NEAR EAST UNIVERSITY

Faculty of Engineering

Department of Electrical and Electronic Engineering

BIOMEDICAL INSTRUMENTATIONS

Graduation Project
EE-400

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ABSTRACT

This project is about the role of technology relation to biomedical equipments. The importance of biomedical instrumentation is frequently increasing due to the humans need for avoiding sickness, the study to the biomedical instruments and the design of them became the spot for many electrical and electronics engineers.

The design of a biomedical instrument mainly can be categorized in three sections the first one is the sensing section where the data measured changes from what ever it is to an electrical signals, the second one is the signal processing section where the signals are modified by the use of amplifiers, filters and so on until we get the required form of the signal the third section is the data display section where monitors, printers, imaging devices, etc. can be involved.

The design of any biomedical instrument can not be possible without having medical information abut the use of the device and the output form which is required as well as the input forms which has to be modified with respect to the scales of the medical studies.

The main object of this project is to provide information about the measuring principles and methods. Making a good knowledge about the basics of biomedical sensors and some signal processing equipments.

To over connect all the information provided in the project I will give a detailed study about some medical devices which are related to the heart with brief medical information about the heart in order to make it topics as clear as possible.

DEDICATED TO UMMY

INTRODUCTION

Since the beginning of the recorded history, humans have interested in fashioning medical tools and finding new ways to heal sick. When people lived in caves, medical technology consisted of primitive tools, such as stones, roots, herbs, and branches, but there is evidence that some surgical procedures were performed. Fossilized skulls have been uncovered that indicate ancient healers drilled holes in the heads of the sick. This procedure, called trephining, was probably performed as a cure for seizures, epilepsy, or severe head pain. The growth of new bone around the holes in the skull is evidence that the individuals who underwent this treatment survived for some period of time.

Although medical technology continued to evolve, it remained quite primitive for thousand pf years, by the year 1000 BC, the field of medicine and its technology represented a haughtily respected profession with temples of healing as the precursors of the first hospitals, Hippocrates (-400 BC), the most notable of these early persons, is said to be the founder of western medicine because he introduced the scientific spirit. As a result of his contribution, diagnostic observation and clinical treatment began to replace superstition.

The area of electronics had a significant impact on the development of new medical technology, men such Richard Caton and Augustus desire proved that the human brain and heart depended on bioelectric events. In 1903, William Einthoven expanded on these ideas after he created the first string galvanometer. Einthoven placed two skin sensors on man and attached them to the end of silvered wire that was suspended through holes drilled in both ends of a large permanent magnet. The suspend silvered wire moved rhythmically as the subject's heart beat. By projecting a tiny light beam across the silvered wire, Einthoven was able to record the movement of the wire as waves on a scroll of moving photographic paper. Thus. The invention of the string galvanometer led to the creation of the electrocardiogram (ECG), which is routinely used today to measure and record the electrical activity of abnormal hearts and to compare those signals to normal ones.

In 1929, Hans Berger created the first electroencephalogram (EEG), which is used to measure and record the electrical activity of the brain. In 1935, electrical amplifiers was used to prove that the electrical activity of the cortex had a specific rhythm, and in 1960 electrical amplifiers were used in devices such as the first implantable pacemaker

that was created by William Chardack and Wilson Greatbatch. These are just a small sample of the many examples in which the field of electronics has been used to significantly advance medical technology.

Much other advancement that ware made in medical technology originated from research in basic and applied physics. In 1895, the X-ray machine, one of the most important technology inventions in the medical field, was created when W.K.Roentgen found that X-ray could be used to give pictures of the internal structures of the body. Thus, the X-ray machine was first imaging device to be created.

Another important addition to medical technology was provided by the invention of the computer, which allowed much faster and more complicated analyses and functions to be performed. One of the first computer-based instrument in the field of machine, the sequential multiple analyzer plus computer (SMAC), was used to store a vast amount of data pertaining to clinical laboratory information. The invention of the computer made it possible for laboratory tests to be performed and analyzed faster and more accurately.

Today, there is a wide variety of medical devises and instrumentation systems. Some are used to monitor patient conditions or acquire information for the diagnostic purposes, e.g., ECG and EEG machines, where as others are used to control physiological functions, e.g., pacemakers and ventilators. Some devices, such as pacemakers, are implantable, where as many others are used noninvasively.

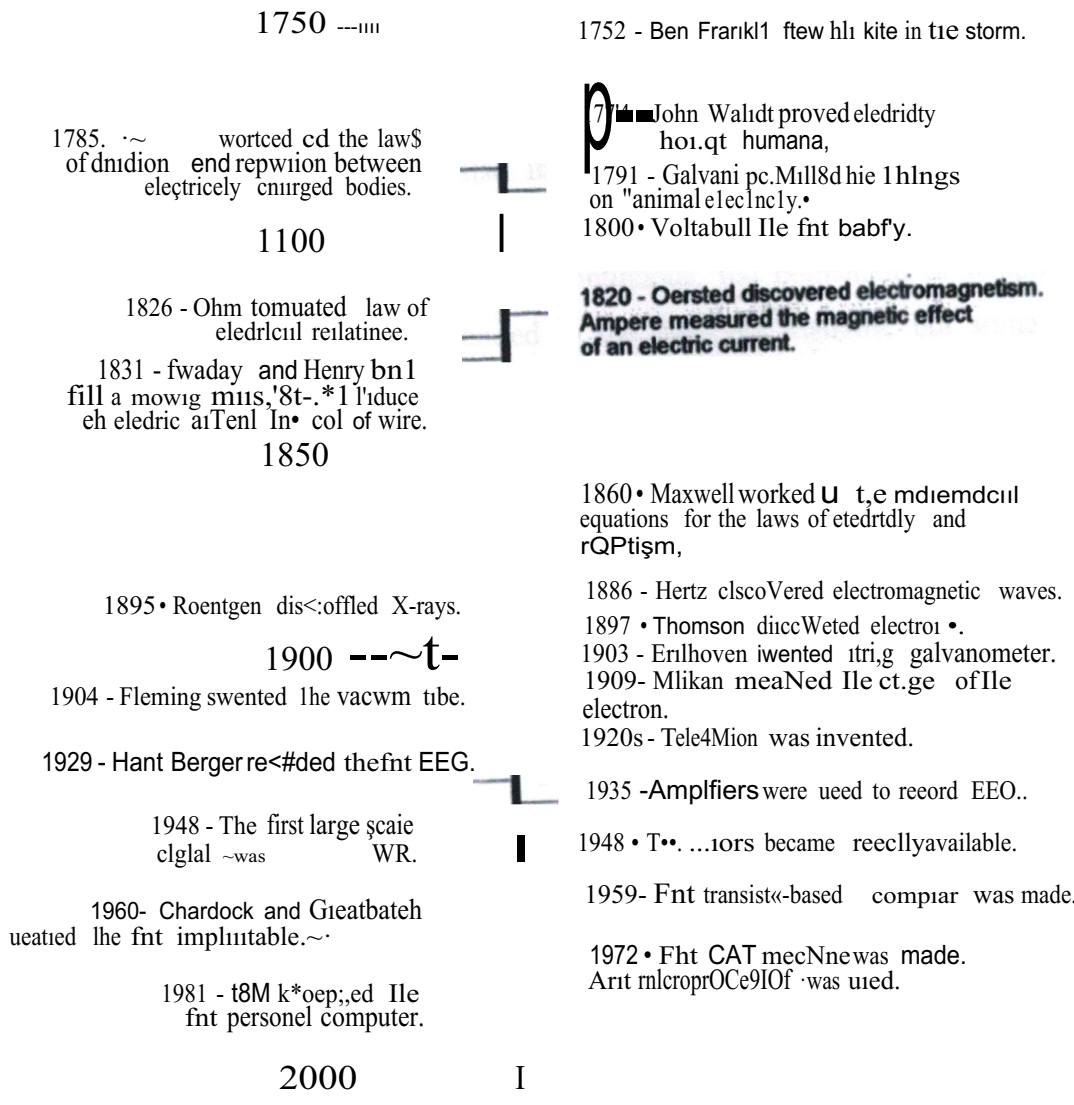


Figure a. The line for major inventions and discoveries that led to modern medical instrumentation.

BASIC INSTRUMENTATION SYSTEM:

The quantity, property, or condition that is measured by instrumentation system is called the measurand (Fig. b). This can be bioelectric single, such as those generated by muscular or the brain, or a chemical or mechanical signal that is converted to an electrical signal. Sensors are used to convert physical measurands to electric outputs. The outputs from these biosensors are analog signals, e.g., continuous signals that are sent to the analog processing and digital conversion block. There, the signals are

amplified, filtered, condition, and converted to the digital. Methods for modifying analog signal e.g., amplification and filtering will be covered later on.

Basic instrumentation systems also include output display devises that enable human operator to view the signal in a format that is easy to understand. These displays maybe numerical or graphical, discrete or continuous, the permanent or temporary. Most output display devises are intended to the observed visually, but some also provide audible output, e.g., a beeping sound with each heartbeat.

In addition to displaying data many instrumentation systems have the capability of storing data. In some devises, the signal is stored briefly so that further processing can take place or so that an operator can examine the data. In other cases, the signals are stored permanently so that different signal processing schemes can be applied at a later time. Holter monitors, for example, acquire 24 h of ECG data that are later processed to determine arithmetic activity and other important diagnostics characteristic.

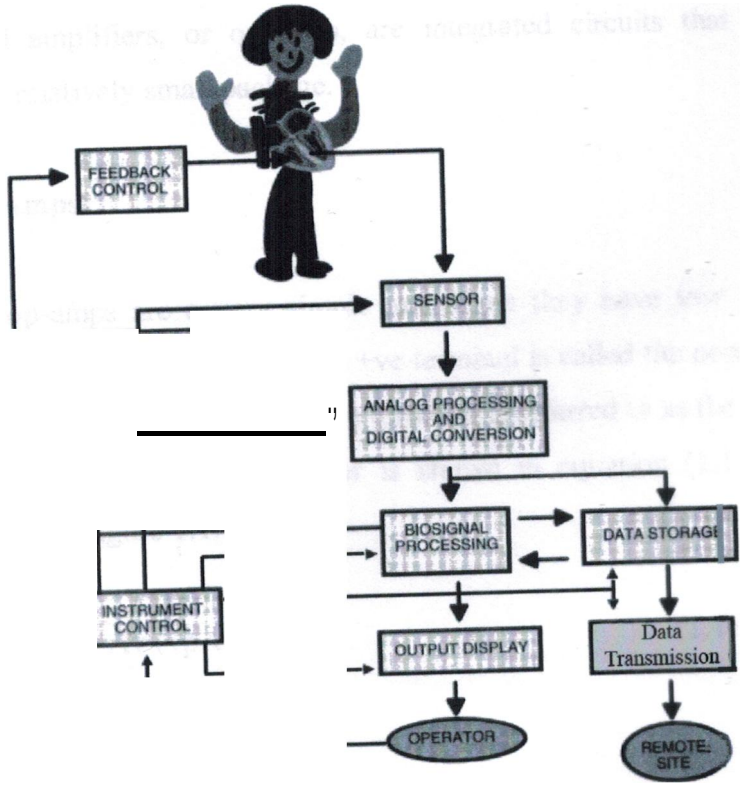


Figure b. Basic instrumentation contains sensors that convert the measurand.

Chapter 1:

Amplifiers and Signal Processing:

1.1 Introduction:

Most bioelectric signals are small, and require amplification. Amplifiers are also used for interfacing transducers that sense body motions, temperature, and chemical concentration. In addition to simple amplification. The amplifier may also modify the signal to produce frequently filtering or nonlinear effects. This chapter emphasizes the *operational amplifier (*op amp) which has revolutionized electronic circuit design. Most circuit design was formerly performed with discrete components, requiring laborious calculations, many components, and large expense. Now a 50-cent op amp, a few resistors, and knowledge of Ohm's law are all that is needed.

1.2 Operational Amplifiers:

Operational amplifiers, or op-amps, are integrated circuits that contain many components in a relatively small package.

1.2.1 Ideal Op Amps:

The ideal op-amps are a very simple amplifiers they have tow inputs and one output the input which is connected to the +ve terminal is called the noninverting input, and the input which is connected to the -ve terminal is referred to as the inverting input, the output voltage of the ideal amplifier is shown in equation (1.1) and the ideal amplifier is shown in figure 1.1.

$$Youı = Av\ Vpn = Av\ (vp-vn) \qquad (1.1)$$

Where

V_{out-} output voltage.

Av: open loop gain

There are two main rules in the ideal op-amps:

When the op-amp output is in its linear range, the two input terminals are at the same voltage.

No current flows into either input terminal of the op amp.

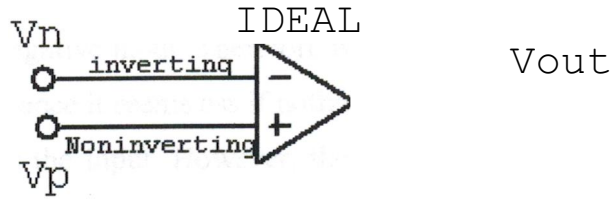


Figure 1.1 Op-amp circuit symbol

1.2.2 Inverters:

Figure 1.2 shows the basic inverter circuit. It is widely used in analog computers as well as for instrumentation. Note that a portion of V_0 is fed back via R_f to the negative input of the op amp. This provides the inverting amplifier with many advantages associated with the use of negative feedback - increase bandwidth, lower, output impedance, and so forth. The output voltage of the inverter is shown in equation (1.2).

$$V_0 = -V_i \frac{R_f}{R_i} \qquad (1.2)$$

Where

R_f: feed back resister.

R_i: input resister.

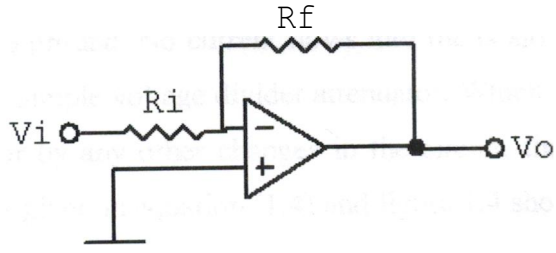


Figure 1.2 An inverting amplifier

1.2.3 Followers:

Figure 1.3 shows circuit for unity-gain follower. Since v, exist at the positive input of op amp, vı must also exist at the negative input. But ve is also coıınected to the negative input. Therefore v0 ~ v,, or the output voltage follows the input voltage. At first glance it seems ass if nothing is gained by using this circuit, since the output is the same **as the input. However, the circuit is very useful as a buffer, to prevent a high source** resistance from being loaded down by low-resistance load. No current flows into the positive input, and therefore the source resistance in the external circuit is not loaded at all. The output voltage of the follower is shown in equation (l.3), and figure 1.3.I **shows the follower circuit.**

$$v_0 = v_i ((R_f+R_i)/R_i) \quad \textbf{(1.3)}$$

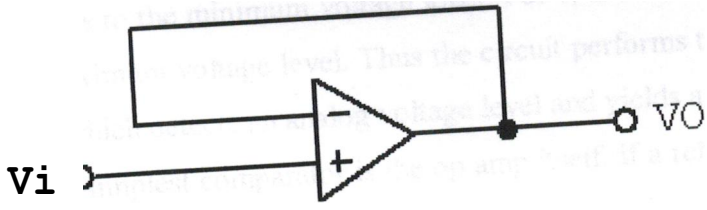


Figure 1.3 A follower amplifier

1.2.4 Differential Amplifiers:

Figure l .4 shows a simple one-op-amp differential amplifier. Current flows from *v,* through *R,* and R4 to ground. No current flows into the positive input of the op amp. Hence R3 and *R,* act as simple voltage divider attenuator. Which is unaffected by having the op amp attached or by any other changes in the circuit, the output voltage of the differential amplifier is given in equation (1.4) and figure 1.4 shows its circuit.

$$v_o = (v_4-v_3)\, R_4/R_3 \quad \textbf{(1.4)}$$

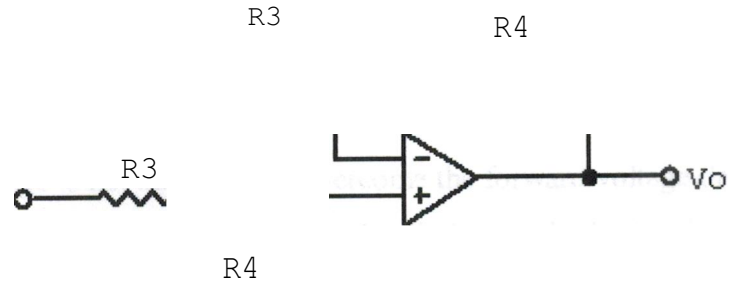


Figure 1.4 A one-op-amp differential amplifier

1.2.5 Comparators:

A comparator is a circuit that compares the input voltage with some reference voltage, the comparator's output flips from one saturation limit to the other, as the negative input of the op amp passes through OV. For v_i greater than comparison level, the v_o goes to the minimum voltage level. For v_i less than the comparison level, v_o goes to the maximum voltage level. Thus the circuit performs the same function as a *Schmitt trigger,* which detects an analog voltage level and yields a logic level output.

The simplest comparator is the op amp itself, if a reference voltage is connected to the positive input and v_i is connected o the negative input, the circuit is completed. The inputs may be interchanged to invert the output, figure l .5 shows the comparator circuit

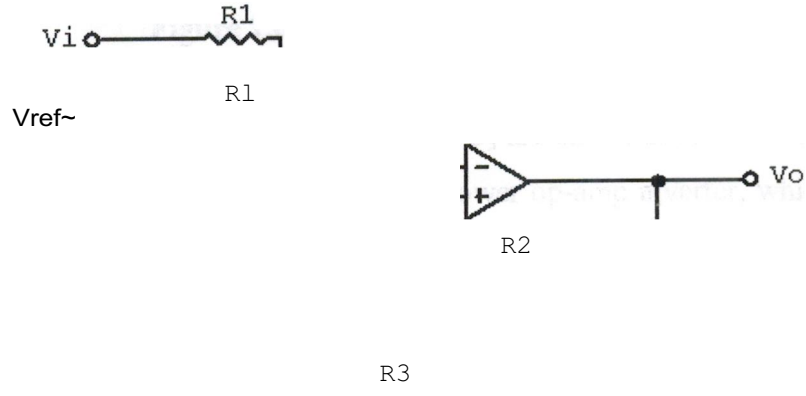


Figure 1.5 Comparator

1.2.6 Rectifiers:

Simple resister-diode rectifiers do not work well for voltages bellow 0.7 V, because the voltage is not sufficient to overcome the forward voltage drop of the diode. This problem can be overcome by placing the diode with in the feedback loop of an op amp, thus reducing the voltage limitation by a factor equal to the gain of the op amp.

Figure 1.6 shows the circuit for full-wave precision rectifier. For $v_i > 0$, *D2* and *D3* conduct, while *D,* and D_4 are backbiased. The top op amp is follower with gain, with a gain 1/x, where *x* is a fraction corresponding to the potentiometer setting. Since D4 is not conducting, the lower op amp does not contribute to the output.

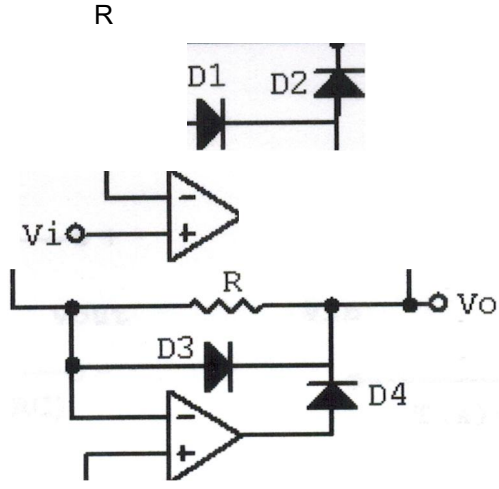


Figure 1.6 Full-wave precision rectifier

For $v_i < 0$, *D,* and D_4 conduct, while D_2 and *D3* are back biased. v_i, which appears at the potentiometer wiper, serves as the input to lower op-amp inverter, which has a gain of - 1/x.since D_2 is not conducting, the upper op amp does no contribute to the output. And since the polarity of the gain switches with the polarity of v_i, $v_0 = | v_i | x$.

The advantage of this circuit over other full-wave rectifier circuits is that the gain can be varied with a single potentiometer and the input resistance is very high. If only a half-way rectifier is needed, either the follower with gain or the inverter can be used

separately, thus requiring only one op amp. The perfect rectifier is frequently used with an integrator to quantify the amplitude of electromyographic signals.

1.3 Filters and Frequency Response:

Filters are used to modify the frequency content of input signals. Low-pass filters attenuate the frequency content of a signal that is above a certain cutoff frequency, fc, Whereas high-pass filter attenuate frequency below the specified cutoff frequency. Band-pass filter are formed by cascading a high-pass and a low pass filter and attenuate the frequencies above and below the cutoff frequencies of the cascaded filters. Band-stop filters are formed by cascading a low-pass and high-pass filter and attenuation the frequencies between the cutoff frequencies of the cascaded filters. First-order low-pass and high-pass filters are shown in the figures (1.7) below.

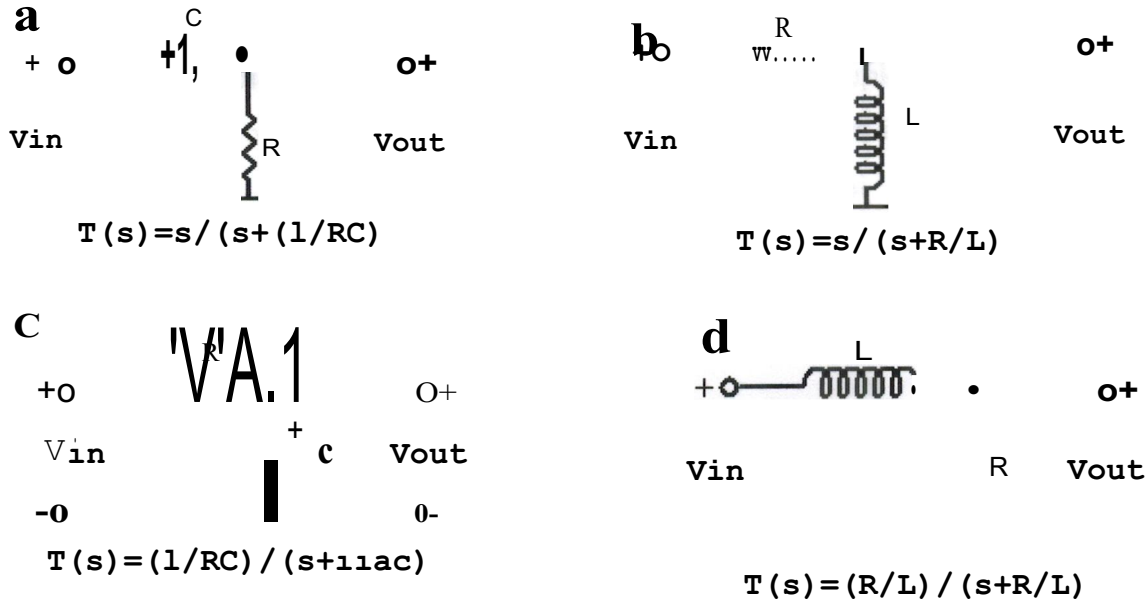


Figure 1.7 First-order low-pass and high-pass filters

Chapter 2:

Basic Transducers and Principles:

Since the beginning of the medicine, physicians have been using their senses to determine various physical parameters of the patient, e.g., position of body organs, temperature of the body, color of the Skin, etc. In an attempt to quantify the measurements of these and additional parameters from the living system, we have seen an increased application of technology to the areas of clinical and biomedical research. In many cases instruments were developed originally for the physical sciences and then adapted for specific medical applications.

This chapter deals with basic mechanisms and principles of transducers used in number of medical instruments. A *transducer* is a device that converts energy from one form to another. An electrical output from the transducer is normally desirable because of the advantage it gives in further signal processing. Material in this chapter shows that there are many methods used to convert physiological events to electrical signals. Dimensional changes may be measured by variation in resistance, inductance, capacitance, and piezoelectric effect. Thermistors and thermocouples are employed to measure body temperatures. Electromagnetic-radiation transducers include thermal and photon detectors. In our discussion of the design of medical instruments in the following chapters, we shall use the principles described in this chapter.

2.1 Displacement Measurements:

The physician and biomedical researcher are interested in measuring the size, shape, and position of the organs and tissues of the body. Variations in these parameters are important in discriminating normal from abnormal function. Displacement transducers can be used in both direct and indirect systems of measurement. Direct measurements of displacement are used to determine the change in diameter of blood vessels and changes in volume and shape of cardiac chambers.

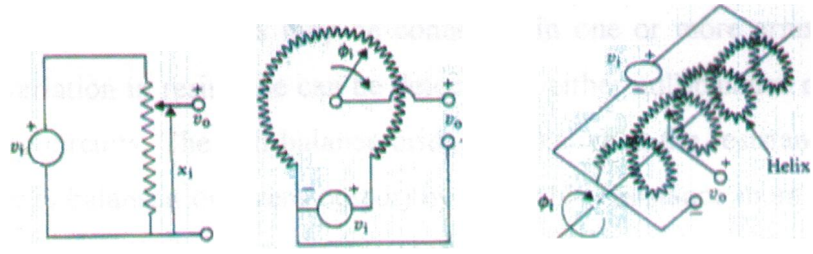
Measurements of indirect displacement are used to quantify movements of liquids through heart valves. An example is the movement of a microphone diaphragm that detects heart murmurs.

The following types of displacement-sensitive measurement methods are described in this section: resistive, inductive, capacitive, and piezoelectric.

2.2 Resistive Transducers:

2.2.1 Potentiometers

Figure 2.1 shows three types of potentiometric devices for measuring displacement. The potentiometer shown in figure 2.1(a) measures translational displacement from 2 to 500 mm. Rotational displacement ranging from 10° to more than 50° are detected as shown in figure 2.1(b) and (c). The resistance elements (composed of wire-wound, carbon-film, metal-film, conducting plastic, or ceramic material) may be excited by either de or ac voltages. These potentiometers produce a linear output (within 0.01% of full scale) as a function of displacement, provided that the potentiometer is not electrically loaded.



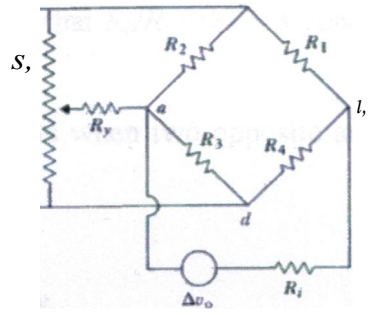
(a) Translational (b) Shaft, turn (c) Multiple-turn

Figure 2.1 Three types of potentiometric devices for measuring displacements

The resolution of these potentiometers is a function of the construction. A continuous stepless conversion of resistance is possible for low-resistance value up to 10 ohm by utilizing a straight piece of wire. For greater variations in resistance, from several ohms to several mega ohms, the resistance wire wound on a mandrel or cord. The variation in resistance is thereby not continuous, but rather stepwise, because the wiper moves from one tum of wire to the next. The fundamental limitation of the resolution is a function of the wire spacing, which may be small as 20 μm. The frictional and inertial components of these potentiometers should be low in order to minimize dynamic distortion of the system.

2.3 Bridge Circuits:

The Wheatstone-bridge circuit is ideal for measuring small changes in resistance. Figure 2.2(a) shows a Wheatstone bridge with an applied de voltage of'v, and a readout meter ~*v0* with internal resistance *R;* It can be shown by the voltage-divider approach that ~*v0* is zero, i.e., the bridge is balanced, when *RI] R2 = RJ R3.*



(a)

Figure 2.2(a) Wheatstone bridge with four active elements

Resistance-type transducers may be connected in one or more arms of a bridge circuit. The variation in resistance can be detected by either null-balance or deflection-balance bridge circuits. The null-balance bridge results when the resistance change of the transducer is balanced out (zero output) by a variable resistance in an adjacent arm of the bridge. The calibrated adjustment required for the null is an indication of the change in resistance of the transducer. The deflection-balance method, on the other hand, utilizes the amount of bridge unbalance to determine the change in transducer resistance.

Assume that all values of resistance of the bridge are initially equal to *Ro* and that *Ro* << *Ri.* An increase in resistance, M, of all resistance still results in a balanced bridge. However, if *R1* and *R3* increase by M and *R2* and *R4* decrease by M, then

$$\Delta v_0 = \frac{\Delta R}{R_0} v_i \qquad (2.1)$$

Because of the symmetry a similar expression results if *R2* and *R4* increase by M and *Rs* and *R3* decreased by M. Note that (2.1), for the four-active-arm bridge, shows that ~*vo* is linearly related to M.

If the meter's internal resistance R_i is now included in the calculations, we get the following relationship for the four-active-arm bridge.

$$V_o = \frac{A(\Delta R/R_0)v}{1 + (R_0/R_i)[1 + (\Delta R/R_0)/2]} \tag{2.2}$$

This relationship is linear provided that $R_0/R_i \ll 1$, a condition that also reduces (2.2) to (2.1).

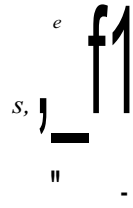
A nonlinear relationship results when two opposite arms of the bridge circuit are changed equally:

$$\frac{V_o}{V} = \frac{A(\Delta R/R_0)v}{2 + \Delta R/R_0 + 2(R_0/R_i)[1 + \Delta R/R_0]} \tag{2.3}$$

A nonlinearity in $\Delta R/R_0$ is present even when $R_0/R_i = 0$.

It is common practice to incorporate a balancing scheme in the bridge circuit [see Fig. 2.2(a)]. Resistor R_y and potentiometer R_x are used to change the initial resistance of one or more arms. This arrangement brings the bridge into balance so that zero voltage output results from "zero" (or "base-level") input of the measured parameter.

To minimize loading effects, R_x is approximately 10 times the resistance of the bridge leg and R_y limits the maximum adjustment. Strain-gage applications normally are a value of R_y = 25 times the resistance of the bridge leg (Cook and Rabinowicz, 1963). Ac balancing circuits are more complicated because a reactive as well as resistive imbalance must be compensated. Figure 2.2(b) shows the additional circuit that could be connected in the bridge for this purpose.



(b)

Figure 2.2(b) Balance circuit for ac-bridge operation

Figure 2.3 shows an application of a mercury-in-rubber strain gage for the measurement of the circumference of the human calf. This device measures the change in strain resistance in terms of bridge imbalance. Variation in dimensions are determined by means of the deflections in calibration shown.

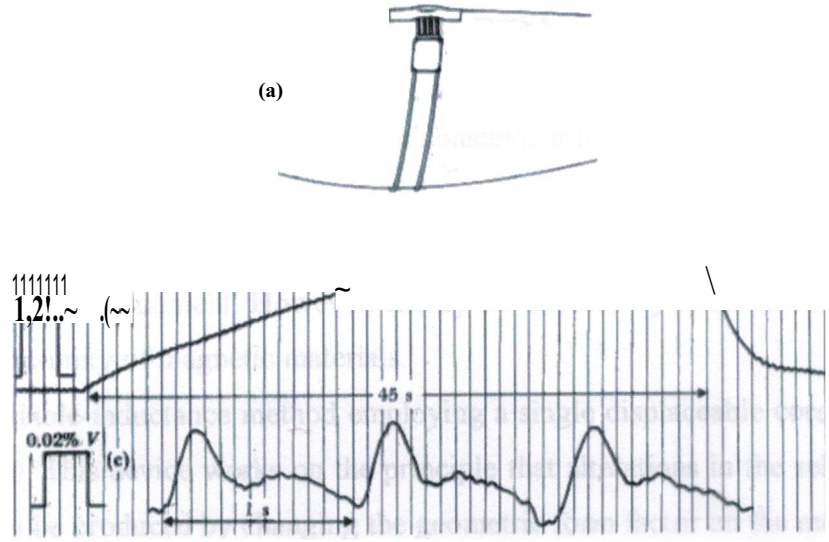


Figure 2.3 Mercury-in-rubber strain-gage plethysmography

2.4 Inductive Transducers:

An inductance L can be used to measure the displacement by varying any three of the coil parameters:

$$L = n^2 G\mu \qquad (2.4)$$

Where

n = number of turns of coil

G = geometric form function

μ = effective permeability of the medium

Each of these parameters can be changed by mechanical means.

Figure 2.4(a) shows self-inductance; Figure 2.4(b), mutual-inductance; and Figure 2.4(c), differential transformers types of inductive displacement transducers. It is usually possible to convert a mutual-inductance system into a self-inductance system by series or parallel connections of the coils. Note in Figure 2.4 that the mutual-inductance device (b) becomes a self-inductance device (a) when terminals *b-c* are connected.

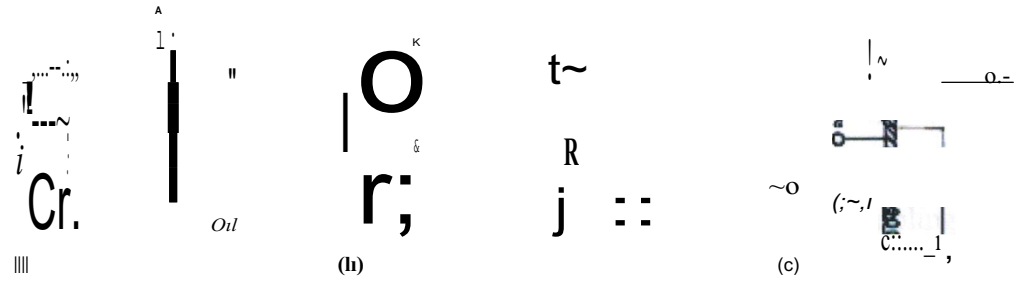


Figure 2.4 Inductive displacement transducers

An inductive transducer has an advantage in not being affected by the dielectric properties of its environment. However, it may be affected by external magnetic fields due to the proximity of magnetic materials.

The variable-inductance method employing a single displaceable core is shown in Figure 2.4(a). This device works on the principle that alterations in the self-inductance of a coil may be produced by changing the geometric form factor on the movement of a magnetic core within the coil. The change in inductance for this device is not linearly related to displacement. The fact that these devices have low power requirements and produce large variations in inductance makes them attractive for radiotelemetry applications. Allard (1962) used a single coil within a movable μ-metal core to measure the displacement of an intracardiac pressure transducer. Since this device has a frequency response that extends beyond 1 kHz, it may be used to measure both pressure and heart sounds.

The mutual-inductance transducer employs two separate coils whose variation in mutual magnetic coupling is used to measure displacement [Fig. 2.4(b)]. Cobbold (1974) describes the application of these devices with respect to measuring cardiac dimensions, monitoring infant respiration, and ascertaining arterial diameters.

Van Citters (1966) provides a good description of applications of mutual-inductance transformers in measuring changes in dimension of internal organs (kidney, major blood vessels, and left ventricle). The induced voltage in the secondary coil is a function of the geometry of the coils (separation and axial alignment), the number of and secondary turns, and the frequency and the amplitude of the excitation voltage. The induced voltage in the secondary coil is a nonlinear function of the separation of the coils. In order to maximize the output signal, a frequency is selected that causes the

secondary coil (tuned circuit) to be in resonance. The output voltage is detected with standard demodulator and amplifier circuits.

The *linear variable differential transformer* (LVDT) is widely used in physiological research and clinical medicine to measure pressure, displacement, and force. As shown in Figure 2.4(c), the LVDT is composed of a primary coil (terminals *a-b)* and two secondary coils *(c-e* and *d-e)* connected in series. The coupling between these two coils is changed by the motion of a high-permeability alloy slug between them. The two secondary coils are connected in opposition in order to achieve a wider region of linearity.

The primary coil is sinusoidally excited, with a frequency between 60 Hz and 20 kHz. The alternating magnetic field induces nearly equal voltages V_{ee} and V_{de} in the secondary coils. The output voltage $V_{ed} = V_{ee} - V_{de}$. When the slug is symmetrically placed, the two secondary voltages are equal and the output signal is zero.

LVDT characteristics include: linearity over a large range; a change of phase by 180° when the core passes through the center position; and saturation on the ends. Specifications of commercially available LVDTs include: sensitivities on the order of 0.5-2 mV for a displacement of 0.0l mm/V of primary voltage; full-scale displacement of 0.1-250 mm; and linearity of ± 0.25%. Sensitivity for LVDTs is much higher than that for strain gages.

A disadvantage of the LVDT is that it requires more complex signal-processing instrumentation. Figure 2.5 shows that essentially the same magnitude of output voltage results with two very different input displacements. The direction of displacement may be determined by using the fact that there is a 180° phase shift when the core passes through the null position. A phase-sensitive demodulator is used for determining the direction of displacement.

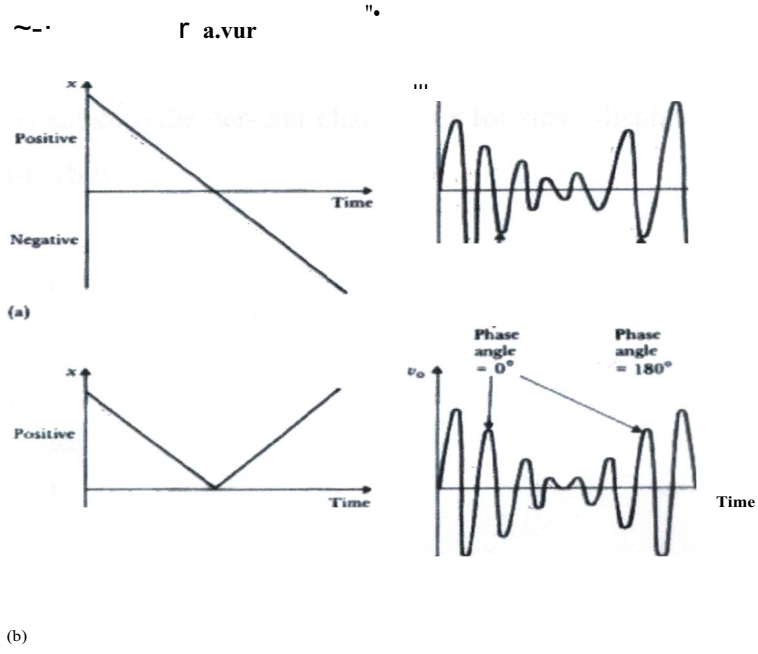


Figure 2.5 The LVDT displacement

2.5 **Capacitive Transducers:**

The capacitance between two parallel plates of area A separated by distance x is

$$C = \epsilon_0 \epsilon_r \frac{A}{x} \qquad (2.5)$$

Where ϵ_0 is the dielectric constant of free space and ϵ_r is the relative dielectric constant of the insulator (1.0 for air). In principle it is possible to monitor displacement by changing any of the three parameters: ϵ_r, A, or x. However, the method that is easiest to implement and that is most commonly used is to change the separation between the plates.

The sensitivity K of a capacity transducer to changes in plate separation, ∂x, is found by differentiating (2.5):

$$K = \frac{\sim C}{,I.x} = \frac{E_0 E_r A}{x_1} \qquad (2.6)$$

Note that the sensitivity increases as the plate separation decreases.

We may develop an expression showing that the percent change in C about any neutral point is equal to the per-unit change in x for small displacements by substituting (2.5) into (2.6). Thus

$$\frac{dC}{dx} \quad \frac{-C}{X} \qquad (2.7)$$

Or

$$\frac{dC}{C} \quad \frac{-dx}{X} \qquad (2.8)$$

The capacitance microphone shown in Figure 2.6 is an excellent example of relatively simple method for detecting variation in capacitance (Doebelin, 1975, Cobbold, 1974). Since this is a de-excited circuit, no current flows when the capacitor is stationary (with separation x_0) and thus $v_1 = E$. A change in position $\sim x = x_1 - x_0$ produces a voltage $v_0 = v_1 - E$. The output voltage V_0 is related to x_1 by

$$\frac{V_0(JOJ)}{X_1(jOJ)} \quad \frac{(EI\,x\ddot{u})JOJr}{jOJT + 1} \qquad (2.9)$$

where

$$\iota: = RC = R\,E_0E, \quad \frac{A}{x_0}$$

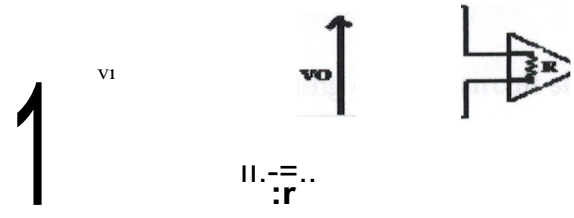


Figure 2.6 capacitance transducer for measuring dynamic displacement changes

Typically, R is 1 MQ or higher, and thus the readout device must have a high (10 MQ or higher) input impedance.

For $on:\gg 1$, $V_0(Ja;)!X_1\{Ja;)=E/x_0$, which is a constant. However, for low frequencies, the response drops off, and is zero when o =O. Thus (2.9) describes a high-pass filter. This frequency response is quite adequate for a microphone that does not measure sound pressure at frequencies below 20 Hz. However, it is inadequate for measuring most physiological variables because of their low-frequency components.

The frequency response of the capacitance transducer may be extended to de by means of an ingenious guarded parallel-plate capacitance transducer, shown in Figure 2.7 (a) (Doebelin, 1975). In addition, this technique (employing high-gain feedback amplifier) gives a linear relationship between displacement and capacitance. The displacement-varying capacitor is placed in the feed-back loop of an operational amplifier circuit, as shown in Figure 2.7 (b).

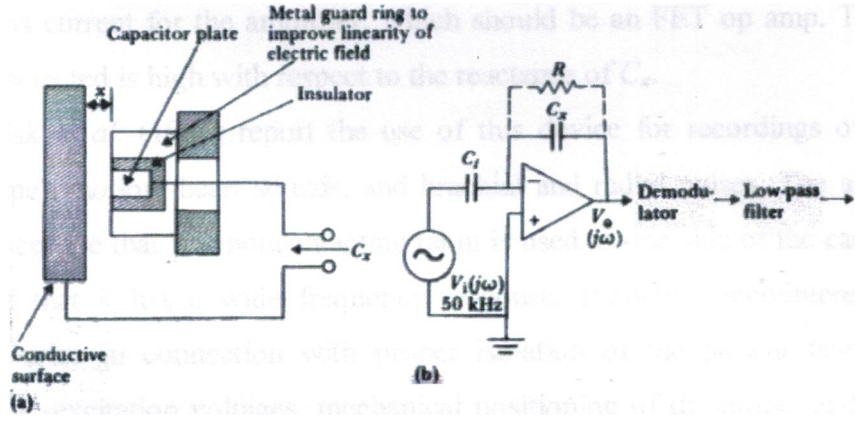


Figure 2.7 (a) Guarded parallel-plate displacement transducer. (b) Instrumentation system with output proportional to capacitance displacement.

The circuit gain of the inverting op-amp circuit shown in Figure 2.7 is given by the negative of the ratio of the feedback impedance to the input impedance; thus

$$\frac{vo(Ja;)}{V;(Ja;)} = \frac{-zAJw)}{-zJpv)} \qquad (2.10)$$

$$= -\frac{1/j\omega C_x}{1/j\omega C_i} \qquad (2.11)$$

$$= \qquad (2.12)$$

Substituting (2.5) in (2.12) yields

$$V_0(j\omega) = \frac{C_i x V_i(j\omega)}{\epsilon_0 \epsilon_r A} = Kx \qquad (2.13)$$

Equation (2.13) shows that the output voltage is linearly related to the plate separation *x.* The source voltage *v;(Jaı)* is a high-frequency source (50 kHz). The output voltage *V₀(Jm)* is an amplitude-modulated signal and the mean value *ofV₀(Jaı),* proportional to x, is found by demodulation and low-pass filtering (10 kHz corner frequency). A discharge resistor *R* must be connected in parallel with *C,* in order to provide bias current for the amplifier, which should be an FET op amp. The value of resistance selected is high with respect to the reactance of *C;*

Podolak *et al.* (1969) report the use of this device for recordings of chest-wall motions, apex motion, heart sounds, and brachial and radial pulses. The advantage of the transducer are that it is noncontacting (skin is used as one side of the capacitor) and linear, and that it has a wide frequency response. Problems encountered with this transducer arise in connection with proper isolation of the patient from the high-amplitude ac-excitation voltages, mechanical positioning of the probe, and respiratory motions during the measuring process.

Differential-capacitor system have the advantage of providing accurate measurements of displacement (Cobbold, 1974). Figure 2.10 (a) shows differential three-terminal capacitor that has the advantage oflinearly relating displacement to (C1-C2)/ (C1+C2). This can be shown by letting *d* be the equilibrium displacement and *x* be the displacement with positive direction up. Then

$$C_1 = \frac{\epsilon_0 \epsilon_r A}{d - x} \quad \text{and} \quad C_2 = \frac{\epsilon_0 \epsilon_r A}{d = x} \qquad (2.14)$$

And manipulation then gives

$$\frac{x}{d} = \frac{C_1 - C_2}{C_1 + C_2} \qquad (2.15)$$

The bridge circuit shown in Figure 2.8 (b) may be used to provide an output voltage proportional to the fractional difference in capacitance dictated by (2.20). Since the differential-capacitor values C1 and C2 are equal at the equilibrium position and C3 is balanced to equal C4, output voltage is given by

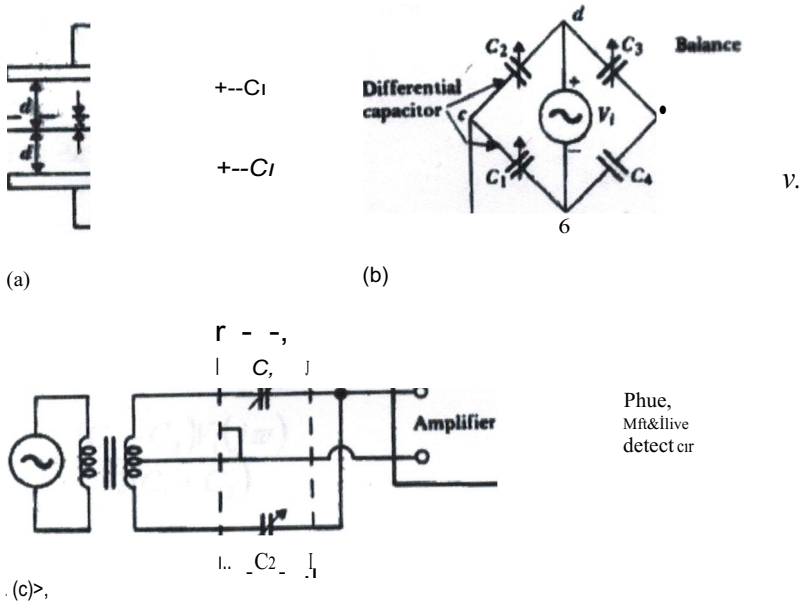


Figure 2.8 (a) Differential 3 terminal capacitor. (b) Capacitance-bridge circuit with output proportional to fractional difference in capacitance. (c) Transformer ratio-arm bridge.

$$V_0 = \frac{V}{2}\frac{C_1 - C_2}{C_1 + C_2} \qquad (2.16)$$

or

$$V_0 = \frac{V}{2d}x \qquad (2.17)$$

Figure 2.10 (b) provides an output voltage proportional to the fractional difference in capacitance. Using the voltage-divider relation, we get

$$V_{ab}(j\omega) = \frac{(1/j\omega C_4)V_i(j\omega)}{1/j\omega C_3 + 1/j\omega C_4} \qquad (2.18)$$

$$_{vcb}\{\text{im}) = \frac{(11\,Jmeı)v;\,(\text{J m})}{1/JmC_1 + 1/JmC2}$$

$$V_0(j\varpi) = V_{ab}(j\varpi) + V_{bc}(j\varpi)$$

$$= \left(\frac{C_3}{C_4 + C_3} - \frac{C_2}{C_1 + C_2}\right)V_i(j\varpi)$$

C3 is adjusted to equal C4; then

$$V_0(j\varpi) = \left(\frac{1}{2} - \frac{C_2}{C_1 + C_2}\right)V_i(j\varpi)$$

$$\_\ (\text{c}_\text{l} - \text{C}_2)\text{v};(\text{Jm})$$
$$- \quad 2(\text{C}_\text{l} + C\imath) \qquad (2.19)$$

Because this relation does not change with frequency, (2.19) reduces to (2.17).

Figure 2.10(c) shows a transformer ratio-arm bridge that can also be used to solve (2.15). Amplifier current is directly related to the degree of bridge unbalance (C1 - C2) that may be found from (2.14):

$$\text{cl} - \text{C2} = \frac{2A_{\text{EoEr}}\,x}{d^{\imath} - x^2} \qquad (2.20)$$

This expression is linear with x for the case $d >> x$, which is the normal operating condition. This type of bridge circuit has high accuracy and sensitivity. Bridge balance is independent of the third terminal shield, which makes possible the measurement of capacitance at various distances from the bridge.

2.6 Piezoelectric transducers:

Piezoelectric transducers are used to measure physiological displacements and record heart sounds. Piezoelectric materials generate an electric potential when mechanically strained, and conversely an electrical potential can cause physical deformation of the material. The principle of operation is that, when an asymmetrical crystal lattice is distorted, a change reorientation takes place, causing a relative displacement of negative and positive charges. The displaced internal charges induce surface charges of opposite polarity on opposite sides of the crystal. Surface charge can be determined by measuring the difference in voltage between electrodes attached to the surfaces.

The total induced charge q is directly proportional to the applied force f

$$q=kf \tag{2.21}$$

Where k= the piezoelectric constant, *CiN*. The change in voltage can be found by assuming that the system acts like a parallel-plate capacitor where the voltage v across the capacitor= charge q/capacitance C. Then by substitution of (2.5), we get

$$v=\frac{kf}{C}=\frac{kfx}{\epsilon_0\epsilon_r A} \tag{2.22}$$

Tables of piezoelectric constants are given in the literature (Lion, 1959; and Cobbold, 1974).

Typical values fork are 2.3 pC/N for quartz and 140 pC/N for barium titanate. For a piezoelectric transducer of 1-cm2 area and 1-mm thickness with an applied force due to a 10-g weight, the output voltage v is 0.23 and 14 mV for the quartz and barium titanate crystals, respectively.

There are various modes of operation of piezoelectric transducers, dependent on the material and the crystallographic orientation of the plate (Lion, 1959). These modes include: the thickness or longitudinal compression; transversal compression; thickness-shear action; and face-shear action.

Piezoelectric materials have a high but finite resistance. As a consequence, if a static deflection x is applied, the charge leaks through the leakage resistor (on the order of 100 GO). It is obviously quite important that the input impedance of the external voltage-measuring device be an order of magnitude higher than that of piezoelectric transducer. It would be helpful to look at the equivalent circuit for the piezoelectric transducer [Figure 2.11(a)] in order to quantify its dynamic-response characteristics.

This circuit has a charge generator q defined by

$$q=kx \tag{2.23}$$

where

k = proportionality constant, *Cim,* and x = deflection.

The circuit may be simplified by converting the charge generator to a current generator, *i.,*

$$i_t = \frac{dq}{dt} = K\frac{dx}{dt} \tag{2.24}$$

The modified circuit is shown in Figure 2.11(b), where the resistances and capacitances have been combined. Assuming that the amplifier does not draw any current, we then have

$$i_t = i_c + i_R \tag{2.25}$$

$$v_0 = v_c = \left(\frac{1}{C}\right)\int i_c dt \tag{2.26}$$

$$i_t - i_R = C\left(\frac{dv_0}{dt}\right) = K\frac{dx}{dt} - \frac{v_0}{R} \tag{2.27}$$

or

$$\frac{V_0(im)}{x(im)} = \frac{KsjaJT}{-jait + 1} \qquad (2.28)$$

where

$Ks = KIC$ (sensitivity, V/m)

$t = RC$ (time constant)

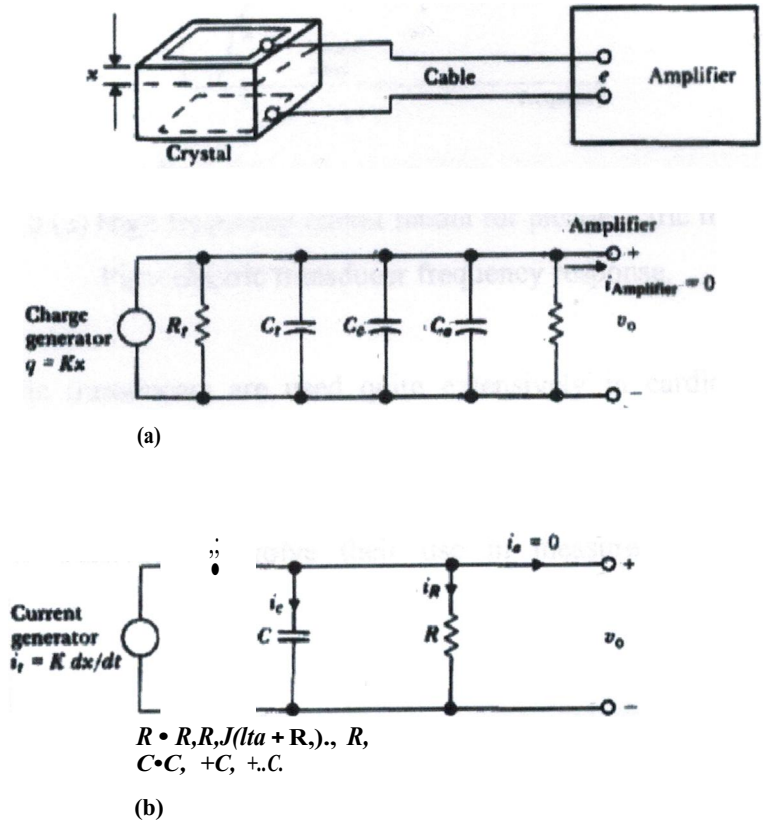
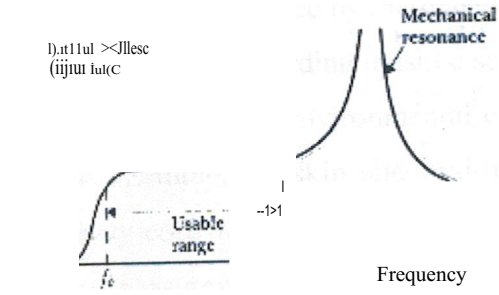


Figure 2.9 (a) Equivalent circuit of piezoelectric transducer. (b) Modified equivalent circuit with resistance and q= charge generator.

Because of its mechanical resonance, the high-frequency equivalent circuit for a piezoelectric transducer is complex. This effect can be represented by adding a series *RLC* circuit in parallel with the transducer capacitance and leakage resistance. Figure 2.10 shows the high-frequency equivalent circuit and its frequency response. Note that in some applications the mechanical resonance is useful for accurate frequency control; for example, in the case of crystal filters.



{b)

Figure 2.10 (a) High frequency circuit model for piezoelectric transducer. (b) Piezoelectric transducer frequency response.

Piezoelectric transducers are used quite extensively in cardiology for external (body-surface), and internal (intracardiac) phonocardiography. They are also used in the detection of Korotkoff sounds in blood-pressure measurements. Additional applications of piezoelectric transducers involve their use in measurements of physiological accelerations.

2.7 **Temperature measurements:**

A patient's body temperature gives important information to the physician about the physiological state of the individual. External body temperature is one of many parameters used to evaluate patients in shock, since the reduced blood pressure of a person in circulatory shock results in low blood flow to the periphery. A drop in the big-toe temperature is a good early clinical warning of shock. Infections, on the other hand, are usually reflected by an increase in body temperature, with a hot flushed skin and loss of fluids. Increased respiration, perspiration, and blood flow to the skin result when high fevers destroy temperature-sensitive enzymes and proteins. Anesthesia decreases body temperature by depressing the thermal regulatory center. In fact, physicians routinely use the technique of including hypothermia in surgical cases in which they wish to decrease a patient's metabolic processes and blood circulation.

In pediatrics, special heated incubators are used for stabilizing the body temperature of infants. Accurate monitoring of temperature and regulatory control systems are used to maintain a desirable ambient temperature for the infant.

In the study of arthritis, physicians have shown that temperatures of joints are closely correlated with the amount of local inflammation. The increased flow due to arthritis and chronic inflammation can be detected by thermal measurements.

The specific site of body-temperature recording must be selected carefully so that it truly reflects the patient's temperature. Also, environmental changes and artifacts can cause misleading readings. For example, the skin and oral-mucosa temperature of a patient seldom reflects true body-core temperature. Robertson (1973) gives a good summary of clinical temperature measurements.

The following types of thermally sensitive methods of measurement will be described in the following sections: thermocouples, thermistors.

2.8 Thermocouples:

Thermoelectric thermometry is based on discovery of Seebeck in 1821. he observed that an *electromotive force (*emf) exists across a junction of two dissimilar metals. This phenomenon is due to the sum of two independent effects. The first effect, discovered by Peltier, is an emf due solely to the contact of two unlike metals and the junction temperature. The net Peltier emf is roughly proportional to the difference between the temperatures of the two junctions. The second effect, credited to Thomson (Lord Kelvin), is an emf due to the temperature gradients along each single conductor. The net Thomson emf is proportional to the difference between the squares of the absolute junction temperatures *(T,* and T_2). The magnitudes of the Peltier and Thomson emfs may be derived from thermodynamic principles (Anonymous, 1974) and either may predominate, depending on the metals chosen.

Knowledge of these two effects is not usually useful in practical applications, so empirical calibration data are usually curvefitted with a power series expansion that yields the Seebeck voltage,

$$E=aT+-b\frac{1}{2}T^{2}+\ldots \qquad (2.29)$$

where *Tis* in degrees Celsius and the reference junction is maintained at 0°C.

Figure 2.1 l(a) is a thermocouple circuit with two dissimilar metals, *A* and *B,* at two different temperatures, Tl and 12. The net emf at terminals *c* - *d* is a function of the difference between the temperatures at the two junctions and the properties of the two metals. In the practical situation, one junction is held at a constant known temperature (i.e., by an ice bath or controlled oven) for a reference in order to determine the desired or unknown temperature.

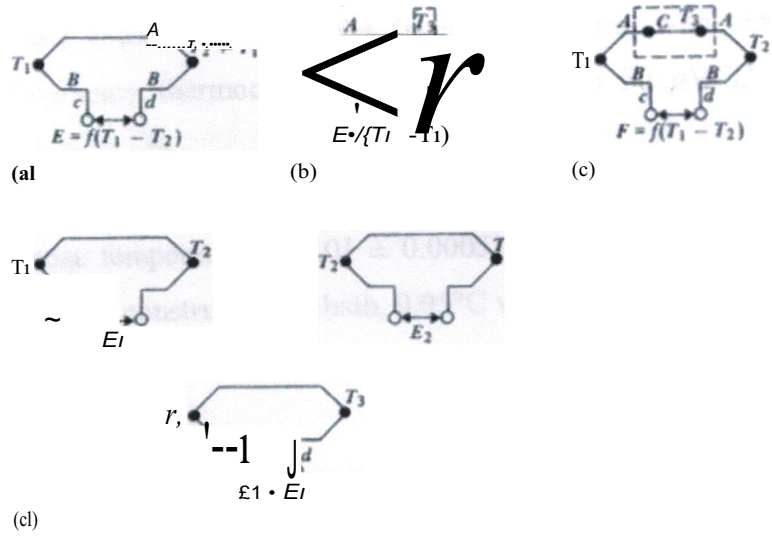


Figure 2.11 Thermocouple circuits.

An understanding of the three empirical thermocouple laws leads to using them properly. The first law, *homogeneous circuits,* states that, in a circuit composed of a single homogeneous metal, one cannot maintain an electric current by the application of heat alone. In Fig. 2.1 l(b), the net emf at *c--d* is the same as in Figure 2.1 l(a) regardless of the fact that a temperature distribution (T3) exists along one of the wires *(A).*

The second law, *intermediate metals,* states that the net emf in a circuit consisting of an interconnection of a number of unlike metals, maintained at the same temperature, is zero. The practical implication of this principle is that lead wires may be attached to the thermocouple without affecting the accuracy of the measured emf, provided that the newly formed junctions are at the same temperature [Figure 2.1 l(c)].

The third law, *successive* or *intermediate temperatures,* is illustrated in Figure 2. ll(d), where emf £l is generated when two dissimilar metals have junctions at temperatures Tl and *T2* and emf £2 results for temperatures *Tı* and *T3.* It follows that an emf £l + £2 results at *c--d* when the junctions are at temperatures *Tı* and *T3.* This

principle makes it possible for calibration curves derived for a given reference-junction temperature to be used to determine the calibration curves for another reference temperature.

The *thermoelectric sensitivity a (*also called the thermoelectric power or the Seebeck coefficient) is found by differentiating (2.29) with respect to *T.* Then

$$a = dE / dT = a + bT + \ldots \tag{2.30}$$

Note that *a* is not a constant, but varies (usually increases) with temperature. The sensitivities of common thermocouples range from 6.5 to 80 μV/°C at 20°C, with accuracies from V,10/0 to 1%.

For accurate readings, the reference junction should be kept in a triple-point-of-water device whose temperature is 0.0l ± 0.0005°C (Doebelin, 1975). Normally the accuracy of a properly constructed ice bath, 0.05°C with a reproducibility of 0.001°C, is all that is necessary. Temperature-controlled ovens can maintain a reference temperature to within± 0.4°C.

Increased sensitivity may be achieved by connecting a number of thermocouples in series, all of them measuring the same temperature and using the same reference junction. An arrangement of multiple-junction thermocouples is referred to as a *thermopile.* Parallel combinations may be used to measure average temperature.

Direct readout of the thermocouple voltage is easily done using a digital voltmeter. Chart recordings may be secured by using a self-balancing potentiometer system. The linearity of this latter device is dependent only on the thermocouple and potentiometer; it is independent of the other circuitry.

Thermocouples have the following advantages: fast response time (time constant as small as 1 ms), small size (down to 12 *μm* diameter), ease of fabrication, and long-term stability. Their disadvantages are: small output voltage, low sensitivity, and need for a reference temperature.

Numerous examples of the use of thermocouples in biomedical research are given in the literature (Hardy, 1962). Since thermocouples can be made small in size, they can be inserted into catheters and hypodermic needles.

2.9 Thermistors:

Thermistors are semiconductors made of ceramic materials that are thermal resistors with a high negative temperature coefficient. These materials react to temperature changes in a way that is opposite to the way metals react to such changes. The resistance of thermistors decreases as temperature increases and increases as temperature decreases (Sachse, 1975).

Sapoff (1971) reviewed the various types of thermistors that have been found to be most suitable for biomedical use. The resistivity of thermistor semiconductors used for biomedical applications is between 0.1 to 100 n ' m. These devices are small in size (they can be made less than 0.5 mm in diameter), have a relatively large sensitivity to temperature changes (-3 to -5 %/°C), and have excellent long-term stability characteristics(± 0.2 % of nominal resistance value per year).

Figure 2.12(a) shows a typical family of resistance-versus-temperature characteristics of thermistors. These properties are measured for the thermistor operated at a very small amount of power such that there is negligible self-heating. This resistance is commonly referred to as *zero-power resistance.* The empirical relationship between the thermistor resistance R_t and absolute temperature Tin Kelvins (K) (the SI unit *Kelvin* does not use a degree sign) is

$$Rt = R_0 e^{[\beta(T_0 - T)/TT_0]} \qquad (2.31)$$

Where

fJ = material constant for thermistor, K

To = standard reference temperature, K

1000

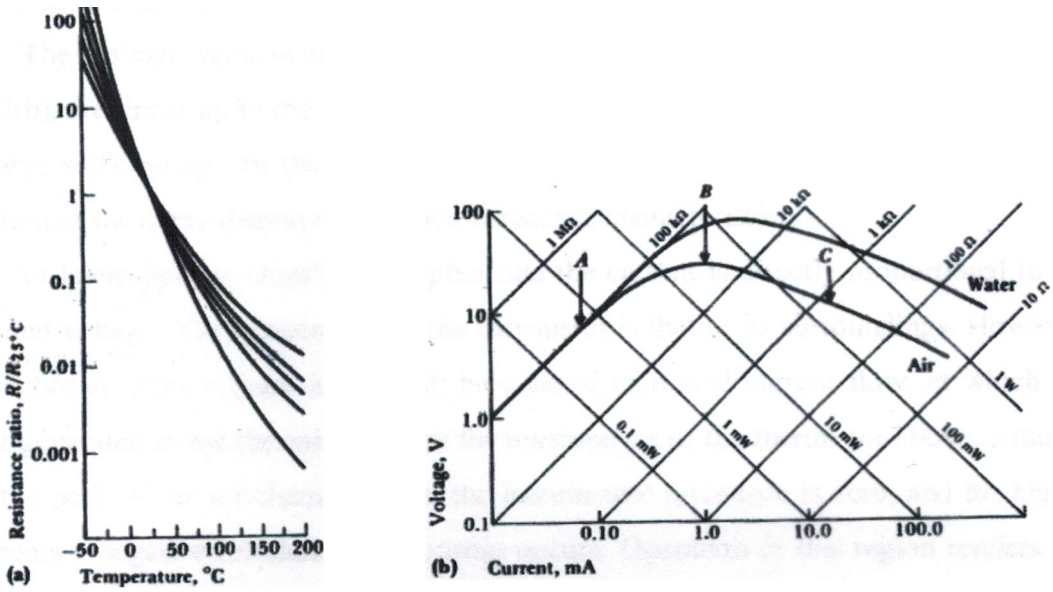


Figure 2.12 (a) Typical thermistor zero-power resistance rauo-temperature characteristics for various materials. (b) Thermistor voltage-versus-current characteristic for a thsrniistor in air and water. The diagonal lines l\ith a positive slope give linear resistance values and $howthe degree of thermistor linearity at low currents. The intersection of the thermistor curves and the diagonal line, with negative slope give the device power dissipation. Point *A* i5 the maximum current value for no appreciable self-heat. Point *8* is the peak voltage. Point *C* .is the maximum safe continuous current in air. [Part (b) is from *Tlmwri.stor Mamul,* EMC-6, © 1974. Fenwal Electronics, Framingham, Mass.; used b)' perniission.J

Figure 2.12 (a) Typical thermistor zero-power resistance ratio-temperature characteristics for various materials. (b) Thermistor voltage-versus-current for a thermistor in air and water.

The value of /J increases slightly with temperature. However, over the limited temperature spans for biomedical work (10 - 20 K), this does not present a problem. /J, also known as the characteristic temperature, is in the range of 2500 - 5000 K. it is usually about 4000 K.

The temperature coefficient *a* can be found by differentiating (2.31) with respect to *T* and dividing by *R;* Thus

$$a = \frac{1}{R1}\frac{dR_l}{dT} = \frac{/J}{T_2} \quad (\%/K) \qquad (2.32)$$

Note from (2.32) that a is a nonlinear function of temperature. This nonlinearity is also reflected in Figure 2.12(a).

The voltage-versus-current characteristics of Thermistors, as shown in Figure 2.12(b), are linear up to the point at which self-heating becomes a problem. When there is large self-heating, the thermistor voltage drop decreases as the current increase. This portion of the curve displays a negative-resistance characteristic.

In linear portion Ohm's law applies and the current is directly proportional to the applied voltage. The temperature of the thermistor is that of its surroundings. However, at higher currents a point is reached, because of increased current flow, at which the heat generated in the thermistor raises the temperature of the thermistor above ambient. At the peak of the *v-i* characteristics, the incremental resistance is zero, and for higher currents a negative-resistance relationship occurs. Operation in this region renders the device vulnerable to thermal destruction.

Figure 2.12(b) shows the difference in the self-heat regions for a thermistor in water and air due to the differences in thermal resistance of air and water. The principle of variation in thermal resistance can be used to measure blood velocity.

The current-time characteristics of a thermistor are important in any dynamic analysis of the system. When a step change in voltage is applied to series circuit consisting of a resistor and a thermistor, a current flows. The time delay for the current to reach its maximum value is a function of the voltage applied, the mass of the thermistor, and the value of the series-circuit resistance. Time delays from milliseconds to several minutes are possible with thermistor circuits. Similar time delays occur when the temperature surrounding the thermistor is changed in a step fashion.

Various schemes for linearizing the resistance-':ersus-temperature characteristics of Thermistors have been proposed (Beakley, 1951; Bryce, 1967; Cobbold, 1974; Doebelin, 1975). The nonlinearity of a thermistor may be reduced by shunting the thermistor by a resistor *Rp.* Figure 2.13(a) shows the scheme for linearization and Figure 2.13(b) shows the plot of resistance versus temperature for the total resistance, with and without linearization.

In a similar way the conductance-temperature characteristics may be linearized by placing a resistance *Rs* in series with the thermistor [Figure 2.13(c)]. Figure 2.13(d) gives the conductance-versus-temper--aturœharacteristics with and without the series resistance. The linearization scheme of Figure 2.13(a) is employed when a constant-current source drives the current and the thermistor voltage is measured. That of Figure

2.13(c) is used when a constant voltage is applied and the current through the thermistor is measured.

Specific values of *Rp* and *Rs* can be found by calculation. In the first case, it is desirable to place the point of inflection of the linearizerd thermistor curve at the midscale of temperature variations. The parallel combination of *Rp* and *R,* is

$$R = \frac{R_p R_t}{R_p + R_t} \tag{2.33}$$

The inflection point lies where the second derivative of *R* with respect to temperature is zero. From (2.31), this gives

$$R_P = R_{tm} \frac{\beta - 2T_m}{\beta + 2T_m} \tag{2.34}$$

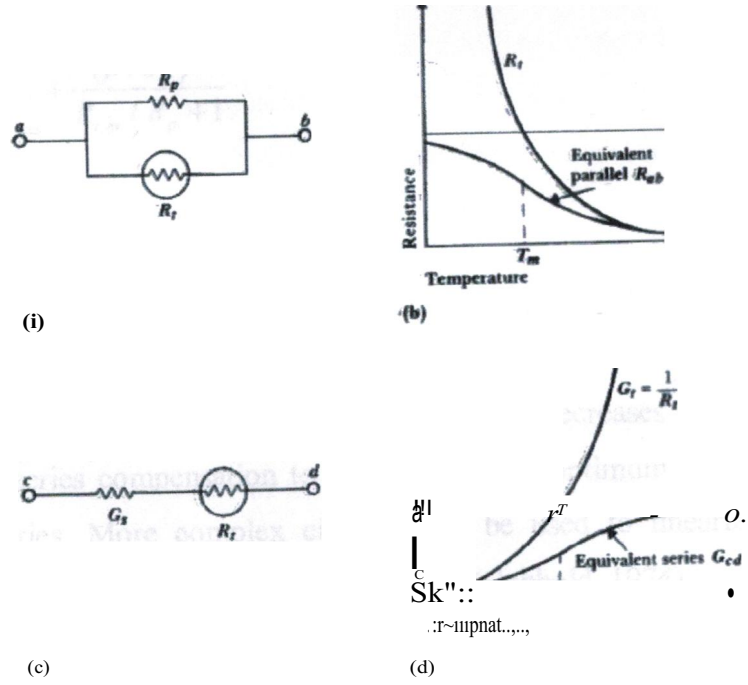


Figure 2.13 Various linearizat.ion -schemes of -thermisıcr characteristics. (a) !Resistor *R~* is connected ın .parallel with the thermistor *R,*. (b) :R.esistanw,.veMus-ıtempenıture characwrişlics for parallel compensation. (c) ·Conductance *G,* is connected in series with the thermistor *G,*. (d) Conduct.ance-versuHemperature characteristics for series compensation. (From *Troıs.ıluun Jor M,Ji«d Mrtuıır,-,ıis: Applüaıum and ·Dmgn.* b R.-S.C. Cobbold. Copyright© 1974,John Wiley and Sons, Inc. Reprinted by pennis.sioıı of john Wiley and Sons, Inc)

Figure 2.13 Various linearization schemes ofthermistot characteristics

Where $R_{t,m}$ is the thermistor resistance value at the midscale temperature T_m. The desired value of R_s for linearizing the conductance-versus-temperature curve may be found using the same approach. In this case,

$$G_s = \frac{1}{R_s} = G_{t,m} \frac{\beta - 2T_m}{\beta + 2T_m} \tag{2.35}$$

Where $G_{t,m}$ is the thermistor conductance value at the midscale temperature.

A specific example with typical values illustrates the improvement in linearity (Beakley, 1951). If we assume that $\beta = 3000$ K and $T_m = 3000$ K, then $G_s = 1.5\ G_{300}$ [from (2.35)]. For a ± 10°C variation in temperature, the deviation in linearity is less than 0.03°C; whereas for a ± 15°C change, it increases to 0.1°C.

As with all improvements in circuit performance, there must be a tradeoff in some other parameter of the system. In this case, the value of the temperature coefficient α is decreased in the parallel and series linearization circuits to

$$\alpha_{\text{parallel}} = \frac{R_{t,m} / R_p + \beta / T_J 2}{R_{t,m} / R_p + 1} \tag{2.36}$$

and

$$\alpha_{\text{series}} = \frac{G_{t,m} / G_s + \beta / T_J 2}{G_{t,m} / G_s + 1} \tag{2.37}$$

Using the same values as above, we find that α decreases from 3.3%/°C for the case with no series compensation to 2%/°C when an optimum value of resistance is inserted in series. More complex circuits may be used to linearize the thermistor characteristics over a wider temperature variation (Cobbold, 1974).

The circuitry used for thermistor readout is essentially the same as for conductive sensors, and many of the same techniques apply. Bridge circuits give high sensivity and good accuracy. The bridge circuit shown in Figure 2.2(b) could be used with $R_3 = R_t$ and R_4 = the thermistor resistance at the midscale value.

Very small differences in temperature can be found using a differential-temperature bridge. It is often necessary to measure such minute differences *in*

biological work (Hardy, 1962). An example would be determining the difference in temperature of two organs or of multiple sites of the same organ.

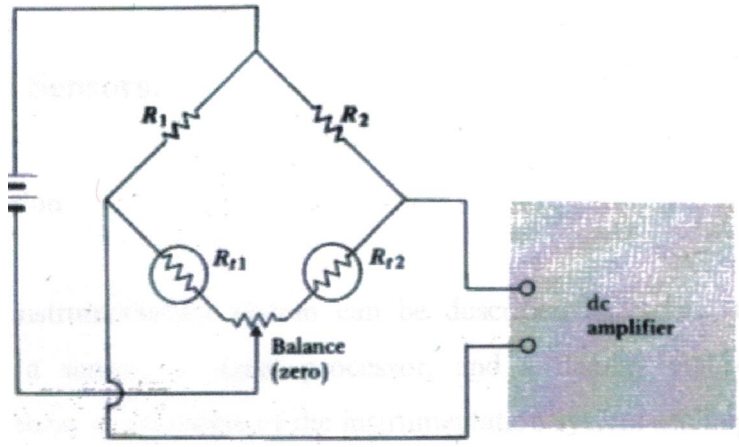
The de differential bridge shown in Figure 2.14(a) can achieve a linearity of better than 1 % of full-scale output when bead thermistors matched to within ±1 % of each other at 25°C are used. The de stability of this bridge is not normally a problem, since the output voltage of the bridge even for temperature differences of 0.01 % is larger than the de drift of good integrated-circuit operational amplifiers (Cobbold, 1974).

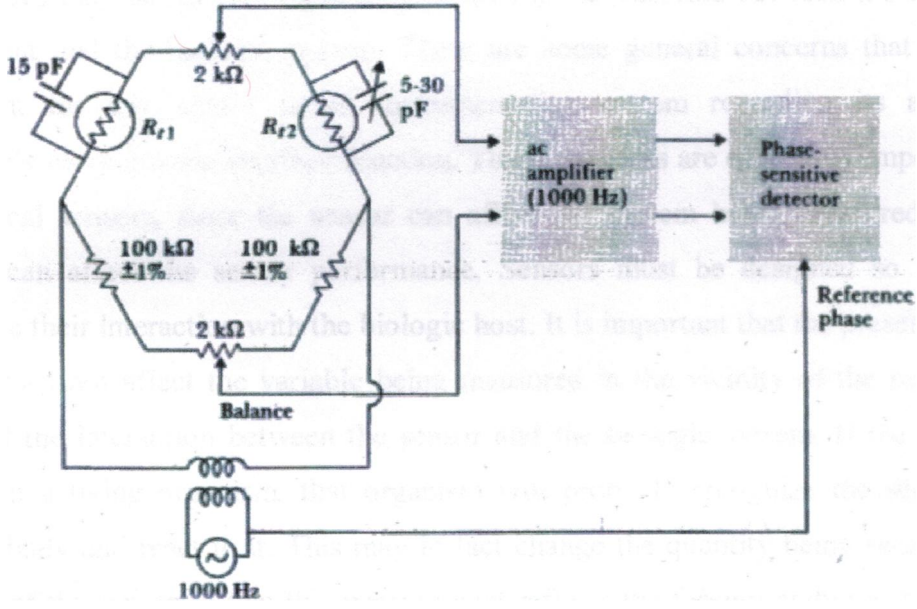
Nancollas and Hardy (1967) have designed an ac-excited differential bridge for use in *calorimetry* (the determination of the heats of reaction of components of cells). Figure 2.14(b) shows this bridge, which achieves a higher sensitivity than the de version. A carrier frequency is selected such that the amplifier and the thermistor noise is minimized. A phase-sensitive-demodulation system is used to detect the signal. The capacitive-reactance imbalance of the two Thermistors can be nulled by placing a fixed capacitor across one of the Thermistors and a variable capacitor across the other.

Operational-amplifier circuits may be used to measure the current in a thermistor as a function of temperature. In essence, this circuit applies a constant voltage to the thermistor and monitors its current with a current-voltage converter.

Various shapes of Thermistors are available: beads, chips, rods and washers (Sapoff, 1971). The glass-encapsulated bead thermistor is the one most commonly used in biomedical applications. The glass coating protects the sensing element from ther hostile environment of the body without significantly affecting the thermal response time of the system. The small size of these Thermistors makes possible their placement at the tip of catheters or hypodermic needles. The thermodilution-catheter system emplyes a four-lumen catheter with a thermistor located near the catheter tip

An additional application of thermistors is in the clinical measurement of oral temperature. Thermistor probes with disposable sheaths are presently used. However, these systems have not been accepted as rapidly as some people expected them to. Many manufacturers are experimenting with completely disposable probes, hoping that this convenience feature will improve their acceptability in clinical use.





(b)

Figure 2.14 (a) dc differential-temperature bridge. (b) ac differential-temperature bridge. R_{t1} and R_{t2} are matched thermistors 100 kΩ (± 1%). (From *Transducers for Medical Measurements: Application and Design*, by R.S.C. Cobbold. Copyright © 1974, John Wiley and Sons, Inc. Reprinted by permission of John Wiley and Sons, Inc.)

Figure 2.14 (a) de differential-temperature bridge. (b) ac differential-temperature bridge.

Chapter 3:

Biomedical Sensors:

3.1 Introduction

Any instrumentation system can be described as having three fundamental components: a sensor, a signal processor, and a display and/or storage device. Although all these components of the instrumentation system are important, the sensor serves a special function in that it interfaces the instrument with the system being measured. In the case of biomedical instrumentation a biomedical sensor (which in some cases may be referred to as a biosensor) is the interface between the electronic instrument and the biologic system. There are some general concerns that are very important for any sensor in an instrumentation system regarding its ability to effectively carry out the interface function. These concerns are especially important for biomedical sensors, since the sensor can affect the system being measured and the system can affect the sensor performance. Sensors must be designed so that they minimize their interaction with the biologic host. It is important that the presence of the sensor does not affect the variable being measured in the vicinity of the sensor as a result of the interaction between the sensor and the biologic system. If the sensor is placed in a living organism, that organism will probably recognize the sensor as a foreign body and react to it. This may in fact change the quantity being sensed in the vicinity of the sensor so that the measurement reflects the foreign body reaction rather than a central characteristic of the host.

Similarly, the biological system can affect the performance of the sensor. The foreign body reaction might cause the host to attempt to break down the materials of the sensor as a way to remove it. This may, in fact, degrade the sensor package so that the sensor can no longer perform in an adequate manner. Even if the foreign body reaction is not strong enough to affect the measurement, just the fact that the sensor is placed in a warm, aqueous environment may cause water to eventually invade the package and degrade the function of the sensor.

Finally, as will be described below, sensors that are implanted in the body are not accessible for calibration.

Thus, such sensors must be extremely stable so that frequent calibrations are not necessary.

Biomedical sensors can be classified according to how they are used with respect to the biologic system. Table 3.1 shows that sensors can range from noninvasive to invasive as far as the biologic host is concerned. The most noninvasive of biomedical sensors do not even contact the biological system being measured. Sensors of radiant heat or sound energy coming from an organism are examples of noncontacting sensors. Noninvasivesensors can also be placed on the body surface. Skin surface thermometers, biopotential electrodes, and strain gauges placed on the skin are examples of noninvasive sensors. Indwelling sensors are those which can be placed into a natural body cavity that communicates with the outside. These are sometimes referred to as minimally invasive sensors and include such familiar sensors as oral-rectal thermometers, intrauterine pressure transducers, and stomach pH sensors. The most invasive sensors are those that need to be surgically placed and that involve some tissue damage associated with their installation. For example, a needle electrode for picking up electromyographic signals directly from muscles; a blood pressure sensor placed in an artery, vein, or the heart itself; or a blood flow transducer positioned on a major artery are all examples of invasive sensors. We can also classify sensors in terms of the quantities that they measure. Physical sensors are used in measuring physical quantities such as displacement, pressure, and flow, while chemical sensors are used to determine the concentration of chemical substances within the host. A subgroup of the chemical sensors that are concerned with sensing the presence and the concentration of biochemical materials in the host are known as bioanalytical sensors, or sometimes they are referred to as biosensors.

Table 3.1 Classification of biomedical Sensors

Table 3.2 Physical Variables sensed by biomedical Sensors

TABLE 3.1 Classification of Biomedical Sensors According to Their Interface with the Biologic Host

Nouiinvasive	Noncontacting
	Body surface
Invasive	huil'ı't1elling
	Implanted

TABLE 3.2 Physical Variables Sensed by Biomedical Sensors

Displacement, velocity, acceleration (linear and angular)
Temperature
Force (weight and mass
Pressure
Flow
Radiant energy (optical

In the following sections, I will be commenting on each type of sensor and present some examples as well as describe some of the important issues surrounding these types of sensors.

3.2 Physical Sensors

Physical variables associated with biomedical systems are measured by a group of sensors known as physical sensors. A list of typical variables that are frequently measured by these devices is given in Table 3.2. These quantities are similar to physical quantities measured by sensors for nonbiomedical applications, and the devices used for biomedical and nonbiomedical sensing are, therefore, quite similar. There are, however, two principal exceptions: pressure and flow sensors.

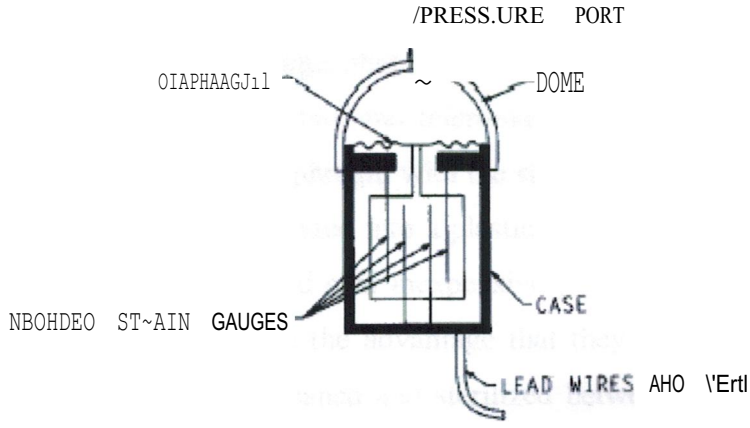


FIGURE 3.1 An unbonded strain gauge pressure transducer.

The measurement of blood pressure and blood flow in humans and other animals remains a difficult problem in biomedical sensing. Direct blood pressure measurement refers to evaluation of the blood pressure using a sensor that is in contact with the blood being measured or contacts it through an intermediate fluid such as a physiologic saline solution. Direct blood pressure sensors are invasive. Indirect blood pressure measurement involves a sensor that does not actually contact the blood. The most familiar indirect blood pressure measurement is the sphygmomanometer cuff that is usually used in most medical examinations. It is a noninvasive instrument. Until recently, the primary sensor used for direct blood pressure measurement was the

unbonded strain gauge pressure transducer shown in Fig. 3.1. The basic principle of this device is that a differential pressure seen across a diaphragm will cause that diaphragm to deflect. This deflection is then measured by a displacement transducer. In the unbonded strain gauge sensor a closed chamber is covered by a flexible diaphragm. This diaphragm is attached to a structure that has four fine gauge wires drawn between it and the chamber walls. A dome with the appropriate hardware for coupling to a pressure source covers the diaphragm on the side opposite the chamber such that when the pressure in the dome exceeds the pressure in the chamber, the diaphragm is deflected into the chamber. This causes two of the fine wires to stretch by a small amount while the other two wires contract by the same amount. The electrical resistances of the wires that are stretched increases while that of the wires that contract decreases. By connecting these wires, or more correctly these unbonded strain gauges, into a Wheatstone bridge circuit, a voltage proportional to the deflection of the diaphragm can be obtained.

In recent years semiconductor technology has been applied to the design of pressure transducers. Silicon strain gauges that are much more sensitive than their wire counterparts are formed on a silicon chip, and micromachining technology is used to form this portion of the chip into a diaphragm with the strain gauges integrated into its surface. This structure is then incorporated into a plastic housing and dome assembly. The entire sensor can be fabricated and sold inexpensively so that disposable, single-use devices can be made. These have the advantage that they are only used on one patient and they do not have to be cleaned and sterilized between patients. By using them on only one patient, the risk of transmitting blood-borne infections is eliminated.

In biomedical applications pressure is generally referenced to atmospheric pressure. Therefore, the pressure in the chamber of the pressure transducer must be maintained at atmospheric pressure. This is done by means of a vent in the chamber wall or a fine bore, flexible capillary tube that couples the chamber to the atmosphere.

This tube is usually included in the electrical cable connecting the pressure transducer to the external instrumentation such that the tube is open to the atmosphere at the cable connecter.

In using this sensor to measure blood pressure the dome is coupled to a flexible plastic tube, and the dome and tube are filled with a physiological saline solution.

As described by Pascal's Law, the pressure in the dome, and hence against the diaphragm, will be the same as that at the tip of the tube provided the tip of the tube is

at the same horizontal level as the dome. Thus by threading the tube into a blood vessel, an invasive procedure, the blood pressure in that vessel can be transmitted to the dome and hence the diaphragm of the pressure transducer. The pressure transducer will, therefore, sense the pressure in the vessel. This technique is known as external direct blood pressure measurement, and the flexible plastic tube that enters the blood vessel is known as a catheter. It is important to remember that the horizontal level of the blood pressure transducer dome must be the same as that of the tip of the catheter in the blood vessel to accurately measure the pressure in that vessel without adding an error due to the hydrostatic pressure in the catheter.

In addition to problems due to hydrostatic pressure differences between the chamber and the dome, catheters introduce pressure errors as a result of the dynamic properties of the catheter, fluid, dome, and diaphragm. These properties as well as air bubbles in the catheter, or obstructions due to clotted blood or other materials, introduce resonances and damping.

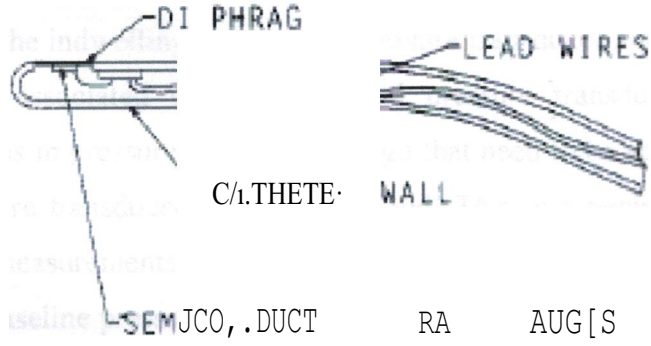


FIGURE 3.2 A catheter DIP pressure traasducer,

These problems can be minimized by utilizing miniature pressure transducers fabricated using microelectronic semi-conductor technology that are located at the tip of a catheter rather than at the end that is external to the body. A general arrangement for such a pressure transducer is shown in Fig. 3.2. As with the disposable sensors, strain gauges are integrated into the diaphragm of the transducer such that they detect very small de flections of this diaphragm. Because of the small size, small diaphragm displacement, and lack of a catheter with a fluid column, these sensors have a much

broader frequency response, give a clearer signal, and do not have any hydrostatic pressure error.

It must be pointed out that the use of such a sensor is not limited to blood pressure measurement. The strain gauge pressure sensor can be used to measure the pressure of any fluid to which it is appropriately coupled.

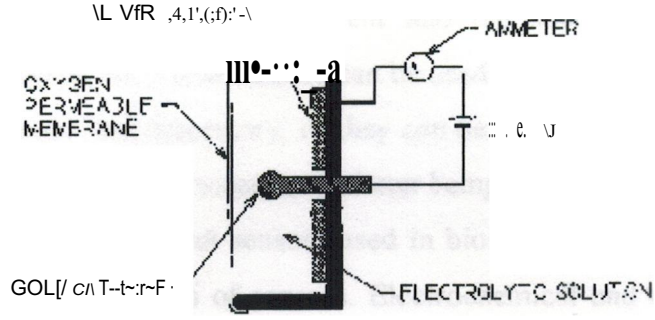


Figure 3.3 The Clark electrode, an amperometric electrochemical sensor of oxygen.

Although the indwelling catheter tip pressure transducer appears to solve many of the problems associated with the external pressure transducer, there are still important problems in pressure transducer design that need to be addressed. Long-term stability of pressure transducers is not very good. This is especially problematic for venous pressure measurements which are carried out at relatively low pressure. Long-term changes in baseline pressure require pressure transducers to be frequently adjusted to be certain of zero pressure. While this can be done relatively easily for external and indwelling pressure transducers, there is no way to carry out this procedure for implanted transducers, since there is not a way to establish zero pressure at the sensor. Thus devices that have very low long-term baseline drift are essential for implantable applications.

The packaging of the pressure transducer also represents a problem that needs to be addressed. Packaging must both protect the transducer and be biocompatible. It also must allow the appropriate pressure to be transmitted from the biologic fluid to the diaphragm. The amount of packaging material required should be kept at a minimum so as not to substantially increase the size of implantable or indwelling sensors. Furthermore, the material must be mechanically stable so that it does not swell or

contract, since this will most likely change the baseline pressure seen by the sensor. These problems need to be overcome before miniature pressure transducers can be used reliably in implantable applications.

3.3 Chemical Sensors

There are many biomedical problems where it is necessary to know the concentration of a particular substance in a biological sample. Chemical sensors provide the interface between an instrument and the specimen to allow one to determine this concentration. These sensors can be used on a biological specimen taken from the host and tested in a laboratory, or they can be used for *In vivo* measurements either as noninvasive or invasive sensors, the latter being the most frequently used.
There are many types of chemical sensors used in biomedical instrumentation. Table 3.3 lists some general categories of sensors. Electrochemical and optical sensors are most frequently used for biomedical measurements both *in vivo* and *in vitro.*

TABLE J_J Classilk.atfoıs of Ghemical Biomedical ::ıemıors

1. Electmcbemic:.tl
   a. Amperometrtc
   b. Petentıometri
   c, Coulometrt
.2. Optical
   a. Colormıetnc
   b, Emission and absorption spectroscopy
   c, Fluorescence
   d; Chemiluminescence
.3. Thermal methods
   a. Calorimetry
   b, Thermoceııducttritş
4!. Nuclear magnetic resonance

An example of an electrochemical sensor is the Clark electrode illustrated in Fig3.3. This consists of an electrochemical cell separated from the specimen being measured by an oxygen-permeable membrane. The cell is driven at a fixed potential of 600 mV, and under these conditions the following reaction occurs at the noble metal cathode:

$$O_2 + 4e^- + H_2O \rightarrow 4OH^-$$

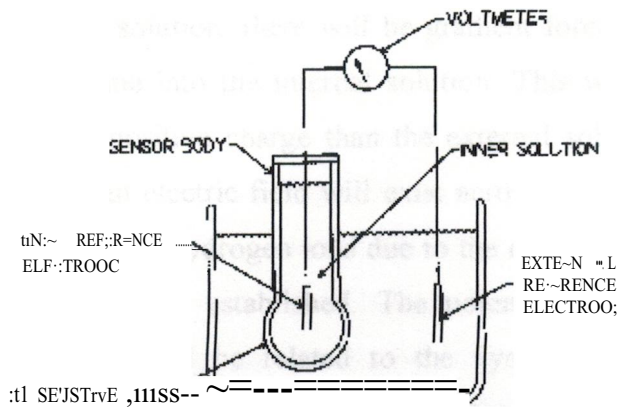


Figure 3.4 Glass pH electrode

This reaction involves the reduction of molecular oxygen that diffuses into the cell through the oxygen permeable membrane. Since the other components of the reaction are in abundance, the rate of the reaction is limited by the amount of oxygen available. Thus, the rate of electrons used at the cathode is directly related to the available oxygen. In other words, the cathode current is proportional to the partial pressure of oxygen in the specimen being measured.

The electrochemical cell is completed by the silver anode. The reaction at the anode involves forming the low-solubility salt, silver-chloride, from the anode material itself and the chloride ion contained in the electrolyte. The cell is designed so that these materials are also in abundance so that their concentration does not affect the sensor performance. This type of sensor is an example of an amperometric electrochemical sensor.

There is another type of electrochemical sensor that is frequently used in biomedical laboratories is the glass pH electrode. The acidity or alkalinity of a solution is characterized by its pH This quantity is defined as

$$pH = - \log_{10} [H^+]$$

where [H] is the activity of the hydrogen ions in solution, a quantity that is related to the concentration of + the hydrogen ions. This sensor only works in an aqueous environment. It consists of an inner chamber containing an electrolytic solution of known pH and an outer solution with an unknown pH that is to be measured. The membrane consists of a specially formulated glass that will in essence allow hydrogen ions to pass in either direction but will not pass other chemical species. If the

concentration of hydrogen ions in the external solution is greater than that in the internal solution, there will be gradient forcing hydrogen ions to diffuse through the membrane into the internal solution. This will cause the internal solution to have a greater positive charge than the external solution so that an electrical potential and, hence, an electric field will exist across the membrane. This field will counteract the diffusion of hydrogen ions due to the concentration difference and so equilibrium will be eventually established. The potential across the membrane at this equilibrium condition will be related to the hydrogen ion concentration difference (or more accurately the activity difference) between the inner and outer solutions. This potential is given by the Nernst equation

$$E = -\frac{RT}{nF} \ln \left(a_{1)} \right.$$
$$a2.$$

where E is the potential measured, R is the universal gas constant, T is the absolute temperature, n is the valence of the ion, and a.and a_2 are the activities of the ions on each side of the membrane. Thus the potential measured across the glass membrane will be proportional to the pH of the solution being studied. At room temperature the theoretical sensitivity of the electrode is approximately 60 mV/pH. It is not practical to measure the potential across the membrane directly and so reference electrodes, sensors that can be used to measure electrical potential of an electrolytic solution, are used to contact the solution on either side of the membrane to measure the potential difference across it. The reference electrodes and the glass membrane are incorporated into the structure shown in Fig. 3.4 known as a glass pH electrode. This is an example of a potentiometric measurement made using an ion-selective membrane.

There are other types of ion-selective membrane potentiometric chemical sensors that are used for biomedical applications. The membranes of these sensors determine the ion being sensed. The membrane can be based upon glass or a polymeric material such as polyvinyl chloride, but the key component is the substance that is added to the membrane that allows it to selectively pass a single ion.

Important problems in the development of chemical biomedical sensors are similar to those discussed above for the pressure sensor. Issues of long-term stability and packaging are critical to the success of a chemical sensor. The package is even more critical in chemical sensors than it was in pressure sensors in that the package must protect portions of the sensor that require isolation from the solutions being

measured while it provides direct contact of the chemically sensitive portions of the sensor to the solution. The maintenance of a window through the package for this contact represents a critical aspect of sensor development. Frequent calibration is also necessary for chemical sensors. Just about every type of chemical sensor requires some sort of calibration using a standard solution with known concentration of the analyte being sensed. The best calibration method is a two-point procedure where two standards are used to establish the slope and the intercept of the calibration line. Some chemical sensors have stable slopes but need to be calibrated in terms of the baseline or intercept. In this case a single-point calibration can be used.

3.4 Bioanalytical Sensors

A special class of sensors of biological molecules has evolved in recent years. These bioanalytical sensors take advantage of one of the following biochemical reactions: (1) enzyme-substrate, (2) antigen-antibody, or (3) ligand-receptor. The advantage of using these reactions in a sensor is that they are highly specific for a particular biological molecule, and sensors with high sensitivity can be developed based upon these reactions. The basic structure of a bioanalytical sensor is shown in Fig. 3.5. There are two principal portions of the sensor. The first contains one component of the biological sensing reaction such as the enzyme or the antibody, and the second component involves a means of detecting whether the biological reaction has taken place. This second portion of a bioanalytical sensor is made up of either a physical or chemical sensor that serves as the detector of the biological reaction. As illustrated in Fig. 3.5, this detector can consist of an.electrical sensor such as used in electrochemical sensors, a thermal sensor, a sensor of changes in capacitance, a sensor of changes in mass, or a sensor of optical properties.

An example of a bioanalytical sensor is a glucose sensor. The first portion of the sensor contains the enzyme glucose oxidase. This enzyme promotes the oxidation of glucose to glucuronic acid and consumes oxygen in the process. Thus, by placing an oxygen sensor along with the glucose oxidase in the bioanalytical sensor, one can determine the amount of glucose oxidized by measuring the amount of oxygen consumed. An even better approach is to have two identical sensor structures in the same package. The only difference is that only one of the sensors contains the enzyme. When there is no glucose present, both sensors will measure the same oxygen partial

pressure. The presence of glucose, however, will cause the sensor with the glucose oxidase to have a reduced partial pressure of oxygen due to the oxygen consumption of the reaction. By making a differential measurement of oxygen partial pressure with both sensors, other factors that can cause an apparent change in oxygen partial pressure such as temperature will have a much lower effect than if a single sensor was used.

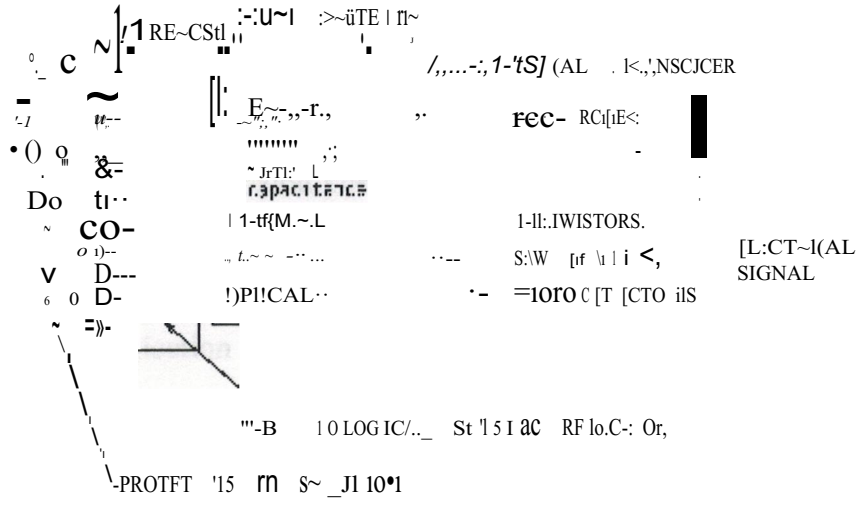


Figure 3.5 The basic structure of a bioanalytical sensor

Stability problems are important for bioanalytical sensors, especially those that are used for long-term measurements. Not only are the stability issues the same as for the physical and chemical sensors, but they are also related to preservation of the biological molecules used in the first stage of the sensor. These molecules can often be degraded or destroyed by heat or exposure to light. Even aging can degrade some of these molecules.

Thus, an important issue in dealing with bioanalytical sensors is the preservation of the biochemical components of the sensor. Not all biochemical reactions are entirely reversible, and so the bioanalytical sensors based on them will not be reversible as well. This may be acceptable for some applications but not for others and must be taken into consideration in choosing a bioanalytical sensor.

3.5 Applications

Biomedical sensors and instrumentation are used in biomedical research and patient care applications. In terms of patient care, sensors are used as a part of instruments that carry out patient screening by making measurements such as blood pressure using automated apparatus. Specimen analysis is another important application of biomedical sensors in patient care. This can include analyses that can be carried out by the patients themselves in their homes such as is done with home blood glucose analyzers. Instrumentation based upon biomedical sensors can be used in the physician's office for carrying out some chemical analyses of patient specimens such as urinalysis or elementary blood chemistries such as serum glucose and electrolytes. Sensors also are a part of large multicomponent automatic blood analyzers used in the central clinical laboratory of major medical centers.

Another application for biomedical sensors is in patient monitoring. Sensors represent the front end of critical care monitors used in the intensive care unit and in the operating and recovery rooms. Measurements cover a wide range of biomedical variables such as continuous recordings of blood pressure and transcutaneousn measurement of the partial pressure of carbon dioxide in the blood. The performance of these instruments is strongly dependent on biomedical sensors. Patient monitoring can also be carried out in the various clinical units of the hospital. Devices such as ambulatory cardiac monitors that allow patients to be observed while they are free to move around if they desire are becoming important in clinical care in "step-down" units for patients who have completed their stay in the intensive care unit. Patient monitoring has even made its way into the home. Horne cardiorespiratory monitors are thought to have some potential value in identifying infants at risk of sudden infant death.

Chapter 4:

Pacemakers:

The heart is an amazing machine. Throughout an average lifetime, it contracts over 2.5 billion times to pump blood throughout the body. Without its proper function, an individual will die within minutes. The heart consists of four chambers. The upper two chambers, the atria, are used as primers for the lower two chambers, the ventricles, which serve as the main pump. Blood delivery will be inefficient if the atria and ventricles do not pump in mechanical synchrony (AV synchrony). Optimum efficiency occurs when the atria contract slightly before the ventricles. Electrical depolarization waves are responsible for controlling the contractions of the heart and thus maintaining AV synchrony. The depolarization waves originate from a specialized set of cells, known as the sinus node, that are modulated by neural input and are located in the top of the right atrium. The sinus node is the heart's natural pacemaker. It is part of the atrioventricular (AV) conduction system, which serves to distribute the wave fronts throughout the heart and to connect the otherwise electrically isolated atria and ventricles. A normal depolarization wave spreads across the atria causing them to contract first, and then, after a brief delay while traversing the AV conduction system, across the ventricles causing them to contract shortly thereafter. With such a demanding, complex organ, it is no wonder there are multiple ways by which it can fail. Failures in the electrical system, known as arrhythmias, may impair the contraction sequence and compromise blood flow. These failures are often the result of some underlying heart disease, but may also have a genetic etiology. While antiarrhythrnic drugs have been available for some time, contemporary treatment of arrhythmias relies heavily on two types of implantable medical devices: pacemakers and implantable cardioverter defibrillators.

4.1 Bradyarrhythmias:

Bradyarrhythrnias are defined as heart rates that are abnormally slow (<60 b.p.m.) [Katz, 1992]. They are generally caused by either sinus node disease or AV conduction disorders. In the former, disease of the body's natural pacemaker cells often results in an unnaturally slow heart rate and significant patient discomfort. Also, The heart rate may

not increase in response to exercise due to a loss of neural control of the sinus node which will inhibit the patient from performing strenuous activities; this is known as chronotropic incompetence. AV conduction disease results from pathology of the cells that electrically connect the atria and the ventricles.

This can result in inefficient blood delivery due to a loss of AV synchrony. Pacemakers are commonly used to attempt to restore a natural heart rate, AV synchrony, and chronotropic competence in patients with these and other diseases. Approximately 115,000 pacemakers are implanted in the U.S. every year [Ellenbogen, 1996].

4.2 Tachyarrhythmias:

Tachyarrhythmias are generally defined as heart rates that are abnormally or inappropriately fast (>100 b.p.m.) [Katz, 1992]. There are many different types of tachyarrhythmias (tachycardias). They are caused by "runaway" depolarization wave fronts that may continue to rapidly activate the same tissue over and over again by a process known as reentry. This can result from a number of underlying physiological problems, such as dying tissue with altered conduction properties due to a blocked coronary artery, around which the wavefront can propagate.

The atria and the ventricles can both experience tachycardias. Although somewhat debilitating, atrial tachycardias are not immediately life threatening; however, most ventricular tachycardias are life threatening. The most serious ventricular tachycardia, ventricular fibrillation, has been defined as the rapid, disorganized, and asynchronous contraction of ventricular muscle [Epstein and Ideker, 1995] during which the heart's ability to distribute blood to the body is completely compromised. If not immediately treated with a defibrillating electrical shock, loss of life will follow in only minutes. Ventricular fibrillation is the most common cause of sudden cardiac death, of which nearly 400,000 people die annually in the U.S. alone [Gillum, 1989]. The Implantable Cardioverter Defibrillator (ICD) was developed in an attempt to terminate ventricular fibrillation and prevent sudden death from occurring.

4.3 Pacemakers:

The pacemaker is a medical device capable of controlling the heart rate through a set of implanted electrode leads (Fig. 4.1). The first devices in 1958 were simple, fixed rate oscillators controlled by two transistors [Elmquist and Senning, 1960]. Weighing more than 180 grams, they had a lifetime of around 3 years and paced only the ventricles [Sanders and Lee, 1996]. More sophisticated dual-chamber pacemakers, which sense and pace both the atria and the ventricles independently, were introduced in the late 1970s [Funke, 1982]. Modem pacemakers have shrunk to less than 15 grams (6 ccs) and evolved into sophisticated, implantable computers capable of complex pacing algorithms, telemetry, extensive diagnostics, data storage, and a lifetime greater than 5 years [Sanders and Lee, 1996].

4.4 Clinical Indications:

Pacemakers are generally indicated for three major disorders, including sinus node disease, AV conduction system disorders, and certain atrial tachyarrhythrnias, as-well as other less-common pathologies. There are varying degrees of each of these disorders and the severity of the symptoms and age of the patient may suggest if a pacemaker is warranted. Symptoms may include syncope, dizziness, seizures, heart failure, depression, and dementia. Although bradycardia accounts for the majority of implantations, pacemakers can be used to treat some tachycardias. Antitachycardia pacing is a special type of pacing that may be indicated for atrial or ventricular tachycardias; however, when managing ventricular tachycardias, an ICD is preferable to a pacemaker so that, if the tachycardia degenerates into ventricular fibrillation, it can be halted with a defibrillation shock. Pacemaker implants may be permanent or temporary.

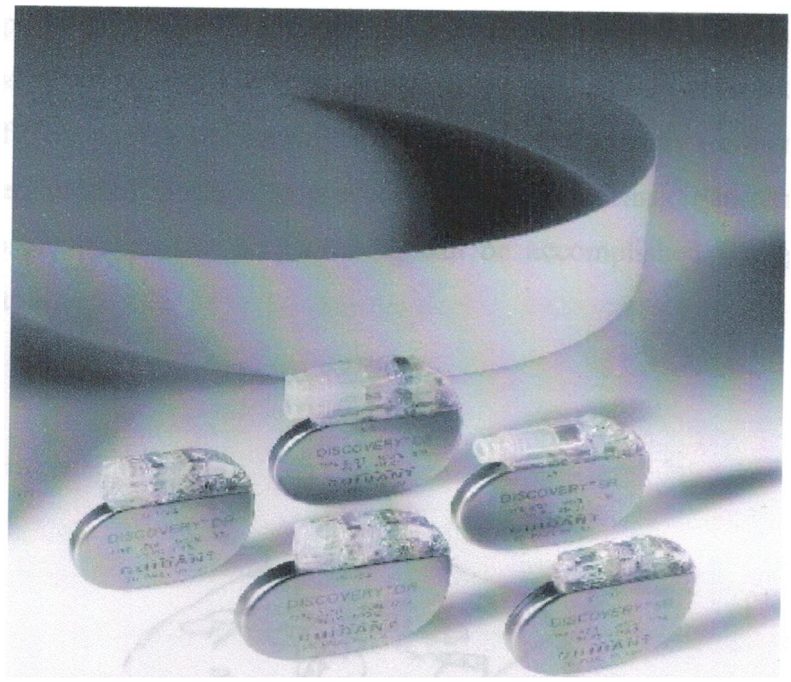


Figure 4.1 the Guidant/CPI Discovery family of pacemakers. (Courtesy of Guidant/CPI, St. Paul, MN.)

4.5 Surgery:

A pacemaker implant is a fairly standard procedure in which the pacing leads are inserted intravenously into the heart and the pacemaker is implanted subcutaneously in a pocket on the chest just below the clavicle. A number of veins have been used to implant the leads, but the cephalic and the subclavian veins are the most common. Access to either of these veins is obtained from the same incision that is used to form the pocket on the chest. A number of tools, such as guidewires, dilator sheaths, and fluoroscopy (real time X-ray), are used to work the lead down the veins into position in the right side of the heart. Depending on the type of pacemaker used, one or two leads may be implanted. In dual-chamber pacemakers, a lead is required in both the ventricles and the atria. (Figure 4.2) shows a diagram of a typical dual-chamber system in the body. The right ventricular lead is usually implanted first and is advanced to the right ventricular apex, where it is fixed. The atrial lead is then advanced to the right atrial appendage, where it is also fixed. A pacing system analyzer is used to test for sufficient electrode contact by measuring impedance, pacing thresholds, and sensing thresholds. The pacing threshold is the smallest charge necessary to stimulate cardiac tissue and

initiate a depolarizing wavefront. The sensing threshold is the smallest acceptable amplitude and slew rate of a sensed cardiac signal. Electrode repositioning may be required if efficient pacing and sensing are not realized. The leads are then connected to the pacemaker, sutured in place to prevent significant pacemaker movement, and the pocket is closed. Pacemaker programming can be accomplished through a wireless telemetry system.

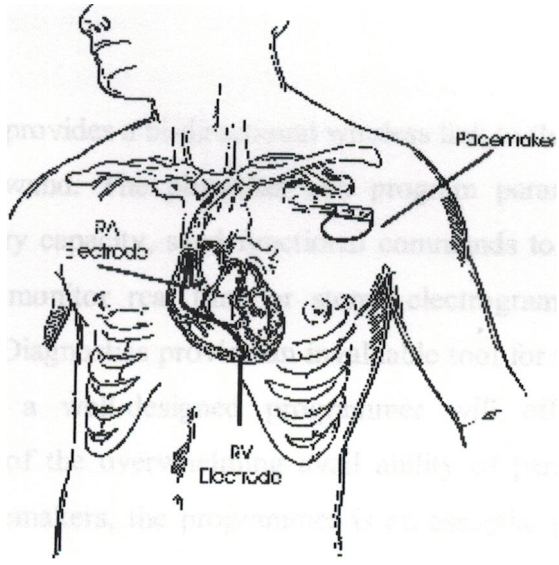


Figure 4.2 Placement of a dual-chamber pacemaker in the body and the leads in heart. The right atrial (RA) electrode is placed in the right atrial appendage and the right ventricular (RV) electrode is placed in the right ventricular apex. Both electrodes are capable of pacing and sensing.

4.6 Design:

The pacemaker must be able to reliably detect the wavefronts on the atria and the ventricles, determine their rate, determine if the chambers are synchronized, and intervene in the appropriate chamber if these conditions are not met. Some patients may receive continuous pacing, while others may rarely need pacing at all. The pacemaker must perform over a period of greater than 5 years, in all types of environments, with maximum reliability, and using the smallest, most comfortable design possible. In addition, it must be adaptable to various types of patients through remotely

programmable parameters and informative diagnostics. A pacemaker system is made up of three major components, including the leads, the pulse generator, and the programmer. The pulse generator (i.e., the pacemaker itself) houses all of the controlling and pacing electronics in a biologically compatible titanium shell. The leads provide the electrical link from the pulse generator to the heart. The programmer allows the physician to remotely program the pacemaker parameters and assess pacemaker function through a telemetry system.

4.7 Programmer:

The programmer provides a bi-directional wireless link to the implanted pacemaker through' a telemetry wand. The physician can program parameters that customize functions, check battery capacity, send functional commands to the pacemaker, check for past events, and monitor real time or stored electrograms measured from the implanted electrodes. Diagnostics provide an invaluable tool for the physician to assess patient welfare, and a well-designed programmer will effectively display this information. Because of the overwhelming avail ability of parameters and functions built into modem pacemakers, the programmer is an essential part of the pacemaker system. The major problem associated with current telemetry systems is the speed of data transfer.

Transfer speeds will need to be significantly increased in the future to keep pace with the increasing number of available diagnostics.

4.8 Leads:

The purpose of the pacemaker lead(s) is to provide a link between the pulse generator and the cardiac tissue in order to efficiently sense and stimulate the heart. The majority of leads are inserted intravenously and attached to the inside of the heart. Modem leads are composed of five major parts, including the connector, conductor(s), insulation, electrode(s), and a fixation mechanism [Kay, 1996]. The electrode design is critical to minimizing current drain during pacing while ensuring reliable sensing. It has been shown that the pacing threshold is a function of the current density at the electrode [Stokes and Bornzin, 1985]. Minimizing the radius of the electrode will maximize current density and therefore reduce the pacing threshold and current drain. In addition,

a small radius will increase the electrode resistance, which also helps to reduce current drain. Conversely, it has been shown that a large electrode surface area decreases sensing impedance and electrode polarization [Kay, 1996]. Electrode polarization is caused by a buildup of charge on the cardiac tissue after a stimulation pulse and can affect the electrode's ability to sense properly. The ideal electrode would, therefore, minimize the radius while maximizing the surface area [Sinnaeve et al., 1987]. This has been accomplished by building electrodes with a small radius but with complex microscopic mesh or porous structure to maximize surface area [Kay, 1996; Bornzin et al., 1983]. Electrode material varies among manufacturers, but is often comprised of a platinum alloy. The conductor serves as the electrical pathway between the pulse generator and the electrodes. It must have low impedance and be able to withstand repeated flexing due to heart motion.

This is generally accomplished using a nickel alloy and coiling the wire to resist stress. There will be one conductor in the lead for unipolar configurations and two conductors for bipolar. Unipolar leads use a single electrode at the tip of the lead with the reference being the metal shell of the pacemaker. Bipolar leads use two closely spaced electrodes near the tip of the lead, which is helpful in rejecting external noise when sensing. The Conductor must be insulated by a material that can withstand flexing and is resistant to harsh biological conditions. Silicone rubber and polyurethane are two commonly used insulating materials. The connector pin provides a physical link between the lead and the pulse generator and was standardized by an international meeting of manufacturers to avoid confusion when mixing brands of leads and pacemakers [Calfee and Saulson, 1986]. Finally, the fixation mechanism is responsible for holding the lead in place on the heart. The two major types of fixation are known as active and passive fixation. The most common active mechanism involves a helical screw that is advanced into the tissue [Markewitz et al., 1988]. The most common passive mechanism uses flexible tines that become entrapped in the cardiac tissue [Furman et al., 1979]. Fibrous tissue often grows around the fixation mechanism due to tissue injury. This further stabilizes the lead but can cause pacing thresholds to increase over time. A good fixation mechanism will minimize tissue injury while ensuring a stable anchor.

Some designs use a steroid-eluting electrode to minimize and stabilize fibrous tissue growth [Timmis et al., 1983].

4.9 Pulse Generator:

The primary function of the pulse generator is to interpret the information gained from the atrial and ventricular electrodes and other sensors to determine if the patient requires pacing and to deliver the pacing pulses, if necessary. A number of sophisticated algorithms are applied by the pacemaker to determine when pacing is necessary. The pulse generator also performs several secondary functions, such as telemetry and diagnostics.

A hermetically sealed titanium shell is used to house the electronics of the pulse generator because titanium is a strong, lightweight metal that is biocompatible with human tissue and does not corrode. Figure 4.3 shows a block diagram of a typical pacemaker pulse generator. A battery supplies the power for the electronics as well as for the pacing pulses. The sensing circuitry is used to amplify the electrical signals that are present on the heart in order to determine the heart rate. If rate-adaptive sensors are used (discussed below), additional sensing circuitry is needed. The output circuitry generates the pacing pulses by storing a charge on a capacitor so it can be delivered to the heart on demand. The backup pacing circuit is capable of asynchronously pacing either the atria or the ventricles at a preprogrammed rate in the event of excess noise. It also serves as a rate-limiting protection circuit to prevent the heart from being paced at an excessive rate due to a main system failure. The pacing control consists of timing circuitry and logic sections; it is responsible for interpreting sensed data and reacting with an appropriate pacing response. A microprocessor can be integrated with the pacing control and is often utilized as an overall system control to allow for flexibility of design. Memory in the form of RAM and RQM is required to store the microprocessor program, pacing parameters, and diagnostics. The telemetry circuit is capable of swapping information with the programmer and is activated by a magnetic reed switch.

The above circuits are currently built using CMOS integrated circuits, VLSI design, and hybrid technology. Continuing advances in the electronics industry will allow for further size reductions.

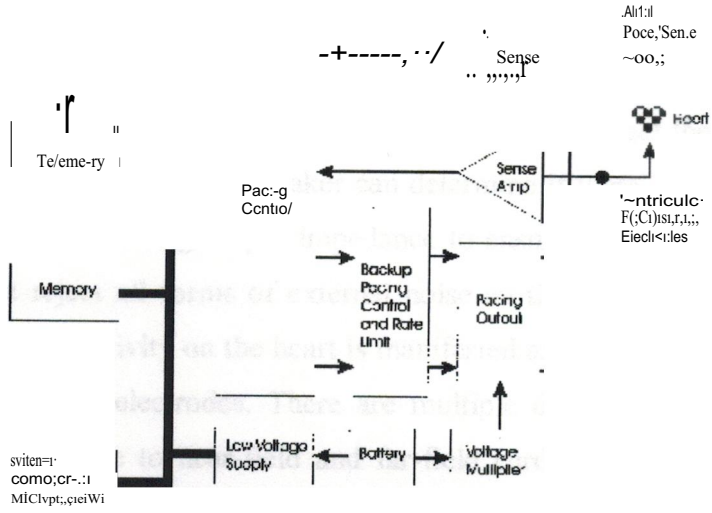


Figure 4.3 Block diagram of typical dual-chamber pacemaker components.

4.10 Battery:

The battery for a pacemaker must be a safe and reliable energy source with a high energy density capable of supplying several microamperes for longer than 5 years. In addition, it must be possible to reliably predict the end of its life so that the pulse generator can be replaced before pacing fails. Because the battery accounts for the majority of pacemaker volume, these requirements must be met while ensuring that the battery is as small as possible. Nearly all modem pacemakers use lithium-iodine technology [Sanders and Lee, 1996]. This battery has a high energy density and a low internal self-discharge, which combine to give a longer lifetime than past batteries. Lithium serves as the anode, iodine combined with poly-2-vinyl pyridine serves as the cathode, and a semisolid layer of lithium iodide serves as the electrolyte. The cell is hermetically sealed to prevent corrosion.

A new battery produces 2.8 V and declines linearly to 2.4 V near the end of its life. Either multiple batteries in series or voltage multipliers can be used to achieve voltages greater than 2.8 V. The status of the battery can be determined by several methods and can be telemetered out to the physician. The current drain of the device ultimately determines the lifetime of the battery and is dependent on many factors, such as circuit operating current, electrode impedance, and frequency, duration, and amplitude of the output pulses. Significant improvements in these areas have enabled the pacemaker battery to shrink in size.

4.11 Amplifier Sense System:

The purpose of the amplifier sense system is to reliably detect the rate of electrical activity of the heart so that the pacemaker can determine if there is a need for therapy. The amplifier must have a high input impedance to ensure adequate signal amplitude. The system must reject all forms of external noise so that no inappropriate counting occurs. The electrical activity on the heart is manifested as detections in an electrogram measured by the sense electrodes. There are multiple deflections in an electrogram during one heartbeat due to near-field and far-field cardiac activity. In a ventricular electrograın, the far-field activity is associated with the depolarization of the atria (P waves), and the near-field activity is associated with the depolarization (R waves) and repolarization (T waves) of the ventricles. The R waves, which are the largest and fastest deflections, indicate a depolarization wavefront located directly below the sensing electrode and are, therefore, used as a means to count the heart rate. Circuitry used to sense R waves usually involve voltage comparators and slew rate detectors.

Since the R wave deflection normally has a larger amplitude and faster slew rate than the other deflections, the circuitry can use reference thresholds to detect the R waves. The thresholds may be dynamic and determined by a complicated algorithm that has been termed autosensing [Jacobson and Kroiss, 1996; Castro et al., 1996; Kim, 1998]. In addition, there may be a brief amplifier blanking period after an R wave is detected during which all further deflections are ignored (so as to avoid potential inappropriate sensing of following T waves).

In dual-chamber pacemakers, it is necessary to measure an atrial electrogram in addition to the ventricular electrogram. Similar detection.strategies are employed in the atria; however, due to the large mass of the ventricles compared to the atria, the far-field ventricular activity in an atrial electrogram is more difficult to reject. A sensed cardiac event is marked by a digital pulse that is input into the timing circuitry. The timing circuitry determines if the heart rate is too slow and also controls all amplifier blanking periods and pacing rates.

In addition to far-field effects, many other sources of external noise exist in an electrograın, such as motion artifact, electrode polarization, noise from the skeletal muscles, and environmental noise (e.g., 60-Hz noise and cellular phones). Using band-pass filters and closely spaced bipolar electrodes minimizes external noise. In the event

of extreme interference, backup pacing circuits can assume control and asynchronously pace the heart until the noise is gone.

4.12 Output Circuitry:

The output circuitry is responsible for delivering the pacing pulses through the electrodes to the cardiac tissue in order to artificially control (capture) the heart. Because the amount of energy needed for capture can vary over the lifetime of a patient (e.g., due to changing electrode impedance or position) and between different patients, it is necessary to be able to deliver a controlled amount of energy per pacing pulse. Many pacemakers use an output voltage much higher than the pacing threshold to ensure capture for every pulse; however, this may unnecessarily waste energy. The minimum reliable pulse voltage necessary for capture is desired in order to minimize the current drain on the battery. Autocapture algorithms are capable of monitoring every pulse for capture and adjusting the output voltage to the minimum necessary value on demand [Jones et al., 1999].

This feature will become more prevalent in future pacemakers. Timing circuitry and output amplifiers are used to control the frequency, pulse width, and amplitude of the stimuli. Capacitors controlled by electronic switches physically deliver the energy. The capacitors are charged by the battery up to the desired voltage in between pacing pulses and then discharged into the heart by the switches at the proper timing. Voltage multipliers can be used to double or triple the battery voltage if necessary.

4.13 Rate Adaptive Pacing:

An important feature of modern pacemakers is their ability to modulate the heart rate based on the metabolic needs of the body. There are many conditions that call for heart rate modulation, such as exercise, fever, stress, or sleep. Because it is under neural control, the ideal rate modulator is a normally functioning sinus node. In the case that the patient has atrioventricular conduction problems, the sinus node and the atria may still be functional; therefore, atrial sensing may be used by the pacemaker to regulate the ventricular rate. Patients with sinus node disease or atrial arrhythmias, however, require an artificial means of regulating heart rate. Many attempts have been made to design metabolic sensors that can be used to naturally modulate the heart rate.

Control variables tested include blood pH [Cammilli, 1977], blood temperature [Alt et al., 1986], venous blood oxygen saturation [Eityzgrlf et al., 1982], respiratory rate [Rossi et al., 1983], minute ventilation [Alt et al., 1987], vibration [Anderson et al., 1983], acceleration [Matula et al., 1992], right ventricular pressure [Yee and Bennett, 1995], and QT interval [Donaldson and Rickards, 1983]. The ideal sensor would be reliable, have low current drain, require no additional surgery, and accurately reflect metabolic needs. All of the above sensors could potentially be used to reflect metabolic needs; however, only a few are currently practical and in use. The most common sensors in pacemakers today are the activity sensors, which attempt to indicate activity level by transducing vibration and acceleration. Piezoelectric crystals functioning as strain gauges can be mounted to the inside of the pacemaker to detect mechanical vibrations [Anderson and Moore, 1986]. In addition, accelerometers can be mounted directly to the hybrid circuit to detect acceleration [Kay, 1996]. Although both of these sensors are subject to motion that may not be due to exercise, accelerometers have generally proven to be more proportional to exercise than strain gages [Kay, 1996]. Another sensor that has been successfully integrated into pacemakers is the minute ventilation sensor. Minute ventilation is representative of the amount of air a -person breathes and can be estimated by measuring the transthoracic impedance over time. This can be accomplished by emitting a train of very small pulses from one pole of a bipolar pacing electrode and measuring the voltage between the other pole and the pacemaker can [Nappholz et al., 1986]. The impedance calculated from the measured voltage rises when a person breathes in and falls when the person breathes out. Combining activity sensors with minute ventilation sensors has proven to be a clinically successful approach to estimating metabolic needs during exercise [Alt et al., 1995].

Chapter 5:

Implantable Cardioverter Defibrillators:

The Implantable Cardioverter Defibrillator (ICD) was first conceived of by Dr. Michael Mirowski in the mid1960s [Mirowski et al., 1970]. He imagined a device that would continuously monitor the hearts of high-risk individuals for life-threatening arrhythmias and intervene by electrical shock to restore normal sinus rhythm.

Just over a decade later, the first patient was successfully implanted with an ICD [Mirowski et al., 1980]. From there, rapid development ensued, and FDA approval was obtained in 1985, at which time Cardiac Pacemakers Incorporated (CPI) took over the marketing and development of the ICD. Since then a number of competitors have arisen and the ICD has evolved into a remarkably sophisticated medical device capable of bradycardia and antitachycardia pacing, low-energy cardioversion, high-energy defibrillation shocks, and extensive diagnostics (Fig. 5.1).

5.1 Clinical Indications:

Initially, ICDs were only indicated for certain patients that had survived an episode of cardiac arrest. Time of intervention is critical to survival of cardiac arrest; only 25% of people that have an episode are successfully resuscitated by first responders [Shuster and Keller, 1993]. ICDs have decreased the first-year mortality rate of these survivors from 30 to 2% [Winkle et al., 1991]. More recently, in addition to cardiac arrest survivors, patients deemed at risk for a first arrest due to sustained ventricular tachyarrhythmias are receiving ICDs as well [Saksena et al., 1996]. In the future, patients with more subtle predictors of sudden death may be indicated for ICDs.

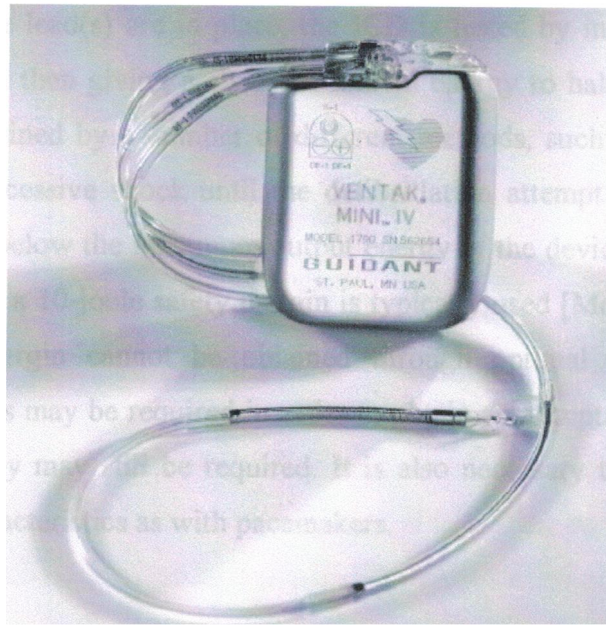


Figure 5.1 The Guidant/CPI Ventak Mini IV ICD with the Endotak lead system attached (a single-pass lead). The Mini IV is a single chamber defibrillator. (Courtesy of Guidant/CPI, St. Paul, MN.)

5.2 Surgery:

The modem ICD is now implanted similarly to a pacemaker. In the past, it was necessary to open the chest (i.e., thoracotomy) in order to suture large patch electrodes directly onto the ventricles and situate the ICD abdominally. Patch electrodes were required to achieve a low defibrillation threshold (DFT), which is a measure of the amount of energy needed to reliably terminate fibrillation (defibrillate). Due to significant advances in the size and energy efficiency ofICD systems, it is now possible to implant the ICD pectorally and insert specially developed electrode leads into the heart intravenously without the need for a thoracotomy. This ensures greater patient comfort and significantly reduces the risk associated with surgery. There are several different lead configurations available, depending on the manufacturer, each with its own advantages. All of these systems place one electrode in the right ventricular apex, rhile the position of the return electrode varies between systems. Figure 5.2 shows a typical system layout in the body. The entire surgery can be performed through a single cision, using only local anesthetics and heavy sedation, and is similar to that of the cemaker. Lead positioning is critical to obtaining low DFTs [Lang et al., 1995; Usuiet

al., 1995]. Once the lead(s) are in place, the ICD is tested by inducing fibrillation by artificial means and then giving a shock of known energy to halt the arrhythmia. The DFT can be determined by a number of different methods, such as by decreasing the energy of each successive shock until the defibrillation attempt is unsuccessful. The DFT must be well below the maximum output energy of the device before a successful implant is declared; a IO-joule safety margin is typically used [Moss et al., 1996]. If an adequate safety margin cannot be obtained through optimal electrode placement, additional electrodes may be required in order to obtain an acceptable DFT. In extreme cases, a thoracotomy may still be required. It is also necessary to thoroughly test the pacing/ sensing characteristics as with pacemakers.

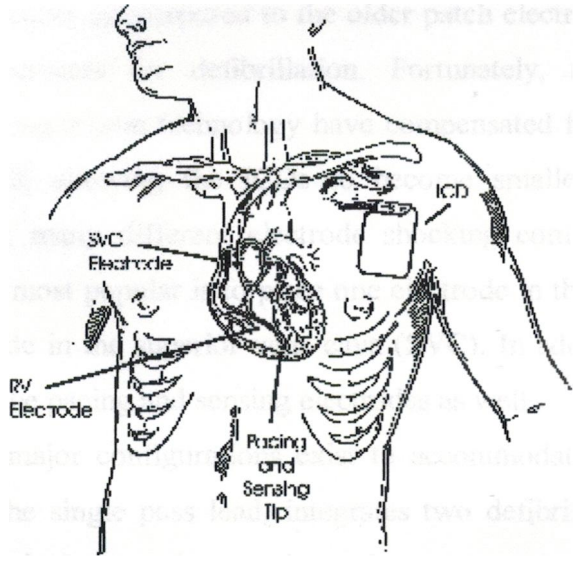


Figure 5.2 Placement of an ICD in the body and a single-pass lead system in the heart. The right ventricular (RV) and the superior vena cava (SVC) electrodes serve as the defibrillation electrodes, and there are pace/sense electrodes at the tip of the lead in the right ventricle.

5.3 Design:

An ICD system consists of three main components: the programmer, the leads, and the pulse generator. The programmer provides a link to the ICD after it has been implanted and is similar to the pacemaker programmer.

The leads deliver the energy from the ICD to the heart for defibrillation, as well as provide for pacing and sensing capabilities. The ICD pulse generator is an ever-evolving technology capable of delivering sophisticated cardiac rhythm management to the patient and diagnostics to the physician. As technology advances, ICDs will become smaller, more reliable, and more versatile.

5.4 Leads:

The leads provide the means by which to deliver the energy of the defibrillation shock from the pulse generator to the heart, as well as pacing and sensing capabilities. They are insulated with either medical-grade silicone rubber or polyurethane, except at the electrodes. A major disadvantage of these leads is that they deliver current in a largely nonuniform manner as compared to the older patch electrodes, which results in higher energy requirements for defibrillation. Fortunately, advances in battery, capacitor, circuit, and waveform technology have compensated for this greater energy requirement while still allowing the ICDs to become smaller. Because electrode position is important, many different electrode shocking configurations have been attempted. One of the most popular is to place one electrode in the right ventricle (RV) and the return electrode in the superior vena cava (SVC). In addition to defibrillation electrodes, there must be pacing and sensing electrodes as well.

Currently, three major configurations exist to accommodate these requirements. The first, known as the single pass lead, integrates two defibrillation coil electrodes (RV, SVC) and ventricular pace/sense electrodes onto a single lead. The second configuration consists of one lead, which contains the RV defibrillation electrode and the ventricular pace/sense electrodes, and a second lead, which contains the return defibrillation electrode. The third configuration consists of one lead containing both defibrillation electrodes and a separate lead containing the ventricular sense/pace electrodes. Some systems use the titanium housing of the ICD as an additional electrode in the "active can" configuration in an attempt to distribute the current more evenly throughout the ventricles. Also, the most modern ICD systems mlh7,,e atrial pace/sense electrodes in addition to ventricular electrodes to achieve dual-chamb pacing and sensing capabilities. Another requirement of the defibriuano Lead is that it has very low impedance due to the large defibrillation currents. but can still with repeated flexing due to millions of heartbeats. This is achieved using a combination of

high-strength, low-impedance metals. The pace/sense electrodes are similar in design to those used by pacemakers. The leads are fixed in place by either a screw-in mechanism or flexible tines.

5.5 **Pulse Generator:**

The pulse generator is the core of the ICD system. It consists of the batteries, capacitors, and accompanying electronics enclosed in hermetically sealed titanium can. The can may be used as a return electrode. A header, typically made of epoxy, is attached to the can and provides the link from the electronics to the leads via silicone-sealed ceramic feedthroughs. The size of the pulse generator has steadily declined since the introduction of the ICD and is currently around 40 cc. Significant efforts are underway to further reduce the size of the pulse generator in order to increase patient comfort. As research in defibrillation progresses, more efficient defibrillation strategies will no doubt be developed and allow the size to be decreased further. Currently, the major barriers to size reduction are the battery and capacitor size required to create waveforms capable of ventricular defibrillation. In addition, designing the electronics for a system that can measure cardiac signals on the order of 100 μV and produce high-energy waveforms on the order of 750 V and 40 A, all within the same small space, presents a significant engineering challenge. A problem associated with this includes high-voltage arcing among internal components. To prevent this, nitrogen gas is sealed inside the can because of its high breakdown voltage barrier.

Figure 5.3 shows a block diagram of the key components of a typical ICD pulse generator. The brain of the ICD is the microprocessor. Most ICD manufacturers use industry-standard microprocessors, such as the Z80, 6502, or 8852, to control the ICD [Warren et al., 1996]. In order to conserve energy, it is desirable to put the microprocessor into a sleep mode as often as possible and to wake it only when necessary, such as when an arrhythmia is suspected. To accomplish this, many of the monitoring and pacing functions are implemented using analog and digital circuits. Modem ICD designs have reduced the size of the circuitry to a small number of integrated circuits on a hybrid chip [Warren et al., 1996].

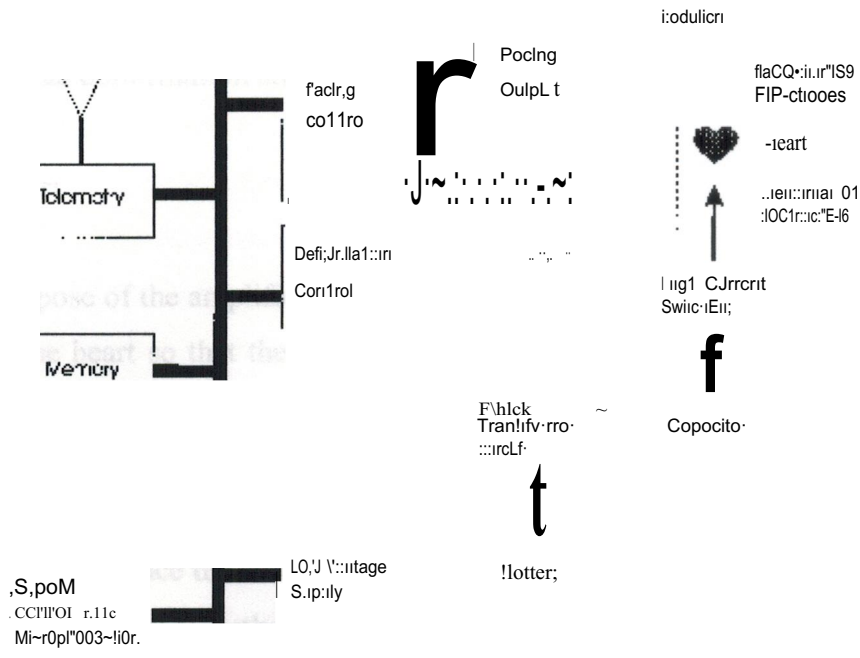


Figure 5.3 Block diagram of typical ICD components.

Memory is required to store the program and individual patient parameters for the operation of the ICD.

Startup code and some of the main program is often stored in ROM, while the remaining program, parameters, patient diagnostics (e.g., electrograms), and event markers are stored in RAM. Clinicians and investigators are increasingly interested in diagnostics obtained from the ICD, which warrants future memory increases. Additional circuitry includes support for the microprocessor, timers, the telemetry interface, and low-voltage

Power supplies, the high-voltage system, the-pacing control, the defibrillation control, and isolation and external protection circuits. The telemetry interface is the link to the external programmer and consists of a coil, which serves as the antenna, support circuitry, and a magnetic reed activator switch. The low-voltage supplies power the analog and digital circuitry as well as the pacing pulses. The defibrillation control determines when defibrillation is necessary and controls the process of defibrillation. The high-voltage system is used to generate the defibrillation shocks and consists of high-current batteries, capacitors, a y-back transformer, and output switching circuits. The pacing control includes the circuitry to deliver pacing pulses, to interpret the signals from the sense amplifiers, and timers that monitor the current heart rate and wake the

microprocessor if necessary. The isolation and protection circuits provide protection against external defibrillation attempts and external noise.

5.6 Amplifier:

The purpose of the amplifier sense system is to reliably detect the rate of electrical activity on the heart so that the ICD can determine if there is a need for intervention. The amplifier must be immune to noise and be able to quickly respond to a large range of heart rates (30 to 360 b.p.m.) [Warren et al., 1996]. In order to obtain an accurate heart rate, it is desirable to digitally count R waves, while rejecting all other electrical activity and noise. Since the R wave is much larger in amplitude than the other waves in the electrogram, a simple method to detect them would be to use a comparator with a set threshold. Unfortunately, the amplitude of R waves is not constant; therefore, a simple comparator circuit is not reliable. For example, during tachycardias and fibrillation, the amplitude of the signals decreases significantly. One technique commonly used to solve this is to use a dynamically adjusting comparator threshold, in which the threshold level exponentially decreases over time until the next R wave is detected, at which time, the threshold level is reset [Brumwell et al., 1996]. This ensures that low-amplitude signals will be detected. Another technique is to use an automatic gain control to slowly increase the gain between detected R waves, while keeping the threshold constant [Brumwell et al., 1996]. To avoid double counting caused by undesired T-wave detection, there is, typically, a brief period of time after each detected R wave during which sensed signals are ignored. Detection schemes are often implemented with carefully designed analog chips, known as Application Specific Integrated Circuits (ASICs), in order to keep the current drain on the order of 10 μA [Warren et al., 1996]. An advantage of these chips is that they provide near-perfect component matching, which is critical in engineering predictable gain control and frequency response.

5.7 Battery:

The design for an ICD battery has many stringent requirements and presents a unique challenge to the engineer.

While the pacemaker battery is optimized for high energy density, a defibrillator battery must sacrifice some energy density for high current capability. An average

defibrillator battery must be able to supply a steady background current of 10 to 20 μA for at least 5 years for monitoring and pacing functions, as well as, provide around 200, 2-A pulses for 10 to 15 seconds each in order to charge the capacitors for multiple defibrillation shocks [Holmes, 1996]. All of these criteria must be met while minimizing the size of the battery and maximizing its safety and reliability. In addition, it is necessary to be able to reliably predict the end oflife of the battery.

Nearly all modern ICDs use lithium silver vanadium oxide battery technology to accomplish these requirements [Liang et al., 1982]. Lithium pressed into a nickel current collector serves as the anode, and silver vanadium oxide serves as the active cathode. The electrolyte is generally a lithium salt dissolved in a mixed organic solvent. This produces approximately 3.2 V, but two cells are often connected in series to give around 6 V. Some newer systems are using single battery technology. A large electrode surface area and low internal impedance are required to achieve the high current pulses [Holmes, 1996]. This is accomplished by folding the anode in an accordion-like fashion and placing cathode plates in the folds. A disadvantage of this battery is that it exhibits a phenomenon in its mid-life known as voltage delay, in which the voltage goes low in the first second or two during a charging pulse. This can cause a prolongation of the capacitor charging time, which can be dangerous to the patient. It is due to an initial high resistance caused by a chemical buildup on the cathode in the cell and can be alleviated by periodic pulsing of the batteries into the capacitors and internally dumping the charge.

This shortens the life of the battery slightly but is not a total waste because the capacitors need this type of reforming as well. Several methods can be used to predict the end of life of a battery. Common indicators are the battery's open-circuit voltage, voltage during charging, and the time it takes to charge the capacitor [Holmes, 1996]. Future advancements in battery technology are critical in reducing defibrillator size and increasing longevity.

5.8 **Charging Circuit:**

In order for a defibrillation shock to occur, it is necessary to convert the 6 V from the battery to an output voltage of up to 750 V to be stored across a capacitor. This is generally done with a de/de converter, or inverter.

Unique design considerations include the large size of the conversion, a demand for high efficiency, and a minimized transformer and circuit size. The circuit includes the battery and a low-voltage, high-current switch at the input, ay-back transformer, and a rectifying diode and storage capacitor at the output. A controlling oscillator typically operates the switch between 30 and 60 kHz for high efficiency [Warren et al., 1996]. This creates a simulated ac current, which is converted by the transformer to the higher voltage. The current in the input stage is, typically, around 2 A. The rectifier diode prevents current from owing back into the secondary winding of the transformer. The voltage on the capacitor increases as a function of the square root of the time that the oscillator is on and typically reaches full capacity in 10 to 15 seconds [Warren et al., 1996]. It is possible for the transformer to be small because of the high-speed switching. In addition, the diameter of the core and the wire windings in the y-back transformer can be small because the converter is only used intermittently to charge the capacitor, which allows for ease of heat dissipation compared to continuous conversion [Bach and Monroe, 1996]. There is a trade-off between the size of the converter and the efficiency. The high clock rates allow the transformer to be small, but also introduce losses in energy due to hysteresis in the coils. A typical ICD charging circuit achieves about 75% efficiency [Bach and Monroe, 1996]. This plays a major role in the charging time and, therefore, the delay before shocking therapy can be delivered.

5.9 Capacitor:

The function of the capacitor is to store the energy generated from the high-voltage charging circuitry and to deliver that energy on demand to the heart over a few milliseconds. The commercially available aluminum electrolytic photo ash capacitor is currently used in the ICD. This is because of its high energy density of 1.7 J/cm3 made possible due to special etching techniques that maximize surface area in the aluminum foil.

Because the capacitors are commercially available and are not custom-designed for defibrillators, there are several shortcomings that ICD manufacturers must deal with. Since the highest energy density aluminum electrolytic capacitors are designed to operate at around 375 V, two of these capacitors must be used in series to attain the necessary 750 V used in most designs; therefore, the capacitors play a major role in determining the size of the defibrillator. Their geometry is not ideal for efficient

packaging. The round shape results in wasted space in the ICD. Perhaps the greatest shortcoming is the requirement that the capacitor be reformed after periods of no use to ensure there is no leakage current during charging. This involves automatic application of the rated voltage to the capacitor for a few minutes every few weeks in order to repair damage that has occurred due to aging. The latest generation capacitors have minimized the need for reforming. As mentioned before, because the battery requires reforming as well, the energy is not completely wasted. Current research in capacitors is centered on reducing the size by increasing the energy density and eliminating the need for reforming.

5.10 Waveform and Output Switching:

Optimizing the defibrillation waveform has been the subject of much investigation. Because a capacitor is used to deliver the energy, the waveform is some form of a decaying exponential. Still, there are many parameters that can be varied when creating a waveform, such as the pulse width, amplitude, decay, and the polarity and number of phases. In the past, monophasic, truncated, exponential waveforms were common. More recently, biphasic waveforms, in which the direction of current is reversed at some point during the waveform by switching the electrode polarity, have become more popular. This is due to the work of Schuder and others, who have shown that biphasic waveforms defibrillate with less energy than monophasic waveforms [Schuder et al., 1984; Feeseretal, 1990].

Output switching circuitry is needed in order to time and create these waveforms. Since the load impedance of the de:fibrillationsystem r3tnges from 20 to 70, it is possible to have peak currents of 40 A in the output circuit. There is, therefore, a need for high-power electronic switches to carry the current, such as Silicon Controlled Rectifiers (SCRs), Metal Oxide Semiconductor Field Effect Transistors (MOSFETs), and Insulated

Gate Bipolar Transistors (IGBTs). In addition, these switches must be mounted so that there are very low junctional resistances to minimize power loss. MOSFETs and IGBTs are often used in bridge circuits to facilitate switching of biphasic waveforms. SCRs were used mostly in generating monophasic waveforms, but are still used in some biphasic waveform circuits. Because these types of switches require around 15 V for control, it is necessary to use a low-power de/de converter to boost the 6 V from

battery. Timing of the switching is either controlled by timing circuitry, or by voltage monitoring circuitry that causes a polarity reversal to occur when the voltage falls to a certain threshold.

CONCLUSION

Biomedical instruments, the instruments that are used by doctors, nurses and people working in the medical field are getting more advanced day by day. It is so obvious that technology and medical equipments are going side by side. These equipments could be made up of simple to more complex electrical circuits and minor to major electrical components.

The project covered topics on basic instrumentation systems to more sophisticated instrumentation systems which makes it related to the human life existence. That is because of the swift growth of science, technology and the dedicated engineers who are working on creating, delivering, modifying and maintaining these equipments.

Major and minor equipments of different types of components such as transducers, bridge circuits, thermocouples, Thermistors and sensors plays a big role on building such an instrumentation.

Sensors serve an important :function in biomedical instrumentation systems in that they provide the interface between the electronic instrument and the biologic system being measured. Very often the quality of the instrument is based upon the quality of the sensor at the instrument's front end. Although electronic signal processing has been developed to a high level, the signals are no better than the quality of the sensors that provide them. Although there have been many advances in biomedical sensor technology, many problems remain. Biomedical sensors will continue to be an import area for research and development in biomedical engineering.

One of the instruments that a human being relies on is pacemakers. The pacemaker is a medical device capable of controlling the heaı:t rate through a set of implanted electrode leads. There are many exciting advancements currently under development for pacemakers. Efforts are being concentrated on making devices more sophisticated but less complicated [Jones et al., 1999]. One approach to realizing these goals is to expand the number and ability of the automatic features, such as autosense and auto capture algorithms.

Pacemakers are trending toward automatic self-optimization abilities that are based on the individual patient's needs. Improvements in rate adaptive sensors and algorithms are key to realizing this goal and represent an area of significant research. In the future, integrated circuit technology will allow for much smaller and more efficient designs.

This, in addition to improved battery technology, will allow for increased memory, advanced signal processing, and faster telemetry. More memory will permit more extensive patient diagnostics. These diagnostics will be displayed on advanced programmer interfaces that are more clinically relevant. Pacemaker lead research may ultimately yield single-pass leads, capable of pacing and sensing in both the atria and the ventricles. Finally, nontraditional pacemaker uses are currently being explored. A major area of interest is in the treatment of congestive heart failure (CHF). CHF is a debilitating and deadly disease characterized by an enlarged heart that is incapable of pumping adequate blood to the body. It is possible that the size of the heart facilitates an electromechanical asynchrony between the ventricles. Recent studies have shown that appropriately positioned and timed pacing stimuli can help to improve cardiac output by synchronizing the ventricles [Foster et al., 1994; Bakker et al., 1994].

In the future, ICDs will continue to evolve into increasingly sophisticated cardiac rhythm management devices.

The ICD is no longer simply a safeguard against ventricular fibrillation; it is, moreover, being called to better manage bradycardias and tachycardias, and may eventually be used to predict and prevent arrhythmias from ever occurring. Management of atrial arrhythmias is also an important emerging frontier. To facilitate these and other demands, a number of advancements are currently being explored [Morris et al., 1999]. New lead systems will be smaller, more reliable, and better designed to manage atrial arrhythmias. Additional sensors may be incorporated, such as pressure transducers to measure hemodynamic stability. More complex rhythm discrimination algorithms will be developed to ensure that appropriate therapy is given at the appropriate time.

Advances in electronics, battery, and capacitor jechnology will allow the ICD to continue to shrink in size.

Diagnostic capabilities will be expanded due to increases in memory, and efforts will be made to dramatically decrease the complexity of programming the ICD. Finally. basic research will produce important advances in arrhythmia management, significance of which cannot yet be imagined.

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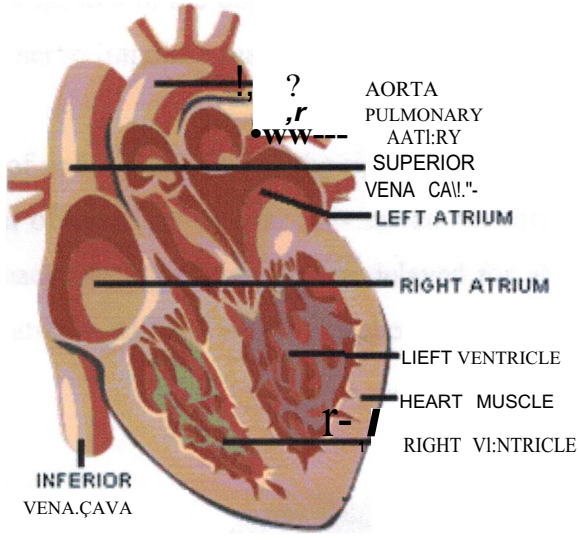
APPENDIX I

Brief information's about heart:

What is the heart?

The heart is the organ that supplies blood and oxygen to all parts of the body. It is about the size of a clenched fist, weighs about 10.5 ounces and is shaped like a cone. The heart is located in the chest cavity just posterior to the breastbone, between the lungs and superior to the diaphragm. The heart is surrounded by a fluid filled sac called the pericardium. Blood is pumped away from the heart through arteries and returns to the heart through veins. The major artery of the body is the aorta and the major veins of the body are the vena cava.



Chambers:

The heart is divided by a partition or septum into two halves. The halves are in turn divided into chambers. The upper two chambers of the heart are called atria and the lower two chambers are called ventricles. Valves allow blood to flow in one direction between the chambers of the heart.

Heart Wall:

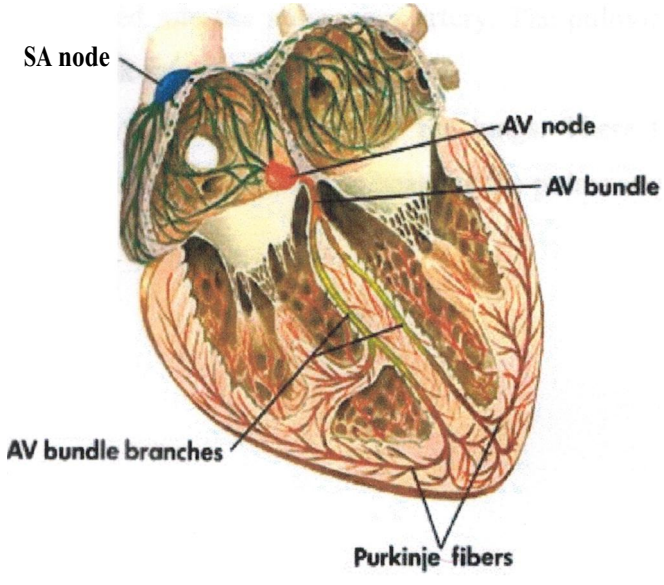
The heart wall is divided into three layers:

1 Epicardium.
2. Myocardium.
3. Endocardium.

Cardiac Conduction:

Cardiac conduction is the rate at-which the heart conducts electrical impulses. Cardiac muscle cells contract spontaneously. These contractions are coordinated by the sinoatrial (SA) node which is also referred to as the pacemaker of the heart. The SA node is composed of nodal tissue that has characteristics of both muscle and nervous tissue. The SA node is located in the upper wall of the right atrium. When the SA node contracts it generates nerve impulses that travel throughout the heart wall causing both atria to contract.

Another section of nodal tissue lies on the right side of the partition that divides the atria, near the bottom of the right atrium. It is called the atrioventricular (AV) node. When the impulses reach the AV node they are delayed for about a tenth of a second. This delay allows the atria to contract and empty their contents first.



The impulses are then sent down the atrioventricular bundle. This bundle of fibers branches off into two bundles and the impulses are carried down the center of the heart to the left and right ventricles.

At the base of the heart the atrioventricular bundles start to divide further into Purkinje fibers. When the impulses reach these fibers they trigger the muscle fibers in the ventricles to contract.

Cardiac Cycle:

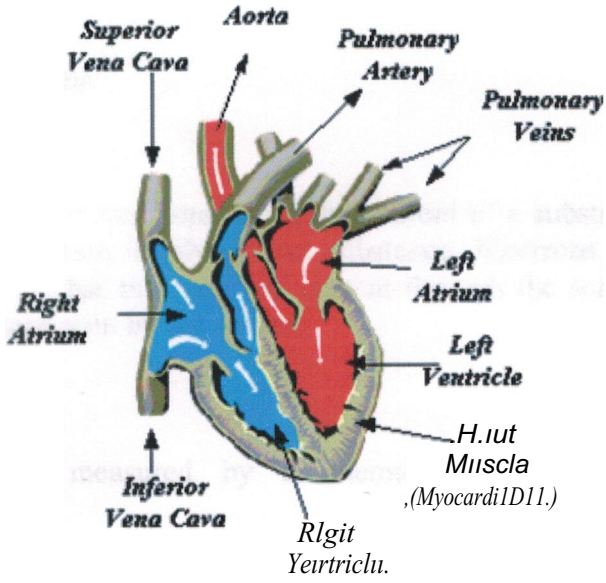
The cardiac cycle is the sequence of events that occur when the heart beats. There are two phases of this cycle:

1. Diastole - Ventricles are relaxed.
2. Systole - Ventricles contract.

During the diastole phase the atria and ventricles are relaxed and the atrioventricular valves are open De-oxygenated blood from the superior and inferior vena cava flows into the right atrium. The open atrioventricular valves allow blood to pass through to the ventricles. The SA node contracts triggering the atria to contract. The right atrium empties its contents into the right ventricle. The tricuspid valve prevents the blood from flowing back into the right atrium.

During the systole phase the right ventricle receives impulses from the Purkinje fibers and contracts. The atrioventricular valves close and the semilunar valves open. The de-oxygenated blood is pumped into the pulmonary artery. The pulmonary valve prevents the blood from flowing back into the right ventricle.

The pulmonary artery carries the blood to the lungs. There the blood picks up oxygen and is returned to the left atrium of the heart by the pulmonary veins.



In the next diastole period, the semilunar valves close and the atrioventricular valves open. Blood from the pulmonary veins fills the left atrium. (Blood from the vena cava is also filling the right atrium.) The SA node contracts again triggering the atria to contract. The left atrium empties its contents into the left ventricle. The mitral valve prevents the oxygenated blood from flowing back into the left atrium.

During the systole phase the atrioventricular valves close and the semilunar valves open. The left ventricle receives impulses from the Purkinje fibers and contracts. Oxygenated blood is pumped into the aorta. The aortic valve prevents the oxygenated blood from flowing back into the left ventricle.

The aorta branches out to provide oxygenated blood to all parts of the body. The oxygen depleted blood is returned to the heart via the vena cava.

APPENDIX II

Terms and Definitions

Amperometric sensor:

An electrochemical sensor that determines the amount of a substance by means of an oxidation-reduction reaction involving that substance. Electrons are transferred as a part of the reaction, so that the electrical current through the sensor is related to the amount of the substance seen by the sensor.

Analyte:

The substance being measured by a chemical or bioanalytical sensor and instrumentation system.

Arrhythmia:

A general term referring to a disorder in the electrical system of the heart.

Atria:

The upper two chambers in the heart that act as primer pumps for the ventricles.

AV synchrony:

The timing that must be maintained between the atria and the ventricles in order to pump blood efficiently.

Bioanalytical sensor:

A special case of a chemical sensor for determining the amount of a biochemical Substance. This type of sensor usually makes use of one of the following types of biochemical reactions: enzyme-substrate, antigen-antibody, or ligand-receptor.

Biomedical sensor:

A device for interfacing an instrumentation system with a biological system such as a biological specimen or an entire organism. The device serves the function of detecting and measuring in a quantitative fashion a physiological property of the biologic system.

Bradyarrhythmia:

A class of arrhythmia that results in an abnormally slow heart rate.

Cardioversion:

Termination of a tachyarrythmia, other than ventricular fibrillation, by a low-energy electrical shock.

Chemical sensor:

The interface device for an instrumentation system that determines the concentration of a chemical substance.

Defibrillation:

Termination of fibrillation by an electrical shock.

Fibrillation:

A type of tachyarrhythmia characterized by a disorganized rhythm that can occur in either the atria or the ventricles and completely compromises their ability to pump blood.

Noninvasive sensor:

The interface device of an instrumentation system that measures a physiologic variable from an organism without interrupting the integrity of that organism. This device can be in direct contact with the surface of the organism or it can measure the physiologic quantity while remaining remote from the organism.

Physical sensor:

An interface device at the input of an instrumentation system that quantitatively measures a physical quantity such as pressure or temperature.

Potentiometric sensor:

A chemical sensor that measures the concentration of a substance by determining the electrical potential between a specially prepared surface and a solution containing the substance being measured.

Sinus node:

Specialized cells in the top of the right atrium, which act as the heart's natural pacemaker.

Tachyarrhythmia:

A class of arrhythmia that results in an abnormally fast heart rate.

Ventricles:

The lower two chambers of the heart, which are responsible for pumping the blood to the body.