

DESIGN AND INSTRUMENTATION OF A CORONARY CARE UNIT

by

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ABSTRACT

In this study, the main principles that must be obeyed in the design and equipment selection of a coronary care unit are investigated along with the architectural steps which could be used in the establishment of such a unit. Information is given about the bedside monitors, central console monitors and other assisting devices which must be present in an optimal coronary care unit (CCU). The operation principles of these devices are explained by means of block diagrams. The computerized forms of these units which are widespread in developed countries and their advantages are also explained.

The characteristics that the hospital's electrical network must have in order for the desired CCU to be realized and the precautions to ensure patient, user and visitor safety are described.

The coronary care unit in the Etfal Hospital, the Cerrahpaşa Hospital, the Haydarpaşa G    s Cerrahisi Hospital and in the Medical University of Istanbul   apa Hospital which are functioning in Istanbul are investigated. Information is given about the existing design and some suggestions to solve the problems that arise are offered.

In short, the major purpose of this thesis is to built up a source of information on how to realize a CCU design at optimal usefulness and efficiency, taking the economy and technical conditions of the country into consideration.

ÖZETÇE

Bu çalışmada, koroner bakım ünitesinin tasarım ve donanımında uygulanması gereken temel ilkelerle birlikte böyle bir ünitenin kuruluşunda kullanılabilecek mimari düzenler incelenmiştir. Optimal bir koroner bakım ünitesinde bulundurulması gereken hasta başı monitörleri, merkezi hasta izleme konsolü monitörleri ve diğer yardımcı cihazların türleri ve bunların ünite içindeki konumları hakkında bilgi verilmiş, bu cihazların çalışma prensipleri öbek çizenekleri yardımıyla anlatılmıştır. Bu arada gelişmiş ülkelerde yaygın olan bu ünitelerin kompüterize donanım şekilleri ve bunların yararları hakkında bilgi verilmiştir.

Tasarlanması amaçlanan koroner bakım ünitelerinin gerçekleştirilebilmesi için hastane elektrik şebekesinin sağlaması gereken özellikler ve hasta, kullanıcı ve ziyaretçilerin güvenceliğini sağlayıcı tedbirler hakkında da bilgi verilmiştir.

Bunun yanısıra İstanbul'da faaliyet gösteren Etfal Hastanesi, Haydarpaşa Göğüs Cerrahisi Hastanesi, Cerrahpaşa Hastanesi ve İstanbul Tıp Fakültesi Hastanesinde bulunan koroner bakım üniteleri incelenmiş ve bu üniteler hakkında bilgi verilerek, karşılaşılan problemlerin çözümünde ışı tutacak temel bazı önerilerde bulunulmuştur.

Özet olarak, bu tezin hazırlanmasında amaç, mevcut ülke ekonomisi ve teknik şartları da gözönüne alınarak optimal yararlılık ve verimde bir koroner bakım ünitesi tasarımının nasıl gerçekleştirilebileceğine ilişkin bir bilgi kaynağı oluşturmaktadır.

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I. THE ESTABLISHMENT AIMS AND TYPES OF INTENSIVE CARE UNITS

1.1 INTRODUCTION

One major consideration of biomedical engineers in our times is the establishment and improvement of various intensive care units, to keep pace with the developments in medicine and electrical-electronics industries. Before going into detailed description of the various trends in the optimal design and equipment of coronary care units, which constitute the main subject of this thesis, the establishment purpose and types of intensive care units will be described shortly for general information. For the sake of brevity the different types of intensive care units' (ICU) are not explained individually and a detailed description is not given here.

Intensive care units are established at hospitals for various purposes. It is important that devices which are best suited to the intensive care unit that is intended to be built are selected to be placed in these units. The purpose is to ensure that the vital physiological parameters of more than one patients are monitored continuously

in the most reliable and economical fashion and that in case of emergency the nurse, doctor or other attending personnel are instantly informed by means of the existing devices and alarm system, enabling them to take the necessary actions urgently.

The point that must be carefully noted is the requirement that the precision, reliability and accuracy of devices employed must be of suitable order for our purposes. Otherwise, the doctors or other attending personnel cannot make the necessary use of the information provided by the devices. This will, in turn, reduce the benefit, in other words the efficiency of the established system crucially. Therefore, when designing intensive care units, the main goal of the unit to be established must be determined and the instruments and personnel which will serve this goal optimally must be selected and the establishment of the unit must be completed with the appropriate placing of the equipment.

1.2 TYPES OF INTENSIVE CARE UNITS

The types of intensive care units are classified here by giving their names.

1. Burn Intensive Care Unit (BICU)
2. Emergency Intensive Care Unit (EICU)
3. Coronary Care Unit (CCU)
4. Surgical Intensive Care Unit (SICU)
5. Neurosurgical Intensive Care Unit (NICU)
6. Mobile Intensive Care Unit (MICU)
7. Maternal-Fetal Intensive Care Unit (MFICU)

It is possible to make some additions to the intensive care units listed above, however this list covers the most common ICU's.

2. CORONARY CARE UNIT (C.C.U)

2.1 INTRODUCTION

There are some heart and cardiovascular variables which should be monitored continuously in the case of a patient suffering from some heart disease. Those variables, which have vital importance, are listed as follows.

1. Electrocardiogram (E.K.G/E.C.G): A record of electric activity of the heart.
2. Heart Rate: The number of heart pulse per minute.
3. Blood Pressure (mm Hg).
4. Cardiac Output.
5. Body Temperature ($^{\circ}\text{C}$).
6. Respiratory Variables: (e.g. number of respirations per minute).

Under this consideration, continuous observation and measurement of heart and cardiovascular variables are the basic goals of coronary care unit organizations. On the other hand, it is sometimes desired to have some of these monitored variables recorded on chart recorders and/or magnetic tapes. As a result of this recording instruments are employed so that doctors, nurses or other medical personnel can review the condition of the patients from time to time.

2.2 INSTRUMENTATION OF CORONARY CARE UNITS

The instruments which are used in coronary care units are listed as follows.

- Electrocardiographs
- Cardiotachometers
- Blood pressure monitors and sphygmomanometers
- Blood gas analyzers
- Cardiac output analyzers
- Arrhythmia monitors
- Cardiac pacemakers
- Defibrillators
- Thermometers
- Respiration detection monitors
- Ventilators
- Inhalators
- Aspirators

- Resuscitator bags
- Humidifiers
- Nebulizers
- Recording instruments (chart recorders, magnetic tapes, video recorders and computers, etc.)
- Oscilloscopes (cathode ray tube display units)
- Alarm units
- Infusion pumps
- Amplifiers
- Electrodes and transducers
- X-ray machines
- Digital indicators
- Metric indicators
- Blood flowmeters
- Oxygen units
- Vacuum units
- Air units.

The basic instruments that should exist in modern coronary unit organizations are listed above. But, some of them are more important than others in that they are continuously used in this kind of units. As a matter of fact some instruments that will be mentioned later are inherently essential for the operation of the C.C.U, and thus they are considered as the most important instruments. Most of the instruments in CCU are fixed either on the bedside or the central nursing station console. However there are also some portable instruments in the unit. Also in modern CCUs, telemetry, telephone and computerized systems are established with the aim of increasing the flexibility and performance.

of the unit. The organization of a CCU should be realized with the optimal number and types of instruments so that high unit efficiency is obtained at the lowest possible cost.

2.3 CORONARY CARE UNIT ORGANIZATION

2.3.1 The Primary Considerations Used During CCU Construction and Installation

1. The system must supply a continuous diagnostic picture of the patient's condition as precisely and reliably as possible.
2. The alarm systems must be adjusted correctly for providing adequate alarms. The sources that create false alarms should be eliminated.
3. The system (unit) should be equipped with instruments that have simple operation and maintenance.
4. All the instruments that exist in the unit should be selected very carefully for obtaining optimal information from the patients. In other words, the instruments which are used for emergency, patient monitoring or treatment must exist in optimal numbers.
5. Compactness is an important property of instruments which are used in CCU. That's why using compact instruments is desirable since they are easy to carry, relatively simple to use and they occupy little space.

6. Location of the central nursing station desk, patient's bed and bedside monitoring equipment should be selected properly for obtaining efficient working conditions.
7. Medical staff organization must be arranged optimally in accordance with the capacity of the CCU. On the other hand there must be sufficient number of assistant personnel in the unit.
8. This kind of coronary care unit should not be located near the high power transformer station or near high voltage transmission lines, because undesirable interferences may occur as a result of magnetic and electrical fields, and the performance of the instruments may deteriorate.
9. The patient's comfort should be taken into consideration as much as possible during the design of the unit.
10. The unit must be efficient, modern and as economical as possible.

2.3.2 Basic Design Characteristics and Construction Models of Coronary Care Units

In the coronary care unit, monitoring equipment are installed both on the bedside of each patient and on a central nurses' station which is placed at the center of the unit. By this way, information about the patient's condition can be obtained continuously from both the bedside and central nurses' station instruments. On the other

hand, required recording systems are also placed both on the bedside and the central nurses' console for obtaining hard copies of the monitored parameters. Moreover, there are some other compact portable and simply portable equipment which are used for both monitoring and recording if it is required. All of them are explained separately as follows.

2.3.2.1 Bedside Monitors and Auxiliary Equipment

Each bedside patient monitoring console should contain the following equipment.

1. Electrocardiograph (E.K.G./E.C.G.)
2. Cardiotachometer and alarm unit
3. Arrhythmia monitor and alarm unit
4. Blood pressure monitor and alarm unit and sphygmomanometer
5. Respiration detection monitor and alarm unit (Respiration rate monitor)
6. Defibrillator
7. Cardiac pacemaker
8. Thermometer and alarm unit (body temperature monitor)
9. Oxygen unit
10. Vacuum unit
11. Air unit
12. Resuscitator bag
13. Humidifier
14. Oscilloscope (cathode ray tube display unit)
15. Recorder unit

The above list includes most of the monitors and auxiliary equipment which are installed on the bedside of each patient. Some of these equipment however have vital importance for the patient so that a coronary care unit cannot be designed without using them. Those monitors and equipment which are considered essential for each bedside unit are listed below:

- * Electrocardiograph
- * Cardiotachometer and alarm unit
- * Arrhythmia monitor and alarm unit
- * Blood pressure monitor and alarm unit and sphygmomanometer
- * Respiration detection monitor and alarm unit
- * Oxygen, vacuum and air units with humidifiers
- * Oscilloscope (cathode ray tube display unit)

A typical four-bed CCU may be designed as in Figure 2.1.

2.3.2.2 Central Nurses' Station (Console) Equipment

The parameters which are monitored from the patients can also be displayed and recorded individually by the central nurses' station equipment.

Using these systems each patients' condition can be continuously observed from the central nurses' console. The instruments which are installed on the central nurses' station are listed as follows.

1. Electrocardiographs (with proper channels)

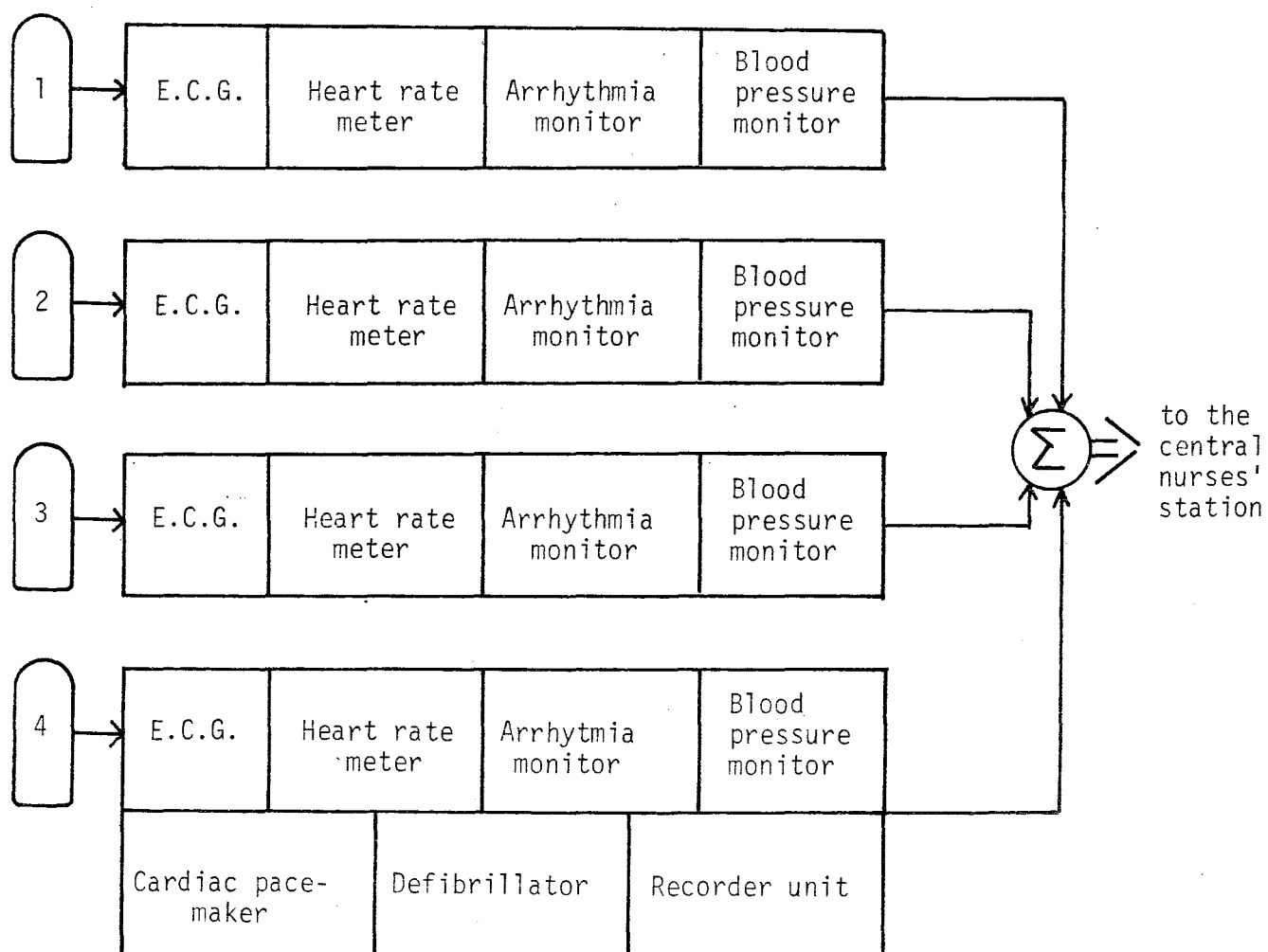


Figure 2.1 - A typical four-bed CCU monitors.

2. Display units for cardiometers and alarm units
3. Arrhythmia displays and alarm units
4. Blood pressure displays and alarm units
5. Respiratory detection displays and alarm units
6. Temperature displays and alarm units

7. Recorders (chart recorders, magnetic tapes, video tapes, computer systems, etc.)
8. Oscilloscope (it has to have appropriate channels dependingly on the number of patients' beds).

The oscilloscope is placed either on the central nursing station or suspended over the station for continuous E.C.G. observation. Each oscilloscope channel has its gain and brightness control switches. They can be adjusted separately. Usually there are some types of recorders on the central nurses' station, which are used for recording monitored variables from the patients. In this way, reexamination of patients' conditions and changes of these conditions over time can be easily studied by medical staff.

All the monitors have their own alarm units. They give warning signals to the medical staff, when the monitored parameters of the patient exceed the adjusted limits. Generally, visible and audible alarms are used. Alarm units are the most important parts of the instruments because they provide information to the medical staff about the abnormal conditions of the patients.

2.3.2.3 Compact Portable Equipment

Generally, a compact portable equipment unit contains the following instruments.

1. Electrocardiograph and recorder
2. Cardiometer

3. Arrhythmia monitor
4. Defibrillator
5. Pacemaker
6. Blood pressure monitor.

Some compact portable units do not have all the instruments which are listed above. They may include only some of them. The reasons for including compact portable units in the CCU can be summarized as follows.

- i. Compact portable units are used as emergency monitors when the bedside monitors are out of order.
- ii. Compact portable unit can be used like bedside monitors, if a patient needs cardiac care, but he cannot be brought to the unit because of shortage of space and other reasons.
- iii. Compact portable instruments which have recorder units are also used for recording the patients' variables when the bedside recorders are out of order.

In short, the compact portable instruments are main auxiliary equipment for the medical staff that can be used in CCU and hospital. The number of compact portable units which must be provided in a CCU, is chosen optimally dependently on the capacity of the unit.

2.3.2.4 Individual Portable Equipment

Individual portable instruments which are used in the coronary care units are listed as follows.

1. Electrocardiographs and recorder units
2. Cardiac pacemakers
3. Infusion pumps
4. Ventilators
5. Respiration detection units
6. Aspirators
7. Inhalators
8. Defibrillators
9. Resuscitator bags
10. Blood gas analyzers.

An optimal number of individual portable instruments should be provided each coronary care unit.

2.3.2.5 Basic Construction Models of Coronary Care Units

There are some important factors which affect the planning model of CCU which can be summarized as follows.

- * Required bed capacity of coronary care unit,
- * Availability of suitable space in the building (hospital),
- * Flexibility of the unit
- * Considerations of efficient unit operation with the optimal number of medical staff.

Mostly, standard capacities of coronary care units are 4, 6, 8, 16, 24 beds. Four, six or eight beds are used in medium size hospitals. It is obvious that, the available area affects the capacity of the unit. If the coronary care unit is added to an already constructed hospital building, two important points should be taken into consideration. One of them is economy, the other is capacity of the unit. In some cases it will be better to construct a new building for the CCU, but sometimes this brings economic problems. That's why decision making among these choices is not always easy. The optimal solution should be found by an organization committee. This will be discussed in detail in Chapter 13.

There are some basic standard planning forms for the design of the unit, but generally some different opinions may arise from team to team which is responsible for designing the CCU. The team includes doctors, biomedical engineers and other personnel (clinical engineers, electrical engineers, technicians, etc.). Some basic standard construction plans are shown as follows.

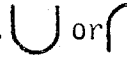
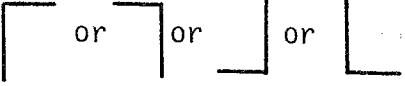
1.  shape planning,
2.  circular planning,
3.  shape planning.

Figure 2.2 gives some details about  shaped coronary care unit design.

The above unit is construct for 8 beds. The central nursing station is placed approximately at the center of the unit and it also has  shape. All the central station monitors are placed there. The

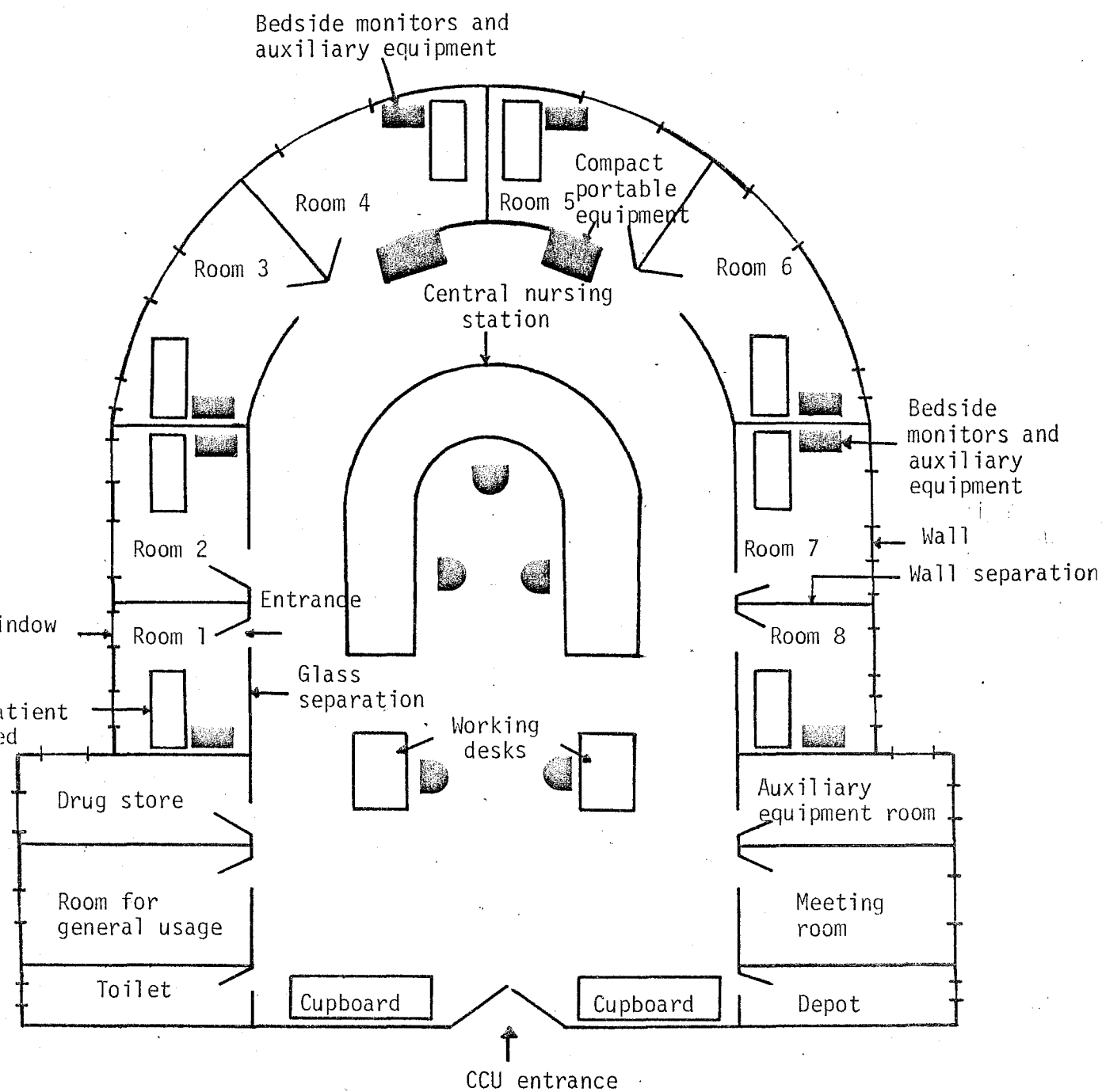


Figure 2.2 - Inverse U shaped CCU design scheme.

8-channels oscilloscope is also placed on or suspended above the station for taking continuous E.C.G. information from the patients.

Figure 2.3 gives some details about  "circular shaped" coronary care unit design. It can also be realized by the same ideas of the shaped unit.

There are some important factors that should be taken into consideration during the design of coronary care unit.

1. The entrance to the patient room must be intelligently designed so that the patient's bed does not have to be placed in front of the door.
2. The patient's bed is also not placed in front of the window. Recommended distance between bed and window is 1.5-2 meters.

Passageway along both sides of the bed should exist for easy manipulation of the patient and instruments.

3. The bedside monitors should be placed properly over the patient, on the right side or left side, for obtaining excellent observation of the patient condition from the monitor screen.

The height of the bedside monitor from the floor is also chosen very carefully for easy adjustment or manipulation. Recommended distance is 1.5-2 meters.

4. One reading lamp and one examination lamp should be installed over the patient bed. On the other hand, lighting fixture which is used for illumination of the room should be placed

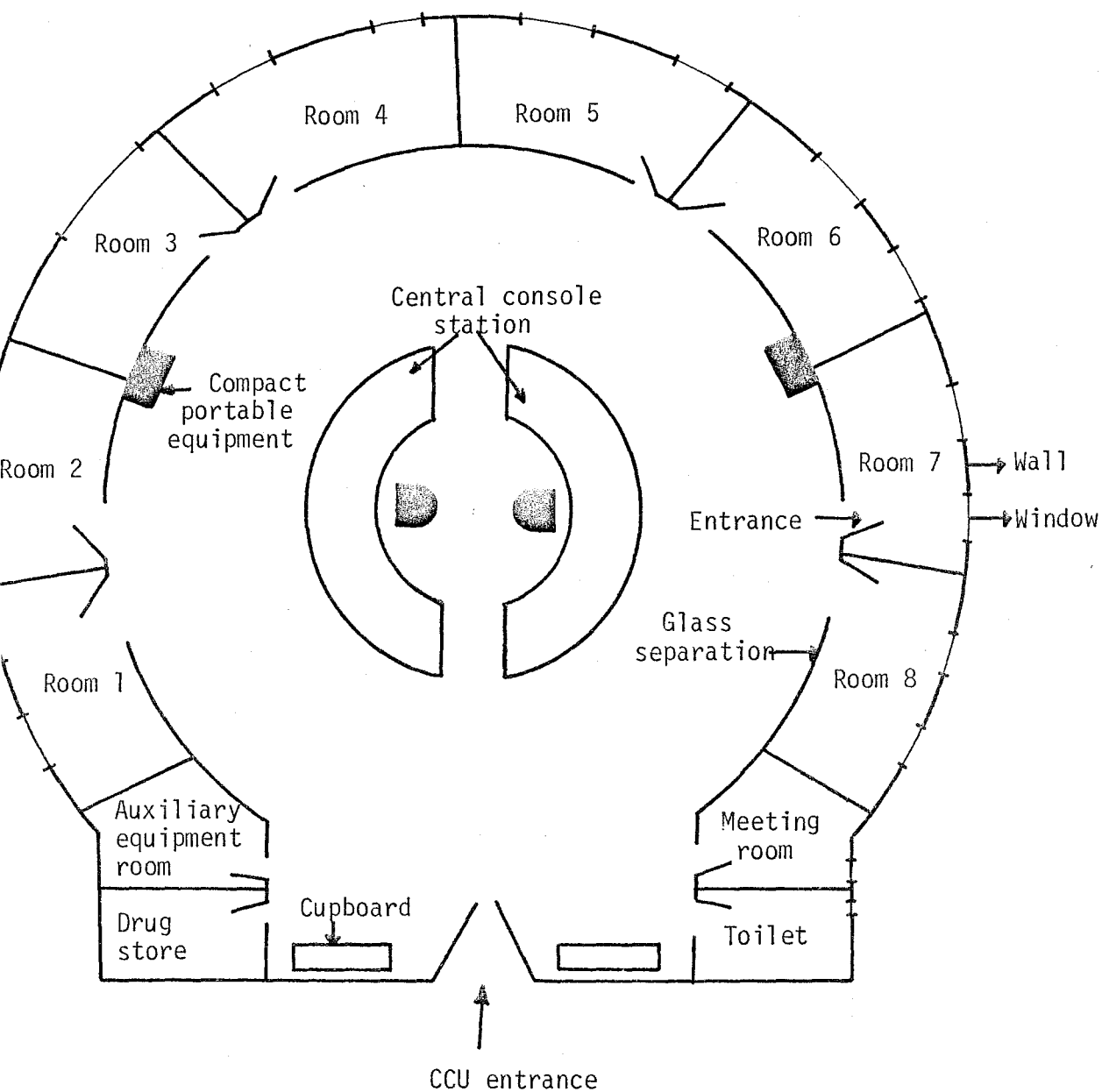


Figure 2.3 - Circular shaped CCU design scheme.

on the ceiling. All of the fixtures must be installed very carefully so as to eliminate parallax problems which may reduce the visibility of monitor screen.

5. Electric outlets are installed on the bedside. They are supplied from two different phases, because if one phase fails the electric supplying should be continued automatically by the other phase.

On the other hand, the number of outlets should be chosen optimally, thus providing flexibility of the instrument usage in the patient room. Recommendation is four outlets or more than four.

6. An emergency generator system should exist for supplying electric power to all installed systems in the coronary care unit when the network fails. So proper connection between network and generator system should be designed by the electrical engineer. A simple schematic diagram is given in Chapter 14, Fig. 14.3 to illustrate this connection.
7. The dimensions of the patient room must be chosen very carefully in order to prevent discomfort of the patient and provide comfortable working condition for the medical staff.

Separation of the patient rooms in the unit is realized by using glasses with curtains. This is a good solution for providing sufficient privacy. In some cases concrete wall separations are used, but generally this solution is not economical. Using only curtain separation between the patient beds is also a common solution, but

this kind of separation is not preferred by the patients because of insufficient privacy. That's why, the most widely used separation materials are glass separations with curtains.

8. A system of two rails is sometimes installed on the ceiling above the patient's bed so that each rail is used for hanging serum bottles or other objects which may hinder the movement of the medical staff. A typical sketch for rail system installation is given in Figure 2.4.

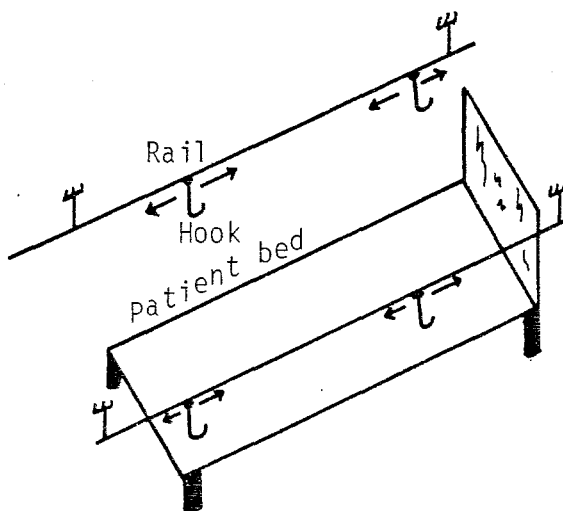


Figure 2.4 - A typical sketch for the rail system installation.

9. Each patient has to have one electric call button on his bed-side for calling attendants or medical staff if he requires help. The digital room number on the central station lits when the call button is pressed by the patient.

10. One commode must exist in each patient room.
11. Floor of the coronary care unit should be covered with the material that has to have some properties. Required properties are listed as follows.
 - * This material should prevent loss of heating
 - * Cleaning of the covered material must be easy
 - * This material should not be noisy when the personnel are walking or carrying equipment on it.Marley is preferable material for this kind of unit.
12. Sufficient number of desks and chairs must be placed in the unit for working medical staff. The medical staff meets there for consulting patient's condition.
13. At least one refrigerator should exist within the coronary care unit. The amount of refrigerator may change dependently on the capacity of the unit.
14. All the modern designed coronary care unit has to have air-conditioned system. It provides both hot and cold air to the system.
15. Telephone line installation should exist in the units for providing communication with doctors or other personnels within the hospital or out of the hospital.

3. ELECTROCARDIOGRAPHY (ECG OR EKG) AND ECG MONITORING IN THE CORONARY CARE UNIT

3.1 INTRODUCTION

The heart is a magnificent natural pump whose pumping action is stimulated by electric activity generated at the sinoatrial node, which is located at the top of the right atrium, with rates varying from 55 to 95 beats per minute in the average adult.

The activity of the heart can be monitored at the body's surface with the use of right technique and equipment. Electrocardiograph is an instrument which is used for recording of the electrical activity of the heart. The obtained curve is called "Electrocardiogram". It provides information about the heart condition. That's why, whenever the patient is monitored in the coronary care unit, the first and most important parameter to be monitored is electrocardiogram.

In this chapter, electrocardiograph and ECG monitoring system will be discussed.

3.2 REPRESENTATION OF A CHARACTERISTIC ECG WAVEFORM

In this section, a normal characteristic ECG waveform is presented with the relation between the heart's electric activity and ECG waveform.

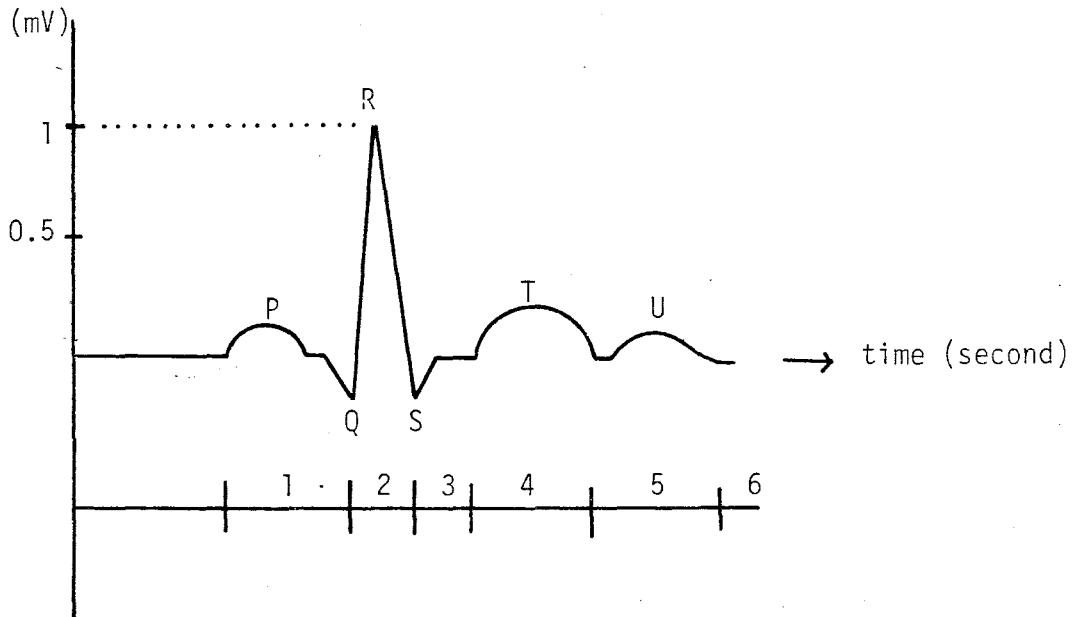


Figure 3.1 - A normal ECG waveform.

1. Atrial depolarization and atrioventricular (AV) conduction.
2. Ventricular depolarization-atrial repolarization.
3. Ventricular contraction begins
4. Ventricular repolarization.

- * The P-wave and P-R Interval: Produced by depolarization of the atria and conduction through atrioventricular node.
- * The QRS Complex: Produced by ventricular depolarization.
- * The ST Segment and T-wave: Produced by ventricular repolarization.

The signal produced by cardiac activity is approximately 1 mV in amplitude, but this value may decrease or increase depending on the type of heart disease. The frequency of the signal is between 0.1-100 Hz (time/second) in d.c.

Some normal values for amplitudes and durations of important ECG parameters are as follows.

<u>Wave Type</u>	<u>Normal Amplitude (mV)</u>
P	0.2
Q	0.1
R	0.5-1.5
S	0.2
T	0.1-0.5
<u>Wave Duration</u>	<u>Time Duration (seconds)</u>
P-R	0.12-0.2
Q-T	0.35-0.44
S-T	0.05-0.15
P	0.11
QRS	0.09

The electrocardiogram provides very useful information about the heart condition to the cardiologist so that a cardiologist compares the normal ECG with the recorded one and diagnoses the disease. That's why electrocardiogram is the most important parameter that is being monitored in coronary care unit from the patient who suffers from the heart disease.

3.3 THE BLOCK DIAGRAM OF AN ECG MONITOR

Figure 3.2 shows a block diagram of a typical ECG monitor system. To understand the overall operation of the system, each block is studied separately.

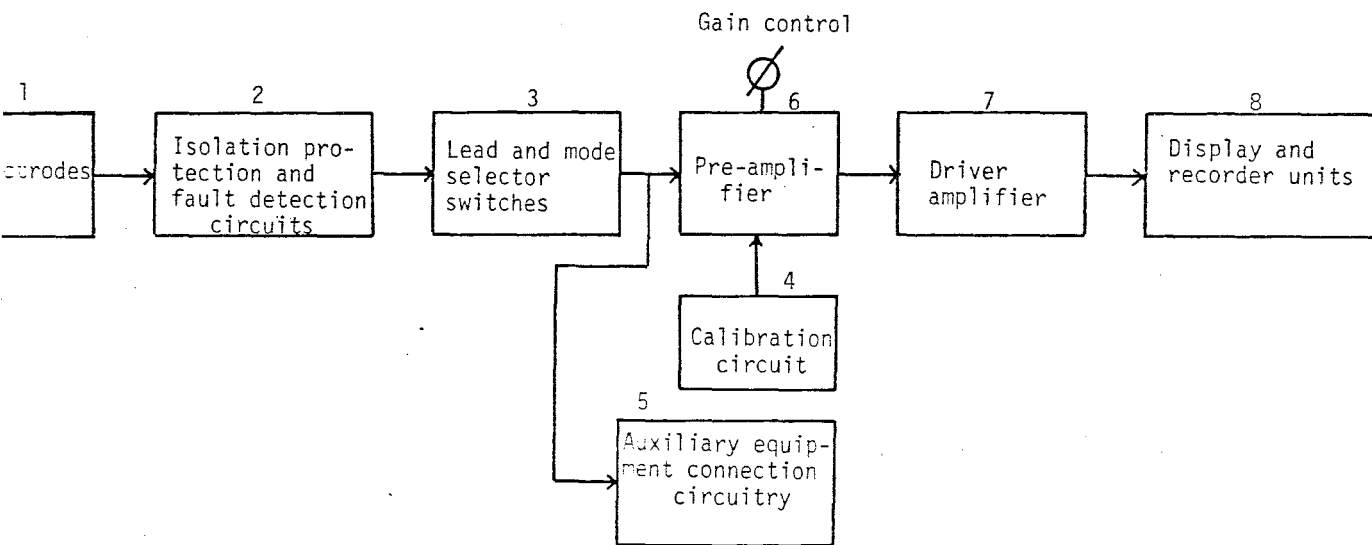


Figure 3.2 - A block diagram of a typical ECG monitor system.

3.3.1 Electrodes

There are several types of biopotential electrodes which are used to measure bioelectric events. In short, biopotential electrodes convert physiological variables into electrical signal. All the biopotential electrode types will not be discussed in this section, because only some of them are used generally for recording and monitoring of

ECG. Under this consideration the most widely used electrodes are summarized as follows.

- * Body Surface Electrodes (Skin-surface Electrodes): Body-surface electrodes are used to obtain bioelectric potentials from the surface of the body. There are several types. They are mostly used for recording of ECG.

All of the electrodes used in electrocardiography come in one of two functional designs. They are either "Direct-Contact Electrodes" or "Floating Electrodes".

1. Direct-contact Electrodes: Direct-contact electrodes have a metal element that contacts directly with the skin. They are generally used for short-term application, because they have skin irritation effect when they are used for long-term application. On the other hand they cause a movement artifact that affects the quality of ECG recording negatively. The types of direct-contact electrodes are explained as follows.

- 1.a) Metal-plate Electrodes: Metal-plate electrodes consist of a metallic conductor in contact with the skin, lead wire terminal and fastening belt for fixing the electrode on the proper place. Metal-plate electrodes are made of silver, nickel or some similar alloy.

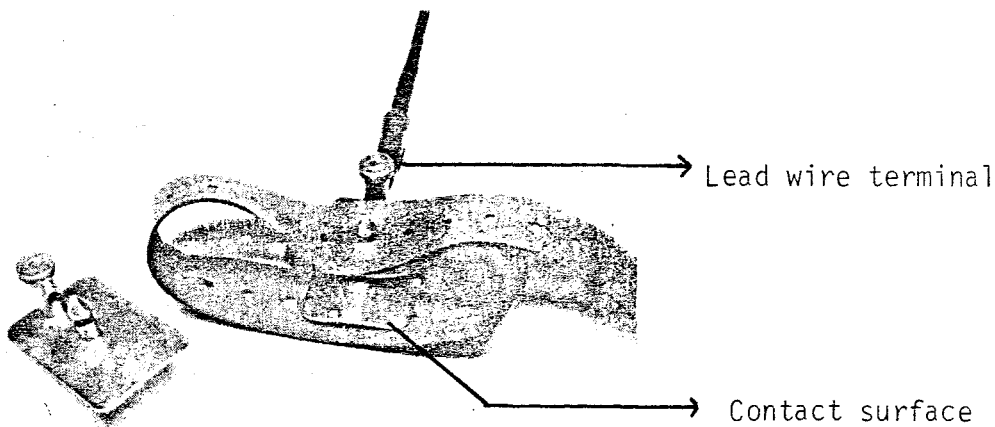


Figure 3.3 - Metal-plate electrode.

1.b) Suction-cup Electrodes: Suction-cup electrodes consist of a metallic conductor in contact with the skin, lead wire terminal and rubber bulb. Fig. 3.4 shows a picture of a suction-cup electrode.

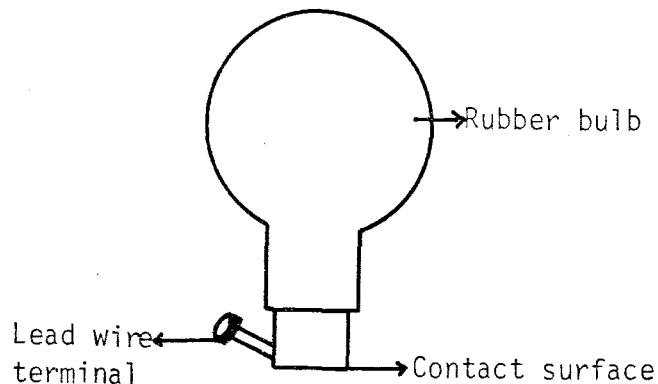


Figure 3.4 - Suction-cup electrode.

2. Floating Electrodes: Floating electrodes ride on a layer of electrolytic jelly or paste interspaced between the skin and the metal. So there is no direct contact between the skin and

the metal part of electrode. A basic diagram is shown in Figure 3.5.

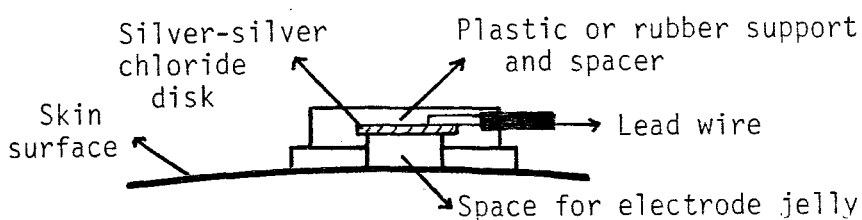


Figure 3.5 - Diagram of floating type skin surface electrode.

The use of floating electrodes such as Ag-AgCl electrodes, disposable electrode, can greatly diminish the motion artifact problem. That's why floating electrodes are widely used especially for long-term application in CCU and ICU. On the other hand they have no skin irritation effect for long-term application. The most widely used electrodes in CCU and ICU are disposable electrodes which are floating electrodes. Their cost is low so they are not reused.

Moreover, there are other types of electrode such as needle electrodes, but they are not widely used for recording ECG, especially in coronary care unit. That's why they are not discussed here.

There is an important point that should be taken into consideration. Placing of electrodes on the skin of the body should be performed as carefully as possible. The skin should be cleared by cleaner solution (alcohol) very carefully and then the electrode paste or jelly

should be applied by massage, before placing the electrode on the skin. Electrode paste or jelly is used for obtaining proper contact between the skin and electrode. Cleaning of the skin by alcohol provides low skin impedance. That's why the above explained procedure should always be performed before the electrode placing on the skin-surface for recording ECG.

There are some factors that affect the electrode performance.

Those are;

- The metal type which is used for manufacturing electrode. Some metals may cause poor electrode response.
- The temperature and humidity of electrode environment can change the impedance of the skin-metal interface.
- The electrode size also affects electrode performance. The size of an electrode determines the current density across the skin electrode interface and, consequently, the resulting signal reproduction.
- In the case of floating electrodes, the paste or electrolyte used produces its own characteristic skin response.

The above listed factors are known as "Fixed Performance Factors". There are other factors that also affect the electrode performance which are called "Variable Factors". Those are listed as follows.

- Variation in electrode composition
- Change of interface impedance resulting from movement of the electrode.

A 50 kHz high-impedance source is connected across the electrodes. Peak amplitudes of the current can be hundreds of microamperes without any risk to the patient, because the microshock hazard to excitable tissue decreases as the frequency increases above 50 Hz. Under the good patient-electrode contact condition, the voltage drop is relatively small between the electrodes. If the electrode connections become poor, as can happen when the electrolyte paste begins to dry, or if one of the electrodes falls off, the impedance between the electrodes increases abruptly. As a result of this, the voltage produced by the 50 kHz current source rises. In the meantime the normal ECG signal passes through a low pass filter and it is processed in the usual way. The threshold detector activates the alarm unit when the voltage reaches to the threshold value. When this condition occurs operators or other medical staff corrects the condition that happened.

3.3.3 Lead Selector and Mode Selector Switches

Each electrode connected to the patient is attached to the lead selector of the electrocardiograph. Lead selector switch provides the desirable connection between the electrodes for ECG recordings. Generally five electrodes are placed on the body. There are standard color codes for identifying each electrode. These are brown for Chest (C), white for right arm (RA), black for left arm (LA), green for right leg (RL), and red for left leg (LL) electrode connection wires.

Leads: Generally, four electrodes are used to record the electrocardiogram; the electrode on right leg (RL) is only for ground reference. But the number of electrodes which are used for continuous ECG monitoring can be reduced. This can be achieved by monitoring only one desirable lead.

The twelve standard leads can be divided into three categories which are "Bipolar Limb Leads" (I, II, III), "Unipolar Limb Leads" (aVR, aVL, aVF) and "Unipolar Chest Leads" ($V_1 - V_6$).

Mode Selector Switch: The mode selector switch is used for selecting operation modes of the ECG monitor.

The bedside patient monitor can be used in two basic operating modes. The first is monitoring mode, used where a gross observation of the electrical activity of the patient's heart is necessary, with little analysis or detail. This ECG waveform can be observed from both the bedside scope and central nurses' station scope.

In the diagnostic mode, the monitor must display an accurate presentation of the electrical activity of the patient's heart. In this mode, the frequency response of the monitor is wider, thus allowing a true presentation of all the necessary details in the ECG waveform when a detailed analysis of the patient's ECG is necessary, the diagnostic mode should be used.

3.3.4 Calibration Circuit Button

One of the most useful but most infrequently used control on a patient monitor is the 1 mV calibration button or switch. It is known that the patient's ECG may vary in magnitude as well as waveform. In order to obtain a meaningful pattern, the size of the display must be adequate. By depressing the calibration button, a reference voltage of 1 mV is applied to the input of the patient monitor. If this reference signal can be adjusted to its proper size on the monitor screen or recorder, then the user knows the monitor is functioning properly and that it has the necessary gain in order to display the ECG at an acceptable size.

3.3.5 Auxiliary Equipment Connection Circuitry

Cardiotachometer or other equipment are connected through this circuitry to the electrocardiograph in order to obtain the necessary monitoring signals.

3.3.6 Pre-Amplifier

The normal amplitude of the ECG waveform is about 1 mV. This value may change dependently on the type of diseases which the patient has (e.g. 0-4 mV). This amplitude is not sufficient for recording and visualizing of ECG wave on the scope. That's why the obtained low amplitude signal from the electrodes is amplified to the desirable level by pre-amplifier systems. On the other hand this block includes

some filters for filtering the signal from artifacts. Filtration of signal from the artifacts should be performed very carefully so that the original signal should not be distorted. In short, filtration and amplification of the signal must be performed as well as possible.

The physiological pre-amplifier should have some properties for performing adequate amplification. These properties are summarized as follows.

- i. It should have high input impedance, in order not to draw high current from the biopotential source. This prevents distortion of the signal.
- ii. It should have good frequency response in order to produce accurate signal amplitude determination. In other words, the amplifier must respond both to high and low frequency signals with the same accuracy.
- iii. It should reject all the undesirable potentials [e.g. 60 Hz AC common-mode (present on all leads), differential AC (relative lead-to-lead values), skin surface DC voltages).
- iv. It must have low output impedance in order to yield maximum signal transfer to the next stage.
- v. It should have optimal selectable bandwidth either for long-term conventional monitoring or short periods of diagnostic study.

The circuit diagram of a pre-amplifier is shown in Figure 3.7.

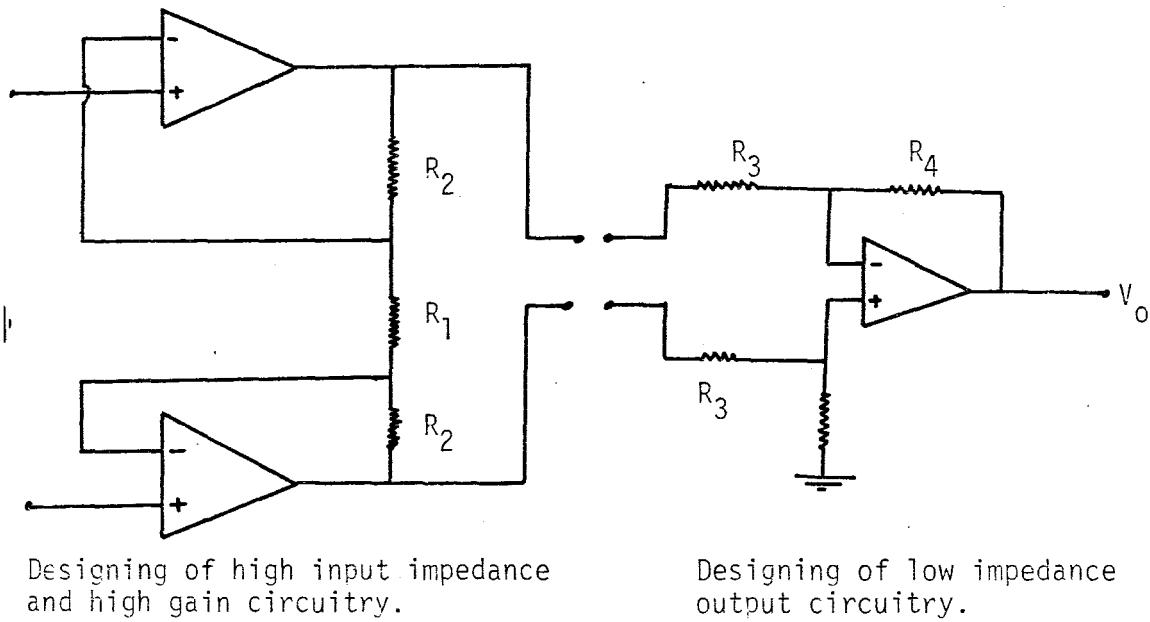


Figure 3.7 - The circuit diagram of a pre-amplifier.

There are some factors that cause signal distortion. These are listed as follows.

- Noise interference
- Interference as a result of other equipment working in the vicinity of the monitor
- Signal distortion as a result of high voltage transmission lines and/or the high power transformer station causing magnetic and electrical fields.

3.3.7 Driver Amplifier

Amplified, filtered, noise-free good quality signal is sent to the driver amplifier for secondary amplification. This amplification should be performed to a level at which deflects the pen of the recorder properly. In other words this secondary amplification provides adequate signal amplitude for proper display.

3.3.8 Display Unit and Display Methods

In hospital monitoring system, whether bedside or central, the oscilloscope (cathode-ray tube) serves as the primary form of display device.

The output signal of the driver amplifier is sent to the display unit which is an oscilloscope. In some case display unit may also contain a chart recorder. Single channel, dual channel and eight channel oscilloscopes are available. The oscilloscope employed in the central console station contain up to eight individual controls for adjustment of various factors such as the brightness, gain and trace speed of each channel. Trace speed can usually be varied from 25-100 mm/sec. to accomodate various heart rates. In short continuous observation of electrocardiogram for individual patient can be performed by using single channel, dual channel or eight channel oscilloscopes.

The chart recorder is used for obtaining a hard copy of electrocardiogram. In other words permanent record is obtained by using single channel or multi channel chart recorder. The chart recorder contains a pen motor and a pen or stylus which records on the moving chart paper.

The chart drive speed adjustment can be performed from approximately 20 mm to 60 mm/second.

In the coronary care unit; there is connection between each bedside display unit and the central nurses' station. All the display ECG values from the patient can also be displayed separately on the multi-channel (usually 8-channel) oscilloscope screen that it is placed on the central console station. On the other hand, the ECG signals are also sent to the recorder unit for obtaining hard-copy of patient's ECG waveform individually.

The type of recorders which are generally installed on the central nursing station are,

1. Chart-recorders (single or multi-channel)
2. Magnetic-tape recorders
3. Video recorders
4. Computer system.

The number of recorders which are installed on the central console station should be selected dependently on the unit capacity. The types of recorders should be chosen optimally. It is obvious that, the same consideration is also valid for multi-channel oscilloscope which is used in coronary care unit.

Display Methods: There are two types of cathode-ray tube tube (CRT) displays that are used for patient monitoring.

- I. Bouncing-ball (conventional) display
- II. Nonfade display.

- I. Bouncing-ball (conventional) display: As it is known, when the electron beam strikes the inner face of the CRT, that portion becomes brightly illuminated and appears as a continuous line to the human eye. As the electron beam moves across and writes a pattern on the face of the CRT, the earlier portion of the trace begins to fade away and finally disappears. The ability of the trace to remain visible on the face of the CRT is known as persistence. The duration of this persistence is determined by the phosphor (coating) inside the CRT. The persistence of the tube will allow the viewer to see only one waveform. This is not suitable for evaluation of the patients' ECG waveforms continuously from the oscilloscope screen. On the other hand in this method, the displayed waveform will not be uniformly bright. In short this display method is old type and it is nothing more than an oscilloscope with the horizontal sweep driven by a slow-speed sweep generator that causes the electron beam to move from left to right at a predetermined rate.

- II. Nonfade display: In this method, CRT is also again used, but in an entirely different way. Incoming amplified ECG signals are converted into digital bits which are electronic pulses. Once converted to digital bits, the information is stored in a special electronic circuits. The bits can be stored indefinitely. For display purposes, they can be recalled from storage and displayed on the CRT without losing

the original bits. This type of display is not a continuous line. It consists of closely spaced dots as shown in Figure 3.8. The basic block representation is shown in Figure 3.9.



Figure 3.8 - ECG pattern made up of dots.

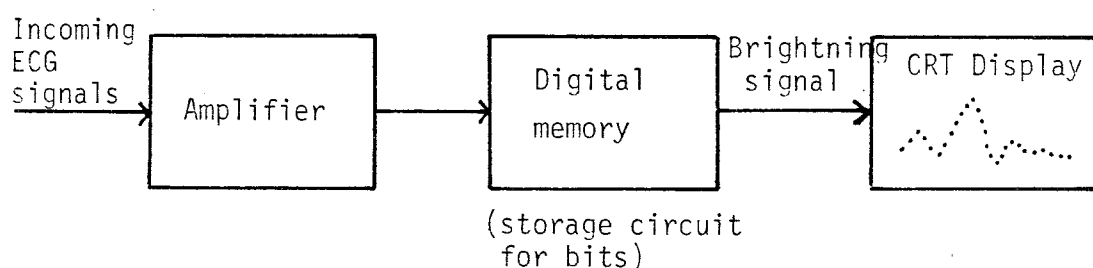


Figure 3.9 - A basic representation blocks for nonfade display.

The digital bits which are electronic pulses produce brightening signal. When a brightening signal is applied to the CRT, the rapidly scanned electron beam is brightened. This brightening signal is applied only when the electron beam passes a location that is to contain a part of the displayed waveform, at which time it produces a dot on the screen. In practice, several waveforms are converted to bits and displayed simultaneously. The storage elements are programmed in such a way as to allow information to be stored from 2 seconds up to 16 seconds and more.

Slowly the old information in the storage elements is continuously replaced with fresh information. On the other hand the display may be stopped at any time in order to allow detailed observation of any part of the ECG pattern.

In addition the nonfade display makes possible the presentation of digital numerical readouts on the face of the monitor screen (e.g., the heart rate).

3.4 FACTORS TO BE TAKEN INTO CONSIDERATION BY DESIGNERS AND OPERATORS OF ELECTROCARDIOGRAPHS

There are some factors that must be taken into consideration in the design and operation of the electrocardiograph. These factors also should be well-known by biomedical engineers and operators. In the following paragraphs a few of the more common problems and their results are described.

3.4.1 Frequency Distortion

Meaningless ECG may be obtained as a result of frequency distortion. There are two distortion types. One of them is known as high frequency distortion, that is, reduction of gain at high frequency. The other is low frequency distortion. It is a gain reduction at a low frequencies. The effects of frequency distortion on ECG is shown in Figure 3.10.a,b,c.

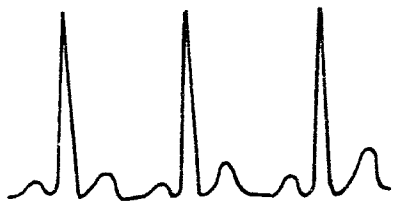


Figure 3.10.a - A normal ECG. The bandwidth of the output unit is 0.02-150 Hz.



Figure 3.10.b - The effect of high-frequency distortion on a normal ECG. The bandwidth of the output unit is 0.02-25 Hz.

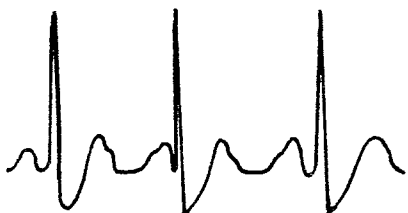


Figure 3.10.c - The effect of low-frequency distortion on a normal ECG for 1-150 Hz.

3.4.2 Saturation or Cut-off Distortion

There are some factors which cause saturation or cut-off.

These are;

- i. High offset voltages at the electrodes,
- ii. Improper amplifier adjustment.

Effects of saturation or cut-off on ECG are shown schematically in Figure 3.11.a,b,c.



Figure 3.11.a - A normal ECG.

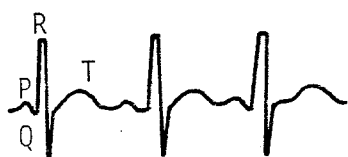


Figure 3.11.b - Clipping of ECG peak as a result of positive saturation effects in the amplifier.



Figure 3.11.c - Clipping of lower voltages in the ECG due to negative saturation or cut-off effect in amplifier.

3.4.3 Ground Loops

Patients may be connected to two or more equipment in the coronary care unit or in any other unit. All electrical equipment which are connected to the patient have their own ground connections, either through the power line, or, in some cases, through a heavy ground wire attached to some ground point in the room. The important point is that ground loop should not exist when two or more equipment are connected to the patient at the same time. For this purpose, the following connection should be realized. In Figure 3.12 shows existence of ground

loop. Both ECG and secondary machine have their ground electrodes that are connected to the patient separately (Point A and B). The

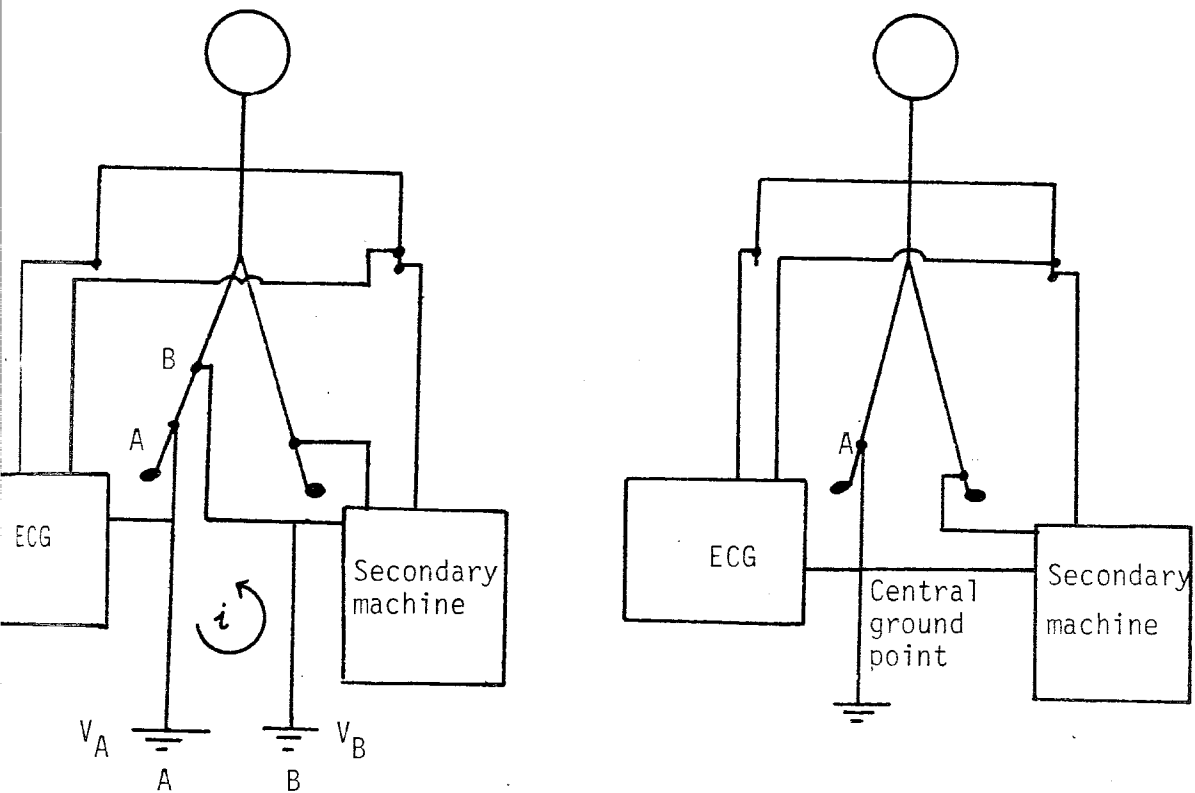


Figure 3.12 - a) Example of a ground loop. $V_B > V_A$ that's why i current flows through the ground loop.

- b) Ground loop can be eliminated by connecting both instruments to the same ground and having only one connection to the patient.

electrocardiograph is grounded through the power line at a particular socket, which is denoted as ground A. The secondary machine is also grounded through the power line, but it is plugged into an entirely different outlet across the room, which has a different ground, denoted as ground B. If ground B is at a slightly higher potential than ground A, a current flows from B to A via the secondary machine's electrode,

the patient and the ground electrode of the electrocardiograph. The current which flows through a ground loop is known as ground loop current which is denoted by i in Figure 3.12.a. This current causes obtaining distorted ECG from the patient as a result of interference. For reducing this problem, both machines should be grounded at the same point by using the configuration shown in Figure 3.12.b. In this case, ground loop does not exist, so no ground loop current flows through the ground connection to the patient, even if the patient is grounded to more than one machine.

In short, ground loop causes distorted ECG waveforms and presents safety problems.

3.4.4 Open Lead Wires

Relatively high potential induction on broken or disconnected leads, as a result of electrical field, causes a wide constant-amplitude deflection of the pen of the electrocardiograph's recorder and signal loss. Such electrical field emanates from the power lines or other sources. On the other hand, such a situation also arises when an electrode is not making good contact with the patient. A modern ECG has poor electrode contact detection circuit that gives warning signal to the operator when this kind of problem happens.

3.4.5 Artifact from Large Electrical Transients

In some situations, the patient may require cardiac defibrillation under the condition of cardiac monitoring. In such a case, a

high-voltage, high-current electrical pulse is applied to the chest of the patient, so that transient potentials can be observed across the electrodes. These potentials can be several orders of magnitude higher than the normal potentials encountered in the ECG. Other electrical sources also can cause similar transients. When this situation occurs, it can cause an abrupt deflection in the ECG, as shown in Figure 3.13. This situation happens as a result of relatively high amplitude pulse application at the amplifier's input that causes saturation.

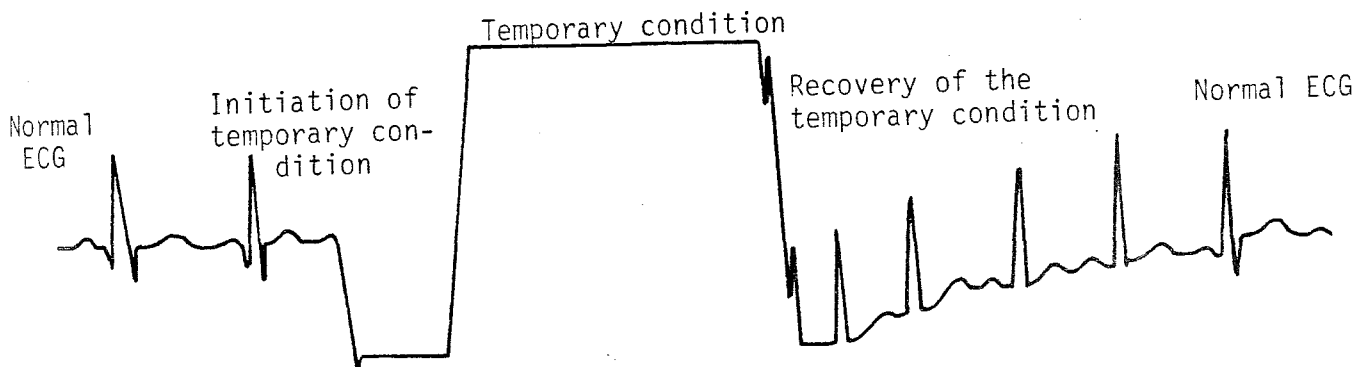


Figure 3.13 - Effect of a voltage transient on an ECG.

There are some other factors that generate relatively high magnitude signal than a normal ECG. These factors are listed as follows.

1. Motion of the electrodes that can produce variations in potential greater than ECG potentials. Motion of electrodes from the patient is detected by a specially designed system

that gives warning signal to operators if electrodes slip from their place.

2. Partial discharging of static electric charge through the body also causes this condition.

3.4.6 Interference from Electrical Systems and Muscular Motions

A major source of artifact when one is recording or monitoring the ECG is the electric-power system. The power lines can affect the recording or monitoring of the ECG and introduce interference at the line frequency in the recorded trace which is shown as follows in Figure 3.14.



Figure 3.14 - 60 Hz power line interference on the ECG.

The other source of artifact is electromyographic interference that occurs as a result of muscular motion. Figure 3.15 shows the electromyographic interference on the ECG.



Figure 3.15 - Electromyographic interference on the ECG.

3.4.7 Interference from Electric Field

Electric-field coupling between the power lines and the electrocardiograph and/or the patient is a result of the electric fields surrounding main power lines and the power cords connecting different pieces of apparatus to electrical outlets. This fields can be present even when the apparatus is not turned on, since current is not necessary to establish the electric field.

The electric field affects the ECG, so there are some basic solutions that can solve easily this problems.

- * The lead wires should be well isolated.
- * Electrode skin impedance should be as low as possible.
- * Input impedances of the amplifiers should be as high as possible.

3.4.8 Interference from Magnetic Field

Another source of interference is magnetic field. Current in power lines establishes a magnetic field in the vicinity of the line. Magnetic fields can also sometimes originate from transformers and ballasts in fluorescent lights. Induction of magnetic field on biomedical instruments affects the operation condition. For example, magnetic field induction on electrocardiograph causes distorted ECG from the patient that may result in wrong diagnosis and monitoring. That's why coronary care unit or intensive care unit should not be constructed in the vicinity of high power lines and transformers.

There is a simple method that avoids magnetic field induction effect on electrocardiograph which is shown schematically in Figure 3.16.a,b. In this case, the lead wires are twisted together. As a result of this the effective area of the single turn coil is reduced so no voltage induction occurs on the system.

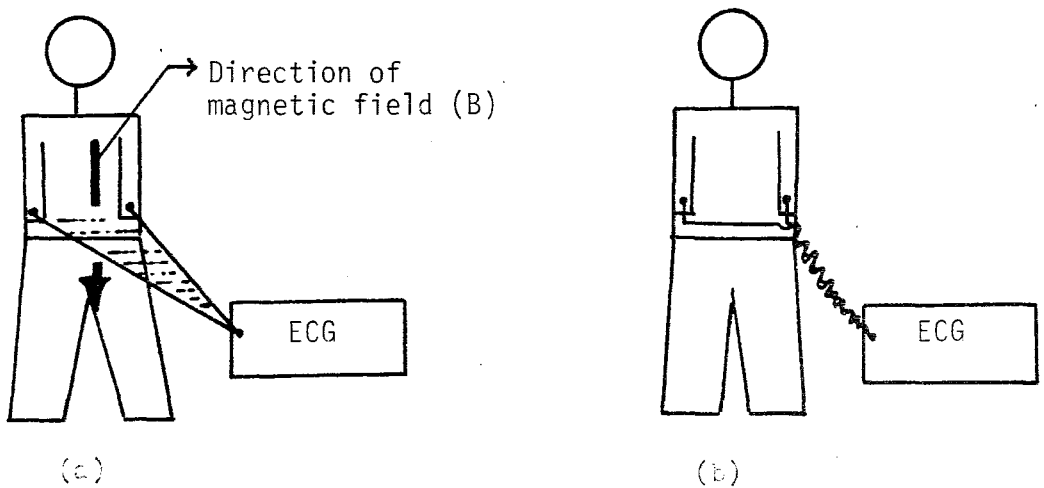


Figure 3.16 - a) Undesirable leads connection because of occurrence of magnetic field induction on the electrocardiograph.
b) Desirable leads connection.

3.4.9 Interference from Other Sources

The other sources of interference which have an effect on the biomedical equipment operation can be listed as follows.

- a. Electromagnetic interference is caused by TV, radar and high frequency generator,
- b. Interference that occurs as a result of diathermy and electrosurgical equipment usage,
- c. X-ray machine causes electromagnetic radiation interference.

The above factors should always be taken into consideration by the biomedical engineers, doctors and operators for efficient unit design and work.

4. CARDIOTACHOMETERS

(RATE-COMPUTERS, CARDIORATES, HEART RATE METER)

4.1 INTRODUCTION

All doctors evaluate the heart rate of all their patients during examination, because the heart rate gives valuable information about the heart condition of patients. That's why it is one of the important variables that should always be taken into consideration during the diagnostic and treatment procedures, especially for the cardiac patients.

The normal range of heart rate for an adult is (60-80) beats per minute (bpm). Slowing down of heart rate below the lower limit of this range is defined as bradycardia. Tachycardia is a condition of faster heart rate than 80 bpm. Both of them are not desirable conditions for the human beings, especially for the cardiac patients, because these conditions indicate existence of cardiac abnormalities which may have vital importance. Under this consideration, continuous observation and evaluation of heart rate for the cardiac patient becomes very important, that's why all the critical care units (CCU, ICU) should be equipped with cardi tachometers or rate computers. They are used for continuous observation and evaluation of the heart rate. The display and alarm units of them should be installed both on each bedside

and on the central console. The medical staff can easily observe the each patient's heart rate separately from the display units that are installed on the central nurses' console unit. On the other hand they can record the heart rates by using recorder units. A schematic installation diagram is given later in Figure 4.4.

4.2 TYPES OF CARDIOTACHOMETERS

There are two basic operation modes that indicate the type of cardiometers. One type is known as the averaging cardiometer and the other one is called the beat-to-beat cardiometer (instantaneous heart rate meters). The modernly designed cardiometer units can work at either one of these operation modes. Mode of operation is selected by mode selector switch.

4.2.1 The Averaging Cardiometers

The averaging cardiometer determines average heart rate by counting the pulses (R-R intervals) over a known period of time. The circuit operates as a frequency-to-voltage converter, yielding an output signal whose magnitude is proportional to the frequency of the input (ECG) signal. Usually the peak of the R-wave is selected as the trigger point for heart rate computing. But some manufacturers may use any other point than R-wave as the trigger point.

Block diagram of an averaging cardiometer is given in Figure 4.1.

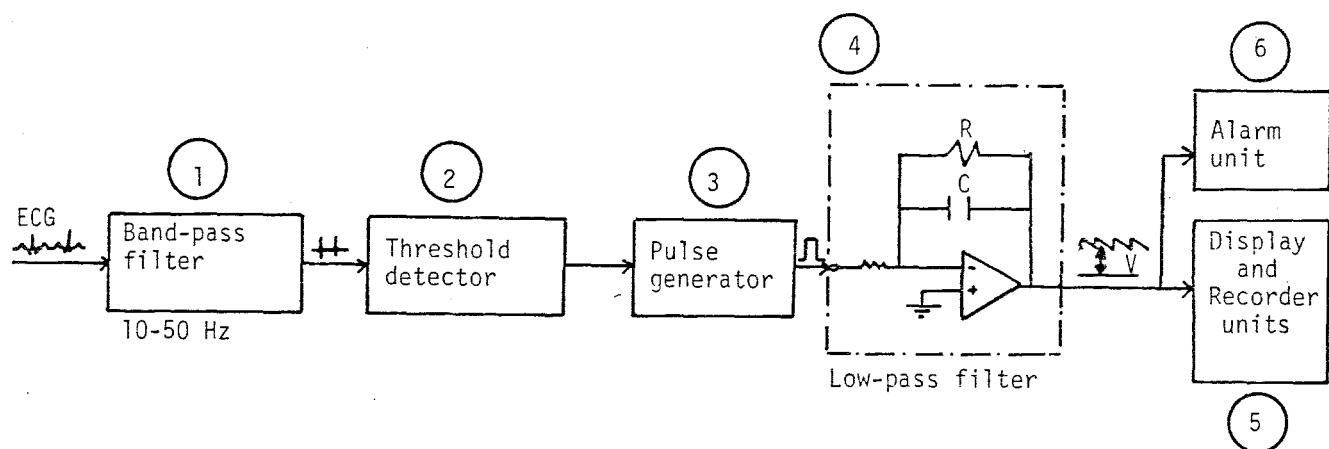


Figure 4.1 - Block diagram of an averaging cardiometer.

First Block: Bandpass Filter

The input signal of the bandpass filter is amplified ECG with an amplitude of approximately 1 V p-p. This signal is passed through the bandpass filter for removing low frequency noise and baseline drift. The filter system also passes only frequencies that are associated with the QRS complex. The obtained wave is sufficient for determination of heart rate and it is input signal of the threshold detector.

Second and Third Blocks: Threshold Detector and Pulse Generator

The threshold detector detects a signal which has an amplitude greater than a fixed level. When this occurs, the pulse generator

generates a pulse for each detected QRS complex. All the generated pulses from the pulse generator have the same amplitude and width. The higher the heart rate, the more frequent the appearance of pulses from the pulse generator. These generated pulses are input of the low-pass filter.

Fourth Block: Low-pass Filter

The low-pass filter is fed by the pulses which have been generated by the pulse generator. The circuit determines the average amplitude of the pulse train coming from the pulse generator. The resistor bleeds off charge from the capacitor, so that a fixed average voltage is reached for any particular pulse rate. For this to occur, the time constant of the RC circuit should be at least several beats in duration (Generally, the values of 5 to 15 seconds are used). The higher the heart rate, the more frequent the appearance of pulses from the pulse generator. These cause a larger charge to built up on the capacitor, which in turn increase the output voltage from the circuit. Since the resistor R shunts the output to the virtual ground, the increased heart rate results in increased current through the resistor. It can be clearly seen that the obtained wave is not pure d.c. that's why pulsation can be observed at the meter display.

Fifth Block: Display and Recorder Units

Basically, there are two kinds of displays. One of them is meter display, the other one is digital display. The digital display is more

frequently used because it has some advantages over the meter display which are;

- i. accurate detection of the heart rate because of the number display,
- ii. easy in viewing, both from nearby as well as from a distance.

On the other hand this block generally includes a recorder (chart recorder, magnetic recorder or other types of recorders). The recorder is used for recording heart rate of patient if it is required or necessary. It may be activated automatically or manually. Automatic recording begins when the alarm condition occurs. It is obvious that the display and recorder units should be installed both on each bedside unit and on the central console for obtaining continuous observation from both places.

Sixth Block: Alarm Unit

The alarm unit includes a comparator which compares the obtained heart rate (voltage) with preadjusted limits. If the calculated heart rate exceeds the preadjusted limits, the alarm unit is activated. It gives audible and visual warning signals to the medical staff. It is clear that the alarm units should be installed both on each bedside and on the central console.

4.2.2 The Beat-to-Beat Cardiometer (Instantaneous Heart Rate Meter)

The beat-to-beat cardiometer determines the reciprocal of the time interval between heart beats for each beat and presents it as the heart rate for that particular interval.

Block diagram of an instantaneous heart rate meter unit is given in Figure 4.2. The alarm and recorder units are not shown in the block diagram.

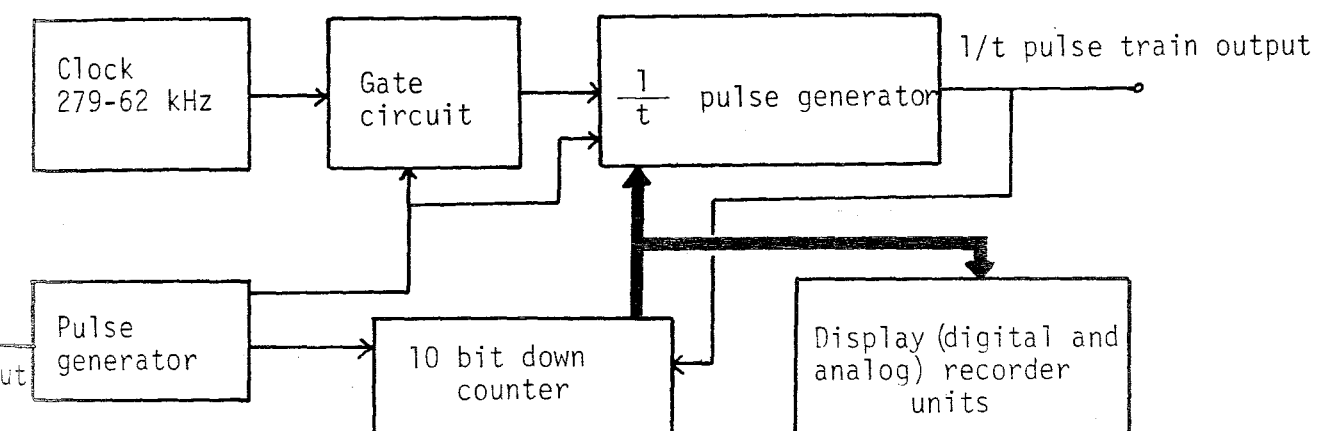


Figure 4.2 - Block diagram of an instantaneous heart rate meter.

The unit was developed for converting the time interval between two successive heart beats to frequency.

The device is basically composed of a $1/t$ pulse generator, a 10 bit down counter and digital and analog displays. The $1/t$ pulse

generator generates a train of pulses with a time interval corresponding to the inverse function of frequency. Down counter counts the pulses occurring between two successive heart beats (R_1 and R_2). The pulse train is generated at the R_1 spike, and the pulses occurring between R_1 and R_2 spikes are counted. The count number of the 10 bit down counter indicates the instantaneous heart rate. In other words when R_1 is sensed, $1/t$ pulse generator begins to generate the pulse train and down counter begins to count until the R_2 -wave occurs. When R_2 is sensed the down counter reset itself and then the same procedure is repeated sequentially at each R-wave to convert the time interval from two successive heart beats to frequency.

The schematic representation of the working principle is shown in Figure 4.3.

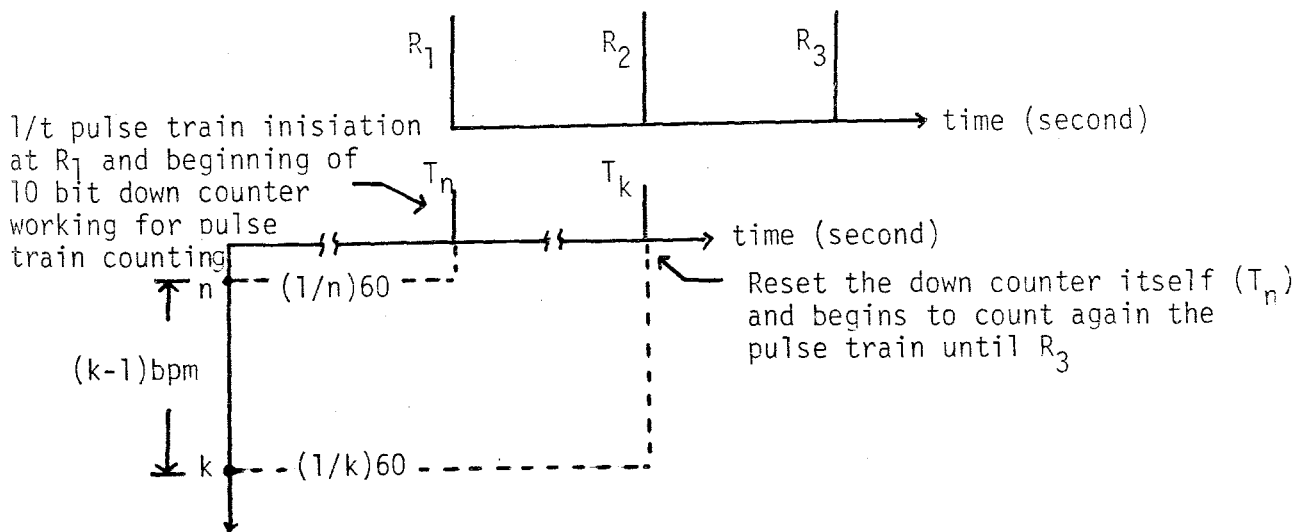


Figure 4.3 The schematic diagram of the working principle of the beat-to-beat cardiometer.

It is obvious that this unit should also have alarm and recorder units. The alarm units should be installed both on each bedside and on the central console like the display units.

A lot of cardiometer unit enables to calculate both instantaneous and average heart rates. The selection of operation mode is performed by the user manually.

4.3 BLOCK DIAGRAM OF A SIMPLIFIED CARDIAC MONITOR INSTALLATION BY USING CARDIOTACHOMETERS

A 4-bed coronary care unit monitoring system installation is shown in Figure 4.4. The design is performed by using cardiac monitors (ECG and cardiometer) with their alarm and recorder units. This simplified design diagram shows the bedside monitors, the central console monitors and their connection links. If it is desired, some additional equipment such as pacemakers, defibrillators, blood pressure monitors and others can be installed on this system. It can be clearly seen that cardiometer is one of the most important instrument that it should always exist in all CCU design.

The designed unit has to have some basic properties which are listed below.

1. The unit supply a continuous diagnostic picture of the patient's condition.
2. It must provide adequate alarm mechanisms as well as protection against false alarms.

3. Required recorder units should be installed on the proper sites within the unit.
4. The unit must be simple to operate and maintain. The detailed information about the CCU design is given in Chapter 2.

Computerized cardiac monitors are also used during the CCU design. This provides automatic recording, storage some information in the computer about the patient's condition and easily reviewing the patient's past etc. But it is obvious that this brings high cost that's why during the preparation of fisibility report all these things should be taken into consideration.

In short all the CCU unit should have sufficient number of cardio-tachometers. On the other hand optimum number of cardi tachometers are also reserved for spare usage within the unit.

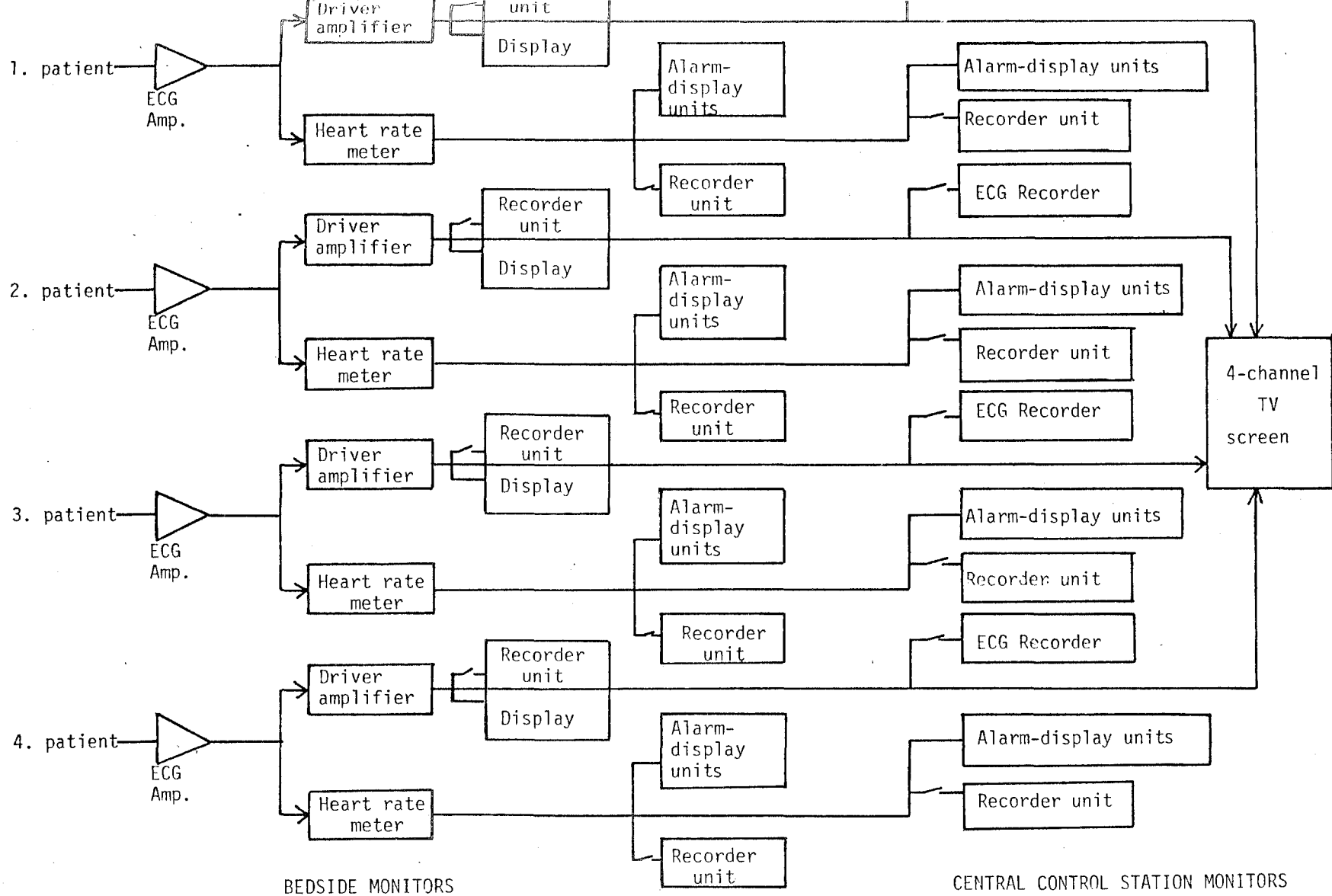


Figure 4.4 - A 4-bed CCU design.

5. ARRHYTHMIA MONITORS

5.1 INTRODUCTION

Computer monitoring of electrocardiographic rhythm, which is a device called computerized arrhythmia monitor, in the coronary care unit has now been in existence for approximately 20 years. This system is capable of detecting a variety of rhythm disorders, turning on appropriate alarms and recording the condition automatically.

Cardiac arrhythmia implies loss of, or deviation from, the normal sinus rhythm of the heart. The normal sinus rhythm is origination of depolarization wave in the sinus node. If a depolarization wave originates in a site of other than the sinus node, an arrhythmia occurs. In short the arrhythmia occurs as a result of some conditions that are listed below.

- Improper functioning of the ventricles
- Irregular atrial activity
- Blocks at different point in the transmission of the impulse through the heart
- Spontaneous generation of abnormal impulses in almost any part of the heart

- Abnormal rhythmicity of the pacemaker itself.

Arrhythmias are named according to their site of origin. If the source of arrhythmia is in the atrium, it is called "atrial arrhythmia". If the source of arrhythmia is in the ventricle, it is called "ventricular arrhythmia".

5.2 DETECTION TYPES OF ARRHYTHMIAS

The cardiac rhythm has very importance for the cardiac patient because it gives valuable information about the cardiac activity and condition to the medical staff. Detection of arrhythmia in early stage provides us to prevent fibrillation occurrence that may have vital importance. That's why continuous cardiac rhythm detection has big importance for the patient who has been cared in the coronary care unit.

Detection of cardiac rhythm can be performed by two ways.

1. Conventional Detection: The patients who requires continuous cardiac rhythm detection, is cared by one nurse. This method requires continuous watching of the patient's ECG or changing heart rate on display unit. It is obvious that this method is not sensitive because detection and evaluation is performed by the nurse. In other words, in the usual settings the detection of an arrhythmia depends upon the ability of nurses to watch ECG display this method is time consuming so that it

is not economical method. That's why this method is not widely used in modern CCU.

2. Computerized Arrhythmia Detections: Computerized arrhythmia detection has the advantages that are listed below.

- Continuous rhythm detection
- Automatic turning on the alarms
- Automatic recording under the alarm conditions
- Automatic source detection of arrhythmias
- Rapid and efficient data storage and retrieval of electrocardiographic information
- Minimum time consumption
- Monitoring in many patients simultaneously.

Because of these advantages, computerized arrhythmia detection method is used in the modern coronary care unit.

5.3 AIM OF USING ARRHYTHMIA MONITORS

There are some reasons for using arrhythmia monitor in coronary care units.

1. Performing continuous cardiac rhythm detection.
2. Detection of the types of arrhythmias, in other words finding the sources of arrhythmias.
3. Counting the frequency of arrhythmias
4. Alarming the arrhythmic conditions of the patient automatically

5. Recording the arrhythmic conditions
6. Determining the nature of the alarm
7. Determining the time of the alarm and etc.

5.4 ALGORITHMS OF ARRHYTHMIA MONITORS

An algorithm is a specific series of computer operations that divides the arrhythmia detection and classification processes into a number of simple tasks.

Most commercially available arrhythmia monitoring systems use some variation or combination of two distinct type of algorithms which are explained below.

5.4.1 Waveform Feature Extraction Algorithm

5.4.2 Template Algorithm

5.4.2.a Template-Matching

5.4.2.b Template-Cross Correlation

In both algorithms, the ECG signal of each patient is sampled and stored for processing. In other words the sampled ECG is compared with the predefined normal ECG by using some specific algorithms for determination of the heart rhythm. In some equipment the predefined normal ECG wave can be stored by the operator depending upon the patient's normal cardiac activity in the past. In other words the feature extraction algorithm classification criteria may be modifiable by the operator or may vary depending on the patient's current ECG waveforms.

5.4.1 Waveform Feature Extraction Algorithm

The feature extraction algorithm measures several QRS characteristics which are listed below.

1. The time interval of consecutive R-R waves
2. The width of QRS complex
3. The area of QRS complex
4. The amplitude of R wave
5. The polarity of R wave
6. The height of R wave.

All the normal values of these mentioned characteristics are stored in the memory unit of the instrument and then the sampled ECG are compared with them and classified as normal or not.

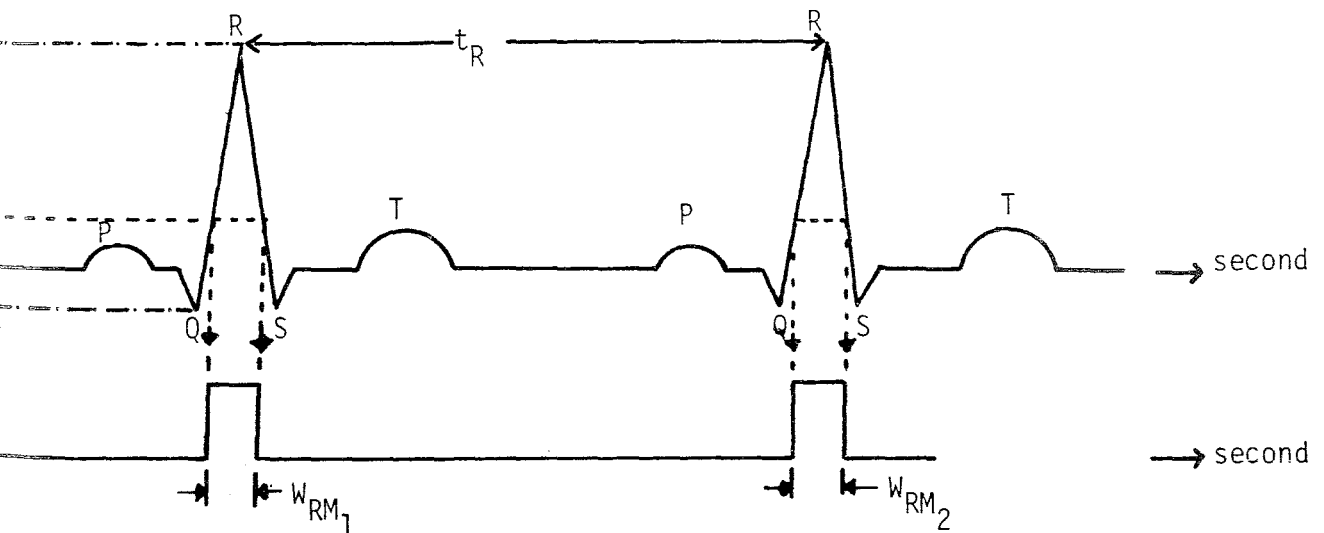


Figure 5.1 - A sample of ECG wave.

In figure 5.1 shows an ECG waveform. This is drawn for giving information about the comparison criteria.

1. Comparison of Consecutive R-R Time Interval:

t_R : The time interval of consecutive R-R wave (seconds)

t_{RN} : The normal range of the time interval of consecutive R-R wave (seconds)

t_{RM} : Measured or sampled value of the time interval of consecutive R-R wave (seconds)

Comparison:

$$t_{RN_{min}} < t_{RM} < t_{RN_{max}}$$

$t_{RN_{min}}$ = Predefined minimum normal time interval of consecutive R-R wave

$t_{RN_{max}}$ = Predefined maximum normal time interval of consecutive R-R wave.

2. Comparison of R Width:

W_R : The width of QRS complex (seconds)

W_{RN} : Predefined normal width of QRS complex (seconds)

W_{RM} : The measured or sampled width of QRS complex (seconds)

Comparison:

$$W_{RN_{min}} < W_{RM} < W_{RN_{max}}$$

$W_{RN_{min}}$ = Predefined normal minimum QRS width value
 $W_{RN_{max}}$ = Predefined normal maximum QRS width value.

All the above mentioned characteristics are compared in a certain sequence. If the sampled characteristics below or exceed the predetermined limits, the QRS is classified as abnormal. On the other hand there are some arrhythmia monitors that can report the source of arrhythmias. When the arrhythmic condition occurs, the unit gives audible and visual alarms and recorder records this condition automatically.

5.4.2 Template Algorithm

This algorithm can be performed by two different ways.

5.4.2.a Template-Matching

16 or 40 points are taken from the normal R wave and then these are defined as normal and stored in the memory unit. The sampled R waves are compared mathematically with predefined normal values within certain tolerance limits. In short, in template-matching (See Figure 5.2 and 5.3) the beat is classified as normal, abnormal or questionable based upon the number of points on the sampled beat that violate the template boundaries (e.g., $\pm 10\%$).

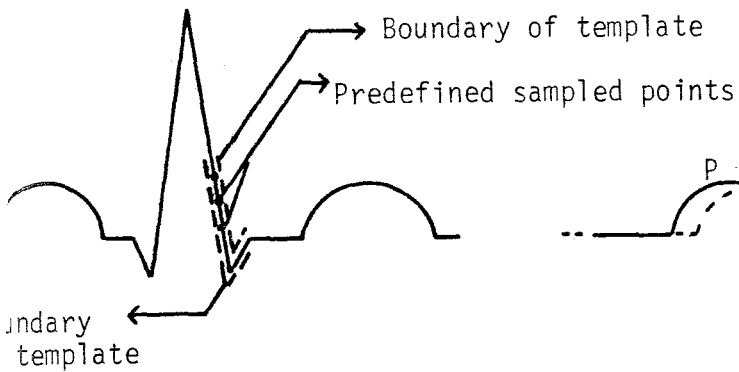


Figure 5.2 - Predefined boundaries and points on template.

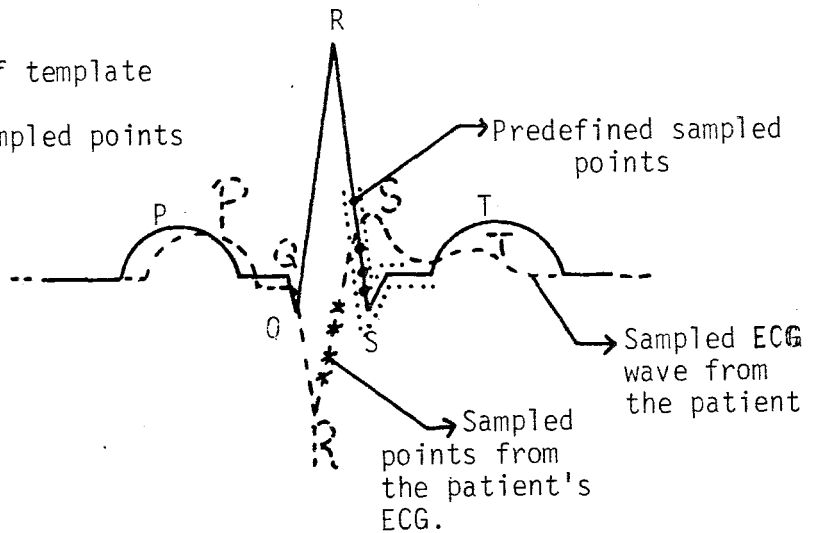


Figure 5.3 - Template-Match.

5.4.2.b Template-Cross Correlation

A second type of template algorithm is cross-correlation. This algorithm uses a calculated correlation coefficient (a number from -1 to +1) to mathematically determine how closely the beat matches one of a set of stored templates. A correlation coefficient greater than or equal to some criterion (e.g., 0.9) constitute a match between the sampled beat and that template.

5.5 BLOCK DIAGRAM OF A COMPUTERIZED ARRHYTHMIA MONITOR

Basic blocks of a computerized arrhythmia monitor are shown in Figure 5.4.

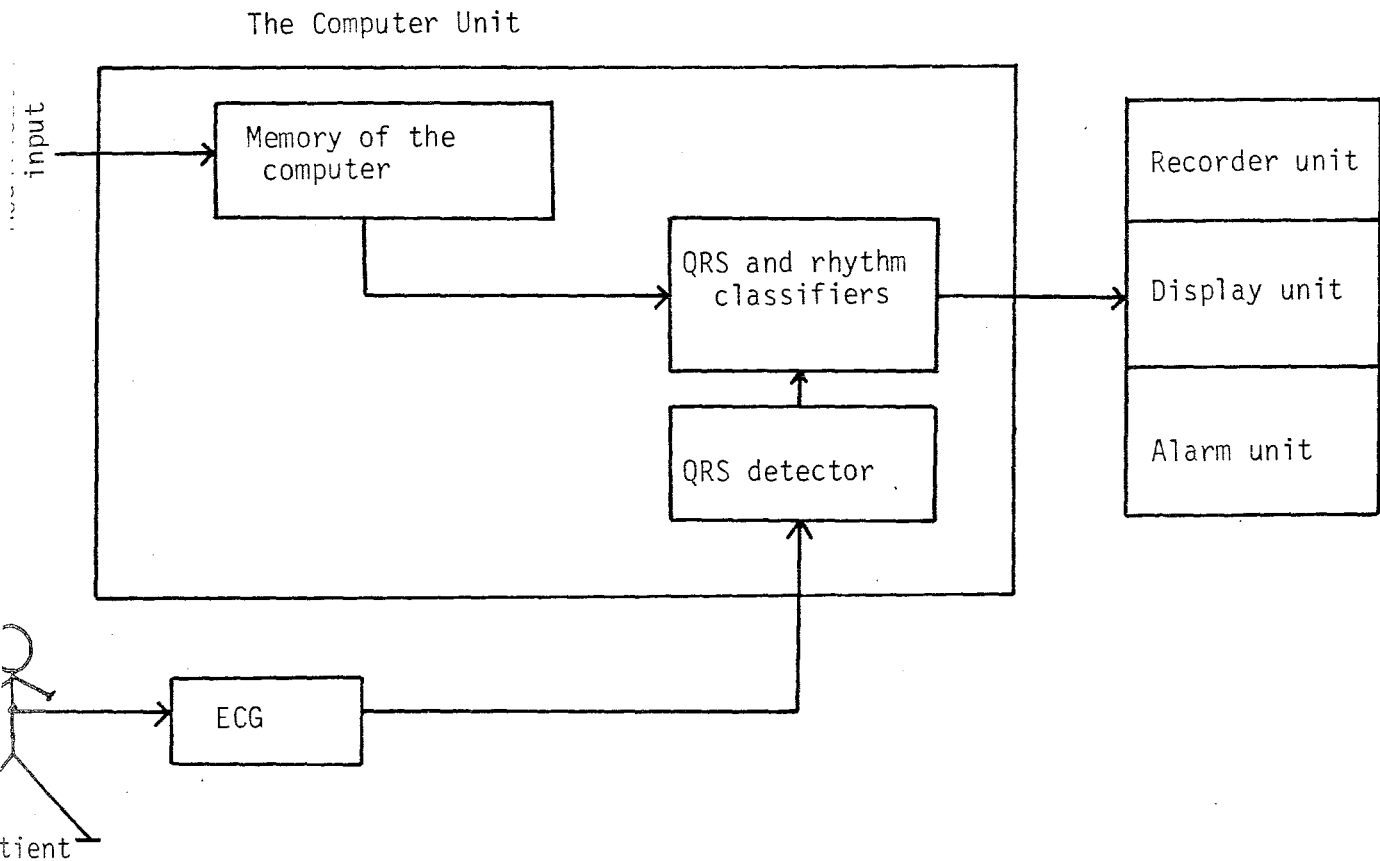


Figure 5.4 - Block diagram of a computerized arrhythmia monitor in coronary care unit.

The ECG signals are taken from the patient who has been cared in the unit. The sampled QRS waves are tested by using some algorithms and then the cardiac rhythm of the patient is classified as normal or abnormal (tachycardia, bradycardia or others). When the heart rhythm of the patient goes wrong, the alarm and recorder units are activated automatically. Display units, audible and visual alarm units are installed both on each bedside unit and on the central console.

Activation of the alarm unit occurs as a result of:

- loss of signal,
- ventricular tachycardia,
- atrial tachycardia,
- bradycardia,
- tachycardia and others.

Many computerized arrhythmia monitors use combinations of both the feature extraction and template algorithms in an attempt to lessen errors. A few systems also use some additional algorithms which are not mentioned here.

5.6 PROBLEMS ASSOCIATED WITH COMPUTERIZED ARRHYTHMIA MONITORS

False identification and alarm unit activation may occur as a result of:

- noise artifacts which are generated from the patient's movement in the bed and/or inadequate skin-electrode contact,
- electrical artifacts which are caused by operation of some equipment near by the system,
- inaccurate alarm limit adjustments,
- loss of signal amplitude which occurs as a result of the patient movement,
- inaccurate sampling for performing template-matching or other methods

- some other factors.

In short, an arrhythmia monitoring system must be accurate in detecting and recording the cardiac abnormality and must also be able to distinguish noise and other artifacts from the arrhythmias. Most of the problems are still related to patient movement artifact causing false identification of premature beats. There are some circuit elements that are used for eliminating and reducing above mentioned problems. But much work needs to be performed to improve this area.

There are some factors that should be taken into consideration for minimizing false alarms. Some of them are listed below.

1. Carefully placing of electrodes on the patient.
2. Obtaining good electrode-skin contact by using conventional procedures.
3. Making proper adjustments of the amplifier sensitivity and gain.
4. Adjusting limits properly and accurately for performing accurate arrhythmia detection.

It is obviously understood that arrhythmia monitors are one of the most important equipment for cardiac patients. They should be installed within the all coronary care units. The number of monitors should determined optimally depending upon the unit capacity. Reserve monitors should also exist within the unit. Display and alarm units should be installed both on each bedside and on the central console. On the other hand recorder unit should also be installed on the proper place of the central console for performing separate recording from each patient.

6. BLOOD PRESSURE MEASUREMENTS TECHNIQUES AND MONITORING EQUIPMENT

6.1 INTRODUCTION

Blood pressure measurement helps the physician determine the functional integrity of the cardiovascular system. In other words blood pressure values give valuable information about the heart and cardiovascular condition to the physicians. That's why evaluation of blood pressure is usually performed during the regular examination. This variable has also special importance for the cardiac patient.

There are two different blood pressure measurement methods. One of them is known as indirect blood pressure measurement which is usually performed by the physician during the regular examination of patient. On the other hand this indirect method is also widely used in CCU or other critical care units. The other measurement method is known as direct blood pressure measurement and is usually used in critical care units, since the patient who is being cared in such a unit may require continuous blood pressure measurement. These two measurement techniques will be explained later.

Two types of pressure are measured which are systolic blood pressure and diastolic blood pressure. Under the period of contraction of the heart muscle (systole), the measured blood pressure is called systolic blood pressure. Under the period of dilation of the heart muscle (diastole), the measured blood pressure is known as diastolic blood pressure. The normal values of systolic and diastolic blood pressure for an adult are given below.

Systolic blood pressure: 95-145 mm Hg (Average: 120 mm Hg)

Diastolic blood pressure: 60-90 mm Hg (Average: 85 mm Hg)

The mentioned normal values may change depending upon age, climate, eating habits and some other factors.

A person who has a blood pressure more than 145 mm Hg is called hypertensive. In contrast a person who has a blood pressure smaller than 60 mm Hg is called hypotensive. In other words, high blood pressure more than 145 mm Hg is defined as hypertension and low blood pressure less than 60 mm Hg is called hypotension. These two abnormal conditions or rapid change in blood pressure in short time interval indicates existence of some problems in the cardiovascular system. But it should be mentioned that, some person may have lower or higher blood pressure than the normal which is not an indicator of the existence of some diseases because it may be an inherent characteristic of the person.

6.2 BLOOD PRESSURE MEASUREMENT TYPES AND TECHNIQUES

6.2.1 Direct Blood Pressure Measurement

The direct blood pressure measurement method is an invasive technique. It requires penetration of the skin that's why this measurement technique is not used during regular examination of patients. This method is frequently used for performing continuous blood pressure monitoring in special care units such as CCU, ICU and others. In other words, this monitoring technique provides continuous evaluation of blood pressure change in time or response of treatment of cardiac patient. The obtained pressure waveform also provides useful information about the heart's pumping action and aortic valve closure.

Generally, the mean arterial blood pressure is monitored because it is less variable than the systolic and diastolic pressures during periods of arrhythmias. The mean arterial pressure is close to the diastolic pressure that can be calculated automatically by the monitoring equipment as $MAP = (1/3)(\text{systolic} - \text{diastolic}) + \text{diastolic}$.

Basically, direct blood pressure measurement is performed by using a catheter, a transducer and a monitoring equipment. Basic block diagram is shown in Figure 6.5. A catheter is a thin flexible tube designed for entry into the blood stream and the heart. A transducer in biomedical applications is defined a specially designed device that converts physiological variables into an electrical signal. By this definition, pressure transducer is a device that converts blood pressure (mechanical motion) into an electrical signal that can be

displayed as the pressure waveform or converted into a numeric display of blood pressure values by using special electronic settings. The magnitude of electrical signal, which is the output of transducer, is proportional to the magnitude of the applied pressure to the transducer. The transducer requires an electrical excitation signal for operation. The type of excitation signal depends on the transducer type. Alternating current (AC) excitation signal is used for resistive, inductive and capacitive transducers. On the other hand direct current (DC) excitation signal is also used for excitation of resistive transducer. An addition, excitation signal should not be too high because high excitation signal may cause:

- i. a nonlinear response,
- ii. thermal drift due to self heating,
- iii. burn-out of bridge elements which are connected to the transducer.

Under these considerations, the range of excitation signal generally varies around 1-10 volts (DC or AC) with about 2.4 kHz (for AC).

As a result, it can be clearly understood that a pressure transducer has two inputs, which are excitation signal and applied blood pressure to the transducer, and one output which is the signal being monitored. The output signal properties depend on the mentioned two inputs.

6.2.1.1 Types of Transducers

Blood pressure transducers may be divided into two general categories, according to the location of the transducer element.

6.2.1.1.A Catheter Tip Transducers (Intravascular pressure transducers)

6.2.1.1.B Fluid-Column (Liquid-Column) External Transducers (Extravascular pressure transducers)

B.1 Resutive

B.2 Inductive

B.3 Capacitive

6.2.1.1.A Catheter Tip Transducers (or needle transducers)

The blood pressure transducer is placed at the tip of the catheter. The catheter is positioned at the site at which the blood pressure is to be measured. In this type of transducer, the liquid coupling is eliminated, so frequency response problem, to be explained later, which is caused by the liquid coupling, is almost eliminated.

One of the working principle of the catheter tip transducer is variable induction (mechano-inductive action). Figure 6.1 shows simplified diagram of a variable inductance catheter tip transducer. The transducer is placed in the blood-stream. F_B is defined as the pressure force of the blood-stream that is applied on the flexible diaphragm of the transducer.

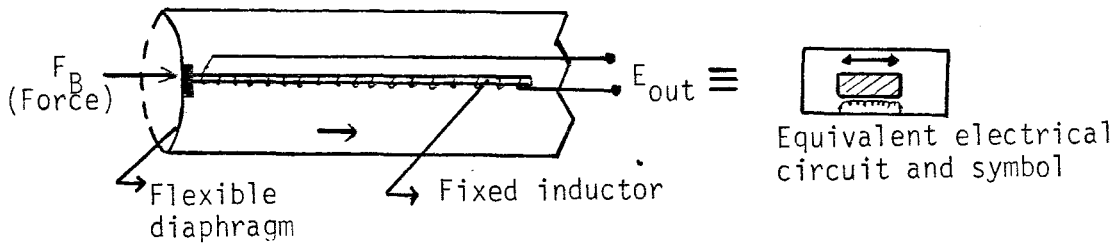


Figure 6.1 - Simplified diagram of a variable inductance catheter tip pressure transducer.

The displacement of iron core occurs as a result of F_B application on the flexible diaphragm. This causes variation of the coil inductance under the fixed excitation signal application to the transducer system. As a result of this voltage across the coil (E_{out}) changes. The change in potential developed is proportional to the pressure change that it is applied to the flexible diaphragm. In short it can be clearly understood that E_{out} is directly proportional to L . The basic electrical formula are given as follows

$$\text{Flux} \rightarrow \psi = L \cdot i$$

$$\text{Voltage} \rightarrow E = d\psi/dt = L(di/dt) + i(dL/dt)$$

$di/dt \rightarrow 0$ Because the excitation signal is constant.

Therefore

$$E_{out} = i(dL/dt)$$

The last equation indicates direct proportionality of E_{out} and L . Changing in L causes changing E_{out} . The obtained output voltage

can easily be monitored by using same special circuits.

Another type of catheter tip transducer has a strain-gage sensor built into the tip of a cardiac catheter. Pressure variation at the site itself produces resistance change in the strain-gage. As a result of this output voltage of the bridge changes depending upon the variation of the blood pressure. The obtained output voltage is monitored by using some amplification and filtering circuits with the display units.

6.2.1.1.B Fluid-Column External Transducers

Figure 6.2 shows a type of extravascular unbonded strain-gage pressure transducer. It is easily understood that pressure transducer is placed out of the body.

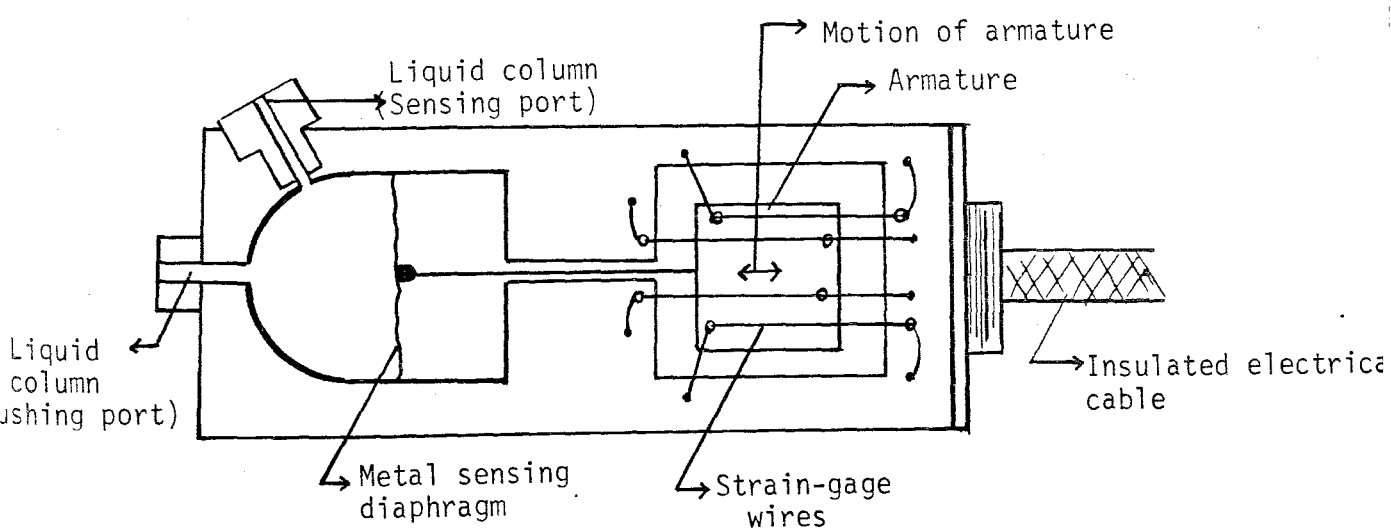


Figure 6.2 - Fluid-column external transducer.

As it is known, the blood pressure transducer converts a mechanical energy into an electrical signal. This conversion is performed by using some electrical elements which are resistors, inductors and capacitors. If this conversion is performed by resistor systems, this kind of transducer is known as strain-gage pressure transducer. The working principle of an unbonded strain-gage pressure transducer is explained below.

The physician inserts the catheter either by means of surgical cut-down, which exposes the artery or vein, or by means of percutaneous insertion, which involves the use of a special needle or guide-wire technique. Blood pressure is transmitted via the catheter liquid column to the transducer dome that contains a diaphragm. The diaphragm is connected to a unbonded strain-gage and this strain-gage system is connected to a Wheatstone bridge. When the diaphragm is deflected by the pressure, the armature moves and then strain on one pair of gages, B and C increases and the strain on other pair of gages, A and D decreases. As a result of this, the balance of the Wheatstone bridge fails and this causes changing output voltage of the bridge system. The output voltage of the bridge circuit is proportional to the applied pressure to the diaphragm through the liquid column. On the other hand the output voltage also depends on the excitation signal. It is usually in the range of 5-10 volts dc or ac for unbonded strain-gage. The same voltages in ac are also valid for inductive or capacitive transducer types which are not mentioned in detail. Because they are not widely used in CCU, ICU. The obtained output voltage is displayed by using some specially designed amplifier, filters and display units.

The unbonded strain gage transducers are widely used for continuous blood pressure monitoring because they have high stability and sensitivity. Sensitivity is expressed as the output voltage per volt of excitation per unit applied pressure, in units of $\mu\text{V}/\text{V}/\text{cm Hg}$ or $\mu\text{V}/\text{V}/\text{mm Hg}$.

Figure 6.3 shows a typical components of a conventional transducer with two-part disposable diaphragm dome.

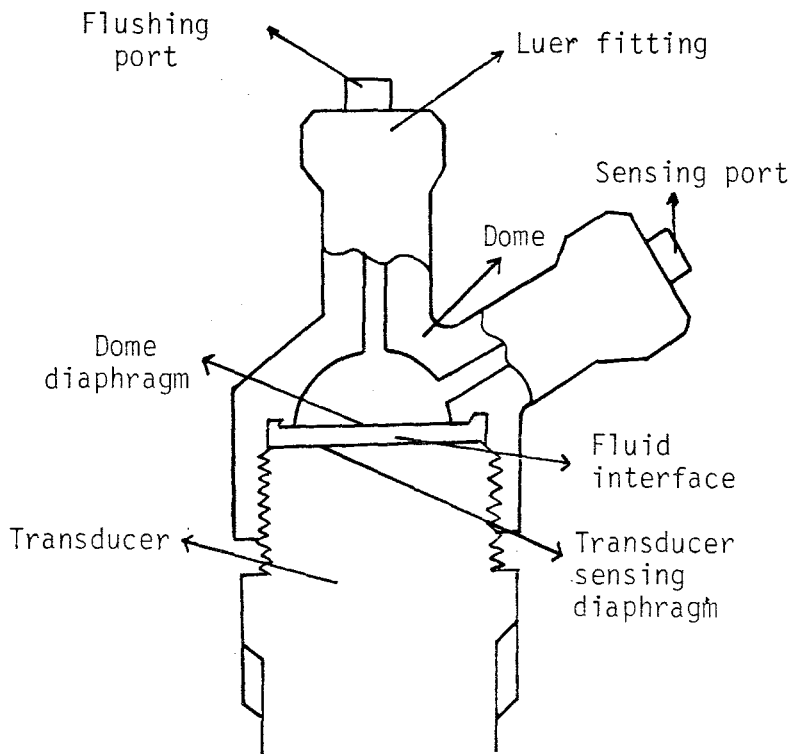


Figure 6.3 - Components of a conventional transducer with two-part disposable diaphragm dome.

Disposable diaphragm domes are becoming very popular and are used almost exclusively in many hospitals in Turkey and abroad. Their main feature is a fluid insulating diaphragm that separates the transducer from the fluid inside the dome (See Figure 6.3).

The advantages of disposable diaphragm domes are listed below.

1. It reduces patient infection risk because there is no direct contact between the fluid and the transducer diaphragm. On the other hand this eliminates the need of sterilization of the transducer.
2. It reduces transducer maintenance costs.
3. It also provides good electrical isolation itself because it has adequate isolation between the electronic circuits and transducer diaphragm.

Moreover, disposable diaphragm dome has some disadvantages which are explained below.

If directions of applying the domes are not followed closely, transducer performance may suffer considerably, and significant errors may result. Dome misapplication can affect the pressure transmission between the dome and transducer and the absolute value of the pressure measurement. If any air is trapped between the dome and transducer diaphragms the pressure wave is damped (See Figure 6.4) which causes wrong interpretation about the blood pressure wave. Other disadvantage of using disposable diaphragm is increased cost. The price of disposable dome is slightly less than the cost of reusable dome and the sterilization cost of reusable dome is rather low.

In addition, for long term monitoring in the CCU or ICU, miniature transducers are also used. They may be more convenient because they are small and lightweight and can be attached to the arm, there by

reducing the strain on the catheter if the patient moves. It has a disadvantage that is inadequate isolation of the system under certain working conditions, when the transducer exterior is wet: a leakage current pathway may exist to the catheter, which may be in or near the patient's heart. This condition may cause important electrical hazards. That's why medical personnel should be careful for preventing occurrence of such electrical hazards.

With all techniques involving externally located transducers, the size (length and diameter) of the needle or catheter is an important factor affecting the frequency response of the system. Fluid systems have a resonant or natural frequency. They respond with maximum sensitivity at that frequency. In other words the response of a fluid-filled system at natural frequency becomes excessively sensitive, resulting in uncontrollable oscillations. Consequently working under this caution is not desirable that's why the working frequency of pressure measuring system should be chosen BELOW the natural frequency. As a result, better results can be obtained if the transducer is placed close to the point of measurement, eliminating the effect of fluid column.

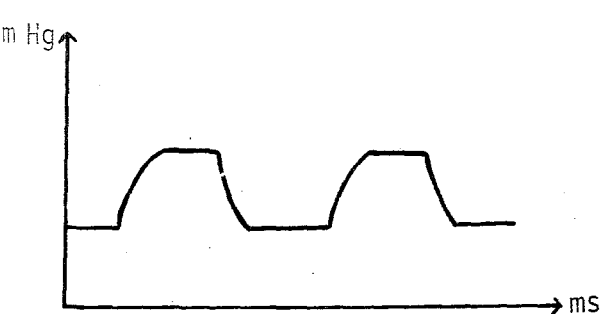
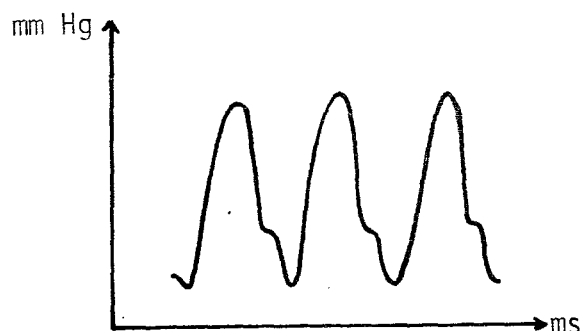


Figure 6.4- a) Damping due to air bubbles.



b) Normal aortic arterial blood pressure waveform.

6.2.1.2 Comparison Between Intravascular and Extravascular Transducers

The extravascular pressure (unbonded strain-gage) transducer is more widely used than the intravascular pressure transducer in the special care units such as CCU, ICU and others. Because the unbonded strain-gage transducer has same advantages over the catheter tip transducer which are listed below.

1. The extravascular pressure strain-gage transducer is more easy to use than the catheter tip pressure transducer.
2. It can be used for longer period of time.
3. Transparent dome of the extravascular pressure transducer provides easy detection of air bubbles within the system.

On the other hand the extravascular pressure transducer has some disadvantages which are explained below.

1. The extravascular pressure transducer has resonant frequency problem which has been mentioned in 6.2.1.1.B. Catheter tip pressure transducer has no such a problem.
2. High probability of air bubbling occurrence within the catheter and dome is important disadvantage of the extravascular pressure transducer. It is known that occurrence of air bubbling within the system affects the system efficiency. On the other hand air bubbling may have vital importance for the patient. Those are some disadvantages of the extravascular pressure transducer.

6.2.1.3 Specific Direct Measurement Techniques

There are four measurement techniques that are used for performing direct blood pressure measurement. Types and place of transducers are taken into consideration during the classification.

- I. Percutaneous Insertion: Percutaneous insertion of a short catheter or small bore needle into a vessel is a method used where the point of measurement is near the point of penetration. The blood pressure is sensed in the vessel just under the skin by the use of needle or catheter. The catheter or needle is connected to a fluid column external blood pressure transducer.

- II. Catheterization: II.1) A first catheterization technique involves guiding a long catheter through the artery or vein to the point of measurement, which may be in one of the major vessels or in the heart itself. The catheter is connected to a fluid column external blood pressure transducer.

 II.2) A catheterization method involving the placement of the transducer through a catheter of the actual site of measurement in the blood stream, or by mounting the transducer on the tip of the catheter.

- III. Implementation of Catheter: Implementation techniques in which the transducer is more permanently placed in the blood vessel or the heart by surgical methods.

6.2.1.4 Block Diagram of a Direct Blood Pressure Measurement Monitor

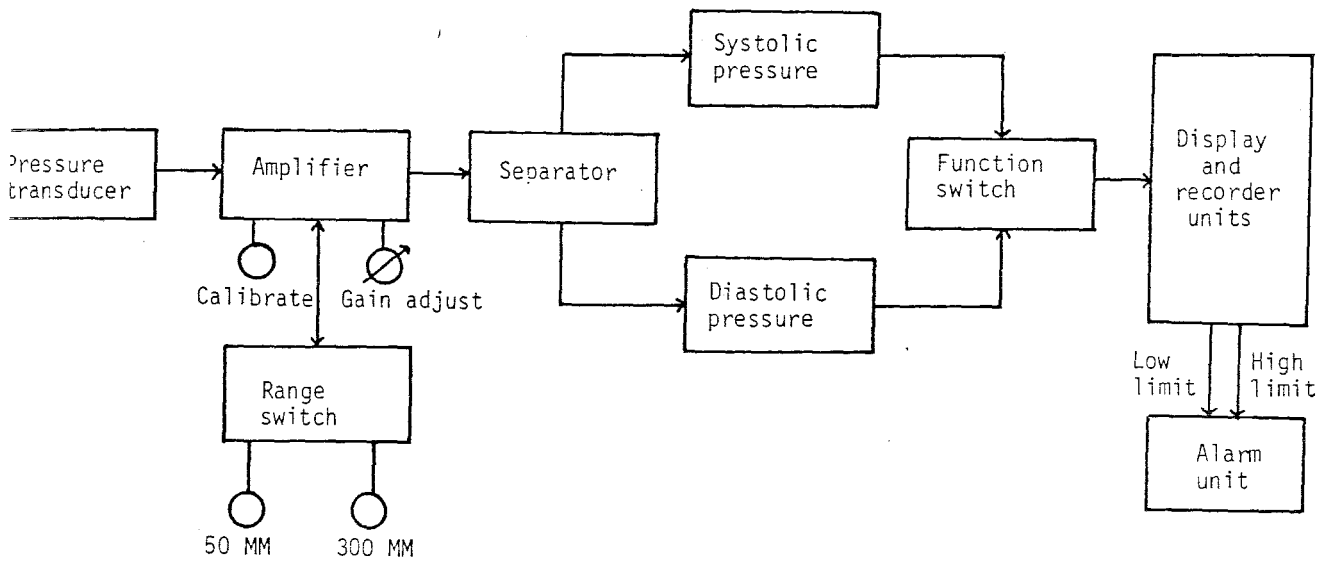


Figure 6.5 - Block diagram of a direct blood pressure monitoring system.

Figure 6.5 shows basic blocks of a direct blood pressure monitoring system. This system is widely used in all the critical care units.

First block represents a pressure transducer which converts the blood pressure into an electrical signal. A fluid column external transducer or catheter tip transducer or miniature fluid-column external transducer is generally used. The obtained signal from the transducer has low magnitude in the order of millivolts so this is not sufficient for monitoring adequately that's why the output signal of the transducer is amplified in the amplifier stage. Amplification of the signal is preformed at a pre-adjusted level. The amplifier unit has gain and

calibration switches. The gain switch is used for adjusting gain of the amplifier. In addition, the calibration of the system is performed by the calibration switch. The system calibration should be done periodically and under the condition of necessity. Basically the calibration procedure of the system is explained as follows.

- * First of all, the atmospheric pressure is applied to the transducer. Under this condition, 0 mm Hg should be read on the display unit. If there is some deflection, the required adjustments should be performed for obtaining above mentioned value.
- * A known pressure is applied to the transducer and then the output is checked. The display should be proportional to the applied pressure.
- * During this procedure, sensitivity of the system should be adjusted properly for obtaining good results. Usually required sensitivity is $50 \mu\text{V/V/cm Hg}$ or $50 \mu\text{V/V/mm Hg}$.
- * Alarm unit should also be checked periodically. First of all, lower and upper limits are adjusted and then low and high pressure should be applied to the transducer for evaluation of alarm unit performance.
- * In addition, electrical isolation of the transducer and the system should also be checked periodically to prevent possible electrical hazards.

On the other hand required pressure range adjustment is performed by using the range switch that may be placed on the amplifier unit. The usual range settings are 0-300 mm Hg for arterial measurement and 0-50 mm Hg for venous measurement. The separator is a specially designed band-pass filter circuit. The amplifier and filter circuits have some properties which are listed below.

1. The amplifier and filter systems should not distort the original signal. In other words the magnitude or phase characteristics of the signal should be the same as the original.
2. The wave shape of the signal should be preserved.

As a result, the bandwidth requirements for the derivative of the blood pressure can be estimated by a Fourier analysis of the derivative signal which are not mentioned here.

Function switch is used for selecting systolic, diastolic and mean blood pressure operation modes manually. On the other hand this block also includes ON/OFF switches.

A meter or digital or oscilloscope display is generally used. Some equipment may have a combination of two or three of the display units. Figure 6.6 shows a typical undistorted arterial pressure waveform which can be viewed from the oscilloscope screen. In addition the pressure monitoring system has also recorder unit. The recorder is used to record the measured blood pressure values. Magnetic type recorder, chart recorder or other types of recorders are used. As

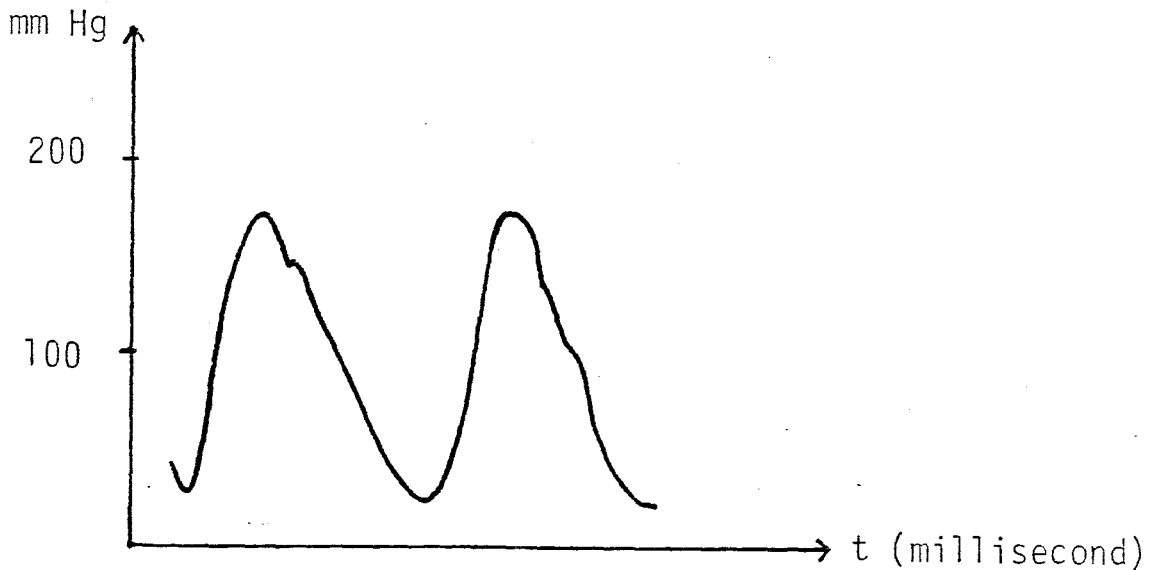


Figure 6.6 - A typical undistorted arterial pressure waveform.

it is known a chart recorder provides hard copy. If the system is computerized generally magnetic recorder unit is used.

The other important block of this system is alarm unit. The alarm unit has low and high blood pressure adjustment switches. Low and high (min and max) limits are adjusted by these switches. If the measured blood pressure values exceeds the upper pre-adjusted limit or falls below the lower limit, the alarm unit gives audible and visible alarm signals to the medical staff.

Display, recorder and alarm units should be installed both on the bedside unit and on the central console system. This installation provides performing continuous blood pressure observation of patients from both the patients' room and the central console unit.

In addition, the required frequency response of the equipment is about 0-300 Hz. It is obviously known that there are some factors which affects the system frequency response. These are;

- type of catheter which is used
- the catheter extension tubing and some other factors.

6.2.2 Indirect Blood Pressure Measurements

Indirect blood pressure measurement is usually used by the physician during the regular examination of patient. This measurement method is also widely used in all the critical care unit when the patient does not require continuous blood pressure monitoring. Indirect blood pressure measurement method is easy to use and it can be automated which will be discussed in 6.2.2.2. But this method has certain disadvantages which are;

- i. It does not provide a continuous observation and recording of blood pressure. That's why pressure variations in time can not be followed by the medical staff continuously.
- ii. Systolic and diastolic and mean blood pressure readings can be obtained, but with no indication of the details of the pressure waveform.

Conventional indirect blood pressure measurement is performed by using a sphygmomanometer and a stethoscope. The sphygmomanometer consists of an inflatable pressure cuff and mercury or aneroid manometer to measure the pressure in the cuff. The cuff consists of a

rubber bladder inside an inelastic fabric covering that can be wrapped around the upper arm and fastened with hooks. The cuff is inflated manually with a rubber bulb and deflated slowly through a needle valve. The stethoscope is a device that carries sound energy from the chest of the patient to the ear of the physician via a column of air. This system is strictly acustical, there is no amplification of sound. The stethoscope is used to hear the heart-beat during the indirect blood pressure measurement in the same way it is used to hear the Korotkoff sound.

6.2.2.1 Procedure of Indirect Blood Pressure Measurement by Using Conventional Method

First of all, the deflated cuff is placed on the upper arm over the brachial artery and then the cuff is inflated by using rubber bulb. Inflation is stopped when the cuff pressure reaches above the systolic blood pressure which is about 250-300 mm Hg. Arterial blood flow almost stops as a result of artery collapsing by the pressure of the cuff that's why no sounds can be heard through the stethoscope which was placed on the brachial artery. When the cuff pressure is slowly reduced there is a pressure value that the sound can be heard through the stethoscope. This sound is called Korotkoff sound which is generated by the turbulence of blood within the artery and the pressure is called systolic blood pressure. As the pressure in the cuff continuous to drop Korotkoff sounds continue until the cuff pressure reaches to the diastolic pressure. The pressure of the

cuff that is indicated on the manometer when the Korotkoff sound disappears is known as diastolic blood pressure. This measurement method is called the auscultatory method of sphygmomanometry.

In addition, there is another method for measuring indirect blood pressure which is called palpatory method. It is similar except that the flow of blood is identified in the artery by palpating the pulse of the patient downstream from the cuff instead of listening for Korotkoff sounds. But generally the auscultatory method is used because diastolic pressure identification in the palpatory method is difficult.

The mentioned indirect blood pressure measurement methods are widely used in CCU, ICU and in other critical care units. The evaluation of blood pressure of patients are performed periodically and the obtained values are registered manually in the files.

On the other hand it should be noted that the conventional indirect blood pressure measurement method is somewhat subjective and often fails when the blood pressure of patient is very low that's why automated systems are beginning to be used in hospitals.

6.2.2.2 Block Diagram of an Automated Indirect Arterial Blood Pressure Monitoring System

Nowdays, generally critical care units such as CCU, ICU and others are equipped with automated indirect blood pressure monitors for performing periodical blood pressure measurements of each patients individually. These monitors are placed on each bedside unit and the display, alarm and recording parts are installed both on each bedside unit and on the central console unit. This installation provides

remote observation and recording of each patient's blood pressure value individually. Figure 6.7 shows block diagram of an automated indirect arterial blood pressure monitor. The basic operational procedure is explained as follows.

First of all the cuff is placed over the brachial artery of the patient. When the "ON" switch, which is placed on the (1) block, is pressed the low pressure air source (compressor) begins to work and at the same time the first solenoid valve (1) opens. By this way, the cuff pressure rises up to the preadjusted upper pressure value (300 mm Hg). This value is sensed by the cuff pressure transducer. When the 300 mm Hg is sensed by the transducer, the first solenoid valve (1) closes and at the same time the compressor stops working. After this the second solenoid valve (2) opens and the cuff pressure begins to fall gradually (3-4 mm Hg/second), (See Figure 6.8.a). The DTK-1M pulse transducer senses the pulses from the artery and it sends the sensed signal to the amplifier unit.

Amplification of the obtained signal is performed by the amplifier. The output from the amplifier is represented by the signal of Figure 6.8.b. The amplified signal follows two different paths which are shown in Figure 6.7. The amplified signal passes to a narrow-band filter and an amplitude selector. The output from the narrow-band filter is represented by the signal of Figure 6.8.c. When steep positive-going parts are present, while the output from the amplitude selector consists of a rectangular pulses Figure 6.8.e. Both the output of shaper and amplitude selector are sent to the coincidence circuit

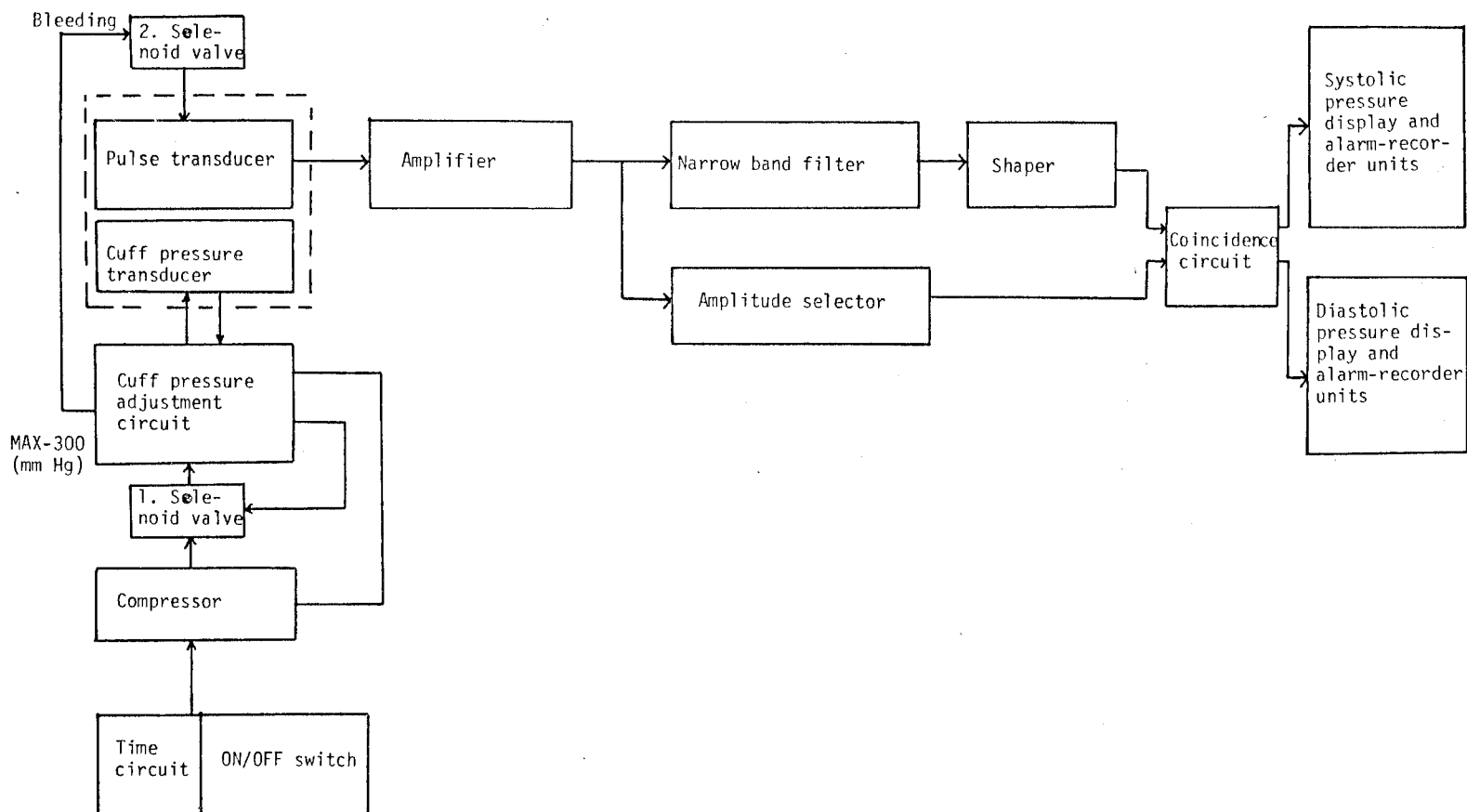


Figure 6.7 - Block diagram of an automated indirect arterial blood pressure monitor.

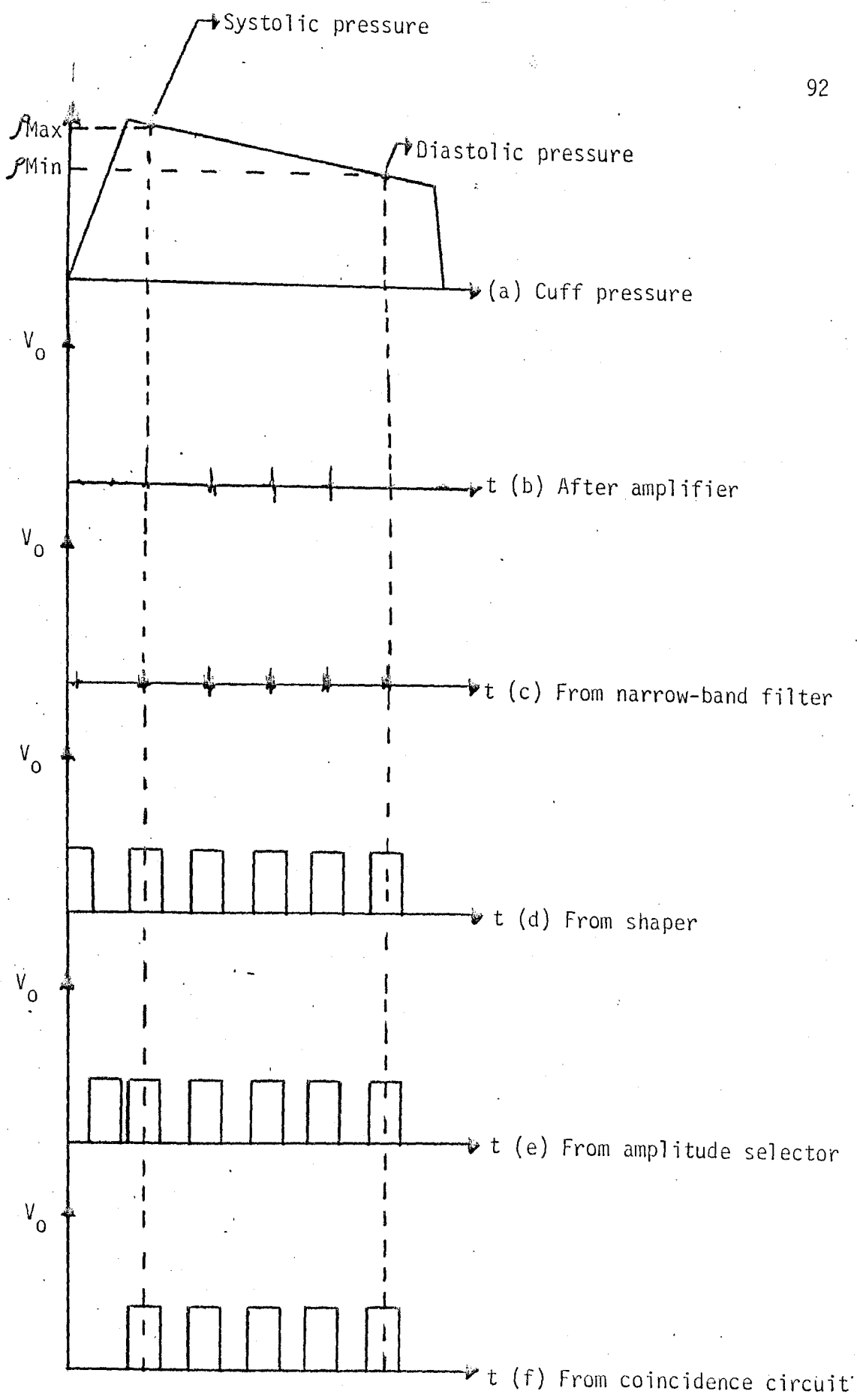


Figure 6.8 Wareform representation of automated indirect blood pressure measurement.

(See Figure 6.8.d and e). The first square waves which are coincided indicates systolic blood pressure and the last coincided square waves indicates diastolic blood pressure (See Figure 6.8.a,d,e,f). For further information the reader is referred to reference number 15.

The systolic and diastolic blood pressure values can be observed on the digital display unit. On the other hand these observed values can be recorded on the magnetic recorder or on the chart recorder for obtaining hard copy.

The system includes an alarm unit. It gives audible and visual alarm signals if the systolic and diastolic blood pressure values go beyond the upper preadjusted limits or falls below the lower adjusted limits. The upper and lower limits can be adjusted manually according to the patient.

The timer is used for adjusting a time interval between two or more consecutive automatic blood pressure measurements in case the physician choses to take more than one measurement.

The pulse transducer was the DTK-1M mentioned above, which is a piezoelectric device with a field-effect transistor as a preamplifier.

The cuff pressure transducer is a quartz piezoresonant device of frequency-modulated type. The device measures the change in the natural frequency of a force-sensitive quartz crystal, in which the frequency change is proportional to the applied force. The output is frequency, which greatly simplified signal processing.

In short, all the patient rooms in the CCU should have an indirect blood pressure equipment (conventional or automated type) and a direct blood pressure monitor. The display, alarm and recorder units

of blood pressure equipment should be installed both on the bedside unit and on the central console. This installation provides continuous direct blood pressure monitoring of the patient. On the other hand the unit should have sufficient number of conventional indirect blood pressure measurement equipment and direct blood pressure monitors for spare usage within the unit. The number of these equipment should be calculated optimally depending upon the unit capacity.

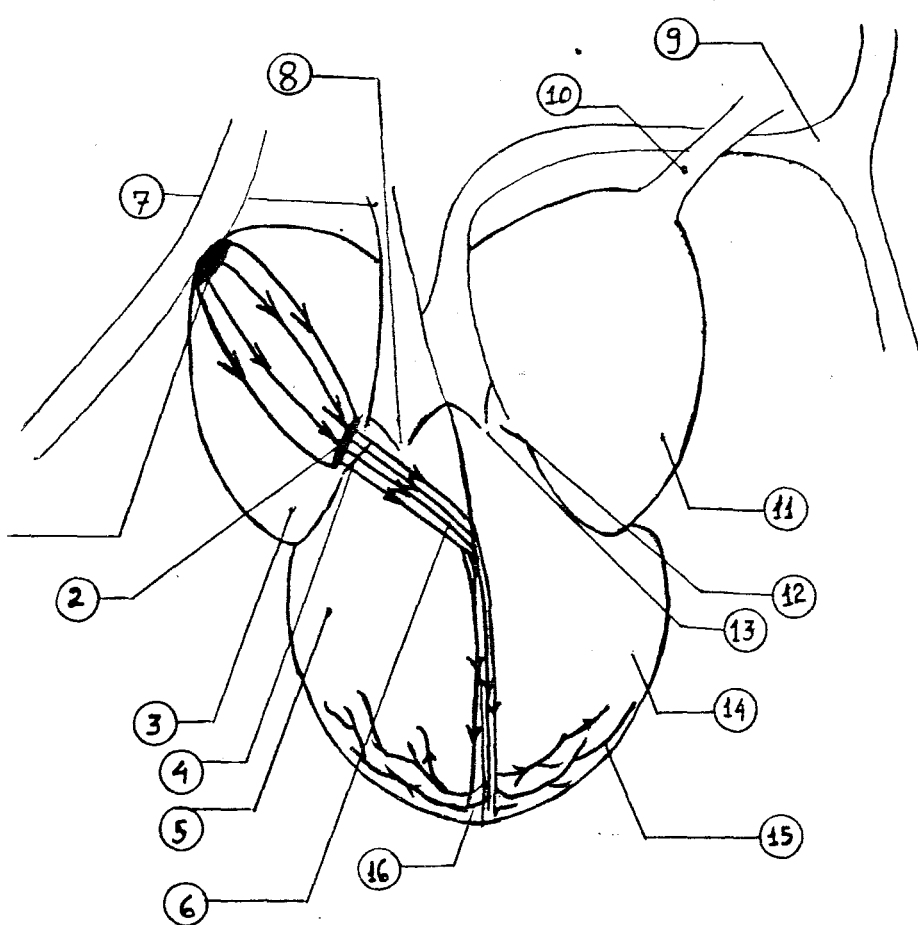
7. CARDIAC PACEMAKERS

7.1 INTRODUCTION

The cardiac pacemaker is an electrical stimulator that enables generation of artificial pacing impulses and delivering them to the heart for regulation of normal sinus rhythm, when the electrical conduction of the heart can not be completed by itself properly. They are often used by the cardiac patients so the number of available pacemakers within the unit should be determined optimally depending upon the employment frequency of them. These factors should be taken into consideration during the design of the unit generally, all the modernly and optimally designed units should have pacemakers which are installed on the each bedside unit. On the other hand portable types of the pacemakers should also be available in the coronary care unit. They are used when the bedside pacemaker systems are failed or during emergency usage.

7.2 ELECTRICAL CONDUCTION SYSTEM OF THE HEART

The basic sections and electrical conduction links of the heart is shown in Figure 7.1. The conduction system of the heart is explained



- | | |
|--------------------------------|---------------------------|
| 1. Sinoatrial node (SA) | 12. Mitral valve |
| 2. Atrioventricular node (AV) | 13. Aortic valve |
| 3. Right atrium | 14. Left ventricle |
| 4. Triscupid valve | 15. Left Purkinje fibers |
| 5. Right ventricle | 16. Right Purkinje fibers |
| 6. Bundle of His | |
| 7. Pulmonary artery | |
| 8. Semilunar (Pulmonary) valve | |
| 9. Aorta | |
| 10. Pulmonary vein | |
| 11. Left atrium | |

Figure 7.1 - Schematic diagram of electrical conduction of the heart.

in the following paragraphs that will be helpful in understanding the need for artificial cardiac pacing.

The cardiovascular system is a closed loop hydraulic system. The heart acts as a self powered two-stage pump which provides blood to the body organs by the systemic circulation and blood to the lungs by pulmonary circulation.

The rhythmic action of the heart is initiated by the sinoatrial (SA) node which is located near the top of the right atrium (RA). It generates action potentials at a regular rate spontaneously. Each pacing impulse is propagated through the myocardium, spreading over the surface of the atria to the atrioventricular (AV) node, which is located within the septum, adjacent to the atrioventricular valves (triscupid valves), and depolarizing the atria. This impulse after reaching the AV node propagates through the His bundle to the ventricles with a certain delay. This link is known as the conduction link of the heart.

A normal sinus rhythm (NSR) is in the range of 60-80 beats/min depending upon the sex, age and personal condition. Any change in NSR is called arrhythmia (abnormal rhythm). If the sinus rhythm exceeds 80 beats/min, it is called tachycardia. If the sinus rhythm falls below the lower normal limit, it is called bradycardia, which means that the heart can not provide sufficient blood circulation that causes syncope (loss of consciousness) as a result of diminished cardiac output. These explained conditions are undesirable and should be corrected as quickly as possible by using cardiac pacemakers.

The heart conduction becomes poor as a result of some diseases. Sometimes it becomes completely failed. Any impairment of the conducting system between the atria and the ventricle is referred to as "Heart Block", which may be first degree, second degree, or other types depending upon the amount of electric activity from the atria to the ventricles.

In short cardiac pacemakers are used for regulation of abnormal sinus rhythm under the following conditions.

- Under bradycardia condition
- Under tachycardia condition
- Under heart block condition.

7.3 FUNCTIONAL PARTS OF THE CARDIAC PACEMAKERS

Basic functional parts of a cardiac pacemaker are electrodes-lead wires, pulse generator, electronic circuits and power source.

7.3.1 Electrodes and Lead Wires

There are two kinds of electrodes which are known as "bipolar" and "unipolar" electrodes. Both of them are used for pacing depending upon the required pacing types and pacemakers.

7.3.1.a Bipolar Electrodes

The schematic representation is shown in Figure 7.2. Two electrodes which are positive (+) and negative (-) are placed in the

lead wire (catheter). The catheter is placed within the heart at a proper place. The stimulus is applied across these two electrodes.

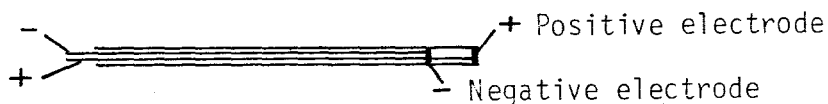


Figure 7.2 - Bipolar electrode.

7.3.1.b Unipolar Electrodes

There is one electrode in the lead wire which is negative. It is implanted into the heart. The positive electrode is remotely attached. It may be chassis of implanted pacemaker or one metallic side of the unit.

Comparison: 1) The lead wire, which includes bipolar electrodes is more thicker than unipolar type. That's why positioning bipolar electrode lead through a vein is more difficult than unipolar one.

2) Interference probability of unipolar electrode is greater than bipolar one, because long distance exist between positive and negative points.

Unipolar and bipolar leads may be "Myocardial" or "Endocardial". Myocardial leads are inserted through the outer surface of the heart (epicardium) and into the heart muscle. There by requiring either exposure of the heart (thoracotomy) or insertion of the lead through

a small incision. The leads of an endocardial (transvenous) electrode rest against the inside wall of the heart chamber. These leads are introduced into the heart through a vein.

7.3.1.1 Problems Associated with Electrodes

There are some basic types of problems that may arise during the pacing of the heart. Those are listed as follows.

1. Fractured electrode wires (lead breakage)
2. Faulty fixation of the electrode within the heart
3. Excess fibrosis at the electrode tip
4. Corrosion
5. Imperfect electrode manufacture.

7.3.1.2 Electrode Production Materials

There are some materials and alloys that are used for electrode and lead production.

a) For Myocardial Application:

Electrode = Platinum - Iridium alloy

Lead = Platinum - Iridium alloy

b) For Endocardial Application:

Electrode = Platinum

Lead = Stainless steel or eligloy (Eligloy = Cobalt + Chromium + Nickel).

7.3.2 Pulse Generator and Electronic Circuits

7.3.2.1 Classification of Cardiac Pacemakers Depending Upon Location of the Pulse Generators

Basic information about the classification of cardiac pacemakers is given in the following paragraphs.

7.3.2.1.a External Pacemaker

External pacemaker consists of an externally pulse generator connected to electrodes. It is obvious that the pulse generator is located outside of the body. It may be located on the bedside unit or on the patient body by using a special connection belt. Strapping on the lower arm or over the waist are usual locations for portable external pacemakers. The positioning of electrodes in the heart are performed under radiological examination.

External pacemakers are used on patients with temporary heart irregularities, such as those encountered in the coronary patient including heart blocks. They are also used for temporary management of certain arrhythmias.

External pacemakers are very widely used in the coronary care unit. That's why sufficient and optimal number of external pacemakers should be available.

7.3.2.1.b Internal Pacemaker

Internal pacemaker consists of an internally pulse generator connected to electrodes. The pulse generator of the cardiac pacemaker is implanted within the body by special surgery. Radiological examination is also used for placing electrodes within the heart. This kind of pacemaker is used for realizing continuous pacing.

Internal pacemakers are not used in the coronary care unit because their application to the patients takes too long, that's why they can not be considered as emergency equipment. In short, it is impossible to use internal pacemakers for quick application.

7.3.2.2 Classification of Cardiac Pacemakers Depending Upon the Types of Pacing Modes

The schematic classification of cardiac pacemakers depending upon the types of pacing modes is shown in Figure 7.3.

There are several pacing techniques with both internal and external pacemakers. The below diagram shows general classification of them. The brief information about the types of pacing modes are given in the following sections.

I. ASYNCHRONOUS or FIXED RATE or COMPETITIVE PACING

Asynchronous pacing is also known as competitive pacing or fixed rate pacing. The pulse generator generates electrical impulses at a fixed rate, regardless of natural cardiac activity. This is the first and simplest generator pacing system. The pacing rate is adjusted by the doctor at a fixed value depending upon the pacing requirement

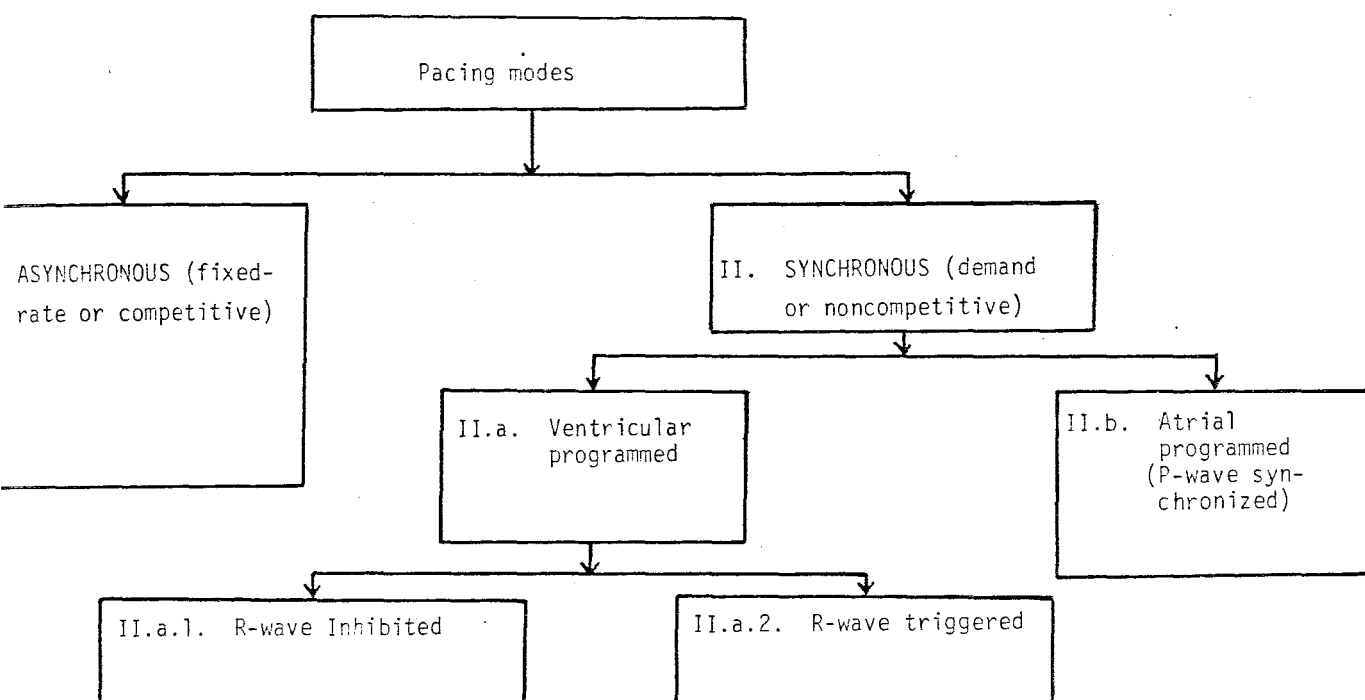


Figure 7.3 - Schematic representation of cardiac pacemakers.

per minute. This pacing type has some disadvantages which are listed below:

- * If the artificial stimulus falls in the repolarization period following a spontaneous ventricular contraction, ventricular fibrillation can result. In other words generator's pulse may be faced by the natural pulse of the heart which causes ventricular fibrillation.

- * The battery life for portable unit is generally shorter because it is in constant operation.

Elimination of these problems can be achieved by using "Synchro-ronous or Demand or Noncompetitive" pacing mode.

Basic block diagram of an asynchoronous pacing system is given in Figure 7.4.

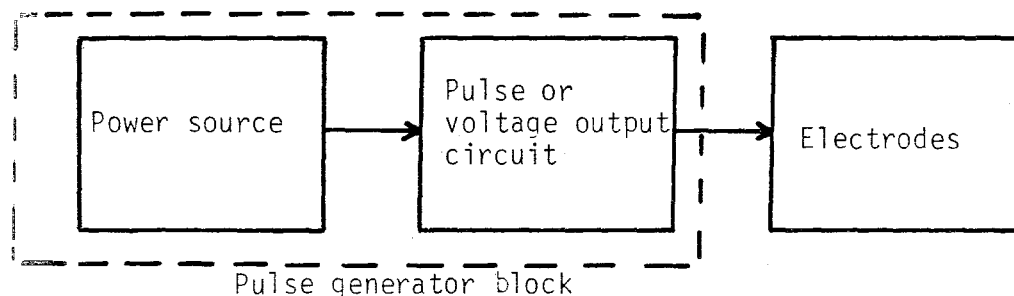


Figure 7.4 - A block diagram of an asynchronous pacemaker.

II. SYNCHRONOUS or DEMAND or NONCOMPETITIVE PACING

The generator system has additional circuitry that produces a pulse only when the sensed heart beat is absent or too infrequent. On the other hand there is some other generator types that produces also a pulse after the natural heart beat but this pulse is generated in the absolute refractory period of the natural heart beat. Detailed information about these pacing modes is given below.

II.a Ventricular Programmed Pacing Systems

II.a.1. R-Wave Inhibited

The pulse generator is connected to the ventricle through

electrodes. The electrode system is able to sense the presence (or absence) of a natural occurring R-wave. If the R-wave is sensed by the electrode, in the preadjusted time interval, the pulse generator does not generate a pulse. In short, the pulse generation by the pacemaker is inhibited when the heart is able to pace itself. But, if the natural R-wave is not sensed by the electrode in the preadjusted time interval, the pacemaker gives pacing pulse to the heart through the electrode system. The schematic representation of the above explanation is given in Figure 7.5.

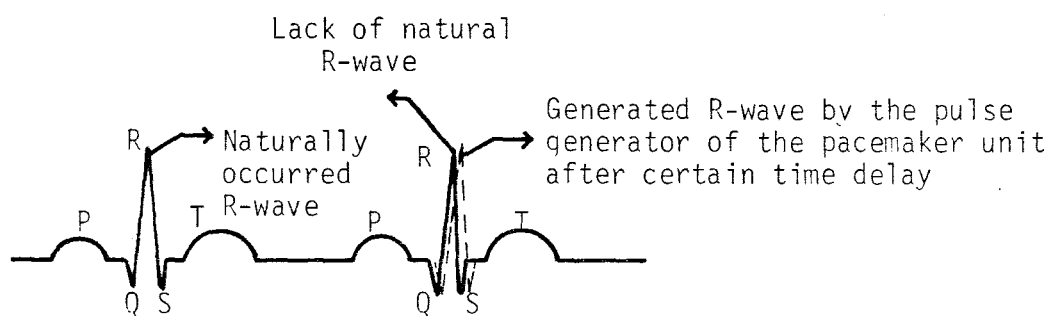


Figure 7.5 - Schematic representation of natural and artificial R-wave generation.

A basic block diagram of the mentioned type pacemaker is given in Figure 7.6.

The pacemaker consists of a power circuit, timing circuit, output circuit, electrodes, amplifier and reset circuit. The system can also work at a fixed-rate, usually 60-80 beats/min if it is necessary to work in fixed rate operation mode. After each stimulus, the timing circuit resets itself, waits for the appropriate interval to provide the next stimulus, and then generates the next pulse. If the natural

R-wave is sensed by the electrode system, the pulse generator does not generate pacing pulse. Under this condition the time circuit again resets itself. This is the most frequently used pacing type.

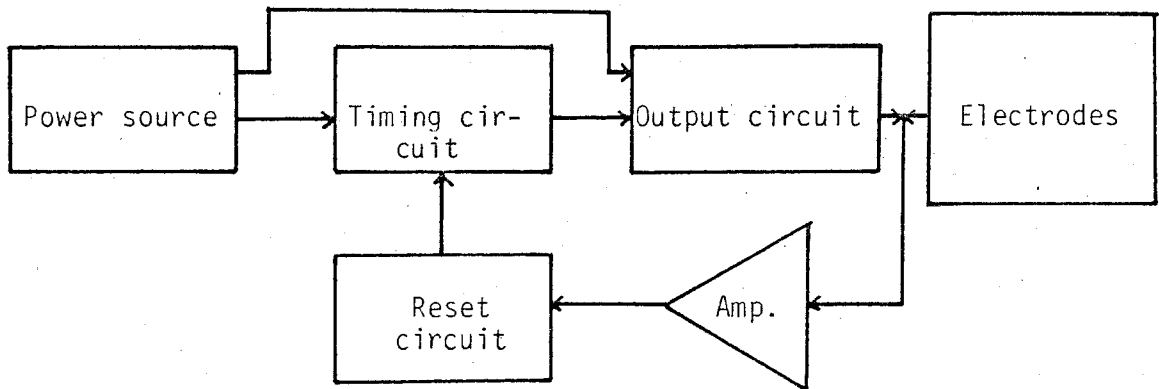


Figure 7.6 - Block diagram of a ventricular programmed demand type pacemaker.

II.a.2 R-wave Triggered

Sensing the natural R-wave is performed by the electrodes. When the natural R-wave is sensed, the generator system generates a pacing pulse (artificial R-wave) in the absolute refractory period of the naturally produced R-wave, so this artificially produced pulse does not affect the heart activity. In this pacing mode operation, the unit is triggered rather than inhibited by each R-wave sensing. When the natural R-wave does not occur in the preadjusted time interval, the generator produces artificial R-wave to pace the heart normally. The schematic representation of this operation mode is shown in Figure 7.7.

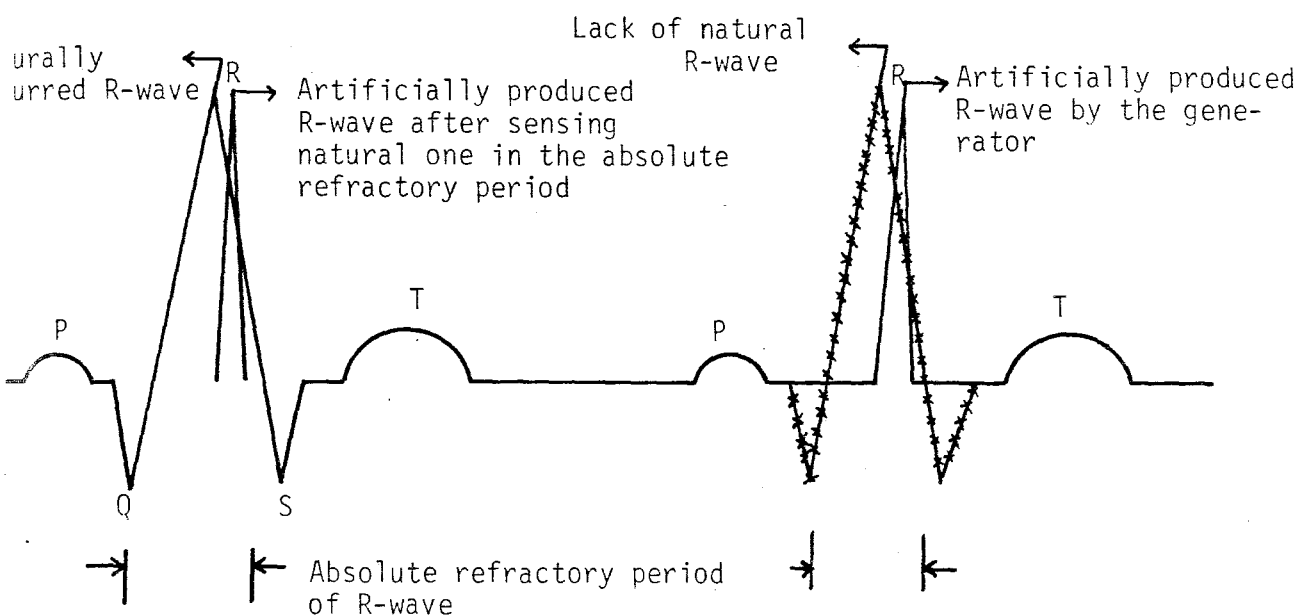


Figure 7.7 - Schematic representation of natural and artificial R-wave.

II.b Atrial Programmed P-Wave Synchronized Pacing

In case of complete heart block, where the atrial are able to depolarize but the impulse fails to depolarize the ventricles, atrial programmed P-wave synchronized pacing is used. In this case, the pulse generator is connected through leads and electrodes to both the atria and the ventricles. When the sinoatrial (SA) node is able to stimulate the atria, the electrical signal corresponding to the atrial contraction (P-wave of the ECG) can be detected by the electrode implanted in the atrium. After this detection, stimulation of the ventricle is

performed by the pulse generator through the ventricular electrode. In this way, the heart is paced at the same rate as the natural pacemaker. When the SA node rate changes because of vagus or sympathetic neural control, the ventricle will change its rate accordingly but not above some maximum rate (e.g. 125/minute).

Rectangular or trapezoidal pulse is suitable for cardiac stimulation. Type of pulse and time duration should be chosen very carefully depending upon the generator type and the needs of the patient. For rectangular shape, the usable time duration is around 0.15-3 milisecond.

7.3.3 Power Sources

The type of power source used for a pulse generator depends on whether the unit is an external or an internal.

7.3.3.1 Power Sources for Externally Used Portable Units

- a. Battery Power: This power source is the most commonly used. Generally Lithium-Iodine or Lithium rechargeable batteries are used as a power source.
- b. Power supplying from the network system: (220 Volt a.c., 50/60 Hz) This is common for bedside unit systems. The required energy is obtained by the specially designed transformer and rectifier which are included within the pacemaker unit.

7.3.3.2 Power Sources for Internally Used Pacemakers

- a. Lithium-Iodine or Lithium rechargeable batteries are mostly used. On the other hand wide researches are done about other types of sources that may be used as a power source for internally used pacemakers.

Generally, required energy range for pacing is around 2.5-5.6 volts, d.c.

7.4 PACING SYSTEM ANALYZER

The pacing system analyzer is a device used to test the various types of pacemakers that are available today. It operates in two different modes. One mode tests the patient/lead system (Determination of the pulse and duration). The other mode of operation tests the pacing and sensing characteristics of the pacer to assure that these characteristics are within manufacturer's specifications (Determination of current and voltage stimulation threshold, lead resistance, failure testing and determination of broken conductor and others).

The above mentioned variables should be tested periodically for externally and internally used pacemakers. That's why all the coronary care unit has to have optimal number of pacing system analyzer for performing required periodic tests.

7.5 PROBLEMS ASSOCIATED WITH PACEMAKERS

Problems may arise due to any or all of the mentioned reasons.

- a. The Effect of External Electromagnetic Radiation on the Cardiac Pacemaker: The sources of electromagnetic radiation that may affect the pacemaker are power plants, radar transmitters, high frequency radio transmitters, commercial television sets, X-ray machines, television transmitters and some others. The cardiac pacemaker unit has to have the specially designed filtering system for preventing effect of external electromagnetic radiation on the cardiac pacemaker.
- b. Problems Associated with Component Failure: Electric circuitry failure or failure in the power source may cause some important problems.
- c. Problems Associated With Electrodes: The detailed explanation is given in Section 7.3.1.1.

There are some basic factors that should be taken into consideration during the selection of cardiac pacemakers. These factors are listed as follows.

- The unit should work optimally in the basic pacing modes. This is very important especially for externally used bedside pacemakers.
- It should be easily used and tested.

- Operation condition of the unit should not disturb the patient.
- It should not have very complex construction and should be easy to repair.

Externally powered cardiac pacemakers are one of the most important instruments that should be installed in the coronary care unit. Optimal number of pacemakers should be available in the unit. Especially portable types should be available in optimal number for spare usage in case their use becomes necessary.

8. DEFIBRILLATORS

8.1 INTRODUCTION

In this chapter, the functions and different types of defibrillators will be discussed in detail since they are one of the most important instruments that are often used in emergency and coronary care units.

A sufficient number of portable defibrillators should be available in the coronary care unit for usage in a case of emergency. On the other hand, defibrillators may be placed on each bedside of the patient, but it is obvious that this brings economical problems. In other words placing a defibrillator at each patient bedside increases the cost of the unit. That's why the number of defibrillators to be employed in the coronary care unit is chosen depending on the bed capacity of the unit. In short, optimal number of defibrillators must be placed in the unit and they should always be in ready condition for first-and usage in 24 hours.

8.2 THE GOAL OF DEFIBRILLATOR USAGE WITHIN THE CORONARY CARE UNIT

The role of defibrillators in the coronary care unit can be summarized as follows.

8.2.A - First of all, defibrillator is used for correcting fibrillation.

As it is known, fibrillation is a condition that the individual myocardial cells contract asynchronously without any pattern relating the contraction of one cell and the next. This serious condition reduces the cardiac output almost to zero. This condition may cause death if it is not corrected within a few minutes. That's why cardiac fibrillation should be corrected as quickly as possible by using special type of instrument which is called DEFIBRILLATOR. Basically, an electric shock is applied to the patient chest by two electrodes (paddles) for correcting asynchronous individual myocardial cell contraction. In other words, resynchronization of myocardial cells can be obtained by applying electric pulse to the chest of the patient.

8.2.A.1 Types of Fibrillation

There are two types of fibrillation. One of them is known as "Atrial Fibrillation" and the other is "Ventricular Fibrillation".

- * Atrial Fibrillation: Fibrillation of atrial muscles is called "Atrial Fibrillation". This is the condition of blood leakage to the ventricles before contraction of the atrium, which causes inefficient circulation since a

small amount of blood always remains in the ventricles. This condition can be quite traumatic for the patient, so it should be corrected.

- * Ventricular Fibrillation: Fibrillation of ventricular muscles or ventricles is known as "Ventricular Fibrillation". Under this condition, the ventricles are unable to pump blood that may cause death if it is not corrected within a few minutes. So it is obvious that, ventricular fibrillation is far more dangerous than atrial fibrillation. Medical staff should always be ready to intervene, if possible, when the patient has ventricular fibrillation. This intervention may often prevent death of the patient. In short, this is one of the reason for cardiac monitoring.

8.2.B - Defibrillator is also used for correcting arrhythmias. This correction process is known as "Cardioversion".

Cardioversion can be performed by using defibrillator which has an ECG monitor within the unit. In other words, a defibrillator has to have an ECG monitor for performing cardioversion because coordination between the defibrillator and the ECG monitor is important in this process. The electric shock or pulse is applied during or immediately after the downward slope of the R-wave, when the heart is in its absolute refractory period. Thus coincidence of the applied pulse with the middle of T-wave is prevented by the specially designed defibrillator unit which will be discussed later. Coincidence of the T-wave with

the applied pulse is undesirable because of the vulnerable period of heart.

There are defibrillators that can be used for both defibrillation and cardioversion. The basic structure of commercially available defibrillators will be discussed in Part 8.3.2.4.

8.3 TYPES OF DEFIBRILLATORS

There are two kinds of defibrillators which are alternating current defibrillations (AC Defibrillator) and direct current defibrillators (DC Defibrillator).

8.3.1 Alternating Current Defibrillations (AC Defibrillators)

Alternating current defibrillators are not in use nowadays, because they have some disadvantages. One of them is ineffective correction of atrial fibrillation. In fact, attempts to correct atrial fibrillation by ac defibrillators often result in more serious ventricular fibrillation. The other disadvantage is myocardial and thoracic tissue damage occurrence during defibrillation process. Thus, ac defibrillator is no longer used. That's why it is not mentioned in detail in this thesis.

8.3.2 Direct Current Defibrillators (DC Defibrillators)

There are several types of direct current defibrillators which are used in the coronary care units. Some of them are explained below.

8.3.2.1 Capacitive-Discharge DC Defibrillators

Capacitive-discharge dc defibrillators are widely used in all coronary care units. The circuit diagram of this type of defibrillator is given in Figure 8.1.

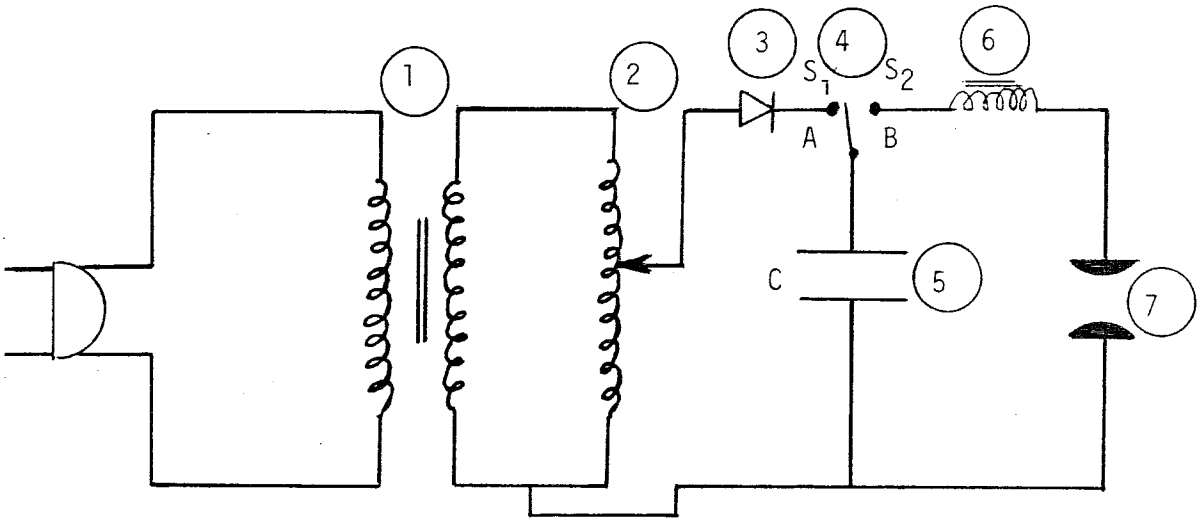


Figure 8.1 - Capacitive discharge defibrillator.

1. Step-up isolation transformer
2. Variable transformer
3. Rectifier
4. Charge-discharge switch
5. Storage capacitor (oil-filled)
6. Choke coil
7. Paddles (electrodes)

A short duration-high amplitude defibrillation pulse, which is shown in Figure 8.2, can be obtained using capacitive-discharge circuit. The input 115 VAC/220 VAC, 60 Hz/50 Hz, passes through an isolation transformer. The variable transformer provides the required voltage that is rectified by the rectifier. When the switch in Figure 8.1 is in position A, the rectified voltage charges the oil-filled storage capacitor at an adjusted energy level. The paddles or electrodes

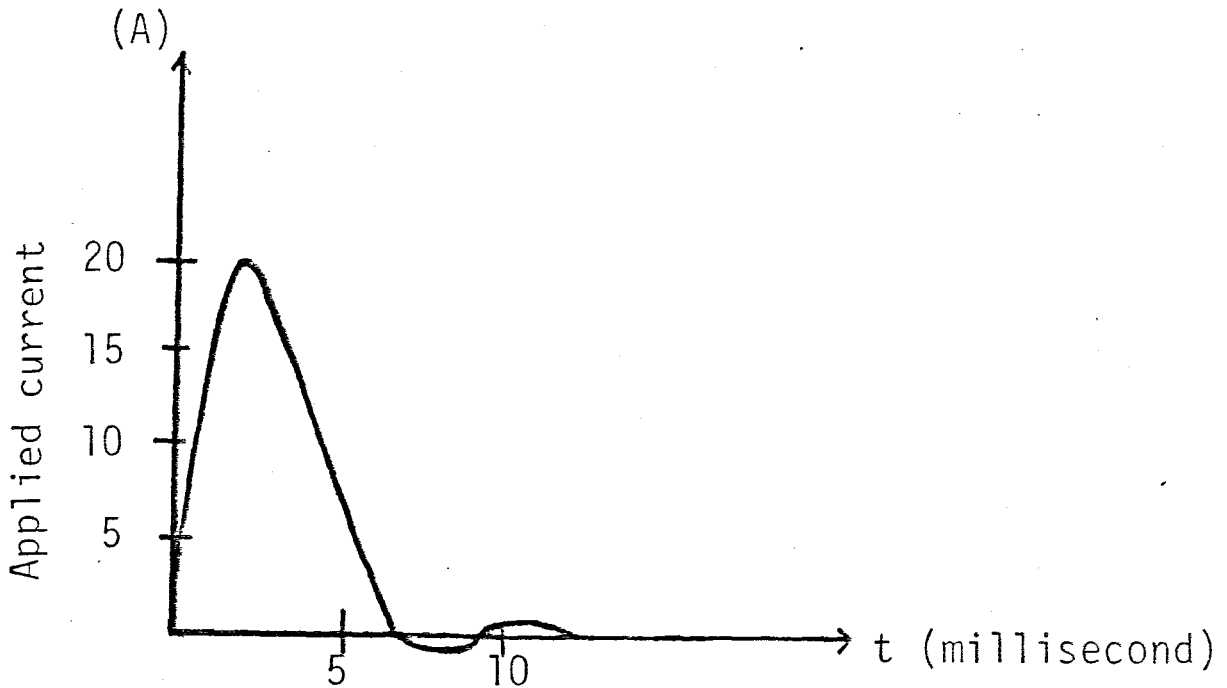


Figure 8.2 - A typical waveform of discharge pulse (monophasic).

are placed on the patient chest, after the application of jelly paste both on the electrode plates and the chest for providing good skin contact. Then the thumb switches are pushed, the charge-discharge switch changes its position from A to B and the charged capacitor C discharges through the choke coil and the electrodes. Choke coil is used for shaping the wave in order to eliminate a sharp, undesirable current spike. In other words it tends to lengthen the pulse, producing a waveshape of the type shown in Figure 8.2. Once the discharge is completed, the switch automatically may return to position A for re-charging capacitor C, but some defibrillators can not perform automatic recharge without receiving a command from the user.

Some data about the defibrillator are listed as follows for an idea.

Waveform : Monophasic and (5-10 m sec) time duration
Output energy levels: 5-700 joules (W-sec)
Charge time : Generally less than 10 sec (It depends
on the maximum energy level that the
capacitor is charged)
Voltage range : 400-7000V (DC)

Power sources

Input voltages : 115 V and 220 V (AC)
Frequency : 50-60 Hz
Battery type : Nickel-cadmium or others.

8.3.2.2 Delay-Line Capacitive Discharge DC Defibrillators

There is a danger of damage to the myocardium and the chest wall because peak voltages as high as 7000 V may be used. To reduce this risk, some improvements are applied to the known capacitive-discharge defibrillator circuits. The obtained result is that dual-peak monophasic waveform of longer duration (approximate 10 msec.) at a much lower voltage is produced. Effective defibrillation can be achieved in adults with lower levels of delivered energy between 50-200 joules.

A typical circuit diagram and waveform are given in Figure 8.3 and 8.4.

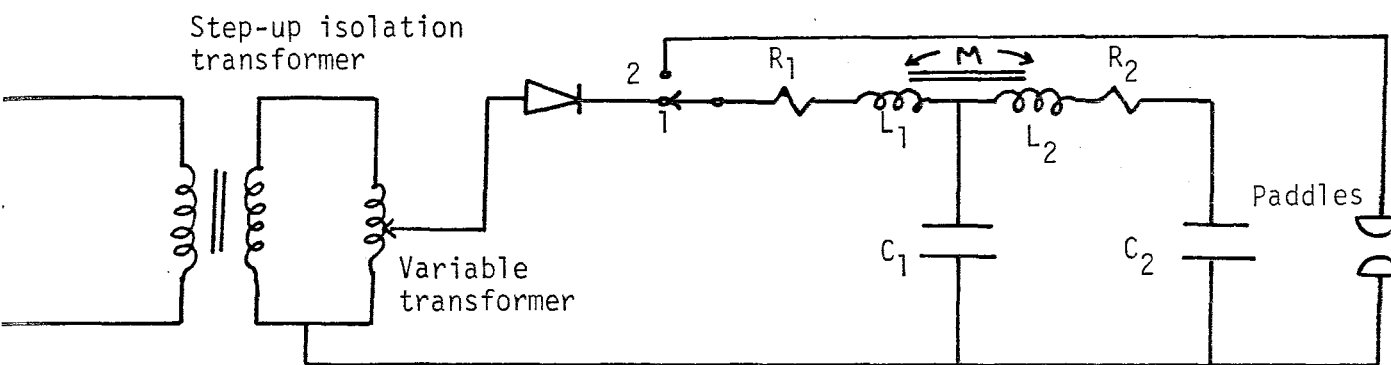


Figure 8.3 - The circuit diagram of delay-line capacitive discharge dc defibrillator.

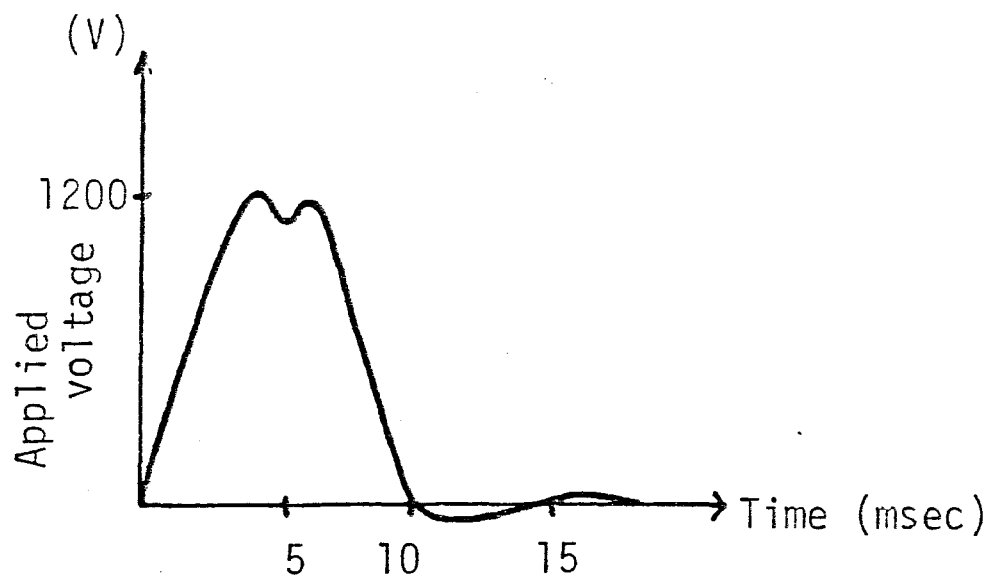


Figure 8.4 - Dual-peak monophasic defibrillator discharge waveform.

If the left part of the circuit is studied, it can be seen obviously that there are no differences between delay line capacitive-discharge and capacitive-discharge dc defibrillators. But there are some differences on the right parts of the circuits. In this case two parallel capacitors (C_1 , C_2) are used instead of one C and two coils (L_1 and L_2) are also employed in the circuit of delay-line capacitive-discharge dc defibrillator. C_1 and C_2 store the same energy as the single C capacitor. However, the discharge characteristic of this system is more rectangular in shape than the capacitive-discharge dc defibrillator. Thus the same energy can be applied to the heart over approximately the same period of time without having to achieve currents as high as those occurring with the single capacitor circuit.

8.3.2.3 Square-Wave DC Defibrillators

In this case, the capacitor is discharged through the subject by turning on a series silicon-controlled rectifier (SCR). When sufficient energy has been delivered to the subject, a shunt SCR short-circuits the capacitor and terminates the pulse. This eliminates the long discharge tail of the waveform. The output may be controlled by varying either the voltage on the capacitor or the duration of discharge.

Advantages of this designs are as follows.

1. It requires less peak current
2. It does not require any inductors
3. It makes it possible to use physically smaller electrolytic capacitor

4. It does not require any relays.

A typical discharge waveform is shown in Figure 8.5.

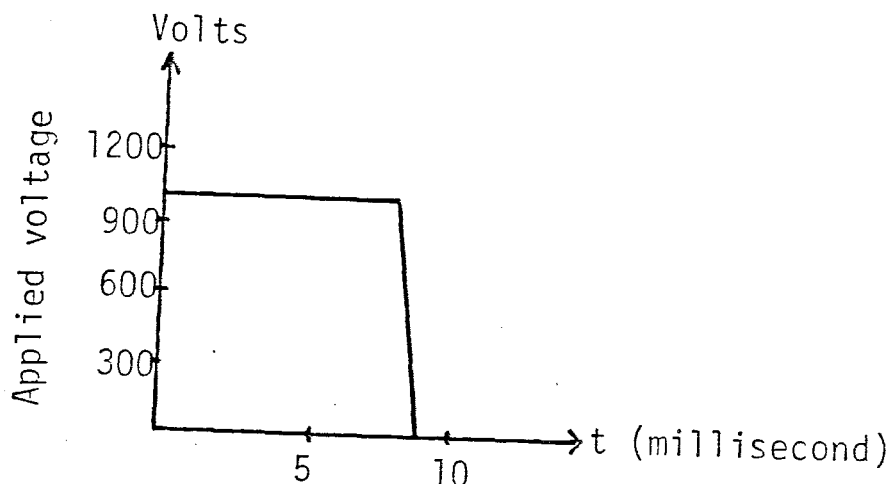


Figure 8.5 - The shape of square-wave discharge.

The amplitude of this waveform is relatively constant, but its duration may be varied to obtain the amount of energy required.

8.3.2.4 Block Diagram of a Commercial DC Defibrillator

In this section, an improved commercial dc defibrillator will be discussed briefly.

It was mentioned formerly that in general commercial defibrillators can be used for correcting both fibrillation and arrhythmias, such as correcting tachycardia (fast heart) to a normal rhythm. Correcting both of them can be achieved by using a dc defibrillator which has a small computer system with an ECG monitor for providing the automatic synchronization pulse. Preventing the coincidence of the pulse with vulnerable portion of the T-wave is obtained by this small computer system. If this coincidence can not be prevented, ventricular

fibrillation may occur during the cardioversion, which is a very dangerous situation.

A basic commercial dc defibrillator block diagram is given in Figure 8.6.

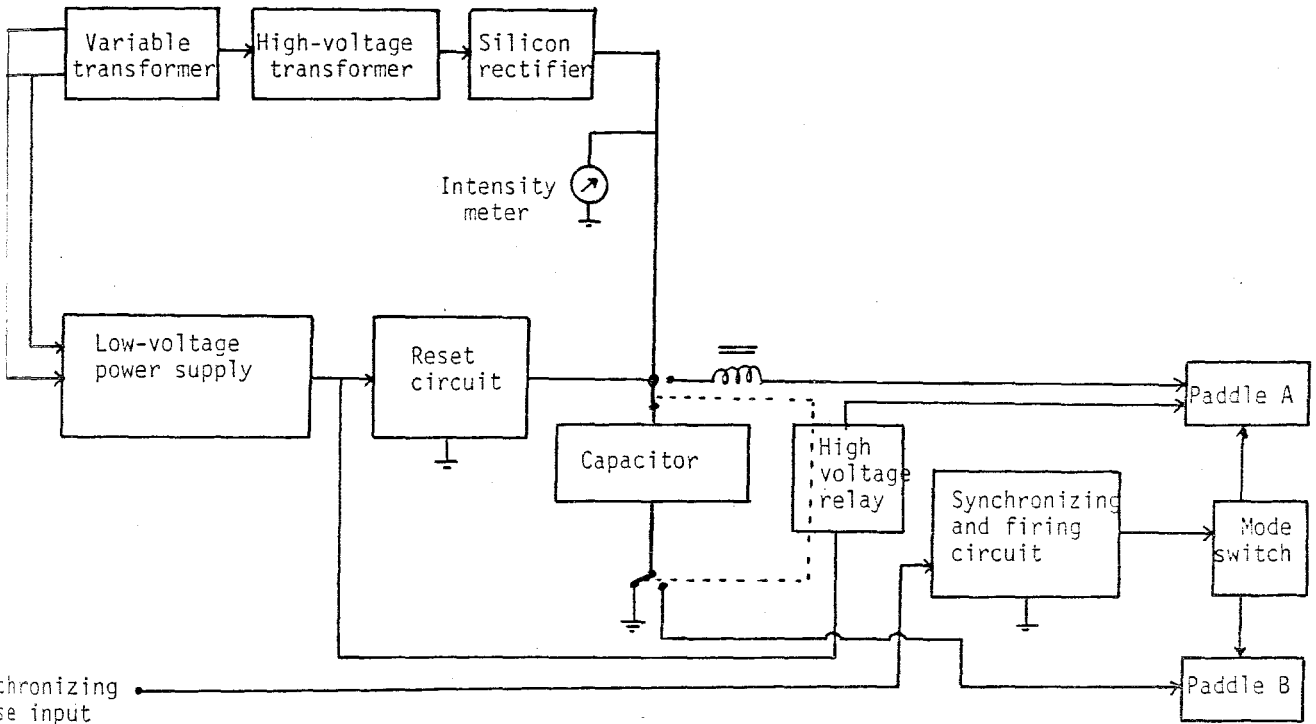


Figure 8.6 - A commercial dc defibrillator.

A variable input transformer allows selection of the voltage that is fed to the rectifier and hence selection of the energy level stored in the capacitor. As the paddles switches are closed by the operator pressing against the patient's chest, the high voltage relay switches the storage capacitor contacts from the Charge to the Discharge position. When the unit is switched off, the reset circuit bleeds off any energy stored in the capacitor.

8.4 ELECTRODES

There are basically two types of electrodes.

8.4.1 Spoon-shaped Electrodes

The spoon-shaped electrodes are applied directly to the heart to achieve the so called internal defibrillation. A basic model for a spoon-shaped electrode is given in Figure 8.7.

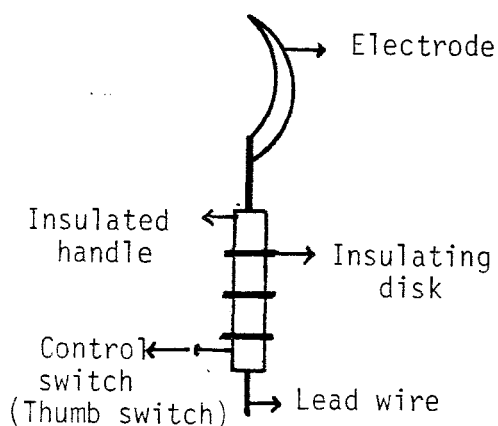


Figure 8.7 - A spoon-shaped internal electrode.

This type of electrodes is not used in coronary care units. It is used during open-heart surgery.

8.4.2 External Electrodes (Paddles)

Figure 8.8 shows the type of electrodes used for external defibrillation. They consist of a large metal disk in a insulated housing that is approximately $80-85 \text{ cm}^2$. Control switches (thumb switches) are located on the handles that are used for discharging the capacitor. Some electrodes have also quick-charge buttons on the handles for providing quick recharge of the system after discharging of the capacitor.

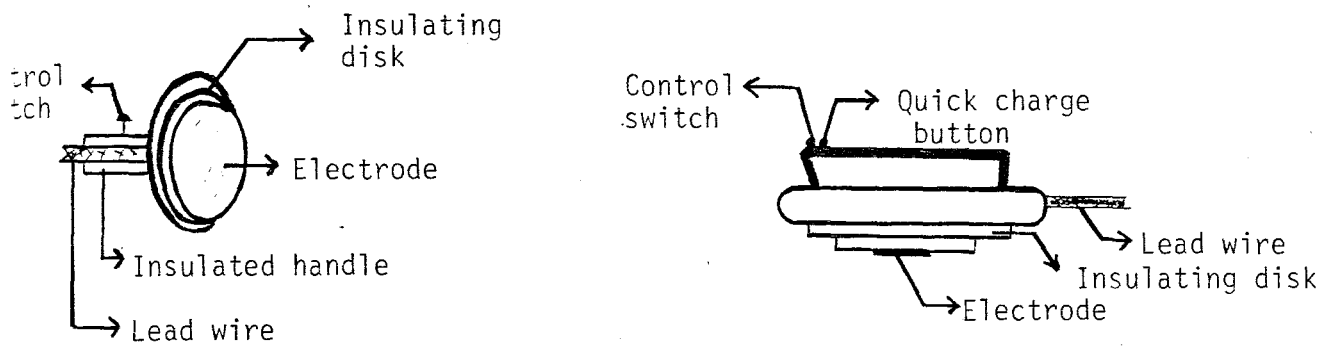


Figure 8.8 - External electrodes

8.5 EVALUATION CRITERIA AND TEST METHODS OF DEFIBRILLATORS

There are some important factors that should be taken into consideration during the selection of defibrillators. On the other hand some test methods exist for condition evaluation of these equipment. So, some evaluation criteria are listed as follows.

1. Delivered energy output: Evaluation and comparison of adjusted or selected energy amount with the delivered energy output of the system under the standard accuracy requirements. A variety of output energies should be operator selectable in the unit. For example minimum setting of 5 joules maximum setting of 700 joules with at least six selections in between. The output waveform should be either a damped sinusoid or a truncated exponential.
2. Energy loss after charging: If discharged one minute after charging, the delivered energy should not be less than 85%

of the delivered energy when discharged immediately after charging.

3. Maximum energy charging time: A defibrillator should require no more than 10 seconds to charge to its maximum energy level.
4. Repeated discharges (Pulse rate test): The unit should be able to perform 15 discharges at maximum energy within five minutes, and then four discharges as quickly as possible, without effecting performance or causing damage to the unit.
5. Synchronization: If the unit can work in both synchronization and defibrillation discharge modes, the unit must always be in the defibrillation mode when power is turned on. Selection of either synchronization or defibrillation mode should be easy and obvious.

When the system operates in synchronization mode, the unit must have a visible or audible R-wave indicator to verify the correct function of the synchronization mode and to warn the operator that the unit is detecting R-wave voltage peaks and will discharge when the control buttons are depressed. Units with internal ECG amplifiers and R-wave detection circuits should have an output jack or lead to send the patient's ECG signal to a monitor or oscilloscope for viewing.

6. Paddles (Electrodes) size and cable length: Paddles should have a large surface area to minimize the possibility of patient burns from high current densities. That's why

acceptable minimum standard paddle size is 50 cm^2 for external paddles and 32 cm^2 for internal paddles (These values are given by Association for the Advancement of Medical Instrumentation "AAMI" and American National Standards Institute "ANSI"). An 18 newtons (4 lb) applied force should be sufficient to stretch the external paddle cables at least 200 cm.

7. Disarm test: Within five seconds after turning off the power, the capacitor should discharge and the paddle electrode voltage should be no greater than 25 V, even if the unit is turned on a gain, to protect operators from accidental shock. The disarm or power-off button should be clearly labelled and located on the front panel.
8. Open-and short-circuit discharge: Discharging maximum energy while holding the electrodes together (short circuit) or while holding the electrodes separated in air (open circuit) should disarm the unit and not affect performance.
9. Effects of line voltage variations: Unit performance should not be affected by the variations in line voltage within the limits that may normally occur in a hospital.
10. Leakage current and grounding resistance: Leakage currents between conductive surfaces and ground should not endanger the operator or patient. Leakage current should be less than $100 \mu\text{A}$ from chassis and external paddles to ground, and less than $50 \mu\text{A}$ from internal paddles to ground. Grounding

resistance between the ground prong on the power plug and exposed chassis should be less than 0.15 ohm (Ω).

11. Leakage current during discharge: The leakage current during discharge from the paddle to ground across a 1000 Ω test load at maximum discharge energy should be less than 50 μ A DC. This test indicates how much current could flow through the body of a person who simultaneously touched either the paddle or the patient's thorax and the ground at the time of defibrillator discharge.
12. Output isolation: The defibrillator output should be isolated to protect the operator and other nearby personnel, to ensure that energy is not diverted away from the patient's heart to another ground point, and to prevent damage to patient monitoring equipment.
13. Ease of use and operator safety: Because it is an emergency resuscitation device, a defibrillator should be safe, fast, and easy to use by clinical personnel. All necessary controls and indicators, should be clearly labelled. Clear operating instructions should be present on the unit's housing.

Operators should be able to easily select the desired energy and charge the unit quickly. Charging should require manual initiation after discharge. Separate visual and audible signals should clearly indicate to the operator that the unit is charging or fully charged. The operating mode should also be clearly indicated.

Defibrillator discharge should be rapid and safe. For external paddles, discharge should be activated only by simultaneous depression of two buttons. For internal paddles, front panel discharge buttons are acceptable.

14. Drop test: Shock or vibration likely to occur under normal conditions of use should not damage the unit or affect performance.
15. Fluid should not damage the unit's housing if spilled on the surface.
16. The unit should be well-constructed with durable materials.
17. A complete operator's manual should be provided with the unit. The manual should indicate all things about the unit clearly. On the other hand service manual should also be provided with the unit.

Some supplementary information about this section is summarized as follows.

1. There are several types of commercial defibrillators that can operate under supply from either a network system or rechargeable batteries which are placed within the units. These batteries should be maintained regularly and they should be changed or recharged if necessary.

2. The delivered energy to the patient is not the same value that can be observed from the energy level indicator, because some energy losses occur during the defibrillation. These are listed as follows.
 - a. Energy lost as a result of chest impedance.
 - b. Energy lost as a result of electrodes.
 - c. Energy lost as a result of the applied jelly paste.
 - d. Energy lost as a result of other subfactors.

9. TEMPERATURE MEASUREMENT

9.1 INTRODUCTION

Body temperature is one of the oldest known diagnostic indicators that gives information about the person's condition to the medical staff. Some diseases increase or decrease the body temperature. The degree of body temperature provides valuable diagnostic information. On the other hand, variation time of body temperature is also as important as the degree of body temperature. That's why temperature-taking from the patient is a routine work at most hospitals. Generally, it is taken at least three times a day by using mercury or electronic thermometers for evaluation of the patient condition over a day. In some cases, continuous body temperature measurement is also used.

In this chapter, the basic types of body temperature measurements and equipment are discussed in the following sections.

9.2 TYPES OF TEMPERATURE MEASUREMENTS

Basically, there are two types of temperature measurements.

9.2.a. Systemic Body Temperature Measurement

Systemic body temperature is the temperature of the internal regions of the body. Systemic body temperature measurement is commonly used in the hospitals. It provides valuable diagnostic information to the medical staff. Conventional mercury thermometer or electronic thermometer is used.

Systemic body temperature can be obtained by using four different measurement methods.

- a. Placing temperature sensing device in the mouth, under the tongue (Normal = 37°C)
- b. Placing temperature sensing device under the armpits (Normal = 36°C)
- c. Placing temperature sensing device in the rectum (Normal = 38°C)
- d. Placing temperature sensing device of the tympanic membrane in the ear.

The first three methods are widely used in the hospitals. The last method is used when the degree of temperature has vital importance. In most cases oral temperature measurement provides sufficient information about the body temperature.

Conventional mercury thermometers are used for taking systemic body temperature from the patient. But today, electronic thermometers are used instead of conventional thermometers especially in modern hospitals. A detail description of the various types of thermometers is given later.

9.2.b. Skin Surface Temperature Measurement

Measurement of the skin temperature at a specific part of the body surface. This type of temperature measurement is not commonly used especially in the CCU. That's why it is not mentioned in detail in this chapter.

9.3 THERMOMETER TYPES FOR USING SYSTEMIC BODY TEMPERATURE MEASUREMENT

There are two types of thermometers which are mercury thermometers and electronic thermometers. Both of them are used in hospitals, especially the electronic thermometers are used in modernly designed hospitals.

9.3.1 Mercury Thermometers

The mercury thermometers are conventional thermometers which are used for taking oral systemic body temperature. They are also used for measuring systemic body temperature from rectum or armpit. In most hospitals, the mercury thermometers are still used.

9.3.2 Electronic Thermometers

The electronic thermometers are used for measuring systemic body temperature as well as the mercury thermometers. They have some properties and advantages so they are widely used in modernly designed hospitals.

The basic properties and advantages of the electronic thermometer are listed as follows.

- a. It can be used in two different modes which are continuous and intermittent modes. In continuous mode, automatic recording can be performed.
- b. It is more accurate than mercury thermometer.
- c. It requires less time for measuring temperature than mercury thermometer (30 sec for electronic thermometer, 3-5 minutes for mercury thermometer).
- d. It eliminates cross-contamination problem by using disposable probe cover.
- e. It provides easy read-out because it has generally digital display unit.

Intermittent thermometer units are typically portable and battery-powered and consists of a temperature-sensing probe and read-out. The measured temperature is displayed digitally or on an analog meter. Digital display is more desirable because it provides easy reading of the temperature as mentioned above. In most instance, the nurse holds the probe in place until the patient temperature is indicated.

9.3.2.1 The Mode of Operation

There are two basic operation modes which are steady-state (monitoring) mode and predictive mode. Some electronic thermometers can operate on both modes. Mode selection can be adjusted by position indicator switch.

9.3.2.1.a Steady-State (Monitor) Mode

In steady-state mode, the thermometer displays the temperature of its sensor. The waiting time for an accurate measurement is the time necessary for the sensor to equilibrate.

9.3.2.1.b Predictive Mode

In predictive mode, thermometer makes an assumption about the final temperature based on the initial rate of probe temperature rise. This mode operation requires less time than steady-state mode operation for measuring temperature.

9.3.2.2 Types of Temperature Sensing Devices (Probes)

Mainly, there are two kinds of probes that are used as a temperature sensing device which are thermocouple and thermistor.

9.3.2.2.a Thermocouple

The thermocouple produces an output voltage nearly proportional to the temperature at the junction of two dissimilar metals. The small voltage generated at the thermocouple is amplified to operate a read-out device or pen recorder.

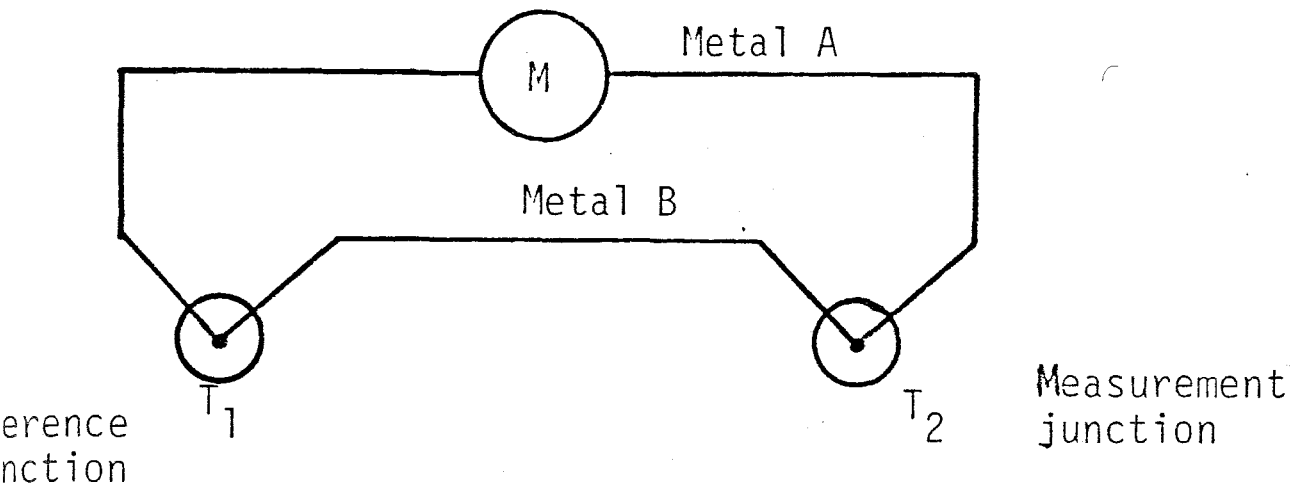


Figure 9.1 - Basic thermocouple configuration.

9.3.2.2.b Thermistor

The thermistor is a semiconductor element whose resistance varies with temperature. This kind of probes are used more frequently than thermocouples because they have greater sensitivity in the temperature range of interest. A simplified block diagram of a temperature monitoring system is given in Figure 9.2.

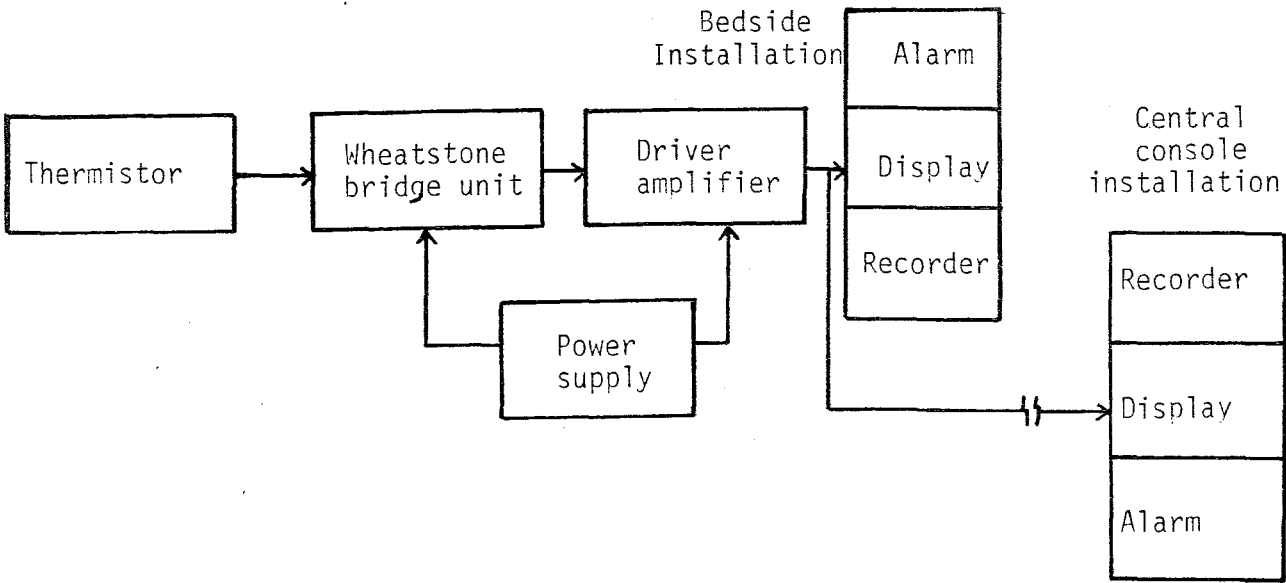


Figure 9.2 - A simplified block diagram of a temperature monitoring system.

The thermistor probe is connected to the Wheatstone bridge. The bridge is balanced by calibration at initial conditions. When the temperature is applied to the thermistor probe, the output voltage of the Wheatstone bridge varies, because the equilibrium resistance value changes as a result of temperature variation on the probe. This output voltage is proportional to the temperature.

$$U = I \cdot R \quad \text{Ohm's Law}$$

$$U_{AB} \propto T \quad (T \uparrow \rightarrow U_{AB} \uparrow)$$

The output voltage is converted into a digital readout automatically for reading body temperature by the medical staff. Some units have alarm circuit that gives warning signal to the user if the body temperature exceeds the adjusted normal limits.

9.4 EVALUATION CRITERIA OF ELECTRONIC THERMOMETERS

Important evaluation criteria and properties of electronic thermometers are listed as follows.

1. Temperature Range and Accuracy: Electronic thermometers should have a temperature range of at least 34-41°C [93.2 - 105.8°F] to insure that temperature measurements can be made on most patient encountered the required accuracy is $\pm 0.1^\circ\text{C}$ over the range of 37-39°C.
2. Sensitivity: The sensitivity of electronic thermometers is their ability to measure accurately small changes in temperature. Usually, overall sensitivity is a function of both the probe and the circuitry used.

3. Readability: Digital or analog meter is used for displaying temperature. Some instruments have both display systems. Digital display has more advantages than analog meter, namely it is easier to read.
4. Portability: Portability property is important for possible electronic thermometers. The thermometers should be light and easy to carry. Generally, electronic thermometers which are used on bedside have their own casing or they are implanted in the bedside unit systems that can not be carried separately. In this case portability of the bedside unit becomes important rather than the portability of the electronic thermometer.
5. Response Time: A correct temperature indication, within the manufacturer's specified accuracy, should be obtained rapidly after insertion of the probe into the patient.
6. Ease of Set-up and Use: The thermometers should be easy to set-up and use. Probe covers should be easily applied and removed with minimal user contact to avoid contamination. An automatic turn-off feature is desirable especially for battery working condition. This property helps in extending the battery life. Probes should be separable from the thermometer to facilitate replacement if they are damaged or contaminated. For portable units, abbreviated operating instructions should be provided on the units.
7. Configuration of Probe and Patient Comfort: The physical configuration of the probe depends upon the size, shape, flexibility and so on. The probe should not disturb the patient during the temperature-taking. It is known that the body temperature may be

affected by the emotional condition of the patient so that the patient should be as comfortable as possible.

8. Batteries/Charges: All the portable electronic thermometers have either disposable batteries or rechargeable batteries. Some units have low battery indicator light that gives signal to the user when the battery life shortens. Unit accuracy and operation should not be affected by battery condition unless a continuous automatic indication of unreliable conditions is provided.
9. Charge Leakage Current: The worst case chassis electrical leakage current to ground for any mode of operation (grounded, ungrounded, reverse polarity) should not exceed 100 microampere. If the charger is not within reach of patients, a chassis leakage current limit of 500 microampere applies. Leakage currents for patient probes should not exceed 50 microampere if the unit can be operated while connected to the AC line.

Some other required properties and factors are listed below.
 - The grounding of the unit should be performed. Resistance to ground from any exposed conductive surface should be less than 0.15 ohm.
 - The thermometer system should not require daily calibration. An easy and reliable method of checking the unit's calibration should be provided. It should check the probe as well as the thermometer itself.

- Operation should not be adversely affected by fluids spilled on the unit.
- Sterilization of the unit by (EtO) should not damage and change the unit performance.
- The operator's manual should be clearly written and comprehensive. It should describe the functions of all controls and include instructions for use, calibration, maintenance, cleaning and sterilization. This manual should be read by the medical staff before using the system.

9.5 BODY TEMPERATURE MEASUREMENT IN THE CORONARY CARE UNIT

Body temperature measurements in the coronary care unit can be performed by two ways which are using conventional mercury thermometers or electronic thermometers. In Turkey, generally mercury thermometers are used instead of electronic thermometers. But it is obvious that the electronic thermometers are widely used in modernly designed hospitals of Europe and the United States of America because they provide some advantages which have been mentioned previously.

The major advantage of electronic thermometer is providing continuous monitoring and recording. That's why during the design of the modern CCU, this factor should be taken into consideration by the biomedical engineer. In short optimum solution should be found. Under this consideration, a simplified block diagram of an electronic thermometer connection to the central nurses' station is shown in Figure 9.3.

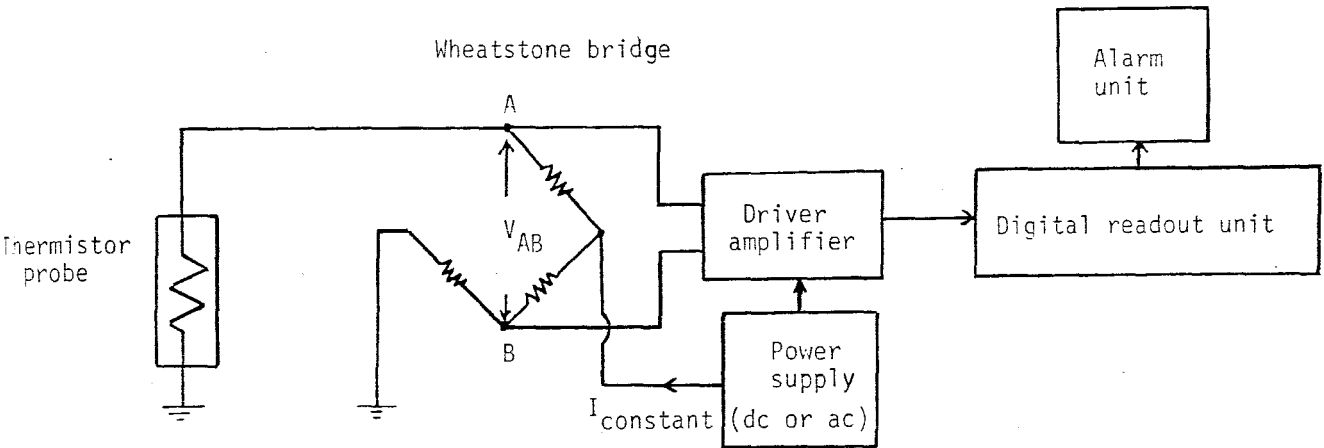


Figure 9.3 - The block diagram of body temperature monitoring system by using thermistor probe.

In this design, each patient bedside unit should have an electronic thermometer probe with its main circuitry. Display and alarm units are installed both on bedside and central nurses' console. The recorder is also placed on the central console. It is used for temperature recording. On the other hand alarm units provide visual and audible warning signals if body temperature of the patient exceeds certain limits.

An optimal number of electronic thermometers or mercury thermometers should be provided in the CCU for using them when the bedside units do not work properly.

10. INSTRUMENTATION OF RESPIRATORY EQUIPMENT IN THE CORONARY CARE UNIT

10.1 INTRODUCTION

As it is known, there is a strong functional interconnection between the cardiovascular and the pulmonary systems. In some cases cardiovascular disorders may cause respiratory malfunctions or vice versa. Under this consideration there are some respiratory therapy equipment that should be installed within all the coronary care units for correction of some respiratory malfunctions. The procedures and instrumentation involved in providing mechanical assistance in respiration and in supplying hypoxic patients with higher than normal concentration of oxygen or other therapeutic gases or medications constitute a field known as RESPIRATORY THERAPY.

Instruments for respiratory therapy include such devices as;

- inhalators
- ventilators
- respirators
- humidifiers
- nebulizers.

In this chapter main respiratory therapeutic and respiratory monitoring equipment are discussed. They should be installed within all the modern coronary care units. Diagnostic instrumentation, which is used for testing some pulmonary functions, is not mentioned because the equipment of diagnostic tests generally are not used in the coronary care unit.

10.2 RESPIRATION RATE MONITOR (APNEA MONITOR) WITH ALARM UNIT

Respiration rate detection is very important for cardiac patient. That's why all the bedside units must have a respiration rate monitor which detects the average respiration rate of the patient continuously. The obtained data are observed on the digital read out systems which are installed on both bedside and in the central nurses' station.

There are many types of transducers that can be used for measuring respiration rate. A few examples are strain gauge and volume displacement transducers, impedance transducers and temperature transducers.

Generally, two techniques are used for clinical respiration rate monitoring. These are;

1. measurement of variations in chest impedance by using impedance transducers
2. detection of the temperature change between inspired and expired air by using temperature transducers.

In the first method, two electrodes are located on each side of the thorax (below the axilla). A high frequency, low current voltage (50 - 60 kHz) is passed between the two electrodes and as the patient

breathes, volume changes within the chest modulate the current, resulting in a respiration rate signal.

In the second method, thermistors placed in the nasal passage via a cannula, change resistance as the temperature of the air surrounding them changes. Expired air is warmer than inspired air and consequently this temperature variation results in a resistance change at the thermistor which is connected to a Wheatstone bridge. The obtained signal is amplified and then it is sent to both the bedside read-out system and the central nurses' console read-out system for performing continuous patient respiration detection. Digital or metric read-out systems are widely used. If it is desired, the obtained data can be recorded by the recorder unit which is installed on the central console. Some type of recorders have selectable patient switch. The switch is adjusted during the patient respiration rate recording.

All the respiratory monitors have alarm units. They give audible and visual alarms when the patient respiration decreases or increases beyond certain predetermined limits.

10.3 RESPIRATORY THERAPY EQUIPMENT

10.3.1 Ventilator and Respirator

The terms ventilator and respirator are used interchangeably to describe equipment that may be employed continuously or intermittently to improve ventilation of the lungs and to supply humidity or aerosol medications to the pulmonary tree. Most ventilators in

clinical settings use positive pressure during inhalation to inflate the lungs with various gases or mixtures of gases (air, oxygen, carbon dioxide, helium, etc.).

Whenever a ventilator is used, its mode of operation and the settings of the various controls must be adjusted to the specific needs of the patient. Under this consideration basic three types of operation mode are summarized as follows.

1. Assist Mode: The assist mode can be used when the patients are able to control their breathing, but unable to inhale a sufficient amount of air without assistance or breathing requires too much effort. The pressure sensor senses the slight negative pressure when the patient attempts inhalation. This triggers the instrument to begin inflating the lungs for helping patient inspiration when he wants to breath.
2. Control Mode: In the control mode breathing is controlled by a timer set to provide the desired respiration rate. The control mode is used when the patients are unable to breathe on their own. In this mode the ventilator has complete control over the patient's respiration and does not respond to any respiratory effort on the part of the patient. In short, the respiration function is completely performed by the instrument.
3. Assist-control Mode: If the patient fails to breath within a predetermined time, a timer automatically triggers the equipment to inflate the lungs. In this operation mode the breathing function of patient is controlled over time. This mode is most frequently used in critical care settings.

On the other hand in addition to the modes described, many ventilators can be triggered manually by means of a control on the panel.

Once inspiration is triggered, inflation of the lungs continuous until one of the following condition occurs.

- a. The delivered gas reaches a predetermined pressure in the proximal or upper airways. This is called PRESSURE-CYCLED ventilator operation.
- b. A predetermined volume of gas has been delivered to the patient. This is known as VOLUME-CYCLED ventilator operation. This is preferable for CCU usage.
- c. The air or oxygen has been applied for a predetermined period of time. This is the characteristic mode of operation for TIME-CYCLED ventilator.

All the ventilators have to have audible and visual alarm systems for safety. When something goes wrong within the unit or in the patient condition, the alarm systems should give alarm to the medical staff as quickly as possible.

The ventilators are vital life-sustaining equipment for the cardiac and pulmonary patients. That's why optimal number of ventilators should exist within the coronary care unit.

10.3.2 Inhilator

Inhilator is used for supplying oxygen or some other therapeutic gas to a patient who is able to breath spontaneously without assistance. Supplying gas is performed through a nasal cannula and cathater or face mask that covers the nose and mouth. The oxygen concentration presented to the patient is controlled by adjusting the flow of gas into the nasal cannula or the mask.

The number of inhilators that are installed in the coronary care unit should be chosen optimally depending upon the capacity of the unit.

10.3.3 Resuscitator or Resuscitator Bag

A resuscitator is an emergency device designed to apply oxygen or to assist breathing on a temporary basis unit the patient is able to breath spontaneously. Generally inhilators, respirators can be used for resuscitation in the coronary care unit. On the other hand there is a specially designed type of resuscitator unit which is called resuscitator bag. It is used easily by hand when it is required. Schematic picture of a resuscitator bag is given in Figure 10.1.

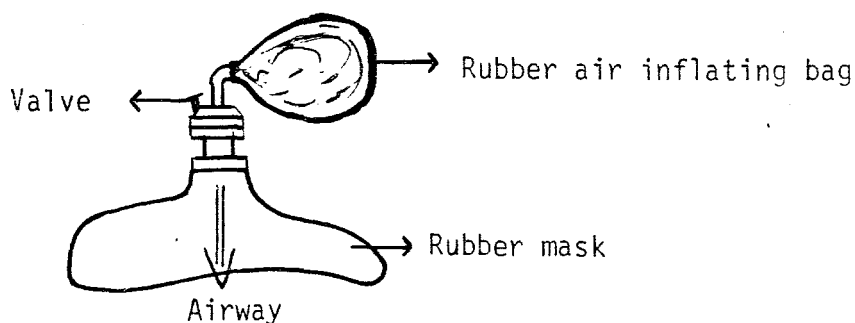


Figure 10.1 - Schematic picture of a resuscitator bag.

10.3.4 Humidifiers

In order to prevent damage to the patient's lung, the air or oxygen applied during respiratory therapy must be humidified by the humidifiers. All the respirators and inhilitators include the humidifiers within their compact units. On the other hand, a sufficient number of humidifiers should be installed on each patient bedside unit for humidifying air and oxygen. If the patient requires to use them. Heat vaporization (steam) or by bubbling an air stream through a jar of water are basic two working principles of the humidifier's operation.

10.3.5 Aspirator and Vacuum Unit

Aspirator is a suction instrument that is used for cleaning the airways of patient from mucous, saliva, blood, etc. It is widely used in the coronary care unit in cases where the patient is not able to clean his throat. On the other hand vacuum units are also installed at each patient bedside and can be used like aspirators.

Optimal number of aspirator equipment should be installed in the coronary care unit. They are generally used as auxiliary suction equipment when the bedside vacuum units fail.

10.3.6 Nebulizer

Nebulizer is used for supplying medication or water in the inspired air as an aerosol when the patient requires such kind of therapy. In a nebulizer the water or medication is faced on with

a high velocity set of oxygen (or some other gas) and thrown against one or more baffles or other surfaces to break the substance into controllable-sized droplets or particles, which are then applied to the patient via a respirator.

The new production in this field is ultrasonic nebulizer. It produces high-intensity sound energy well above the audible range. When the ultrasonic energy is applied to water or medication, a high volume of minute particles is produced. This instrument has an important advantage that the ultrasonic unit does not depend on the breathing gas for operation. Thus the therapeutic agent can be administered during oxygen therapy or a mechanical ventilation procedure.

The ultrasonic nebulizer is more expensive than the conventional type. That's why choosing the type of nebulizers and number of them should be determined optimally during the coronary care unit design.

10.4 THE LIST OF REQUIRED BEDSIDE RESPIRATORY EQUIPMENT

A modern coronary care unit has to have some respiratory equipment with their read-out systems and recorders. In this section the most important of them, which should be installed on each patient bedside, are listed below.

- Oxygen unit (2 units)
- Vacuum unit (3 units)
- Air unit (1 unit)
- Humidifier unit (depending upon the installed number of
above listed units)
- Resuscitator bag (1 unit)

- Respiration rate monitor and alarm unit (1 unit)

On the other hand there are prefabricated headwall systems that are specially designed for use in intensive, coronary, and other special care units as a means of organizing the myriad of services and devices at the head of the patient's bed. They include all the earlier mentioned units in sufficient numbers. In some cases using this kind of panels is less expensive than the conventional installation. Under this consideration decision making on the installation type and number of units, that should be realized on each patient bedside, must be performed optimally for obtaining optimal efficiency.

II. BLOOD GAS ANALYZERS

II.1. INTRODUCTION

The amount of oxygen and carbondioxide in the blood provides a good indication of the effectiveness of both the cardiovascular and respiratory systems. That's why blood gas measurements are important for the physicians because they can obtain valuable information about the patient's condition.

The quantities are usually given as partial pressure which are directly related to concentration levels of blood gases and are expressed in millimeters of mercury (mm Hg). P_{O_2} indicates the partial pressure of oxygen. P_{CO_2} indicates the partial pressure of carbondioxide and pH denotes hydrogen ion concentration in the blood. Abrupt and abnormal changes in their values from the normal ranges may cause death. That's why they have vital importance for the human beings. Under this consideration, in some cases patients require continuous analysis of the mentioned variables in special care units within the hospitals on 24 hour basis. In short evaluation of the P_{O_2} , P_{CO_2} , pH and derived variables have great importance during diagnostic and treatment procedures. For this reason,

all the special care units such as CCU, ICU and others have to have optimum number of blood gas analyzers for intermittent or continuous evaluation of the patients' blood gases.

11.2 TYPES, NORMAL VALUES AND ASSESSMENT OF BLOOD GASES

Normal ranges of P_{O_2} , P_{CO_2} and pH for an adult are listed below. The normal ranges are given for arterial blood because usually arterial blood is evaluated.

<u>Types</u>		<u>Normal (mm Hg)</u> <u>(for arterial blood)</u>	<u>kP_a (kilo Pascal)</u>
a)	P_{O_2}	(90 - 100)	(12-13.3)
b)	P_{CO_2}	(35 - 40)	(4.7-5.3)
c)	pH	(7.38 - 7.44)	

Some assessments of P_{CO_2} , P_{O_2} , and pH are explained briefly in the following paragraphs.

- a) The P_{O_2} Value: The P_{O_2} value is a measure of the degree of O_2 content in the blood.

Lower than the normal value of P_{O_2} indicates one or more of the following:

- Abnormal pulmonary function because of a disease state, bronchial obstruction, pulmonary embolus, diffusion problem or loss of functional alveoli (paralysis). This conditions cause insufficient oxygenation of blood.
- Inadequate circulatory transport of oxygen because of a decrease in cardiac output, vascular problems, alterations in hemaglobin or increased oxygen demand.

- Low O_2 content during inspiration under the normal pulmonary function as a result of insufficient alveolar oxygenation or impaired alveolar elimination of CO_2 .
- Existence of anatomical heart defect.

b) The P_{CO_2} Value: The P_{CO_2} level is an indicator of the adequacy of ventilation.

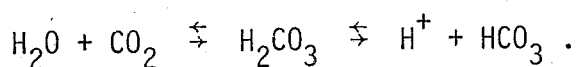
Decrease of P_{CO_2} value may occur as a result of the following conditions:

- Hyperventilation may cause to lower P_{CO_2} value. Under this condition elimination of CO_2 exceeds production. In short, this can result from the body's attempt to increase oxygen delivery to the tissue or from acid-base disturbance.

Increase in P_{CO_2} value may occur as a result of the following conditions.

- Under the condition of hypoventilation or ventilation failure (e.g., CO_2 production exceeds elimination) these conditions occur as a result of cardiac arrest, drug overdose, chronic metabolic acid-base disturbance or chronic obstructive lung disease.

c) The pH Value: Hydrogen ion concentration indicates acid-base condition of blood. It is calculated by $pH = -\log_{10}[H^+]$. The reaction is



Decrease of pH has the same meaning of increasing hydrogen ion $[H^+]$ quantity in blood. This condition occurs as a result of one or more of the following:

- Under the respiratory acidosis condition. Respiratory acidosis through decreased pulmonary ventilation, increases the P_{CO_2} level. This increase in carbon dioxide leads to increased carbonic acid and hydrogen ions, thus resulting in acidosis. Respiratory acidosis may be caused by obstruction of the respiratory tract pathways, pneumonia and others.
- Metabolic acidosis, may cause lowering pH. This condition occurs as a result of increasing metabolic acid production in the blood plasma.

Increasing pH means decreasing hydrogen ion $[H^+]$ concentration in blood. This condition may occur as a result of the following:

- Respiratory alkalosis, through increased pulmonary ventilation, decreases the P_{O_2} level.
- Metabolic alkalosis. This occurs as a result of decreasing metabolic acid production or abnormal acid loss.

With this point of view, necessity of periodic evaluation, or continuous evaluation of P_{CO_2} , P_{O_2} , pH and derived parameters can easily be understood. These are the reasons for installing blood gas analyzers in the special care units and in the hospital laboratories.

11.3 BLOCK DIAGRAM OF A BLOOD GAS ANALYZER

Basically, there are three type of blood gas analyzers which are automatic, semiautomatic and manual analyzers. Automatic analyzer has some capabilities which are automatic calibration, tubing, fault warning, sample chamber washing, report of results and self-diagnostic capability. Semiautomatic and manual analyzers basically require operator-initiation of one or more of the mentioned functions.

Basic parts of a blood gas analyzer unit are listed below.

1. Electrode Systems: There are three type of electrode systems which are P_{O_2} system (cathode: platinum wire, anode: Ag/AgCl as reference electrode), P_{CO_2} system (cathode: AgCl, anode: Ag/AgCl as reference electrode) and pH system (active electrode: AgCl, reference electrode = Hg_2Cl_2 , calomel).
2. Electrode Selector Switches: These switches are used for selection of desired electrode systems which are going to perform measurements.
3. Electronic Circuits and Switches: Calibration, calculation of derived parameters and other functions are performed by these circuits and switches.
4. Display and Recorder Units: All the units have digital or metric displays with recorder units. Recorder provides taking hard copy of the measured variables.

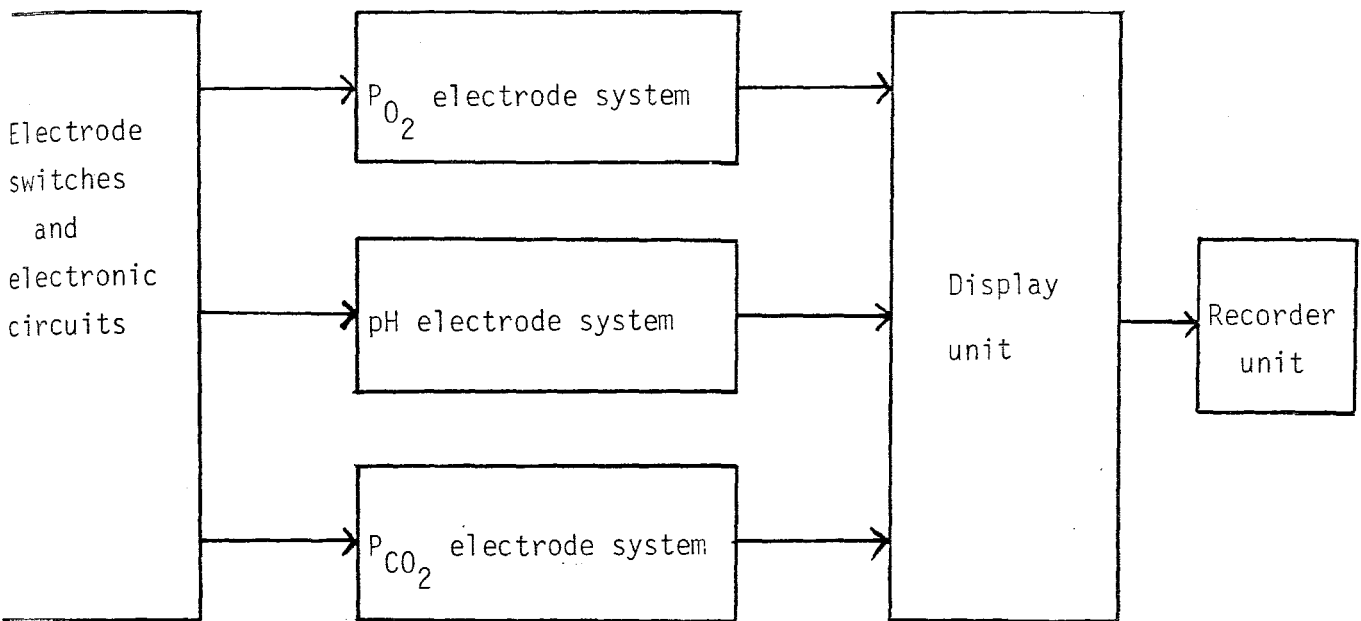


Figure 11.1 - Block diagram of a blood gas analyzer unit.

The automatic analyzer can also calculate some parameters by using measured values these are bicarbonate concentration, standard bicarbonate, base excess, buffer base, oxygen saturation, and some others.

The unit and electrode systems require routine maintenance and calibration. They should be performed periodically by technicians or biomedical engineers. On the other hand, the unit should be operated by well-trained users, that's why training courses should be organized periodically.

11.4 EVALUATION CRITERIA

There are no completely defined formal standards for evaluating blood gas analyzers, but some criteria can be explained based on discussion with users of the device.

1. Range, Accuracy and Precision: Blood gas analyzer should accurately and reproducibly measure pH, P_{O_2} , P_{CO_2} through the following clinically appropriate range of values: pH, 6.8-7.8; P_{CO_2} , 10-150 mm Hg; P_{O_2} , 20-500 mm Hg.

Indicated values should be within the following accuracy criteria:

pH, ± 0.02 ; P_{CO_2} , ± 2 mm Hg or 5% (whichever is greater); P_{O_2} , ± 3 mm Hg or 5% (whichever is greater).

2. Effect of Sample Temperature Variation: Blood gas analyzers should accurately analyze samples with temperatures ranging from 4 to 37°C.
3. Effect of Ambient Temperature: Analyzer performance should not be affected by reasonable fluctuations in ambient temperatures.
4. Ease of Use: Using blood gas analyzers should be easy as well as possible sample introduction into the unit, cleaning, maintenance, repairing of the unit should not be difficult. Displays should be easy to see and interpret. Alarms should be interpreted easily by the user for correcting conditions. That's why labelling of the unit should be well done. On the other hand the manual should include routing care and troubleshooting instructions.

5. Effect of Line Voltage Variation on Electro-magnetic Interference (EMI): Small line voltage variations should not affect the unit operation. On the other hand the unit should not be affected by interference from radio-frequency sources that are likely to be nearby during use.

Delay in analysis of collected blood may change the measured values through several mechanisms. That's why the analysis must be well done as quickly as possible. In short, under this consideration it becomes obvious that all the special care units like CCU, ICU, etc. should include blood gas analyzers. The number of blood analyzer should be chosen optimally depending upon the unit capacity and type.

I2. INFUSION PUMPS

12.1 INTRODUCTION

Manually adjusted flow clamps on gravity flow systems cannot always maintain the flow rates and total volume accuracy required for infusion of critical drugs and parenteral nutrition solutions. Therefore electro-mechanical devices, which are called infusion pumps, are used in hospitals. Especially some of the diseases require very careful drug administration for their treatment. In such a case, using infusion pumps becomes necessary.

Using infusion pumps is not very common in the hospitals in Turkey, because the necessity of their usage has not yet been adopted by the medical staff. That's why, presentation of infusion pump in this thesis is considered necessary for giving information about their components and usage advantages. It is obvious that, types and necessary number of the infusion pumps should be determined optimally for obtaining optimal unit efficiency within the hospital.

12.2 AIM OF USING INFUSION PUMPS

Infusion pumps provide regular flow rates and total volume accuracy required for infusion of critical drugs and parenteral nutrition solutions to the patients who need special administration for treatment of some types of diseases. In some cases infusion time and flow rate constency of the drugs carries extreme importance, especially for some cardiac patients. Under this conditions, using infusion pumps should be necessary for treating some cardiac diseases properly instead of manually clamped gravity flow systems. The basic advantages and properties of infusion pumps are listed below.

1. It provides regular flow rates under the required volume accuracy and constency.
2. The volumetric amount of the infused drug can be controlled under the required accuracy and precision.
3. The system gives audible and visible alarms if the rapid overinfusion (runaways) occurs. On the other hand, it also gives warning signals when the drug bottle becomes empty (before drip chamber empties).
4. It has specially designed circuitry that terminates flow when something goes wrong within the unit or in the connection between the patient and the unit. The system also gives alarm under this conditions.
5. The system has fluid embolism detector (air detector) which detects air within the system. When the detector detects

air bubbles, the unit gives alarm and also terminates flow automatically.

Some advantages and properties of the infusion pump unit are mentioned above. Manually clamped gravity flow system has none of these properties. That's why infusion pumps should be optimally used in the hospital units, if special types of treatment is required.

12.3 FUNCTIONAL PARTS OF AN INFUSION PUMP

The basic functional parts of an infusion pump are;

1. Pump Unit: It exerts pressure to the drug solution
2. Controller Unit: It regulates the gravity flow.
3. Photoelectric Drop Sensor Unit: It provides feedback for rate control, triggers alarm to warn case of empty bottle (before drip chamber empties) or obstruction in line.
4. Volumetric Drop Sensor Unit: It determines the volume of the drops. It is included in the controller unit.
5. Alarm Unit: Infusion pump has to have two kinds of alarm units. One of them is audible, the other is visible. Both of them should be working properly.
6. Air Detector Unit: Detection of air within the unit and in the catheter can be performed by this specially designed detector unit. The place of this unit is in the controller unit.

Basic block diagram of an infusion pump is given in Figure 12.1.

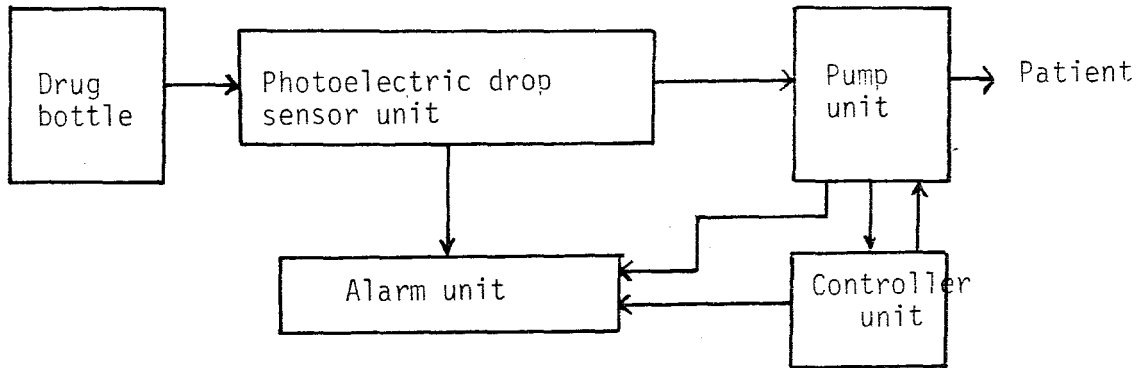


Figure 12.1 - Basic block diagram of an infusion pump unit.

12.4 IMPORTANT FACTORS FOR PROPER OPERATION OF INFUSION PUMPS

There are some basic factors that should be taken into consideration during the installing of infusion pumps within the hospital units.

- i. Operator training: Operator training is very important, because inadequate information about the system operation may cause equipment misuse. That's why technical course should be programmed to the medical staff before the using the infusion pump units by them.
- ii. Routine check of equipment: Routine check of equipment should be performed by the medical staff before the unit is operated.

- iii. Regular cleaning: The unit should be cleaned regularly by the user. Inadequate cleaning may resulting low unit working efficiency.
- iv. Regular preventive maintenance: Regular preventive maintenance should be performed by the technician staff of the hospital.
- v. In short, the selected infusion pumps should be versatile, safe, cost effective and simple to use.

12.5 EVALUATION CRITERIA OF INFUSION PUMPS

There are some evaluation criteria of infusion pumps that should be kept in mind during the selection and usage of them. The criteria are divided into the following categories.

1. Flow rate (range, accuracy and consistency)
2. Safety
3. Ease of use and servicing
4. Environmental factors.

1. Flow Rate

- 1.a Range and Accuracy: A general purpose infusion pump should have a flow rate range of 1-300 ml/hr.
A pump should maintain all flow rate settings within $\pm 10\%$ with all fluids currently used for parenteral administration. The error obtained with any combination of pump and suitable

administration set should not span a range greater than 10%. The pump should give audible and visible alarm signal if it is unable to maintain this accuracy under any condition and it should terminate flow or switch to a keep-vein open (KVO) rate if the error is positive.

In case of normal intravenous usage, the pump should work within the mentioned limits properly against a back pressure of up to 70 cm H₂O. This figure accounts for maximum expected venous pressure (25 cm H₂O) and any back pressure caused by situating a pump below the patient during transport.

- 1.b Flow Rate Continuity: A pump should provide continuous, even flow at rates of 1-125 ml/hr to be suitable for infusion of rapid-acting critical drugs.
- 1.c Flow Rate Error Change After 24-hour Operation: A pump's flow rate should remain accurate within $\pm 10\%$ under normal operating conditions after 24 hours of continuous use. This is very important, because some patients may require continuous medical infusion in 24-hours or sometimes more than a day.
- 1.d Accuracy with Elevated Back Pressure: A pump should remain accurate within $\pm 10\%$ at all back pressures up to its maximum output (occlusion) pressure. For the pump to be suitable for intra-arterial infusion, its acclusion pressure should exceed

300 mm Hg (6 psig). This figure accounts for maximum expected mean arterial pressure and for possible location of the pump 50 cm below the patient.

On the other hand, there are mainly three factors that should be taken into consideration during the evaluation of infusion pumps.

These are:

- * Variation of IV fluid container height within 1 m above and below the pump should not cause the flow rate error to exceed $\pm 10\%$ under normal operating condition.
- * The drop sensor should be fastened to IV set as securely as possible so that it should not move during the transportation of the infusion pump. The sensor should not count erratically if mispositioned or attached to a tilted or overfilled drip chamber unless the pump is able to detect this malfunction and give alarm.
- * The pump tubing, chamber or cassette should be designed to prevent mispositioning during installation. If mispositioning occurs, it should not compromise patient safety.

2. Safety

The modernly designed infusion pump has some alarm circuits that give audible and visible alarm signals to the medical staff if something goes wrong within the system or between the instrument and patient.

This alarm unit prevents the occurrence of many undesirable dangerous conditions which may cause death of the patient if it is not corrected. In short alarm unit provides usage of the infusion pump safely.

- * A pump should alarm and terminate flow or switch to a keep-vein open (KVO), if any empty container exists or if enough air has entered the line either to create a flow rate error greater than $\pm 10\%$ or to pose a patient hazard if allowed to embolize. On the other hand the system should detect a depleted fluid container preferably in time to permit the operator to replace it with a new container without disconnecting the IV set from the patient.
- * A infusion pump's controls and accessories should resist tampering by the patient, and the pump set should resist accidental removal. Tampering at accidental set removal should not permit an excessively rapid infusion to occur. If the pump set is removed, or if connections are broken to permit gravity flow or air in the line, the pump should terminate operation and give alarm signal immediately to the medical staff.
- * A pump should terminate flow and alarm when the maximum output (occlusion) pressure is reached.
- * A pump should operate properly and maintain a flow rate accuracy within $\pm 10\%$ during transport.
- * Leakage current from chassis to ground should be less than 100 microamperes in any configuration (e.g. grounded,

ungrounded, ungrounded with reverse polarity). Chassis-to-ground pin resistance should be less than 0.15 ohm. On the other hand the effect of electrical failure of the pump on other devices should be minimized, preferably by a circuit breaker.

- * A battery system should exist in the pump unit for supplying electric energy automatically when the network is broken off. Some units have an alarm indicator lamp that lits when the battery energy decreases.
- * Shutting off the pump should not automatically erase the rate and volume-to be infused settings or the volume delivered and duration-of-infusion displays.

3. Ease of Use and Servicing

An infusion pump should be simple to use and require little formal training for a medical staff to become proficient. It should be easy to transport. Service manual should be available for preventive maintenance and repairing.

4. Environmental Factors

- * Pump operation should not be adversely affected by fluid spills.
- * It should be unaffected by electromagnetic interference

from nearby devices and it should also not be affected by line voltage variation in between certain limits.

The above factors are the most important that should be taken into consideration during the selection of infusion pumps which are installed in hospitals or in the coronary care units.

The medical staff should be familiar with the advantages of using infusion pumps. Under this consideration using infusion pumps in the coronary care units and hospitals becomes popular.

The number of infusion pumps to be employed in the coronary care unit is chosen depending upon the bed capacity of the unit and generally required usage frequency by one patient. Consequently, the usage advantages of infusion pumps should be known scientifically by the medical staff for wide and correct applications of them in all hospital units.

13. BASIC PRINCIPLES AND FACTORS FOR OPTIMAL CORONARY CARE UNIT DESIGN

13.1 INTRODUCTION

There are some general basic principles that should be taken into consideration during the hospitals' sections design. It is evident that all the different units have that special design properties and techniques so that general, special factors on properties of the unit should be kept in mind for optimal unit design within the hospital. In this section basic rules and factors concerning the coronary care unit design will be discussed.

13.2 ORGANIZATION OF PROJECT COMMITTEE

Organization of the project committee is the first step. This committee should always be organized, before any design activities, according to the unit type. It is responsible for preparing desired unit design and organization. It has at least four or five members whose profession is closely related to the unit type. The number of members in the committee may change depending upon the hospital

organization. Generally it includes two or more doctors, a biomedical engineer and a clinical engineer. A committee director is chosen between them.

The project committee meets and discusses the basic principles about the unit design. Doctors give some idea to the other members about the required and desired unit properties that the unit has to have and they give idea to the biomedical and clinical engineers about the instruments that they need in the unit organization. The function of the biomedical engineer in the committee organization is designing and projecting engineering aspects of the coronary care unit under the medical knowledge. It can be clearly understood that there should be grift information transfer between the committee members for realizing optimal unit design.

13.2.1 Responsibilities of Project Committee

The basic responsibilities of the project committee are ordered as follows:

1. First of all, the committee takes a decision on projecting a coronary care unit. Then it determines the capacity of the unit by taking into consideration the following factors.
 - Available area for the unit,
 - The hospital capacity,
 - Construction type of the unit (n,u,L,J or others)
 - Economy.

Determination of the unit capacity should always be done optimally by the factors that have been mentioned above. In some cases, the coronary care unit is added to an already constructed hospital building. In this case capacity is affected by three main factors that are available unit area, hospital capacity and economy. Sometimes it will be better to construct a new building for realizing desired unit, but sometimes this brings economic problems. That's why decision making among these choices should be performed very carefully for realizing optimal unit design. It should not be forgotten that the designed CCU should serve for all required needs optimally. This can be obtained by a carefully prepared feasibility report on it.

2. The project committee should realize separation and furniture organization of the patients' room. The place of the patient bed, the commode, the position and place of the bedside monitor and other accessories. The patient room organization is very important because it affects directly the working conditions and efficiency.
3. The organization committee also prepares the list of equipment that should be installed within the coronary care unit. This list does not include the model of the equipment, but includes the name and required number of instruments. This list is usually known as preliminary equipment list. After this, a sub-committee is organized in the project committee for researching and obtaining any information about the equipment that are available in the market. The sub-committee has a few members which are a biomedical engineer and two doctors or more. In short this sub-committee prepares reports

on the required instruments by including types and models for each one of them. The prepared reports are discussed in the main committee. As a result of this, models and numbers of the equipment which are to be installed in the unit are chosen optimally under the existing installation constraints.

4. Medical and assistant staff organization is also realized by the project committee. Number of doctors, nurses, assistants and other personnel which work in the coronary care unit should be determined optimally. The tasks of the personnel should be clearly and briefly defined in the job control cards for preventing confusion.

5. Organization of a technical department under the direction of the biomedical engineer is the other important task of the project committee. The biomedical engineer is responsible for the technical department. The technicians are chosen by the biomedical engineer and the working performance and skills of them are also controlled by him.

The other main task of the project committee is organization of education staff which is responsible for preparing courses, seminars to the all medical personnel and technicians working in the hospital. This organization is very important because it always studies and researches about new developments and techniques and prepares report on them for giving information to the project committee from time to time.

6. The task of the project committee does not finish after the realization of the coronary care unit. It should meet at least weekly for reviewing the unit working conditions and for discussing about new developments in the world that may be applied. Problems and some other findings are also discussed during this meeting. This is a very important for realizing optimal CC unit as time goes on.

13.3 ORGANIZATION OF TECHNICAL STAFF

The organization of technical staff should be realized under the direction of the biomedical engineer during the unit design. It has a very important rule during the realization of the unit. In other words, the technicians help the biomedical engineer during the installing and placing of the equipment within the coronary care unit. The education and skills of the technicians affect the unit working efficiency and performance so they should be chosen very carefully by the biomedical engineers. The number of technicians should also be chosen optimally depending upon the unit capacity and the number of equipment which have been installed. In short this organization should be sufficiently flexible in order to be able to adapt the unit to new technological developments. On the other hand all the separate units in the hospital like CCU, ICU or other types do not have their own individual technicians so that one or two technical teams are responsible for two or more than two units. This is for economy of organization.

In Turkey, a few hospitals have their own sufficiently organized technical personnel. Many hospitals have no technicians or biomedical engineers. That's why a list of problems arise when something goes wrong

in the units. For solving this problem, training and education of biomedical technicians and engineers should be given important consideration. The education program should be prepared by the universities and the technical schools with the cooperation of the government health organization. If this problem is not solved as quickly and satisfactorily as possible, it will become more and more severe and eventually may reach intolerable dimensions.

13.3.1 Basic Tasks of the Technical Staff Organization

The technical staff which work in the hospital have some duties which are listed briefly as follows:

1. Preparing the list of the equipment which are used in the hospital units.
2. Performing preventive maintenance and calibration according to a prepared program.
3. Repair of equipment failures.
4. Preparing optimal stock control programs for spare parts and particularly for those parts which have frequent failures.
5. Acting as a coordinator between the manufacture and the hospital for repair and maintenance.
6. Preparing preventive electrical hazards program.
7. Following new technical improvements and preparing reports on them for improving the unit working conditions.

8. The organization of documentation center. All the equipment's manuals, handbooks and other technical magazines and papers should be preserved in this center. They are used if they are needed.
9. Programming of technical courses and seminars for medical technicians and others.

13.4 EDUCATION OF MEDICAL STAFF IN HOSPITAL ORGANIZATION

All the hospitals have to have an optimally organized education center. It should be organized under the direction of the biomedical engineer. This organization provides more information and high skills to the medical staff about the biomedical and technical subjects by programming seminars and courses. On the other hand this organization arranges seminars and invites some doctors, engineers or other technical and medical persons for providing working cooperation between them. This organization should have sufficient number of members for performing all duties as well as possible.

The important point is that the project committee should be aware of the necessity of an education center organization during the design of the hospital units.

13.5 BASIC FACTORS THAT SHOULD BE TAKEN INTO CONSIDERATION DURING THE EQUIPMENT SELECTION FOR REALIZING AN OPTIMAL CORONARY CARE UNIT

There are some basic factors that should be kept in mind during the selection of instruments which are installed in the unit. These are;

- a. The selected equipment should fit the foreseen locations in the unit,
- b. The selection of equipment types, models and numbers should be performed carefully for optimal unit design,
- c. The technological aspects of the selected equipment should fit their desired function
 - i) The equipment should not have a very complex structure
 - ii) The maintenance and repair should be relatively easy
 - iii) The operation principles of the instruments should be simple enough so that they are easily learnt by prospective users.
 - iv) The selected equipment should be suitable for the overall working conditions in the unit
 - v) Flexibility should be given proper attention. The selected equipment should be either of modular type where introduction of additional modules improves performance or they should be easily integrated with other equipment in the unit.

14. ELECTRICAL SAFETY

14.1 INTRODUCTION

In all units such as CCU, ICU and others in the hospital, patients are surrounded by electrically powered medical equipment. Although these devices are intended to save and maintain life, they can also endanger the patient in a number of ways under certain conditions.

The safety of the patient and the medical staff is dependent on the level of proper electrical safety of the network installation and the electromedical apparatus in a medical establishment. There are some ways for obtaining a safe plant in the hospital environment which will be discussed as follows. On the other hand there are many organizations, particularly in the United States, such as the National Fire Protection Association (NFPA), The Association for the Advancement of Medical Instrumentation (AAMI), The National Electric Manufacturers Association (NEMA), The Electronics Industries Association (EIA), The American National Standards (IEC) and others, which are continually developing and revising codes and standards for obtaining optimum safe conditions, within the hospital environment. However clear and widely accepted codes and standards for electrical safety have not yet emerged.

14.2 PHYSIOLOGICAL EFFECTS OF ELECTRICAL CURRENTS

Electrical accidents are caused by the interaction of electric current with the tissue of the body. The contact point of the interaction is important, because effects of current on the body depend on the contact point of interaction.

The physiological effects of the current depend on;

- * The magnitude and frequency of the current,
- * The resistance of the current pathway,
- * The time duration of the current flow,
- * The physical condition of the body.

Threshold of Perception: The threshold of perception is defined as the minimum current that an individual can detect. This threshold varies considerably among individuals, and according to the measurement conditions. Lowest value of threshold current with moistened hand is about 0.5 mA at 50-60 Hz and 2-10 mA in dc.

Let-go Current: The let-go current is defined as the maximum current for which the subject can withdraw voluntarily.

Fig. 14.1 summarizes physiological effects of electrical current in various voltages. One-second hand-to-hand skin contact condition is taken into consideration. Reactions may vary somewhat because hand-to-hand skin resistance may vary from 1000 ohms for damp skin to over 1,000,000 ohms for dry skin.

Alternating Current (50-60 Hz)	Direct current	Effect
1 mA	5-10 mA	Threshold of perception
5 mA	25 mA	Accepted as maximum harmless current intensity
10-20 mA	50 mA	"Let-go" current before sustained muscular contraction
30-80 mA	100-900 mA	Pain. Possible fainting, exhaustion, possible physical injury
100-300 mA	500-1000 mA	Ventricular fibrillation
5-10 A	10-15 A	Sustained myocardial contraction. Temporary respiration paralysis. Burns if current density is high.

Figure 14.1-Summarizes the average human reactions to various voltages for one-second hand-to-hand skin contact.

14.2.1 Types of Shock

There are two types of electrical shock which are termed as microshock and macroshock.

14.2.1.a Microshock

The effect of an electric current applied directly to the heart is called microshock. Direct current application to the heart may cause ventricular fibrillation if the current is around 20 μ A. The generally accepted safety limit for microshock is 10 μ A. As it is known, desynchronization of cardiac muscle tissue is called fibrillation. Under this condition the heart is unable to pump blood which may cause death.

In some situations fibrillation can be corrected by using defibrillator but in some conditions correction cannot be achieved and that causes death.

Microshock problems are usually associated with leakage currents and improper use of instruments. To minimize these leakage currents, some protective and preventive methods are used which will be discussed later.

Electrically Susceptible Patient: A patient that has direct electrical connection to his heart via a catheter is called electrically susceptible patient.

The following clinical devices make patients electrically susceptible to microshock.

1. Electrode of externalized cardiac pacemakers
2. Electrodes for intracardiac ECG measuring device.
3. Liquid-filled catheters placed in the heart to measure blood pressure, withdraw blood samples or inject substances such as dye or drugs into the heart.

14.2.1.b Macroshock

The effect of current when no direct connection to the heart exists is referred to as macroshock.

Many devices have a metal chassis and cabinet that can be touched by medical personnel and patients. If the chassis and cabinet are not grounded, then an insulation failure or shorted capacitor between the

black hot power lead and the chassis result in 220 volts potential between the chassis and any grounded object. If a person simultaneously touches the chassis and any grounded object, a macroshock results.

14.3 BASIC SOURCES OF ELECTRICAL HAZARDS

1. Insulation breakdown within the biomedical equipment or in the power distribution system.
2. Mechanical fault inside an electrical devices that may cause leakage current.
3. Contact between hot wire and equipment case.
4. Leakage current formation as a result of capacitive or inductive coupling. Stray capacitance in power transit and power line may cause formation of leakage current.
5. Leakage current formation as a result of voltage division which are result of failures in the circuit components and dirty connection points.

14.4 METHODS OF ACCIDENT PREVENTION AND DESIGN TYPES OF POWER DISTRIBUTION FOR CORONARY CARE UNITS

There are some basic rules and methods that should be taken into consideration during equipment design and electric power distribution. These methods are used for protecting patient against shock. On the other hand these methods also prevent all visitors and medical staff against electrical hazards. As it is known electrically susceptible

patients need some extra protection against microshock because they have a higher risk of microshock than a normal patient.

There are basically a few fundamental methods for protecting patient against shock. These are;

1. The patient should be completely isolated and insulated from all grounded objects and all surfaces of electrical current.
2. All conductive surfaces within reach of the patient should be maintained at the same potential. This is known as equipotential grounding system which is discussed later.
3. The power distribution system has to have some properties which are listed below.
 - * The system should include some specially designed current limiters and isolation equipment such as isolation transformers.
 - * The three-wire system should be used (Hot wire → black, cold or neutral wire → white, ground wire → green)
 - * Three prong type receptacles should be used within all of the hospital units.
 - * Maximum potentials permitted between any two exposed conductive surfaces in the vicinity of the patient for critical care areas such as CCU, ICU should not exceed 100 mV (f < 1 kHz measured across 1 k Ω resistance)
4. Electromedical equipment should have efficient insulation.

14.4.1 Equipotential Grounding

One of the most effective protection methods of patients against shock is designing equipotential grounding system. This system protects patients against both macroshock and microshock. That's why this system should always be designed within all hospital sections. Figure 14.2 shows the principle of an equipotential grounding system in one room of the coronary care unit.

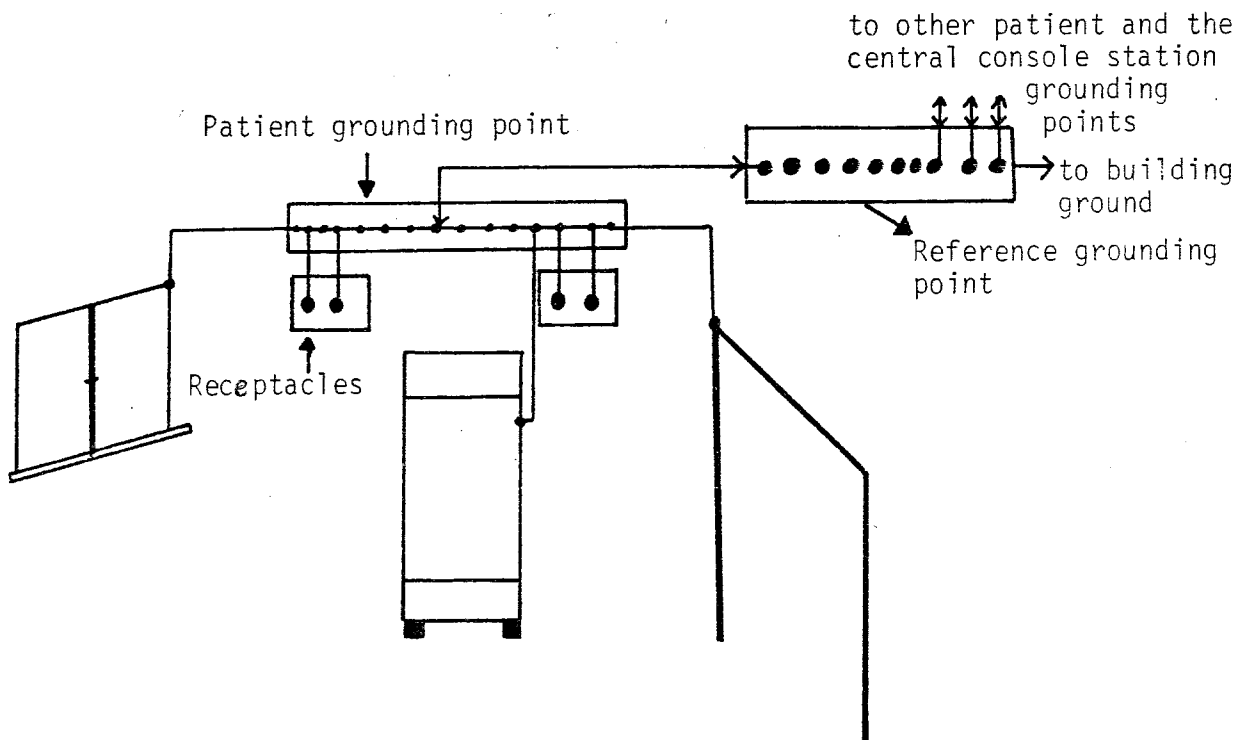


Figure 14.2 - Equipotential grounding system.

Equipotential grounding system protects electrically susceptible patients by keeping all conductive surfaces and receptacle grounds in the patient's environment at the same potential. In other words this

is a special grounding system that keeps all metallic objects in the area that could possibly come in contact with staff or patients at the same electrical potential. This grounding system is effective as long as good ground connections exist.

The equipotential grounding system has a patient grounding point, a reference grounding point, and connections, as shown in Figure 14.2. The patient grounding point is connected individually to all receptacle grounds, metal bed, metal door, lamp frame, window frames, water pipes and any other conductive surfaces. The resistance of such connections should not exceed 0.1 ohm. Also the potential difference between receptacle grounds should not exceed 20 mV (regardless of whether or not the system is energized). The potential difference between receptacle grounds and conductive surfaces should not exceed 100 mV. Each patient grounding point must be connected individually to a reference building service ground. On the other hand all the metallic surfaces which exist within the CCU unit should also be connected to a reference ground electrode.

14.4.2 Power Isolation Transformers and Monitoring

Even installing a good separate grounding system for each patient cannot prevent possibly hazardous voltages that can result from ground faults. A ground fault is a short circuit between the hot conductor and ground that injects large currents into the grounding system.

Isolation of both conductors from ground is commonly achieved with an isolation transformer. A typical isolated power system is

shown in Figure 14.3. This system should employ line isolation monitors (LIM). This device alternately checks the two wires of the distribution system for isolation from ground. In other words this monitor measures the total possible leakage current which is called as total hazard current.

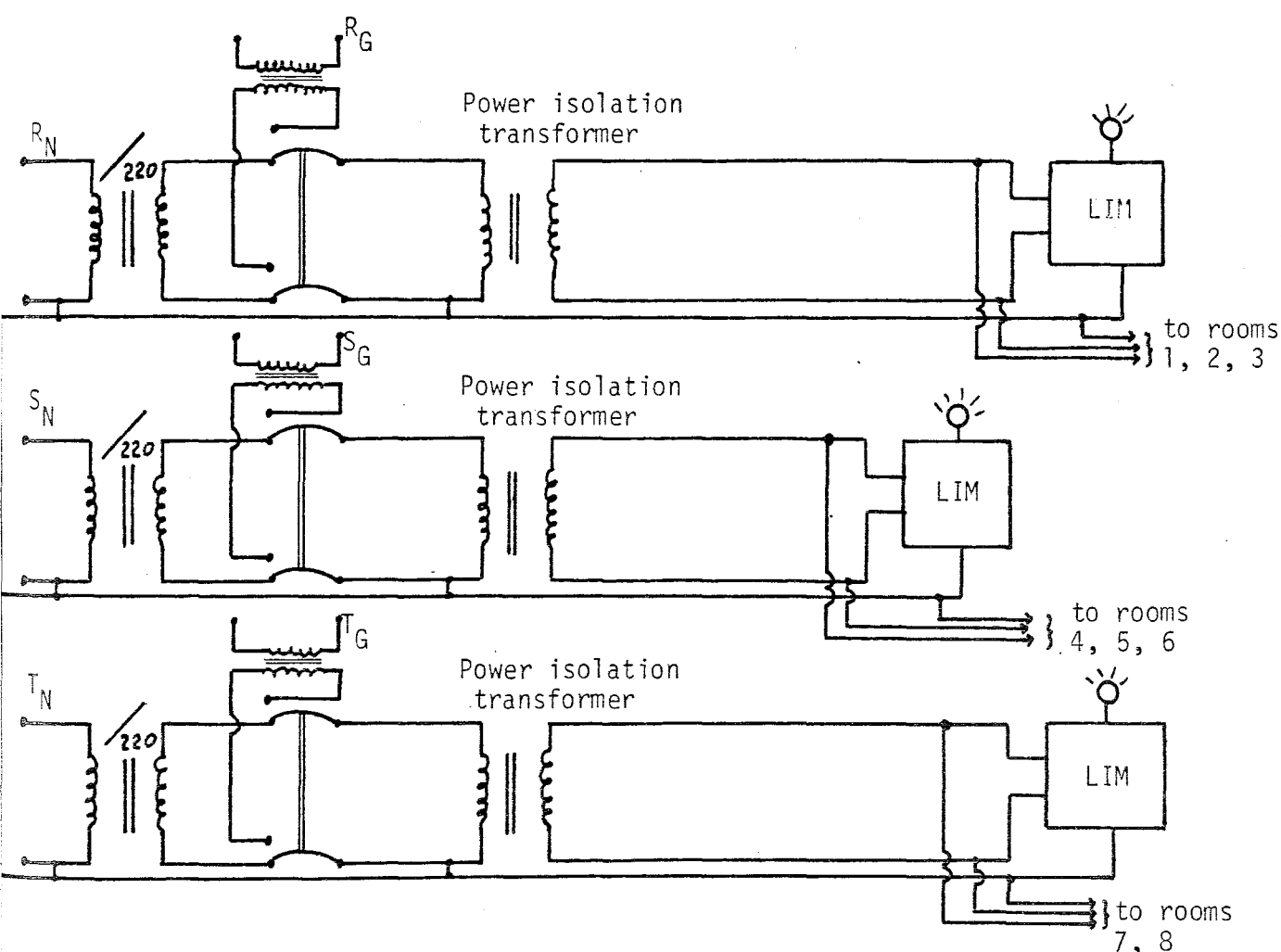


Figure 14.3 - The basic scheme of power distribution system. R_N, S_N, T_N : Phases of the network. R_G, S_G, T_G : Phases of the generator system. The switches alter their position automatically when the network fails. As a result of this the system is powered by the generator.

When the total hazard current exceeds 1.7 to 2.0 mA for normal line voltage the alarm unit is activated. It gives audible and visual signals. Under this condition the working of the system stops until the correction is performed. Opening of the system is performed by circuit breakers.

It is sufficient to use one isolation transformer for performing isolation of all receptacles which are being feeded by a phase. This system is not widely used abroad or in Turkey, because it brings high cost problems. When this kind of distribution system is not used, the biomedical equipment should have their own isolation systems. Generally modern electromedical equipment have their isolation systems which may be optical isolation or transformer isolation. In view of this using special isolation systems is probably the best way to protect patients from most macroshock and microshock hazards if the power distribution system is not isolated.

14.4.3 Equipment Insulation

Insulation of biomedical equipment has special importance to protect patient against possibly hazardous conditions. In the designing of electromedical equipment great care is taken to prevent personnel from accidentally contacting the hot wire by the use of special insulating techniques and materials.

There are basically two types of insulation. One of them is known as primary insulation (Class I). It is the normal functional insulation between energized conductors and the chassis. The other insulation is protective insulation (Class II). This is also called

secondary insulation. A separate secondary layer of insulation between the chassis and the outer case protects personnel even if a ground fault to the chassis occurs. The outer case of the equipment is made of insulating material. In some cases all switches and control buttons, which are placed on the equipment, are also insulated.

In addition to the already explained accident prevention methods, there are some other factors that should be taken into consideration.

- * If it is possible, operation at low voltage ($< 8\text{ V}$) is used. But it should be known that low voltage ac-powered equipment can still cause microshock if the current is applied directly to the heart (e.g., external battery powered cardiac pacemaker).
- * If the power supply fails whenever several biomedical equipment are under working conditions, the equipment which has a vital importance for the patient should automatically begin to work. But if automatic working of the instrument may create a dangerous condition, the equipment should not begin to work automatically, but it should give warning signals to the medical staff for performing readjustment of the instrument.
- * Specially designed low-leakage power cards ($< 1.0\text{ }\mu\text{A/m}$) are used for reduction of leakage current. In other words leakage current inside the chassis can be reduced by using layouts and insulating materials that minimize the capacitance between all hot conductors and the chassis. On the other hand if the instrument has cord-storage compartment, the cord should be placed within this compartment when the equipment is stored for spare usage.

14.5 MAINTENANCE PROGRAM AND STAFF EDUCATION

A formal preventive maintenance of all equipment and inspection of power network distribution system should be performed periodically by the technical staff under the supervision of a biomedical engineer. Any adequate maintenance program could detect early, the following:

1. Frayed cords and plugs
2. Direct on low-resistance pathways from hot line to chassis
3. Broken ground wires
4. Uncalibrated equipment
5. Poor ground connection
6. Leakage from motor to frame in electrical bed and some others.

All the maintenance program for special care units such as CCU and ICU should include the following:

1. All the receptacles, plugs, voltage of all terminals should be checked periodically every month. Output power of all defibrillators are also controlled periodically every month.
2. Testing of leakage currents and potentials between instruments in the critical areas should be performed twice a month. On the other hand required calibrations of equipment should also performed very carefully periodically as frequently as possible.
3. All the externally powered cardiac pacemakers and blood pressure transducers should be controlled after the every usage.

4. The network voltage of the hospital, all receptacles, ground wire and lines that are used for performing equipotential grounding system should be checked periodically once a year.

In addition careful records should be kept of the inspection and maintenance procedure. That's why special tables and control cards should be prepared by the technical staff. On the other hand required safety analyzers and test equipment should be always available.

Furthermore education program for the medical staff should be prepared periodically. By this way, medical personnel can learn what they should do or not do and how they should work with electromedical equipment. Moreover the maintenance team and the biomedical engineer should be in contact with all personnel utilizing medical equipment, discussing with them their experiences in the case of equipment and trying to obtain up-to-date information from them concerning the equipment's operation. In short it can be clearly understood that all electromedical equipment users should be thoroughly familiar with instrument operation and the hazards resulting from misuse.

As a result adequate electrical safety in health care facilities can be achieved at moderate cost by combining a good-power-distribution system, careful selection of well-designed equipment and a modest training program for medical personnel.

15. REPORTS ON HOSPITAL STUDIES AND OPINIONS ABOUT THEIR CORONARY CARE UNIT ORGANIZATIONS

15.1 INTRODUCTION

In this chapter, organizations of the visited coronary care units will be discussed. The basic problems, which were observed during these visits, will be explained and then some opinions will be listed. Four different coronary care units were studied. Those were the coronary care unit organizations of the Cerrahpaşa Hospital, Haydarpaşa Gögüs Cerrahisi Hospital, the Etfal Hospital and the Medical University Hospital of Istanbul (Çapa Hospital).

15.2 CORONARY CARE UNIT ORGANIZATION IN THE CERRAHPAŞA HOSPITAL

In the Cerrahpaşa Hospital, the coronary care unit was established in 1973. The unit capacity is four beds. There is an additional bed in the unit. It is used as a spare place. But this bed was not equipped with the bedside equipment. That's why it is not included in the unit capacity. The schematic representation of the unit is shown in Figure 15.2.1.

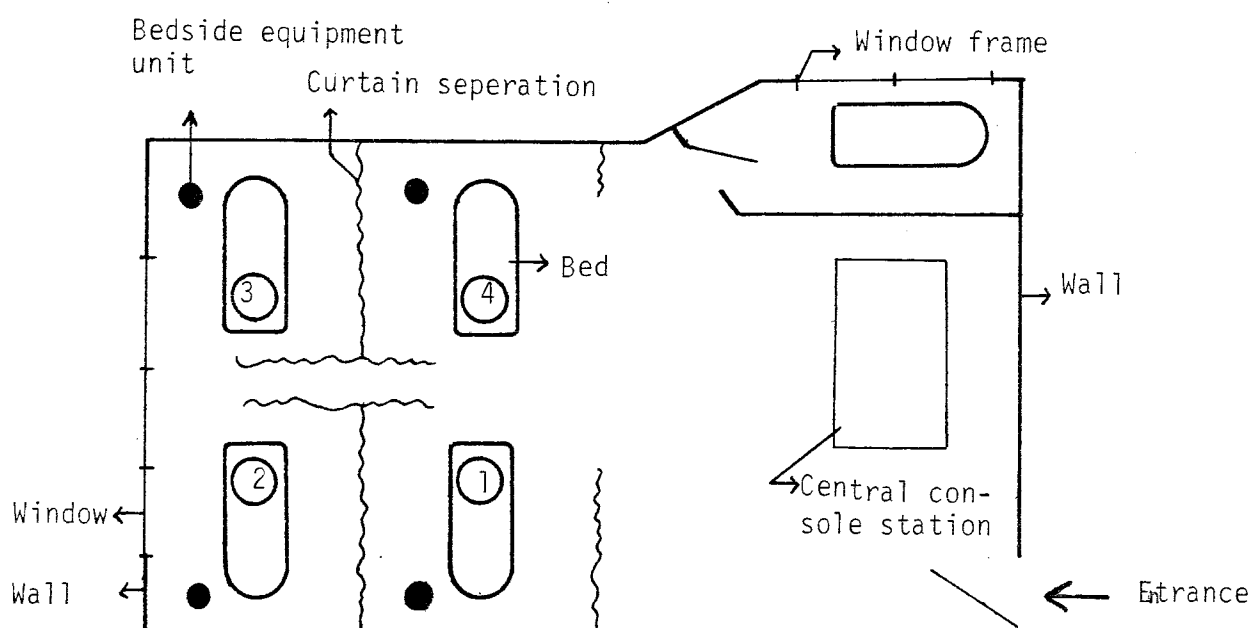


Figure 15.2.1 - Design scheme of the coronary care unit in the Cerrahpaşa Hospital.

The shape of the unit is almost rectangular. The separations of the patient rooms were realized by curtains. Marley was used as a floor covering material. The unit has no air-condition system. Generator system is available.

The bedside monitors in these four beds although manufactured by the same company unfortunately were not of the same model. The equipment list of the each bedside is given in Table 15.2.1.

The electrocardiograms and heart rates of the patients in this unit are being monitored continuously from the bedside equipment. These variables are also being displayed continuously on the central console. A 4-channel scope was installed on the central console unit. This scope

TABLE 15.2.1 - The Bedside Equipment List

Bed Number	ECG monitor with scope	Blood pressure monitor and alarm unit	Cardiotachometer and alarm unit	Arrhythmia monitor	Body temperature monitor	Respiration rate monitor	Cardiac pacemaker	Defibrillator	Resuscitator bag	Oxygen Unit	Air Unit	Vacuum unit	Humidifier	Recorder unit	Grounded bedside recaptacles	EEG monitor	Bedside lamp
1	Yes	No	Yes	No	No	No	No	No	No	No	No	No	No	No	4	No	No
2	Yes	No	Yes	No	No	No	No	No	No	No	No	No	No	No	4	No	No
3	Yes	No	Yes	Yes	No	No	No	No	No	No	No	No	No	No	4	No	No
4	Yes	No	Yes	No	Yes	Yes	No	No	No	No	No	No	No	No	4	Yes	No

is being used to perform continuous ECG observation of each patient. One ECG recorder unit was also installed on the central console. This unit is used to record the patients' ECG. In addition, four digital heart rate meters were installed on the central console, but the obtained measurements are not meaningful because the cardiotachometers and display units are not working properly. The installed heart rate monitor have alarm units, but they are also not working properly.

There is one line and battery powered cardiac pacemaker in the unit. This pacemaker works in two different modes which are fixed rate and demand pacing modes.

Two portable defibrillators are available within the unit. One of them has ECG scope but it has no recorder unit.

There are two portable ECG monitors. One of them is an obsolete model.

One manual resuscitator bag and one sphygmomanometer is available in the unit.

The personnel organizations of the unit is shown as follows.

<u>Personnel Organization</u>	<u>Daytime</u>	<u>Nighttime</u>
Doctor	2	1
Nurse	1	-
Untrained medical staff	2	2

Problems and Suggestions

When the Table 15.2.1 is studied carefully, it can be clearly understood that the unit was not established properly. Some equipment, which are very important for the cardiac patient, are not available such as blood pressure monitors, arrhythmia monitors, oxygen units, vacuum units and some others. These instruments should be installed on each bedside unit for obtaining efficient unit design. Moreover, all the heart rate monitors are not operating properly, because the 50 Hz ac. interference problems have not been solved yet. On the other hand the required calibration of the equipment is not being performed properly. These are some of the reasons which render taking adequate measurements from the patients almost impossible.

On the other hand a 4-channel scope was installed on the central console unit. This scope is too small to observe ECG of the patient continuously, because it has small screen. A small screen may cause some viewing problems and tire the eyes of the operator and sometimes cause at him the state of sleepiness.

The bedside illumination fixture was not installed. The unit was illuminated by using commercial fluorescence fixtures. This illumination is not sufficient for optimal coronary care unit design.

There are not any infusion pumps within the unit. Manually adjustable gravity flow clamp systems are being used.

The patient secrecy could not be achieved sufficiently, because only curtain was used as a separator.

The unit has no air-condition system. It will be better to have an air condition system installed, because only two patient rooms have windows (See Figure 15.2.1).

The medical personnel organization is not sufficient. Only one nurse is working within the unit during the day. She is not working at night. In addition two doctors and two untrained medical staff are working during the day. By night, one doctor and two untrained medical personnel are working within the unit. It can be clearly understood that minimum one more nurse should join the organization and she should work by night.

All the installed bedside equipment should be reorganized. In other words, required additional instruments should be installed on each bedside (e.g. blood pressure monitor, oxygen unit, vacuum unit, resuscitator bag and some other important instruments).

It will be better to change the installed 4-channel scope. Using large screen scope will be better for continuous electrocardiogram viewing.

Bedside illumination fixture should be installed on each bedside.

Maintenance and calibration programs should be organized as quickly as possible by the technical staff.

If it is possible, one air-condition should be installed in the unit for obtaining airy working condition.

Technical staff should be in contact with the medical personnel for finding what kind of problems exist within the unit. For example, why the heart rate of the patients cannot be displayed properly? Which equipment should be replaced by the new one? What kind of equipment does the unit need?

Minimum one nurse should join the medical staff organization. She should work at night within the unit.

As a result, well-trained technical staff organization under the direction of a biomedical engineer should solve the problems optimally as quickly as possible for obtaining efficient and optimal coronary care unit.

15.3 CORONARY CARE UNIT ORGANIZATION IN THE HAYDARPAŞA GÖĞÜS CERRAHİSİ HOSPITAL

The first section of the coronary care unit was established in 1974. The capacity of this section is five beds. Establishment of the second section of the coronary care unit was finished in 1982. The capacity of this section is four beds. In addition two more beds were placed within the unit, but the bedside equipment of these two beds were not connected to the central console station. These two bedside units are shown in Figure 15.3.1 by square shape. Only the nine bedside equipment were connected to the central stations. As it is shown in Figure 15.3.1, the five bedside equipment were connected to the first central console station and the other four bedside equipment were connected to the second central console station. The design scheme of this coronary care unit is given in Figure 15.3.1.

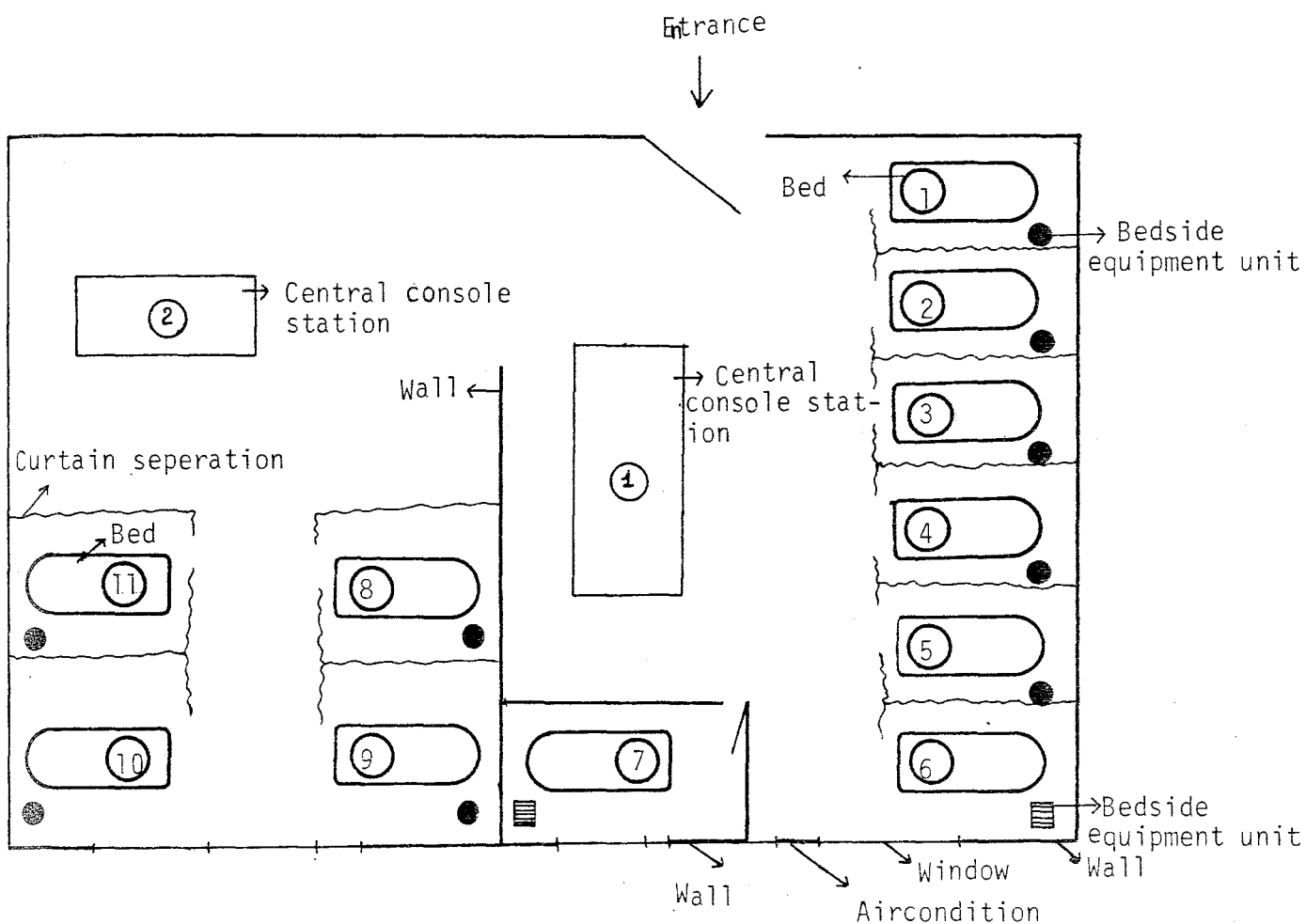


Figure 15.3.1 - Schematic representation of the coronary care unit.

The shape of the overall unit is rectangular. The curtains were used as a separator between the patients. Marley was used as a floor covering material. One air-condition was installed within the unit. The generator system is available.

The manufacture firm of the five bedside equipment is the same, but the installed five equipment do not perform the same functions. On the other hand the manufacture firm of the other six bedside equipment is also the same, but their models are different. In short it can be clearly understood that standardization was not kept in mind during the selection of the bedside equipment. The bedside equipment list is given in Table 15.3.1.

TABLE 15.3.1 - List of the Bedside Equipment. The Sixth and Seventh Bedside Equipment was not Connected to the Central Console Station.

Bed number	ECG monitor with scope	Blood pressure monitor and alarm unit	Cardiotachometer and alarm unit	Arrhythmia monitor	Body temperature monitor	Respiration rate monitor	Cardiac pacemaker	Defibrillator	Resuscitator bag	Oxygen unit	Air unit	Vacuum unit	Humidifier	Recorder unit	Grounded bedside receptacles	Bedside lamp
1	Yes	Yes	Yes	No	No	No	No	No	No	1	No	1	1	No	4	Yes
2	Yes	Yes	Yes	No	No	No	No	No	No	1	No	1	1	No	4	Yes
3	Yes	No	Yes	No	No	No	No	No	No	1	No	1	1	No	4	Yes
4	Yes	No	Yes	No	No	No	No	No	No	1	No	1	1	No	4	Yes
5	Yes	No	Yes	No	No	No	No	No	No	1	No	1	1	No	4	Yes
6	Yes	Yes	Yes	No	No	No	No	No	No	1	No	1	1	No	4	Yes
7	Yes	No	No	No	No	No	No	No	No	1	No	1	1	No	4	Yes
8	Yes	No	Yes	No	No	No	No	No	No	1	No	1	1	No	2	Yes
9	Yes	Yes	Yes	No	No	No	No	No	No	1	No	1	1	No	2	Yes
10	Yes	No	Yes	No	No	No	No	No	No	1	No	1	1	No	2	Yes
11	Yes	No	Yes	No	No	No	No	No	No	1	No	1	1	No	2	Yes

All bedsides were equipped with the wall mounted sphygmomanometer which is used for performing indirect blood pressure measurement of the patient.

The first five beds (1,2,3,4,5) were connected to the first central console station. This station was equipped with a 8-channel cathode ray tube display unit, a recorder unit, a cardiomemory unit and five digital heart rate display units. Continuous ECG observation of the patients are being performed by the 8-channel display unit. It was installed over the central console station. Recording of the patients' ECG can be performed by the recorder unit. The installed cardio-memory unit is not functioning. The five digital heart rate meters are being used for performing continuous observation of the heart rate of each patient. The installed heart rate display units have also alarm units. The other four beds (8,9,10,11) were connected to the second central console station which was equipped with a 4-channel cathode ray tube display unit, a recorder unit and four digital heart rate displays.

There are three compact portable equipment within the unit. One of them includes, a ECG with recorder, a cardiorate and a defibrillator unit. The second one includes a ECG with recorder and a heart rate meter. The third one includes a ECG without recorder but with a heart rate meter. On the other hand, there is one portable examination lamp in the unit. Two respirators are also available within the unit. The unit has no blood gas analyzer. If measurement of blood gas is required, the blood sample is sent to the post-operative intensive care unit which has a modern fully automated blood gaz analyzer.

<u>Personnel organization</u>	<u>Daytime</u>	<u>Nighttime</u>
Doctor	4	2
Nurse	5	4
Untrained medical staff	6	2

Problems and Suggestions

The heart rate measurements are not being performed properly. Because the equipment, which is used to measure the heart beat, are not being maintained and calibrated periodically. On the other hand 50 Hz ac. interference problem has not been solved yet. These are the reasons of faulty measurement. That's why these problems should be eliminated as quickly as possible.

All the bedside equipment do not have direct blood pressure monitor. It is recommended that direct blood pressure monitors are installed on each bedside unit. Because direct blood pressure measurement is very important for the cardiac patient.

The sixth and seventh beds should be connected to the central console station, otherwise these two beds cannot be taken into account of the unit capacity as long as they are not connected to the central console.

The seventh bed has no cardiometer. The cardiometer unit should be installed on the bedside unit as quickly as possible.

The technical staff organization should be organized under the direction of a biomedical engineer. This organization should make a proper maintenance and calibration programs for all equipment. In addition optimal required equipment list should be prepared by a medical committee whose members are doctors and a biomedical engineer.

There is no equipment standardization within the unit. Standardization should be obtained as completely as possible, otherwise some confusions may arise during the maintenance and calibration of the equipment. It is evident that learning operation instructions of the equipment should not be easy by the user if several types of equipment are used within the unit at the same time. For these reasons, standardization is important during the selection of equipment.

Nobody knew where the service manuals of all the equipment were preserved. In other words, there are not any documents about the equipment that are being used within the unit. From this point of view it can be clearly understood that there is no good organized documentation center. In short a documentation center should be organized as quickly as possible.

As a conclusion, organization of a medical committee should be formed and then all the problems, developments and some other findings should be discussed in the meetings for obtaining optimal and efficient coronary care unit operation.

15.4 CORONARY CARE UNIT ORGANIZATION IN THE ETFAL HOSPITAL

The coronary care unit organization in this hospital was established in 1982. The unit capacity is six beds. The shape of the room is almost rectangular covering about 100 m^2 . The patient room separation was achieved by using curtains. One air-condition was installed in the unit. Marley was used as a floor covering material. Generator is not available. The design scheme of the unit is shown in Figure 15.4.1.

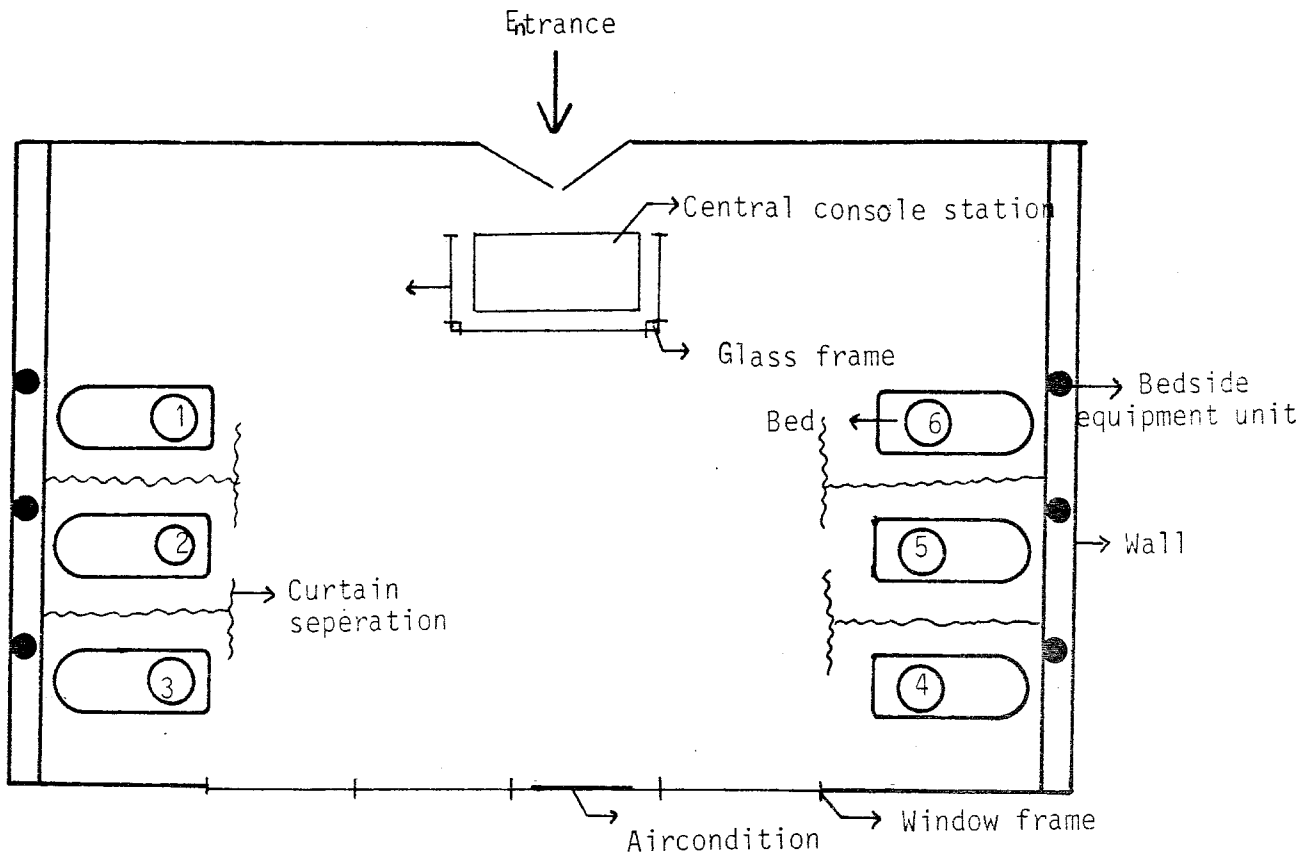


Figure 15.4.1 - Schematic design of the coronary care unit in the Etfal Hospital.

Five beds have the same type bedside monitors, but the sixth one has different monitor type. The equipment list of each bedside unit is given in Table 15.4.1.

TABLE 15.4.1 - The Equipment List of the Bedside Unit.

Bed number	ECG monitor with scope	Blood pressure monitor with alarm unit	Cardiotachometer and alarm unit	Arrhythmia monitor	Body temperature monitor	Respiration rate monitor	Cardiac pacemaker	Defibrillator	Resuscitator bag	Oxygen unit	Air unit	Vacuum unit	Humidifier	Recorder unit	Grounded bedside receptacles	Bedside Lamp
1	Yes	No	Yes	No	No	No	No	No	No	1	No	1	1	No	3	No
2	Yes	No	Yes	No	No	No	No	No	No	1	No	1	1	No	3	No
3	Yes	No	Yes	No	No	No	No	No	No	1	No	1	1	No	3	No
4	Yes	No	Yes	No	No	No	No	No	No	1	No	1	1	No	3	No
5	Yes	No	Yes	No	No	No	No	No	No	1	No	1	1	No	3	No
6	Yes	Yes	Yes	No	No	Yes	No	No	No	1	No	1	1	No	3	No

Electrocardiograms and heart rates are being monitored by these installed equipment. But heart rate monitoring is not being performed properly, because calibration of the units are not being performed properly and periodically. On the other hand 50 Hz ac interference problem has also not been solved yet by the technical staff. The interesting point is that the central console station was not equipped with a cathode-ray tube display unit. In short, the electrocardiogram of the patient cannot be observed continuously from the central console unit. Only digital displays of the heart-rate monitors and a 6-channel ECG recorder was installed in the central console station.

There is one compact portable unit that includes ECG monitor, defibrillator and cardiac pacemaker. This pacemaker unit works on two different modes which are fixed rate and inhibited modes.

There is only one conventional sphygmomanometer in the unit. It is used for indirect blood pressure measurement. Direct blood pressure measurement is usually not performed within the unit.

Manual resuscitator bag is not available in this unit. It is borrowed from ICU when it is necessary to use it.

Respirator units, infusion pumps are also not available. The personnel organization is shown as follows.

<u>Personnel Organization</u>	<u>Daytime</u>	<u>Nighttime</u>
Doctor	1	1
Nurse	3	1
Untrained medical staff	2	1

Problems and Suggestions

The place of the coronary care unit within the hospital was chosen fairly well. But the unit has a lot of problems such as lack of equipment and technical staff organization. In short this unit can not be called a coronary care unit under this organization. In view of this first of all technical staff organization should be realized under the direction of a biomedical engineer. Then this organization should prepare a list about the required equipment that they should be installed as quickly as possible for obtaining optimum coronary care unit design.

As it is known the unit has no cathode-ray tube display unit. First of all this display unit should be installed on the central console station as quickly as possible.

Wall-mounted conventional sphygmomanometer unit should be installed on each bedside of the patient.

Minimum two resuscitator bags should exist within the unit.

Installation of blood pressure monitor on each bedside unit should be done as quickly as possible.

The list of required auxiliary equipment should be prepared such as cardiac pacemaker, defibrillator.

Maintenance and calibration program should be prepared by the technical staff which should work under the direction of a biomedical engineer.

Present problems should be listed and then they should be solved by the technical staff organization.

Those are some suggestions that they should be followed by the technical and medical staff, who works in the Etfal Hospital, for preparing optimal and efficient working condition within the coronary care unit.

15.5 CORONARY CARE UNIT ORGANIZATION IN THE MEDICAL UNIVERSITY OF ISTANBUL (Çapa Hospital)

The coronary care unit was established around 1976-77. The capacity of the unit is eight beds. The shape of the unit is almost inverted "U" shape. A similar design shape of this unit is shown in Chapter two, Figure 2.2. . Glass, curtain and wall was used as a

separation material between the patient rooms. All the patients have their own separate room. That's why secrecy was obtained very perfectly. Marley was used as a ground covering material. Aircondition system is not available within the unit, but the generator is available. In short the unit is very airy and the localization of the patient bed, the bedside equipment and the central console station were fairly well organized. Nevertheless the unit has some problems which will be discussed later.

The list of each bedside equipment unit is given in Table 15.5.1.

There is no equipment standardization for the bedside equipment that are being used. Some bedside units have blood pressure monitors but some of them have not. Five rooms have wall-mounted sphygmomanometer units for performing indirect blood pressure measurement. In short, different type of bedside equipment were installed within the unit, that's why the same type of variables are not being monitored from the each bedside equipment unit. The great part of the cardiometer and blood pressure equipment are not operating properly, because their maintenance and calibration are not being performed periodically and suitably. Only a few of them (one or two) are working properly.

All the bedside equipment were connected to the central console station. A 8-channel cathode ray tube display unit was installed over the central console for performing continuous observation of each patient's ECG. The central console station was also equipped with two recorder units, eight digital blood pressure display units, eight digital heart rate meters and alarm units. The recorder units are

TABLE 15.5.1 - The Bedside Equipment List of Each Patient.

Bed number	ECG monitor with scope	Blood pressure monitor and alarm unit	Cardiotachometer and alarm unit	Arrhythmia monitor	Body temperature monitor	Respiration rate monitor	Cardiac pacemaker	Defibrillator	Resuscitator bag	Oxygen unit	Air unit	Vacuum unit	Humidifier	Recorder unit	Grounded bedside recaptacles	Bedside lamp
1	Yes	No	Yes	No	No	No	No	No	No	Yes	No	Yes	2	No	5	Yes
2	Yes	No	Yes	No	No	No	No	No	No	Yes	No	Yes	2	No	5	Yes
3	Yes	Yes	Yes	No	No	No	No	No	No	Yes	No	Yes	2	No	5	Yes
4	Yes	Yes	Yes	No	No	No	No	No	No	Yes	No	Yes	2	No	5	Yes
5	Yes	Yes	Yes	No	No	No	No	No	No	Yes	No	Yes	2	No	5	Yes
6	Yes	Yes	Yes	No	No	No	No	No	No	Yes	No	Yes	2	No	5	Yes
7	Yes	No	Yes	No	No	No	No	No	No	Yes	No	Yes	2	No	5	Yes
8	Yes	Yes	Yes	No	No	No	No	No	No	Yes	No	Yes	2	No	5	Yes

being used for taking hard copy of the electrocardiogram. The blood pressure display units and heart rate meters were not operating properly because some of them have not been calibrated and some of them have not proper connection to the patient. In addition the central console station was also equipped with the cardio memory equipment which were not operating. In short only recorder units and 8-channel display unit are operating properly.

There are two portable defibrillators within the unit. They include ECG monitors and recorders, but they have not any scopes. These equipment are being used for performing defibrillation and cardioversion. On the other hand one compact portable electrocardiograph unit is available. It includes recorder, heart-rate meter and defibrillator. Furthermore there is one more portable electrocardiograph.

Generally two or three portable cardiac pacemakers always exist within the unit. If more than two or three are required, they are borrowed from the catheterization laboratory.

Two infusion pumps, an automated blood gas analyzer, a ventilator, two resuscitator bags, a portable x-ray machine, an aspirator, two patient examination beds and one refrigerator is available within the unit. The personnel organization of the unit is shown as follows.

<u>Personnel organization</u>	<u>Daytime</u>	<u>Nighttime</u>
Doctor	1	1
Nurse	3	2
Untrained medical staff	1 or 2	1

Problems and Suggestions

The hospital does not have a well-trained technical staff organization that should work under the direction of a biomedical engineer. There is also not a consultant committee which gives any information and solutions to the equipment users and doctors about the problems and recent developments. In view of this, first of all a well-trained technical organization should be realized by a biomedical

engineer. This organization staff should be in contact with the doctors and equipment users for obtaining information about the problems. On the other hand the equipment lists should be prepared and then proper calibration and maintenance programs should be followed according to the prepared equipment lists. The broken equipment should be repaired as quickly as possible and the unrepairable equipment should be replaced by new ones. It is obvious that the standardization of the instruments should be taken into consideration during the replacement of the equipment. All the basic important variables such as electrocardiogram, blood pressure, heart rate, respiration rate should be measured from the installed bedside equipment. Nevertheless, at the same time all the imperfectly installed equipment should be reorganized.

All the equipment that was installed in the coronary care unit should be operated properly by the doctors and nurses. That's why some courses and seminars should be organized for providing information to the medical staff about the medical equipment usage. During the visiting of the unit, it was observed that only one nurse can use the blood gas analyzer unit. The other medical personnel even doctors do not know how the blood gas analyzer unit works. In short education programs should be organized as perfectly as possible within the hospital environment.

Some basic problems and suggestions are mentioned above. If the problems, which are explained briefly, are solved as quickly as possible, the optimal efficient unit organization may be obtained.

16. COMPUTER FOR CORONARY CARE MONITORING

16.1 INTRODUCTION

The modern digital computer is a special type of calculating machine capable of automatically performing a long and complicated sequence of operations as directed by a set of instructions stored within the machine. In addition to its computation ability, the computer can store and retrieve large quantities of information and can automatically alter its sequence of instructions on the basis of calculated results.

Using digital computers in the medical fields such as patient monitoring in the coronary care unit has become popular in recent years as a result of recent developments in the microprocessor field. As it is known the computerized system provides rapid and accurate calculations of biological variables and also provides automatic display, recording and alarming. Nevertheless, establishing computerized systems such as computerized monitoring system bring financial problems for the hospital organization. That's why during the decision making on designing of a unit such as CCU, ICU and others, feasibility reports should be prepared very carefully for obtaining optimal and efficient unit design within the hospital environment.

16.2 THE DIGITAL COMPUTER IN PATIENT MONITORING

When the patient monitoring system includes a digital computer, the ability of the equipment to detect physiological condition of the patient for providing useful information to the physician can be greatly increased, because such a system has automatic monitoring, display, alarming and recording properties. On the other hand keeping medical history and retrieving all the information which has been recorded into the computer memory can be done correctly, easily and quickly.

Basic computerized monitoring organization is shown in Figure 16.1.

The system's hardware is located in a specially designed and furnished room in the hospital. All the minicomputers which are installed within the unit are connected to the main computer center. The minicomputers are used for preventing over loading of the main computer memory unnecessarily. In other words some information that they are not being used as a long time is not sent to the main computer memory for preventing over loading condition. All the drawn links provide information between the terminals. In some design types, collecting information about one patient condition can be performed from the bedside terminal which is installed on each patient bedside unit. In short, from each of the installed terminals, the staff can chose the parameters to be automatically monitored for a given patient, enter and retrieve data and view of the displays in digital form or graphical form.

In the computerized patient monitoring system, the computer is simply attached to a conventional analog patient monitor to store and analyse information. The obtained results can be displayed and recorded

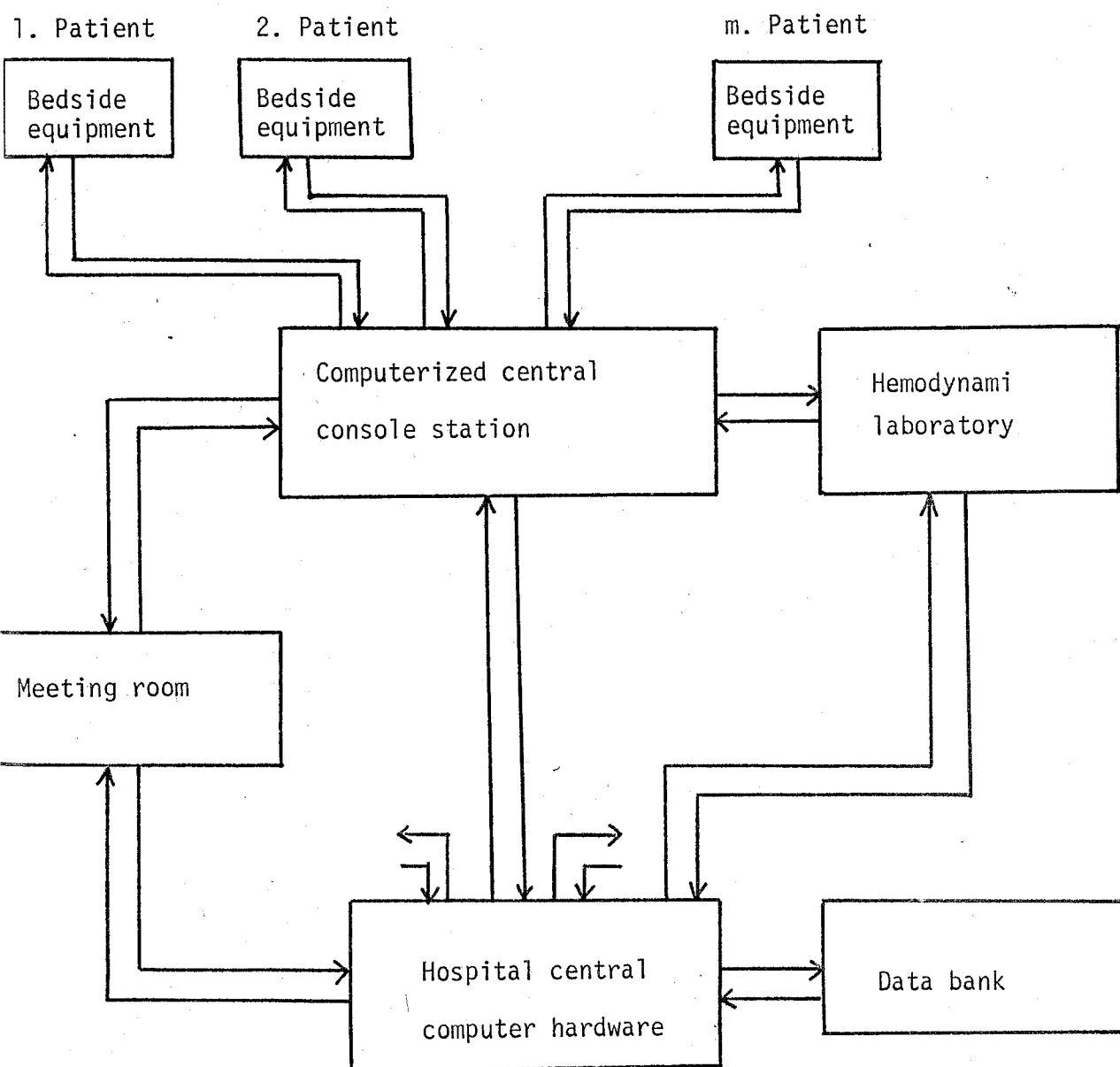


Figure 16.1 - Basic blocks of computerized monitoring organization.

automatically. For computer entry the obtained analog signals should be converted into digital form and then the obtained digital output data can be converted into analog form for display. For this reason all the computer systems have to have analog-to-digital and digital-to-analog converters.

More often, computerized equipment in addition of storing, analysing, displaying and recording of data can filter the signals from the noise and artifacts. On the other hand it acts as an alarm unit. It gives audible and visual alarms if something goes wrong.

Typically analyzed and derived parameters for monitoring are:

- Electrocardiogram Detection of premature beats in predetermined time interval,
Detection of successive anomalous beat number (e.g. area increase, QRS increase, polarity reversal)
Detection of multi formal beat.
- Arrhythmia Arrhythmia detection by R-R interval and sampling of waves determination.
The object of the arrhythmia analysis program is simply to detect and classify abnormal beat and also alarming the dangerous conditions.
- Blood pressure Systolic, diastolic and mean blood pressure monitoring.
- Respiration rate
- Body temperature

and some others (e.g. blood gas analyzing).

16.3 COMPARISON BETWEEN COMPUTERIZED AND CONVENTIONAL MONITORING SYSTEMS

As it is known, the conventional patient monitoring methods are being used widely in the hospitals in Turkey as well as in foreign countries. Because the conventional noncomputerized monitoring system is easier to use and it also requires lower installation cost with respect to the computerized monitoring system. On the other hand the conventional patient monitoring instruments have not complicate structures that's why calibrations and maintenance of them are easier than the complicated computerized equipment. Furthermore the conventional systems do not require special training of the medical staff such as education of programming languages. Nevertheless, the conventional patient monitoring systems have some disadvantages which are:

- * high time consuming for evaluation of the data with the great number of medical staff requirement for obtaining efficient patient monitoring,
- * impossibility of retrieval of the entered data or/and calculated data from the different places within the hospital environment,
- * low storing capacity.

The advantages of computerized patient monitoring are listed below:

- * high storage and calculation capacity

- * Low time consuming for evaluation of the data
- * Less medical personnel necessity
- * Possibility of manually patient data entering, retrieving information on-line and keeping medical records.
- * Collecting, displaying and reporting large quantities of data information at a rapid rate
- * Providing flexible unit design
- * Elimination of voluminous patient files, and creation of files in the computer memory
- * Increasing unit working efficiency.

In view of this, all the mentioned factors under the economical condition of the hospital and the country and the education programs of the universities should be taken into consideration during the decision making on what kind of equipment and patient monitoring systems are going to be installed in the unit for obtaining an optimal and efficient unit. In short feasibility reports on the unit design should be prepared carefully by the well trained medical staff and a biomedical engineer.

CONCLUSION

The main goal that was aimed at in the preparation of this thesis was to determine a procedure to be followed in setting up a coronary care unit. In addition to the selection of the necessary equipment their basic operation principles and their optimum placement in the unit that ensures best performance of the unit was investigated. The architectural design of the coronary care unit, the properties of the electrical network and methods of protection against electrical hazards were also discussed in a practical manner suited to our times.

On the other hand, the coronary care units established in four hospitals currently functioning in Istanbul were investigated. In addition to giving information about these CCU's, their major shortcomings are determined and simple solutions for these are suggested in the thesis. In the preparation of the thesis the economy and industry of the country are taken into consideration therefore the employment of highly complicated computerized monitoring systems in CCU's already established or yet to be established is not stated as a requirement. However, the instruments of a computerized unit and their main benefits are mentioned in a chapter.

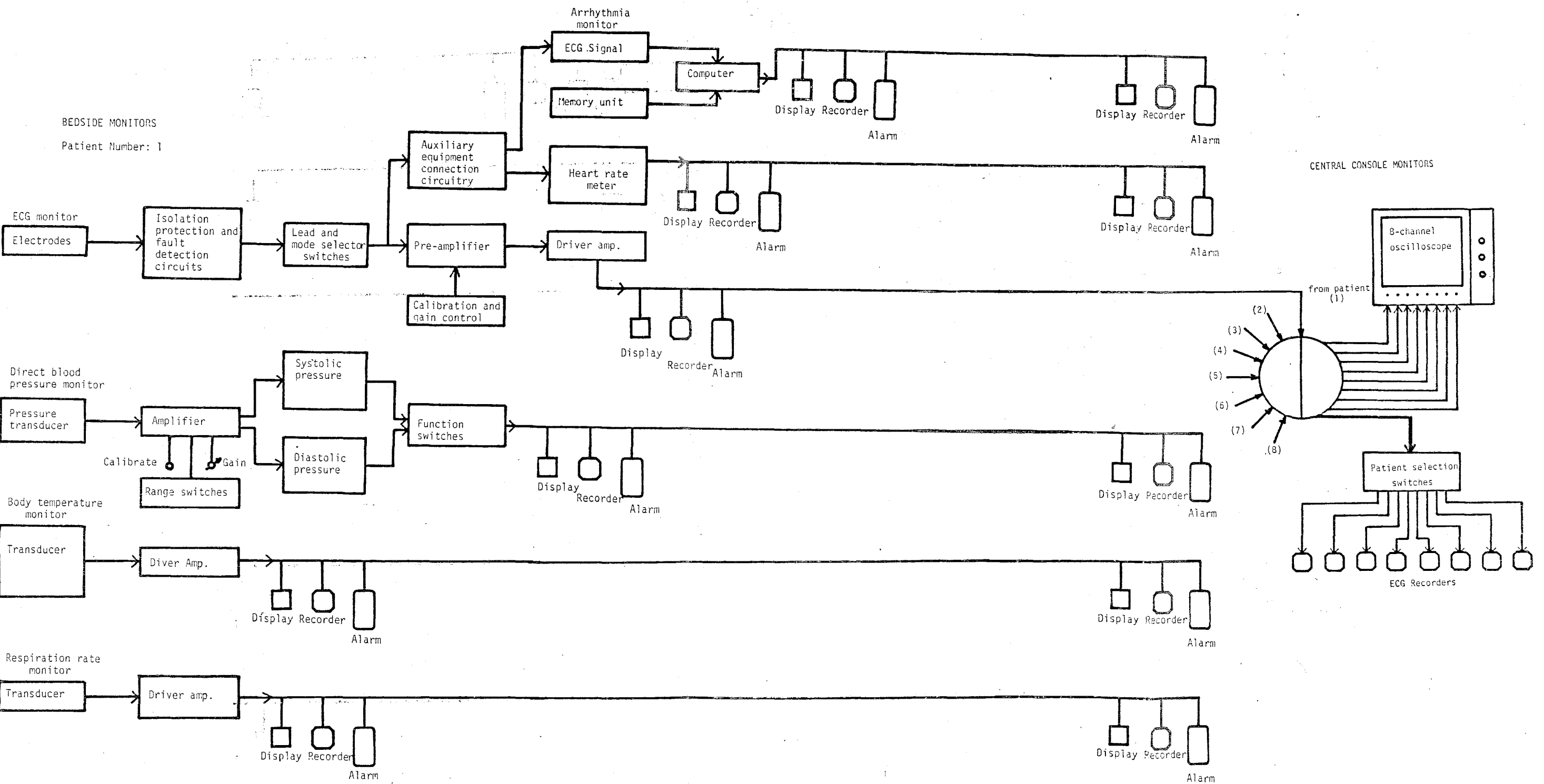
One important point that must be noted is that most of the mentioned devices are produced in our country. It is certain that the employment of these devices in the coronary care units, that are aimed to be set up optimally will both cause the improvement of the products in time and at the same time have a positive effect on the economy of the country. One remark that must be made here is the necessity of manufacturing firms to cooperate with sufficient number of biomedical engineers. In this way, the production of the devices will be supervised by biomedical engineers having thorough technical knowledge. It is also our opinion that the biomedical engineers employed by the manufacturers will help develop and improve the close cooperation that must be established between the manufacturing firms and the users of the products.

It is my hope that this thesis constitutes useful source of information for the initiators and administrators of CCU's as well as the general reader.

APPENDIX

I

A schematic representation of the bedside and central console monitors



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