(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
9 February 2006 (09.02.2006)

PCT

(10) International Publication Number
WO 2006/015230 A2

(51) International Patent Classification: Not classified

(21) International Application Number:
PCT/US2005/027027

(22) International Filing Date: 28 July 2005 (28.07.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/592,032 28 July 2004 (28.07.2004) US

(63) Related by continuation (CON) or continuation-in-part (CIP) to earlier application:
US 60/592,032 (CON)
Filed on 28 July 2004 (28.07.2004)

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

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for all designations*

— *of inventorship (Rule 4.17(iv)) for US only*

Published:

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

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

(54) **Title:** NON-INVASIVE, NON-INTRUSIVE SMART ESOPHAGEAL OR ENDOTRACHEAL CATHETER WITH SENSOR ARRAY

(57) **Abstract:** The present invention concerns devices used for monitoring vital statistics of an individual. The present invention includes a catheter for insertion into the trachea or the esophagus of a patient that is equipped with a plurality of sensors. The catheter may comprise a feeding tube for insertion into the esophagus of an infant such that the infant may be selectively fed while a number of physiological measurements are taken and monitored by healthcare professionals. The invention has an advantage of being consolidated into a single non-invasive, non-intrusive unit, and therefore is less harmful to patients, easier to deploy, and more cost effective.

WO 2006/015230 A2

NON-INVASIVE, NON-INTRUSIVE SMART ESOPHAGEAL OR ENDOTRACHEAL CATHETER WITH SENSOR ARRAY

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims priority from U.S. Provisional Patent Application Serial Number 60/592,032 filed July 28, 2004.

FIELD OF THE INVENTION

The present invention relates to devices for monitoring physiological indicators such as blood pressure, heart rate, CO_2 expulsion, etc. The present invention provides a Non-Intrusive Physiological (NIP) monitor and display system.

SUMMARY OF THE INVENTION

Many hospitals include maternity wards that specialize in the care of healthy premature and at-risk infants. These wards are typically partitioned into three levels, depending on the level of care required, wherein Level I provides at least monitoring of stable conditions, feeding, emergency transport, and emergency care; Level II provides at least the level of care of Level I plus care for newborns weighing 1500 g or greater, continuing care of low birth weight infants, short-term or transport ventilation support, care for mild to moderate respiratory distress syndrome, suspected neonatal sepsis, hypoglycemia, and mild to moderate post-resuscitation; and Level III provides at least the level of care of Level II plus care for severe respiratory distress syndrome, sepsis, severe post-resuscitation, significant congenital cardiac and other diseases, severe complications and critical care, assisted ventilation on short or long-term basis, specialist consultations, surgery and recovery care, and transport care as required.

Although premature growth infants are generally healthy, they may be at risk because it may not be apparent which of their physiological, and especially neurological, systems are not yet fully developed. Thus, during times of temporary

stress, perhaps caused by an environmental stimuli or by feeding (gavage or bottle), bathing, medical testing and/or handling, extra demands on the complex interactions of the infant's immature physiological system may be created. This may result in adverse effects to the infant, such as the loss of thermal regulatory control, cessation of breathing, or brady or tachy cardia, etc., which requires immediate medical care. Presently the typical nursing staff caring for growth infants gradually gains insight into the ability of each individual to cope with these stimuli from their interactions with the infant. These interactions provide qualitative measures of the physiological stability of the infant.

Special care must be exercised in handling and monitoring of low birth weight infants, which are often very thin and fragile, and weigh 1500 grams or less. For example, the fatty layer under the exterior layer of transparent skin has not yet developed in these infants such that one can see the delicate pattern of blood vessels beneath. Thus, the skin is very sensitive and easily bruised, such that superficial damage may occur when a monitor lead is placed on the infant's body for a even short period of time. In addition, skin injury may be caused by tape or electrode adhesives. Survival of many infants requires minimal manipulation or interference to thus prevent unnecessary stress and/or injury.

Premature intensive care infants generally range from 500 to 1500 grams in weight and often have circulatory, respiratory, neurological, or metabolic defects or suffer from gastrointestinal dysfunction. To prevent death from fatigue or shock, these infants require precise continuous monitoring of all vital respiratory, circulatory, and thermal regulatory functions. One drawback of existing monitors is that they are unable to predict future risk. More specifically, existing monitors only alert the caregiver to the presence of apnea, brady cardia, regurgitation, and crying.

Another drawback of existing monitoring systems is that each infant station in a ward often includes an array of isolated instruments from several manufacturers, requiring a plurality of cables and/or tubes to be interconnected to the infant. While

assessing latent health parameters this configuration is generally hazardous, intrusive, disjointed, complex, fragile, and expensive.

Accordingly, embodiments of the present invention provide a Non-Intrusive Physiological (NIP) monitor that provides a continuous quantitative assessment of the physiological status and strength of the infant via an intelligent esophageal catheter, feeding (gavage) tube that includes an array of specialized sensors and/or stimulators that measure the respiratory, circulatory, and thermal regulatory systems of the infant. No additional tape, catheters, wires or electrodes are required for monitoring.

Further embodiments of the present invention provide a device to measure an infant's respiratory system. For growth infants, the respiratory measure and apnea monitor can be derived from a safe electrical impedance measure of the thorax. The quadrapolar impedance electrodes of one embodiment are located on the esophageal catheter, eliminating the need for a chest expansion sensor. Thus, continuous indicators of tidal volume and breathing rate are provided without the need to time a breath, several breaths, or attempt an estimate of the depth of a breath.

For intensive care infants, the respiratory measure and apnea monitor can be derived from a measure of end tidal expired carbon dioxide captured in a breathing mask that is interconnected to the feeding tube, which also eliminates the need for the chest expansion sensor. This is the body's primary sensor for regulating breathing depth and rate and is recognized by anesthesiologists and emergency physicians as the most anticipatory assessment of the respiratory system.

Embodiments of the present invention may also provide a device to measure an infant's body temperature. More specifically, in one embodiment, the body temperature is derived from a sensor located in the esophagus generally at the level of the diaphragm. The temperature measurement at this location is preferred over rectal thermometers because it is a true central measure of the core temperature of an infant respondent to the thoracic and abdominal condition. Current requirements involving the use of a rectal thermometer are contradictory, since it is desirable to insert the thermometer greater than 3 cm to accurately reflect an infant's core temperature.

Unfortunately, the sigmoid colon turns at a right angle at about 3 cm and insertion to a depth greater than 3 cm risks intestinal perforation. According to other embodiments of the present invention, the body temperature sensor is as close to the hypothalamus as possible. Accordingly, the body temperature sensor may be moved towards the proximal end of the catheter as compared to a sensor positioned at the level of the diaphragm.

Further embodiments of the present invention provide a device that measures the infant's circulatory system. The circulatory measure of one embodiment of the invention is derived from a Doppler ultrasound sensor with unique signal processing. This processor takes into account both stroke volume and heart rate to produce a relative estimate of cardiac output, eliminating the need for a blood pressure sensor. The measure of cardiac output is the desired true measure of the performance of the heart, and is much preferred over a blood pressure measure that requires a knowledge of the peripheral vascular resistance to assess the blood volume flow. The ultrasound sensor derives stroke volume from the amplitude of a reflected signal, and flow from the frequency shift. The signal processor's use of signal amplitude enhances the signal to noise ratio, thereby allowing the use of a smaller transducer that is compatible with the esophageal catheter. Further, this hemodynamic measure is greatly preferred over the indirect measures of urinary activity or an attempt to estimate rapid small heart pulsation. The Doppler hemodynamic measure provides a reliable anticipatory measure of patient risk because an increase in cardiac output may be an indication of reoccurring patient ductus arteriosus or an indication of stomach, intestine, kidney, liver, or lung dysfunction.

Still further embodiments of the present invention provide a device that monitors cardiac activity of an infant. More specifically, embodiments of the invention include three electrodes that furnish an esophageal electrocardiogram (ECG). The ECG provides a continuous indication of arrhythmia, conduction disturbances, and chemical imbalance from premature ventricular contractions, as well as electrical potential and interval measurements. This method of measurement is

desirable since anesthesiologists have demonstrated that dysrhythmias were detected 54% and 42% with leads II and V5, respectively, whereas the esophageal lead provides information that led to the correct detections and diagnosis about 100% of the time. In addition, the three ECG electrodes may be used for pacing therapy, and may be used as stimulating electrodes to treat bradycardia, tachycardia and dysrhythmias.

Embodiments of the present invention provide a device that measures stress. More specifically, embodiments may provide a quantitative measure of stress that is derived from heart rate and heart rate variability. These electrical and Doppler hemodynamic measures provide a reliable anticipatory measure of patient risk.

Further embodiments of the invention provide various other measurements to indicate the well-being of the infant. For example, two of the quadrapolar electrodes may be used to provide an activity indicator. In addition, a pH sensor may be provided that helps predict apnea caused by GastroEsophageal Reflux. A toe or arm oxygen saturation sensor may be used for infants at risk for Retinopathy of Prematurity, which generally require ventilators and oxygen. Ventilation data may then be derived from a nasal thermistor, the CO_2 sensor, or the thoracic impedance sensor.

The integrated system of embodiments of the present invention is safe, economical, and utilizes the existing feeding tube to provide an array of real time quantitative anticipatory cardiopulmonary critical parameters. Further, embodiments of the system produce a display of the esophageal ECG, aortic flow, and ventilation that may be in the form of a chart. The system may also produce a digital display and trend of core temperature, esophageal pH, Respiration Rate, CO_2, Heart Rate and Heart Rate Variability, and other monitored parameters. In addition, the system provides relative digital indicators of tidal volume, minute ventilation, stroke volume, cardiac output and activity. The digital parameters may be combined into a single digit summary indicating the physiological state of the patient: *i.e.*, an improved Apgar Score. The system incorporates expert systems and/or fuzzy logic and may

include alarms for apnea, excess CO_2, bradycardia, tachycardia, low core temperature, low cardiac output, low pH, etc.

Thus, embodiments of the present invention employ a temperature predictor of thoracic or abdominal problems, an EEG predictor and treater of arrhythmias, a hemodynamic measure of changes of cardiac output, and a measure of respiratory response to patient state (CO_2). This information is provided by sensors that are integrated into a simple feeding tube that is already in use in the industry to allow for quantitative triage via an expert system indicator of a physiological state. As a result, in the context of growth infants, a non-intrusive and economical quantitative measure may be provided. Further, the hospital benefits from less liability by reducing the number of infant interactions while reducing work load on hospital staff. In the context of infants under intensive care, a system may be provided that increases the level of quality of patient care while reducing workforce stress by reducing the number and types of equipment generally used. The hospital may also reduce costs associated with procurement and maintenance of many different monitoring units and systems.

In use with premature growth infants and with premature ICU infants, embodiments of the present invention provide a substantially continuous assessment of the physiological status and strength of the infant, without adding stress by providing an instrumented flexible feeding tube, with no extraneous catheters, wires or electrodes, that produces quantitative measures of the respiratory, circulatory and thermal regulatory systems of the infant. In use with infants in intensive care, the sensors may be interconnected to an endotracheal tube of various sizes for patient monitoring during anesthesia, respiratory intensive care, cardiac intensive care, surgical intensive care, emergency intensive care, burn unit care, as well as any other types of intensive care.

Military and homeland security personnel may also use embodiments of the present invention for emergency triage, wherein effective use of limited resources often requires the immediate assessment of each battle casualty or disaster victim. A

monitored esophageal catheter in accordance with embodiments of the present invention may be quickly inserted into each patient, in less than about 30 seconds per individual. The system then provides an indicator, in one embodiment a number from 1 through 5, that corresponds to the patient's state to provide triage information. For example, the 3's are treated first, the 2's are evacuated first, followed by the 4's, 5's and 1's. Therefore, within minutes, the vital condition of all patients would be known, allowing clinicians to determine the priority of need and proper location of treatment. One skilled in the art will appreciate that other indication methods, such as color codes and/or real time video or sound displays may be provided without departing from the scope of the invention. In addition, it should be noted that the system may include internal protocols to vary the indicators based on a specific care situation. More specifically, data collected and analyzed in an infant care situation will generally differ in a disaster triage situation. Thus, the internal protocols may be physically or remotely altered to suit the current needs.

In accordance with embodiments of the present invention, a system that may be used by veterinarians and zoo keepers is provided. Veterinarians generally require an economical system that is designed to accommodate faster rate parameters than human monitors provide and that may be operated by a single practitioner. In addition, the minimal animal manipulation provided by the device will appeal to all animal healthcare providers. Thus, embodiments of the present invention may provide a physiological monitor with extended parameter ranges to accommodate small animals (less than about 3 Kgm, ~100 oz). The monitor may provide heart rate, breathing rate, carbon dioxide concentration, cardiac output, tidal volume, and body temperature using an esophageal catheter and a mask. A single instrumented miniature catheter will provide immediate indication of the animal's status without the time consuming application of an array of sensors. The cardiac output measure may incorporate a novel signal processor that has been demonstrated to be of greater value than conventional hemodynamic pressure and flow monitors. The display may be a simple single large numeric wireless indicator that can be wall mounted, however,

other display methods are contemplated and are within the scope of the invention. A hemodynamic audio ultrasound indicator may also be provided.

Thus, embodiments of the present invention provide a non-invasive, non-intrusive esophageal or endotracheal catheter that includes a plurality of sensors, which decreases risk of harm to the patient, efficiently displays the sensor input, and is cost effective to the healthcare provider. In accordance with embodiments of the present invention, the catheter may comprise a lumen, a stylet and/or a weight at the distal end.

Further, embodiments of the invention provide a monitoring device, comprising:

a patient monitoring device, comprising a feeding catheter with a first end and a second end, said catheter adapted to receive nourishment;

a plurality of sensors interconnected to said catheter proximate to said second end;

a mask for the delivery of breathing air, interconnected to said catheter proximate to said first end;

and wherein said sensors are adapted to obtain data related at least to core body temperature, blood flow, heart rate, and pH of the patient.

The Summary of the Invention is neither intended nor should it be construed as being representative of the full extent and scope of the present invention. The present invention is set forth in various levels of detail in the Summary of the Invention as well as in the attached Drawings and the Detailed Description and no limitation as to the scope of the present invention is intended by either the inclusion or non-inclusion of elements, components, etc. in this Summary of the Invention. Additional aspects of the present invention will become more readily apparent from the Detailed Description, particularly when taken together with the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a partial view of a distal end of a catheter in accordance with embodiments of the present invention;

Fig. 2 is a partial view of a proximal end of a catheter that includes a breathing mask or sample tube in accordance with embodiments of the present invention;

Fig. 3 is a schematic depiction of a plurality of bassinets for growth infants and a plurality of isoletts for ICU infants interconnected to a monitoring station in accordance with embodiments of the present invention;

Fig. 4A is a view of a bassinet or a isolett and a view of associated telemetry in accordance with embodiments of the present invention;

Fig. 4B depicts a feeding tube with sensors in accordance with embodiments of the present invention;

Fig. 5 depicts a monitoring station output in accordance with embodiments of the present invention with digital display, real time scrolling chart display, and telemetry;

Fig. 6 is a schematic depiction of a carbon dioxide detector that may be employed by some embodiments of the present invention;

Fig. 7 is a schematic depiction of a heart rate meter that may be employed by some embodiments of the present invention;

Fig. 8 is a schematic depiction of a pH meter that may be employed by some embodiments of the present invention;

Fig. 9 is a schematic depiction of a respiration rate meter that may be employed by some embodiments of the present invention;

Fig. 10 is a schematic depiction of a respiratory impedance amplifier that may be employed by some embodiments of the present invention;

Fig. 11 is a schematic depiction of an activity meter that may be employed by some embodiments of the present invention;

Fig. 12 is a schematic depiction of an esophageal electro-cardiogram that may be employed by some embodiments of the present invention;

Fig. 13 is a schematic depiction of an esophageal electro-cardiogram with pacing that may be employed by some embodiments of the present invention;

Figs. 14A and 14B are schematic depictions of esophageal and nasal temperature sensors that may be employed by some embodiments of the present invention; and

Figs. 15A and 15B are a schematic depictions of Doppler ultrasound signal processing for obtaining a circulatory measure that may be employed in some embodiments of the present invention.

DETAILED DESCRIPTION

Referring now to Figs. 1-15, a non-invasive, non-intrusive esophageal or endotracheal patient monitoring system that employs at least a monitoring station 1 and a sensored catheter 2 is described. More specifically, embodiments of the present invention employ an endotracheal catheter or an esophageal feeding catheter 2 with a proximal or first end 6 and a distal or second end 4. The catheter 2 may be formed from a pliable material, for example to facilitate insertion in a patient. A plurality of sensors 7 for monitoring the cardiovascular activity, respiratory activity, temperature, or other vital signs or parameters of an infant 8 are mounted to the catheter 2 and configured to be as smooth as possible to prevent trauma to the esophagus or trachea. A mask 10 or other device may be interconnected to the catheter 2 to allow for monitoring of the carbon dioxide output of the patient or infant 8. The present invention thus provides a device to monitor patients or infants 8 without requiring the attachment of individual sensors to the infant 8, which in some cases is harmful to the infant 8.

Referring now to Fig. 1, the distal or second end 4 of the catheter 2 is shown. More specifically, Fig. 1 illustrates a plurality of sensors interconnected to the catheter 2 proximate to the distal end. These sensors may include a Doppler ultrasound aortic flow meter 12, a pH sensor 20, a plurality of electrodes 7 for ECG and respiratory impedance, and a thermistor 11. Embodiments of the present invention have

electrodes spaced one centimeter apart for data readings, as will be described in greater detail elsewhere herein. The catheter 2 of some embodiments of the present invention is constructed of silicone, rubber, PVC, a combination of materials such as a combination of silicone and PVC, or any other compliant material adapted for safe insertion into a patient's trachea or esophagus. The sensors shown herein are interconnected to the catheter 2 by way of pressure fitting, adhesives, heat welding, fasteners, or other binding techniques.

Wires interconnected to the sensors may be embedded within the catheter 2. Alternatively, the wires may be threaded through an interior passageway of the catheter 2, situated alongside the catheter 2, or affixed outside the catheter 2. Embodiments of the present invention may employ sealed apertures proximate to the sensors in the catheter 2, through which the wires for the sensors are threaded, to prevent the seepage of items passed through the catheter 2 at those apertures. The wires branch from the walls of the catheter 2 towards the proximal end for interconnection to a monitoring device. Although lead wires have been described herein, other forms of data transmission may be employed, such as wireless transmissions, without departing from the scope of the invention. In addition, the sensors described herein may also be totally or partially embedded in the catheter or attached to the outer surface of the catheter. As such, as used herein, "sensor" may refer to the data collection portion of the device, as well as all associated wires, controllers, transmitters and signal processing components.

Referring now to Figs. 2a and 2b, a mask 10 of the present invention is shown. More specifically, embodiments of the present invention may employ a mask 10 interconnected near the first or proximal end 6 of the catheter 2 that allows the patient's breathing output may be monitored to evaluate the amount of CO_2 expelled. Although one tube is shown herein that interfaces with the mask 10, one skilled in the art will appreciate that a catheter 2 comprising a feeding tube may be used to supply nutrients to the patient, while a second air delivery tube may be used for sampling exhaled CO_2. The mask 10 of some embodiments of the present invention are known

in the art and may be scaled to any size as will be appreciated by one skilled in the art. As an alternative to a mask 10, a nasal sample tube 10a may be included. As can be appreciated by one of skill in the art, a mask 10 used to collect air exhaled by an infant should be designed to ensure that the infant does not re-inhale previously exhaled air. As can also be appreciated, mask 10 and CO_2 monitoring system are configured to eliminate humidity and condensation in the mask or sampling tube or to compensate for such condensation such that it does not interfere with sample measurement or analysis. Catheter 2 is connected to supporting equipment such as monitor 1 and food supply by electrical connectors 2a and tubing connectors, such as a Luer Lock, as is known in the art.

Referring now to Fig. 3, a ward for the care of infants 8 is shown that employs the present invention. A plurality of catheters 2 with monitoring stations 1 connected thereto may be employed, wherein health care professionals may quickly and easily monitor the condition of a number of patients under their care. Alternatively, the information from each individual monitoring station 1 or from each catheter 2 in accordance with embodiments of the present invention may be forwarded to a centralized monitoring station to allow a health care professional to easily monitor the condition of a plurality of patients without having to walk to each individual bassinet, isolett, cot, or bed. The transmission of data to a centralized monitoring station may be achieved by wired or wireless communication devices well known in the art.

Referring now to Fig. 4A, a bassinet in accordance with embodiments of the present invention is shown. More specifically, this figure illustrates a bassinet configuration in which a monitoring station 1 is located proximate to the patient 8. Also shown is a catheter 2 interconnected to the monitoring station 1.

Referring now to Fig. 4B, a catheter 2 in accordance with embodiments of the present invention is shown. A plurality of sensors for the monitoring of various physiological parameters are interconnected proximate to the distal end 4 of the catheter 2. The length of the catheter 2 is such that the sensors are located near the ideal locations in the patient's body for the monitoring of specific physiological

indicators. For example, in a particular embodiment the ultra sound sensor is located on the device such that when the device is inserted into a patient the sensor will be adjacent to the ascending or descending aorta, while the electrical sensing electrodes are placed to line up directly behind the atria and the CO_2 sensor is placed at the naris. One of skill in the art will appreciate that different configurations spacing of sensors may be employed, depending upon the intended use and the size of the patient. In addition, one skilled in the art will appreciate that the length of the catheter 2 extending from the mask 10 to the proximal end 6 may vary as required. Furthermore, the catheter 2 may be any size. In addition, the catheter may incorporate a sample tube, drug infusion tube, and/or feeding tube. In accordance with embodiments of the present invention, the catheter may further comprise a lumen, a stylet, and/or a weight at the distal end.

Referring now to Fig. 5, a monitoring station 1 of embodiments of the present invention is shown. More specifically, the output derived from the plurality of sensors is shown. The monitoring station 1 may be located proximate to the patient or may be situated in a centralized viewing area, and allows health care professionals to view the monitored physiological data of various individuals under their care. It is envisioned that the output may be altered depending on the protocol of care for the patient and the viewing preferences of the health care professional. In accordance with embodiments of the invention raw chart displays 22 are show along with continuous decimal displays 24. As will be appreciated by one skilled in the art, this data may be saved on a magnetic disk or otherwise such an analysis of a patient's condition over an extended period time may be performed.

Referring now to Figs. 6-15, schematics of various sensors and associated circuits employed in accordance with embodiments of the present invention are shown. However, one skilled in the art will appreciate that various other types and configurations of sensors and circuits may be employed without departing from the scope of the invention.

Referring now again to Figs. 1-15, the system derives real time outputs from an array of devices such as an esophageal thermistor (E Th), a nasal thermistor (N Th), a carbon dioxide (CO_2) sensor, a Doppler ultra sound (US) sensor, a bipolar impedance (2-P Z) sensor, a quadrapolar impedance (4-P Z) sensor, and the esophageal pH (pH) sensor. Ventilation may also be obtained from either the nasal thermistor or the CO_2 sensor. Basic signal conditioning of one embodiment produces at least three raw chart display outputs 22 for ventilation, ECG, and blood flow and at least three decimal display outputs 24 for core temperature, pH, and activity.

Ventilation, ECG and blood flow are further processed to provide respiratory rate (RR) and heart rate (HR) as well as relative measures of tidal volume (TV) and stroke volume (SV). These measures are combined in pairs by a computer processor to produce relative indications of minute ventilation (MV) and cardiac output (CO). Additional processor summary algorithms for trends, activity, heart rate variability and physiological stability may be realized in a computer signal processor and displayed via a computer monitor.

Esophageal core temperature and nasal temperature measurements are obtained via precision thermistors 11. Each thermistor is preferably biased with a current source that is derived from a precision voltage reference. An analog to digital (A-D) converter provides an interface to a computer that calculates the resulting esophageal temperature. Ventilation is conditioned in one embodiment with a band pass filter with gain and displayed on a display screen as raw unscaled data from the A-D output. Signal conditioning for the esophageal ECG utilizes an instrumentation amplifier followed by band limiting from about 0.16 to about 50 Hz. The circuit may also contain a notch filter with a fixed gain of 500, and multichannel A-D may be used for all analog input channels. Pacing may be provided by a QRS detector, programmable clock and current source stimulator. Arrhythmia detection may be derived from a comparison of the natural heart rate and the relative Doppler ultrasound measure of cardiac output.

The CO_2 sensor of one embodiment may incorporate a source sensor. Although an infra red (IR) source will be greater than two watts, the signal that passes through a very narrow optical window (necessary for selection of an IR wavelength that is sensitive to CO_2 and insensitive to water vapor) will be typically less than a micro watt. Conventional IR CO_2 detectors use a mechanical chopper to modulate the very weak signal, which is contaminated with severe drift by the IR detector and preamplifier, onto a carrier. Subsequently, the modulated signal may be magnified with a high gain AC amplifier without intermittent saturation due to very low frequency noise and drift. Embodiments of the present invention provide a system that utilizes a pulsed IR source that eliminates the need for a mechanical chopper, reducing bearing induced noise as well as expensive tuning and maintenance.

In operation, the IR source may be pulsed at a maximum frequency of 8 Hertz, passed through the expired gas in a sample chamber, amplified, filtered, and synchronously detected. A detector clock will be delayed to match the time delay introduced by the high gain amplifier. Following detection, the signal is additionally amplified and filtered and converted for processing in the computer. The resulting raw analog signal will be displayed and processed for respiration rate. A pump is used with a gas sample tube. In addition, the mask 10 is designed to insure that there is substantially no dead space that would possibly introduce expired gas to the infant 8. A sample tube arrangement or a small mask are two designs that may be employed for individuals that do not require assisted ventilation, however patients using a ventilator generally require a sample tube arrangement.

Conventional medical Doppler blood flow meters of one embodiment of the invention use appropriate circuit design to insure that the measurement is entirely dependent on the frequency shift (flow) and completely insensitive to amplitude (the number of reflectors or red blood cells). In an effort to enhance the signal to noise ratio from a very small pair of ultrasound crystals (one for transmit and the other for receive), the system of one embodiment includes a unique feature that has the effect of

combining the reflected surface area of the blood (amplitude) with the flow measurement (frequency shift) to obtain a relative measure of cardiac output.

The transmitter and receiver design of one embodiment of the blood flow meter are conventional for a Doppler bi-directional flow meter wherein a phase sensitive direct conversion process is utilized. The system may contain a reference oscillator with a power amplifier to drive the transmit crystal. The receiver consists of a preamplifier and a pair of mixers that are driven by orthogonal reference oscillator signals and the received input, which results in a reference oscillator frequency (carrier) at zero hertz and a baseband frequency shifted flow signal. The baseband orthogonal signals (I & Q) are fed into a flow processor that calculates the relative measure of cardiac output, both average and dynamic, as well as a conventional audio flow signal. The audio flow signal may be monitored for adverse changes in both rate and strength. As with any Doppler flow sensor, for optimum signal strength, the sensors may be oriented toward the blood flow vessel by mounting the crystals on a downward angle in an epoxy base. However, because of the excellent signal to noise characteristics of this processor, the sensor system is expected to work well with the slight downward angle (*i.e.* towards the aorta) and due to numerous tissue boundary reflections of the transmitted signal.

The respiration rate meter of one embodiment is based on an interval measurement that is derived from the magnitude of a ramp generator that was driven by a fixed reference voltage and reset at the zero crossing of each breath. Two cascaded one shots may be triggered at each positive to zero crossing of the processed ventilation waveform. The first oneshot sample provides a 100 mS sample of the final value of the ramp just prior to reset and the second sample resets the ramp. The sample will be held until the next update of the ramp final voltage at the next ventilation zero crossing. Software in the computer converts the interval measurement to the respiration rate.

The heart rate meter of one embodiment generates a precise quanta of energy with each heart beat and averages it in a low pass filter with a long time constant. The

presence of each beat is the result of a QRS detection. The band limited and amplified ECG waveform may be passed through a 40 Hz band pass filter with a Q of about 2. Subsequent to the filter, the waveform is passed through a sign detector. The sign detector determines the larger peak, positive or negative, and passes the positive peak undisturbed and inverts the negative peak. The resulting peak triggers a 200 mS one shot if it exceeds a fixed threshold assumed to be above the P and/or T waves. The one shot provides the quanta of energy that is integrated in an unconditionally stable low pass filter. The resulting DC voltage output of the low pass filter is scaled to produce an exact measure of heart rate with software in the computer.

It is well known that blood synchronously perfusing the thoracic capillary beds with respiration changes the impedance of the chest. Thus, injecting a current into chest tissue and measuring the resulting voltage provides a relative estimate of the impedance and consequently ventilation. Additionally, it is known that electrode motion, which is typically caused by patient activity, results in a large voltage across the current source electrodes. Therefore, breathing may be isolated from electrode motion with an additional set of electrodes, used only by a high impedance voltage sensing circuit and not for current injection. The voltage sense electrodes are arranged in-between the current source electrodes to establish a four point (Kelvin Bridge) resistance measure. In addition, activity may be detected by measuring the voltage developed across the current application electrodes. Thoracic impedance may provide a measure of both ventilation and activity via the same balanced high frequency (*e.g.*, 10 KHz) current source and the same set of electrodes. More specifically, when current is applied to the extreme electrodes with the center electrode grounded, the voltage resulting on the remaining electrodes is tuned to the oscillator frequency, rectified and band limited to provide tidal volume and minute ventilation. Activity is derived from the same current source as well as the same set of current source electrodes, wherein the voltage is amplified and band limited and rectified to provide an estimate of patient activity.

The pH detector of one embodiment of the invention is an antimony hydrogen ion sensor with internal reference developed for pediatric esophageal, GERD measurements. Alternatively, the pH detector may comprise an IC sensor. In accordance with embodiments in which the device provides 55 mV per each pH, amplification may be provided for proper computer A-D scaling. A 60 Hz notch filter can also be added to remove line noise picked up by the leads. Further, signal conditioning for an intensive care pH sensor may involve the same process.

Embodiments of the present invention may be configured to be used in conjunction with an implantable device, such as a heart pump or drug injection pump. One of skill in the art will appreciate that customization of the placement and sensitivity of sensors may be required for such applications. Use of an embodiment of the present invention in conjunction with implanted devices provides the advantage of real time monitoring in order to control another implanted device more accurately, either manually or as part of an integrated system.

Embodiments of the present invention may employ a computer system with conventional processor algorithms that use averaging software, *i.e.*, the neural net, fuzzy logic, and trend analysis. The aforementioned functions may also be performed by discrete electronics, integrated circuits, a gate array, a microprocessor, a personal computer or any combination thereof without departing from the scope of the invention. Accordingly, the system will integrate a family of monitors into one simple, safe and convenient sensing and monitoring device. Moreover, this integration also allows for the integration of data for the determination of overall patient state. For example, the integrated data, once analyzed by the system may convert the data into a "score" indicative of the patient's current state, much like an APGAR score for newborns. When multiple patients are under the care of limited nursing staff, continuous summary scores of each patient allow the nursing staff to reduce time spent in assessing physiological stability and allow the staff to focus nursing resources on the patient at the greatest risk.

Further, continuous integrated monitoring and scoring allows for averaging data with a trend analysis algorithm which indicates the onset of changes in the patient state. In a particular embodiment, the trend analysis algorithm will contain weights which emphasize or de-emphasize the significance of recent and past parameter values in view of known parameters, such as patient weight, age or medical conditions such as disease or a congenital condition. Accordingly, the system may provide an indication of the onset of events or anticipate the risk of a future event occurring, rather than merely documenting past conditions.

While various embodiments of the present invention have been described in detail, it is apparent that modifications and alterations of those embodiments will occur to those skilled in the art. However, it is to be expressly understood that such modifications and alterations are within the scope and spirit of the present invention.

What is claimed is:

1. A non-invasive patient assessment and monitoring system comprising:

a catheter with a first end and a second end;

a plurality of sensors interconnected to said catheter proximate to said second end, wherein said sensors are adapted to obtain data related to a patient's vital signs; and

a computer system adapted to receive said data and assign a score reflective of the patient's vital condition.

2. A non-invasive method of patient assessment and monitoring, comprising:

inserting a catheter having a number of sensors into one of a trachea and an esophagus of a patient;

obtaining data related to a patient's vital signs from said sensors;

analyzing said data via a computer system adapted to receive said data and assign a score reflective of the patient's vital condition.

3. A non-invasive patient assessment and monitoring system comprising:

a catheter with a first end and a second end, wherein said catheter includes a feeding tube;

a plurality of sensors interconnected to said catheter proximate to said second end, said sensors including at least a thermistor, a plurality of electrodes, a pH sensor, and an ultrasound sensor;

at least one of a mask and a sample tube operable to capture expelled air, interconnected to said catheter proximate to said first end;

a computer system adapted to receive data from said sensors relating to at least one of a body temperature, blood flow, heart rate, acidity and amount of CO_2 in exhaled air and assign a score reflective of the patient's vital condition.

4. The invention of Claim 1 or 2, wherein said catheter includes a feeding tube.

5. The invention of Claim 1 or 2, wherein said catheter comprises one of an esophageal and an endotracheal tube.

6. The invention of Claim 1 or 2, wherein said sensors comprise at least a thermistor, a plurality of electrodes, a pH sensor, and an ultrasound sensor.

7. The invention of Claim 1 or 2, wherein said system further comprises at least one of a mask and a sample tube operable to capture expelled air, interconnected to said catheter proximate to said first end.

8. The invention of Claim 1, 2 or 3, wherein said catheter includes at least one of a lumen, a stylet, and a distal weight.

9. The invention of Claim 1, 2 or 3, wherein said system further comprises an algorithm adapted to indicate the onset of changes in the patient's condition.

10. The invention of Claim 1, 2 or 3, wherein said system further comprises an algorithm adapted to monitor the patient's condition and predict changes in the patient's condition.

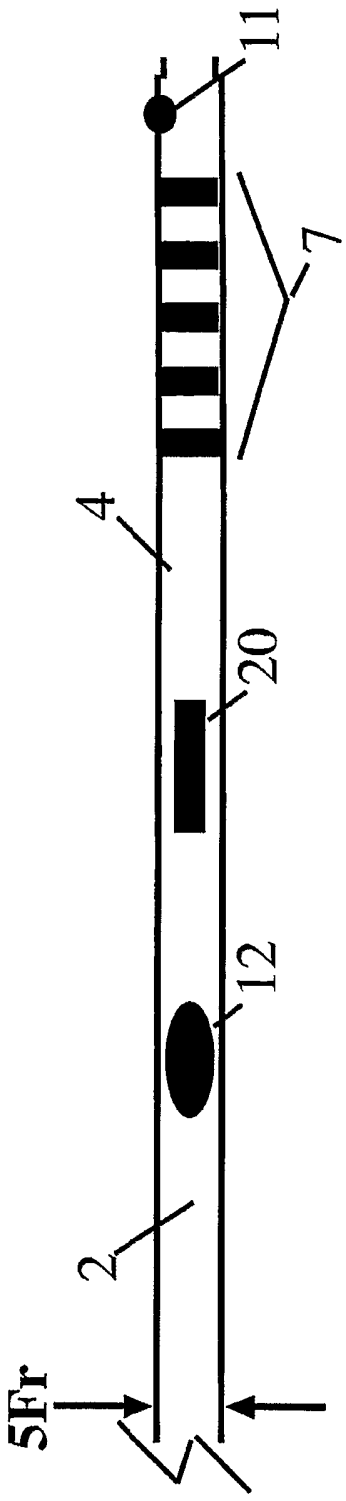


Fig 1

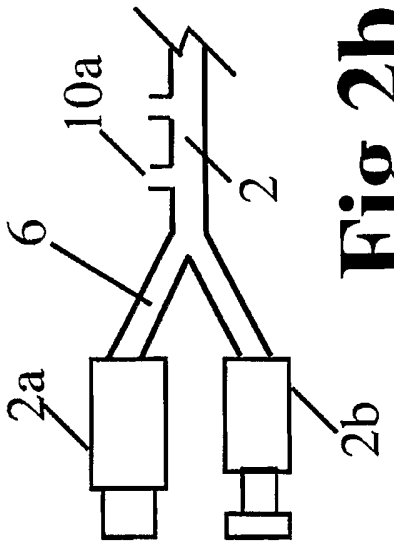


Fig 2b

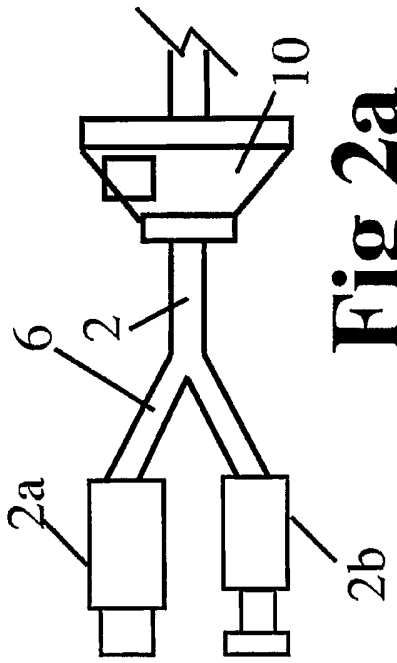


Fig 2a

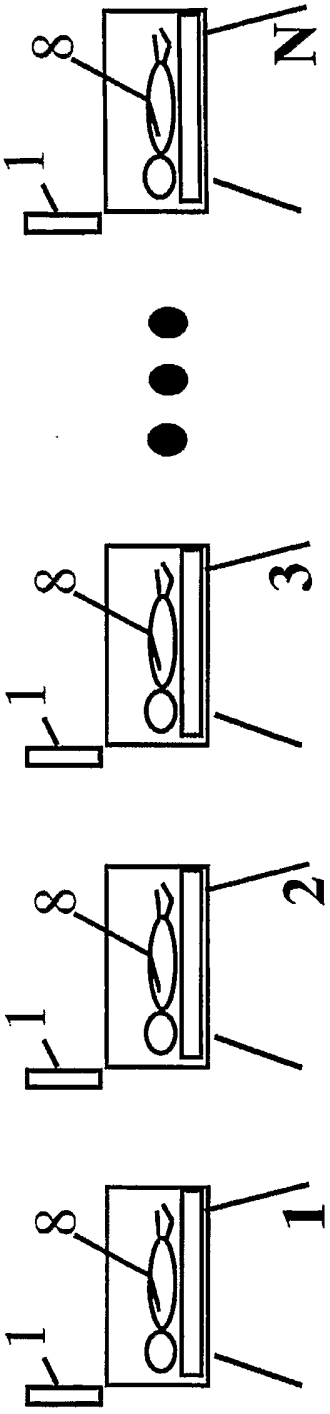


Fig 3

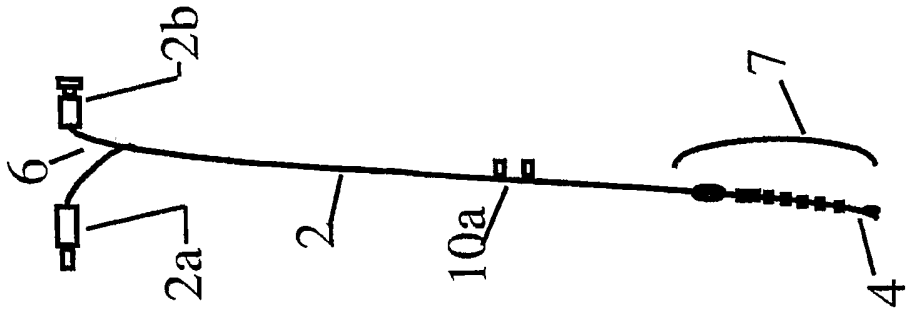

6
2b
2a
2
10a
7
4

Fig 4b

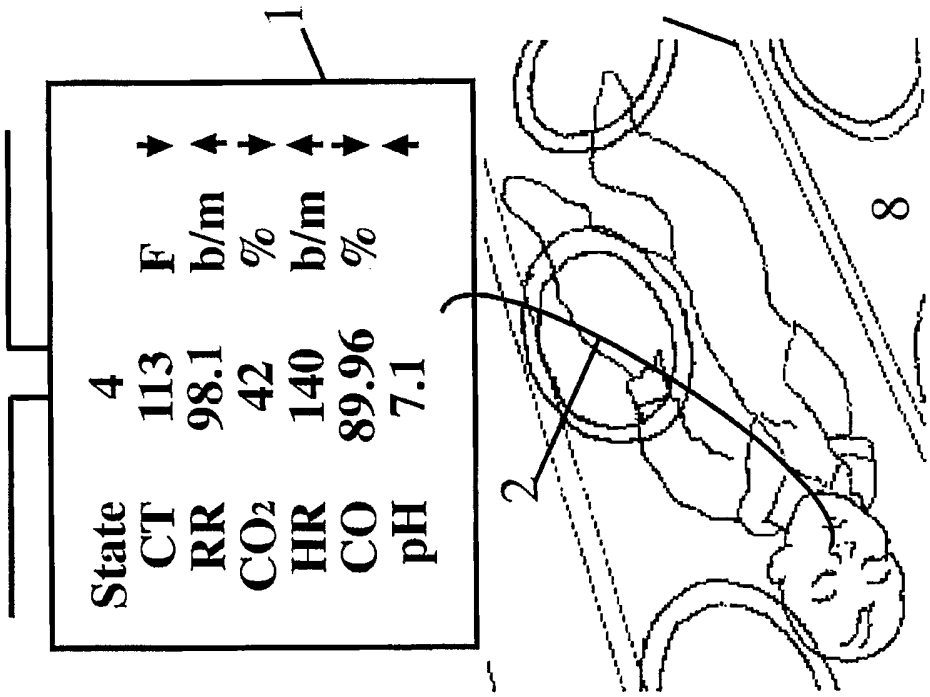

State 4
CT 113 F
RR 98.1 b/m
CO2 42 %
HR 140 b/m
CO 89.96 %
pH 7.1
1
2
8

Fig 4a

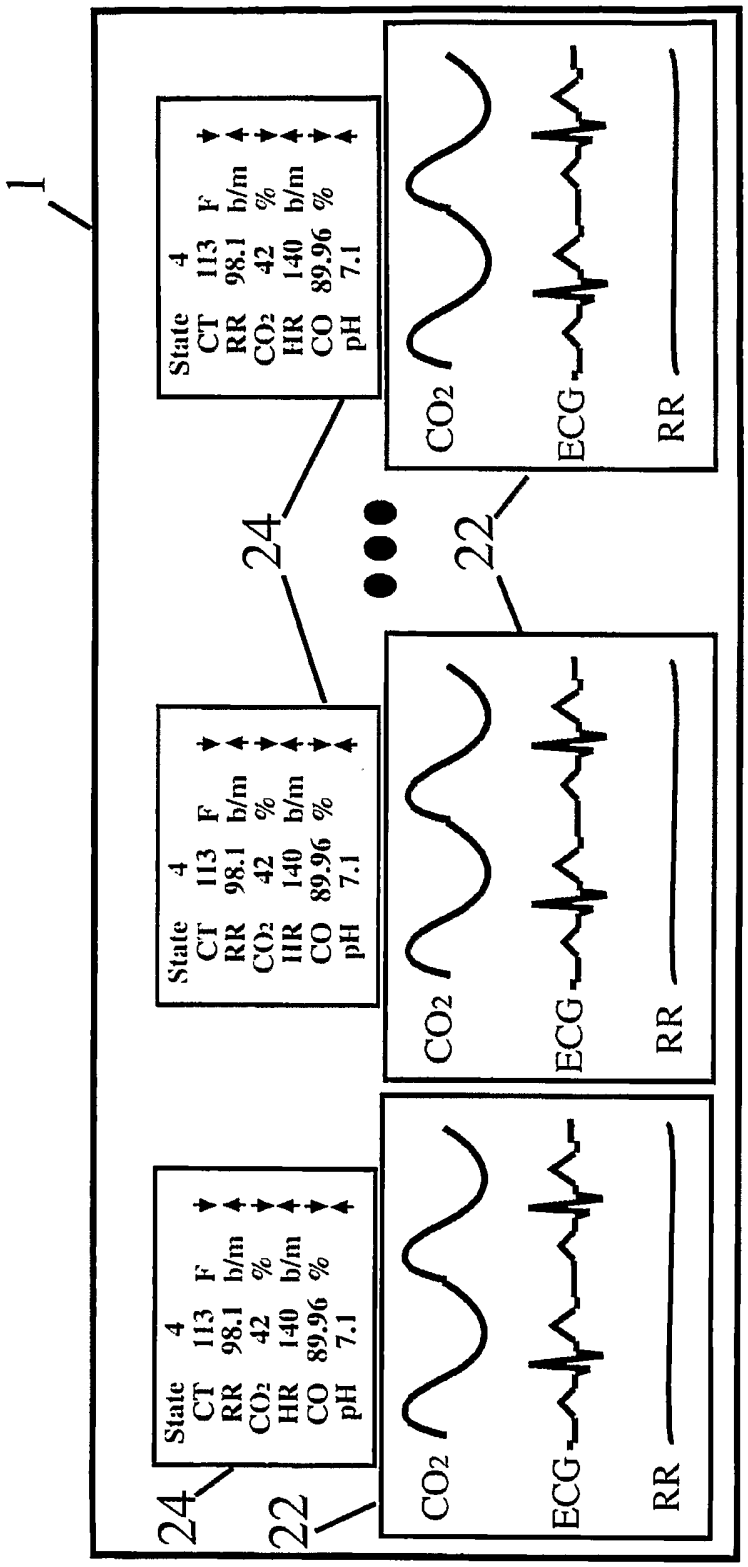

1
State 4
CT 113 F
RR 98.1 b/m
CO2 42 %
HR 140 b/m
CO 89.96 %
pH 7.1
24
22
CO2
ECG
RR

Fig 5

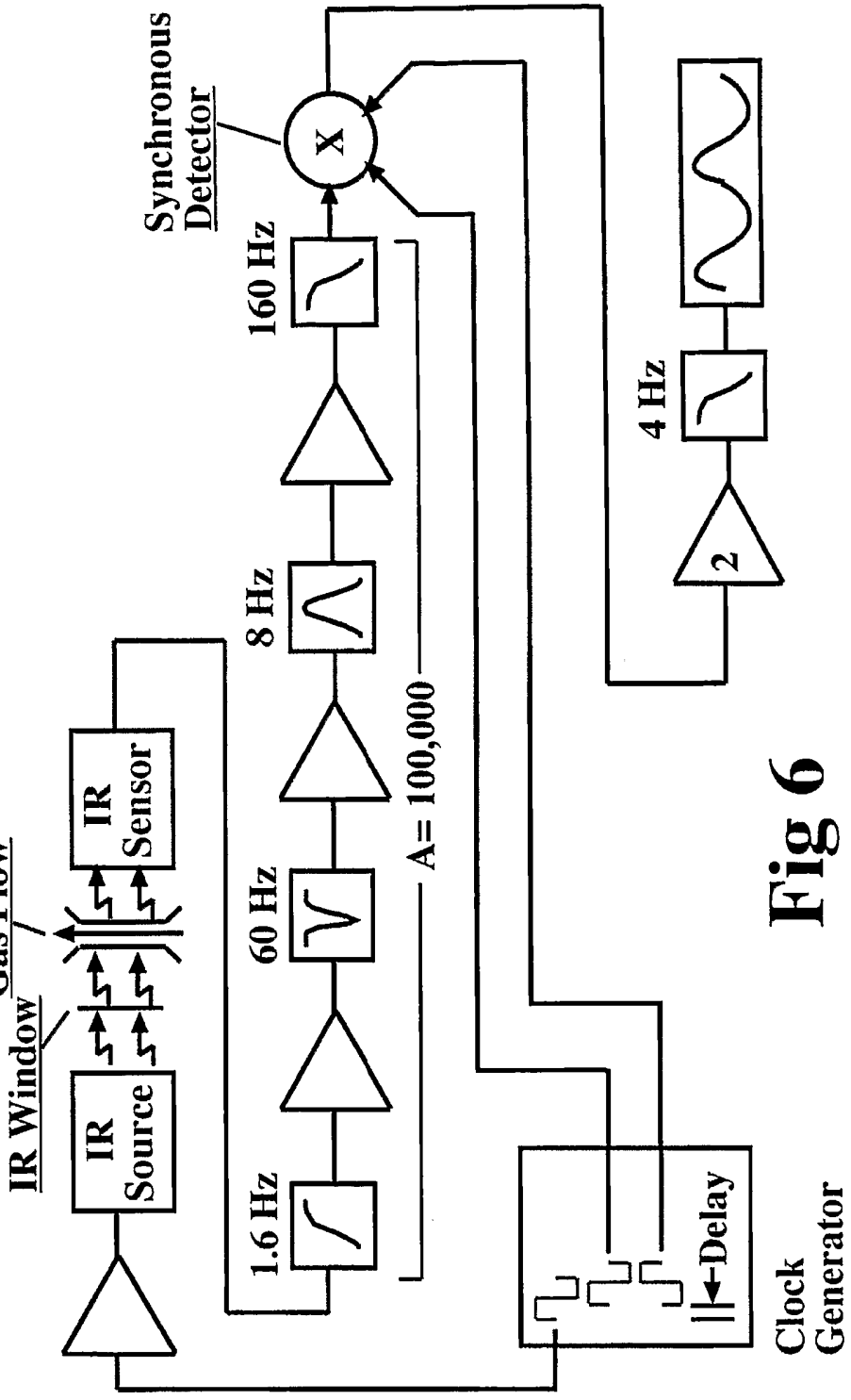

Synchronous Detector
X
160 Hz
8 Hz
60 Hz
1.6 Hz
A= 100,000
4 Hz
2
IR Sensor
Gas Flow
IR Window
IR Source
Delay
Clock Generator

Fig 6

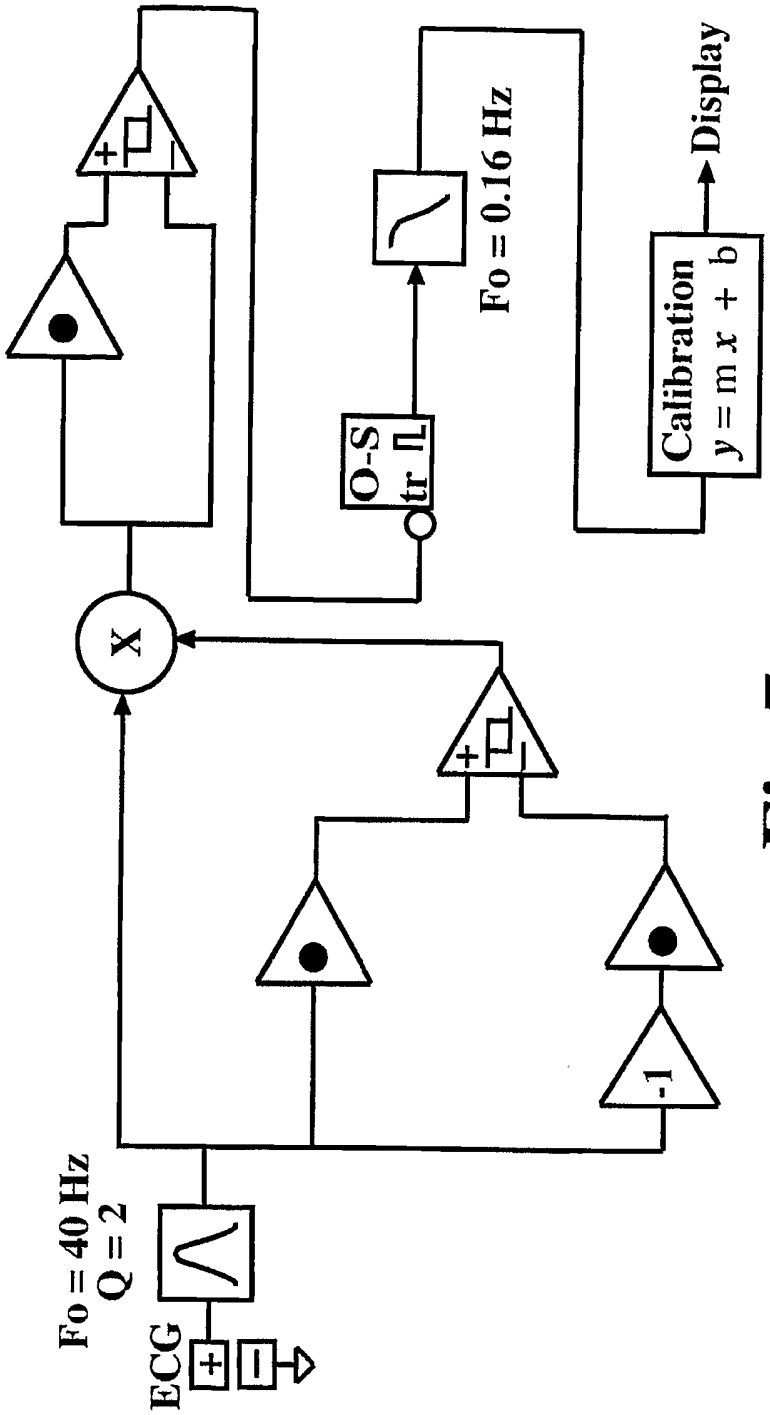


Fig 7

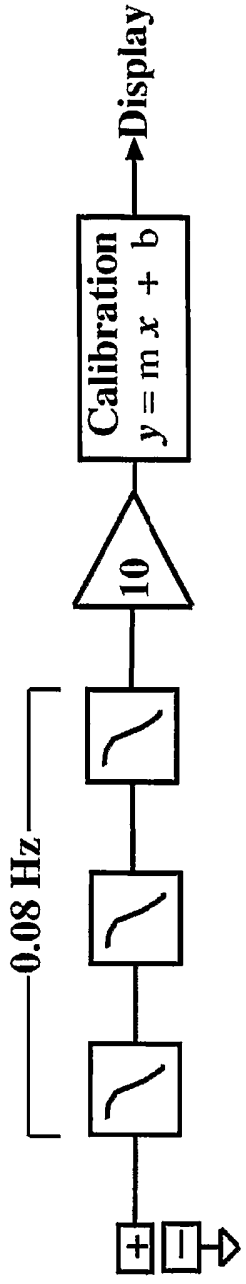


Fig 8

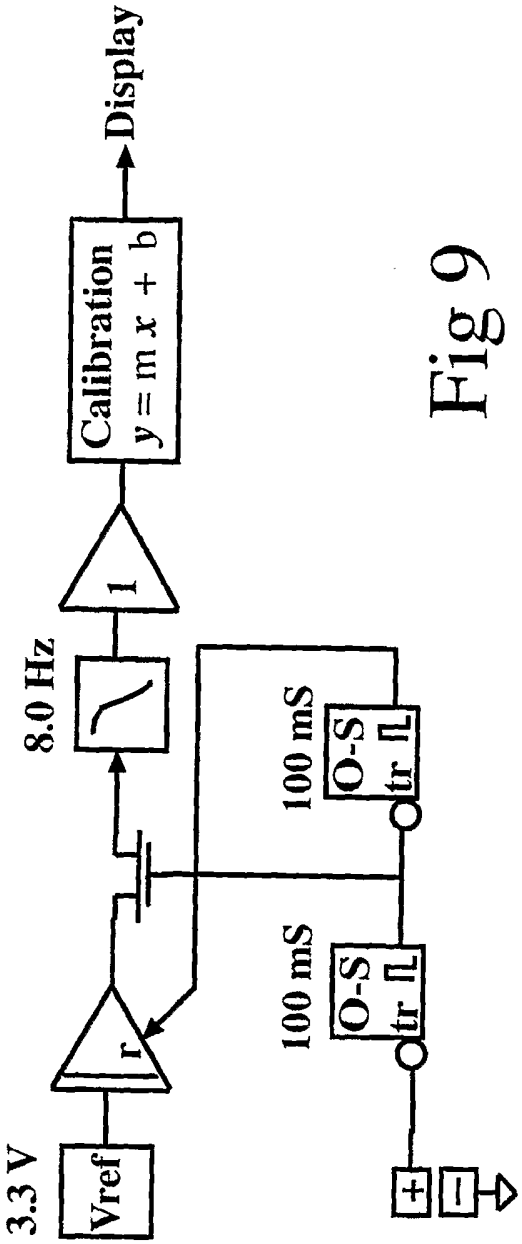

Display
Calibration
y = m x + b
1
8.0 Hz
100 mS
O-S
tr
100 mS
O-S
tr
3.3 V
Vref
+
-

Fig 9

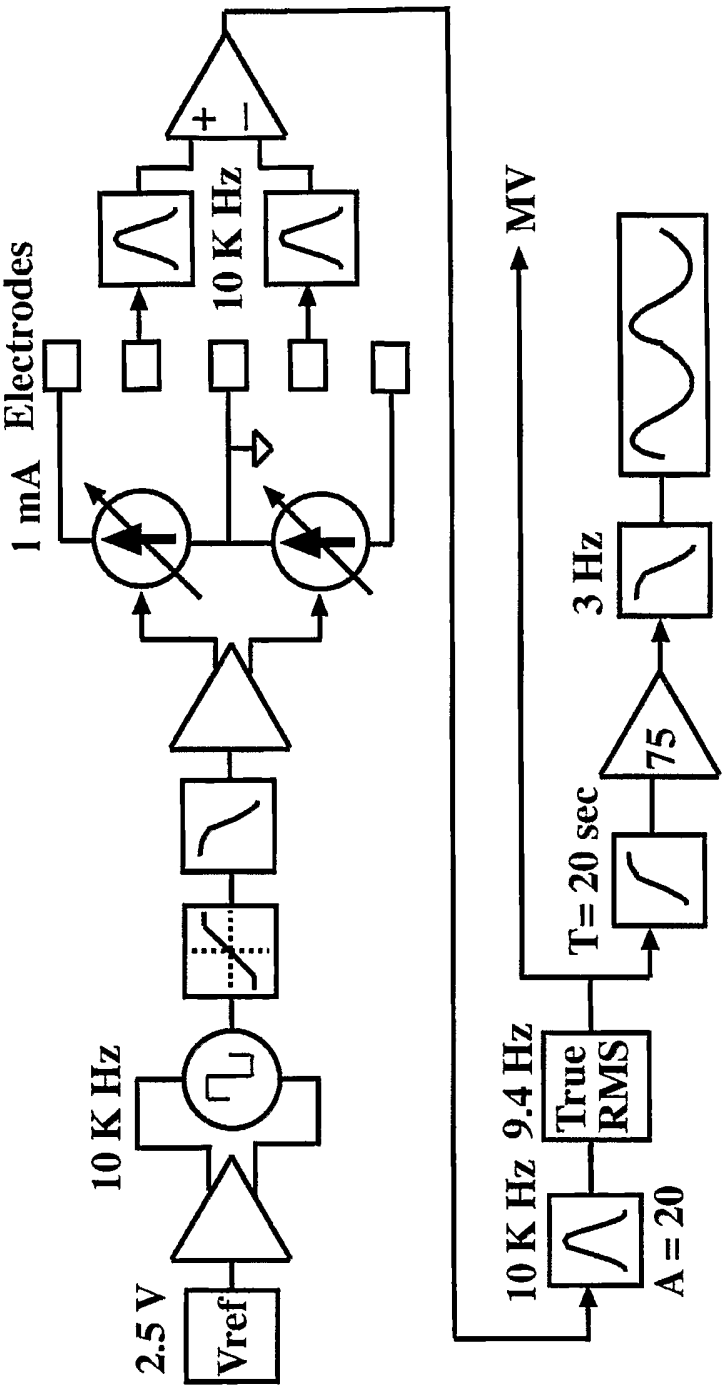

2.5 V
Vref
10 K Hz
1 mA
Electrodes
10 K Hz
MV
10 K Hz
A = 20
9.4 Hz
True
RMS
T= 20 sec
75
3 Hz

Fig 10

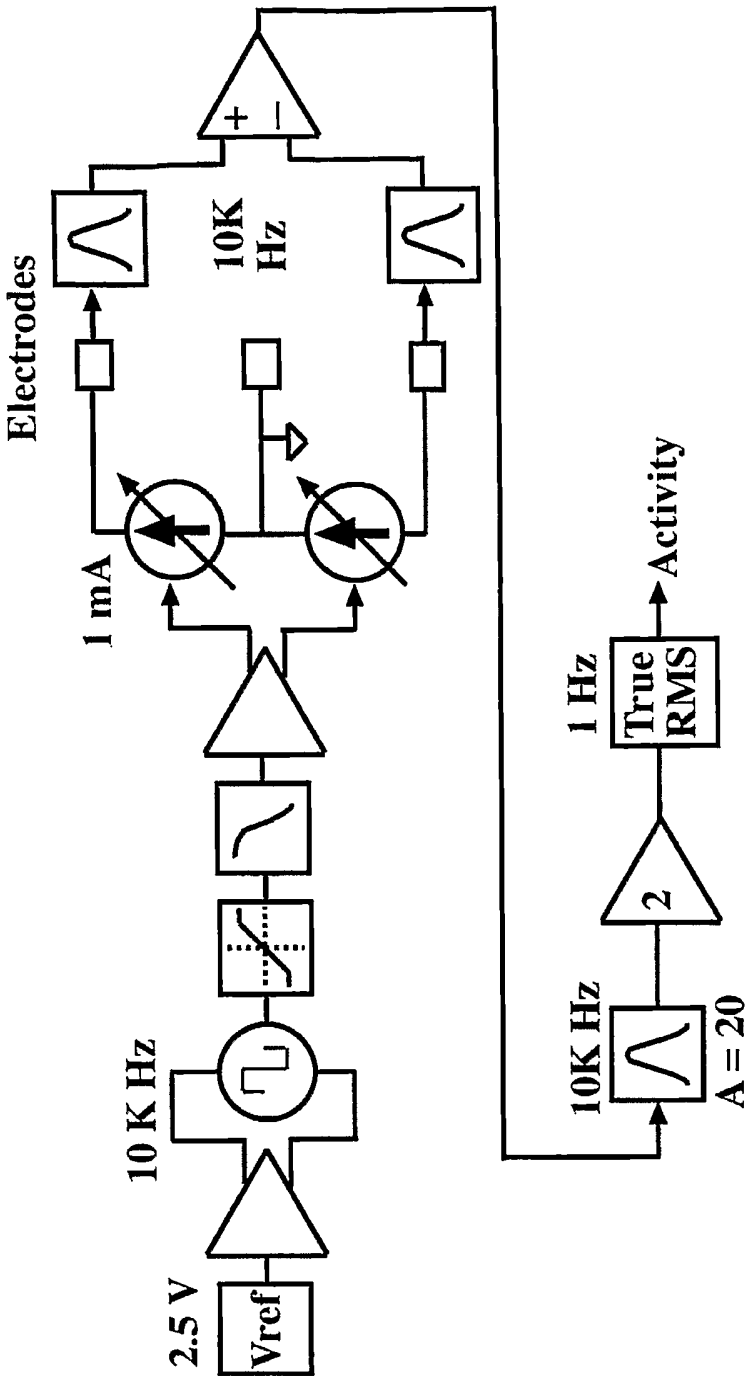

Electrodes
10K Hz
1 mA
10 K Hz
2.5 V
Vref
10K Hz
A = 20
2
1 Hz
True RMS
Activity

Fig 11

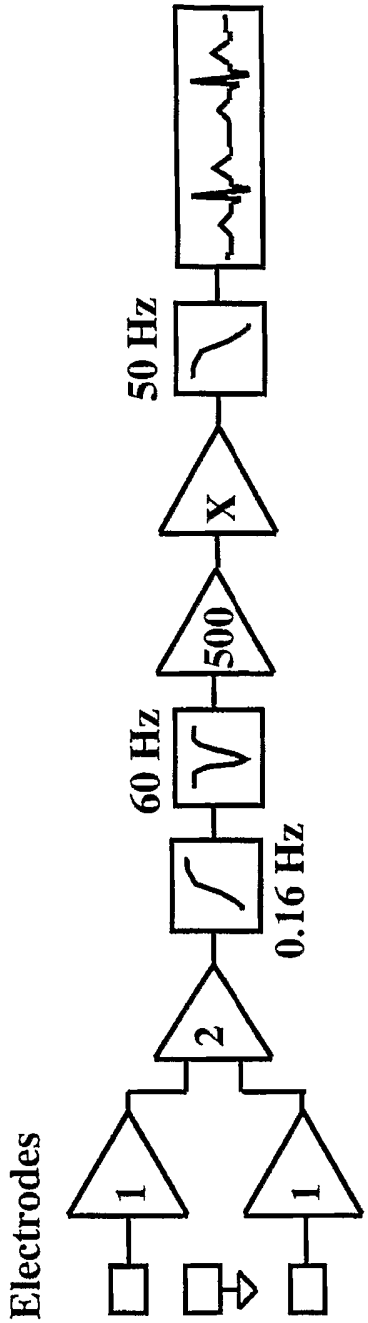


Fig 12

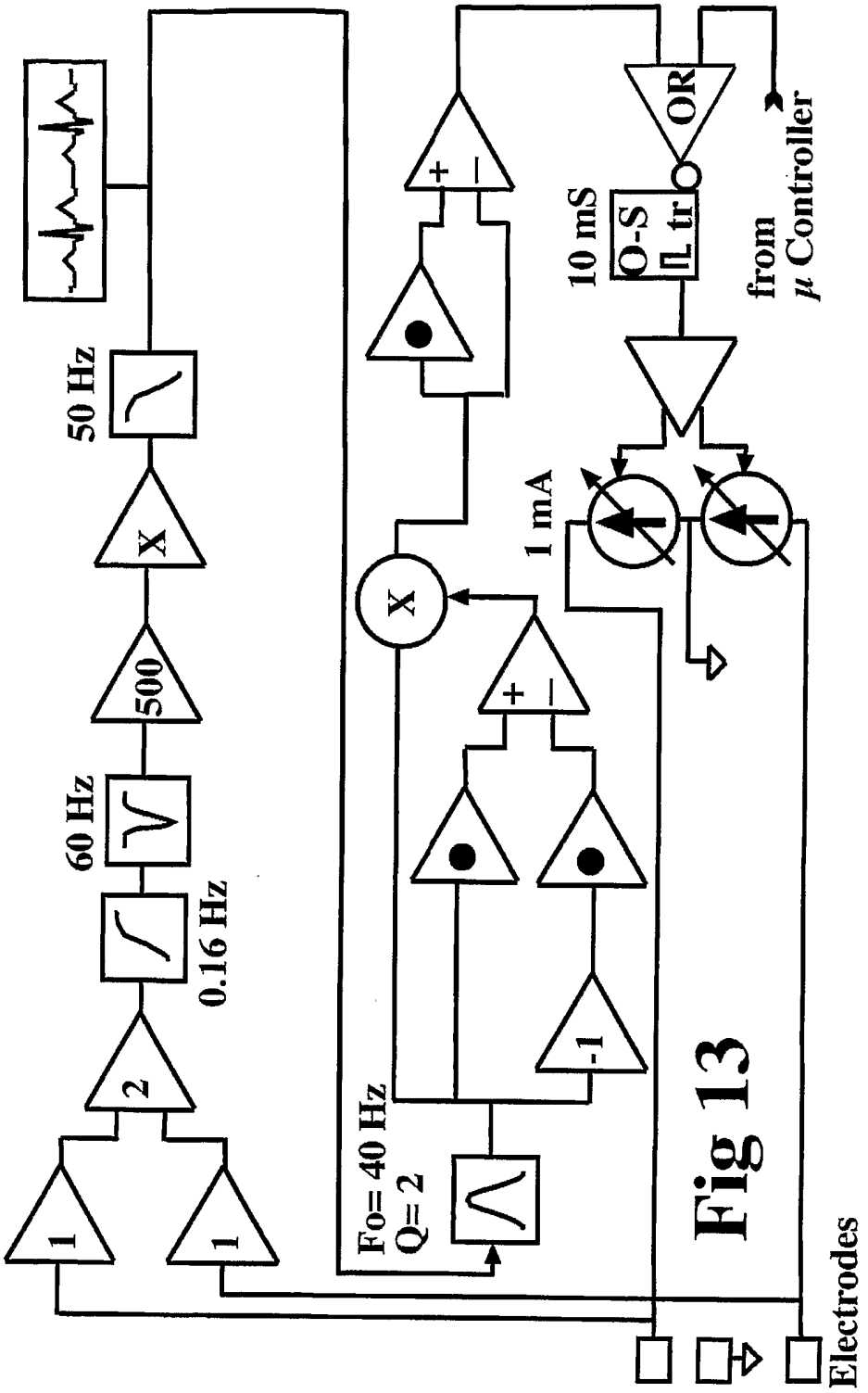

50 Hz
60 Hz
0.16 Hz
500
X
2
1
1
Fo= 40 Hz
Q= 2
X
+
−
-1
1 mA
10 mS
O-S
OR
from
μ Controller
Electrodes

Fig 13

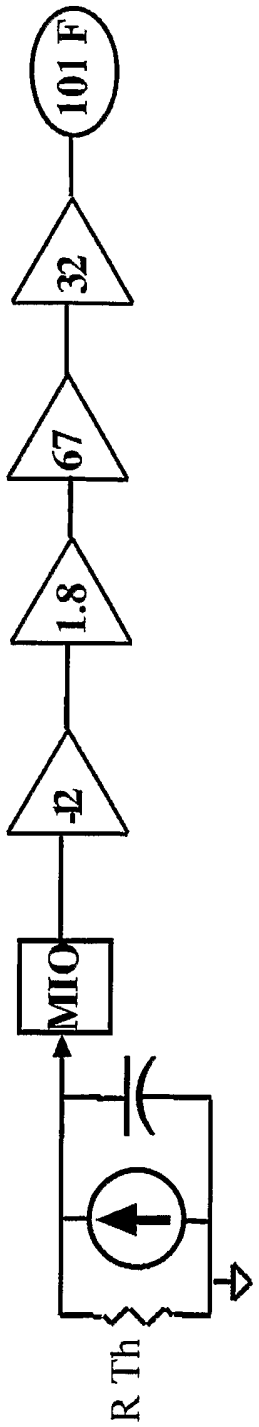


Fig 14 A

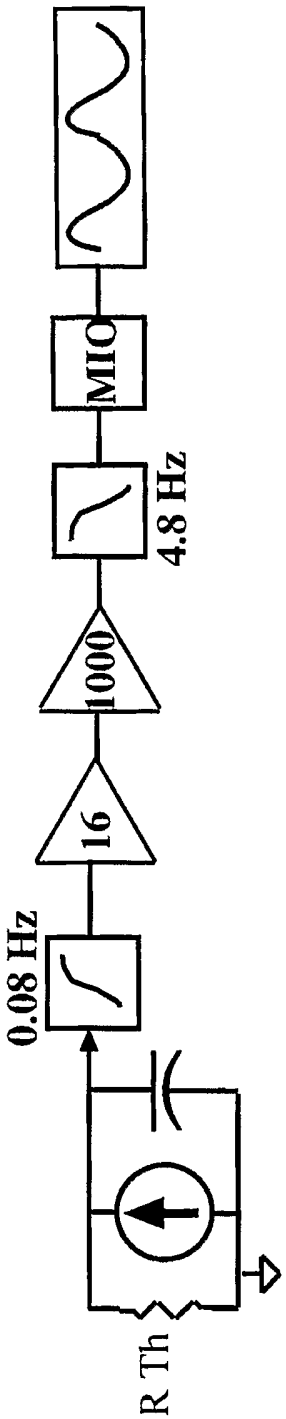


Fig 14 B

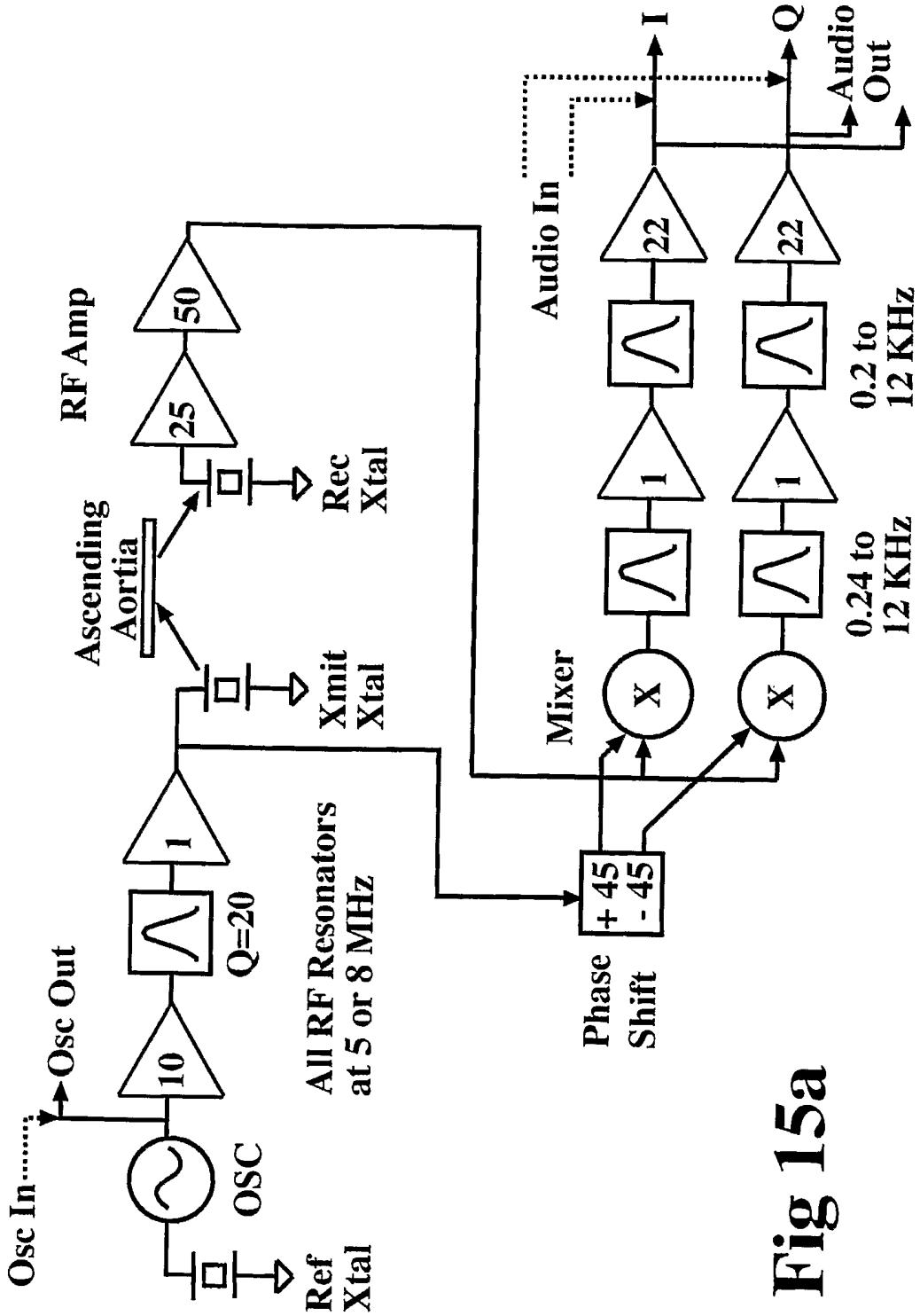

Osc In
Osc Out
10
OSC
Ref Xtal
Q=20
1
All RF Resonators at 5 or 8 MHz
Xmit Xtal
Ascending Aortia
Rec Xtal
25
50
RF Amp
Phase Shift
+ 45
- 45
Mixer
X
X
1
1
Audio In
22
22
I
Q
Audio Out
0.24 to 12 KHz
0.2 to 12 KHz

Fig 15a

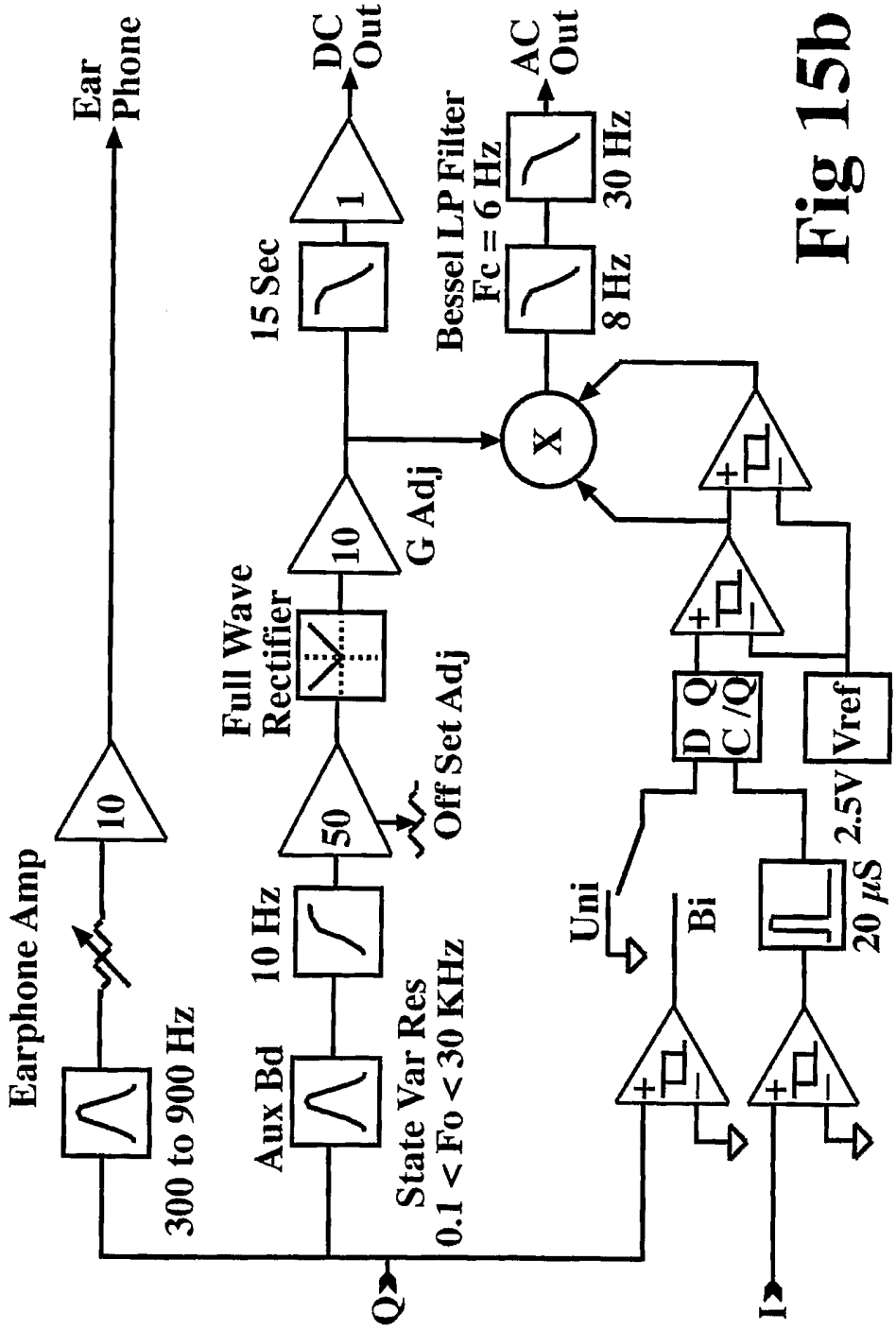

Ear Phone
DC Out
AC Out
15 Sec
1
Bessel LP Filter
Fc = 6 Hz
30 Hz
8 Hz
X
10
G Adj
Full Wave Rectifier
50
Off Set Adj
10 Hz
Aux Bd
State Var Res
0.1 < Fo < 30 KHz
Earphone Amp
10
300 to 900 Hz
D Q
C /Q
Vref
2.5V
20 µS
Uni
Bi
Q
I

Fig 15b