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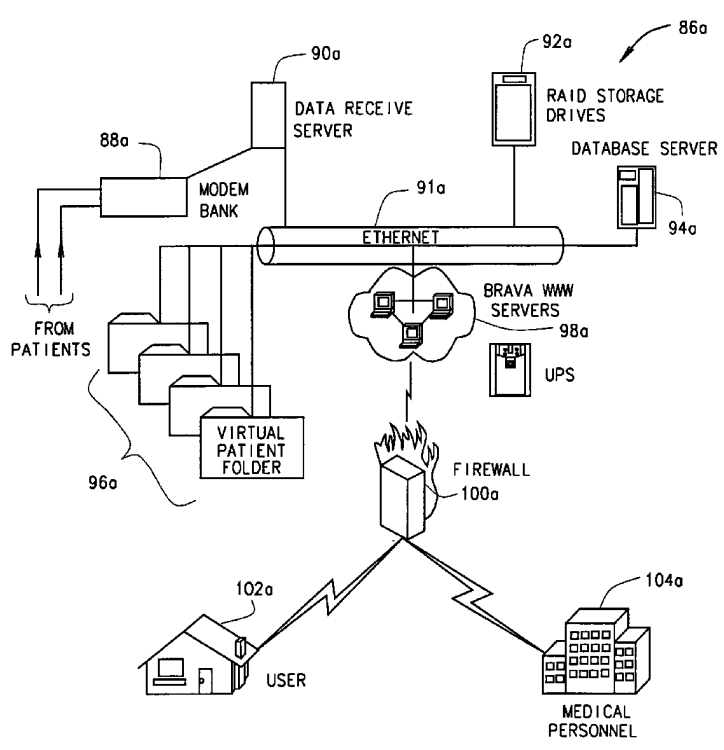

(57) Abstract: A patient monitoring device includes a microprocessor controller having a clock circuit and memory coupled to one or more sensors such that as the medical appliance is properly fitted to and worn by the patient, the sensors provide an electrical signal confirming that which may be then timed to provide data which confirms a patient's compliance with a recommended protocol. Additionally, other sensors may be used to collect data relating to various operational parameters of the device including the amount of negative pressure presented under a vacuum dome, as desired. A preferred embodiment includes a controller having a microcomputer and sensor for monitoring and collecting data relating to a patient's compliance with a prescribed regimen. The controller is battery operated and is recharged by placing the controller into a cradle which has a wall plug for providing power. The cradle also has a modem and phone connection so that as the controller rests in the cradle, compliance data contained within the controller is automatically transmitted by a modem over the phone line connection to a central location. The central location includes a data network for receiving the patient compliance data, processing and storing it in virtual patient files, and one or more web servers host a web site for displaying the patient data in its processed form.

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PATIENT COMPLIANCE MONITOR AND METHOD FOR COLLECTING PATIENT COMPLIANCE DATA AND DISPLAY THEREOF OVER A COMPUTER NETWORK

Background of the Invention

There are numerous instances where persons desire enlargement of the soft tissue in their bodies. The inventor herein has worked extensively in this area by inventing and patenting various devices and methods for growing and enlarging soft tissue through different means. Generally, these devices have been focused on enlarging a woman's breasts, although other various applications have also been disclosed and described in the inventor's prior patent filings. Also, generally, these inventions operate under a principal of applying a controlled tension to a patient's soft tissue such as by applying a vacuum, or through a mechanical structure which induces a tension. Various problems have been solved by the inventor in inventing these devices, many of which have contributed to the efficacy and suitability of these devices for application to a human patient. Various embodiments of these devices have been demonstrated through various trials to be effective when used in a prescribed manner.

A problem which exists universally, and which the inventor herein has encountered with his various inventions, is that of patient compliance. Even the best of medical devices can be rendered ineffective or produce less than desirable results should the patient fail to use the device in the manner in which it is prescribed. In particular, it is anticipated that the inventor's devices will be prescribed by a medical practitioner for a patient's wear using a protocol relating to wear times and pressures induced or tensions exerted in the soft tissue. It is expected that a medical practitioner will be able to judge these after a careful examination of the patient and through selection of a prescribed treatment regimen. Although this information will be reliably communicated to a patient, at present there is little guarantee that a patient will indeed follow that prescribed regimen to thus achieve desirable results.

There are various kinds of medical devices which may be prescribed by doctors for home use by a patient. Many of these are in the physical therapy area but may also include devices intended to provide a therapeutic regimen for the patient. One example of such a device includes a device developed and patented by one of the co-

inventors hereof for enlarging soft tissue including a female's breasts. These devices are disclosed in the following patents: U.S. Patent No. 5,695,445; U.S. Patent No. 5,676,634; U.S. Patent No. 5,662,583; U.S. Patent No. 5,701,917 and U.S. Patent No. 5,536,233. With this particular device, due to its personal nature, the patient may well choose to perform the prescribed regimen within the privacy of her own home. However, as this device has been developed for commercialization, a product has been designed and will be offered to the public which may be discreetly worn and be virtually undetectable in normal daily activities. With either of these choices, a patient must wear the device for some period of time and at specified vacuums in order to achieve the desired soft tissue enlargement. While it is entirely possible for a patient to manually keep track of and record her wearing times, vacuum pressure settings, and other events relating to her regimen such as un-intentioned loss of pressure, this requirement interferes with the convenience and intended simplicity of use which is highly desired in a personal product such as this. However, for more important medical reasons, it is highly desired to obtain accurate data relating to the patient's use of the medical device as such data may very well explain the success or failure that the patient achieves. Furthermore, more obstacles presented to a patient in connection with her use of a medical device would be expected to interfere with its use and the resulting patient compliance. There are even health and safety concerns which could be monitored more closely should the patient be more accurate in recording her compliance with her prescribed regimen.

As many of these medical devices are prescribed by physicians, the opportunity to collect reliable data is often times limited to those patient visits which occur at prescribed intervals. While in the doctor's office, the patient may be physically examined and tests made to determine how the patient is reacting to the use of the medical device. This may then be compared with the patient compliance data which the patient may have personally recorded and which may be less than 100% accurate. Therefore, a doctor or other medical professional does not reliably have accurate data with which to judge the efficacy of the prescribed regimen and thus reliably make adjustments in that regimen as he or she sees fit in order to improve the patient's condition. For example, with the breast enlargement device, when the patient visits the doctor's office, the

breasts may be measured in order to ascertain any increase in size. However, the doctor must rely upon the patient's own data for compliance with the prescribed regimen. Therefore, while the doctor may measure marked under performance of the effect of the medical device on the patient, this may be entirely due to the patient's failure to follow the prescribed regimen which the doctor will be unable to detect as the patient for her own reasons may not provide correct or truthful data. Should the doctor have reliable patient compliance data then the doctor could feel comfortable in adjusting the regimen in order to increase the chances of success through the patient's use of the medical device.

There are still additional reasons which make it highly desirable to have accurate patient compliance data for a medical device used on an outpatient basis. One of these additional reasons includes the desirability of collecting data for a large group of individuals which may then be used to make considered judgments relating to the medical device efficacy and recommended regimen for optimal results. For these kinds of studies, accurate data is imperative and short of controlling the environment in which the patients exist for extended periods of time, the inventors are unaware of any prior art solution to this problem of collecting accurate patient compliance data for medical device use. Still another reason for collecting accurate data is that immediate feedback and positive re-enforcement may be provided to the patient which encourages her to follow the regimen. In other words, should a patient understand that compliance data will be accurately collected and made available, the patient will be encouraged to live up to her doctor's recommendations and know that the doctor will be able to follow her compliance and discuss her performance with her in a positive way. Furthermore, a patient may feel the psychological reward of knowing that she has complied with her doctor's prescribed regimen as well as achieving the expected results through use of the medical device. The doctor may also use this accurate compliance data in order to correct the patient should she not only under-use but over-use the device in an effort to achieve even greater results by increasing her wearing times or vacuum pressures beyond that which is recommended. This can help prevent unintended side effects through over-use of any medical device.

In order to solve these and other problems in the prior art, the inventor herein has succeeded in designing and developing a patient monitoring device which may be readily integrated into a control for any of the inventor's prior embodiments of a soft tissue enlargement device. This patient monitoring device can include a microprocessor controller having a memory and being linked to one or more sensors. These sensors may sense for example a temperature reading such that when the device is placed adjacent the patient's soft tissue, the patient's natural body heat is sensed by the temperature sensor to thereby indicate that the device is being properly worn. Still another possibility for a sensor includes a pressure sensor which can be placed in any of the vacuum lines or under the vacuum domes provided as part of the soft tissue enlargement device to sense when the pump which draws the negative pressure or vacuum has indeed created such a negative pressure or vacuum. This indicates that the patient is indeed wearing the device as the vacuum or negative pressure is created between the device and the patient's soft tissue. Still another sensor, a third sensor, could also be coupled to the microprocessor controller and provide an additional input of a differential nature, e.g., pressure taken at a different part of the device, or another temperature sensor, or any other convenient parameter which may be monitored and which will provide an indication that the patient is indeed wearing the device as prescribed. For example, a mechanical push button or snap switch having a relatively light pressure actuator may be conveniently placed in a strap or other part of the device which would be actuated as the device would be fastened or secured properly to the patient's body. Other types of sensors could be thought of by those of skill in the art as would be appropriate to the particular device and application.

By using a microprocessor controller, a clock and memory may be provided as part of the controller or in separate microchips so that the length of time that the sensor is above a preselected threshold can be determined and indicate the amount of time that the patient has been wearing the soft tissue enlargement device. Thus, the amount of time that the soft tissue enlargement device remains unworn may be readily determined as well as the amount of time that the device is being worn, and these times may also be indexed to a time of day to provide an additional degree of reliability for the data

being collected. As with any typical microprocessor controller, an output port of the controller may be used to communicate the data to another computer, a display such as a computer monitor, a printer, or other recorder as might be desired to collect the data. In still other applications, it might be desired to tele-communicate the data collected by the patient monitor through a communication link such as through a LAN, WAN, or even the Internet.

As a further solution to shortcomings in the prior art, and in order to provide some of the advantages as noted above, the inventors herein have further succeeded in designing and developing a method and apparatus for collecting patient compliance data as a medical device is used, a convenient and unobtrusive way to self-communicate that compliance data over any communications link such as the internet to a central location, and process that compliance data and make it available not only to the patient but also the medical professional in a secure but readily accessible form.

More particularly, and as explained in the illustrative example of the breast enlargement device, the inventors have succeeded in designing and developing a portable controller or "smart box" which is battery operated and which controls a miniature vacuum pump included as part of the bra-like device in its intended commercial embodiment. A vacuum sensor is also provided for collecting data relating to the induced vacuum contained within the bra and a clock function such as might be provided by a micro-clock circuit or chip, times the duration of the vacuum applied by the medical device to the patient's breasts. With this device, vacuum pressures and durations may be readily collected as data and stored in onboard memory included as part of a microcomputer. Thus, patient compliance data for this particular device which would include vacuum pressures and durations is readily collected as the battery operated smart box is used to apply the vacuum through the bra-like medical device.

As the controller is battery operated, the patient will be conditioned through her experiences with other battery-operated devices such as cell phones and the like to place the controller into a cradle for charging of the on-board batteries. For convenience, the controller is preferably separable from the bra. The accompanying cradle includes not only an AC power cord for connection to a typical wall socket with the associated battery charger circuits for charging the controller's rechargeable batteries, but also a

phone line connection and modem for downloading the data from the microcomputer memory and transmitting it over the telephone lines through either a dial-up connection, modem, or internet service provider to a central location which is preferably a digital processor device such as a computer server or the like. Thus, through this aspect of the invention, patient compliance data is automatically collected without patient intervention and the patient is conditioned to seek recharging of the batteries for the controller which when performed will preferably automatically "download" the data from the microcomputer through a modem to a central data processor. Alternatively, a command button or the like may be provided for the patient to push to force the download to occur.

Upon collecting data, the central data processor will preferably process the data and ready it for display. This processing may include nothing more than associating it with a particular patient but may also include further processing in order to present the data in various formats such as bar graphs, charts, and the like not only on an individual basis but also in comparison to other averages or patient data. This processed data is then preferably provided to one or more servers for display over a web site having a secure access. Various levels of security may be provided, as desired. For example, each patient may be given an individual password which allows her to access her own individual data. At the same time, a medical professional or doctor may be given a password which allows him or her to have access to the patients that he or she is treating. Lastly, a global password may be provided to one or more select individuals who oversee the entire web site and who may also oversee the conduct of the device use as well as its physiological impact on the various patients from a global perspective.

As briefly described, it is readily apparent that a novel method and apparatus have been described which provides a solution to many of the difficult problems surrounding independent and private use of a medical device in an outpatient setting including an unobtrusive way of collecting the data, making that data selectively available to individual patients as positive feedback and re-enforcement to encourage their compliance and display their progress, a vehicle for a doctor or other medical professional to monitor the progress of a patient on an individual basis as well a group of

patients, and a methodology for monitoring a large number of patients, collecting and analyzing data relating to those patients, and making judgments with respect to the efficacy of a medical device as associated with particular regimens. All of this is achieved in a cost effective way using the power of the Internet as a tool for communicating between patient, doctor, and a central data collection monitor and service.

While the principal advantages and features of the present invention have been described above, a fuller understanding of the invention and its many various aspects may be attained through reference to the drawings and detailed description of the preferred embodiment which follows.

Brief Description of the Drawings

Fig. 1 is a schematic block diagram of a patient compliance monitoring device of the present invention;

Fig. 2 is a block diagram of a controller or "Smartbox" for a medical device;

Fig. 3 is a block diagram of a cradle for receiving the controller; and

Fig. 4 is a schematic diagram of a computer network including the Internet for receiving data, processing data, and displaying it on a secure web site.

Detailed Description of the Preferred Embodiment

The patient compliance monitoring device 20 of the present invention is shown in the figure to include a controller 22 which may be a microprocessor, microcomputer, digital logic device, PAL, or other such suitable controller including one as may be embodied in an ASIC, as would be known to those of skill in the art. A clock or timing circuit 24 and memory 26 may be separately provided or provided as part of controller 22 as desired and appropriate under the circumstances of the particular devices chosen to embody these functions. However, this is considered to be a matter of design choice and not significant with respect to the operation or best mode choice for the present invention. Similarly, a power supply circuit 28 is shown and may include a battery with wave form smoothing or filtering again as would be known to those of skill in the art. The active clinical device 30 may be considered as a soft tissue enlargement device as shown in any of the inventor's prior patent filings such as those which disclose a pair of vacuum domes for

enclosing the breasts of a female patient. An electromechanical pump 32 may be provided and used to draw a negative pressure within the domes of the active clinical device 30 to apply the protocol as prescribed for enlarging soft tissue. Various embodiments of these devices may be found in the inventor's prior patent filings and it is not considered to be significant for purposes of enablement or best mode that any one or the other of these structures be utilized as long as they are chosen with care by one of ordinary skill in the art. A first sensor 34 may be mechanically mounted within the active clinical device 30 and used to sense the pressure, or negative pressure as the case may be, exerted by the active clinical device 30 over the soft tissue desired to be enlarged, as taught by the inventor previously. The particular location chosen for placement of the sensor 34 is considered to be a matter of design choice. However, it may be placed conveniently in any of the vacuum lines associated with the electromechanical pump 32, underneath either of the two vacuum domes, or elsewhere as desired and which may be determined with minimal experimentation to provide the most reliable sensor readings. A second sensor 36 may also be physically mounted to the active clinical device 30 and may be placed anywhere as convenient to come in contact with the patient's skin or other soft tissue such that it is heated by the patient's body as the active clinical device 30 is worn. Thus, as the active clinical device 30 is used, the temperature sensor 36 senses an elevated temperature over room temperature and provides a reliable indication that the patient is indeed wearing the active clinical device 30. A third sensor 38 may also be provided and allows for additional verification of patient compliance or other data to be collected as the patient wears the active clinical device 30. For example, the third sensor 38 may be still another pressure sensor placed in a different location within the active clinical device 30 to provide a more reliable reading or verification that the patient is indeed wearing the device 30. So another example of a possible sensor 38 would be a small mechanical snap switch or the like which would have a slight pressure actuator such that as the device is mechanically positioned on the patient's body, this sensor 38 is actuated and again provides an indication that the patient is wearing the device. Still other possibilities for sensor 38 may be envisioned as would be apparent to those of skill in the art.

In use, as the patient properly applies the active clinical device 30 to her body, one or more of the sensors 34-38 are actuated and provide an electrical signal to the controller 22. Controller 22 may associate this signal with a time stamp provided by clock 24 and thus keep track of or time the amount of elapsed time that the patient has the active clinical device 30 in an operative mode on her body. This collective data may then be stored in memory 26 through various regimens and protocols to provide a body of data corresponding to the patient's compliance. Then, at any desired time or, upon demand, or in response to query, or otherwise as desired, a communication link 40 may be used to transfer the data stored in memory 26 through controller 24 and through an output port to download data to a central office or otherwise for data collection, analysis, and other purposes as may be desired. Ultimately, it would be anticipated that this patient compliance data may be used to counsel the patient to encourage her as she makes use of the medical device 30. For example, should a patient exhibit minimal compliance, the patient may be provided that feedback and become aware that the device itself has a means of tracking her usage. Such knowledge of tracking may itself encourage the patient to become more compliant. Furthermore, patient compliance may then also be used as a parameter to determine the relative efficacy of the medical device 30 and its correlation to the degree of patient compliance with a recommended regimen or even independently of same.

A more specific example as shown in Fig. 2 includes a controller 20a as a self-contained battery operated unit which is portable and which is preferably detachable from the bra (not shown) having a pair of cups within which a vacuum is drawn in order to enlarge a female's breasts as is taught in the co-inventor's prior patents mentioned above, the disclosures of which are incorporated herein by reference. More particularly, the controller 20a includes at its heart a microcomputer 22a having a program memory 24a within which is stored software for controlling the operation of the controller. An example of such software is shown in the flowchart of Exhibit A, although other application software may also be used to perform the functional tasks as described herein. The microprocessor may have also an associated A/D converter 26a as well as a plurality of RS-232 ports 28a for receiving and transmitting data, as is known by those of skill in the art. A plurality of LED ports 30a are

preferably provided to provide data to the cradle (see below) to indicate the relative vacuum pressure at any particular time during the regimen. An associated data memory 32a stores the data collected by the microcomputer 22a and readies it for transmission as is explained below. Each Smartbox is preferably encoded with a UIN or Unique Identification Number for identifying it when data is downloaded to the central site, as explained below. This UIN is also preferably used to set up and identify the virtual patient folders so that data received at the central site is reliably associated with other patient data in what may be a disk drive or other memory where the virtual patient folder is maintained. The patient is then preferably given this UIN to use as part of her sign on so that she is reliably provided access to only her data file. This provides still another level of security for data collected using the present invention.

Also included in the controller 20a is a set of rechargeable batteries 34a which power an electromechanical power supply 36a for operating associated electromechanical devices including a vacuum pump 38a. The batteries 34a also power the logic supply 40a which powers the microcomputer 22a. A vacuum sensor 42a which may be a temperature compensated, calibrated differential vacuum sensor such as those produced by using Micro Electro Mechanical Systems (MEMS) Technology senses the vacuum within the domes and generates data which is amplified by an instrumentation amplifier 44a for communication to the microcomputer 22a. This data is associated with timing data produced by a clock 46a, which may be any appropriate electronic chip or circuit, such that the microcomputer collects not only the relative vacuum pressure but also its duration as the medical device is used. A buzzer 48a or other alarm device may be used to indicate to the patient that the vacuum seal has been breached, or for other conditions to provide feedback to the patient and permit her to adjust the device in order to insure its proper use. An on/off button 50a provides a master control for the controller and an alarm button 52a may be useful in disabling the buzzer 48 once the patient is alerted to the particular issue at hand, or to otherwise silence the alarm and prevent its becoming an embarrassment should the patient be wearing the device in a public area. A cradle link connector 54a provides an electromechanical linkage between the controller 20a and the cradle so that the two may

be physically, electronically, and electrically interconnected as desired for battery recharge as well as data download.

In the preferred embodiment of the controller, the data memory 32a is sufficiently large to enable a continuous recording of 217 days worth of data by collecting one sample every ten minutes. This methodology may of course be modified as desired to meet specific applications. The rechargeable batteries 34a are preferably nickel metal hydride cells and as noted there are preferably two power conversion sub units on board for supplying power to electronic and electromechanical components. The electronic components are chosen to be five volt components. However, as is known by those of skill in the art, the power unit may be readily modified for 3.3 volts or other lower operating voltages. The topology used for the logic power supply 40a is boost topology with 75% efficiency. The electromechanical power supply 36 is preferably programmable for different applications. In the present preferred embodiment example, a controlled vacuum is created inside the bra domes. Thus, a vacuum pump 38a is employed in the controller 20a. For this application, power supply 36a uses the sepic topology for supplying voltages higher and lower than the battery voltages with a 55 to 70 percent efficiency. Nickel metal hydride battery cells are preferably used to avoid the inherent safety problems of lithium cells and to supply better power density than nickel cadmium cells. The programming for the microcomputer includes memory handling routines, electro-mechanical device control routines, sensor measurement routines, serial communication routines for communication over the RS-232 ports 28a, serial communication protocols for these same ports, and numerous mathematical functions for implementing algorithms, all which are well known by those of skill in the art and as partly exemplified in Exhibit A. While the controller 20a of the preferred embodiment has been developed for maintaining a preselected vacuum range within the bra domes, collecting and recording measured vacuum values and duration in a non-volatile memory, communicating with the user by means of two momentary switch buttons (on/off and alarm) and an audible buzzer 48a, calculating progress algorithms and transferring any and all patient compliance data to and from a base unit, it is envisioned that the controller 20a of the present invention may also be employed for other numerous patient data

related applications requiring portability, small size, reliability and connectivity.

Referring now to Fig. 3, a cradle 56a includes a cradle control board 58a having a smart box link connector 60a for connection to the smart box or controller 20a through its cradle link connector 54a. Also, a voltage regulator 62a provides voltage to a fast battery charge controller 64a and is provided power by an AC plug-in 66a to provide the power for charging the batteries 34a carried on the controller 20a in a manner well known to those of skill in the art. The cradle board 58a also includes a modem 68a which may either be provided separately or as part of cradle board 58a and serves to transfer data over the RJ-11 phone connection 70a, as known in the art. A second RJ-11 line connector 72a may be provided with switching relays 74a to allow the phone line to be shared with other appliances such as other phones, etc. A flex connector 74a connects the cradle board 58a to a display board 76a. The display board 76a has a corresponding flex connector 78a and includes a modem LED 80a to indicate operation of the modem, a fast charge LED 82a to indicate charging action for the batteries, and treatment phase LEDs 84a to indicate to the user her treatment phases. For example, for the device of the preferred embodiment, the LEDs may indicate to the patient that she has worn the bra for a prescribed period of time at a prescribed vacuum during a specified number of days and thereby indicate that she is ready to go on to the next treatment regimen. Failure to move on means that the patient stays in the same treatment phase and must continue with that wear schedule until she successfully achieves the prescribed number of hours in a prescribed number of days.

In operation, the patient is typically expected to utilize the cradle daily for recharging the Smartbox batteries, although daily recharging is not required. However, when connected, the patient may also observe her treatment phases through the set of treatment phase LEDs 84a, which may be six LEDs indicating to the patient her progress against her prescribed treatment regimen as explained above, and to also transfer patient compliance data over the modem. Connection parameters for the modem are preferably stored and programmed into the modem memory. This information may be overridden by the controller should the need arise such as for example to change the dial in connection phone number for the modems. The

communication protocol is a modified E1381-95 to facilitate longer modem delays. The data may be preferably transferred in blocks with parity checks to maintain data integrity.

Referring now to Fig. 4, a computer network such as a local area network (LAN) 86a is preferably provided at a central location for collecting the data through a bank of modems 88a and supplying that data to a data receive server 90a for processing thereof. An ethernet network 92a is shown for interconnecting the data receive server 90a with a bank of raid storage drives 92a and a data base server 94a. The data base server 94a may perform the data processing of data received by data receive server 90a depending upon the data handling requirements. A set of virtual patient folders 96a are established and may be stored conveniently at any location in the network 86a and which contain the data files for the individual patients providing data relating to their compliance. A plurality of web servers 98a are provided and provide a secure access for this processed data over the Internet through a firewall 100a for access by individual patients 102a and medical personnel 104a.

Attached hereto as Exhibit B are a set of web page printouts detailing the preferable design of a web site for displaying the data in a secure manner to patients as well as medical professionals. Exhibit B consists of 18 pages which may be briefly described as follows. Page 1 is a typical home page introducing the user to the web site and allowing further navigation therefrom. Page 2 is a sign on or log in page requiring a log in name and password which provides the security for access to the rest of the web site. Page 3 asks for the user to select a doctor to display patients or other information. Page 4 allows search by patient name or Smartbox number in order to find and display data relating to a particular patient. The next page asks for the user to select which information is desired to be displayed from a menu of various information including personal information, general medical information, demographics, etc. The next page displays information relating to the patient's first day of treatment and provides baseline information. The next page provides results information relating to patient compliance. The next page is intended for view by an individual patient and provides individual feedback relating to that particular patient's compliance as well as a listing of other available information for selection to be viewed. The next page illustrates a pressure chart for presenting the data to

the patient relating to their individual compliance. The next page is a wear pattern bar chart illustrating individual patient compliance data. The next page illustrates the patient's breast size as measured by the medical professional during the patient's office visit, and the increased breast size resulting from the patient's compliance. The next page illustrates and compares on a graph the patient's individual performance as compared with average performance history. The next page illustrates in chart format a patient's chest circumference and the following page illustrates the patient's weight as the protocol proceeds through various weeks of use. The next page illustrates in chart fashion the average volume increase of all users of the device versus the individual patient's actual growth experience. The next page illustrates the individual patient's volume increase compared with the average volume increase for patients within the same demographic group. The next page illustrates reports to the patient relating to their individual performance. The last page provides reports of additional information available to the patient.

As can be seen from the web pages of Exhibit B, the individual patient's compliance data may be processed and presented for viewing by the individual patient as well as her medical professional in a manner which is very informative with secure access guaranteeing privacy of the data. Furthermore, this data may be provided virtually instantaneously as the data is automatically downloaded through the Smartbox being placed in the cradle by the patient which then automatically transmits the data back to the network which itself may immediately process the data and update the data files for viewing over the Internet. With this arrangement, a patient is encouraged to download her data and to immediately get the feedback available to her through rapid processing of that data. In this way, a patient is provided information almost immediately after it is collected relating to her compliance and her progress through use of the medical device. This form of automatic data collection and presentation in an immediate manner back to the patient is highly desirable as it encourages patient compliance and ensures data integrity.

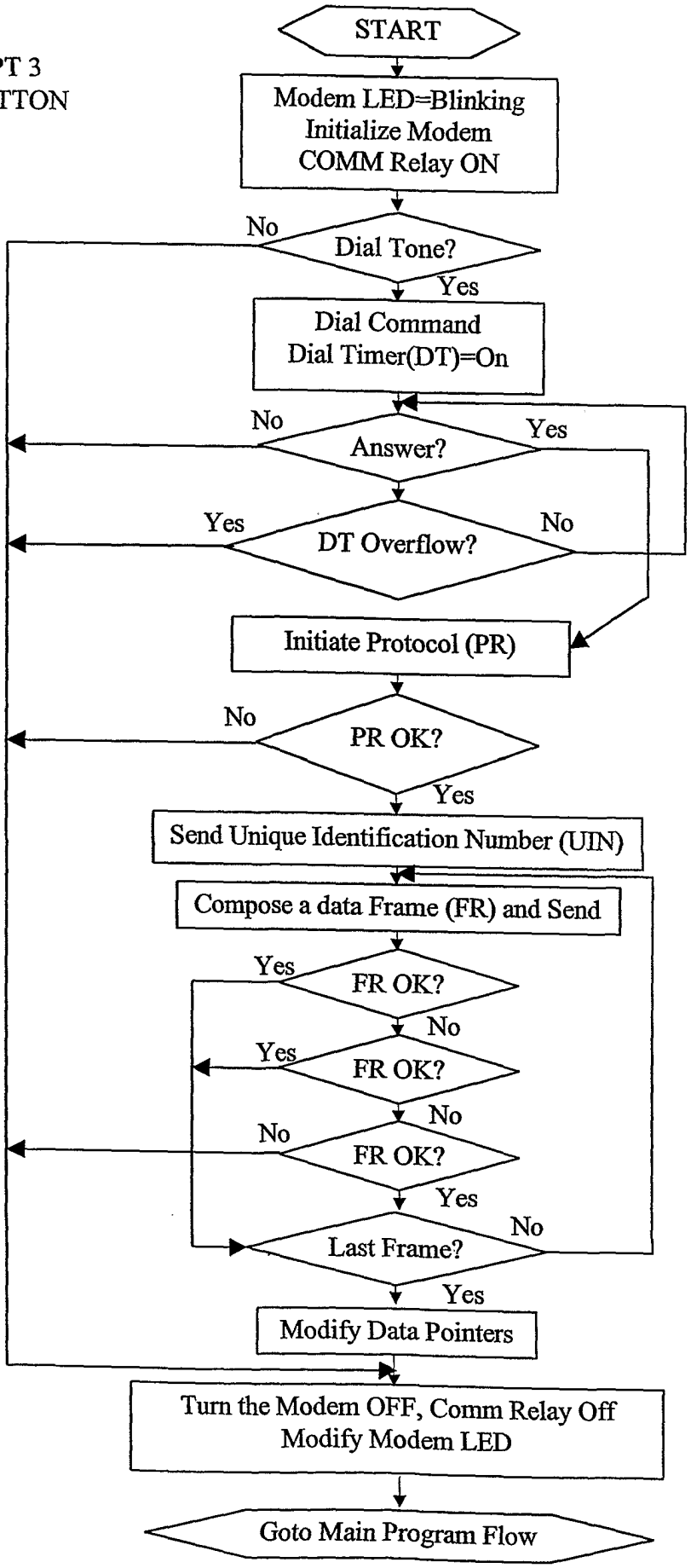
The medical professional preferably has the capability to enter data directly in the web site. This data entry makes it easy for the doctor to post the data obtained from the patient during her visit.

Thus, the web site is interactive to a certain extent, at least for the doctor. By refusing this same feature to the patient, data integrity is assured.

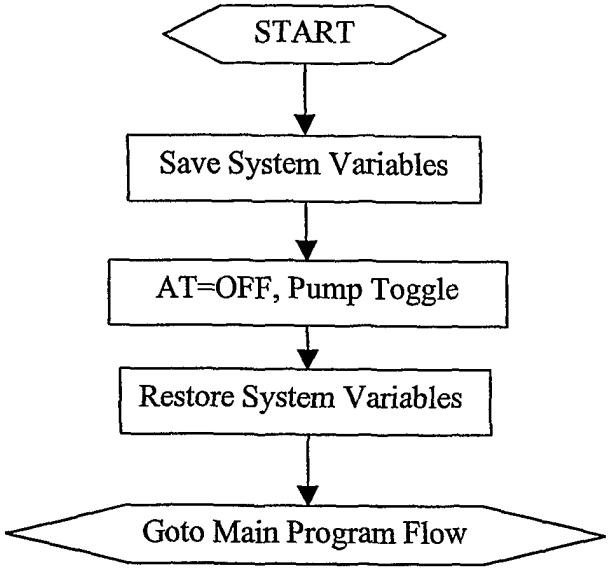
Various changes and modifications of the various aspects of this invention would be apparent to those of skill in the art. These changes and modifications are intended to be included as part of the invention. For example, different medical devices may readily be utilized as part of the invention. Furthermore, while the inventors have preferably used an SQL server, assigning all of the smart boxes a unique identification number which is used along with sales and user documents to create a virtual patient folder, other methodologies may well be utilized to establish and maintain individual data files for patients. Furthermore, the data selected to be included is deemed to be relevant by the inventors for this particular medical device, although additional and varying kinds and forms of data may well be determined to be important and useful in other applications. Still another aspect of the Internet web site is that users including patients are only permitted to view data contained within the web site while medical professionals, including doctors, have the ability to input data directly, such data corresponding to measurement data and other data taken from the patient at the time that the patient visits the doctor. An ethernet network is shown for use in establishing a LAN at the central site. However, those of ordinary skill in the art realize that other kinds of communication or network protocols may be used to achieve the same results. Furthermore, while the Internet has been chosen as the preferable access link for the patient and doctor, a dial up network connection may be permitted or any other connection protocol as would be viewed as convenient and cost efficient by the users. Still other changes and modifications would be apparent and these are all intended to be included within the scope of the invention which should be viewed as limited only by the scope of the claims appended hereto and their legal equivalents.

Exhibit A

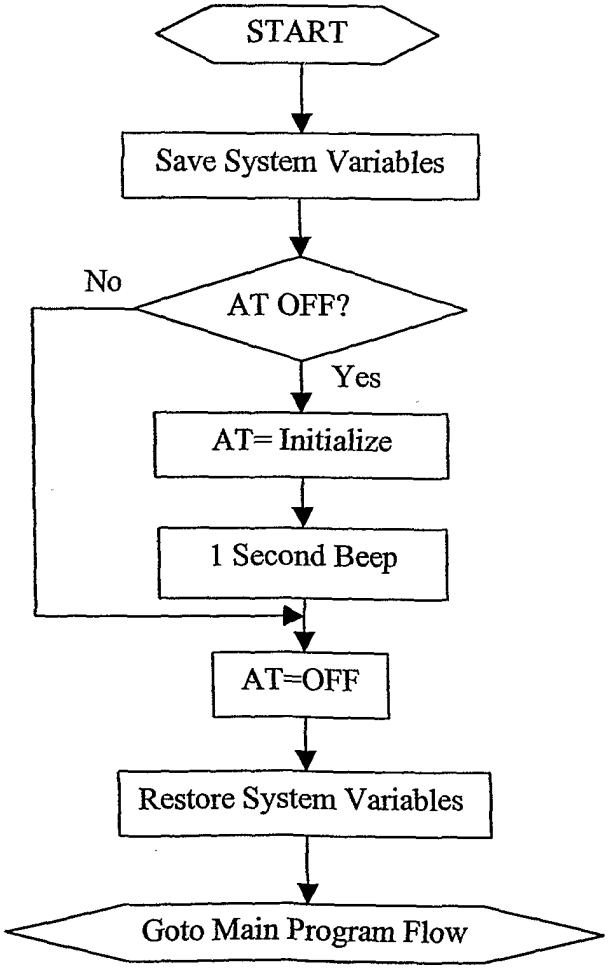
INTERRUPT 3
MODEM BUTTON

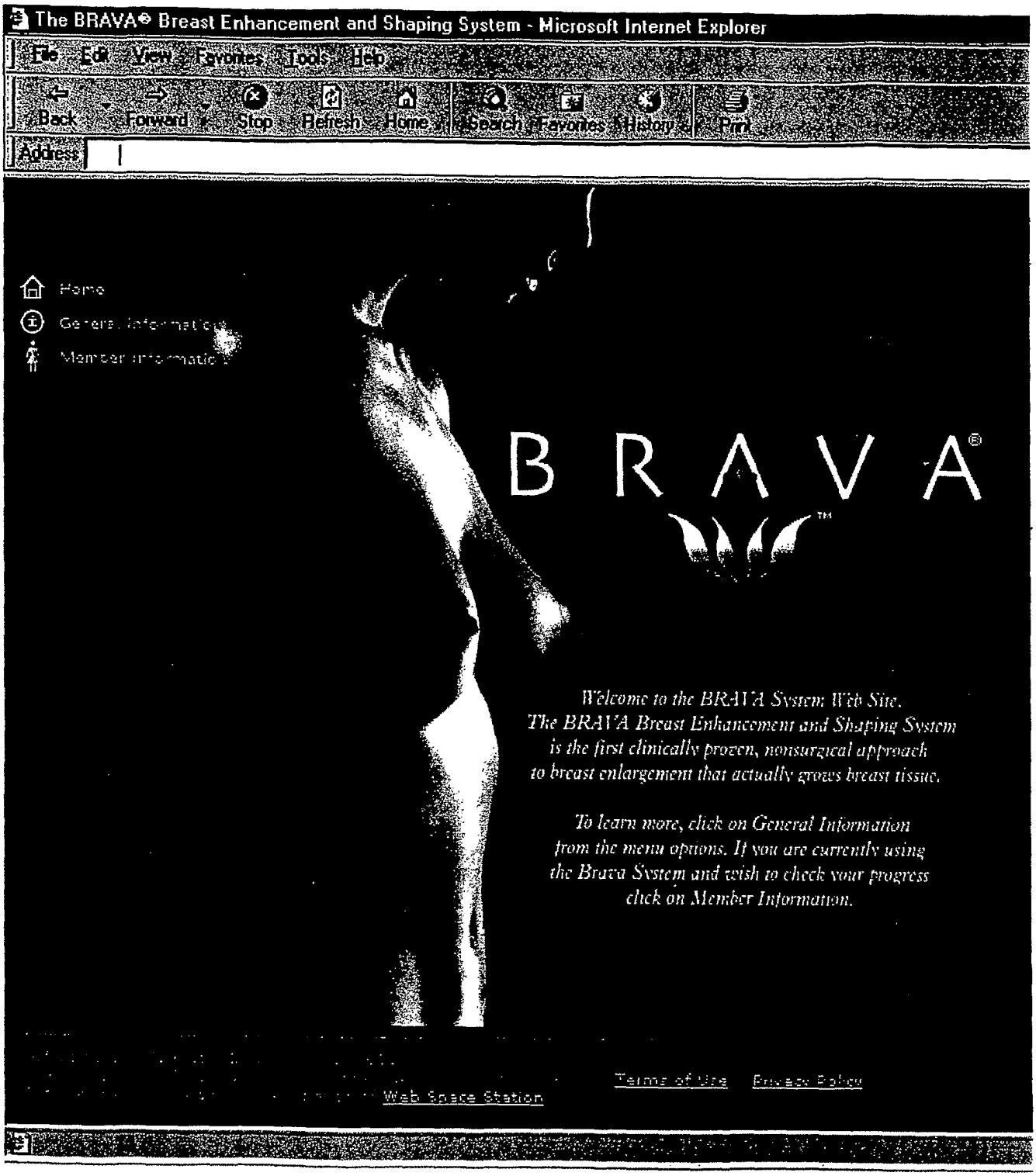


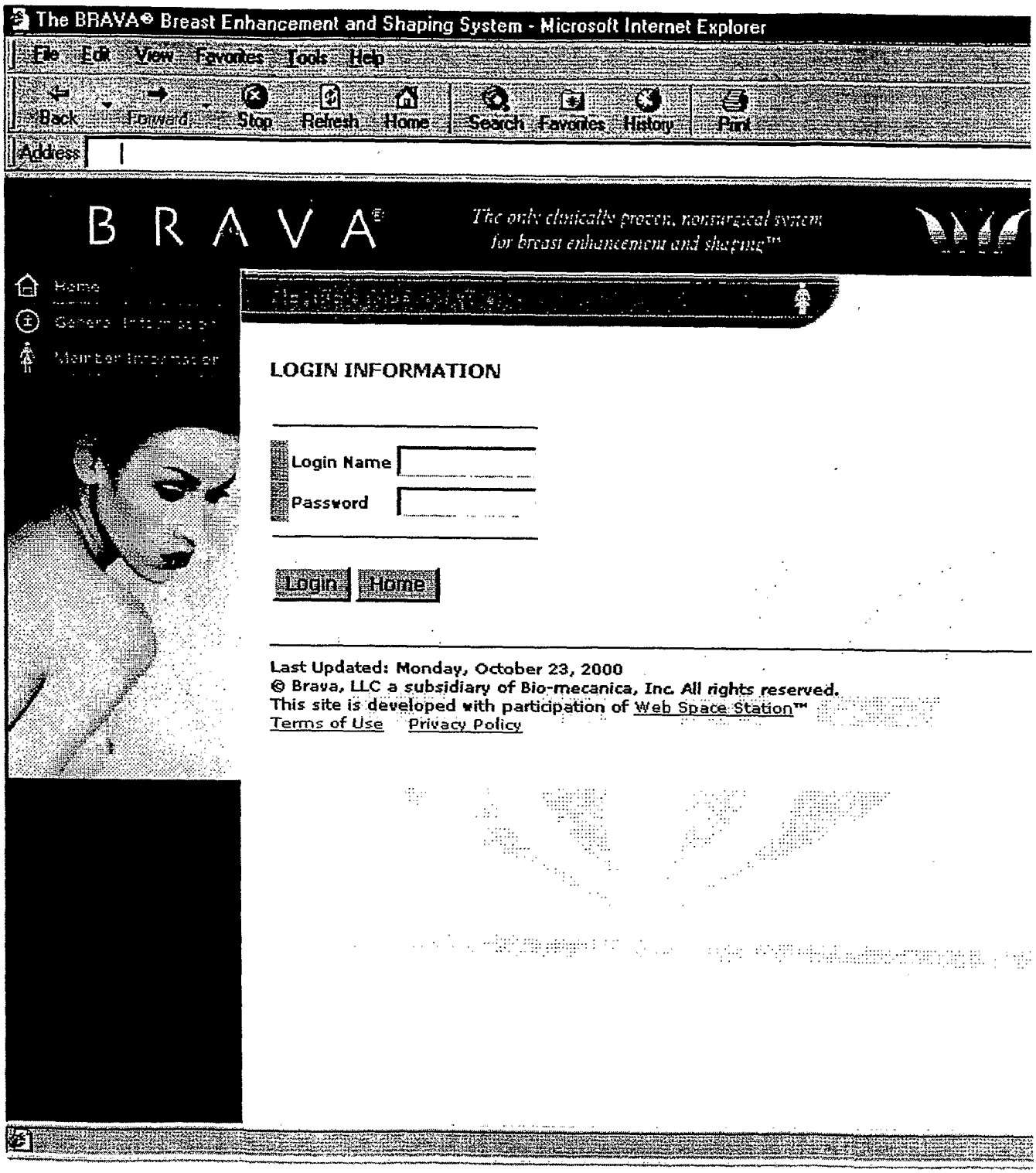
INTERRUPT 1 (ON-OFF BUTTON)



INTERRUPT 2 (ALARM BUTTON)




The BRAVA® Breast Enhancement and Shaping System - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Forward Stop Refresh Home Search Favorites History Print
Address
Home
General Information
Member Information
BRAVA™
Welcome to the BRAVA System Web Site.
The BRAVA Breast Enhancement and Shaping System
is the first clinically proven, nonsurgical approach
to breast enlargement that actually grows breast tissue.
To learn more, click on General Information
from the menu options. If you are currently using
the Brava System and wish to check your progress
click on Member Information.
Terms of Use
Privacy Policy
Web Space Station


The BRAVA® Breast Enhancement and Shaping System - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Forward Stop Refresh Home Search Favorites History Print
Address
BRAVA®
The only clinically proven, nonsurgical system for breast enhancement and shaping™
Home
LOGIN INFORMATION
Login Name
Password
Login Home
Last Updated: Monday, October 23, 2000
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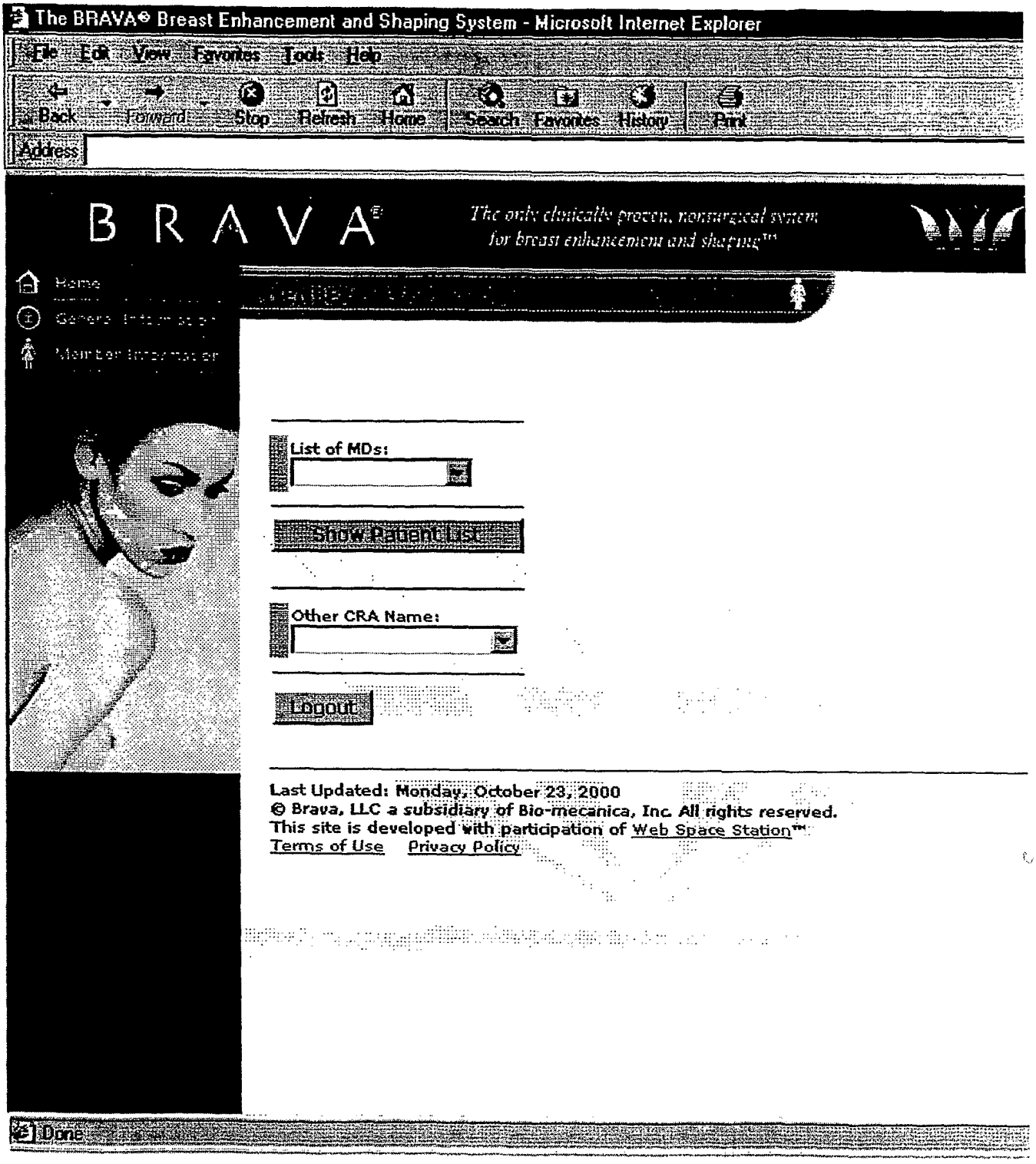
The BRAVA® Breast Enhancement and Shaping System - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Forward Stop Refresh Home Search Favorites History Print
Address
BRAVA®
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Home
List of MDs:
Show Patient List
Other CRA Name:
Logout
Last Updated: Monday, October 23, 2000
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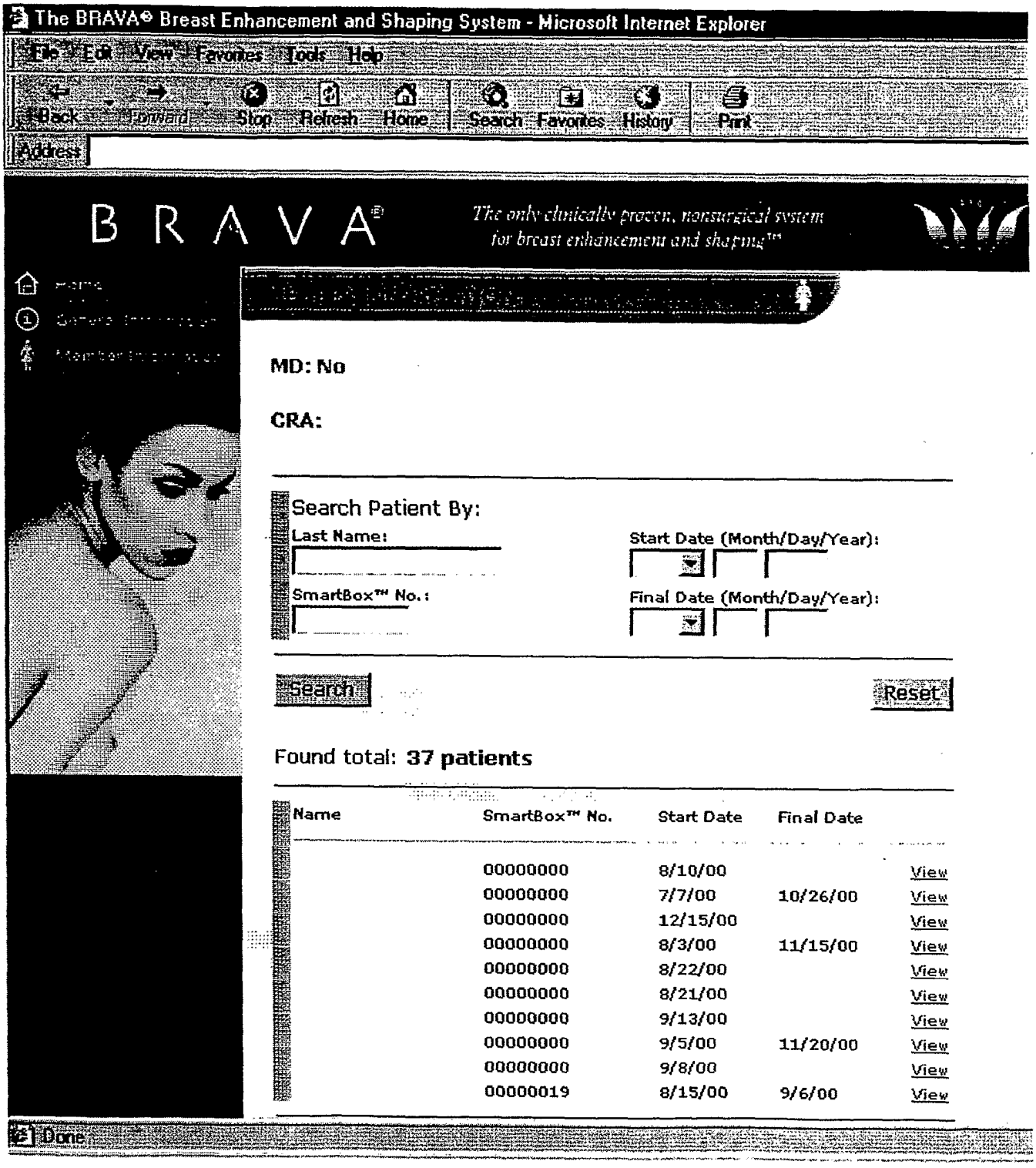
Done


The BRAVA® Breast Enhancement and Shaping System - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Forward Stop Refresh Home Search Favorites History Print
Address
BRAVA®
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MD: No
CRA:
Search Patient By:
Last Name:
Start Date (Month/Day/Year):
SmartBox™ No.:
Final Date (Month/Day/Year):
Search
Reset
Found total: 37 patients
Name
SmartBox™ No.
Start Date
Final Date
00000000 8/10/00 View
00000000 7/7/00 10/26/00 View
00000000 12/15/00 View
00000000 8/3/00 11/15/00 View
00000000 8/22/00 View
00000000 8/21/00 View
00000000 9/13/00 View
00000000 9/5/00 11/20/00 View
00000000 9/8/00 View
00000019 8/15/00 9/6/00 View
Done

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Back Forward Stop Refresh Home Search Favorites History Print

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INFORMATION PAGE for

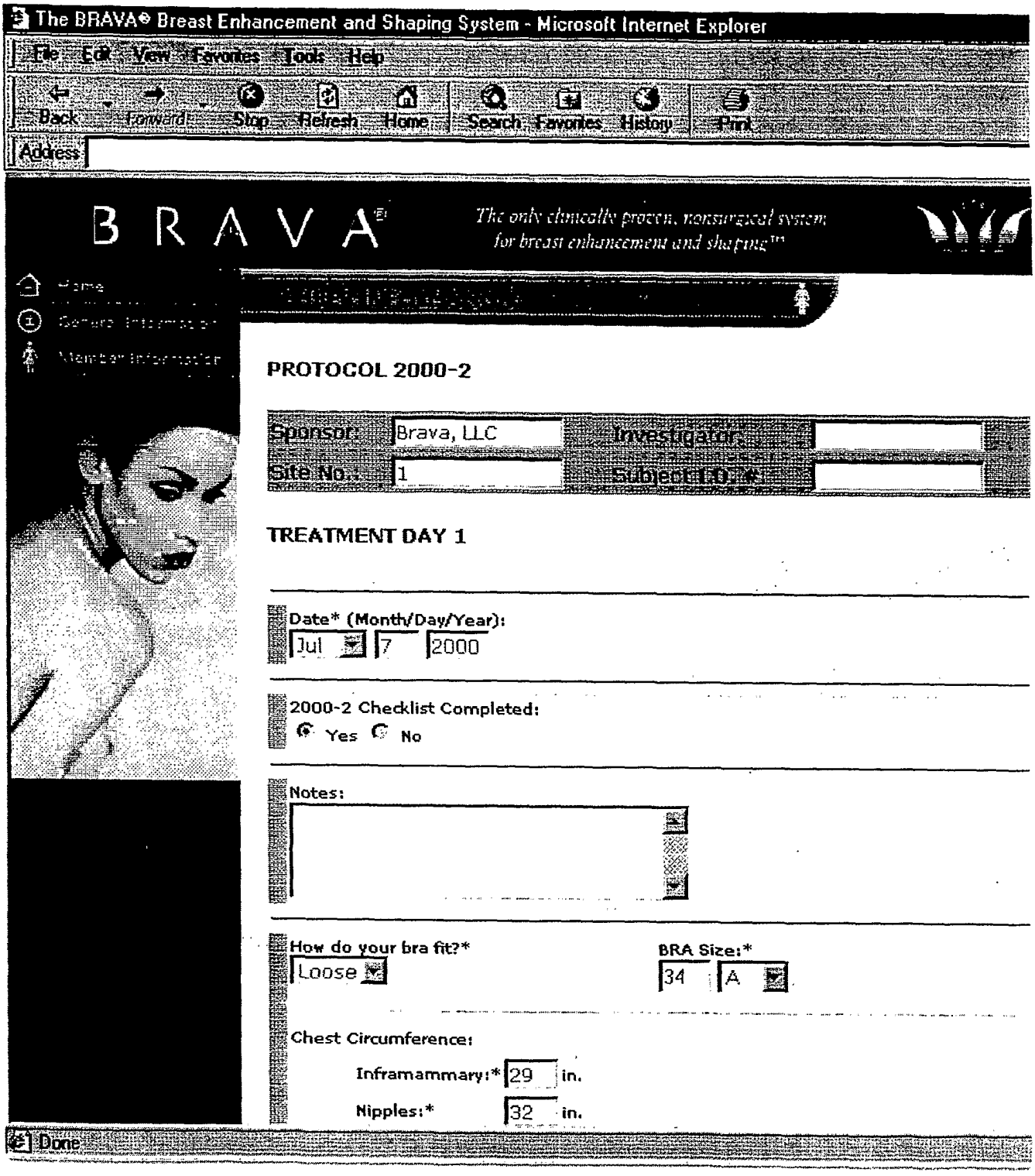
Treatment Phase: 1 Day: 0

- ✔ Personal Info
- ✔ General Medical Info
- ✔ Checklist
- ✔ Demographics
- Generic Telephone Calls
- Follow-up Telephone Calls
- ✔ Baseline Day

- ✔ Treatment, Day 1
- ✔ Treatment Period, Week 1
- ✔ Treatment Period, Week 4
- ✔ Treatment Period, Week 7
- ✔ Treatment Period, Week 10
- Follow-up, Week 14

- ✔ Collection of Device
- ✔ Adverse Events Report
- ✔ Concomitant Medications
- Study Summary

View Phases' Details(No Setbacks)


The BRAVA® Breast Enhancement and Shaping System - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Forward Stop Refresh Home Search Favorites History Print
Address
BRAVA
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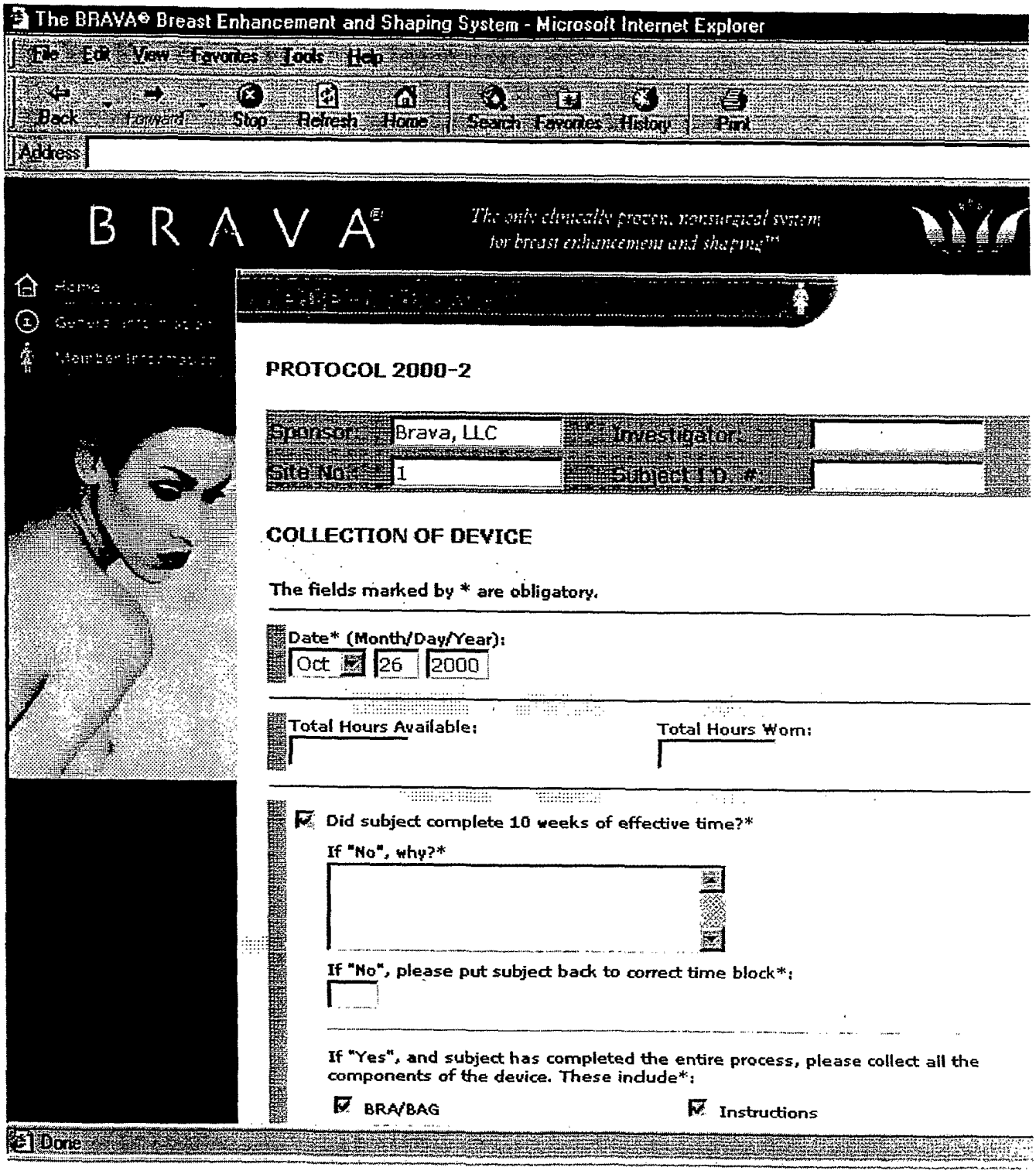
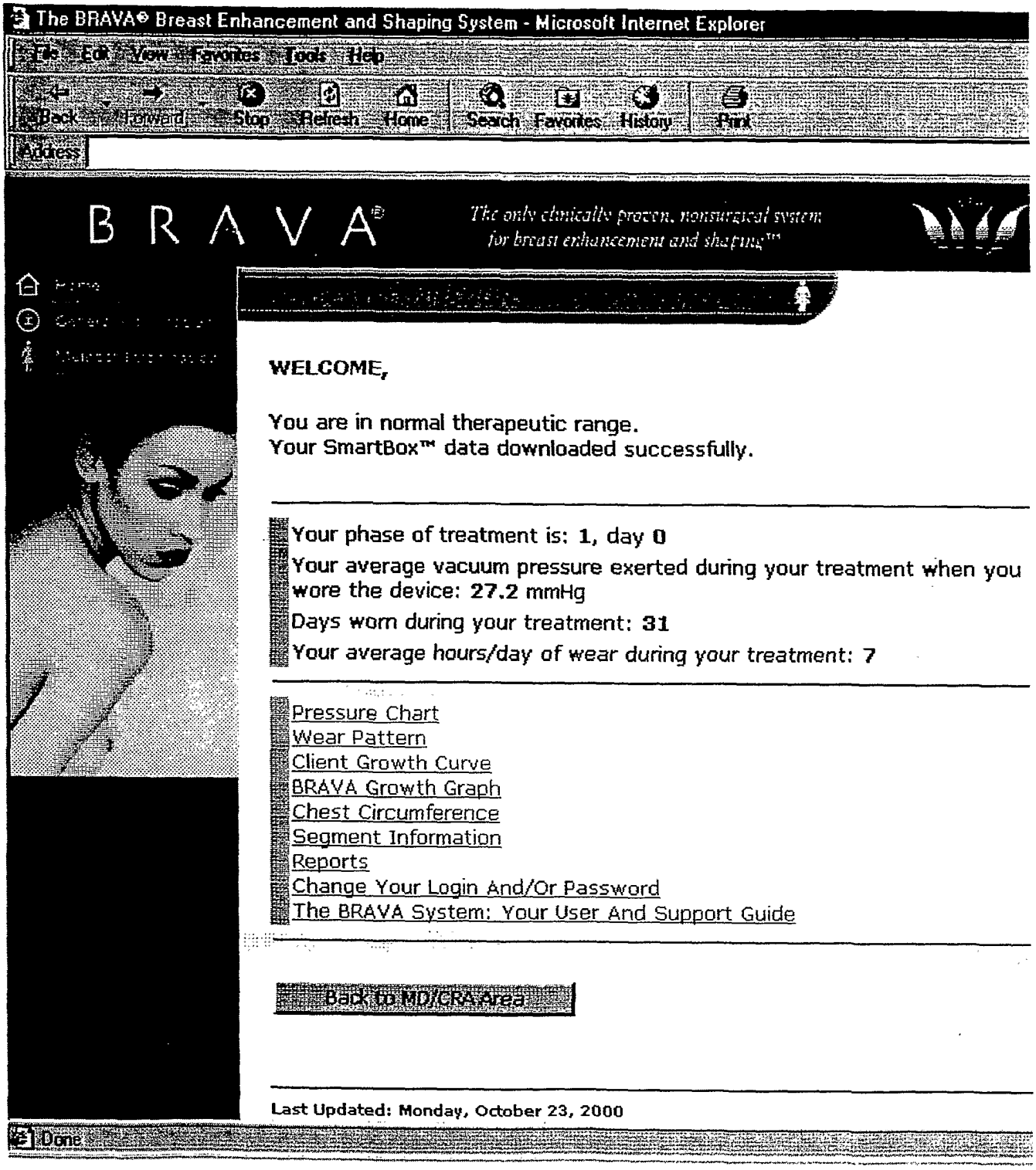
Home
PROTOCOL 2000-2
Sponsor: Brava, LLC
Investigator:
Site No.: 1
Subject I.D.:*
TREATMENT DAY 1
Date* (Month/Day/Year):
Jul 7 2000
2000-2 Checklist Completed:
Yes No
Notes:
How do your bra fit?*
Loose
BRA Size:*
34 A
Chest Circumference:
Inframammary:* 29 in.
Nipples:* 32 in.
Done


The BRAVA® Breast Enhancement and Shaping System - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Forward Stop Refresh Home Search Favorites History Print
Address
BRAVA®
The only clinically proven, non-surgical system for breast enhancement and shaping™
Home
PROTOCOL 2000-2
Sponsor: Brava, LLC
Investigator:
Site No*:
1
Subject I.D. #:
COLLECTION OF DEVICE
The fields marked by * are obligatory.
Date* (Month/Day/Year):
Oct
26
2000
Total Hours Available:
Total Hours Worn:
Did subject complete 10 weeks of effective time?*
If "No", why?*
If "No", please put subject back to correct time block*:
If "Yes", and subject has completed the entire process, please collect all the components of the device. These include*:
BRA/BAG
Instructions
Done


The BRAVA® Breast Enhancement and Shaping System - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Forward Stop Refresh Home Search Favorites History Print
Address
BRAVA®
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WELCOME,
You are in normal therapeutic range.
Your SmartBox™ data downloaded successfully.
Your phase of treatment is: 1, day 0
Your average vacuum pressure exerted during your treatment when you wore the device: 27.2 mmHg
Days worn during your treatment: 31
Your average hours/day of wear during your treatment: 7
Pressure Chart
Wear Pattern
Client Growth Curve
BRAVA Growth Graph
Chest Circumference
Segment Information
Reports
Change Your Login And/Or Password
The BRAVA System: Your User And Support Guide
Back to MD/CRA Area
Last Updated: Monday, October 23, 2000
Done

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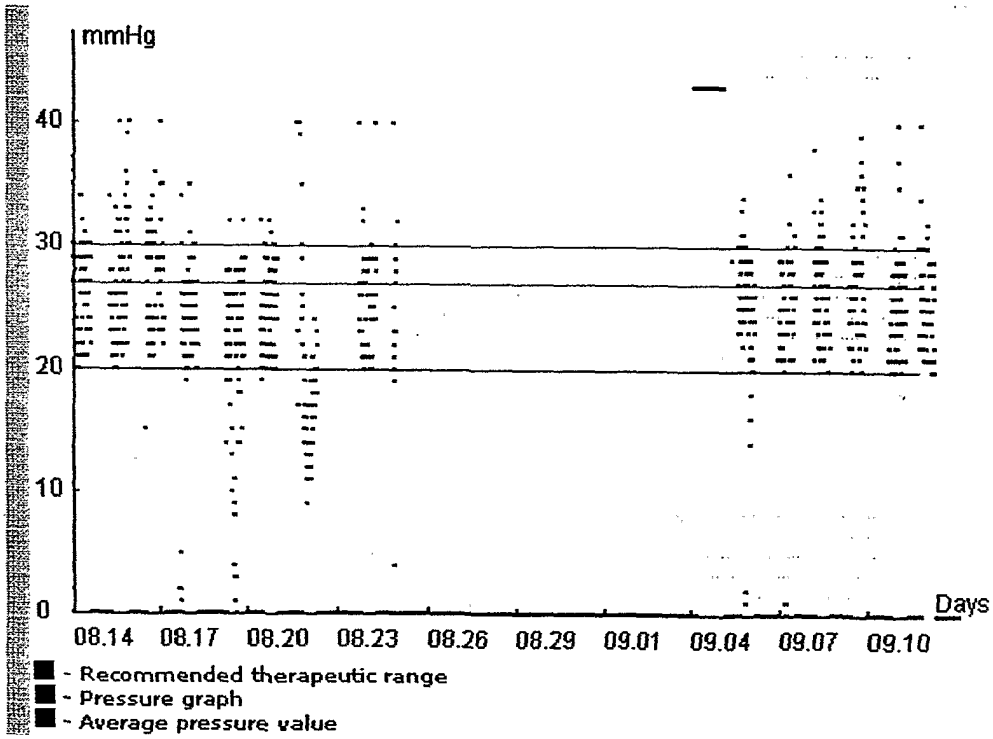
PRESSURE CHART

The Pressure Chart below indicates the average pressure exerted by the SmartBox™ within the domes during the period of time the BRAVA® System was worn. The information is read in millimeters of mercury (mmHg). An appropriate range of pressure is between 20 and 30 mmHg.



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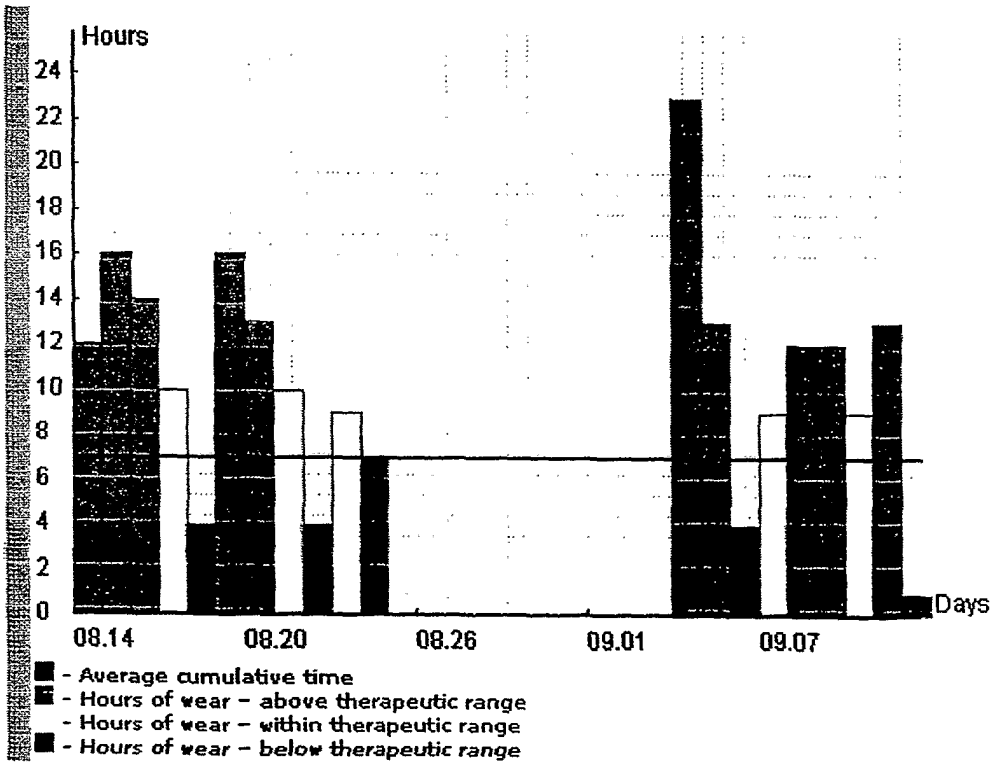
WEAR PATTERN

The Wear Pattern Graph illustrates the average cumulative time, per day you wore the BRAVA® System. The Y-axis indicates hours and the X-axis indicates days.



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Back Forward Stop Refresh Home Search Favorites History Print

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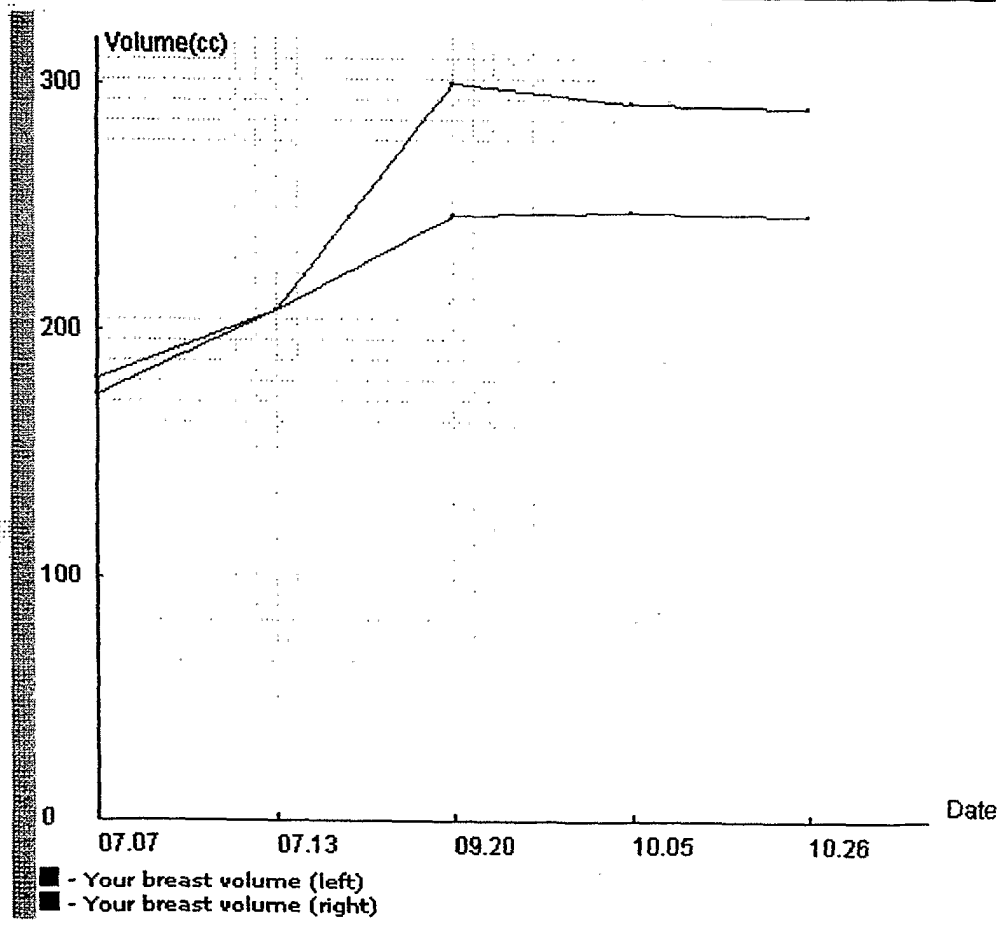
Member Information

CLIENT GROWTH GRAPH

The Client Growth Curve illustrates your breast volume measurement taken during your office visits. The Y-axis illustrates the volume in cubic centimeters (cc) and the X-axis depicts the date (real date) that each measurement was taken.



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Back Forward Stop Refresh Home Search Favorites History Print

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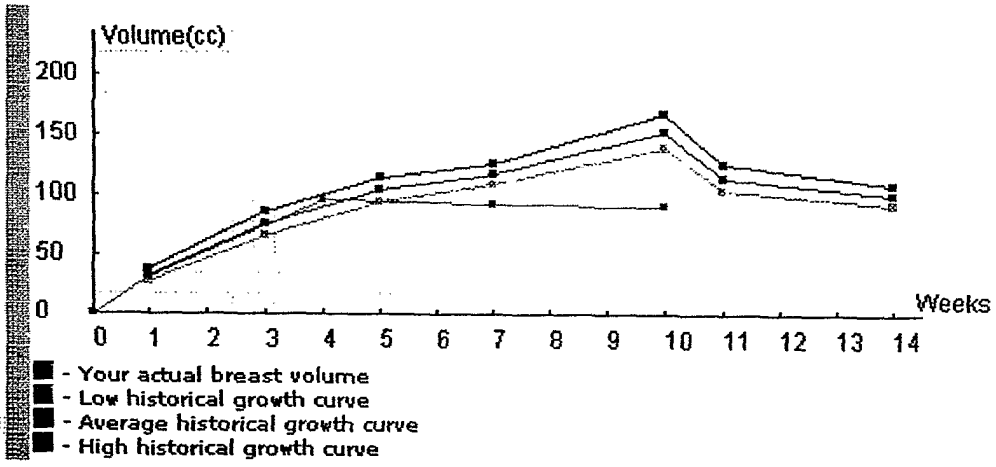
BRAVA® GROWTH GRAPH

The BRAVA System Growth Graph compares your actual measurement against historical data. The green points are your actual breast volume in cubic centimeters (cc) as measured during your visits. The gray line illustrates the historical growth curve. The Y-axis indicates volume in cc and the X-axis indicates the date at which the measurement was taken. If you have followed the protocol treatment, your data points should coincide with the historical data.



Back to Main Menu

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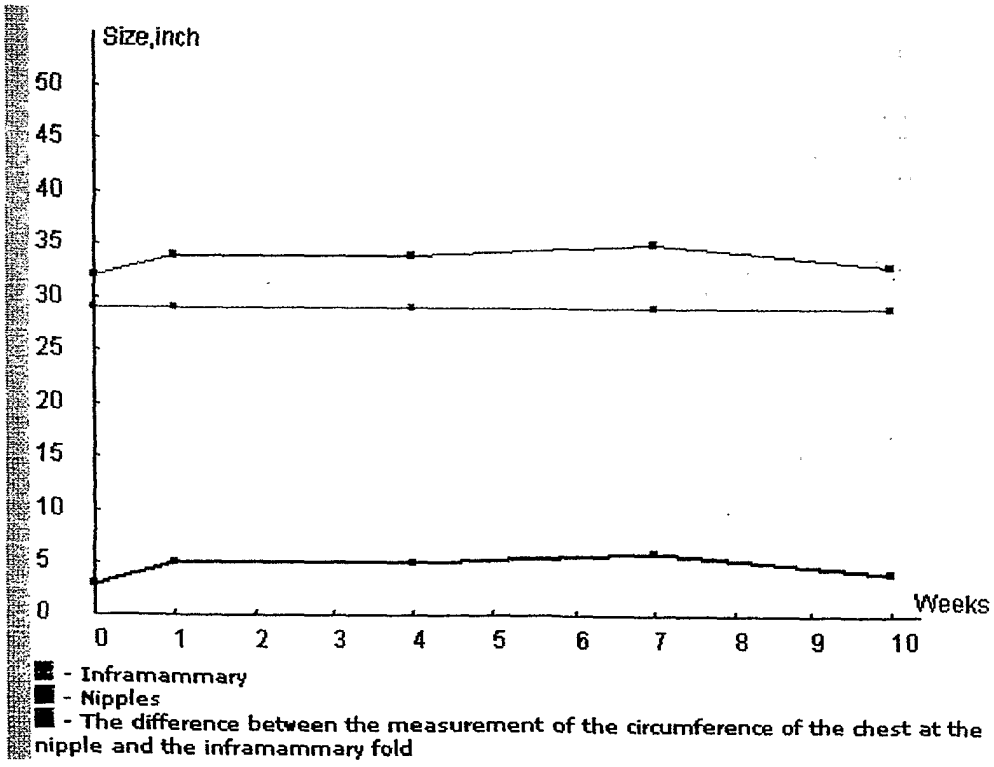
CHEST CIRCUMFERENCE

Another important measurement of volume variance is the difference between the measurement of the circumference of the chest at the nipple and the inframammary fold. The Chart below illustrates the increase in inches. The Y-axis depicts inches and the X-axis depicts the date of measurement.

a. Inframammary, Nipples



b. Weight

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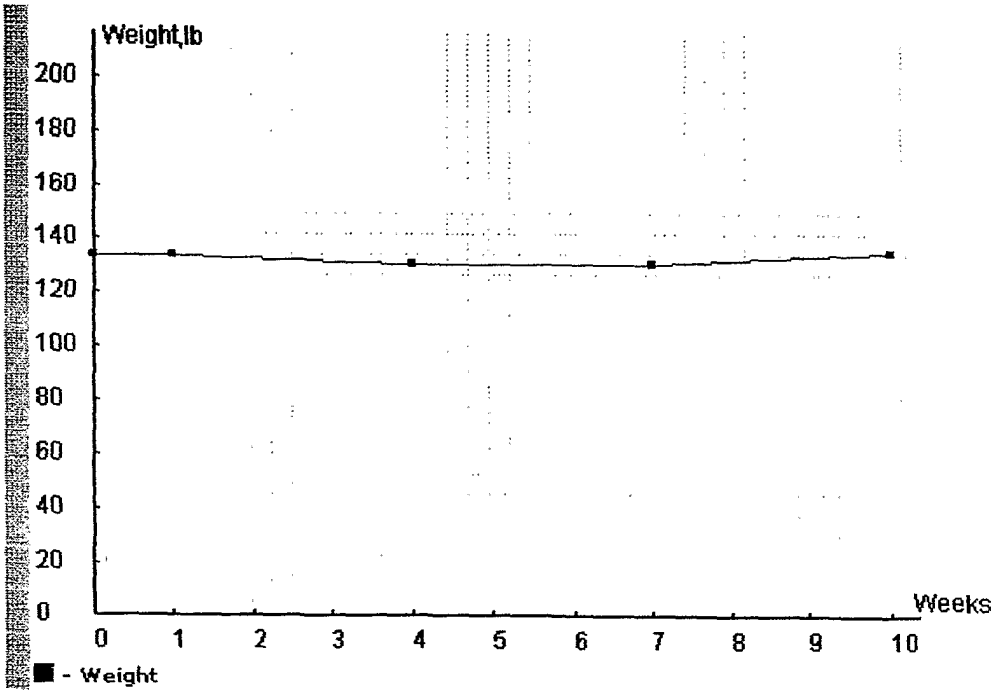
0 1 2 3 4 5 6 7 8 9 10

■ - Inframammary
■ - Nipples
■ - The difference between the measurement of the circumference of the chest at the nipple and the inframammary fold

b. Weight



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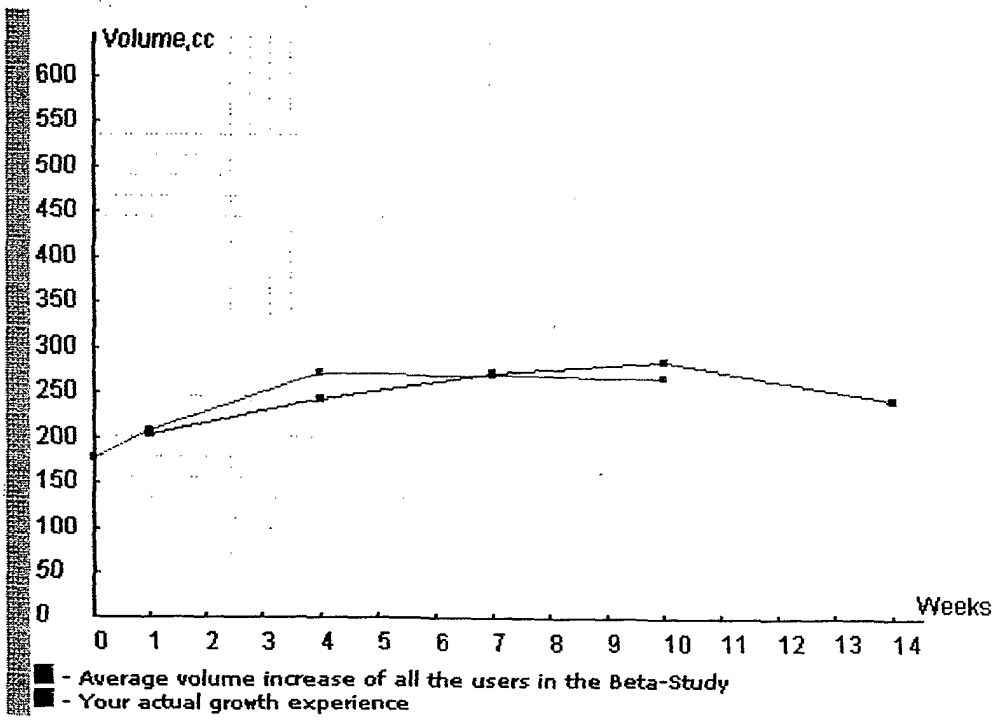
SEGMENT INFORMATION

a. Average of All Users

The chart below depicts the average volume increase in cubic centimeters of all the users in the Beta-Study (blue) as measured at the specific time in the Protocol treatment vs. your actual growth experience (green) in cubic centimeters (cc).



b. Average within Your Same Demographic Group

The chart below depicts the average volume increase in cubic centimeters of users (blue), in the Beta Study, within your demographic segment as grouped by age and whether or not you had children vs. your actual

Done

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File Edit View Favorites Tools Help

Back Forward Stop Refresh Home Search Favorites History Print

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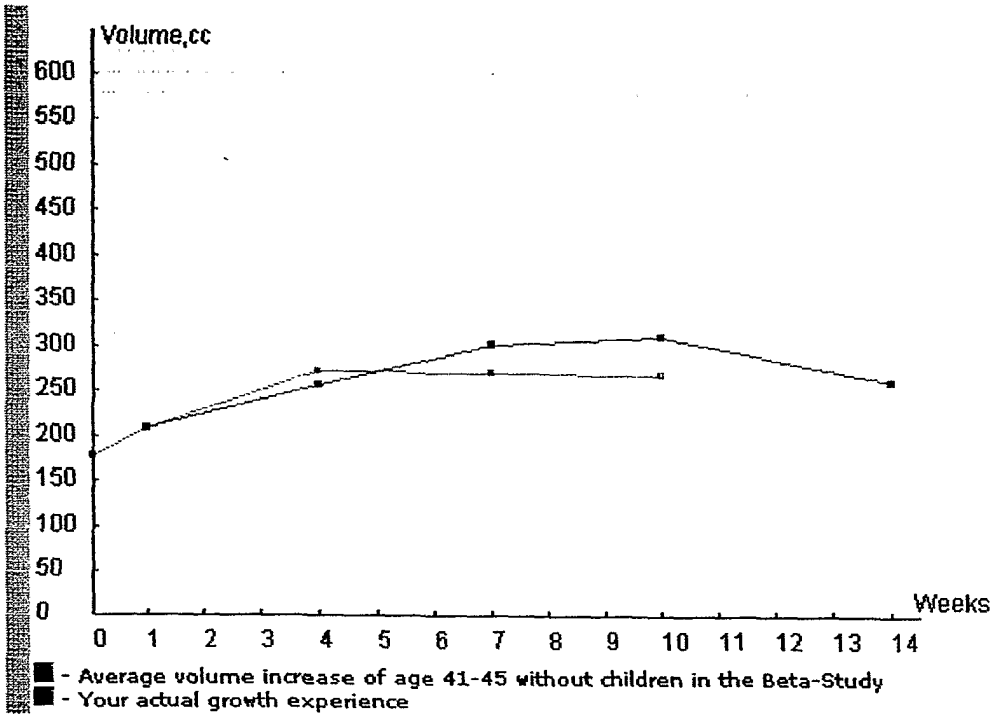
b. Average within Your Same Demographic Group

The chart below depicts the average volume increase in cubic centimeters of users (blue), in the Beta Study, within your demographic segment as grouped by age and whether or not you had children vs. your actual growth experience (green) in cubic centimeters (cc).



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PERORT PAGE for

BASELINE REPORT

The Baseline Report provides administrative information as well as the first measurements taken of you.

Subject ID:	
CRA Name:	
MD Name:	
Patient Visit Date:	7/7/00
Weight,lb:	134
Nipples - Inframm.,inch:	3

STATUS REPORT

This report provides absolute values and is created every time a measurement is made.

Patient Visit Date	Nipple - Inframm. inch.	Weight lb.	Breast Vol. Left cm^3	Breast Vol. Right cm^3
7/13/00	5	134	208	208

VARIANCE REPORT

This report is generated after a new measurement is taken and a data change of more than 5% is noted.

Patient Visit Date	Var Nipple-Inframm. inch./%	Var Weight lb./%	Var Breast Vol. Left cm^3/%	Var Breast Vol. Right cm^3/%

Done

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Back Forward Stop Refresh Home Search Favorites History Print

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Home

Patient Information

Member Information

MD Name:

Patient Visit Date: 7/7/00

Weight,lb: 134

Nipples – Infram.,inch: 3

STATUS REPORT

This report provides absolute values and is created every time a measurement is made.

Patient Visit Date	Nipple - Infram. inch.	Weight lb.	Breast Vol. Left cm^3	Breast Vol. Right cm^3
7/13/00	5	134	208	208

VARIANCE REPORT

This report is generated after a new measurement is taken and a data change of more than 5% is noted.

Patient Visit Date	Var Nipple-Infram. inch./%	Var Weight lb./%	Var Breast Vol. Left cm^3/%	Var Breast Vol. Right cm^3/%
7/13/00	2/66	0/0	34/19	28/15

Back to Main Menu

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What is claimed is:

1. A medical device adapted to be worn by a patient and having a control for automatically collecting information relating to patient compliance with a recommended treatment protocol, and a separate communication cradle, said cradle being configured to connect to said control and having a communications link to thereby transmit said patient compliance information to a host.

2. The medical device of claim 1 wherein said communications link comprises an Internet connection.

3. The medical device of claim 2 wherein said control includes a battery and said cradle includes a battery charger, said battery charger being connected in circuit with the control battery when said control is connected to the cradle for charging thereof.

4. The medical device of claim 2 wherein said control has a micro-controller including a microcomputer for controlling its operation.

5. The medical device of claim 4 wherein said microcomputer further comprises a memory for storing the patient compliance information.

6. The medical device of claim 5 wherein said control further comprises a sensor for monitoring patient compliance and an alarm, said microcomputer being programmed to sound said alarm in response to an indication of non-compliance by the patient.

7. The medical device of claim 6 wherein the control further comprises an input to permit the patient to disable the alarm.

8. The medical device of claim 7 wherein the cradle further comprises an indicator for indicating a relative measure of patient compliance to the patient.

9. A medical device adapted to be worn by a patient and having a control for automatically collecting information relating to patient compliance with a recommended treatment protocol, said control being configured to connect to a communications link to thereby transmit said patient compliance information to a host.

10. The medical device of claim 9 wherein said control further comprises a micro-controller, said micro-controller including a microcomputer.

11. The medical device of claim 10 further comprising a sensor connected to the microcomputer for sensing patient compliance.

12. A method for collecting data corresponding to patient compliance with a recommended protocol for wearing a medical device, the method comprising the steps of providing a medical device, said medical device having a sensor for sensing when said device is being

operatively worn by a patient, providing a communication connection for transmitting data from said device over a communication link, and providing a data collector, said data collector being adapted to receive data over said communication link transmitted by said communication connection.

13. The method of claim 12 further comprising a cradle, the communication connection being located within the cradle, and wherein the method further comprises the step of placing the device in the cradle for transmitting data.

14. The method of claim 13 wherein said data collector further comprises a digital data processor, and the method further comprises the steps of processing the data by the digital data processor and providing restricted access to said processed data by at least said patient.

15. The method of claim 14 wherein said communication link comprises the internet, wherein the step of providing restricted access to said processed data includes the step of providing a restricted access web site on the internet which at least the patient can access to view his processed data.

16. The method of claim 15 wherein the step of providing a restricted access web site includes the step of providing restricted access to a medical professional for all of the processed data on the web site relating to a number of patients.

17. A method for collecting data relating to a patient's compliance with a recommended regimen for usage of a medical device and providing feedback to said patient relating to said compliance, said method comprising the steps of providing a sensor in said medical device for sensing operative use of said medical device, communicating data corresponding to said operative use to a digital data processor, processing said patient data, and providing restricted access to said processed patient data by said patient.

18. The method of claim 17 further comprising a cradle for receiving said medical device, and wherein the step of communicating data includes placing the medical device in the cradle.

19. The method of claim 18 wherein the step of providing restricted access to said processed data includes the step of posting the processed data on a restricted access internet web site.

20. The method of claim 19 wherein the step of providing restricted access to said processed data includes the step of providing restricted access to a medical professional for his patients.

21. A medical device adapted to be worn by a patient and having a control for automatically collecting information relating to patient compliance with a recommended treatment protocol, a cradle for receiving and operatively connecting to the control of said medical device as said medical device is placed therein, said cradle having a communications link which is activated upon placing the control for the medical device therein, said communications link being adapted to activate and transmit data contained within the control to a predetermined destination over the communications link.

22. The medical device of claim 21 wherein the communications link comprises a link to the Internet.

23. The medical device of claim 22 wherein the control is separable from the medical device for placing in the cradle.

24. The medical device of claim 23 wherein the control includes a microcomputer and at least one sensor connected thereto, said microcomputer having a memory for storing data received from said sensor.

25. The medical device of claim 24 wherein the communications link includes a modem and a telephone port for connection to a telephone line for transmitting data over the telephone line to said predetermined destination.

26. The medical device of claim 25 wherein said predetermined destination includes at least one server, and wherein said server is connected to the internet at least intermittently and hosts a web site for displaying the processed data.

27. The medical device of claim 26 wherein a plurality of said medical devices are connectable to their respective cradles for transmitting data to the at least one server, and said server web site is configured to display data for all of said patients.

28. The medical device of claim 27 wherein said web site has a security layer for restricting access to said web site.

29. A medical appliance having a patient monitoring device comprising at least a first sensor to sense a patient biological parameter, said first sensor being connected to and supplying data to a controller, the controller including a download port for transferring data collected by said first sensor relating to the patient use of said medical appliance.

30. The medical appliance of claim 29 further comprising a timer associated with the controller for providing a time correlation to said collected data.

31. The medical appliance of claim 30 further comprising an electromechanical device for applying a force to the patient, and a second sensor for sensing the output of said electromechanical device, the second sensor being connected to said controller and supplying data thereto.

32. The medical appliance of claim 31 wherein said medical appliance is worn by said patient, and wherein said first sensor comprises a temperature sensor positioned to sense the patient's temperature as the medical appliance is worn to thereby provide an indication of patient compliance.

33. The medical appliance of claim 32 further comprising a memory associated with said controller for storing said collected data prior to download through said download port.

34. The medical appliance of claim 33 wherein said electromechanical device comprises a pump for creating a negative pressure within a dome, and said second sensor comprises a pressure sensor for sensing the negative pressure created by said pump.

35. The medical appliance of claim 34 further comprising a third sensor, said third sensor being adapted and positioned to sense another device parameter and being connected to said controller for transmitting collected data thereto.

36. A medical device adapted for being worn by a patient in order to administer a prescribed protocol, said device having a patient monitor for determining if and for how long a patient wears said device as prescribed.

37. The medical device of claim 36 wherein said medical device comprises a soft tissue enlargement device having a tensioning applicator for applying a tension to a patient's soft tissue, and said patient monitor having a temperature sensor positioned for being heated by said patient as the medical device is worn to thereby provide an indication that said device is being worn.

38. The medical device of claim 37 further comprising a timer for correlation with said temperature sensor output to thereby provide data corresponding to how long said patient is wearing the device.

39. The medical device of claim 38 further comprising a second sensor for determining when the tensioning device is applying a tension to the patient's soft tissue, all of said sensors being connected to a controller for collecting and storing said data.

40. The medical device of claim 39 wherein said controller has a download port for transferring said collected data out of said device, as desired.

41. The medical device of claim 40 wherein said controller comprises a microprocessor and a memory.

42. The medical device of claim 41 wherein said tensioning device comprises a pair of vacuum domes, each of said domes being adapted to enclose a female patient's breast.

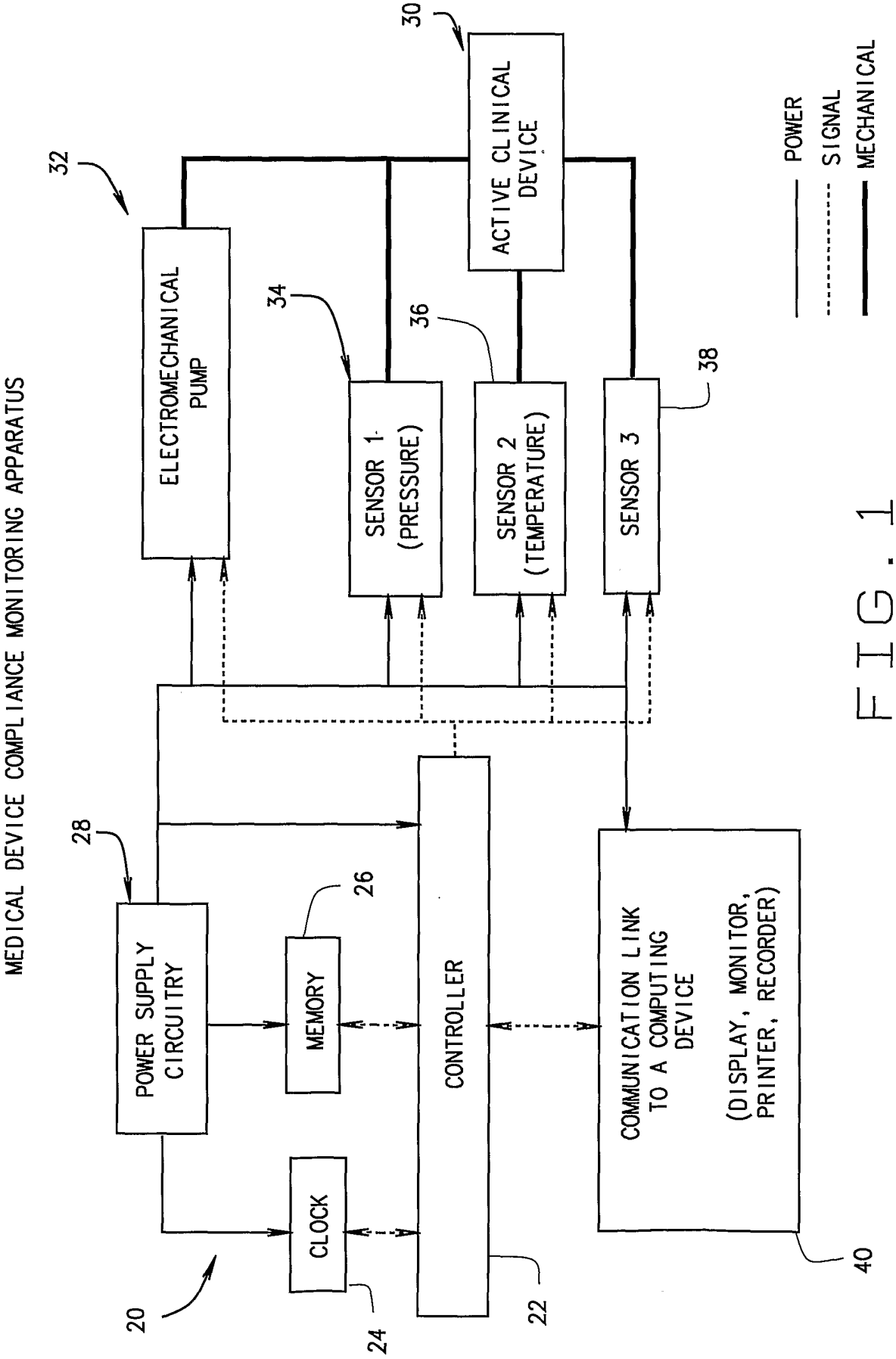
MEDICAL DEVICE COMPLIANCE MONITORING APPARATUS
20
22
24
26
28
30
32
34
36
38
40
POWER SUPPLY CIRCUITRY
MEMORY
CLOCK
CONTROLLER
ELECTROMECHANICAL PUMP
SENSOR 1 (PRESSURE)
SENSOR 2 (TEMPERATURE)
SENSOR 3
ACTIVE CLINICAL DEVICE
COMMUNICATION LINK TO A COMPUTING DEVICE
(DISPLAY, MONITOR, PRINTER, RECORDER)
POWER
SIGNAL
MECHANICAL

FIG. 1

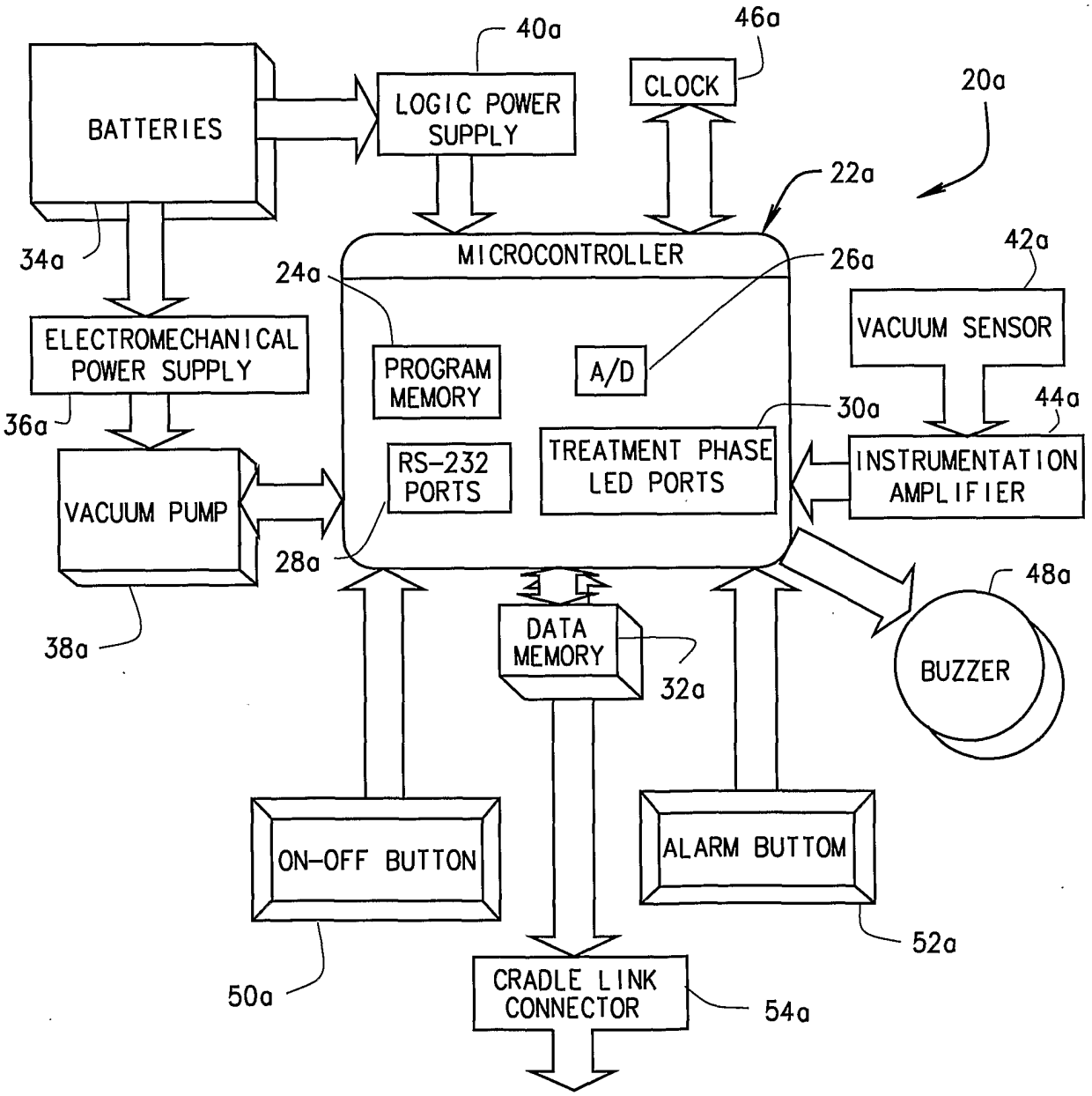
BATTERIES
40a
LOGIC POWER SUPPLY
46a
CLOCK
20a
22a
MICROCONTROLLER
24a
26a
42a
VACUUM SENSOR
34a
ELECTROMECHANICAL POWER SUPPLY
PROGRAM MEMORY
A/D
36a
30a
44a
RS-232 PORTS
TREATMENT PHASE LED PORTS
INSTRUMENTATION AMPLIFIER
VACUUM PUMP
28a
48a
DATA MEMORY
32a
BUZZER
38a
ON-OFF BUTTON
ALARM BUTTOM
52a
50a
CRADLE LINK CONNECTOR
54a

FIG. 2

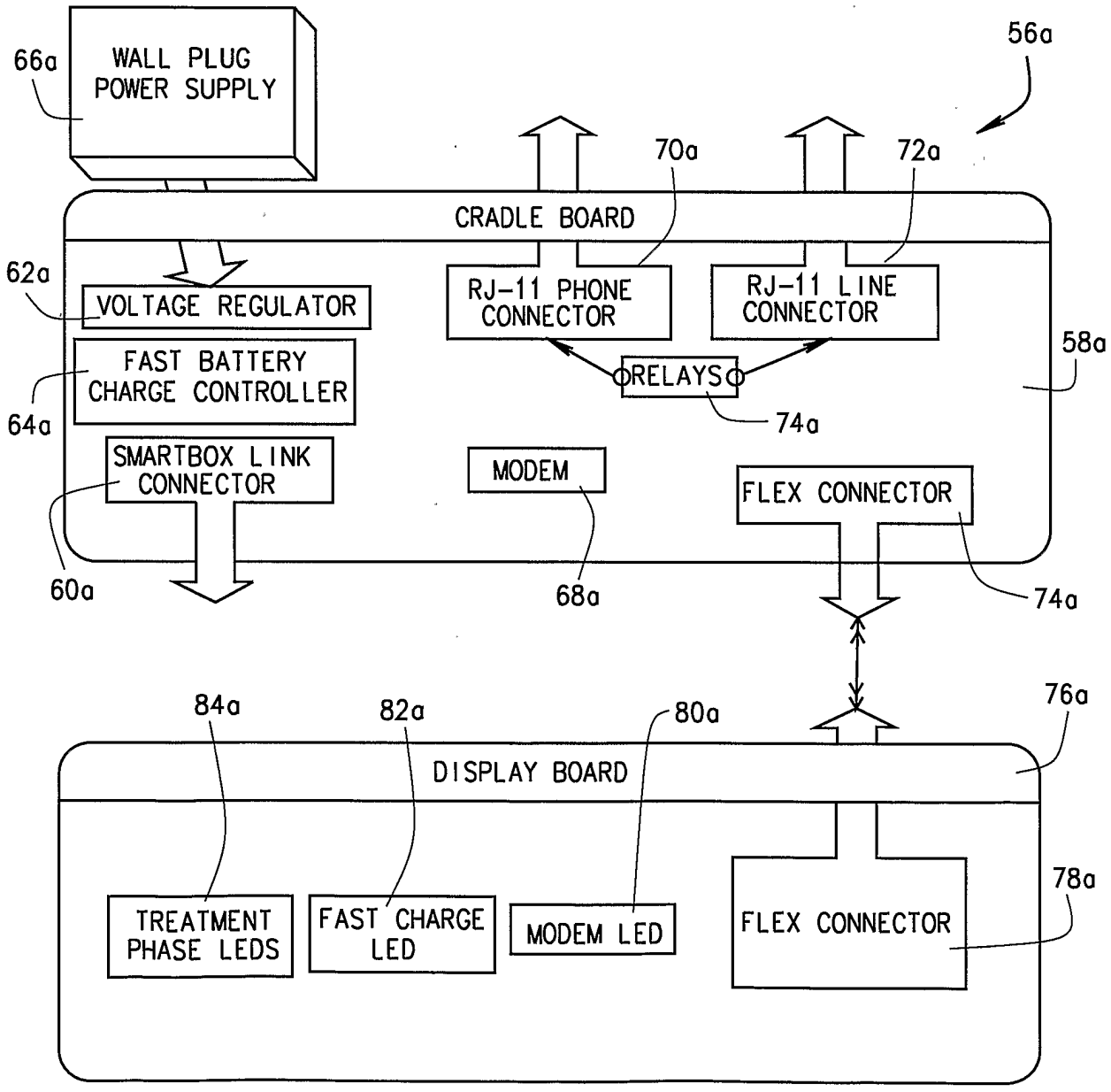
66a
WALL PLUG POWER SUPPLY
56a
70a
72a
CRADLE BOARD
62a
VOLTAGE REGULATOR
RJ-11 PHONE CONNECTOR
RJ-11 LINE CONNECTOR
58a
FAST BATTERY CHARGE CONTROLLER
RELAYS
64a
74a
SMARTBOX LINK CONNECTOR
MODEM
FLEX CONNECTOR
60a
68a
74a
84a
82a
80a
76a
DISPLAY BOARD
TREATMENT PHASE LEDS
FAST CHARGE LED
MODEM LED
FLEX CONNECTOR
78a

FIG. 3

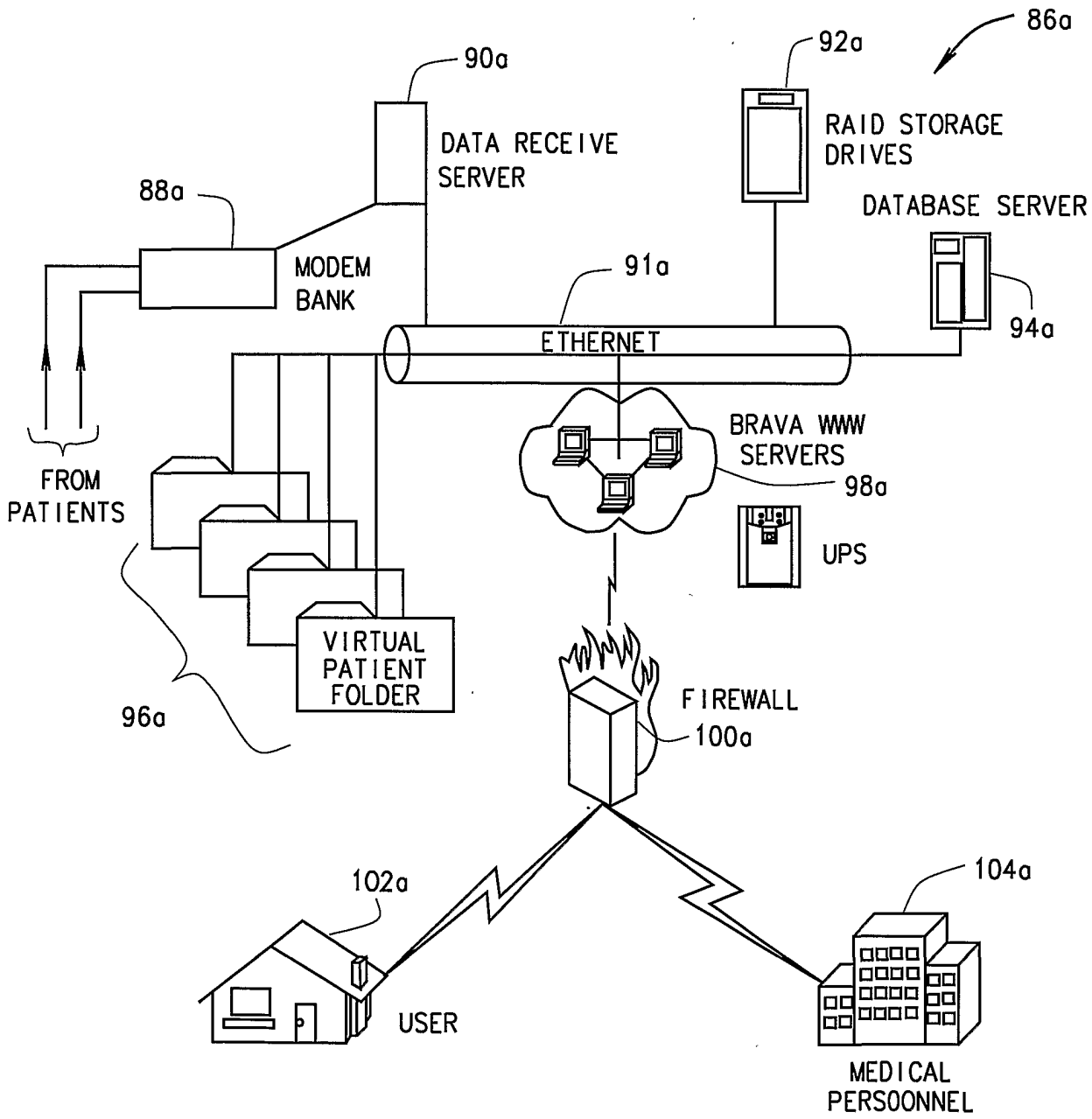
86a
92a
90a
RAID STORAGE DRIVES
DATA RECEIVE SERVER
88a
DATABASE SERVER
MODEM BANK
91a
94a
ETHERNET
BRAVA WWW SERVERS
98a
FROM PATIENTS
UPS
VIRTUAL PATIENT FOLDER
96a
FIREWALL
100a
102a
104a
USER
MEDICAL PERSOONNEL

FIG. 4

专利名称(译)	患者依从性监测		
公开(公告)号	EP1284641A2	公开(公告)日	2003-02-26
申请号	EP2001926952	申请日	2001-04-12
申请(专利权)人(译)	BIO-MECANICA INC.		
当前申请(专利权)人(译)	BIO-MECANICA INC.		
[标]发明人	FREYRE CARLOS V KURU MURAT KHOURI ROGER K		
发明人	FREYRE, CARLOS, V. KURU, MURAT KHOURI, ROGER, K.		
IPC分类号	A61B5/00 A61H9/00 G06F19/00 G06Q50/00		
CPC分类号	A61B5/0002 A61H9/005 A61H2205/081 A61H2230/00 G06F19/3481 G16H10/60 G16H15/00 G16H20/30 G16H40/67 Y10S128/904		
优先权	09/572348 2000-05-17 US 09/809986 2001-03-16 US		
外部链接	Espacenet		

摘要(译)

患者监测设备包括微处理器控制器，其具有时钟电路和耦合到一个或多个传感器的存储器，使得当医疗器具适当地安装到患者并由患者佩戴时，传感器提供电信号，确认可以随后定时提供确认患者遵守推荐方案的数据。另外，根据需要，可以使用其他传感器来收集与装置的各种操作参数有关的数据，包括在真空圆顶下呈现的负压的量。优选实施例包括具有微计算机和传感器的控制器，用于监视和收集与患者对规定方案的依从性有关的数据。控制器是电池供电的，并且通过将控制器放入具有用于提供电力的墙上插头的支架来进行再充电。支架还具有调制解调器和电话连接，以便当控制器放置在支架中时，控制器中包含的合规性数据由调制解调器通过电话线连接自动传输到中心位置。中心位置包括用于接收患者依从性数据，处理并将其存储在虚拟患者文件中的数据网络，以及一个或多个网络服务器主持用于以其处理的形式显示患者数据的网站。