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(54) **AUTOMATED INTERPRETIVE MEDICAL CARE SYSTEM**

AUTOMATISCHES INTERPRETIERENDES MEDIZINISCHES VERSORGUNGSSYSTEM  
SYSTEME DE SOINS MEDICAUX A INTERPRETATION AUTOMATISEE

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(72) Inventors:  
• **KRAUS, Baruch**  
**Brookline, MA 02445 (US)**  
• **HAMPTON, David, Robert**  
**Woodinville, WA 98072 (US)**  
• **CARLEBACH, Ephraim**  
**43307 Ra'anana (IL)**

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(74) Representative: **Becker Kurig Straus**  
**Bavariastrasse 7**  
**80336 München (DE)**

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(73) Proprietors:  
• **CHILDREN'S MEDICAL CENTER CORPORATION**  
**Boston**  
**Massachusetts 02115 (US)**  
• **Medtronic Physio-Control Inc.**  
**Redmond, WA 98073 (US)**  
• **Oridion Medical, Ltd.**  
**Jerusalem 97774 (IL)**

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**Description**

## FIELD OF THE INVENTION

**[0001]** The present invention relates to the use of respiratory information in automated medical status assessment.

## - BACKGROUND OF THE INVENTION

**[0002]** The following U.S. Patent and publication are believed to represent the current state of the art: US Patent 4,440,177 to Anderson et al, describes a respiratory analyzer system. Reference is also made to NIH publication on. 97-4051 entitled "Guidelines for the Diagnosis and Management of Asthma" pp 108-109, 1991.

**[0003]** EP 0 699 414 discloses a disease management system employing inter alia capnography techniques. The slope of the capnogram may give an indication about the state of the lungs and about manifestation of asthma and its severity. The system gives an indication be e.g. means of a colour coded scheme.

**[0004]** DE 2812379 discloses a device using respiratory volume flow and CO<sub>2</sub> partial pressure to diagnose and assess the severity of emphysema.

**[0005]** WO 99/62403 discloses an anaesthesia monitoring system adapted to give an alarm in response to the CO<sub>2</sub> maximum in exhaled air exceeding a threshold value.

**[0006]** US 5921920 discloses a patient monitoring system capable of monitoring multiple physiological parameters; some of these parameters are displayed as a polygon in a polar diagram, from which conclusions regarding the state of the patient may be drawn.

## SUMMARY OF THE INVENTION

**[0007]** The present invention seeks to provide improved apparatus for monitoring, diagnosing and treating at least one medical respiratory condition.

**[0008]** The invention is as defined in the appended claims.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0009]** The present invention will be understood and appreciated more fully from the following detailed description, taken in conjunction with the drawings in which:

Figs. 1A, 1B and 1C are simplified pictorial illustrations showing a medical care system and methodology employing at least one parameter relating at least to respiration for automatically providing an output indication relating to at least one medical condition in accordance with a preferred embodiment of the present invention in three different types of care environments;

Fig. 2 is a flowchart illustrating operation of the em-

bodiments of Figs. 1A -1C;

Fig. 3 is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology in an on-scene environment for detecting the presence and severity of bronchospasm, gauging the response to treatment and recommending disposition of a spontaneously breathing patient; Fig. 4 is a flowchart illustrating operation of the embodiment of Fig. 3;

Fig. 5 is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology in an on-scene environment for detecting the presence and severity of bronchospasm, gauging the response to treatment and recommending disposition of mechanically ventilated patients; Figs. 6A and 6B are flowcharts illustrating operation of the embodiment of Fig. 5;

Fig. 7 is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology in an ambulance environment for detecting the presence and severity of bronchospasm, gauging the response to treatment and recommending disposition of spontaneously breathing patients; Figs. 8A and 8B are flowcharts illustrating operation of the embodiment of Fig. 7;

Fig. 9 is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology in an ambulance environment for detecting the presence and severity of bronchospasm, gauging the response to treatment and recommending disposition of mechanically ventilated patients; Figs. 10A, 10B and 10C are a flowcharts illustrating operation of the embodiment of Fig. 9;

Figs. 11 is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology in an ambulance environment for detecting the severity of bronchospasm, gauging the response to treatment and recommending disposition of spontaneously breathing patients;

Fig. 12 is a flowchart illustrating operation of the embodiment of Fig. 11;

Fig. 13 is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology in an ambulance environment for detecting the presence and severity of bronchospasm, gauging the response to treatment and recommending disposition of mechanically ventilated patients; Figs. 14A and 14B are flowcharts illustrating operation of the embodiment of Fig. 13;

Fig. 15 is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology operative in a hospital environment for distinguishing between heart failure and emphysema, where emphysema is present;

Figs. 16A and 16B are flowcharts illustrating operation of the embodiment of Fig. 15;

Fig. 17 is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and

methodology operative in a hospital environment for monitoring intubation status of a patient;  
 Fig. 18 is a flowchart illustrating operation of the embodiment of Fig. 17;  
 Fig. 19 is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology operative in a hospital environment for monitoring respiratory status of a patient in a first clinical scenario;  
 Fig. 20 is a flowchart illustrating operation of the embodiment of Fig. 19;  
 Figs. 21A and 21B are simplified pictorial illustrations of an automatic medical diagnostic and treatment system and methodology operative in a hospital environment for monitoring intubation status of a patient in a second clinical scenario;  
 Figs. 22A, 22B and 22C are flowcharts illustrating operation of the embodiment of Figs. 21A and 21B;  
 Figs. 23A and 23B are simplified pictorial illustrations of a diagnostic and treatment system and methodology operative in a physician's office environment for detecting the presence and severity of bronchospasm, gauging the response to treatment and recommending disposition of a spontaneously breathing patient in a first clinical scenario;  
 Figs. 24A and 24B are flowcharts illustrating operation of the embodiment of Figs. 23A and 23B;  
 Figs. 25A and 25B are simplified pictorial illustrations of an automatic medical diagnostic and treatment system and methodology operative in a physician's office environment for detecting the presence and severity of bronchospasm, gauging the response to treatment and recommending disposition of a spontaneously breathing patient in a second clinical scenario;  
 Figs. 26A and 26B are flowcharts illustrating operation of the embodiment of Figs. 25A and 25B;  
 Figs. 27A and 27B are simplified pictorial illustrations of an automatic medical diagnostic and treatment system and methodology in an ambulance environment for detecting the presence and severity of bronchospasm from an allergic reaction, gauging the response to treatment and recommending disposition;  
 Fig. 28 is a flowchart illustrating operation of the embodiment of Figs. 27A and 27B;  
 Fig. 29 is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology in an ambulance environment for distinguishing between upper airway obstruction and lower airway obstruction, gauging the response to treatment and recommending disposition;  
 Fig. 30 is a flowchart illustrating operation of the embodiment of Fig. 29;  
 Fig. 31 is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology operative in a hospital environment for distinguishing between heart failure and emphysema in a scenario in which heart failure is present;

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Figs. 32A and 32B are flowcharts illustrating operation of the embodiment of Fig. 31;  
 Fig. 33 is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology operative in a hospital environment for treating pulmonary edema;  
 Figs. 34A and 34B are flowcharts illustrating operation of the embodiment of Fig. 33;  
 Fig. 35 is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology operative in a hospital environment for anesthesia monitoring;  
 Fig. 36 is a flowchart illustrating operation of the embodiment of Fig. 35;  
 Fig. 37 is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology operative in a hospital environment for diagnosis and treatment of pulmonary embolism;  
 Fig. 38 is a flowchart illustrating operation of the embodiment of Fig. 37;  
 Figs. 39A and 39B are simplified pictorial illustrations of an automatic medical diagnostic and treatment system and methodology operative in a hospital environment for determination of correct nasogastric tube placement;  
 Fig. 40 is a flowchart illustrating operation of the embodiment of Figs. 39A and 39B;  
 Fig. 41 is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology operative in a hospital environment for diagnosis and treatment of myocardial infarction;  
 Fig. 42 is a flowchart illustrating operation of the embodiment of Fig. 41;  
 Fig. 43 is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology operative in a hospital environment for diagnosis and treatment of cardiogenic shock;  
 Fig. 44 is a flowchart illustrating operation of the embodiment of Fig. 43;  
 Fig. 45 is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology operative in a hospital environment for diagnosis and treatment of cardiac arrest;  
 Fig. 46 is a flowchart illustrating operation of the embodiment of Fig. 45;  
 Fig. 47 is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology operative in a hospital environment for diagnosis and treatment of cardiac ischemia;  
 Fig. 48 is a flowchart illustrating operation of the embodiment of Fig. 47;  
 Fig. 49 is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology operative in a hospital environment for monitoring sedation; and  
 Fig. 50 is a flowchart illustrating operation of the embodiment of Fig. 49;  
 Fig. 51 is a simplified pictorial illustration of an auto-

matic medical diagnostic and treatment system and methodology operative in a hospital environment for drug titration during sedation; and

Fig. 52 is a flowchart illustrating operation of the embodiment of Fig. 51.

#### DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

**[0010]** Reference is now made to Figs. 1A, 1B and 1C, which are simplified pictorial illustrations showing a medical care system and methodology employing at least one parameter relating at least to respiration for automatically providing an output indication relating to at least one medical condition in accordance with a preferred embodiment of the present invention in three different types of care environments.

**[0011]** Turning to Fig. 1A, it is seen that in an out of hospital environment, such as a doctor's office or other ambulatory care facility, various patient physiologic activities are sensed and measured, including respiratory physiologic activities, preferably via an oral airway adapter and/or a nasal or nasal/oral cannula 100, such as a Model Nasal FilterLine Adult XS 04461, O<sub>2</sub>/CO<sub>2</sub> Nasal FilterLine Adult 007141, or Smart CapnoLine Adult (Oral/nasal FilterLine) 007414, commercially available from Oridion Ltd., of Jerusalem Israel, typically coupled with a capnograph 102, such as a Microcap<sup>®</sup>, commercially available from Oridion Ltd., of Jerusalem Israel. Other patient physiologic activities relating to cardiac function (e.g. electrocardiogram (ECG)), cerebral perfusion (e.g. CEREBRAL OXIMETRY), oxygenation (e.g. pulse oximetry) and systemic circulation (e.g. ...blood pressure (NIBP)), may also be sensed and measured by suitable instrumentation 104.

**[0012]** The outputs of the capnograph 102 and possibly of additional instrumentation 104 are preferably supplied to a suitably programmed automatic diagnostic and treatment computer 110, which typically analyzes the respiration parameter output of the capnograph 102, and also typically has an associated display 112, the display being at least one of a visual display, such as a computer screen, a virtual display, or a printed form of a display. Optionally further physiologic activities are outputted from capnograph 102 and instrumentation 104, and provided as outputs via computer 110 and display 112, which preferably contain diagnostic statements, which preferably characterize the type and severity of a medical condition, as well as treatment recommendations.

**[0013]** Turning to Fig. 1B, it is seen that in an ambulance environment, various patient physiologic activities are sensed and measured, including respiratory physiologic activities, preferably via an oral airway adapter and/or a nasal or nasal/oral cannula 100, such as a such as a Nasal FilterLine Adult XS 04461, O<sub>2</sub>/CO<sub>2</sub> Nasal FilterLine Adult 007141, or Smart CapnoLine Adult (Oral/nasal FilterLine) 007414, commercially available from Oridion Ltd., of Jerusalem Israel, typically coupled with

a capnograph 113, such as a Microcap<sup>®</sup>, commercially available from Oridion Ltd., of Jerusalem Israel. Other patient physiologic activities relating to cardiac function (e.g. ECG), cerebral perfusion (e.g. CEREBRAL OXIMETRY), oxygenation (e.g. pulse oximetry) and systemic circulation (e.g. NIBP), may also be sensed and measured by suitable instrumentation 114.

**[0014]** The outputs of the capnograph 113 and possibly of additional instrumentation 114 are preferably supplied to a suitably programmed automatic diagnostic and treatment computer 116, having an associated display 118, which typically analyzes the respiration parameter output of the capnograph 113 and possibly other parameters and provides an output which preferably contains diagnostic statements, which preferably characterize the type and severity of a medical condition, as well as treatment recommendations.

**[0015]** Preferably some or all of the outputs of computer 116 are transmitted in a wireless manner by a transmitter 119, such as via radio or a cellular telephone link, preferably to a dispatch center or patient receiving facility.

**[0016]** Turning to Fig. 1C, it is seen that in a hospital environment, such as an emergency department, medical ward or intensive care unit (ICU), various patient physiologic activities are sensed and measured, including respiratory physiologic activities, preferably via an oral airway adapter and/or a nasal or nasal/oral cannula 120, such as a Nasal FilterLine Adult XS 04461, O<sub>2</sub>/CO<sub>2</sub> Nasal FilterLine Adult 007141, or Smart CapnoLine Adult (Oral/nasal FilterLine) 007414, commercially available from Oridion Ltd., of Jerusalem Israel, typically coupled with a capnograph 122, such as a Microcap<sup>®</sup>, commercially available from Oridion Ltd., of Jerusalem Israel. Other patient physiologic activities relating to cardiac function (e.g. ECG), cerebral perfusion (e.g. CEREBRAL OXIMETRY), oxygenation (e.g. pulse oximetry) and systemic circulation (e.g. NIBP), may also be sensed and measured by suitable instrumentation 124.

**[0017]** The outputs of the capnograph 122 and possibly of additional instrumentation 124 are preferably supplied to a suitably programmed automatic diagnostic and treatment computer 126 at the patient's bedside and/or at a central monitoring station, having an associated display 128, which typically continuously analyzes the respiration parameter output of the capnograph 122 and possibly other parameters and provides an output which preferably contains diagnostic statements, which preferably characterize the type and severity of a medical condition, as well as treatment recommendations.

**[0018]** Reference is now made to Fig. 2, which is a flowchart illustrating operation of the embodiments of Figs. 1A-1C.

**[0019]** In a sensing stage, the patient's physiologic activity preferably is monitored by collecting an expired air sample via cannula 100, and conveying the sample to an analyzer, integrally part of a capnograph, such as capnograph 102 (Fig. 1A), 113 (Fig. 1B), and 122 (Fig. 1C). Simultaneously, some of the patient's other physiological

parameters may be sensed, sampled and monitored employing suitable instrumentation 104 (Fig. 1A), 114 (Fig. 1B), and 124 (Fig. 1C). These parameters include, but are not limited to, cardiac activity, ventilation and systemic and cerebral perfusion, and oxygenation parameters.

**[0020]** Data including the parameters monitored and sampled by, for example, instrumentation 104 are relayed to computer 110. The measured patient parameters are analyzed by computer 110 and advisory statements, preferably including at least one of diagnostic statements as to the character and severity of a medical condition and therapeutic recommendations may be displayed on a display 112, or transmitted to a remote location. Changes in the measured patient parameters are recorded over time by computer 110 and the resulting trends may be displayed on display 112 or transmitted. The trends may also be employed for generating trend based advisory statements, preferably including at least one of diagnostic statements as to the character and severity of a medical condition and therapeutic recommendations.

**[0021]** Typically, the exhaled carbon dioxide of the patient is measured continuously over thirty seconds by capnograph 102. Additionally or alternatively, patient may be measured for shorter or longer durations. The end tidal value of the exhaled carbon dioxide (ETCO<sub>2</sub>) profile is digitized as a waveform and may be stored for analysis in the memory of suitably programmed automatic diagnostic and treatment computer 110. Additionally or alternatively, the waveform may be stored and analyzed by other means,

**[0022]** Thereafter, in an analyzing stage, the measured patient parameters, such as the .. limits of inspiration and expiration are delineated and/or marked on computer 110. The initial slope in the increase of the exhaled carbon dioxide concentration up to 80% of the maximum (henceforth designated as "slope") and angle of rise up to 80% of the maximum carbon dioxide exhaled are measured.

**[0023]** In a rule application step, the following rules defining the patient status preferably are applied by computer 110, for example, to the CO<sub>2</sub> profile measured by capnograph 102:

If: -

- a) the time duration to reach 80% of the maximum CO<sub>2</sub> concentration (designated henceforth as "run" or "CO<sub>2</sub> run") is greater than 0.3 seconds; and,
- b) the slope of the increase in concentration of CO<sub>2</sub> is less than 100 mm Hg/sec (designated henceforth as "slope" or "CO<sub>2</sub> slope");

then: an alert signal such as "ALERT: BRONCHOSPASM PRESENT" or "ALERT: ASTHMA PATIENT" is displayed on display 112 associated with computer

110.

**[0024]** If the patient is an asthma patient according to the definition of the previous step, then the patient receives the appropriate treatment. Thereafter, a second set of exhaled carbon dioxide profile measurements are taken by capnograph 102, and the differences between the initial measurements and these second set of measurements are computed by computer 110. The following decision rule is preferably applied:

If:

- a) the difference in the run is less than 0.1 sec; and
- b) the difference in the slope is less than +15mm Hg /sec;

then,

a message is displayed on display 112 such as "ADMIT PATIENT TO HOSPITAL". Additionally or alternatively, further tests may be performed for checking the severity of the patient's condition as are described hereinbelow.

**[0025]** If the patient is not yet in hospital, as is portrayed in Figs. 1A and 1B, then a typical message is "ADMIT TO HOSPITAL". Whereas, if the patient is already in the hospital environment (Fig. 1C), a typical message is "PATIENT REQUIRES URGENT TREATMENT BY PHYSICIAN." Additionally or alternatively, further tests may be performed for checking the severity of the patient's condition as are described hereinbelow.

**[0026]** If the values of the difference in the run and the difference in the slope are beyond those of the decision rule, then another message may be displayed such as "PATIENT IMPROVING" on display 112.

**[0027]** Reference is now made to Fig. 3, which is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology in an on-scene environment for detecting the presence and severity of bronchospasm, gauging the response to treatment and recommending disposition of the patient. As seen in Fig. 3, in an on scene environment, such as at a patient's home, after a patient calls EMS after having sensed shortness of breath, various patient physiologic activities are sensed and measured, including respiratory physiologic activities, preferably via an oral airway adapter and/or a nasal or nasal/oral cannula 130, such as a Model Nasal FilterLine Adult XS 04461, O<sub>2</sub>/CO<sub>2</sub> Nasal FilterLine Adult 007141, or Smart CapnoLine Adult (Oral/nasal FilterLine) 007414, commercially available from Oridion Ltd., of Jerusalem Israel, typically coupled with a capnograph 132, such as a Microcap®, commercially available from Oridion Ltd., of Jerusalem Israel. Other patient physiologic activities relating to cardiac function (e.g. ECG), systemic oxygenation (e.g. pulse oximetry), cerebral oxygenation (e.g. cerebral oximetry) and systemic circulation (e.g. NIBP), typically sensed by means of chest electrodes 134, a finger sensor 136, a forehead/

scalp sensor 138, cannula 130 and a blood pressure cuff (sphygmomanometer) 140 respectively, may also be sensed and measured by suitable instrumentation 154.

[0028] The outputs of the capnograph 132 and preferably of additional instrumentation 154 are preferably supplied to a suitably programmed automatic diagnostic and treatment computer 144, having an associated display 146, which typically analyzes the respiration parameter output of the capnograph 132, and preferably other physiologic activities and provides an output which preferably contains a diagnostic statement, here "ALERT: MODERATE BRONCHOSPASM PRESENT". The severity of the patient's condition is defined by measured parameters as described hereinbelow.

[0029] The patient is preferably given breathing treatment, such as a beta agonist nebulizer treatment and following such treatment and/or in the course thereof, the physiologic activities of the patient continue to be monitored. This monitoring is employed by computer 160 to indicate the response to the breathing treatment and the current status of the bronchospasm condition. The patient is then transferred to an ambulance.

[0030] Reference is now made additionally to Fig. 4, which illustrates the operation of the system and methodology of the system of the present invention in the context of Fig. 3. The patient previously attached to a multi-parameter monitor including a capnograph 132 and suitable instrumentation 154, by means of cannula 130 and preferably also by means of chest electrodes 134, finger sensor 136, forehead sensor 138 and blood pressure cuff 140, is monitored continuously for at least thirty seconds. Neurological status of the patient is acquired by any suitable technique, including visual and electroencephalograph (EEG) monitoring. Values of CO<sub>2</sub> concentration, ECG, NIBP and the SPO<sub>2</sub> (the percent saturation of the hemoglobin molecule with oxygen) in units of % saturation (designated as %SAT herein), are continuously monitored, and carbon dioxide waveforms are preferably digitized as a capnogram 169 and together with other waveforms are stored in computer 144.

[0031] At least one expired air sample is collected and conveyed for analysis by capnograph 132. The following gold standards of base pulmonary function measures are as follows: FEV1 is defined as the Forced Expiratory Volume over 1 second; and is a measure of flow. FVC is the Forced Vital Capacity and is a measure of volume.

The character ratio is FEV1 / FVC. This is the ratio of flow to volume: markedly less than in bronchospasm, and close to a value of 1 in patients of normal status and those with restrictive disease.

Severity of a pulmonary disease may preferably be defined by FEV1: Reduced flow and / or volume over the first second, as compared to normal. This applies to both obstructive and restrictive disorders.

[0032] Forced expiratory volume (FEV) values are preferably determined employing a correlation from at least one capnographic measurement, and are denoted herein as CAP-FEV or CAP-FEV1 (measured over one

second). The severity criteria is assessed from the capnogram using a measure that we refer to as Cap-FEV1, to emphasize it's relation to the gold-standard FEV1 and it's derivation from the Capnogram. The area under capnogram 169 is measured over the first second. This, the CAP-FEV1 is computed as (SUM [CO<sub>2</sub>] (First second)) or, at 40 Hz device sampling rate, (SUM (n=0:40) [CO<sub>2</sub>] n). The units are "% of expected value", or "%". Additionally or alternatively, the CAP-FEV1 may be determined by standard spirometry techniques known in the art as is FEV1.

[0033] The capnographic analysis preferably includes molecular correlation spectroscopy (MSC), but may also be performed employing infrared analysis. The outputs of the capnograph 132 and possibly of additional instrumentation 154 are preferably supplied to suitably programmed automatic diagnostic and treatment computer 144, having associated display 146, which typically analyzes the respiration parameter output of the capnograph 132.

[0034] In an analyzing step, computer 144 marks the onset and offset limits of a capnogram 169, pulse waveforms, and the QRS complex (of the ECG). The actual parameters measured include, but are not limited to heart rate (HR), BP, the systolic to diastolic ratio (SYS / DIA). SPO<sub>2</sub>, AND ETACO<sub>2</sub>. The slope of CO<sub>2</sub> (mm Hg/sec), and CO<sub>2</sub>, "run", of the capnogram 132, measured to 80% of maximum CO<sub>2</sub> concentration, are calculated by computer 144.

[0035] Following each treatment, computer 144 computes the differences between consecutive measurements of the various patient parameters. Thereafter, in a diagnostic rule application step, the following diagnostic rules are preferably applied to the measured parameters by computer 144:

1) If:

- a) the blood pressure values are within the normal range;
- b) the respiratory rate is normal;
- c) CO<sub>2</sub> run is less than or equal to 0.3 sec;
- d) CO<sub>2</sub> slope is more than or equal to 100 mm Hg/sec;
- e) SPO<sub>2</sub> is greater or equal to than 95 %SAT ; and
- f) ETACO<sub>2</sub> is less than or equal to 45 mm Hg;

then,  
display 146 shows the message "VITAL SIGNS WITHIN NORMAL LIMITS."

2) In contrast, if:

- a) CO<sub>2</sub> run is greater than 0.3 sec;
- b) CO<sub>2</sub>: slope is less than 100 mm Hg/sec;
- c) SPO<sub>2</sub> is more than or equal to 91%SAT but less than 95%SAT; and

d)  $\text{ETCO}_2$  is less than 45 mm Hg;

then,

the message "MODERATE BRONCHOSPASM PRESENT" is displayed on display 146.

3) If the parameters measured are yet further removed from the acceptable range, such as if:

- a) CAP-FEV 1 (forced expiratory volume in one second) is less than 50%;
- b)  $\text{SPO}_2$  is less than 92% SAT; and
- c)  $\text{ETCO}_2$  (end tidal value of the exhaled carbon dioxide) is greater than 45 mm Hg;

then,

a message such as "SEVERE BRONCHOSPASM PRESENT" is displayed on display 146.

**[0036]** It should be understood from this example that the severity of the a respiratory disorder, whether restrictive or obstructive, may be determined by CAP-FEV1 measurements. The use of the capnographic measurements for diagnosis of whether the respiratory disorder is restrictive or obstructive is described in Fig. 30 hereinbelow. Similarly, the ratio CAP-FEV1/FVC (forced vital capacity) may be applied to diagnose whether the patient is suffering from a restrictive or obstructive breathing disorder as is described hereinabove.

**[0037]** Reference is now made to Fig. 5, which is also a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology in an on-scene environment for detecting the presence and severity of bronchospasm, gauging the response to treatment and recommending disposition of the patient. As seen in Fig. 5 and similarly to that described hereinabove with reference to Fig. 3, in an on scene environment, such as at a patient's home, after a patient calls EMS after having sensed shortness of breath, various patient physiologic activities are sensed and measured, including respiratory physiologic activities, preferably via an oral airway adapter and/or a nasal or nasal/oral cannula 150, such as a Model Nasal FilterLine Adult XS 04461,  $\text{O}_2/\text{CO}_2$  Nasal FilterLine Adult 007141, or Smart CapnLine Adult (Oral/nasal FilterLine) 007414, commercially available from Oridion Ltd., of Jerusalem Israel, typically coupled with a capnograph 152, such as a Microcap<sup>®</sup>, commercially available from Oridion Ltd., of Jerusalem Israel. Other patient physiologic activities relating to cardiac function (e.g. ECG), systemic oxygenation (e.g. pulse oximetry), cerebral oxygenation (e.g. cerebral oximetry) and systemic circulation (e.g. NIBP), typically sensed by means of chest electrodes 154, a finger sensor 156, a forehead/scalp sensor 158 and a blood pressure cuff 160 respectively, and may also be sensed and measured by suitable instrumentation 154.

**[0038]** The outputs of the capnograph 152 and preferably of additional instrumentation 154 are preferably sup-

plied to a suitably programmed automatic diagnostic and treatment computer 160, having an associated display 162, which typically analyzes the respiration parameter output of the capnograph 152 and preferably other physiologic activities and provides an output which preferably contains a diagnostic statement, here "ALERT: SEVERE BRONCHOSPASM PRESENT".

**[0039]** The patient is given breathing treatment, such as a beta agonist nebulizer treatment and following such treatment and/or in the course thereof, the physiologic activities of the patient continue to be monitored. This monitoring is employed by computer 160 to indicate the response to the breathing treatment and the current status of the bronchospasm condition. In the scenario of Fig. 3, the patient fails to respond sufficiently to the breathing treatment and this is indicated by a status statement, here "POOR RESPONSE TO TREATMENT, CONDITION CRITICAL". A treatment recommendation may also be provided, such as "CONSIDER INTUBATION".

**[0040]** Intubation is performed and correct intubation tube placement is confirmed by continuing monitoring of the physiologic activities of the patient. A status statement, here "ADEQUATE  $\text{CO}_2$  WAVEFORM - TUBE IN TRACHEA" and a treatment recommendation, here "SECURE TUBE" appear.

**[0041]** The patient is then transferred to an ambulance. While the physiologic activities of the patient continue to be monitored and serve to confirm continued proper placement of the intubation tube in the trachea. A status statement, here "TUBE IN TRACHEA" appears. Typically, the position of the tube is continuously monitored by computer 160, and a status statement "MONITORING TUBE POSITION" appears on display 162.

**[0042]** Reference is now made additionally to Figs. 6A and 6B, which illustrate the operation of the system and methodology of the system of the present invention in the context of Fig. 5. In a monitoring step, the patient, attached to a multi-parameter monitor including a capnograph 152 and instrumentation 154, by means of cannula 150 and preferably also by means of chest electrodes 164, finger sensor 166, forehead/scalp sensor 158 and blood pressure cuff 168, is monitored. Neurological status of the patient is acquired by any suitable technique.

**[0043]** At least one expired air sample is collected and conveyed to capnograph 152. Further measurements of ECG and blood pressure are monitored by standard techniques, employing chest electrodes 164 and blood pressure cuff 168 respectively. The actual parameters measured include, but are not limited to heart rate, blood pressure  $\text{ETCO}_2$  and  $\text{SPO}_2$  (SYS / DIA).  $\text{SPO}_2$ , NIBP, and cerebral oximetry values, and these parameters are measured and/or determined continuously by techniques as detailed hereinabove. These parameter values are typically digitized as waveforms and are further stored for analysis by computer 160.

**[0044]** In an analyzing step, the onset and offset limits of capnograph 152, pulse waveforms, and the QRS complex (ECG) measured by additional instrumentation 154,

are delineated and marked by computer 160. The limits of the capnogram, the pulse waveform and QRS onset and offset are determined and recorded in computer 160. The slope of the capnogram (mm Hg/sec), and the run and thereof is measured to 80% of maximum CO<sub>2</sub> concentration are calculated by computer 160.

**[0045]** Thereafter, in a diagnostic rule application step, the following diagnostic rules are applied to the measured parameters by computer 160:

1. if:

- a) the blood pressure values are within the normal range;
- b) respiratory rate is normal;
- c) CO<sub>2</sub> run is less than or equal to 0.3 sec;
- d) CO<sub>2</sub> slope is more than or equal to 100 mm Hg/sec;
- e) SPO<sub>2</sub> is greater than or equal to 95% SAT; and
- f) ETCO<sub>2</sub> is less than or equal to 45 mm Hg;

then,

computer 160 displays a message "NO BRONCHOSPASM PRESENT" on display 162.

2) In contrast, if:

- a) CO<sub>2</sub> run is greater than 0.3 sec;
- b) CO<sub>2</sub> slope is less than 100 mm Hg/sec;
- c) SPO<sub>2</sub> is more than or equal to 91% SAT, but less than 95% SAT; and
- d) ETCO<sub>2</sub> is less than 45 mm Hg;

then,

computer 160 provides the message "MODERATE BRONCHOSPASM PRESENT" on display 162.

3) If the parameters measured are yet further removed from the acceptable range, such as if:

- a) CAP-FEV1 is less than 50%;
- b) SPO<sub>2</sub> is more than or equal to 90% SAT, but is less than 91% SAT; and
- c) ETCO<sub>2</sub> is greater than 45 mm Hg, but less than or equal to 60 mm Hg;

then,

computer 160 provides a message "SEVERE BRONCHOSPASM PRESENT" on display 162.

4. If the parameters measured are still yet further removed from the acceptable range, such as if:

- a) SPO<sub>2</sub> is less than 90% SAT;
- b) the respiratory rate is less than 8 per minute;
- c) ETCO<sub>2</sub> is greater than 60 mm Hg; and
- d) the neurological parameters are poor;

then,

computer 160 issues a message on display 162 stating "RESPIRATORY FAILURE; CONDITION CRITICAL; CONSIDER INTUBATION".

**[0046]** Subsequently, in an intubation stage, a standard intubation procedure is followed, as is described hereinabove in Fig. 5. Thereafter, an operator, typically a physician or paramedic, confirms that the intubation monitoring mode has been activated, and the patient is monitored for a successful outcome of the intubation. Thereafter, computer 160 displays a message stating "MONITORING FOR INTUBATION" on display 162.

**[0047]** The next step entails a checking procedure, wherein the ETCO<sub>2</sub> value is measured by capnograph 152.

**[0048]** The following checking rule is preferably applied.

1) If:

- a) the ETCO<sub>2</sub> value is more than 15;

then,

a display is provided by computer 160 stating "GOOD WAVEFORM, TUBE IN TRACHEA, CONFIRM AND SECURE TUBE" on display 162.

**[0049]** Thereafter, the ETCO<sub>2</sub> value is measured again by capnograph 152, and recorded by computer 160. The following monitoring rules are preferably applied.

1) If:

- a) the ETCO<sub>2</sub> value is more than 15 mm Hg;

then,

a message is displayed by computer 160 on display 162 stating "MONITORING TUBE IN POSITION: NO DISLODGE MENT."

2) Whereas, if:

- a) the ETCO<sub>2</sub> value is less than or equal to 15 mm Hg; or
- b) there is a loss in the tracking of the waveform by capnograph 152;

then,

a message is displayed by computer 160 stating "ALERT: CHECK FOR TUBE DISLODGE MENT" on display 162.

**[0050]** Reference is now made Fig. 7, which is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology in an ambulance environment for detecting the presence and severity of bronchospasm, gauging the response to treat-

ment and recommending disposition of spontaneously breathing patients. As seen in Fig. 7, in an ambulance environment, various patient physiologic activities are sensed and measured, including respiratory physiologic activities, preferably via an oral airway adapter and/or a nasal or nasal/oral cannula 170, such as a Model Nasal FilterLine Adult XS 04461, O<sub>2</sub>/CO<sub>2</sub> Nasal FilterLine Adult 007141, or Smart CapnoLine Adult (Oral/nasal Filter-Line) 007414, commercially available from Oridion Ltd., of Jerusalem Israel, typically coupled with a capnograph 172, such as a Microcap<sup>®</sup>, commercially available from Oridion Ltd., of Jerusalem Israel. Other patient physiologic activities relating to cardiac function (e.g. ECG), systemic oxygenation (e.g. pulse oximetry), cerebral oxygenation (e.g. cerebral oximetry) and systemic circulation (e.g. NIBP), typically sensed by means of chest electrodes 174, a finger sensor 176, a forehead/scalp sensor 178 and a blood pressure cuff 180 respectively, may be received and analyzed by additional instrumentation 182.

**[0051]** The outputs of the capnograph 172 and possibly of additional instrumentation 182 are preferably supplied to a suitably programmed automatic diagnostic and treatment computer 184, having an associated display 186, which typically analyzes the respiration parameter output of the capnograph 172 and possibly other parameters and provides an output which preferably contains a diagnostic statement, here "ALERT: MODERATE BRONCHOSPASM PRESENT". A breathing treatment is administered after which a diagnostic statement which indicates the patient status and the severity of the respiratory condition is preferably presented, here "GOOD RESPONSE TO TREATMENT, CONDITION IMPROVING". Additional breathing treatment is typically administered after which a diagnostic statement which indicates the current patient status and the severity of the respiratory condition is preferably presented, here "NO BRONCHOSPASM PRESENT, CONDITION STABLE".

**[0052]** Preferably, response to treatment statements as well as disposition recommendations may be appended to patient status statements, here "RAPID RESPONSE TO TREATMENT, CONDITION REMAINS STABLE, DISCHARGE TO HOME LIKELY".

**[0053]** Preferably some or all of the outputs of computer 184 are transmitted in a wireless manner by a transmitter 188, such as via radio or a cellular telephone link, preferably to a dispatch center or patient receiving facility.

**[0054]** Reference is now made additionally to Figs. 8A and 8B, which illustrate the operation of the system and methodology of the system of the present invention in the context of Fig. 7. In a monitoring step, the patient in an ambulance environment, attached to a multi-parameter monitor including capnograph 172, by means of cannula 170 and preferably also by means of chest electrodes 174, finger sensor 176, scalp/forehead sensor 178 and blood pressure cuff 178, is monitored continuously. Neurological status of the patient is acquired by any suitable technique. Values of the CO<sub>2</sub> concentration monitored by capnograph 172, and ECG, NIBP, cerebral ox-

imetry and SPO<sub>2</sub> values, monitored by additional instrumentation 182 are supplied to computer 184, and are typically measured continuously over a period of 30 seconds, by techniques as detailed hereinabove. The parameter data may be digitized as waveforms and are further stored for analysis by computer 184. Thereafter, the limits of the capnogram, the pulse waveform and QRS onset and offset are determined by computer 184. The heart rate, blood pressure ETCO<sub>2</sub> and SPO<sub>2</sub> values are measured. The initial slope of the capnogram and the run, monitored by capnograph 172, are calculated by computer 184. Additionally, neurological findings, monitored by means of an EEG are inputted to computer 184.

**[0055]** In an analyzing step, the onset and offset limits of the capnogram, pulse waveforms, and the QRS complex.(ECG) are marked by computer 184.

**[0056]** Following each treatment, the differences between consecutive measurements of the various patient parameters are evaluated by computer 184. After each treatment, in a diagnostic rule application step, the following diagnostic rules are preferably applied to the measured parameters by computer 184:

1) If:

- a) the blood pressure values are within the normal range;
- b) the respiratory rate is normal;
- c) CO<sub>2</sub> run is less than or equal to 0.3 sec;
- d) CO<sub>2</sub> slope is more than or equal to 100 mm Hg/sec;
- e) SPO<sub>2</sub> is greater than or equal to 95% SAT; and
- f) ETCO<sub>2</sub> is less than or equal to 45 mm Hg;

then,  
display 162 shows the message "NO BRONCHOSPASM PRESENT"

2) In contrast, if:

- a) CO<sub>2</sub> run is greater than 0.3 sec;
- b) CO<sub>2</sub> slope is less than 100 mm Hg/sec;
- c) SPO<sub>2</sub> is more than or equal to 91% SAT less than 95% SAT; and
- d) ETCO<sub>2</sub> is less than 45 mm Hg;

then,  
the message "MODERATE BRONCHOSPASM PRESENT" is displayed on display 186.

3) If the parameters measured are yet further removed from the acceptable range, such as if:

- a) CAP-FEV1 is less than 50%;
- b) SPO<sub>2</sub> is less than 92% SAT; and
- c) ETCO<sub>2</sub> is greater than 45 mm Hg;

then,  
a message such as "SEVERE BRONCHOSPASM  
PRESENT" is displayed on display 186.

**[0057]** The findings of the last stage are stored by computer 184 and/or transmitted to a dispatch/receiving center, typically located at a hospital or medical center [ref. no]. A connection is established with the dispatch/receiving center [ref. no], and the data is forwarded thereto. A medical supervisor typically watches display of the received data, and consequentially transmits the recommended treatment and/or transport recommendations back to the ambulance.

**[0058]** After each time interval, the difference between consecutive measures of each parameter are calculated by computer 184: Thereafter, the following monitoring rules are preferably applied to the measured parameters by computer 184.

1) If:

- a) the difference in the run values is greater than +0.1 sec; and
- b) the difference in the slope is more negative than -15 mm Hg/sec;

then,  
computer 184 displays on display 186 "BRONCHOSPASM WORSENING".

2) If:

- a) the difference in the run values is more negative than -0.1 sec; and
- b) the difference in the slope is more than +15 mm Hg/sec;

then,  
computer 184 displays on display 186 "BRONCHOSPASM IMPROVING".

3) If:

- a) the difference in the slope is more than or equal to -15 mm Hg/sec and less than or equal to +15 mm Hg/sec;

then,  
computer 184 displays on display 186 "UNCHANGED".

The change in patient's vital functional activities, including SPO<sub>2</sub> and ETCO<sub>2</sub>, over the time interval are calculated by computer 184.

4) If:

- a) the decrease in SPO<sub>2</sub> is more than -5% SAT; or

- b) the increase in the ETCO<sub>2</sub> is more than +5 mm Hg;

then,  
computer 184 displays on display 186 "VITAL SIGNS DETERIORATING."

5) If:

- a) the increase in SPO<sub>2</sub> is greater than +5 % SAT; or
- b) the decrease in the ETCO<sub>2</sub> is less than -5 mm Hg;

then,  
computer 184 displays on display 186 "VITAL SIGNS IMPROVING".

6) If:

- a) the change in SPO<sub>2</sub> is greater than or equal to -5 % SAT, but less than or equal to +5 %; or
- b) the change in the ETCO<sub>2</sub> is more than or equal to -5 mm Hg, or less than or equal to +5 mm Hg;

then,  
computer 184 displays on display 186 "VITAL SIGNS UNCHANGED."

Computer 184 preferably combines the results of these monitoring rules to display an integrated display 186 such as "BRONCHOSPASM WORSENING; VITAL SIGNS UNCHANGED."

**[0059]** Thereafter, in a transmission stage, the connection with the receiving center is maintained. The receiving center periodically receives updates of the patient's condition, who is in the ambulance en route to the hospital, in order to prepare in the most fitting and efficient transfer of the patient upon arrival to the hospital.

**[0060]** Following the transmission stage, the following exit rules are preferably applied to the measured parameters by computer 184:

1) If:

- a) the blood pressure values are within normal limits;
- b) the respiratory rate is within normal limits;
- c) the value of the CO<sub>2</sub> run is less than 0.3 seconds; and
- d) the CO<sub>2</sub> slope is greater than 100 mm Hg/sec;

then,  
Computer 184 preferably displays on display 186 "NO BRONCHOSPASM PRESENT".

**[0061]** If the patient's record complies with this exit rule, then a copy of the patient's record is handed off from

computer 184 to the receiving center, for example, in the form of a chart. Typically, the receiving center stores this chart, so that it may be used as a baseline for continued monitoring of the patient.

**[0062]** Reference is now made to Fig. 9, which is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology in an ambulance environment for detecting the presence and severity of bronchospasm, gauging the response to treatment and recommending disposition of mechanically ventilated patients. As seen in Fig. 9 and similarly to that described hereinabove with reference to Fig. 5, in an ambulance environment various patient physiologic activities are sensed and measured, including respiratory physiologic activities, preferably via an oral airway adapter and/or a nasal or nasal/oral cannula 200, such as a Model Nasal FilterLine Adult XS 04461, O<sub>2</sub>/CO<sub>2</sub> Nasal FilterLine Adult 007141, or Smart CapnoLine Adult (Oral/nasal FilterLine) 007414, commercially available from Oridion Ltd., of Jerusalem Israel, typically coupled with a capnograph 202, such as a Microcap<sup>®</sup>, commercially available from Oridion Ltd., of Jerusalem Israel. Other patient physiologic activities relating to cardiac function (e.g. ECG), systemic oxygenation (e.g. pulse oximetry), cerebral oxygenation (e.g. cerebral oximetry) and systemic circulation (e.g. NIBP), typically sensed by means of chest electrodes 204, a finger sensor 206, a forehead/scalp sensor 208 and a blood pressure cuff 209 respectively, may also be sensed and measured by suitable instrumentation 210. Other patient physiologic activities relating to cardiac function (e.g. ECG), cerebral perfusion (e.g. CEREBRAL OXIMETRY), oxygenation (e.g. pulse oximetry) and systemic circulation (e.g. NIBP), may also be sensed and measured by suitable instrumentation 212

**[0063]** The outputs of the capnograph 202 and preferably of additional instrumentation 212 are preferably supplied to a suitably programmed automatic diagnostic and treatment computer 214 having an associated display 216, which typically analyzes the respiration parameter output of the capnograph 202 and preferably other physiologic activities and provides an output which preferably contains a diagnostic statement, here "ALERT: SEVERE BRONCHOSPASM PRESENT".

**[0064]** The patient is given breathing treatment, such as a beta agonist nebulizer treatment and following such treatment and/or in the course thereof, the physiologic activities of the patient continue to be monitored. This monitoring is employed by computer 214 to indicate the response to the breathing treatment and the current status of the patient condition. In the scenario of Fig. 9, the patient fails to respond sufficiently to the breathing treatment and this is indicated by a status change statement, here "POOR RESPONSE TO TREATMENT, CONDITION WORSENING". A treatment recommendation may also be provided, such as "CONSIDER INTUBATION".

**[0065]** Intubation is performed and correct initial tube placement is confirmed followed by continuous monitoring of the physiologic activities of the patient, which indi-

cate current tube position. Where intubation is successful, a status statement, here: "ADEQUATE CO<sub>2</sub> WAVEFORM - TUBE IN TRACHEA" and a treatment recommendation, here "SECURE TUBE" appear. Where intubation is not successful, a status statement, here: "NO CO<sub>2</sub> WAVEFORM-TUBE IN ESOPHAGUS" and a treatment recommendation, here "REINTUBATE" appear.

**[0066]** Following successful intubation, continuous monitoring may provide a status statement such as "ADEQUATE CO<sub>2</sub> WAVEFORM-TUBE IN TRACHEA-NO DISLOGEMENT" may appear. If tube dislodgment occurs at any time following intubation, a status statement appears, here "CO<sub>2</sub> WAVEFORM ABSENT" preferably accompanied by a treatment recommendation, here "CHECK FOR TUBE DISLOGEMENT".

**[0067]** Preferably some or all of the outputs of computer 214 are transmitted in a wireless manner by a transmitter 218, such as via radio or a cellular telephone link, preferably to a dispatch center or patient receiving facility.

**[0068]** Reference is now made additionally to Figs. 10A-10C, which illustrate the operation of the system and methodology of the system of the present invention in the context of Fig. 9.

**[0069]** In a monitoring step, the patient in an ambulance environment, attached to a multi-parameter monitor including capnograph 202 and instrumentation 212, by means of cannula 200 and preferably also by means of chest electrodes 204, finger sensor 206, scalp/forehead sensor 208 and blood pressure cuff 209, is monitored continuously. Neurological status of the patient is acquired by any suitable technique. Values of the CO<sub>2</sub> concentration monitored by capnograph 202, and ECG, NIBP, cerebral oximetry and SPO<sub>2</sub> values, monitored by additional instrumentation 212 are supplied to computer 214, and are typically measured continuously over a period of 30 seconds, by techniques as detailed hereinabove. The parameter data may be digitized as waveforms and are further stored for analysis by computer 214. Thereafter, the onset and offset limits of the capnogram, the pulse waveform and QRS onset and offset are determined by computer 214. The heart rate, blood pressure ETCO<sub>2</sub> and SPO<sub>2</sub> values are measured. The initial slope of the capnogram and the run, monitored by capnograph 202, are calculated by computer 214. Additionally, neurological findings, monitored by means of an EEG are inputted to computer 214.

**[0070]** Following each treatment, the differences between consecutive measurements of the various patient parameters are evaluated by computer 214. After each treatment, in a diagnostic rule application step, the following diagnostic rules are preferably applied to the measured parameters by computer 214:

1) If:

- a) the blood pressure values are within the normal range;
- b) the respiratory rate is normal;

- c) CO<sub>2</sub> run is less than or equal to 0.3 sec;
- d) CO<sub>2</sub> slope is more than or equal to 100 mm Hg/sec;
- e) SPO<sub>2</sub> is greater than or equal to 95% SAT; and
- f) ETCO<sub>2</sub> is less than or equal to 45 mm Hg;

then,  
display 216 shows the message "NO BRONCHOSPASM PRESENT."

2) In contrast, if:

- a) CO<sub>2</sub> run is greater than 0.3 sec;
- b) CO<sub>2</sub> slope is less than 100 mm Hg/sec;
- c) SPO<sub>2</sub> is more than or equal to 91% SAT but less than 95% SAT; and
- d) ETCO<sub>2</sub> is less than 45 mm Hg;

then,  
the message "MODERATE BRONCHOSPASM PRESENT" is displayed on display 216.

3) If the parameters measured are yet further removed from the acceptable range, such as if:

- a) CAP-FEV 1 is less than 50%;
- b) SPO<sub>2</sub> is less than 91% SAT; and
- c) ETCO<sub>2</sub> is greater than 45 mm Hg;

then,  
a message such as "SEVERE BRONCHOSPASM PRESENT" is preferably displayed on display 216.

**[0071]** The findings of the last stage are stored by computer 214 and/or transmitted to a dispatch/receiving center, typically located at a hospital or medical center]. A connection is established with the dispatch/receiving center, and the data is forwarded thereto. A medical supervisor typically watches display of the received data, and consequentially transmits the recommended treatment and/or transport recommendations back to the ambulance.

**[0072]** After each time interval, the difference between consecutive measures of each parameter are calculated by computer 214: Thereafter, the following monitoring rules are preferably applied to the measured parameters by computer 214.

1) If:

- a) the difference in the run values is greater than 0.1 sec; and
- b) the difference in the slope is more negative than -15 mm Hg/sec;

then,  
computer 214 displays on display 216 "BRON-

CHOSPASM WORSENING".

2) If:

- a) the difference in the run values is more negative than -0.1 sec; and
- b) the difference in the slope is more positive than +15 mm Hg/sec;

then,  
computer 214 displays on display 216 "BRONCHOSPASM IMPROVING".

3) If:

- a) the difference in the slope is more than or equal to -15 mm Hg/sec and less than or equal to +15 mm Hg/sec;

then,  
computer 214 displays on display 216 "BRONCHOSPASM UNCHANGED".

The change in patient's vital functional activities, including SPO<sub>2</sub> and ETCO<sub>2</sub>, over the time interval are calculated by computer 214.

4) If:

- a) the decrease in SPO<sub>2</sub> is more negative than -5 % SAT; or
- b) the increase in the ETCO<sub>2</sub> is more positive than +5 mm Hg;

then,  
computer 214 displays on display 216 "VITAL SIGNS DETERIORATING."

5) If:

- a) the change in SPO<sub>2</sub> is greater than +5 % SAT; or
- b) the change in the ETCO<sub>2</sub> is more negative than -5 mm Hg;

then,  
computer 214 displays on display 216 "VITAL SIGNS IMPROVING ".

6) If:

- a) the change in SPO<sub>2</sub> is greater than or equal to -5 % SAT, but less than or equal to +5 % SAT; or
- b) the change in the ETCO<sub>2</sub> is more than or equal to -5 mm Hg, but less than or equal to +5 mm Hg;

then,  
computer 214 displays on display 216 "VITAL

SIGNS UNCHANGED."

**[0073]** Computer 214 preferably combines the results of these monitoring rules to display an integrated display such as "BRONCHOSPASM WORSENING; VITAL SIGNS UNCHANGED."

**[0074]** In a checking rule step, the following rule is preferably applied:

1) A patient appears to be entering respiratory failure phase if:

- a) the  $SPO_2$  is less than 90% SAT;
- b) the respiratory rate is less than 8/min;
- c)  $ETCO_2$  is greater than 60 mm Hg; and
- d) the patient's neurological symptoms are qualified as being "bad";

then,

computer 214 displays "RESPIRATORY FAILURE; CONDITION CRITICAL; CONSIDER INTUBATION." on display 216.

**[0075]** Following this, in an alert data transmission stage, a high priority update is transmitted via transmitter 218 from computer 214 to notify the dispatch / receiving centers of the significant deterioration and change in the patient's condition.

**[0076]** Once these changes in the patient's condition have been confirmed by an operator, the patient is consequentially intubated according to standard techniques and capnograph 202 is activated in intubation monitoring mode by computer 214. Once the successful intubation of the patient is verified by data comparison of the patient's capnogram and standardized capnograms for intubation in computer 214, the computer displays "MONITORING FOR INTUBATION".

**[0077]** Thereafter, the following check rule is preferably applied to the patient's capnogram:

1. If:

- a)  $ETCO_2$  is greater than 15 mm Hg;

then,

computer 214 displays "GOOD WAVEFORM, TUBE IN TRACHEA. CONFIRM AND SECURE TUBE."

**[0078]** In the next step, the following monitoring rules are preferably applied to the patient's capnogram:

1) If:

- a) the value of  $ETCO_2$  is greater than 15 mm Hg;

then,

computer 214 displays "MONITORING TUBE POSITION: NO DISLODGE MENT" on display 216.

2) If:

- a) the value of  $ETCO_2$  is less than or equal to 15 mm Hg; or
- b) there is a loss of the waveform;

then,

computer 214 displays "ALERT: CHECK FOR TUBE DISLODGE MENT" on display 216.

**[0079]** Computer 214 transmits the data monitored via transmitter 218 to the receiving center. The receiving center periodically receives updates of the patient's condition, who is in the ambulance en route to the hospital, in order to prepare in the most fitting and efficient transfer of the patient upon arrival to the hospital.

**[0080]** A copy of the patient's record is handed off from computer 184 via transmitter 218 to the receiving center, for example, in the form of a chart. Typically, the receiving center stores this chart, so that it may be used as a baseline for continued monitoring of the patient.

**[0081]** Reference is now made to Fig. 11, which is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology in a hospital environment, such as a medical ward, emergency department or ICU, for detecting the presence and indicating the severity of bronchospasm, gauging the response to treatment and recommending treatment and disposition of spontaneously breathing patients. As seen in Fig. 11, in a hospital environment, various patient physiologic activities are sensed and measured, including respiratory physiologic activities, preferably via an oral airway adapter and/or a nasal or nasal/oral cannula 220, such as a Model Nasal FilterLine Adult XS 04461,  $O_2/CO_2$  Nasal FilterLine Adult 007141, or Smart CapnoLine Adult (Oral/nasal FilterLine) 007414, commercially available from Oridion Ltd., of Jerusalem Israel, typically coupled with a capnograph 222, such as a Microcap<sup>®</sup>, commercially available from Oridion Ltd., of Jerusalem Israel. Other patient physiologic activities relating to cardiac function (e.g. ECG), systemic oxygenation (e.g. pulse oximetry), cerebral oxygenation (e.g. cerebral oximetry) and systemic circulation (e.g. NIBP), typically sensed by means of chest electrodes 224, a finger sensor 226, a forehead/scalp sensor 228 and a blood pressure cuff 230 respectively.

**[0082]** The outputs of the capnograph 222 and possibly of additional instrumentation 230 are preferably supplied to a suitably programmed automatic diagnostic and treatment computer 232, having an associated display 234 which typically analyzes the respiration parameter output of the capnograph 222 and possibly other parameters and provides an output which preferably contains a diagnostic statement, here "ALERT: MODERATE BRONCHOSPASM PRESENT". A breathing treatment is administered after which a diagnostic statement which indicates the patient status and the severity of the respiratory condition is preferably presented, here "GOOD RE-

SPONSE TO TREATMENT, CONDITION IMPROVING" . Additional breathing treatment is typically administered after which a diagnostic statement which indicates the current patient status and the severity of the respiratory condition is preferably presented, here "NO BRONCHOSPASM PRESENT, CONDITION STABLE".

[0083] Preferably, response to treatment statements as well as disposition recommendations may be appended to patient status statements, here "RAPID RESPONSE TO TREATMENT, CONDITION REMAINS STABLE, DISCHARGE TO HOME LIKELY".

[0084] Reference is now made additionally to Fig. 12, which illustrates the operation of the system and methodology of the system of the present invention in the context of Fig. 11. The patient in the hospital environment, preferably attached to a multi-parameter monitor including capnograph 222 and instrumentation 230, by means of cannula 220 and preferably also by means of chest electrodes 230, finger sensor 226, scalp/forehead sensor 228 and blood pressure cuff 236, is monitored continuously. The neurological status of the patient is acquired by any suitable technique. Values of CO<sub>2</sub> concentration, ECG, NIBP and SPO<sub>2</sub> are continuously measured, typically over a period of 30 seconds, and carbon dioxide waveforms are preferably digitized as a capnogram and other waveforms and stored.

[0085] The parameter data may be digitized as waveforms and are further stored for analysis by computer 232. Thereafter, the onset and offset limits of the capnogram, the pulse waveform and QRS onset and offset are determined by computer 232. The heart rate, blood pressure ETCO<sub>2</sub> and SPO<sub>2</sub> values are measured. The initial slope of the capnogram and the run, monitored by capnograph 222, are calculated by computer 232. Additionally, neurological findings, monitored by means of an EEG are inputted to computer 232.

[0086] Following each treatment, the differences between consecutive measurements of the various patient parameters are evaluated by computer 232. After each treatment, in a diagnostic rule application step, the following diagnostic rules are preferably applied to the measured parameters by computer 234:

1) If:

- a) the blood pressure values are within the normal range;
- b) the respiratory rate is normal;
- c) CO<sub>2</sub> run is less than or equal to 0.3 sec;
- d) CO<sub>2</sub> slope is more than or equal to 100 mm Hg/sec;
- e) SPO<sub>2</sub> is greater than or equal to 95% SAT; and
- f) ETCO<sub>2</sub> is less than or equal to 45 mm Hg;

then,

display 234 shows the message "VITAL SIGNS WITHIN NORMAL LIMITS."

2) In contrast, if:

- a) CO<sub>2</sub> run is greater than 0.3 sec;
- b) CO<sub>2</sub> slope is less than 100 mm Hg/sec;
- c) SPO<sub>2</sub> is more than or equal to 91% SAT, but less than 95% SAT; and
- d) ETCO<sub>2</sub> is less than 45 mm Hg;

then,

the message "MODERATE BRONCHOSPASM PRESENT" is displayed on display 234.

3) If the parameters measured are yet further removed from the acceptable range, such as if:

- a) CAP-FEV1 is less than 50%;
- b) SPO<sub>2</sub> is less than 92% SAT; and
- c) ETCO<sub>2</sub> is greater than 45 mm Hg;

then,

a message such as "SEVERE BRONCHOSPASM PRESENT" is displayed on display 234.

[0087] The findings of the last stage are stored by computer 232 and/or transmitted to a dispatch/receiving center, typically located at a hospital or medical center. A connection is established with the dispatch/receiving center, and the data is forwarded thereto. A medical supervisor typically watches display of the received data, and consequentially transmits the recommended treatment and/or transport recommendations back to the hospital.

[0088] After each time interval, the difference between consecutive measures of each parameter are calculated by computer 232: Thereafter, the following monitoring rules are preferably applied to the measured parameters by computer 232.

1) If:

- a) the difference in the run values is greater than 0.1 sec; and
- b) the difference in the slope is less than -15 mm Hg/sec;

then,

computer 232 displays on display 234 "BRONCHOSPASM WORSENING".

2) If:

- a) the difference in the run values is more negative than -0.1 sec; and
- b) the difference in the slope is more than +15 mm Hg/sec;

then,

computer 232 displays on display 234 "BRON-

CHOSPASM IMPROVING".

3) If:

- a) the difference in the slope is greater than or equal to -15 mm Hg/sec, but less than or equal to +15 mm Hg/sec; and
- a) the difference in the run values is greater or equal to -0.1 sec; but less than or equal to +0.1 sec;

then, computer 232 displays on display 234 "BRONCHOSPASM UNCHANGED".

The change in patient's vital functional activities, including SPO<sub>2</sub> and ETCO<sub>2</sub>, over the time interval are calculated by computer 232.

4) If:

- a) the change in SPO<sub>2</sub> is greater than -5 % SAT; or
- b) the change in the ETCO<sub>2</sub> is more than +5 mm Hg;

then, computer 232 displays on display 234 "VITAL SIGNS DETERIORATING."

5) If:

- a) the change in SPO<sub>2</sub> is greater than +5 % SAT; or
- b) the change in the ETCO<sub>2</sub> is less than -5 mm Hg;

then, computer 232 displays on display 234 "VITAL SIGNS IMPROVING

6) If:

- a) the change in SPO<sub>2</sub> is greater than or equal to -5 % SAT , and less than or equal to +5 % SAT; or
- b) the change in the ETCO<sub>2</sub> is more than or equal to -5 mm Hg, but less than or equal to +5 mm Hg;

then, computer 232 displays on display 234 "VITAL SIGNS UNCHANGED."

[0089] Computer 232 preferably combines the results of these monitoring rules to display an integrated display 234 such as "BRONCHOSPASM WORSENING; VITAL SIGNS UNCHANGED."

[0090] Following the monitoring stage, the following exit rules are preferably applied to the measured param-

eters of the patient by computer 232:

1) If:

- a) the blood pressure values are within normal limits;
- b) the respiratory rate is within normal limits;
- c) the value of the CO<sub>2</sub> run is less than 0.3 seconds;
- d) the CO<sub>2</sub> slope is greater than 100 mm Hg/sec; and
- e) ETCO<sub>2</sub> is less than 45 mm Hg;

then,

Computer 232 preferably displays on display 234 "NO BRONCHOSPASM PRESENT"

[0091] (If the patient's record complies with this exit rule, then a copy of the patient's record is handed off from computer 232 to the receiving center, for example, in the form of a chart. Typically, the receiving center stores this chart, so that it may be used as a baseline for continued monitoring of the patient).

[0092] Reference is now made to Fig. 13, which is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology in an ambulance environment for detecting the presence and severity of bronchospasm, gauging the response to treatment and recommending disposition of mechanically ventilated patients. As seen in Fig. 13 and similarly to that described hereinabove with reference to Figs. 5 and 9, in a hospital environment, such as a medical ward, emergency department or ICU, various patient physiologic activities are sensed and measured, including respiratory physiologic activities, preferably via an oral airway adapter and/or a nasal or nasal/oral cannula 250, such as a Model Nasal FilterLine Adult XS 04461, O<sub>2</sub>/CO<sub>2</sub> Nasal FilterLine Adult 007141, or Smart CapnoLine Adult (Oral/nasal FilterLine) 007414, commercially available from Oridion Ltd., of Jerusalem Israel, typically coupled with a capnograph 252, such as a Microcap®, commercially available from Oridion Ltd., of Jerusalem Israel. Other patient physiologic activities relating to cardiac .function (e.g. ECG), systemic oxygenation (e.g. pulse oximetry), cerebral oxygenation (e.g. cerebral oximetry) and systemic circulation (e.g. NIBP), typically sensed by means of chest electrodes 254, a finger sensor 256, a forehead/scalp sensor 258 and a blood pressure cuff 260 respectively, may also be sensed and measured by suitable instrumentation 262.

[0093] The outputs of the capnograph 252 and preferably of additional instrumentation 262 are preferably supplied to a suitably programmed automatic diagnostic and treatment computer 264 having an associated display 266, which typically analyzes the respiration parameter output of the capnograph 252 and preferably other physiologic activities and provides an output which preferably contains a diagnostic statement, here "ALERT: SEVERE

BRONCHOSPASM PRESENT".

**[0094]** The patient is given breathing treatment, such as a beta agonist nebulizer treatment and following such treatment and/or in the course thereof, the physiologic activities of the patient continue to be monitored. This monitoring is employed by computer 264 to indicate the response to the breathing treatment and the current status of the patient condition. In the scenario of Fig. 13, the patient fails to respond sufficiently to the breathing treatment and this is indicated by a status change statement, here "POOR RESPONSE TO TREATMENT, CONDITION WORSENING". A treatment recommendation may also be provided, such as "CONSIDER INTUBATION".

**[0095]** Intubation is performed and correct initial tube placement is confirmed followed by continuous monitoring of the physiologic activities of the patient, which indicate current tube position. Where intubation is successful, a status statement, here: "ADEQUATE CO2 WAVEFORM - TUBE IN TRACHEA" and a treatment recommendation, here "SECURE TUBE" appear. Where intubation is not successful, a status statement, here: "NO CO2 WAVEFORM-TUBE IN ESOPHAGUS" and a treatment recommendation, here "REINTUBATE" appear.

**[0096]** Following successful intubation, continuous monitoring may provide a status statement such as "ADEQUATE CO2 WAVEFORM-TUBE IN TRACHEA-NO DISLOGEMENT" may appear. If tube dislodgment occurs at any time following intubation, a status statement appears, here "CO2 WAVEFORM ABSENT" preferably accompanied by a treatment recommendation, here "CHECK FOR TUBE DISLOGEMENT".

**[0097]** Preferably some or all of the outputs of computer 262 are transmitted in a wireless manner by a transmitter 268, such as via radio or a cellular telephone link, preferably to a dispatch center or patient receiving facility.

**[0098]** Reference is now made additionally to Figs. 14A and 14B, which illustrate the operation of the system and methodology of the system of the present invention in the context of Fig. 13.

**[0099]** The patient in the hospital environment, preferably attached to a multi-parameter monitor including capnograph 252 and instrumentation 262, by means of cannula 250 and preferably also by means of chest electrodes 254, finger sensor 256, scalp/forehead sensor 258 and blood pressure cuff 260, is monitored continuously. The neurological status of the patient is acquired by any suitable technique. Values of CO<sub>2</sub> concentration, ECG, NIBP and SPO<sub>2</sub> are continuously measured, typically over a period of 30 seconds, and carbon dioxide waveforms are preferably digitized as a capnogram and other waveforms and stored by computer 264.

**[0100]** Thereafter, the onset and offset limits of the capnogram, the pulse waveform and QRS onset and offset are determined by computer 264. The heart rate, blood pressure ET<sub>CO</sub><sub>2</sub> and SPO<sub>2</sub> values are measured. The initial slope of the capnogram and the run, monitored by capnograph 252, are calculated by computer 264. Additionally, neurological findings, monitored by means of an

EEG are inputted to computer 264.

**[0101]** Following each treatment, the differences between consecutive measurements of the various patient parameters are evaluated by computer 264. After each treatment, in a diagnostic rule application step, the following diagnostic rules are preferably applied to the measured parameters by computer 264:

1) If:

- a) the blood pressure values are within the normal range;
- b) the respiratory rate is normal;
- c) CO<sub>2</sub> run is less than or equal to 0.3 sec;
- d) CO<sub>2</sub> slope is more than or equal to 100 mm Hg/sec;
- e) SPO<sub>2</sub> is greater than or equal to 95 % SAT; and
- f) ET<sub>CO</sub><sub>2</sub> is less than or equal to 45 mm Hg;

then,  
display 266 shows the message "VITAL SIGNS WITHIN NORMAL LIMITS."

2) In contrast, if:

- a) CO<sub>2</sub> run is greater than 0.3 sec;
- b) CO<sub>2</sub> slope is less than 100 mm Hg/sec;
- c) SPO<sub>2</sub> is greater than or equal to 91% SAT, but less than 95% SAT; and
- d) ET<sub>CO</sub><sub>2</sub> is less than 45 mm Hg;

then,  
the message "MODERATE BRONCHOSPASM PRESENT" is displayed on display 266.

3) If the parameters measured are yet further removed from the acceptable range, such as if:

- a) CAP-FEV1 is less than 50%;
- b) SPO<sub>2</sub> is less than 91% SAT; and
- c) ET<sub>CO</sub><sub>2</sub> is greater than 45 mm Hg;

then,  
a message such as "SEVERE BRONCHOSPASM PRESENT" is displayed on display 266.

**[0102]** The findings of the last stage are stored by computer 264 and/or transmitted by transmitter 268 to a dispatch/receiving center, typically located at a hospital or medical center. A connection is established with the dispatch/receiving center [ref. no], and the data is forwarded thereto. A medical supervisor typically watches display of the received data, and consequentially transmits the recommended treatment and/or transport recommendations back to the hospital.

**[0103]** After each time interval, the difference between consecutive measures of each parameter are calculated

by computer 264: Thereafter, the following monitoring rules are preferably applied to the measured parameters by computer 264.

1) If:

- a) the difference in the run values is greater than +0.1 sec; and
- b) the difference in the slope is more negative than -15 mm Hg/sec ;

then, computer 264 displays on display 266 "BRONCHOSPASM WORSENING".

2) If:

- a) the difference in the run values is more negative than -0.1 sec ; and
- b) the difference in the slope is more positive than +15 mm Hg/sec;

then, computer 264 displays on display 266 "BRONCHOSPASM IMPROVING".

3) If:

- a) the difference in the run values is greater or equal to -0.1 sec but less than or equal to +0.1 sec; or
- b) the difference in the slope is more than or equal to -15 mm Hg/sec but less than or equal to +15 mm Hg/sec;

then, computer 264 displays on display 266 " BRONCHOSPASM UNCHANGED".

The change in patient's vital functional activities, including SPO<sub>2</sub> and ETCO<sub>2</sub>, over the time interval are calculated by computer 264.

4) If:

- a) the change in SPO<sub>2</sub> is greater than -5 % SAT; or
- b) the change in the ETCO<sub>2</sub> is more than +5 mm Hg;

then, computer 264 displays on display 266 "VITAL SIGNS DETERIORATING."

5) If:

- a) the change in SPO<sub>2</sub> is greater than +5 % SAT; or
- b) the change in the ETCO<sub>2</sub> is less than -5 mm

Hg;

then, computer 264 displays on display 266 "VITAL SIGNS IMPROVING ".

6) If:

- a) the change in SPO<sub>2</sub> is greater than or equal to -5 % SAT, but less than or equal to +5 % SAT; or
- b) the change in the ETCO<sub>2</sub> is more than or equal to -5 mm Hg, but less than or equal to +5 mm Hg;

then, computer 264 displays on display 266 "VITAL SIGNS UNCHANGED."

**[0104]** Computer 264 preferably combines the results of these monitoring rules to display an integrated display 266 such as "BRONCHOSPASM WORSENING; VITAL SIGNS UNCHANGED."

**[0105]** In a checking rule step, the following rule is preferably applied.:

1) A patient appears to be entering respiratory failure phase if:

- a) the SPO<sub>2</sub> is less than 90% SAT;
- b) the respiratory rate is less than 8/min;
- c) ETCO<sub>2</sub> is greater than 60 mm Hg; and
- d) the patient's neurological symptoms are qualified as being "bad";

then, computer 264 displays "RESPIRATORY FAILURE; CONDITION CRITICAL; CONSIDER INTUBATION." on display 266.

**[0106]** Once these changes in the patient's condition have been confirmed by an operator, the patient is consequentially intubated according to standard techniques and capnograph 252 is activated in intubation monitoring mode by computer 264. Once the successful intubation of the patient is verified by data comparison of the patient's capnogram and standardized capnograms for intubation in computer 264, the computer displays "MONITORING FOR INTUBATION".

**[0107]** Thereafter, the following check rule is preferably applied to the patient's capnogram:

1. If:

- a) ETCO<sub>2</sub> is greater than 15 mm Hg;

then, computer 264 displays "GOOD WAVEFORM, TUBE IN TRACHEA. CONFIRM AND SECURE TUBE."

**[0108]** In the next step, the following monitoring rules are preferably applied to the patient's capnogram:

1) If:

a) the value of  $\text{ETCO}_2$  is greater than 15 mm Hg;

then,

computer 266 displays "MONITORING TUBE POSITION: NO DISLODGE MENT" on display 268.

2) If:

a) the value of  $\text{ETCO}_2$  is less than or equal to 15 mm Hg; or

b) there is a loss of the waveform;

then,

computer 264 displays "ALERT: CHECK FOR TUBE DISLODGE MENT" on display 266.

**[0109]** Reference is now made to Fig. 15, which is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology in a hospital environment operative for distinguishing between heart failure and emphysema in a situation where a hospital patient becomes short of breath. As seen in Fig. 15, in a hospital environment, various patient physiologic activities are sensed and measured, including respiratory physiologic activities, preferably via an oral airway adapter and/or a nasal or nasal/oral cannula 270, such as a Model Nasal FilterLine Adult XS 04461,  $\text{O}_2/\text{CO}_2$  Nasal FilterLine Adult 007141, or Smart CapnoLine Adult (Oral/nasal FilterLine) 007414, commercially available from Oridion Ltd., of Jerusalem Israel, typically coupled with a capnograph 272, such as a Microcap, commercially available from Oridion Ltd., of Jerusalem Israel. Other patient physiologic activities relating to cardiac function (e.g. ECG), systemic oxygenation (e.g. pulse oximetry), cerebral oxygenation (e.g. cerebral oximetry) and systemic circulation (e.g. NIBP), typically sensed by means of chest electrodes 274, a finger sensor 276, a forehead/scalp sensor 278 and a blood pressure cuff 280 respectively, may also be sensed and measured by suitable instrumentation 282.

**[0110]** The outputs of the capnograph 272 and possibly of additional instrumentation 282 are preferably supplied to a suitably programmed automatic diagnostic and treatment computer 284, having an associated display 286 which typically analyzes the respiration parameter output of the capnograph 272 and possibly other parameters and provides an output which preferably contains a diagnostic statement, here "SEVERE BRONCHOSPASM PRESENT". This diagnostic statement would suggest treatment for emphysema rather than for heart failure. Breathing treatment is administered after which a diagnostic statement which indicates the patient status and the severity of the respiratory condition is preferably presented, here "MODERATE BRONCHOSPASM, CONDI-

TION IMPROVING"

**[0111]** Reference is now made additionally to Figs. 16A and 16B, which illustrates the operation of the system and methodology of the system of the present invention in the context of Fig. 15. Figs. 16A and 16B illustrate the utility of using the capnograph in both diagnostic and monitoring modes -as an aid to diagnosis and monitoring respectively.

The patient in the hospital environment, preferably attached to a multi-parameter monitor including capnograph 272 and the suitable instrumentation, by means of cannula 270 and preferably also by means of chest electrodes 274, finger sensor 276, forehead/scalp sensor 278 and blood pressure cuff 280, is monitored continuously.

The neurological status of the patient is acquired by any suitable technique. Values of  $\text{CO}_2$  concentration, ECG, NIBP and  $\text{SPO}_2$  are continuously measured, typically over a period of 30 seconds, and carbon dioxide waveforms are preferably digitized as a capnogram and other waveforms and stored on computer 284.

**[0112]** In the above exemplified scenario (Fig. 15), the medical team initially do not know whether the patient's symptoms are indicative of a breathing-related medical problem, such as emphysema, or from a heart related medical problem, such as heart failure. The following methodology assists and enables the medical team to reach the correct diagnosis. In contrast, in Fig. 11 above, there were no indications that the patient's diagnosis could include a heart-related episode.

**[0113]** Thereafter, the onset and offset limits of the capnogram, the pulse waveform and QRS onset and offset are determined by computer 284. The initial slope of the capnogram and the run are determined and stored in computer 284.

**[0114]** At a startup stage, computer 284 checks to verify that a valid signal is received from capnograph 272. In a case where the signal is indicative of there being obstructive lung disease, due to the sluggish run time for example or an acute angled initial slope, then the mode of monitoring on capnograph 272 is shifted to its bronchospastic monitoring mode.

**[0115]** In a monitoring rule stage, the following rule is preferably applied to the values of the end tidal value of exhaled carbon dioxide:

1) If:

a)  $\text{ETCO}_2$  is greater than 15 mm Hg;

then,

computer 284 displays on display 286 "GOOD WAVEFORM QUALITY; CRITERIA FOR BRONCHOSPASM MET: STARTING MONITORING".

**[0116]** Thereafter a cycle of alternating I) sampling step (data collection and measurement) and II) diagnostic rule application to the previous sample step I) is initiated.

## I) Sampling Step

**[0117]**

- a) A sample of expired air is taken and conveyed from cannula 270 to capnograph 272.
- b) The carbon dioxide concentration is measured continuously by capnograph 272 as a capnogram.
- c) The capnogram is digitized as waveform and store for analysis by computer 284.
- d) Computer 284 marks onset and offset limits of the capnogram.
- e) The waveform quality of the capnogram is assessed by employing the criteria that an acceptable quality is defined by:

- i) the root mean square (rms) of the noise of the waveform must be less than 2 mm Hg; and
- ii) the breath-to-breath correlation must be greater than 0.85.

- f) The slope and the run are determined by computer 284.

## II) Diagnostic Rule Application Step

**[0118]** In a diagnostic rule application step, the following diagnostic rules are preferably applied to the measured parameters of I) Sampling step by computer 284:

## 1) If:

- a) the blood pressure values are within the normal range;
- b) the respiratory rate is normal;
- c) CO<sub>2</sub> run is less than or equal to 0.3 sec;
- d) CO<sub>2</sub> slope is more than or equal to 100 mm Hg/sec;
- e) SPO<sub>2</sub> is greater than or equal to 95% SAT ; and
- f) ETCO<sub>2</sub> is less than or equal to 45 mm Hg;

then,  
display 286 shows the message "NO BROCHOSPASM PRESENT."

## 2) In contrast, if:

- a) CO<sub>2</sub> run is greater than 0.3 sec;
- b) CO<sub>2</sub> slope is less than 100 mm Hg/sec;
- c) SPO<sub>2</sub> is greater than or equal to 91% SAT, but less than 95% SAT; and
- d) ETCO<sub>2</sub> is less than 45 mm Hg;

then,  
the message "MODERATE BRONCHOSPASM PRESENT" is displayed on display 286.

3) If the parameters measured are yet further removed from the acceptable range, such as if:

- a) CAP-FEV1 is less than 50%;
- b) SPO<sub>2</sub> is less than 91% SAT; and
- c) ETCO<sub>2</sub> is greater than 45 mm Hg;

then,  
a message such as "SEVERE BRONCHOSPASM PRESENT" is displayed on display 286.

**[0119]** At any one of the diagnostic rule application steps, it may be verified that the patient is suffering from bronchospasm. Once bronchospasm is verified, the operator switches capnograph 272 to a serial comparison mode. The medical team applies the appropriate interventions to the patient to treat the bronchospasm.

**[0120]** Thereafter, a cycle of alternating I) sampling step (data collection and measurement) and II) monitoring rule application step to the previous sample step I) is initiated.

## I) Sampling Step

25 **[0121]**

- a) A sample of expired air is taken and conveyed from cannula 270 to capnograph 272.
- b) The carbon dioxide concentration is measured continuously by capnograph 272 as a capnogram.
- c) The capnogram is digitized as waveform and store for analysis by computer 284.
- d) Computer 284 marks onset and offset limits of the capnogram.
- e) The waveform quality of the capnogram is assessed by employing the criteria that an acceptable quality is defined by:

- i) the root mean square (rms) of the noise of the waveform must be less than 2 mm Hg; and
- ii) the breath-to-breath correlation must be greater than 0.85.

- f) The slope and the run are determined by computer 284.

## II) Monitoring Rule Application Step

**[0122]** After each time interval, the difference between consecutive measures of each parameter are calculated by computer 284: Thereafter, the following monitoring rules are preferably applied to the measured parameters by computer 284.

## 1) If:

- a) the difference in the run values is greater than 0.1 sec; and

b) the difference in the slope is less than -15 mm Hg /sec;

then,

computer 284 displays on display 286 "BRONCHOSPASM WORSENING". 5

2) If:

- a) the difference in the run values is more negative than -0.1 sec; and 10  
 b) the difference in the slope is more than +15 mm Hg/sec;

then,

computer 284 displays on display 286 "BRONCHOSPASM IMPROVING"

3) If:

- a) the difference in the run is more than or equal to -0.1 sec, but is less than or equal to 0.1 sec; or 20  
 b) the difference in the slope is more than or equal to -15 mm Hg/sec and less than or equal to +15 mm Hg/sec;

then,

computer 284 displays on display 286 "BRONCHOSPASM UNCHANGED".

The change in patient's vital functional activities, including SPO<sub>2</sub> and ETCO<sub>2</sub>, over the time interval are calculated by computer 284. 30

4) If:

- a) the change in SPO<sub>2</sub> is more negative than -5 % SAT; or 35  
 b) the change in the ETCO<sub>2</sub> is more than +5 mm Hg;

then,

computer 284 displays on display 286 "VITAL SIGNS DETERIORATING."

5) If:

- a) the change in SPO<sub>2</sub> is greater than +5 % SAT; or 45  
 b) the change in the ETCO<sub>2</sub> is less than -5 mm Hg;

then,

computer 284 displays on display 286 "VITAL SIGNS IMPROVING".

6) If:

- a) the change in SPO<sub>2</sub> is greater than or equal

to -5 % SAT, but less than or equal to +5 % SAT; or

b) the change in the ETCO<sub>2</sub> is more than or equal to -5 mm Hg, but less than or equal to +5 mm Hg;

then,

computer 284 displays on display 286 "VITAL SIGNS UNCHANGED."

**[0123]** Computer 284 preferably combines the results of these monitoring rules to display an integrated display 286 such as "BRONCHOSPASM WORSENING; VITAL SIGNS UNCHANGED."

**[0124]** Once the medical interventions have concluded and the patient's disposition has been determined, the operator switches the capnograph back to its diagnostic mode. 15

**[0125]** Reference is now made to Fig. 17, which is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology in a hospital environment, operative for continuously monitoring correct tube position in an intubated patient. As seen in Fig. 17, in a hospital environment, various patient physiologic activities are sensed and measured, including respiratory physiologic activities, preferably via an oral airway adapter and/or a nasal or nasal/oral cannula 300, such as a Model Nasal FilterLine Adult XS 04461, O<sub>2</sub>/CO<sub>2</sub> Nasal FilterLine Adult 007141, or Smart CapnoLine Adult (Oral/nasal FilterLine) 007414, commercially available from Oridion Ltd., of Jerusalem Israel, typically coupled with a capnograph 302, such as a Microcap<sup>®</sup>, commercially available from Oridion Ltd., of Jerusalem Israel. Other patient physiologic activities relating to cardiac function (e.g. ECG), systemic oxygenation (e.g. pulse oximetry), cerebral oxygenation (e.g. cerebral oximetry) and systemic circulation (e.g. NIBP), typically sensed by means of chest electrodes 304, a finger sensor 306, a forehead/scalp sensor 308 and a blood pressure cuff 310 respectively, may also be sensed and measured by suitable instrumentation 312. 20 25 30 35 40

**[0126]** The outputs of the capnograph 302 and possibly of additional instrumentation 312 are preferably supplied to a suitably programmed automatic diagnostic and treatment computer 314, having an associated display 316 which typically analyzes the respiration parameter output of the capnograph 302 and possibly other parameters and provides an output which preferably contains a diagnostic statement, here "ALERT !!! LOSS OF CO<sub>2</sub> WAVEFORM" preferably accompanied by a treatment recommendation, here CHECK FOR TUBE DISLODGEMENT". Following re-intubation, a revised diagnostic statement, here "CO<sub>2</sub> WAVEFORM RESTORED, TUBE IN TRACHEA," preferably accompanied by a treatment recommendation, here "SECURE TUBE" appears. 45 50

**[0127]** Reference is now made additionally to Fig. 18, which illustrates the operation of the system and methodology of the system of the present invention in the context of Fig. 17. 55

**[0128]** The patient in the hospital environment, preferably attached to a multi-parameter monitor including capnograph 302 and instrumentation 312, by means of cannula 200 and preferably also by means of chest electrodes 304, finger sensor 306, forehead/scalp sensor 308 and blood pressure cuff 310, is monitored continuously. The neurological status of the patient is acquired by any suitable technique. Expired air is collected via cannula 300 and is conveyed to the capnograph 302.

**[0129]** Values of CO<sub>2</sub> concentration, ECG, NIBP and SPO<sub>2</sub> are continuously measured, typically over a period of 30 seconds, and carbon dioxide waveforms are preferably digitized as a capnogram and together with other waveforms are stored on computer 314.

**[0130]** The onset and offset limits of the patient's capnogram from capnograph 302 are delineated by computer 314.

**[0131]** The waveform quality of the capnogram is assessed by employing the criteria that an acceptable quality is defined by:

- i) the root mean square (rms) of the noise of the waveform must be less than 1 mm Hg; and
- ii) the breath-to-breath correlation must be greater than 0.85.

**[0132]** If the quality is unacceptable, further samples are collected until a sample of acceptable quality, according to the above two criteria, is taken.

**[0133]** The next step entails a checking procedure, wherein the ETCO<sub>2</sub> value is measured by capnograph 302.

**[0134]** The following checking rule is preferably applied.

1) If:

- a) the ETCO<sub>2</sub> value is more than 15 mm Hg;

then,

a display is provided by computer 314 stating "GOOD WAVEFORM, TUBE IN TRACHEA, CONFIRM AND SECURE TUBE" on display 316.

**[0135]** If the intubation is successful, the operator confirms this, by for example, entering the relevant code into computer 314, and capnograph 302 is then entered into an intubation monitoring mode. The patient is monitored continuously. Thus, computer 314 displays "MONITORING INTUBATION" on display 316.

**[0136]** If there is a loss of the signal from capnograph 302, it may be indicative that the cannula tube 300 has slipped away from the patient's trachea. In such a case, the computer preferably displays "ALERT: CHECK FOR TUBE DISLODGEEMENT".

**[0137]** Thereafter a cycle of alternating I) sampling step (data collection and measurement) and II) diagnostic rule application to the previous sample step I) is initiated.

I) Sampling Step

**[0138]** In this sampling step, an exhaled air sample from cannula 300 is periodically collected, conveyed and measured by capnograph 302. The carbon dioxide concentration value is determined continuously by capnograph 302. Computer 314 digitizes the capnograph signals as a waveform and store the waveform for analysis.

**[0139]** Thereafter, the ETCO<sub>2</sub> value is determined.

II) Diagnostic Rule Application Step.

**[0140]** The following diagnostic rules are applied to each sample:

1) If:

- a) The value of ETCO<sub>2</sub> is greater or equal to 15 mm Hg; and
- b) There is no loss in the waveform from capnograph 302;

then,

computer 314 displays "MONITORING TUBE POSITION: NO DISLODGMET" on display 316.

2) If:

- a) The value of ETCO<sub>2</sub> is less than or equal to 15 mm Hg; or
- b) There is a loss in the waveform from capnograph 302;

then,

computer 314 displays "ALERT: CHECK FOR TUBE DISLODGMET" on display 316.

**[0141]** This cycle typically proceeds until the patient monitoring is halted by the medical team or operator.

**[0142]** Reference is now made to Fig. 19, which is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology, operative in a hospital environment, for continuously monitoring the respiratory status of a spontaneously breathing patient in first operational scenario. As seen in Fig. 19, in a hospital environment, various patient physiologic activities are sensed and measured, including respiratory physiologic activities, preferably via an oral airway adapter and/or a nasal or nasal/oral cannula 330, such as a Model Nasal FilterLine Adult XS 04461, O<sub>2</sub>/CO<sub>2</sub> Nasal FilterLine Adult 007141, or Smart CapnoLine Adult (Oral/nasal FilterLine) 007414, commercially available from Oridion Ltd., of Jerusalem Israel, typically coupled with a capnograph 332, such as a Microcap<sup>®</sup>, commercially available from Oridion Ltd., of Jerusalem Israel. Other patient physiologic activities relating to cardiac function (e.g. ECG), systemic oxygenation (e.g. pulse oximetry), cerebral oxygenation (e.g. cerebral oximetry) and sys-

temic circulation (e.g. NIBP), typically sensed by means of chest electrodes 334, a finger sensor 336, a forehead/scalp sensor 338 and a blood pressure cuff 340 respectively, may also be sensed and measured by suitable instrumentation 342.

**[0143]** The outputs of the capnograph 332 and possibly of additional instrumentation 342 are preferably supplied to a suitably programmed automatic diagnostic and treatment computer 344, having an associated display 346 which typically analyzes the respiration parameter output of the capnograph 332 and possibly other parameters and provides an output which preferably contains a diagnostic statement, here "PATIENT STABLE-NO CHANGE IN CLINICAL PARAMETERS. If a change occurs in the patient respiratory status, a diagnostic statement, here "ALERT: MILD BRONCHOSPASM PRESENT" appears on the display 346, indicating to medical personnel that a bronchospastic condition is present. Following administration of breathing treatment, an updated diagnostic statement appears, here "GOOD RESPONSE TO TREATMENT, NO BRONCHOSPASM PRESENT".

**[0144]** Reference is now made additionally to Fig. 20, which illustrates the operation of the system and methodology of the system of the present invention in the context of Fig. 19.

**[0145]** The patient in the hospital environment, preferably attached to a multi-parameter monitor including capnograph 332 and instrumentation 342, by means of cannula 330 and preferably also by means of chest electrodes 334, finger sensor 336, forehead/scalp sensor 338 and blood pressure cuff 340, is monitored continuously. The neurological status of the patient is acquired by any suitable technique. Expired air is collected via cannula 300 and is conveyed to the capnograph 332.

**[0146]** Values of CO<sub>2</sub> concentration, ECG, NIBP and SPO<sub>2</sub> are continuously measured, typically over a period of 30 seconds, and carbon dioxide waveforms are preferably digitized as a capnogram and together with other waveforms are stored on computer 344.

**[0147]** The onset and offset limits of the patient's capnogram from capnograph 332 are delineated by computer 344.

**[0148]** The waveform quality of the capnogram is assessed by employing the criteria that an acceptable quality is defined by:

- i) the root mean square (rms) of the noise of the waveform must be less than 2 mm Hg; and
- ii) the breath-to-breath correlation must be greater than 0.85.

**[0149]** If the quality is unacceptable, further samples are collected until a sample of acceptable quality, according to the above two criteria, is taken.

**[0150]** The next step entails a checking procedure, wherein the ETCO<sub>2</sub> value is measured by capnograph 332. The slope and run values of the capnogram from

capnograph 332 are determined by computer 344.

**[0151]** At startup, the following checking rule is preferably applied.

5 1) If:

- a) the ETCO<sub>2</sub> value is more than 15 mm Hg;

then,

10 a display is provided by computer 344 stating "GOOD WAVEFORM, QUALITY: MONITORING FOR BRONCHOSPASM".

**[0152]** If the monitoring is successful, the operator confirms this, by for example, entering the relevant code into computer 344, and capnograph 332 is then entered into a diagnostic monitoring mode. The patient is monitored continuously by capnograph 332.

**[0153]** Thereafter a cycle of alternating I) sampling step (data collection and measurement) and II) diagnostic rule application to the previous sample step I) is initiated.

I) Sampling Step

25 **[0154]**

- a) A sample of expired air is taken and conveyed from cannula 330 to capnograph 332.
- b) The carbon dioxide concentration is measured continuously by capnograph 332 as a capnogram.
- c) The capnogram is digitized as waveform and store for analysis by computer 344.
- d) Computer 344 marks onset and offset limits of the capnogram.
- e) The waveform quality of the capnogram is assessed by employing the criteria that an acceptable quality is defined by:

- 40 i) the root mean square (rms) of the noise of the waveform must be less than 2 mm Hg; and
- ii) the breath-to-breath correlation must be greater than 0.85.

45 f) The slope and the run are determined by computer 344.

II) Diagnostic Rule Application Step

**[0155]** In a diagnostic rule application step, the following diagnostic rules are preferably applied to the measured parameters of I) Sampling step by computer 344:

1) If:

- 55 a) the blood pressure values are within the normal range;
- b) the respiratory rate is normal;
- c) CO<sub>2</sub> run is less than or equal to 0.3 sec;

- d) CO<sub>2</sub> slope is more than or equal to 100 mm Hg/sec;
- e) SPO<sub>2</sub> is greater than or equal to 95% SAT ; and
- f) ETCO<sub>2</sub> is less than or equal to 45 mm Hg;

then,

display 346 shows the message "NO BRONCHOSPASM PRESENT."

2) In contrast, if:

- a) CO<sub>2</sub> run is greater than 0.3 sec;
- b) CO<sub>2</sub> slope is less than 100 mm Hg/sec;
- c) SPO<sub>2</sub> is greater than or equal to 91% SAT, but less than 95% SAT; and
- d) ETCO<sub>2</sub> is less than 45 mm Hg;

then,

the message "MODERATE BRONCHOSPASM PRESENT" is displayed on display 346. The patient then receives suitable breathing treatment as is shown in Fig. 19 hereinabove.

3) If the parameters measured are yet further removed from the acceptable range, such as if:

- a) CAP-FEV1 is less than 50%;
- b) SPO<sub>2</sub> is less than 91 % SAT; and
- c) ETCO<sub>2</sub> is greater than 45 mm Hg;

then,

a message such as "SEVERE BRONCHOSPASM PRESENT" is displayed on display 346.

**[0156]** Reference is now made to Figs. 21A and 21B, which are simplified pictorial illustrations of an automatic medical diagnostic and treatment system and methodology, operative in a hospital environment, for continuously monitoring the respiratory status of a spontaneously breathing patient in a second clinical scenario. As seen in Figs. 21 A and 21B, in a hospital environment, various patient physiologic activities are sensed and measured, including respiratory physiologic activities, preferably via an oral airway adapter and/or a nasal or nasal/oral cannula 350, such as a Model Nasal FilterLine Adult XS 04461, O<sub>2</sub>/CO<sub>2</sub> Nasal FilterLine Adult 007141, or Smart CapnoLine Adult (Oral/nasal FilterLine) 007414, commercially available from Oridion Ltd., of Jerusalem Israel, typically coupled with a capnograph 352, such as a Microcap<sup>®</sup>, commercially available from Oridion Ltd., of Jerusalem Israel. Other patient physiologic activities relating to cardiac function (e.g. ECG), systemic oxygenation (e.g. pulse oximetry), cerebral oxygenation (e.g., cerebral oximetry) and systemic circulation (e.g. NIBP), typically sensed by means of chest electrodes 354, a finger sensor 356, a forehead/scalp sensor 358 and a blood pressure cuff 360 respectively, may also be sensed and measured by suitable instrumentation 362.

**[0157]** The outputs of the capnograph 352 and possibly

of additional instrumentation 362 are preferably supplied to a suitably programmed automatic diagnostic and treatment computer 364, having an associated display 366 which typically analyzes the respiration parameter output of the capnograph 352 and possibly other parameters and provides an output which preferably contains a diagnostic statement, here "PATIENT STABLE-NO CHANGE IN CLINICAL PARAMETERS. If a change occurs in the patient respiratory status, a diagnostic statement, here "ALERT: MILD BRONCHOSPASM PRESENT" appears on the display 346, indicating to medical personnel that a bronchospastic condition is present. Following administration of breathing treatment, an updated diagnostic statement appears, here "NO RESPONSE TO TREATMENT, MODERATE BRONCHOSPASM PRESENT". Additional breathing treatment is administered and thereafter an updated diagnostic statement appears, here "NO RESPONSE TO TREATMENT, SEVERE BRONCHOSPASM PRESENT", which may prompt the physician to transfer the patient to the ICU.

**[0158]** Reference is now made additionally to Figs. 22A-22C, which illustrates the operation of the system and methodology of the system of the present invention in the context of Figs. 21 A and 21B.

**[0159]** The patient in the hospital environment, preferably attached to a multi-parameter monitor including capnograph 352, is monitored continuously for at least 30 seconds. Expired air is collected via cannula 350 and is conveyed to the capnograph 352.

**[0160]** Values of the CO<sub>2</sub> concentration is continuously measured, typically over a period of 30 seconds, and carbon dioxide waveforms are preferably digitized as a capnogram and together with other waveforms are stored on computer 364.

**[0161]** The onset and offset limits of the patient's capnogram from capnograph 352 are delineated by computer 364.

**[0162]** The waveform quality of the capnogram is assessed by employing the criteria that an acceptable quality is defined by:

- i) the root mean square (rms) of the noise of the waveform must be less than 2 mm Hg; and
- ii) the breath-to-breath correlation must be greater than 0.85.

**[0163]** If the quality is unacceptable, further samples are collected until a sample of acceptable quality, according to the above two criteria, is taken.

**[0164]** The next step entails a checking procedure, wherein the ETCO<sub>2</sub> value is measured by capnograph 352. The slope and run values of the capnogram from capnograph 352 are determined by computer 364.

**[0165]** At startup, the following checking rule is preferably applied.

- 1) If:

a) the  $\text{ETCO}_2$  value is more than 15 mm Hg;

then,

a display is provided by computer 364 stating "GOOD WAVEFORM, QUALITY: MONITORING FOR BRONCHOSPASM".

**[0166]** If the monitoring is successful, the operator confirms this, by for example, entering the relevant code into computer 364, and capnograph 352 is then entered into a diagnostic monitoring mode. The patient is monitored continuously by capnograph 352.

**[0167]** Thereafter a cycle of alternating I) sampling step (data collection and measurement) and II) diagnostic rule application to the previous sample I) is initiated.

#### I) Sampling Step

##### **[0168]**

a) A sample of expired air is taken and conveyed from cannula 350 to capnograph 352.

b) The carbon dioxide concentration is measured continuously by capnograph 352 as a capnogram.

c) The capnogram is digitized as waveform and store for analysis by computer 364.

d) Computer 364 marks onset and offset limits of the capnogram.

e) The waveform quality of the capnogram is assessed by employing the criteria that an acceptable quality is defined by:

i) the root mean square (rms) of the noise of the waveform must be less than 2 mm Hg; and

ii) the breath-to-breath correlation must be greater than 0.85.

f) The slope and the run are determined by computer 364.

#### II) Diagnostic Rule Application Step

**[0169]** In a diagnostic rule application step, the following diagnostic rules are preferably applied to the measured parameters of I) Sampling step by computer 364:

1) If:

a) the blood pressure values are within the normal range;

b) the respiratory rate is normal;

c)  $\text{CO}_2$  run is less than or equal to 0.3 sec;

d)  $\text{CO}_2$  slope is more than or equal to 100 mm Hg/sec;

e)  $\text{SPO}_2$  is greater than or equal to 95% SAT; and

f)  $\text{ETCO}_2$  is less than 45 mm Hg;

then,

display 366 shows the message "NO BRONCHOSPASM PRESENT."

2) In contrast, if:

a)  $\text{CO}_2$  run is greater than 0.3 sec;

b)  $\text{CO}_2$  slope is less than 100 mm Hg/sec;

c)  $\text{SPO}_2$  is greater than or equal to 91% SAT, but less than 95% SAT; and

d)  $\text{ETCO}_2$  is less than 45 mm Hg;

then,

the message "MODERATE BRONCHOSPASM. PRESENT" is displayed on display 366.

3) If the parameters measured are yet further removed from the acceptable range, such as if:

a) CAP-FEV1 is less than 50%;

b)  $\text{SPO}_2$  is less than 91 % SAT; and

c)  $\text{ETCO}_2$  is greater than 45 mm Hg;

then,

a message such as "SEVERE BRONCHOSPASM PRESENT" is displayed on display 366.

**[0170]** At any one of the diagnostic rule application steps, it may be verified that the patient is suffering from bronchospasm. Once bronchospasm is verified, the operator switches capnograph 352 to a serial comparison mode. The medical team applies the appropriate interventions to the patient to treat the bronchospasm.

**[0171]** The patient is attached multi-parameter monitor leads and instrumentation 362, by means of cannula 350 and preferably also by means of chest electrodes 354, finger sensor 356, forehead/scalp sensor 358 and blood pressure cuff 360, is monitored continuously. The neurological status of the patient is acquired by any suitable technique.

**[0172]** Values of the  $\text{CO}_2$  concentration monitored by capnograph 352, and ECG, NIBP, cerebral oximetry and  $\text{SPO}_2$  values, monitored by additional instrumentation 362 are supplied to computer 364, and are typically measured continuously over a period of 30 seconds, by techniques as detailed hereinabove. The parameter data may be digitized as waveforms and are further stored for analysis by computer 364. Thereafter, the limits of the capnogram, the pulse waveform and QRS onset and offset are determined by computer 364.

**[0173]** The next step entails a checking procedure, wherein the  $\text{ETCO}_2$  value is measured by capnograph 352. The initial slope of the capnogram and the run, monitored by capnograph 352, are calculated by computer 364.

**[0174]** At startup, the following checking rule is preferably applied.

1) If:

a) the  $ETCO_2$  value is more than 15 mm Hg;

then,

a display is provided by computer 344 stating "GOOD WAVEFORM, QUALITY: MONITORING FOR BRONCHOSPASM".

**[0175]** If the monitoring is successful, the operator confirms this, by for example, entering the relevant code into computer 364, and capnograph 352 is then entered into a diagnostic monitoring mode. The patient is monitored continuously by capnograph 352.

**[0176]** Thereafter, a cycle of alternating I) sampling step (data collection and measurement) and II) monitoring rule application step to the previous sample step I) is initiated.

I) Sampling Step

**[0177]**

a) A sample of expired air is taken and conveyed from cannula 350 to capnograph 352.

b) The carbon dioxide concentration is measured continuously by capnograph 352 as a capnogram.

c) The capnogram is digitized as waveform and store for analysis by computer 364.

d) Computer 364 marks onset and offset limits of the capnogram.

e) The waveform quality of the capnogram is assessed by employing the criteria that an acceptable quality is defined by:

i) the root mean square (rms) of the noise of the waveform must be less than 2 mm Hg; and

ii) the breath-to-breath correlation must be greater than 0.85.

f) The slope and the run are determined by computer 364.

II) Monitoring Rule Application Step

**[0178]** After each time interval, the difference between consecutive measures of each parameter are calculated by computer 364: Thereafter, the following monitoring rules are preferably applied to the measured parameters by computer 364. (

1) If:

a) the difference in the run values is greater than +0.1 sec; and

b) the difference in the slope is more negative than -15 mm Hg/sec;

then,

computer 364 displays on display 366 "BRON-

CHOSPASM WORSENING".

2) If:

a) the difference in the run values is more negative than -0.1 sec ; and

b) the difference in the slope is more than +15 mm Hg/sec;

then,

computer 364 displays on display 366 "BRONCHOSPASM IMPROVING".

3) If:

a) the difference in the run values is equal to or greater than -0.1 sec, but less than or equal to +0.1 sec; or

b) the difference in the slope is more than or equal to - 15 mm Hg but less than or equal to +15 mm Hg/sec;

then,

computer 364 displays on display 366 "BRONCHOSPASM UNCHANGED".

The change in patient's vital functional activities, including  $SPO_2$  and  $ETCO_2$ , over the time interval are calculated by computer 364.

4) If:

a) the decrease in  $SPO_2$  is more than -5% SAT; or

b) the increase in the  $ETCO_2$  is more than 5 mm Hg;

then,

computer 364 displays on display 366 "VITAL SIGNS DETERIORATING."

5) If:

a) the increase in  $SPO_2$  is more than 5 % SAT; or

b) the decrease in the  $ETCO_2$  is greater than -5 mm Hg;

then,

computer 364 displays on display 366 "VITAL SIGNS IMPROVING".

6) If:

a) the change in  $SPO_2$  is greater than or equal to -5 % SAT but less than or equal to +5% SAT; or

b) the change in the  $ETCO_2$  is more than or equal to - 5 mm Hg or less than or equal to +5 mm Hg;

then,

computer 364 displays on display 366 "VITAL SIGNS UNCHANGED".

Computer 364 preferably combines the results of these monitoring rules to display an integrated display 366 such as "BRONCHOSPASM WORSENING; VITAL SIGNS UNCHANGED."

**[0179]** Once the medical interventions have concluded and the patient's disposition has been determined, the operator switches the capnograph back to its diagnostic mode.

**[0180]** Reference is now made to Figs. 23A and 23B, which are simplified pictorial illustrations of an automatic medical diagnostic and treatment system and methodology operative in a physician's office environment for detecting the presence and severity of bronchospasm, gauging the response to treatment and recommending disposition of a spontaneously breathing patient in a first clinical scenario. As seen in Figs. 23A and 23B, a child having an asthma attack is brought to a physician's office. Various patient physiologic activities are sensed and measured, including respiratory physiologic activities, preferably via an oral airway adapter and/or a nasal or nasal/oral cannula 400, such as a Model Nasal FilterLine Adult XS 04461, O<sub>2</sub>/CO<sub>2</sub> Nasal FilterLine Adult 007141, or Smart CapnoLine Adult (Oral/nasal FilterLine) 007414, commercially available from Oridion Ltd., of Jerusalem Israel, typically coupled with a capnograph 402, such as a Microcap, commercially available from Oridion Ltd., of Jerusalem Israel. Other patient physiologic activities relating to cardiac function (e.g. ECG), systemic oxygenation (e.g. pulse oximetry), cerebral oxygenation (e.g. cerebral oximetry) and systemic circulation (e.g. NIBP), typically sensed by means of chest electrodes 404, a finger sensor 406, a forehead/scalp sensor 408 and a blood pressure cuff 410 respectively, may also be sensed and measured by suitable instrumentation 412.

**[0181]** The outputs of the capnograph 402 and preferably of additional instrumentation 404 are preferably supplied to a suitably programmed automatic diagnostic and treatment computer 416 having an associated display 418, which typically analyzes the respiration parameter output of the capnograph 402 and preferably other physiologic activities and provides an output which preferably contains a diagnostic statement, here "MODERATE BRONCHOSPASM PRESENT".

**[0182]** The patient is given breathing treatments, such as beta agonist nebulizer treatments and following such treatments and/or in the course thereof, the physiologic activities of the patient continue to be monitored. This monitoring is employed by computer 160 to indicate the response to the breathing treatments and the current status of the bronchospasm condition. When the breathing treatments are successful, a status message, here "GOOD RESPONSE TO TREATMENT", is presented accompanied by a disposition recommendation, here "CONSIDER DISCHARGE TO HOME" and the physician may allow the child to return home after the treatment.

**[0183]** Reference is now made additionally to Figs. 24A and 24B, which illustrate the operation of the system and methodology of the system of the present invention in the context of Figs. 23A and 23B. The patient in the clinical environment, preferably attached to a multi-parameter monitor including capnograph 402, is monitored continuously for at least 30 seconds. Expired air is collected via cannula 400 and is conveyed to the capnograph 402.

**[0184]** Values of the CO<sub>2</sub> concentration is continuously measured, typically over a period of 30 seconds, and carbon dioxide waveforms are preferably digitized as a capnogram and together with other waveforms are stored on computer 416.

**[0185]** The onset and offset limits of the patient's capnogram from capnograph 402 are delineated by computer 416.

**[0186]** The waveform quality of the capnogram is assessed by employing the criteria that an acceptable quality is defined by:

- i) the root mean square (rms) of the noise of the waveform must be less than 2 mm Hg; and
- ii) the breath-to-breath correlation must be greater than 0.85.

**[0187]** If the quality is unacceptable, further samples are collected until a sample of acceptable quality, according to the above two criteria, is taken.

**[0188]** The next step entails a checking procedure, wherein the ETCO<sub>2</sub> value is measured by capnograph 402. The slope and run values of the capnogram from capnograph 402 are determined by computer 416.

**[0189]** At startup, the following checking rule is preferably applied.

1) If:

- a) the ETCO<sub>2</sub> value is more than 15 mm Hg;

then,

a display is provided by computer 416 stating "GOOD WAVEFORM, QUALITY: MONITORING FOR BRONCHOSPASM".

**[0190]** If the monitoring is successful, the operator confirms this, by for example, entering the relevant code into computer 416, and capnograph 402 is then entered into a diagnostic monitoring mode. The patient is monitored continuously by capnograph 402.

**[0191]** Thereafter a cycle of alternating I) sampling step (data collection and measurement) and II) diagnostic rule application to the previous sample step I) is initiated. The sampling step is typically performed every 15 minutes for one hour after the treatment.

I) Sampling Step

**[0192]**

- a) A sample of expired air is taken and conveyed from cannula 400 to capnograph 402.  
 b) The carbon dioxide concentration is measured continuously by capnograph 402 as a capnogram 417.  
 c) The capnogram is digitized as waveform and store for analysis by computer 416.  
 d) Computer 416 marks onset and offset limits of the capnogram.  
 e) The waveform quality of the capnogram is assessed by employing the criteria that an acceptable quality is defined by:

- i) the root mean square (rms) of the noise of the waveform must be less than 2 mm Hg; and  
 ii) the breath-to-breath correlation must be greater than 0.85.

- f) The slope and the run are determined by computer 416.

## II) Diagnostic Rule Application Step

**[0193]** In a diagnostic rule application step, the following diagnostic rules are preferably applied to the measured parameters of I) Sampling step by computer 416:

1) If:

- a) the blood pressure values are within the normal range;  
 b) the respiratory rate is normal;  
 c) CO<sub>2</sub> run is less than or equal to 0.3 sec;  
 d) CO<sub>2</sub> slope is more than or equal to 100 mm Hg/sec;  
 e) SPO<sub>2</sub> is greater than or equal to 95% SAT; and  
 f) ETCO<sub>2</sub> is less than or equal to 45 mm Hg;

then,  
 display 418 shows the message "NO BRONCHOSPASM PRESENT."

2) In contrast, if:

- a) CO<sub>2</sub> run is greater than 0.3 sec;  
 b) CO<sub>2</sub> slope is less than 100 mm Hg/sec;  
 c) SPO<sub>2</sub> is more than or equal to 9.1% SAT, but less than 95% SAT; and  
 d) ETCO<sub>2</sub> is less than 45 mm Hg;

then,  
 the message "MODERATE BRONCHOSPASM PRESENT" is displayed on display 418.

3) If the parameters measured are yet further removed from the acceptable range, such as if:

- a) CAP-FEV1 is less than 50%;  
 b) SPO<sub>2</sub> is less than 91 % SAT; and

- c) ETCO<sub>2</sub> is greater than 45 mm Hg;

then,  
 a message such as "SEVERE BRONCHOSPASM PRESENT" is displayed on display 418.

**[0194]** At any one of the diagnostic rule application steps, it may be verified that the patient is suffering from bronchospasm. Once bronchospasm is verified, the operator switches capnograph 402 to a serial comparison mode. The medical team applies the appropriate interventions to the patient to treat the bronchospasm.

**[0195]** The following rule is preferably applied to the capnogram by computer 416:

1) If:

- a) the value of CAP-FEV1 is greater than 50%; and  
 b) the slope is greater or equal to 100 mm Hg/sec; and,  
 c) the angle of rise of the carbon dioxide concentration is greater than a predetermined value in degrees

then,  
 computer 416 displays a message on display 418: "GOOD RESPONSE TO TREATMENT: CONSIDER DISCHARGE HOME."

**[0196]** Reference is now made to Figs. 25A and 25B, which are simplified pictorial illustrations of an automatic medical diagnostic and treatment system and methodology operative in a physician's office environment for detecting the presence and severity of bronchospasm, gauging the response to treatment and recommending disposition of a spontaneously breathing patient in a second clinical scenario. As seen in Figs. 25A and 25B, a child having an asthma attack is brought to a physician's office. Various patient physiologic activities are sensed and measured, including respiratory physiologic activities, preferably via an oral airway adapter and/or a nasal or nasal/oral cannula 420, such as a Model Nasal Filter-Line Adult XS 04461, O<sub>2</sub>/CO<sub>2</sub> Nasal FilterLine Adult 007141, or Smart CapnoLine Adult (Oral/nasal Filter-Line) 007414, commercially available from Oridion Ltd., of Jerusalem Israel, typically coupled with a capnograph 422, such as a Microcap, commercially available from Oridion Ltd., of Jerusalem Israel. Other patient physiological activities relating to cardiac function (e.g. ECG), systemic oxygenation (e.g. pulse oximetry), cerebral oxygenation (e.g. cerebral oximetry) and systemic circulation (e.g. NIBP), typically sensed by means of chest electrodes 424, a finger sensor 426, a forehead/scalp sensor 428 and a blood pressure cuff 430 respectively, may also be sensed and measured by suitable instrumentation 432.

**[0197]** The outputs of the capnograph 422 and prefer-

ably of additional instrumentation 424 are preferably supplied to a suitably programmed automatic diagnostic and treatment computer 426 having an associated display 428, which typically analyzes the respiration parameter output of the capnograph 422 and preferably other physiologic activities and provides an output which preferably contains a diagnostic statement, here "MODERATE BRONCHOSPASM PRESENT".

**[0198]** The patient is given breathing treatments, such as beta agonist nebulizer treatments and following such treatments and/or in the course thereof, the physiologic activities of the patient continue to be monitored. This monitoring is employed by computer 426 to indicate the response to the breathing treatments and the current status of the bronchospasm condition. When the breathing treatments are not successful, a status message, here "POOR RESPONSE TO TREATMENT", is presented accompanied by a disposition recommendation, here "CONSIDER ADMISSION TO HOSPITAL" and the physician may send the child to the hospital.

**[0199]** Reference is now made additionally to Figs. 26A and 26B, which illustrate the operation of the system and methodology of the system of the present invention in the context of Figs. 25A and 25B.

**[0200]** The patient in the clinical environment, preferably attached to a multi-parameter monitor including capnograph 422, is monitored continuously for at least 30 seconds. Expired air is collected via cannula 420 and is conveyed to the capnograph 422.

**[0201]** Values of the CO<sub>2</sub> concentration is continuously measured, typically over a period of 30 seconds, and carbon dioxide waveforms are preferably digitized as a capnogram and together with other waveforms are stored on computer 426.

**[0202]** The onset and offset limits of the patient's capnogram from capnograph 422 are delineated by computer 426.

**[0203]** The waveform quality of the capnogram is assessed by employing the criteria that an acceptable quality is defined by:

- i) the root mean square (rms) of the noise of the waveform must be less than 2 mm Hg; and
- ii) the breath-to-breath correlation must be greater than 0.85.

**[0204]** If the quality is unacceptable, further samples are collected until a sample of acceptable quality, according to the above two criteria, is taken.

**[0205]** The next step entails a checking procedure, wherein the ETCO<sub>2</sub> value is measured by capnograph 422. The slope and run values of the capnogram from capnograph 422 are determined by computer 426.

**[0206]** At startup, the following checking rule is preferably applied.

- 1) If:

- a) the ETCO<sub>2</sub> value is more than 15 mm Hg;

then,

a display is provided by computer 426 stating "GOOD WAVEFORM, QUALITY: MONITORING FOR BRONCHOSPASM".

**[0207]** If the monitoring is successful, the operator confirms this, by for example, entering the relevant code into computer 426, and capnograph 422 is then entered into a diagnostic monitoring mode. The patient is monitored continuously by capnograph 422.

**[0208]** Thereafter a cycle of alternating I) sampling step (data collection and measurement) and II) diagnostic rule application to the previous sample step I) is initiated. The sampling step is typically performed every 15 minutes for one hour after the treatment.

#### I) Sampling Step

##### **[0209]**

a) A sample of expired air is taken and conveyed from cannula 420 to capnograph 422.

b) The carbon dioxide concentration is measured continuously by capnograph 422 as a capnogram.

c) The capnogram is digitized as waveform and store for analysis by computer 426.

d) Computer 426 marks onset and offset limits of the capnogram.

e) The waveform quality of the capnogram is assessed by employing the criteria that an acceptable quality is defined by:

- i) the root mean square (rms) of the noise of the waveform must be less than 2 mm Hg; and
- ii) the breath-to-breath correlation must be greater than 0.85.

f) The slope and the run are determined by computer 426.

#### II) Diagnostic Rule Application Step

**[0210]** In a diagnostic rule application step, the following diagnostic rules are preferably applied to the measured parameters of I) Sampling step by computer 426:

- 1) If:

a) the blood pressure values are within the normal range;

b) the respiratory rate is normal;

c) CO<sub>2</sub> run is less than or equal to 0.3 sec;

d) CO<sub>2</sub> slope is more than or equal to 100 mm Hg/sec;

e) SPO<sub>2</sub> is greater than or equal to 95% SAT; and

f)  $\text{ETCO}_2$  is less than or equal to 45 mm Hg;

then,

display 428 shows the message "NO BRONCHOSPASM PRESENT."

2) In contrast, if:

- a)  $\text{CO}_2$  run is greater than 0.3 sec;
- b)  $\text{CO}_2$  slope is less than 100 mm Hg/sec;
- c)  $\text{SPO}_2$  is greater than or equal to 91% SAT, but less than 95% SAT; and
- d)  $\text{ETCO}_2$  is less than 45 mm Hg;

then,

the message "MODERATE BRONCHOSPASM PRESENT" is displayed on display 428.

3) If the parameters measured are yet further removed from the acceptable range, such as if:

- a) CAP-FEV1 is less than 50%;
- b)  $\text{SPO}_2$  is less than 91 % SAT; and
- c)  $\text{ETCO}_2$  is greater than 45 mm Hg;

then,

a message such as "SEVERE BRONCHOSPASM PRESENT" is displayed on display 428.

**[0211]** At any one of the diagnostic rule application steps, it may be verified that the patient is suffering from bronchospasm. Once bronchospasm is verified, the operator switches capnograph 422 to a serial comparison mode. The medical team applies the appropriate interventions to the patient to treat the bronchospasm.

**[0212]** The following rule is preferably applied to the capnogram by computer 426:

1) If:

- a) the value of CAP-FEV1 is less than 50%; and
- b) the slope is less than 100 mm Hg/sec; and,
- c) the angle of rise of the carbon dioxide concentration is less than a predetermined value in degrees;

then,

computer 426 displays a message on display 428: "POOR RESPONSE TO TREATMENT: CONSIDER ADMISSION TO HOSPITAL INTENSIVE CARE."

**[0213]** Reference is now made to Figs. 27A and 27B, which are simplified pictorial illustrations of an automatic medical diagnostic and treatment system and methodology in an ambulance environment for detecting the presence and severity of bronchospasm from an allergic reaction, gauging the response to treatment and recommending disposition. As seen in Figs. 27A and 27B, a child complains of difficulty breathing. The parent summons an ambulance and similarly to that described here-

inabove with reference to Fig. 9, in an ambulance environment various patient physiologic activities are sensed and measured, including respiratory physiologic activities, preferably via an oral airway adapter and/or a nasal or nasal/oral cannula 450, such as a Model Nasal Filter-Line Adult XS 04461,  $\text{O}_2/\text{CO}_2$  Nasal FilterLine Adult 007141, or Smart CapnoLine Adult (Oral/nasal Filter-Line) 007414, commercially available from Oridion Ltd., of Jerusalem Israel, typically coupled with a capnograph 452, such as a Microcap, commercially available from Oridion Ltd., of Jerusalem Israel. Other patient physiologic activities relating to cardiac function (e.g. ECG), systemic oxygenation (e.g. pulse oximetry), cerebral oxygenation (e.g. cerebral oximetry) and systemic circulation (e.g. NIBP), typically sensed by means of chest electrodes 454, a finger sensor 456, a forehead/scalp sensor 458 and a blood pressure cuff 460 respectively, may also be sensed and measured by suitable instrumentation 462. Other patient physiologic activities relating to cardiac function (e.g. ECG), cerebral perfusion (e.g. CEREBRAL OXIMETRY), oxygenation (e.g. pulse oximetry) and systemic circulation (e.g. NIBP), may also be sensed and measured by suitable instrumentation 462.

**[0214]** The outputs of the capnograph 452 and preferably of additional instrumentation 462 are preferably supplied to a suitably programmed automatic diagnostic and treatment computer 464 having an associated display 466, which typically analyzes the respiration parameter output of the capnograph 452 and preferably other physiologic activities and provides an output which preferably contains a diagnostic statement indicating the presence of lower airway obstruction, here "ALERT: MODERATE BRONCHOSPASM PRESENT". The presence of bronchospasm definitively indicates lower airway obstruction.

**[0215]** The patient is given breathing treatment, such as a beta agonist nebulizer treatment and following such treatment and/or in the course thereof, the physiologic activities of the patient continue to be monitored. This monitoring is employed by computer 464 to indicate the response to the breathing treatment and the current status of the patient condition. In the scenario of Figs. 14A and 14B, the patient fails to respond sufficiently to the breathing treatment and this is indicated by a status change statement, here "POOR RESPONSE TO TREATMENT, CONDITION CRITICAL". A treatment recommendation may also be provided, such as "CONSIDER INTUBATION".

**[0216]** Intubation is performed and correct initial tube placement is confirmed followed by continuous monitoring of the physiologic activities of the patient, which indicate current tube position. In this scenario, where intubation is successful, a status statement, here: "ADEQUATE  $\text{CO}_2$  WAVEFORM - TUBE IN TRACHEA" and a treatment recommendation, here "SECURE TUBE" appear.

**[0217]** Following successful intubation, continuous monitoring may provide a status statement such as "ADEQUATE  $\text{CO}_2$  WAVEFORM-TUBE IN TRACHEA-NO

DISLOGEMENT". If tube dislodgment occurs at any time following intubation, a status statement would appear, such as "CO<sub>2</sub> WAVEFORM ABSENT" preferably accompanied by a treatment recommendation, such as "CHECK FOR TUBE DISLOGEMENT".

[0218] Preferably some or all of the outputs of computer 464 are transmitted in a wireless manner by a transmitter 468, such as via radio or a cellular telephone link, preferably to a dispatch center or patient receiving facility.

[0219] Reference is now made additionally to Fig. 28, which illustrates the operation of the system and methodology of the system of the present invention in the context of Figs. 27A and 27B. Fig. 28 illustrates an example of the system and methodology applied to assessing whether a patient has an upper or lower airway obstruction, in the duration of the patient being transferred by ambulance.

[0220] In the scenario described in Figs. 27A and 27B hereinabove, it is presumed that the patient may be having an allergic reaction. The operator switches capnograph 452 into an assessing mode so as to enable an assessment to be made whether and if the patient has an upper or a lower airway disorder.

The patient previously attached to a multi-parameter monitor including a capnograph 452 and suitable instrumentation 462, by means of cannula 450 and preferably also by means of chest electrodes 454, finger sensor 456, forehead sensor 458 and blood pressure cuff 460, is monitored continuously for at least thirty seconds. Neurological status of the patient is acquired by any suitable technique, including visual and electroencephalograph (EEG) monitoring. Values of CO<sub>2</sub> concentration, ECG, NIBP and (the percent saturation of the hemoglobin molecule with oxygen) SPO<sub>2</sub> are continuously monitored, and carbon dioxide waveforms are preferably digitized as a capnogram 452 and together with other waveforms are stored in computer 464.

[0221] At least one expired air sample is collected and conveyed for analysis by capnograph 452. The outputs of the capnograph 452 and possibly of additional instrumentation 462 are preferably supplied to suitably programmed automatic diagnostic and treatment computer 464, having associated display 466, which typically analyzes the respiration parameter output of the capnograph 452.

[0222] In an analyzing step, the onset and offset limits of a capnogram 469, pulse waveforms, and the QRS complex (of the ECG) are marked by computer 464. The actual parameters measured include, but are not limited to heart rate (HR), BP, the systolic to diastolic ratio (SYS / DIA). SPO<sub>2</sub>, AND ETCO<sub>2</sub>. The slope of CO<sub>2</sub> (mm Hg/sec), and CO<sub>2</sub> "run", of the capnogram 469, measured to 80% of maximum CO<sub>2</sub> concentration, are calculated by computer 464.

[0223] Following each treatment, the differences between consecutive measurements of the various patient parameters are computed by computer 464. Thereafter, in a diagnostic rule application step, the following diag-

nostic rules are preferably applied to the measured parameters by computer 464:

1) If:

- a) the blood pressure values are within the normal range;
- b) the respiratory rate is normal; and
- c) ETCO<sub>2</sub> is less than 45 mm Hg;

then,  
display 466 shows the message "VITAL SIGNS STABLE".

2) In contrast, if:

1) If:

- a) the blood pressure values are not within the normal range;
- b) the respiratory rate is not normal; and
- c) ETCO<sub>2</sub> is more than or equal to 45 mm Hg;

then,  
display 466 shows the message "RESPIRATORY IMPAIRMENT".

[0224] Additionally, the following rules may also be applied:

3) If:

- a) CO<sub>2</sub> run is less than or equal to 0.3 sec; and
- b) CO<sub>2</sub> slope is more than or equal to 100 mm Hg/sec;

then,  
display 466 shows the message "NO BRONCHOSPASM PRESENT: CONSIDER UPPER AIRWAY OBSTRUCTION".

4) If:

- a) CO<sub>2</sub> run is more than 0.3 sec;
- b) CO<sub>2</sub> slope is less than 100 mm Hg/sec;

then,  
display 466 shows the message "BRONCHOSPASM PRESENT: CONSIDER LOWER AIRWAY OBSTRUCTION".

[0225] The findings of the last stage are stored by computer 464 and/or transmitted via transmitter 468 to a dispatch/receiving center, typically located at a hospital or medical center. A connection is established with the dispatch/receiving center, and the data is forwarded thereto. A medical supervisor typically watches display of the received data, and consequentially transmits the recom-

mended treatment and/or transport recommendations back to the ambulance.

**[0226]** After each time interval, the difference between consecutive measures of each parameter are calculated by computer 464: Thereafter, the following monitoring rules are preferably applied to the measured parameters by computer 464.

1) If:

- a) the difference in the run values is greater than +0.1 sec; and
- b) the difference in the slope is more negative than -15 mm Hg/sec;

then,  
computer 464 displays on display 466 "BRONCHOSPASM WORSENING".

2) If:

- a) the difference in the run values is more negative than -0.1 sec; and
- b) the difference in the slope is more positive than +15 mm Hg/sec;

then,  
computer 464 displays on display 466 "BRONCHOSPASM IMPROVING".

3) If:

- a) the difference in the run is greater or equal to -0.1 sec, but less than or equal to +0.1 sec; or
- b) the difference in the slope is more than or equal to -15 mm Hg/sec and less than or equal to +15 mm Hg/sec;

then,  
computer 464 displays on display 466 "BRONCHOSPASM UNCHANGED".

The change in patient's vital functional activities, including SPO<sub>2</sub> and ETCO<sub>2</sub>, over the time interval are calculated by computer 464.

4) If:

- a) the decrease in SPO<sub>2</sub> is more negative than -5% SAT; or
- b) the increase in the ETCO<sub>2</sub> is more than +5 mm Hg;

then,  
computer 184 displays on display 186 "VITAL SIGNS DETERIORATING".

5) If:

- a) the increase in SPO<sub>2</sub> is more than +5 % SAT; or
- b) the decrease in the ETCO<sub>2</sub> is more than -5 mm Hg;

then,  
computer 464 displays on display 466 "VITAL SIGNS IMPROVING".

6) If:

- a) the change in SPO<sub>2</sub> is greater than or equal to -5 % SAT, but less than or equal to +5% SAT; or
- b) the change in the ETCO<sub>2</sub> is more than or equal to -5 mm Hg, but less than or equal to +5 mm Hg;

then,  
computer 464 displays on display 466 "VITAL SIGNS UNCHANGED."

**[0227]** Computer 464 preferably combines the results of these monitoring rules to display an integrated display 466 such as "BRONCHOSPASM WORSENING; VITAL SIGNS UNCHANGED."

**[0228]** In a checking rule step, the following rule is preferably applied:

1) A patient appears to be entering respiratory failure phase if:

- a) the SPO<sub>2</sub> is less than 90% SAT;
- b) the respiratory rate is less than 8/min;
- c) ETCO<sub>2</sub> is greater than 60 mm Hg; and
- d) the patient's neurological symptoms are qualified as being "bad";

then,  
computer 464 displays "RESPIRATORY FAILURE; CONDITION CRITICAL; CONSIDER INTUBATION." on display 466.

**[0229]** Following this, in an alert data transmission stage, a high priority update is transmitted via transmitter 468 from computer 464 to notify the dispatch / receiving centers of the significant deterioration and change in the patient's condition.

**[0230]** Once these changes in the patient's condition have been confirmed by an operator, the patient is consequentially intubated according to standard techniques and capnograph 452 is activated in intubation monitoring mode by computer 464. Once the successful intubation of the patient is verified by data comparison of the patient's capnogram and standardized capnograms for intubation in computer 464, the computer displays "MONITORING FOR INTUBATION".

**[0231]** Thereafter, the following check rule is preferably applied to the patient's capnogram:

1. If:

a)  $\text{ETCO}_2$  is greater than 15 mm Hg;

then,

computer 464 displays "GOOD WAVEFORM, TUBE IN TRACHEA. CONFIRM AND SECURE TUBE."

**[0232]** In the next step, the following monitoring rules are preferably applied to the patient's capnogram:

1) If:

a) the value of  $\text{ETCO}_2$  is greater than 15 mm Hg;

then,

computer 214 displays "MONITORING TUBE POSITION: NO DISLODGE MENT" on display 216.

2) If:

a) the value of  $\text{ETCO}_2$  is less than or equal to 15 mm Hg; or

b) there is a loss of the waveform;

then,

computer 464 displays "ALERT: CHECK FOR TUBE DISLODGE MENT" on display 466.

**[0233]** Computer 464 transmits the data monitored via transmitter 468 to the receiving center. The receiving center periodically receives updates of the patient's condition, who is in the ambulance en route to the hospital, in order to prepare in the most fitting and efficient transfer of the patient upon arrival to the hospital.

**[0234]** A copy of the patient's record is handed off from computer 464 via transmitter 468 to the receiving center, for example, in the form of a chart. Typically, the receiving center stores this chart, so that it may be used as a baseline for continued monitoring of the patient.

**[0235]** Reference is now made to Fig. 29, which is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology in an ambulance environment for distinguishing between upper airway obstruction and lower airway obstruction, such as distinguishing between asthma and croup, bronchiolitis and croup, and allergic reactions affecting the upper or lower airways. As seen in Fig. 29, a person complains of difficulty breathing. An ambulance is summoned and similarly to that described hereinabove with reference to Fig. 17, in an ambulance environment various patient physiologic activities are sensed and measured, including respiratory physiologic activities, preferably via an oral airway adapter and/or a nasal or nasal/oral cannula 470, such as a Model Nasal FilterLine Adult XS 04461,  $\text{O}_2/\text{CO}_2$  Nasal FilterLine Adult 007141, or Smart CapnLine Adult (Oral/nasal FilterLine) 007414, commercially available from Oridion Ltd., of Jerusalem Israel, typically

coupled with a capnograph 472, such as a Microcap, commercially available from Oridion Ltd., of Jerusalem Israel. Other patient physiologic activities relating to cardiac function (e.g. ECG), systemic oxygenation (e.g. pulse oximetry), cerebral oxygenation (e.g. cerebral oximetry) and systemic circulation (e.g. NIBP), typically sensed by means of chest electrodes 474, a finger sensor 476, a forehead/scalp sensor 478 and a blood pressure cuff 480 respectively, may also be sensed and measured by suitable instrumentation 482. Other patient physiologic activities relating to cardiac function (e.g. ECG), cerebral perfusion (e.g. CEREBRAL OXIMETRY), oxygenation (e.g. pulse oximetry) and systemic circulation (e.g. NIBP), may also be sensed and measured by suitable instrumentation 482.

**[0236]** The outputs of the capnograph 472 and preferably of additional instrumentation 482 are preferably supplied to a suitably programmed automatic diagnostic and treatment computer 484 having an associated display 486, which typically analyzes the respiration parameter output of the capnograph 472 and preferably other physiologic activities and provides an output which preferably contains a diagnostic statement differentiating upper airway obstruction from lower airway obstruction, here "ELEVATED RESPIRATORY RATE. NO BRONCHOSPASM PRESENT". The absence of bronchospasm in this scenario strongly suggests upper airway obstruction.

**[0237]** The patient is given an intravenous or intra-muscular medication, such as adrenaline, and following such treatment and/or in the course thereof, the physiologic activities of the patient continue to be monitored. This monitoring is employed by computer 484 to indicate the response to the treatment and the current status of the patient condition. In the scenario of Fig. 29, the patient responds to the treatment and this is indicated by a status change statement, here "CONDITION STABLE". Preferably some or all of the outputs of computer 484 are transmitted in a wireless manner by a transmitter 488, such as via radio or a cellular telephone link, preferably to a dispatch center or patient receiving facility.

**[0238]** Reference is now made additionally to Fig. 30, which illustrates the operation of the system and methodology of the system of the present invention in the context of Fig. 29. The patient is treated in an ambulance environment as is described hereinabove in Fig. 29; and the patient is being assessed to see whether his/her upper or lower airway is obstructed. The methodology illustrates the case where an upper obstruction is found.

**[0239]** In the scenario described in Fig. 29 hereinabove, it is presumed that the patient may be having an allergic reaction. The operator switches capnograph 452 into an assessing mode so as to enable an assessment to be made whether and if the patient has an upper or a lower airway disorder.

**[0240]** The patient previously attached to a multi-parameter monitor including a capnograph 472 and suitable instrumentation 482, by means of cannula 470 and preferably also by means of chest electrodes 474, finger sen-

sensor 476, forehead sensor 478 and blood pressure cuff 480, is monitored continuously for at least thirty seconds. Neurological status of the patient is acquired by any suitable technique, including visual and electroencephalograph (EEG) monitoring. Values of CO<sub>2</sub> concentration, ECG, NIBP and SPO<sub>2</sub> are continuously monitored, and carbon dioxide waveforms are preferably digitized as a capnogram 472 and together with other waveforms are stored in computer 484.

**[0241]** At least one expired air sample is collected and conveyed for analysis by capnograph 472. The outputs of the capnograph 472 and possibly of additional instrumentation 482 are preferably supplied to suitably programmed automatic diagnostic and treatment computer 484, having associated display 486, which typically analyzes the respiration parameter output of the capnograph 472.

**[0242]** In an analyzing step, the onset and offset limits of a capnogram 489, pulse waveforms, and the QRS complex (of the ECG) are marked by computer 484. The actual parameters measured include, but are not limited to heart rate (HR), BP, the systolic to diastolic ratio (SYS / DIA), SPO<sub>2</sub>, AND ETCO<sub>2</sub>. The slope of CO<sub>2</sub> (mm Hg/sec), and CO<sub>2</sub> "run", of the capnogram 489, measured to 80% of maximum CO<sub>2</sub> concentration, are calculated by computer 484.

**[0243]** Following each treatment, the differences between consecutive measurements of the various patient parameters are computed by computer 484. Thereafter, in a diagnostic rule application step, the following diagnostic rules are preferably applied to the measured parameters by computer 484:

1) If:

- a) the blood pressure values are within the normal range;
- b) the respiratory rate is normal; and
- c) ETCO<sub>2</sub> is less than 45 mm Hg;

then,  
display 486 shows the message "VITAL SIGNS STABLE".

2) In contrast, if:

1) If:

- a) the blood pressure values are not within the normal range;
- b) the respiratory rate is not normal; and
- c) ETCO<sub>2</sub> is more than or equal to 45 mm Hg;

then,  
display 486 shows the message "RESPIRATORY IMPAIRMENT".

**[0244]** Additionally, the following rules may also be applied:

3) If:

- a) CO<sub>2</sub> run is less than 0.3 sec;
- b) CO<sub>2</sub> slope is more than 100 mm Hg/sec;

then,  
display 486 shows the message "NO BRONCHOSPASM PRESENT".

4) If:

- a) CO<sub>2</sub> run is more than 0.3 sec;
- b) CO<sub>2</sub> slope is less than 100 mm Hg/sec;

then,  
display 486 shows the message "BRONCHOSPASM PRESENT: CONSIDER LOWER AIRWAY OBSTRUCTION".

**[0245]** The findings of the last stage are stored by computer 484 and/or transmitted via transmitter 488 to a dispatch/receiving center, typically located at a hospital or medical center. A connection is established with the dispatch/receiving center, and the data is forwarded thereto. A medical supervisor typically watches display of the received data, and consequentially transmits the recommended treatment and/or transport recommendations back to the ambulance.

**[0246]** A copy of the patient's record is handed off from computer 464 via transmitter 488 to the receiving center, for example, in the form of a chart. Typically, the receiving center stores this chart, so that it may be used as a baseline for continued monitoring of the patient.

**[0247]** Reference is now made to Fig. 31, which is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology for distinguishing between heart failure and emphysema in a scenario in which heart failure is present. As seen in Fig. 31, various patient physiologic activities are sensed and measured, including respiratory physiologic activities, preferably via an oral airway adapter and/or a nasal or nasal/oral cannula 500, such as a Model Nasal FilterLine Adult XS 04461, O<sub>2</sub>/CO<sub>2</sub> Nasal FilterLine Adult 007141, or Smart CapnoLine Adult (Oral/nasal. FilterLine) 007414, commercially available from Oridion Ltd., of Jerusalem Israel, typically coupled with a capnograph 502, such as a Microcap<sup>®</sup>, commercially available from Oridion Ltd., of Jerusalem Israel. Other patient physiologic activities relating to cardiac function (e.g. ECG), systemic oxygenation (e.g. pulse oximetry), cerebral oxygenation (e.g. cerebral oximetry) and systemic circulation (e.g. NIBP), typically sensed by means of chest electrodes 504, a finger sensor 506, a forehead/scalp sensor 508 and a blood pressure cuff 510 respectively, may also be sensed and measured by suitable instrumentation 512.

**[0248]** The outputs of the capnograph 502 and possibly of additional instrumentation 512 are preferably supplied to a suitably programmed automatic diagnostic and treatment computer 514, having an associated display 516 which typically analyzes the respiration parameter output of the capnograph 517 and possibly other parameters and provides an output which preferably contains a diagnostic statement differentiating heart failure from emphysema, here "ABNORMAL CO<sub>2</sub> WAVEFORM CONSISTENT WITH MODERATE CONGESTIVE HEART FAILURE".

**[0249]** This diagnostic statement indicates that treatment is required for heart failure rather than for emphysema. Intravenous and/or sublingual medications such as nitroglycerin, morphine and LASIX<sup>R</sup> are administered after which a diagnostic statement which indicates the patient status and the severity of the cardio-respiratory condition is preferably presented, here "MILD CONGESTIVE HEART FAILURE, CONDITION IMPROVING"

**[0250]** Reference is now made additionally to Figs. 32A and 32B, which illustrate the operation of the system and methodology of the system of the present invention in the context of Fig. 31. The patient is treated in an ambulance environment as is described hereinabove in Fig. 15, and the patient is being assessed to see whether his/her upper or lower airway is obstructed. The methodology illustrates the case where an upper obstruction is found.

**[0251]** In the scenario described in Fig. 31 hereinabove, it is presumed that the patient may be suffering from either emphysema or a heart failure in an ambulance. It is shown hereinbelow how the patient is diagnosed as having a heart failure.

**[0252]** The patient, previously attached to a multi-parameter monitor including a capnograph 502 and suitable instrumentation 512, by means of cannula 500 and preferably also by means of chest electrodes 504, finger sensor 506, forehead sensor 508 and blood pressure cuff 510, is monitored continuously for at least thirty seconds. Neurological status of the patient is acquired by any suitable technique, including visual and electroencephalograph (EEG) monitoring. Values of CO<sub>2</sub> concentration, ECG, NIBP and SPO<sub>2</sub> are continuously monitored, and carbon dioxide waveforms are preferably digitized as a capnogram 517 and together with other waveforms are stored in computer 514.

**[0253]** At least one expired air sample is collected and conveyed for analysis by capnograph 472. The outputs of the capnograph 502 and possibly of additional instrumentation 512 are preferably supplied to suitably programmed automatic diagnostic and treatment computer 514, having associated display 516, which typically analyzes the respiration parameter output of the capnograph 502.

**[0254]** In an analyzing step, the onset and offset limits of a capnogram 517, pulse waveforms, and the QRS complex (of the ECG) are marked by computer 514. The actual parameters measured include, but are not limited

to heart rate (HR), BP, the systolic to diastolic ratio (SYS / DIA), SPO<sub>2</sub>, AND ETCO<sub>2</sub>. The slope of CO<sub>2</sub> (mm Hg/sec), and CO<sub>2</sub> "run", of the capnogram 517, measured to 80% of maximum CO<sub>2</sub> concentration, are calculated by computer 514.

**[0255]** Following each treatment, the differences between consecutive measurements of the various patient parameters are computed by computer 514. Thereafter, in a diagnostic rule application step, the following diagnostic rules are preferably applied to the measured parameters by computer 514:

1) If:

- a) the blood pressure values are within the normal range;
- b) the respiratory rate is normal; and
- c) ETCO<sub>2</sub> is less than 45 mm Hg;

then,  
display 516 shows the message "VITAL SIGNS WITHIN NORMAL LIMITS".

2) In contrast, if:

- a) the value of Diminished CAP-FEV1 is a 40:10 point ratio; and,
- b) Normal CAP-FEV1/FVC (FORCED VITAL CAPACITY);
- c) CO<sub>2</sub> run is less than 0.3 sec;
- d) CO<sub>2</sub> slope is more than 100 mm Hg/sec;

then,  
display 516 shows the message "HEART FAILURE PRESENT".

**[0256]** Additionally, if a heart failure is present then the following rules may also be applied:

3) If:

- a) the value of CAP-FEV1 is less than 80%;

then  
display 516 shows the message "MODERATE HEART FAILURE PRESENT".

4) If:

- a) the value of CAP-FEV 1 is less than 80%;
- b) the value of SPO<sub>2</sub> is less than 91 % SAT; and
- c) the value of ETCO<sub>2</sub> is less than 45 mm Hg;

then,  
display 516 shows the message "SEVERE HEART FAILURE PRESENT".

**[0257]** Thereafter a cycle of alternating I) sampling step

(data collection and measurement) and II) diagnostic rule application to the previous sample step I) is initiated.

#### I) Sampling Step

##### [0258]

- a) A sample of expired air is taken and conveyed from cannula 500 to capnograph 502.
- b) The carbon dioxide concentration is measured continuously by capnograph 502 as capnogram 517.
- c) The capnogram is digitized as waveform and store for analysis by computer 514.
- d) Computer 514 marks onset and offset limits of the capnogram.
- e) The waveform quality of the capnogram is assessed by employing the criteria that an acceptable quality is defined by:

- i) the root mean square (rms) of the noise of the waveform must be less than 2 mm Hg; and
- ii) the breath-to-breath correlation must be greater than 0.85.

- f) The slope and the run are determined by computer 514.

#### II) Diagnostic Rule Application Step

**[0259]** In a diagnostic rule application step, the following diagnostic rules are preferably applied to the measured parameters of I) Sampling step by computer 514:

##### 1) If:

- a) the blood pressure values are within the normal range;
- b) the respiratory rate is normal;
- c) CO<sub>2</sub> run is less than or equal to 0.3 sec;
- d) CO<sub>2</sub> slope is more than or equal to 100 mm Hg/sec;
- e) SPO<sub>2</sub> is greater than or equal to 95% SAT ; and
- f) ETCO<sub>2</sub> is less than or equal to 45 mm Hg;

then,

display 516 shows the message "NO HEART FAILURE PRESENT."

##### 2) If:

- a) the value of CAP-FEV1 is more than 50%, but less than or equal to 80%; and
- b) the value of SPO<sub>2</sub> is greater or equal to 91% SAT but less than 95% SAT;

then

display 516 shows the message "MODERATE HEART FAILURE PRESENT".

##### 3) If:

- a) the value of CAP-FEV is less than 80%;
- b) the value of SPO<sub>2</sub> is less than 91 % SAT; and
- c) the value of ETCO<sub>2</sub> is less than 45 mm Hg;

then,

display 516 shows the message "SEVERE HEART FAILURE PRESENT".

**[0260]** Reference is now made to Fig. 33, which is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology operative in an ambulance environment for treating pulmonary edema. As seen in Fig. 33, various patient physiologic activities are sensed and measured, including respiratory physiologic activities, preferably via an oral airway adapter and/or a nasal or nasal/oral cannula 550, such as a Model Nasal FilterLine Adult XS 04461, O<sub>2</sub>/CO<sub>2</sub> Nasal FilterLine Adult 007141, or Smart CapnoLine Adult (Oral/nasal FilterLine) 007414, commercially available from Oridion Ltd., of Jerusalem Israel, typically coupled with a capnograph 552, such as a Microcap, commercially available from Oridion Ltd., of Jerusalem Israel. Other patient physiologic activities relating to cardiac function (e.g. ECG), systemic oxygenation (e.g. pulse oximetry), cerebral oxygenation (e.g. cerebral oximetry) and systemic circulation (e.g. NIBP), typically sensed by means of chest electrodes 554, a finger sensor 556, a forehead/scalp sensor 558 and a blood pressure cuff 560 respectively, may also be sensed and measured by suitable instrumentation 562.

**[0261]** The outputs of the capnograph 552 and possibly of additional instrumentation 562 are preferably supplied to a suitably programmed automatic diagnostic and treatment computer 564, having an associated display 566 which typically analyzes the respiration parameter output of the capnograph 552 and possibly other parameters and provides an output which preferably contains a diagnostic statement indicating the presence and severity of congestive heart failure, here "ABNORMAL CO<sub>2</sub> WAVEFORM CONSISTENT WITH SEVERE CONGESTIVE HEART FAILURE".

**[0262]** This diagnostic statement indicates that treatment is required for heart failure. Intravenous and/or sublingual medications such as nitroglycerin, morphine and LASIX R are administered after which a diagnostic statement which indicates the patient status and the severity of the cardio-respiratory condition is preferably presented, here "MODERATE CONGESTIVE HEART FAILURE, CONDITION IMPROVING".

**[0263]** Reference is now made additionally to Figs. 34A and 34B, which illustrate the operation of the system and methodology of the system of the present invention in the context of Fig. 33.

The patient previously attached to a multi-parameter monitor including a capnograph 552 and suitable instrumentation 562, by means of cannula 550 and preferably

also by means of chest electrodes 554, finger sensor 556, forehead sensor 558 and blood pressure cuff 560, is monitored continuously for at least thirty seconds. Neurological status of the patient is acquired by any suitable technique, including visual and electroencephalograph (EEG) monitoring. Values of CO<sub>2</sub> concentration, ECG, NIBP, SPO<sub>2</sub>, and cerebral oximetry are continuously monitored, and carbon dioxide waveforms are preferably digitized as a capnogram 567 and together with other waveforms are stored in computer 564.

**[0264]** At least one expired air sample is collected and conveyed for analysis by capnograph 552. The outputs of the capnograph 552 and possibly of additional instrumentation 562 are preferably supplied to suitably programmed automatic diagnostic and treatment computer 564, having associated display 566, which typically analyzes the respiration parameter output of the capnograph 552.

**[0265]** In an analyzing step, the onset and offset limits of a capnogram 567, pulse waveforms, and the QRS complex (of the ECG) are marked by computer 564. The actual parameters measured include, but are not limited to heart rate (HR), BP, the systolic to diastolic ratio (SYS / DIA). SPO<sub>2</sub>, AND ETCO<sub>2</sub>. The slope of CO<sub>2</sub> (mm Hg/sec), and CO<sub>2</sub> "run", of the capnogram 567, measured to 80% of maximum CO<sub>2</sub> concentration, are calculated by computer 564.

**[0266]** Following each treatment, the differences between consecutive measurements of the various patient parameters are computed by computer 564. Thereafter, in a diagnostic rule application step, the following diagnostic rules are preferably applied to the measured parameters by computer 564:

1) If:

- a) the blood pressure values are within the normal range;
- b) the respiratory rate is normal; and
- c) ETCO<sub>2</sub> is less than 45 mm Hg;

then,

display 566 shows the message "VITAL SIGNS WITHIN NORMAL LIMITS".

2) In contrast, if:

- a) the value of Diminished CAP-FEV1 is a 40:10 point ratio;
- b) Normal CAP-FEV/FVC;
- c) CO<sub>2</sub> run is less than 0.3 sec; and,
- d) CO<sub>2</sub> slope is more than 100 mm Hg/sec;

then,

display 566 shows the message "BRONCHOSPASM IS PRESENT".

**[0267]** Additionally, if bronchospasm is present then the following rules may also be applied:

3) If:

- a) the value of CAP-FEV 1 is less than 80%;

then

display 566 shows the message "MODERATE BRONCHOSPASM IS PRESENT".

4) If:

- a) the value of CAP-FEV1 is less than 80%;
- b) the value of SPO<sub>2</sub> is less than 91 % SAT; and
- c) the value of ETCO<sub>2</sub> is less than 45 mm Hg;

then,

display 566 shows the message "SEVERE BRONCHOSPASM PRESENT".

**[0268]** Thereafter a cycle of alternating I) sampling step (data collection and measurement) and II) diagnostic rule application to the previous sample step I) is initiated:

I) Sampling Step

**[0269]**

- a) A sample of expired air is taken and conveyed from cannula 550 to capnograph 552.
- b) The carbon dioxide concentration is measured continuously by capnograph 552 as capnogram 567.
- c) The capnogram is digitized as waveform and store for analysis by computer 564.
- d) Computer 564 marks onset and offset limits of the capnogram.
- e) The waveform quality of the capnogram is assessed by employing the criteria that an acceptable quality is defined by:
  - i) the root mean square (rms) of the noise of the waveform must be less than 2 mm Hg; and
  - ii) the breath-to-breath correlation must be greater than 0.85.

- f) The slope and the run are determined by computer 564.

II) Diagnostic Rule Application Step

**[0270]** In a diagnostic rule application step, the following diagnostic rules are preferably applied to the measured parameters of I) Sampling step by computer 564:

1) If:

- a) the blood pressure values are within the normal range;
- b) the respiratory rate is normal;
- c) CO<sub>2</sub> run is less than or equal to 0.3 sec;

- d) CO<sub>2</sub> slope is more than or equal to 100 mm Hg/sec;
- e) SPO<sub>2</sub> is greater than or equal to 95% SAT ; and
- f) ETCO<sub>2</sub> is less than or equal to 45 mm Hg;

then,

display 566 shows the message "NO BRONCHOSPASM PRESENT."

2) In contrast, if:

- a) CO<sub>2</sub> run is greater than 0.3 sec;
- b) CO<sub>2</sub> slope is less than 100 mm Hg/sec;
- c) SPO<sub>2</sub> is more than or equal to 91% SAT, but less than 95% SAT; and
- d) ETCO<sub>2</sub> is less than 45 mm Hg;

then,

the message "MODERATE BRONCHOSPASM PRESENT" is displayed on display 566.

3) If the parameters measured are yet further removed from the acceptable range, such as if:

- a) CAP-FEV1 is less than 50%;
- b) SPO<sub>2</sub> is less than 91% SAT; and
- c) ETCO<sub>2</sub> is greater than 45 mm Hg;

then,

a message such as "SEVERE BRONCHOSPASM PRESENT" is displayed on display 566.

**[0271]** At any one of the diagnostic rule application steps, it may be verified that the patient is suffering from bronchospasm. Once bronchospasm is verified, the operator switches capnograph 552 to a serial comparison mode. The medical team applies the appropriate interventions to the patient to treat the bronchospasm.

**[0272]** Reference is now made to Fig. 35, which is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology operative in a hospital or EMS environment for diagnosing and treating respiratory failure. As seen in Fig. 35, various patient physiologic activities are sensed and measured, including respiratory physiologic activities, preferably via an oral airway adapter and/or a nasal or nasal/oral cannula 570, such as a Model Nasal FilterLine Adult XS 04461, O<sub>2</sub>/CO<sub>2</sub> Nasal FilterLine Adult 007141, or Smart CapnoLine Adult (Oral/nasal FilterLine) 007414, commercially available from Oridion Ltd., of Jerusalem Israel, typically coupled with a capnograph 572, such as a Microcap, commercially available from Oridion Ltd., of Jerusalem Israel. Other patient physiologic activities relating to cardiac function (e.g. ECG), systemic oxygenation (e.g. pulse oximetry), cerebral oxygenation (e.g. cerebral oximetry) and systemic circulation (e.g. NIBP), typically sensed by means of chest electrodes 574, a finger sensor

576, a forehead/scalp sensor 578 and a blood pressure cuff 580 respectively, may also be sensed and measured by suitable instrumentation 582.

**[0273]** Following intubation of the patient and prior to securing the tube, the outputs of the capnograph 572 and possibly of additional instrumentation 582 are preferably supplied to a suitably programmed automatic diagnostic and treatment computer 584, having an associated display 586 which typically analyzes the respiration parameter output of the capnograph 572 and possibly other parameters and provides an output which preferably contains a diagnostic statement indicating proper intubation, here "TUBE IN TRACHEA".

**[0274]** The system determines whether characteristics of the capnograph waveform amplitude are normal. If the CO<sub>2</sub> levels as indicated by the capnograph waveform amplitude are below normal a diagnostic statement indicating right mainstem bronchus intubation is presented, here "ABNORMAL WAVEFORM, CHECK FOR RIGHT MAINSTEM BRONCHUS INTUBATION".

**[0275]** Following repositioning of the tube, the system provides a patient status statement, here "WAVEFORM NORMALIZED, TUBE IN TRACHEA".

**[0276]** Reference is now made additionally to Fig. 36, which illustrates the operation of the system and methodology of the system of the present invention in the context of Fig. 35.

The patient in an ambulance, preferably attached to a multi-parameter monitor including capnograph 572, is monitored continuously for at least 30 seconds. Expired air is collected via cannula 570 and is conveyed to the capnograph 572.

**[0277]** Values of the CO<sub>2</sub> concentration is continuously measured, typically over a period of 30 seconds, and carbon dioxide waveforms are preferably digitized as a capnogram and together with other waveforms are stored on computer 584.

**[0278]** The onset and offset limits of the patient's capnogram from capnograph 572 are delineated by computer 584.

**[0279]** The waveform quality of the capnogram 587 is assessed by employing the criteria that an acceptable quality is defined by:

- i) the root mean square (rms) of the noise of the waveform must be less than 1 mm Hg; and
- ii) the breath-to-breath correlation must be greater than 0.85.

**[0280]** If the quality is unacceptable, further samples are collected until a sample of acceptable quality, according to the above two criteria, is taken.

**[0281]** The next step entails a checking procedure, wherein the ETCO<sub>2</sub> value is measured by capnograph 572. The slope and run values of the capnogram from capnograph 572 are determined by computer 584.

**[0282]** At startup, the following checking rule is preferably applied.

1) If:

a) the  $\text{ETCO}_2$  value is more than 15 mm Hg;

then,

a display is provided by computer 584 stating "GOOD WAVEFORM, TUBE IN TRACHEA".

**[0283]** In a checking step, repeated checks for abnormal waveform shape of capnogram 587. The following rules are preferably applied to the capnogram shape:

1) If:

a) an abnormal waveform shape is observed;

then,

computer 584 displays "TUBE IMPROPERLY POSITIONED: CHECK FOR RIGHT MAINSTEM INTUBATION" on display 586.

2) If:

a) a normal waveform shape is observed;

then,

computer 584 displays "TUBE PROPERLY POSITIONED: CONFIRM BREATH SOUNDS AND SECURE TUBE" on display 586.

**[0284]** When tube is secure as is confirmed by an operator, the operator typically inputs a code into computer 584 to activate an intubation monitoring mode in capnograph 572. The capnogram is monitored continuously for loss of signal. Loss of signal from capnograph 572 is indicative of the tube having slipped away from the trachea. As long as there is a regular signal, computer 584 displays "MONITORING INTUBATION" on display 586.

**[0285]** Reference is now made to Fig. 37, which is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology operative in a hospital environment for diagnosing and treating pulmonary embolism. As seen in Fig. 37, various patient physiologic activities are sensed and measured, including respiratory physiologic activities, preferably via an oral airway adapter and/or a nasal or nasal/oral cannula 600, such as a Model Nasal FilterLine Adult XS 04461;  $\text{O}_2/\text{CO}_2$  Nasal FilterLine Adult 007141, or Smart CapnoLine Adult (Oral/nasal FilterLine) 007414, commercially available from Oridion Ltd., of Jerusalem Israel, typically coupled with a capnograph 602, such as a Microcap, commercially available from Oridion Ltd., of Jerusalem Israel. Other patient physiologic activities relating to cardiac function (e.g. ECG), systemic oxygenation (e.g. pulse oximetry), cerebral oxygenation (e.g. cerebral oximetry) and systemic circulation (e.g. NIBP), typically sensed by means of chest electrodes 604, a finger sensor 606, a forehead/scalp sensor 608 and a blood pressure cuff 610 respectively, may also be sensed and measured

by suitable instrumentation 612.

**[0286]** The outputs of the capnograph 602 and possibly of additional instrumentation 612 are preferably supplied to a suitably programmed automatic diagnostic and treatment computer 614, having an associated display 616 which typically analyzes the respiration parameter output of the capnograph 602 and possibly other parameters and provides an output which preferably contains a diagnostic statement alerting hospital staff to the possible presence of pulmonary embolism. A typical such statement is "ALERT: ABNORMAL WAVEFORM CONSISTENT WITH PULMONARY EMBOLISM". Following intravenous medication for dissolving blood clots in the lungs, the system determines whether characteristics of the  $\text{CO}_2$  waveform amplitude and shape are approaching normal and preferably provides a patient status statement, here "WAVEFORM NORMALIZING, GOOD RESPONSE TO TREATMENT".

**[0287]** Reference is now made additionally to Fig. 38, which illustrates the operation of the system and methodology of the system of the present invention in the context of Fig. 37.

**[0288]** The patient, preferably attached to a multi-parameter monitor including capnograph 602 and instrumentation 612, by means of cannula 600 and preferably also by means of chest electrodes 604, finger sensor 606, scalp/forehead sensor 608 and blood pressure cuff 610, is monitored- continuously. The neurological status of the patient is acquired by any suitable technique. Values of  $\text{CO}_2$  concentration, ECG, NIBP and  $\text{SPO}_2$  are continuously measured, typically over a period of 30 seconds, and carbon dioxide waveforms are preferably digitized as a capnogram 617 and other waveforms and stored by computer 614.

**[0289]** Thereafter, the onset and offset limits of the capnogram, the pulse waveform and QRS onset and offset are determined by computer 614. The heart rate, blood pressure  $\text{ETCO}_2$  and  $\text{SPO}_2$  values are measured. The initial slope of the capnogram and the run, monitored by capnograph 602, are calculated by computer 614. Additionally, neurological findings, monitored by means of an EEG are inputted to computer 614.

**[0290]** At various intervals, the differences between consecutive measurements of the various patient parameters are evaluated by computer 614. After each treatment, in a diagnostic rule application step, the following diagnostic rule is preferably applied to the measured parameters by computer 614:

1) If:

a) the heart rate is greater than 100/min;

b) the  $\text{SPO}_2$  is less than 90% SAT;

c) the  $\text{EtCO}_2$  is less than 35 mm Hg;

d) the amplitude (area under curve) of the  $\text{CO}_2$  waveform is less than a predetermined value;

e) the ECG is normal; and

f) the respiratory rate is greater than 15/min;

display 616 shows the message "ALERT: VITAL SIGNS CONSISTENT WITH ACUTE PULMONARY EMBOLISM".

**[0291]** After each time interval, the difference between consecutive measures of each parameter are calculated by computer 614: Thereafter, the following monitoring rules are preferably applied to the measured parameters by computer 614.

1) If:

- a) the decrease in the SPO<sub>2</sub> values is greater than -5 % SAT; or
- b) the difference in the ETCO<sub>2</sub> slope is greater than +5 mm Hg;

then,

computer 614 displays on display 616 "PATIENT STATUS: DETERIORATING".

2) If:

- a) the increase in the SPO<sub>2</sub> values is greater than +5 % SAT; or
- b) the difference in the ETCO<sub>2</sub> slope is more than -5 mm Hg;

then,

computer 614 displays on display 616 "PATIENT STATUS:IMPROVING".

3) If:

- a) the difference in the SPO<sub>2</sub> values is more positive than or equal to -5% SAT, but less than or equal to +5%; or
- b) the difference in the ETCO<sub>2</sub> slope greater than or equal to -5 mm Hg, but less than or equal to +5 mm Hg;

then,

computer 614 displays on display 616 "PATIENT STATUS:UNCHANGED".

**[0292]** Following the monitoring stage, the following exit rules are preferably applied to the measured parameters of the patient by computer 232:

1) If:

- a) the ECG values are within normal limits;
- b) the respiratory rate is within normal limits;
- c) the heart rate is within normal limits;
- d) the SPO<sub>2</sub> value is greater than 95% SAT; and
- e) the ETCO<sub>2</sub> value is less than 45 mm Hg;

then,

Computer 614 preferably displays on display 616 "VITAL SIGNS STABLE".

**[0293]** (If the patient's record complies with this exit rule, then a copy of the patient's record is handed off from computer 616 to the receiving center, for example, in the form of a chart. Typically, the receiving center stores this chart, so that it may be used as a baseline for continued monitoring of the patient).

**[0294]** Reference is now made to Figs. 39A and 39B, which are simplified pictorial illustrations of an automatic medical diagnostic and treatment system and methodology operative in a hospital environment for determining correct placement of a nasogastric tube in a patient. As seen in Figs. 39A and 39B, following insertion of a nasogastric tube in a patient, various patient physiologic activities are sensed and measured, including respiratory physiologic activities, preferably via an oral airway adapter and/or a nasal or nasal/oral cannula 630, such as a Model Nasal FilterLine Adult XS 04461, O<sub>2</sub>/CO<sub>2</sub> Nasal FilterLine Adult 007141, or Smart CapnoLine Adult (Oral/nasal FilterLine) 007414, commercially available from Oridion Ltd., of Jerusalem Israel, typically coupled with a capnograph 632, such as a Microcap, commercially available from Oridion Ltd., of Jerusalem Israel. Other patient physiologic activities relating to cardiac function (e.g. ECG), systemic oxygenation (e.g. pulse oximetry), cerebral oxygenation (e.g. cerebral oximetry) and systemic circulation (e.g. NIBP), typically sensed by means of chest electrodes 634, a finger sensor 636, a forehead/scalp sensor 638 and a blood pressure cuff 640 respectively, may also be sensed and measured by suitable instrumentation 642.

**[0295]** The outputs of the capnograph 632 and possibly of additional instrumentation 642 are preferably supplied to a suitably programmed automatic diagnostic and treatment computer 644, having an associated display 646 which typically analyzes the respiration parameter output of the capnograph 632 and possibly other parameters and provides an output which preferably contains a status statement alerting hospital staff to the possible misplacement of the nasogastric tube. A typical such statement is "NASOGASTRIC (NG) TUBE IN LUNG". This status statement is preferably accompanied by a treatment recommendation:, here "REPOSITION NASOGASTRIC TUBE". Following repositioning of the nasogastric tube, a status statement confirming proper placement is preferably provided, here "NASOGASTRIC TUBE IN STOMACH". This statement is preferably accompanied by a treatment recommendation, here "SECURE TUBE".

**[0296]** Reference is now made additionally to Fig. 40, which illustrates the operation of the system and methodology of the system of the present invention in the context of Figs. 39A and 39B.

The patient, preferably attached to a multi-parameter monitor including capnograph 632, is monitored continuously for at least 30 seconds. Expired air is collected via cannula 630 and is conveyed to the capnograph 632.

**[0297]** Values of the CO<sub>2</sub> concentration is continuously measured, typically over a period of 30 seconds, and carbon dioxide waveforms are preferably digitized as a capnogram 647 and, together with other waveforms, is stored on computer 644.

**[0298]** The onset and offset limits of the patient's capnogram from capnograph 632 are delineated by computer 644.

**[0299]** The waveform quality of the capnogram 647 is assessed by employing the criteria that an acceptable quality is defined by:

- i) the root mean square (rms) of the noise of the waveform must be less than 1 mm Hg; and
- ii) the breath-to-breath correlation must be greater than 0.85.

**[0300]** If the quality is unacceptable, further samples are collected until a sample of acceptable quality, according to the above two criteria, is taken.

**[0301]** The next step entails a checking procedure, wherein the ETCO<sub>2</sub> value is measured by capnograph 632. The slope and run values of the capnogram from capnograph 632 are determined by computer 644.

**[0302]** The following checking rules are preferably applied.

1) If:

- a) the ETCO<sub>2</sub> value is less than or equal to 15 mm Hg; or
- b) there is a loss of the waveform of capnogram 647;

then,

a display is provided by computer 644 stating "NO WAVEFORM PRESENT, NG TUBE NOT IN TRACHEA".

2) If:

- a) the ETCO<sub>2</sub> value is more than or equal to 15 mm Hg; or
- b) profile of exhaled gas is detected as a waveform of capnogram 647;

then,

a display is provided by computer 644 stating "CO<sub>2</sub> DETECTED, NG TUBE IN TRACHEA."

**[0303]** Reference is now made to Fig. 41, which is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology operative in a hospital environment for determining the presence of acute myocardial infarction in a patient. As seen in Fig. 41, following a patient complaint of chest pains, various patient physiologic activities are sensed and measured, including respiratory physiologic activities, preferably via an oral airway adapter and/or a nasal or

nasal/oral cannula 650, such as a Model Nasal FilterLine Adult XS 04461, O<sub>2</sub>/CO<sub>2</sub> Nasal FilterLine Adult 007141, or Smart CapnoLine Adult (Oral/nasal FilterLine) 007414, commercially available from Oridion Ltd., of Jerusalem Israel, typically coupled with a capnograph 652, such as a Microcap, commercially available from Oridion Ltd., of Jerusalem Israel. Other patient physiologic activities relating to cardiac function (e.g. ECG), systemic oxygenation (e.g. pulse oximetry), cerebral oxygenation (e.g. cerebral oximetry) and systemic circulation (e.g. NIBP), typically sensed by means of chest electrodes 654, a finger sensor 656, a forehead/scalp sensor 658 and a blood pressure cuff 660 respectively, may also be sensed and measured by suitable instrumentation 662.

**[0304]** The outputs of the capnograph 652 and possibly of additional instrumentation 662 are preferably supplied to a suitably programmed automatic diagnostic and treatment computer 664, having an associated display 666 which typically analyzes the respiration parameter output of the capnograph 652 and possibly other parameters and provides an output which preferably contains a diagnostic statement alerting hospital staff to the possibility of occurrence of acute myocardial infarction. A typical such statement is "VITAL SIGNS CONSISTENT WITH HEART ATTACK. CONDITION CRITICAL". Following sublingual and/or intravenous administration of a medicament such as nitroglycerin and morphine, a patient status statement is preferably provided, here "GOOD RESPONSE TO TREATMENT. CONDITION IMPROVING".

**[0305]** Reference is now made additionally to Fig. 42, which illustrates the operation of the system and methodology of the system of the present invention in the context of Fig. 41.

The patient, preferably attached to a multi-parameter monitor including capnograph 652 and suitable instrumentation 662, by means of cannula 650 and preferably also by means of chest electrodes 654, finger sensor 656, forehead/scalp sensor 658 and blood pressure cuff 660, is monitored continuously. The neurological status of the patient is acquired by any suitable technique. Values of CO<sub>2</sub> concentration, HR, BP (SYS/DIA) ECG, NIBP and SPO<sub>2</sub> are continuously measured, typically over a period of 30 seconds, and carbon dioxide waveforms are preferably digitized as a capnogram 667 and other waveforms and stored on computer 664.

**[0306]** Thereafter, the onset and offset limits of the capnogram, the pulse waveform and QRS onset and offset are determined by computer 664. The initial slope of the capnogram and the run are determined and stored in computer 664.

**[0307]** At various intervals, the differences between consecutive measurements of the various patient parameters are evaluated by computer 664. After each treatment, in a diagnostic rule application step, the following diagnostic rules are preferably applied to the measured parameters by computer 664:

1) If:

- a) there is a localized elevation in the ST segment in the ECG; and
- b) the  $\text{ETCO}_2$  is declining at least by 2 mm Hg/min over five minutes;

then,

display 666 shows the message "ACUTE MYOCARDIAL INFARCTION (MI) SUSPECTED".

2) If:

- a) the  $\text{SPO}_2$  value is less than 91 % SAT; and
- b) the  $\text{ETCO}_2$  value is less than 30 mm Hg;

then,

display 666 shows the message "VITAL SIGNS CRITICAL".

**[0308]** After each time interval, the difference between consecutive measures of each parameter are calculated by computer 664: Thereafter, the following monitoring rules are preferably applied to the measured parameters by computer 664.

1) If:

- a) the difference in the ST elevation in the ECG is greater than 0.1 mm and
- b) the difference in the  $\text{ETCO}_2$  slope is less than -1 mm Hg/ min;

then,

computer 664 displays on display 666 "PATIENT STATUS: WORSENING".

2) If:

- a) the difference in the ST elevation in the ECG is less than - 0.1 mm and
- b) the difference in the  $\text{ETCO}_2$  is more than 1 mm Hg/ min;

then,

computer 664 displays on display 666 "PATIENT STATUS: IMPROVING".

3) If:

- a) the difference in the ST elevation in the ECG is more than or equal to - 0.1 mm but less than or equal to 0.1 mm; or
- b) the difference in the  $\text{ETCO}_2$  is more than or equal to -1 mm Hg/ min and is less than or equal to 1 mm Hg/ min;

then,

computer 664 displays on display 666 "PATIENT STATUS: UNCHARGED".

**[0309]** Reference is now made to Fig. 43, which is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology operative in a hospital environment for determining the presence of cardiogenic shock in a patient. As seen in Fig. 43, various patient physiologic activities are sensed and measured, including respiratory physiologic activities, preferably via an oral airway adapter and/or a nasal or nasal/oral cannula 670, such as a Model Nasal FilterLine Adult XS 04461,  $\text{O}_2/\text{CO}_2$  Nasal. FilterLine Adult 007141, or Smart CapnoLine Adult (Oral/nasal FilterLine) 007414, commercially available from Oridion Ltd., of Jerusalem Israel, typically coupled with a capnograph 672, such as a Microcap, commercially available from Oridion Ltd., of Jerusalem Israel. Other patient physiologic activities relating to cardiac function (e.g. ECG), systemic oxygenation (e.g. pulse oximetry), cerebral oxygenation (e.g. cerebral oximetry) and systemic circulation (e.g. NIBP), typically sensed by means of chest-electrodes 674, a finger sensor 676, a forehead/scalp sensor 678 and a blood pressure cuff 680 respectively, may also be sensed and measured by suitable instrumentation 682.

**[0310]** The outputs of the capnograph 672 and possibly of additional instrumentation 682 are preferably supplied to a suitably programmed automatic diagnostic and treatment computer 684, having an associated display 686 which typically analyzes the respiration parameter output of the capnograph 672 and possibly other parameters and provides an output which preferably contains a diagnostic statement alerting hospital staff to the possibility of occurrence of cardiogenic shock. A typical such statement is "VITAL SIGNS CONSISTENT WITH CARDIOGENIC SHOCK. CONDITION CRITICAL". Following intravenous administration of a medicament such as dopamine dobutamine, a patient status statement is preferably provided, here "CONDITION IMPROVING".

**[0311]** Reference is now made additionally to Fig. 44, which illustrates the operation of the system and methodology of the system of the present invention in the context of Fig. 43.

The patient, preferably attached to a multi-parameter monitor including capnograph 672 and suitable instrumentation 682, by means of cannula 670 and preferably also by means of chest electrodes 674, finger sensor 676, forehead/scalp sensor 678 and blood pressure cuff 680, is monitored continuously. The neurological status of the patient is acquired by any suitable technique. Values of  $\text{CO}_2$  concentration, HR, BP (SYS/DIA) ECG, NIBP and  $\text{SPO}_2$  are continuously measured, typically over a period of 30 seconds, and carbon dioxide waveforms are preferably digitized as a capnogram 667 and other waveforms and stored on computer 684.

**[0312]** Thereafter, the onset and offset limits of the capnogram, the pulse waveform and QRS onset and offset are determined by computer 684. The initial slope of the

capnogram and the run are determined and stored in computer 684.

[0313] At various intervals, the differences between consecutive measurements of the various patient parameters are evaluated by computer 684.

[0314] After each interval, in a diagnostic rule application step, the following diagnostic rules are preferably applied to the measured parameters by computer 684:

1) If:

- a) the systolic blood pressure is less than 90 mm Hg;
- b) the heart rate is more than 100/min;
- c) the respiratory rate is more than 15/min; and
- d) and the ET $\text{CO}_2$  is less than 35 mm Hg;

then, display 686 shows the message "ALERT: CONSIDER CARDIOGENIC SHOCK".

2) If:

- a) the S $\text{PO}_2$  value is less than 91% SAT; and
- b) the ET $\text{CO}_2$  value is less than 30 mm Hg;

then, display 686 shows the message "VITAL SIGNS CRITICAL".

[0315] After each time interval, the difference between consecutive measures of each parameter are calculated by computer 684: Thereafter, the following monitoring rules are preferably applied to the measured parameters by computer 684.

1) If:

- a) the difference in the systolic blood pressure is less than -5 mm Hg; and
- b) the difference in the ET $\text{CO}_2$  is less than -1 mm Hg/ min;

then, computer 664 displays on display 666 "PATIENT STATUS:WORSENING".

2) If:

- a) the difference in the systolic blood pressure is more than 5 mm Hg; and
- b) the difference in the ET $\text{CO}_2$  is more than 1 mm Hg/ min;

then, computer 664 displays on display 666 "PATIENT STATUS:IMPROVING".

3) If:

- a) the difference in the systolic blood pressure is more than or equal to -5 mm Hg and less than or equal to +5 mm Hg; and/or
- b) the difference in the ET $\text{CO}_2$  is more than or equal to -1 mm Hg/ min and is less than or equal to 1 mm Hg/ min;

then, computer 684 displays on display 686 "PATIENT STATUS:UNCHANGED".

[0316] Reference is now made to Fig. 45, which is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology operative in a hospital environment for determining the presence of cardiac arrest in a patient. As seen in Fig. 45, a patient who is found to be unconscious and unresponsive is subsequently connected to the system of the present invention. Various patient physiologic activities are sensed and measured, including respiratory physiologic activities, preferably via an oral airway adapter and/or a nasal or nasal/oral cannula 700, such as a Model Nasal FilterLine Adult XS 04461, O $_2$ /CO $_2$  Nasal FilterLine Adult 007141, or Smart CapnoLine Adult (Oral/nasal FilterLine) 007414, commercially available from Oridion Ltd., of Jerusalem Israel, typically coupled with a capnograph 702, such as a Microcap, commercially available from Oridion Ltd., of Jerusalem Israel. Other patient physiologic activities relating to cardiac function (e.g. ECG), systemic oxygenation (e.g. pulse oximetry), cerebral oxygenation (e.g. cerebral oximetry) and systemic circulation (e.g. NIBP), typically sensed by means of chest electrodes 704, a finger sensor 706, a forehead/scalp sensor 708 and a blood pressure cuff 710 respectively, may also be sensed and measured by suitable instrumentation 712.

[0317] The outputs of the capnograph 702 and possibly of additional instrumentation 712 are preferably supplied to a suitably programmed automatic diagnostic and treatment computer 714, having an associated display 716 which typically analyzes the respiration parameter output of the capnograph 702 and possibly other parameters and provides an output which preferably contains a diagnostic statement alerting hospital staff to the possibility of occurrence of cardiac arrest. A typical such statement is "ALERT: CARDIAC ARREST". Following treatment, typically including intubation and intravenous administration of a medicament such as adrenaline, during external cardiac massage, a patient status statement, indicating the effectiveness of the treatment is preferably provided, here "EFFECTIVE CARDIAC COMPRESSIONS." The system also preferably diagnoses the return of spontaneous circulation and prompts the caregiver to check for the presence of a pulse, here by means of a diagnostic statement and a treatment recommendation such as "RETURN OF SPONTANEOUS CIRCULATION.

CHECK FOR PULSE".

**[0318]** Reference is now made additionally to Fig. 46, which illustrates the operation of the system and methodology of the system of the present invention in the context of Fig. 45.

**[0319]** The patient, preferably attached to a multi-parameter monitor including capnograph 702 and suitable instrumentation 712, by means of cannula 700 and preferably also by means of chest electrodes 704, finger sensor 706, forehead/scalp sensor 708 and blood pressure cuff 710, is monitored continuously. The neurological status of the patient is acquired by any suitable technique. Values of CO<sub>2</sub> concentration, HR, BP (SYS/DIA) ECG, NIBP and SPO<sub>2</sub> are continuously measured, typically over a period of 30 seconds, and carbon dioxide waveforms are preferably digitized as a capnogram 717, and is stored on computer 714 together with other waveforms.

**[0320]** Thereafter, the onset and offset limits of the capnogram, the pulse waveform and QRS onset and offset are determined by computer 714. The initial slope of the capnogram and the run are determined and stored in computer 714.

**[0321]** At various intervals, the differences between consecutive measurements of the various patient parameters are evaluated by computer 714.

**[0322]** After each time interval, the difference between consecutive measures of each parameter are calculated by computer 714: Thereafter, the following monitoring rules are preferably applied to the measured parameters by computer 714.

1) If:

- a) the heart rate is less than 30/min; and
- b) the ETCO<sub>2</sub> value is less than 15 mm Hg;

then,

computer 714 displays on display 716 "NO RETURN OF CIRCULATION".

2) If:

- a) the heart rate is more than or equal to 30/min; and
- b) the ETCO<sub>2</sub> value is more than or equal to 15 mm Hg;

then,

computer 714 displays on display 716 "RETURN OF CIRCULATION".

**[0323]** Reference is now made to Fig. 47, which is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology operative in a out of hospital environment for determining the presence of acute cardiac ischemia in a patient.

**[0324]** As seen in Fig. 47, while a patient, undergoes treadmill testing in a doctor's office, various patient phys-

iological activities are sensed and measured, including respiratory physiologic activities, preferably via an oral airway adapter and/or a nasal or nasal/oral cannula 730, such as a Model Nasal FilterLine Adult XS 04461, O<sub>2</sub>/CO<sub>2</sub> Nasal FilterLine Adult 007141, or Smart CapnoLine Adult (Oral/nasal FilterLine) 007414, commercially available from Oridion Ltd., of Jerusalem Israel, typically coupled with a capnograph 732, such as a Microcap, commercially available from Oridion Ltd., of Jerusalem Israel. Other patient physiologic activities relating to cardiac function (e.g. ECG), systemic oxygenation (e.g. pulse oximetry), cerebral oxygenation (e.g. cerebral oximetry) and systemic circulation (e.g. NIBP), typically sensed by means of chest electrodes 734, a finger sensor 736, a forehead/scalp sensor 738 and a blood pressure cuff 740 respectively, may also be sensed and measured by suitable instrumentation 742.

**[0325]** The outputs of the capnograph 732 and possibly of additional instrumentation 742 are preferably supplied to a suitably programmed automatic diagnostic and treatment computer 744, having an associated display 746 which typically analyzes the respiration parameter output of the capnograph 732 and possibly other parameters and provides an output which preferably contains a diagnostic statement, here "VITAL SIGNS NORMAL", which indicates normal patient condition. At some point thereafter, a further diagnostic statement appears, here, "ALERT: ACUTE CARDIAC ISCHEMIA". Upon noticing this statement, the physician causes the patient to lie down and administers oxygen treatment to the patient. The system assesses the patient's response to the treatment and provides a patient status message, here "VITAL SIGNS NORMAL".

**[0326]** Reference is now made additionally to Fig. 48, which illustrates the operation of the system and methodology of the system of the present invention in the context of Fig. 47.

**[0327]** The patient, preferably attached to a multi-parameter monitor including capnograph 732 and suitable instrumentation 742, by means of cannula 730 and preferably also by means of chest electrodes 734, finger sensor 736, forehead/scalp sensor 738 and blood pressure cuff 740, is monitored continuously. The neurological status of the patient is acquired by any suitable technique. Values of CO<sub>2</sub> concentration, HR, BP (SYS/DIA) ECG, NIBP and SPO<sub>2</sub> are continuously measured, typically over a period of 30 seconds, and carbon dioxide waveforms are preferably digitized as a capnogram 747, and is stored on computer 744 together with other waveforms.

**[0328]** Thereafter, the onset and offset limits of the capnogram, the pulse waveform and QRS onset and offset are determined by computer 744. The initial slope of the capnogram and the run are determined and stored in computer 744.

**[0329]** In the next step, when the monitoring has been verified by the operator, that it is functioning correctly, the baseline cardiorespiratory pattern is stored in computer 744.

**[0330]** Thereafter, computer 744 and/or the operator activates capnograph 732 in a monitoring mode. The patient is monitored continuously by capnograph 732 for any significant change in the cardiorespiratory pattern. The following monitoring rule is preferably applied to capnogram 747 by computer 744.

1) If:

a) a significant change in the cardiorespiratory pattern is apparent;

then,  
computer 744 displays "MONITORING STRESS RESPONSE" on display 746.

**[0331]** Thereafter, a cycle of alternating I) sampling step (data collection and measurement) and II) diagnostic rule application to the previous sample step I) is initiated.

I) Sampling step

**[0332]**

a) A sample of expired air is taken and conveyed from cannula 400 to capnograph 732.

b) The carbon dioxide concentration is measured continuously by capnograph 744 as a capnogram 747.

c) The capnogram is digitized as waveform and store for analysis by computer 744.

d) Computer 744 marks onset and offset limits of the capnogram.

e) The waveform quality of the capnogram is assessed by employing the criteria that an acceptable quality is defined by:

i) the root mean square (rms) of the noise of the waveform must be less than 2 mm Hg; and

ii) the breath-to-breath correlation must be greater than 0.85.

f) The slope and the run are determined by computer 744.

II) Diagnostic Rule Application Step

**[0333]** In a diagnostic rule application step, the following diagnostic rules are preferably applied to the measured parameters of each sample in I) Sampling step by computer 744:

1 ) If:

a) there are no signs of ischemia (no elevation from baseline in the ECG ST segment; and no changes from baseline in the T-waves;

b) there are no changes towards ischemia (rising ST-segment values on ECG from baseline, and dropping  $ETCO_2$  values  $> 5$  mm Hg from baseline);

then,  
Computer 744 displays on display 746 "NO SIGNS OF ACUTE CARDIAC ISCHEMIA".

2) If:

a) there are signs of ischemia ; or

b) there are changes towards ischemia; then,

**[0334]** Computer 744 displays on display 746 "ALERT: SIGNS OF ACUTE CARDIAC ISCHEMIA".

**[0335]** Reference is now made to Fig. 49, which is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology operative in a hospital or outpatient environment for sedation and/or anesthesia monitoring. As seen in Fig. 49, while a patient is under sedation and/or anesthesia, typically in the course of a medical procedure, various patient physiologic activities are sensed and measured, including respiratory physiologic activities, preferably via an oral airway adapter and/or a nasal or nasal/oral cannula 800, such as a Model Nasal FilterLine Adult XS 04461,  $O_2/CO_2$  Nasal FilterLine Adult 007141, or Smart CapnoLine Adult (Oral/nasal FilterLine) 007414, commercially available from Oridion Ltd., of Jerusalem Israel, typically coupled with a capnograph 802, such as a Microcap, commercially available from Oridion Ltd., of Jerusalem Israel. Other patient physiologic activities relating to cardiac function (e.g. ECG), systemic oxygenation (e.g. pulse oximetry), cerebral oxygenation (e.g. cerebral oximetry) and systemic circulation (e.g. NIBP), typically sensed by means of chest electrodes 804, a finger sensor 806, a forehead/scalp sensor 808 and a blood pressure cuff 810 respectively, may also be sensed and measured by suitable instrumentation 812.

**[0336]** The outputs of the capnograph 802 and possibly of additional instrumentation 812 are preferably supplied to a suitably programmed automatic diagnostic and treatment computer 814, having an associated display 816 which typically analyzes the respiration parameter output of the capnograph 802 and possibly other parameters and provides an output which preferably contains a diagnostic statement confirming proper respiration, here "NORMAL WAVEFORM RHYTHM".

**[0337]** If at a later stage during the medical procedure, a deviation from the patient's normal  $CO_2$  waveform rhythm is sensed, a further diagnostic statement is provided, here "ALERT: SIGNIFICANT DEVIATION IN WAVEFORM RHYTHM". This statement is preferably accompanied by a treatment recommendation, here "REDUCE SEDATION LEVEL". Following reduction in the sedation level, a diagnostic statement which indicates the patient status is preferably presented, here "NOR-

MAL WAVEFORM RHYTHM RESTORED".

**[0338]** Reference is now made additionally to Fig. 50, which illustrates the operation of the system and methodology of the system of the present invention in the context of Fig. 49.

**[0339]** The patient, preferably attached to a multi-parameter monitor including capnograph 802, is typically monitored continuously for at least 30 seconds. Additionally or alternatively, the patient may be monitored for shorter or longer durations. Expired air is collected via cannula 800 and is conveyed to the capnograph 802.

**[0340]** Values of the CO<sub>2</sub> concentration are continuously measured, typically over a period of 30 seconds, and carbon dioxide waveforms are preferably digitized as a capnogram 817 and, together with other waveforms, is stored on computer 814.

**[0341]** The onset and offset limits of the patient's capnogram from capnograph 802 are delineated by computer 814.

**[0342]** The waveform quality of the capnogram 817 is assessed by employing the criteria that an acceptable quality is defined by:

- i) the root mean square (rms) of the noise of the waveform must be less than 1 mm Hg; and
- ii) the breath-to-breath correlation must be greater than 0.85.

**[0343]** If the quality is unacceptable, further samples are collected until a sample of acceptable quality, according to the above two criteria, is taken.

**[0344]** The next step entails a checking procedure, wherein the ET<sub>CO</sub><sub>2</sub> value is measured by capnograph 632. The slope and run values of the capnogram from capnograph 632 are determined by computer 644.

**[0345]** The following checking rule is preferably applied.

1) If:

- a) the ET<sub>CO</sub><sub>2</sub> value is more than 15 mm Hg;

then,

a display is provided by computer 814 stating "NORMAL WAVEFORM RHYTHM".

**[0346]** After the waveform rhythm has been confirmed by an operator, the capnograph is entered into its monitoring mode, either by the operator or by computer 814. Capnograph 802 then monitors for any changes in the breathing pattern of the patient.

**[0347]** Thereafter, computer 814 displays "MONITORING SEDATION" on display 646.

**[0348]** The next step entails a cycle of alternating I) sampling step (data collection and measurement) and II) diagnostic rule application to the previous sample step I) is initiated.

I) Sampling Step

**[0349]** In this sampling step, an exhaled air sample from cannula 800 is periodically collected, conveyed and measured by capnograph 802. The carbon dioxide concentration value is determined continuously by capnograph 802. Computer 814 digitizes the capnograph signals as a waveform and store the waveform for analysis.

**[0350]** Thereafter, the ET<sub>CO</sub><sub>2</sub> value is determined.

II) Diagnostic Rule Application Step.

**[0351]** The following diagnostic rules are applied to each sample:

1) If:

- a) The value of ET<sub>CO</sub><sub>2</sub> is greater than or equal to 15 mm Hg; and
- b) There is no loss in the waveform from capnograph 802; and
- c) The respiratory rate is greater than or equal to 12/min;

then,

computer 814 displays "NORMAL VENTILATORY WAVEFORM AND RHYTHM" on display 816.

2) If:

- a) The value of ET<sub>CO</sub><sub>2</sub> is less than 15 mm Hg; or
- b) There is a loss in the waveform from capnograph 802; or
- c) The respiratory rate is less than 10/min; or
- d) There is a decline in ET<sub>CO</sub><sub>2</sub> of 50%; or
- e) There is a 50% increase in the pattern variability; or
- f) There is a 50% decrease in the pattern similarity;

then,

computer 814 displays "ALERT: DIMINISHED VENTILATORY WAVEFORM" on display 816.

**[0352]** This cycle typically proceeds until the patient monitoring is halted by the medical team or operator.

**[0353]** Reference is now made to Fig. 51, which is a simplified pictorial illustration of an automatic medical diagnostic and treatment system and methodology operative in a hospital or outpatient environment for sedation and/or anesthesia titration. As seen in Fig. 51, when a patient is being sedated prior to carrying out of a medical procedure, various patient physiologic activities are sensed and measured, including respiratory physiologic activities, preferably via an oral airway adapter and/or a nasal or nasal/oral cannula 900, such as a Model Nasal FilterLine Adult XS 04461, O<sub>2</sub>/CO<sub>2</sub> Nasal FilterLine Adult 007141, or Smart CapnoLine Adult (Oral/nasal Filter-

Line) 007414, commercially available from Oridion Ltd., of Jerusalem Israel, typically coupled with a capnograph 902, such as a Microcap, commercially available from Oridion Ltd., of Jerusalem Israel. Other patient physiologic activities relating to cardiac function (e.g. ECG), systemic oxygenation (e.g. pulse oximetry), cerebral oxygenation (e.g. cerebral oximetry) and systemic circulation (e.g. NIBP), typically sensed by means of chest electrodes 904, a finger sensor 906, a forehead/scalp sensor 908 and a blood pressure cuff 910 respectively, may also be sensed and measured by suitable instrumentation 912.

**[0354]** The outputs of the capnograph 902 and possibly of additional instrumentation 912 are preferably supplied to a suitably programmed automatic diagnostic and treatment computer 914, having an associated display 916 which typically analyzes the respiration parameter output of the capnograph 902 and possibly other parameters and provides an output which preferably contains a patient status statement confirming proper respiration, here "NORMAL RESPIRATORY PATTERN".

**[0355]** If, following the administration of additional medication, a deviation from the patient's normal CO<sub>2</sub> waveform shape, amplitude or periodicity is sensed, a further status statement is provided, here "ALERT: MILD HYPOVENTILATION PRESENT". Following the administration of additional medication which increases the sedation level, an additional diagnostic statement which indicates the patient status is preferably presented, here "ALERT MODERATE HYPOVENTILATION PRESENT". This alert indicates that at this point, titration of medication is complete and the medical procedure may be commenced. Following completion of the medical procedure, monitoring continues until a further status statement, here "NORMAL RESPIRATORY PATTERN RESTORED" indicates normal respiration and that the patient may be safely discharged.

**[0356]** Reference is now made additionally to Fig. 52, which illustrates the operation of the system and methodology of the system of the present invention in the context of Fig. 51.

**[0357]** The patient, preferably attached to a multi-parameter monitor including capnograph 902, is monitored continuously for at least 30 seconds. Expired air is collected via cannula 900 and is conveyed to the capnograph 902.

**[0358]** Values of the CO<sub>2</sub> concentration is continuously measured, typically over a period of 30 seconds, and carbon dioxide waveforms are preferably digitized as a capnogram 917 and, together with other waveforms, is stored on computer 914.

**[0359]** The onset and offset limits of the patient's capnogram from capnograph 902 are delineated by computer 914.

**[0360]** The waveform quality of the capnogram 917 is assessed by employing the criteria that an acceptable quality is defined by:

- i) the root mean square (rms) of the noise of the waveform must be less than 2 mm Hg; and
- ii) the breath-to-breath correlation must be greater than 0.85.

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**[0361]** If the quality is unacceptable, further samples are collected until a sample of acceptable quality, according to the above two criteria, is taken.

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**[0362]** Thereafter, the ETCO<sub>2</sub> value and the respiratory rate are determined.

**[0363]** At startup a checking procedure is performed, wherein the ETCO<sub>2</sub> value is measured by capnograph 902. The slope and run values of the capnogram from capnograph 902 are determined by computer 914.

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**[0364]** The following checking rule is preferably applied.

1) If:

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- a) the ETCO<sub>2</sub> value is more than 15 mm Hg;

then,

a display is provided by computer 914 stating "GOOD WAVEFORM QUALITY; MONITORING LEVEL OF SEDATION."

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**[0365]** After the waveform rhythm has been confirmed by an operator; the baseline breathing pattern is stored in computer 914. Capnograph 902 is entered into its monitoring mode, either by the operator or by computer 914. Capnograph 902 then monitors for any changes in the breathing pattern of the patient.

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**[0366]** The next step entails a cycle of alternating I) sampling step (data collection and measurement) twice per minute and II) diagnostic rule application to the previous sample step I) is initiated.

35

I) Sampling Step

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**[0367]** In this sampling step, an exhaled air sample from cannula 900 is periodically collected, conveyed and measured by capnograph 902. The carbon dioxide concentration value is determined continuously by capnograph 902. Computer 914 digitizes the capnograph signals as a waveform and computer 914 stores the waveform for analysis.

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Computer 914 marks onset and offset limits of the capnogram.

**[0368]** The waveform quality of the capnogram is assessed by employing the criteria that an acceptable quality is defined by:

50

- i) the root mean square (rms) of the noise of the waveform must be less than 2 mm Hg; and
- ii) the breath-to-breath correlation must be greater than 0.85.

55

**[0369]** Thereafter ETCO<sub>2</sub> and the respiratory rate are

measured, and the results stored on computer 914.

II) Diagnostic Rule Application Step.

[0370] The following diagnostic rules are applied to each sample:

1) If:

- a) The value of ETCO<sub>2</sub> is greater than or equal to 15 mm Hg, but less than 50 mm Hg;
- b) There is no loss in the waveform from capnograph 902; and
- c) The respiratory rate is greater than 12/min;

then, computer 914 displays "NORMAL RESPIRATORY PATTERN" on display 916.

2) If:

- a) The respiratory rate is more than or equal to 10/min, but less than 12/min;

then, computer 914 displays "MILD HYPOVENTILATION" on display 916.

3) If:

- a) The value of ETCO<sub>2</sub> is greater than or equal to 50 mm Hg, but less than 60 mm Hg; and
- b) The respiratory rate is more than or equal to 6/min, but less than 10/min;

then, computer 914 displays "MODERATE HYPOVENTILATION" on display 916.

4) If:

- a) The value of ETCO<sub>2</sub> is greater or equal to 60 mm Hg; or
- b) There is a loss in the waveform; or
- c) The respiratory rate is less than 6/min;

then, computer 914 displays "ALERT: SEVERE HYPOVENTILATION OR APNEA" on display 916.

[0371] It should be understood that the rules, such as monitoring and diagnostic rules exemplified hereinabove are not meant to be limiting only to those and the numerical values therein that have been shown herein, and that these rules could be applied using similar or different numerical values and could incorporate further rules applied to other parameters. The rules provided herein may be provided as continuous or discontinuous rules, and

may additionally or alternatively be applied in other combinations of continuity or discontinuity. Furthermore, it should be understood that the term "time interval" may include the time required for a treatment to be effective in a patient, and the word "treatment" may also be used to denote the time required for the treatment to be effective, such as in the phrase 'after each treatment'.

[0372] It will be appreciated by persons skilled in the art that the present invention is not limited by what has been particularly shown and described hereinabove. Rather the scope of the present invention includes both combinations and subcombinations of the features described hereinabove as well as modifications and variations thereof which would occur to a person of skill in the art upon reading the foregoing description and which are not in the prior art.

Claims

1. A system employing at least one medical parameter relating to the respiration of a patient for providing an indication relating to at least one medical condition, the system comprising:

a medical data input interface adapted to provide the at least one medical parameter relating to the respiration of the patient, wherein said data input interface comprises at least one monitoring device operative to continuously monitor the at least one medical parameter, wherein the at least one monitoring device comprises a capnograph and wherein the at least one medical parameter comprises an expired air carbon dioxide concentration; and a medical parameter interpretation functionality adapted to receive the at least one medical parameter relating to the respiration of said patient and wherein the medical parameter interpretation functionality includes:

a medical condition diagnosis functionality adapted to diagnose the presence of the at least one medical condition, and a medical condition severity indication functionality adapted to indicate the degree of severity of the at least one medical condition, wherein said medical parameter interpretation functionality is further operative to provide a measurement of a run of time taken to reach 80% maximum exhaled CO<sub>2</sub> concentration and a slope of the increase in the carbon dioxide concentration to provide an alert responsive to the run being greater than 0.3 seconds and the slope being less than 100 mm Hg/sec.

2. A system according to claim 1, wherein said at least

one monitoring device is operative to continuously monitor a plurality of medical parameters.

3. A system according to any of the claims 1 and 2, wherein said at least one monitoring device is operative to collect a sample of expired air from said patient. 5
4. A system according to any of claims 1 to 3, wherein said at least one monitoring device further includes at least one of the following: 10

an electrocardiogram monitoring device;  
 a blood pressure monitoring device;  
 an electroencephalogram monitoring device;  
 an NI blood pressure monitoring device;  
 a respiratory rate monitoring device;  
 a heart rate monitoring device ;  
 a systemic perfusion monitoring device; and  
 an exhaled air monitoring device. 15 20

5. A system according to claim 1, wherein said at least one monitoring device is operative to digitize the waveform. 25
6. A system according to any of claims 1 to 5, wherein at least one of the at least one monitoring device and the medical parameter interpretation functionality is further operative to provide an angle of rise to 80% maximum exhaled CO<sub>2</sub> concentration. 30
7. A system according to any of claims 1 to 6, wherein said medical parameter interpretation is functionality is further operative to provide an indication of at least one of: 35
- defective functioning of the monitoring device ;  
 and  
 defective placing of the monitoring device ,  
 responsive to a value of at least one of the measurements. 40

8. A system according to any of claims 1 to 7, wherein the at least one medical parameter further comprises at least one of: 45
- a visual parameter;  
 a breathing parameter;  
 an oxygen parameter;  
 an ECG parameter;  
 a heart function parameter;  
 a neurological parameter;  
 a blood pressure parameter; and  
 an EEG parameter. 50

9. A system according to any of claims 1 to 6, wherein the medical parameter interpretation functionality is operative to provide an indication of the patient's sta- 55

tus being within a normal range if all of the following requirements are fulfilled:

- a) the blood pressure values are within the normal range;  
 b) the respiratory rate is normal;  
 c) CO<sub>2</sub> run is less than or equal to 0.3 sec;  
 d) CO<sub>2</sub> slope is more than or equal to 100 mm Hg/sec;  
 e) SPO<sub>2</sub> is greater or equal to than 95%; and  
 f) ETCO<sub>2</sub> is less than or equal to 45 mm Hg;

wherein the medical parameter interpretation functionality is further operative to provide an indication of the patient's status being outside a normal range if at least one of the requirements a) to f) is not fulfilled.

10. A system according to claim 9, wherein the medical parameter interpretation functionality is operative to provide a recommendation to perform at least one of the following treatments responsive to the indication of the patient's status being outside a normal range: 25

intubation of the patient;  
 hospitalization of the patient;  
 treat the patient with medication; and  
 transfer of the patient to an intensive care unit.

11. A system according to claim 8, wherein said visual parameter includes a visual appearance of said patient; or  
 wherein said breathing parameter includes at least one of a respiratory rate of the patient, a forced expiratory value, and a forced vital capacity value; or  
 wherein the oxygen parameter includes at least one of PO<sub>2</sub>, and SPO<sub>2</sub>; or  
 wherein the ECG parameter includes at least one of a QRS parameter, and an ST segment; or  
 wherein the heart function parameter includes a heart rate parameter; or  
 wherein the neurological function parameter includes a reflex parameter; or  
 wherein the blood pressure parameter includes at least one of a blood pressure measurement, and a systolic: diastolic ratio. 35 40 45

12. A system according to any of the claims 1 and 8, wherein said medical parameter interpretation functionality is operative to provide said at least one output indication responsive to a pattern of changes in said at least one medical parameter over time. 50

13. A system according to any of the claims 1, 8, and 9, wherein said medical parameter interpretation functionality is further operative to provide an output indication responsive to a pattern of changes in the 55

degree of severity of said at least one medical condition over time.

14. A system according to any of the preceding claims, further comprising a treatment recommendation functionality. 5
15. A system according to any of the preceding claims, further comprising a transmitter functionality adapted to convey said output indication to a remote location. 10

#### Patentansprüche

1. System, bei dem mindestens ein medizinischer Parameter die Atmung eines Patienten betreffend verwendet wird, um einen Hinweis auf mindestens einen medizinischen Zustand zu liefern, welches umfasst:

eine medizinische Dateneingabe-Schnittstelle, die angepasst ist, den mindestens einen medizinischen Parameter die Atmung des Patienten betreffend zu liefern, worin die Dateneingabe-Schnittstelle mindestens eine Überwachungseinrichtung umfasst, die funktionsfähig ist, den mindestens einen medizinischen Parameter kontinuierlich zu überwachen, worin die mindestens eine Überwachungseinrichtung einen Kapnographen umfasst und worin der mindestens eine medizinische Parameter eine Kohlendioxid-Konzentration der ausgeatmeten Luft umfasst; und  
eine Interpretations-Funktionalität des medizinischen Parameters, die angepasst ist, den mindestens einen medizinischen Parameter die Atmung des Patienten betreffend aufzunehmen und worin die Interpretations-Funktionalität des medizinischen Parameters umfasst:

eine Diagnose-Funktionalität des medizinischen Zustands, die angepasst ist, die Anwesenheit des mindestens einen medizinischen Zustandes zu diagnostizieren, und eine Anzeige-Funktionalität des Schweregrads des medizinische Zustands, die angepasst ist, das Ausmaß der Schwere des mindestens einen medizinischen Zustandes anzuzeigen, worin die Interpretations-Funktionalität des medizinischen Parameters weiter funktionsfähig ist, eine Messung einer Laufzeit zu liefern, die genommen wird, um 80 % einer maximal ausgeatmeten CO<sub>2</sub>-Konzentration und einen Nachlassen des Anstiegs der CO<sub>2</sub>-Konzentration zu liefern, um einen Alarm zu liefern, der ausgelöst wird, wenn der Lauf größer als 0,3 Se-

kunden und das Nachlassen unter 100 mm Hg/Sek. ist.

2. System nach Anspruch 1, worin die mindestens eine Überwachungseinrichtung funktionsfähig ist, um mehrere medizinische Parameter zu überwachen.
3. System nach einem der Ansprüche 1 und 2, worin die mindestens eine Überwachungseinrichtung funktionsfähig ist, um eine Probe von dem Patienten ausgeatmeter Luft zu gewinnen.

4. System nach einem der Ansprüche 1 bis 3, worin die mindestens eine Überwachungseinrichtung weiter mindestens eines der Folgenden enthält: 15

eine Elektrokardiogramm-Überwachungseinrichtung;  
eine Blutdruck-Überwachungseinrichtung;  
eine Elektroenzephalogramm-Überwachungseinrichtung;  
eine NI-Blutdruck-Überwachungseinrichtung;  
eine Atmungsgeschwindigkeits-Überwachungseinrichtung;  
eine Herzschlags-Überwachungseinrichtung;  
eine systemische Perfusions-Überwachungseinrichtung;  
eine Überwachungseinrichtung der ausgeatmeten Luft.

5. System nach Anspruch 1, worin die mindestens eine Überwachungseinrichtung funktionsfähig ist, die Wellenform zu digitalisieren. 20

6. System nach einem der Ansprüche 1 bis 5, worin mindestens eine der mindestens einen Überwachungseinrichtung und die Interpretations-Funktionalität des medizinischen Parameters weiter funktionsfähig ist, einen Anstiegswinkel von 80 % der maximal ausgeatmeten Luft zu liefern. 25

7. System nach einem der Ansprüche 1 bis 6, worin die Interpretations-Funktionalität des medizinischen Parameters weiter funktionsfähig ist, als Antwort auf einen Wert der mindestens einen Messung einen Hinweis zu liefern auf mindestens eines von: 30

einem fehlerhaften Betrieb der Überwachungseinrichtung; und  
einer fehlerhaften Anordnung der Überwachungseinrichtung.

8. System nach einem der Ansprüche 1 bis 7, worin der mindestens eine medizinische Parameter weiter mindestens eine umfasst von: 35

einem visuellen Parameter;  
einem Atmungs-Parameter;

- einem Sauerstoff-Parameter;  
 einem ECG-Parameter;  
 einem Herzfunktions-Parameter;  
 einem neurologischen Parameter;  
 einem Blutdruck-Parameter;  
 einem EEG-Parameter.
9. System nach einem der Ansprüche 1 bis 6, worin die Interpretations-Funktionalität des medizinischen Parameters funktionsfähig ist, einen Hinweis zu liefern, dass der Zustand des Patienten in einem normalen Bereich ist, wenn alle der folgenden Anforderungen erfüllt sind:
- a) die Blutdruck-Werte sind in dem normalen Bereich;  
 b) die Atmungsrate ist normal;  
 c) der CO<sub>2</sub>-Lauf ist größer oder gleich 100 mm Hg/Sek.;  
 d) SP0<sub>2</sub> ist größer oder gleich 95 %; und  
 e) ETCO<sub>2</sub> ist kleiner oder gleich 45 mm Hg;
- worin die Interpretations-Funktionalität des medizinische Parameters weiter funktionsfähig ist, einen Hinweis zu liefern, dass der Zustand des Patienten außerhalb eines normalen Bereichs liegt, wenn mindestens eine der Anforderungen a) bis f) nicht erfüllt ist.
10. System nach Anspruch 9, worin die Interpretations-Funktionalität des medizinischen Parameters funktionsfähig ist, eine Empfehlung als Antwort auf den Hinweis, dass der Zustand des Patienten außerhalb des normalen Bereichs liegt, zu liefern, mindestens eine der folgenden Behandlungen durchzuführen,:
- Intubierung des Patienten;  
 Einlieferung des Patienten in ein Krankenhaus;  
 Behandlung des Patienten mit Arzneimittel; und  
 Überführung des Patienten in eine Intensivstation.
11. System nach Anspruch 8, worin der visuelle Parameter ein visuelles Erscheinungsbild des Patienten umfasst; oder
- worin der Atmungs-Parameter mindestens einen umfasst von einer Atmungsrate des Patienten, einem Atmungswert unter Belastung, und einem Wert des Atemvolumens der Lunge unter Belastung; oder
- worin der Sauerstoff-Parameter mindestens einen umfasst von P0<sub>2</sub> und SP0<sub>2</sub>; oder
- worin der ECG-Parameter mindestens einen umfasst von einem QRS-Parameter und einem ST-Segment; oder
- worin der Herzfunktions-Parameter einen Herzschlag-Parameter umfasst; oder
- worin der neurologische Funktions-Parameter einen Reflex-Parameter umfasst; oder

worin der Blutdruck-Parameter mindestens eine umfasst von einer Blutdruckmessung und einem Verhältnis Systole : Diastole.

- 5 12. System nach einem der Ansprüche 1 bis 8, worin die Interpretations-Funktionalität des medizinischen Parameters funktionsfähig ist, als Antwort auf ein Muster an Änderungen in dem mindestens einen medizinischen Parameter über die Zeit mindestens eine Ausgabe-Anzeige zu liefern.
- 10
13. System nach einem der Ansprüche 1, 8 und 9, worin die Interpretations-Funktionalität des medizinischen Parameters weiter funktionsfähig ist, um mindestens als Antwort auf ein Muster an Änderungen in dem Ausmaß der Schwere des mindestens einen medizinischen Parameters über die Zeit eine Ausgabe-Anzeige zu liefern.
- 15
- 20 14. System nach einem der Ansprüche, welches weiter eine Funktionalität für eine Behandlungsempfehlung umfasst.
- 25 15. System nach einem der Ansprüche, welches weiter eine Transmitter-Funktionalität umfasst, die angepasst ist, die Ausgabe-Anzeige an eine entfernte Stelle zu liefern.

### 30 Revendications

- 35 1. Système employant au moins un paramètre médical lié à la respiration d'un patient pour fournir une indication liée à au moins une condition médicale, le système comprenant :
- une interface de saisie de données médicales adaptée pour fournir ledit au moins un paramètre médical lié à la respiration du patient, dans lequel ladite interface de saisie de données comprend au moins un dispositif de surveillance fonctionnel pour suivre de manière continue ledit au moins un paramètre médical, dans lequel ledit au moins un dispositif de surveillance comprend un capnographe et dans lequel ledit au moins un paramètre médical comprend une concentration de dioxyde de carbone dans l'air expiré; et
- une fonctionnalité d'interprétation de paramètre médical adaptée pour recevoir ledit au moins un paramètre médical lié à la respiration dudit patient et dans lequel la fonctionnalité d'interprétation de paramètre médical comprend:
- une fonctionnalité de diagnostic de condition médicale adaptée pour diagnostiquer la présence de ladite au moins une condition médicale, et une fonctionnalité d'indi-

- cation de la gravité de la condition médicale adaptée pour indiquer le degré de gravité de ladite au moins une condition médicale, dans lequel ladite fonctionnalité d'interprétation de paramètre médical est en outre fonctionnelle pour fournir une mesure de temps écoulé pour atteindre 80% de la concentration maximale exhalée de CO<sub>2</sub> et une courbe de l'augmentation de la concentration de dioxyde de carbone pour fournir une alerte réagissant à un cycle d'une durée supérieure à 0,3 seconde et à une courbe inférieure à 100 mm Hg/sec.
2. Système selon la revendication 1, dans lequel ledit au moins un dispositif de surveillance est fonctionnel pour suivre de manière continue une pluralité de paramètres médicaux.
3. Système selon l'une des revendications 1 et 2, dans lequel ledit au moins un dispositif de surveillance est opérationnel pour recueillir un échantillon d'air expiré dudit patient.
4. Système selon l'une quelconque des revendications 1 à 3, dans lequel ledit au moins un dispositif de surveillance comporte en outre au moins l'un des éléments suivants:
- un dispositif de surveillance par électrocardiogramme;
  - un dispositif de surveillance de tension artérielle;
  - un dispositif de surveillance par électroencéphalogramme;
  - un dispositif de surveillance de tension artérielle NI;
  - un dispositif de surveillance de fréquence respiratoire;
  - un dispositif de surveillance de fréquence cardiaque;
  - un dispositif de surveillance de perfusion systémique; et
  - un dispositif de surveillance d'air expiré.
5. Système selon la revendication 1, dans lequel ledit au moins un dispositif de surveillance est opérationnel pour numériser la forme d'onde.
6. Système selon l'une quelconque des revendications 1 à 5, dans lequel au moins l'un desdits au moins un dispositif de surveillance et de la fonctionnalité d'interprétation de paramètre médical est en outre fonctionnel pour constituer un angle de progression jusqu'à 80% de la concentration maximale de CO<sub>2</sub> expiré.
7. Système selon l'une quelconque des revendications
- 1 à 6, dans lequel ladite fonctionnalité d'interprétation de paramètre médical est en outre fonctionnelle pour fournir une indication d'au moins l'un des éléments parmi:
- fonctionnement défectueux du dispositif de surveillance;
  - et placement défectueux du dispositif de surveillance, en réaction à une valeur d'au moins l'une des mesures.
8. Système selon l'une quelconque des revendications 1 à 7, dans lequel ledit au moins un paramètre médical comprend en outre au moins l'un des éléments suivants:
- un paramètre visuel;
  - un paramètre respiratoire;
  - un paramètre d'oxygène;
  - un paramètre ECG;
  - un paramètre de fonction cardiaque;
  - un paramètre neurologique;
  - un paramètre de tension artérielle; et
  - un paramètre EEG.
9. Système selon l'une quelconque des revendications 1 à 6, dans lequel la fonctionnalité d'interprétation de paramètre médical est opérationnelle pour fournir une indication de l'état du patient, à savoir qu'il va bien si toutes les conditions suivantes sont réunies:
- a) les valeurs de tension artérielle sont dans la fourchette normale;
  - b) la fréquence respiratoire est normale;
  - c) le cycle CO<sub>2</sub> est inférieur ou égal à 0,3 sec;
  - d) la courbe CO<sub>2</sub> est supérieure ou égale à 100 mm Hg/sec;
  - e) SP0<sub>2</sub> est supérieure ou égale à 95%; et
  - f) ETCO<sub>2</sub> est inférieur ou égal à 45 mm Hg;
- dans lequel la fonctionnalité d'interprétation de paramètre médical est en outre opérationnelle pour fournir une indication de l'état du patient, à savoir qu'il y a un problème si au moins l'une des conditions a) à f) n'est pas réunie.
10. Système selon la revendication 9, dans lequel la fonctionnalité d'interprétation de paramètre médical est opérationnelle pour fournir une recommandation visant à réaliser au moins l'un des des traitements suivants en réaction à l'indication de l'état du patient, à savoir qu'il y a un problème:
- intubation du patient;
  - hospitalisation du patient;
  - traitement du patient par médicament; et
  - transfert du patient dans une unité de soin intensif.

11. Système selon la revendication 8, dans lequel ledit paramètre visuel comprend l'aspect visuel dudit patient; ou  
 dans lequel ledit paramètre respiratoire englobe au moins l'un des éléments parmi la fréquence respiratoire du patient, une valeur expiratoire forcée, et une valeur de capacité vitale forcée; ou  
 dans lequel le paramètre d'oxygène comporte au moins l'un de PO2 et SP02; ou  
 dans lequel le paramètre ECG comporte au moins l'un d'un paramètre QRS et d'un segment ST; ou  
 dans lequel le paramètre de fonction cardiaque comporte un paramètre de fréquence cardiaque; ou dans lequel le paramètre de fonction neurologique comporte un paramètre de réflexe; ou dans lequel le paramètre de tension artérielle englobe au moins l'un des éléments parmi une mesure de tension artérielle et un rapport systolique:diastolique. 5 10 15
12. Système selon l'une des revendications 1 et 8, dans lequel ladite fonctionnalité d'interprétation de paramètre médical est fonctionnelle pour fournir ladite au moins une indication de sortie réagissant à un schéma de changements dudit au moins un paramètre médical dans le temps. 20 25
13. Système selon l'une quelconque des revendications 1, 8, et 9, dans lequel ladite fonctionnalité d'interprétation de paramètre médical est en outre fonctionnelle pour fournir une indication de sortie réagissant à un schéma de changements du degré de gravité dudit état de santé dans le temps. 30
14. Système selon l'une quelconque des revendications précédentes, comprenant en outre une fonctionnalité de recommandation de traitement. 35
15. Système selon l'une quelconque des revendications précédentes, comprenant en outre une fonctionnalité d'émetteur adaptée pour acheminer ladite indication de sortie vers un emplacement à distance. 40

45

50

55

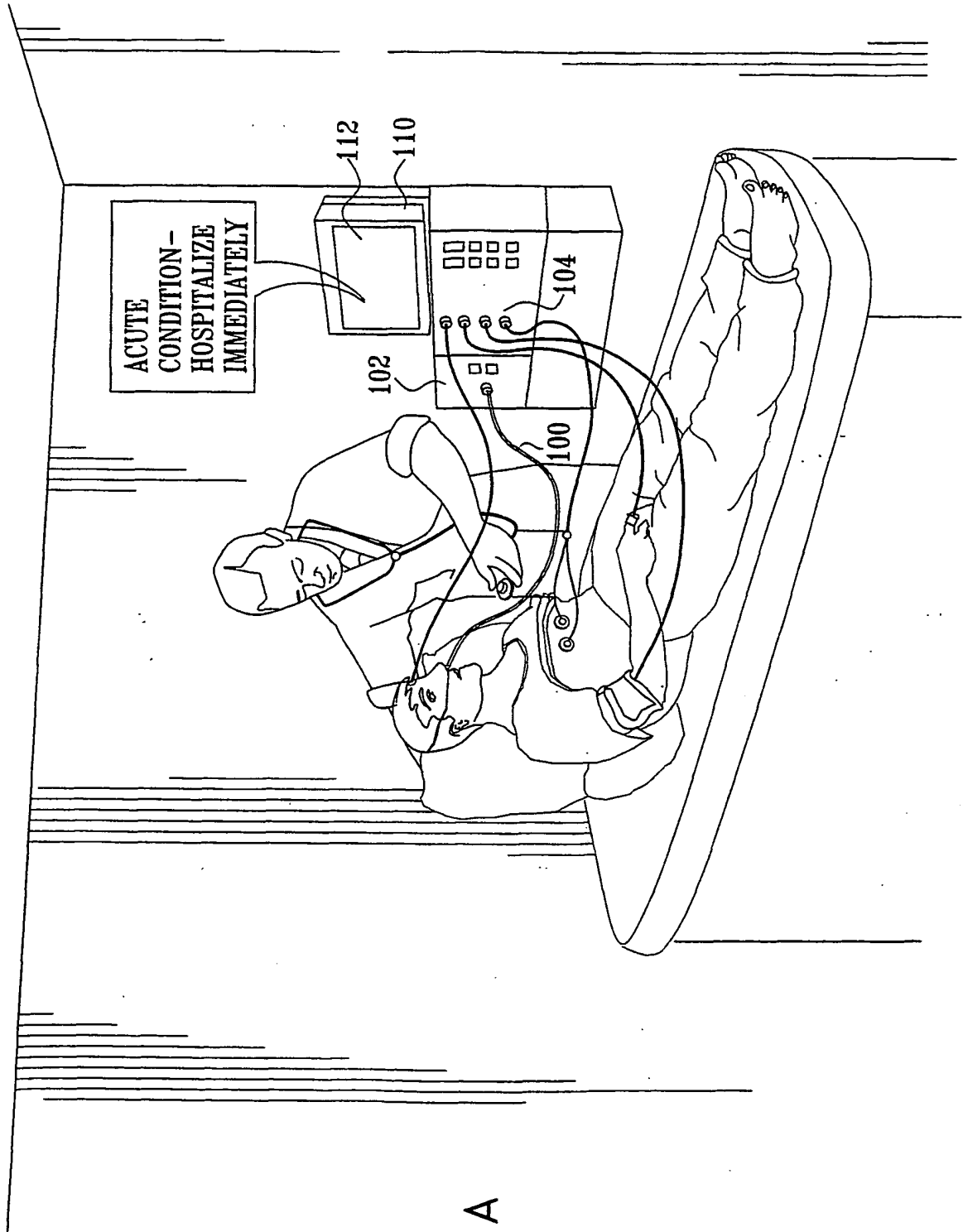


FIG. 1A

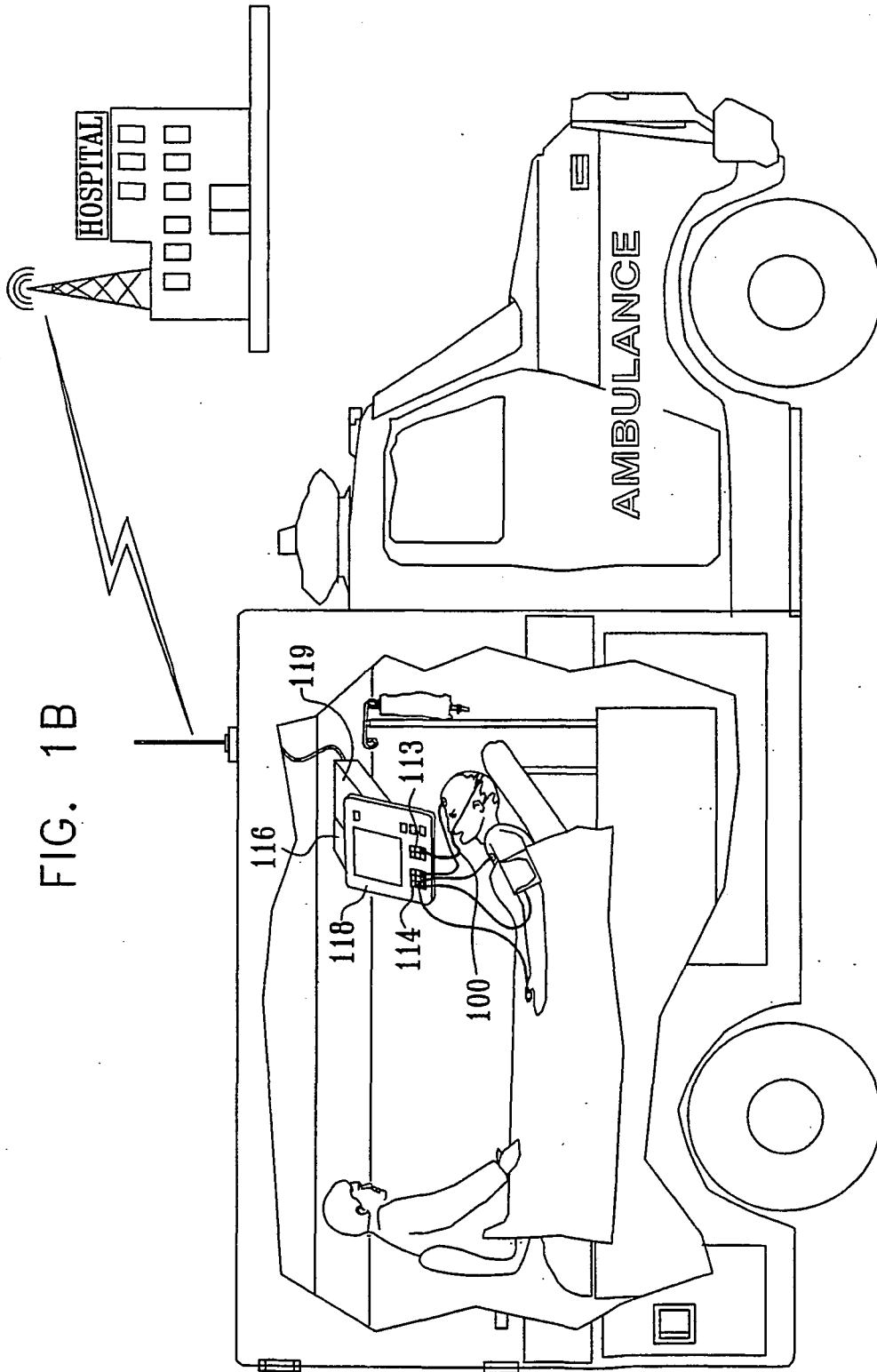


FIG. 1B

FIG. 1C

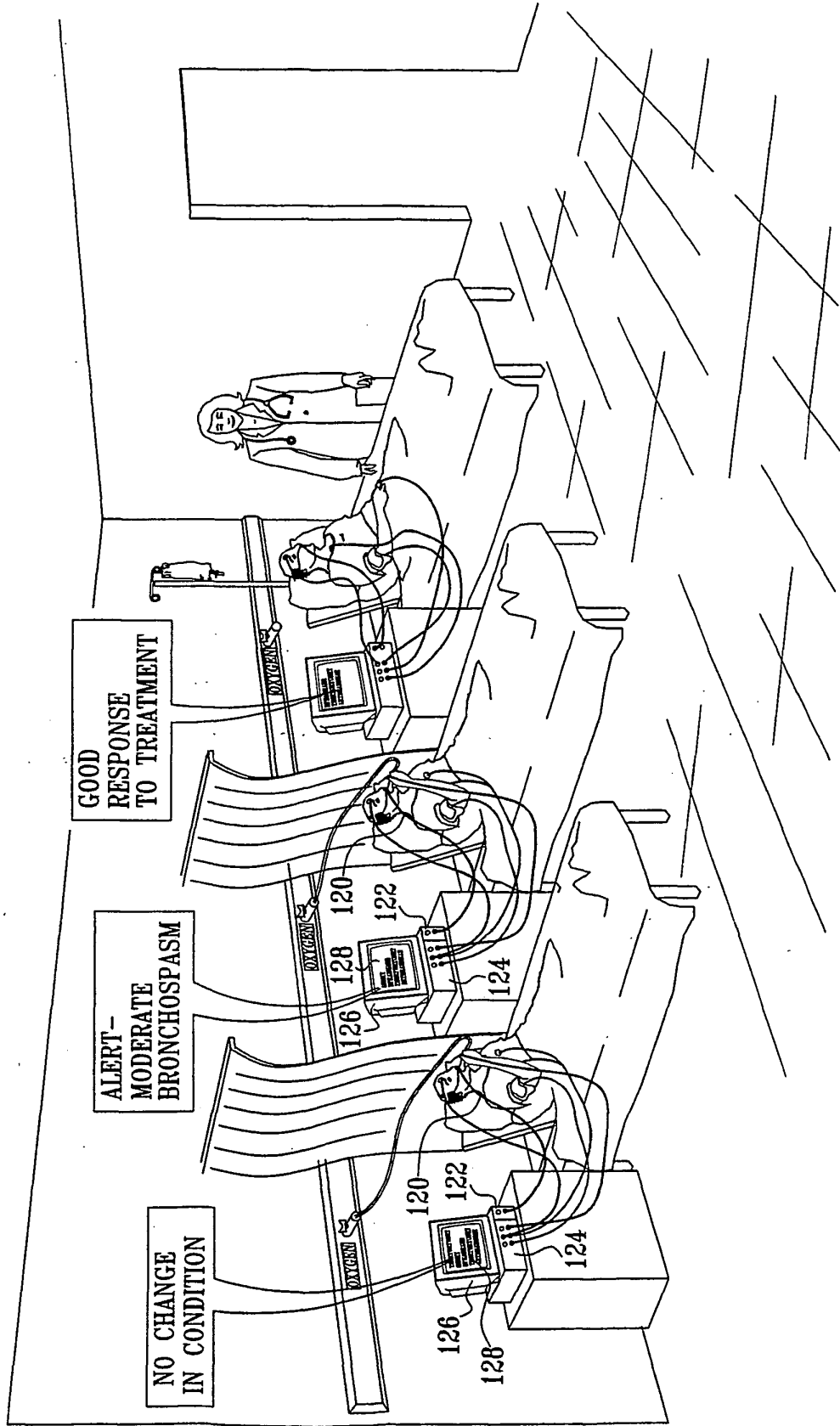


Fig. 2

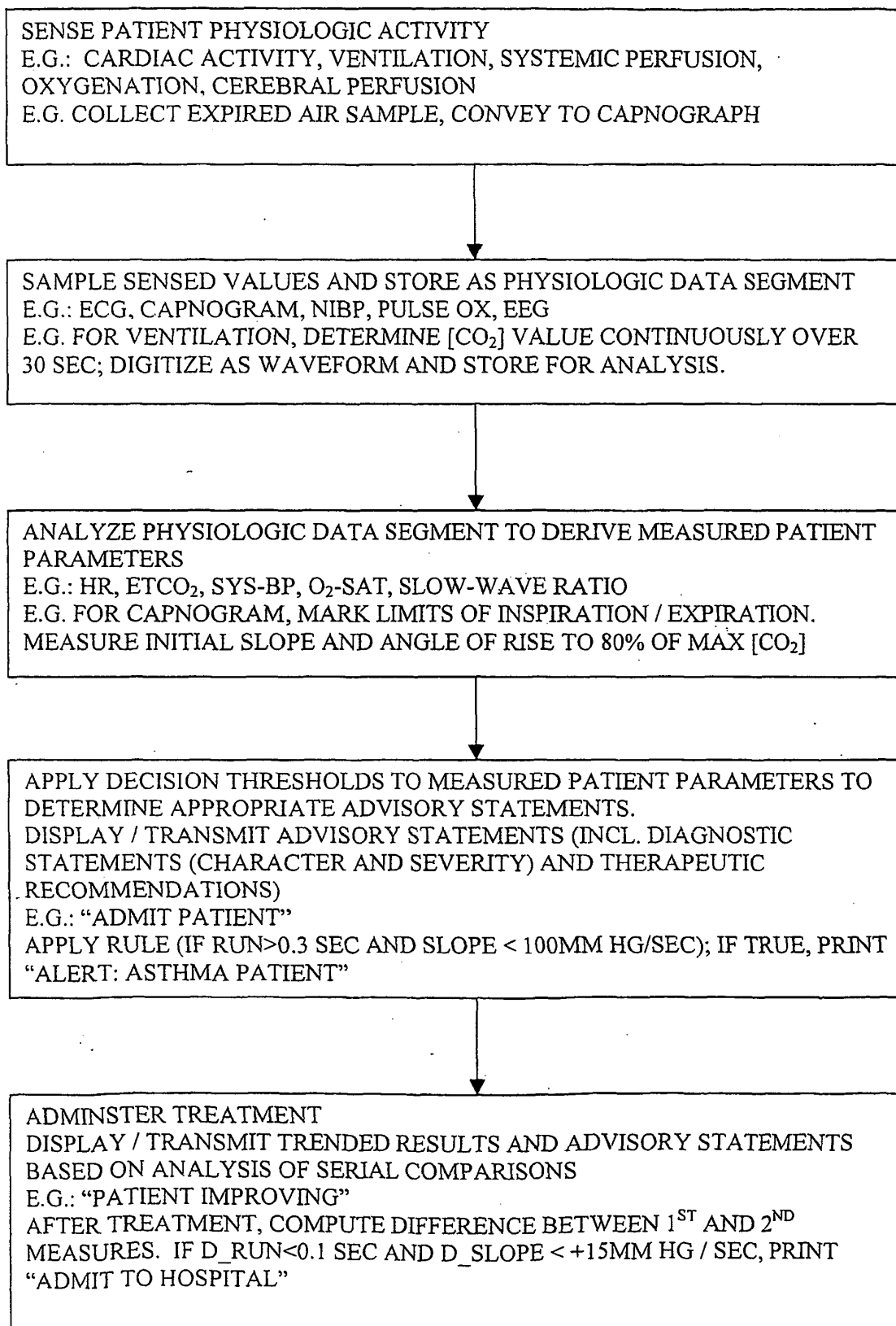
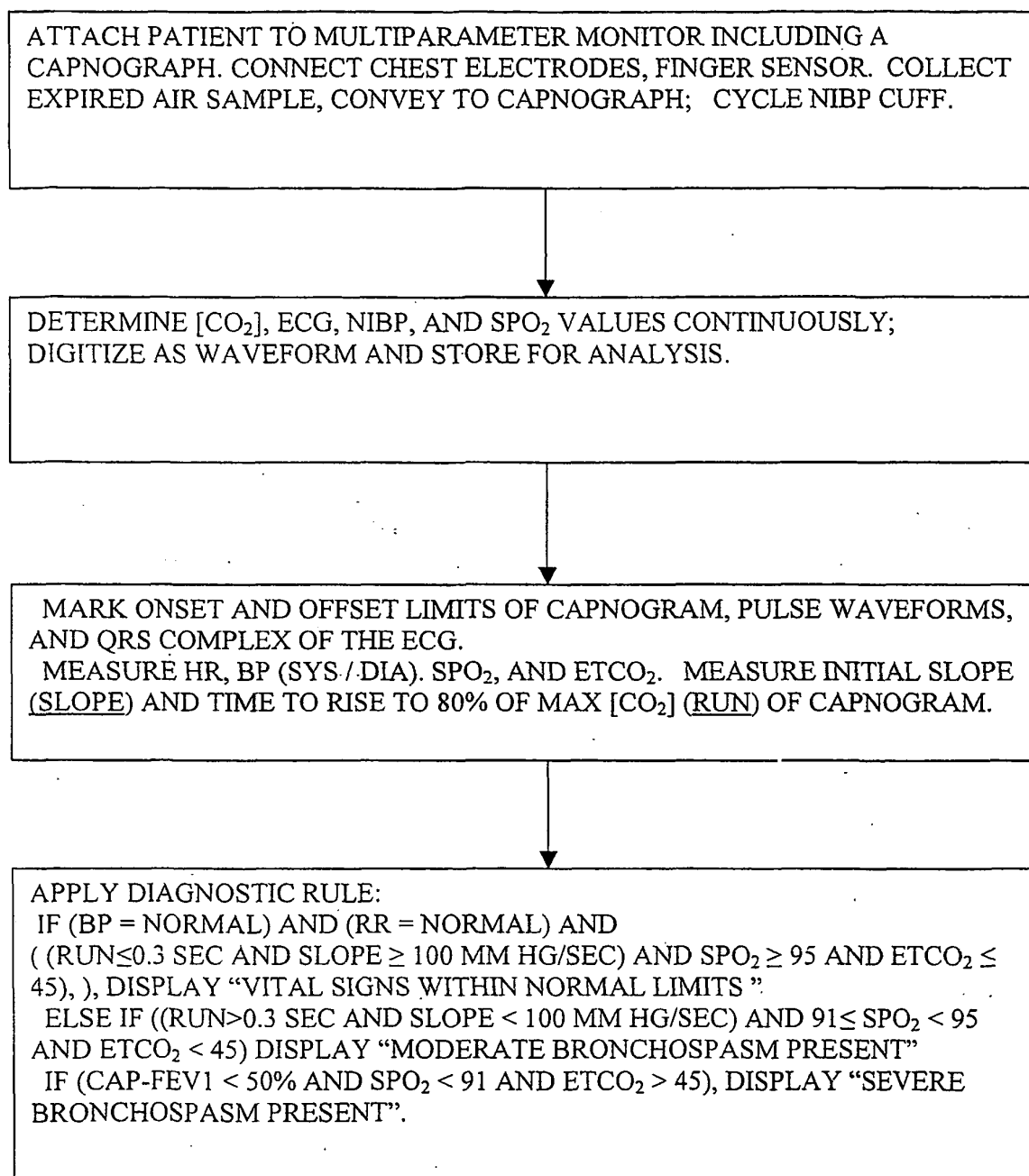




Fig. 4



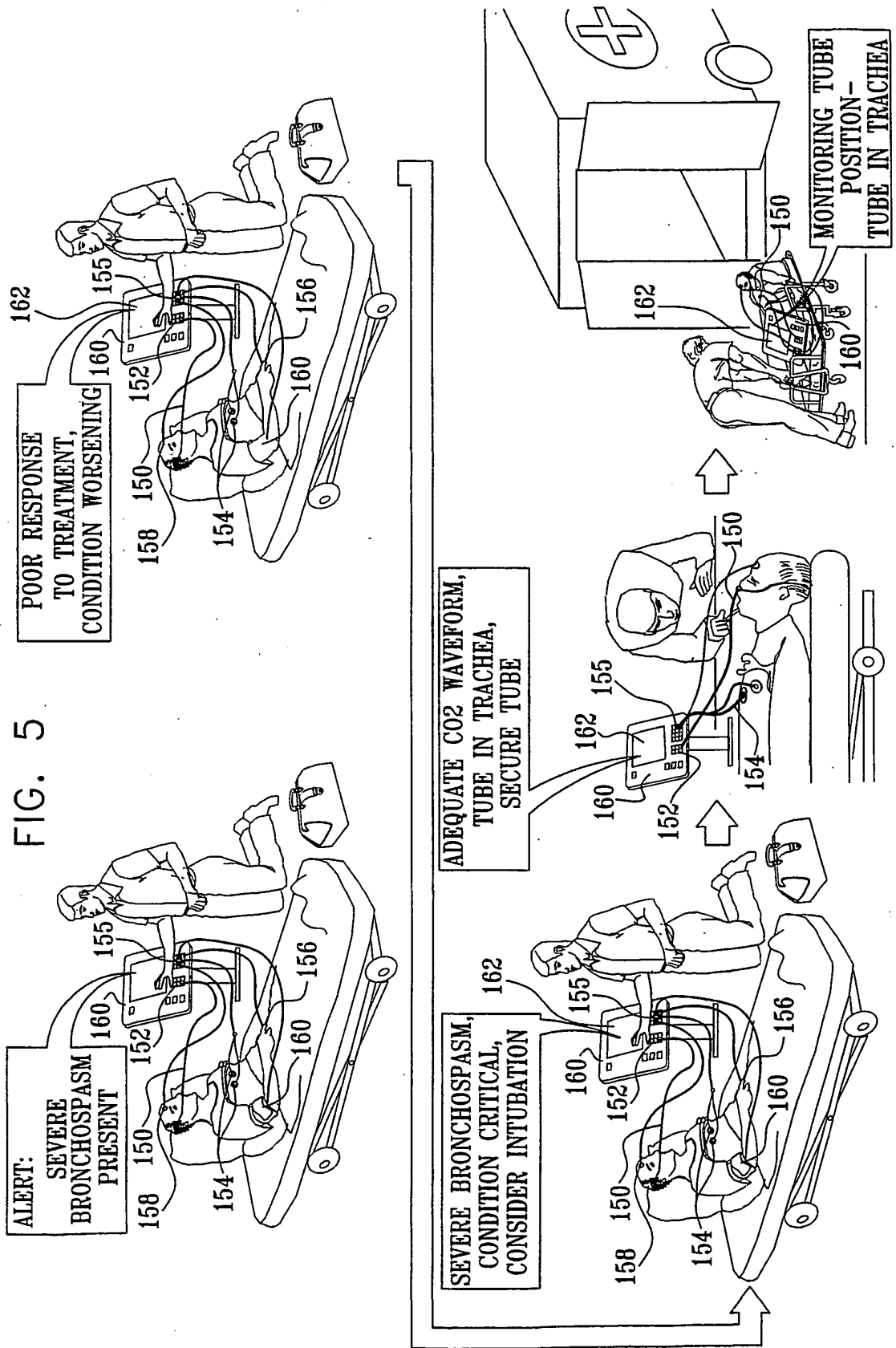


FIG. 5

Fig. 6A

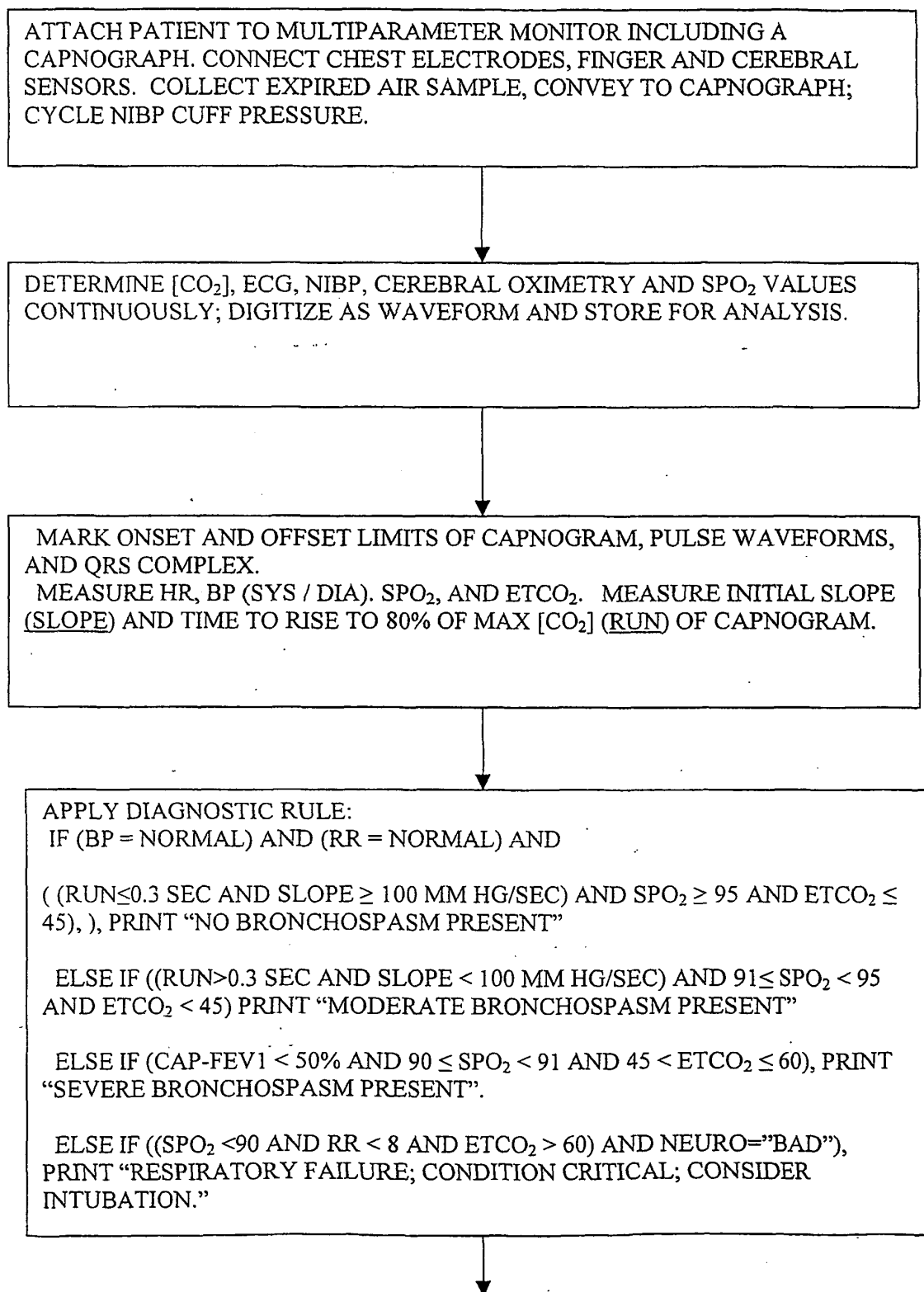
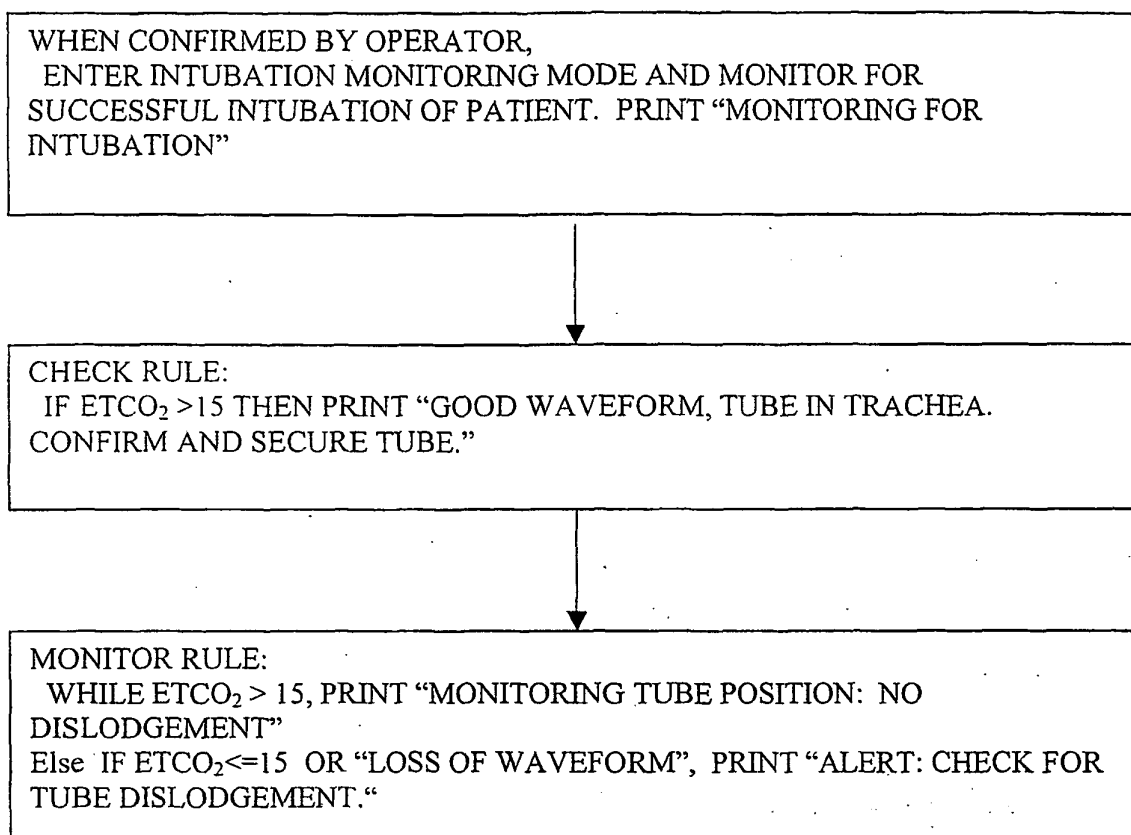


Fig. 6B



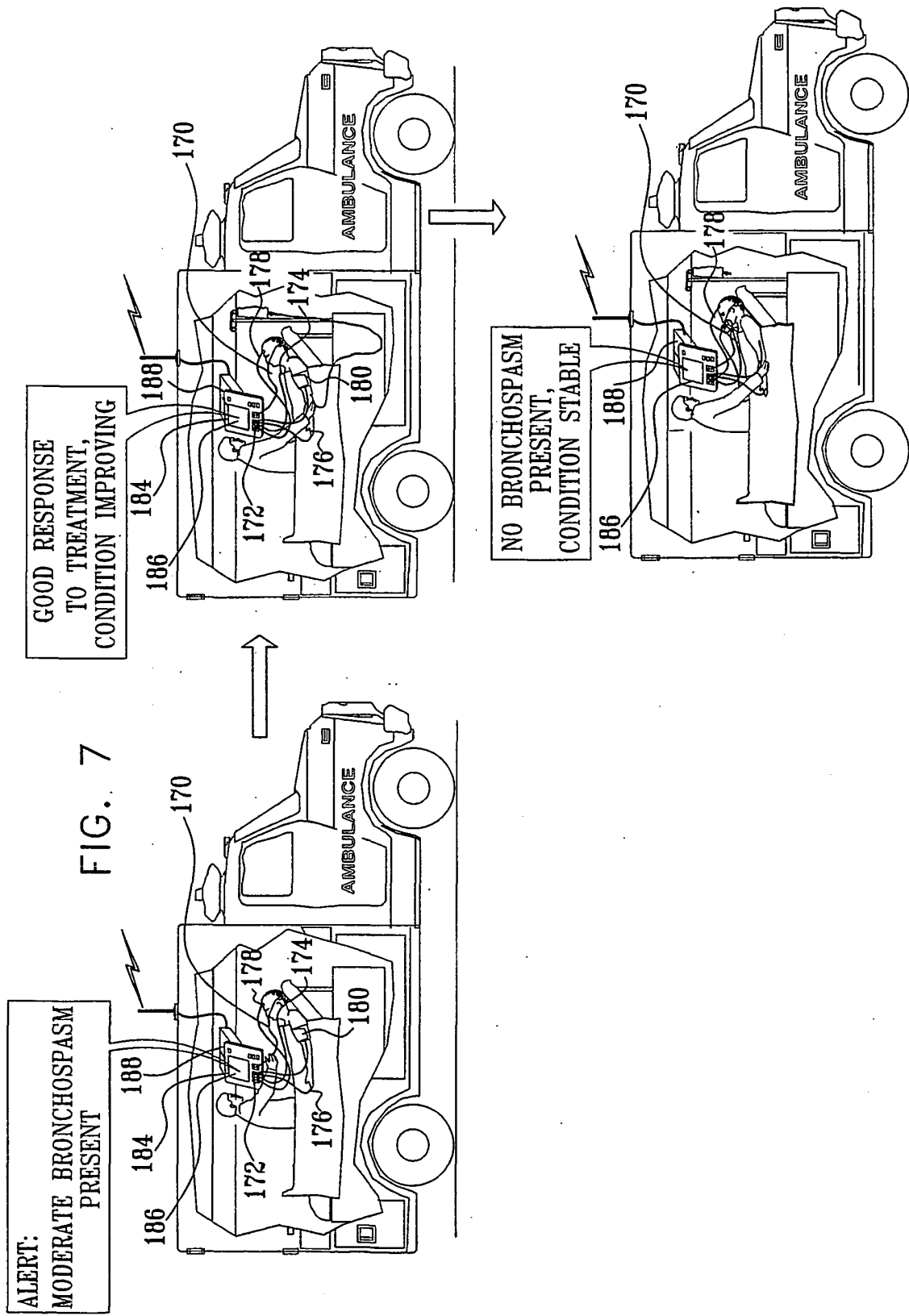


Fig. 8A

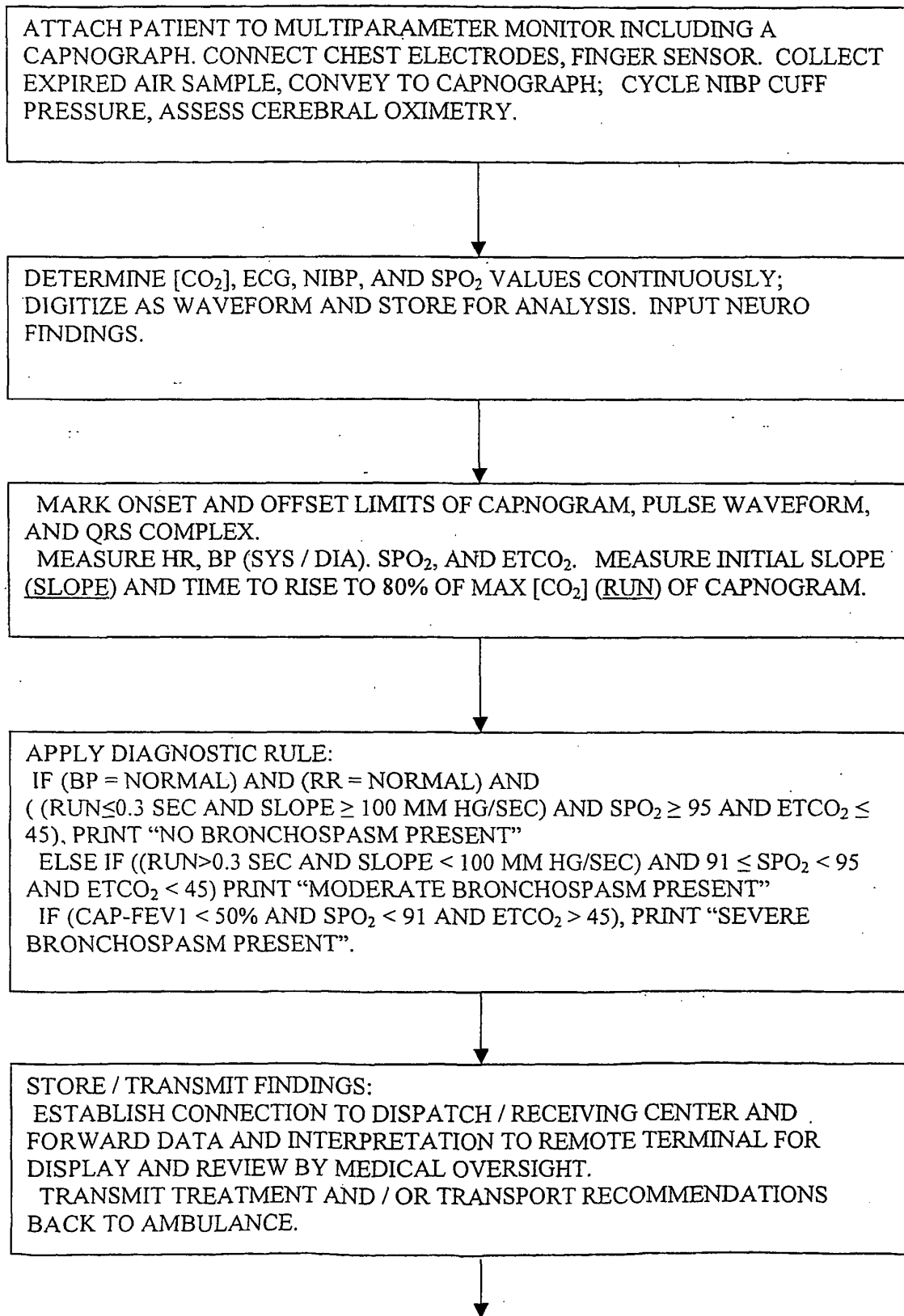
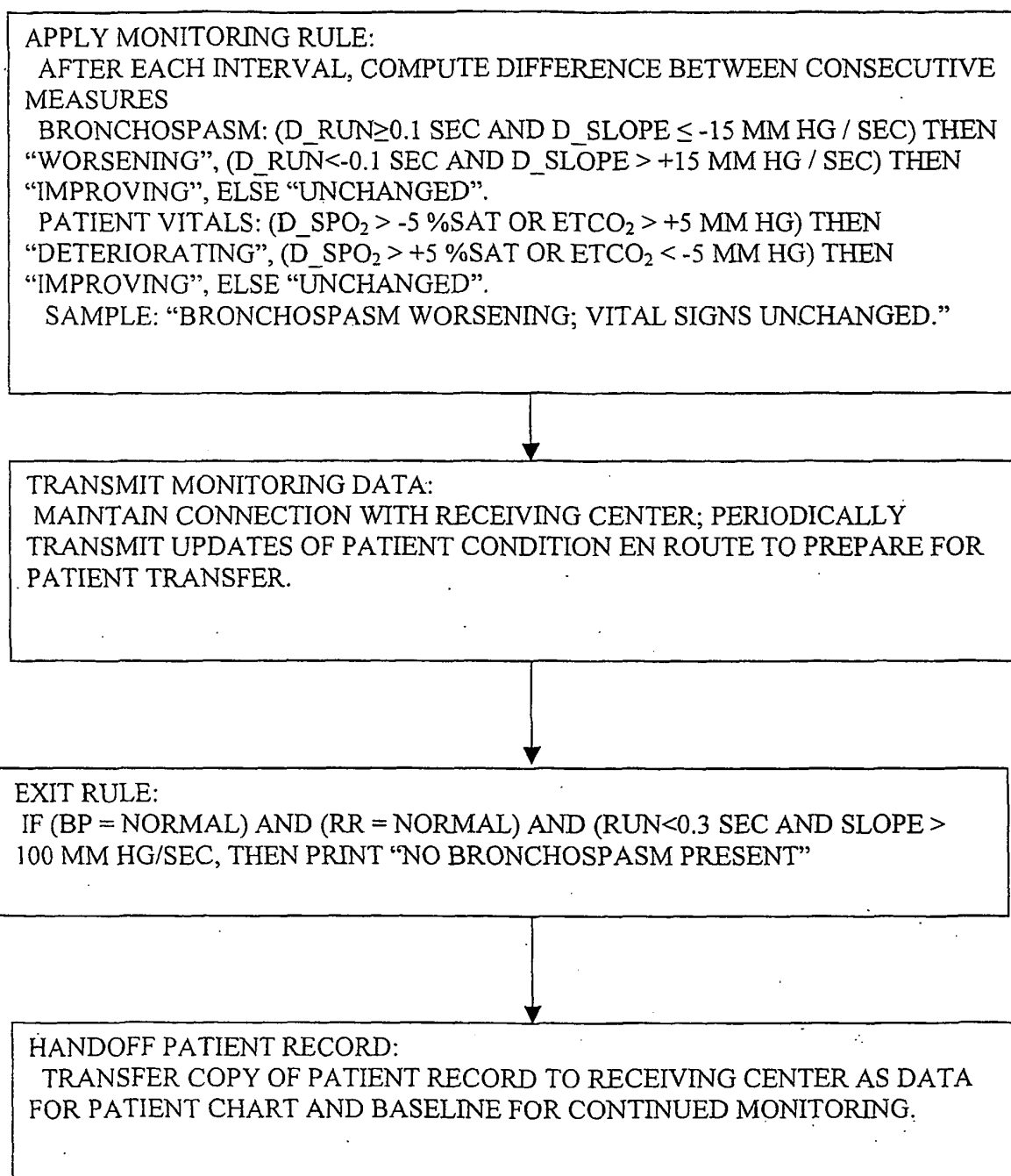


Fig. 8B



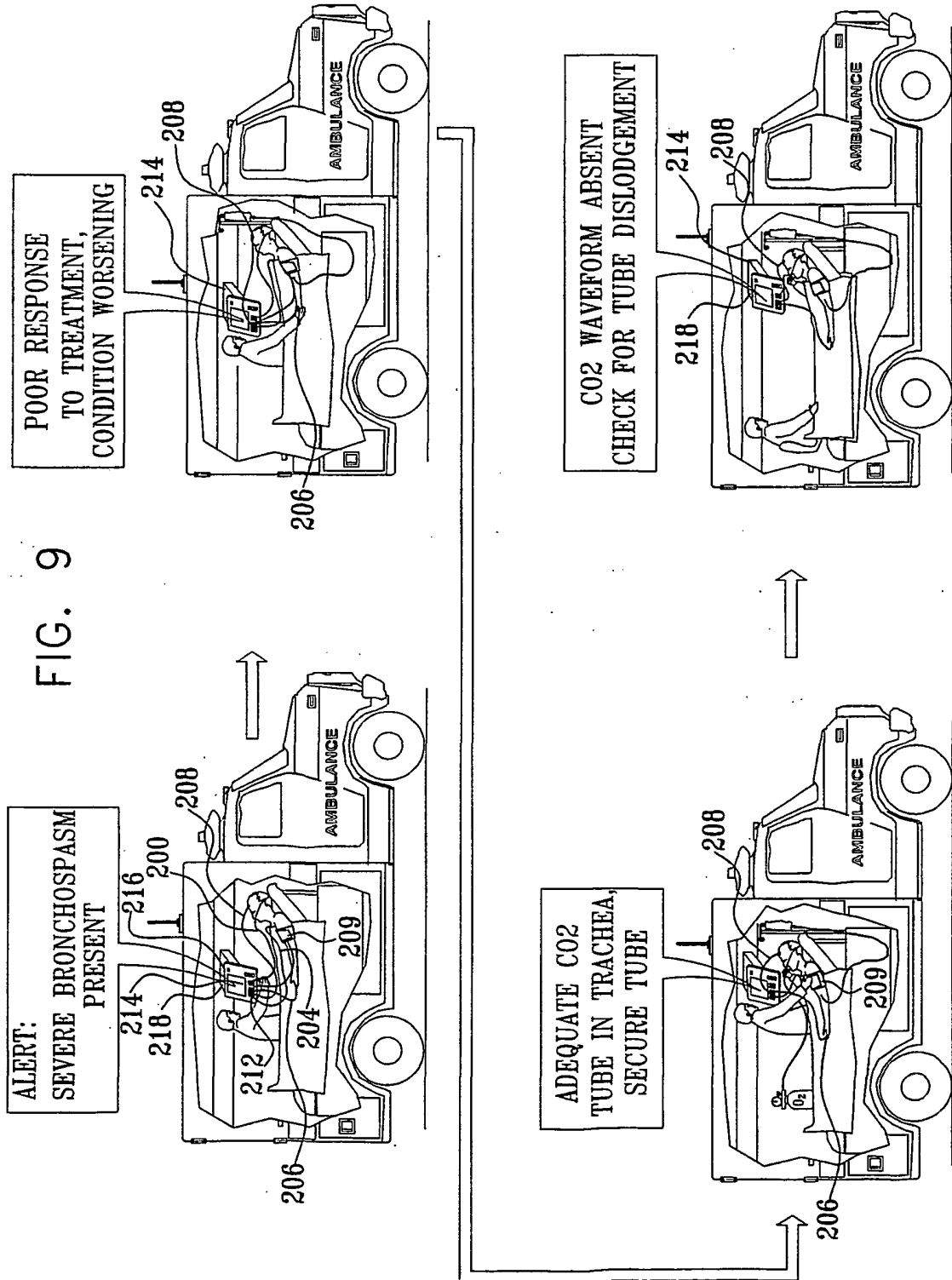


Fig. 10A

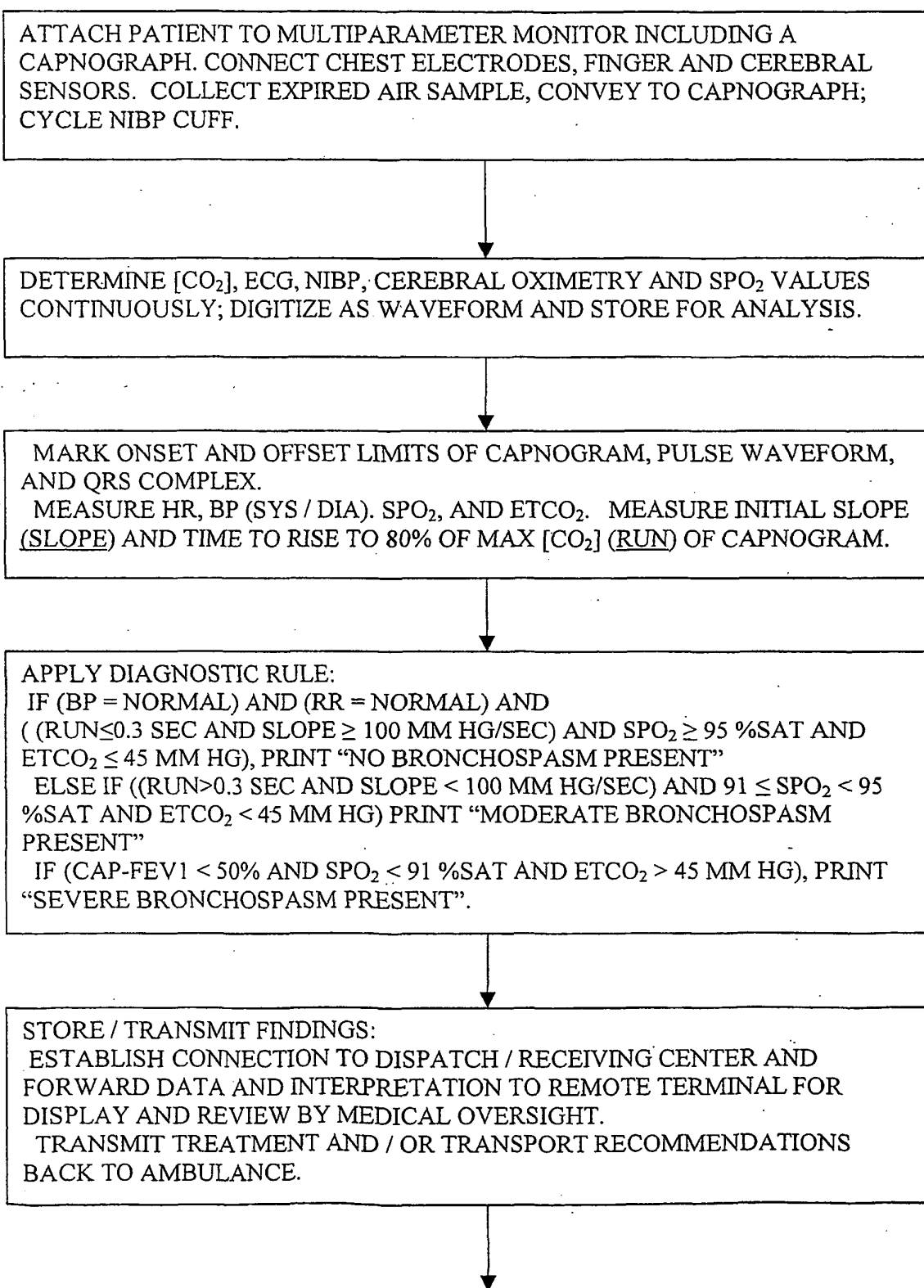


Fig. 10B

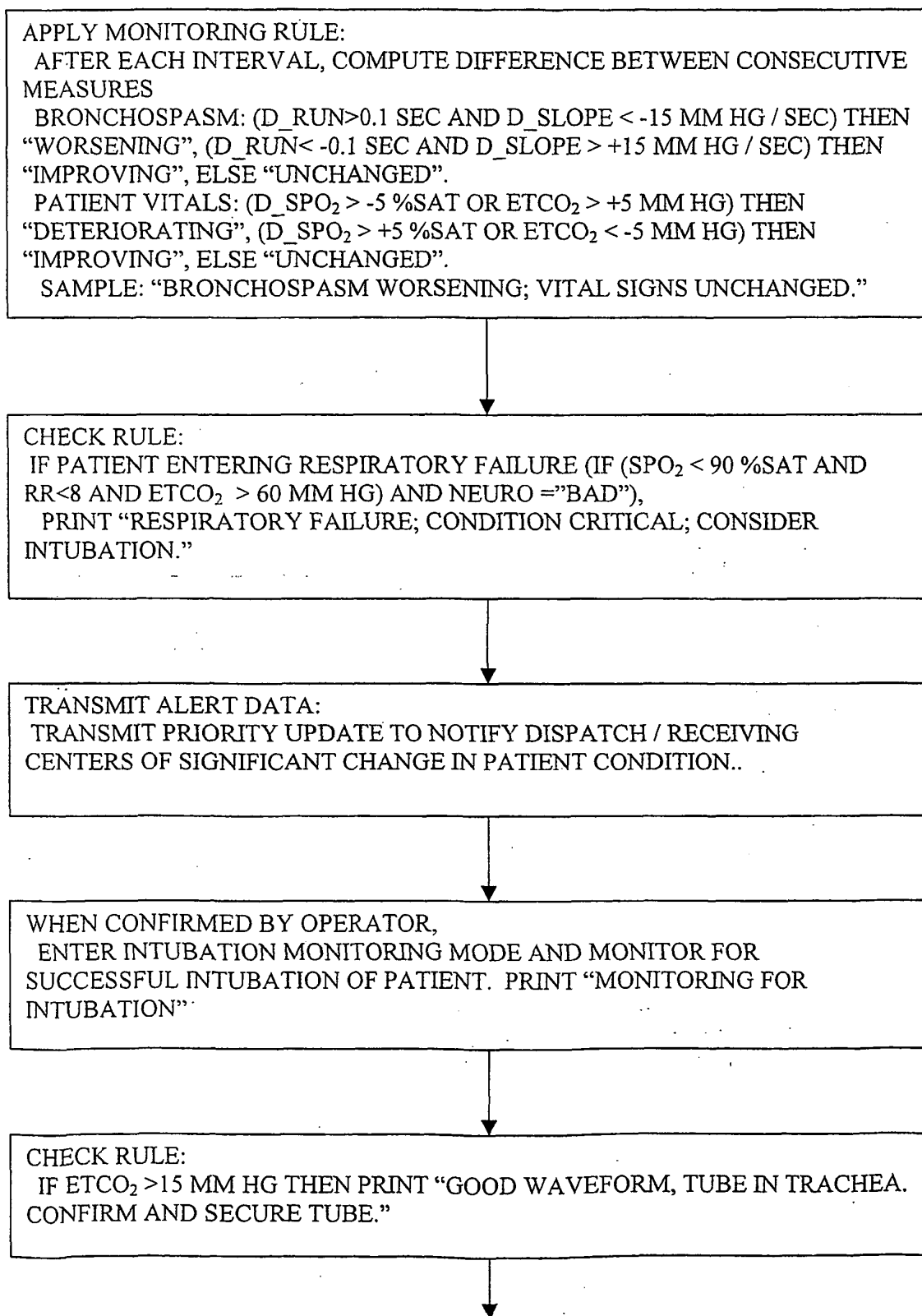
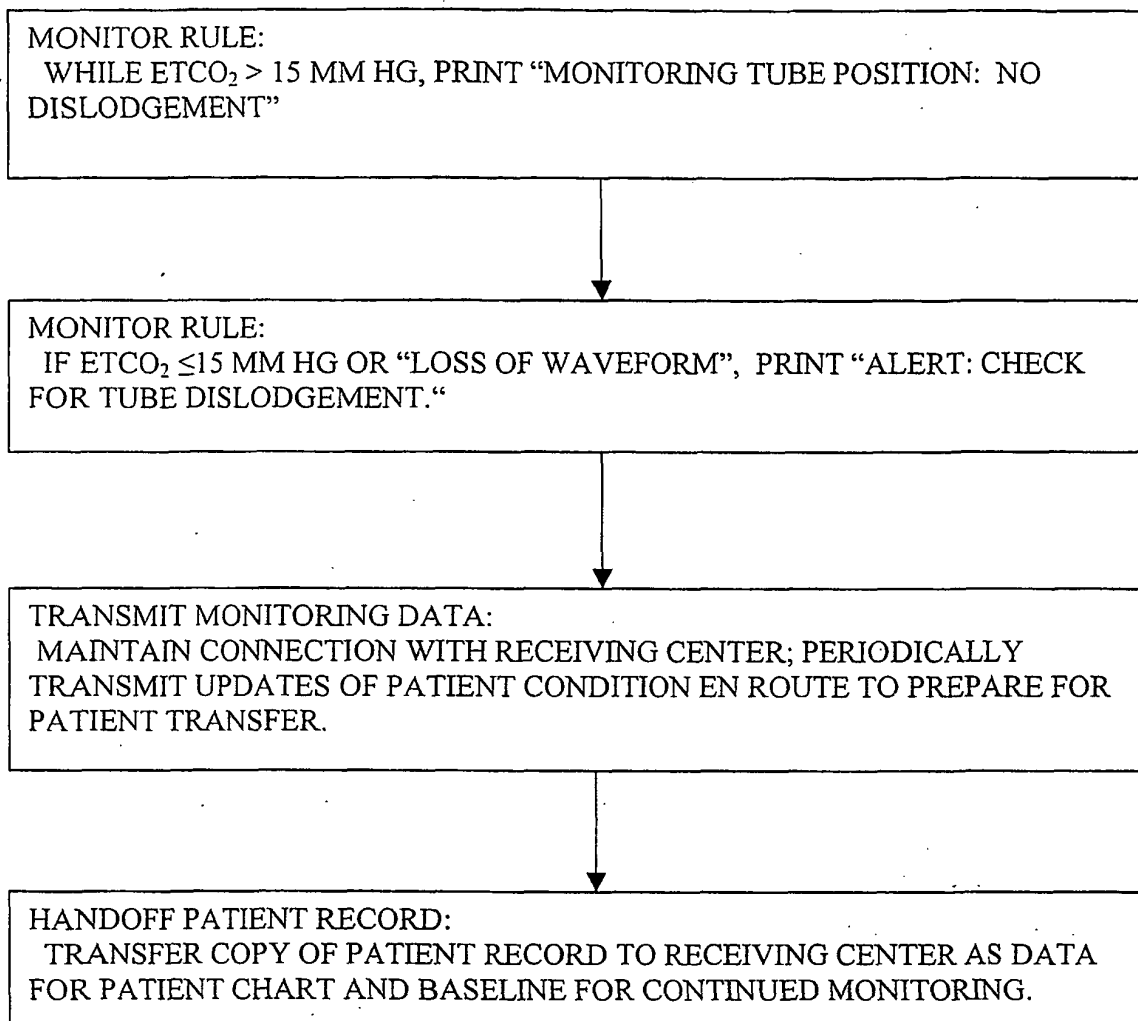


Fig. 10C



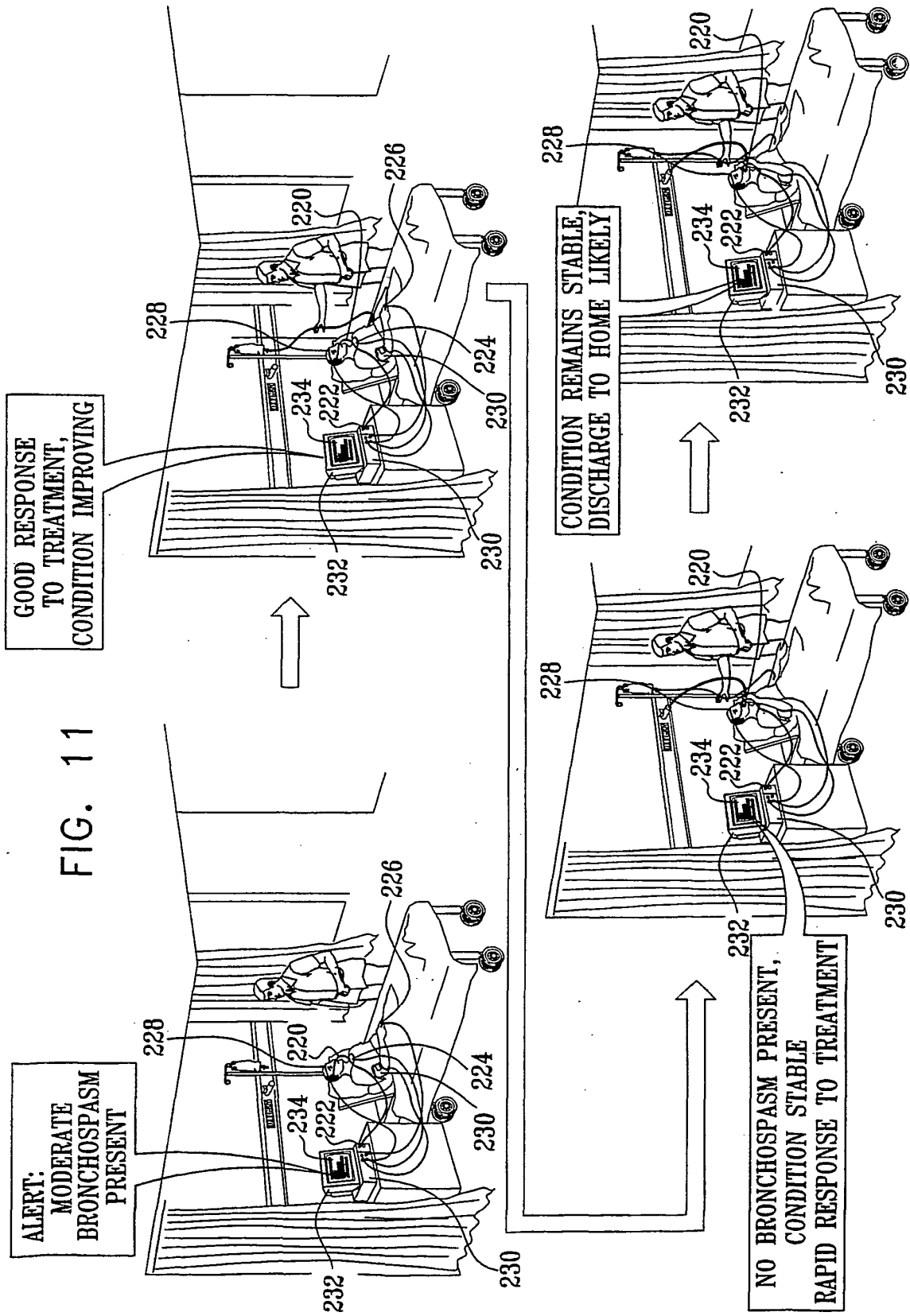
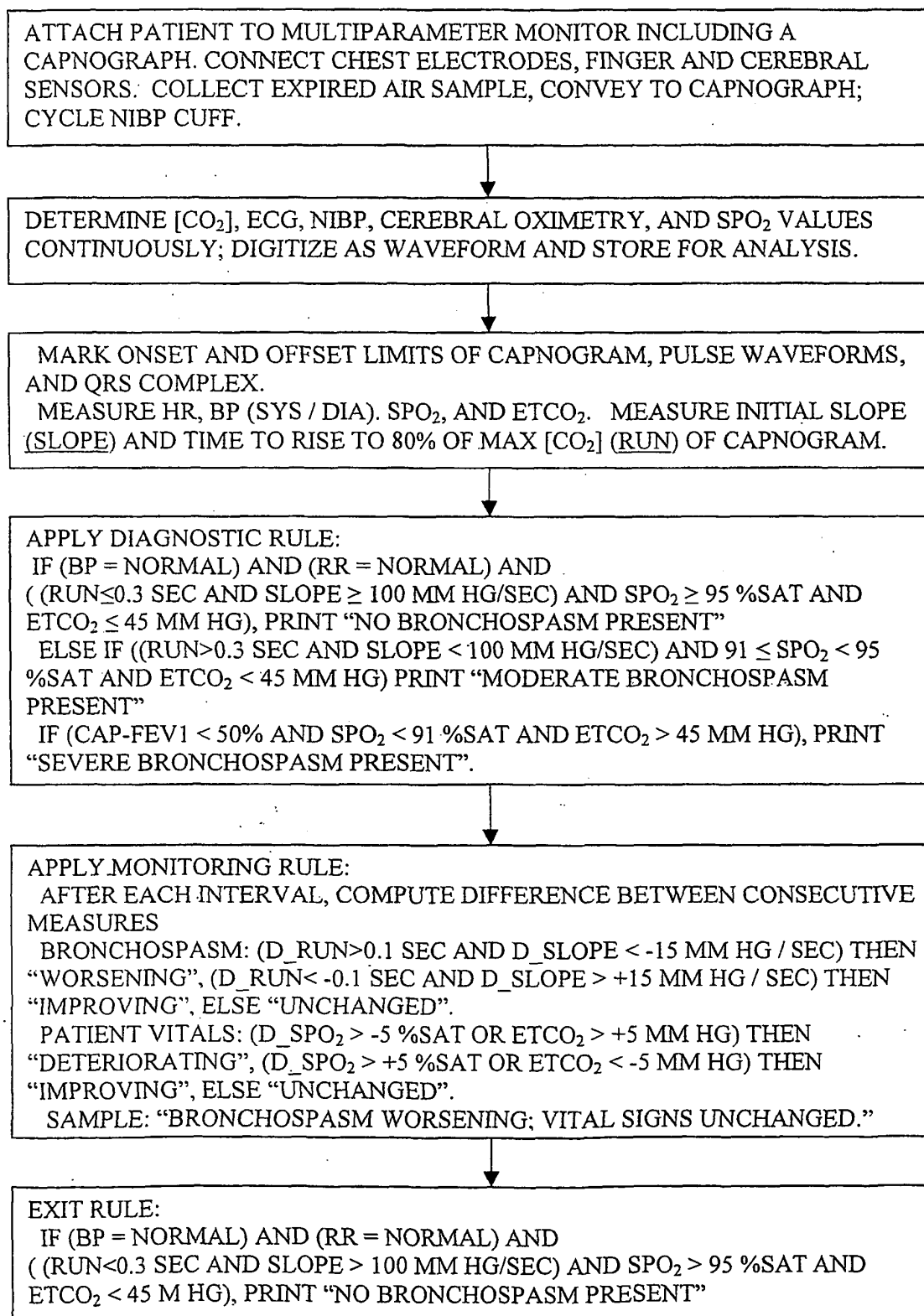


FIG. 11

Fig. 12



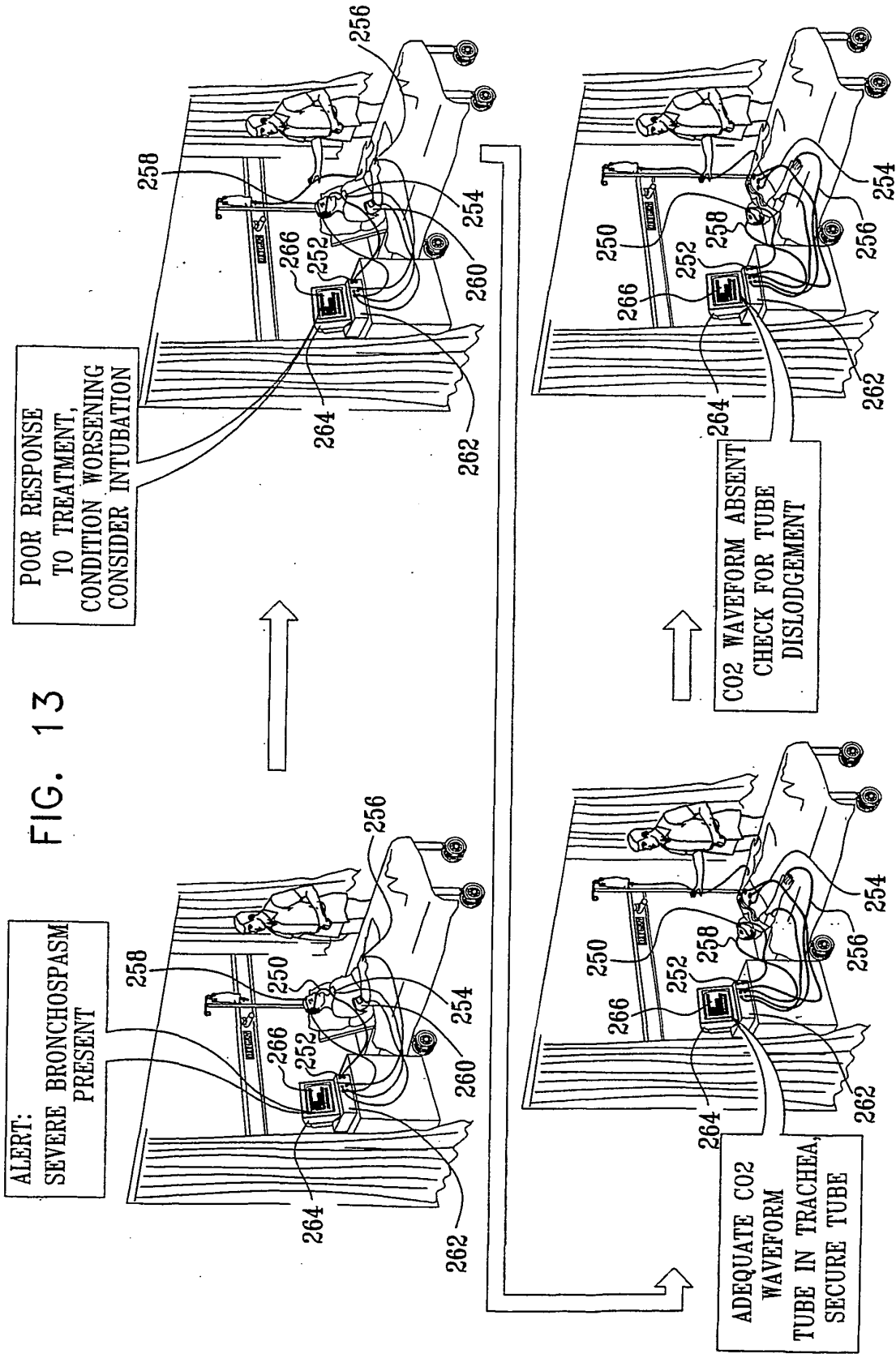


FIG. 13

Fig. 14A

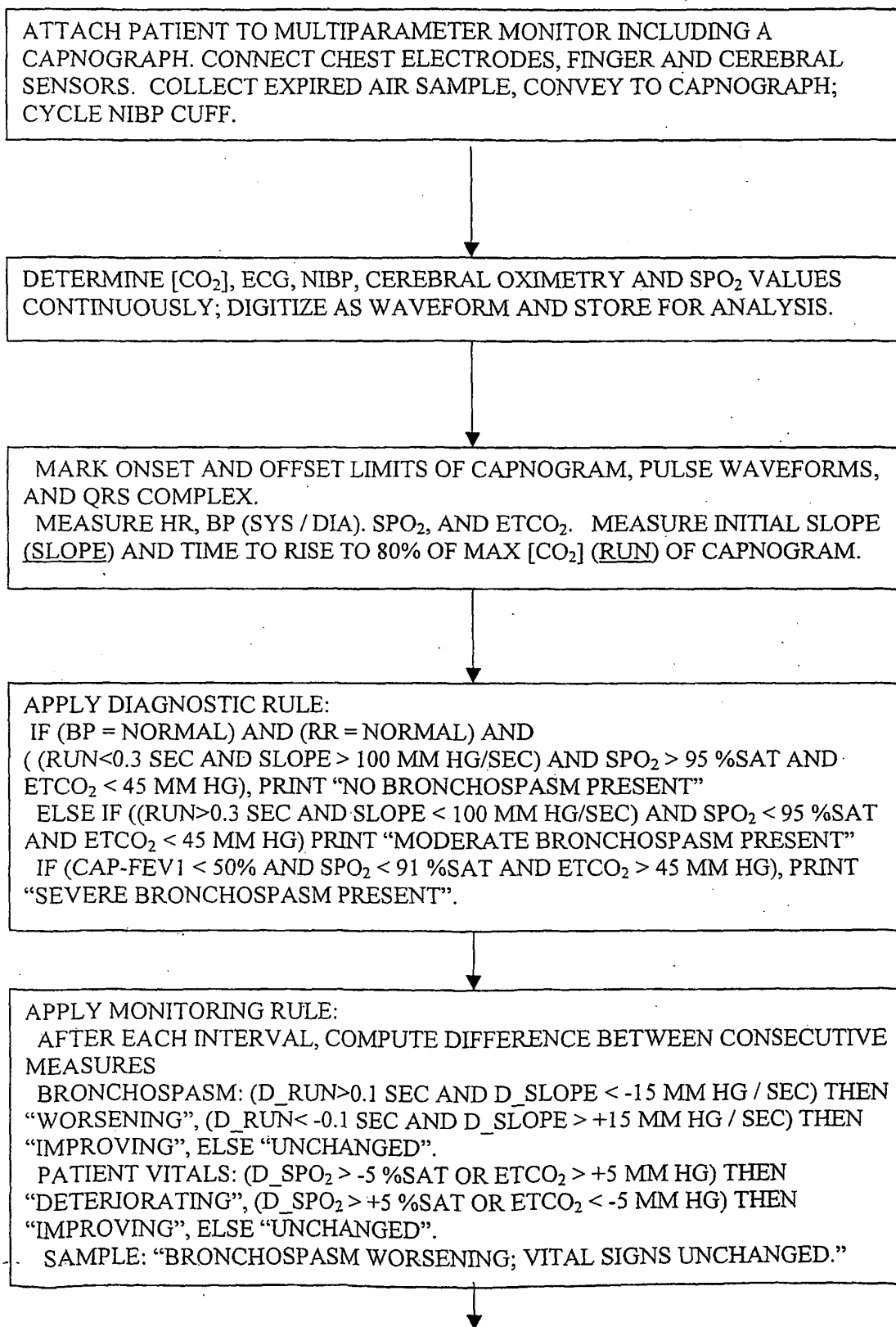


Fig. 14B

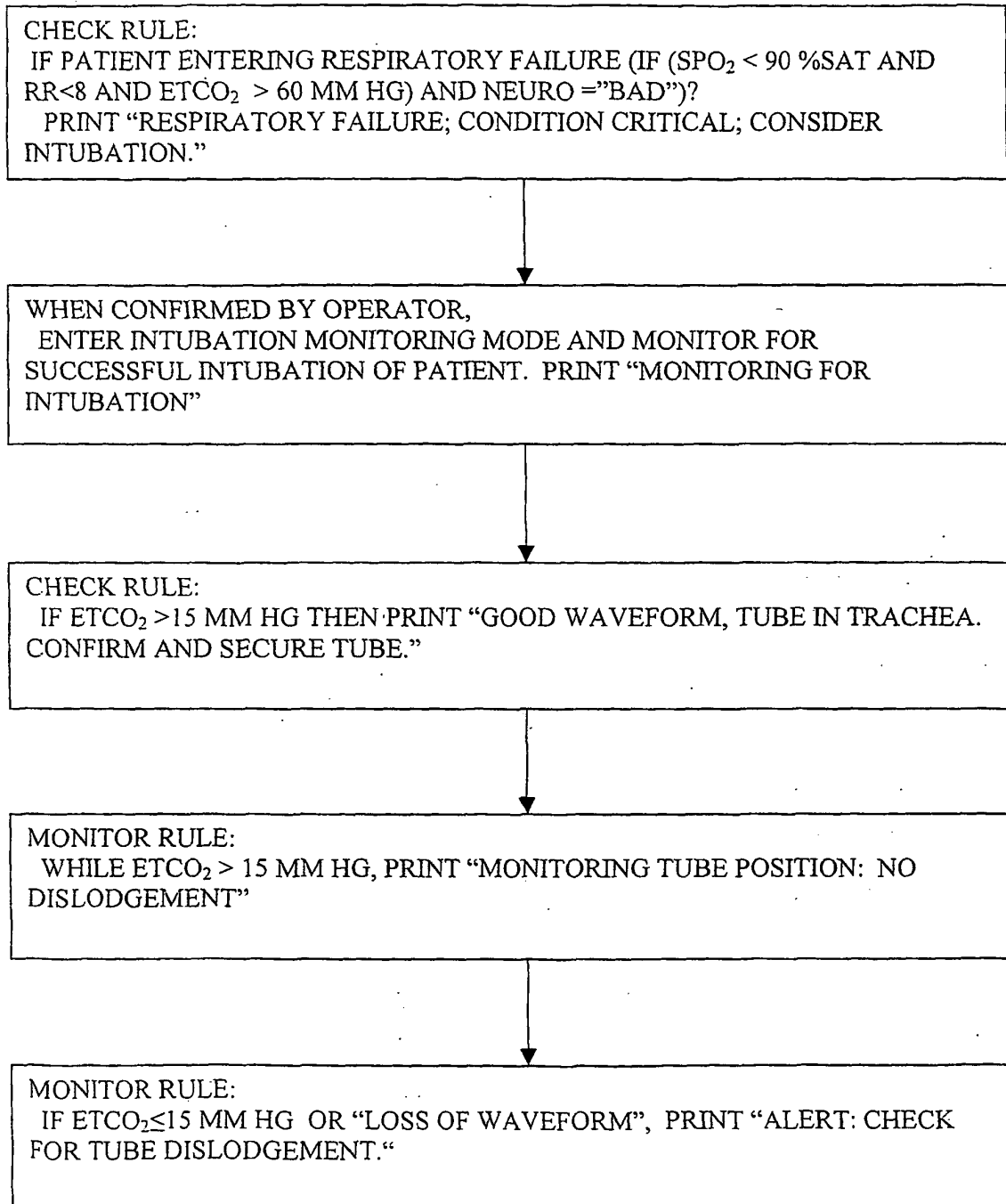


FIG. 15

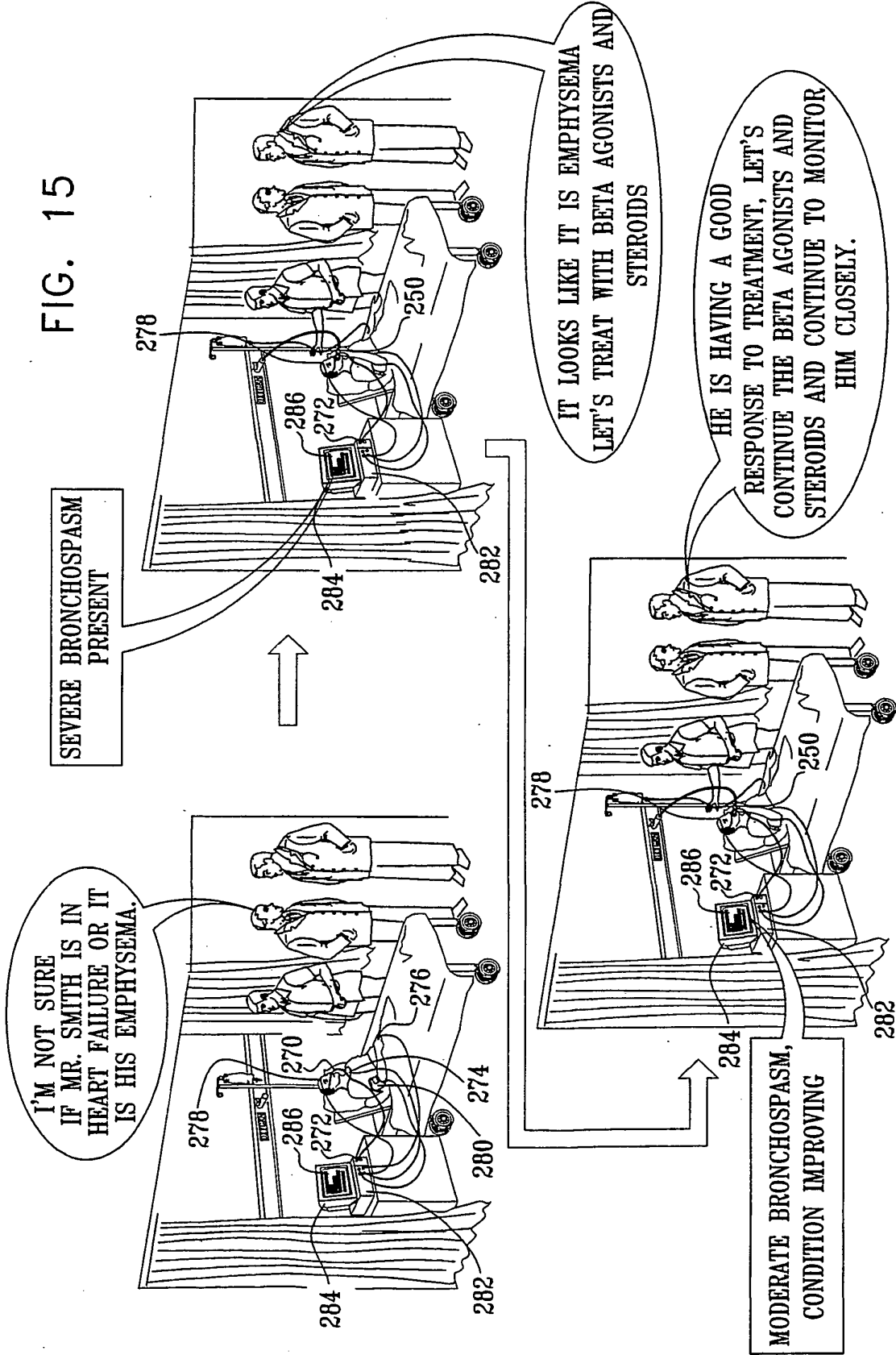


Fig. 16A

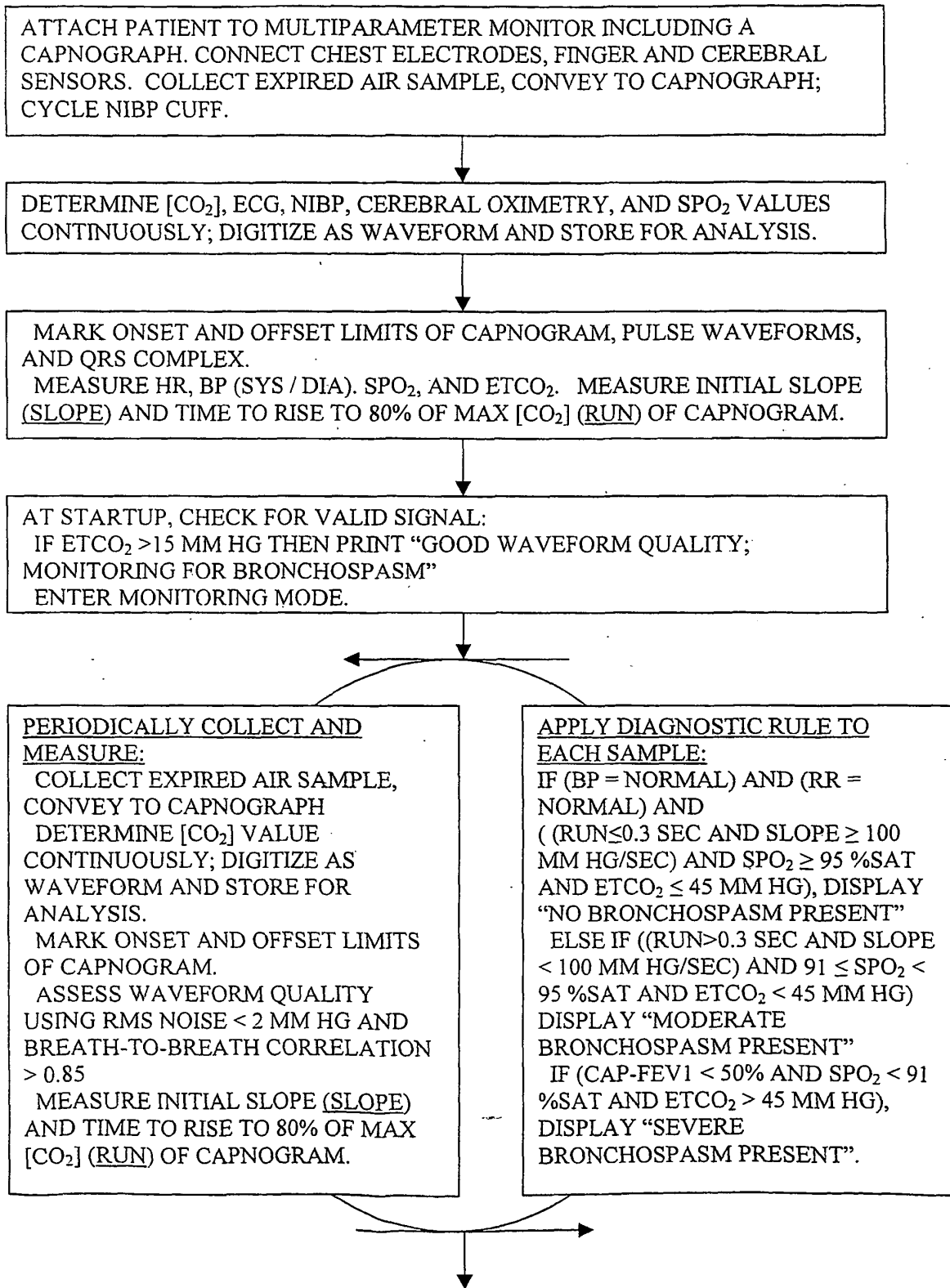
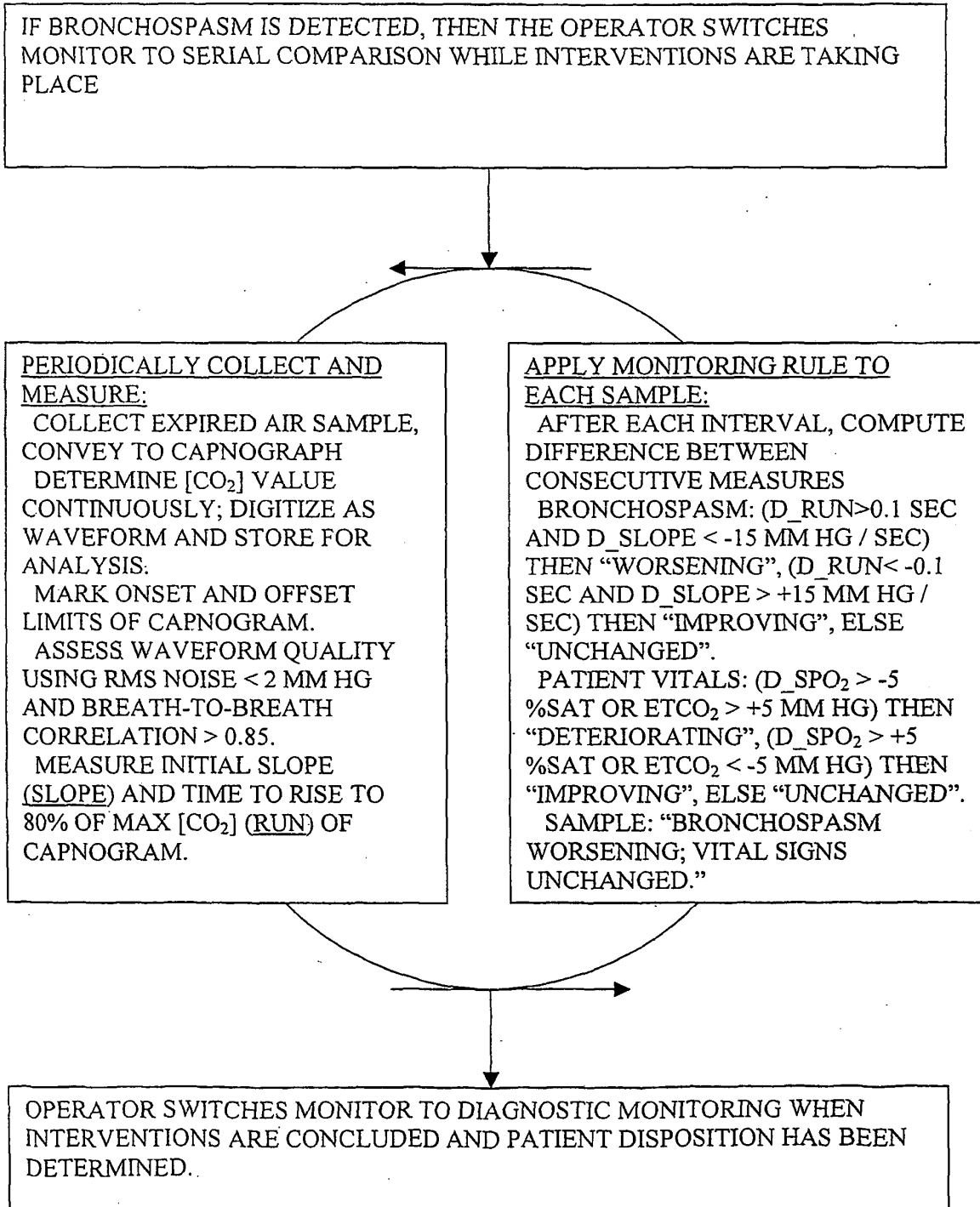


Fig. 16B



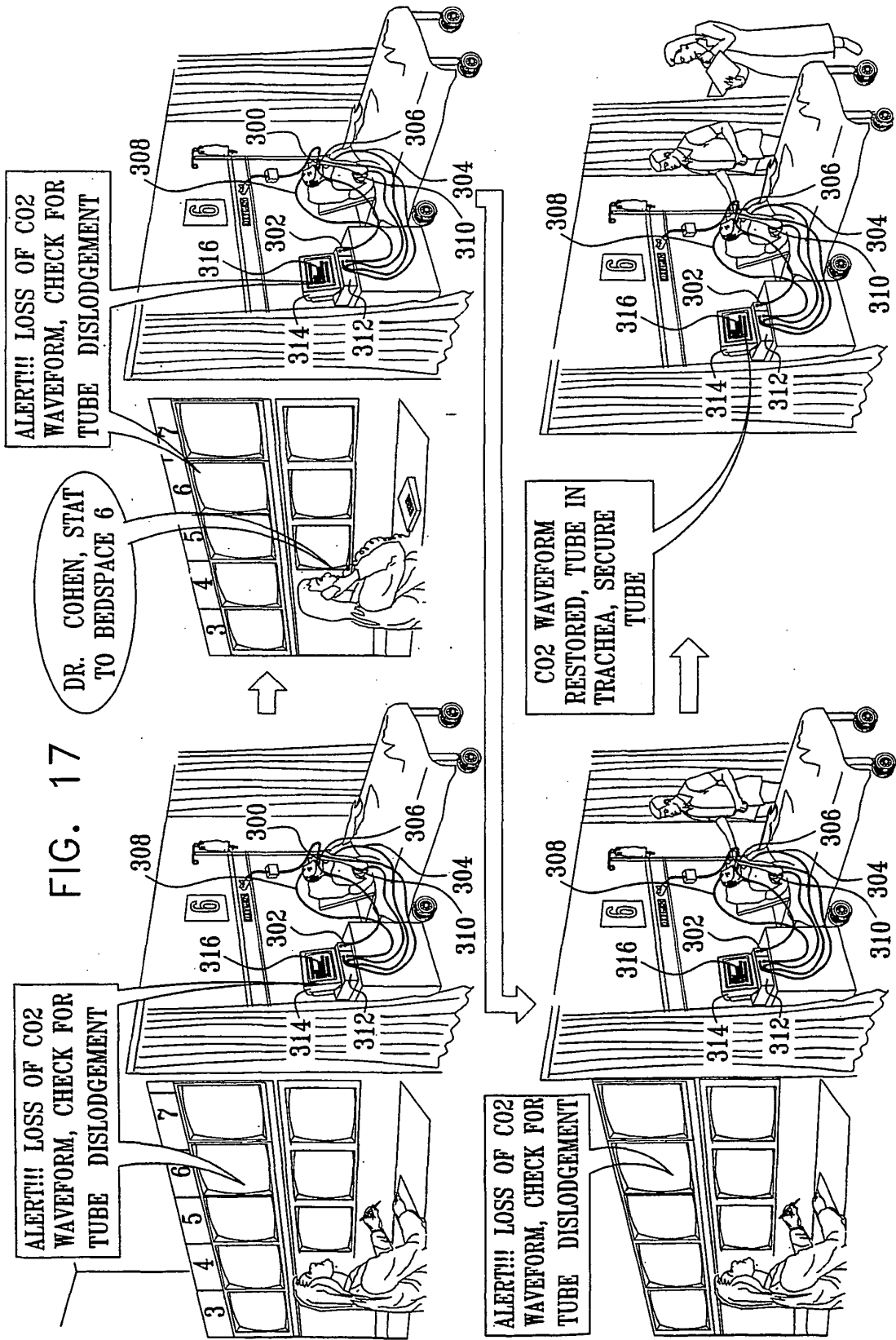
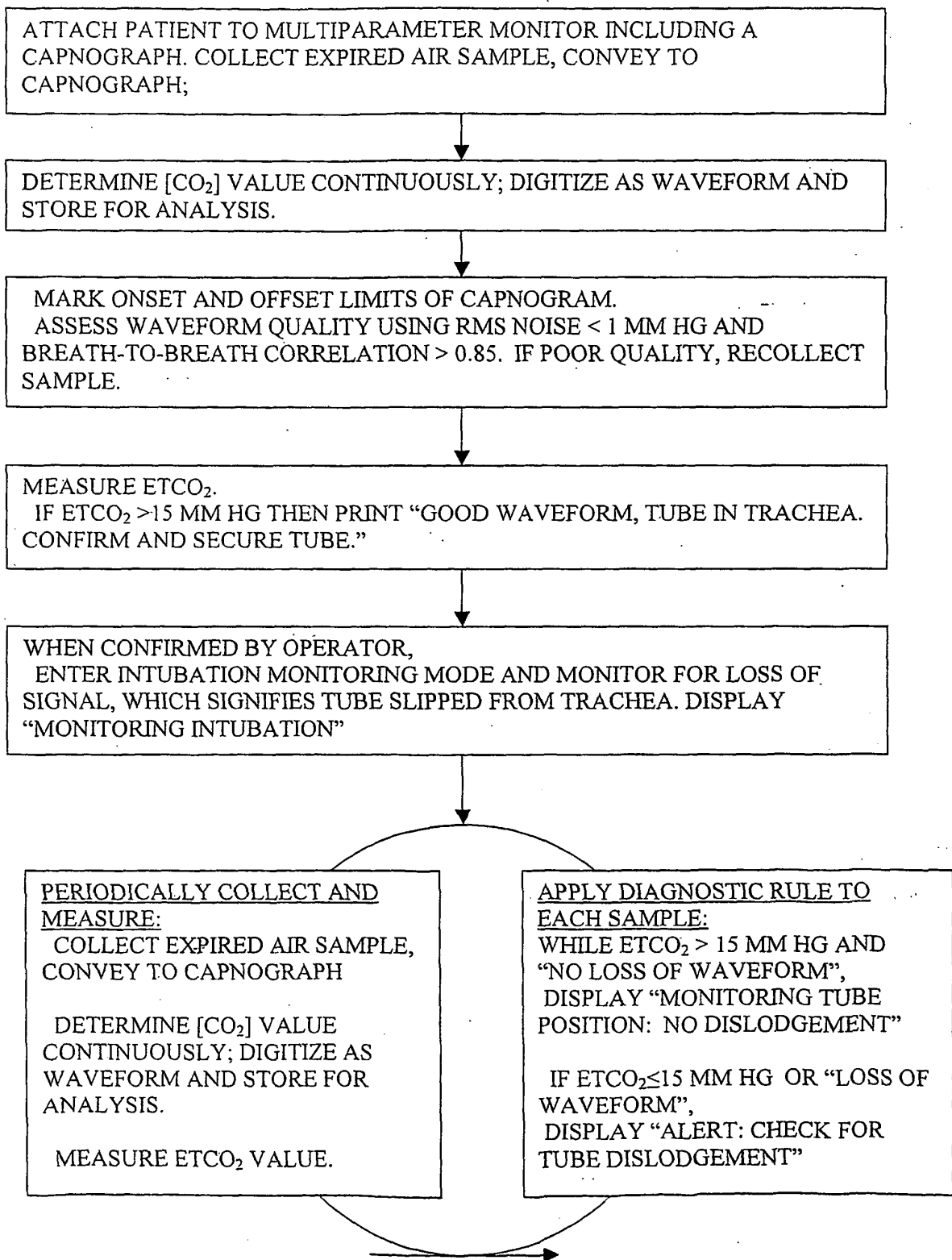


FIG. 17

Fig. 18



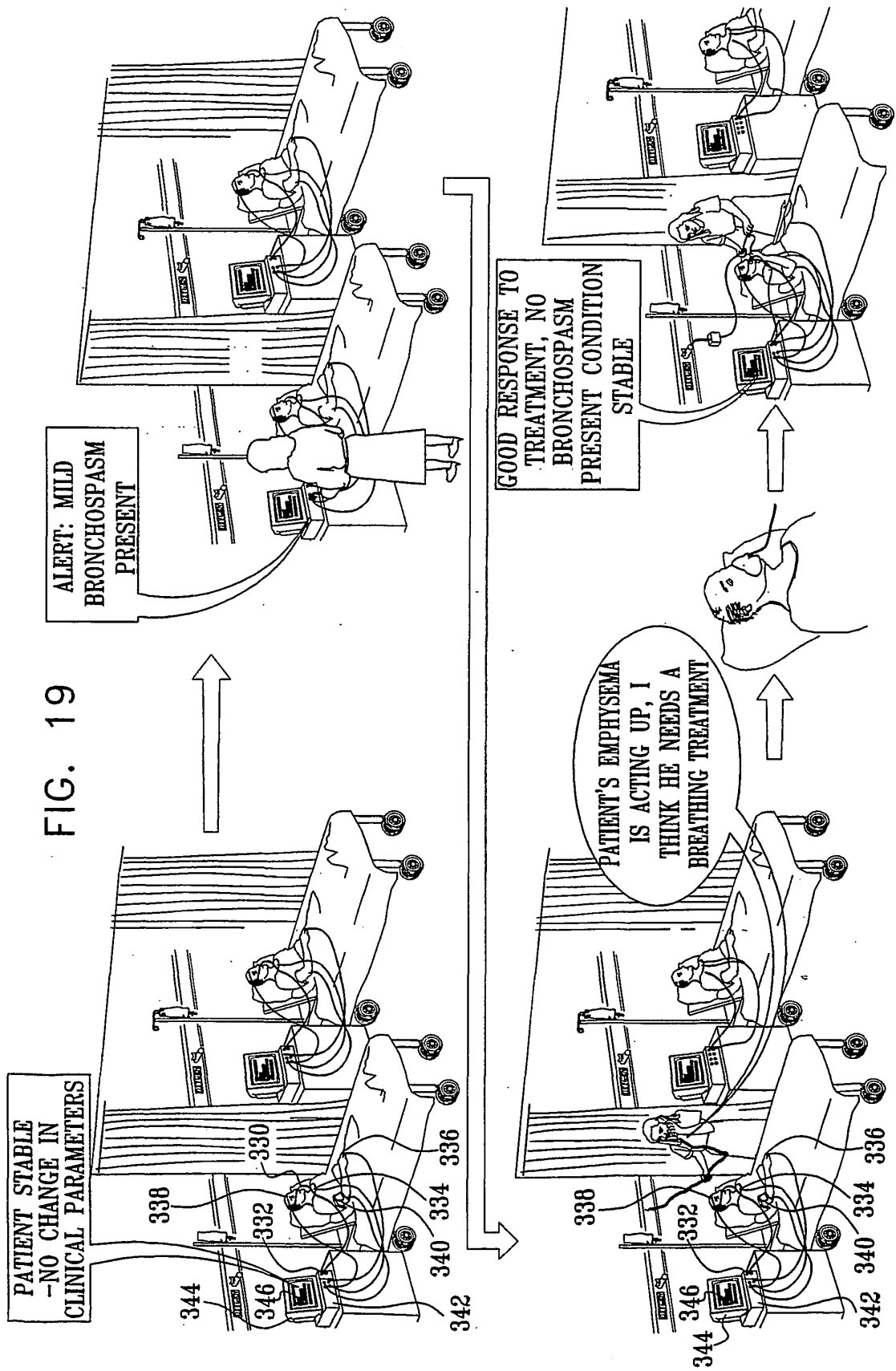
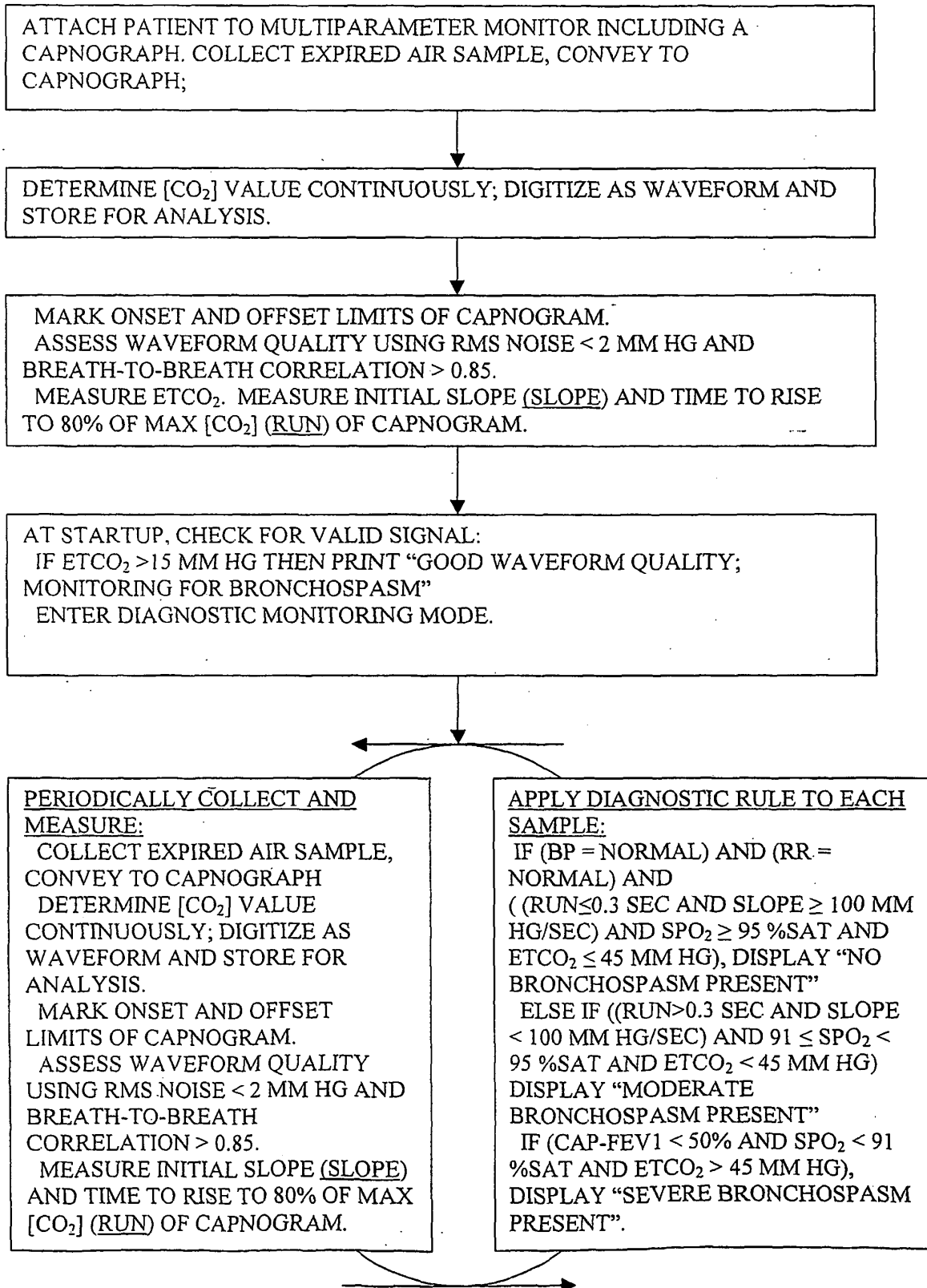


Fig. 20



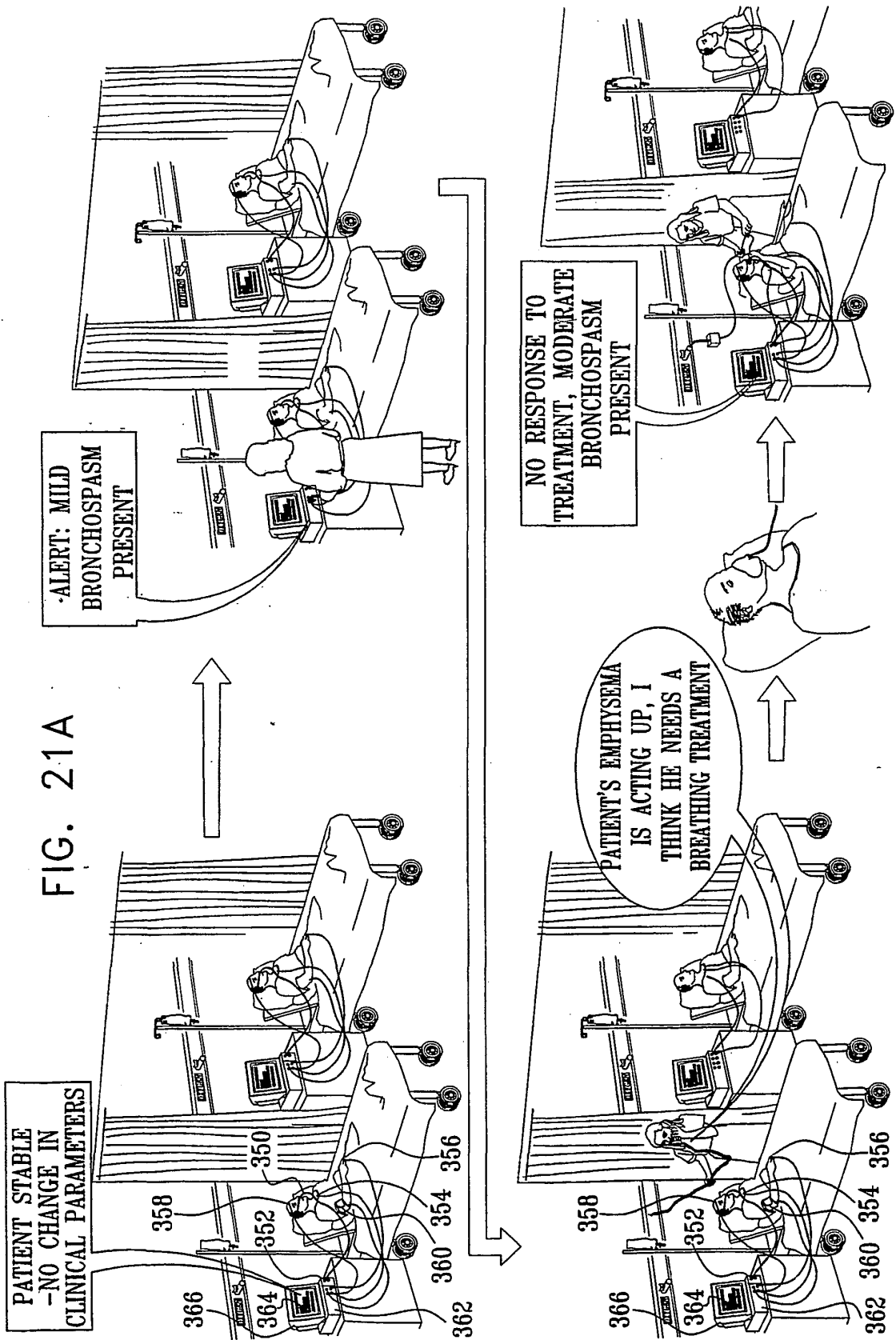


FIG. 21A

FIG. 21B

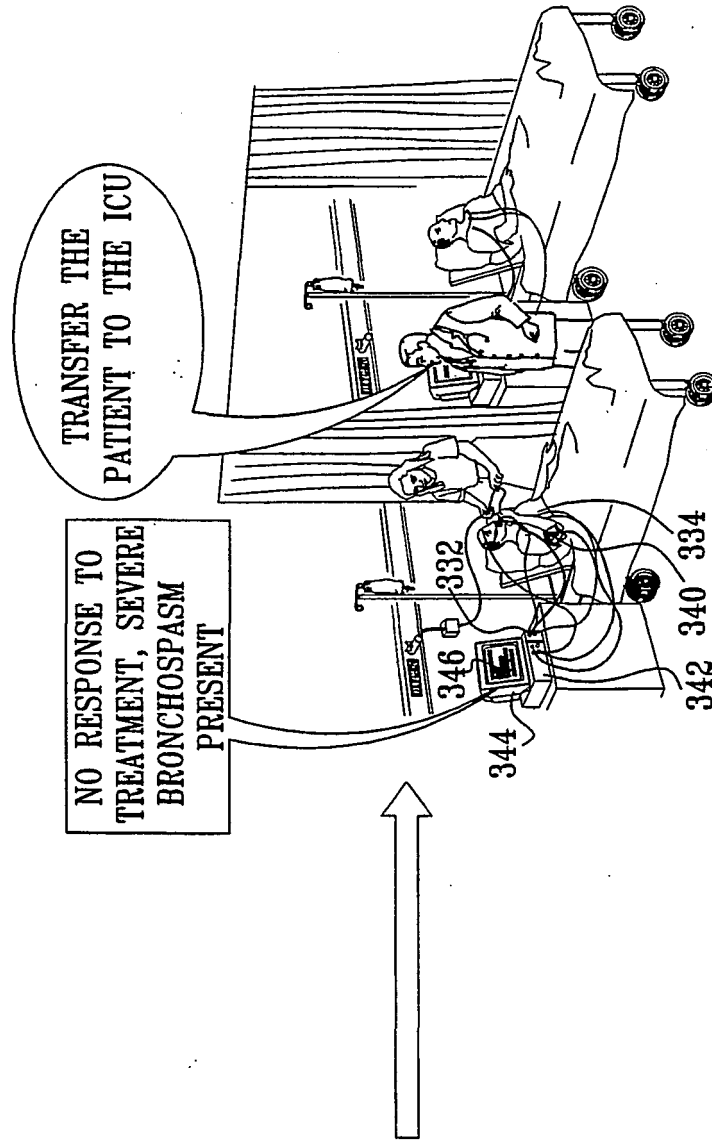


Fig. 22A

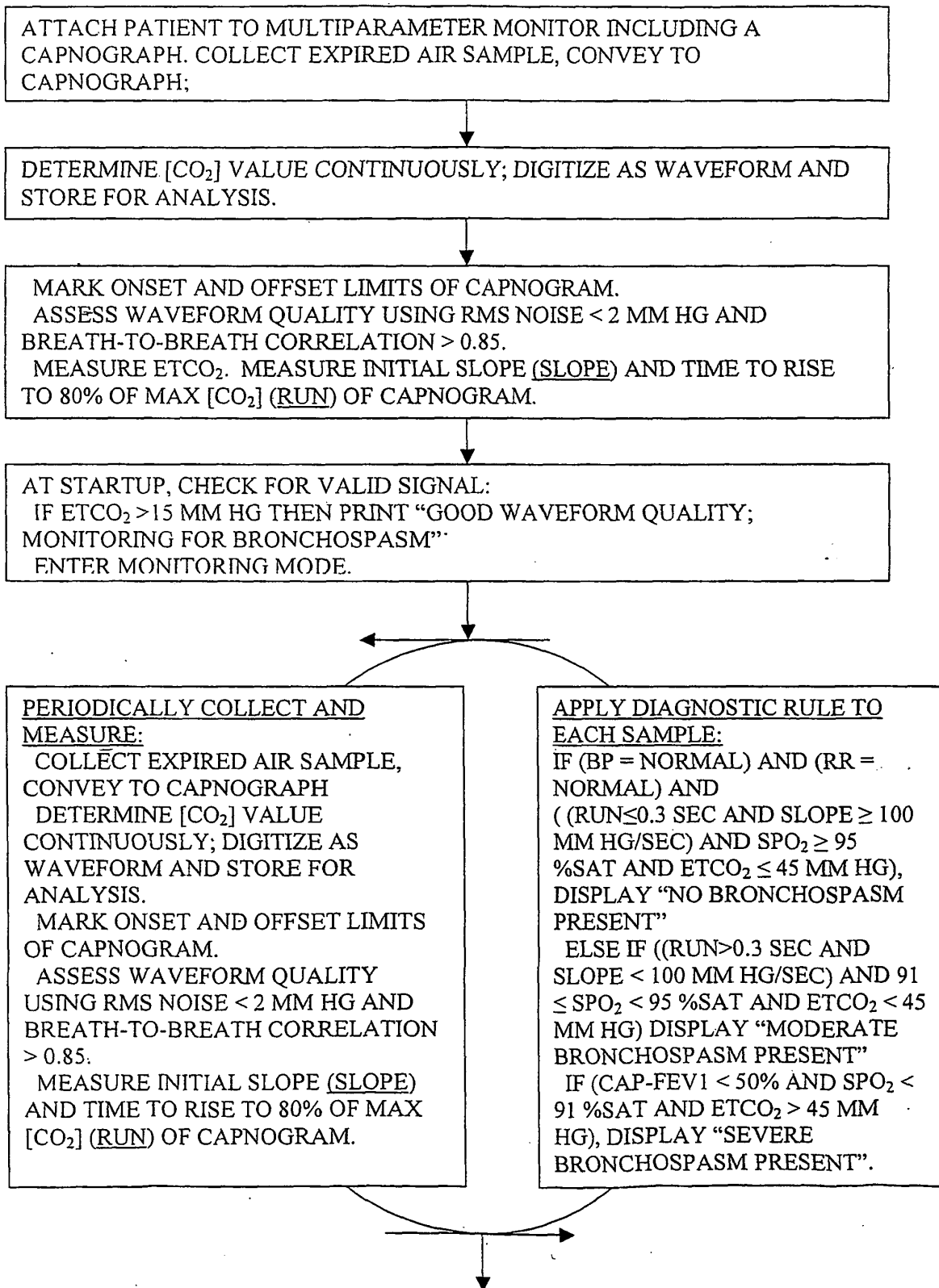


Fig. 22B

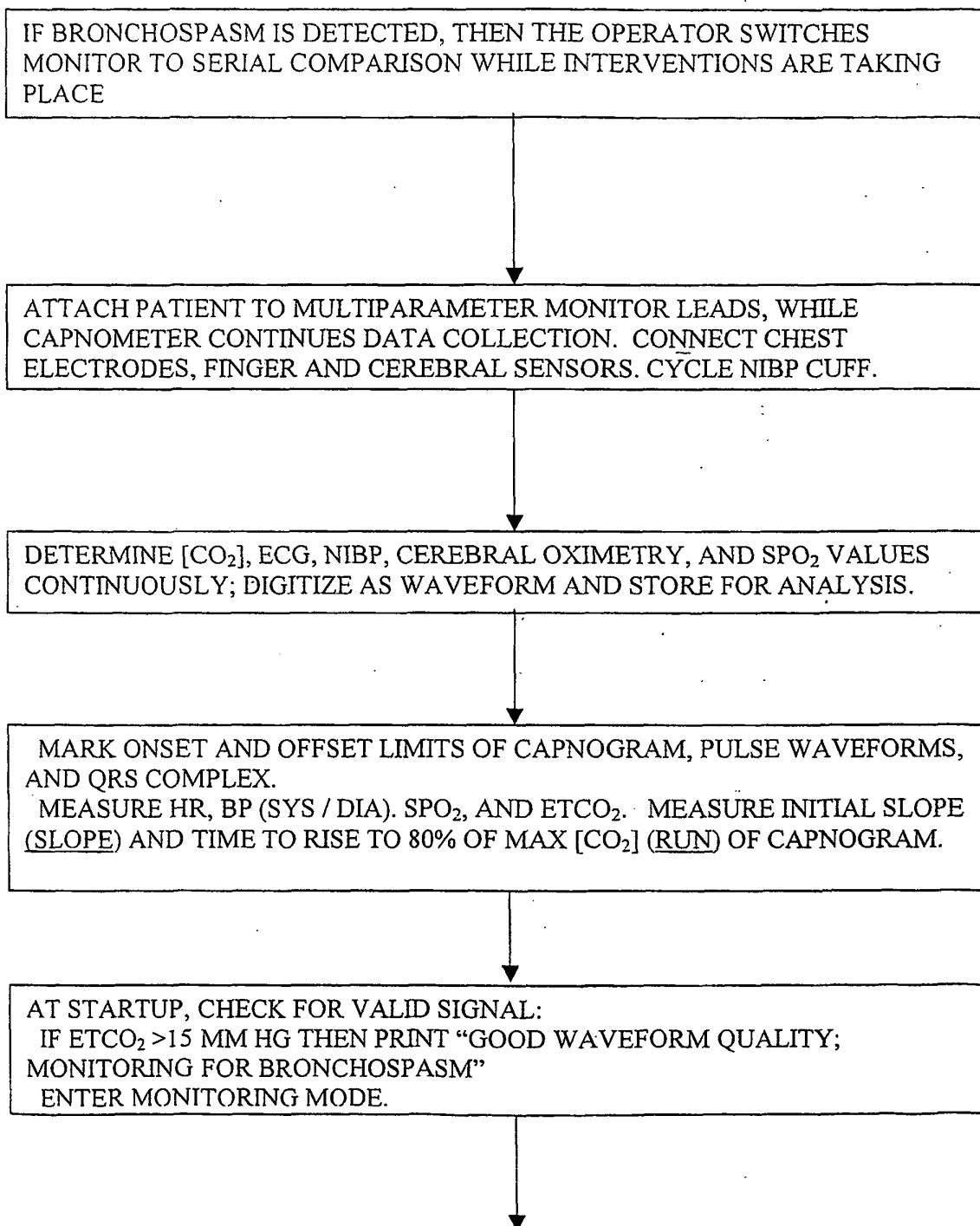


Fig. 22C

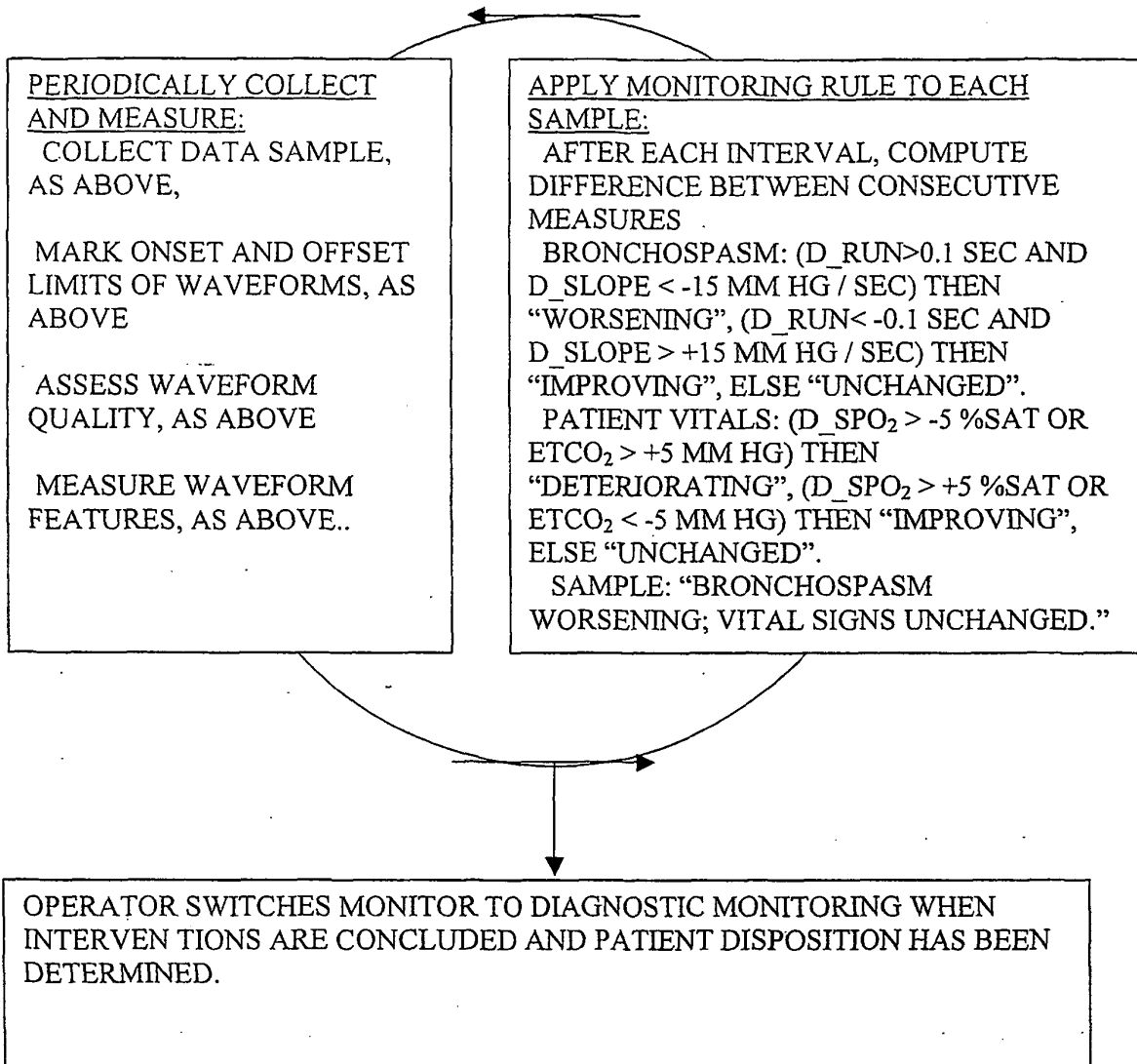


FIG. 23A

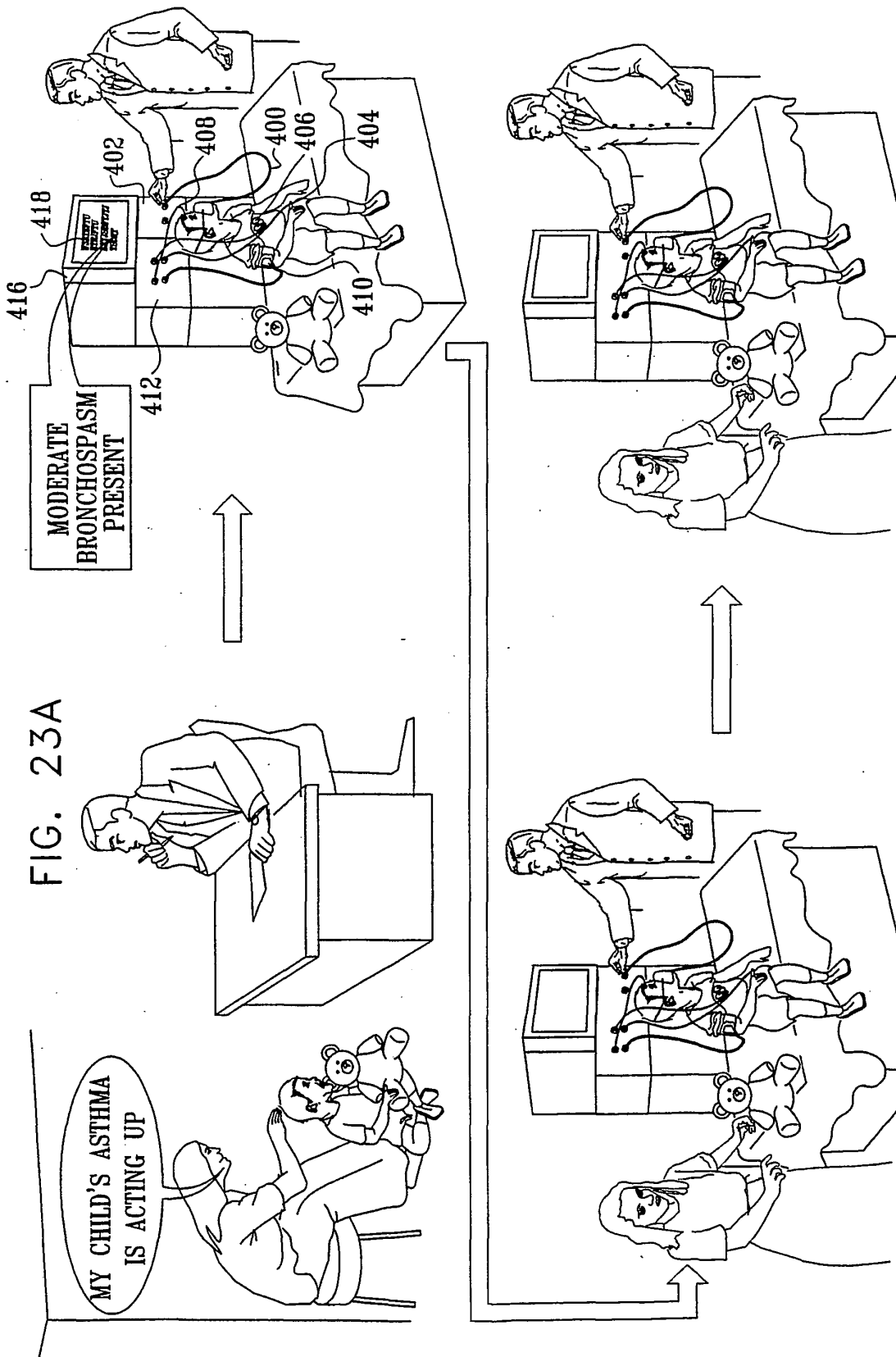


FIG. 23B

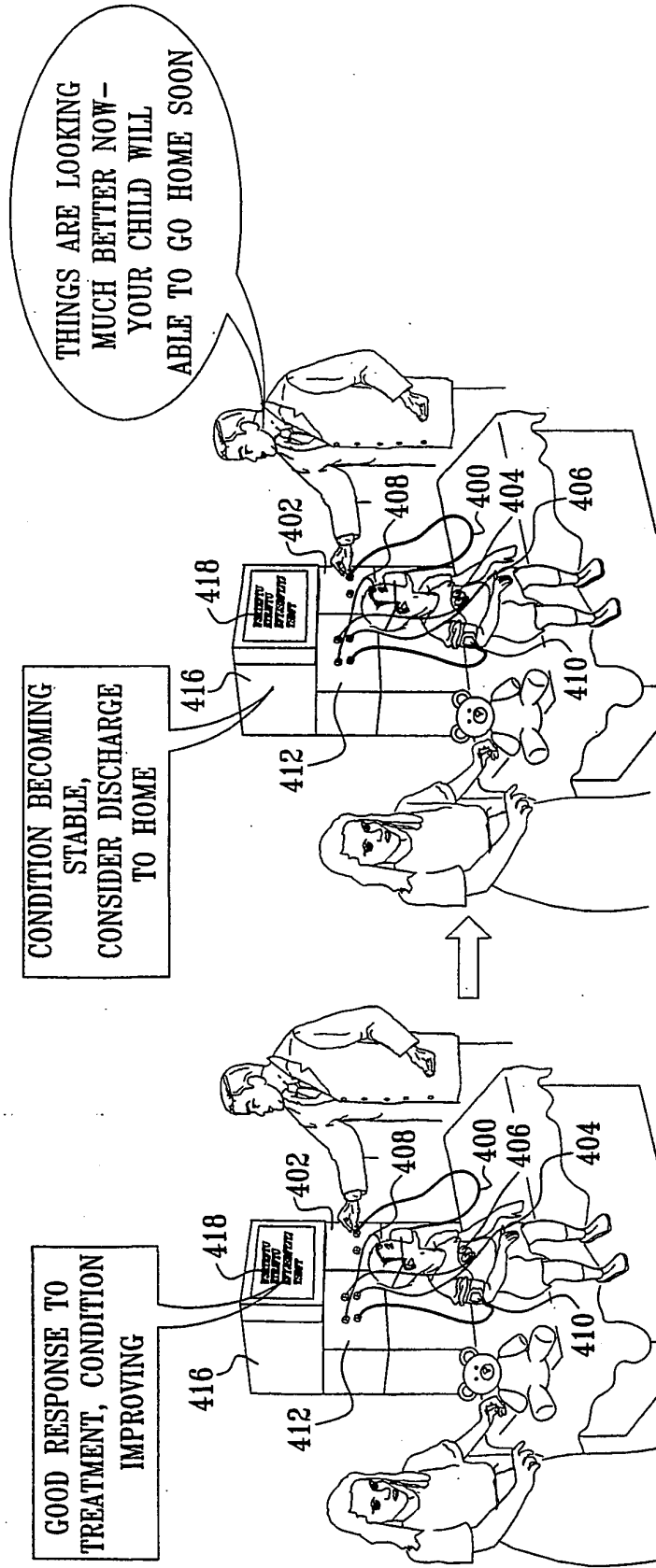


Fig. 24A

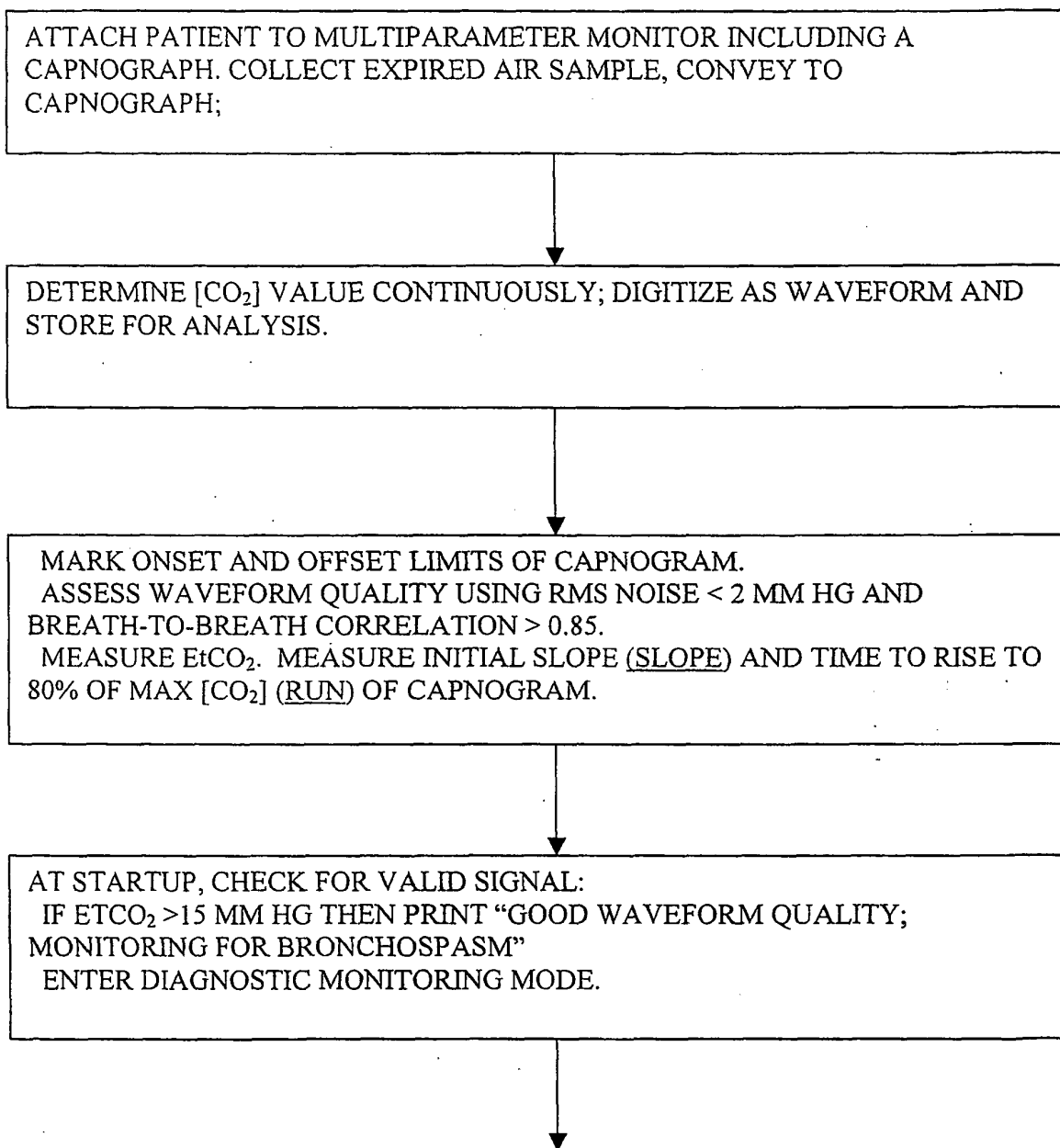
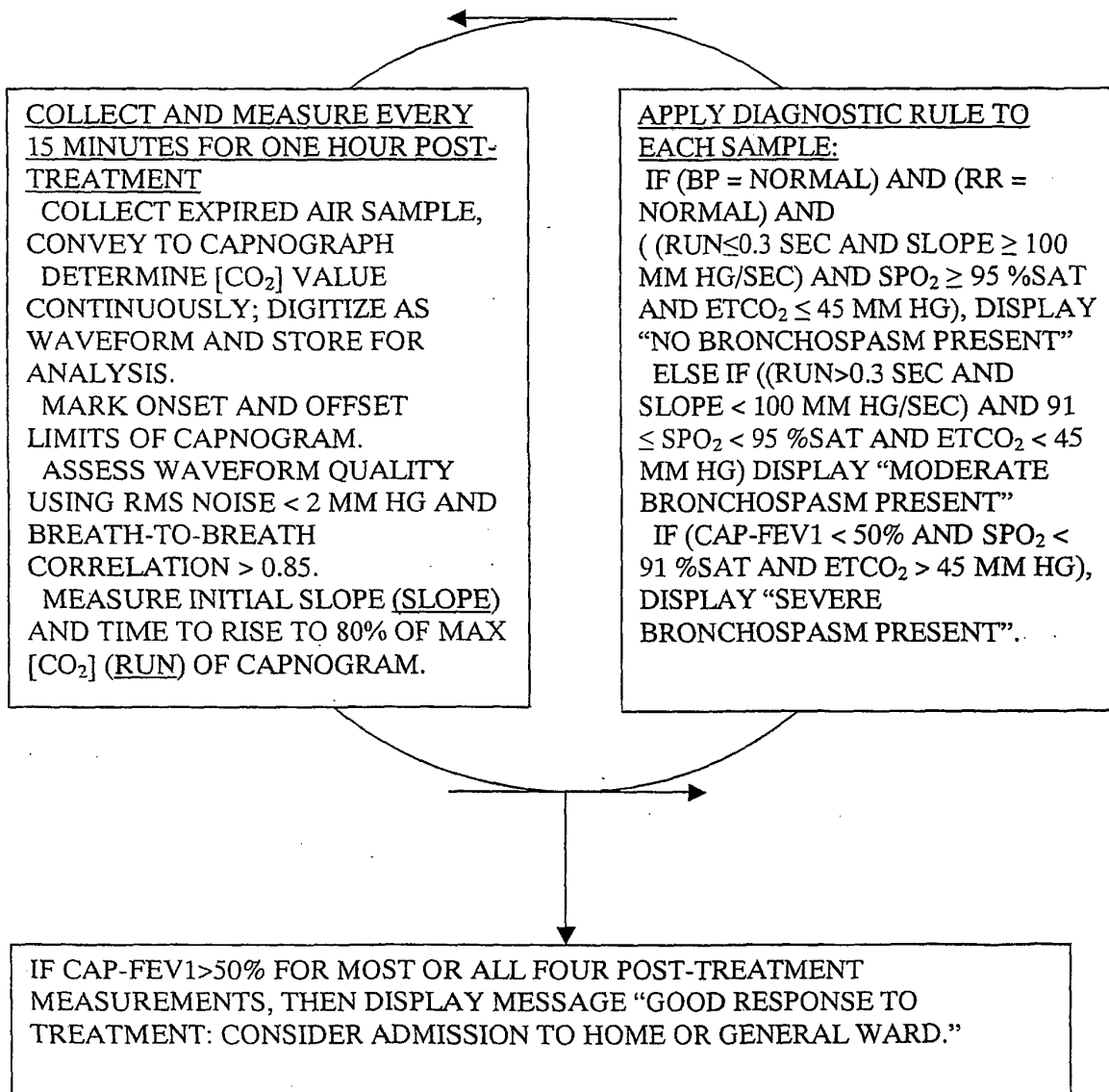


Fig. 24B



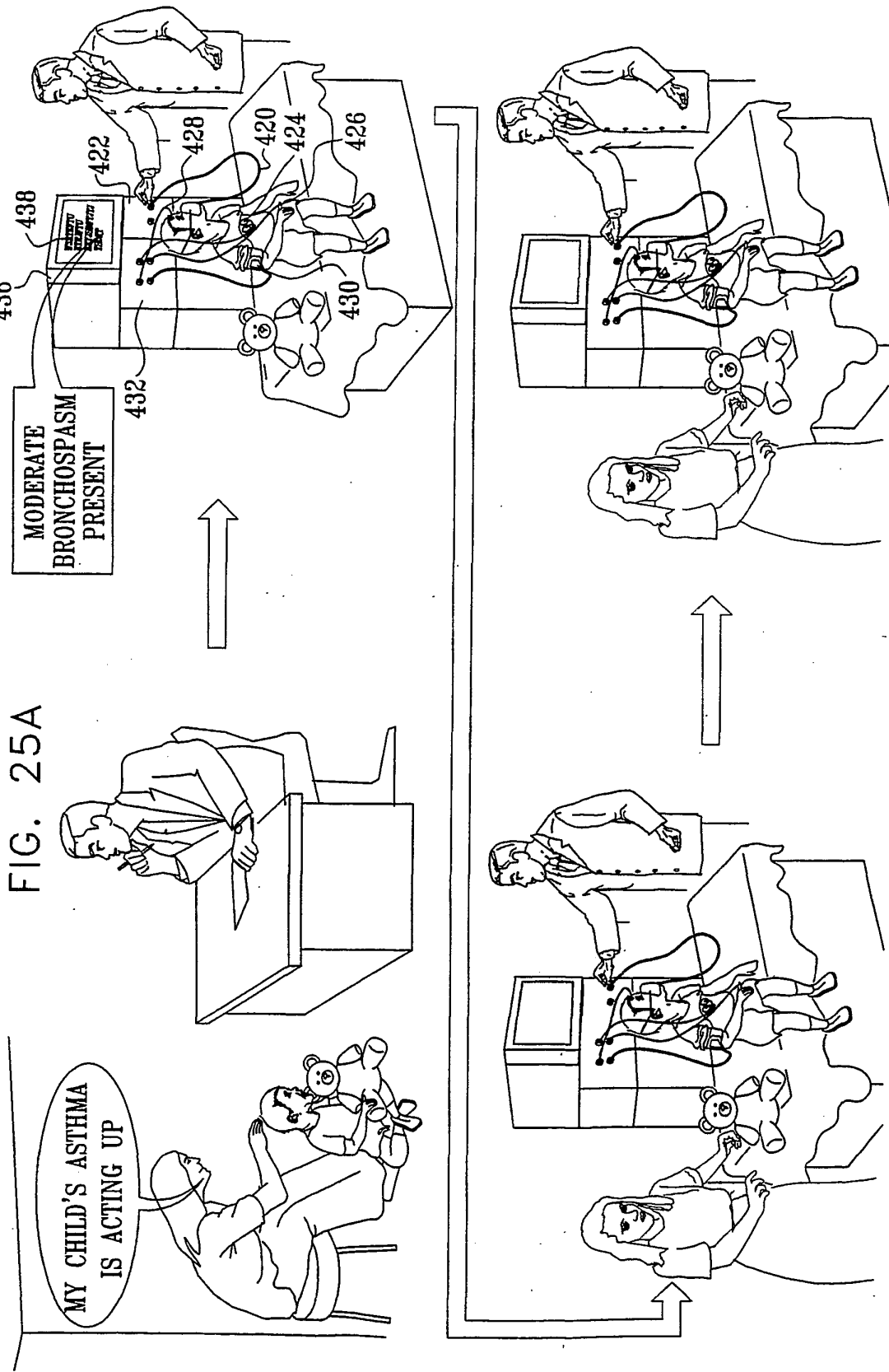


FIG. 25B

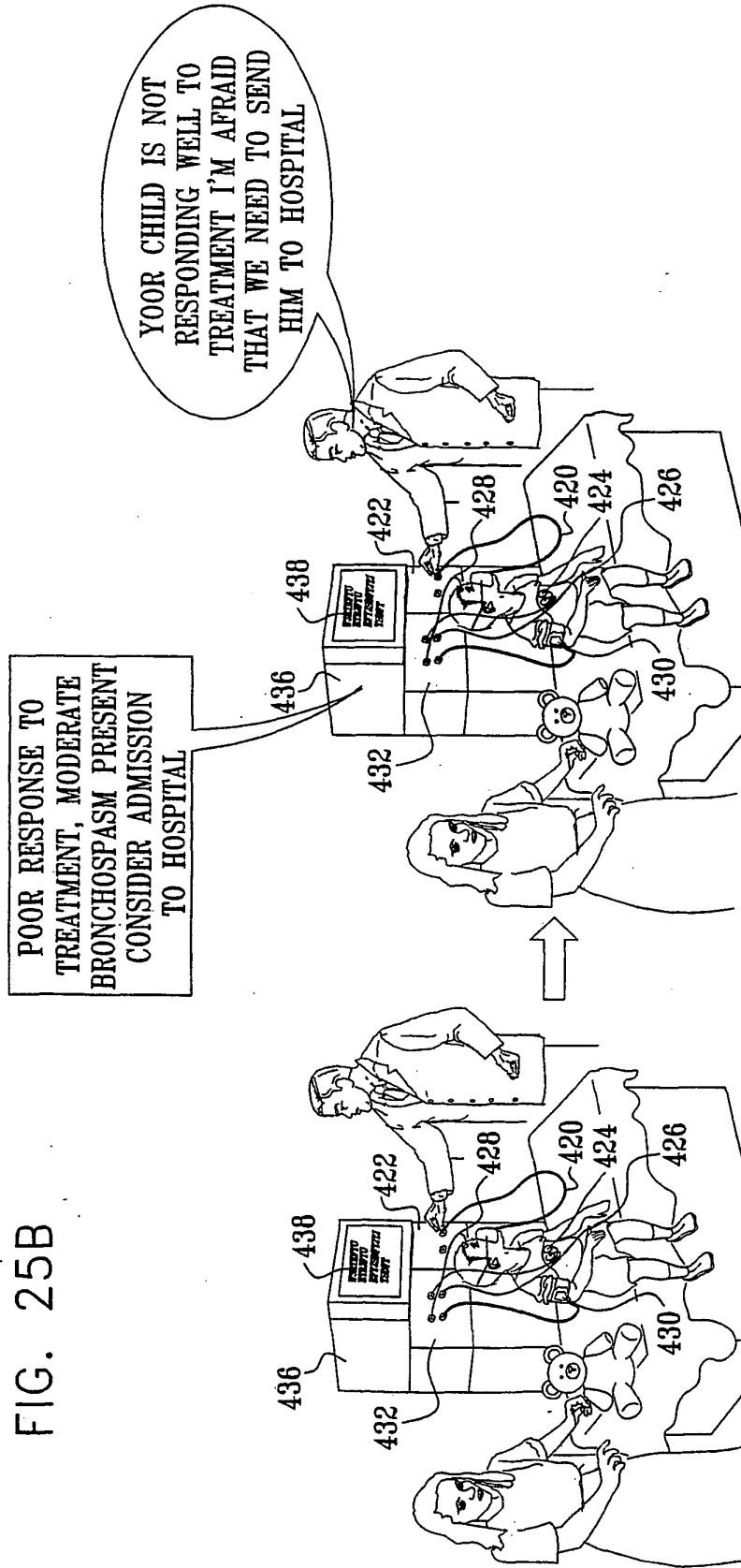


Fig. 26A

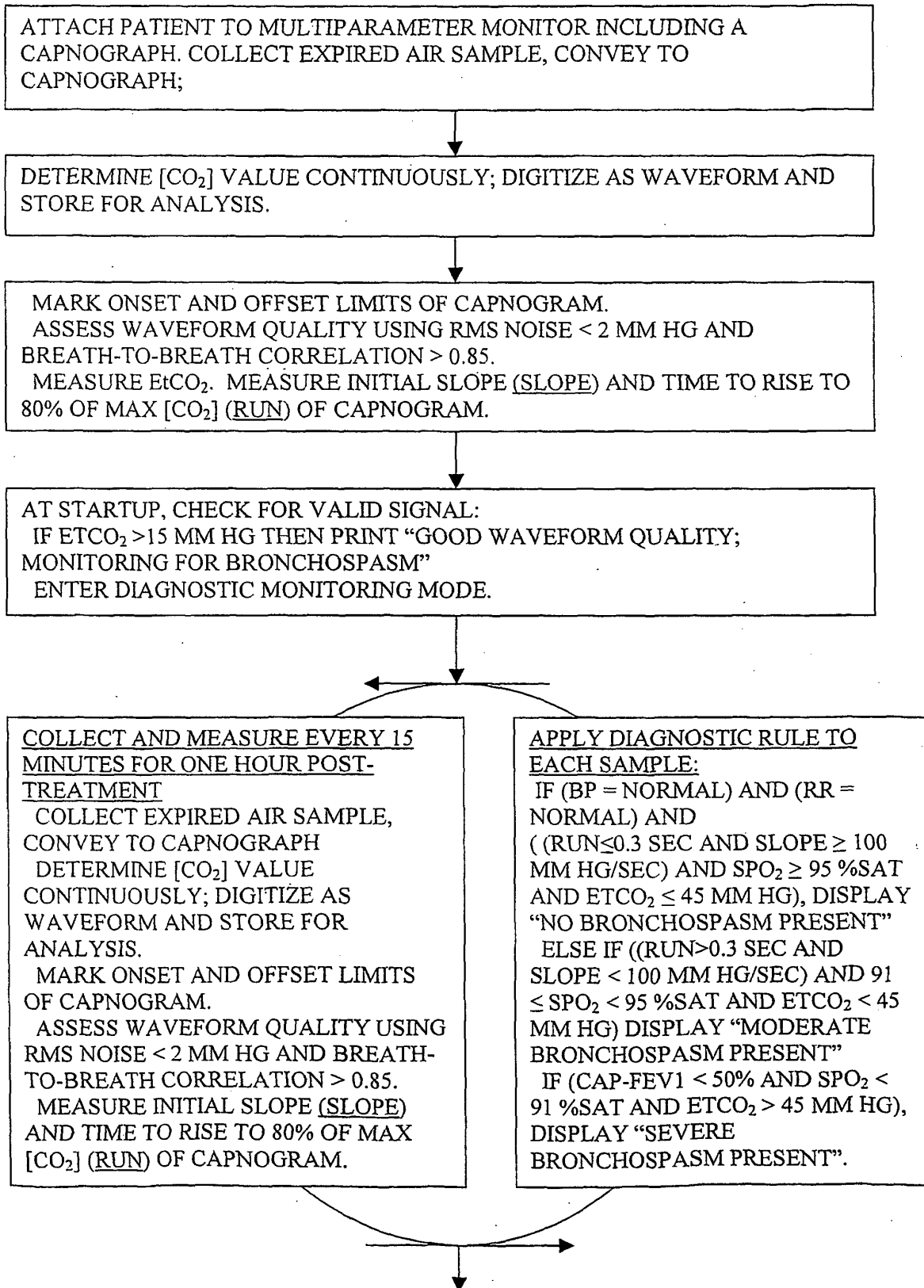
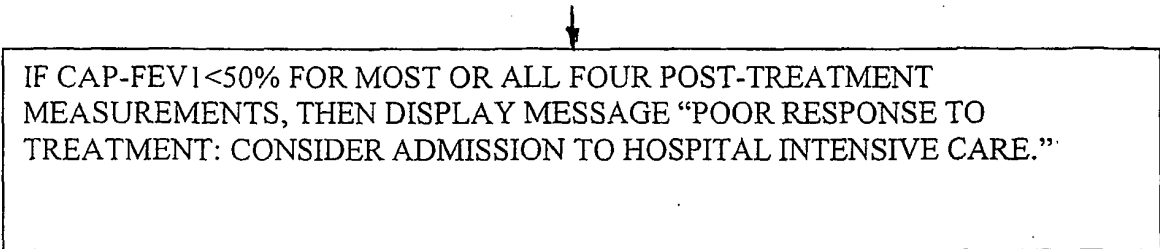
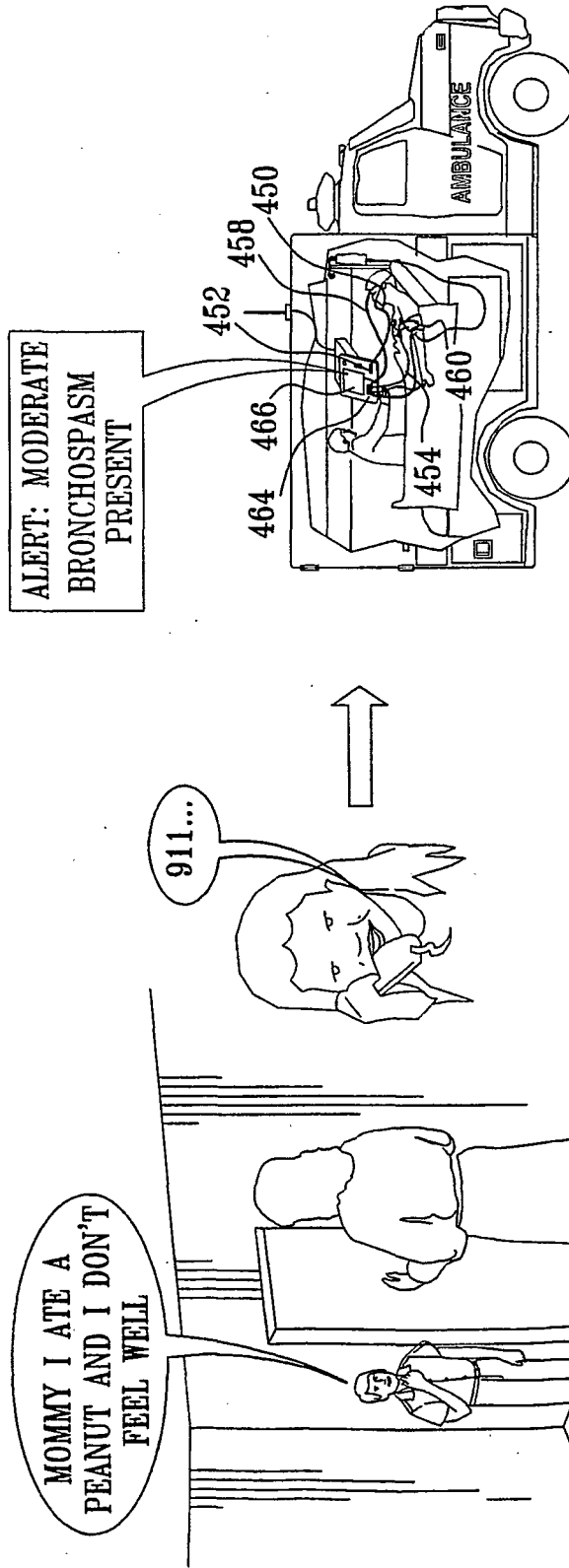


Fig. 26B



IF CAP-FEV1 < 50% FOR MOST OR ALL FOUR POST-TREATMENT MEASUREMENTS, THEN DISPLAY MESSAGE "POOR RESPONSE TO TREATMENT: CONSIDER ADMISSION TO HOSPITAL INTENSIVE CARE."

FIG. 27A



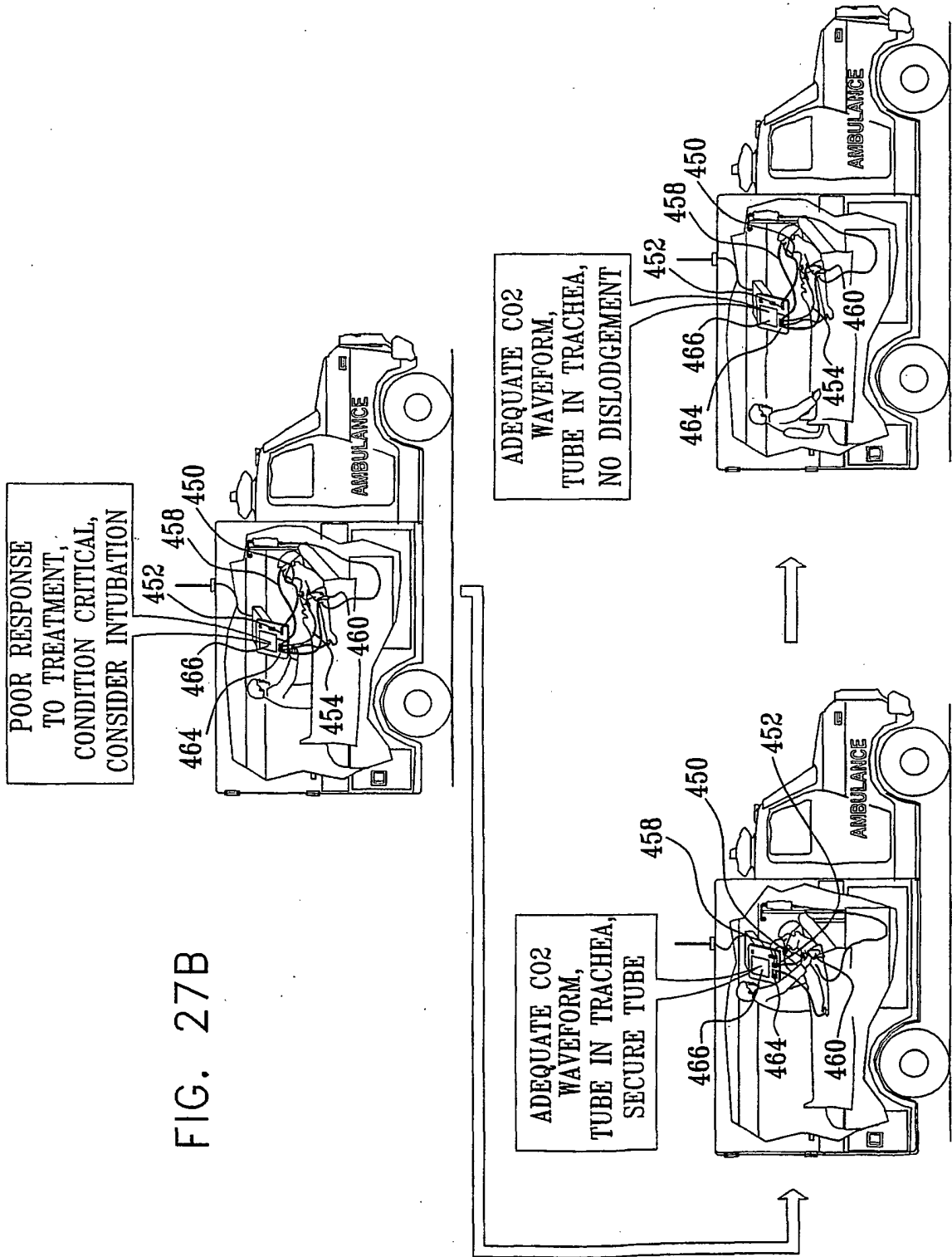


FIG. 27B

Fig. 28

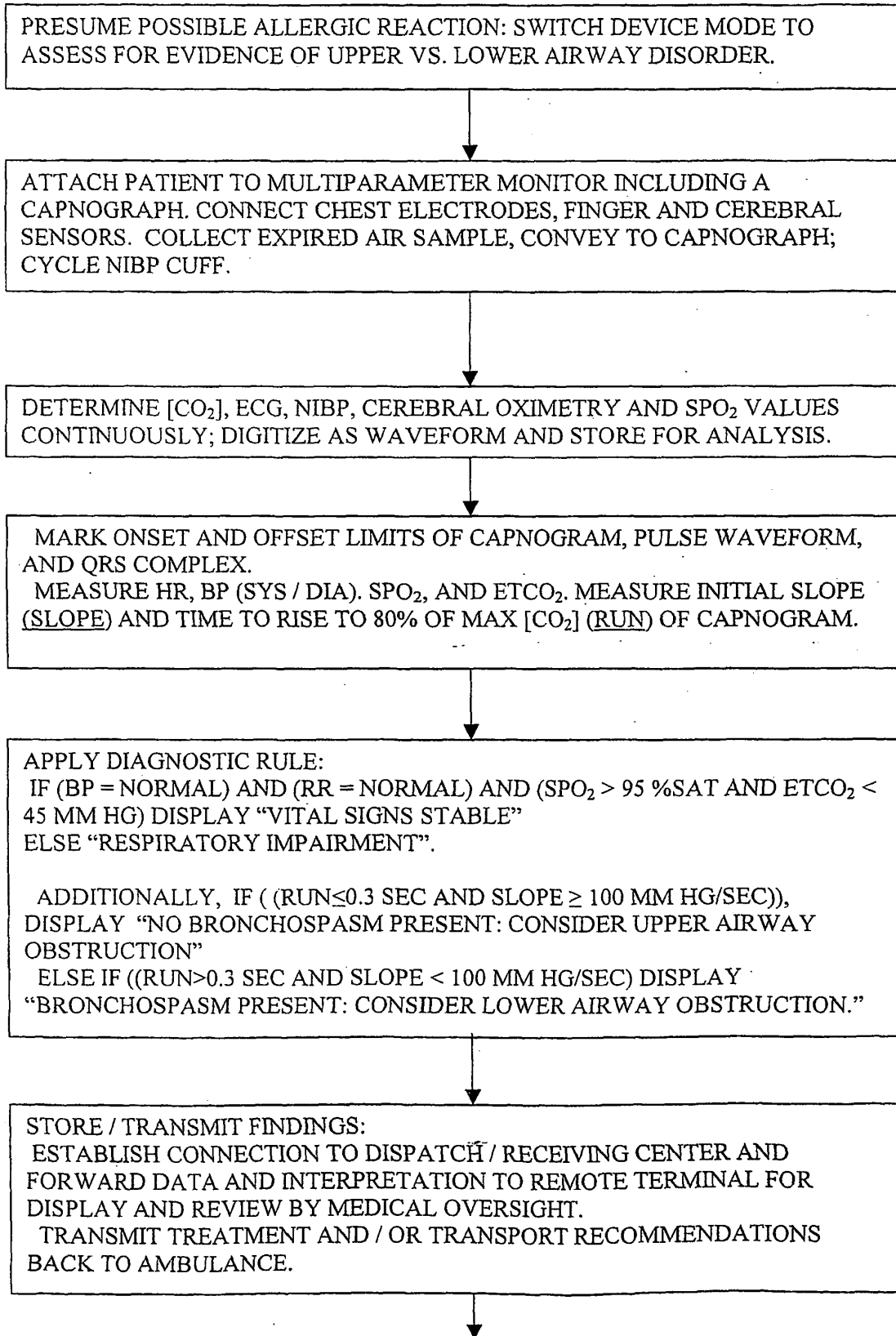


FIG. 29

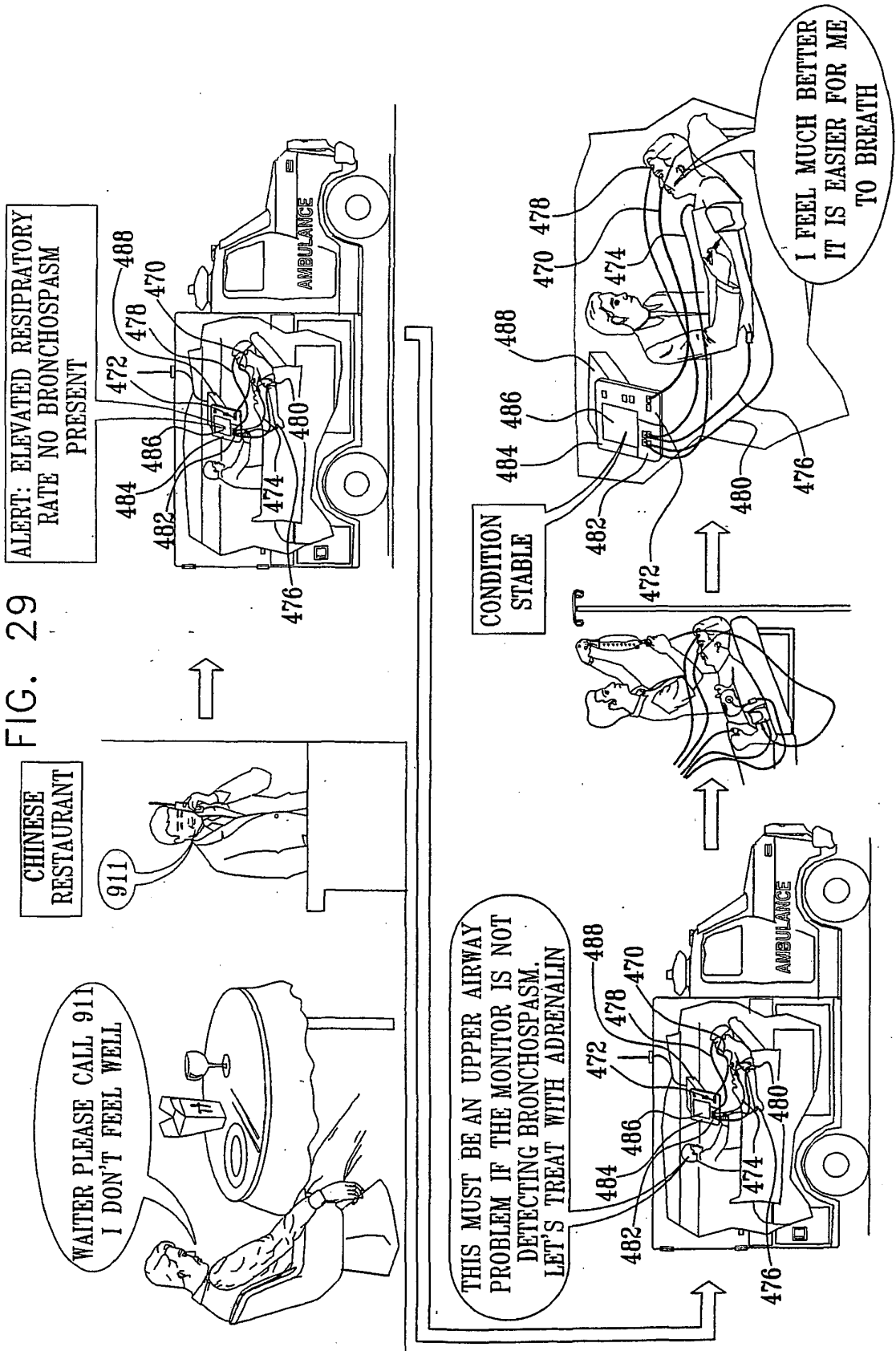
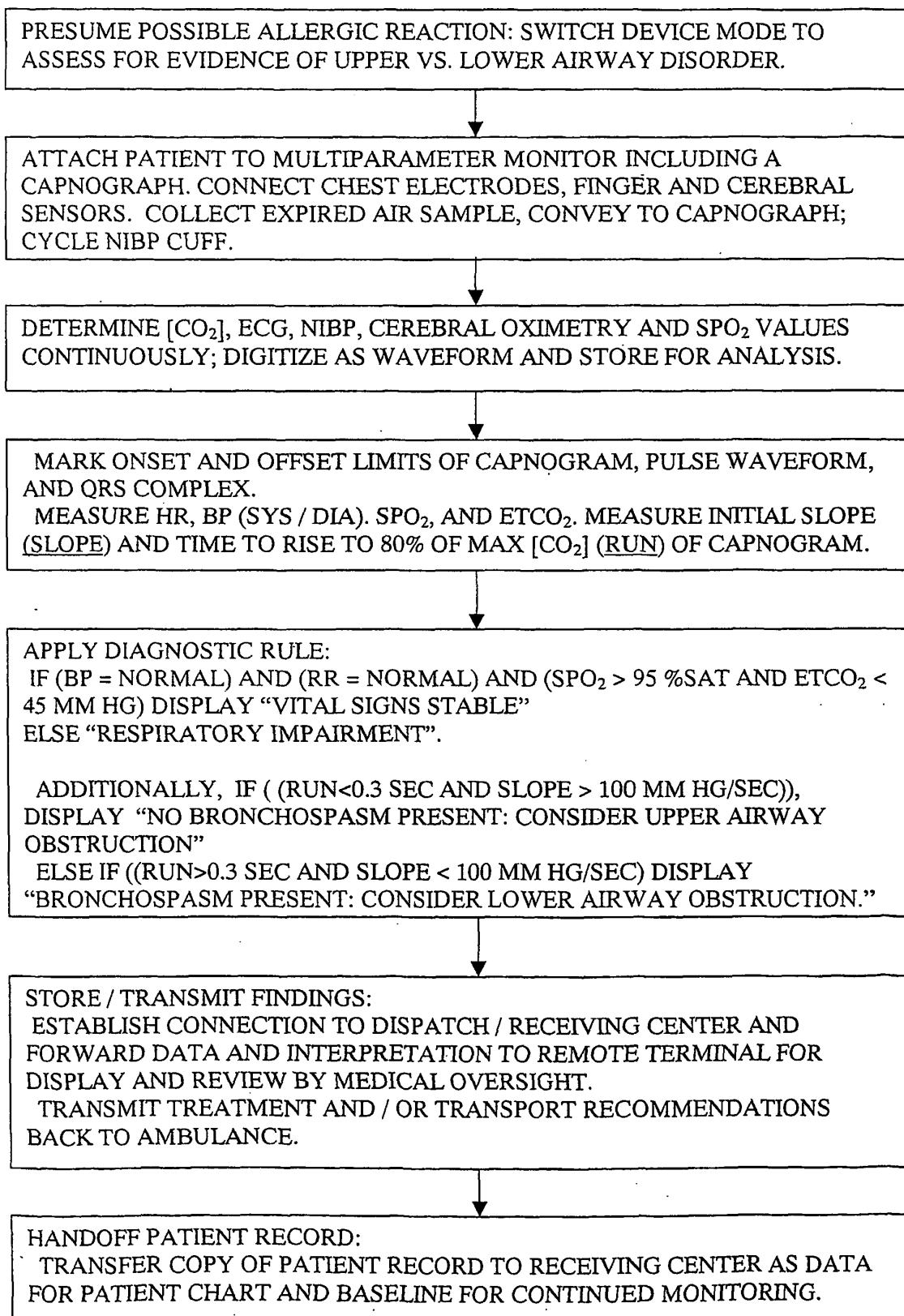


Fig. 30



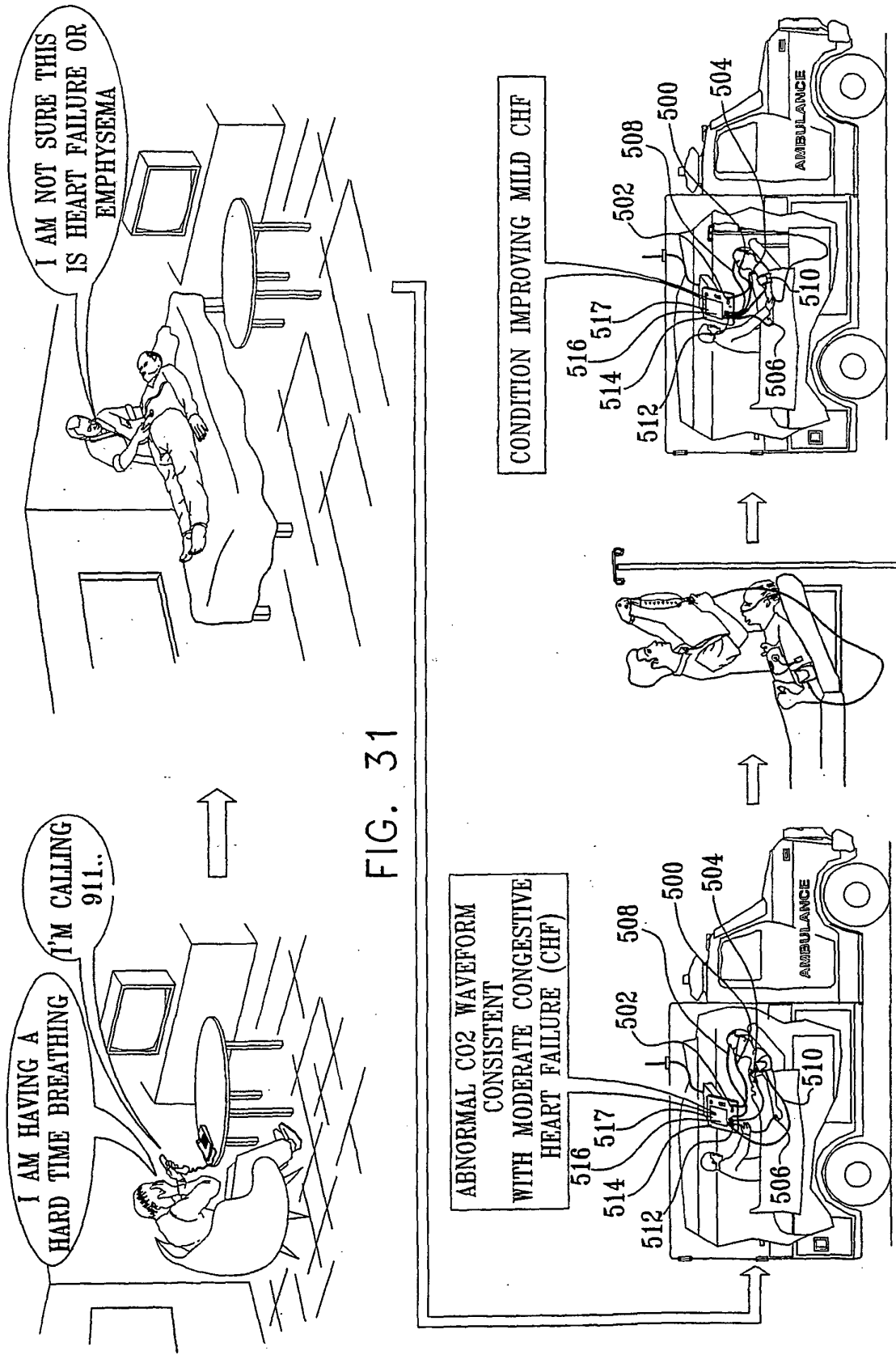


FIG. 31

Fig. 32A

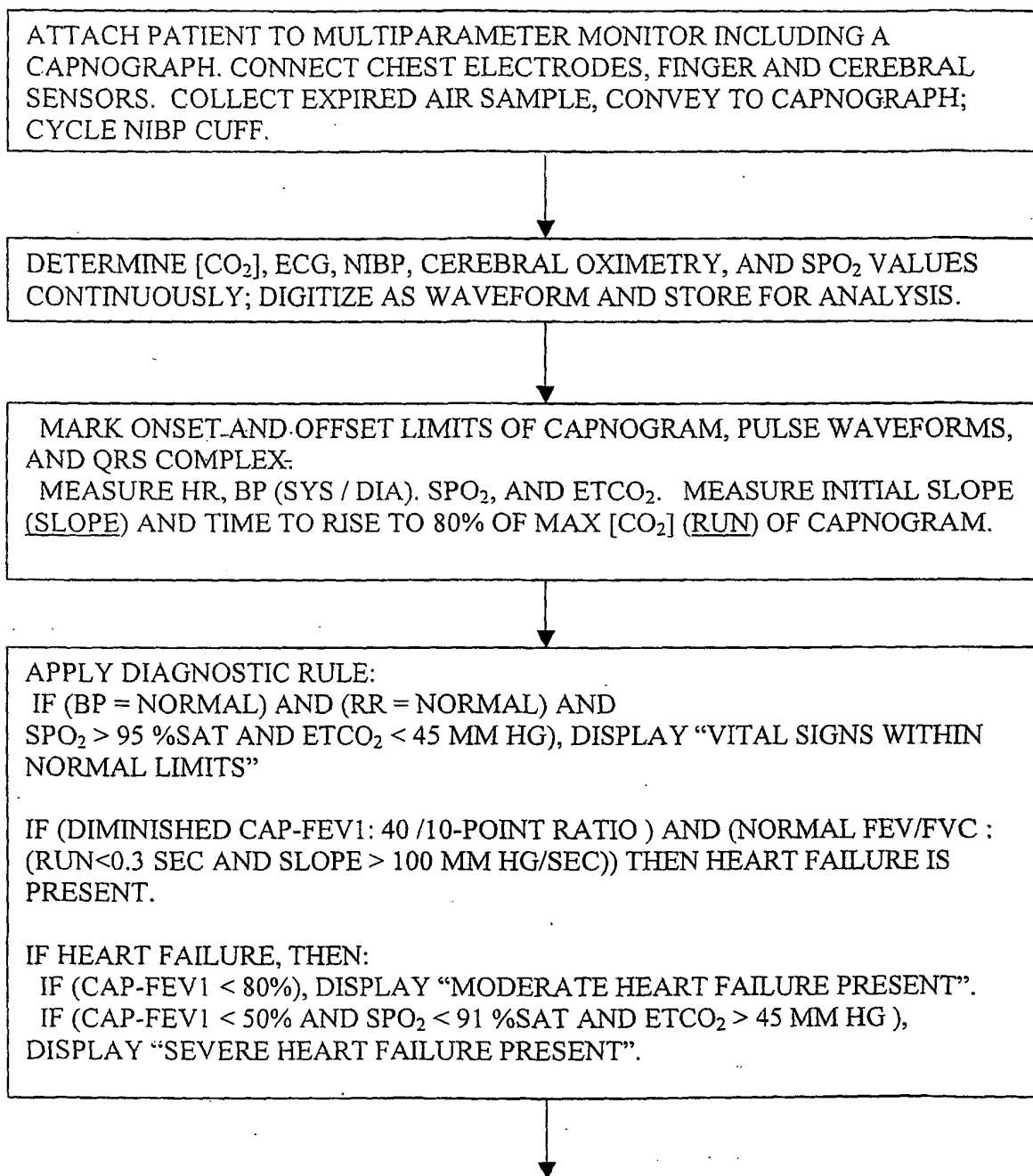
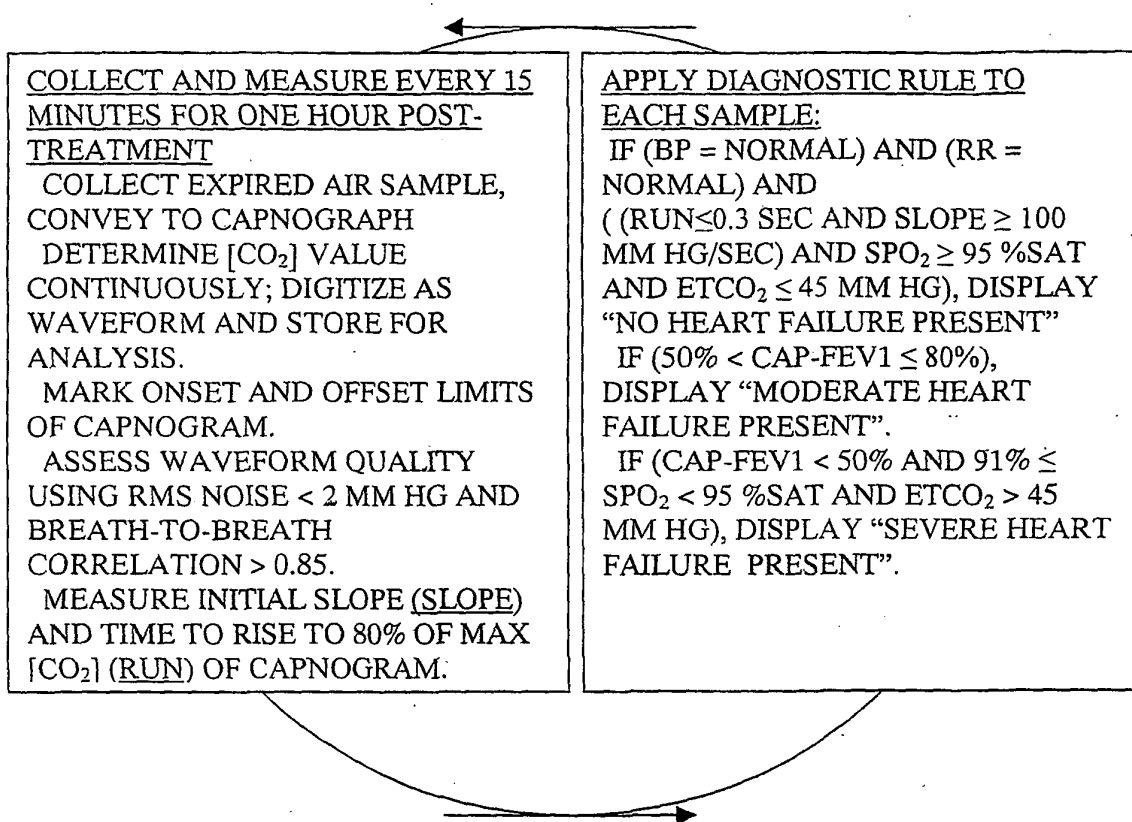


Fig. 32B



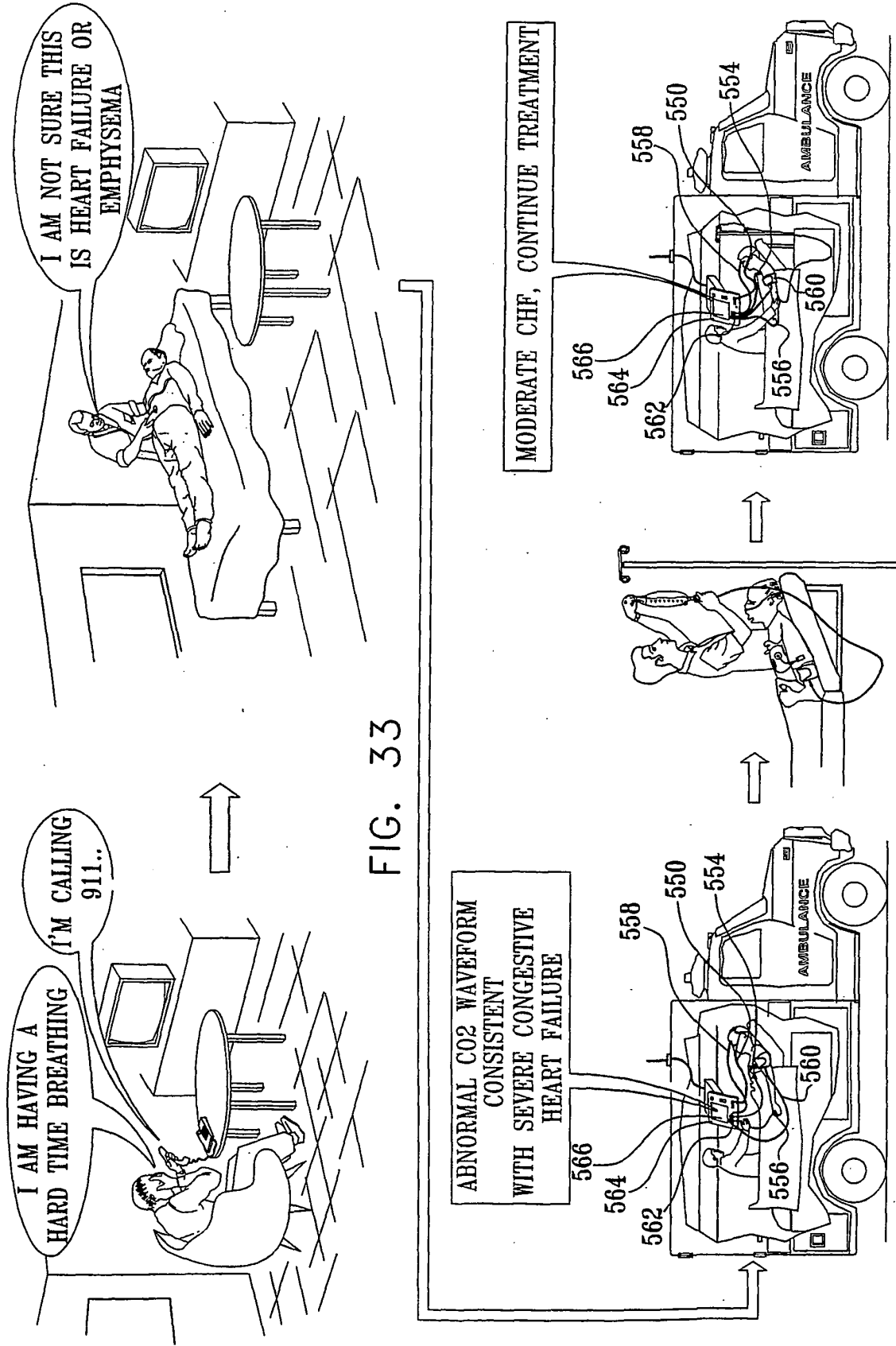


FIG. 33

Fig. 34A

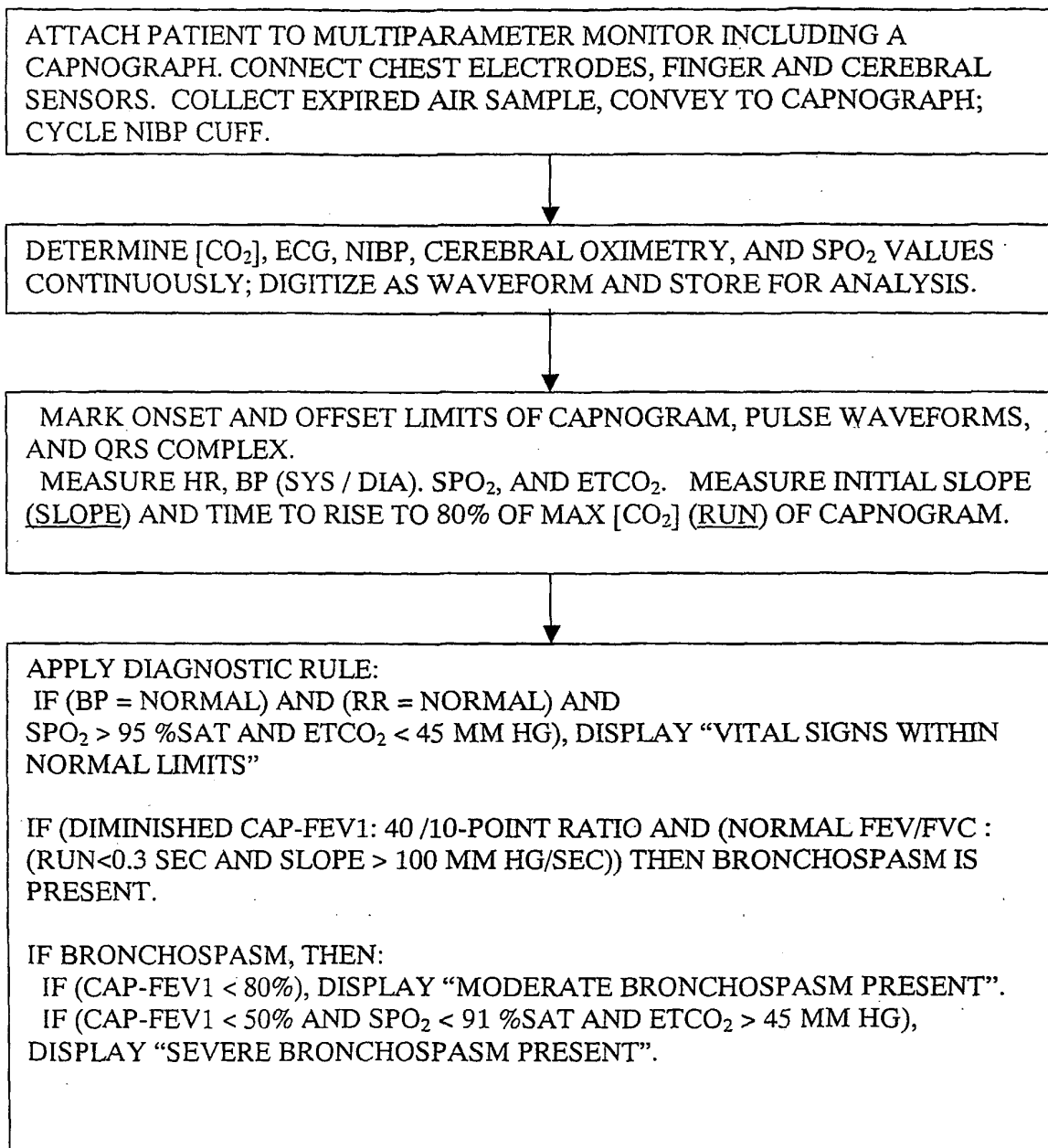
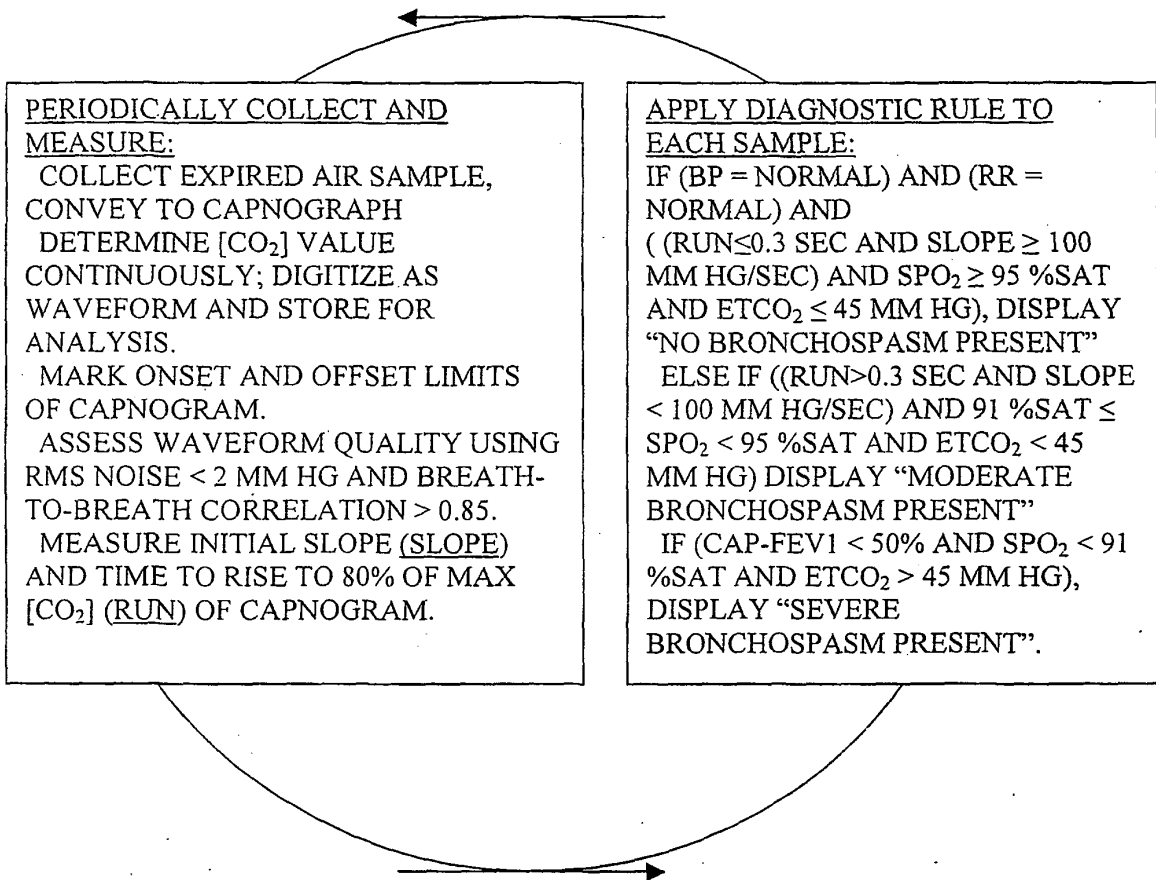


Fig. 34B



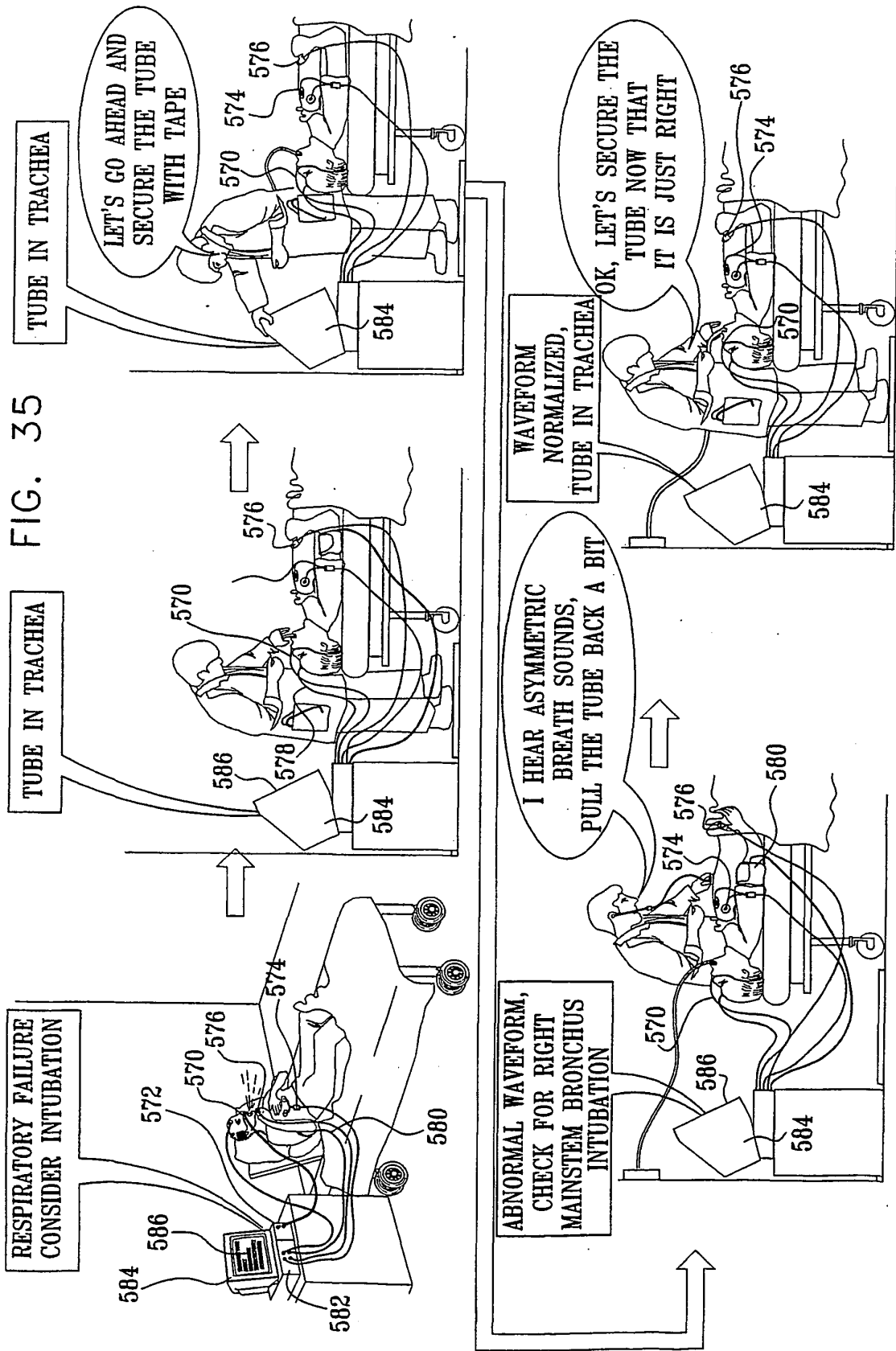
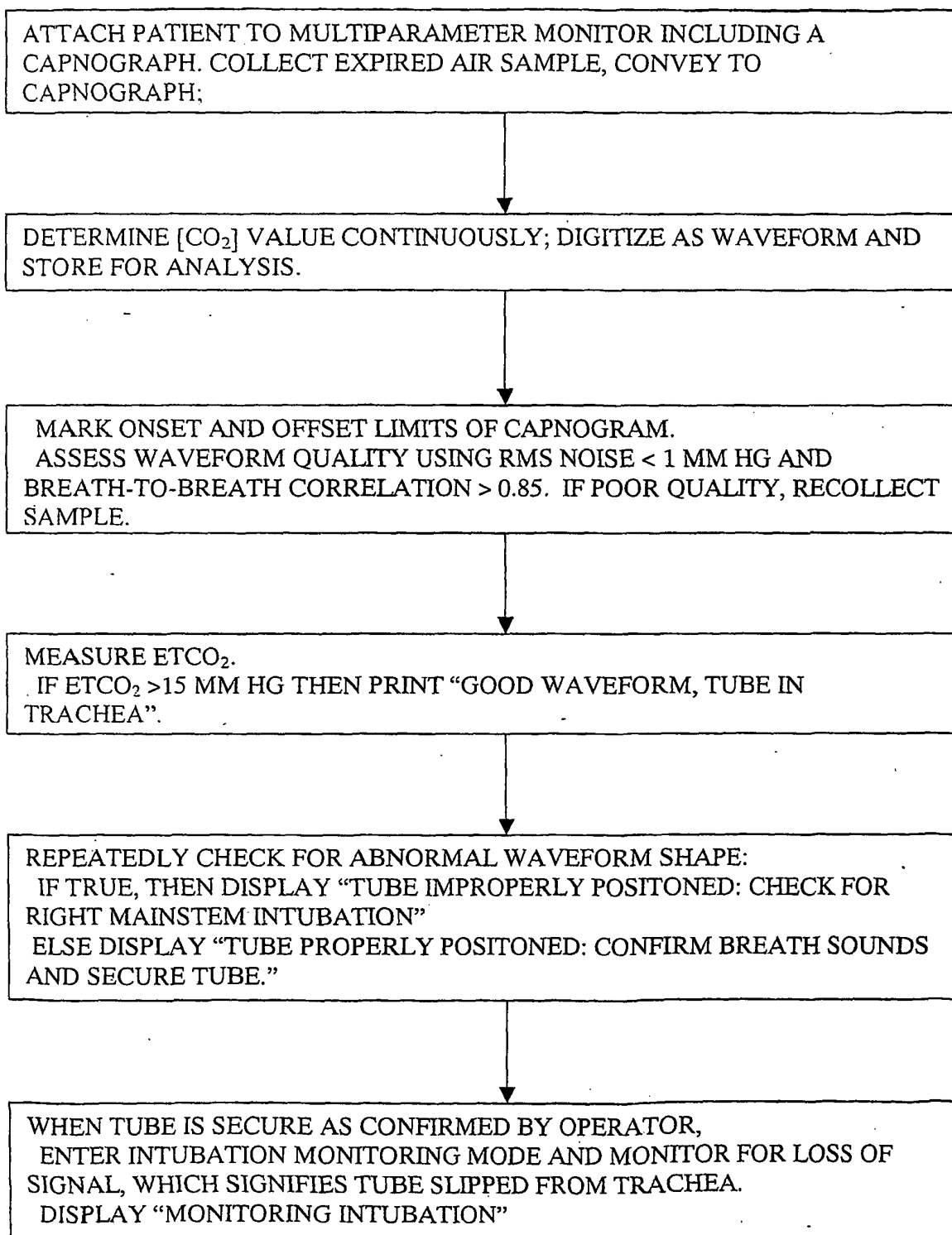


Fig. 36



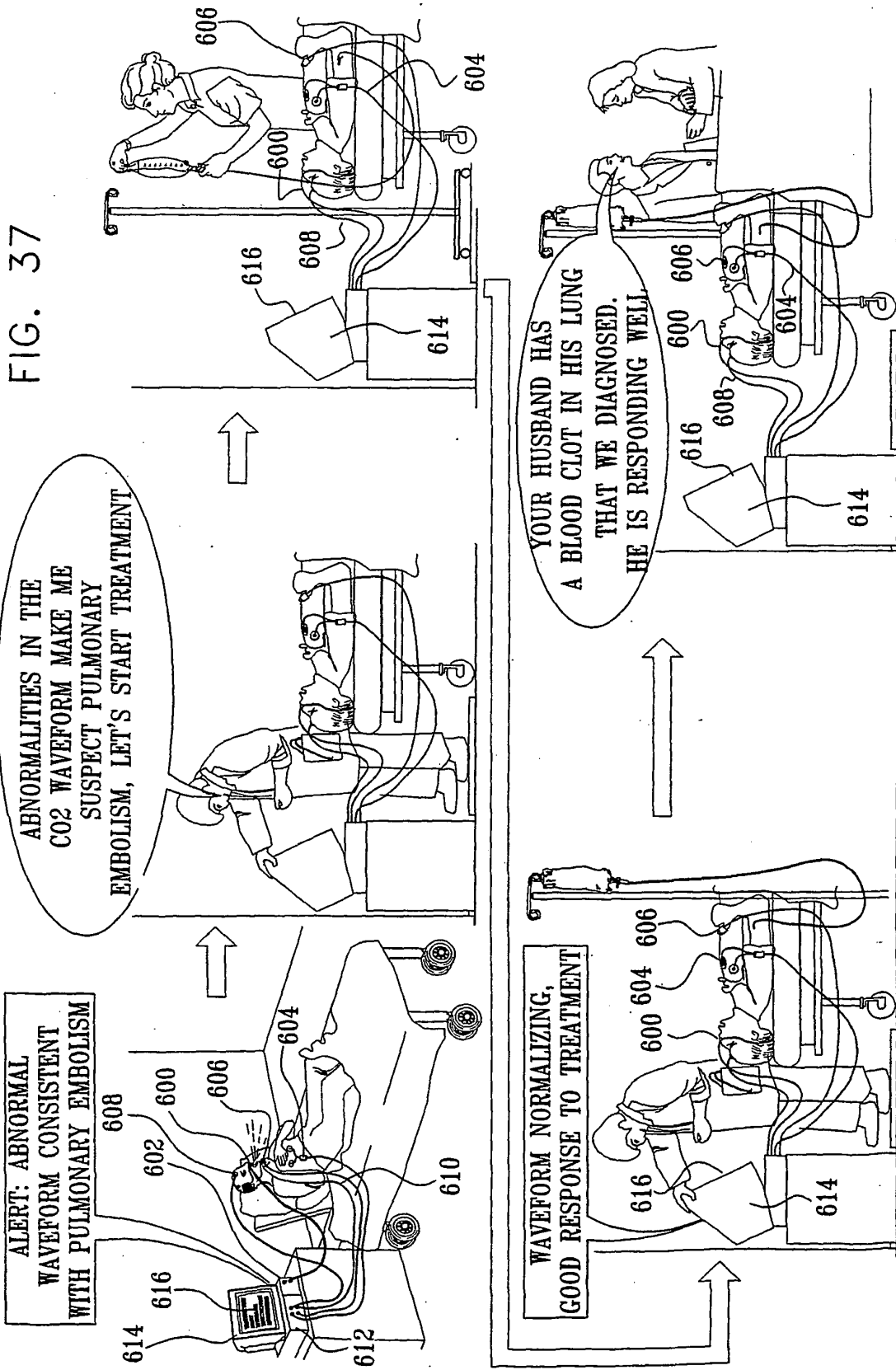


FIG. 37

Fig. 38

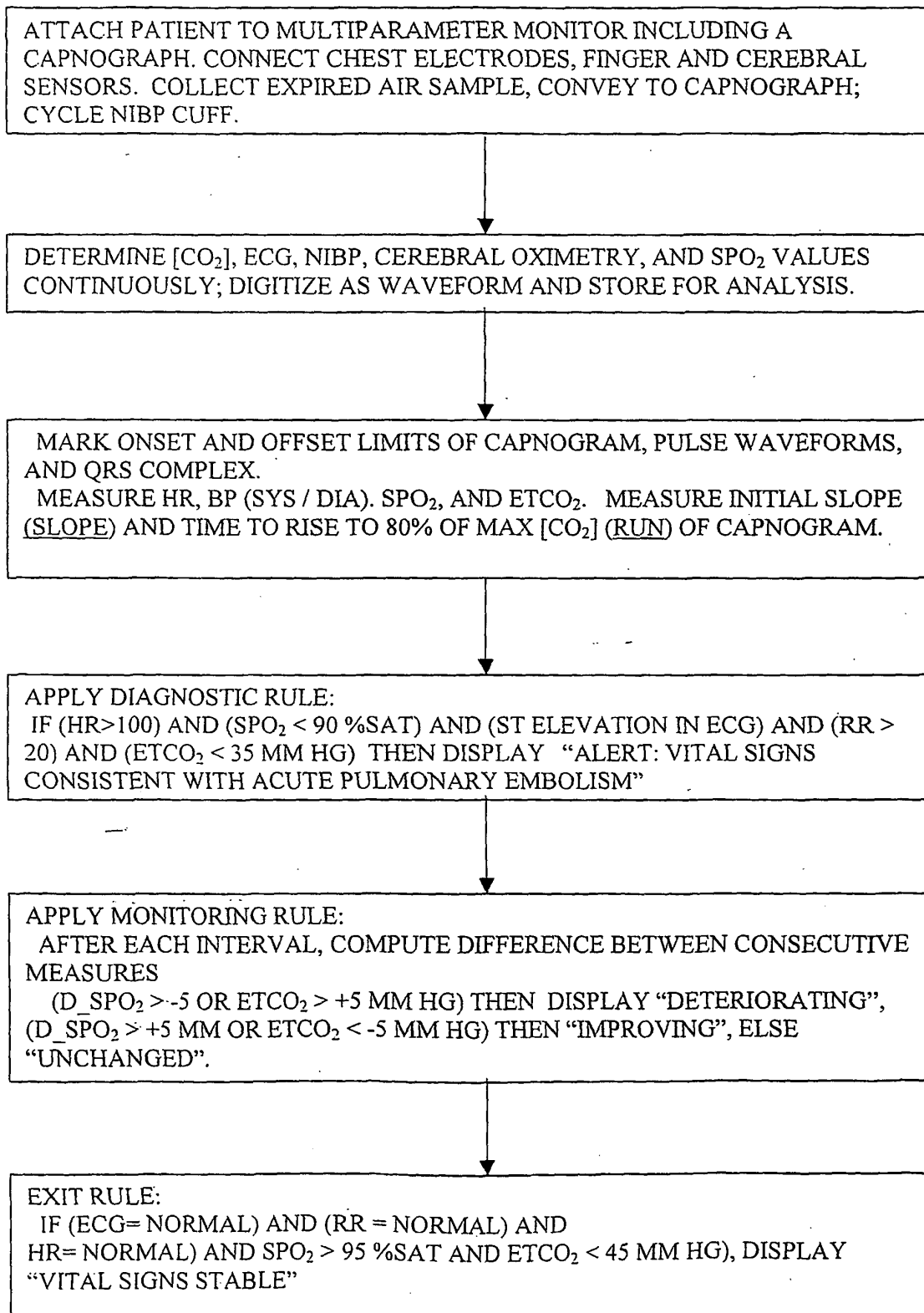


FIG. 39A

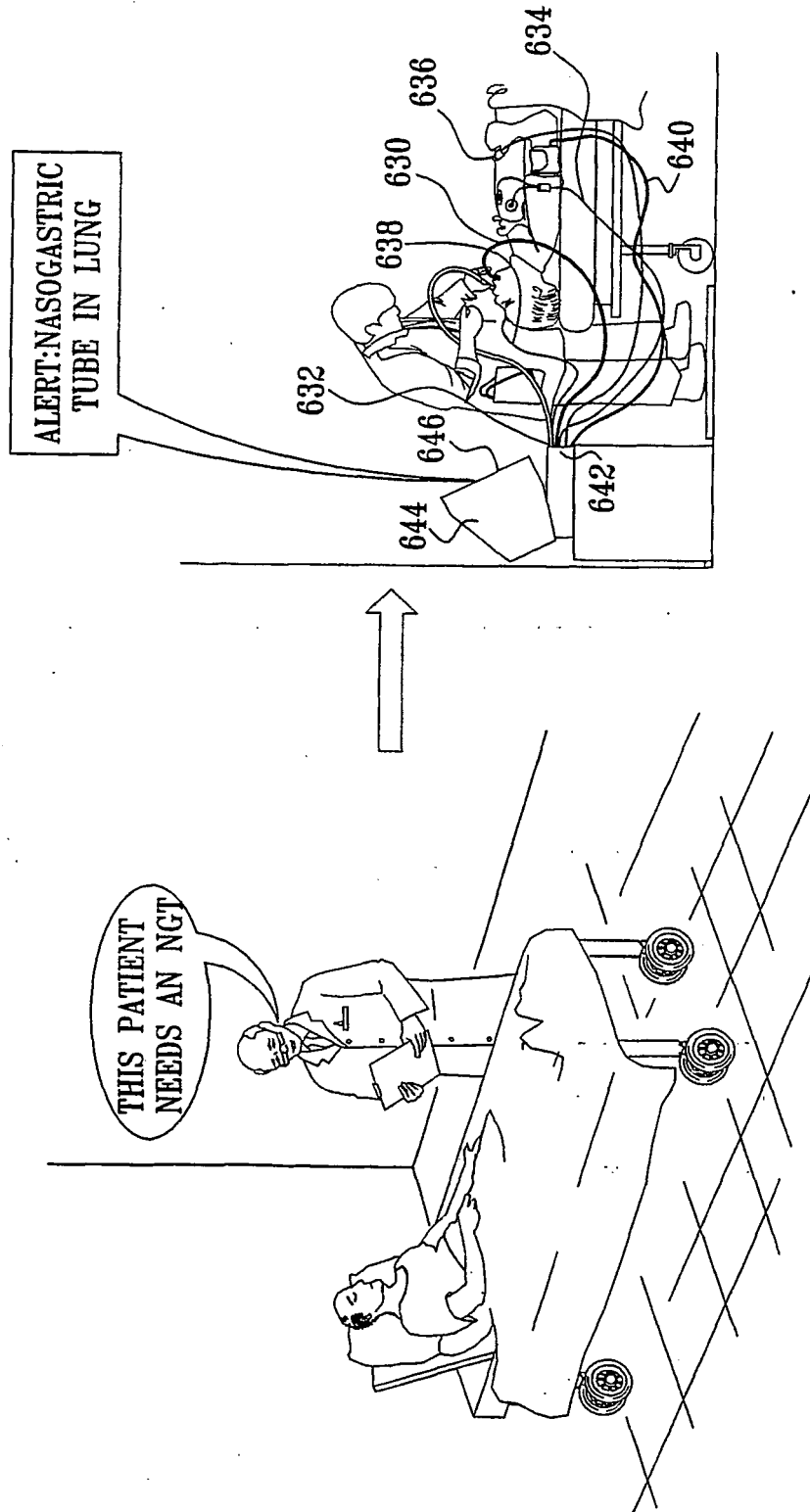


FIG. 39B

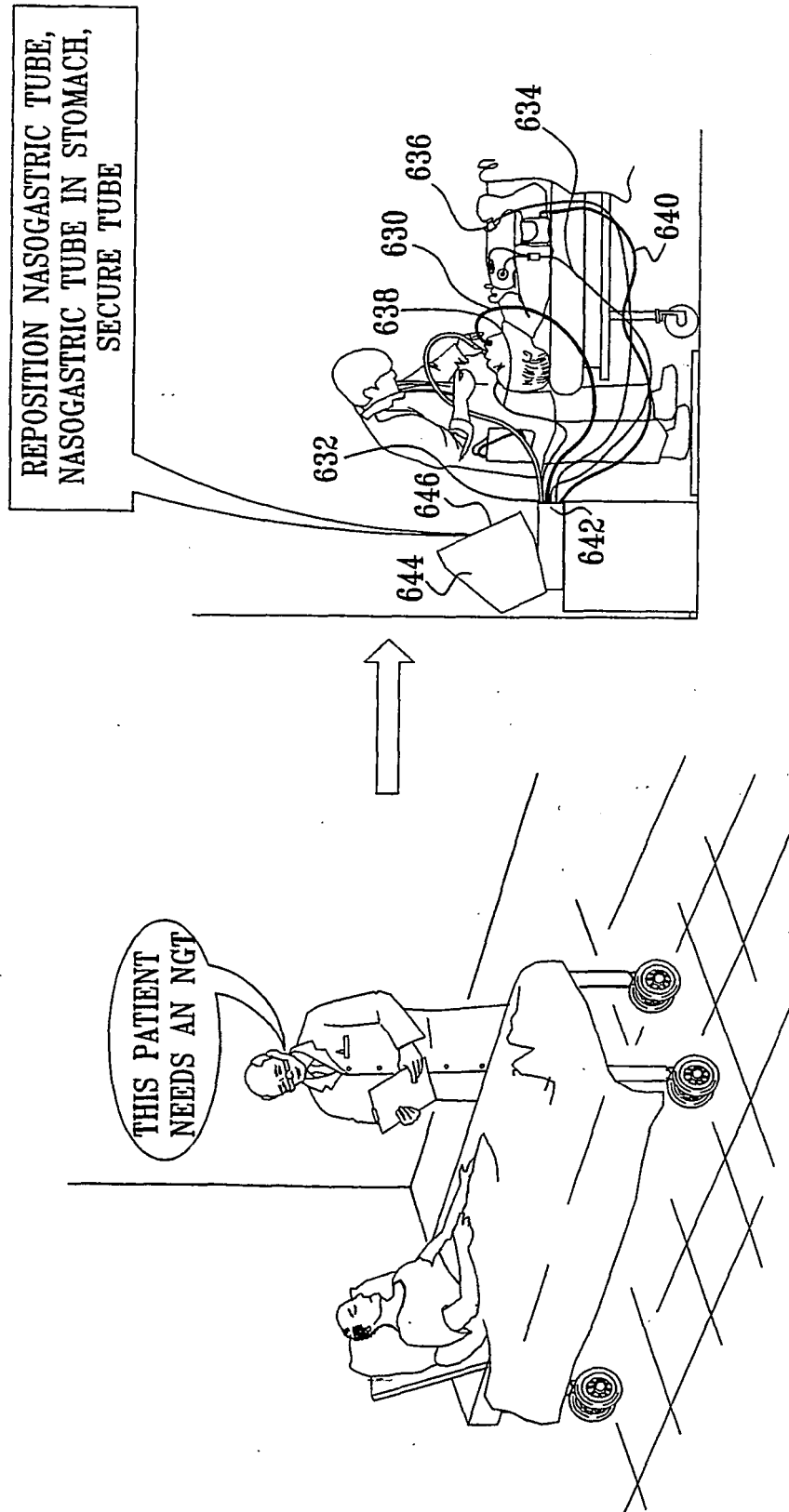


Fig. 40

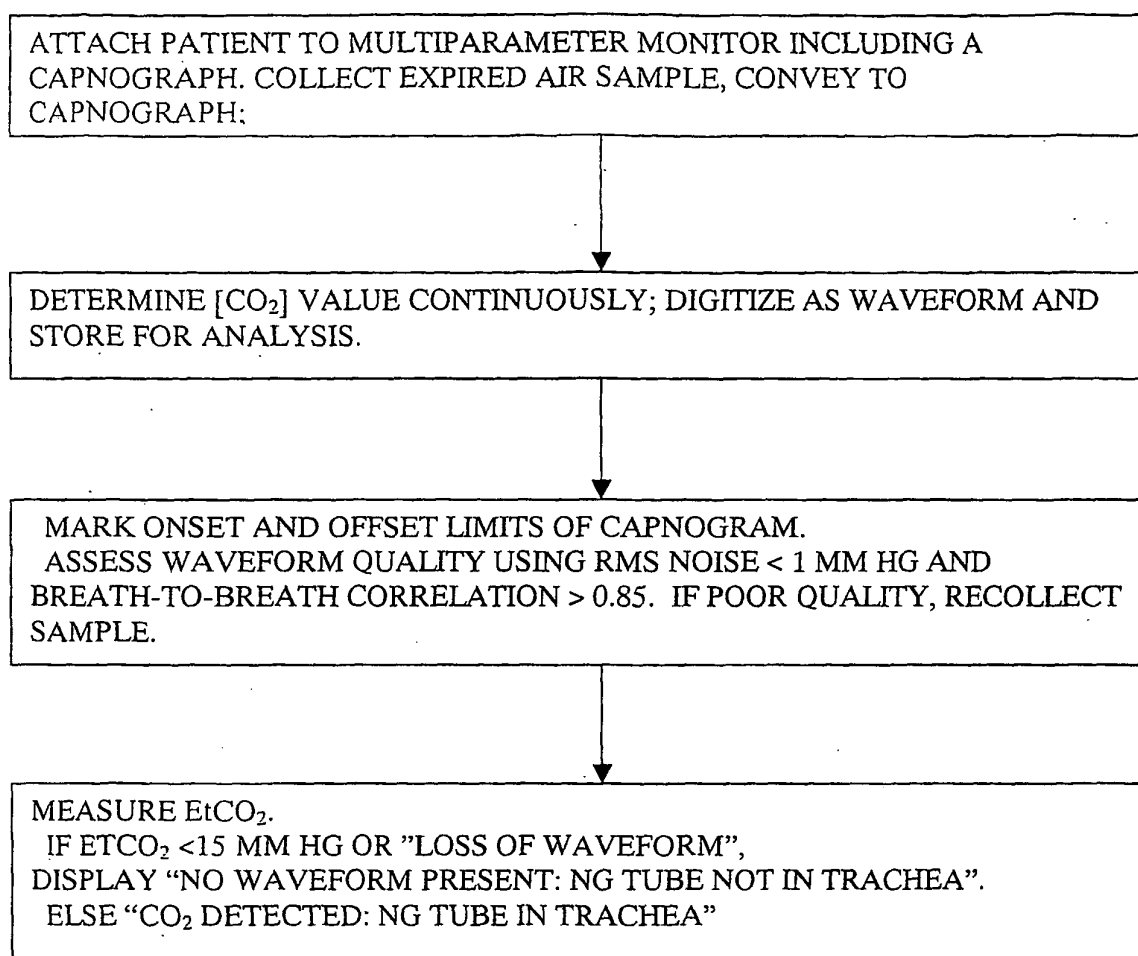


FIG. 41

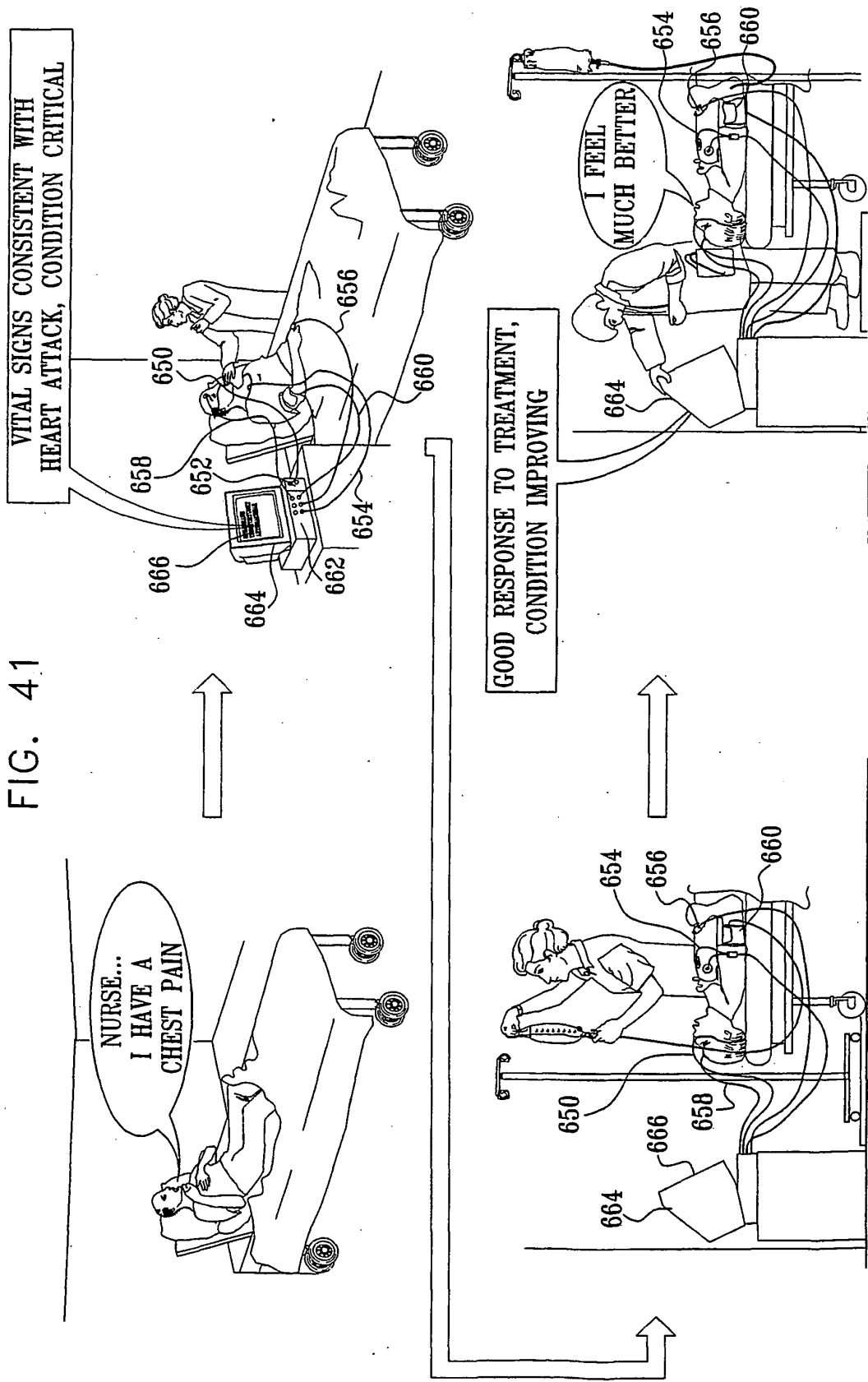
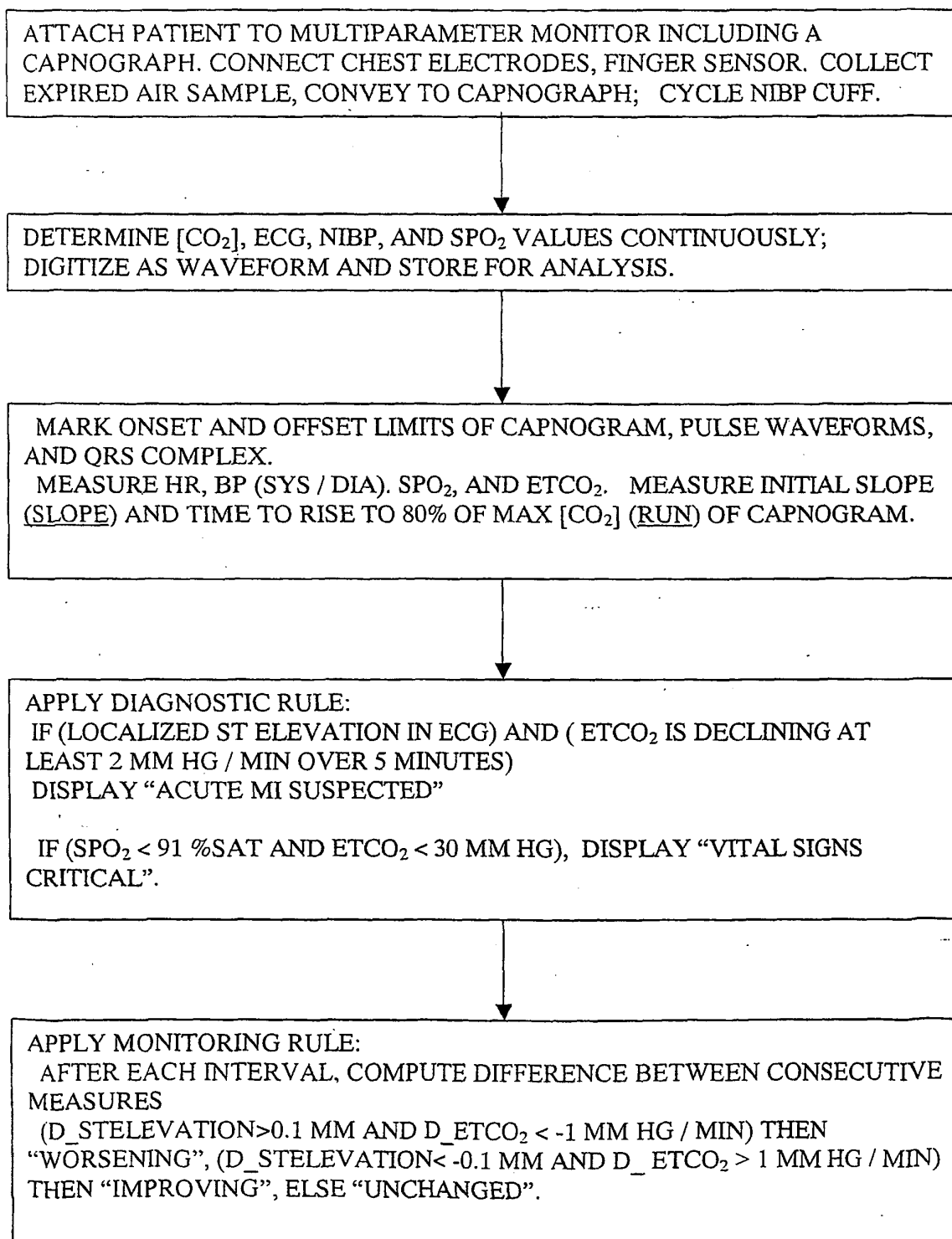


Fig. 42



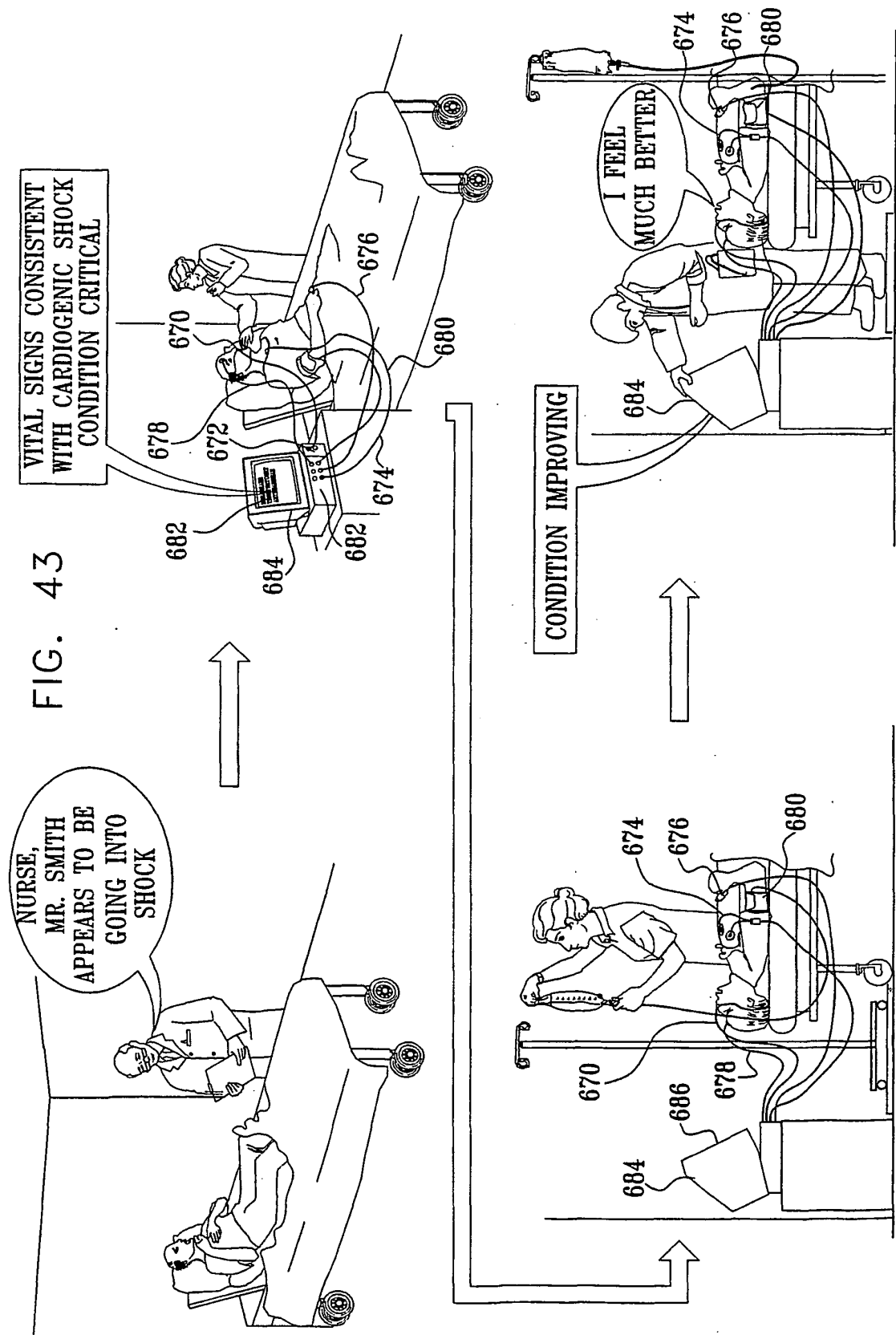


Fig. 44

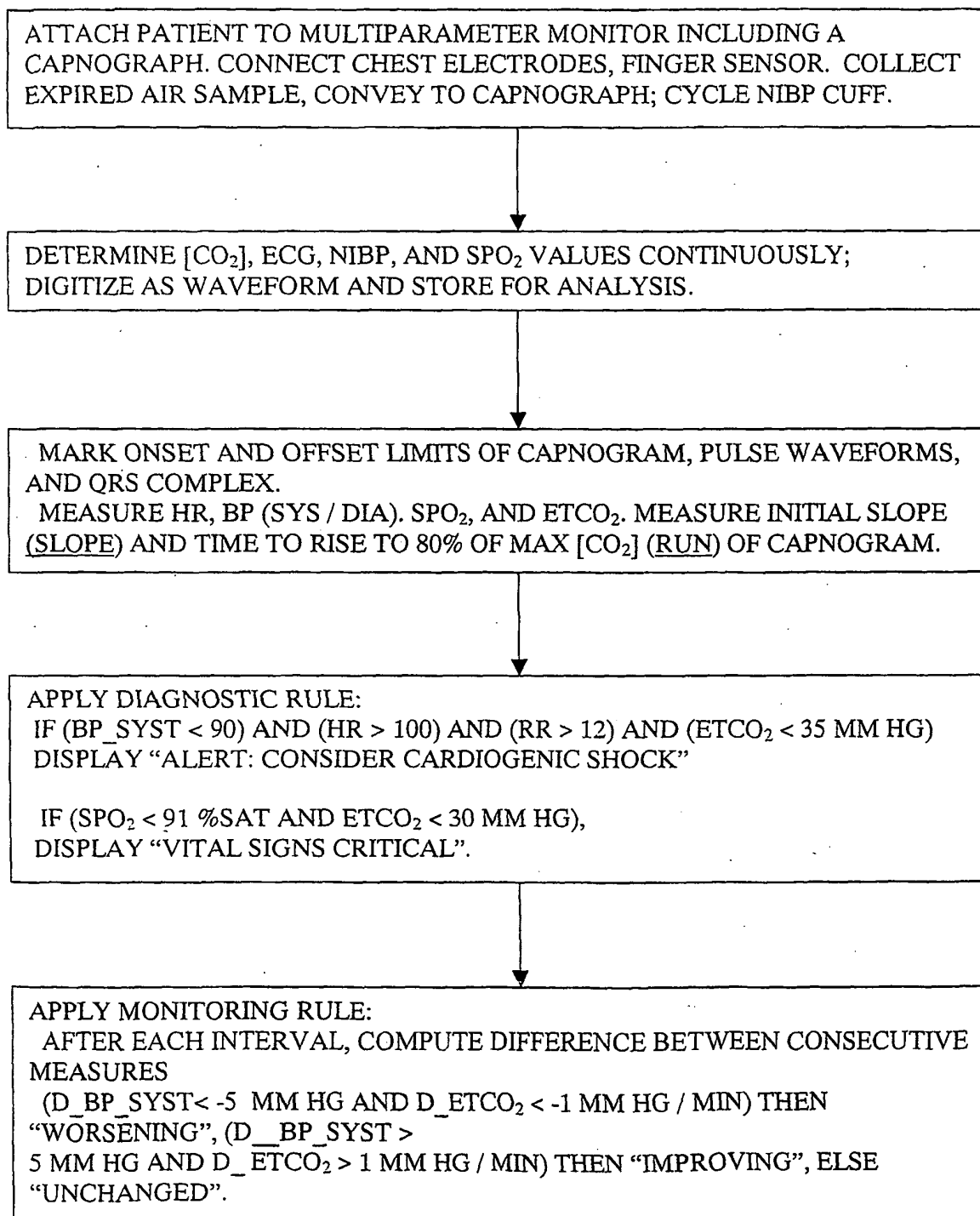


FIG. 45

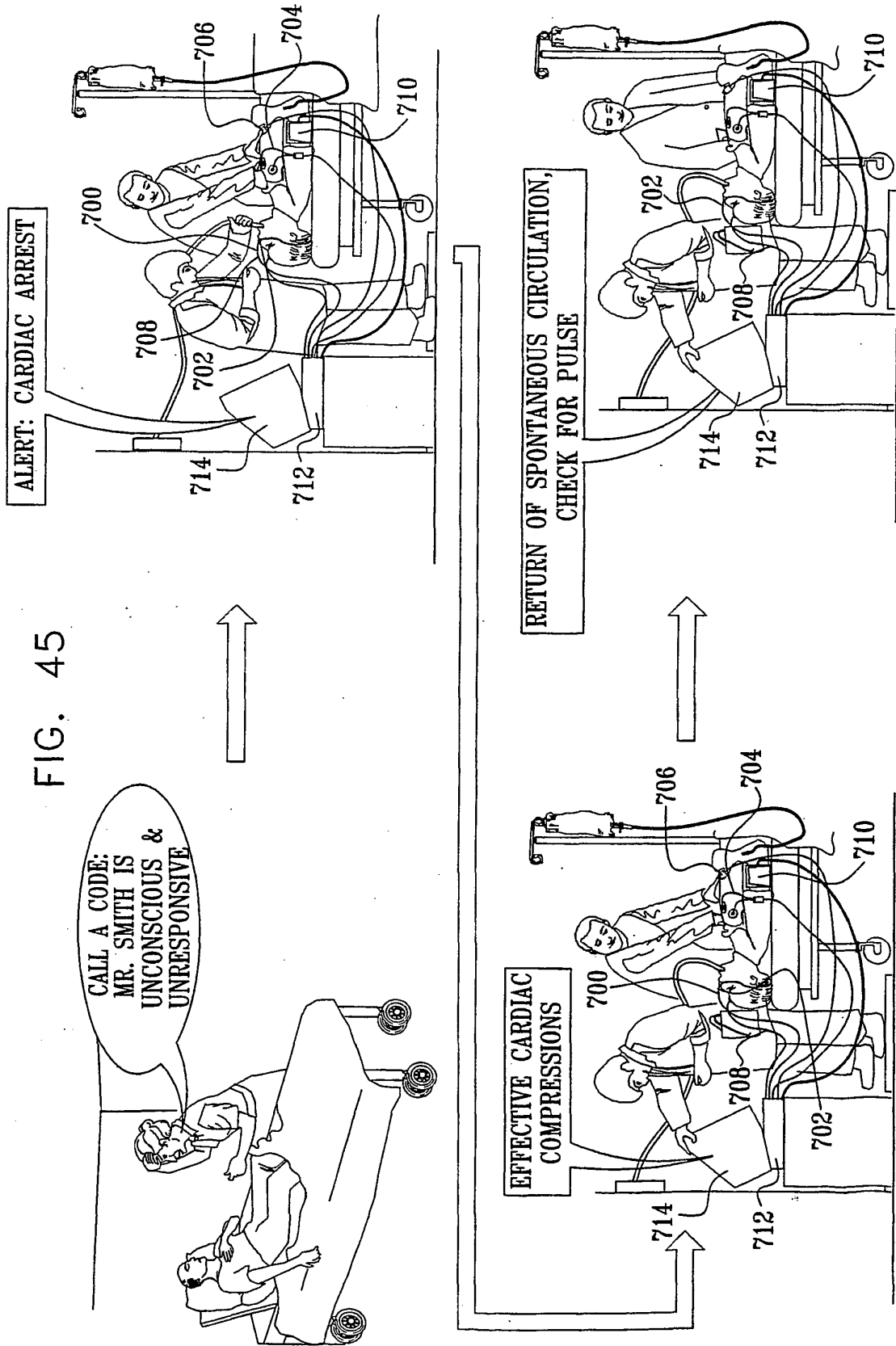


Fig. 46

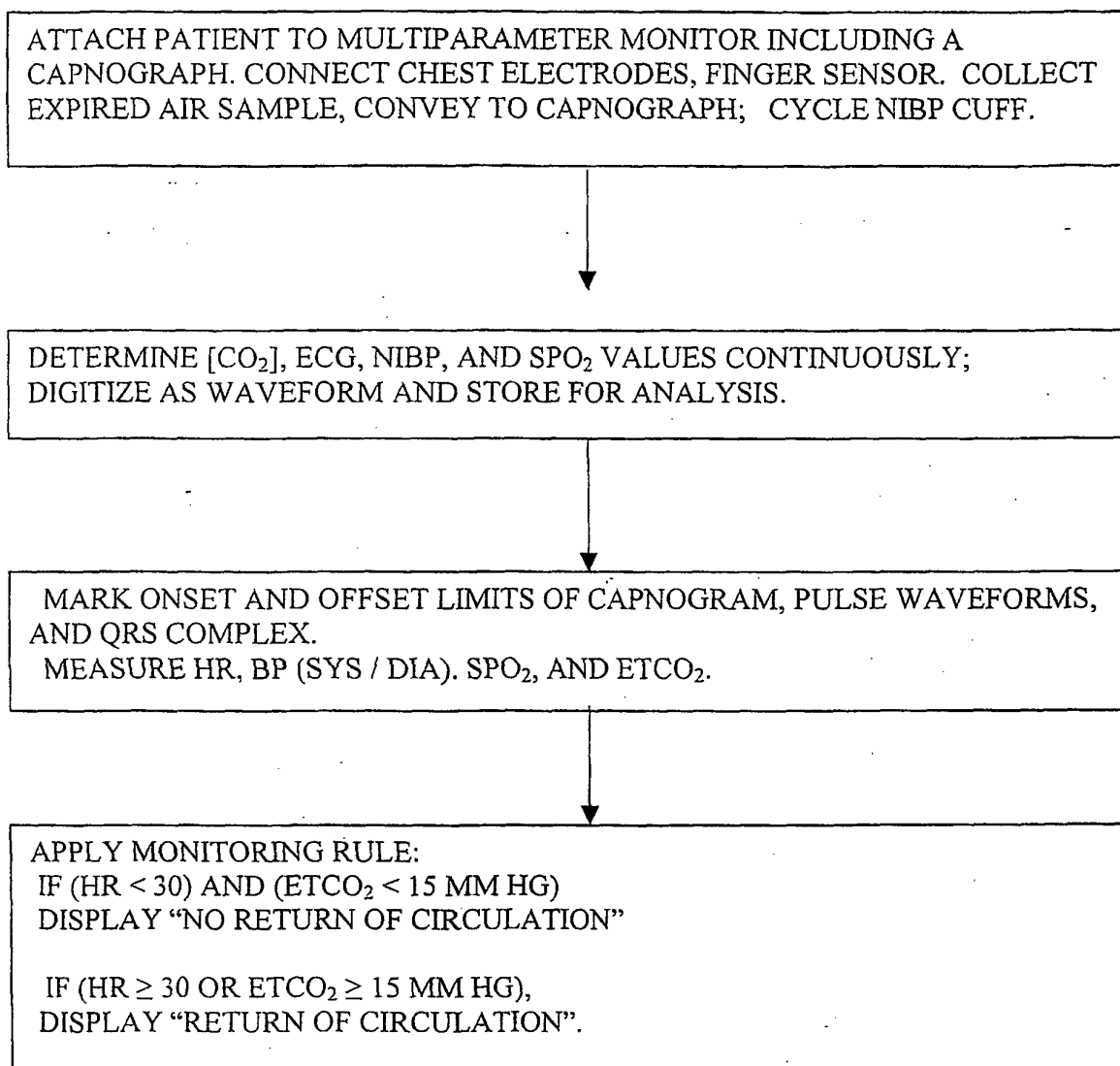


FIG. 47

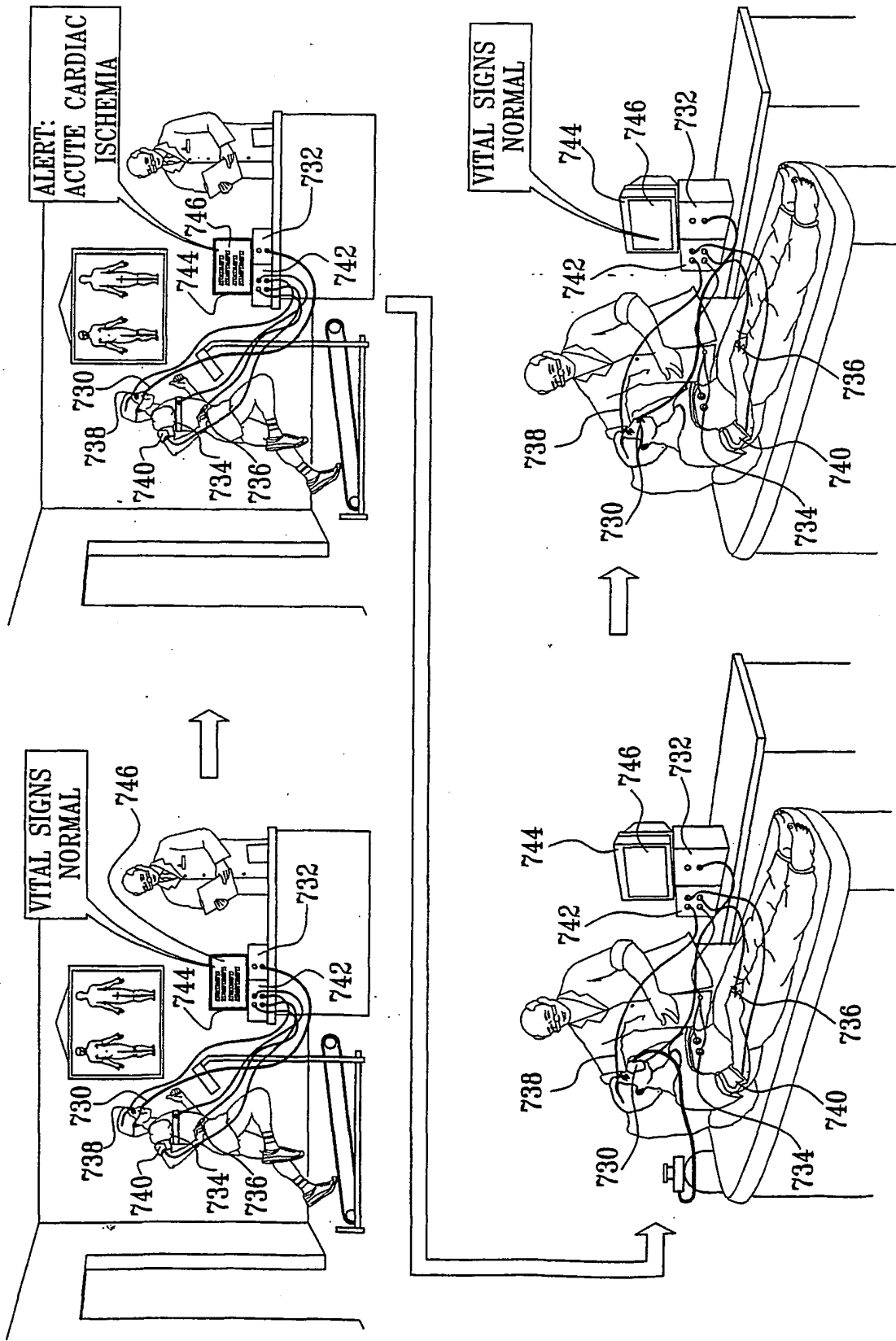
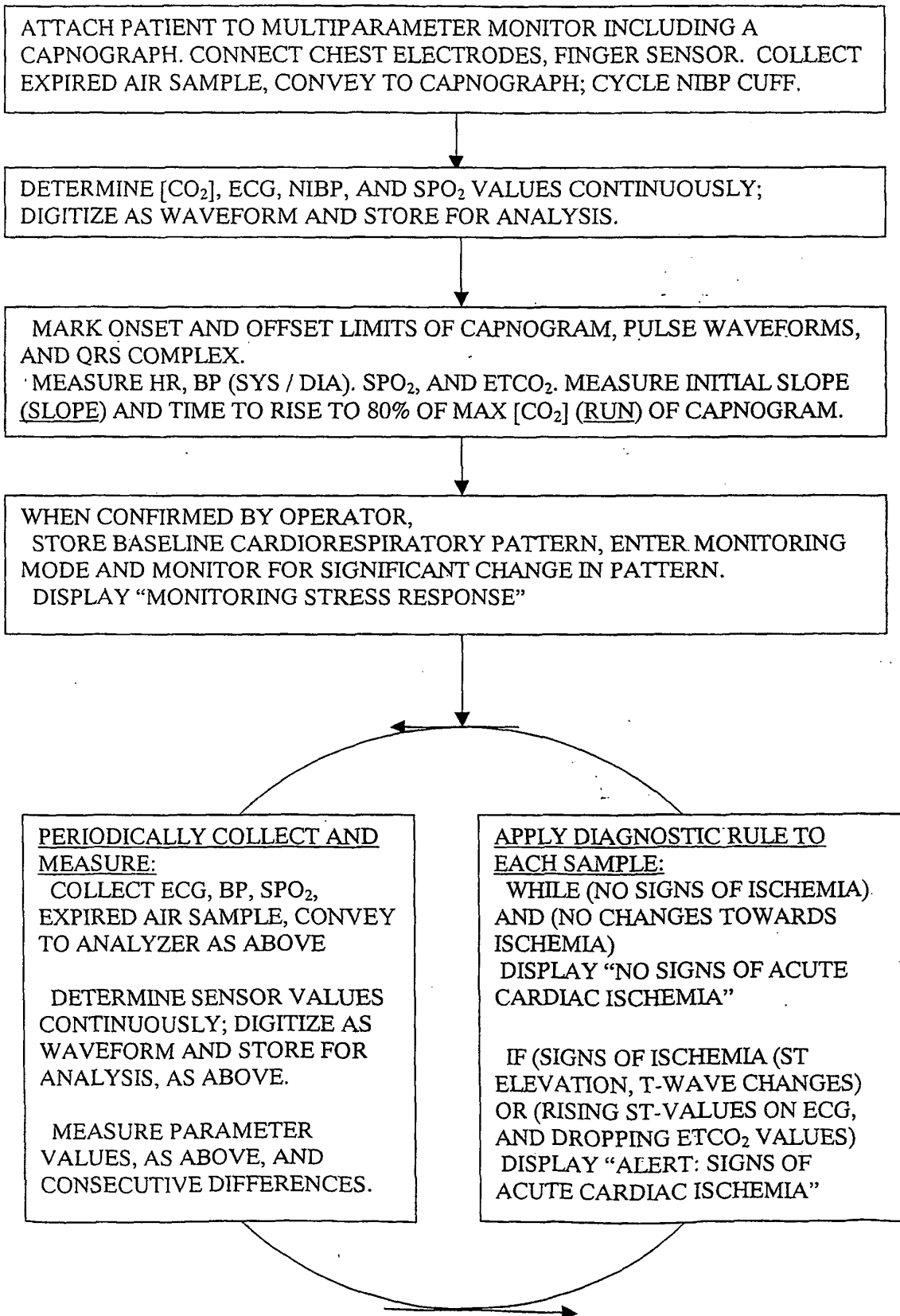


Fig. 48



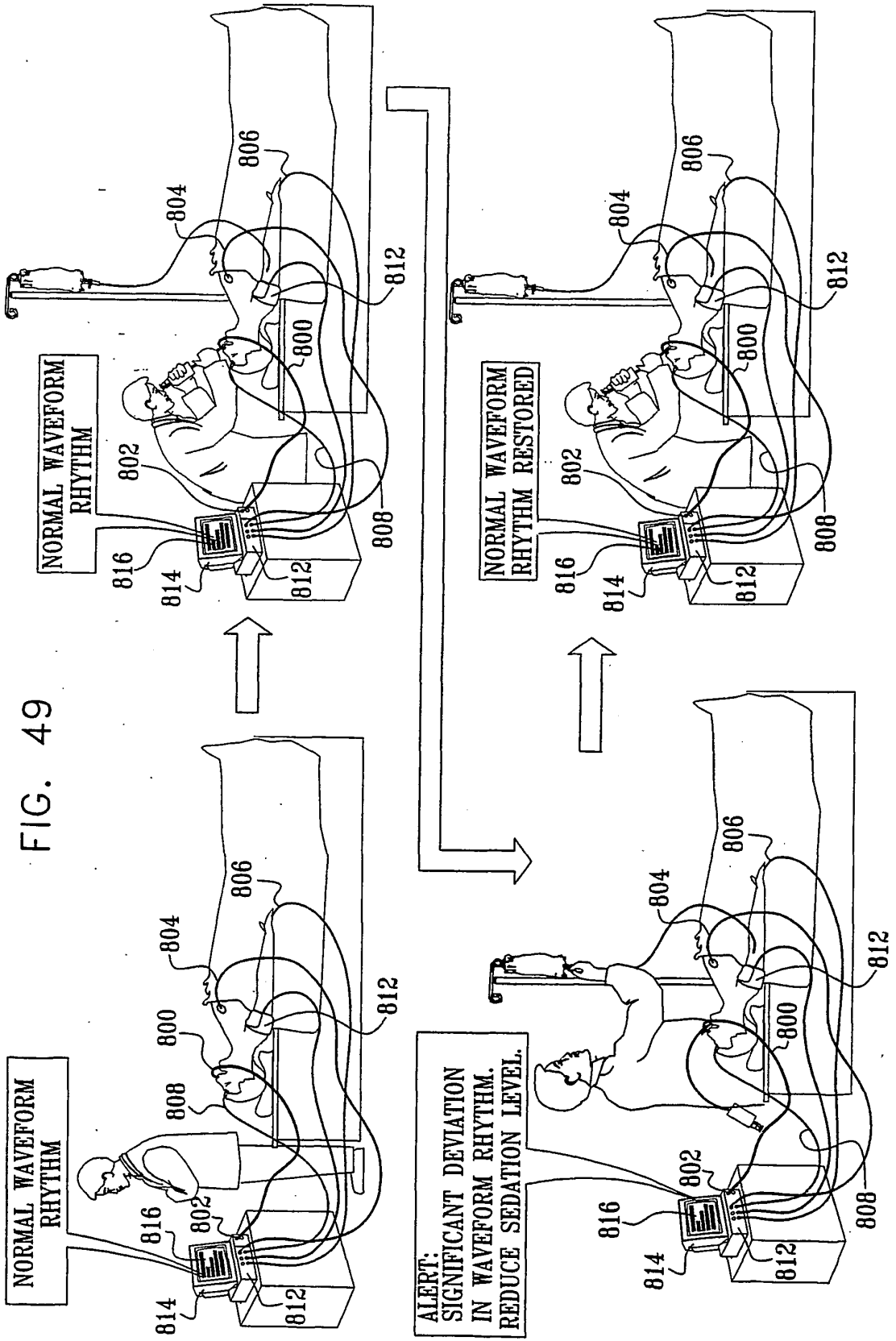
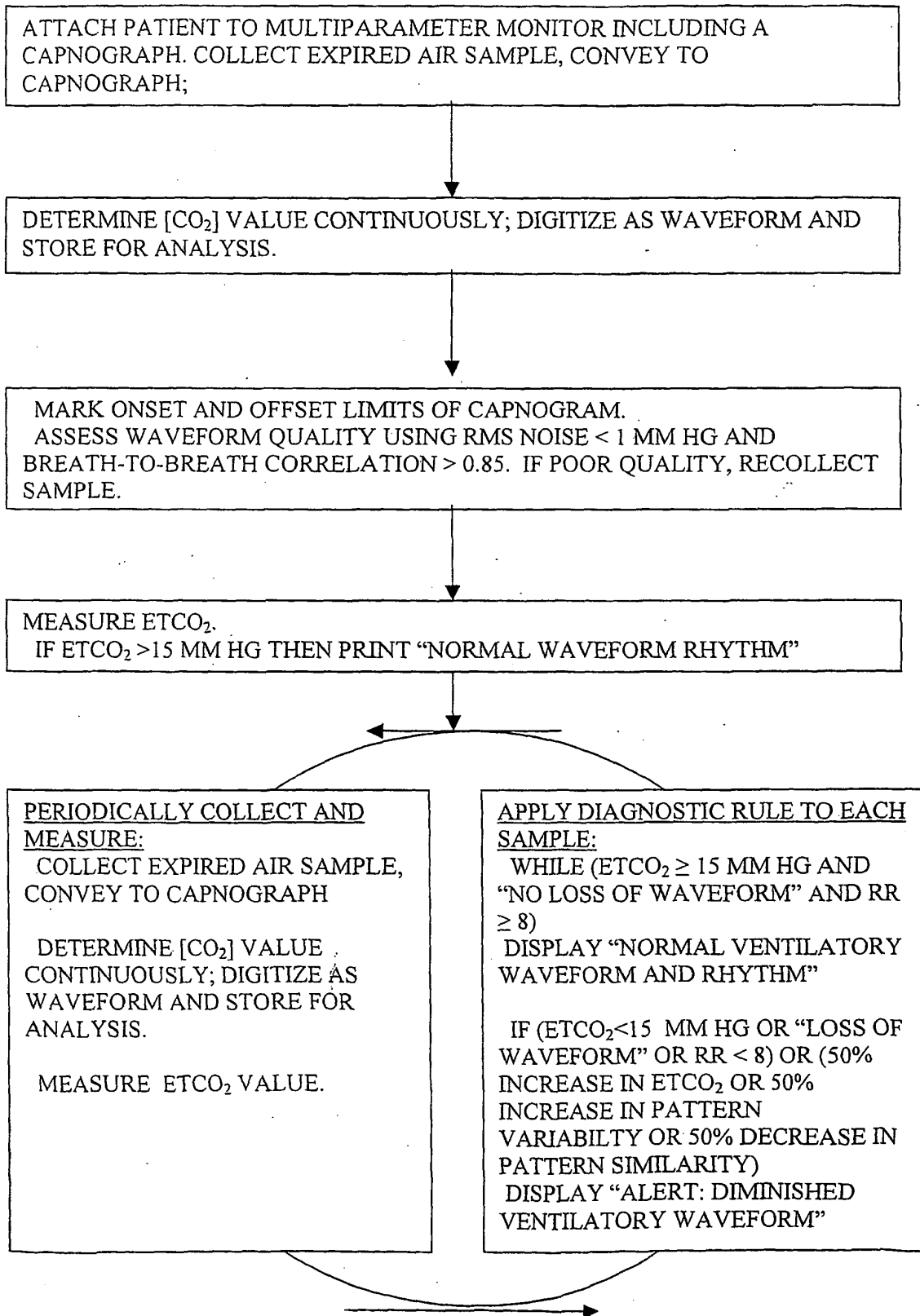
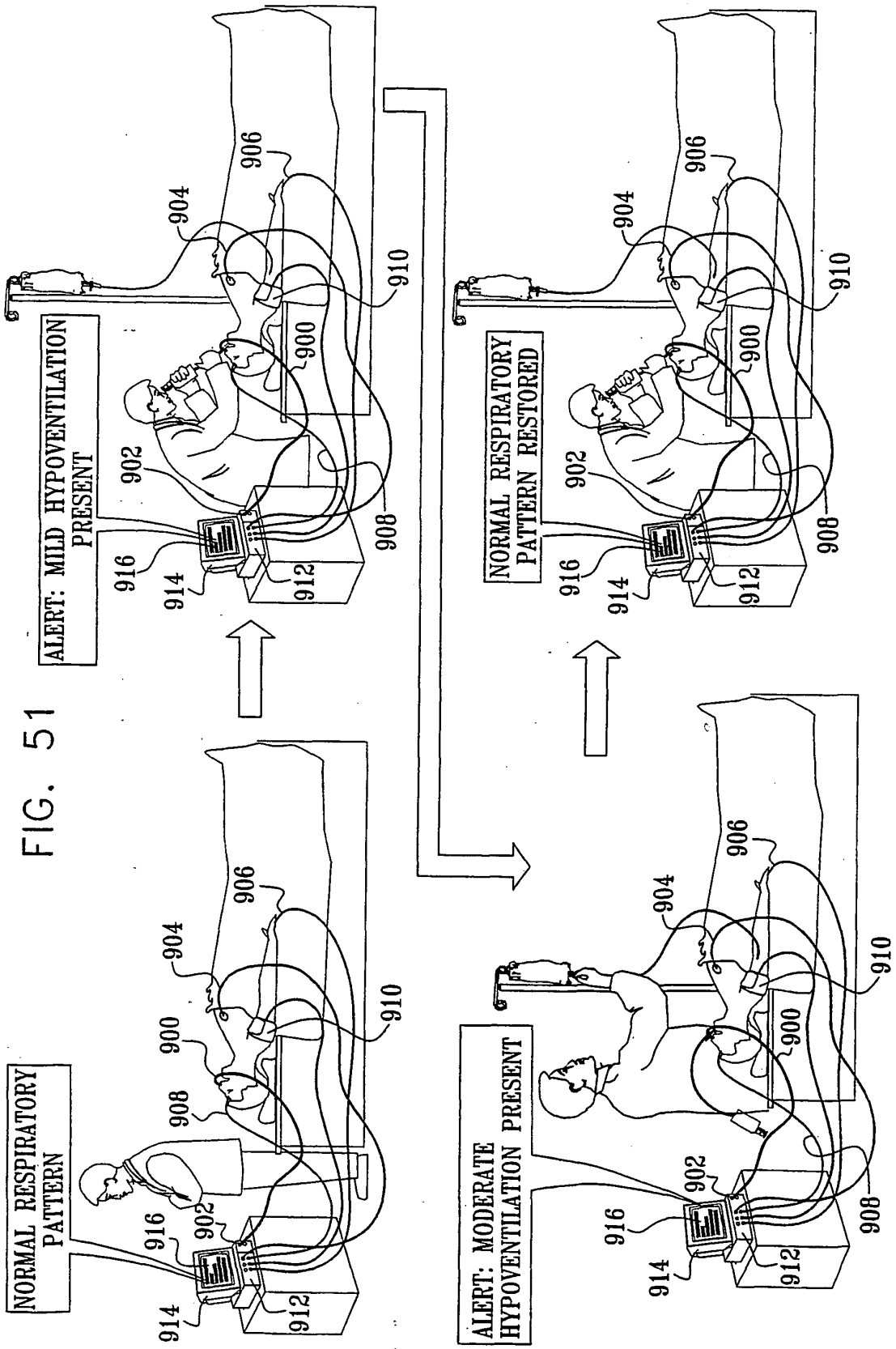


FIG. 49

Fig. 50







**REFERENCES CITED IN THE DESCRIPTION**

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- US 5921920 A [0006]

**Non-patent literature cited in the description**

- Guidelines for the Diagnosis and Management of Asthma. NIH publication on. 97-4051, 1991, 108-109 [0002]

专利名称(译)	自动解释医疗系统		
公开(公告)号	<a href="#">EP1349491B1</a>	公开(公告)日	2013-04-17
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[标]申请(专利权)人(译)	儿童医学中心公司 奥莱登医学有限公司		
申请(专利权)人(译)	儿童医学中心CORPORATION ORIDION MEDICAL , LTD.		
当前申请(专利权)人(译)	儿童医学中心CORPORATION ORIDION MEDICAL , LTD.		
[标]发明人	KRAUS BARUCH HAMPTON DAVID ROBERT CARLEBACH EPHRAIM		
发明人	KRAUS, BARUCH HAMPTON, DAVID, ROBERT CARLEBACH, EPHRAIM		
IPC分类号	A61B5/0205 G06F19/00 A61B5/00 A61B5/022 A61B5/024 A61B5/0402 A61B5/0476 A61B5/08 A61B5/083		
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优先权	60/251828 2000-12-07 US 60/251829 2000-12-07 US		
其他公开文献	EP1349491A4 EP1349491A2		
外部链接	<a href="#">Espacenet</a>		

摘要(译)

提供了用于监视，诊断和治疗患者的至少一种医学呼吸状况的改进的装置和方法，包括适于提供至少一种与患者的呼吸有关的至少一种医学参数的医学数据输入接口，以及医学参数。解释功能（104、110），适于接收至少与患者的呼吸（102）有关的至少一种医学参数，并提供与至少一种医学的严重程度有关的至少一种输出指示（112）至少一种医学参数指示的疾病。

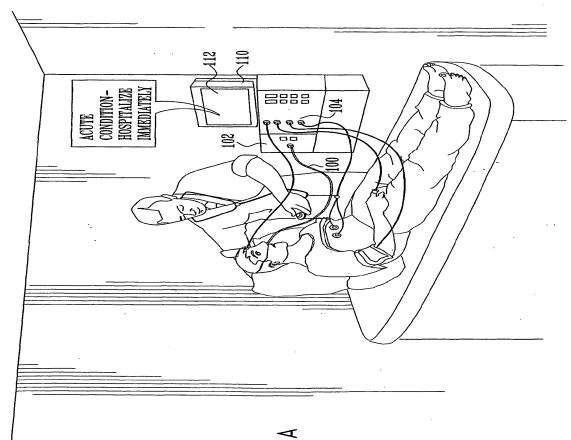


FIG. 1A