

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
14 October 2004 (14.10.2004)

PCT

(10) International Publication Number
WO 2004/088480 A2

(51) International Patent Classification⁷: **G06F**

A.; 22912 El Pacifica Drive, Laguna Hills, CA 92653 (US). **MANERA, Alexandria**; 22912 El Pacifica Drive, Laguna Hills, CA 92653 (US).

(21) International Application Number:
PCT/US2004/009687

(22) International Filing Date: 29 March 2004 (29.03.2004)

(74) Agent: **CROCKETT, K. David**; Crockett & Crockett, 24012 Calle de la Plata, Suite 400, Laguna Hills, CA 92653 (US).

(25) Filing Language: English

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(26) Publication Language: English

(30) Priority Data:
10/401,638 28 March 2003 (28.03.2003) US

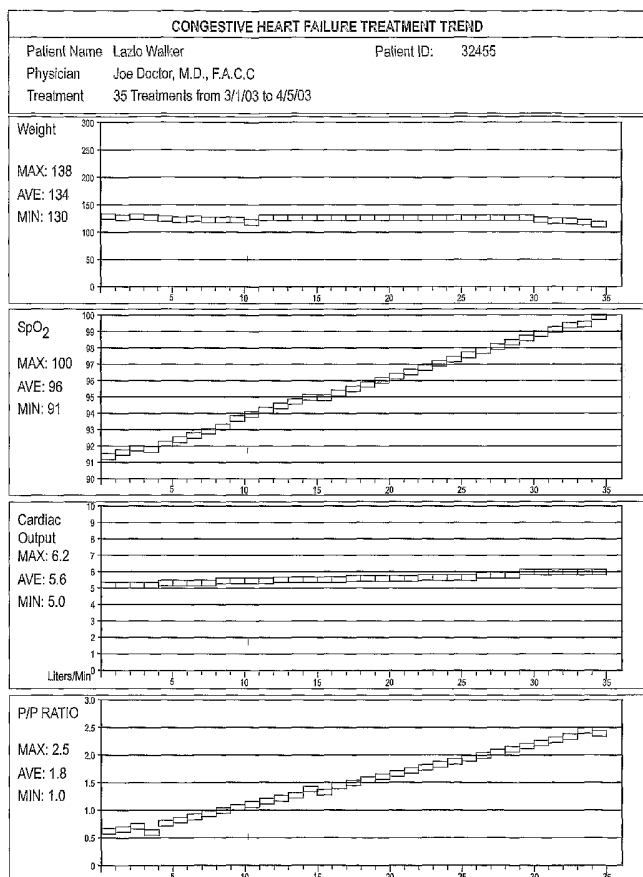
(71) Applicant (for all designated States except US): **APPLIED CARDIAC SYSTEMS, INC** [US/US]; 22912 El Pacifica Drive, Laguna Hills, CA 92653 (US).

(72) Inventors: **BURNS, Kenneth, L.**; 22912 El Pacifica Drive, Laguna Hills, CA 92653 (US). **MANERA, Loren**,

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH,

[Continued on next page]

(54) Title: SYSTEM AND METHOD FOR GENERATING EXTERNAL COUNTERPULSATION



(57) Abstract: A system for performing ECP and recording ECP system data, patient cardiac parameter data, and other data, and presenting the data in displays that are accessible to the operator in formats that assist in consistent treatment, interpretation of treatment data, and confirmation of therapeutic effect.

WO 2004/088480 A2



GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

System and Method for Generating External CounterpulsationReportsField of the Inventions

The inventions described below relate the field of
5 external counterpulsation.

Background of the Inventions

External counterpulsation (ECP) is a noninvasive
treatment for congestive heart failure, stable and unstable
angina pectoris, acute myocardial infarction, cardiogenic
10 shock and other cardiac disease. External counterpulsation
refers to the method of squeezing a patient's lower body in
syncopation with the patient's heart beat (that is, the lower
body is squeezed between each heart beat). To accomplish
this, a series of compressive air cuffs are wrapped around
15 each leg; one at calf level, another slightly above the knee
and the third on the thigh, and perhaps a cuff over the
buttocks. A computerized control system interprets the
patient's ECG, and operates valves and an air supply to
inflate and deflate the bladders in synchronization with the
20 R-wave of the patient's cardiac cycle. The R-wave represents
the start of the diastole, which is the period during which
the chambers of the heart expand and fill with blood. During
diastole, the air cuffs are inflated sequentially (from the
distal bladder on the calves to the proximal bladders on the
25 upper thighs or buttocks), compressing the calves, lower
thighs and upper thighs, and all the muscles and blood vessels
of the leg. This squeezing action results in an increase in
diastolic pressure, generation of retrograde arterial blood
flow and an increase in venous return. The cuffs are deflated
30 simultaneously just prior to systole, which produces a rapid

drop in vascular resistance to blood flow, a decrease in ventricular workload and an increase in cardiac output.

When used to treat the chronic condition of congestive heart failure, many treatment sessions, spread out over
5 several weeks, are used. A full course of therapy usually consists of 35 one-hour treatments, which may be offered once or twice daily, usually 5 days per week. In the short term, this method of therapy is thought to deliver more oxygen to the ischemic myocardium by increasing coronary blood flow
10 during diastole, while at the same time reducing the demand for oxygen by diminishing the work requirements of the heart. Long-term benefit has been established by numerous studies. While researcher are still trying to determine why the therapy works, research has indicated that the therapy leads to
15 increased coronary collateral flow to ischemic regions of the heart (though the mechanism leading to the effect is unknown). Clinical trials have demonstrated that the beneficial effects of ECP, including increased exercise time until onset of ischemia and a reduction in the number and severity of anginal
20 episodes. These effects are not only sustained between treatments, but may persist for several months or years after the entire course of therapy.

The effectiveness of ECP treatment for chronic conditions is determined by the changes in diastolic pressure, systolic
25 pressure, heart rate observed over the course of treatment. Currently, doctors and clinicians administering ECP to patients review a few strips of ECG and blood pressure data to determine if ECP performed on a particular patient is being performed properly and having a beneficial effect on the
30 patient. Indications of beneficial effect include increased cardiac output, and, depending on the particular cause or manifestation of angina pectoris and/or congestive heart failure improved ECG, lower diastolic blood pressure, and a

lower heart rate. Currently, a few paper strips which the operator collects during each session are collected in the patients chart for comparison of cardiac parameters during each session. No other data is collected, because it is not currently used. There is no generally accepted endpoint for the therapy, and no generally accepted method for determining if further therapy would be useful for a particular patient. Hence, the industry has settled on an apparently arbitrary 35 hour course of therapy. The treatment is offered on the basis that the patient will respond to therapy, and that 35 sessions will be sufficient. If a patient is well treated with 35 sessions, all is well and good for that patient. If, however, the patient would benefit from a longer course of treatment, none will be provided because there is no method of identifying these patients. If the patient would have been well treated with substantially less than 35 sessions, the complete 35 session therapy would then be considered to include a substantial amount of unnecessary treatment. The current absence of any mechanism for tracking and analysis makes it impossible to objectively determine if further treatment would be warranted.

Summary

The systems and method described below provide for improved performance of external counterpulsation therapy and improved reporting of the effects of external counterpulsation therapy. When external counterpulsation therapy is provided in multiple sessions to treat chronic heart disease, cardiac parameters are recorded continuously for each session. The parameters and/or pictorial representations are stored in a computer memory for recall, and may be recalled in formats particularly conducive to ensuring that therapy is applied on a consistent basis, ascertaining the effectiveness of the

therapy and its possible endpoint, and identifying trends in patient treatment.

The system is used in conjunction with an external counterpulsation system. The ECP system may be our own NCP-2
5 ECP system, or systems provided by companies such as Vasomedical or CardioMedics. The system includes several inflatable cuffs for the legs and buttocks of the patient, ECG monitors, blood pressure monitors (plethysmographs), high pressure air supply, valves and actuators, and a computer to
10 control the operation of the system and record system parameters and cardiac parameters reported by the ECG monitors and blood pressure monitors. The system may also include a cardiac output monitoring system and bladder evacuation system.

15 Brief Description of The Drawings

Figure 1 illustrates an external counterpulsation system.

Figure 2 illustrates the timing of bladder inflation in relation to the patient's ECG to provide ECP therapy.

20 Figure 3 illustrates conventional strips used by doctors to assess the progress of ECP.

Figures 4 and 4a illustrate an interactive display provided by the system to track and control external counterpulsation variables.

25 Figure 5 illustrates the consolidated report of cardiac parameters over a treatment session.

Figure 6 illustrates a selected strip report provided by the system.

Figure 7 illustrates an interactive strip display provided by the system.

Figure 8 is a table of cardiac parameters for an external counterpulsation session.

Figures 9 and 9a are graphical displays of cardiac parameters for an external counterpulsation session.

5 Figures 10 and 10a are tables of ECP system parameters and cardiac parameters for a complete course of ECP therapy.

Figures 11, 12 and 13 are graphical displays of ECP system parameters and cardiac parameters for a complete course of ECP therapy.

10 Detailed Description of the Inventions

Figure 1 illustrates an external counterpulsation system. The system includes several bladders adapted for placement on the patient the patient 1. The bladders 2, 3, 4 and 5 are placed around the legs of the patient, and are operably
15 attached to an inflation and deflation system 6. Each of the bladders is marked with sizing indicia 7, so that the bladders can be fastened to certain and reproducible tightness. An ECG monitoring system 8 and blood pressure monitoring system 9 are operably attached to the patient. A pulse oximetry monitoring
20 system 10 is also attached to the patient. Also, a cardiac output monitoring system 11, such as an impedance cardiograph, may be attached to the patient. A control system 12 includes a computer, a keyboard and input devices, and a display. The computer is programmed to control the inflation and deflation
25 system in response to the patient's ECG, and record ECG data reported from the ECG monitoring system, blood pressure data reported from the blood pressure monitoring system, blood oxygen content data reported by the pulse oximetry monitoring system, and cardiac output data reported by the cardiac output
30 monitoring system. For convenience, ECG data, blood pressure data, blood oxygen data, heart rate and cardiac output may be

referred to as cardiac parameters. The control system is also operable to generate displays necessary for an operator interface and generate reports, for display or printing, in predetermined formats as described below.

5 Operation of the bladders is controlled by the control system so that the bladders are inflated to compress the lower body during the diastolic period of the heartbeat so as to increase blood pressure during the diastolic period to a level higher than systolic pressure. This timing relationship
10 between the heartbeat and the bladder inflation is illustrated in Figure 2. As illustrated in Figure 2, the ECG trace 20 is exemplary of a normal patient's ECG, showing the typical Q, R, S, T waves indicative of various stages of the electrophysiological activity of the heart. The P wave
15 represents the start of a heartbeat, specifically the contraction of the atria which initiates the heartbeat. The Q and R waves represent the contraction of the left ventricle. This represents the heartbeat, that is, the systole, in which the heart is forcing blood out into the body. After the R
20 wave peaks, the heart relaxes and the chambers of the heart expand and take in blood. The ST portion of the ECG represents depolarization and re-polarization of the ventricles (the return of the heart to baseline), preparatory to the following heartbeat. ECG trace 21 illustrates the ECG
25 of a particular patient with ischemia, as indicated by the elevated ST wave (every patient will exhibit a different ECG, depending on his particular cardiac ailment). The bladder inflation line 22 indicates that the control system is inflating the bladders after detecting the R wave. The
30 patient's nominal blood pressure, as it would be without external compression, is represented by line 23, which illustrates the systolic blood pressure significantly higher than diastolic blood pressure. The patient's blood pressure during augmentation is shown in line 24, which shows that the

systolic blood pressure is lower than the augmented diastolic blood pressure. Counterpulsation is performed with the goal of increasing the ratio of diastolic pressure to systolic pressure from its typical levels (80/120, or .75, for example) to a level of about 1.2 (for example, 144 diastolic/120 systolic) or higher. Ratios in the range of 1.0 to 1.5 are observed in patients. The ratio is a commonly used expression of the level of augmentation.

Conventionally, proper performance of external counterpulsation therapy is monitored by reviewing selectively generated strip charts, taking from a very small period within the hour-long session. Figure 3 illustrates a typical strip chart provided to doctors to report the performance of ECP. These strip charts have previously been generated by an operator, on the fly, during an ECP session. Three such strips are shown in the figure. Each strip includes the patient's ECG trace **30**, the system inflation/deflation trace **31**, and the patient's blood pressure trace, reported continuously (trace **32**). The session time and cuff pressure are hand-written by the operator. This report is useful for ensuring that bladder inflation is occurring during diastole, after the desired delay after the R-wave, and that the counterpulsation is having the desired effect on diastolic blood pressure. It also confirms that the ratio is increased from the normal range to a level above 1.0. However, these strips represent three six-second periods during the course of a session. No record of the rest of the session is generated, and all the patient data lost.

Because counterpulsation therapy requires many sessions, many variables can affect the success of the therapy. To eliminate the significant variables of cuff placement and ECG electrode placement, or to detect variations in the treatment that have caused beneficial or deleterious effects on the

therapy, the control system provides a Daily Treatment Record as shown in Figures 4 and 4a. The daily treatment record provides a multi-page display 40 which includes a patient identification field 41, fields 42 for entry of patient
5 reported symptoms, a previous treatment information field 43 for display of ECP system parameters such as cuff pressure and utilization percentage (average) for the prior session, and fields 44 for entry of pre-session cardiac parameters measured from the patient immediately before starting an ECP session.
10 The control system is programmed to display previous treatment data and current session ECP parameters in appropriate corresponding sub-fields.

The second page of the display, shown in Figure 4a, includes a cuff placement field 45, an electrode placement
15 field 46, and a pad placement field 47. In the cuff placement field, the control system accepts input from the operator relating the cuff size used on the patient, and the tightness of the cuff used in the session. As indicated in Figure 1, the various cuffs are provided in several sizes, and each cuff
20 is provided with indicia indicating the tightness achieved when secured on the patient with different degrees of overlap of the fastening areas. The operator, having selected a suitable size, and having sized the cuffs to the patient, enters the size and tightness in the fields provided. (During
25 the course of therapy, the operator may adjust the tightness of the cuffs (or change the cuff to a different size) as necessary to obtain the desired augmentation, and then enter those changes in the appropriate fields.) During an initial ECP session, the operator will enter the size and tightness of
30 all cuffs used on the patient, and the placement of each of the ECG leads. After the initial therapy session, the control system is operable to call up the patient's recorded data upon instructions from the operator.

In the electrode placement field 46, the control system accepts input from the operator relating to the placement of electrode leads, and presents graphic representation 48 of the patient. A three-electrode ECG is typically used, and the lead may be marked or colored to indicate proper placement. In the display, the electrode icons are colored green, black and white (marked G, B and W in the black and white figure), to correspond to common green, black and white electrodes used for three-lead ECG. The operator, having selected appropriate electrode placement on the patient's body, enters the electrode locations by dragging the icons G, B and W to the corresponding position on the graphic representation of the patient. During an initial ECP session, the operator chooses the electrode sites according the guidelines for the ECG system. In subsequent sessions after the initial therapy session, the control system is operable to call up the patient's recorded data upon instructions from the operator, including the initial session electrode placement and/or electrode placement for any prior session. This assists the operator in maintaining consistency in electrode placement (electrode placement variations will result in ECG distortions, from session to session, making evaluation difficult).

In the pad placement field 47, the control system presents another graphic representation 49 of the patient, with icons representing various pads that are provided for patient comfort. The operator places the pads in the initial ECP session, and may arrange them to make the patient comfortable, and records the preferred pad locations by manipulating the pad icons 50 in the pad placement field so that they appear relative to the patient graphic in positions corresponding to actual placement on the patient. Additionally, any lesions, other patient supports in use, etc. may be recorded with additional icons 51.

Figure 5 illustrates a portion of the new report provided by the control system, which may be provided in printed form or on a computer display. The system collects all measured data, collected from the patient and the ECP system, during every session of ECP therapy, and Figure 5 shows a fifteen-minute portion of the data (the entire report to the session includes four pages) in a formatted table 52. As shown in the figure, full ECG, inflation/deflation time, and augmented blood pressure data is recorded continuously, for the entire ECP session. The ECG data, inflation time data, and blood pressure data are presented in trace format in the numerous trace display fields 53. The session time (in minutes), heart rate (in beats per minute) and ratio are reported in tabular form in tabular data display fields 54. One trace display field and one tabular data display field is provided for each minute of therapy, and these fields report the instantaneous data and averaged data for each minute. Each trace display field includes an ECG trace 30, a blood pressure trace 32, and an inflation/deflation trace 55 comprising a series of compression icons 56. The compression icons report, in easily visible bar graph format, the delay time and inflation time and deflation time provided for every counterpulsation. These three graphical elements are presented in synchronized relationship, so that the temporal relationship between the ECG, counterpulsation, and blood pressure can be easily understood. The data presented represents continuous data for the entirety of the session (notwithstanding the obvious fact that any of the data which is picked up and transmitted digitally is subject to discrete sampling).

An operator reviewing the report of Figure 5 may review the entire report, including data for the entire hour-long session, and appreciated data trends that indicate quality of the counterpulsation therapy provided to the patient. The operator may manipulate shaded cursors 57, 58 and 59 to select

time periods of particular interest for expansion into a larger format shown in Figure 6. The cursors are labeled as cursor 1, 2 and 3 (or other distinct indicia) so that they may be correlated to the strips generated for Figure 6. The
5 cursors are depicted as shaded blocks or windows, but they may be provided in any other form that allows operator manipulation and location of the cursor to be used as an input of the desired time period to be expanded

Figure 6 illustrates a selected strip report generated by
10 the system based on time periods selected by the operator through manipulation of strip selecting cursors 57, 58 and 59. The selected strips display 61 presents the time periods selected in Figure 5. They are presented in larger scale, for closer analysis of the relationship between the ECG, counter-
15 pulsations, and augmented blood pressure, and include a trace display field 62 and a tabular data field 63. As can be more clearly seen in the figure, the compression icons 64 that make up the inflation/deflation trace 55 comprise two horizontally oriented segments. The first segment 65, indicated in one of
20 the many icons shown in the figure, represents the time in which the bladders are pressurized, and its horizontal extent corresponds to the duration of the inflation of the bladders (the counterpulsation). (The time between the R wave and the start of the compression icon represents the delay enforced by
25 the system between recognition of the R wave and initiation of counterpulsation.) The second segment 66 represents the deflation time, and its horizontal extent corresponds to the time taken to deflate the bladders. (The bladders may be deflated passively, but it is preferable to evacuate the
30 bladders by applying suction, to provide very rapid deflation.) The control system calculates a percentage, which we refer to as the utilization percentage, of the available time for compression during which compression is actually accomplished, and reports this utilization percentage in the

tabular data field. Thus, in the various strips shown, the utilization is reported as 60%, 72%, and 88%. The control system also calculates the average cuff pressure applied to the cuffs (in pounds per square inch), the average peak-to-
5 peak ratio, and the average heart rate (in beats per minute).

The utilization percentage is an artificially designated ratio that can be defined in several ways, and we have chosen to calculate based on the available time between R waves (minus the inflation delay of 100 millisecond and the pre-R
10 wave refractory period of 150 milliseconds, imposed based on a prediction of the time of the next coming R wave predicted on a running average of previous R wave intervals). The inflation period includes the time the system is inflating the bladders, and excludes the deflation period. Thus, ratio is
15 calculated by dividing the actual inflation time by the R wave interval less the delay and refractory periods. Utilization percentages of 80% to 90% are preferable, and consistent operation of ECP systems at lower percentages are expected to yield lower therapeutic benefit.

20 For closer inspection of the augmentation ratios, the control system generates an interactive display shown in Figure 7. This display is similar to the selected strips shown in Figure 6, and includes similar tabular data field and trace display field. Appropriate interface is provided to
25 permit adjustment of the gain on the various traces, so that the vertical scale may be selectively increased or decreased by the operator. In addition, guides A, S and B are provided in the display. These cursors may be manipulated by the operator, and set respectively at the point which the operator
30 decides corresponds to the peak augmented pressure, peak systolic pressure, and the baseline pressure. When the operator sets the cursors, the control system calculates the augmentation ratio for the indicated heartbeat. The

calculated ratio is reported in the tabular data field, regardless of the gain applied to the blood pressure trace. The guides may be manipulated with a cursor or handle in the interface, and moved into superimposition on any portion of the blood pressure trace. The control system calculates the ratio based on the pixels of the display, so that the pixel distance between the augmented pressure cursor, systolic pressure cursor and baseline pressure cursor may be made without regard to the gain applied to the image or the absolute pressures involved. Referring back to Figure 6, the peak-to-peak ratio shown in the data fields may be calculated and entered upon operator input and selection of an exemplary pressure wave, as shown in Figure 7, or it may be calculated by the control system, based on an average of values calculated from the pressure trace.

Figure 8, 9 and 9a illustrate reports useful for determining session trends in the ECP therapy. Figure 8 is a table of cardiac parameters for an external counterpulsation session provide a tabular daily treatment record which provides a record of a single ECP session, and includes a table listing minute-by-minute average, maximum, and minimum values of cardiac parameters and system parameters. Heart rate (BPM), cuff pressure, utilization percentage and peak-to-peak ratio are reported for each minute of therapy. Using this chart, the operator may select any reported minute (by movement of a cursor or selecting a data field) and navigate to an expanded report of the time period selected. In response to the selection made by the operator, the control system provides an expanded report, in format such as that illustrated in. Figures 9 and 9a illustrate graphical versions of the display of Figure 8, and include graphs of heart rate (BPM), cuff pressure, utilization, and P/P ratio for a session selected by the operator. Review of Figure 9 provides the operator with confirmation that heart rate of the

patient was acceptable, that cuff pressure was in fact ramped up to 6 psi and maintained at 6 psi for most of the session, that utilization was high for the session. It also indicates that the peak-to-peak ratio is at an expected value, given
5 that the patient identification field at the top of the display indicates that this report pertains to the second ECP session. Figure 9a present similar data in a different form, and indicates that cuff pressure is unexpected low for much of the session, that utilization is low for much of the session,
10 but peak-to-peak ratio appears normal for an early ECP session. On the basis of this data, the operator may adjust ECP parameters to achieve the desired levels. In both Figures 9 and 9a, data fields corresponding to the graphs list the minimum, maximum and average values of the parameter indicated
15 in the graph. These values may pertain to the entire treatment session, or to operator selected time periods. As with the other displays, the time frames may be selected by highlighting a time period, dragging cursor over a time period, or other input means.

20 Figure 10 provides records of augmentation trends of each session, and displays ECP parameters and patient cardiac parameters in tabular form. Figure 10 also includes fields for reporting self-reported conditions (angina, medicines being taken, skin problems, adverse events, etc.). Figure 10a
25 provides records of augmentation trends over the entire multi-session therapy, along with augmentation trends of each session (shown in the lower window). Figure 10a includes a graph of augmentation over time in the multi-session trend field 67, and the trend line 68 immediately conveys the
30 expected upward trend in augmentation ratio. In either Figure, selection of a session by the operator, such as by highlighting of a session (illustrated in Figure 10) or by movement of a cursor along the trend line, is taken by the control system as the operator input for directing the control

system to display a more detailed report of the selection session. In response to the selection, the control system generates a detailed session report such as the reports shown in Figures 8, 9 or 9a.

5 Figures 11 and 12 and 13 are graphical displays of ECP system parameters and cardiac parameters for a complete course of ECP therapy. Figure 11 is a display summarizing heart rate data, cuff pressures, utilization percentages, and peak-to-peak ratios data over the course of 35 treatment sessions. As
10 can be appreciated from the display, cuff pressure has been consistently high after ramping up during the initial sessions, the utilization percentage has been high after ramping up during the initial sessions. However, the peak-to-peak ratio achieved during therapy was sub-optimal during most
15 of the therapy, and increased to effective levels only during the last several sessions. With this data collected and presented according to the display, the operator may establish a basis for continuing therapy beyond the standard 35-session therapy. Figure 12 is a another display summarizing heart
20 rate data, cuff pressures, utilization percentages, and peak-to-peak ratios data over the course of 35 treatment session of another patient. In this display, the percent utilization and peak-to-peak ratio are unexpectedly low for several sessions (sessions 19-21), and this can be traced to the lower cuff
25 pressures recorded during those sessions. Again, this provides an objective basis for providing additional treatment sessions, so that the industry standard 35-session therapy actually comprises 35 effective session. Figure 13 is a
30 another display summarizing patient weight data, pulse oximetry data, cardiac output data and peak-to-peak ratios over the course of 35 treatment session of another patient. This display is particularly useful for CHF patients, as it display the pulse oximetry and cardiac output data from the patient, and as it is expected that these cardiac parameters

should be improved by ECP, the display provides documentation of the effect on the patient.

In clinical use, the various reports are useful to monitor the proper performance of ECP during each session.

5 The data is measured continuously and is provided to the operator for real time control of the therapy. A medical facility can thus control a number of ECP systems simultaneously, using a single operator, and a central control system. The central control system can obtain data and
10 reports generated by each ECP system through networking means (local area networks, telemetry, wireless communications, internet communications, etc.) and exercise control of programmable variables through the same networking means, and exercise personal control over physical conditions, such as
15 pad tightness, comfort pads, etc. In this system, any adjustments to the therapy that require a physician's input can be obtained without the need for a physician in immediate proximity to the patients.

The existence of conditions such as angina pectoris and
20 congestive heart failure is indicated by self-reported symptoms, such as chest pain, shortness of breath, weight gain, etc. The ECP therapy leads to relief of these symptoms in most patients. To track these symptoms, the control system provides fields for input of patient reports of these symptoms
25 as they exist prior to treatment, on a daily basis during treatment, and post-treatment. Congestive heart failure may also be objectively indicated by measurable cardiac parameters such as the ECG, blood pressure, blood flow sounds (indicative of poorly functioning heart valves, for example), and
30 breathing sounds (indicative of fluid in the lungs) and cardiac output (volume of blood pumped per minute). To track these cardiac parameters, the control system provides fields for input of these parameters as they exist prior to

treatment, on a daily basis during treatment, and post-treatment. Alleviation of the patient reported symptoms and improvement in the cardiac parameters may thus be tracked and correlated with ECP therapy performance. Additionally,

5 broader experience with a number of patients, combined with ability to retrieve ECP system data and correlate with patient cardiac data, is expected to result in refinement of the therapy and statistically based enhancements and adjustments to ECP parameters.

10 While the preferred embodiments of the devices and methods have been described in reference to the environment in which they were developed, they are merely illustrative of the principles of the inventions. Other embodiments and configurations may be devised without departing from the

15 spirit of the inventions and the scope of the appended claims.

We claim:

1. A system for performing multiple sessions of external
counterpulsation therapy on a patient and recording and
presenting data relative to the therapy to an operator, said
5 system comprising:

one or more inflatable bladders adapted to compress the
patient;

and inflation system for inflating the inflatable
bladders;

10 a blood pressure monitoring system operable to
continuously detect the patient's blood pressure and
transmit blood pressure data;

ECG monitoring system operable to continuously detect the
patient's ECG and transmit ECG data;

15 a computerized control system operable to control the
inflation system, receive and record ECG data from the
ECG monitoring system, receive and record data from the
blood pressure monitoring system; said control system
programmed to operate the inflation system in response
20 to the ECG data;

wherein the computerized control system is further
programmed to:

present a first display comprising;

25 fields for entry of patient data and ECP system
parameters applicable to the patient;

wherein for sessions subsequent to an initial
session, the display is presented in a form

containing values of patient data and ECP system parameters of a prior session;

record cardiac parameters for substantially the entirety of each treatment session;

5 present a second display comprising one or more trace data fields and present an ECG trace generated from the ECG data, a blood pressure trace generated from the blood pressure data, and an inflation/deflation data trace corresponding to the control systems operation of
10 the inflation system in the trace data fields;

presenting substantially continuous ECG data, blood pressure data, and inflation/deflation data corresponding to the entirety of a treatment session in the trace data fields in the second display.

15 2. The system of claim 1 wherein:

the control system is further programmed to display substantially continuous ECG data, blood pressure data, and inflation/deflation data corresponding to entirety of treatment session in the second display in multiple
20 display pages, with each display page displaying portion of the single record.

3. The system of claim 1 wherein:

the control system is further programmed to calculate a utilization percentage corresponding to the percentage
25 of available compression time during which the system inflates the bladders and present the utilization percentage within the first display.

4. The system of claim 2 wherein:

the control system is further programmed to calculate a utilization percentage corresponding to the percentage of available compression time during which the system inflates the bladders and present the utilization percentage within the second display.

5. The system of claim 1, 2, 3 or 4 wherein the control system is further programmed to display a cursor in relationship to the trace data field and interpret operator manipulation of the cursor as input as to desired small time periods represented within the trace data field, and thereafter present a third display comprising an enlarged trace data field covering a time period consisting of the desired small time period.

6. The system of claim 1, 2, 3 or 4 wherein the control system is further programmed to present a plurality of cursors in logical proximity to the blood pressure trace, and interpret operator manipulation of the cursors as input as to operator determined systolic blood pressure, augmented diastolic blood pressure, and baseline blood pressure, and thereafter compute an augmentation ratio and display the augmentation ratio.

7. The system of claim 5 wherein the control system is further programmed to present a plurality of cursors in logical proximity to the blood pressure trace, and interpret operator manipulation of the cursors as input as to operator determined systolic blood pressure, augmented diastolic blood pressure, and baseline blood pressure, and thereafter compute an augmentation ratio and display the augmentation ratio with the third display.

8. The system of claim 1, 2, 3 or 4 wherein the control system is further programmed to present a fourth display comprising a multi-session trend field, and present a graph of augmentation pressure per therapy session.

9. The system of claim 8 wherein the control system is further programmed to present a session selection cursor within the fourth display and permit operator manipulation of the session selection cursor along the graph to locate the session selection cursor in logical relation to the therapy session numbers of the graph, and interpret operator manipulation of session selection cursor as selection of a particular session, and thereafter selectively present the second display or generate a fifth display comprising a graph of a cardiac parameter over time for the selected session.

10. The system of claim 1, 2, 3 or 4 wherein the control system is further programmed to present a fourth display comprising a summary data for multiple sessions, and present a table of augmentation ratio per therapy session.

11. The system of claim 10 wherein the control system is further programmed to present a session selection cursor within the fourth display and permit operator manipulation of the session selection cursor in the table to locate the session selection cursor in logical relation to the therapy session summary data, and interpret operator manipulation of session selection cursor as selection of a particular session, and thereafter selectively present the second display or generate a fifth display comprising a graph of a cardiac parameter over time for the selected session.

12. The system of claims 1, 2, 3 or 4 further comprising:

a central control system remotely locatable relative to the control system;

network means for transmitting cardiac parameters from the control systems to a central control system;

said central control system being operable to view the displays generated by the control system.

- 5 13. A system for performing multiple sessions of external counterpulsation therapy on a patient and recording and presenting data relative to the therapy to an operator, said system comprising:

10 one or more inflatable bladders adapted to compress the legs and buttocks of the patient;

and inflation system for inflating the inflatable bladders;

15 a blood pressure monitoring system operable to continuously detect the patient's blood pressure and transmit blood pressure data;

ECG monitoring system operable to continuously detect the patient's ECG and transmit ECG data;

20 a computerized control system operable to control the inflation system, receive and record ECG data from the ECG monitoring system, receive and record data from the blood pressure monitoring system; said control system programmed to operate the inflation system in response to the ECG data;

25 wherein the computerized control system is further programmed to:

present a first display comprising;

fields for entry of patient data including patient identification, size and tightness of bladders

applied to the patient, and location of electrodes placed on the patient;

fields for entry of patient reported symptoms of chronic heart disease;

5 wherein for sessions subsequent to an initial session, the display is presented in a form containing values of patient data and patient reported symptoms of a prior session;

10 record cardiac parameters for substantially the entirety of each treatment session;

present a second display comprising one or more trace data fields and present an ECG trace generated from the ECG data, a blood pressure trace generated from the blood pressure data, and an inflation/deflation data trace corresponding to the control systems operation of the inflation system in the trace data fields;

15 presenting substantially continuous ECG data, blood pressure data, and inflation/deflation data corresponding to entirety of treatment session in the trace data fields in the second display.

20 14. The system of claim 13 wherein:

the control system is further programmed to display substantially continuous ECG data, blood pressure data, and inflation/deflation data corresponding to entirety of treatment session in the second display in multiple display pages, with each display page displaying portion of the single record.

25 15. The system of claim 13 wherein:

the control system is further programmed to calculate a utilization percentage corresponding to the percentage of available compression time during which the system inflates the bladders and present the utilization percentage within the first display.

16. The system of claim 14 wherein:

the control system is further programmed to calculate a utilization percentage corresponding to the percentage of available compression time during which the system inflates the bladders and present the utilization percentage within the second display.

17. The system of claim 13, 14, 15 or 16 wherein the control system is further programmed to display a cursor in relationship to the trace data field and interpret operator manipulation of the cursor as input as to desired small time periods represented within the trace data field, and thereafter present a third display comprising an enlarged trace data field covering a time period consisting of the desired small time period.

18. The system of claim 13, 14, 15 or 16 wherein the control system is further programmed to present a plurality of cursors in logical proximity to the blood pressure trace, and interpret operator manipulation of the cursors as input as to operator determined systolic blood pressure, augmented diastolic blood pressure, and baseline blood pressure, and thereafter compute an augmentation ratio and display the augmentation ratio.

19. The system of claim 17 wherein the control system is further programmed to present a plurality of cursors in logical proximity to the blood pressure trace, and interpret operator manipulation of the cursors as input as to operator

determined systolic blood pressure, augmented diastolic blood pressure, and baseline blood pressure, and thereafter compute an augmentation ratio and display the augmentation ratio with the third display.

5 20. The system of claim 13, 14, 15 or 16 wherein the control system is further programmed to present a fourth display comprising a summary data for multiple sessions, and present a table of augmentation ratio per therapy session.

10 21. The system of claim 20 wherein the control system is further programmed to present a session selection cursor within the fourth display and permit operator manipulation of the session selection cursor in the table to locate the session selection cursor in logical relation to the therapy session summary data, and interpret operator manipulation of
15 session selection cursor as selection of a particular session, and thereafter selectively present the second display or generate a fifth display comprising a graph of a cardiac parameter over time for the selected session.

20 22. The system of claim 13, 14, 15 or 16 wherein the control system is further programmed to present a fourth display comprising a summary data for multiple sessions, and present a table of augmentation ratio per therapy session.

25 23. The system of claim 22 wherein the control system is further programmed to present a session selection cursor within the fourth display and permit operator manipulation of the session selection cursor in the table to locate the session selection cursor in logical relation to the therapy session summary data, and interpret operator manipulation of
30 session selection cursor as selection of a particular session, and thereafter selectively present the second display or generate a fifth display comprising a graph of a cardiac parameter over time for the selected session.

24. The system of claims 13, 14, 15 or 16 further comprising:

a central control system remotely locatable relative to
the control system;

network means for transmitting cardiac parameters from
the control systems to a central control system;

said central control system being operable to view the
displays generated by the control system.

Fig. 1

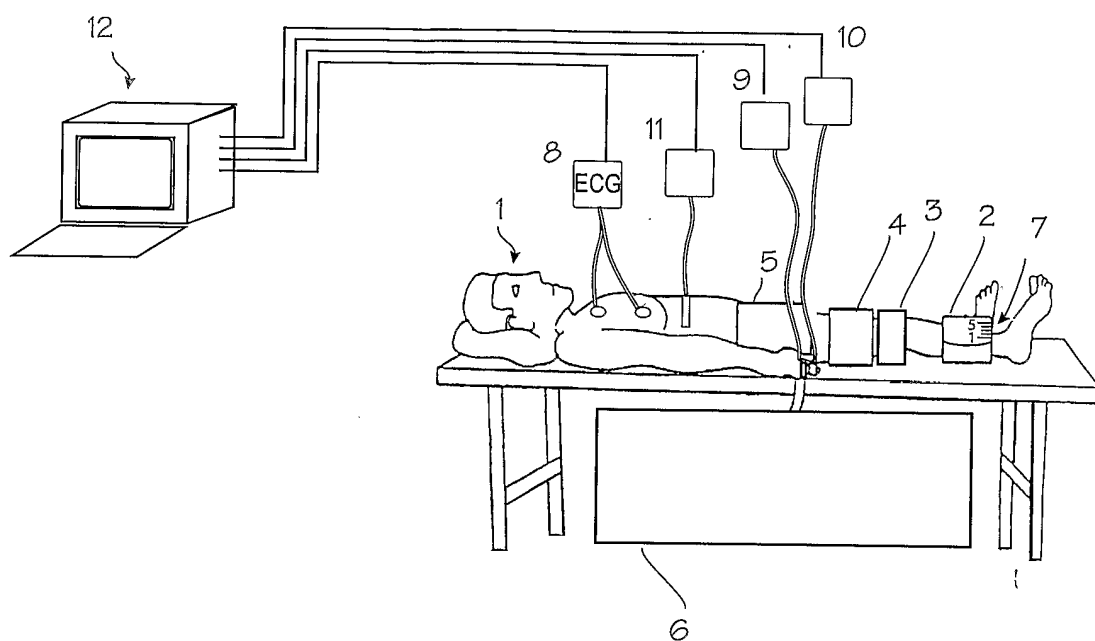


Fig. 2

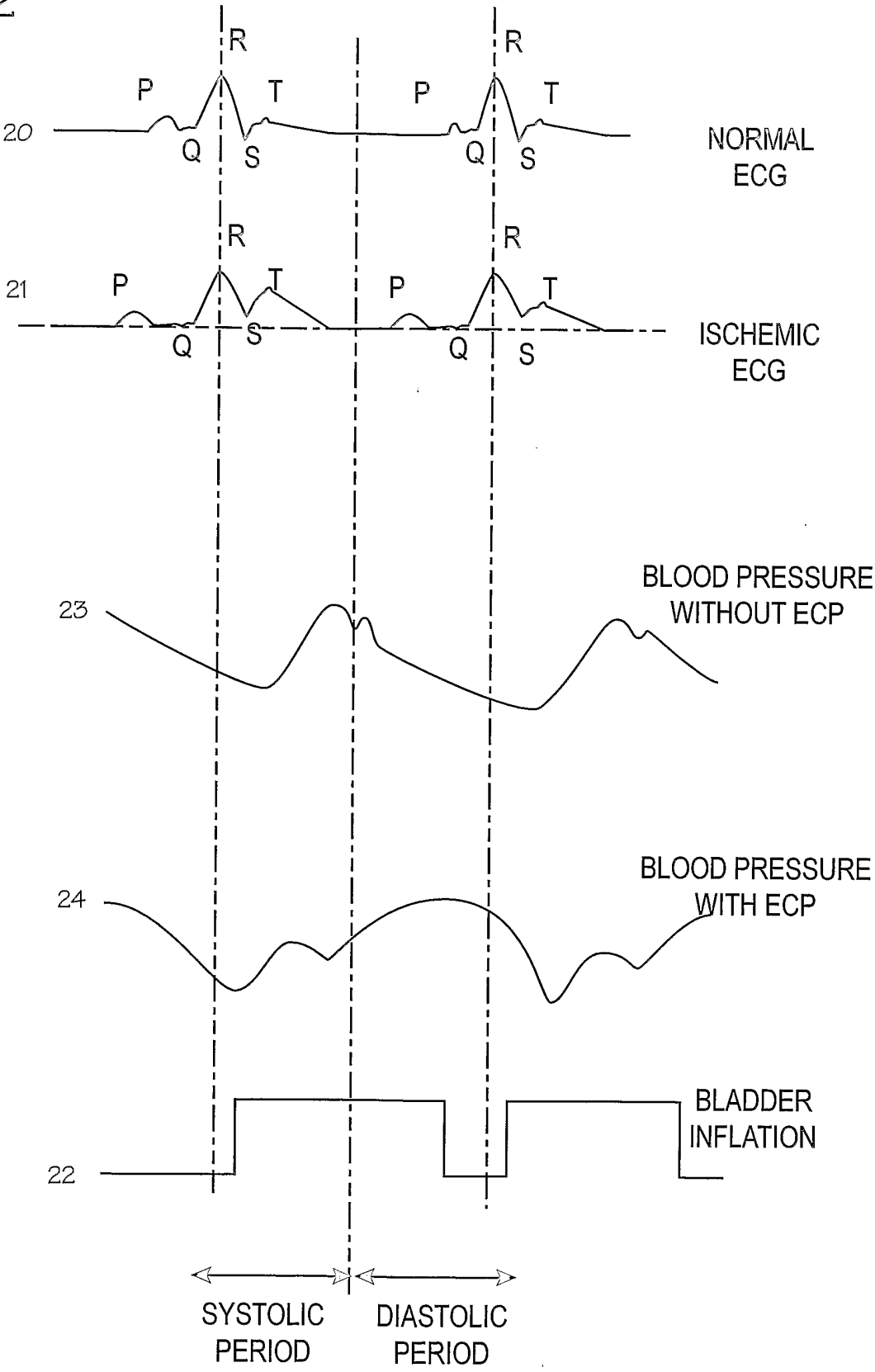


Fig. 3

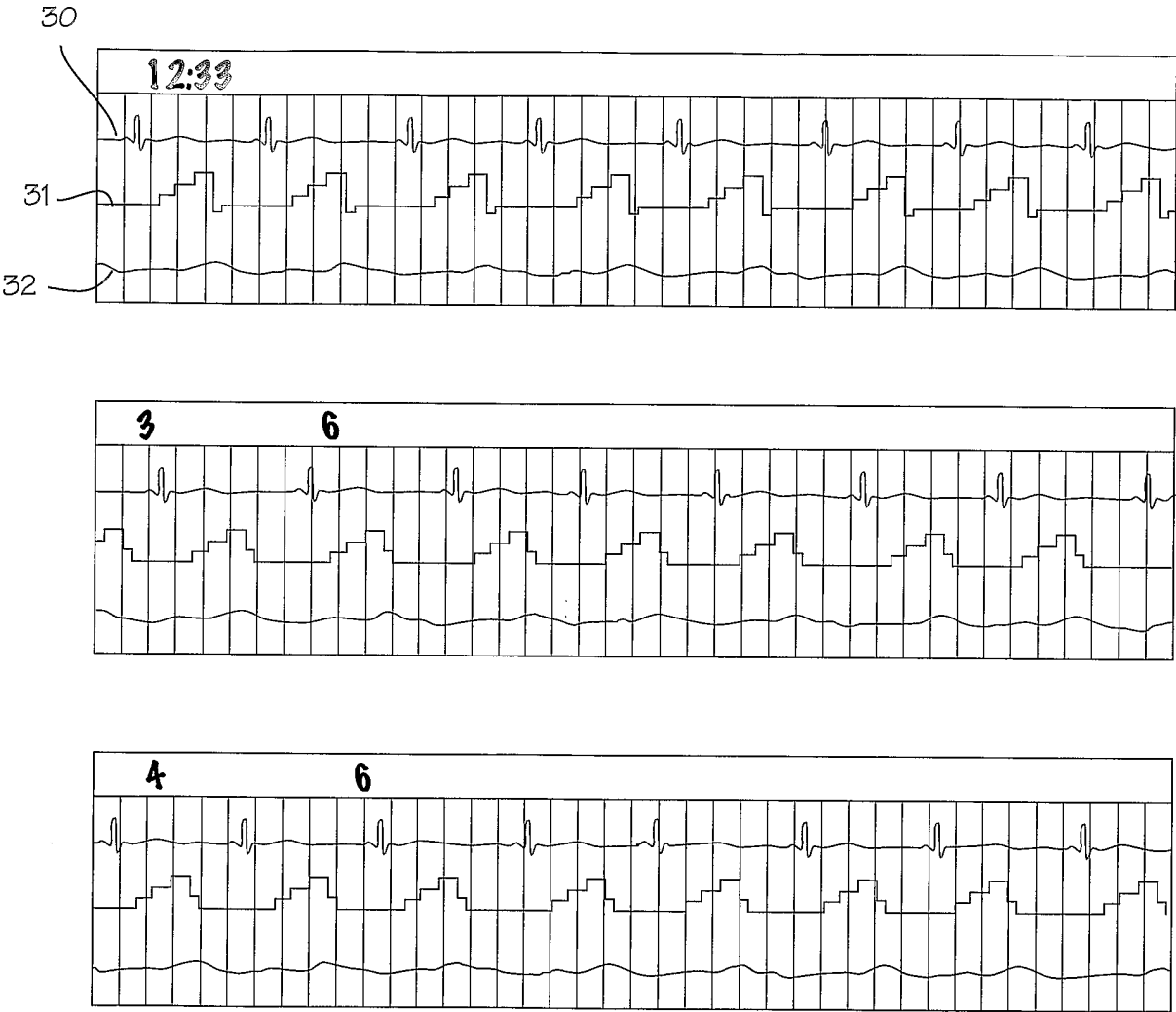


Fig. 4

DAILY TREATMENT RECORD

Patient Name Marge Innovera Patient ID: 32453
 Physician Joe Doctor, M.D., F.A.C.C.
 Treatment 2 of 4 2/24/2003 at 9:42 Clinician

24-Hour Evaluation (Patient Response)

Angina Episodes ☐ No

1 Amt of Nitro Taken
 Duration of Pain
 Severity (1-10)
 Description
 Activity at the time

2 Amt of Nitro Taken
 Duration of Pain
 Severity (1-10)
 Description
 Activity at the time

3 Amt of Nitro Taken
 Duration of Pain
 Severity (1-10)
 Description
 Activity at the time

Medication Changes ☐ No
 If Yes:
 Increases in Energy ☐ No
 Desc:
 Activity at the time OK
 Desc:

Resting Vital Signs
 Temp:
 BP:
 HR:
 Pulse Ox:
 Weight
 Cardiac Rhythm Normal Sinus Rhythm, Bradycardia
 Adverse Event During Treatment ☐ No

Vital Signs after Treatment
 BP:
 HR:
 Pulse Ox:
 Weight

If > 180 Systole and/or > 100 Diastole, Notify MD
 If < 35 or > 125, notify MD
 If < 90%, do not start treatment and notify MD

Inflation Time Utilization
 Available 780 mSec
 Utilized 580 mSec
 Percentage Utilized 74.3 %

Pressure 8.0 8.0 8.0
 P/P Ratio 0.0 0.0 0.0
 Total Treatment 00:00
 Treatment Notes

Today's Treatment

Resting Vital Signs
 Temp:
 BP:
 HR:
 Pulse Ox:
 Weight
 Cardiac Rhythm Atrial Fibrillation, Tachycardia
 Adverse Event During Treatment ☐ No

Vital Signs after Treatment
 BP:
 HR:
 Pulse Ox:
 Weight

If > 180 Systole and/or > 100 Diastole, Notify MD
 If < 35 or > 125, notify MD
 If < 90%, do not start treatment and notify MD

Inflation Time Utilization
 Available 780 mSec
 Utilized 580 mSec
 Percentage Utilized 74.3 %

Pressure 8.0 8.0 8.0
 P/P Ratio 0.0 0.0 0.0
 Total Treatment 00:01
 Treatment Notes

Fig. 4a

40

DAILY TREATMENT RECORD			
Patient Name		Marge Innovera	
Physician		Joe Doctor, M.D., F.A.C.C	
Treatment		2 of 4 2/24/2003 at 9:42	
		Clinician	
		LEFT	RIGHT
Calf Cuff Size/Tightness		S, 4	S, 4
Thigh Cuff Size/Tightness		ML, 5	ML, 5
Buttock Cuff Size/Tightness		XL, 6	XL, 6

44

Electrode Placement

47

45

Locations Skin Problems and Padding

48

46

Anterior

50

49

Posterior

Kind	Location	Description	Treatment
Skin	Post. Left Lateral Lower Thigh		
Skin	Post. Right Medial Upper Thigh		
Skin	Ant. Left Lateral Lower Thigh		
Pad	Ant. Right Mid Waist		
Pad	Ant. Left Mid Waist		
Pad	Post. Left Mid Waist		
Pad	Post. Right Mid Waist		
Pad	Post. Right Lateral Mid Thigh		
Pad	Post. Left Medial Mid Thigh		
Pad	Post. Right Lateral Mid Calf		
Pad	Body		
Pad	Ant. Right Lateral Mid Thigh		
Pad	Ant. Left Medial Mid Thigh		
Pad	Ant. Right Lateral Mid Calf		
Pad	Ant. Left Medial Mid Calf		

Fig. 5

51

53

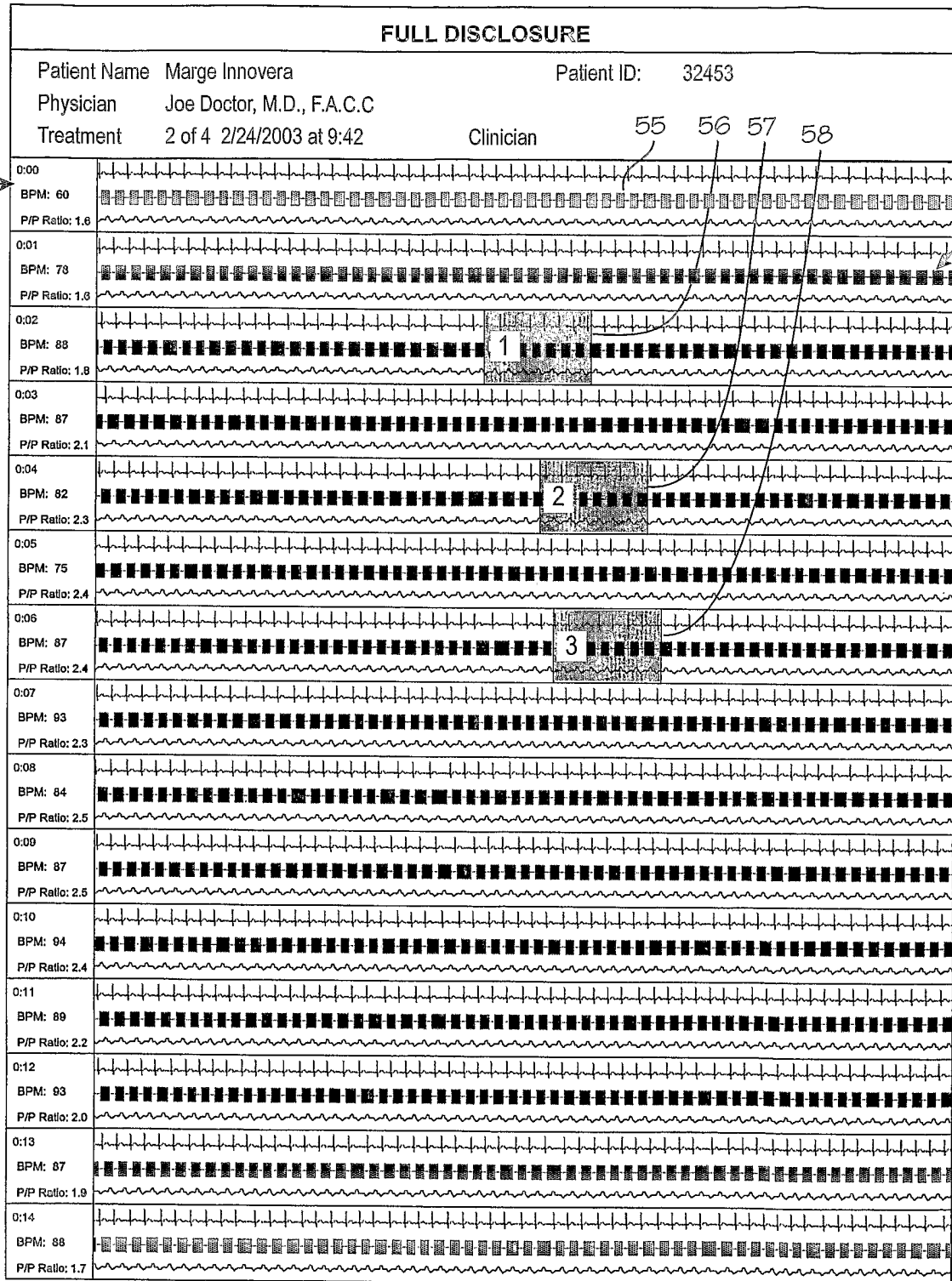


Fig. 6

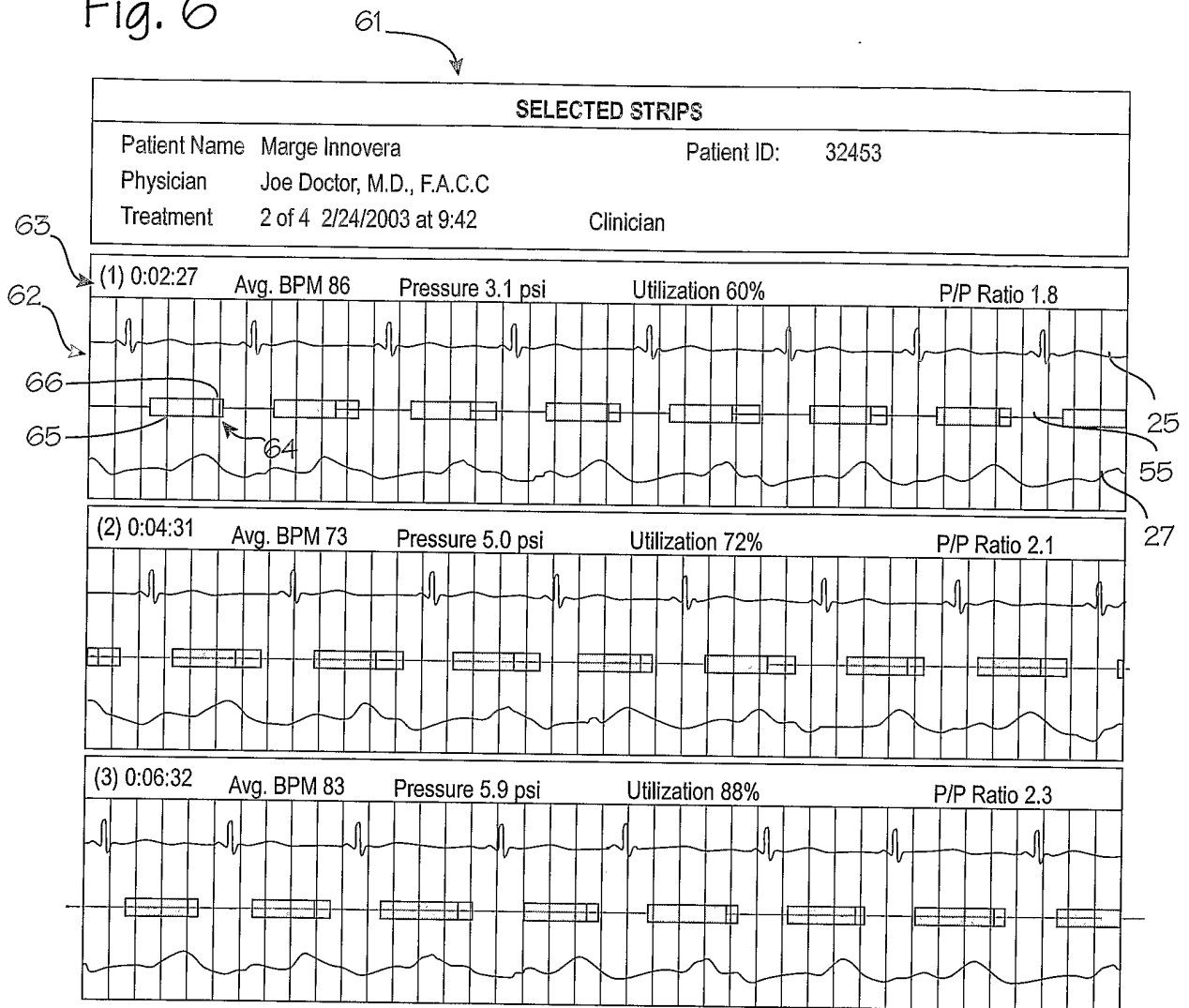


Fig. 7

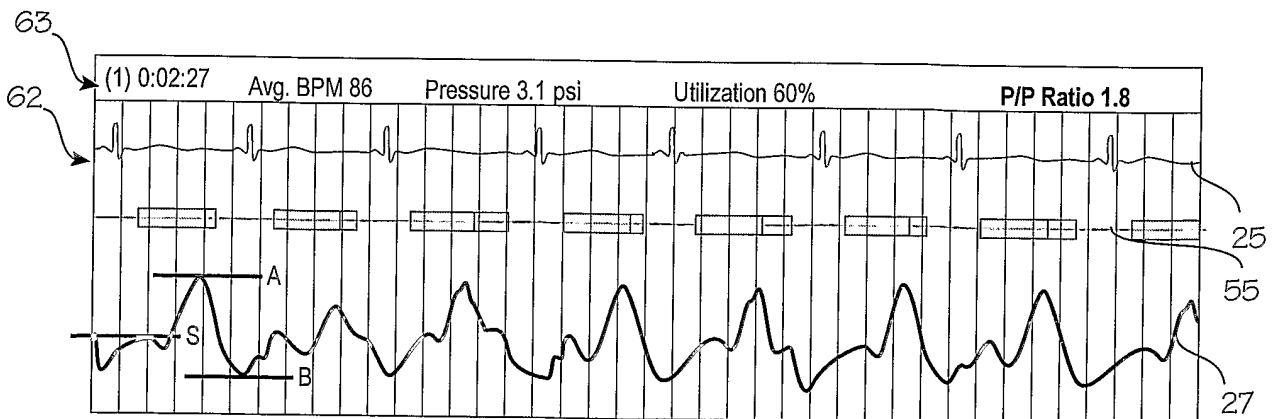


Fig. 8

DAILY TREATMENT RECORD TABULAR SUMMARY																										
Patient Name Marge Innovera													Patient ID: 32453													
Physician Joe Doctor, M.D., F.A.C.C																										
Treatment 14 of 14 3/14/2003 at 9:42													Clinician													
TIME	BPM			PRESS URE			UTILIZATION			P/P RATIO			TIME	BPM			PRESS URE			UTILIZATION			P/P RATIO			
	MN	AV	MX	MN	AV	MX	MN	AV	MX	MN	AV	MX		MN	AV	MX	MN	AV	MX	MN	AV	MX	MN	AV	MX	
0:01	82	82	82	2.4	2.8	3.2	25	31	43	1.5	1.5	1.5	0:31	82	82	82	6.8	7.1	7.5	43	56	78	1.5	1.5	1.5	
0:02	82	82	82	2.4	2.8	3.2	25	31	43	1.5	1.5	1.5	0:32	82	82	82	6.8	7.1	7.5	43	56	78	1.5	1.5	1.5	
0:03	82	82	82	2.4	2.8	3.2	25	31	43	1.5	1.5	1.5	0:33	82	82	82	6.8	7.1	7.5	43	56	78	1.5	1.5	1.5	
0:04	82	82	82	2.4	2.8	3.2	25	31	43	1.5	1.5	1.5	0:34	82	82	82	6.8	7.1	7.5	43	56	78	1.5	1.5	1.5	
0:05	82	82	82	2.4	2.8	3.2	25	31	43	1.5	1.5	1.5	0:35	82	82	82	6.8	7.1	7.5	43	56	78	1.5	1.5	1.5	
0:06	82	82	82	2.4	2.8	3.2	25	31	43	1.5	1.5	1.5	0:36	82	82	82	6.8	7.1	7.5	43	56	78	1.5	1.5	1.5	
0:07	82	82	82	2.4	2.8	3.2	25	31	43	1.5	1.5	1.5	0:37	82	82	82	6.8	7.1	7.5	43	56	78	1.5	1.5	1.5	
0:08	82	82	82	2.4	2.8	3.2	25	31	43	1.5	1.5	1.5	0:38	82	82	82	6.8	7.1	7.5	43	56	78	1.5	1.5	1.5	
0:09	82	82	82	2.4	2.8	3.2	25	31	43	1.5	1.5	1.5	0:39	82	82	82	6.8	7.1	7.5	43	56	78	1.5	1.5	1.5	
0:10	82	82	82	2.4	2.8	3.2	25	31	43	1.5	1.5	1.5	0:40	82	82	82	6.8	7.1	7.5	43	56	78	1.5	1.5	1.5	
0:11	82	82	82	2.4	2.8	3.2	25	31	43	1.5	1.5	1.5	0:41	82	82	82	6.8	7.1	7.5	43	56	78	1.5	1.5	1.5	
0:12	82	82	82	2.4	2.8	3.2	25	31	43	1.5	1.5	1.5	0:42	82	82	82	6.8	7.1	7.5	43	56	78	1.5	1.5	1.5	
0:13	82	82	82	2.4	2.8	3.2	25	31	43	1.5	1.5	1.5	0:43	82	82	82	6.8	7.1	7.5	43	56	78	1.5	1.5	1.5	
0:14	82	82	82	2.4	2.8	3.2	25	31	43	1.5	1.5	1.5	0:44	82	82	82	6.8	7.1	7.5	43	56	78	1.5	1.5	1.5	
0:15	82	82	82	2.4	2.8	3.2	25	31	43	1.5	1.5	1.5	0:45	82	82	82	6.8	7.1	7.5	43	56	78	1.5	1.5	1.5	
0:16	82	82	82	2.4	2.8	3.2	25	31	43	1.5	1.5	1.5	0:46	82	82	82	6.8	7.1	7.5	43	56	78	1.5	1.5	1.5	
0:17	82	82	82	2.4	2.8	3.2	25	31	43	1.5	1.5	1.5	0:47	82	82	82	6.8	7.1	7.5	43	56	78	1.5	1.5	1.5	
0:18	82	82	82	2.4	2.8	3.2	25	31	43	1.5	1.5	1.5	0:48	82	82	82	6.8	7.1	7.5	43	56	78	1.5	1.5	1.5	
0:19	82	82	82	2.4	2.8	3.2	25	31	43	1.5	1.5	1.5	0:49	82	82	82	6.8	7.1	7.5	43	56	78	1.5	1.5	1.5	
0:20	82	82	82	2.4	2.8	3.2	25	31	43	1.5	1.5	1.5	0:50	82	82	82	6.8	7.1	7.5	43	56	78	1.5	1.5	1.5	
0:21	82	82	82	2.4	2.8	3.2	25	31	43	1.5	1.5	1.5	0:51	82	82	82	6.8	7.1	7.5	43	56	78	1.5	1.5	1.5	
0:22	82	82	82	2.4	2.8	3.2	25	31	43	1.5	1.5	1.5	0:53	82	82	82	6.8	7.1	7.5	43	56	78	1.5	1.5	1.5	
0:23	82	82	82	2.4	2.8	3.2	25	31	43	1.5	1.5	1.5	0:53	82	82	82	6.8	7.1	7.5	43	56	78	1.5	1.5	1.5	
0:24	82	82	82	2.4	2.8	3.2	25	31	43	1.5	1.5	1.5	0:54	82	82	82	6.8	7.1	7.5	43	56	78	1.5	1.5	1.5	
0:25	82	82	82	2.4	2.8	3.2	25	31	43	1.5	1.5	1.5	0:55	82	82	82	6.8	7.1	7.5	43	56	78	1.5	1.5	1.5	
0:26	82	82	82	2.4	2.8	3.2	25	31	43	1.5	1.5	1.5	0:56	82	82	82	6.8	7.1	7.5	43	56	78	1.5	1.5	1.5	
0:27	82	82	82	2.4	2.8	3.2	25	31	43	1.5	1.5	1.5	0:57	82	82	82	6.8	7.1	7.5	43	56	78	1.5	1.5	1.5	
0:28	82	82	82	2.4	2.8	3.2	25	31	43	1.5	1.5	1.5	0:58	82	82	82	6.8	7.1	7.5	43	56	78	1.5	1.5	1.5	
0:29	82	82	82	2.4	2.8	3.2	25	31	43	1.5	1.5	1.5	0:59	82	82	82	6.8	7.1	7.5	43	56	78	1.5	1.5	1.5	
0:30	82	82	82	2.4	2.8	3.2	25	31	43	1.5	1.5	1.5	0:60	82	82	82	6.8	7.1	7.5	43	56	78	1.5	1.5	1.5	

Fig. 9

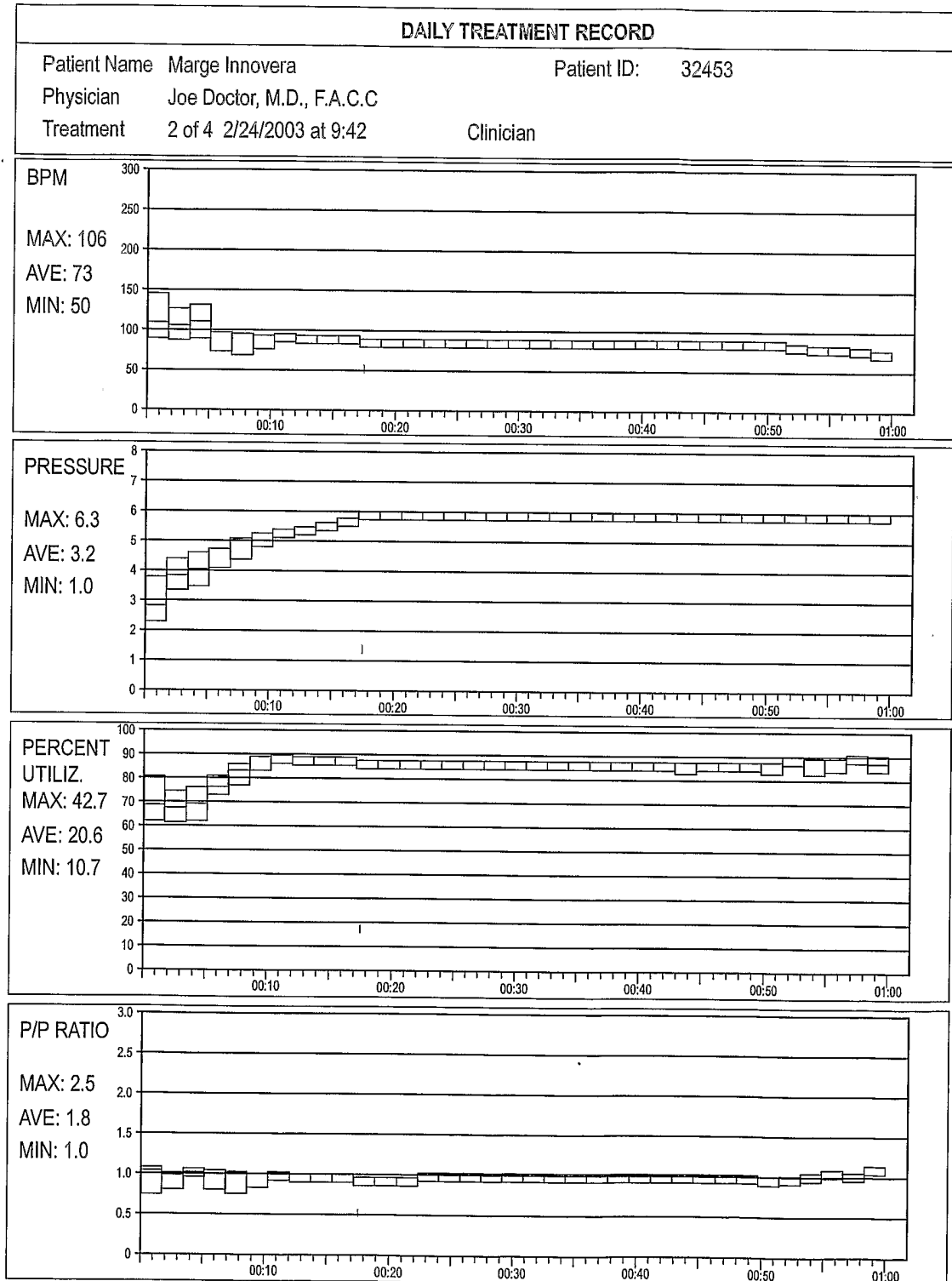


Fig. 9a

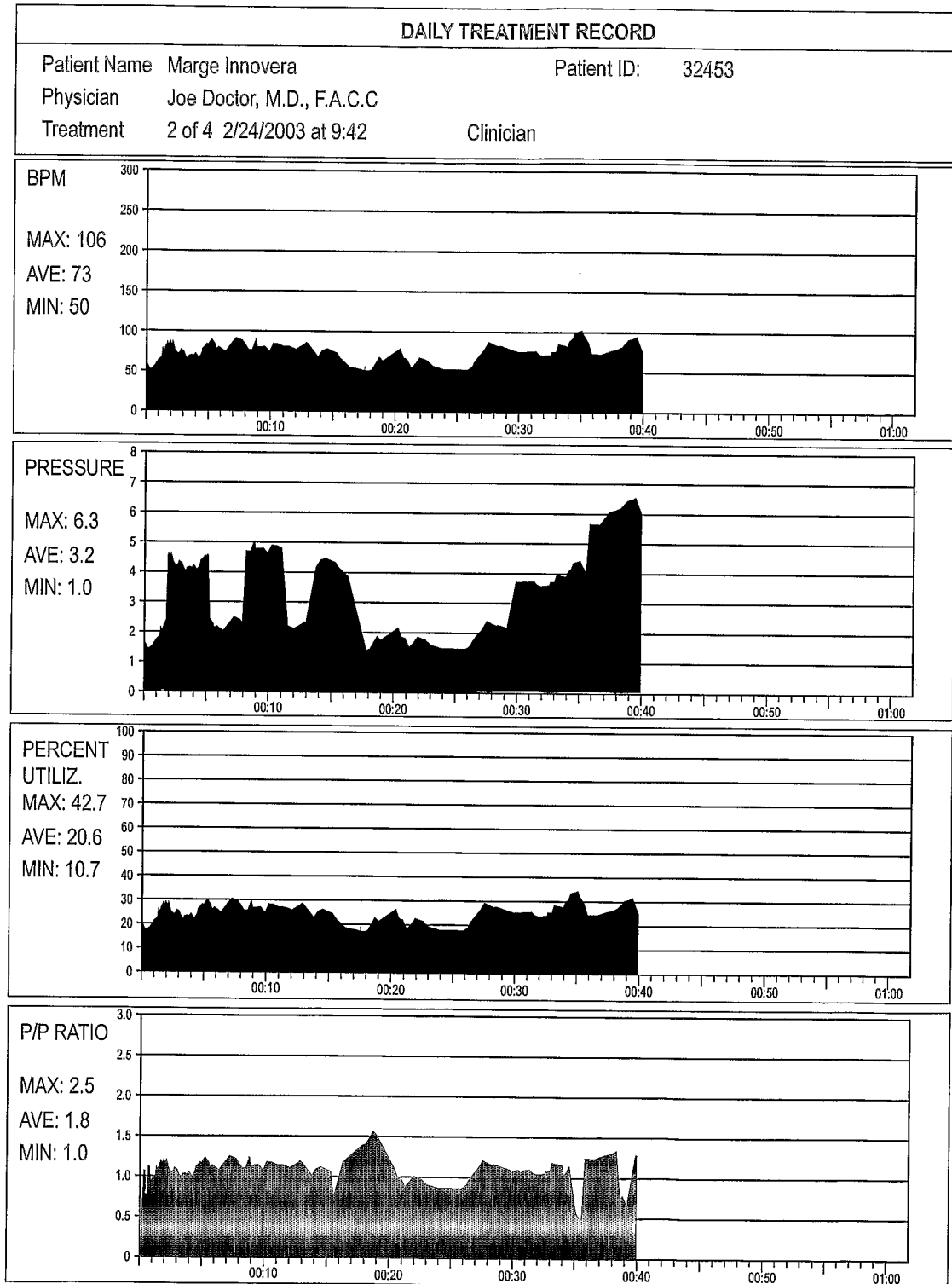


Fig. 10

SUMMARY OF TREATMENTS												
Patient Name Marge Innovera					Patient ID: 32453							
Physician Joe Doctor, M.D., F.A.C.C												
Treatment 35 Treatments from 3/1/03 to 4/5/03												
GENERAL	PRE POST				P/P	BPM	PRESS	UTIL	TREATMENT			
3/1/200	BP	21	61	MAX	0	60	0.0	74.3	Angina:	+Energy:	Cardiac R.	Arthy Tachy:
1 Time 1:00	HR	31	71	AV G	0	60	0.0	74.3	Med Chg:	Skin OK:	Adverse Events:	
T: 98.6 Wt: 11	OX	41	81	MIN	0	60	0.0	74.3	Blank	NO		
3/14/2003 at 10:03	BP	21	61	MAX	2.5	150	0.0	100.0	Angina:	+Energy:	Cardiac R.	NSR, Brady
2 Time: 00:54	HR	31	71	AV G	1.5	83	0.0	60.1	Med Chg:	Skin OK:	Adverse Events:	
Temp: 33 Wt: 11	OX	41	81	MIN	0.9	50	0.0	13.1	Blank	NO		
3/14/2003 at 10:04	BP	21	61	MAX	2.5	134	0.0	100.0	Angina:	+Energy:	Cardiac R.	
3 Time: 00:47	HR	31	71	AV G	1.4	102	0.0	83.7	Med Chg:	Skin OK:	Adverse Events:	
Temp: 33 Wt: 11	OX	41	81	MIN	0.5	50	0.0	20.9	Blank	NO		
3/14/2003 at 10:04	BP	21	61	MAX	2.5	176	0.0	100.0	Angina:	+Energy:	Cardiac R.	
4 Time: 00:54	HR	31	71	AV G	1.6	112	0.0	87.4	Med Chg:	Skin OK:	Adverse Events:	
Temp: Wt: 11	OX	41	81	MIN	0.6	50	0.0	18.6	Blank	NO		
3/14/2003 at 13:47	BP	21	61	MAX	2.4	135	0.0	100.0	Angina:	+Energy:	Cardiac R.	
5 Time: 00:49	HR	31	71	AV G	1.4	115	0.0	87.8	Med Chg:	Skin OK:	Adverse Events:	
Temp: Wt: 11	OX	41	81	MIN	1.0	100	0.0	26.3	Blank	NO		
3/14/2003 at 13:49	BP	21	61	MAX	1.4	60	0.0	100.0	Angina:	+Energy:	Cardiac R.	
6 Time: 00:00	HR	31	71	AV G	1.0	60	0.0	100.0	Med Chg:	Skin OK:	Adverse Events:	
Temp: Wt: 11	OX	41	81	MIN	0.7	60	0.0	100.0	Blank	NO		
3/14/2003 at 13:51	BP	21	61	MAX	2.5	151	0.0	100.0	Angina:	+Energy:	Cardiac R.	
7 Time: 00:54	HR	31	71	AV G	1.7	97	0.0	79.5	Med Chg:	Skin OK:	Adverse Events:	
Temp: Wt: 11	OX	41	81	MIN	1.0	50	0.0	10.4	Blank	NO		
3/14/2003 at 13:55	BP	21	61	MAX	2.8	120	0.0	100.0	Angina:	+Energy:	Cardiac R.	
8 Time: 00:46	HR	31	71	AV G	1.3	93	0.0	54.3	Med Chg:	Skin OK:	Adverse Events:	
Temp: Wt: 11	OX	41	81	MIN	0.1	50	0.0	10.9	Blank	NO		
3/14/2003 at 13:56	BP	21	61	MAX	2.7	107	0.0	100.0	Angina:	+Energy:	Cardiac R.	
9 Time: 00:57	HR	31	71	AV G	1.5	93	0.0	47.2	Med Chg:	Skin OK:	Adverse Events:	
Temp: 9 Wt: 11	OX	41	81	MIN	0.1	51	0.0	13.6	Blank	NO		
3/14/2003 at 13:59	BP	21	61	MAX	1.4	64	0.0	100.0	Angina:	+Energy:	Cardiac R.	
10 Time: 00:00	HR	31	71	AV G	1.0	60	0.0	99.1	Med Chg:	Skin OK:	Adverse Events:	
Temp: Wt: 11	OX	41	81	MIN	0.8	58	0.0	95.8	Blank	NO		
* * * * *												

Fig. 10a

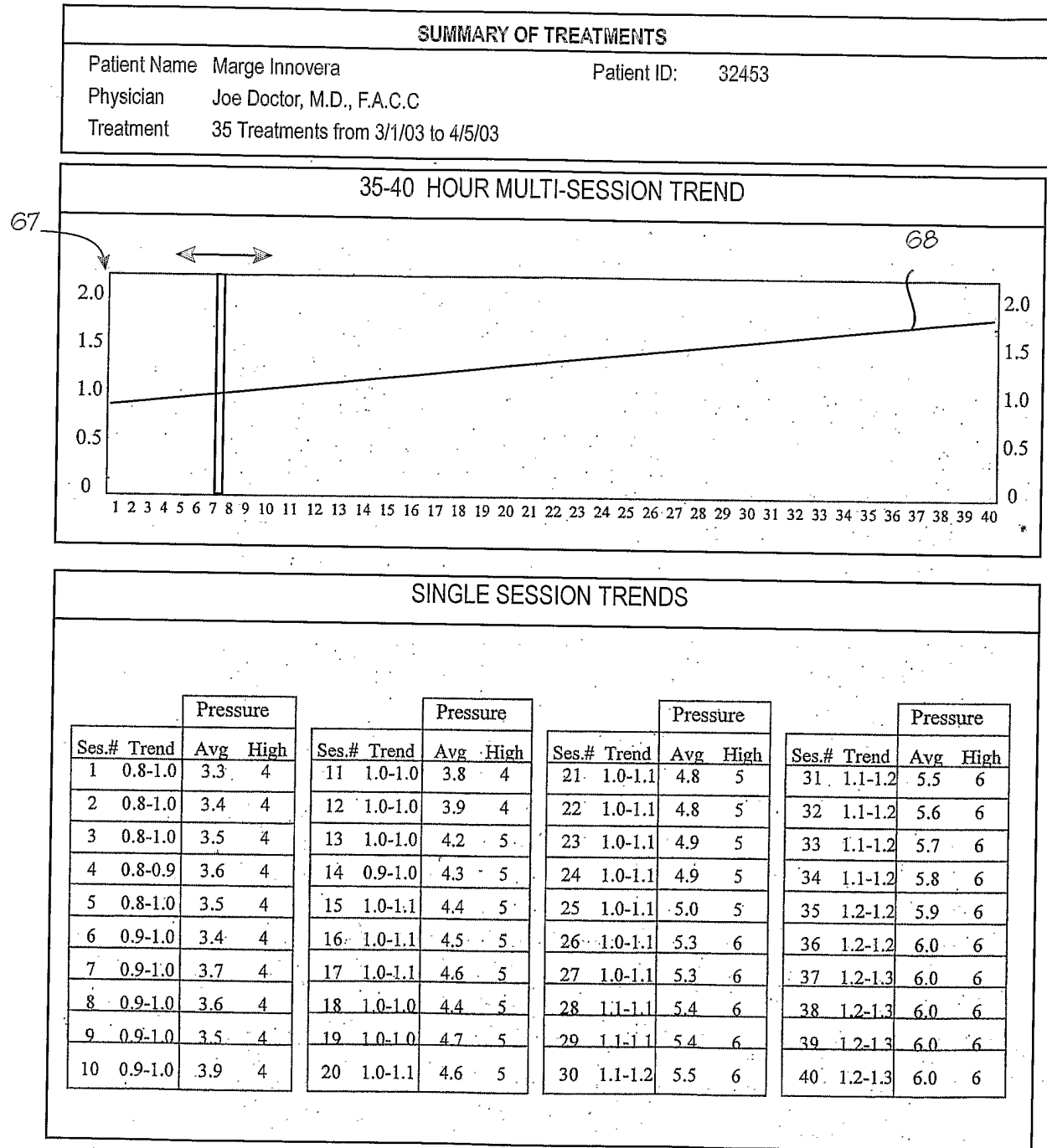


Fig. 11

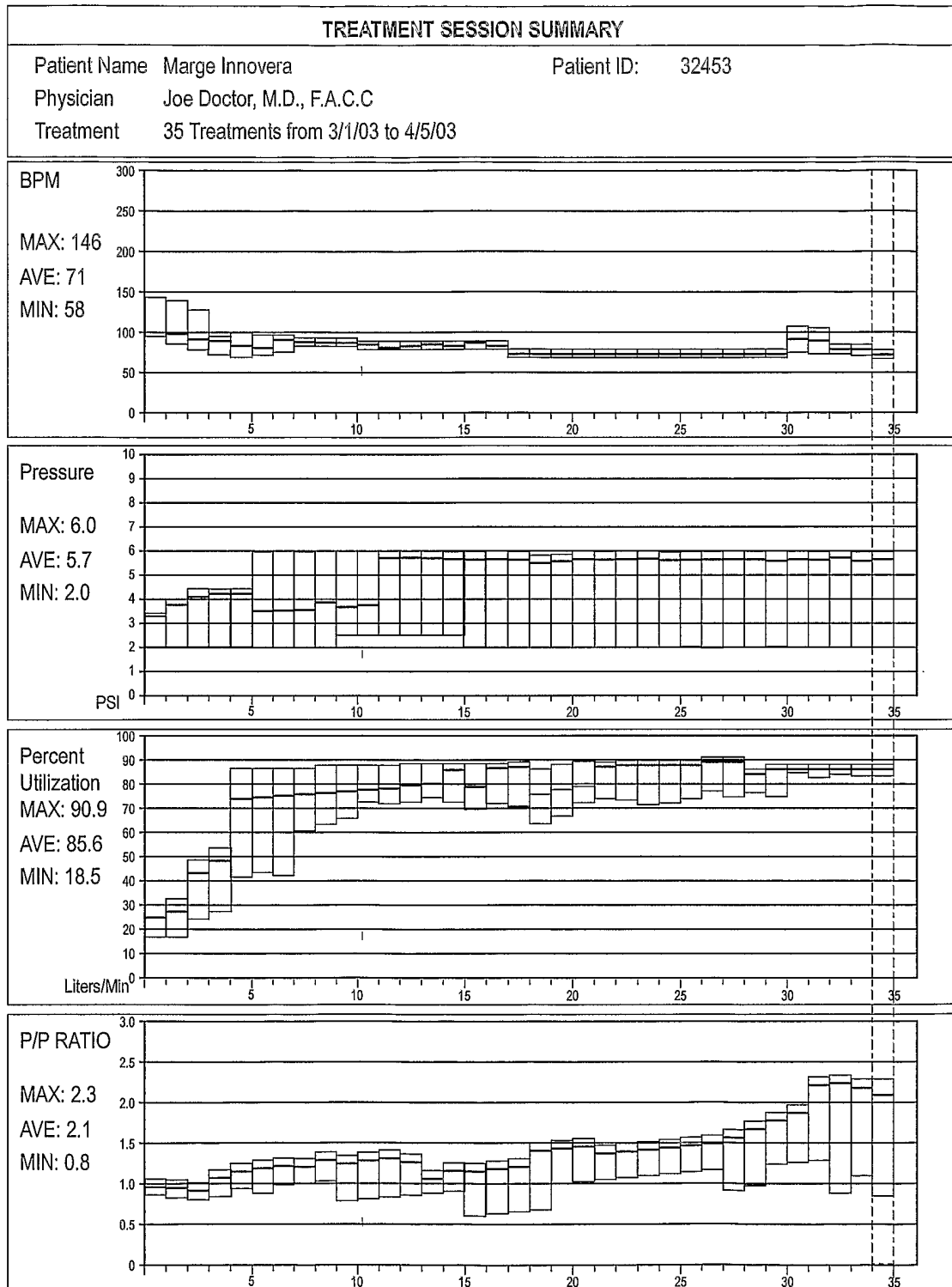


Fig. 12

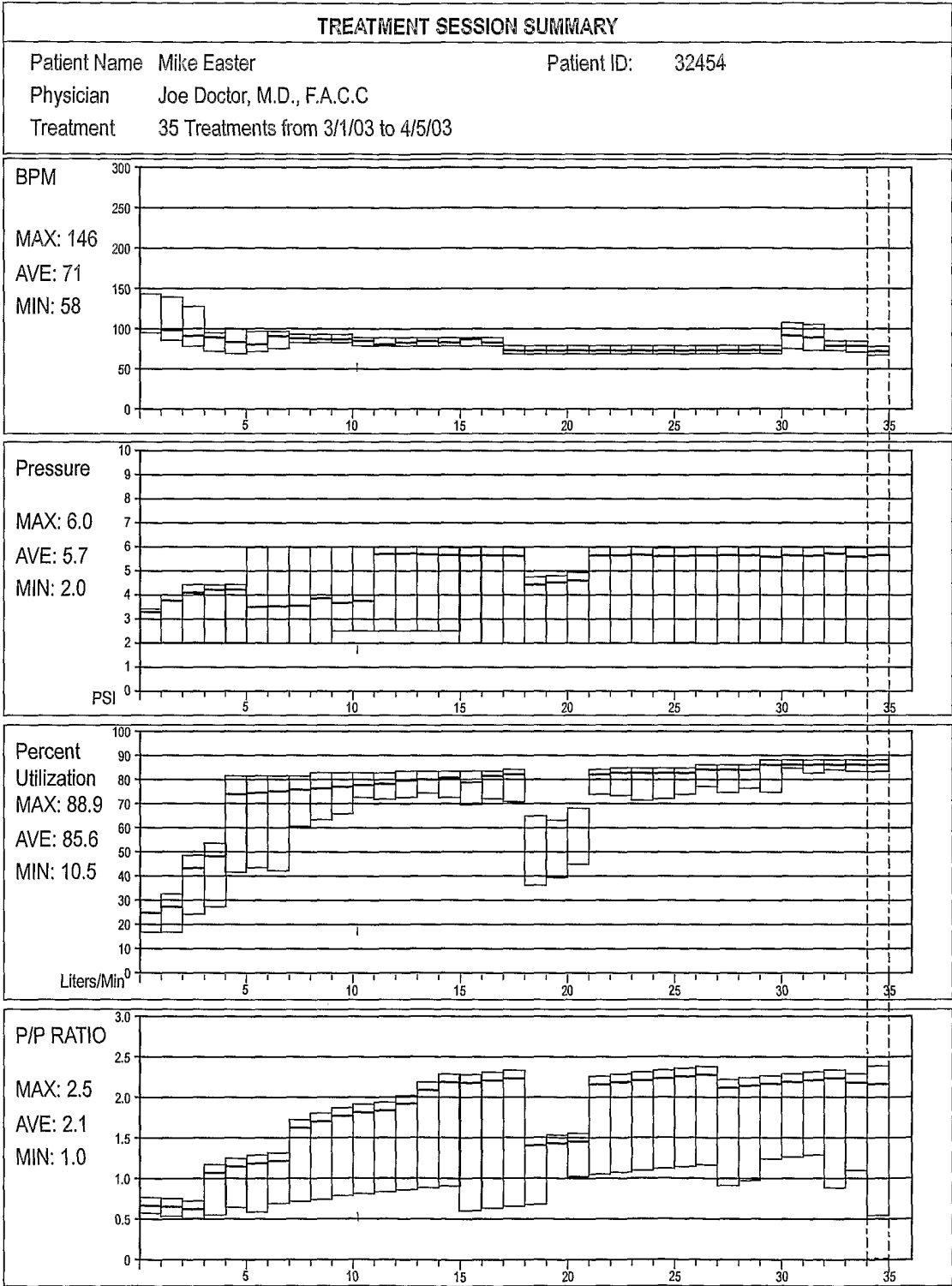


Fig. 13

