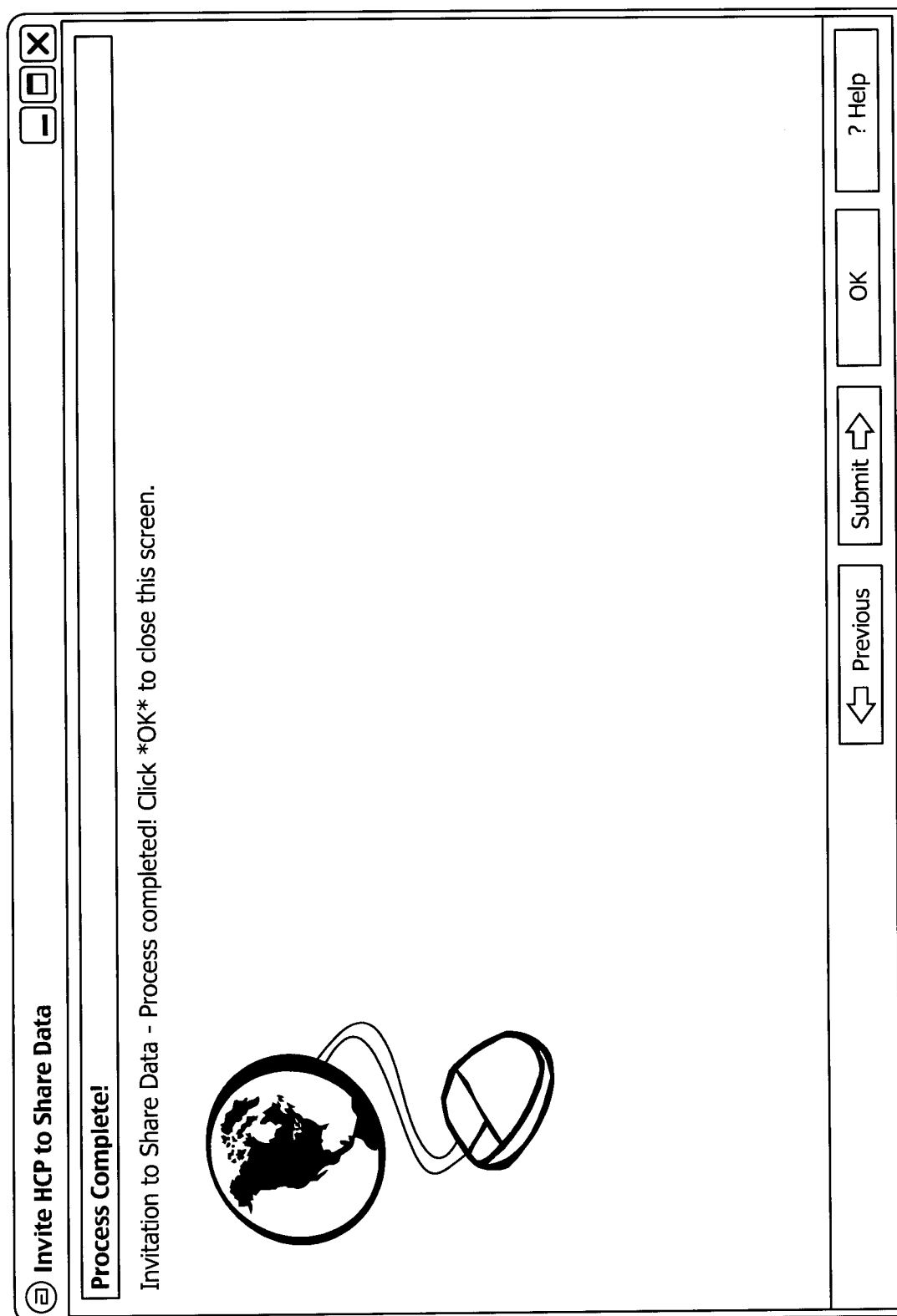
Submit

Cancel

? Help

FIG. 155

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**FIG. 156**

Messages From CoPilot Host		
Date	From	Subject
11/7/2004	Millard Fillmore	Attention: Access Authorization has been granted to you
An invitation to share data on the FreeStyle CoPilot Health Management System has been sent to you by Dwayne White...		

FIG. 157

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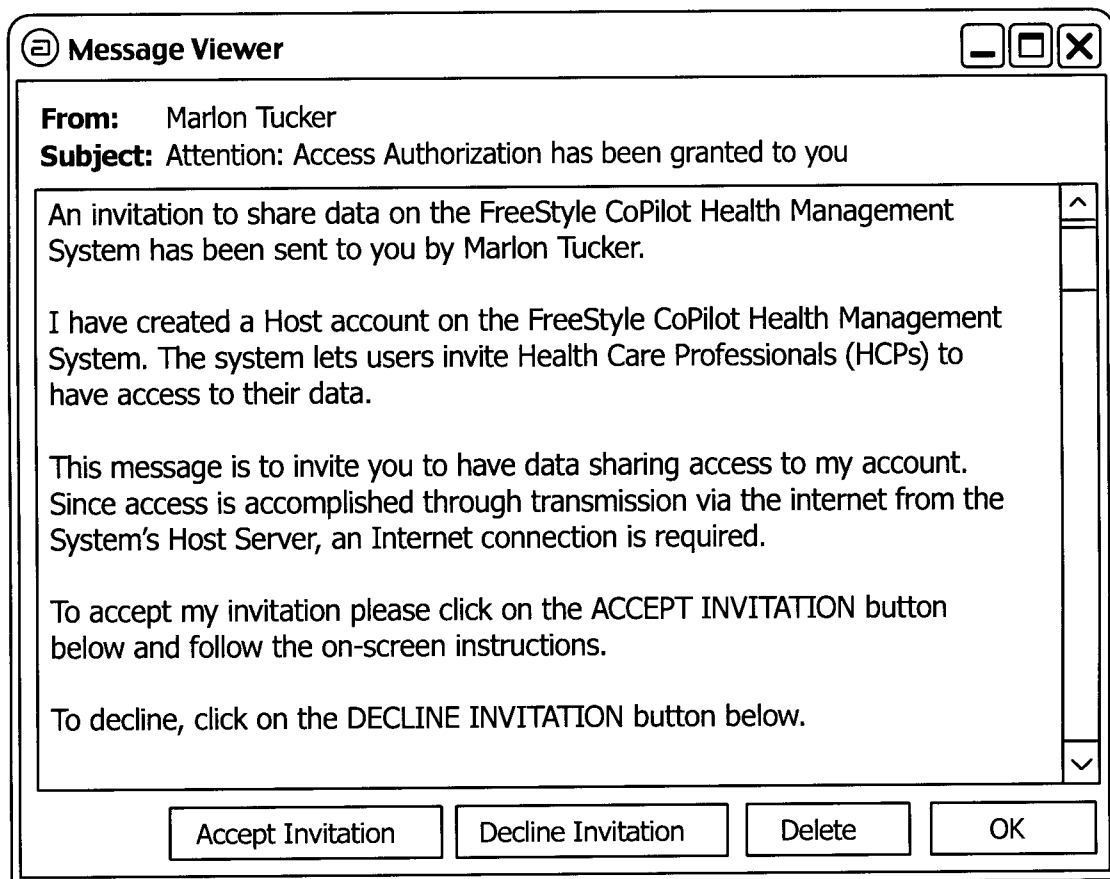


FIG. 158

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Invite HCP to Share Data

Step 1: Invite to Share Data

This feature assists you in inviting an HCP to access your data. After you specify the HCP to whom you wish to grant this access, they will be sent an invitation message identifying you and giving instructions on how to accept the invitation, if they choose to do so.

Select the appropriate option below and click NEXT.

- ☐ Search Host HCP Database to find an HCP from the list of existing accounts
- ☐ Enter the Host HCP Account Number given to you by your HCP
- ☒ Send an email invitation to an HCP who does not have an existing account

Previous Next ? Help Cancel

FIG. 159

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ⓐ Invite HCP to Share Data

✕

□

▢

Step 2: Send an e-mail invitation to an HCP who does not have an account

Enter the name and e-mail address of the HCP whom you wish to invite. Then click NEXT to continue.

Name

Dr. Mary Crawford

E-mail Address:

mcrawford@anynet.net

⏪ Previous

Next ⏩

Cancel

? Help

FIG. 160

Invite HCP to Share Data

Step 3: Assign Access Level for selected HCP

Specify the Access Level that you wish to assign
(You may change this level at any time)

☒ Read Only Access

☐ Full Access (Read and Enter Data)

After assigning and Access Level, click SUBMIT. A message will be sent to the HCP advising them of your wish that they have access to your data.

You will be notified by a message on your Main Menu screen when the HCP has accepted your invitation. Be sure to Synchronize regularly to the Host Server to keep current with your messages.

Note: If you receive no messages confirming acceptance by the HCP within a reasonable period of time, you should follow-up with the HCP yourself as the system will not generate repeat invitation messages.

Previous

Submit

Cancel

? Help

FIG. 161

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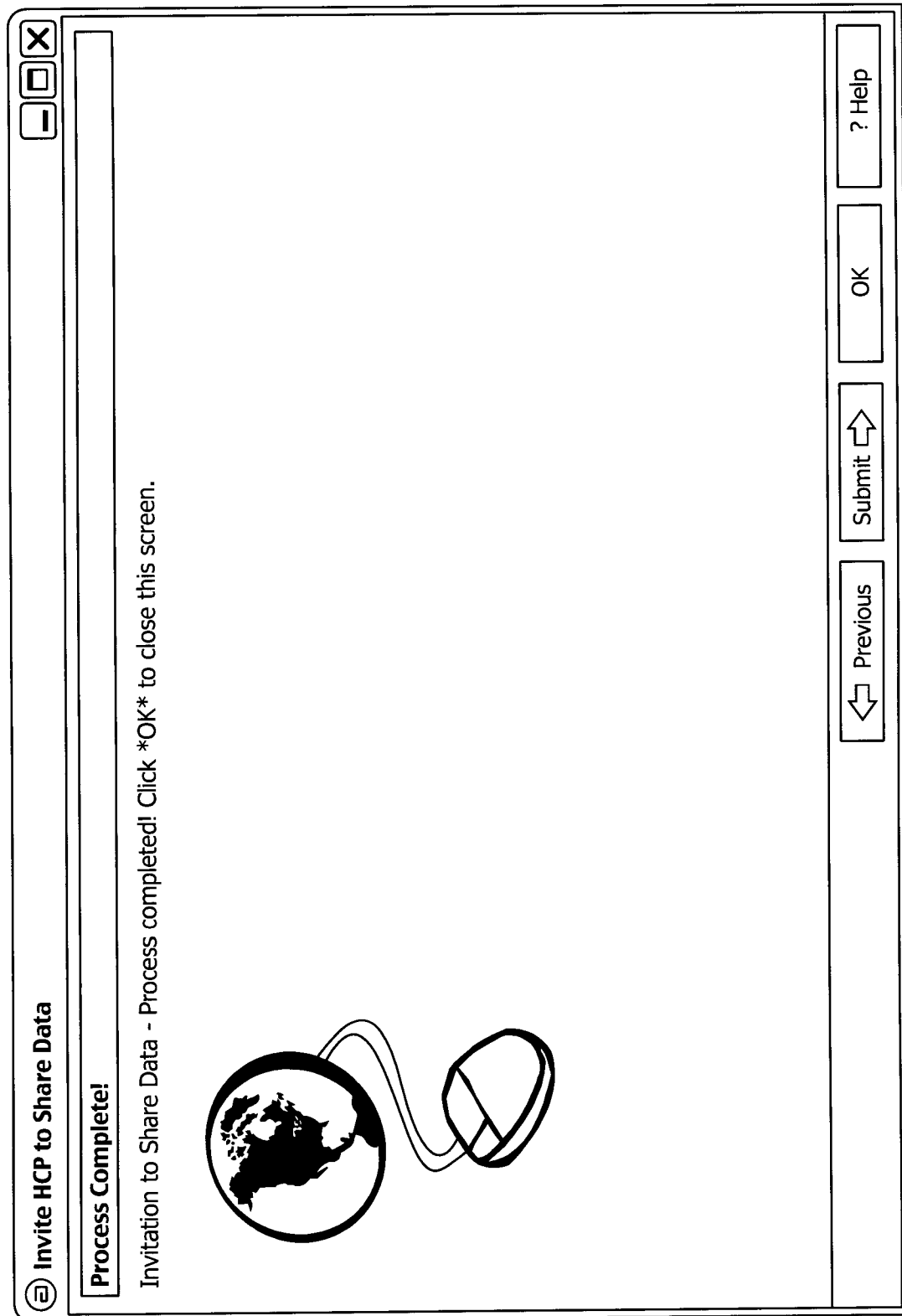


FIG. 162

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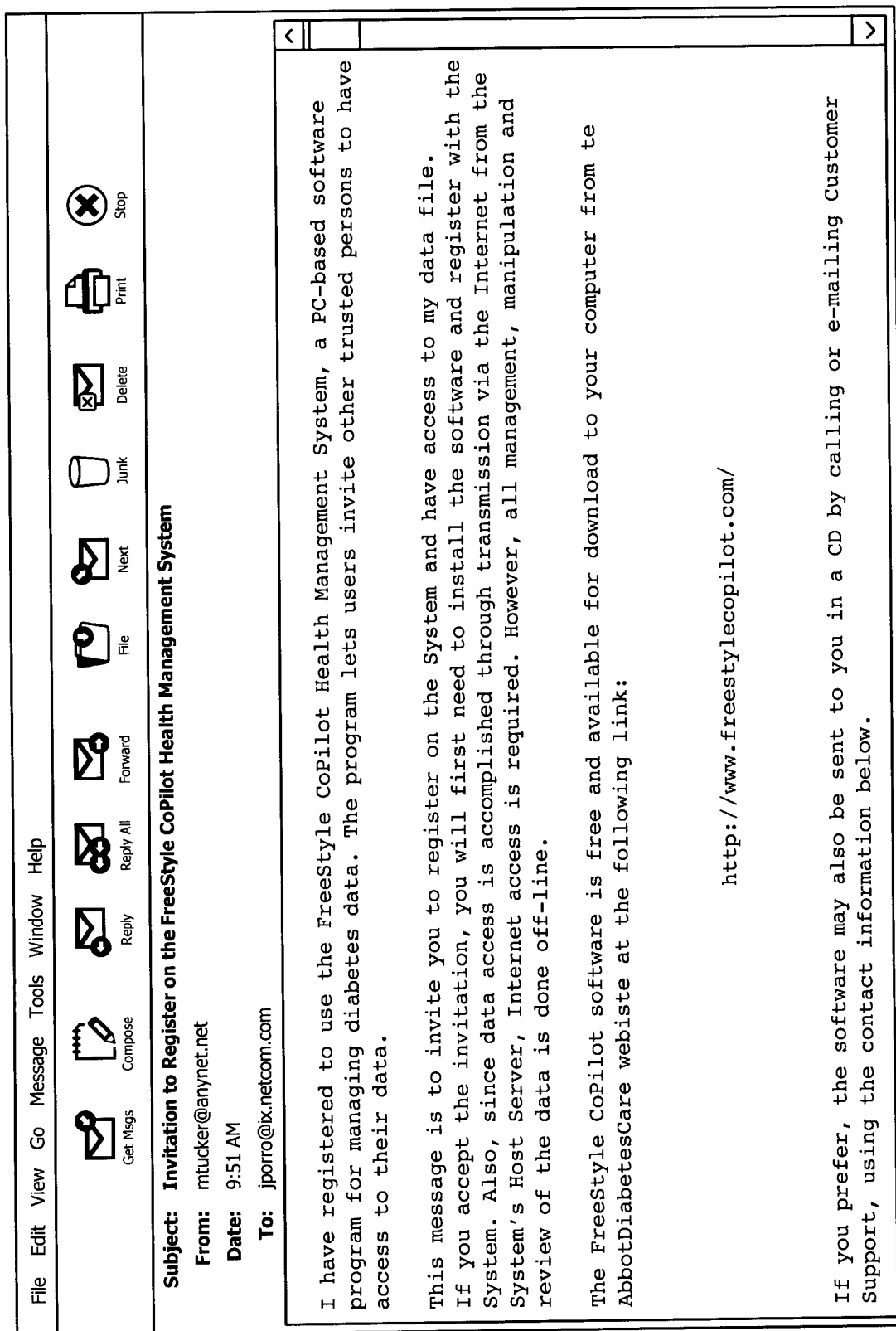
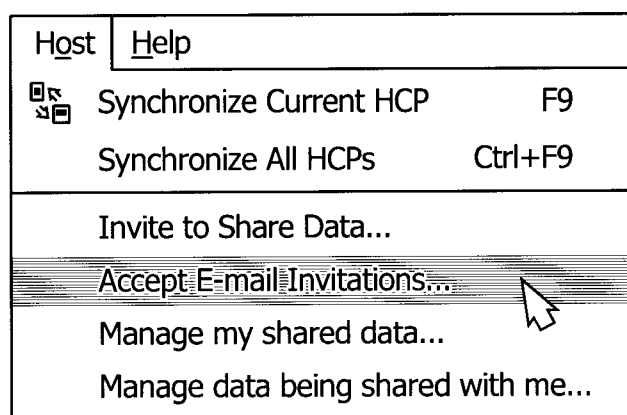


FIG. 163

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Invitation Code: A_Guw5I5dnOKaQbAsvhASx

FIG. 164**FIG. 165**

Accept Invitation

Accept Invitation

Enter the Invitation Code Number that appears on the invitation message that you received, the click NEXT to continue.

Invitation Code: A_Guw515dnOKaQbAschASx

Previous

Next

Cancel

? Help

FIG. 166

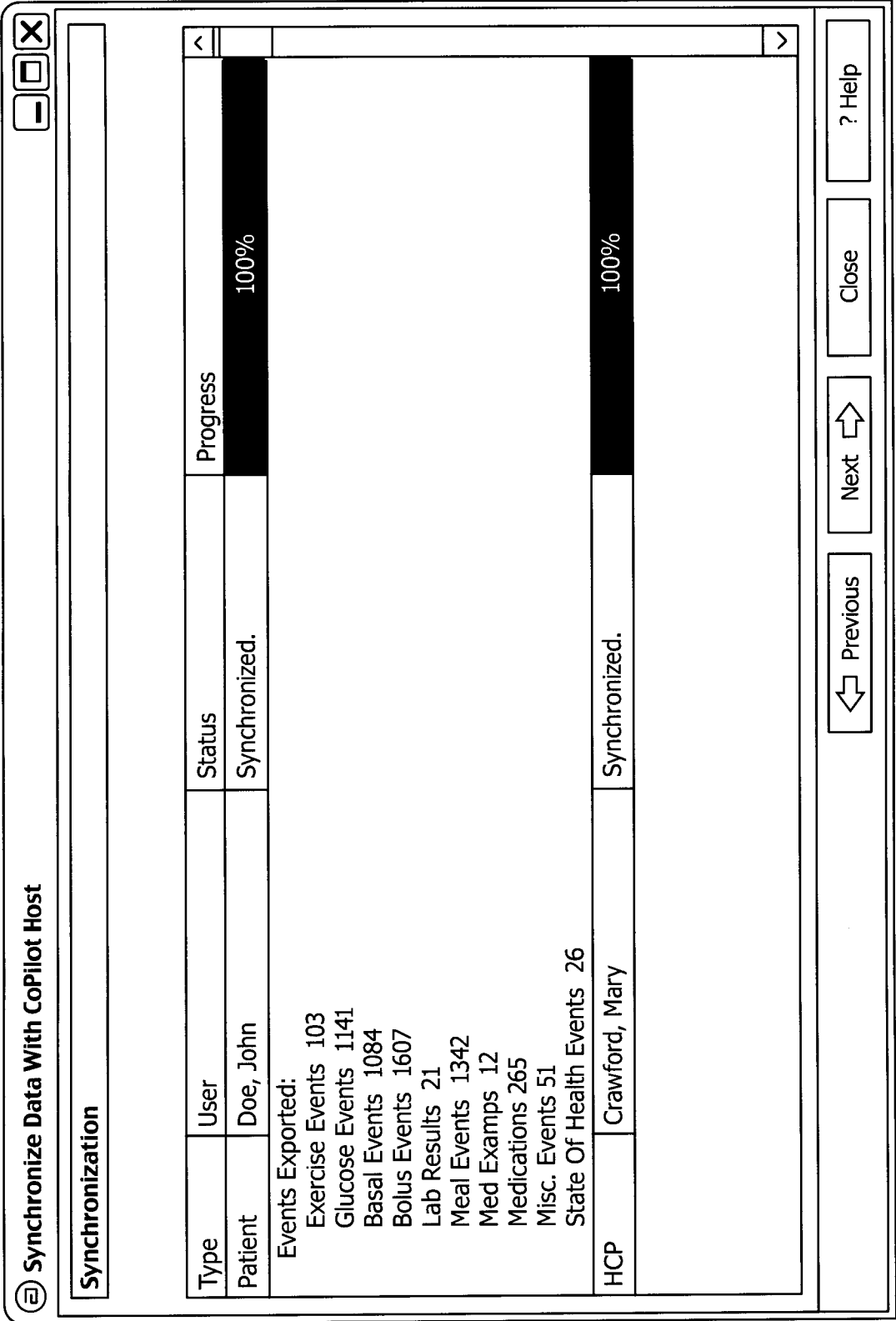


FIG. 167

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Host	Help
	Synchronize F9
	Synchronize All Ctrl+F9
Invite to Share Data...	
Manage my shared data...	

FIG. 168

Host	Help
	Synchronize Current HCP F9
	Synchronize All HCPs Ctrl+F9
Invite to Share Data...	
Accept E-mail Invitations...	
Manage my shared data...	
Manage data being shared with me...	

FIG. 170

Manage my shared data

Parties Authorized by: Anita Bryant

Access Level	Access Level	First Name	Last Name	City	State
READ ONLY	123885	William	Reade	Anyplace	AK

Grant NO Access

Grant Read Only Access

Grant Full Access

Close

FIG. 169

Manage data being shared with me

People sharing data with: Dr. William REade

Access Level	Access Level	First Name	Last Name	City	State
READ_ONLY	123881	Anita	Bryant		

Unsubscribe

Close

FIG. 171

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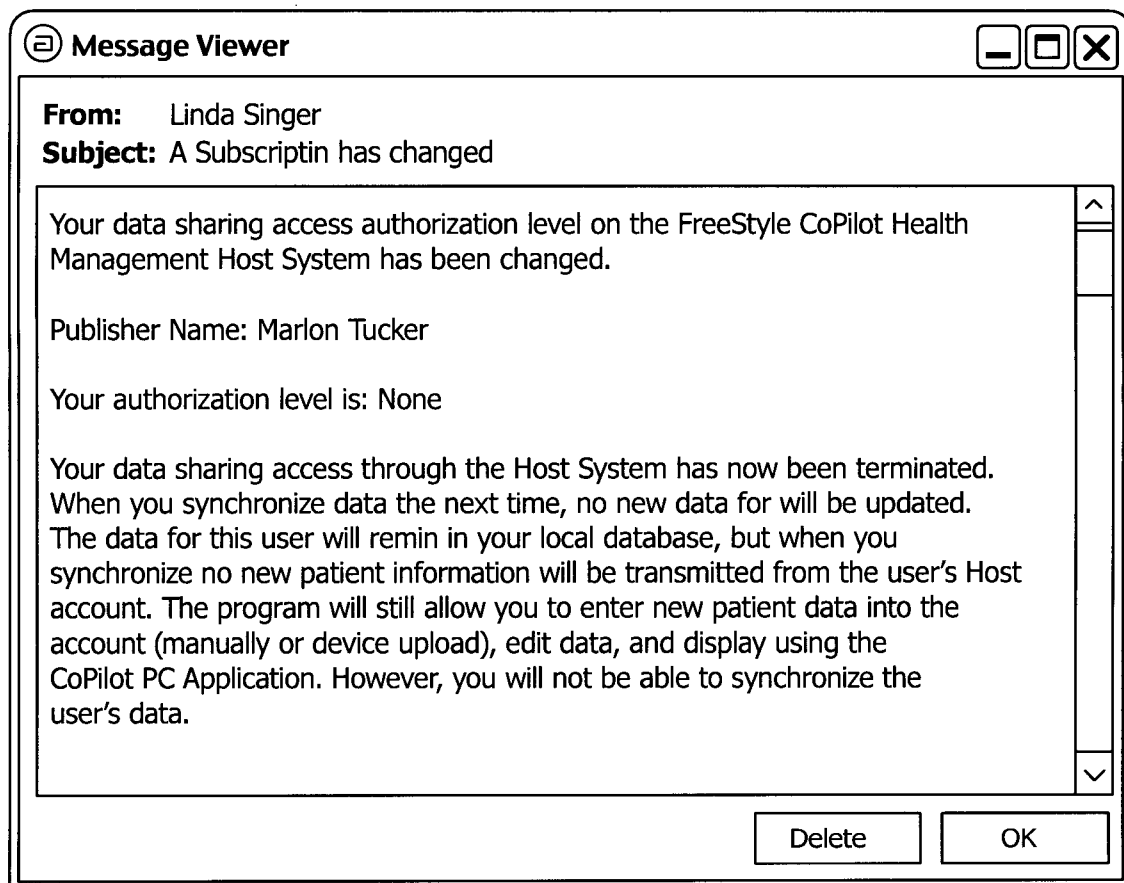


FIG. 172

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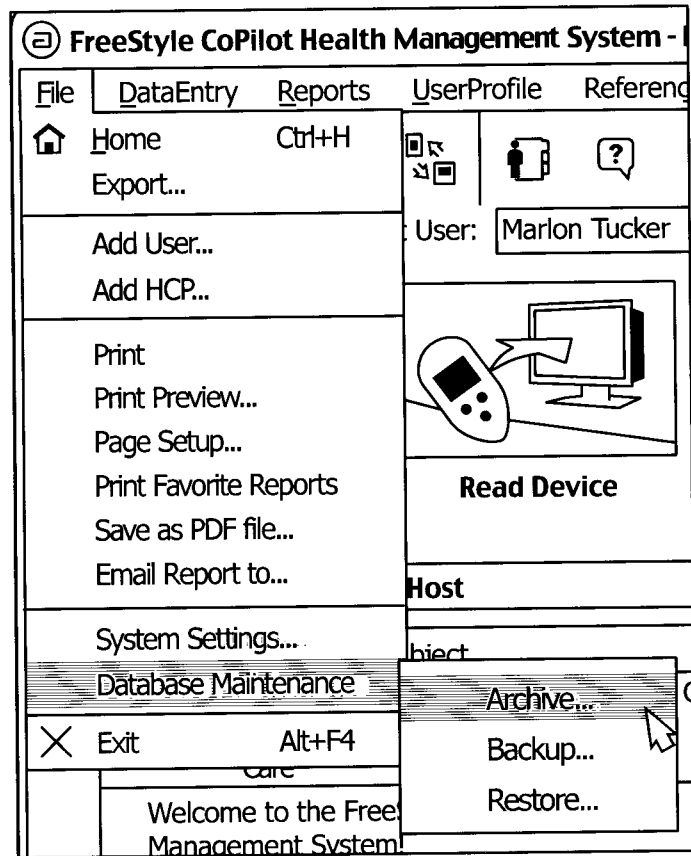


FIG. 173

Archive Event Data			
Select a date:	3/15/2004	▼	
After selecting a date, click the OK button to archive all events prior to and including this date.			
OK	Cancel	Apply	? Help

FIG. 174

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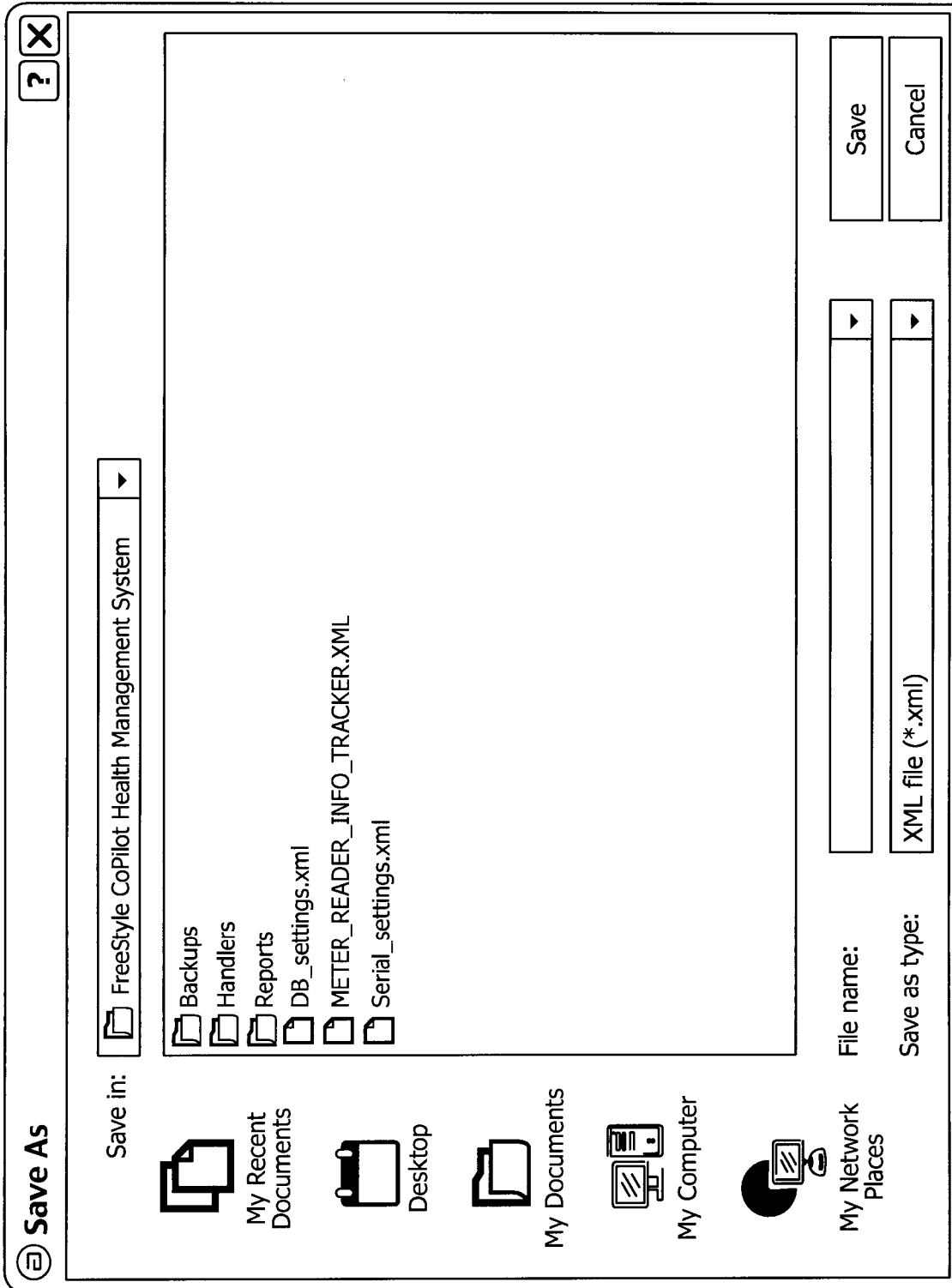


FIG. 175

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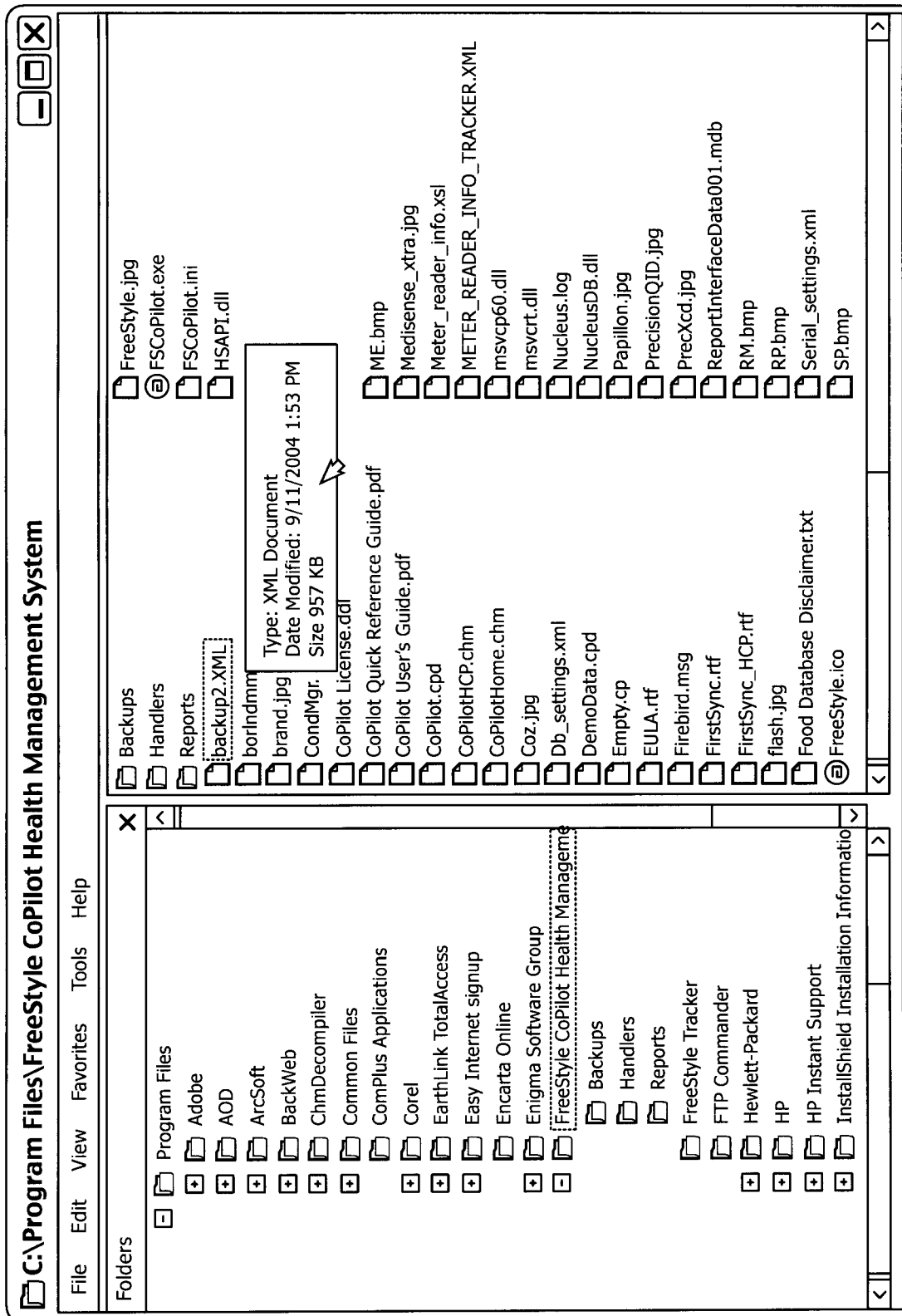


FIG. 176

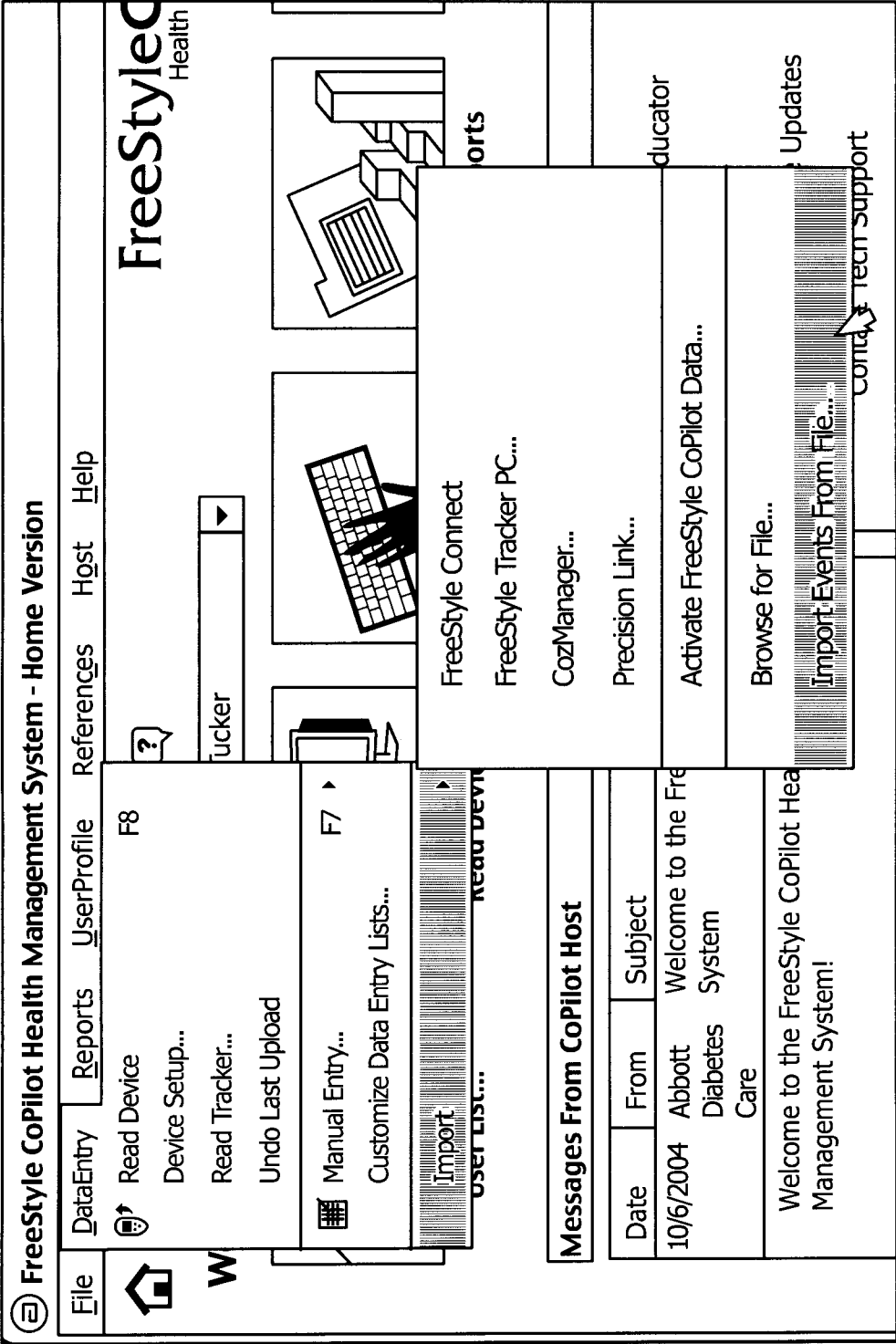


FIG. 177

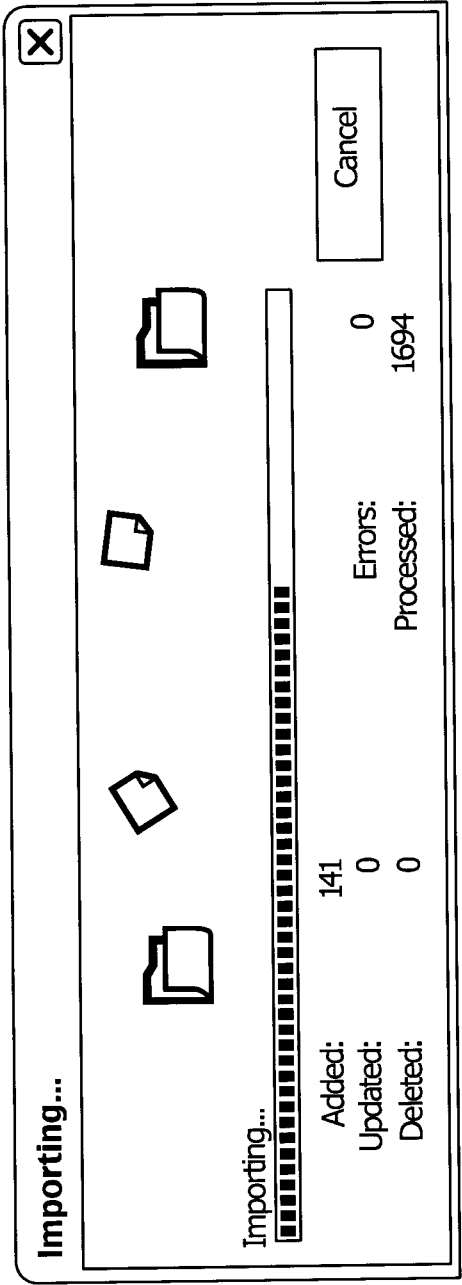


FIG. 178

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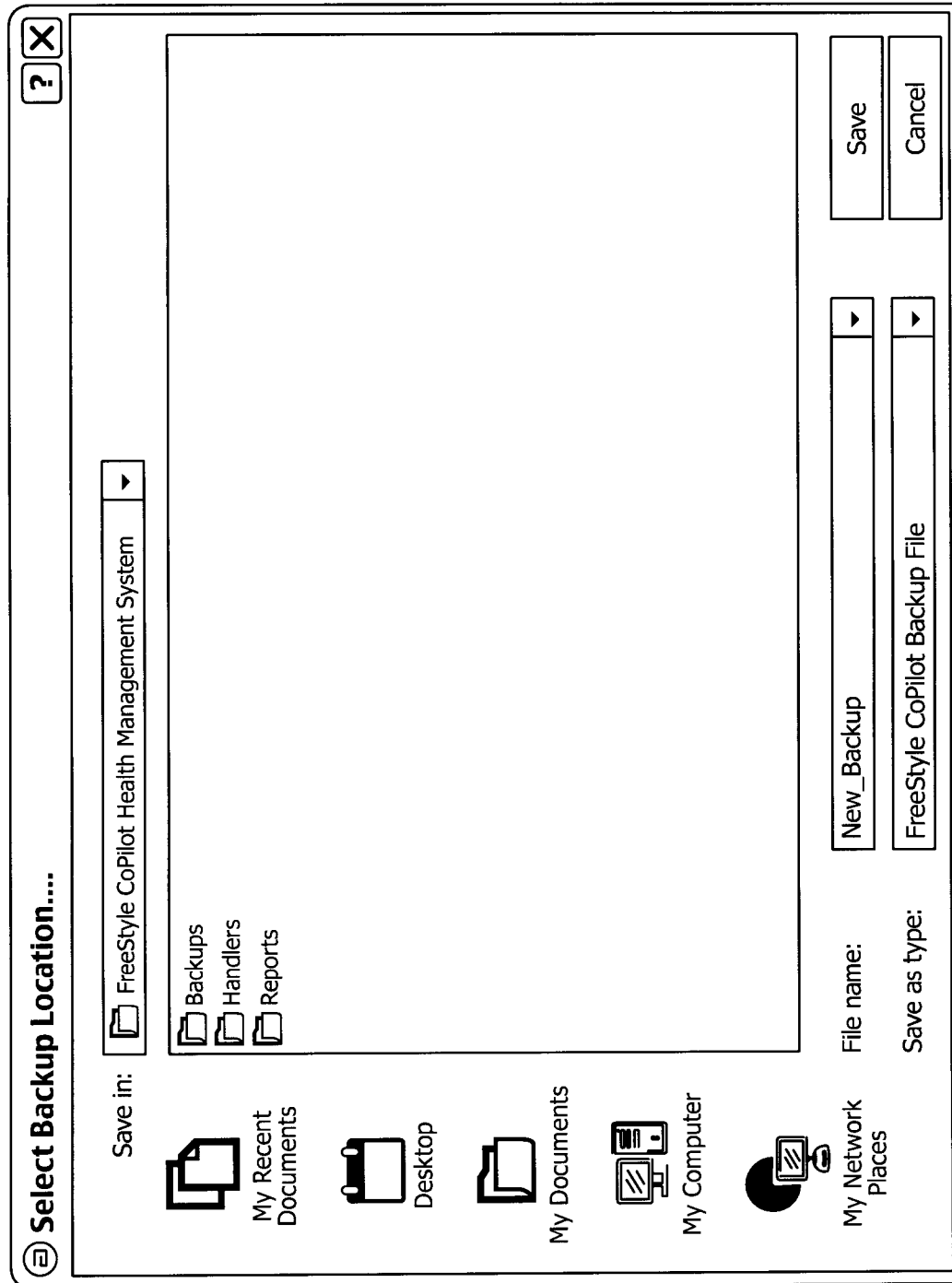
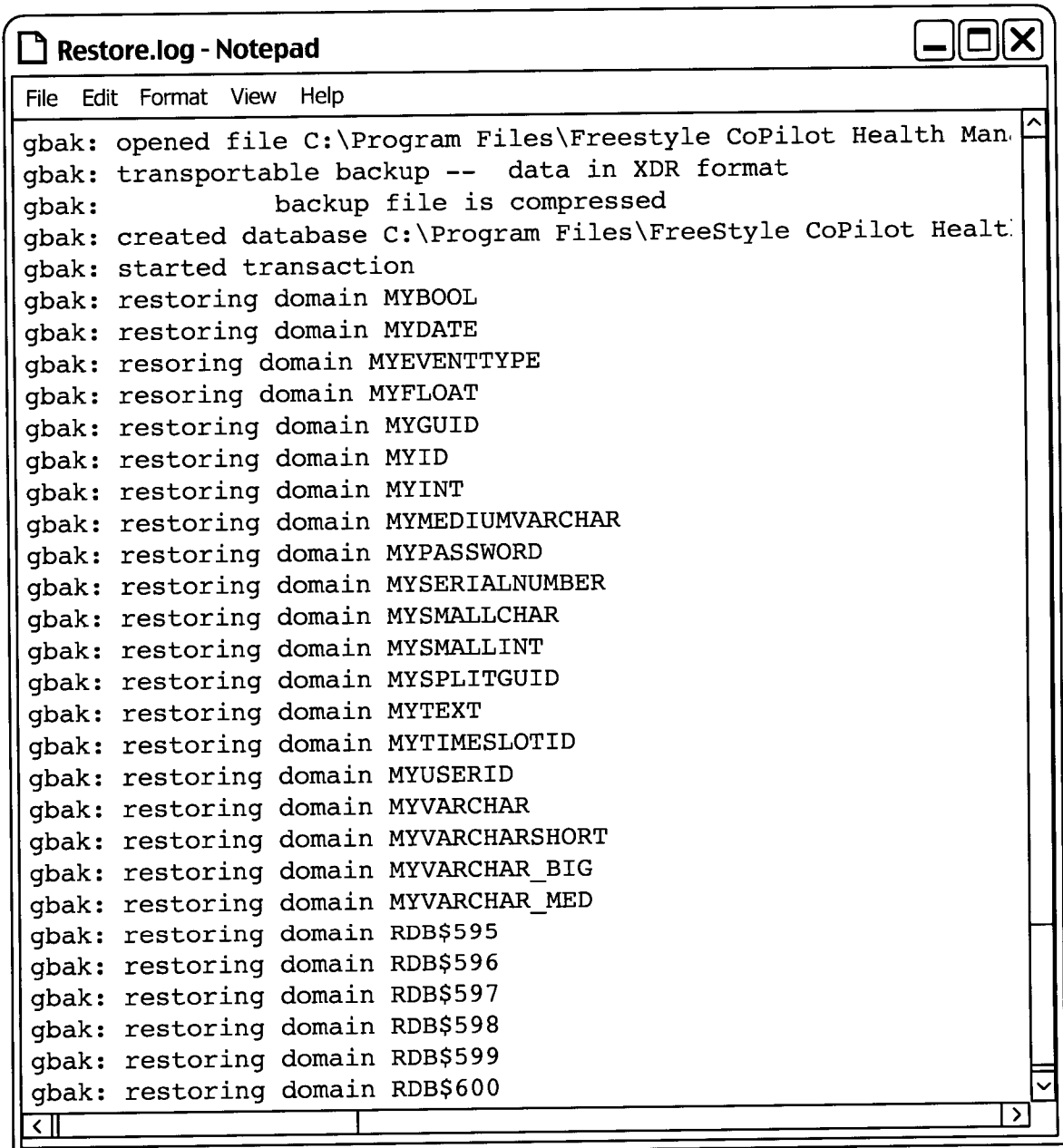


FIG. 179

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The screenshot shows a Notepad window with the title bar 'Restore.log - Notepad'. The window contains a log of database restoration commands and their progress. The commands are as follows:

```
gbak: opened file C:\Program Files\Freestyle CoPilot Health Man.  
gbak: transportable backup -- data in XDR format  
gbak: backup file is compressed  
gbak: created database C:\Program Files\FreeStyle CoPilot Health  
gbak: started transaction  
gbak: restoring domain MYBOOL  
gbak: restoring domain MYDATE  
gbak: restoring domain MYEVENTTYPE  
gbak: restoring domain MYFLOAT  
gbak: restoring domain MYGUID  
gbak: restoring domain MYID  
gbak: restoring domain MYINT  
gbak: restoring domain MYMEDIUMVARCHAR  
gbak: restoring domain MYPASSWORD  
gbak: restoring domain MYSERIALNUMBER  
gbak: restoring domain MYSMALLCHAR  
gbak: restoring domain MYSMALLINT  
gbak: restoring domain MYSPLITGUID  
gbak: restoring domain MYTEXT  
gbak: restoring domain MYTIMESLOTID  
gbak: restoring domain MYUSERID  
gbak: restoring domain MYVARCHAR  
gbak: restoring domain MYVARCHARSHORT  
gbak: restoring domain MYVARCHAR_BIG  
gbak: restoring domain MYVARCHAR_MED  
gbak: restoring domain RDB$595  
gbak: restoring domain RDB$596  
gbak: restoring domain RDB$597  
gbak: restoring domain RDB$598  
gbak: restoring domain RDB$599  
gbak: restoring domain RDB$600
```

FIG. 180

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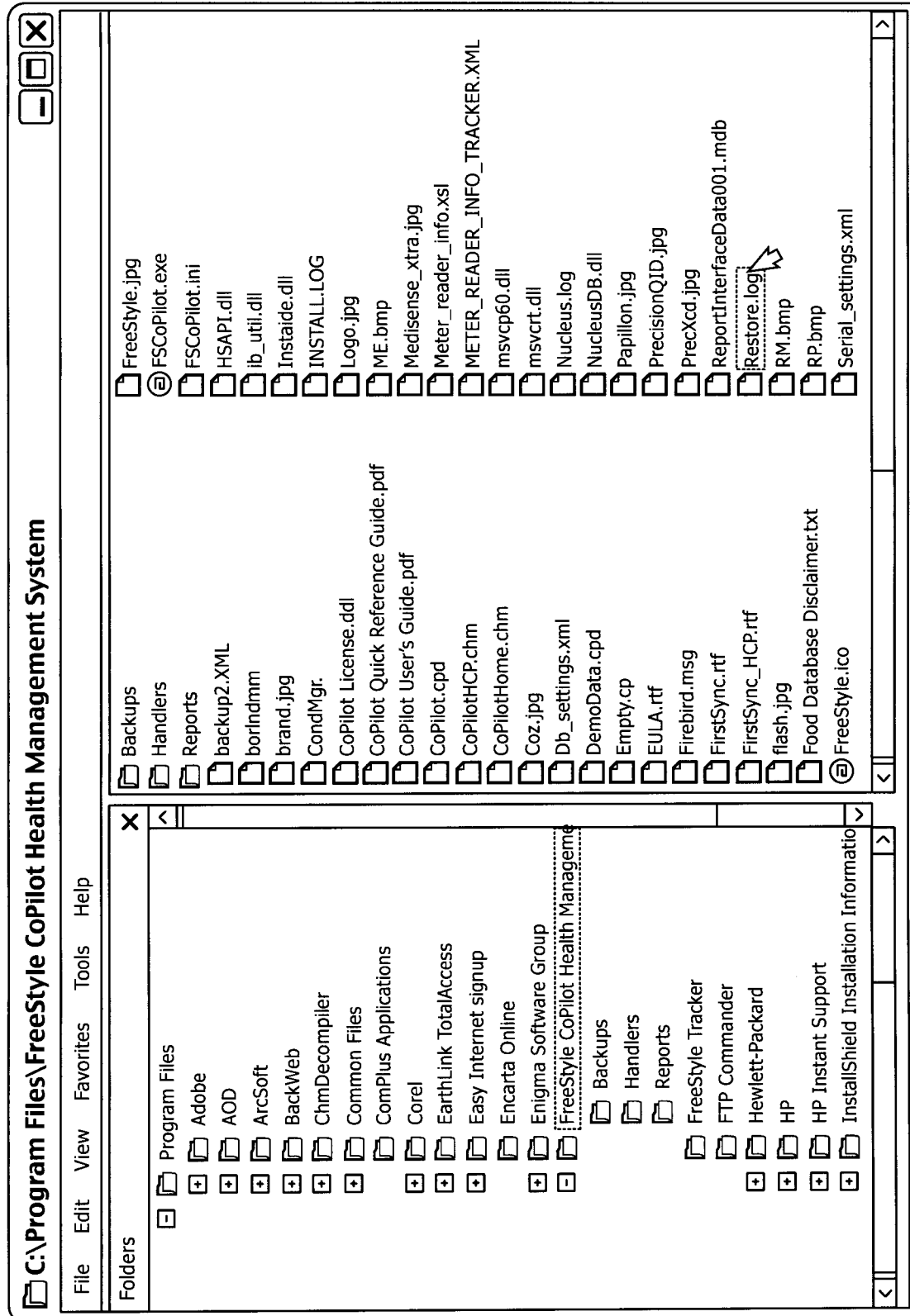
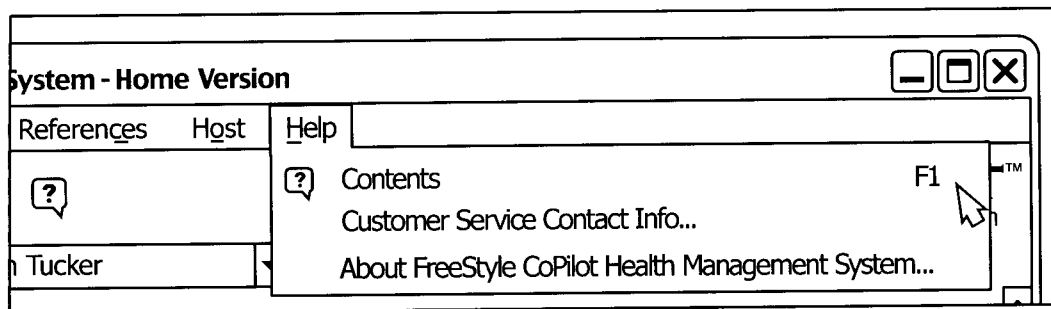


FIG. 181

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**FIG. 182**

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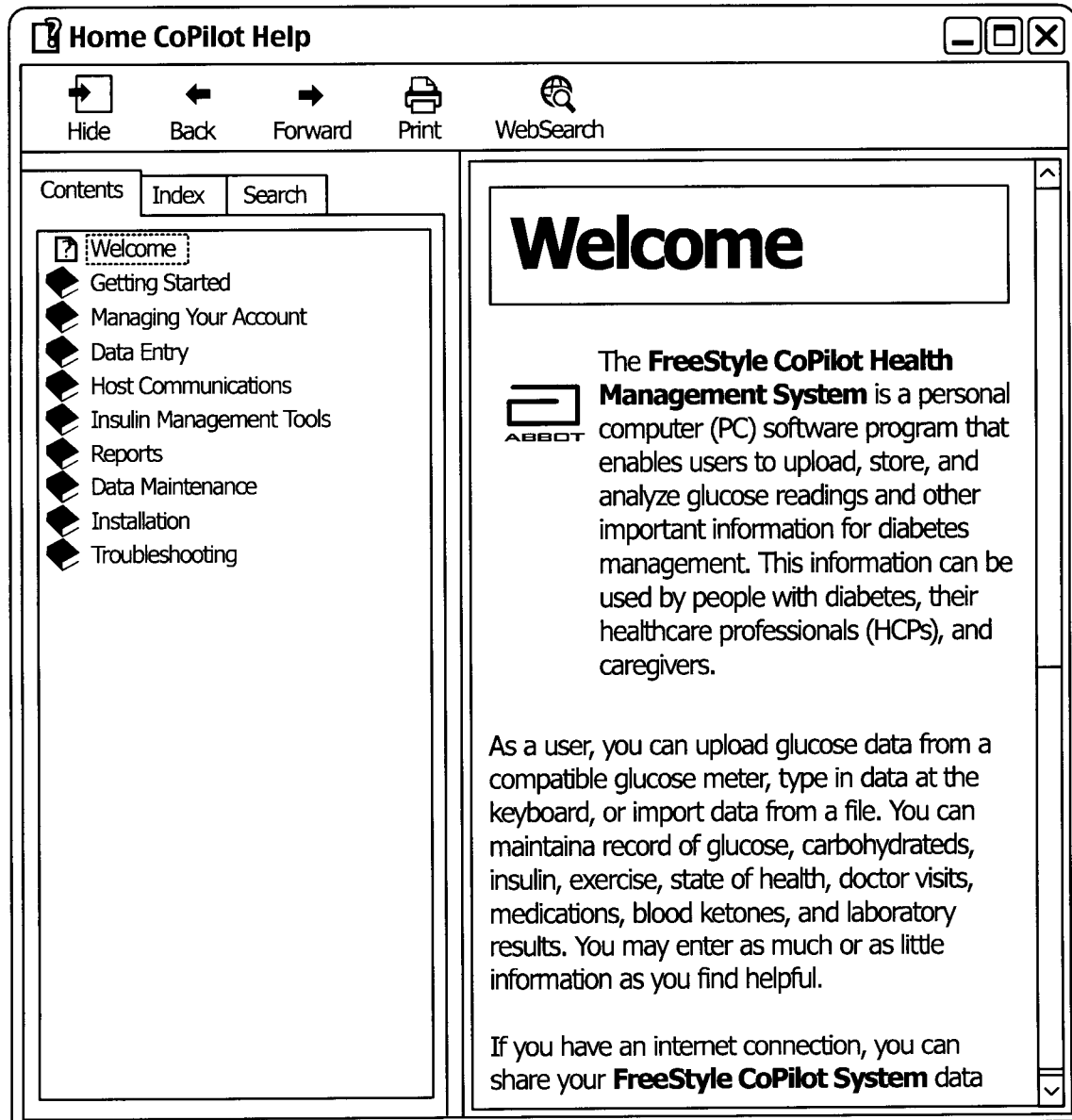


FIG. 183

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Contents

Index

Search

Type in the keyword to find:

CoPilot Host

Model

Hide Data

selecting

Glucose

Filters . All Report View Filters

Time Periods Selection

Sort

Diary List

Display Time Periods

Features . The Diary List

Un-Hide

Show Hypo/Hyper

Selecting

Show Glucose Targets

When

Raw Data

Background

Manual Data Entry

read

Host Login Account

Create

obtained

establish

Display

FIG. 184

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The screenshot shows a search interface with three tabs: 'Contents', 'Index', and 'Search'. The 'Search' tab is active. Below the tabs, there is a label 'Type in the keyword to find:' followed by a text input field containing the word 'meal'. To the right of the input field is a button labeled 'List Topics'. Below this, there is a label 'Select Topic to display:' followed by a list box containing the following items: 'Daily Combination', 'Data Entry', 'Generate Report Views', 'Glucose Average', 'Glucose Modal Day', 'Glucose Pie Chart', 'Home User Glucose Targets', 'Home User Options', 'Insulin Management Tools', 'Logbook', 'Manual Data Entry', 'Prescribed Plan', 'Record a Glucose Reading', 'Record a Meal', 'Selection List Customization', 'Statistics', and 'Weekly Pump'. To the right of the list box is a vertical scrollbar with up and down arrows. Below the list box is a button labeled 'Display'.

Contents Index Search

Type in the keyword to find:

meal

List Topics

Select Topic to display:

- Daily Combination
- Data Entry
- Generate Report Views
- Glucose Average
- Glucose Modal Day
- Glucose Pie Chart
- Home User Glucose Targets
- Home User Options
- Insulin Management Tools
- Logbook
- Manual Data Entry
- Prescribed Plan
- Record a Glucose Reading
- Record a Meal
- Selection List Customization
- Statistics
- Weekly Pump

Display

FIG. 185

The screenshot shows a help menu with a title bar labeled 'Help'. Below the title bar, there is a list of items: 'Contents' (with a question mark icon), 'Customer Service Contact Info...' (with a question mark icon), and 'About Free Style CoPilot Health Management System...' (with an information icon). The 'Contents' item is highlighted, and a mouse cursor is pointing at it. The 'F1' key is displayed to the right of the 'Contents' item.

Help

? Contents F1

? Customer Service Contact Info...

i About Free Style CoPilot Health Management System...

FIG. 186

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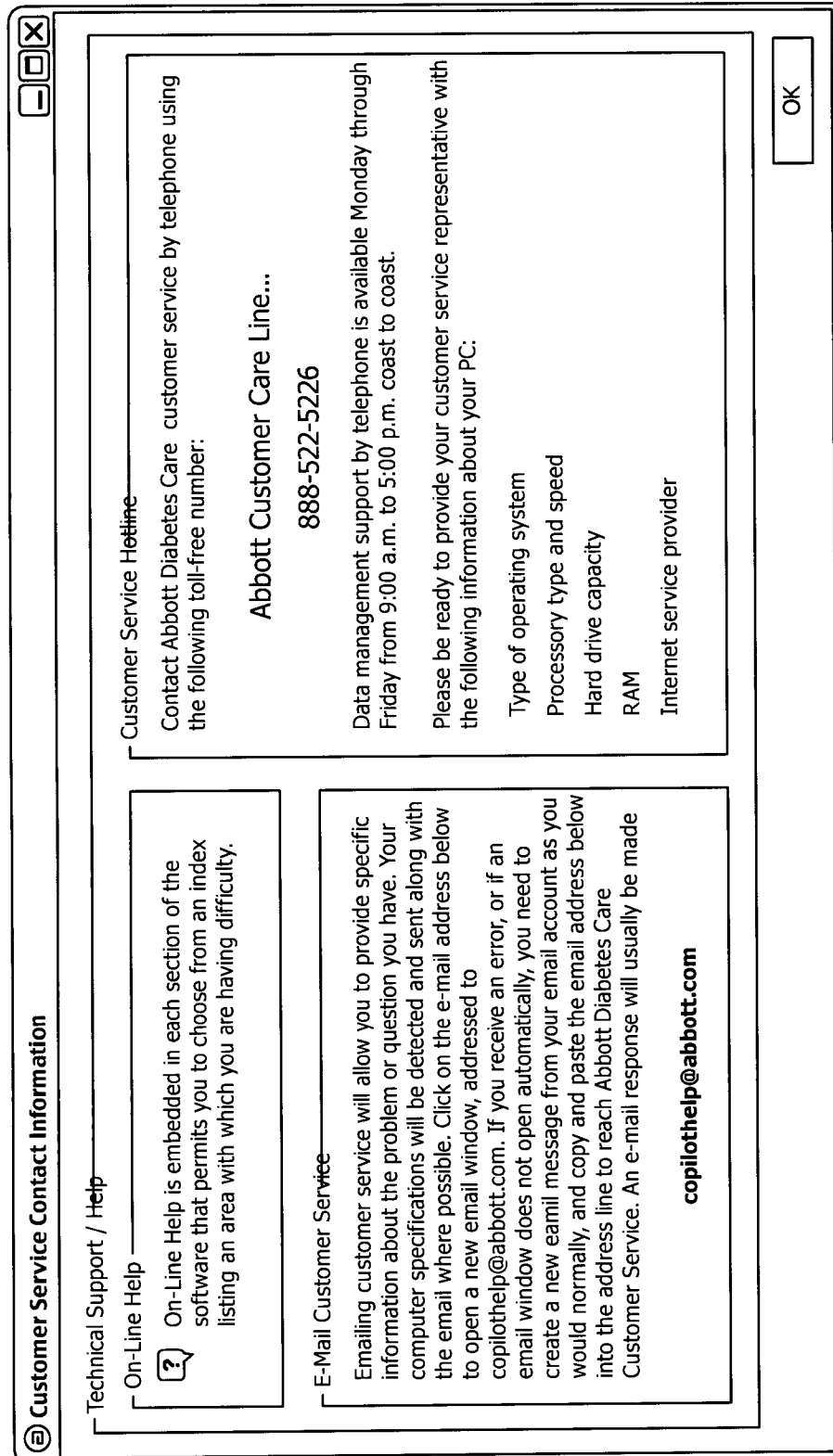


FIG. 187

