PATIENT MONITORING

Modern medicine allows for the monitoring of high-risk patients so that medical treatment can be applied adequately as their condition worsens. To detect changes in the physiological condition of each patient, appropriate monitoring is applied routinely according to the patient's condition, at least in well-equipped hospitals. Patient monitoring usually means the physiological monitoring of high-risk patients using appropriate instruments.

In hospitals, there are many sites where patient monitoring is especially important. For example, in the operating room, instruments such as a pulse oximeter are used for monitoring anesthesia; in the intensive care unit, vital signs are monitored; in the coronary care unit, the patient's electrocardiogram (ECG) is routinely monitored and analyzed automatically; and in the incubator, the vital signs of the infant as well as the internal environment of the incubator are monitored. In addition, during examinations such as cardiac catheterization, and therapeutic procedures such as hyper- or hypothermia therapy, patient monitoring is required for ensuring safety. Even in the general ward, monitoring is performed fairly often when some risks are suspected. By using a telemetry system, the patient is not constrained to a bed. Even out of the hospital, patient monitoring is still performed in some situations. In the ambulance, postresuscitation management requires the use of a cardiac monitor. In the home where medical care such as oxygen therapy and intravenous infusion therapy is carried out, monitoring instruments are helpful. A so-called Holter recorder is used in which 24-h ECG is recorded for detecting spontaneous events such as cardiac arrhythmia.

There are many parameters that are used for patient monitoring: Among them are heart rate, ECG, blood pressure, cardiac output, rate of respiration, tidal volume, expiratory gas content, blood gas concentrations, body temperature, metabolism, electroencephalogram (EEG), intracranial pressure, blood glucose levels, blood pH, electrolytes, and body motion. Many types of monitoring techniques and instruments have been developed to enable measurement of these parameters.

For high-risk patients, monitoring should be performed continuously. The real-time display of the trend or waveform of each parameter is helpful especially in a patient who is experiencing cardiopulmonary function problems, because if a sudden failure of respiration or circulation is not detected immediately it may result in the physiological state of the patient becoming critical. The reliability of monitoring is quite important. In some situations, invasive procedures for monitoring are allowed if they are considered essential. For example, an indwelling arterial catheter is used when instantaneous blood pressure has to be monitored continuously. However, invasive methods are undesirable if the patient's condition is less critical. In some situations, noninvasive methods are preferred. Because noninvasive methods are always more difficult to perform or less accurate than invasive methods, the development of reliable noninvasive monitoring techniques is highly desirable; many smart noninvasive techniques have already been developed and supplied commercially.

Safety is an important feature of any monitoring device because monitoring is performed for a long period of time for the critically ill patient. Electric safety is strictly required especially when the monitoring device has electric contacts to the patient body. Sometimes, two or more monitors are applied to a patient. Leakage current should be avoided under any failure of each device. Electromagnetic compatibility is also important. Monitoring instruments should be immune to any possible electromagnetic interference from telemetering devices, mobile telephones or other noice sources such as electrosurgery.

Many patient monitors have an automatic alarm function. When a monitoring item is expressed as a single value such as heart rate, blood pressure, or body temperature, the alarm condition is determined by setting a level or range, and the monitor gives an alarm sign, such as *warning* and *urgent,* according to the patient's condition. When the monitoring item is expressed in a waveform, such as the ECG, the alarm system needs to be able to perform real-time waveform analyses. In any alarm system, two kinds of error—false positives and false negatives—may occur. In critically ill patients, a false negative may be fatal. While false positives may be tolerated to some extent, repeated false alarms may seriously disturb the clinical staff. In general, any alarm system requires some logic, and some times highly intelligent signal processing is required.

CONVENTIONAL PATIENT MONITORING TECHNIQUES

Electrocardiogram Monitoring

For sudden heart failure, urgent treatment is required. Monitoring of heart function is therefore quite important. The ECG is the most convenient method of monitoring the electrical function of the heart, whereas the mechanical pump function of the heart is best monitored by examining the patient's blood pressure and cardiac output. An ECG signal can be obtained by attaching electrodes to the body surface. For patient monitoring, electrodes are always attached to the torso as shown in Fig. 1(a), whereas the standard lead system in which electrodes are attached to the limb and chest is used in ordinary ECG examinations for diagnosis. Disposable ECG electrodes, as shown in Fig. 1(b), are commonly used for long-term monitoring. A stable ECG can be obtained using these electrodes for a day or longer.

The ECG waveform thus obtained is always displayed on a CRT monitoring screen with ordinary sweep speeds, together with other parameters. Unusual waveforms such as premature ventricular contractions can be identified visually. However, it is unlikely that someone would be able to watch the monitor screen all of the time. Most ECG monitors have a built-in computer that automatically detects abnormal waveforms and triggers the alarm. To reduce as much as possible the number of false alarms, both false negatives and false positives, highly intelligent algorithms for detecting abnormal waveforms, such as arrhythmias, have been developed

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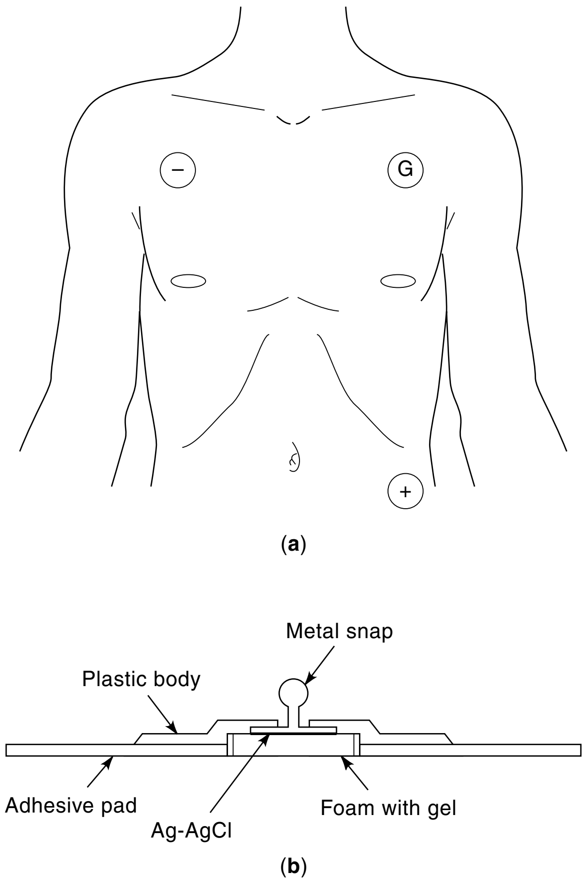

Figure 1. Typical electrode locations for ECG monitoring (a), and a cross-section of a disposable foam electrode (b).

and installed in intensive care monitoring systems (1). Most bedside ECG monitoring systems have a real-time display and large data storage facility that allows for retrospective observation. Some of them have a memory capacity that is able to record an ECG for up to 24 h. Radiotelemetering is convenient, even in bedside monitoring. Eliminating the cable connection to the patient is advantageous not only to make the patient less restricted, but also to attain electrical safety. However, electromagnetic compatibility should be secured when it is used together with other instruments.

For ambulatory patients, Holter ECG monitoring is performed in which the ECG is recorded typically for 24 h. The typical Holter recorder records the ECG on an audio cassette tape for 24 h, then the tape is brought to the hospital, the recorded ECG is played back by a scanner at 60 or 120 times the recording speed, and analyzed automatically so that different kinds of arrhythmias and other abnormalities may be classified and counted. To detect and record only pathological waveforms, a digital recorder with solid-state memory can be used; for example, a system can detect automatically the change in ECG during transient myocardial ischemia and record up to 18 episodes that are only 6 s each (2). Although longer time digital recording needs a very large memory capacity, 24 h recording is realized using a small hard disk drive in a system in which the ECG data is first stored in a solid-state memory and then transferred to the disk over short periods of time (3).

Blood Pressure Monitoring

Arterial blood pressure monitoring is essential in a patient whose circulation is unstable, and is commonly performed during cardiovascular surgery and postoperative care. There are two methods of blood pressure monitoring—direct and indirect. In the direct method, a catheter is introduced into the artery as shown in Fig. 2, and a pressure transducer is connected to the proximal end of the catheter. To avoid blood clotting in the catheter, a small amount of saline is supplied either continuously or intermittently. Intraarterial pressure can be measured accurately enough as long as the transducer is adequately calibrated. Either a strain-gage or capacitive type of pressure transducer is commonly used for this purpose. Disposable pressure transducers are convenient because sterilization of the transducer before use is troublesome. In addition, the performance of disposable pressure transducers is comparable or even better than that of expensive reusable pressure transducers (4).

The catheter-tip pressure transducer which has a pressure-sensing element at the tip is sometimes used for intraarterial pressure monitoring. It has many advantages: It has no time delay and has a flat frequency response over a wider range; saline injection is unnecessary; and it is less affected by the mechanical motion of the catheter. However, it is fragile and expensive. Many different principles can be used in detecting pressure at the tip, such as semiconductor strain gauges, and capacitive and optical principles. Some transducers have many pressure-sensing elements near the tip. For example, a model is available that has up to six pressure sensing elements in an 8F size tip (outer diameter 2.67 mm) (Mikro-Tip, Millar Instruments, Inc., Houston Texas).

While the direct blood pressure measurement method is accurate and reliable, it is an invasive procedure, and, thus, an indirect noninvasive method is preferred for less critical patients. The most common method of indirect blood pressure measurement is the auscultatory method in which a pressure cuff is attached to the upper arm. The cuff is deflated from a position somewhat above the systolic pressure, and both the systolic and diastolic pressures are determined by monitoring a sphygmomanometer while listening for the Korotkoff sound using a stethoscope. While the auscultatory method is the standard method of clinical blood pressure measurement, and is actually performed for patient monitoring such as during anesthesia, it is neither automatic nor continuous. Hence, a noninvasive continuous blood pressure monitor had been in demand. Two methods have now become available: the vascular unloading method and the tonometry.

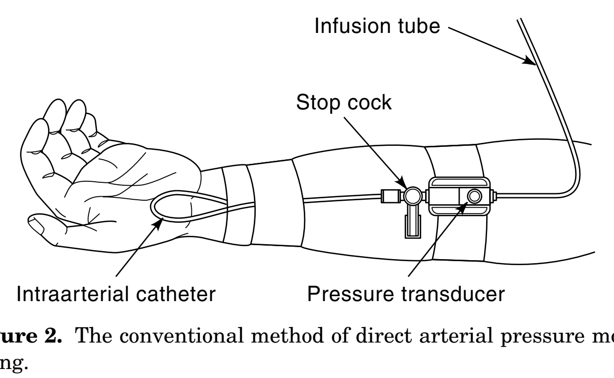

Figure 2. The conventional method of direct arterial pressure monitoring.

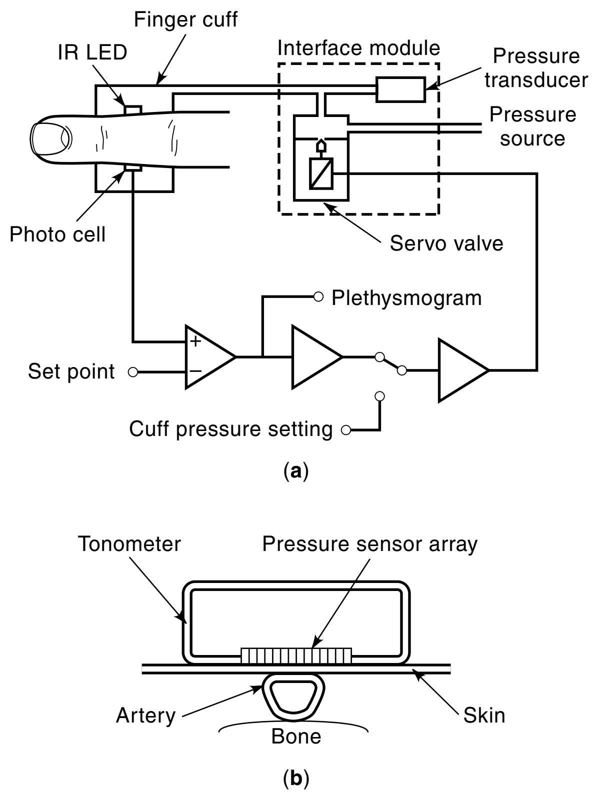

Figure 3. Indirect methods of instantaneous arterial pressure monitoring: (a) vascular unloading technique, and (b) tonometry.

The vascular unloading method is used to measure instantaneous intraarterial pressure by balancing externally applied pressure to the intravascular pressure using a fast pneumatic servo-controlled system (5). As shown schematically in Fig. 3(a), a cuff is attached to a finger, and near-infrared light transmittance is measured at the site where the cuff pressure is affected uniformly. Because absorption at near-infrared is mainly due to the hemoglobin in blood, the change in light absorption corresponds to the change of blood volume at optical pass, thus a pulsatile change in transmitting light intensity is observed from the pulsation of the artery. It is possible to compensate for the pulsatile change of arterial blood volume by introducing a servocontrol in which cuff pressure is controlled by the intensity of the transmitted light so that an increase of arterial blood increases light absorption and the signal increases cuff pressure so as to obstruct further increase of arterial flow. If such a servocontrol works fast enough and with a sufficient loop gain at an adequate level of light intensity, a condition is realized where the intraarterial and the cuff pressures are balanced. At this condition, the circumferential tension of the arterial wall is reduced to zero; such a situation is called vascular unloading. It has been shown that accurate blood pressure together with instantaneous arterial pressure waveforms can be obtained when an adequate servocontrol system is introduced and adjusted correctly (6). A commercial unit that uses this principle has been developed (Finapress, Ohmeda, Englewood, Colorado). In this system, the interface module, which has a pneumatic servovalve is attached to the back of the hand so that the connection from the valve to the finger cuff is minimized, thus reducing the time delay.

Tonometry is a method of measuring internal pressure from the reaction force. When a flat plate is pressed onto a flexible deformable boundary membrane to which internal pressure is exerted, internal pressure can be measured from the outside regardless of the transverse tension developed in the membrane. This principle has been applied successfully in intraocular pressure measurement, and it is also applicable to arterial blood pressure measurement (7). As shown in Fig. 3(b), the tonometry transducer, the tonometer, is applied to the skin surface so that an artery is just beneath the sensing element, and a part of the arterial wall is flattened. To detect the pressure at the center of the arterial flattening, a multiple-element transducer is used, and the value at the center of the pressure distribution is detected automatically. Measurement is always performed on the radial artery at the wrist. A tonometer is now commercially available (Jentow, Nihon Colin Co., Komaki-shi Japan).

Sometimes, blood pressure is monitored in an ambulatory patient. For this purpose, a fully automated portable sphygmomanometry system is used. A pressure cuff is attached to the upper arm, and is inflated intermittently at selected intervals. The Korotkoff sound is detected by a microphone, and systolic and diastolic pressures are determined and stored in a memory. Commercial models are now available (e.g., Medilog ABP, Oxford Medical Ltd., Oxford, UK) (8).

Cardiac Output Monitoring

Cardiac output is the volume of blood ejected by the heart per unit time. Because the capacity of circulatory transport is proportional to cardiac output, and the level of metabolism is limited by the capacity of oxygen transport, cardiac output has to be maintained above a level corresponding to the oxygen demand. Even if blood pressure is normal, cardiac output drops when peripheral vascular resistance is increased. Thus, to establish the state of circulatory function correctly, monitoring both blood pressure and cardiac output is desirable. However, there is no well approved noninvasive method of cardiac output monitoring. In practice, the thermodilution method has been used most commonly in critically ill patients both during surgery and in intensive care units, although it is an invasive procedure.

In the thermodilution method, a Swan-Ganz thermodilution catheter is introduced into the pulmonary artery through the superior vena cava and right heart as shown in Fig. 4. Approximately 10 mL of cold saline at near 0°C is injected instantaneously into the right atrium, and the temperature change is recorded by a thermistor placed in the pulmonary artery. Cardiac output is then obtained by the amount of cold saline divided by the area of the blood temperature record that lies under the baseline (9). It has been confirmed by many studies that the thermodilution method of cardiac output measurement is reliable and accurate enough for most clinical purposes. Although the monitoring is not continuous, measurement is repeatable, and the catheter can be placed for several days while the patient is in an intensive care unit.

The measurement of thoracic impedance has been studied as a method of assessing cardiac output. According to the original Kubicek's method (10), four band electrodes are used so that two are attached around the neck and two around the upper abdomen. An ac current in the 20 to 100 kHz range at a current level within the range from 10 μA to a few milli-

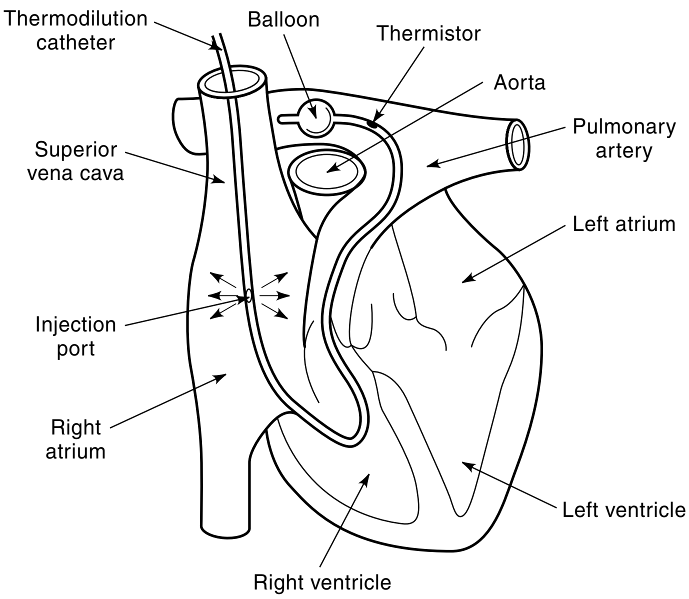

Figure 4. Thermodilution method for cardiac output measurement.

amps is supplied through the outer electrode pair, and the induced voltage is measured from the inner electrode pair. The stroke volume is computed from the slope of the thoracic impedance change in the ejection phase assuming a homogeneous cylindrical model for large arteries. The cardiac output is expressed by the stroke volume times the heart rate. Although inconsistencies remain among the reports that have evaluated the impedance method in contrast to other methods of cardiac output measurement, its noninvasiveness is a great advantage and thus further improvements are desirable.

Respiratory Monitoring

Respiratory monitoring involves monitoring of ventilation and respiratory gases. While ventilation of the lung can be assessed by observing movements of the thorax, it can be measured quantitatively by either gas flow in the airway or volume changes of the lung. During anesthesia or under artificial ventilation where the patient is intubated, gas flow in the airway can be monitored by inserting a flowmeter between the endotracheal tube and the breathing circuit. Many different types of flowmeters such as a rotameter, pneumotachograph, hot-wire anemometer, ultrasound flowmeter, and vortex flowmeter have been used. Most of them provide instantaneous gas flow rates. Tidal volume can be obtained by integrating the flow rate for the inspiratory or expiratory phase. Under artificial ventilation using a volume-limit type of mechanical ventilator, tidal volume is determined simply by presetting the ventilator.

Spontaneous breathing in unintubated patients can be monitored by the respiratory motion of the thorax and abdomen. A simple method of monitoring such motion is to measure the circumferential length or cross-sectional area of the thorax and abdomen. A flexible belt containing a zigzag-fashioned wire can be used as a transducer. When it is attached to the thorax or abdomen so as to form a single-turn coil, its inductance changes with respiratory motion, and tidal volume can be obtained with considerable accuracy (11). A commercial model of this type is currently available (Respitrace, AMI Inc., Sedona, Arizona).

Lung volume change can also be monitored by measuring the electrical impedance across the thorax (12). Impedance is measured by placing electrodes at both sides of the thorax, applying an ac current, and detecting the voltage that develops between the electrodes. Although thoracic impedance depends largely upon electrode position, the size and shape of the body, and body fluid distribution, it can be a quantitative monitor of lung volume changes when it is calibrated adequately using a spirometer.

Respiratory gas is also a common parameter that is used for patient monitoring; monitoring the level of carbon dioxide in expired air is especially important during anesthesia and in intensive care where artificial ventilation is performed. In physiological conditions, the carbon dioxide content in the body fluids, particularly in the arterial blood, is always maintained within a narrow range by the regulatory mechanism of respiration, but it may vary largely under artificial ventilation when the setting of the ventilator is inadequate. The arterial carbon dioxide partial pressure is related to the carbon dioxide content in expired air and especially to the value at the end of the expiratory phase. Carbon dioxide in the expired air can be monitored beat-by-beat by a carbon dioxide analyzer, called a capnometer, in which carbon dioxide content is measured by infrared absorption (13). There are two types of capnometer: the side-stream capnometer and the mainstream capnometer. In the side-stream capnometer, the sensor is located in the main unit, and a small amount of gas flow branched from the patient's airways is pumped continuously to it through a fine tubing. In the mainstream capnometer, a cuvette with an infrared source and a detector is inserted between the endotracheal tube and the breathing circuit as shown in Fig. 5. Although the mainstream capnometer has the advantage of no time delay, it has disadvantages, such as the condensation of water vapor to the window and loading a weight to the connector.

The mass spectrometer has also been used for continuous respiratory gas monitoring (14). It can be used to analyze many gasses simultaneously, not only physiological gasses such as oxygen, carbon dioxide, and nitrogen but also anesthetic gas such as nitrous oxide, halothane, enflurane, and isoflurane. In addition, many patients can be monitored with the aid of a mass spectrometer by using an inlet select unit. In fact, a single mass spectrometer system is capable of ser-

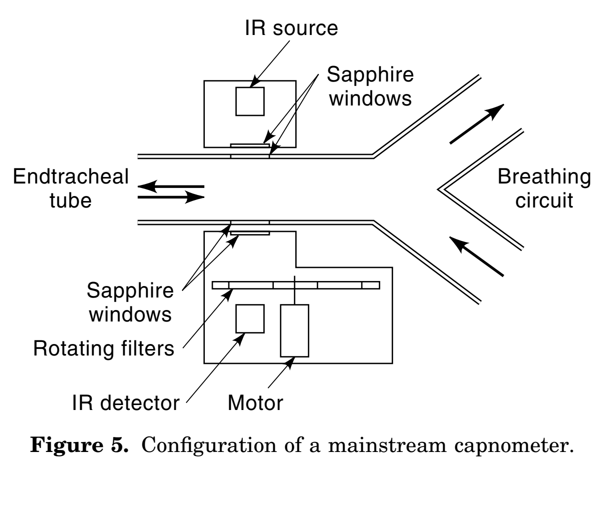

Figure 5. Configuration of a mainstream capnometer.

vicing up to sixteen patients (Lifewatch Monitor, Perkin-Elmer Co., Pomona, California).

Blood Gas Monitoring

Blood gas always means the oxygen and carbon dioxide contents of the blood. Because most of the oxygen in the blood exists in combination with hemoglobin, the oxygen content of the blood can be expressed in terms of the ratio of the amount of oxyhemoglobin to that of total hemoglobin; this ratio is called the oxygen saturation. A small amount of oxygen, usually less than 1%, remains in the plasma as dissolved oxygen, and its amount is expressed in terms of oxygen partial pressure. Although there is a relationship between oxygen saturation and oxygen partial pressure, this relationship is nonlinear so that saturation increases steeply with increasing oxygen partial pressure when the latter lies in the range 20 to 40 mm Hg (2.7 to 5.3 kPa), but tends to saturate when the oxygen partial pressure reaches above 60 mm Hg (8 kPa). In normal arterial blood, oxygen saturation is above 98%, and oxygen partial pressure is approximately 100 mm Hg (13.3 kPa). The main purpose of monitoring oxygen level is to confirm the oxygen transport which sustains metabolic demand.

Carbon dioxide is highly soluble in body fluids, and it is also converted, reversibly, to bicarbonate ions. Therefore, blood plasma as well as interstitial fluids have an apparently large storage capacity for carbon dioxide. However, changes in the carbon dioxide content of the body fluids causes a change in the acid-base balance of those body fluids, which is expressed by pH. Thus, it is important to maintain an adequate carbon dioxide level in the body fluids. It is therefore monitored by measuring the partial pressure of carbon dioxide of arterial blood.

Blood gas levels can be measured by taking a blood sample and analyzing it using a blood gas analyzer which provides information about the partial pressures of oxygen and carbon dioxide, and about the pH of the blood. However, in a patient whose respiration is unstable, blood gas values may fluctuate so that frequent measurement is required, and hence continuous blood gas monitoring is preferred.

Arterial blood oxygen saturation can be monitored noninvasively using a pulse oximeter (15). Due to the difference in the spectral absorption of oxyhemoglobin and reduced hemoglobin, the oxygen saturation of a particular blood sample can be determined by absorption measurements at two wavelengths, typically in a red band between 600 nm and 750 nm and in an infrared band between 850 nm and 1000 nm. However, the tissue *in vivo* contains both arterial and venous blood, and hence light absorption occurs by both components. To obtain the arterial component selectively, the pulsatile component is extracted. As shown in Fig. 6(a), light absorption is usually measured in a finger. Two light-emitting diodes of different wavelengths, for example 660 nm and 910 nm, are operated alternately, and the transmitted light is detected by a photocell. The pulsatile components of both wavelengths are then extracted by a bandpass filter. Arterial oxygen saturation is determined from the ratio of these two components.

Although the pulse oximeter is reliable enough and has been used successfully for patient monitoring in most cases, measurement sites of the transmittance measurement are limited, and thus a reflection-type pulse oximeter in which backscattered light is measured has been developed (16). In back-scattered light measurement, a difficulty arises due to the fact that the optical pathlength may vary when absorption is varied, although it is not changed as much in transmission measurement. In principle, this difficulty can be solved by using more than three wavelengths, however, a reflection-type pulse oximeter with comparable performance to the transmission-type oximeter has not yet been developed. In some applications, the reflection-type oximeter is highly appreciated. For example, it is applied to fetal monitoring during labor in which the sensor is applied to the skin of the fetal head (17).

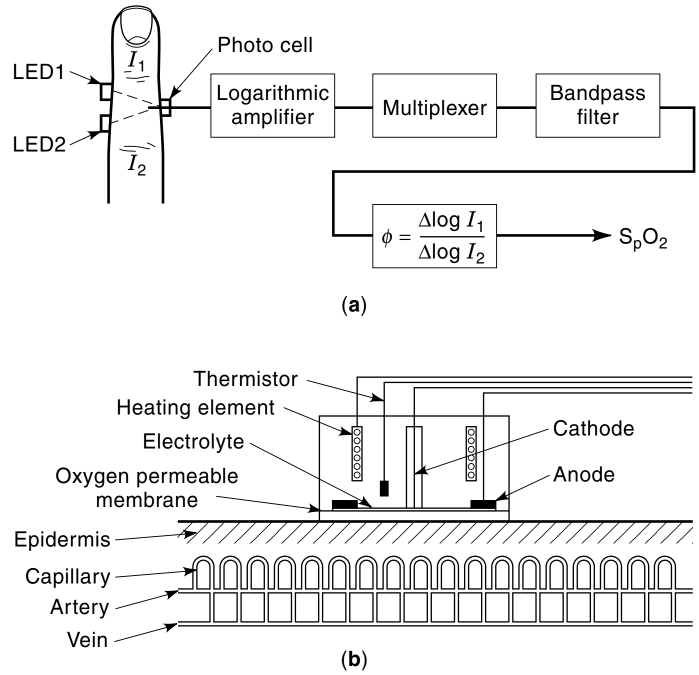

Figure 6. Pulse oximetry (a), and transcutaneous oxygen electrode (b).

The oxygen content in arterial blood can also be measured continuously and noninvasively with the aid of a transcutaneous oxygen electrode (18,19). The configuration of the probe is shown in Fig. 6(b). The principle employed is that of polarographic measurement, by which current drains proportionally to the amount of oxygen that reaches the cathode by diffusion through the oxygen permeable membrane. Because the oxygen flux is determined by the gradient in oxygen partial pressure at the membrane, and the oxygen partial pressure at the electrode surface is reduced to zero by the electrode reaction; the current that results from the oxygen flux depends upon the oxygen partial pressure on the outside of the membrane. When the probe is used for measuring arterial oxygen partial pressure, the electrode body is heated to approximately 42 or 43 °C. At this temperature, arteriovenous shunts in the skin tissue fully open, thus allowing large amounts of blood to flow through the tissue, far more than is required nutritionally, so that the venous blood has almost the same oxygen content as that of the arterial blood. Consequently, the oxygen partial pressure in the tissue reaches almost the same level as that of the arterial blood, and thus the arterial oxygen partial pressure can be measured transcutaneously.

Both the pulse oximeter and the transcutaneous oxygen electrode can be used for monitoring blood oxygenation; however, each method has advantages and disadvantages. The pulse oximeter is safe, easy to use, inexpensive, and sensitive at lower partial pressures. However, for higher oxygen partial pressure where oxygen saturation is almost 100%, a pulse oximeter can not detect any change in oxygen partial pressure. Higher oxygen partial pressures may occur during, for example, oxygen therapy. In such a condition, oxygen partial pressure may vary in wider range, and thus a transcutaneous oxygen electrode can be a good monitor of gas exchange in the lung.

Carbon dioxide partial pressure in the blood can also be measured transcutaneously using a heated carbon dioxide electrode, similar to the transcutaneous oxygen electrode. The carbon dioxide electrode consists of a pH electrode covered with a carbon dioxide permeable membrane (20). This type of electrode has been used for neonatal monitoring. The combined oxygen and carbon dioxide electrode which consists of a transcutaneous carbon dioxide electrode and a transcutaneous oxygen electrode is also available (21).

Body Temperature Monitoring

The term *body temperature* usually means the body core temperature, which is the temperature of the central part of the body. Many different techniques have been used for monitoring body temperature (22). Although different body parts have different temperatures, such differences are small when the temperature is stable, so that body temperature can be monitored fairly well at many measurement sites. Body temperature is usually measured by a clinical thermometer at the oral cavity. Recently, the tympanic thermometer is also used. For continuous monitoring, it is measured at the rectum, esophagus, bladder, auditory canal, tympanum, nasal cavity, or digestive tract. However, when body temperature varies, significant differences in observed temperatures may occur between sites. Thus when rapid changes of body temperature have to be monitored the measurement site used is important.

Rectal temperature has been used widely in patient monitoring because the rectum is a convenient site into which a thermometer probe can be inserted far enough to protect it from heat loss. Rectal temperature is always higher than oral temperature as well as temperatures of other sites, and has been considered to be a reliable indicator of body core temperature. However, when body temperature varies, changes in rectal temperature are delayed comparable to those of other, more central parts of the body, and thus rectal temperature cannot be accurate enough for monitoring in such conditions.

The esophagus has been used most frequently as a site for body temperature monitoring during anesthesia. Esophageal temperature is measured by inserting a probe through the mouth or nose so that the sensor tip is positioned at near-heart level. Under stable conditions, esophageal temperature is intermediate between oral and rectal temperature, and follows internal temperature changes rapidly.

Bladder temperature can be monitored using a thermistor-tipped bladder catheter as shown in Fig. 7(a). Although bladder temperature is close to rectal temperature in stable conditions, it follows internal temperature changes rapidly. Bladder temperature is recommended as a measurement site for core temperature, particularly for patients in whom bladder catheterization is indicated.

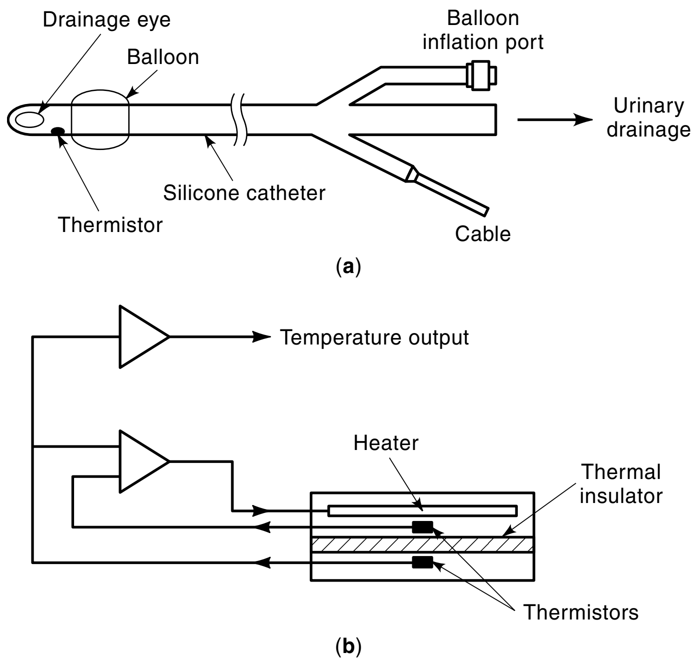

Figure 7. Two methods of body temperature monitoring: (a) thermistor-tipped bladder catheter, and (b) zero-heat-flow method.

Body temperature can also be monitored across the skin using the zero-heat-flow method as shown in Fig. 7(b) (23). The probe that is used in this method has two thermistors to detect heat flow across the probe. It also has a heater, and the heater current is controlled so that the temperatures of two thermistors are equal, which means that we can compensate for the heat flow from the skin to the outer air. Under such conditions, the probe can be regarded as an ideal thermal insulator. When the skin surface is insulated, the temperature gradient in the tissue near the surface will vanish, and finally the temperature of the surface of the skin will reach that of the deep tissue. A commercial model (Coretemp, Terumo Co., Tokyo) has now been developed for which disc-shaped probes of different sizes, from 15 mm to 80 mm in diameter, are available. By applying a probe to the forehead, chest, or abdomen, body temperature can be monitored continuously for several days in intensive care units (24). Simultaneous monitoring of body core and peripheral temperatures by applying probes to the forehead and to the sole of a patient's foot, temperature differences between the body core and the limbs can be observed which can be a useful index of peripheral circulation (25).

Intracranial Pressure Monitoring

The brain is surrounded by the skull, and the inner pressure of the skull is almost uniform and is called the intracranial pressure. Normal intracranial pressure is about 10 mm Hg (1.3 kPa), referring to the zero-pressure level in upper cervical spine. However, because of the high stiffness of the skull, a small increase in cranial volume causes a significant increase in intracranial pressure. Increases in intracranial pressure are serious, because they cause obstruction of the cerebral blood circulation. Such a situation can occur following intracranial bleeding, cerebral edema, growth of tumors, infectious lesions, and parasites. Therefore, intracranial pressure is measured and continuous monitoring is performed in such patients, especially when increase in intracranial pressure is likely to occur.

To estimate intracranial pressure, spinal measurement has been used. Because communication exists between the spinal fluid and the fluid in the ventricles, cerebral pressure can be measured by puncturing the lumbar vertebra. However, such a technique cannot be used for monitoring intracranial pressure. To monitor intracranial pressure continuously, an invasive method has to be used, except in neonates who have natural openings of the skull, the fontanelles, through which intracranial pressure can be measured noninvasively.

Both extracranial measurement using a liquid-filled tube and intracranial measurement using an implantable transducer are possible, and there are many different approaches for each method (26). In extracranial measurement, a liquid-filled tube is introduced into a ventricle, subdural space, or subarachnoidal space via a burr hole made in the skull, as shown in Fig. 8(a), and a pressure transducer is connected to the proximal end of the tube. A catheter-tip pressure transducer can also be used in place of the fluid-filled tube.

A pressure transducer that fits into a bore hole made in the skull, as shown in Fig. 8(b), may also be used. In this configuration, the diaphragm of the pressure transducer can be adjusted to the epidural surface so that the error due to deformation of the dura mater can be minimized. A telemetry system is also attempted in which a small transmitter is assembled in the transducer unit and the signal is received by a coil placed on the skin. The elimination of the cable connection is advantageous to avoid infection.

In the neonate, the skull is not completely formed so that openings called the fontanelles exist, and intracranial pressure can be monitored noninvasively by placing a transducer on a fontanelle as shown in Fig. 8(c). The diaphragm of the pressure transducer has to be in coplanar alignment with the skin surface so that the tension of the skin tissue does not affect the measurement. When the transducer is adequately fixed, intracranial pressure can be monitored for 24 h or more.

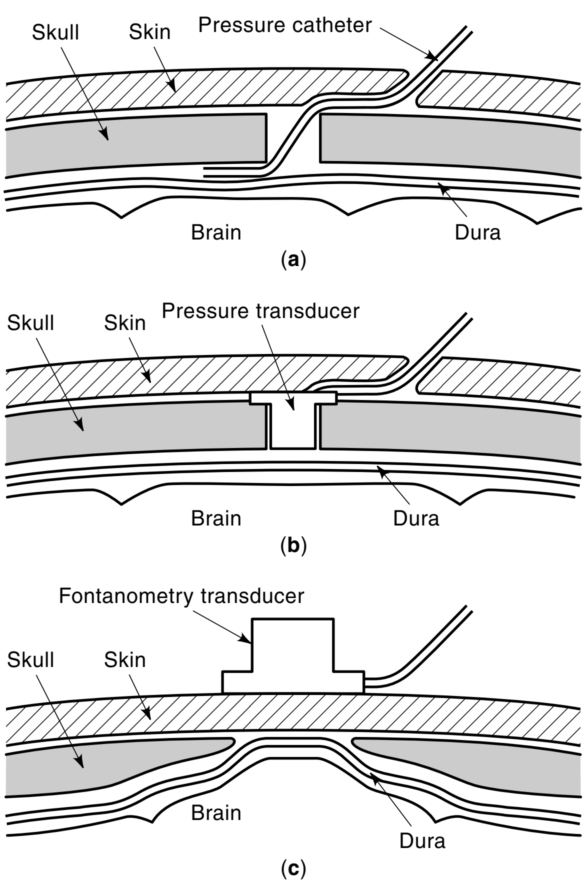

Figure 8. Methods of intracranial pressure monitoring: (a) placement of a pressure catheter in the subarachnoidal space, (b) implanting a transducer in a bore hole through the skull, and (c) fontanometry.

ADVANCED TECHNOLOGY FOR PATIENT MONITORING

There are many clinical requirements in patient monitoring for which the present technology is still insufficient. Many biochemical parameters are still difficult to monitor continuously, and the use of biosensors has been investigated extensively. The importance of monitoring brain function in critically ill patients has been recognized, and new technniques are becoming available. Patient monitoring in extreme situations are required, such as in a strong electromagnetic field during magnetic resonance imaging (MRI) examination or during hyperthermia therapy using electromagnetic heating. Home monitoring requires the development of monitoring systems that can be operated without the aid of medical personnel.

Monitoring Biochemical Parameters Using Biosensors

Although blood analysis is the most important clinical examination, it requires the procedure of blood sampling. Frequent examination is required in some cases. For example, blood glucose has to be measured many times a day in diabetic patients. If a sensor attached to the body can detect chemical parameters in the body fluid continuously, frequent blood sampling becomes unnecessary, and the precise control of blood glucose will be possible, which is the goal of the artificial pancreas. Biosensors are promising for this purpose. The biosensor is a device in which components of biological origin, such as enzymes, antibodies, cells, or even microorganisms, are used to analize specific chemical species selectively (27). By immobilizing an adequate quantity of biological components on a sensor, the species to be analyzed is detected by ordinary electrochemical, optical, or acoustic sensing principles.

However, there are many difficulties when biosensors are used for patient monitoring. Because the skin is impermeable for most chemical species except gas, a biosensor has to be inserted into the body space to make direct contact with the body fluid. To implant a sensor into the tissue, invasive procedures are required, and it is also necessary that the sensor is nontoxic and biocompatible. When used in the blood vessels, its surface should be anticoagulant. Once a sensor is placed in the body, recalibration is difficult; hence long-term stability is required. Despite such difficulties, extensive studies have been done in *in vivo* chemical measurement using biosensors (28). Although still not accepted for clinical routine use, monitoring for fairly long periods of time has been attained. For example, a ferrocene-mediated type of glucose sensor covered with a newly designed biocompatible membrane could be used for 7 days without calibration, and for 14 days with *in vivo* calibration by comparison with blood sampling data (29).

As a solution for the difficulty of the *in vivo* application of biosensors, *ex vivo* measurement has been attempted in which a small amount of body fluid is drained from the body and perfused through a flow-through sensor cell. An advantage of this type of *ex vivo* measurement is the easiness of calibration and replacement of the sensor. However, continuous drainage causes loss of body fluids. Microdialysis could be a solution to this difficulty. The microdialysis probe has a semipermeable membrane at the tip, and a fluid is perfused through it by a fine double-lumen catheter at a very low flow rate. When the probe is placed in the subcutaneous tissue, small molecules, such as glucose, are able to diffuse through the membrane from the body fluid to the perfusion solution, and is then analyzed by a biosensor. In microdialysis, the permeability of the membrane affects the measurement. To realize accurate measurements through the membrane without being affected by the membrane permeability, the application of a null method was proposed (30). In this system, the perfusion solution is adjusted using a servocontrol system so that concentrations at the inlet and the outlet of the probe are equal. This method is advantageous, not only for eliminating the effect of the change in membrane permeability but also for eliminating the effect of drift and sensitivity change of the sensor.

As a less-invasive chemical measurement method, the effluent fluid analysis has been attempted (31). If the outermost layer of the skin, the stratum corneum, is removed by stripping with an adhesive tape many times and negative pressure is then applied to the skin surface, a small amount of fluid, called effluent fluid, can be collected. It has been shown that blood glucose can be monitored quasicontinuously using this method.

Monitoring Brain Function

Monitoring brain function is required during anesthesia, in a patient who lacks consciousness, and in the neonate. Electroencephalography (EEG) has been used widely for monitoring the electrical activity of the brain. The responses of the brain to sensory inputs such as visual and auditory stimulation can be examined monitoring the resultant slight changes in the EEG waveform that are known as evoked potentials. While the amplitude of the evoked potentials is smaller than that of ordinary EEG activity, it can be extracted by averaging many responses. The function of the motor system can be examined by stimulating the mortor cortex. A strong magnetic pulse can be used for this purpose. The magnetic stimulation induces eddy currents that cause firing of motor neurons, and visible muscle contractions or muscular activities visualized in the form of an electromyograms are induced if the function of the motor system is normal (32).

Brain function is sustained by the oxygen supply through the cerebral circulation, and thus a sufficient supply of oxygen to the brain is of primary importance. When the blood supply to the brain is decreased, the oxygen partial pressure in the tissue decreases, and consequently the oxygen saturation of venous blood returning from the brain will also decrease. When decreasing cerebral circulation is suspected, jugular venous oxygen saturation can be measured. For continuous monitoring, a regional oxygen saturation catheter is placed in the jugular vein. A fiber-optic regional oxygen saturation catheter is commercially available for this purpose (Baxter Healthcare Corp., Edward-Critical Care, Irvine, California).

In the neonate, cerebral oxygen supply and utilization can be monitored noninvasively using near-infrared spectroscopy. This technique is based on the measurement of transmitted light across the head. Even though the intensity of the transmitted light through the head is on order of 10^{-15} of that of the incident light, it is still detectable using a low-noise photomultiplier tube. This technique provides information about the level not only of oxygen saturation of hemoglobin but also of oxidized cytochrome oxidase in the brain tissue (33). Cytochrome oxidase is an enzyme that catalyzes cellular energy production, and the amount of oxidized cytochrome oxidase is related to cellular oxygen consumption. An instrument that monitors oxygen saturation and oxidized cytochrome oxidase levels is commercially available (NIRO-500, Hamamatsu Photonics Co., Hamamatsu, Japan).

Monitoring under Strong Electromagnetic Fields

Patient monitoring is required even in extreme conditions, such as under strong electromagnetic fields. Hyperthermia cancer therapy is a typical case of this kind. Hyperthermia cancer therapy is based on the fact that cancer cells are weaker than normal cells at high temperatures near the limit of survival, that is, in the range of 42° to 45°C. To treat the malignant tumor, local heating by applying a strong radio frequency (RF) field has been used. Heating should affect cancer cells; however, normal cells have to be protected. Therefore, precise temperature measurement under strong RF fields is required. Although conventional temperature sensors, such as ordinary thermistors and thermocouples, cannot be used, many different techniques have been attempted. For example, fiber-optic temperature sensors have been developed for this purpose. To convert temperature into an optical signal, several techniques have been developed. Among them are liquid crystal, fluorescence, birefringent crystals with polarizers, and the semiconductor band-edge absorption shifts. Some of these are commercially available (e.g., Fluroptic Thermometer, Luxtron Corp., Mountain View, California). However, such probes can only measure temperature at a particular point. For precise temperature control while under RF heating, temperature distribution imaging in the strong RF field is demanded.

Magnetic resonance imaging employs strong magnetic field and RF pulses. The ferromagnetic material in the field is magnetized and distorts the image. In conductive material, eddy currents are induced and the magnetic field produced by the induced currents also distorts the image. Radio frequency pulses interfere with electronic instruments, so that ordinary monitoring systems cannot be used near the scanner. For patient monitoring in such a situation, monitoring devices should be made using nonmagnetic and nonconductive materials. In fact, there are some techniques that can be used such as a blood pressure cuff with plastic connectors, chest wall movement sensors for a respiratory monitor, and pneumatic pulse monitoring using a finger cuff (34). Fiber-optic probes would also be applicable.

Patient Monitoring at Home

For chronically ill patients, the continuation of medical treatment at home would be more comfortable than to stay in a hospital apart from their family. Medical treatment at home is preferable not only for the patient, but it reduces medical expenses. However, when the treatment involves frequent examinations of physiological parameters, it is difficult to perform such procedures at home in the same way as in the hospital. Even in such patients, medical treatment would be given if adequate patient monitors were available. For example, in diabetic patients, the treatment of administering insulin can be controlled even at home by measuring blood glucose frequently; convenient devices for blood glucose measurement are commercially available. Oxygen therapy using oxygen delivery systems is also possible at home, but monitoring arterial oxygen saturation using a pulse oximeter is recommended to secure the treatment.

Many kinds of home health care devices have been developed, are commercially available, and are used routinely at home (35). To secure the function of such devices and to avoid risks due to malfunctioning or inadequate operation of the devices, patient monitoring would be helpful. If more reliable monitoring systems become available, more effective treatments will become acceptable in home care.

The application of health monitoring at home is not limited to critically ill patients. Even in apparently healthy people, abnormalities are found quite often during screening in physiological or biochemical examinations. Early diagnoses can be made using such data, and, consequently, each disease that is diagnosed earlier can be treated more reliably than cases in which a desease is diagnosed only after the appearance of apparent symptoms. If fully automated monitoring instruments are installed in the home, and physiological parameters can be monitored without performing any tedious operations, abnormalities would be identified much easier. The concept of home health monitoring is considered a new possibility in health care technology (36).

To realize this concept, ordinary clinical examinations such as the ECG measurement by limb lead are rarely employed. However, ECG can be observed automatically without any measurement operation in specific situations. For example, when one takes a bath in a bathtub, ECGs can be recorded through water from electrodes attached to the inside wall of the tub. Also, ECGs can be recorded using conductive cloth electrodes on a bed or even from a toilet seat. Other paramaters such as body weight can be measured accurately using a specially designed load cell installed on a toilet. Temperature sensors installed beneath a bed sheet provides information about the time a patient spent in the bed and about body motion during sleep which can provide information on sleep disturbances. Simple infrared sensors and magnetic switches installed in each room and on appliances or water taps can provide a fairly complete record of the daily activities of the isolated living person. Although this kind of technology is not yet well developed, there are many possibilities that would allow for patient monitoring in the home.

Automated home health monitoring would be especially effective for the elderly, because physiological function declines with age, and gradual changes are rarely recognized. The normal ranges of health parameters for each individual would be determined accurately from long-term records so that even a slight change in such parameters can be identified. If a long-term record of health parameters is obtained, it would be utilized for a retrospective analysis when symptoms appear, and would be utilized not only for accurate diagnosis but also for epidemiological studies in a population if such data are accumulated for many people. It is expected that this approach would contribute to a reduction in the need for medical services and, consequently, a reduction in medical expenses.

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PATTERN-BASED ORGANIZATION.

See SELF-ORGANIZING FEATURE MAPS.