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Technical Information Report

AAMI TIR4:1989

Apnea monitoring by means of thoracic impedance pneumography

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TIR4 Apnea Monitoring by Thoracic Impedance Pneumography

AAMI TIR No. 4-1989

Apnea Monitoring by Means of
Thoracic Impedance Pneumography

Approved February 1989

Association for the Advancement of Medical Instrumentation
3330 Washington Boulevard, Suite 400
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FOREWORD

The AAMI Apnea Monitoring Committee, which developed and authorized the distribution of this technical information report, has the following members:

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The committee had the following additional member at the time this technical information report was balloted:

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Comments on this report are invited and should be sent to AAMI, 3330 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.

RATIONALE FOR THE TECHNICAL INFORMATION REPORT

This technical information report (TIR) addresses one of the apnea detection methods most commonly used in hospitals and home markets. At present, a great deal of information is available on impedance pneumography, and the purpose of this document is to summarize this information. Because impedance pneumography is an indirect measurement, it does not detect all forms of apnea, but it has proven to be a practical and effective apnea detection method for a large patient population.

When the committee was formed, there was substantial interest in generating a TIR on impedance pneumography for apnea detection. There are many other methods of apnea detection, but because of the large numbers of installed impedance-pneumography-based apnea monitors, it was felt that this measurement technology should be addressed first. The committee also felt that limiting the scope of the document to transthoracic impedance pneumography would allow consensus on the issues to be more easily achieved. It is not the intent of this TIR to exclude other apnea detection methods, and the committee hopes that they can be added to the document at a later time.

This TIR should provide information that would be useful in developing a voluntary standard for impedance pneumography as a detection method for apnea. The information was collected from a broad range of clinical and technical resources. Special clinical information was derived from the American Academy of Pediatrics' 1978 and 1985 reports on apnea and the report on the National Institutes of Health consensus conference, "Infantile Apnea and Home Monitoring," September 29 and 30 and October 1, 1987. Technical information was gathered from manufacturers, clinical engineers, and researchers in the field.

APNEA MONITORING BY MEANS OF THORACIC IMPEDANCE PNEUMOGRAPHY

1. Introduction

1.1 Overview. This report addresses the current state of the art in the design and clinical application of apnea monitoring by transthoracic electrical impedance. The impedance technique is only one of several methods of detecting apnea in infants, but currently it is by far the most frequently used. (Over 95% of the home apnea monitors now on the U.S. market use this technique for measuring respiration.) Therefore, the authors of this report chose to concentrate mainly on this particular technique. Impedance monitoring of respiratory effort is also used to follow the course of patients being weaned from ventilatory support and during postanesthetic recovery periods. However, this application is beyond the scope of this report.

Apnea monitoring by transthoracic electrical impedance is principally indicated for use in the management of three populations of infants:

(1) Hospitalized premature infants outgrowing developmental problems with respiratory frequency control

(2) Full-term infants, hospitalized or at home, who have had a significant, unexplained respiratory arrest, and preterm infants who are ready for discharge but are manifesting persistent apnea

(3) Apparently healthy infants born into a family in which a previous infant died with a pathologic

assessment of sudden infant death syndrome (SIDS) or was found to have a significant apnea problem after birth (Ariagno 1984)

In 1972, Steinscheider reported that two of five infants noted to have apnea lasting for more than 20 seconds later died of SIDS episodes, and he was the first to suggest the use of respiration monitors to manage apnea at home. In a report of follow-up and evaluation of infants presenting apnea at several weeks of age, 4 of 84 infants died despite the use of a monitor of thoracic impedance alone (Kelly et al. 1978). All four of these infants were being actively monitored at the time of death. Other reports (for example, Yount and Lewman 1987) suggest that parental noncompliance is a more common cause of death.

Although a number of groups have documented the association of persistent apnea with later death, an extensive series of observations from five large obstetrical services in England showed no association of prolonged central apnea (of greater than 20 seconds' duration) and profound bradycardia (less than 50 beats per minute [BPM]) with death in either full-term or preterm infants (Southall et al. 1982, 1983). In a more extensive and blinded review of the same data, prolonged mixed apnea (of greater than 15 seconds' duration), coupled with bradycardia (of 20% of the previous rate) and periodic breathing (lasting longer than 5 minutes), was found to be associated with later SIDS risk in preterm infants (Yount et al. 1988). The same team found that, for 22 full-term infants who later died of SIDS, there was no association with any of these patterns (unpublished data).

In 1978, after a vigorous debate, the American Academy of Pediatrics (AAP) recommended use of monitoring equipment in managing prolonged apnea. The definition given for apnea was "cessation of breathing for 20 seconds or longer, or a briefer episode associated with bradycardia, cyanosis, or pallor" (American Academy of Pediatrics 1978). The original AAP statement was later modified to clarify some of the clinical and medical-legal issues as well as the limitations of equipment (American Academy of Pediatrics 1985). These issues were also explored at a National Institutes of Health consensus development conference (National Institutes of Health 1987).

1.2 The Apnea Monitoring System. An understanding of the techniques of infant apnea monitoring is important in determining the most appropriate monitor to use on a patient and in using it in the best possible way. In considering the technical aspects of an apnea monitor system, one should be concerned with the method by which breathing effort, ventilation, or apnea is sensed and the method by which this information is processed to determine whether apnea of greater than a preset duration is present. It is also important to know the potential errors associated with the monitoring system so that the conditions that produce such errors can be avoided.

An apnea monitor can be considered a general biomedical electronic instrumentation system. Such a system consists of three major parts (Figure 1). The *sensor* serves as the interface between the electronic circuits and the biologic system. It converts the biologic variable being measured into an electronic signal that can be processed to obtain the desired information. This processing is carried out by the signal processor, which modifies the raw signal from the sensor so that the desired data can be derived, displayed, and recorded. An important function of the signal processor is to determine whether the lungs are being ventilated and, if not, to determine how long there has been no ventilation. The display and recording part of the system represents another type of biologic interface, one that provides information from the instrument to the people responsible for the care of the patient. In apnea monitors used in the home, this interface provides the alarm; in monitors capable of recording pneumograms or providing hard copy, this part of the instrument includes the memory and recording apparatus as well.

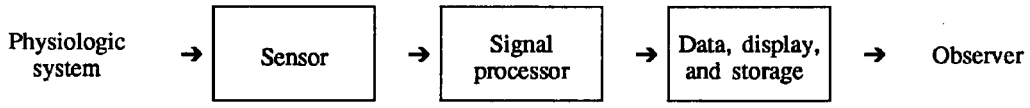

Figure 1. Block diagram of a general medical electronic instrument. (Reprinted from: National Institutes of Health. Infantile apnea and home monitoring. Bethesda, MD: NIH; 1987)

1.3 Methods of Sensing Ventilation. Alveolar ventilation and breathing effort can be sensed either directly or indirectly. In direct methods, the sensor is coupled to the airway and measures the movement or other properties of air transported into and out of the lungs. In indirect methods, the sensor monitors variables relevant to air movement but not air movement itself. Indirect methods involve no contact with the airway or with the air being moved into or away from the lungs. Indirect sensors are usually noninvasive and can be mounted on or near the body surface.

There are many more indirect sensors of ventilation than direct ones. These devices can be attached to the subject more easily than direct sensors and are less likely to interfere with breathing patterns. The transthoracic electrical impedance method is used in most commercially available apnea monitors for both hospital and home use. In this method, the ac electrical impedance across the chest varies with respiratory effort. The measurement of these small variations is the basis for the majority of infant apnea monitors in use today, both at home and in the hospital (Baker and Geddes 1970; Nyboer 1970; Olsson et al. 1970; Pacela 1966).

Each method of sensing respiration-related variables has advantages and disadvantages in terms of reliability, invasiveness, relative cost, and other factors. Table 1 highlights the relative merits of the various methods; it is not designed to be detailed or quantitative, but rather to help put the various methods in proper perspective.

1.4 Understanding Transthoracic Electrical Impedance. The chest contains various materials, ranging from bone to air. Each of these materials has different electrical properties and is located in a different portion of the chest. A schematic cross-section of the chest in Figure 2 indicates the relative size of the major components of the chest and their approximate relationship to each other. The materials of the chest vary in electrical resistivity (the amount of electrical resistance between opposite faces of a cube of that material), which is an important determinant of electrical impedance in the body.

Table 2 ranks chest materials in ascending order of electrical resistivity. Two of the major components of the chest, blood and air, are at opposite ends of the scale. Furthermore, the volume of each of these materials varies with time over the cardiac and breathing cycles. Blood has relatively low resistivity, which varies over the cardiac cycle owing to changing blood volumes in the heart and in the vascular compartment. Air, on the other hand, has high electrical resistivity and hence impedance, and it undergoes wide volume changes in the lungs during normal breathing. Thus, the impedance of the lungs will increase as they fill with air.

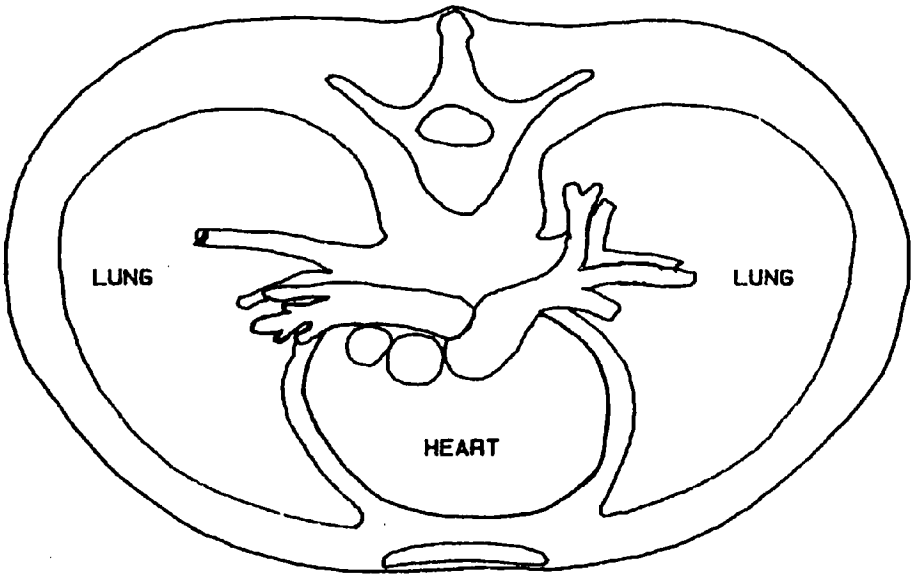

Figure 2. Cross-section of an infant's thorax showing anatomic structures and tissues and their relative sizes and positions. (Reprinted from: National Institutes of Health. Infantile apnea and home monitoring. Bethesda, MD: NIH; 1987)

Table 1

Relative Characteristics of Various Sensors of Breathing

	Noninvasive or Not Connected to Airway	Measures Quantitative Tidal Volume	Sensitive to Motion Artifact	Special Training Necessary for Use	Relative Costs	Sensitive to Cardiogenic Artifact	Senses Obstructive Apnea	Sensitive to Small Breaths
Pneumo-tachograph	-	+	-	+	$$$	-	+	+
Spirometry	-	+	-	+	$$$	-	+	+
CO_2 sensor	+/-	-	-	-	$	-	+	+
Nasal thermistor	+/-	-	+/-	-	$	-	+	+
Sound sensor (air flow)	+	-	+	-	$	-	+	+
Whole-body phlethys-mograph	+	+	-	+	$$$	-	+	+
Contacting motion sensors	+	-	+	+/-	$/$$	-	-	+/-
Noncon-tacting motion sensors	+	-	+	-	$	-	-	-
Electromy-ography	+	-	+	+	$	-	-	+/-
Breath sounds	+	-	+	-	$	+	-	-/+
Intra-esophageal pressure	-	-	-	+	$	-	-	+
Transthor-acic electrical impedance	+	-	+	-	$	+	-	-

Note: This table presents only general concepts, and there may be specific examples of sensors that do not conform. + is Yes; - is No; +/- is Yes or No, depending on the sensor and its use. Adapted from: National Institutes of Health. Infantile apnea and home monitoring. Bethesda MD: NIH 1987.

Table 2

Materials in the Chest Region Listed in Ascending Order of Electrical Resistivity

1. Blood
2. Muscle
3. Bone
4. Fat
5. Air

Note: Reprinted from: National Institutes of Health. Infantile apnea and home monitoring. Bethesda, MD: NIH; 1987.

Impedance variations due to volume changes in blood or air could be measured by means of electrodes placed on the heart or lungs, respectively. The electrical impedance between a pair of electrodes is

determined by dividing the voltage difference between the two electrodes by the current that passes between them. When the electrodes are placed on the actual structure, as described above, relatively large changes in impedance would be seen as the volumes of the respective structures change. It is not possible, of course, to place electrodes directly on the structures that are to be measured, and thus it is not possible in practice to see the large impedance differences that result from direct connections.

1.5 Impedance Monitoring of Respiratory Effort. Transthoracic electrical impedance was first introduced as a clinical method of measuring respiratory effort in the 1960s, after research in Europe and the United States had demonstrated the convenience and ease of access of the method for monitoring infants.

Continuous recording of thoracic impedance signals as a means of documenting apnea frequency and the clinical state of research subjects was first employed by Pacela (1966) and Daily et al. (1969). The routine recording of thoracic impedance and of the electrocardiogram (ECG) as an assessment of the clinical status of intensive care patients has become common. Continuous recording of thoracic impedance was used to document the effect of methyl xanthine treatment and was first described as a "pneumogram" by Stein and Shannon (1975) in the United States.

Since that time, increasing use of the technique has produced valuable insights into infant behavior that would not have been possible without the development of the infant monitor coupled with a slow-speed tape recorder (Kelly et al. 1978, 1980; Kelly and Shannon 1981; Hunt et al. 1985). Other groups have found limitations in using thoracic impedance and have used additional or alternative transducers for greater diagnostic accuracy (Dransfield and Fox 1980; Beckerman et al. 1982; Southall et al. 1982; Richards et al. 1984; Yount 1986). The use of respiration alarm systems for adults has increased in recent years in an effort to follow the course of patients as they are being weaned from ventilatory support and recovering from anesthesia.

Thoracic impedance monitoring is currently the most frequently used means of assessing respiratory effort. Transthoracic impedance is easily measured in the vast majority of patients who are susceptible to apnea and who are observed with monitors containing apnea and low-respiratory-rate alarms. A major advantage is the ability to detect ECG activity with the same electrodes. The major disadvantages are the small signal size compared with the signal size of the large, variable-base impedance monitor and the large, variable amount of noise originating from both the physiologic sources and the electrode attachment.

2. Patient Transducers and Connections

2.1 Overview. The impedance technique requires the application of a small ac electrical signal (typically 100 microamperes or less) across a pair of electrodes placed transthoracically on the infant. The frequency of the alternating current is typically in the range of 20 to 100 kHz. The electrode-body impedance is typically 100 to 1,000 ohms, varying with electrode type, size, dryness, and placement; skin dryness or oiliness; and frequency used to drive the electrodes.

The actual change in body impedance due to respiration, typically 0.1 to 3 ohms, can vary with the depth of inspiration and expiration, body position, electrode position, and the electronic technique used to extract the change in impedance from the drive signal. Motion and pressure on the electrodes will generate artifact that can easily be an order of magnitude greater than the respiratory impedance changes, making reliable detection of the respiratory signal difficult. The electrode-skin interface connection and the cables represent major sources of the false alarms and safety problems encountered during long-term infant monitoring in the home.

2.2 Electrode Considerations. An ideal infant monitoring electrode would be easy to attach, have a low profile, have low, stable ac and dc impedance, create no skin irritation, be low in cost, and utilize reliable, low-profile connectors and lead systems.

2.2.1 Electrode Attachment. Because home monitoring can last 8 to 10 months, it is imperative that a relatively

simple-to-apply electrode system be used.

The carbon rubber electrodes originally developed for transcutaneous electrical nerve stimulators (TENS devices) in the early 1970s have emerged as the most popular long-term electrodes for apnea monitoring. The carbon electrodes are placed on a fabric belt with a velcro-like attachment. The belt is then snugly tightened around the chest of the infant, with the lead wires from the electrodes usually connected so that they exit towards the infant's feet before the patient cable is attached.

Pregelled electrodes are usually used in the hospital; they are occasionally used in the home if the infant is on a short-term monitoring program or if adequate signal quality is difficult to obtain with carbon electrodes. Self-adhering electrodes, such as Karaya-base electrodes, are also used to a limited extent.

Dry, carbon-filled, elastomer electrodes have interfacial impedances that can be unstable when the electrodes are first applied. This instability can result in a wandering baseline on recordings of transthoracic impedance. Placing a drop or two of normal saline on the electrodes before they are placed on the skin makes the interface between the electrodes and the skin more stable, resulting in a more stable baseline. A study of carbon-filled elastomer electrodes applied to infants showed that the use of saline solution improved the quality of the recordings in 16 of 31 cases (Neuman 1985).

2.2.2 Electrode Profile. It is important that the electrode and the attachment lead have a relatively low profile, particularly for older infants who are very active and who roll over on their electrode systems. It is also important that the electrodes be flexible enough to conform to body contours and thus maintain good contact. It is desirable that electrodes used in hospitals not interfere with roentgenograms.

2.2.3 Electrode Placement. For practical purposes, electrodes must be placed on the skin surface. Most of the current passing between the electrodes remains in the chest wall and does not pass through the heart and lungs; consequently, the changes in the resistivity of these organs do not contribute as much as the chest wall to the overall variation in impedance between skin electrodes. Figure 3 indicates the relative distribution of current through the chest wall when electrodes are placed on the mid-axillary lines. It can be seen that most of the current is conducted along the chest wall, so its impedance would dominate any measurement. Different monitor manufacturers recommend different electrode placements for optimum performance, but it is typically recommended that the two active electrodes be placed transthoracically. Some manufacturers do not require a third or reference electrode. For hospital use, the electrode position will usually be dictated by the lead configuration desired for diagnostic ECGs.

2.2.4 Impedance. Because the electrode system acts as both a stimulation electrode to measure the impedance change and a monitoring electrode to pick up the ECG signal for heart rate measurement, it is important to define the ac and dc impedance parameters. The American National Standard, *Pregelled ECG Disposable Electrodes* (Association for the Advancement of Medical Instrumentation 1984b), is a good reference guide for disposable electrodes; however, carbon electrodes have entirely different physical and electrical properties and a new set of standards must be developed for them.

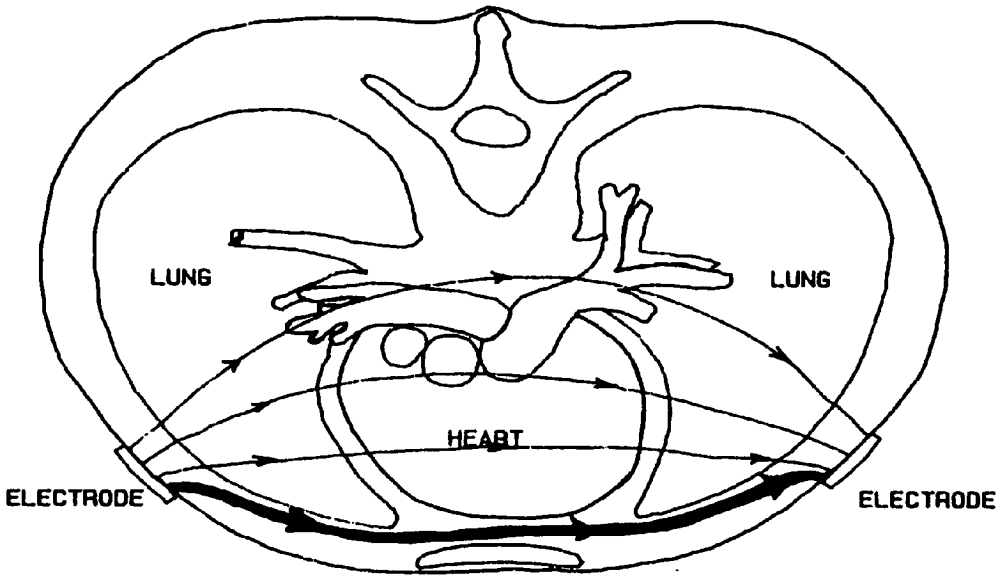

Figure 3. Cross-sectional view of the thorax showing approximate electrical current pathways and magnitude when a transthoracic impedance apnea monitor is used. (Reprinted from: National Institutes of Health. Infantile apnea and home monitoring. Bethesda, MD: NIH; 1987)

2.2.5 Skin Irritation. Skin irritation can be a major problem during long-term monitoring. Because the electrodes are applied several times a day, skin delamination or irritation may occur if the electrode has a strong adhesive attachment or if a salt-base electrode gel is used. In addition, a very humid environment can make it difficult for some electrode systems to adhere properly, which causes many false alarms.

The carbon electrode with a small amount of water placed on it, without electrode gel, seems to cause the fewest skin reactions. Naturally self-adhering electrodes (that is, Karaya electrodes) and similar electrodes of synthetic material are also reported to work well during long-term monitoring.

2.2.6 Electrode Cost. The long-term cost of monitoring can be a major consideration. The electrode-cable system should be cost-effective, especially since many insurance programs do not cover accessories such as electrodes and the user is responsible for this cost.

The typical user cost of a carbon rubber electrode and pigtail cable can vary from 20 cents to 50 cents a day. Each pair will usually last at least two to three months. The typical cost of a disposable electrode and pigtail cable can vary from two to four times the cost of carbon rubber electrodes.

2.3 Connectors. The reliability of the electrode-cable attachment is important in reducing the number of false alarms due to disconnections. The electrode snap attachment used in the hospital environment is usually satisfactory for short-term monitoring when there is little or no infant movement, but it does not work well in the home environment of an active baby.

Carbon electrodes are usually attached with pin connectors, which are relatively low-profile, reliable, and inexpensive. The pin was developed in the early 1970s for TENS pain control devices, for which chronic pain patients had to wear electrodes over extended periods of time.

In 1985, the Food and Drug Administration (FDA) reported instances in which pigtail cables had been inadvertently plugged into ac power extension cords by apneic infants' siblings, with the result that several infants were electrocuted or burned. As pigtail cables are usually 24 to 36 in long, it is very important that the exposed connectors be designed so that they cannot be plugged into any power outlet. This is considered a mandatory requirement for most home monitoring programs.

Another potential hazard is that as infants become more active, they can wrap themselves up in the cables and strangle. A quick-disconnect cable might be a solution to this potential problem; however, if the cable

disconnects during normal use, it may cause too many false alarms and the lead would not be marketable. Careful routing of the lead wires down the infant's legs, under clothing, and exiting near the foot, together with safe and proper positioning of the patient cable, can reduce some of the problems associated with monitoring an active infant.

2.4 Methods of Signal Processing. The electrical signals from the apnea monitor sensor must be processed to recognize breathing activity, measure the respiration rate, and determine when apnea is present. The same general method of signal processing is used for all sensors, although different sensing systems require signal processors of differing complexity because of the nature of the individual signals.

A general block diagram of a transthoracic impedance type of apnea monitor is shown in Figure 4. The functions of the system can be categorized as impedance measurement, breath detection, artifact rejection, apnea identification, and alarms (Neuman 1984). Each of these functions can be carried out with varying degrees of complexity. The most recently designed infant apnea monitors employ sophisticated signal processing to get the most information out of a less-than-optimal signal.

The impedance measurement portion of the circuit contains a signal generator that produces the excitation signal applied to the electrodes. Frequently, this is a sinusoidal constant-current-amplitude source that produces a wave having a preset peak current. As this current is passed through the lead wire-electrode-body system (Figure 5), it encounters the total impedance of that system, and a voltage proportional to this impedance appears across the monitor input. Variations in this voltage reflect the variations in impedance from all sources, including ventilation. Therefore, it is important that the current source have a constant amplitude; if it does not, variations in current amplitude would also result in voltage variations, and it would not always be possible to distinguish whether these resulted from impedance variations or current source variations. Excitation signal frequency is also an important consideration in minimizing artifactual impedance variations.

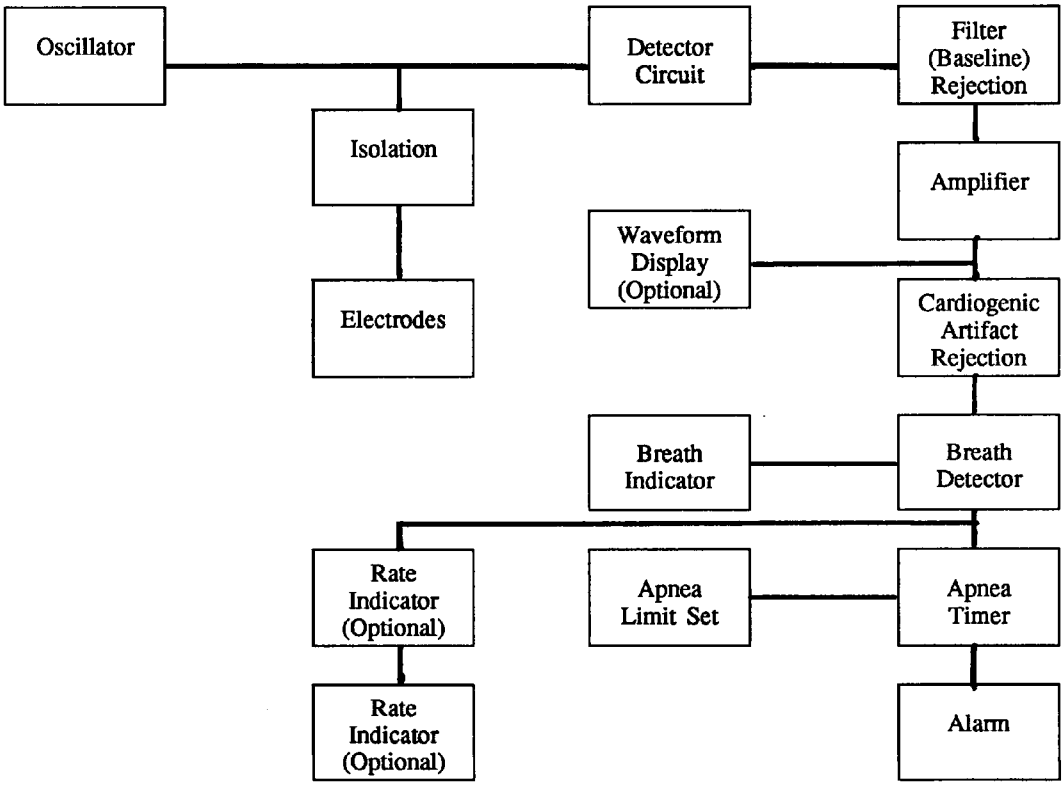

Figure 4 Functional block diagram of a transthoracic electrical impedance type of apnea monitor. (Reprinted from: National Institutes of Health. Infantile apnea and home monitoring. Bethesda, MD: NIH; 1987)

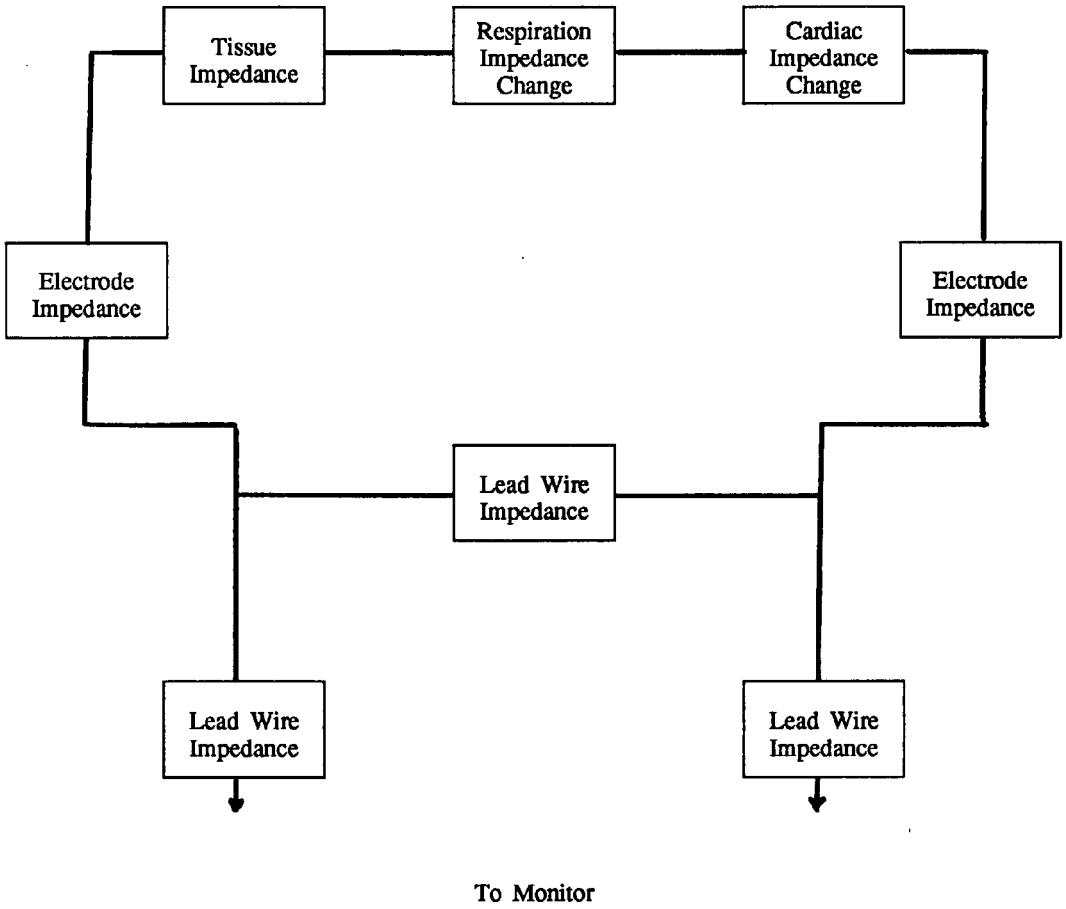

Figure 5 Block diagram showing the different components of the actual electrical impedance measured by a transthoracic electrical impedance apnea monitor. (Reprinted from: National Institutes of Health. Infantile apnea and home monitoring. Bethesda, MD: NIH; 1987)

The quality of the respiration detection portion of the signal processor plays an important role in determining the overall efficacy of an apnea monitor. Detection of infant breathing is a simple matter when the impedance respiration waveform appears as a regular pattern, as shown in Figure 6a. Unfortunately, the respiration waveform is not always this easy to interpret; frequently, patterns such as those in Figure 6b are seen and must be interpreted. Cardiogenic artifact also complicates the signal detection problem. It is important to note that, before a machine can be designed to detect a breath from the respiration signal, the designer must be able to look at patterns such as those seen in Figure 6 and identify where the breaths occur.

2.5 Preamplifiers. A preamplifier, located close to the infant, might improve the measurement quality of low-level impedance and ECG signals. Neuman (1984) has reported on a hybrid microelectronic circuit that would provide high-level signals to the monitor. The major considerations for the preamplifier are cost, performance, and reliability.

Reimbursement for apnea monitoring is a major factor in determining which technological features are added to existing monitoring systems. If the preamplifier were to simplify the electronics required in the basic monitor, a better cost-benefit ratio could be achieved, making a market acceptance of the new product likely.

2.6 Electronic Circuit. The measurement of transthoracic electrical impedance involves more than placing electrodes on the chest surface. The electrodes must be connected to an electronic circuit that generates a signal used for impedance measurement. This circuit is most often ac in the frequency range of 20 to 100 kHz (Olsson et al. 1970). The circuit determines the voltage and current and calculates impedance, and it often provides a constant current amplitude so that the voltage will be directly proportional to the impedance

seen by the circuit. The impedance seen by the electronic circuit, however, represents more than just the transthoracic impedance (Kerns 1984). There are impedances associated with the electrode itself and the interface between the electrode and the body. Additional impedance is associated with the electrode lead wire and patient cable that connect the electronic instrument to the subject (Figure 5). The electrode and lead-wire impedances are in series with the transthoracic impedance, and the electrical impedance measured by the circuit represents the sum of all of these contributions. The actual impedances of each block in Figure 5 are dependent on the devices used. Generally, the total transthoracic impedance is approximately 500 ohms, with a variation due to respiration of no more than 2 ohms; thus, the respiration signal that is measured is less than 0.5% of the baseline.

To further complicate the situation, each of the other components in the system can vary in electrical impedance by at least the respiration variation. The impedance between the electrode and the infant's skin strongly depends on the electrode-skin interface. As electrodes move with respect to the skin surface, this impedance can vary by much more than 2 ohms.

The frequency of the ac signal used to determine the impedance also affects the impedance of each component in the circuit of Figure 5. As the frequency increases, the greater portion of the current is confined near the surface of a conductor, consequently, the sensitivity of the impedance method to changes in lung volume can decrease. On the other hand, higher frequency excitation reduces the effect of electrode-skin interfacial impedance. The changes in impedance associated with movement of the lead wires become more pronounced at higher frequencies. Therefore, most manufacturers have used excitation frequencies in the range of 20 to 100 kHz, a frequency range in which the results are optimal.

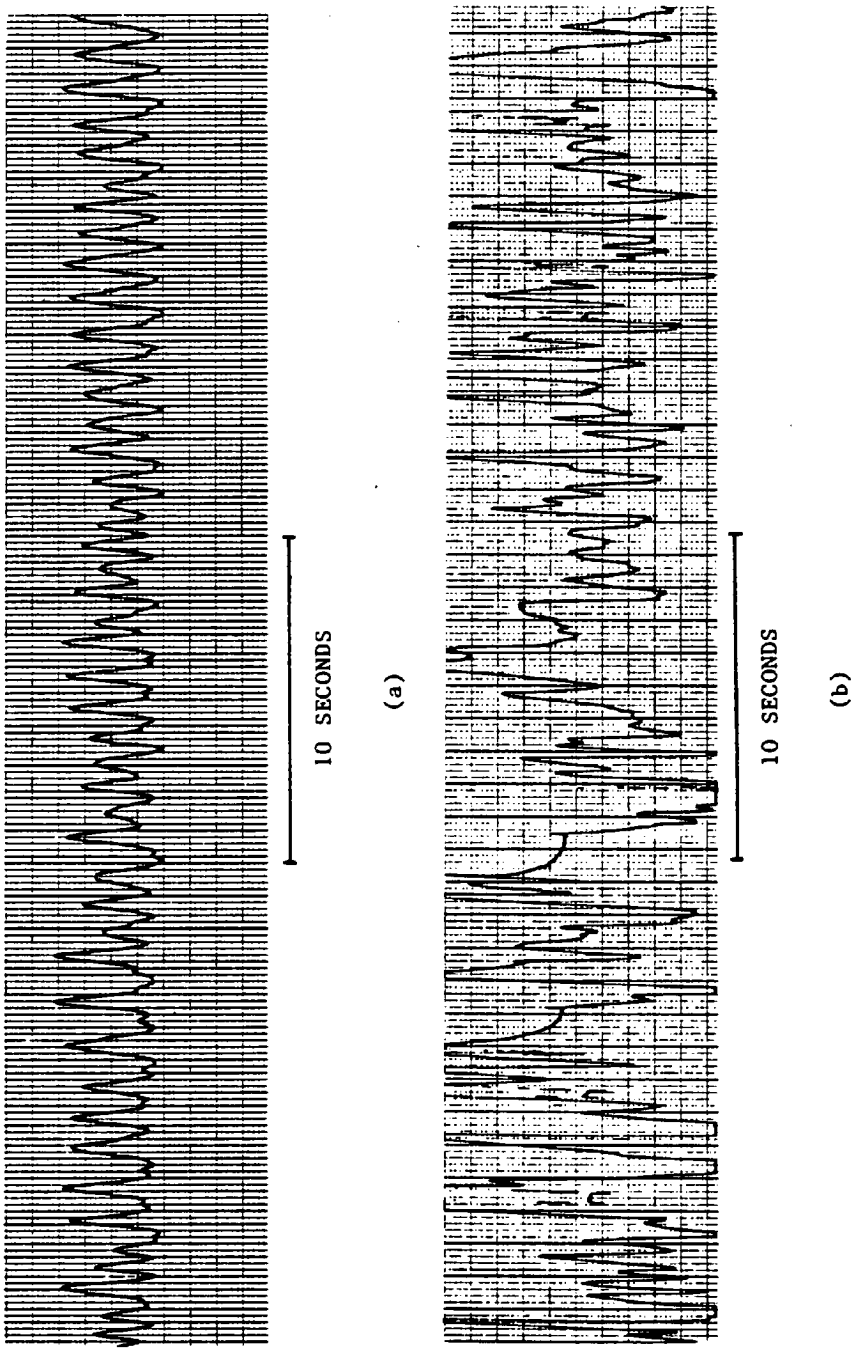

Figure 6. Two examples of transthoracic electrical impedance respiration signals in which (a) represents a regular signal during quiet sleep with little artifact and (b) shows a signal with sufficient artifact to make breath detection difficult. (Reprinted from: National Institutes of Health. Infantile apnea and home monitoring. Bethesda, MD: NIH; 1987.)

2.7 Telemetry. Many clinicians have suggested eliminating the lead-patient cable. The lead-cable-electrode system represents a major problem area for long-term infant monitoring. Telemetry would appear to answer many of the problems currently identified.

Unfortunately, a reliable telemetry system that will transmit both the impedance and heart rate signals does not exist in practical form. Several companies have developed alternative respiration measurement techniques and have coupled these systems to an FM telemetry transmitter to transmit alarm conditions to a bedside monitor. These new systems do not provide the respiration and heart rate information needed for a traditional 12- or 24-hour pneumogram.

Electronic technology is advancing rapidly. It is possible that, with custom-designed CMOS circuits, a multichannel transmitter system may be developed that is small enough to be placed on an infant and that can measure both respiration and heart rate and transmit the measurements to a bedside monitor.

The major considerations for the telemetry unit are cost, performance, and reliability. At present, use of telemetry would appear to add $600 to $1,000 to the monitor's cost. This probably translates into an additional $100 per month in rental charges by the home care dealer. A telemetry system, if developed, would appear to offer significant advantages for monitoring infants over six months of age.

3. The State of the Art of Current Monitor Design

3.1 Overview. Most monitors are designed for either home or hospital use, with a few designated for use in either location. Designs are tailored for use on neonates or infants. Variations in user expertise, location and environment, and physiologic changes in the growing child require that manufacturers provide a series of monitors.

Monitors are available with various combinations of features to meet the needs of particular monitoring situations. One or more of the features listed in Table 3 will be found in each monitoring system.

Additional features may include an alarm disabling function, tone or alarm loudness adjustment, adjustable brightness of display, remote alarm, connection to recorder or modem, battery operation, low-battery indication, telemetry, event memory, trending, and alarm reset.

Table 3

Performance Features of Commercially Available Apnea Monitors

Apnea Detection	*Breathing Rate*	*Heart Rate*
Apnea alarms	Event occurrence	Event occurrence
Alarm delay adjustment	Sensitivity adjustment	Sensitivity adjustment
Event counter	Alarm limits	Alarm limits
Cardiac artifact	Rate display	Rate display
detection/rejection	Waveform	Waveform
	Loose lead indicator	Loose lead indicator

Owing to the lack of user expertise, monitors for home use tend to have limited displays and a low number of adjustable parameters. The physician may preset the device to ensure proper monitoring of the patient, and there is often mechanical or electrical protection to prevent tampering with the control settings. Size, weight, and ease of transport are important if the monitor is to be used portably.

Hospital apnea monitors, especially those used in critical care areas, are usually integrated with systems that monitor other physiologic parameters. The system may stand alone or have a modular form. Maximum adjustability of parameters is usually provided. The system may be connected to a hospital information system for transfer of data to other areas of the hospital. It is important that hospital monitors provide stable displays in the presence of noise and voltage variations on the power lines.

3.2 Capabilities of Currently Available Impedance-Type Monitors. As noted previously, transthoracic impedance is by far the most frequently used method to detect apnea. The performance characteristics of the best impedance monitors currently available are described in Table 4. These devices lack a few essential features in some situations. Thus, this technology, although useful in monitoring infants, at present is not optimal. Home monitors range from 190 to 360 cu in, and hospital monitors range from 360 to 3,300 cu in. Home monitors weigh 3 to 5 lbs, and hospital monitors weigh from 5 to 65 lbs. The cost of home monitors ranges from $1,000 to $3,000, and that of hospital monitors from $2,500 to $11,000. Size, weight, and cost are determined by the number of functions monitored, the number of adjustments and displays, the

technologies used, and the degree of ruggedness.

3.3 Features: Advantages and Disadvantages

3.3.1 Optimal Characteristics of a Monitor. For a cardiorespiratory monitor to be clinically useful in detecting life-threatening events, a minimum set of operating requirements must be met (Table 5). The ability to recognize apneas of duration equal to or greater than a predetermined limit is essential. Ideally, the monitor should respond to all types of apnea, including central, obstructive, and mixed. It is desirable that the device also be able to discriminate among and identify these three types of apnea. Identification of an abnormally low breathing rate is also important. Heart rate detection and identification are essential when previously set bradycardia and tachycardia limits have been exceeded. Monitors must be safe, noninvasive, and easily used by unskilled individuals. They must accurately identify alarm conditions with a minimum of false-positive or false-negative alarms. The alarms must alert the individual responsible for the infant's care. Monitors must be capable of monitoring their own internal essential functions, such as battery condition and electrode viability, so that proper functioning can be ensured.

Desirable characteristics of cardiorespiratory monitors are listed in Table 5 as well. For the most part, these features are not included in commercially available devices, and their usefulness in identifying life-threatening events is not well established. However, the availability of these features would allow additional research into optimal monitoring.

3.3.2 Manual versus Automatic Sensitivity. The sensitivity of the means for detecting the occurrence of a heart beat or respiratory effort may be adjusted either manually or automatically. Sensitivity may be reflected in the amplitude of a cathode ray tube (CRT) waveform or the range of a numerical indicator.

Table 4

Performance Characteristics of the Best Currently Available Impedance Cardiorespiratory Monitors

Essential Performance Characteristics	*Desirable Performance Characteristics*
+ Bradycardia detection	- Hypoxemia detection
+ Tachycardia detection	- Hypoventilation detection
+ Central apnea detection	- Tidal volume estimation
- Obstructive apnea detection	- Heart rate variability and pattern estimation
- Mixed apnea detection	- Arrhythmia detection
+ Respiratory frequency determination	± Event capture capability
+ Monitor dysfunction determination	± Built-in self-test
± Alarm efficacy	- Wireless
- False alarm incidence	
± Ease of use	
+ Safety	
+ Noninvasive	

Note: Reprinted from: National Institutes of Health. Infantile apnea and home monitoring. Bethesda, MD: NIH; 1987.
+ The best available monitors have this feature.
- The best available monitors do not sufficiently meet this performance requirement.
± This requirement is only partially met.

Table 5

Essential and Desirable Features of Infant Cardiorespiratory Monitors

Essential Features	*Desirable Features*
Bradycardia detection	Hypoxemia detection
Tachycardia detection	Hypoventilation detection
Central apnea detection	Tidal volume estimation
Obstructive apnea detection	Arrhythmia detection
Mixed apnea detection	Event capture capability
Respiratory frequency measurement	Built-in self-test
Device dysfunction monitoring	Wireless operation
Alarm efficacy estimation	Heart rate variability and pattern
Low false-alarm incidence	Complex respiration pattern detection (periodic breathing duration and frequency)
Ease of use	
Safety	
Noninvasiveness	

Note: Reprinted from: National Institutes of Health. Infantile apnea and home monitoring. Bethesda, MD: NIH; 1987.

Automatic sensitivity adjustment is desirable when changes in the level of the monitored function are slower than the averaging algorithm of the detector. Short periods of rapid changes may cause rate meter errors, but they do not usually cause an alarm, as normal detection will resume when the changes stop. Automatic sensitivity adjustment depends on the monitored signal shape and the detection algorithm.

Manual sensitivity adjustment may be required when continuous movement of the patient or rapid changes of the monitored function occur; manual sensitivity adjustment will allow intermittent detection and prevent inappropriate alarms. It may also be required when unusual waveform shapes confuse the sensitivity detection circuitry or algorithm, but the operator must ensure that the adjustment is checked frequently enough to allow for changes in the physiologic state of the patient.

Automatic adjustment of the rate indicator range or the CRT display sensitivity can be very problematic when frequent, large changes are occurring in the monitored function, because the display will change continually in position or aspect ratio. Display and signal detection sensitivity adjustments are often separated to allow the operator flexibility in setting up the monitor. Some monitors allow for both automatic and manual adjustment.

3.3.3 Range and Number of Alarms. Alarms are available in various visual and audio presentations. A monitor alarm may be triggered by apnea, respiration rate, heart rate, respiration and heart rate coincidence, or a combination of these variables. In addition, some monitors have alarms that alert the operator to low battery condition, loss of ac power, or loose or broken leads. There may be alarms for other variables as well, and remote alarms are available.

When selecting a monitor, the prospective user should review the types and combinations of alarms to ensure that the device is suitable for the intended patient, the monitoring site, and the monitoring situation. Alarms on apnea monitors can sound like alarms on other medical equipment, so it is helpful if devices in proximity have alarms that sound different or have additional visual alarms. The user should also determine how much flexibility is needed in setting the alarms and in guarding against improper settings.

3.3.3.1 Visual Alarms. Visual alarms are available in the form of light-emitting diode (LED), neon,

incandescent, electroluminescent, and liquid crystal displays. Alarms may also be part of the CRT or readout display in the form of a blinking signal or a change in color. The size of the display varies from 1/8 in to over 1 in diameter. The color of the display is either yellow or red, with yellow indicating caution and red indicating a need for immediate action.

It is important to ensure that the size and location of alarms are appropriate for the intended use of the monitor. A 1/8-in display may not attract attention if the user is more than 6 ft away from the monitor. The brightness of the display should be appropriate for the light level of the room and the location of the user. Liquid crystal displays are not self-luminating and, therefore, are not appropriate for a dark room, unless they are illuminated by the monitor. The viewing angle for such displays is usually small, typically less than 30 degrees from the perpendicular.

3.3.3.2 Auditory Alarms. Auditory alarms are available in pure or combination tones. The sound may be steady, warbling, or intermittent. Most alarms using a pure tone have a frequency of about 2 kHz, since this is the frequency at which many small speakers are most efficient. Some monitors allow the user to vary the pitch. The user should choose alarms that can readily be differentiated from other auditory sounds in the immediate area. It is important to ensure that the sound level can be set appropriately for all locations of use.

3.3.3.3 Rate Alarms. Most monitors allow the user to set alarms for respiration rate, heart rate, and duration of apnea. Rate alarms are usually set with thumb wheels or circular knobs or by means of an up-and-down key on the rate meter. Apnea alarms usually have several, fixed, selectable settings between 10 and 40 seconds. Loose-lead and power alarms are fixed and operator-independent. Some monitors have a bradycardia alarm that sounds when heart rate falls below a predetermined value, typically between 60 and 120 BPM, depending on the patient. Common high-heart-rate alarm settings are 220 to 230 BPM.

High-respiration-rate alarm limits can be set at 60 breaths per minute or higher, and low-respiration-rate alarm limits are commonly set at 3 to 15 breaths per minute. Some devices provide broader ranges of settings for flexibility. Accuracy specifications vary and are not available from all manufacturers. Apnea alarm accuracies are similarly variable. The user should choose a monitor having a range and accuracy of settings that match the patient and the monitoring need.

3.3.4 Signal Displays. Monitors are available that display waveforms or rates of monitored functions. Most hospital monitors display both. Home monitors usually display only respiration rate; some display only out-of-limit alarms. CRT displays are calibrated in ohms per centimeter for respiration and millivolts per centimeter for the ECG. Rates are displayed on analog meters or digital readouts, and monitor use dictates which type of display is most appropriate. Digital readouts are the easiest to read and the most durable, whereas analog meters show the rate of change more clearly. Binary (on or off) readouts are the easiest to interrupt and cause the least confusion.

The input circuits of the monitor and signal processing algorithms determine the accuracy of information displayed. Input circuits in present monitors have band passes conforming to the commonly accepted recommendations of 0.5 to 40 Hz for monitoring of the ECG. The characteristics for respiration display are not standardized. The band pass is limited so that electrical and mechanical noise will be rejected, but too much limiting distorts the display of analog waveforms and may confuse the algorithmic processing of some waveforms. Algorithms employ filtering, smoothing, and noise rejection to ensure the accuracy of displayed information.

To detect and interpret respiratory effort, algorithms must reject signals generated by the electrode-body interface, body movement, the surrounding environment, and cardiovascular artifact. In addition, the algorithms must contend with variations in signal size and shape.

Filtering is used to reject artifacts whose frequency components are outside those of interest in the respiration signal. Single-pole, multiple-pole, or notch filtering techniques may be used. It is important that

these filters do not distort the variations of the respiration signal in ways that will cause it to be misinterpreted by the detection algorithms. In addition, filters must not distort nonrespiration signals in a way that will cause them to be counted as respiratory effort.

To reject artifacts whose frequency components are within the frequency range of the respiration signal, techniques such as automatic gain control, differentiation, integration, templating, duration timing, QRS coincidence, and amplitude versus frequency versus rate are used in the algorithms. In today's products, these techniques are implemented by means of digital logic and microprocessors.

Detecting the presence and rate of the respiratory effort accurately is a difficult process owing to the large variations in the signal as it is affected by body movement, outside stimulus, and physiologic variations. The impedance detection and measurement elements of the monitor can be examined for variables such as duration, slope, repetition rate, patterns, and amplitude. In addition, coincidence or lack of coincidence with other physiologic events can be investigated.

Comparing these variables with known characteristics of the respiratory waveform via a predetermined algorithm is the method used by the monitoring device in deciding whether respiratory effort has occurred. The accuracy of the determination depends on the algorithm's ability to extract the signal from other physiologic or external events that cause changes in the transthoracic impedance.

If events other than respiratory effort cause the impedance to change in a manner that looks like respiratory effort, the algorithm will make a false-positive determination. On the other hand, if events distort the respiratory waveform, a false-negative determination will be made. Therefore, algorithms usually look for rhythm and do averaging as an additional filtering mechanism. A determination of arrest is usually delayed for 10 to 20 seconds to reduce the incidence of unnecessary alarms.

Overall *accuracy* depends on the total monitoring environment, including the environment surrounding the patient, the patient-monitor interface, the patient connections, the monitor, the detection algorithms, and the display of results. It is important that these elements are evaluated together when monitoring is undertaken. The monitor and its incorporated algorithms and displays must be compatible with the monitoring situation if accuracy is to be maintained. Measuring respiratory effort via impedance pneumography is difficult. Although today's monitors will err at times, an acceptable level of accuracy can be maintained if the total monitoring situation is controlled.

3.3.5 Continuous Physiologic Data Recording. Multichannel recorders employing several different techniques for sensing ventilation may be useful in assessing infant breathing problems. Two general types of hard-copy recordings are used to evaluate infants with potentially life-threatening apneas: polysomnograms and pneumograms.

3.3.5.1 Polysomnograms. Multichannel, simultaneous, continuous recordings of biophysical variables related to the pulmonary and cardiovascular systems, taken while the subject sleeps, are known as polysomnograms. The actual variables monitored can vary from one study to the next, but they usually include the ECG or heart rate; one or more measures of respiratory activity, such as transthoracic electrical impedance, abdominal movement (as measured by a strain gauge), or nasal thermistor readings; measures of infant activity and movements; measures of sleep state, such as eye movements or the electroencephalogram; and measures of infant blood gas status taken by techniques such as pulse oximetry and the monitoring of transcutaneous oxygen and carbon dioxide tensions. The number of channels of data in polysomnograms is at least 3 and can be more than 12. Studies generally last overnight to include as much infant sleep time as possible.

The primary application of polysomnography has been in research on infant sleep patterns and related physiologic phenomena. There is no conclusive evidence at present that polysomnographic evaluation of infants considered to be at risk for SIDS, apparent life-threatening event (ALTE), or other life-threatening events is of any value as a screening technique. In specific individual cases, however, such evaluation may

contribute to overall patient assessment. Currently, there is no standardized technique for polysomnography, and the method should be considered primarily as a research tool.

3.3.5.2 Pneumograms. Pneumography is a hard-copy monitoring technique that has been widely applied in the risk assessment of infants. A two-channel recording known as a pneumogram, pneumocardiogram, cardiorespirogram, or trend record of the respiration waveform and heart rate has been used to assess 18- to 24-hour continuous breathing patterns in infants. Generally, the respiration signal is obtained by the transthoracic electrical impedance technique, and the heart rate is derived from the electrocardiogram. Some investigators add a third channel to the pneumograph to record the signal from a nasal thermistor or abdominal strain gauge. Pneumograms can be recorded in the hospital or in the patient's home. Some commercially available transthoracic impedance infant apnea monitors provide for the attachment to the instrument of a miniature two-channel magnetic tape recorder that can record up to 24 hours of data on a single cassette tape. This recording can be played back through a special apparatus to generate a chart of the two channels of data, or it can be analyzed directly by a computer system.

Because pneumography involves recording respiration signals by means of the transthoracic electrical impedance technique, many of the limitations of this technique in continuous monitoring are also seen in the resulting pneumograms. Nevertheless, when pneumograms are evaluated by trained observers, information such as qualitative respiration patterns; the occurrence, duration, and frequency of apnea; heart rate patterns; and interrelationships between heart rate and respiration rate can be determined. The technical quality of pneumograms recorded on 24-hour magnetic tape cassettes and played back at a later time is generally not as good as that of the two equivalent channels on polysomnograms recorded on multichannel chart recorders and laboratory instrumentation-grade magnetic tape recorders. This fact, along with the previously mentioned limitations of transthoracic electrical impedance as a method of sensing ventilation, means that such characteristics as relative tidal volume, central or obstructive apnea, and sleep state cannot be quantitatively assessed.

Until recently, pneumograms consisted of special, expensive studies that were performed just a few times during the treatment of infants considered to be at risk of life-threatening events. Recent advances in apnea monitoring technology make it possible to store hard-copy recordings of events that result in an alarm condition or to store continuous recordings for several hours. Electronic memory units built into the apnea monitor store the data for later playback into a computer or chart recorder. The quality of these recordings from electronic memory is generally much better than the quality of recordings from the miniature magnetic tape recorders. Monitor manufacturers are presently discussing the possibility of not only recording "significant" events, but also transmitting these data over telephone lines to a central location where they can be assessed by both human observer and machine.

3.4 Safety Considerations. Whenever electronic devices are used in patient care, safety issues should be of concern. A major consideration is the electrical shock hazard. Most home apnea monitors are powered with rechargeable batteries, which minimizes or, in some cases, completely eliminates the electrical shock hazard. Electrical shock is not, however, the only safety issue associated with infant monitors. There is always the potential for the monitor to be used incorrectly and to injure the infant. There has been a report of an older sibling connecting an infant's electrode lead wires to an electrical power outlet (Food and Drug Administration 1985). Active infants can become ensnarled in the lead wires and patient cables, which may result in strangulation. Monitor wires, connectors, or electrodes may enter the infant's mouth and lead to a pulmonary or gastrointestinal obstruction. These kinds of hazards should be considered in the design of infant monitors.

4. Testing

4.1 Overview. The primary purpose of testing is to verify that a device meets its specifications and design intent. Laboratory or bench testing and clinical or field testing are performed by the device manufacturer. In addition, some prospective users conduct tests during prepurchase evaluation or incoming inspection, and

certain performance characteristics can be "self-tested" by the device.

It is important to have *in vitro* techniques for the testing of apnea monitors to determine if they meet their performance specifications. Although several evaluation methods exist, none is entirely adequate because the monitor deals with signals that vary greatly and exhibit many different patterns. Most laboratory simulation and clinical testing has been done with the transthoracic electrical impedance type of monitor.

Further work to develop reliable methods of evaluating apnea monitors is needed. Not only must better hardware for infant respiration and apnea simulators be developed, but appropriate test conditions and indexes must be determined. At present, there are no standards for infant apnea monitors, so the prospective user has no way of knowing whether a monitor meets the requirements of an application without actually testing it on human subjects. Furthermore, the FDA has no reliable methods for determining if apnea monitors are efficacious for use on infants.

4.2 Laboratory (Bench) Testing. Laboratory testing is typically divided into two categories: electrical testing and environmental testing.

4.2.1 Electrical Testing. Electrical testing typically parallels the product specifications.

4.2.1.1 Switch Settings

(1) Power ON/OFF Switch. It should be verified that the safety interlock system performs as specified. Manufacturers have devised a number of schemes to accomplish the same purpose-to ensure that the operator is aware that the power to the device has been turned on or off. These schemes include an alarm requiring reset; two-handed operation using a reset button that must be depressed in conjunction with operation of the ON/OFF switch; and a mechanical interlock requiring that the switch knob be pulled out in conjunction with toggling the switch on or off.

(2) Sensitivity Control. The following tests should be performed for both the manual sensitivity adjustment mode and the automatic sensitivity adjustment mode:

(a) Measure the respiration-triggering sensitivity as a function of respiration rate and respiration impedance change throughout the range of baseline impedance specified.

(b) Measure the heart rate-triggering sensitivity as a function of rate and amplitude throughout the range specified.

(c) Measure artifact rejection.

(d) Measure the system's response to cardiogenic amplitude and frequency.

(e) Measure the recovery time for large input signals that saturate the input amplifiers.

(f) In addition to the preceding tests, the following tests should be performed in the automatic mode: measure the monitor's response to transient changes in baseline impedance that simulate momentary interruption of electrode contact or large movement artifacts, and measure the monitor's response to dynamic changes in both heart rate and respiration rate.

(3) Apnea Duration Switch. Apnea duration time, as well as tolerance and potential overlap between settings, should be verified for each switch setting for both nominal and worst case critical timing component tolerances.

(4) Bradycardia Rate Switch. Bradycardia rate and tolerance should be verified for each switch setting for both nominal and worst-case critical timing component tolerances. It

should also be verified that interval averaging is operating as specified.

(5) Tachycardia Rate Switch. Tachycardia rate and tolerance should be verified for each switch setting for both nominal and worse-case critical timing component tolerances. It should also be verified that interval averaging is operating as specified.

(6) Recording Control Switches. It should be verified that output at the recorder connector is within specification.

4.2.1.2 Visual Displays. Viewing distance, angle of view, and function should be verified for each visual display. Monitors typically provide some or all of the following visual displays: heart beat, respiration, apnea, bradycardia, tachycardia, lead fault, low battery, battery charging, and monitor fault.

4.2.1.3 Audible Alarms. Intensity (in decibels), duty cycle, and functionality should be verified for patient alarms (apnea, bradycardia, tachycardia), equipment alarms (low battery, lead fault, monitor fault), and remote alarms.

4.2.1.4 Battery. Battery capacity should be verified under nominal settings, typically 165 and 30 BPM. Low-battery alarm voltage, time, and battery voltage, and time to equipment shutdown should be determined. Charging time should be verified under nominal conditions. Device performance should be verified throughout the usable range of voltages.

4.2.1.5 Electrical Isolation. The device should meet the requirements for isolated patient connection specified in ANSI/AAMI ES1-1985, *Safe Current Limits for Electromedical Apparatus* (Association for the Advancement of Medical Instrumentation 1985).

4.2.2 Environmental Testing. Devices are typically tested for temperature and humidity tolerance.

4.2.2.1 Temperature. Both storage and operating temperatures should be verified against the manufacturer's specifications. Additionally, some manufacturers may perform temperature cycling tests to identify potential component reliability concerns and, hence, to improve the overall reliability of the device. Devices may also be tested at high temperatures before shipment to stress components and identify potential early component failures. This technique is referred to as "high-temperature burn-in." Care must be taken to ensure that the safe operating temperature of the batteries is not exceeded. Higher temperatures can be used for burn-in if the batteries are removed from the device prior to testing.

4.2.2.2 Humidity. Humidity testing is performed to verify that device performance is within specifications. Product specifications and test methods are unique to each manufacturer and are not typically identified in user documentation.

4.2.2.3 Electromagnetic Compatibility (EMC). It should be verified that the device functions according to specifications in the presence of electromagnetic interference (EMI). At present, there are no established standards for testing apnea monitors for EMC; each manufacturer establishes its own test criteria. Common sense dictates that apnea monitors perform safely and efficaciously in the presence of common household appliances.

4.2.2.4 Electrostatic Discharge (ESD). Voltages higher than 20 kV are possible (as, for example, when a person walks across a nylon rug on a dry day). A typical simulated discharge is from a 150- to 200-picofarad capacitor charged to the appropriate specified voltage. Following such a discharge, a monitor should continue to meet its performance specifications.

4.2.2.5 Shock and Vibration. Shock and vibration testing may be performed at the component, subassembly, or final product level. Product specifications and test methods are unique to each manufacturer and are not typically identified in user documentation.

4.2.2.6 Shipping and Packaging. Testing may be performed with the device in its carrying case, final shipping

container, or both. Again, product specifications and test methods are unique to each manufacturer and are not typically identified in user documentation.

4.3 Clinical Testing. Clinical testing is performed by the manufacturer after all laboratory testing is completed. The device is tested on patients under normal operating conditions. A parallel form of apnea monitoring must be used to ensure patient safety. Clinical testing is performed for one or more of the following reasons: to verify that the device performs within its specifications and design intent under actual intended operating conditions; to verify that the device meets the quality, reliability, and regulatory requirements in all countries in which the device will be sold; and to verify that the device meets the market need (often referred to as "test marketing" or "customer acceptance testing").

Clinical testing is performed according to a written protocol to ensure the uniform collection of data. A sufficient number of devices should be tested, under each of the conditions for which the device is intended to be used, and a sufficient number of subjects should be included in the study to yield statistically significant results. Devices used for clinical testing must be produced under conditions complying with good manufacturing practices (GMP) regulations, as specified by the FDA. Data collected during clinical testing should be analyzed and summarized in a written report. The clinical report should identify the number of devices tested, the number of subjects, the test conditions, any discrepancies with specifications, and any corrective actions to be taken.

4.4 Self-Testing. Equipment designed with microprocessor technology should incorporate at least two self-testing mechanisms, one for "initialization" testing and one for "background" or "watchdog" testing. The first test should occur each time the monitor is turned on. This self-test, also referred to as "power on reset," should clear random-access memory (RAM), establish initial conditions for logic circuitry, turn on each visual alarm to verify that the light functions, and perform checks on units that contain read-only memory (ROM) or electrically programmable read-only memory (EPROM) separate from the microprocessor. This last check is particularly important for programmable memory, because ESD or high frequencies can sometimes alter the memory content.

The "background test" or "watchdog test" is used to verify basic processor operation. This test is performed at specified time intervals coded into the operating software and occurs in such a manner that normal operation of the monitor is unaffected.

4.5 Performance Testing

4.5.1 Testing by Electronic Simulators. Electronic simulators have been developed for use in testing apnea monitors. These simulators connect directly to the electrode inputs of the apnea monitor, in the place of a patient. To represent the respiration signal, most simulators provide a sinusoidally varying resistance, which can be controlled in terms of baseline resistance, amplitude of resistance change, and frequency of resistance change. Pushing a button on the simulator produces an apnea by keeping the resistance constant for the period of time that the button is depressed. The simulator also provides an electrocardiographic signal that can be varied in amplitude and frequency.

Although simulators of this type can be used to test the basic function of impedance apnea monitors, the respiratory signal is not truly representative of the type of infant breathing signal likely to be seen in practice. This means that monitors can work well with such a simulator but can perform poorly when connected to patients.

Simulated respiration can be made more representative of physiologic signals by the use of multiple simulators. One simulator is used as an ECG generator, providing the ECG signal with the respiration component set to the same rate as the ECG rate to simulate cardiovascular artifact. Three other simulators with the ECG component turned off can be connected in series with the first. One simulator is used for low-amplitude breaths, another is used for high-amplitude breaths or sighs, and the last is set to a slow rate to simulate body movement. If the two simulators used for low- and high-amplitude breaths are in phase,

together they can generate breathing amplitudes not available on most simulators. Since the simulators are in series, the total base impedance is equal to the sum of all the simulators' base impedances.

A monitor that used a phase relationship between the ECG QRS complex and the respiration to reject cardiovascular artifact could only be tested with physiologic signals. Presently available simulators do not supply this phase relationship.

Although multiple simulators represent an improvement over a single simulator, this test method still does not represent the range of breathing signals seen clinically by an apnea monitor. At present, the only way that this range can be seen is to test the monitor on infants. It is not possible, of course, to have an infant produce a particular breathing pattern, so it is necessary to evaluate the behavior of the monitor on several infants. Furthermore, not only is there the problem of obtaining a full range of respiration patterns with which to test the monitor, but there is no absolute standard against which to compare the monitor when tested on infants. For this reason, it is best to record two or more respiration signals from the infant, using separate transducers, along with the monitor response. In this way, the respiration signal can be examined to determine what type of patterns the monitor is seeing.

4.5.2 Testing By Real Respiration Signals. Appropriate performance standards and standardized test methods are needed for evaluating apnea monitors, because simulators of apneic breathing patterns are limited in their ability to represent real-life situations. Yount and Bowman state that it is important to evaluate monitors with real rather than artificial respiration signals, and they have proposed methods of doing so (Yount 1987; Bowman 1987). Bowman and coworkers have developed equipment to enable respiration signals to be recorded and played back to one monitor or several monitors simultaneously to determine their response to the respiration pattern (Bowman 1987). This type of work needs to be developed further, not only for transthoracic electrical impedance-type monitors but for other sensors as well.

4.5.3 Wide-Band Amplifiers and Voltage-to-Impedance Converters. Two test devices in use that have been publicly described by two manufacturers and ECRI are the wide-band amplifier and the voltage-to-impedance converter (National Institutes of Health 1987; ECRI 1974, 1980). These devices allow the direct comparison of monitor performance in applications including clinical testing, bench testing, and repeatable recording and playback testing.

The input characteristics of a wide-band amplifier are similar to those of an impedance monitor except for its wider frequency bandwidth (linear 0.01 to 7 Hz). The voltage signals of ECG and respiration are obtained by applying a small ac signal (typically 100 microamperes or less) through a simulator or across a pair of electrodes placed transthoracically on the patient. The frequency of the alternating current can be in the 20- to 100-kHz range. The impedance change, along with the alternating current, creates a corresponding respiration voltage signal, which is amplified through the wide-band amplifier. The ECG signal appears as a voltage across the electrodes and is also amplified through the wide-band amplifier. These two voltage signals can then be recorded on tape or by computer to be played back at a later time, or the signals can be connected directly to the voltage-to-impedance converter.

The voltage-to-impedance converter is a device that converts the respiration voltage signal into a corresponding impedance. The ECG signal remains a voltage signal. The impedance and ECG signals are then duplicated at multiple, electrically isolated ports, a procedure that allows two or more monitors to be tested at the same time with the same inputs, while eliminating interference between the monitors being tested.

When these two test devices are used in a clinical application, a patient is connected by one pair of electrodes to two monitors simultaneously via the wide-band amplifier and voltage-to-impedance converter. Each monitor's LED responses, output signals, and alarm signal are then recorded on a multi-channel strip chart recorder. This system eliminates interference between monitors while providing each with a duplicate signal.

The system in Figure 7 can be used to perform in vitro monitor comparison testing without a tape recorder. A simulator or multiple simulators can be used as the input.

When used in conjunction with a tape recorder or computer, the wide-band amplifier and voltage-to-impedance converter can be used to record and play back both physiologic and simulated signals. Close tape editing can provide a rapid succession of recorded events to test multiple monitor functions in a short period of time. At the beginning of each tape, a simulated calibration signal of known amplitude should be recorded to match signal amplitudes when the recording is played back. Computers are not currently used digitally to record the data, but this technique would avoid the problems associated with tape quality degradation.

Incorporating a record-playback system with the wide-band amplifier and voltage-to-impedance converter makes monitor performance testing repeatable. With the acceptance and standardization of equipment and physiologic or simulated test signals, some form of standardized impedance monitor performance testing could be achieved.

Before being tested, the system to be used must be calibrated by matching the monitor's signal output amplitudes when driven directly by a simulator to those when driven by a simulator through the system. Performance and signal quality comparisons should also be made to verify that the monitor's performance has not been altered by the system.

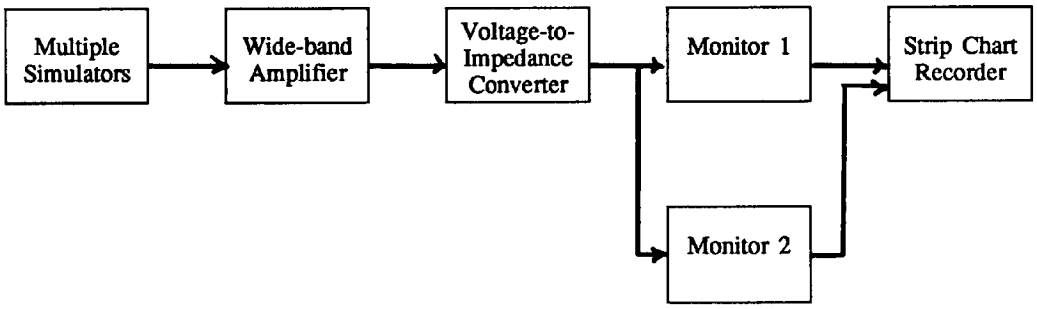

Figure 7. System for comparative bench testing of two apnea monitors.

5. Clinical Applications of Transthoracic Electrical Impedance Monitors

5.1 Overview. When the special task force of the American Academy of Pediatrics recommended monitor use for apnea (American Academy of Pediatrics 1978) and when the AAP Committee on the Fetus and Newborn modified and extended that statement (American Academy of Pediatrics 1985), they were purposefully vague about the specific methods of monitor use. There is clearly a need to develop a standard set of definitions of infant behavior that are broadly based and not dependent on a single transducing technique. These clinical guidelines on what constitutes abnormal and normal waveforms could then be translated into a device standard useful to the monitor industry. At this time, with our limited knowledge of infant behavior, the development of a standard for thoracic impedance is made necessary by the frequency of that method's use and does not imply that this technique is the best means of documenting infant behavior.

The monitoring of transthoracic electrical impedance has allowed clinicians to begin to manage apnea more effectively, particularly in infants, and important observations have been made that would not have been possible otherwise. As the complexity of infant behavior is better understood and documented, however, it is possible that techniques and devices designed to respond more accurately to each infant's needs will have to be developed. It is also to be hoped that monitoring techniques will be developed that are less disruptive of normal infant care in hospital and home and less intrusive upon normal marital and family life. The needs are obvious to anyone familiar with the current "state of the art" (Nelson 1978; Yount 1984).

5.2 Patterns of Apnea. Three patterns of apnea are recognized as commonly occurring, clinically significant

changes in ventilation.

5.2.1 Central Apnea. Central apnea is due to the absence of respiratory effort. There is currently no explanation for why a large fraction of very immature infants, a small, high-risk group of maturing premature infants, and some full-term infants have episodes. The behavior is seen both as a suddenly increasing secondary symptom of infectious, biochemical, or metabolic imbalances and as a chronic, recurrent, unexplained behavior attributed to immaturity or subtle injury in the nervous system (Parmalee et al. 1972; Kattwinkel 1977; Fleming et al. 1978; Brouillette and Thach 1979; Thach and Stark 1979).

5.2.2 Obstructive Apnea. In obstructive apnea, respiratory effort does not stop, but inappropriate closure of the laryngeal or pharyngeal airway prevents airflow. The continued effort prevents a thoracic impedance detection system from alarming (Warburton et al. 1977). There is frequently a reflex change in heart rate to a plateau level 20% or more below the resting value, as occurs with many central apnea episodes. This heart rate change is often a reliable means of detecting either central or obstructive apnea (Guntheroth 1982; Rigatto 1977), but in some patients it is necessary to measure airflow or oxygen levels if the bradycardic reflex is absent or unreliable.

5.2.3 Mixed Apnea. Mixed apnea consists of central pauses, ineffectual small efforts, and obstructed efforts, all within the same discrete event. This behavior can be detected with simple signal processing only if there are central pauses long enough to exceed the 14- to 15-second upper limit of normal for spontaneous post-sigh and REM sleep-related pauses. A respiratory rate alarm might detect some episodes, but heart rate or oxygen alarms are usually necessary. A common form of mixed apnea in premature infants consists of a sequence of central apnea followed by increasingly ineffectual or obstructed breaths (Figure 8). The end of the episode is defined by the onset of a large respiratory effort that is followed within two seconds by a rapid rise in heart rate and within five seconds by a rise in oxygen saturation. The degree of change in heart rate and the level of the plateau reached varies with each infant. Thoracic movement often does not accurately depict the point of onset of many of these events, giving the appearance that bradycardia occurs without an antecedent central pause.

If apnea lasts for 20 seconds or more, a measurable depletion of the reservoir of oxygen available to the tissues begins to occur in most infants. This is due to the higher relative rate of oxygen consumption from the reservoir in the lungs and blood in most infants than that in adults, and it may be complicated by the loss of a fraction of the oxygen reservoir due to the expiratory depletion of the gas volume in the lung below the usual level at the end of each breath.

5.2.4 Expiratory Apnea. A few patients have been reported to experience a sudden, in some instances fatal, expiratory loss of lung volume in a fourth, less common respiratory pattern called expiratory apnea (Southall et al. 1984; Talbert and Southall 1985).

5.3 Detecting Apnea and Establishing Monitor Settings. Apnea monitors for hospital and home use have the common application goals of recognizing and signaling correctly for central apnea of abnormal duration and, in some models, of recognizing low respiratory rates. As indicated in the brief overview of the different forms of apnea (see 5.2), only some apneic events can be recognized by detection of the absence of respiratory effort. In addition, the filtering or exclusion of cardiovascular interference from the respiration detection circuitry has been achieved with varying degrees of success (Shannon et al. 1975; Warburton et al. 1977; Southall 1980). Because of the complex nature of apnea and the difficulty of reliably detecting many infant episodes, the 1985 AAP report advised use of respiration and heart monitors or, in some instances, heart monitors alone, but never a respiratory-effort sensor alone.

As in most of medicine, to avoid harm, the "abnormal" or diseased group of patients must be distinguishable from those who are not abnormal or have healed. Significantly, apnea of duration greater than 15 seconds has never been documented after two weeks of age in healthy infants. It may occur in the first few days of life of a few healthy full-term infants, but it does not return even with mild respiratory illnesses. The normal

range of infant respiratory rate is 18 to 60 breaths per minute, with short (10 to 15 seconds) slower periods (10 to 20 breaths per minute) and rapid periods (60 to 150 breaths per minute) occurring as occasional normal transient behavior.

The resting heart rate in full-term infants ranges from 95 to 160 BPM in the first two weeks of life and rises by 10 to 15 BPM during the next few weeks; four to eight weeks after birth, resting heart rate begins to fall gradually as the infant matures. Transients to 230 BPM are common with activity, and a few infants exhibit rapid vasovagal slowing of heart rate or minor variations in atrial conduction that can be a problem for heart rate alarms based on a too-narrow (less than 5 to 10 seconds) time window or on fewer than 4 beats (Richards et al. 1984; Hoppenbrouwers et al. 1979). Monitor settings should take these normal variations into account but should be adjusted for the individual infant at a higher than normal range if the child exhibits unique behavior (Figure 8). For most infants, the low heart rate alarm should be set for at least 100 BPM and the apnea alarm for 15 seconds; these levels should be adjusted only as the maturation of the infant requires. It is important to establish goals in monitor use for each infant and to select equipment designed to accommodate those goals (Yount 1984). Setting heart rate alarms at 20% below the resting rate in quiet sleep will often serve to adjust for the normal changes with time and yet will allow mixed and obstructive apnea to be closely followed.

A typical goal in the cardiorespiratory monitoring of infants from the various high-risk groups (see 1.1) is to assist the medical team or parents in recognizing episodes of significant apnea that are self-resolved as well as episodes that an infant is still manifesting when caretakers respond to an alarm. These infants are otherwise in generally good health, and it is expected that any abnormal behavior will subside during the rapid growth and maturation of their first several weeks to months of life. It is vital that equipment accurately recognize and alarm for prolonged central apnea and for the central component of mixed apnea if it lasts longer than 15 seconds. It is equally important that the equipment not create a false impression of illness by an excessive number of alarms or poor signal processing.

Despite the problems in interpreting the signal as an indication of respiratory effort (Yount et al. 1986), there will be a continuing demand to record the respiration signal as a means of documenting monitor responses and estimating the stability of infant behavior. The electronics that amplify, filter, and stabilize the signal vary in relation to efforts to optimize the alarm circuitry, and they can significantly change the appearance of the signal, obscuring or changing the appearance of the pattern of respiratory effort. It would seem appropriate to define a standard diagnostic means of signal processing that would be analogous to the standards for diagnostic ECG devices (Association for the Advancement of Medical Instrumentation 1983) as distinct from ECG monitors (Association for the Advancement of Medical Instrumentation 1984a). This is an obvious and urgent need, given the current pattern of clinical practice in using monitors as the source of pneumograms and the wide variety of signal processing techniques used by manufacturers.

Accurately determining when an infant has become stable enough to need a monitor no longer depends on accurate equipment with a low incidence of false-positive alarms and absolutely reliable apnea detection. Also necessary are good education of clinical staff, parents, and medical equipment distributors and a social services support system. The best equipment can be misused in ways that defeat its design goals. A major frustration to clinicians, engineers, and manufacturers is that insufficient research and communication have resulted in the creation of devices with wide variations in design, signal reproduction capacity, and reliability in both the hospital and home environments (ECRI 1974, 1980, 1987; Bowman and Yount 1987).

Some infants can be monitored by heart rate changes alone with reliable recognition of all apneas of significant duration. Others can become cyanotic during prolonged central apnea without even a short bradycardia. A few infants exhibit mixed or obstructive apnea producing hypoxia without any early useful pattern change in either heart rate or breathing effort and must be assessed by more expensive and complex airflow or oxygen monitors.

It is not generally expected that any one 15- to 20-second cessation of respiration will produce death, but

such an episode represents an exceptionally long interval for a very young infant to stop breathing under involuntary control while asleep. It is assumed that the tendency to have recurrent apnea must be detected accurately and observed until it is clear that the infant has matured safely and no longer has recurrent episodes with sleep disturbances and respiratory illnesses. A number of clinical studies suggest that the abnormality may return or become frequent during a respiratory illness or other mild stress and may produce progressive, damaging hypoxia and hypercarbia. These changes in body chemistry do not stimulate vigorous respiratory activity or arousal in some apnea-prone infants (Hunt 1981; Hunt et al. 1981; van der Hal et al. 1985) and may produce progressive hypercarbia with acidosis severe enough to cause a total cardiorespiratory arrest.

Respiratory effort is expressed through two skeletal muscle groups. The main effort comes from the diaphragm and accounts for at least 80% of the most effective breaths in quiet sleep and essentially all effective ventilation in REM sleep (Honma et al. 1984; Duffty et al. 1981). The intercostal muscles may work in or out of phase with the diaphragmatic effort, depending on the sleep state. Diaphragmatic fatigue has been implicated as a potential source of physiologically significant apnea in low-birth-weight infants (Muller et al. 1979; Lopes et al. 1983) and may be an important mechanism in other age groups as well (Bellemare and Grassino 1982).

Two infants connected to a thoracic impedance recording unit were reported to have manifested bradycardia first and then recognizable apnea. This difference in behavior may be due to the more limited capacity of the thoracic impedance signals to reflect accurately the volume of effort when intercostal activity persists with diminished or absent diaphragmatic effort. According to careful multichannel records, four full-term infants were observed to have prolonged central apnea at the diaphragm associated with small intercostal movements that were functionally inadequate but appropriately detected by thoracic impedance circuitry as respiratory efforts (Yount, personal communication, 1988). Two of these children died of SIDS when the home monitor was inadvertently turned off overnight. Medical personnel and the families reported only transient bradycardia without apparent central apnea during the several weeks of monitor use prior to the infants' deaths. During most of these recorded events, the infant's heart rate fell to a plateau no less than 85 to 90 BPM from a resting value higher than 120 BPM. These cases may reflect an inherent limitation in the use of thoracic impedance as a measure of infant respiratory behavior prior to some SIDS events, and they illustrate the complexity of defining an arbitrary level of bradycardia based only on infant age.

Despite relatively large numbers of recorded respiration sampling in healthy full-term infants, no cessation of diaphragmatic effort lasting longer than 15 seconds has been recorded after two weeks of age. The significance of unusually long apneic behavior in any given infant is unknown. In a recent study, more than 100 infants, aged 37 weeks postconception and older, were documented initially to have a record of abdominal activity showing central, mixed, or obstructive apnea of at least 15 seconds' duration that was either spontaneously resolved or required only simple stimulation (Yount and Lewman 1987). Of these infants, eight later died of apparent SIDS when taken off the monitor by parents and physicians not following the apnea program guidelines.

Most apnea-prone infants exhibit the behavior with decreasing frequency and eventually tolerate respiratory illnesses and disturbances in sleep that were previously associated with increased apnea of significant duration. A few of these infants continue to have central apnea after sighing that lasts longer than 15 or 20 seconds. As they reach sufficient body size and their oxygen consumption diminishes, they maintain an acceptable oxygen level during these "abnormal" episodes without breathing and are no longer at significant risk of decompensation during episodes of stress. It is important that both the majority of totally normal infants and this small subgroup with persistent benign apnea be safely weaned from the monitor, and it is at this time that a manageable balance in the false-positive alarm rate is essential. After months of devoted response to alarms, the parents of an apnea-prone infant often need counseling and reassurance that it is safe to discontinue the monitor.

Because of the inherent problems associated with avoiding both false-positive alarms and unrecognized

apnea, most equipment is designed and used so that some false-positive alarms are accepted in order to try to guarantee that the device will never fail to recognize central apnea. Increasingly, there are efforts to record respiration continuously at home and in the hospital using the signal from the bedside thoracic impedance monitor. There is more and more evidence that some false-positive apneas are caused by amplitude changes in the signal and do not represent real changes in the baby's minute ventilation. In some cases, these amplitude changes may be due to changes in skin contact and a slow response from the saturated amplifiers. In some infants, very adequate diaphragmatic effort is obvious with abdominal sensors and virtually absent on the thoracic impedance signal. During these intervals, the cardiovascular waves in the thoracic impedance signal may be equal to or larger than the respiratory waves, despite unchanged or very adequate tidal volume and minute ventilation (Figure 9).

5.3.1 Simple Threshold Detection. The occurrence of a breath can be registered by notation of the times at which the respiration signal crosses a predetermined threshold level. This level must be well-chosen because the amplitude of respiration can vary, as illustrated in Figure 6. Figure 10a shows an example of fixed-threshold respiration detection. A breath is indicated whenever the signal exceeds the threshold value. The threshold value should be high enough so that noise and baseline artifact do not cross it and erroneously indicate a breath, but it must be low enough so that the monitor will detect low-amplitude breaths and not falsely indicate apnea. It is difficult to meet these requirements with a fixed threshold, so other techniques are preferred.

5.3.2 Automatic Gain Control. The fixed-threshold method of detection can be improved by preceding the detector with an amplifier that has an automatic gain control. This circuit causes the amplifier to vary its gain according to the signal strength at its input so that weak signals are amplified more than strong ones. In this way, it is possible to increase weak respiration signals so that they will cross a relatively high-level fixed threshold. Although this method makes the fixed-threshold detection scheme more reliable, it increases the risk that the automatic gain control will amplify the respiration signal during an apnea, thereby making cardiogenic artifact or noise much larger. This can cause a "breath" to be recognized incorrectly.

5.3.3 Adaptive Threshold Detection. Some of the problems of fixed threshold detection can be overcome using an adaptive threshold. In this case, the machine determines the threshold level by looking at the amplitudes of previous breaths. Figure 10b illustrates how this works. The threshold level is a fixed fraction of the peak amplitude of the previously detected breaths. Because this threshold may still be too high if the previous breath had a large amplitude and if subsequent breaths are of relatively low amplitude, this threshold is not fixed but decreases slowly with time, enabling the system once again eventually to detect low-amplitude breaths and to reset the threshold level. The risk with this type of system is that the threshold will eventually drop low enough for the system to detect noise or cardiogenic artifact during an apnea and will cause the monitor to identify a breath incorrectly; in that case, the machine will not determine the correct apnea duration.

5.3.4 Peak Detector. The peak of the breathing signal waveform is recognized by the peak detector regardless of the amplitude of the signal (Figure 10c). This detection method recognizes when the signal increases and when it reaches its maximum value before beginning to decrease. The basic peak detector can recognize more than one peak in a complex respiration wave, as illustrated in Figure 10c, which can cause the measured respiration rate to exceed its actual value.

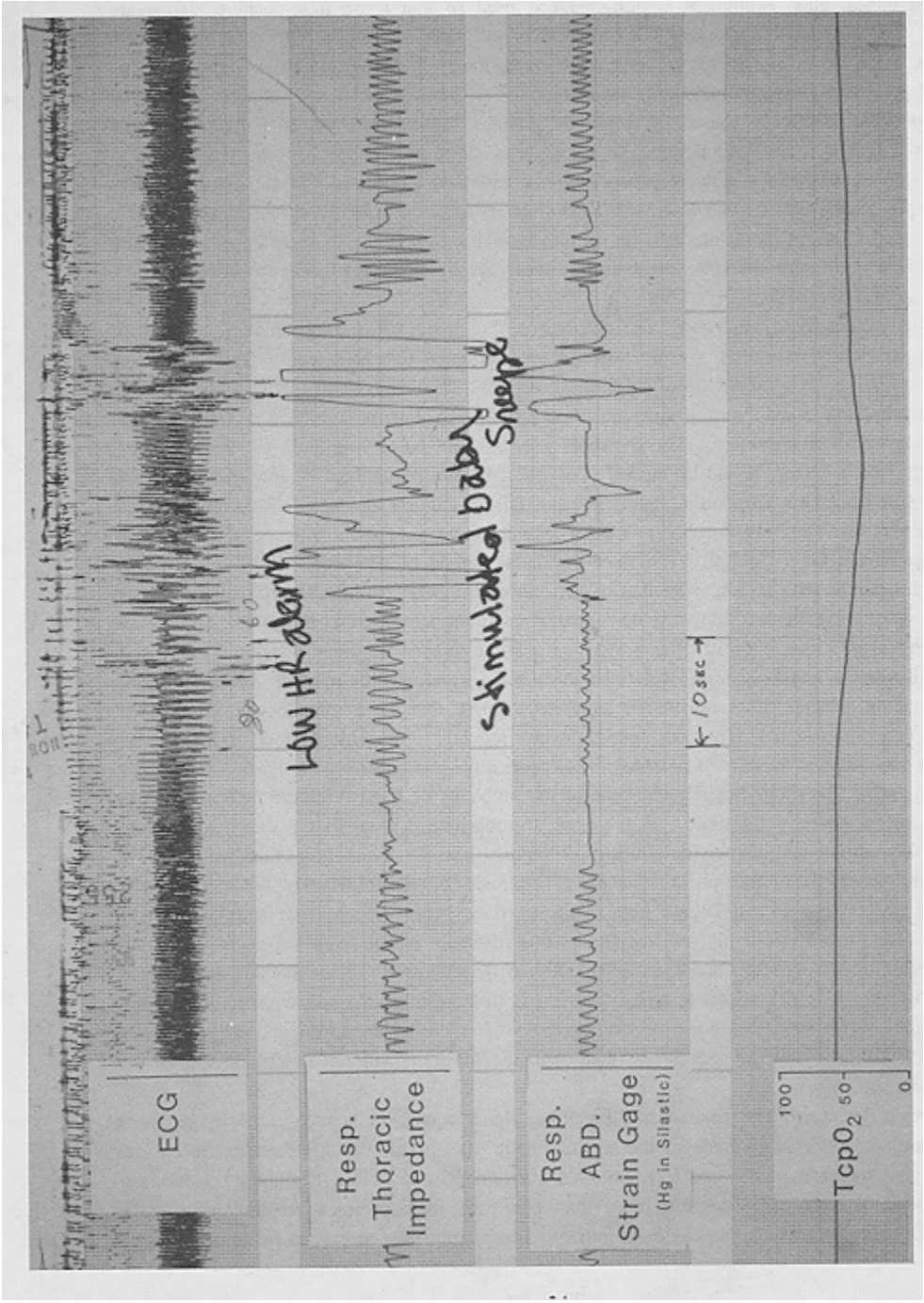

Figure 8. Mixed apnea. The interpretation of the child's thoracic activity seems to be transducer-dependent. When the thoracic impedance signal is analyzed, the behavior appears obstructed. When the abdominal strain gauge is analyzed, a central pause can be seen at the beginning of the episode so it would be classified as a mixed apnea. The respiratory effort includes a major shift in the direction and amplitude of the thoracic impedance signal with a simultaneous reduction at the abdominal strain gauge signal.

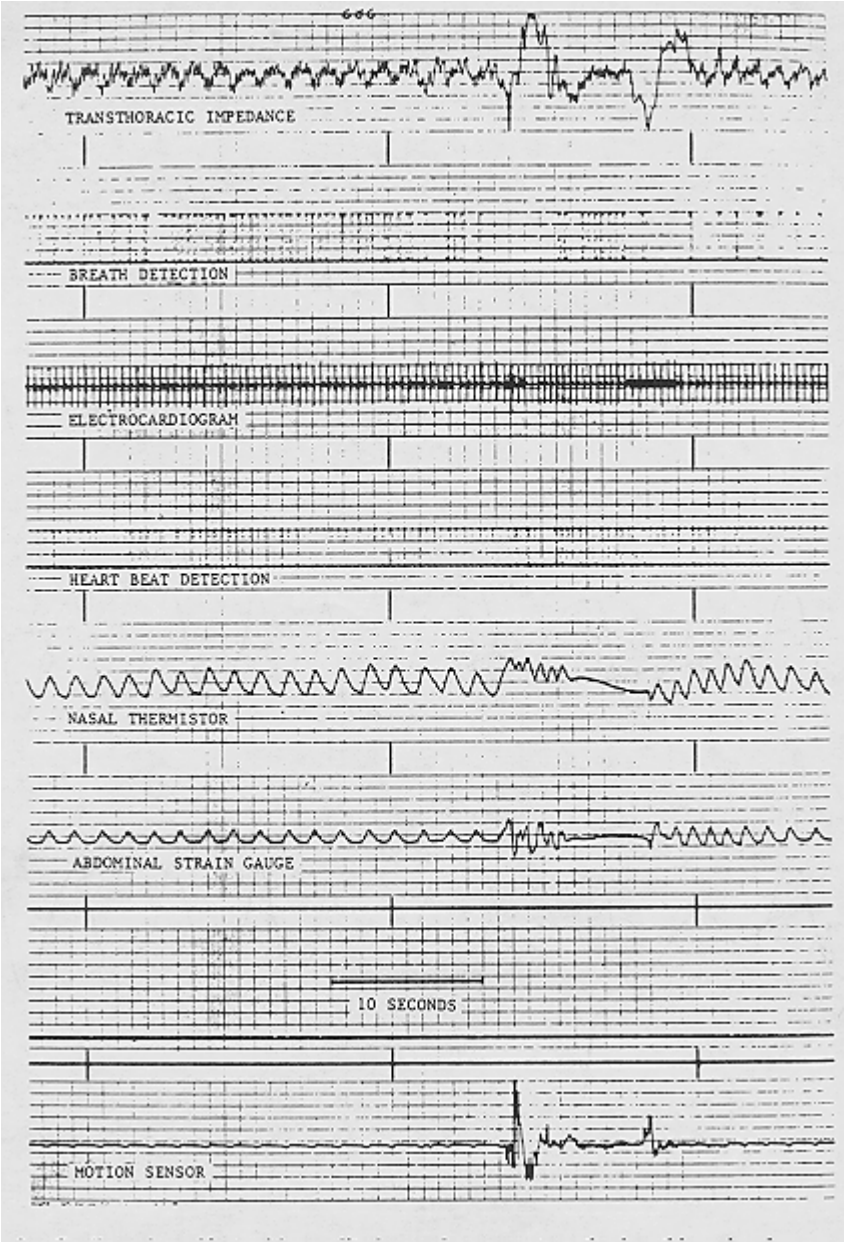

Figure 9. Cardiogenic artifact with amplitude nearly as great as the breathing signal can appear on the transthoracic electrical impedance signal while not appearing on simultaneously recorded nasal thermistor or abdominal strain gauge signals. Note the differences between these three signals during the 5-second apnea. (Reprinted from: National Institutes of Health. Infantile apnea and home monitoring. Bethesda, MD: NIH; 1987)

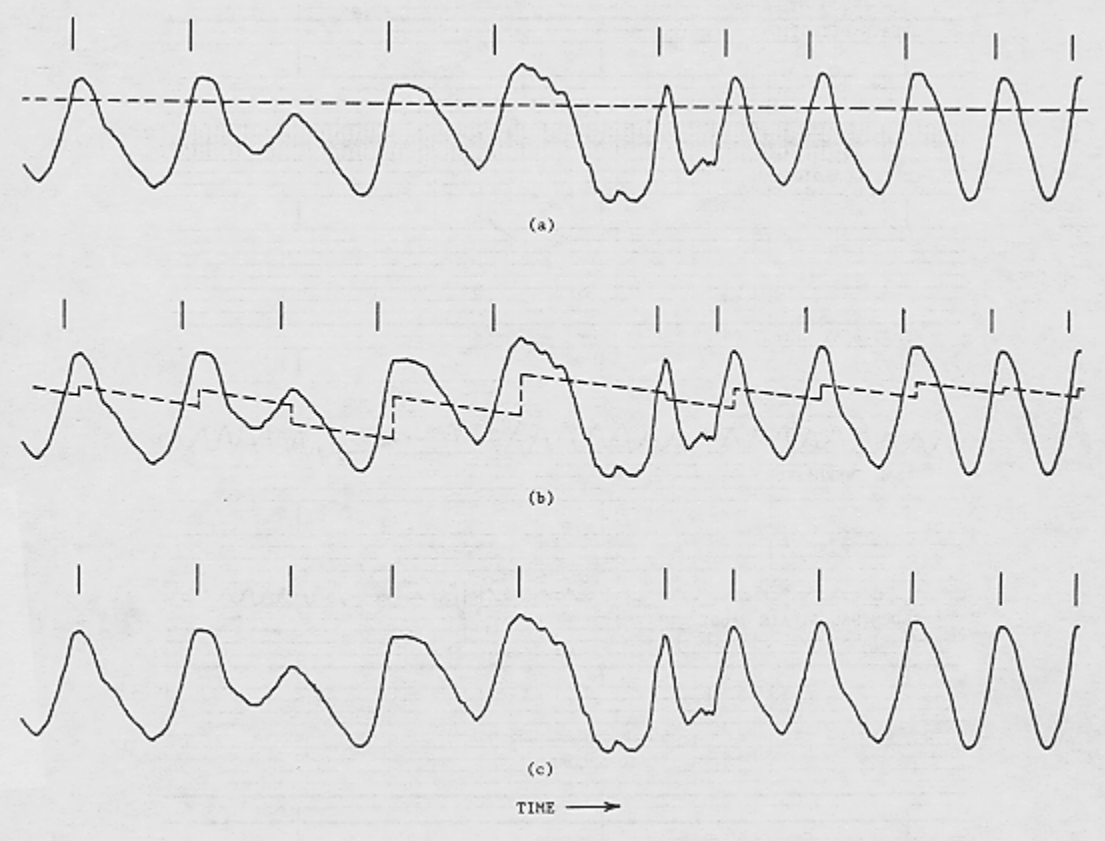

Figure 10. Examples of three different methods of breath detection used in infant apnea monitors: (a) fixed threshold crossing; (b) adaptive threshold crossing; and (c) peak detection. (Reprinted from: National Institutes of Health. Infantile apnea and home monitoring. Bethesda, MD: NIH; 1987)

5.3.5 Filtering. Frequency domain analysis* of an infant respiration signal reveals that most of the information is contained in the frequency band of 0 to 6 Hz. Because artifactual signals can exist outside this frequency range as well as within it, most apnea monitors filter the respiration signal so that only the frequencies containing information are processed. This filtering can distort the waveform and introduce artifact that can affect breath detection. Figure 11 shows a respiration signal taken from an impedance apnea monitor before and after filtering. The rapid changes of the unfiltered signal are not seen in the filtered signal. This phenomenon can be better illustrated by introducing an impedance step into the apnea monitor by means of a respiration simulator. The step is sharp in the unfiltered signal but smooth in the filtered one. Sometimes such a step, when filtered, can fool a monitor into indicating that a breath has been taken.

5.3.6 Pattern Recognition. Microprocessor electronic circuitry allows the foregoing techniques and others to be applied to recognition of breaths in the sensor output signal (Laxminarayan et al. 1983). Microcomputer pattern recognition algorithms can be designed to recognize threshold crossing, peaks and valleys, and the slope, amplitude, width, and interval of respiration wave. More sophisticated algorithms can be trained to recognize breaths that appear similar to preprogrammed waveforms. Another important aspect of computer recognition of patterns is that the computer can be programmed to ask questions such as: Is the measured value physiologically possible? Does the waveform look more like artifact than information? Is the rate too fast? Does the signal correspond so closely with the cardiac cycle that it might be cardiogenic artifact? Is there more than one peak per breath? Is the signal similar to previous breaths seen from the patient? In the future, with expert systems and artificial intelligence, it should be possible to train a computer to read respiration signals in the same way that a well-trained human does.

All of the preceding techniques have advantages and disadvantages in detecting breaths. Each method

imposes constraints on the signal that determine whether artifact will be detected or breaths missed. Even the sophisticated computer methods suffer from faults such as these and present limitations in breath detection. It is, therefore, important that the method of breath detection used in an apnea monitor be known to the clinicians who apply the monitor. In this way, they can recommend monitors that use the signal-processing techniques most appropriate for a particular patient.

5.3.7 Cardiogenic Artifact. The volume of the heart varies during the cardiac cycle, so the contribution of the blood to the overall transthoracic impedance will change from systole to diastole. To a lesser extent, the vascular compartment of the chest wall and lungs also change in blood volume during the cardiac cycle; this influences the transthoracic impedance as well. This influence is illustrated in Figure 12, which shows a recording of transthoracic impedance from an infant during breathing and during a period of apnea. The cardiogenic artifact is best seen during apnea, where it appears as small impedance variations occurring at the heart rate. It is also present, however, during breathing and appears as a modulation of the respiration waveform. In Figure 6, the cardiogenic artifact is relatively small compared with the impedance changes caused by breathing, and it is possible to differentiate between breathing and apnea by observing the record. This is not always the case when recording transthoracic impedance.

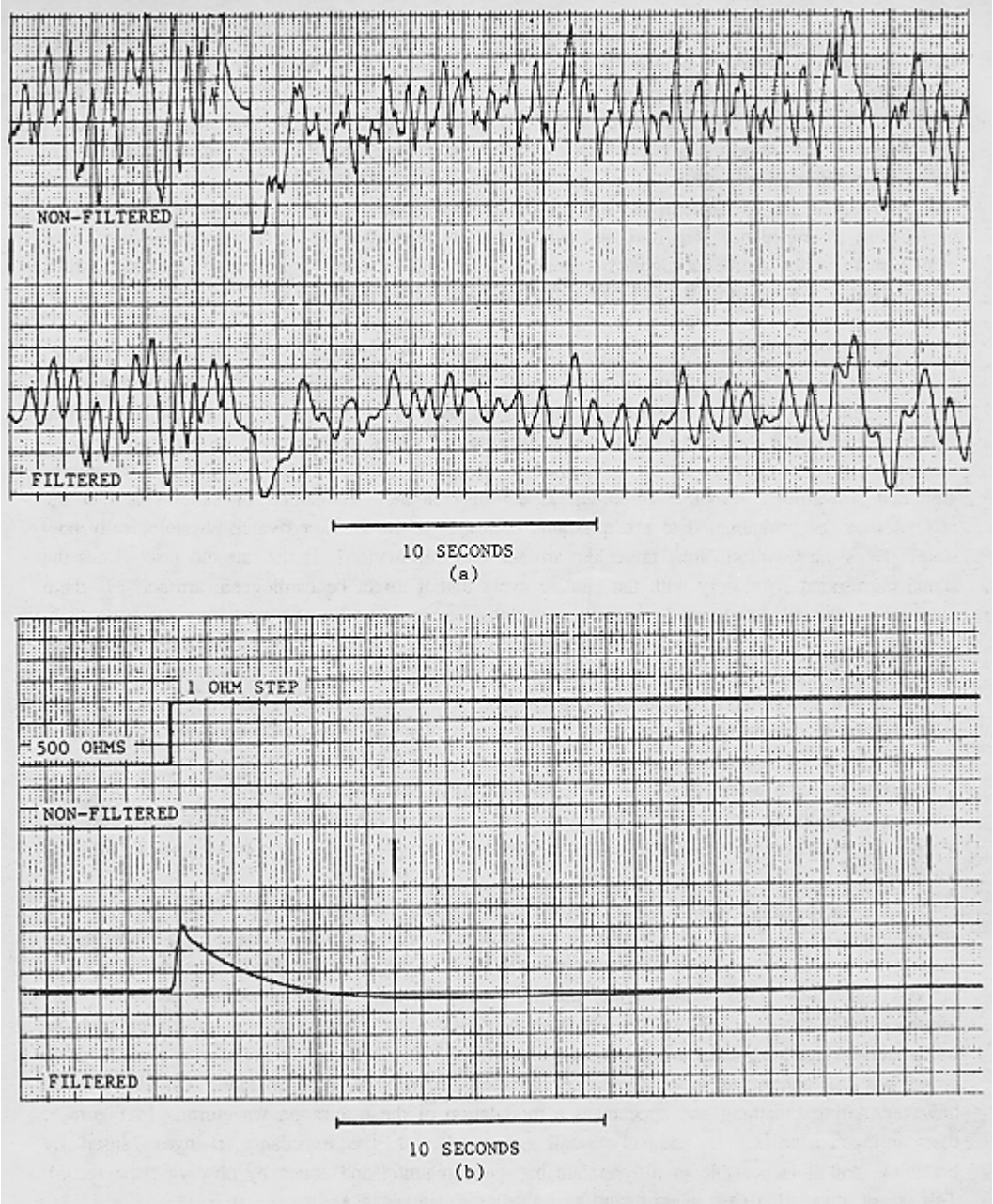

Figure 11. The effect of filtering on respiration signals: (a) noise reduction and (b) step response of a filter. (Reprinted from: National Institutes of Health. Infantile apnea and home monitoring. Bethesda, MD: NIH; 1987)

Figure 9 illustrates periods of breathing and apnea in which the cardiogenic artifact is so strong that it is difficult to determine which impedance variations are caused by breathing and which by cardiogenic artifact. These two sources of transthoracic impedance variation can be distinguished only when the recording is compared with the ECG and with simultaneous recordings of other respiration sensors, such as an abdominal strain gauge or nasal thermistor. It can be seen that in this case the cardiogenic artifact consists of two components during each cardiac cycle.

Although cardiogenic artifact is a major problem in measuring breathing efforts by the transthoracic electrical impedance method, this interference can be seen at times in the output from almost every direct-method sensor. Several methods have been used to deal with cardiogenic artifact in the transthoracic electrical impedance type of apnea monitor. Cardiogenic artifact occurs at the heart frequency and its

harmonics, whereas the principal component of the breathing signal is at the respiration frequency. In infants, the heart frequency is often higher than the respiration frequency, although this is not always the case. If the respiration signal with cardiogenic artifact is passed through a low-pass filter (that is, a filter that removes high frequencies from a signal), the cutoff frequency of which is higher than expected respiration rates but lower than likely heart rates, much of the cardiogenic artifact can be removed without seriously distorting the respiration signal. The problem with this approach is the selection of the cutoff frequency for the filter. A frequency that is higher than the maximum respiration rate and less than the minimum heart rate is generally not to be found; estimates of such a frequency have to be changed according to infant age. Also, because bradycardia can be associated with apnea, the heart rate might drop below the filter cutoff frequency during times of apnea, allowing cardiogenic artifact to get into the respiratory channel just as it should be avoided (Figure 13).

Low-pass filtering does have merit if the above limitations can be taken into consideration in the design of the filtering system. Although a filter cannot be useful when the heart rate is less than the respiration rate, a filter can help if its cutoff frequency can be determined on the basis of the apparent respiration and heart rates of the infant. Such adaptive filtering techniques have been used successfully in commercial monitors.

Because most transthoracic electrical impedance-type apnea monitors also determine heart rate from the ECG, the cardiac signal can be used to help identify when a respiration signal consists principally of cardiogenic artifact. The time relationship between the cardiogenic artifact and the ECG varies from patient to patient and depends on heart rate (Yount and Neuman 1985). It is possible to detect the association between the ECG and cardiogenic artifact using microprocessor-based algorithms or rate-comparison circuitry. If the respiration signal consists only of cardiogenic artifact, as would be the case during a period of apnea, an electronic circuit could recognize that fact and disable the breath-detection circuitry so that the artifact is not mistaken for breaths. This approach has also been used in commercial monitoring devices. It, too, has limitations because an infant could breathe at the same rate as the heart beats, as illustrated in Figure 14. If one were to look at the signal from the transthoracic impedance channel alone, one might identify a period of apnea at the point where the respiration rate increases to be the same as the heart rate. This signal looks very much like cardiogenic artifact, and one might be fooled into thinking that it is indeed artifact, even though there is no cardiogenic artifact on the breathing signal before and after this segment.

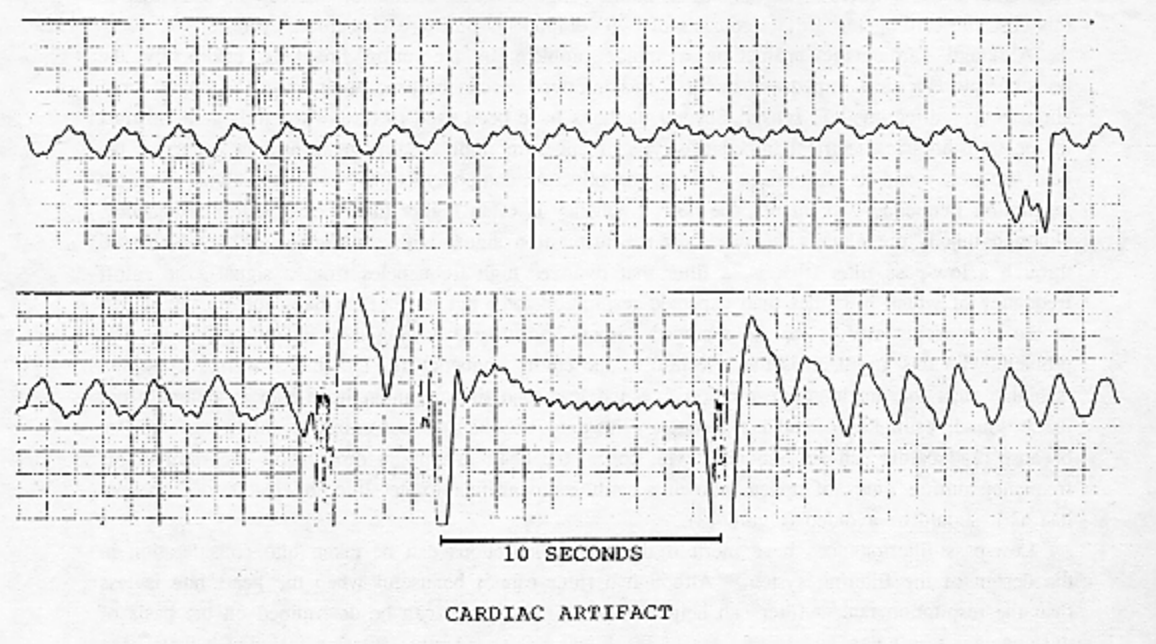

Figure 12. Examples of cardiogenic artifact in a transthoracic electrical impedance respirogram. The top tracing shows how cardiogenic artifact makes low-amplitude breathing signals difficult to interpret. The bottom tracing shows the appearance of cardiogenic artifact during a brief apnea. (Reprinted from: National Institutes of Health. Infantile apnea and home monitoring. Bethesda, MD: NIH; 1987)

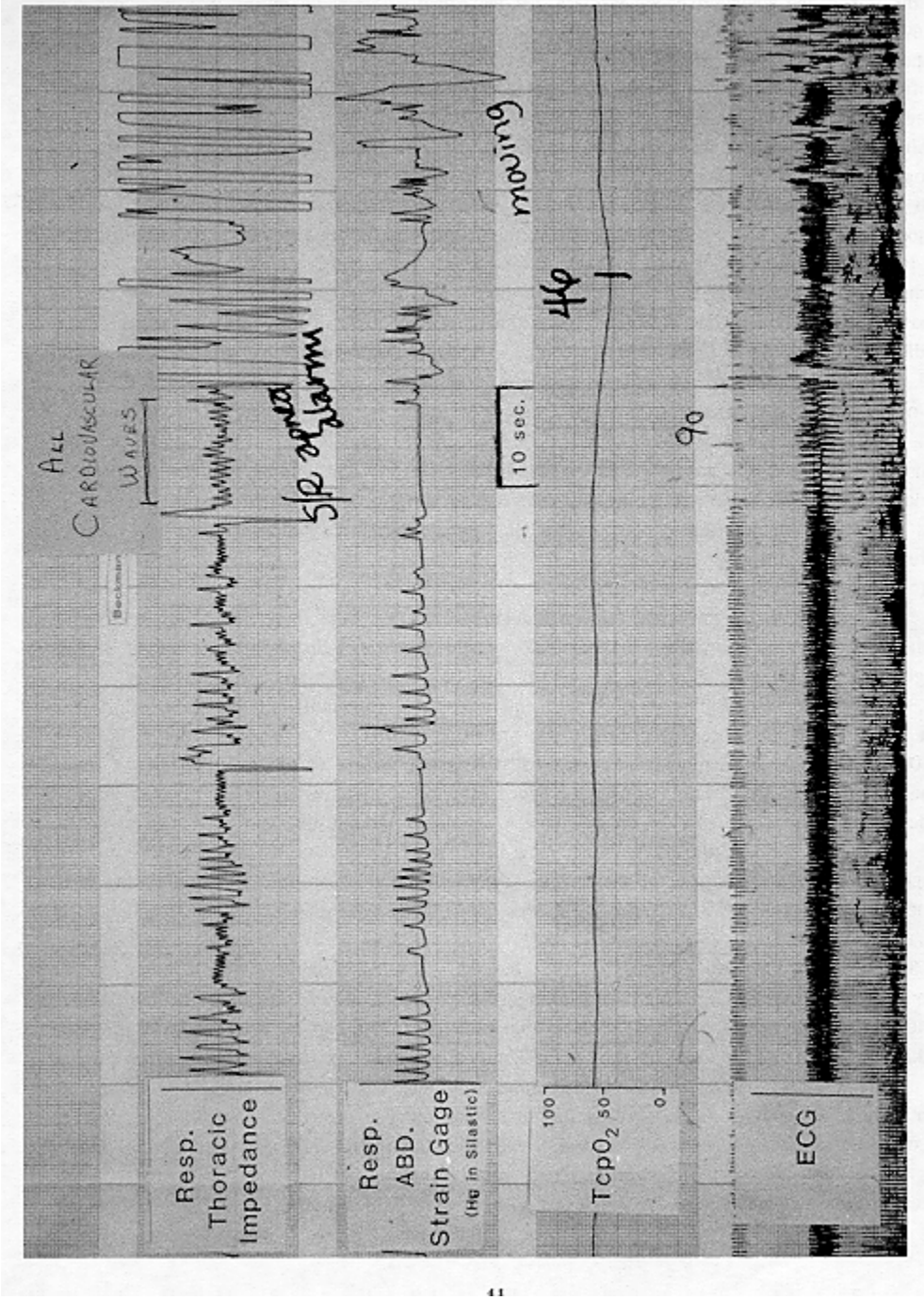

Figure 13. An example of a 90-BPM heart rate change, a drop in oxygen level to 46, and a major increase in cardiovascular waves.

When the abdominal strain gauge or nasal thermistor information is included on the chart along with the impedance signal, it becomes clear that the infant is breathing during this episode but at an elevated rate. A transthoracic electrical impedance monitor was tested on this signal, and Figure 14 shows the respiration detection signal from the monitor. This device was deceived into identifying the high respiration rate as cardiogenic artifact and therefore did not respond to most of the breaths during this episode.

Although each of the above methods of signal processing can help eliminate the effects of cardiogenic artifact, none completely removes this interference. Consequently, there are situations in which cardiogenic artifact can still cause false triggering of the respiration detection circuitry in the monitor. Figure 15a and

Figure 15b show the failure of a $5,000 hospital monitor to detect both what looks like central apnea with bradycardia and short apnea within periodic breathing. Figure 15c shows a monitor in a neonatal intensive care unit triggering on cardiovascular waves because of the baseline undulation produced by an "apnea treatment" mattress. The mattress clearly causes a periodic false triggering at exactly the frequency at which it was "stimulating" the body to prevent apnea. This device prevented only the apnea alarm.

None of the signal processing techniques described in the previous paragraphs is 100% efficacious. Actual breaths are sometimes missed, and breath detectors sometimes recognize phantom breaths during periods of apnea. Cardiogenic artifact can still get through circuits designed to eliminate it. Even so, some monitoring systems seem to perform better on one type of signal while others do better with a different signal. Particular circumstances may dictate use of one type of monitor and signal processor over another. It is important, then, for the clinician prescribing apnea monitoring equipment to understand the differences between signal processing techniques and to choose the monitor most appropriate for a particular patient, thus minimizing false alarms. For the clinician to obtain this knowledge, the recording system should not distort the physiologic signals through excessive filtering, automatic gain control, and limited amplifier frequency response.

5.3.8 Secondary Measures of Apnea. Primary methods of ventilation, breathing effort, and apnea measurement have been described in the preceding sections. As previously noted, they are not 100% efficacious and can indicate apnea when it is not present or fail to alarm during actual apnea. To improve the overall efficacy of apnea monitoring systems, many instruments monitor and determine alarm conditions for an additional physiologic variable that can be related to apnea. These techniques involve the measurement of heart rate, transcutaneous oxygen tension, and hemoglobin oxygen saturation. Of these three, determination of heart rate is currently the most commonly used, but noninvasive pulse oximetry is rapidly increasing in experimental and clinical applications.

5.3.8.1 Heart Rate Monitoring. During thoracic impedance monitoring, the heart rate is determined from the ECG. Heart rate monitors are almost always included in transthoracic electrical impedance apnea monitors, because the same electrodes can be used for measuring the transthoracic impedance and picking up the ECG. In apnea monitors based on other types of sensors, the ECG is also frequently used to determine heart rate, but additional electrodes are needed. Recently, monitors using a motion-sensing pad under the infant to detect breathing movements have been designed to pick up heart rate as well. Such monitors detect the ballistocardiogram (movements of the infant due to the ejection of blood from the heart), and techniques to separate cardiac and respiratory movements may be developed to a level at which useful results can be obtained constantly. The simple separation in infants of heart rate and breathing is always complicated by the wide overlapping range of rates that can occur in normal and abnormal behavior.

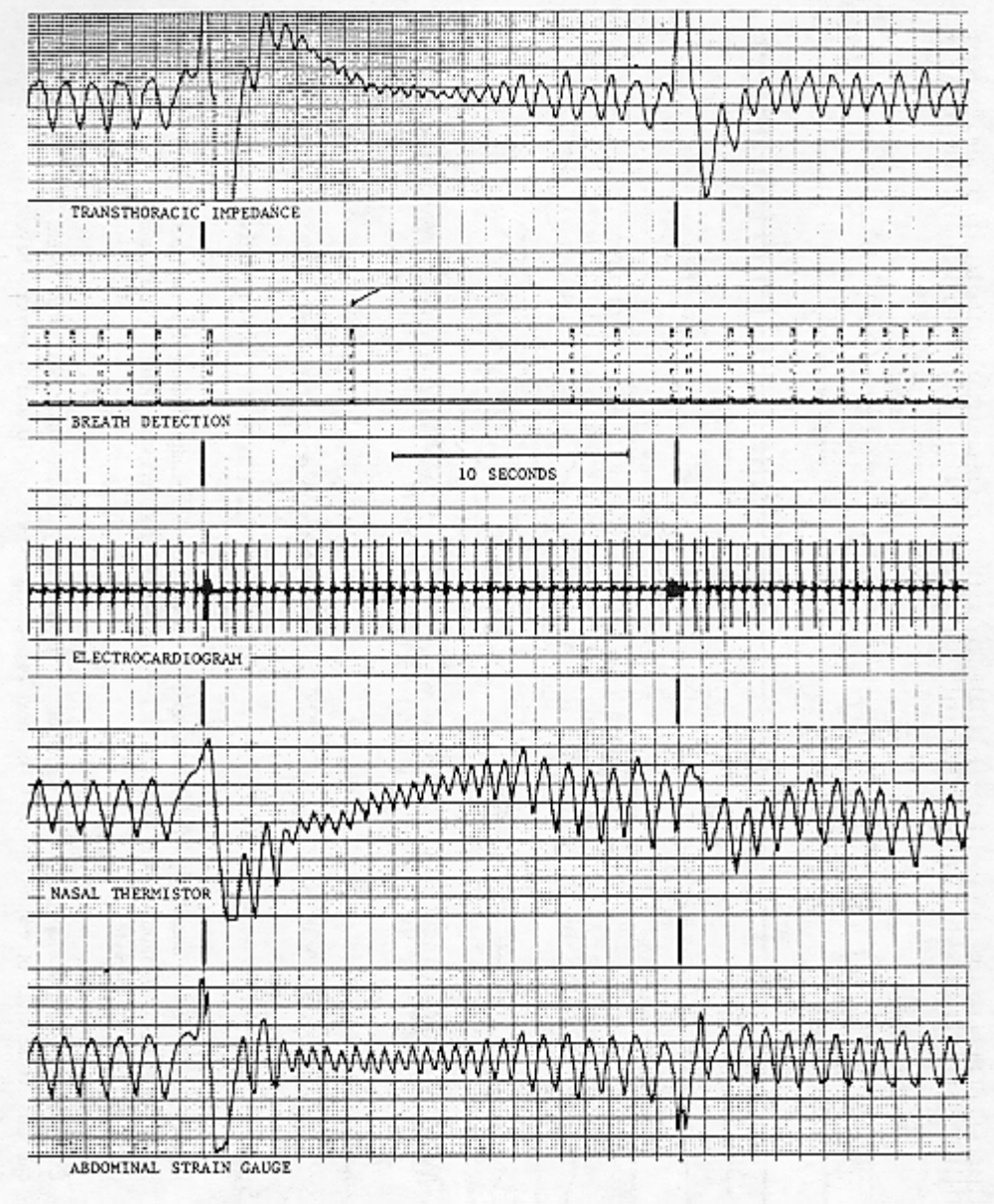

Figure 14. An example of a breathing episode in which the monitor is deceived into identifying rapid shallow breaths on the impedance signal as cardiogenic artifact because they occur at the heart rate. Examination of the simultaneously recorded nasal thermistor and abdominal strain gauge signals show these unusual patterns to be actual breaths. (Reprinted from: National Institutes of Health. Infantile apnea and home monitoring. Bethesda, MD: NIH; 1987)

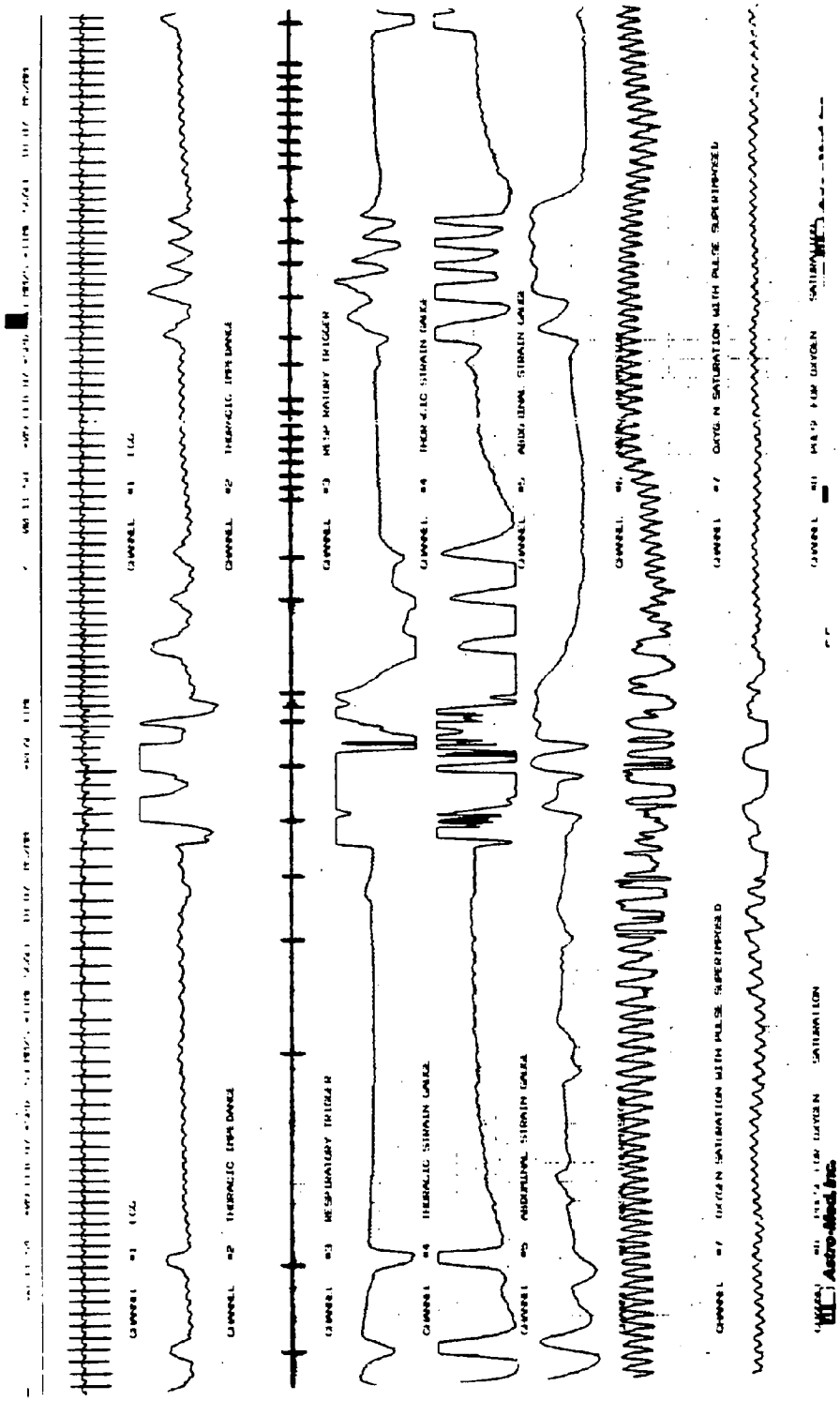

Figure 15a. A $5,000 hospital monitor misses apnea with bradycardia. Elapsed time--1 second per 5 mm (large box). A monitor fails to detect a 21-second mixed apnea episode, despite a heart rate of 60 to 70 for 10 seconds.

Example of two respiration triggers for extremely small respiratory efforts--many physicians would call this 21 seconds of central apnea. The next two central apneas of 10 and 9 seconds have multiple false triggers.

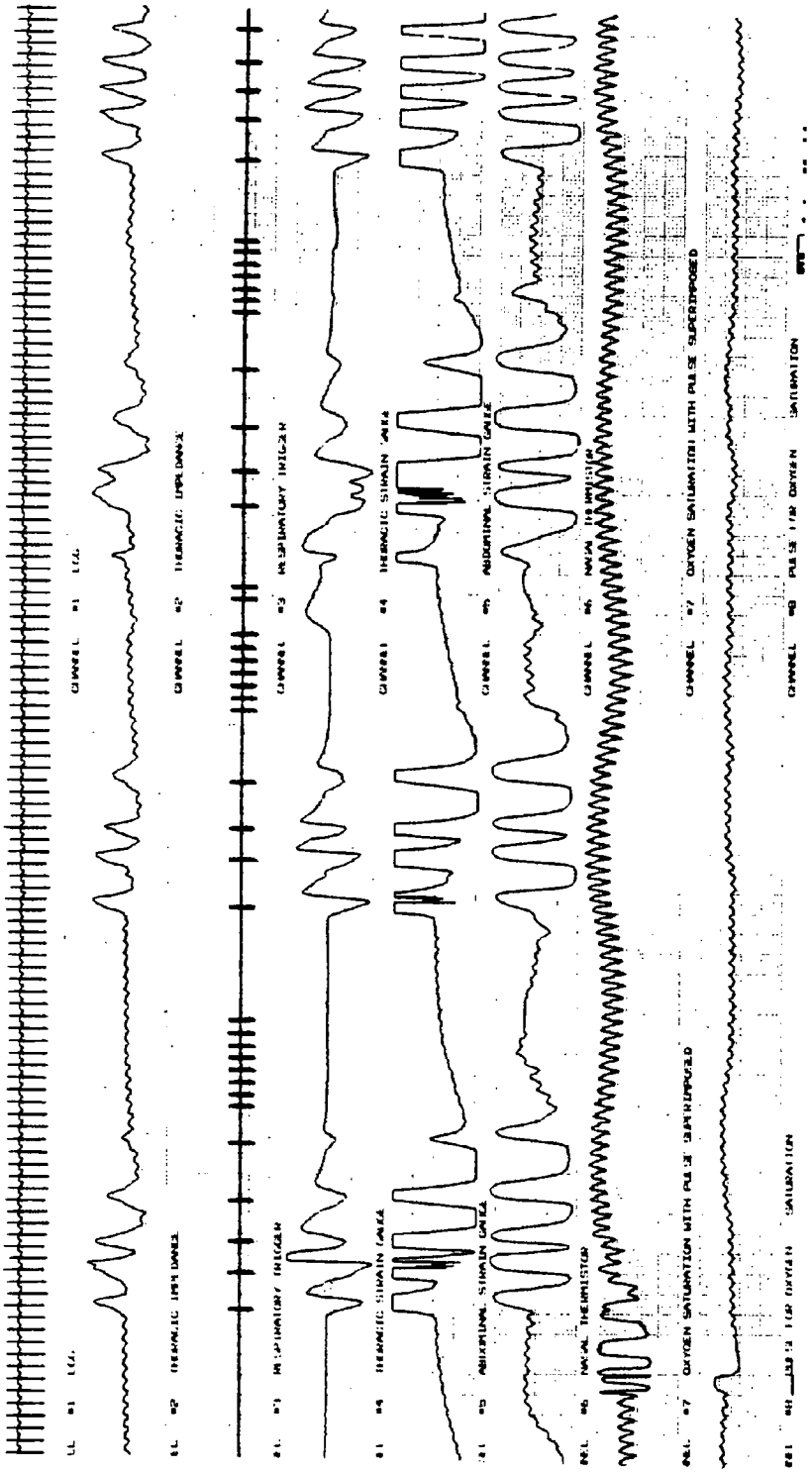

Figure 15b. The failure of a monitor to detect the short pauses (8 to 10 seconds) of periodic breathing. Pulse saturation drops 12 to 15% with each pause.

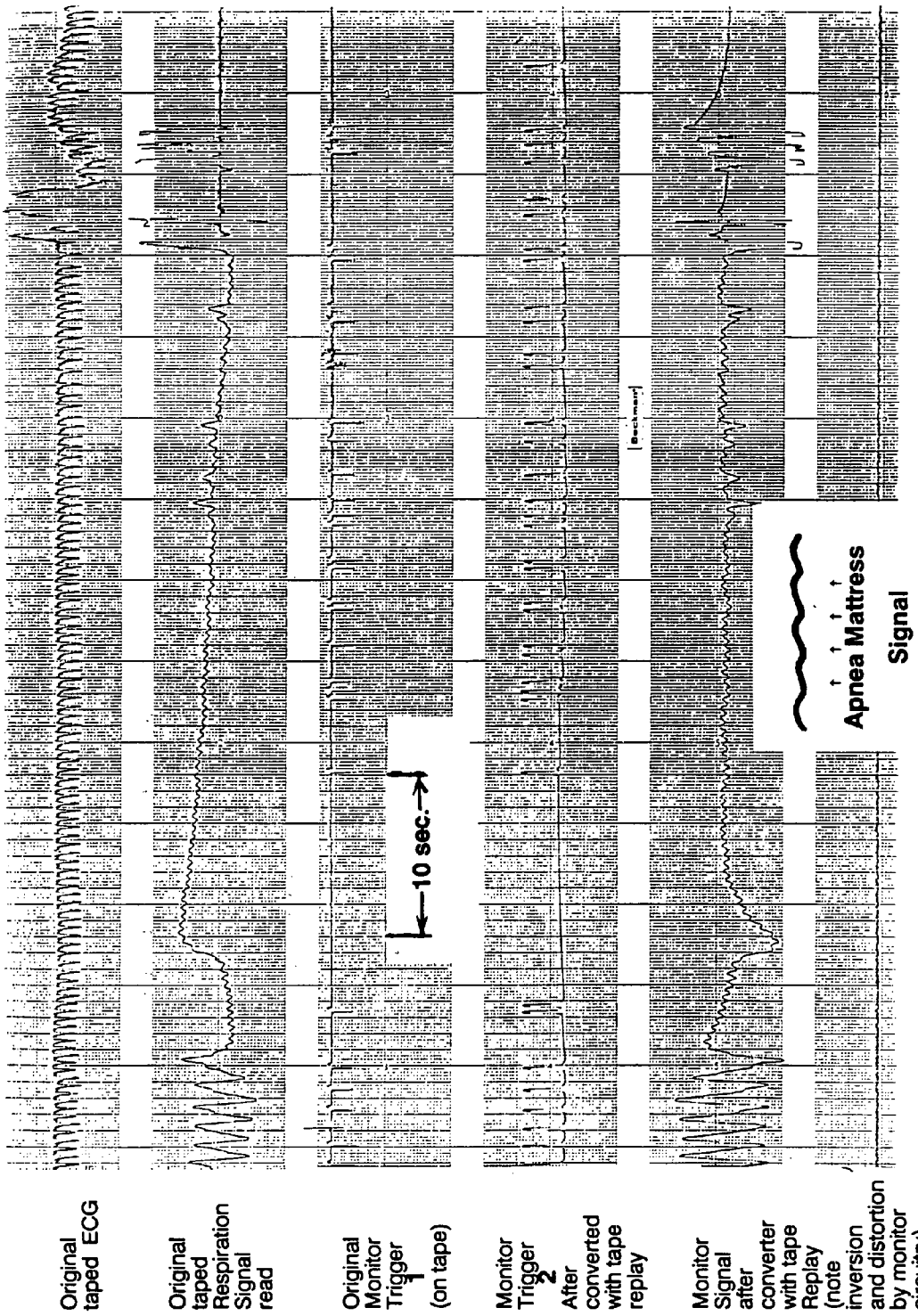

Figure 15c. This example illustrates the subtle effect of an undulating apnea treatment mattress causing very slight baseline changes on the respiration record that were falsely recorded as breaths, both as originally when recorded with the breathing signal and when the signal was replayed through the voltage-to-impedance converter.

The input of an ECG type of heart rate monitor connects to the chest electrodes, and a filter circuit separates the ECG from the electrical impedance excitation voltage (Figure 16). This filter can be a simple, first-order, low-pass filter because the frequencies contained in the ECG are considerably lower than those used for transthoracic impedance measurement. It is important that all monitor circuits connected to the electrodes present a high-input impedance, whether at the impedance excitation frequency or the ECG frequencies, so that there is no loading of the electrodes. This will minimize motion artifact and signal distortion.

The ECG is amplified and passed through a band-pass filter to create a signal that can be processed to determine heart rate. The filter helps minimize the amount of artifact in the electrical signal by passing those frequencies of the ECG that are primarily related to the QRS complex. This process distorts the configuration of the ECG but makes heart rate detection more reliable. A simple fixed-threshold detector or peak detector similar to those described for respiratory signal processing can then be used to determine the occurrence of a QRS complex.

A cardiotachometer circuit measures the rate at which the QRS complexes occur. Many apnea monitors use an averaging cardiotachometer; this circuit determines the average number of heart beats per predetermined interval, which can range from as few as 3 to more than 15 heartbeats. An instantaneous beat-to-beat cardiotachometer determines the heart rate for each R-R interval; this type of cardiotachometer must be used when it is necessary to determine the beat-to-beat variability of the heart rate. The output of the cardiotachometer is a signal proportional to the heart rate in BPM.

The alarm system in the heart rate monitor indicates when the heart rate has fallen below or risen above preset values. The alarm circuit compares the heart rate measured by the cardiotachometer with the upper and lower limits set by the monitor operator or previously programmed into the instrument. If the heart rate remains between these limits, no alarm condition occurs. If the heart rate is outside of the limits, the alarm is activated. The AAMI cardiac monitor standard specifies that the time to alarm should not exceed 10 seconds (Association for the Advancement of Medical Instrumentation 1984a).

False alarms can occur with heart rate monitors as they do with apnea monitors, although they are not nearly as frequent. False-positive tachycardia alarms are usually the result of artifactual signals that are erroneously counted by the cardiotachometer as R-waves and registered as extra "heartbeats," thus resulting in a falsely elevated heart rate. An artifact of this type can be the result of electrode polarization and motion. A layer of electrolyte ions builds up adjacent to the electrode surface on the skin; the motion of the electrode with respect to this polarization layer results in the relocation of electrical charge, which manifests itself as a signal on the electrode. There are two ways to avoid this problem. One is to minimize the buildup of the charge itself by using nonpolarizable electrodes, such as silver-silver chloride electrodes. The second is to design electrodes and their attachments to the infant so that relative motion between the electrode and the skin can be eliminated. Neither technique can in itself eliminate the problem, but both can reduce significantly the effect of artifact so that heart rates can usually be determined correctly when the patient is not extremely active.

In the present state of the art, heart rate monitors are more reliable than some apnea monitors. Some investigators believe that the monitoring of heart rate alone is sufficient to identify life-threatening conditions, and it has been recommended that all infant apnea monitors incorporate heart rate monitors (American Academy of Pediatrics 1985). Bradycardia is often associated with prolonged apnea and can easily be detected by cardiac monitors. Because heart rate monitors are less complicated than respiration monitors, they can be much less expensive as well. Work is needed to evaluate home monitors that measure heart rate only. There may be advantages in reliability and cost relative to the respiration monitors currently in use.

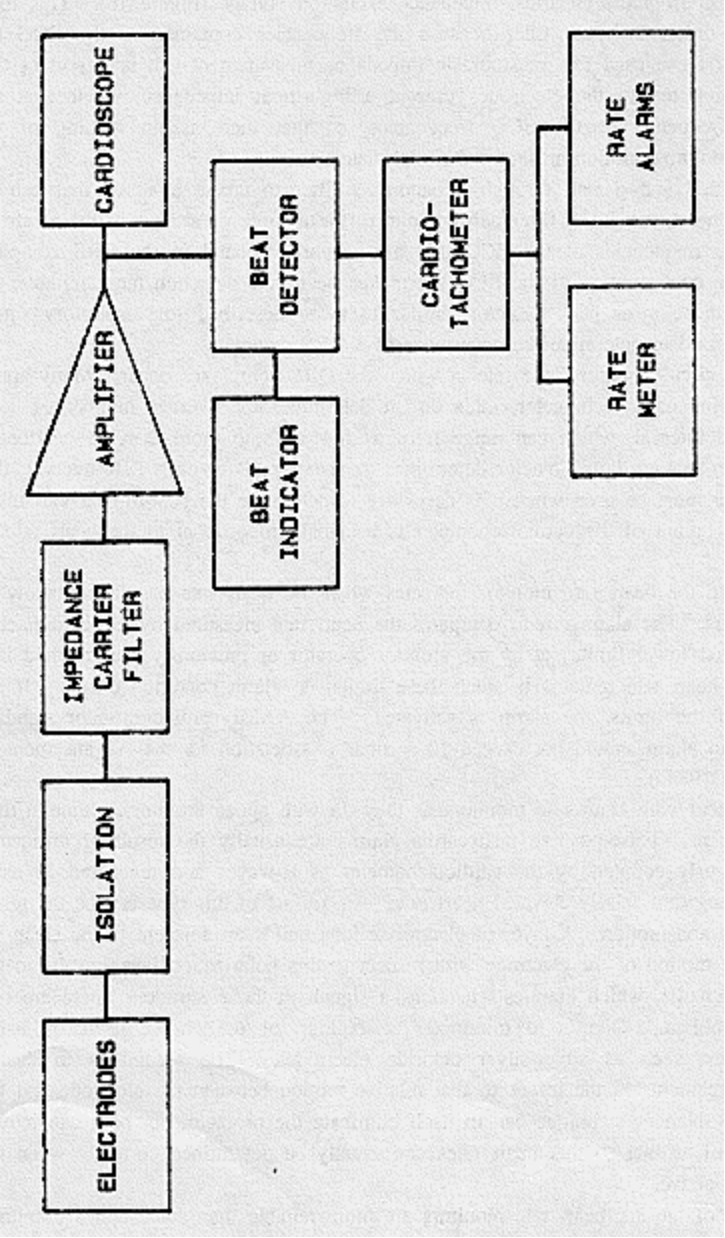

Figure 16. A functional block diagram of a cardiac monitor. (Reprint from: National Institutes of Health. Infantile apnea and home monitoring. Bethesda, MD:NIH; 1987.)

5.3.8.2 Transcutaneous Oxygen Sensors. The partial pressure of oxygen in the blood of the dermal capillary loops can be determined noninvasively by a transcutaneous oxygen sensor (Huch et al. 1981; Neuman et al. 1984). This sensor consists of an electrochemical Clark electrode placed in close contact with the skin. The membrane on the Clark electrode and the layer of skin between the dermal capillary loops and the sensor surface constitute an oxygen-permeable membrane. It is possible to determine the partial pressure of oxygen in the capillary blood from measurements of the cathode current of the Clark electrode. By heating the electrode and the region of skin around it to a temperature of 44°C, it is possible to increase greatly the perfusion of the dermal capillaries. This causes the capillary blood to be similar to the arterial blood supplying the capillaries, because the perfusion is greater than required for metabolic purposes. Thus, the oxygen tension in the capillary blood is similar to that of the arterial blood; in actuality, it is even higher than that of the arterial blood because of the increased capillary blood temperature caused by the heated sensor. The transcutaneous measurement of this partial pressure of oxygen has been found to correlate with central arterial oxygen tension in neonates.

Because apnea means that the lungs are no longer ventilated, the source of oxygen for the arterial blood decreases as apnea proceeds. By measuring arterial oxygen tension, it is possible to detect apnea through the recognition of the drop in oxygen tension. The major problem with the transcutaneous oxygen tension technique of apnea detection lies in the relatively slow response time of the transcutaneous oxygen sensor. It takes such a sensor 15 to 20 seconds to respond to a change in arterial oxygen tension. Because the arterial oxygen tension does not begin to drop immediately upon the occurrence of apnea, this technique can only be used to measure prolonged apnea and is not reliable for determining when apnea duration exceeds a preset period of time. The technique can be useful, however, in confirming apnea determined by primary measurements and in indicating problems when the primary measurement does not detect apnea. This technique can also be helpful in detecting drops in arterial oxygen tension due to hypoventilation.

There is a practical limitation to transcutaneous oxygen tension measurement. Because the sensor must be heated to 44°C to obtain good correlation with arterial oxygen tensions, it cannot remain in one location on the skin for more than four hours without the risk of skin damage. The need to move the electrode every four hours creates problems for home use of the technique. Some investigators have developed transcutaneous oxygen devices consisting of more than one sensor incorporated in the same package (Huch and Huch 1985). The electronic circuit switches between sensors every hour or two so that no one point on the skin is heated for a prolonged period of time.

5.3.8.3 Pulse Oximetry. The recent availability of instrumentation for noninvasive measurement of the oxygen saturation of peripheral blood has allowed the development of a new method of monitoring the effectiveness of ventilation in infants. This optical technique passes light at two different wavelengths through a limb or digit; in infants, the foot is often used. Light is transmitted from small light-emitting semiconductor diodes on the plantar surface and detected by a small photosensor located directly above on the opposite side of the foot. The amount of light transmitted at one wavelength, an isobestic point, is sensitive to the blood volume in the transmission path but insensitive to the oxygen saturation of the hemoglobin. At the other wavelength, the transmitted light is sensitive both to blood volume and hemoglobin oxygen saturation. By processing the detected signals from both sensors, the monitor is able to determine the percentage of saturation of the hemoglobin (Yoshiya et al. 1980).

For both wavelengths, the actual light intensity seen at the photo detector has a pulsatile component that correlates with heartbeat, corresponding to the change in blood volume in the tissue located between the light source and the detector over the cardiac cycle. This volume increases at systole and decreases at diastole. Therefore, the oxygen saturation of the hemoglobin in arterial blood can be estimated by measuring the signal when the blood volume is near its peak value, because the fresh bolus of blood entering the capillary bed is being sampled before it has substantially exchanged oxygen and carbon dioxide with the tissue. Consequently, unlike the transcutaneous oxygen tension technique, it is not necessary to heat the sampling site to obtain an estimate of arterial oxygen content.

The signal processing used in pulse oximeters must identify the point of maximum blood volume and must sample the data. Most pulse oximeters average the data from several samples before presenting the results on a digital display. The total number of pulses that are averaged varies from one type of device to another and sometimes can be varied in a particular device. The greater the number of pulses averaged, the slower the response time of the pulse oximeter, which affects the transient response of the instrument (Strohl et al. 1986). In general, however, pulse oximeters can be made to respond more rapidly than transcutaneous oxygen tension instruments.

There are two limitations to the use of the pulse oximeter. First, the circulation to the limb where the sensor is located must be sufficient to allow the pulsations in blood volume to be detected by the sensor. Thus, infants with compromised peripheral circulation may not give reliable signals. Second, as the infant moves the limb to which the sensor is attached, the relative motion between the sensor and the tissue causes artifact, which frequently makes it impossible to measure the oxygen saturation. Many monitors have

circuits to recognize and reject this transient artifact so that erroneous results are not presented.

5.3.9 Accuracy Problems Encountered in Transthoracic Impedance Monitoring. In addition to the inaccuracies inherent in transthoracic impedance estimates of ventilation, certain inaccuracies arise from particular signal processing designs. For example, some monitors markedly attenuate the amplitude of signals occurring at a rate faster than 90 to 100 per minute. Although this technique helps reduce the interference from the more rapid cardiovascular signals when counting breaths with a simple threshold or peak detector, it makes short episodes of faster respiration (100 to 120 breaths per minute) appear, on casual review of the record, to be apnea. Episodes of rapid breathing normally appear spontaneously for short intervals, usually ranging from 5 to 10 seconds but occasionally lasting 15 to 20 seconds. Longer episodes, which are especially likely during respiratory illness or fever, can trigger alarms; and if the signal is recorded at low resolution, the amplitude change can resemble apnea.

A problem of even more concern has been discovered recently. The filters processing incoming respiration signals in some monitors cause oscillations to occur in totally flat episodes of central apnea when cardiovascular waveforms are increasing and slowing. Both the breath detection circuitry and the clinician examining the tracing obtained after this conditioning perceive these oscillations to be respiratory effort. Unless a second signal of respiratory effort or an unfiltered impedance record is compared simultaneously, apnea may be unrecognized or inappropriately declared "obstructive" if the bradycardia is considered significant.

In these examples, what initially appears to be a logical choice of signal processing for alarm purposes may defeat the efforts of clinicians to use the same signal to judge the adequacy of respiration on a hard-copy record. Monitoring for an alarm system and recording behavior for diagnosis appear to require independent systems of processing (Bowman and Yount 1987).

5.4 Display and Recording. The display function of an apnea monitor reveals the results of the sensing and signal processing functions. This display can vary greatly in complexity. One of the simplest forms of display is the apnea alarm, which is usually an audible and visible alarm produced when a measured apnea lasts longer than a predetermined period of time. Such a display is a binary type of signal that indicates whether or not a condition has been met. It is important that such a display be capable of arousing the attention of the individuals responsible for the care of the patient. Therefore, an audible alarm must be loud enough to be heard and recognized by the caretaker, and the visual alarm must be visible from a reasonable distance.

More complex displays are also used with apnea monitors, especially hospital monitors. One such display provides a digital readout of the current respiration rate and can also indicate electrode baseline impedance for the purpose of evaluating electrode system viability. Visual displays can also show the respiration waveform on a CRT screen or strip chart recorder. Such displays are useful to the clinician observing the breathing pattern and can help the operator to set appropriate monitor gain levels and identify artifact on the signals.

Computer memory techniques have also been used for displaying data from infant apnea monitors. These data can be processed and presented in a manner meaningful to the clinician. Apnea histograms, recordings of significant events, and interesting patterns can be stored for later analysis.

Hard-copy readouts of data can also be obtained from apnea monitors. The most elementary approach is to connect the output of the monitor to a chart recorder that plots the respiration signal as it is monitored. The result is long charts of data that require tedious analysis to find significant information. This limitation can be reduced by combining the recording function with the memory and apnea detection methods described previously. The memory can be designed to store the respiratory signal for the most recent time interval, for example, the last five minutes. When the monitor detects an "apnea," the respiration signal leading up to this event as well as the event itself can be played back on the chart recorder for analysis. Some

manufacturers are even considering the possibility of storing this information in the monitor and automatically transmitting it over the telephone lines to a central location where it can be read. If therapeutic intervention is necessary, the parents can be immediately contacted. The advantage of these techniques is that events causing alarms are documented, making it is possible to identify true and false alarms and to determine whether any unusual breathing patterns preceded an alarm.

Any techniques of data storage and transmission will be only as reliable as the information contained in the transducing technique employed. All sensors have the potential to falsely signify central apnea or to make central apnea appear to be obstructive. To avoid clinical errors, a standard form of respiration signal processing for "record analysis" will be required in many monitors.

6. Directions For Future Technological Development. The limitations of current techniques of infant cardiorespiratory monitoring point out the need for additional research in monitor technology. Clearly, there is a need for better monitors. New sensors of breathing, particularly nonimpedance sensors suitable for use in the home, need to be developed and evaluated critically. Furthermore, methods of signal processing should be expanded and tested. Particular attention should be paid to sensors and signal processing techniques that make apnea detection more reliable and offer the possibility of determining the different types of apnea. Monitoring systems must be evaluated critically with respect to accepted volume standards such as the pneumotachograph. Changes in technology will undoubtedly broaden and increase clinical understanding and improve clinical practice. Not only must systems efficaciously detect various types of apnea, but they must also identify relative tidal volume and hypoventilation. Thoracic impedance measurement--or indeed any known simple thoracic measurement of respiratory effort alone--can never do this because of the distribution of respiratory effort and because of the inherent limitations of the thoracic technique.

   The direct measurement methods generally interfere with infant activity more than the indirect methods. Some indirect methods, however, have limited efficacy. While all methods are able to reliably detect breathing movements and central apnea during quiet sleep, motion artifact reduces system efficacy when an infant is active. Some behaviors, such as seizure episodes, present complex patterns of inadequate breathing with overlying body movement. Cardiogenic artifact is a problem with transthoracic impedance monitors, and few monitors based on indirect sensing techniques are able consistently to detect obstructive apnea.

   Signal processing techniques should be applied to extract breathing and apnea information from indirect apnea sensors. Relatively straightforward signal processing techniques are used in instruments available today, but more sophisticated signal processing could improve monitor efficacy by means of electronic microprocessor technology. Processing to minimize the effect of artifact is especially important.

   Further research is needed to develop better, more reliable, and less invasive and restrictive sensors of infant respiration. Methods to differentiate central, obstructive, and mixed apnea are needed. Sensors should be tailored for different population groups so that clinicians can better determine what type of monitor is best for particular patients. More sophisticated signal processing can also improve the efficacy of infant apnea monitors. The use of multiple inputs for signal processing decisions can improve the overall reliability of a monitor, just as it does in polysomnography. It is important that instrument manufacturers disclose the general signal-processing approach used in the design of their instruments, because different methods have different advantages and disadvantages, and what is optimal for one patient might not be so for the next. Once again, the clinician needs to understand the various types of monitors to prescribe the best apnea-monitoring system for a particular patient. It is not unusual to think of apnea monitors in terms of indications and contraindications, much the way as is done with drugs.

   The use of heart rate monitors needs further consideration. Although it has been suggested that heart rate-only monitors may be adequate for detecting and alarming on life-threatening events, studies are needed to test this hypothesis. Furthermore, heart rate monitors used alone or with monitors of other variables should be considered from the standpoint of signal processing. At present, heart rate monitors only alarm on

conditions of bradycardia or tachycardia. The usefulness of other features of the heart rate in identifying life-threatening events needs to be evaluated.

Beat-to-beat variability, acceleration and deceleration patterns, and actual electrocardiogram configuration may prove to be important. Arrhythmia detection may also provide useful information.

Although investigators are beginning to study the use of pulse oximetry for infant monitoring, additional data are needed. New, less-expensive instrumentation appropriate for home use should be developed and the usefulness of this instrumentation for hypoxemia detection determined. Pulse oximetry in combination with respiration and heart rate monitoring should be evaluated.

Many home infant monitors in use today provide information only when alarm conditions occur. Much of the information gathered by the monitor is discarded. Through technological innovation, this information could be compressed and stored in the monitor so that the clinician managing the patient could analyze changes in respiration patterns. Today, either patients must enter the hospital or a special apparatus must be used to obtain pneumograms for the evaluation of breathing disorders. If apnea monitors are prescribed, the respiration pattern is monitored for the pneumogram, but most of this information is not utilized. The technology for storing selected samples of such information will improve the clinical management of these cases and perhaps reduce the amount of time that the infant must remain on the monitor.

In view of the variety of methods of sensing respiration patterns and the number of commercial devices on the market today, it is important that standards and methods of evaluation be developed. Although efforts are under way to establish performance standards for transthoracic impedance apnea monitors, the process is slow and little progress has been made to date. Improved methods of simulating infant breathing patterns are needed so that monitors can be tested in the laboratory. A catalog of standard respiration patterns likely to be encountered when monitoring infants should be developed. If monitoring is indeed useful in reducing the incidence of SIDS, then technical improvements in monitoring devices will improve the outcome and help to make the applications of monitors more practical.

7. Applicable Standards. The following published standards may be applicable to apnea monitoring equipment.

Association for the Advancement of Medical Instrumentation. Diagnostic electrocardiographic devices (ANSI/AAMI EC11-1982). Arlington, VA: AAMI; 1983.

——. Cardiac monitors, heart rate meters and alarms (ANSI/AAMI EC13-1984). Arlington, VA: AAMI; 1984a.

——. Pregelled ECG disposable electrodes (ANSI/AAMI EC12-1983). Arlington, VA: AAMI; 1984b.

——. Safe current limits for electromedical apparatus (ANSI/AAMI ES1-1985). Arlington, VA: AAMI; 1985.

Canadian Standards Association. Standard for electromedical equipment (C22.2-125). Ontario, Canada: CSA; 1984.

International Electrotechnical Commission. Medical electronic equipment. Part 1: General requirements (IEC 601-1). Geneva: IEC; 1977.

——. Medical electronic equipment. Part 2: Cardiac monitors (IEC 601-2-4). Geneva: IEC; 1983.

National Fire Protection Association. National electrical code (ANSI/NFPA-70). Quincy, MA: NFPA; 1984.

——. National health care facility code (NFPA-99). Quincy, MA: NFPA; 1987. Section 9-5.1.8 addresses operating instructions, maintenance details, and testing procedures. Section 9-5.1.10 addresses low-voltage and battery-powered appliances. Section 9-5.3 addresses manufacturers' safety tests for patient-care-related electrical appliances.

Underwriters Laboratories. Standard for medical and dental equipment (UL-544). Northbrook, IL: UL; 1985.

Section 4, "Frame and Enclosure," addresses requirements for rigidity, fire and electrical shock protection, and loosening or displacement of parts.
Section 5.21, "Attaching Cords," addresses fire and shock protection and cord capacity.
Section 7, "Internal Wiring," addresses enclosure requirements, pass-through holes, insulation, routing away from hazards, clamps, and guides.
Section 8, "Patient Care Equipment," addresses leakage currents, insulated conductive parts, and voltage limits.
Section 21, "Grounding," addresses enclosed metal parts requiring connection to grounding cord, and the color coding of grounding conductors.
Section 27, "Leakage Currents," addresses current limits to patients.
Section 28, "Applied Patient Current," addresses application of an electrical potential to a patient.
Section 44, "Electrical Ratings," addresses supply voltage, frequency, and input in amperes, volts, or watts.
Sections 45 and 46, "General Markings," address letter size, visibility, and location of labels. Section 49, "Installation and Operating Instructions," addresses procedures for intended application.

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