

FREQUENCY OF FALSE ELECTROCARDIOGRAM ALARMS IN THE  
INTENSIVE CARE UNIT/CORONARY CARE UNIT

by

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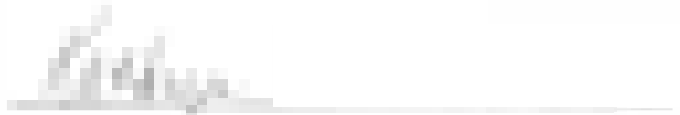
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## ABSTRACT

The purpose of this study was to determine how often a false electrocardiogram (ECG) alarm occurred in an intensive care unit (ICU) or coronary care unit (CCU). Nine patients were monitored for 12-1/2 hours. The false alarms that occurred were documented and the cause was noted. Five patients were male with a mean age of 64 years, and four were female with a mean age of 57. Two patients were studied in the Respiratory (RICU), two in the Thoracic (TICU), and five in the CCU.

The investigator studied whether a monitor could be developed that would be able to decrease the false alarm frequency by using a multiple ECG signal system, or a multiple physiologic signal system with the addition of an arterial pressure waveform. Fourteen false alarms occurred during the monitoring period with one true alarm. The frequency of false alarms was 4.2 in the RICU, 12.6 in the TICU, and 10.5 in the CCU; showing a much higher rate of false alarms per patient in the RICU.

The frequency of false alarms could have been reduced by 60% with the addition of a multiple ECG signal

system. Use of a multiple physiologic signal system however, would eliminate all of the false alarms and, therefore, would be a better system. No monitor that utilizes such a system has been developed, but it would be a great benefit to reduce the stress and noise level in the ICU/CCU.

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## CHAPTER I

### INTRODUCTION AND REVIEW OF LITERATURE

#### Purpose

The purpose of this study was to determine the frequency of false heart rate alarms which occur during monitoring of patients in intensive care units (ICUs). At the same time, an analysis of potential reduction in false heart rate alarms was examined by using multiple signals (three electrocardiogram [ECG] signals and an arterial pressure waveform). Frequent false heart rate alarms in an intensive care unit (ICU) are distressing to patients and an added stressor for the nursing staff. If the false alarm frequency can be reduced by using multiple signals, a bedside monitor could be developed to reduce the false alarm rate. Such a monitor would then be an asset to the nursing staff, as well as an added protection for the patient.

#### Problem Statement

Frequent false alarms are disturbing to nursing personnel and patients, and can lead to alarms being shut off or a widening of alarm limits, thereby increas-

ing the possibility of a true alarm being missed (Porciello, 1980; Zeelenberg, Duetsch, Engelse & Corbeij, 1977).

Most ECG monitors currently in use, alarm only high or low heart rate conditions. Many factors can cause false heart rate alarms by interfering with the accurate detection of the ECG signal from which the heart rate is determined. Some factors include: loose ECG cables; dried electrode gel; muscle artifact; electrode movement; baseline shift; shivering; and 60 Hz baseline noise on the monitor (Feldman, 1977; Feldman & Hubelbank, 1977; Smith, 1984; Zeelenberg et al., 1977). A missed true alarm is catastrophic to the patient. The use of multiple physiologic signals (three ECG signals, arterial pressure waveform) to determine heart rate, may reduce the incidence of false alarms. If the multiple signal concept is valid and reliable, the alarms would then be more accurate, thus relieving nursing staff of added stress and protecting patients.

The focus of this study was to assess how often false ECG alarms occurred in an ICU/CCU setting during a 12.5 hour period of time.

#### Review of Literature

In the early 1960s, the need for a centralized facility to monitor patients with acute myocardial infarctions was recognized. The coronary care unit (CCU)

was established to fulfill this need (Goble, Sloman & Robinson, 1966). The primary impetus was the necessity of monitoring patients' cardiac status in order to manage life-threatening arrhythmias (Bloomfield, Slivka, Vossler & Edelstein, 1970). Sixty percent of deaths in patients with myocardial infarction (MI) occurred within the first week, and the majority of those within the first 24 hours (Breu & Gawlinski, 1981; Goble et al., 1966; Lustig, Cohen, Ransil & Abelmann, 1978). A significant reduction (30 to 50%) in patient mortality resulted from early detection of arrhythmias (Bain, Siskind & Neilson, 1981; Hulting, 1979; Muirhead, 1980). The benefit of this monitoring system was soon realized and became a routine part of patient care in intensive care units (critical care - Consensus Conference, 1983).

Several studies support the finding that early detection of arrhythmias reduced mortality rate. In an early study (Goble et al., 1966), the mortality rate in patients with severe myocardial infarction was 45%; with 25% of those occurring within the first 24 hours, and 50% within the first week. The incidence of serious arrhythmias associated with mortality was 56%.

In another analysis of the relationship between arrhythmias and mortality, sinus tachycardia, supraventricular tachycardia, and third degree atrioventricular block were associated with a mortality rate of approxi-

mately 50% (Bloomfield et al., 1970). In this study, the incidence of arrhythmias and mortality associated with each was recorded before and after the establishment of a CCU. Mortality associated with ventricular fibrillation was reduced from 71% to 44%; that of ventricular tachycardia from 50% to 14%; and atrial fibrillation from 60% to 12.5%. The reduction in mortality was attributed to recognition and prompt treatment of the arrhythmia.

Several other studies indicate that most conventional heart rate alarm systems on ECG monitors were inaccurate and frequently failed to detect isolated premature ventricular depolarizations (PVDs), premature atrial depolarizations (PADs), and serious ventricular arrhythmias (Frost, Yanowitz & Pryor, 1977; Romhilt, Bloomfield, Chou & Fowler, 1973; Vetter & Julian, 1975). Documentation has shown that one PVD can trigger ventricular tachycardia or ventricular fibrillation (Feldman, 1977). The heart rate alarm system is also not sensitive to transient changes in the heart rate and a sudden conduction disturbance may not be detected due to the built-in time delay (Hulting, 1979).

The primary motivation for the development of computerized arrhythmia detection and alarm systems was the high failure rate of the conventional heart rate alarm system to detect lethal arrhythmias. With an



increase in the number of patients being monitored simultaneously, the accuracy of visual monitoring decreased. Constant observation of the monitor screen became very tedious, and the demands on the unit personnel greater. Computerized monitoring is not totally infallible. However, it has a very high detection rate when compared with visual monitoring and conventional alarm systems (Hultgren, Shettigar & Specht, 1975; Muirhead, 1980; Romhilt et al., 1973; Sanders & Harrison, 1982; Vetter & Julian, 1975).

One study simultaneously monitored patients with a computer system and a conventional analog heart rate alarm system. In both systems, the false heart rate alarms were primarily due to artifact from patient movement. The computer generated 79 alarms, 37 (47%) of which were false alarms. During the same period, 167 analog alarms occurred, of which only 13 (8%) were true alarms. Computerized monitoring showed significant advantages in that false alarms due to artifact decreased by 75%, and recognition of true alarms increased by two and one half times (Frost et al., 1977).

Computerized monitoring of arrhythmias is costly to implement and many hospitals cannot afford to establish such a system. Therefore, most ICU/CCUs rely on the conventional ECG monitors and nurses to detect arrhythmias. A good signal is vital to ECG monitoring,

whether conventional or computerized (Sanders & Harrison, 1982; Smith, 1984; Zeelenberg et al., 1977). The signal is transmitted to the monitor from three electrodes through a cable. Many factors can interfere with the detection and transmission of this signal the most important of which is the patient-electrode interface. Problems with the skin, gel, electrode, and cable can cause artifact or breaks in the signal transmission. Baseline shifts which occur with patient movement also cause artifact and contribute a source of error (Feldman, Hubelbank, Haffajee & Kotilaineau, 1979; Lustig et al., 1978). Muscle interference, increased or decreased ECG signal amplitude, 60 Hz baseline interference-signal artifact, and increased or decreased amplifier sensitivity, can cause high noise levels in the system and produce false alarms (Frost et al., 1977; Lustig et al., 1978; Shah, Arnold, Haberern, Bliss, McClelland & Clarke, 1977; Smith, 1984; Uhley, Brown, Friedman, Rosenblum, Sherman, Stucki & Wilson, 1970; Zeelenberg et al., 1977). Frequent false alarms cause decreased staff compliance with, and confidence in the system; staff and patient annoyance and irritation; and, patient anxiety and apprehension. The major danger, however, is that frequent false alarms will decrease staff sensitivity to the alarm situation so that when a true alarm occurs, it will be ignored or there will be a delay in responding

to it (Feldman et al., 1979).

A study done in Italy tested the reliability of the assumption that use of alarms in the CCU reduced the workload of the nurses and doctors as well as improved the quality of care (Porciello, 1980). The results were very subjective as questions relating to perceived reliability of the monitor alarms were asked of the 22 staff nurses and 11 doctors in 11 different CCUs. No testing was done at that time to verify the perceptions, and the types of monitors in use were not identified except that they all had heart-rate acoustic and flashing light alarms. According to those interviewed, 3% said that the alarms never occur; 19% that "many" patients and 50% "more than one" patient had cardiac arrests or serious arrhythmias that failed to trigger the alarm. Almost all of those interviewed (94%) believed that the alarms occurred falsely and nine out of the 11 CCUs had turned off the audible alarm soon after the equipment was installed. Most of those interviewed (69%) believed that the alarms were useful. The remaining 31% believed the alarms were needless and one of those commented that they were harmful because of the disturbing effect on the patient. Seventy-two percent said they never rely on the alarms. Six CCU nurses accustomed to working with both the simple heart-rate and Argus Sentinel computerized arrhythmia alarms

were asked why they disregarded the computer alarm. Their unanimous reply was that the computer did not give any additional real information over the bedside heart-rate alarm.

Multiple signal systems are not new but few institutions use these systems routinely for monitoring in ICU/CCU settings. Two-signal systems have been used for several years in ambulatory (Holter) ECG monitoring so that artifact-free signals can be selected for analysis (Bragg-Remschel & Harrison, 1980; Nolle, 1977). Two-signal systems have been developed for research purposes using one skin signal with one intraatrial signal and one skin signal with another from the endotracheal tube (Bernard, Sajet, Demeester, Vainsel & Rey, 1977; Mantle, Strand & Wixson, 1978; Mylrea, Calkins, Carlson & Saunders, 1983), but these are invasive and therefore have limited applicability as routine measures in the ICU/CCU. Twelve and 15 electrode systems, which run three signals simultaneously, are routinely used for diagnostic purposes. Feldman in several papers, foretold the tendency towards multisignal systems to improve discrimination against artifact and noise in the system (Feldman, 1977; Feldman & Hubelbank, 1977). The TELAVIV System developed by Rosenberg and Tartakovsky (1979) was designed for analysis of long-term ECG records. The authors demonstrated increased sensitivity

and specificity using three signals; however, they were not used in an ICU/CCU setting. All authors point out the primary advantage of a multiple signal system: to discriminate noise and artifact from true aberrancy. Use of this type of monitor in an ICU/CCU setting would decrease the number of false alarms, increase patient/staff compliance and satisfaction, and decrease the alarm "Irritation Factor."

Due to the physical setting and nature of CCUs, patients are subjected to sensory overload. Noise is one of the major sources of stress and frequently limits the quantity and quality of sleep which often results in sleep deprivation. Response to noise depends on the patient's ability to interpret the source and meaning of the noise. The ICU patient may perceive all noises as confusing and/or potentially life-threatening. Stressors act synergistically rather than additively and can thus cause the body to overreact to acute illness. Patients with an MI can experience tachycardia, arrhythmias and hypertension because of excessive epinephrine release and increased sympathetic tone due to increased stress (Hansell, 1984; Harris, 1984). Noise reduction by reducing false ECG alarms should help to decrease the stress of both patients and nurses.

#### Conceptual Framework

As part of routine ICU care, all patients are

attached to an ECG monitor that measures heart rate, and alarms if the preset limits are violated. Many factors can affect the detection of the heart rate and cause false alarms. False positive alarms are those that indicate an increased or decreased aberrant heart rate when the heart rate is within the alarm limits. Factors that can cause false positive heart rate alarms include: increased amplitude of the ECG signal, artifact, 60 Hz baseline noise, muscle movement, baseline shift, increased sensitivity of the ECG amplifier, and shivering. A false negative alarm occurs when an alarm state is present and no alarm is triggered on the monitor. Factors that can interfere with the transmission of the ECG signal include: decreased ECG signal amplitude, loose or disconnected cables, loose or disconnected electrodes, dried electrode gel, and poor electrode contact (Meltzer, Pinneo & Kitchell, 1977; Smith, 1984). Most heart rate monitors have a ten second time delay in the heart rate alarm which is used to minimize isolated episodes of artifact and decrease the number of false alarms. It also results in episodes of single ectopic heart beats or multiples thereof being ignored (Hulting, 1979).

Frequent false alarms annoy and irritate staff and patients. The patient may become anxious and apprehensive as well. Frequent false alarms may cause the

nursing staff to become insensitive to or delay in responding to a true alarm, thus posing a danger to the patient (Sanders, Alderman & Harrison, 1974).

One approach to resolving this potential problem is use of additional ECG signals and/or the arterial pressure waveform to determine the heart rate. This would permit monitoring of multiple signals so that if one signal fails, the others remain intact and reflect the true status of the patient. Thus false alarms might be reduced by having alternative monitoring signals available, to be relied upon when one of the signals fails (see Figure 1).

The heart rate is displayed on the bedside monitor and two additional ECG monitors. False alarms can be generated by many factors such as increased or decreased waveform amplitude; increased or decreased sensitivity, 60 Hz interference, muscle movement, baseline shifts, shivering, loose/disconnected leads or cables, loose/disconnected electrodes or wires, dried electrode gel, or poor electrode pad contact. Frequent false alarms can lead to decreased nursing sensitivity to alarms, nurse and/or patient annoyance and irritation, ignorance of a true alarm state, patient anxiety and, decreased patient and/or nurse reliance on the monitoring system.

The use of multiple physiologic signals however, will decrease the false alarm frequency by decreasing

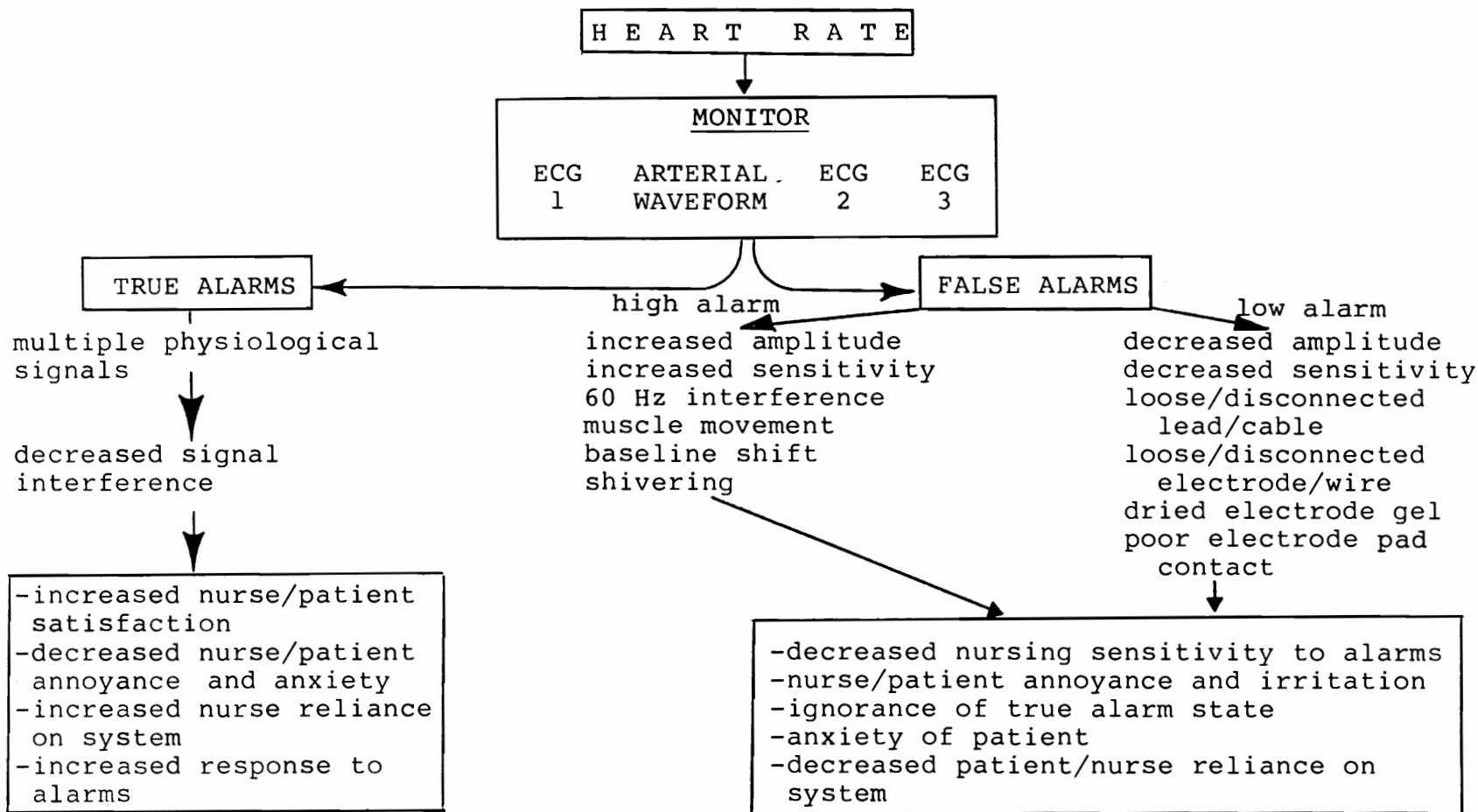


Figure 1. Model representing the conceptual framework.



signal interference. A reduction in the false alarm rate results in increased nurse and/or patient satisfaction, decreased nurse and/or patient annoyance and anxiety, and enhanced nurse response to alarms.

#### Conceptual Definitions of Variables

For the purposes of this study, the following key variables were conceptually defined:

1. ECG signal: The transmission of electrical impulses originating from the heart passing through skin electrodes to a signal processor with heart rate analog meter, and displayed on a Cathode Ray Tube (CRT) screen, with signal storage on magnetic tape.

a. Single signal ECG monitoring system: The use of three electrodes to transmit electrical impulses to the CRT. The three electrodes consist of positive, negative, and ground electrodes. The impulse current flows from the negative to the positive electrode as diagrammed in Figure 2.

b. Three signal ECG monitoring system: Use of the single signal system with the addition of two more ECG signals consisting of six more electrodes. See Figure 2 for placement.

2. Arterial pressure waveform signal: The transmission of the arterial blood pressure waveform through a pressure transducer to a signal processor with analog

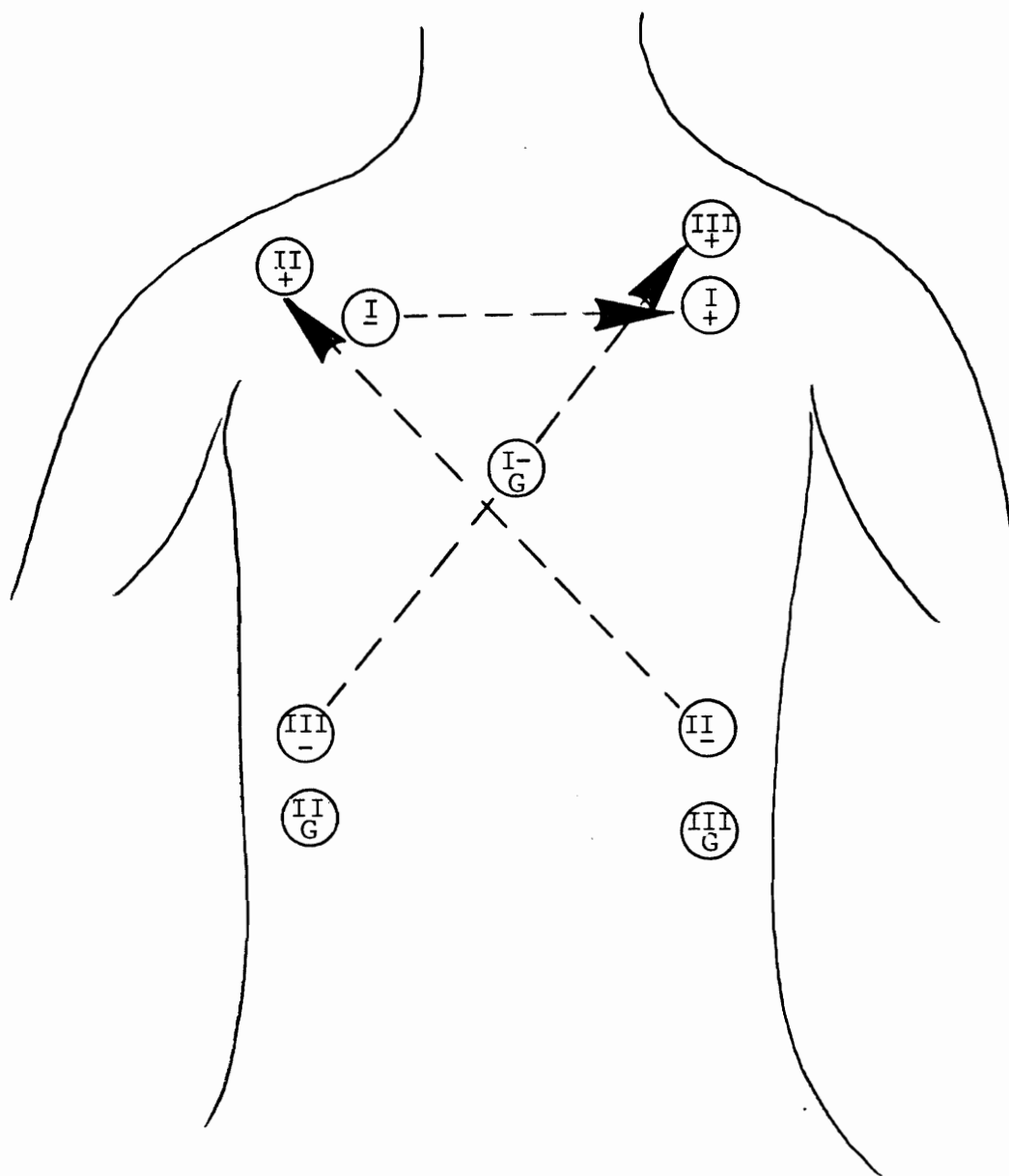


Figure 2. Electrode placement sites.  $\ominus$  site of negative electrode;  $\oplus$  site of positive electrode;  $\odot$  site of ground electrode;  $-----\blacktriangleright$  direction of electrical current.

display on the monitor and storage on magnetic tape.

3. Multiple physiologic signals: The three signal ECG monitoring system plus the arterial pressure waveform signal.

4. True alarm: An alarm that is triggered on all the physiologic monitoring signals which is due to an arrhythmia and is life-threatening.

5. False ECG alarms: An alarm that is triggered on the single signal ECG system which is due to artifact or cause other than an arrhythmia, and is not life-threatening.

6. Twelve and one half hour period: A period of time during which the patient's ECG and arterial pressure waveform signals are monitored continuously and recorded on magnetic tape by the investigator.

7. Frequency of false ECG alarms: The number of false ECG alarms occurring during a 12.5 hour monitoring period.

#### Research Questions

The following research questions were proposed for this study:

1. What is the frequency of false ECG alarms in an ICU/CCU during a 12.5 hour period?

2. Can the frequency of false ECG alarms be reduced using: a) three ECG signals, and b) a multiple physiologic signal monitoring system with the addition of

an arterial pressure waveform?

Operational Definitions  
of Variables

For the purpose of this study, the following variables were operationally defined:

1. Single signal ECG monitoring system: The ECG signal in place at the start of the study and designated as channel 1 on a magnetic tape recording. Three electrodes transmit one signal to the monitor screen. The signal usually is in the modified chest lead I (MCL<sub>1</sub>) position, but may be in any chest lead position.

2. Three signal ECG monitoring system: Use of the single signal plus two additional signals consisting of six electrodes. The two additional signals were in the positions for chest leads I and II (see Figure 2), and designated as channels 3 and 4 on a magnetic tape recording.

3. Multiple physiologic signals: Combination of the three signal ECG monitoring system and the arterial pressure waveform. The arterial pressure waveform was designated as channel 2 on a magnetic tape recording.

4. False ECG alarms: The presence of artifact or lack of signal on channel 1 on the magnetic tape (single signal ECG monitoring system) causing an audible and visible alarm on the monitor.

a. A high rate alarm may be triggered by

artifact or noise that the ECG monitor counts as an ECG signal and exceeds the preset limit of 150 beats/minute. Causes of artifact or noise include: increased signal amplitude, increased amplifier sensitivity, 60 Hz baseline interference, muscle movement, baseline shift and shivering.

b. A low rate alarm may be triggered by the ECG monitor not sensing ECG signals and the heart rate falls below the preset limit of 50 beats/minute. Causes of ECG complexes not being sensed include: decreased signal amplitude, decreased amplifier sensitivity, loose or disconnected leads or patient cable, loose or disconnected electrodes or wires, dried electrode gel, poor electrode contact.

5. ICU/CCU: The intensive and coronary care units at a local community hospital - Coronary Care Unit, Thoracic Intensive Care Unit, and Respiratory Intensive Care Unit, designated specifically for patient monitoring and treatment of acute life-threatening physiologic disorders.

#### Rationale and Significance

Many factors can interfere with monitoring and measuring heart rate. These factors cause heart rate alarms to be generated which alert the ICU/CCU nurse to a potentially dangerous situation for the patient. Repeated false heart rate alarms are annoying to the

ICU/CCU staff, cause stress to the staff and patient, and may result in the alarm limits being adjusted so that the false alarms are decreased or eliminated. This situation, however, may result in a true alarm being ignored, missed, or delayed until the situation is more serious or irreversible. This study was conducted to assess the frequency of false alarms occurring in the ICU/CCU setting and determine the feasibility of developing a monitor to decrease the false alarms by using multiple ECG or physiologic signals.

A monitor utilizing several physiological signals simultaneously and which can filter noise in the system by choosing the best and clearest signal to determine the heart rate, would be a more valid and reliable indicator of true alarms. Such a monitor would also decrease the stress level for staff and patients as well as increase confidence in the system. Cost to the patient may be negligible as monitors are a routine part of patient monitoring in the ICU/CCU setting. With a more reliable monitoring system, patient safety would be increased as there would be fewer false alarms and therefore more attention would be paid to those that did occur.

## CHAPTER II

### DESIGN OF THE STUDY

#### Design

This was a descriptive study. Patients were monitored for 12.5 hours and were observed for frequency of false and true alarms continuously by the investigator during that period. The 12.5 hour period was arbitrarily determined.

The data obtained included the frequency of true and false ECG alarms, and were categorized according to type (true or false); the unit from which the data were obtained: Coronary Care Unit (CCU), Thoracic Intensive Care Unit (TICU), and Respiratory Intensive Care Unit (RICU); and the cause of the alarm if known.

#### Data Collection Site

Data were collected in a 520 bed university-affiliated community hospital in Salt Lake City. The CCU, TICU, and RICU were settings for the data collection. The CCU had a 12 bed capacity for acute coronary care patients. This unit generally had fewer invasive lines inserted and patients were allowed to rest for longer periods of time as compared to the other intensive care

units. The TICU had a ten bed occupancy for thoracic and open-heart surgery patients. Most patients in the TICU recovered rapidly and were transferred to a general care area within three to four days. The RICU had a three bed capacity for major respiratory and hemodynamically compromised patients. Most patients in the RICU were severely ill and required frequent interventions by the staff.

#### Population and Sample

The population of this study consisted of patients in the CCU, TICU, and RICU with ECG and arterial pressure waveform monitoring already in place.

The sample was chosen by convenience from the respective ICUs and determined as follows: Each unit was assessed daily for patients with arterial pressure waveform monitoring, as ECG monitoring was done routinely on all patients in the ICU/CCU. Few patients in the CCU needed arterial pressure waveform monitoring and the sample size was difficult to obtain. Therefore, if a patient in the CCU met the sample requirements, the patient's permission was then sought. Almost all patients in the TICU and RICU had arterial pressure waveform monitoring. If no patient was available for study in the CCU, the TICU was assessed, and if no available patients were there, the RICU was assessed. This was continued until the sample size for each unit was



obtained. Five patients were studied in the CCU, two in the TICU, and two in the RICU.

### Instruments

The tools selected for the study included:

1. ECG electrodes.
2. Hewlett-Packard cardiac monitor with an analog heart rate alarm meter with a ten second time delay.
3. Arterial catheter and pressure transducer.
4. FM tape recorder.
5. Magnetic tape with four channel recording.
6. Observation data sheet.

The ECG electrodes were Red Dot silver/silver chloride electrodes. They were manufactured by the 3M Company and were pregelled and self-adhering.

The Hewlett-Packard bedside cardiac monitor (Models #7808-A, 7807-A, 7807-C) with ECG and two pressure channels had an analog heart rate alarm with high and low settings (see Appendix B for specifications). The monitor screen displayed both the ECG and arterial pressure waveform simultaneously. A switch on the front of the monitor under the analog heart rate meter allowed the monitor to calculate the heart rate from either the ECG signal or arterial pressure waveform. The analog heart rate meter had a ten second delay from the stimulus before an alarm was triggered.

The arterial catheter was an additional method

of determining heart rate. The catheter was inserted into either the radial, femoral, or brachial artery. For the radial or brachial catheters, the Sorenson C.A.P. Interfusor Model # G10-018 was used. The computer technicians inserted these catheters according to the procedure as outlined by the Procedural Protocols for Radial, Artery Catheters (Clemmer, 1982). The tip of the radial artery catheter lays in the subclavian artery at approximately the level of the shoulder. The femoral artery catheters were custom-made in the hospital from 4.6 Fr. polyethylene radioopaque tubing varying from 30-40 cm in length, attached to a three-way stopcock with an O-ring and a 30 cm length of high pressure tubing. The femoral catheters were inserted by trained physicians using the Seldinger technique (Clemmer, 1982). The tip of the femoral artery catheter lay in the abdominal aorta. The arterial catheters were connected to pressure transducers: Bentley Model 800 with nondisposable domes, and Statham P50 with nondisposable domes. The transducers had a fixed gain set by the Biophysics Department, LDS Hospital when purchased. The transducer's gain was checked when cleaned, zeroed, and sterilized between patient use. If they would not zero, the gain was assumed to be altered and was then checked by the Biophysics Department. The gain was also checked if the blood pressure measured by the transducer was dramatically different from the

blood pressure obtained by cuff pressure measurement. The selected instruments were in general use in the ICUs where data were collected.

The FM tape recorder and magnetic tapes were chosen as a simple and reliable method of recording four simultaneous signals for a 12 hour period. Each ECG signal was recorded on a separate channel as was the arterial pressure tracing. The tapes were recorded at a slow speed for monitoring and then played back at faster than real time for data analysis. The tapes were changed as needed (see Appendix B for specifications).

The Observation Data Sheet was developed to enable the investigator to document sources of false ECG alarms during the observation period (see Appendix B).

#### Procedure and Protocol

The two additional ECG signals and the tape recorder were initiated, maintained and discontinued by the investigator. The patient was selected and informed consent obtained. The investigator changed the tapes as needed throughout the 12.5 hour monitoring period, approximately every hour and a half. The ECG electrodes and arterial catheter were maintained by the investigator and the ICU staff as per hospital policy and procedure.

At the start of each 12.5 hour monitoring period the following procedure was followed:

A. Before initiating the study, the investigator:

1. Determined which of the ICUs being used as data collection sites had patients with arterial catheters in place.

2. The method of patient selection was as follows:

- a. if only the ICU had a patient with an arterial catheter in place, that patient's consent was sought.

- b. if two or more units had patients with arterial catheters including the CCU, patients in the CCU were chosen first as it was more difficult to obtain a patient sample from there due to fewer patients needing arterial pressure waveform monitoring.

- c. the TICU was next selected, and then the RICU.

3. The nurse taking care of the patient was consulted to determine contraindications to the study (e.g., surgery, tests out of the unit, emotionally labile etc.).

B. During the study, the following procedure was adhered to:

1. The investigator was introduced as a graduate nursing student.

2. The proposed study was explained:

- a. what the purpose of the study was

- b. what would be done and length of the

study

c. any questions were answered.

3. Consent form was signed by the patient or family member; or a verbal consent was obtained if the patient was unable to sign the consent form, and witnessed by the nurse caring for the patient.

4. The tape recorder and attached monitors were plugged into electrical outlets.

5. Cables from the tape recorder were jacked into the back of the bedside monitor for ECG signal 1 and the arterial pressure waveform signal to be recorded.

6. The ECG electrodes used in routine ICU monitoring were left in place and designated as ECG 1 and recorded on channel 1 on the FM tape. The arterial pressure waveform was recorded on channel 2 of the FM tape.

7. Six additional ECG electrodes for ECG signals 2 and 3 were applied to the skin after the sites were prepared with alcohol to clean the skin. The electrodes were placed in the positions as diagrammed in Figure 2: one on each shoulder and two on each side of the lower chest or upper abdomen. The ECG signals were then recorded on channels 3 and 4 of the FM tape.

8. The two ECG monitors located on the tape recorder were turned on and a good signal obtained on

the cathode ray tube (CRT) screen.

9. An FM four channel tape reel was threaded through the tape recorder and labeled with the patient's initials, patient number in the study, number of tape, and date (see Figure 3 for diagram of equipment).

10. All channels were checked on the tape recorder analog meter to ensure the signals were being received.

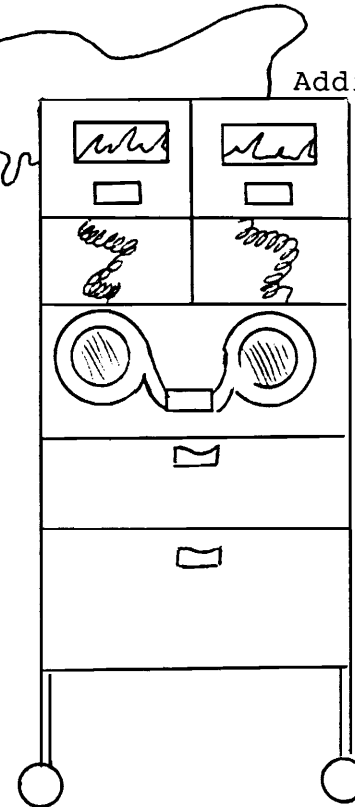
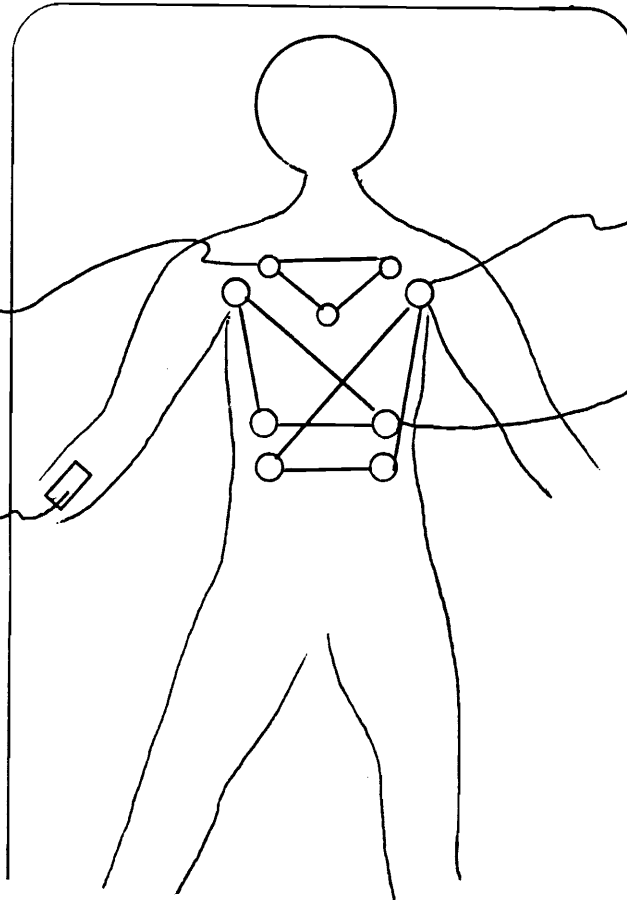
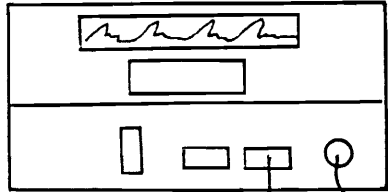
11. The alarm limits on the analog heart rate meter of the bedside ECG monitor were set at low and high heart rates of 50 and 150 and not changed during the study. The alarm system was set on the ECG mode. Routine monitoring equipment and alarms were not bypassed or altered. No alarm systems were available for the two additional ECG signals being monitored.

12. The tape recorded at a speed of 3 3/4 ips and was replaced approximately every one and a half hours by the investigator. Eight tapes were used for each patient study. Tapes were rewound as soon as they were completed.

13. All false alarms that occurred on the bedside ECG monitor during the study were marked on the data collection sheet by time to identify the position of the false alarm on the tape.

14. Demographic data was collected: diagnosis, age, and sex, as well as whether the alarm limits were

Bedside monitor:  
ECG I  
Arterial Pressure  
Waveform



Additional  
ECG  
moni-  
tors  
ECG II;  
ECG III

FM  
Tape  
Recorder

Figure 3. Diagram of monitoring equipment.

already set when the study began.

15. At the end of the 12.5 hour monitoring period, the tape recorder was stopped, the cables to the bedside ECG monitor unplugged, and the additional ECG electrodes removed. All routine monitoring was continued.

C. After the study was completed:

1. Cables connecting the tape recorder to the attached ECG monitors were plugged in for viewing the four taped signals.

2. The tapes were run at a speed of 15 ips, approximately five times the recorded real time.

3. Signals were viewed for false alarms, true alarms, and alarm states in ECG signals II, III, and the arterial pressure waveform. False alarms were documented on the observation data collection sheet when they occurred during the taping period.

4. False alarms were alarms triggered by noise or artifact and were identified by noting the time recorded on the observation data collection sheet and locating the corresponding place on the tape. True alarms were those triggered by a change in the patient's heart rate, above or below the preset alarm limits and were also documented on the observation data collection sheet, and the time noted. Missed alarms were determined by observing the tapes for periods of arrhythmia when



no alarms were triggered.

5. The false alarms were then assessed to determine whether they would have been eliminated by the use of additional ECG signals or multiple physiological signals. Criteria for determining if the false alarm would have been eliminated were based on whether the artifact or stimulus triggering the false alarm was present in the other signals. If the triggering event was present in the additional ECG signals but not the arterial pressure waveform; then it was determined that the use of multiple physiological signals would have eliminated the false alarm but not solely by the use of additional ECG signals. If the alarm stimulus appeared in all signals, it was then determined that the use of multiple physiological signals would not have eliminated the false alarm.

6. Strip chart recordings of the false alarms and examples of patient signals were made by jacking the cables of the monitors on the tape recorder to two two channel strip recorders, and recording the taped signals on Gould strip recorder paper at a speed of 25 millimeters/second.

## CHAPTER III

### FINDINGS

#### Sample Characteristics

A total of 27 patients was studied from the Intensive Care Unit/Coronary Care Unit (ICU/CCU) population, but due to technological or methodological problems, data from only nine patients were used for analysis. Several patients were eliminated due to technological problems such as a fault in the additional ECG cables and failure of the additional ECG signals to record on the data tape. Several other patients were not included in the data sample due to the data tapes being reused after analysis before strip chart recordings were made of the false alarms. The data were gathered over a five month period of time.

Two patients from the Respiratory ICU (RICU), two from the Thoracic ICU (TICU), and five from the CCU were included in the sample. The sample was selected according to the method outlined in the Procedure and Protocol (see Chapter II). A summary of the biographical data is presented in Table 1. The mean age for the sample patients was 60.4 years with a range of 28-74. Four of the nine patients (44%) were female, and

Table 1

## Sample Description by Frequency Distribution per ICU

Unit	Sex	Age	Diagnosis
RICU ( <u>n</u> =2)	M	44	Sepsis, respiratory failure
	F	28	Adult respiratory distress syndrome
	Range	28-44	
	Mean	68	
TICU ( <u>n</u> =2)	F	62	Coronary artery bypass graft (2)
	M	70	Coronary artery bypass graft (5)
	Range	62-70	
	Mean	66	
CCU ( <u>n</u> =5)	M	67	Anterior wall myocardial infarction
	F	62	Status postcardiac arrest
	M	73	Status postcardiac arrest
	F	74	Rule out myocardial infarction
	M	64	Ventricular arrhythmias
Range	62-74		
Mean	68		
TOTAL			
Male	5		
Female	4		

the remainder (46%) were male. No attempt was made to limit the age range or obtain an equal number of male and female patients.

### Analysis

This was a descriptive study and statistics used were frequencies and percentages. The data were analyzed by the investigator from strip chart recordings made from the data tapes. The frequency of false alarms was determined from the data sheets and verified by the recordings on the data tapes. Each tape was one hour and 35 minutes in length resulting in 12.5 hours of taping per patient.

The false alarms, as noted on the data collection sheet, were identified from the tapes and then analyzed as to whether additional ECG signals or multiple physiologic signals would have eliminated them. The criteria used to assess whether they would have been eliminated were if the same artifact or stimulus triggering the false alarm was present in all three ECG signals or in all four physiologic signals. If it was, then the investigator concluded that the multiple signals would not have reduced the frequency of false alarms. The data were analyzed in relation to the research questions.

### Research Question One

Research question one stated:

What is the frequency of false ECG alarms in an ICU/CCU during a 12.5 hour period?

Fourteen false alarms occurred during the 113 hours of monitoring by tape, giving a frequency rate of one alarm every 7.8 hours (see Table 2). One true alarm also occurred during the monitoring period.

Four of the false alarms (28%) were due to an ECG lead disconnection from the ECG electrode. Two of the four were caused by the ECG leads being intentionally removed for x-rays to be taken. Ten (72%) were caused by artifact or amplitude changes so the waveform was not sensed by the monitor. The one true alarm occurred in all the physiological signals.

The frequency of false alarms by unit studied is also outlined in Table 2. The RICU had a frequency rate of one alarm every 4.2 hours; the TICU a frequency rate of one alarm per 12.6 hours and the CCU one alarm every 10.5 hours.

### Research Question Two

Research question two stated:

Can the frequency of false ECG alarms be reduced using: i) three ECG signals, and ii) a multiple physiologic signal monitoring system with the addition of an arterial pressure waveform?

Table 2  
False Alarms Distributed by ICU and Time of Occurrence

Unit	Subject No.	Hours monitored and tape recorded												f	f/hour	
		1	2	3	4	5	6	7	8	9	10	11	12			
RICU	1				☒										1	
	2							☒	X	X					5	4.2
TICU	1	☒											☒		2	
	2														0	12.6
CCU	1	X													1	
	2							X							1	
	3				X	X									2	
	4			X		X									2	
	5												*		0	10.5

Note. X=ECG false alarm; \*=true alarm; ☐ =ECG leads removed; f=frequency of false alarms per patient; f/hour=frequency of false alarms per unit, hours monitored, divided by number of false alarms.

### Three ECG Signals (i)

Of the 14 false alarms that occurred during the monitoring period, four (28%) were due to displacement of the ECG leads. Two false alarms were due to chest x-rays being taken when all ECG leads were removed, including the additional ECG leads II and III (Figure 4 -- all strip recordings have been reduced. Each square box equals 5 cms). Therefore, those two false alarms (14%) were not eliminated by the use of additional ECG signals. Ten false alarms (71%) were caused by artifact (8) or a decreased height of the waveform amplitude (2). Three of the false alarms due to artifact (38%), occurred in all three ECG signals. They would not have been eliminated by the use of additional ECG signals (Figures 5, 6). Four false alarms (50%) did not have artifact occur in ECG signals II and III, and those signals would have eliminated the false alarms (Figures 11-14 in Appendix C). One false alarm (12%) also had a lead off in ECG signal III (Figure 15 in Appendix C), but ECG signal II would have monitored both of those signals. Therefore, 62% of the false alarms due to artifact would have been eliminated by the use of a multiple ECG signal monitoring system.

The two false alarms due to a decrease in the height of the waveform did not occur in the additional ECG signals. Those false alarms would have been eliminated by the use of a three signal ECG monitoring system

Figure 4. RICU-1. False alarm due to ECG I being removed for x-ray. Arterial pressure waveform tracing stable. ECG II and III also removed for x-ray. Paper speed: 6.25 mm/sec.



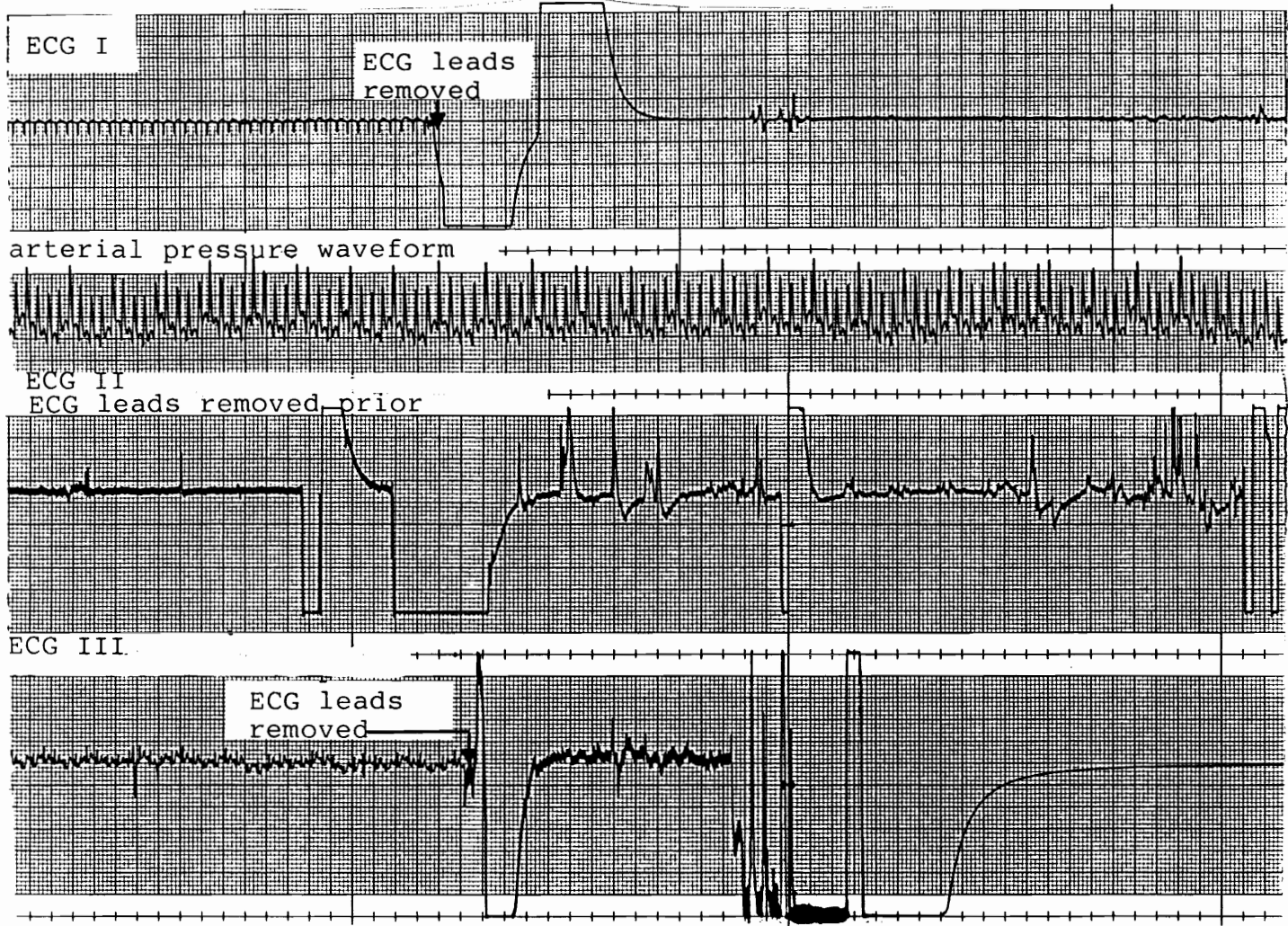


Figure 5. RICU-2. False alarm due to artifact in ECG signal I due to patient getting up in chair. Artifact also present in ECG II, III. Arterial pressure waveform tracing stable. Paper speed: 25 mm/sec.

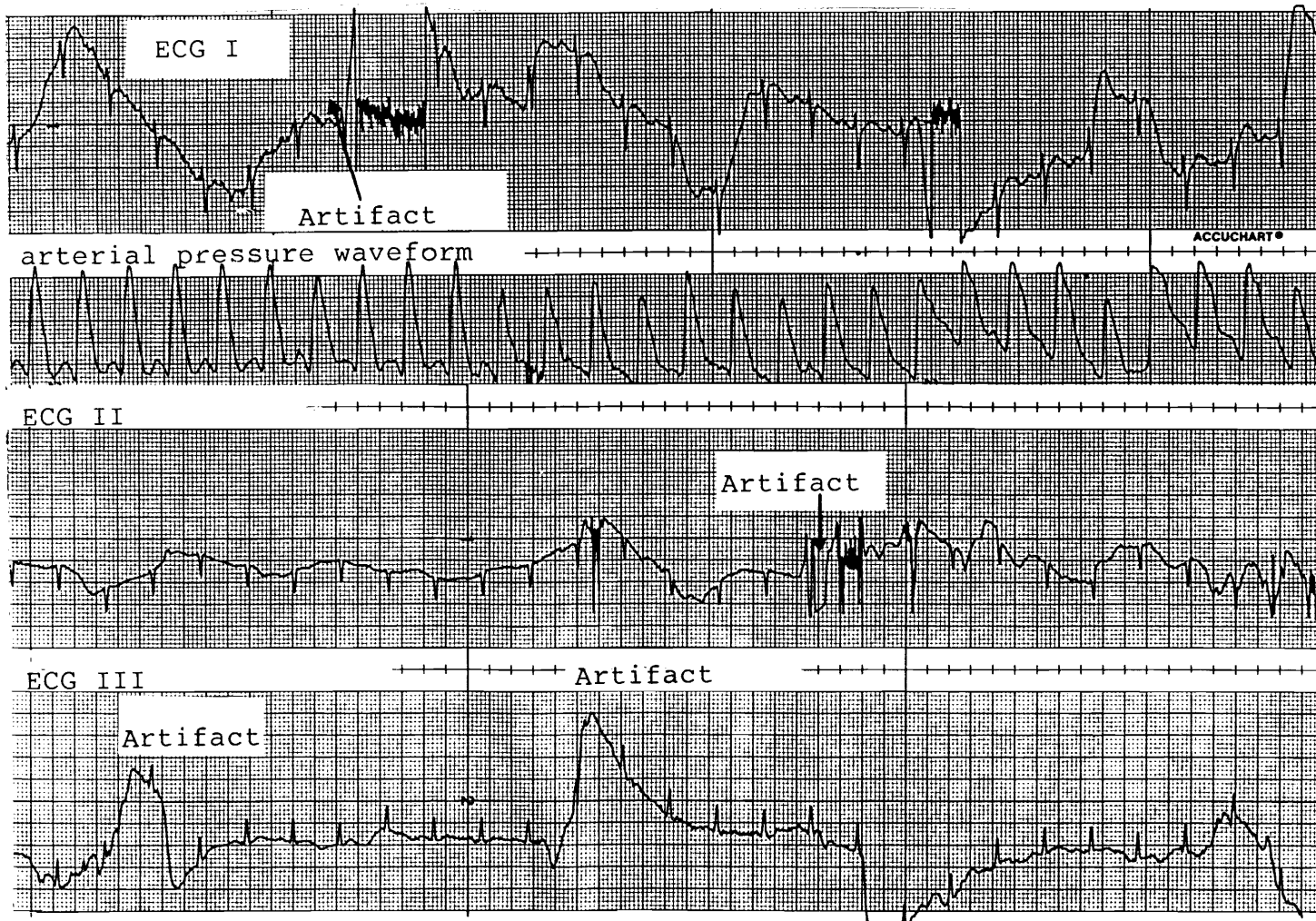
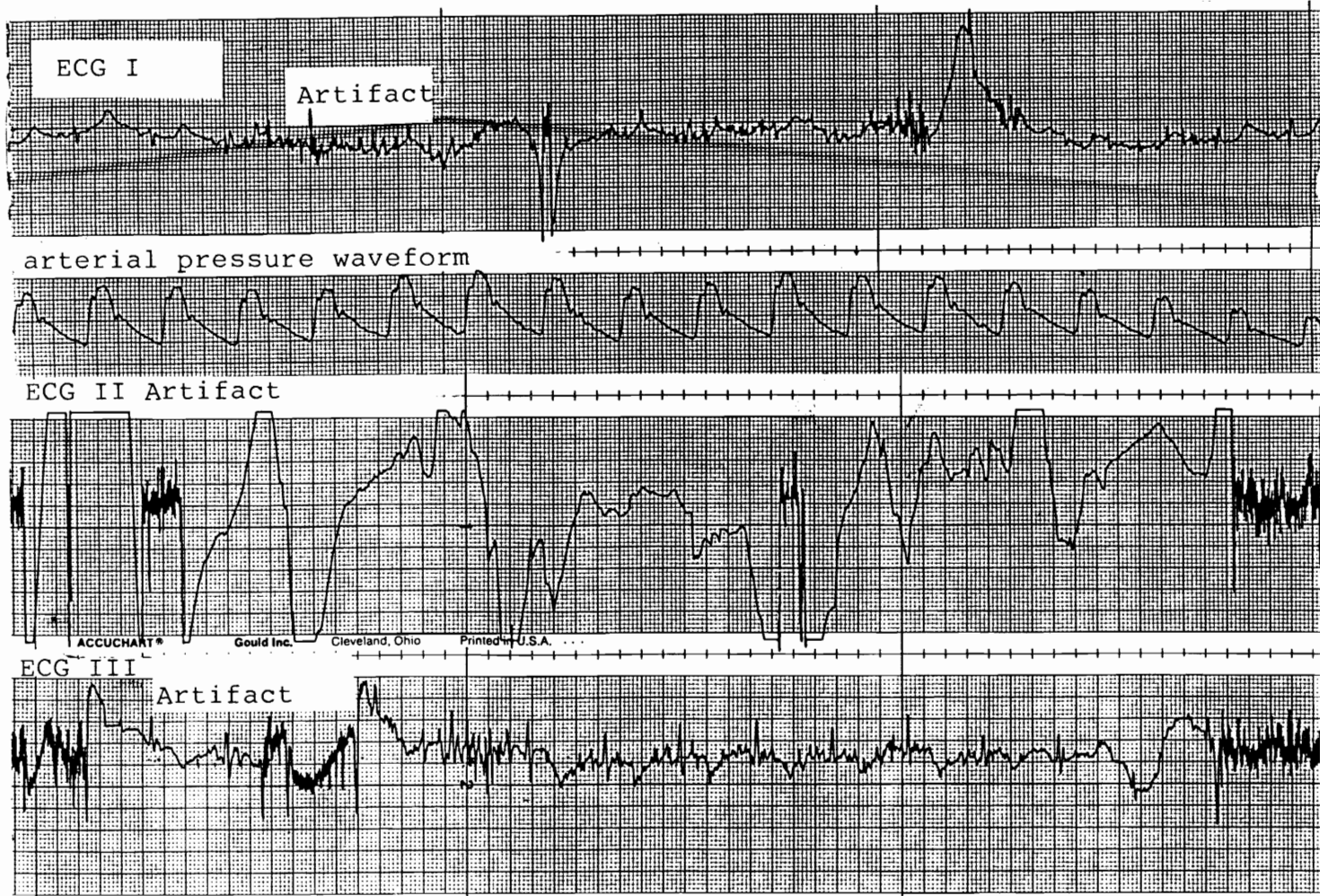


Figure 6. CCU-2. False ECG alarm from artifact in ECG I due to patient movement. Artifact also in ECG II, III. Arterial pressure waveform stable. Paper speed: 25 mm/sec.



(Figure 7).

#### Multiple Physiologic Signals (ii)

Two of the false alarms that occurred due to the ECG leads being removed for x-rays were monitored by the arterial pressure waveform. The other two false alarms were monitored by the additional ECG signals. Only one of the ten false alarms due to artifact or height of waveform change was not eliminated by the arterial pressure waveform as an arterial sample was being drawn. That false alarm would have been eliminated by the use of multiple ECG signals.

The one true alarm occurred in all of the physiologic signals (Figure 8).

Examples of the remaining false alarms; alarm states in ECG signals II, III, and arterial pressure waveform; and normal tracing, are included in Appendix C (Figures 11-24).

Figure 7. CCU-4. False alarm due to decreased height of waveform in ECG I. ECG II, III stable, arterial pressure waveform stable. Paper speed: 25 mm/sec.

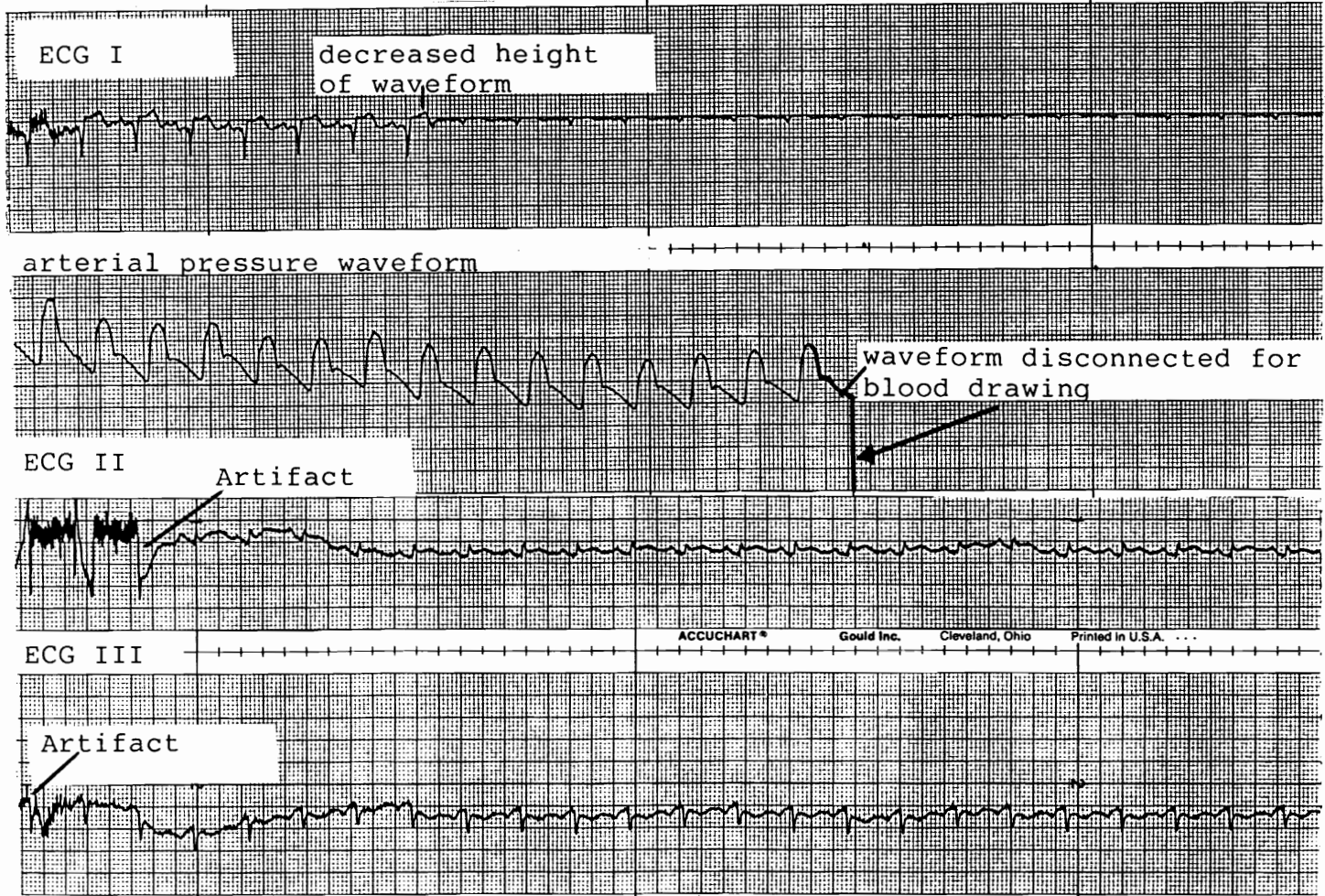
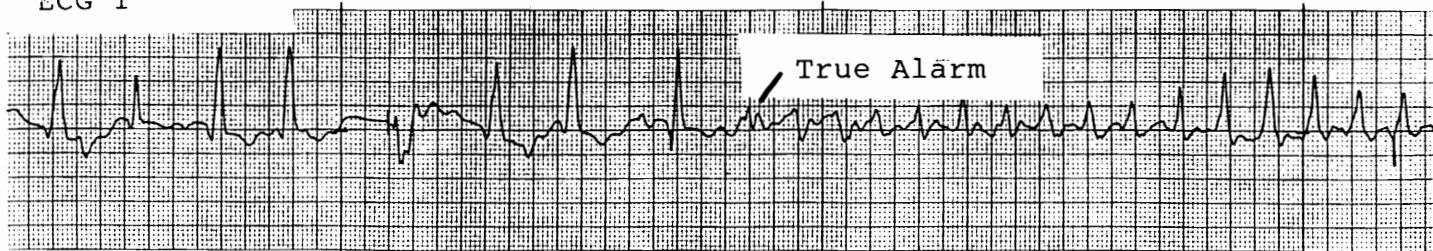




Figure 8. CCU-5. True alarm. Ventricular fibrillation present in all signals. Paper speed: 25 mm/sec.

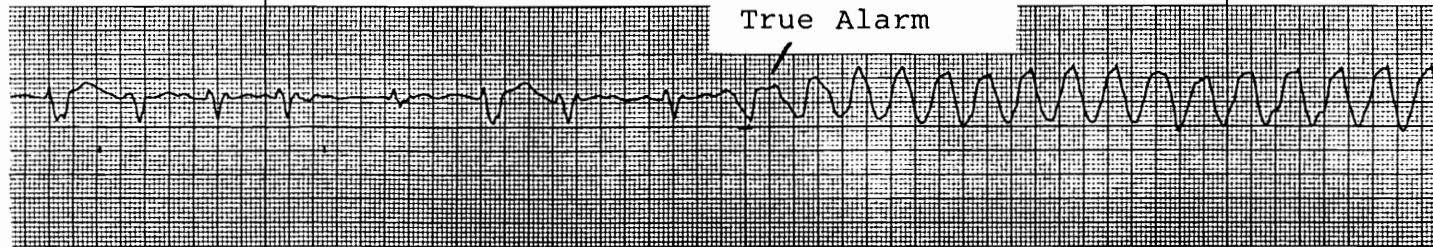
ECG I



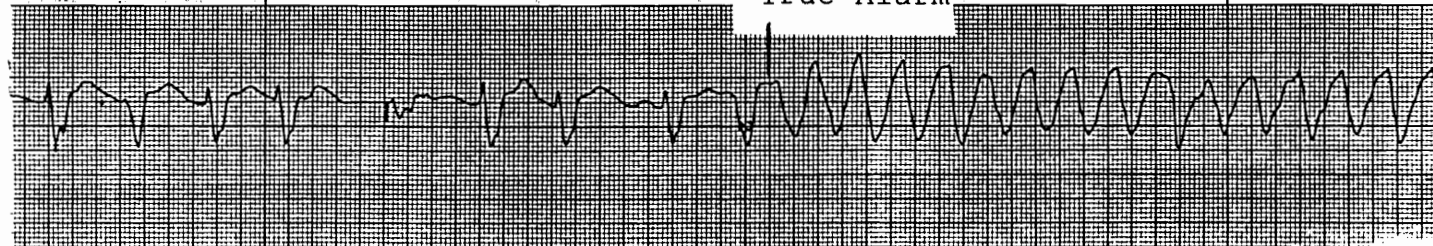
arterial pressure waveform



ECG II



ECG III



## CHAPTER IV

### DISCUSSION OF RESULTS

#### Sample

No attempt was made to limit the sample in terms of age or sex. The major criterion for inclusion was whether the patient had an arterial pressure monitoring catheter in place at the start of the study. Two patients who gave consent were not included because tests away from the ICU would interrupt the recording period.

Technical difficulties with the monitoring equipment required the elimination of several patients' data. An electrical short in the monitor that displayed ECG signal I and the arterial pressure waveform resulted in the arterial pressure waveform not being recorded. In another two patients, ECG signals II and III did not record on the tapes for an unknown reason. One patient's tapes were recorded over before they could be analyzed. In six patients studied, a short time period (less than two minutes) of tape recording had no tracings recorded which probably resulted from the tape sliding off the recording rollers. Nine patients' data were unable to be used as the false alarms were not recorded on hard copy after analysis before being

used to tape another patient's data.

#### Research Question One

Research question one stated:

What is the frequency of false ECG alarms in an ICU/CCU during a 12.5 hour period?

A total of 14 false alarms occurred during the monitoring period. The RICU had a much higher frequency of false alarms compared with the other two units studied, even though only two patients were studied (Table 2). The TICU and the CCU had similar frequency rates even though five patients were studied in the CCU as compared with two in the TICU. This may be explained by the nature of the units studied. The RICU emphasized physical activity such as getting up in a chair; riding a bed bike; and respiratory therapy treatments such as chest physical therapy in different body positions. This type of activity causes movement of the electrodes and artifact. The patients studied in the CCU and TICU were not as active. The patients in the CCU that were unstable enough to have arterial pressure monitoring in place, were on bedrest and rest was emphasized. TICU patients studied were first day postsurgery and had little activity except for turning and incentive spirometry breathing treatments.

Within the total sample, eight false alarms were due to artifact and Table 3 identifies the causes of

Table 3  
False Alarms by ICU and Cause

Unit	Subject	No. of Alarms	Cause(s)
RICU	1	1	Leads removed for x-ray
	2	5	Coughing ( $\bar{n}=2$ ) Up in chair ( $n=1$ ) Movement ( $\bar{n}=1$ ) Decreased height of the waveform ( $\bar{n}=1$ )
TICU	1	2	Leads removed for x-ray ( $\bar{n}=1$ )
	2	0	Lead off ( $\bar{n}=1$ )
CCU	1	1	Bath
	2	1	Movement
	3	2	Commode ( $\bar{n}=1$ ) Movement ( $\bar{n}=1$ )
	4	2	Lead off ( $\bar{n}=1$ ) Decreased height of the waveform ( $\bar{n}=1$ )
	5	1	True alarm

the false alarms. Artifact was defined as the ECG signal moving abarrently or disappearing due to patient activity or equipment malfunction. Two false alarms were due to a decrease in height of the ECG waveform amplitude and the monitor did not sense the waveform.

There was no relationship between the occurrence of false alarms and the time they occurred during the study. Five false alarms occurred during the first four hours of the study, four during the next four hours, and five during the last four hours. The true alarm occurred during the last hour of the study. These findings are probably due to the nature of ICUs. Activity is generally consistent throughout the day in ICUs. The activity level may decrease during the night and therefore the false alarm rate may be lower, but this should be further investigated to be substantiated. As the activity level and the false alarm rate may be higher during the daytime when there are more stimuli, the alarms can be more annoying to the staff and more apt to be ignored or disabled.

#### Research Question Two

Research question two stated:

Can the frequency of false ECG alarms be reduced using: i) three ECG signals, and ii) a multiple physiologic signal monitoring system with the addition of an arterial pressure waveform?

Three ECG signals (i)

Two of the 14 false alarms (14%) were caused by all the ECG leads being removed from the chest for x-rays to be taken. A monitoring system using three ECG signals would not have eliminated those two false alarms. Eight of the 14 false alarms were due to artifact (57%). Three of the eight alarms due to artifact occurred in all three ECG signals and would not have been eliminated by the use of a three signal ECG monitoring system. The remaining five false alarms due to artifact would have been eliminated by using additional ECG signals. Of the 14 false alarms, two that were due to a decrease in the height of the ECG waveform, and two that were due to ECG signal I being disconnected, did not occur in the additional ECG signals. A reduction of 64% in the frequency of false alarms would therefore be achieved with use of a three signal ECG system.

The alarm systems were not functioning on the monitors being used to visualize the two additional ECG signals II and III. If alarm systems had been functioning, a much higher false alarm frequency would have been recorded for the additional ECG signals (Table 4). When the ECG recordings were analyzed for the presence of an alarm state, a false alarm would have occurred 17 times in ECG signal II, five times in ECG signal III, and five times in both signals at the same time.

Table 4  
 Potential Alarm States in all ECG Signals and  
 Arterial Pressure Waveform (APW)

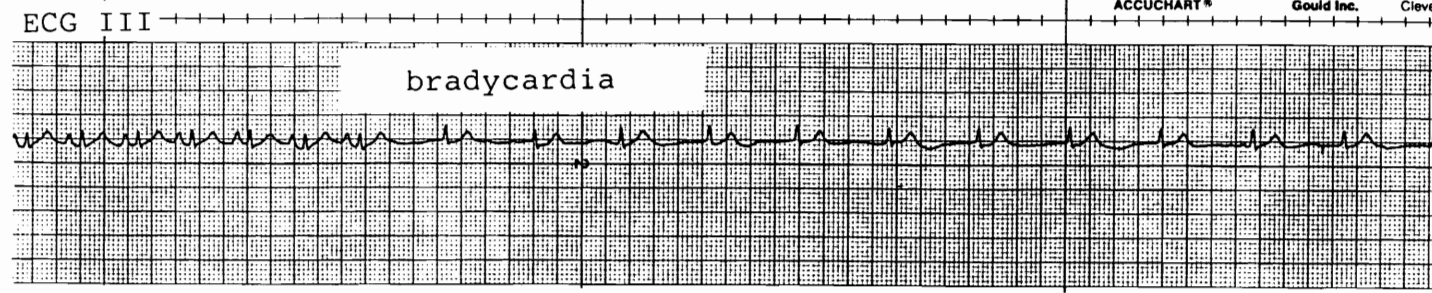
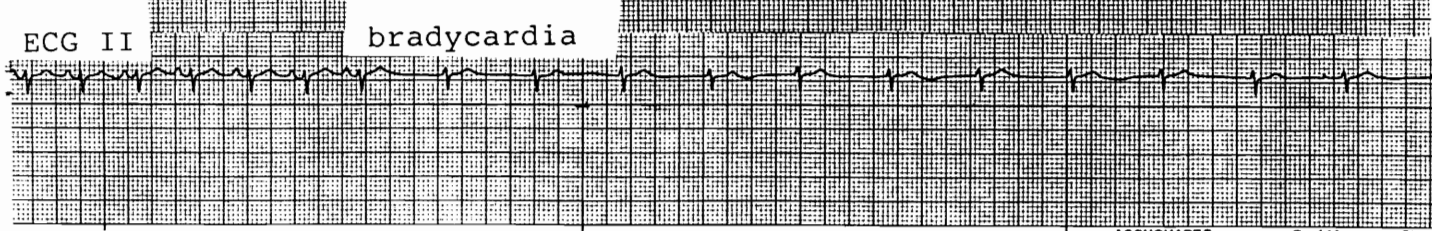
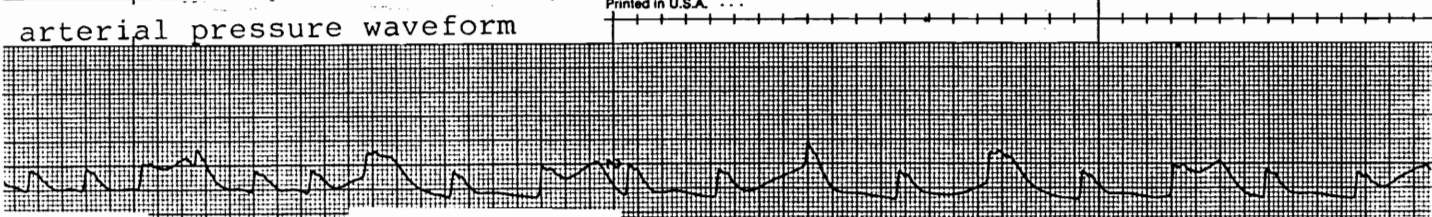
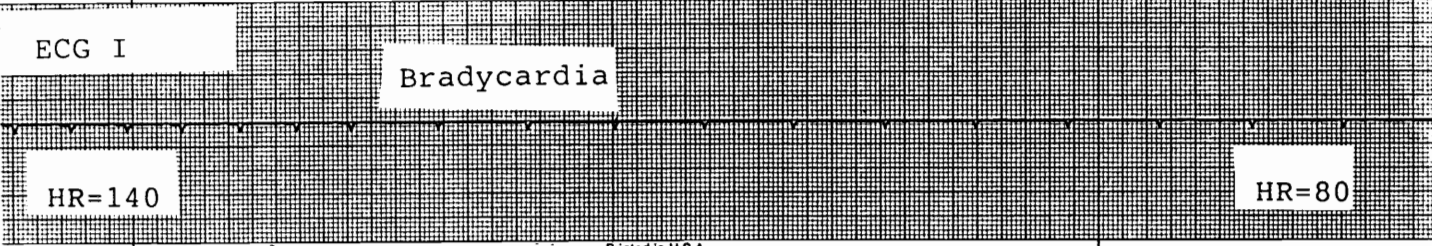
Unit ECG	Pt. No.	False Alarm Potential Alarm States					APW
		I	I,II,III	II	III	II,III	
RICU	1		1				7
	2	5		4			1
TICU	1	1	1		1		4
	2						3
CCU	1	1		1		2	2
	2	1		1			3
	3	2			2	1	8
	4	2		7	1		2
	5	True alarm		4	1	2	16
Totals	9	12	2	17	5	5	46



None of those alarm states occurred simultaneously in ECG signal I. The causes of the alarm states were due to artifact, patient movement, and equipment malfunction such as electrode pads or leads off the patient's chest. Nine of the false alarms did not occur in both of the additional ECG leads. Between the original and additional monitoring system there is a difference in the frequency of nine false alarms to 27 alarm states. Even though the addition of two more ECG signals would have decreased the frequency of false alarms occurring in ECG signal I by 64%, the overall frequency rate including all ECG signals, would have increased almost four times. A "smart alarm" that could automatically switch the monitoring signal to the best waveform when artifact occurred would decrease the overall false alarm frequency from 41 (14 plus 17) to 31, or 76%.

Almost all patients studied had episodes of arrhythmias ranging from isolated and multiple premature atrial and ventricular contractions to short runs of bradycardia. None of the arrhythmias caused an alarm except for the true alarm, because they were of short duration and did not overcome the ten second time delay on the monitor. Patient 1 in the RICU had bilateral tension pneumothoraces causing bradycardia and hypotension in cycle with the ventilator breaths (Figure 9). No alarm occurred as the bradycardia was not below the low limit of 50

Figure 9. RICU-1. Bradycardia occurred in all signals due to bilateral tension pneumothoraces; no alarm was activated as the change in rhythm was within 50-150 limits. Paper speed: 25 mm/sec.



set on the heart rate alarm although it was a significant change from the original heart rate. The true alarm occurred in CCU patient 5 who had multiple ventricular arrhythmias and developed ventricular tachycardia that progressed into ventricular fibrillation (Figure 8).

#### Multiple Physiologic Signal Monitoring System

All the false alarms generated in ECG I would have been eliminated by the use of a multiple physiologic signal monitoring system. Use of the arterial pressure waveform as a source for monitoring the heart rate would have reduced the false alarm frequency from 14 to one, or by 93%. The one remaining false alarm would have been eliminated by the multiple ECG signals. This is a much greater reduction than by the use of a three signal ECG monitoring system alone (Figure 10).

The arterial pressure waveform was not switched to an alarm system as the study procedure stipulated that the monitor alarm was set on the ECG signal instead of the arterial pressure waveform. The arterial pressure waveform was disconnected 46 times (Table 4), producing possible alarm states. Only two of those alarm states would not have been eliminated by the use of ECG signals, and those occurred during the true alarm. A "smart alarm" system that could select one signal (ECG or arterial pressure waveform) producing the best waveform

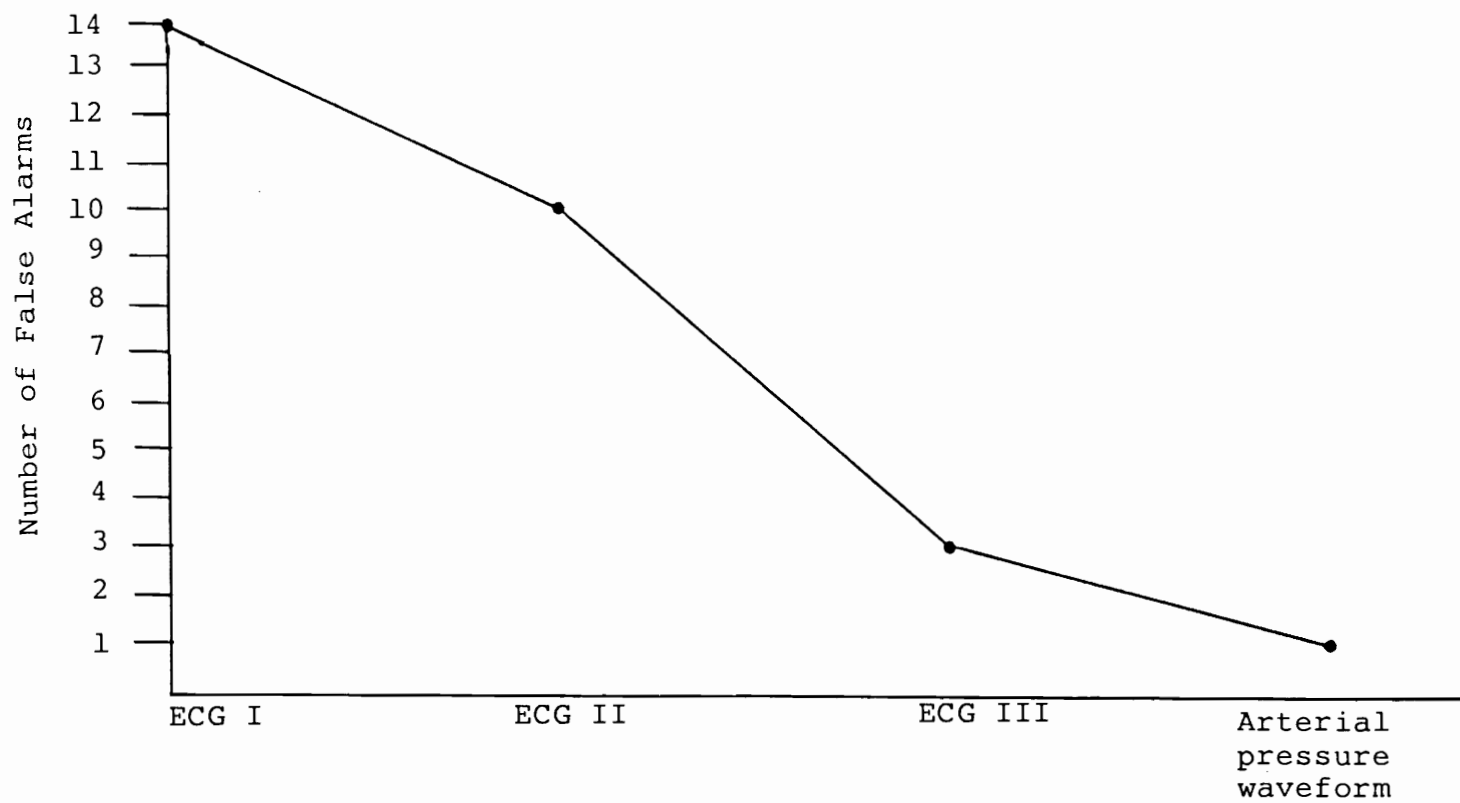


Figure 10. Possible reduction in false alarm frequency with the addition of multiple physiological signals.

to monitor the heart rate, would eliminate virtually all but true alarms.

Four patients had radial artery catheters and five had femoral artery catheters in place. Alarm states would have occurred when the transducer was being zeroed, the catheter was disconnected for blood to be drawn, or when the signal was damped. The occurrence of alarm states was essentially equal for the two types of catheters with 24 alarm states for radial catheters, and 23 for femoral.

#### Other Findings

An unanticipated finding was that many of the alarm systems had been disabled prior to initiation of data collection. Out of the nine patients, only three (33%) had alarm limits set (Table 5). The monitors used in the ICUs have the option of setting the alarm system to the arterial pressure waveform or the ECG signal. Three were set on the ECG signal and two of those were disabled. Six (67%) were set on the arterial pressure waveform, of which only two had alarm limits set. The high number of alarm systems found disabled is disturbing, especially since the alarm system was disabled on the patient who had a true alarm. The alarms may have been disabled due to frequent annoying false alarms or may not have been set when the patient was admitted to the unit. The greater number of alarm systems set on the

Table 5

## Sites of Arterial Catheters and Settings of Alarm Limits

Unit	Pt. No.	A/E	Setting	F/R
RICU	1	A	On	F
	2	A	On	R
TICU	1	A	Off	R
	2	A	Off	R
CCU	1	A	Off	F
	2	E	On	F
	3	E	Off	F
	4	E	Off	R
	5	A	Off	F

Note. A=arterial pressure waveform signal; E=ECG signal; F=femoral artery site; R=radial artery site.

arterial pressure waveform signal may be due to less likelihood of artifact from patient movement.

These findings may relate to the study done by Porciello (1980). He found that nine of 11 CCUs had turned off the audible alarm on the monitoring equipment sometime after installation because of frequent false alarms.

One patient (CCU patient 1) had skin burns from a reaction to the ECG electrode pads. This has been described previously in the literature (Orpin, 1982) as due to delivery of electric energy. The skin burns in the patient studied appeared to be due to local skin reaction or skin sensitivity to the salts contained in the electrode gel rather than actual electrical activity as described by Wright (1982). It occurred with all the ECG electrode pads and had disappeared by the next day.

The ECG monitors used in the ICUs had a ten second time delay built into the heart rate monitor. Several of the documented false alarms were not ten seconds or more in duration. A pilot study was done to document the actual time delay of the monitors. The investigator moved the low alarm limits above, and the high limit below, the patient's heart rate. An independent observer documented the time taken for the alarm to sound. As no documentation was made in the patient



record as to what monitor each patient was on, all the monitors in the ICUs (15) in use were studied. The results are contained in Table 7 in Appendix B. The RICU had a mean time of 7.8 seconds to alarm; for all three monitors, the TICU 18.0 seconds for eight out of ten monitors; and the CCU 6.5 seconds for two out of the four monitors. Out of the 26 alarms (13 high and 13 low), only two (8%) were set on ten seconds. The majority (62%) were set on seven to nine seconds. One high alarm in the TICU was triggered but did not alarm, and the timing was stopped after 45 seconds. If that alarm limit was removed from the TICU mean time, the adjusted mean would be 6.6 seconds. The unexpected finding was that four high alarms (4%) alarmed immediately. The observed false alarms were high alarms and this accounts for why some false alarms occurred that were less than ten seconds in duration.

#### Summary and Implications

The frequency of false ECG alarms was less than the investigator expected from personal clinical experience. A possible explanation may be that patients tried to lie quietly because of the study being done. The investigator had to tell several patients as well as nurses that the patients could move around freely, even though they had been informed at the time consent was obtained.

One explanation for the perceived higher frequency may be that the study focused on one patient while all false alarms that occur during a shift are noted by the staff. If each patient only had two false alarms per eight hour shift, multiplied by ten or 12 patients per unit, the overall frequency would be 20 to 24 false alarms per eight hour shift. This would greatly increase the noise level in the ICU, as well as stress for both patients and staff. The frequency of alarm states found in the additional ECG signals and arterial pressure waveform was higher: 73. This combined with the false alarm frequency of ECG I would give a frequency of 87 alarms per eight hour shift.

The focus of this study was to determine whether the use of i) multiple ECG signals, and ii) a multiple physiologic monitoring system, including an arterial pressure waveform, would decrease the false ECG alarm frequency. The findings indicate that the use of a multiple physiologic monitoring system would provide the most significant decrease in false alarm frequency. All the false alarms would have been eliminated with this system as compared to a 64% reduction using a multiple ECG signal system alone.

All the additional monitoring systems (ECG and arterial pressure waveform) had alarm states occur during the study period which would have increased the false

alarm frequency had alarm systems been active. The multiple physiologic monitoring system would still have had the greatest impact in reducing false alarms, as all but true alarms would conceivably be covered by one of the signals. However, a monitor would have to be developed that would automatically search for the best signal should an alarm state occur in the signal being monitored: the so-called "smart alarm."

An example of a "smart alarm" function would be when chest x-rays are being taken and all ECG leads are removed. The monitor would then automatically switch to the arterial pressure waveform and prevent a false alarm. If blood was then drawn from the arterial pressure catheter, or the waveform damped, the monitor would automatically monitor one of the ECG signals. Not all patients in ICUs have arterial pressure catheters, and therefore, the multiple ECG signals would be useful to decrease the false alarm frequency with the monitor selecting which signal had the best waveform. In this manner, false alarms would be decreased and the noise and stress levels in the ICU reduced. The greater the number of patients in the unit, the higher the number of potential false alarms. A multiple signal physiologic monitoring system would reduce or eliminate the occurrence of false alarms.

One reason given by the CCU staff for the alarms

being disabled is that the computerized arrhythmia recognition system functions as an alarm and therefore the bedside heart rate alarm system is not needed. The other ICUs do not have such a backup system; and the thought that alarms for patient safety and monitoring are being turned off is disturbing. Nursing staff float between units and cannot be expected to remember which have backup systems. All alarm systems should be kept active at all times. Patients who are stable and improving are not watched as closely as those who are unstable and critical. Increased activity also leads to increased false alarms as indicated by the high false alarm frequency in the RICU. These two conditions may lead to alarms being turned off. In the experience of the investigator, patients have arrested and resuscitation efforts have been unsuccessful due to alarms being disabled and the arrest not recognized until too late.

Four of the patients studied (44%) did not survive (Table 6). The true alarm occurred on CCU patient 5 whose alarm was not active at the start of the study. The alarm was the alerting factor of the change in heart rhythm which may not have occurred until later had the alarm limits not been set per study protocol.

The assumed time delay of ten seconds was found to be different than the actual measured delay. If

Table 6  
Survival of Patients Monitored

Unit	Pt. No.	Survived/Expired	Cause
RICU	1	E	ARDS and anoxic brain injury
	2	E	Sepsis, chronic obstructive lung disease
TICU	1	S	
	2	S	
CCU	1	S	
	2	S	
	3	S	
	4	E	Cardiographic shock
	5	E	Ventricular fibril- lation

the ten second delay had been in effect on all the monitors, many of the false alarms may not have occurred. As it is out of the realm of nursing at this time to calibrate such monitors internally, the Biophysics Department should be alerted to check the monitors and make adjustments as needed. Frequent false alarms may indicate that the internally calibrated time delay has changed.

#### Limitations and Recommendations for Further Research

The small sample size limits generalizability of the findings to other populations. Due to factors listed in the sample section of Chapter III, the sample size was limited to nine patients. A randomly selected and larger sample size would strengthen generalizations to other ICU populations.

The monitoring system used for the additional ECG signals was a major limitation in this study. The equipment was of an older model and in poor condition. There was no functioning alarm system and the electrode lead attachments were of poor quality and did not hold well on the electrode pad. Replication of the study using a system that is fully functional may yield a more reliable frequency of potential and actual false alarms, and differentiate between patient artifact and equipment distortion.

The monitors and tape recorder were bulky and occupied a lot of space in the cramped ICUs. The ECG cables were draped over the side or end of the bed and were frequently manipulated or disturbed causing artifact and distortion which may have accounted for some of the alarm states recorded in ECG signals II and III. Thus, a better multiple ECG signal system may eliminate many of the possible false alarm states recorded in ECG signals II and III.

The frequency of false alarms occurring in the arterial pressure waveform was unavailable as the study procedure stipulated that the alarm was set on the ECG signal, and the system could not monitor both at the same time. A larger study sample utilizing a multiple physiological signal system developed with a "smart alarm" would be valuable to ascertain whether the hypothesis would be supported that such a system could be useful and cost effective in the reduction of false alarms. A monitor that consisted of a three ECG signal system would have a wider application as many ICU patients do not have arterial pressure catheters.

Dressings on the chest area due to incisions and invasive monitoring necessitated ECG electrode pads sometimes being placed on the abdomen. Abdominal electrode placement increases signal artifact due to respiratory movement. An examination of the effect of electrode

pad position on signal noise may help to decrease respiratory variation and artifact.

The study was conducted for convenience during day-time hours--generally from between 8-10 AM to 8-10 PM. The activity level is generally considered to be higher during the daytime hours due to tests and number of procedures being performed. This assumption may not be true and the false alarm frequency may have been lower if the investigation had been done at night. A 24-hour study to observe periods of activity relating to false alarms may document whether periods of activity may change the false alarm frequency.

The finding of a large number of inactivated alarms is disconcerting. A larger study over a longer period of time is needed to determine whether the results obtained in this study are representative of ICUs in general or to the particular institution studied. The findings of Porciello (1980) seem to indicate that the practice is more widespread among ICUs.

The relationship between patients with a high amount of activity and treatment, and a high number of false ECG alarms such as in the RICU, may have implications for the type of monitoring used in such units. Stable patients with little activity and intervention may need only multiple ECG signal monitoring systems, while unstable patients, those with frequent treatments or high



activity level may benefit most from a multiple signal physiologic monitoring system.

APPENDIX A

CONSENT FORM

Consent for Participation in  
Investigational Study

Title of Study: Incidence of False ECG alarms in Intensive Care Unit settings.

Information

This study is being conducted to determine the frequency of false heart rate alarms occurring in the Intensive Care Unit/Coronary Care Unit. False heart rate alarms occur when an alarm sounds but the heart rate is actually normal. The study will involve tape recording of the heart rate signal continuously for a 24-hour period. Additionally, I will be observing the monitor to document the causes of the false alarms for a 12 hour period. The procedure will involve the use of five more electrode pads which will be placed on your chest in addition to the original three electrodes. All electrode signals, plus the pressure signal from your arterial catheter, will be tape recorded.

There are no side effects, risks, or discomforts anticipated from this study. In the event you sustain physical injury resulting from participation in this research project, the University of Utah will provide you, without charge, emergency and temporary medical treatment not otherwise covered by insurance. Furthermore, if your injuries are caused by negligent acts or omissions of University employees acting in the course and scope of their employment, the University may be liable, subject to limitations prescribed by law, for additional medical costs and other damages you sustain. If you believe that you have suffered a physical injury as a result of participation in this research project, please contact the Office of Research Administration, phone number 581-6903.

The potential benefit to be gained by this study is that the monitoring of heart rate for you and future patients may be more accurate by the elimination of false alarms.

This study will be conducted at no cost to you.

Confidentiality of individual data and study results will be maintained. All information gained from this study will be identified by ICU/CCU and a patient identification code.

The alternative to participation in this study

is the routine monitoring and care supplied by the regular nursing staff.

As Principal Investigator, I will be available to answer any questions that you have concerning this study.

At any time during the study you are free to withdraw from the project without prejudice to your care.

Consent

I have read the foregoing and my questions have been answered. I desire to participate in this study and give permission for information gathered in this study to be released to Kathleen Ellstrom, R.N.

\_\_\_\_\_ Date

\_\_\_\_\_ Signature of Patient/Relative

\_\_\_\_\_ Witness

Verbal Consent

I have observed that \_\_\_\_\_ has been informed of the procedures, potential risks and benefits of participating in the study entitled "Incidence of False ECG alarms in the Intensive Care settings" as written above, and that verbal consent to participate in the study has been given.

\_\_\_\_\_ Date

\_\_\_\_\_ Witness

\_\_\_\_\_ Witness

APPENDIX B

DATA COLLECTION SHEET, SPECIFICATIONS OF  
INSTRUMENTS AND SURVEY OF MONITORS



Specifications for Hewlett-  
Packard Monitor

Physical Description

Size: HP half module, 6" high, 8" wide, and 12" deep.

Weight: Approximately 10 lbs.

Color: Blue cabinet with white front panel.

Mounting: Combining hardware permits vertical or side-by-side grouping with other 780 units.

Front Panel Controls: Pushbutton switches - Power, Reset-Alarm (2), Pace and Cal. Rotary controls - ECG sensitivity, Pace current and Pace rate.

Indicators: Meter readout of Heart Rate, illuminated indication of Low, High, QRS flash, and Pace. Also included is a power ON indicator lamp.

Rear Panel Connectors: ECG cable, Pacing cable (2), AC power in, AC power out, Remote, Defibrillator, Pulse waveform input, Scope output, and Sync output.

Specifications

Power Requirements: 115/230 volts ( $\pm 10\%$ ), 50 or 60 cycles.

ECG. Voltage Gain: 250 to 2500 (1000 nominal).

Bandwidth: 0.5 to 50 cps (-3 db), 2 to 50 cps during INSTO (Gain reduced approx, 20%).

Input Circuit: Differential, internally protected against damage by defibrillator potentials. Patient is isolated from chassis by at least 30K ohms to

minimize the shock hazard from auxiliary equipment.

Insto: Actuated by either alarm reset button (reduces internal time constant by a factor of 10).

Calibration: 1 MV in series with input.

Inphase Rejection Ratio: 1000 minimum.

Output: ECG waveform (at 1 volt level, single-ended) available on remote connector and on Scope Signal connector. Output impedance is 1.5K.

Cardiotach. Input: Either ECG waveform (triggering on "R" waves) or Pulse waveform (either plethysmograph from the 780-16 or arterial pressure from the 780-9) (triggering on the pressure rise). Selection is by means of a switch on the front panel under the meter.

Range: 0 to 300 beats per minute.

Accuracy:  $\pm 3$  beats.

Flash Indication: A small lamp on the front panel flashes with each detected QRS complex or pulse wave.

Readout: Edge mounted 3-1/2 inch meter calibrated in beats per minute. 0 to 300 BPM full scale (100 BPM half scale),  $\pm 3\%$ .

Output: Linear output voltage of one (1) volt per 100 BPM,  $\pm 1\%$ . Minimum load resistance is 1000 ohms.

Plethysmograph Amplifier: An amplifier is provided for amplifying the plethysmograph waveform as obtained from the Sanborn pick-up. An internal switch



(in the PLETH position) connects the input of this amplifier to the Pulse Wave Input connector on the rear panel and provides bias for the plethysmograph pick-up. In the ART position the Plethysmograph amplifier is not used.

**Alarm Limits:** Both High and Low Limit indicators are integrated into the meter front and are independently adjustable.

**Alarm Delay:** The time interval between exceeding an alarm limit and the actuation of alarm indication is internally adjustable for each alarm to a maximum of ten seconds.

**Alarm Indication:** Push button switches on either side of the heart rate meter illuminate at time of alarm. Reset is accomplished by depressing any alarm switch.

Specifications for Hewlett-Packard  
Tape Recorder

Two new instrumentation tape recorders, the 3964A, 4-channel and 3968A, 8-channel, utilizing a 1/4-inch format are designed to meet the demands of the individual and OEM users. Versatility, portability, and durability are three important characteristics of these new and exciting recorders. Excellent performance is assured in both the laboratory and the field.

These reasonably priced units are equipped with many standard features usually found only on more expensive recorders.

The 13064A Tape Degausser completely erases all previous magnetic recordings from an entire reel of tape by saturating the tape alternately in both polarities with a large AC magnetic field.

3964A/3968A Standard Features

"E-to-E" mode for FM recording: input signal is automatically transferred to the output when in fast forward, rewind, or stop. Simplifies recorder setup and calibration.

Tech/Tach servo: In the reproduce mode the capstan servo can be controlled either by the internal tach frequency or for maximum time base accuracy from a prerecorded signal on one of the data channels.

Equalization: direct data cards can be easily equalized for a wide variety of tapes.

Remote control: multipin connector located at rear of instrument provides remote control and status (TTL or contact closure) for all tape speeds and operational modes.

AC/DC calibrator: provides internal AC/DC voltage source for setting up input and output levels for each of the data channels. Voltage levels and channel monitoring selected with pushbutton ease.

Flutter compensation: available with the flip of a switch. Flutter modulation introduced during the record mode is eliminated providing an improvement in FM signal-to-noise ratio by up to 12 dB.

Voice capability: recorded data can be voice anno-

tated on Channel 4 of 3964A or Channel 8 of 3968A with press-to-talk microphone.

Unipolar operation for FM recording: when a signal has a positive only or negative only deviation, the FM input reference level can be offset to plus or minus full deviation to permit full utilization of the channel's dynamic range.

Re-recording (dubbing): FM data cards can be set up for dubbing, allowing duplicate recordings to be made with minimum degradation to signal-to-noise.

### 3964A and 3968A Specifications

#### Transport specifications

Tape Width: 1/4 inch (6.3 mm).

Reel size: standard 7-inch (18 mm) plastic reel; totally enclosed by reel cover.

Heads: 3964A - one four-track record and one four-track reproduce using in-line track configuration.  
3968A - one eight-track record and one eight-track reproduce. Interfaced odd-even track configuration.

Tape speeds: 15/32 ips (1.19 cm/s), 15/16 ips (2.38 cm/s), 1-7/8 ips (4.75 cm/s), 3-1/4 ips (9.52 cm/s), 7-1/2 ips (19.05 cm/s), 15 ips (38.10 cm/s).

Capstan drive: DC motor with phaselock servo.

Tape speed accuracy:  $\pm 0.2\%$  (tach servo).

Time base error (tape servo):

Tape speeds	15	7-1/2	3-1/4	1-7/8	15/16	15/32
TBE (microsec)	$\pm 4$	$\pm 5$	$\pm 7.5$	$\pm 15$	$\pm 25$	$\pm 50$

Flutter:

Tape Speed (ips)	Pass Band (Hz)	Flutter (% p-p)	Tape Speed (ips)	Pass Band (Hz)	Flutter (% p-p)
15	0.2-2500	0.35	1-7/8	0.2-312	0.50
7-1/2	0.2-1250	0.35	15/16	0.2-445	0.70
3-3/4	0.2-625	0.40	15/32	0.2-78	1.50

Tape motion controls: forward, reverse record; forward, reverse play; fast forward; fast rewind; stop; pushbutton selectable.

Start and stop times (typical):

Tape speeds	15	7-1/2	3-3/4	1-7/8	15/16	15/32
Start (sec)	3	1.50	0.90	0.50	0.50	0.50
Stop (sec)	0.30	0.30	0.30	0.30	0.30	0.30

Rewind time (typical): 1800 foot (549 m) reel in 100 seconds; 2300 foot (701 m) reel in 145 seconds.

Braking: fail-safe mechanical differential brakes.

End-of-tape sensing: tape drive stops automatically at the end of tape.

Reel revolution counter: 4-digit revolution counter with pushbutton reset.

FM record/reproduce specifications (using 3M-888 Tape or equivalent):

Tape Speed	Carrier Center Frequency	Passband <sup>1</sup> (Hz)	Signal-to-Noise Ratio	
			3964A	3968A
15	27	DC-5000	48	46
7-1/2	13.50	DC-2500	48	46
3-3/4	6.75	DC-1250	48	46
1-7/8	3.38	DC-625	46	46
15/16	1.69	DC-312	44	44
15/32	0.85	DC-156	40	40

Note. <sup>1</sup>Frequency response over passband is  $\pm 1.0$  dB referenced to  $\pm 0\%$  of upper bandedge frequency.

<sup>2</sup>Signal measured with carrier deviation  $\pm 40\%$  of upper passband without flutter compensation. Output filters of reproduce amplifiers selected for constant amplitude response. May also be selected for linear phase (transient) response.

Flutter compensation: can improve signal-to-noise by up to 4 dB under static conditions and as much as 12 dB under conditions of vibration. Selected by rear panel switch.

Distortion: total harmonic distortion <1.2% @ 15 to 1-7/8 ips, <2% @ to 15/32 ips.

Linearity:  $\pm 1\%$  of peak-to-peak output for best straight line through zero at  $\pm 40\%$  deviation.

DC Drift:  $\pm 0.1\%$  (max) of full scale output per  $^{\circ}\text{C}$ .

Input level: 1 V to 30 V (peak-to-peak): continuously adjustable.

Input impedance: 100 k nominal, shunted by <100 pF single-ended.

Output level: 1 to 5 V (peak-to-peak): continuously adjustable.

Output impedance: 50 ohms nominal, single-ended.

Non-bias recording: available by internal jumper selection.

Direct record/reproduce specifications (using 3M-888 Tape or equivalent)

Tape Speed (ips)	Passband ( $\pm 3$ dB) <sup>1</sup>		S/N Ratio (dB) <sup>2</sup>	
	3964A (Hz)	3968A (Hz)	3964A	3968A
15	70-64000	500-6400	38	36
7-1/2	50-32000	250-32000	38	36
3-3/4	50-16000	100-16000	38	36
1-7/8	50-8000	100-8000	33	36
15/16	50-4000	100-4000	38	36
15/32	50-2000	100-2000	37	35

Note. <sup>1</sup>Reference to 10% of upper bandedge.

<sup>2</sup>Referenced to a 500 Hz sine wave with a maximum of 1% third harmonic distortion when reproduced at 3-1/4 ps.

Input level: 1 V to 30 V (p-p): continuously adjustable.

Input impedance: 100 k nominal, single-ended.

Output level: 0.5 to 5 V (p-p): continuously adjustable.

Output impedance: 50 ohms nominal, single-ended.

Signal monitoring

Meter modes: peak AC or DC (selected by front panel switch).

Meter accuracy (peak AC mode): better than  $\pm 1/2$  dB for signals with duty cycle of 20% or greater.

Selector: front panel pushbuttons select metered channels.

Calibrator

Signal source: pushbutton selectable internal or external signal source.

Internal signal source: peak AC and  $\pm$ DC levels of 0, 1.0, 1.414, 2.5, 5.0, and 10.0 volts.

Level of accuracy:  $\pm 2\%$  of selected voltage.

AC frequency: 500 Hz  $\pm 5\%$   $< 0.25\%$  second or third harmonic distortion.

Voice annotation

Modes of operation: data only, voice only, or data interrupted by voice.

Microphone: dynamic, hand-held, with press to talk switch.

Record level: automatic leveling.

Monitoring: built-in speaker, headphone jack.

General Specifications

Size: 3964A - 400 mm (15.7") H x 427 mm (16.8") W X 256 mm (10.1") D. 3968A - 445 mm (17.5") H X 427 mm (16.8") W X 256 mm (10.1") D.

Weight: 3964A - 29.5 kg (65 lb). 3968A - 31.3 kg (69 lb).

Power requirements: 100, 120, 220, or 240 V,  $+5\%$ ,  $-10\%$ , 48-440 Hz, 110 W average.

Temperature: storage,  $-40^{\circ}\text{C}$  to  $75^{\circ}\text{C}$ ; operating,  $0^{\circ}\text{C}$  to  $55^{\circ}\text{C}$ ; tape limit,  $10^{\circ}\text{C}$  to  $40^{\circ}\text{C}$ .

Altitude: storage, 15 240 m (50,000 ft.): operating,

4500 m (15,000 ft.).

Humidity: the system, excluding tape limitations, will operate from 10% to 95% RH (25°C to 40°C), non-condensing.

Shock: 30 g maximum (11 ms) non-operating.

Mounting: supplied with rack mounting kit for standard 19-inch equipment racks.

#### 13064A Specifications

Tape size: 1/4-inch (6.33 mm) tape on reels up to 10-1/2 inch (266 mm) in diameter.

Erase: 60 dB minimum.

Duty cycle: one minute ON - three minutes OFF.

Dimensions: 133 mm W X 184 mm D X 76.2 mm H (5-1/4" X 7-1/4" X 3").

Weight: net 4.3 kg (9-1/2 lb). Shipping, 4.5 kg (10 lb).

Power requirements: 115 V ac  $\pm 10\%$ , 50-60 Hz (option 001). 230 V ac  $\pm 10\%$ , 50-60 Hz (option 002).

Table 7  
Monitors Checked

Unit	Bed No.	Monitor No.	High Alarm (seconds)	Low Alarm (seconds)
RICU	1	5B-1	8	7
	2	Shop-4	7	9
	3	5B-3	8	8
		Range		7-9
		Mean		7.8
TICU	1	4A-1	1	10
	2	4A-3	8	9
	3	4A-7	> 45	5
	4	4A-4	8	9
	6	4A-5	8	6
	8	4A-10	1	8
	9	4A-6	1	9
	10	4A-9	8	8
		Range		1->45
		Mean		18
CCU	1	4052	1	6
	4	4054	9	10
	Range		1-10	
	Mean		6.5	



APPENDIX C

STRIP CHART RECORDINGS

Figure 11. CCU-3. False alarm due to artifact in ECG I from patient movement. ECG II, III and arterial pressure waveform tracing stable. Paper speed: 25 mm/sec.

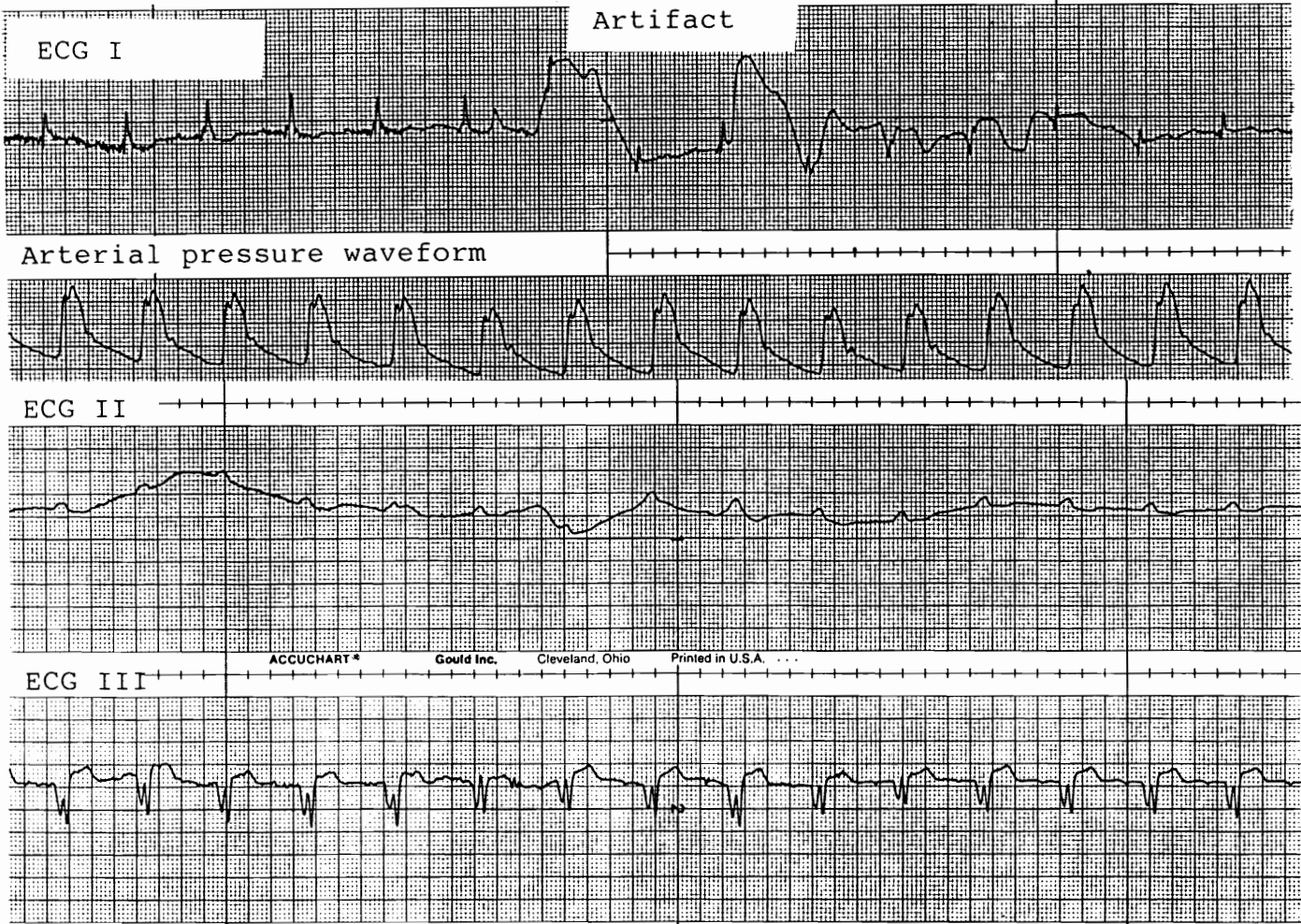


Figure 12. RICU-2. False alarm due to artifact in ECG I from patient movement. ECG II, III and arterial pressure waveform stable. Paper speed: 25 mm/sec.

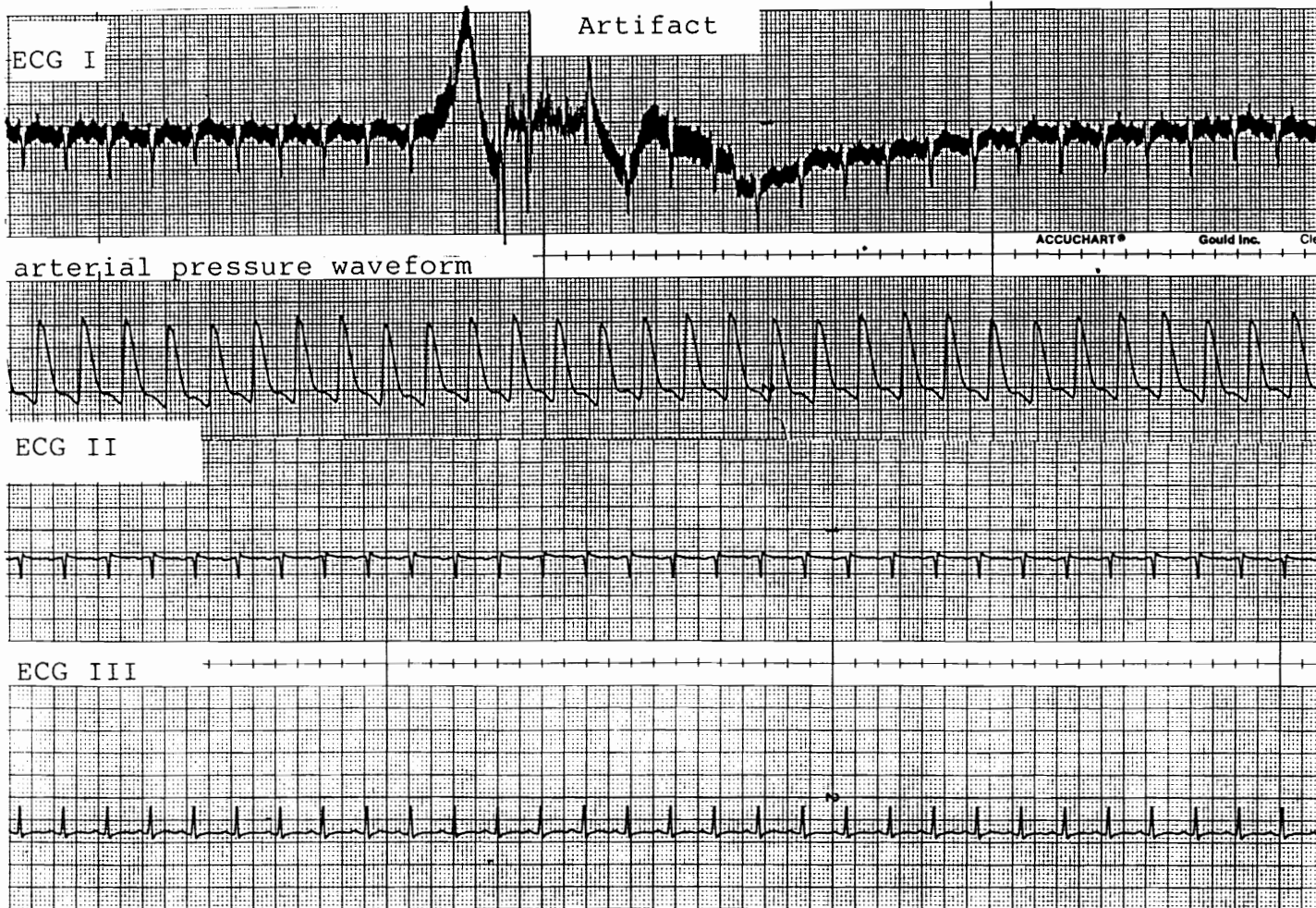
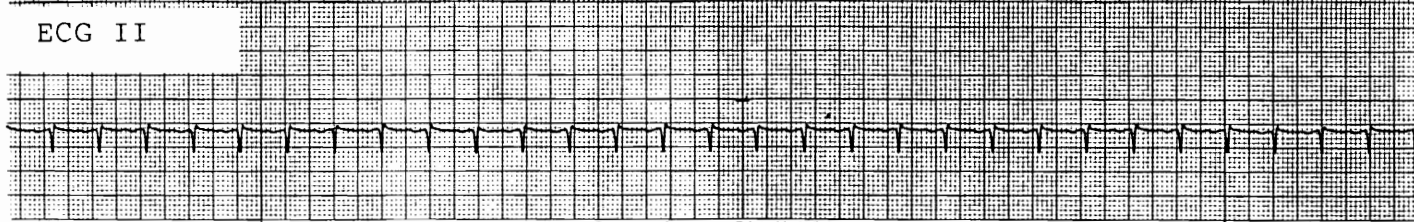
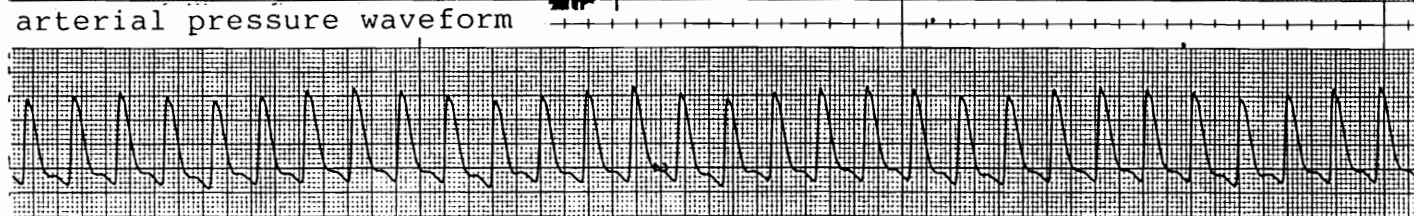
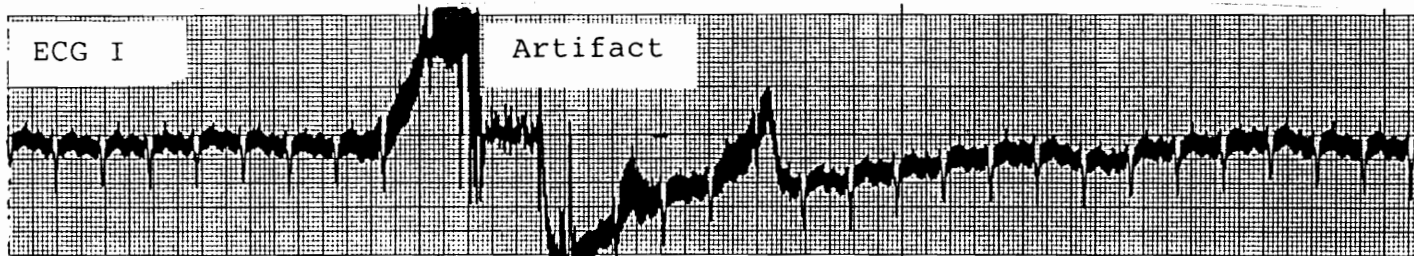


Figure 13. RICU-2. False alarm due to artifact in ECG I from patient coughing. ECG II, III and arterial pressure waveform tracing stable. Paper speed: 25 mm/sec.



ACCUCHART<sup>®</sup> Gould Inc. Cleveland, Ohio Printed in U.S.A.

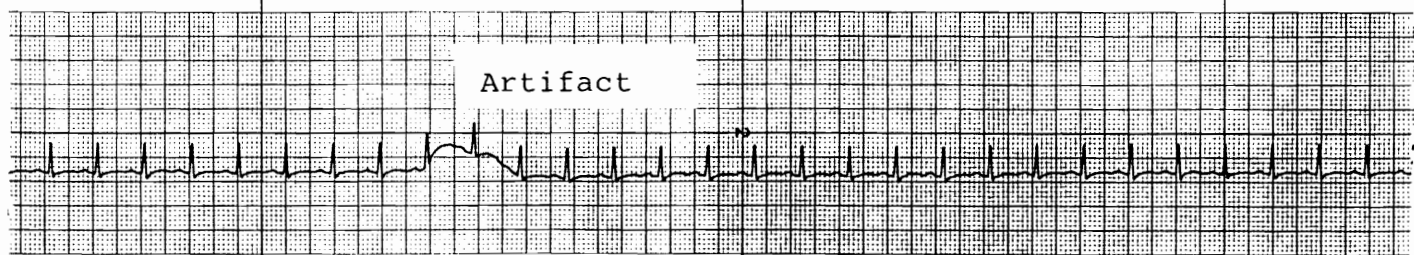


Figure 14. CCU-3. False alarm due to artifact in ECG I due to patient getting up for commode. Minor artifact also present in ECG II, III and arterial pressure waveform tracing. Paper speed: 25 mm/sec.



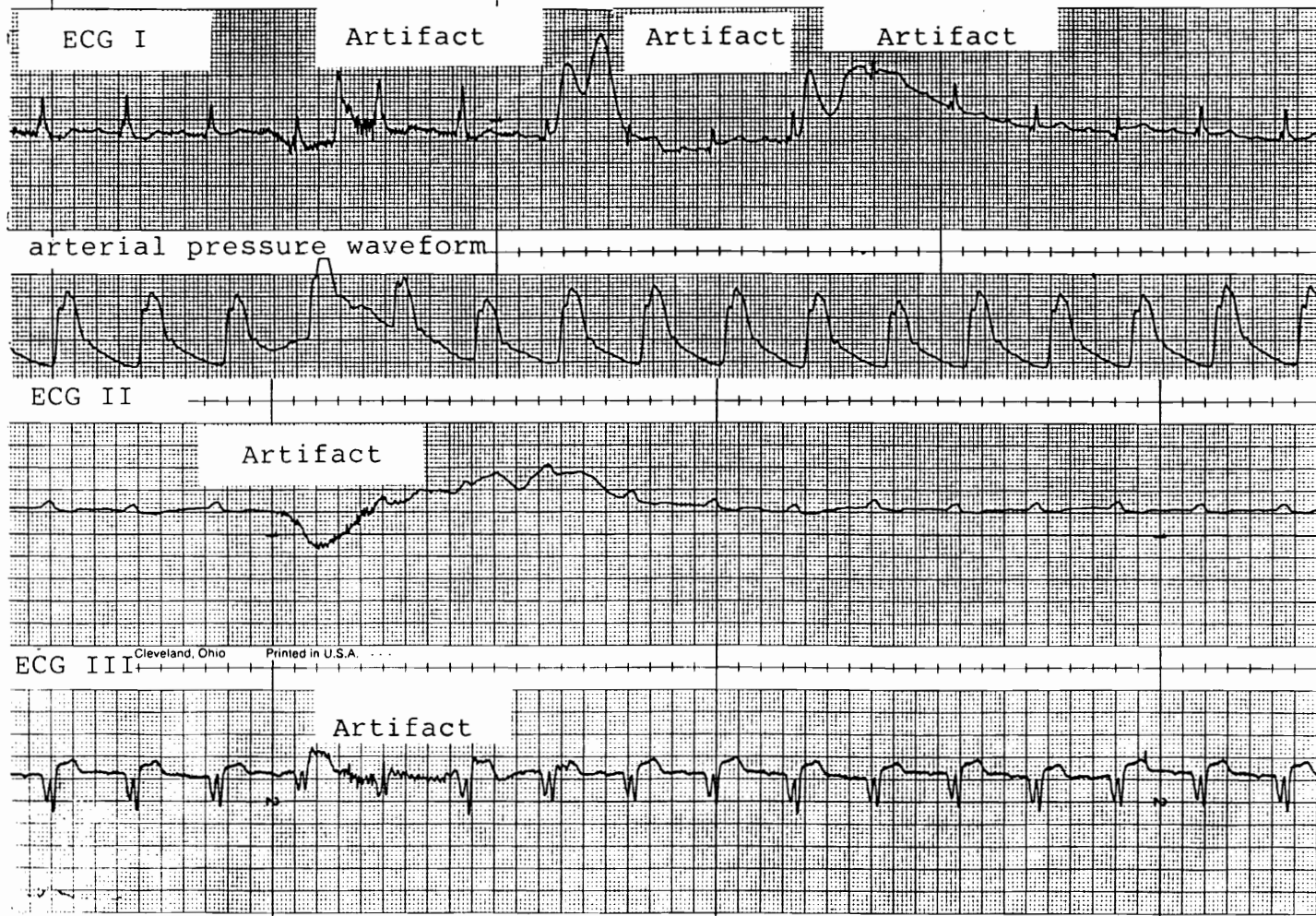


Figure 15. RICU-2. False alarm in ECG I due to patient coughing. False alarm due to artifact (lead off), ECG III. ECG II stable with minor baseline variation. Arterial pressure waveform tracing stable. Paper speed: 25 mm/sec.

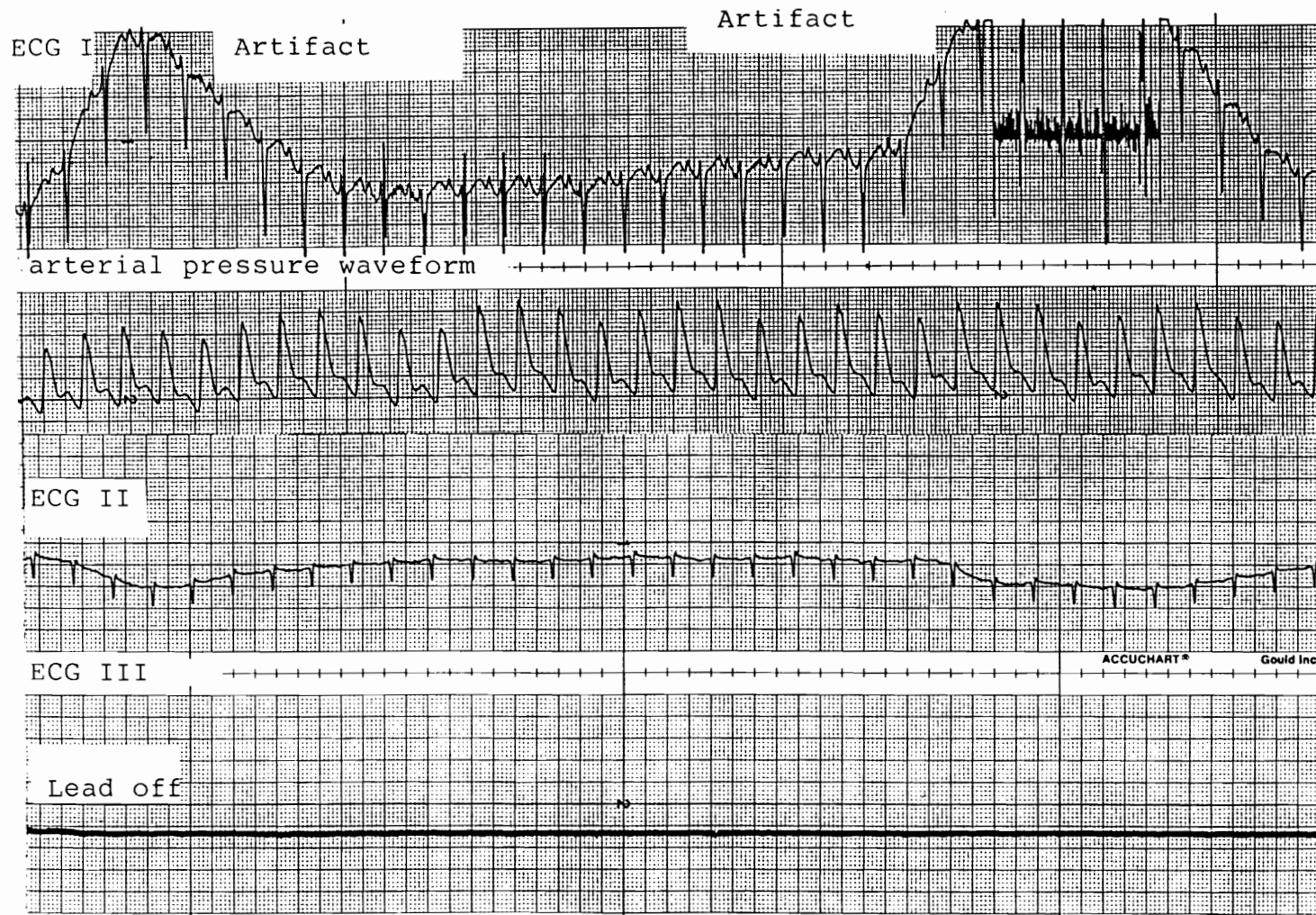
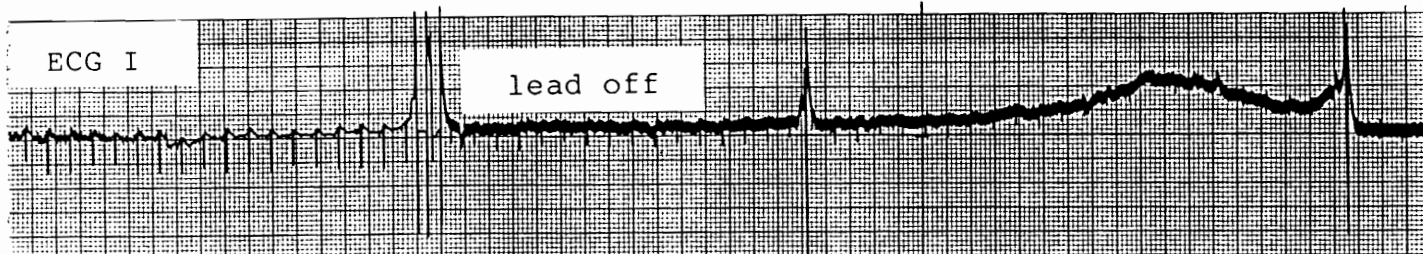


Figure 16. TICU-1. False alarm due to ECG I lead off, arterial pressure waveform disconnected for blood to be drawn. ECG II and III stable. Paper speed: 25 mm/sec.



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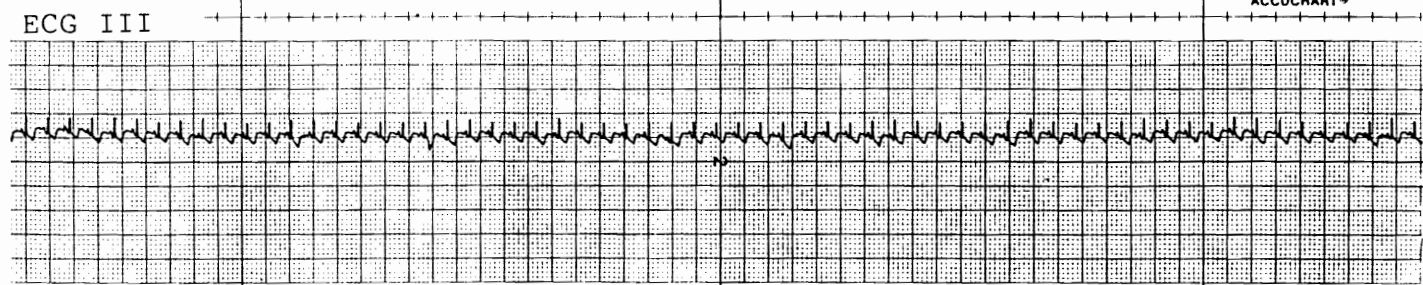
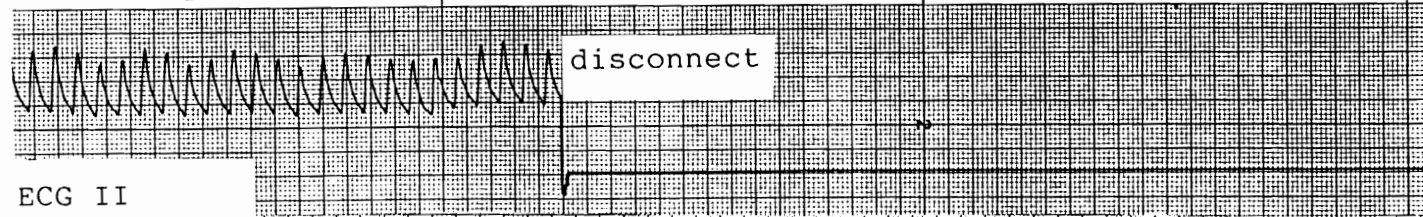


Figure 17. CCU-4. ECG II lead off. ECG I, III, and arterial pressure waveform stable. Paper speed: 25 mm/sec.

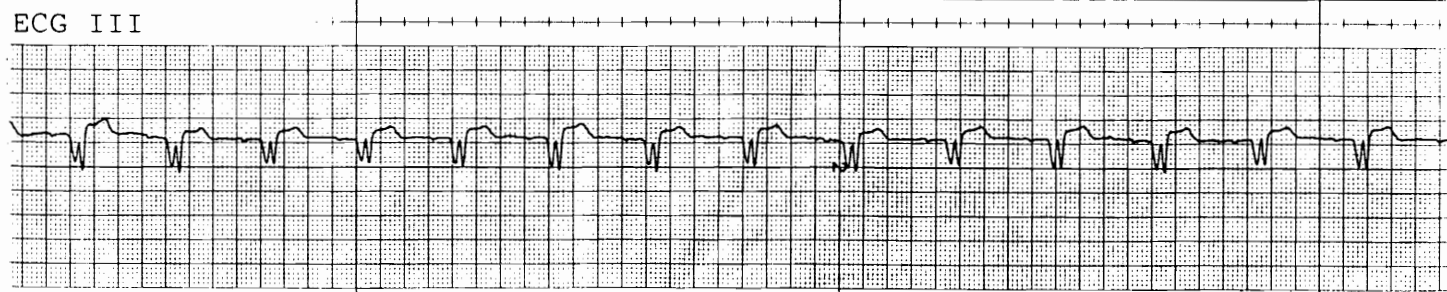
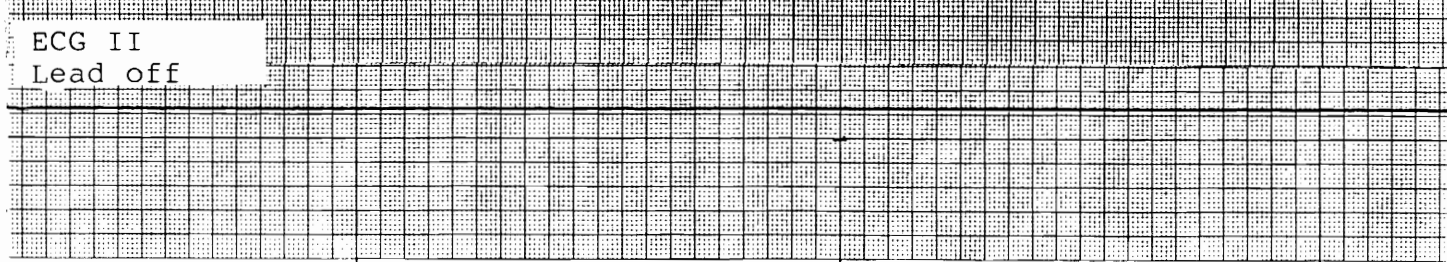
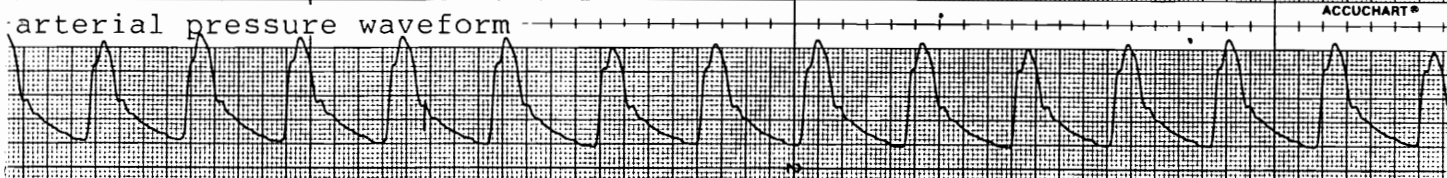
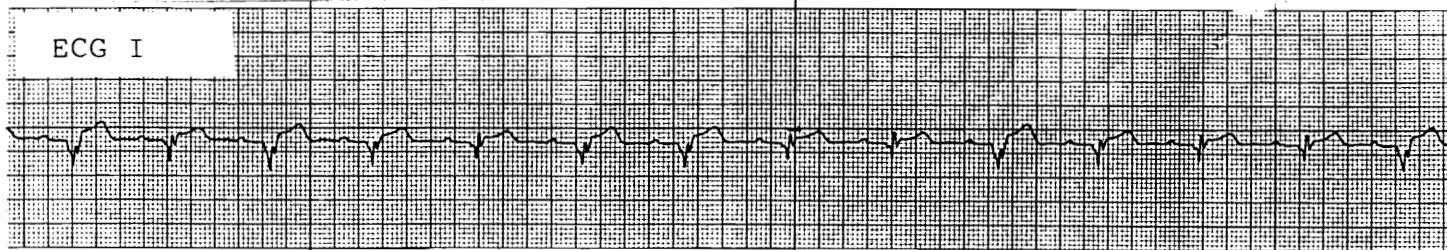
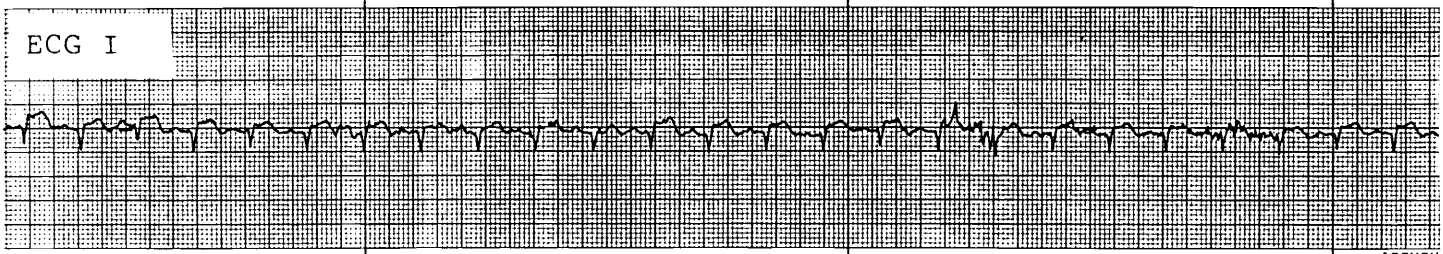
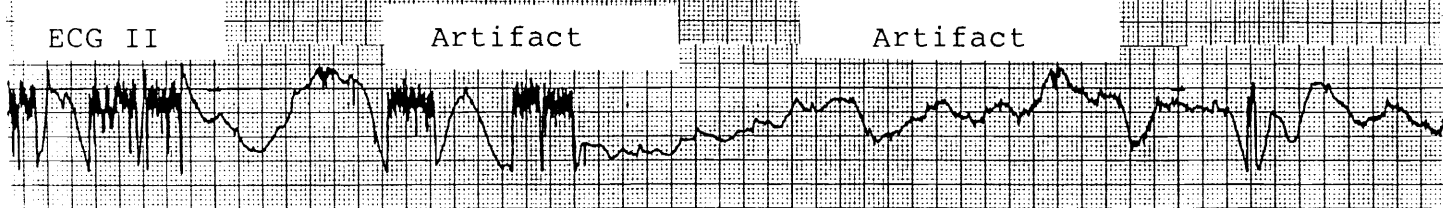
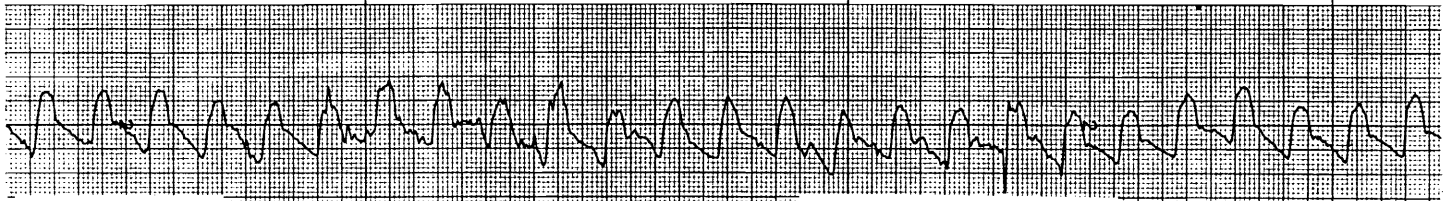


Figure 18. TICU-2. Artifact ECG II, lead off ECG III.  
ECG I stable with minor artifact present  
in arterial pressure waveform tracing.  
Paper speed: 25 mm/sec.





arterial pressure waveform



ECG III - Lead off

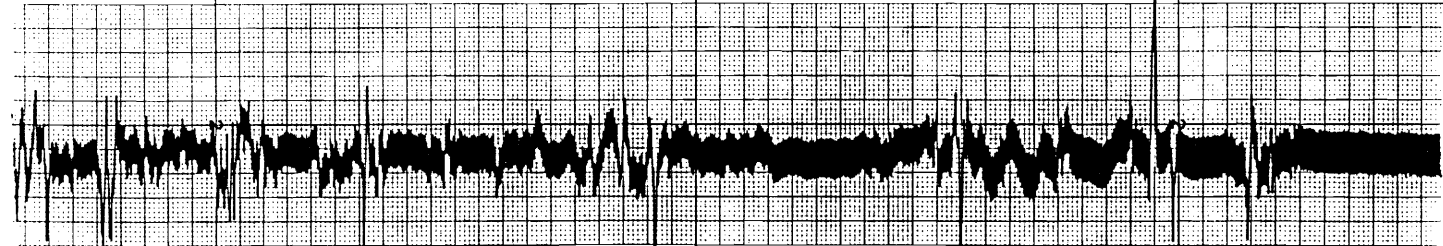


Figure 19. RICU-2. Artifact ECG II and III. ECG I and arterial pressure waveform stable. Paper speed 25 mm/sec.

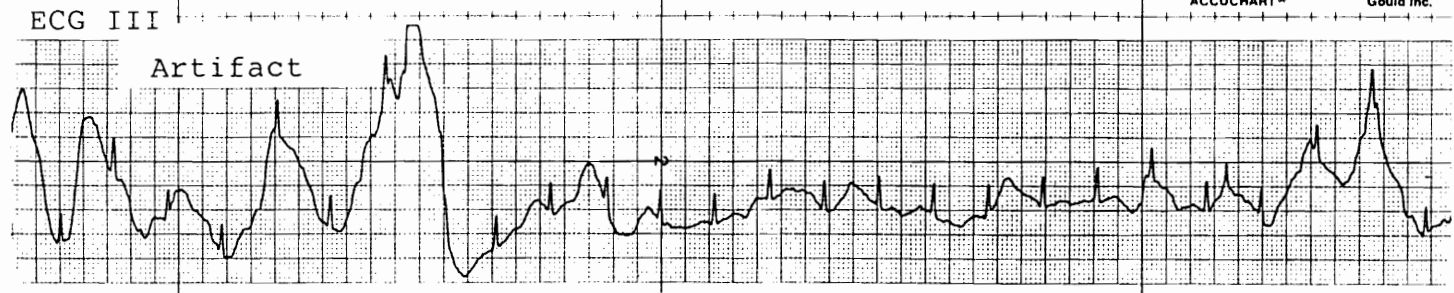
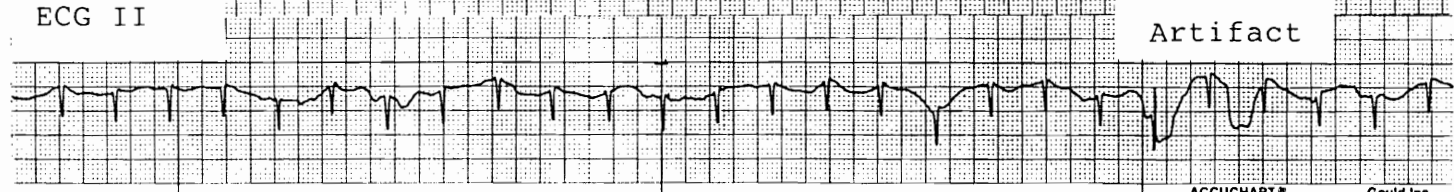
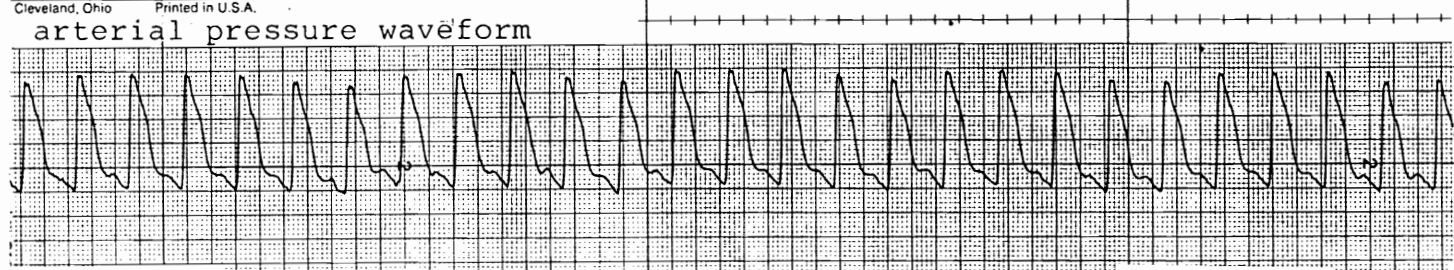
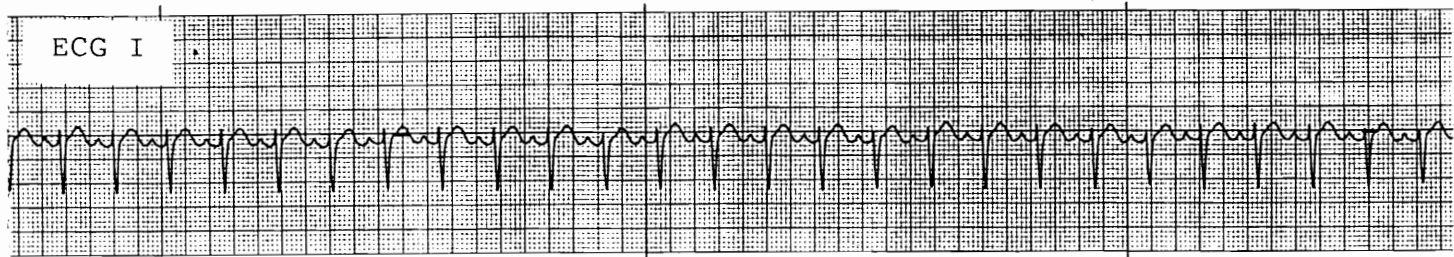
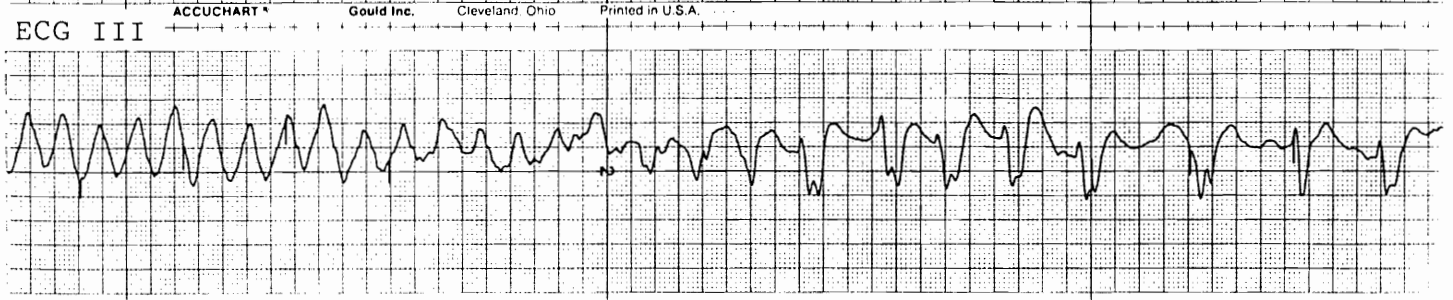
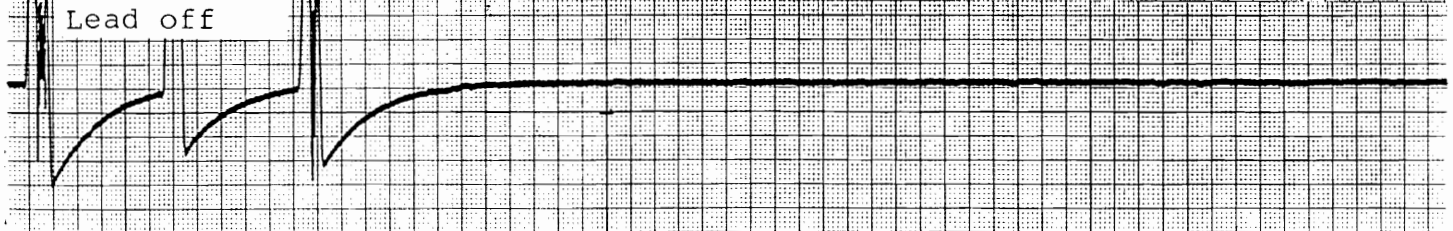
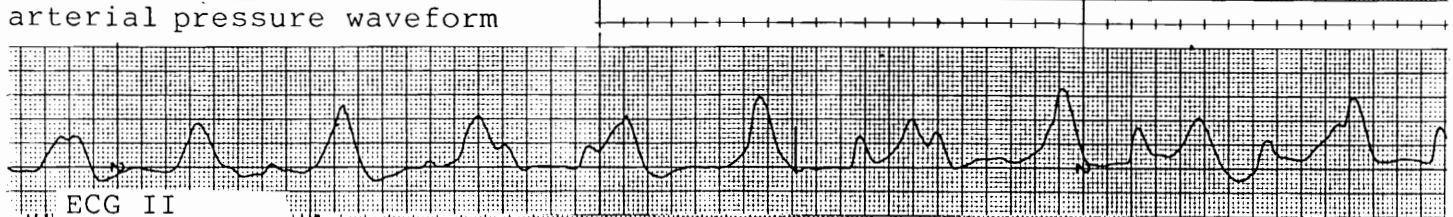


Figure 20. CCU-5. Recovery from true alarm in signals ECG I, III and arterial pressure waveform tracing. ECG II lead off. Paper speed 25 mm/sec.



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Figure 21. TICU-2. Normal rhythm -- paced. Paper speed 25 mm/sec.

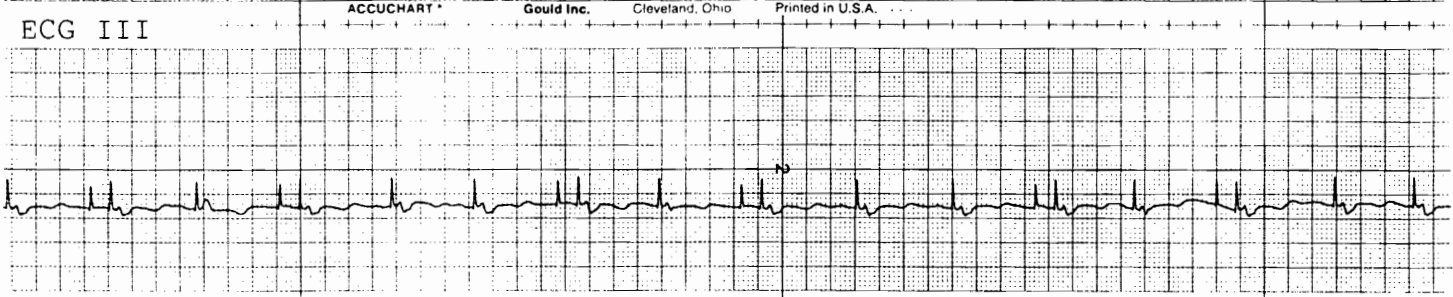
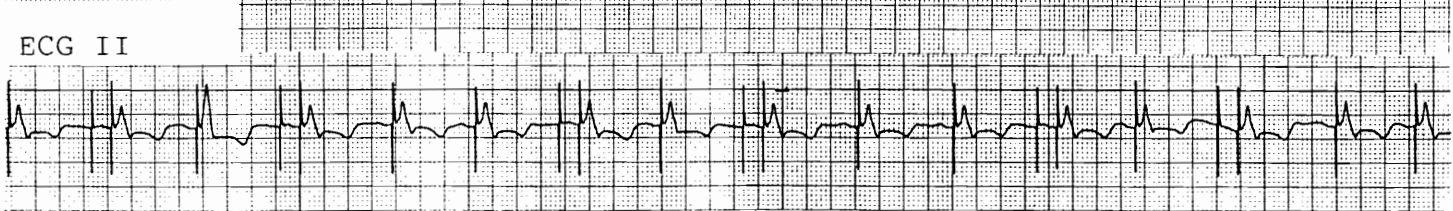
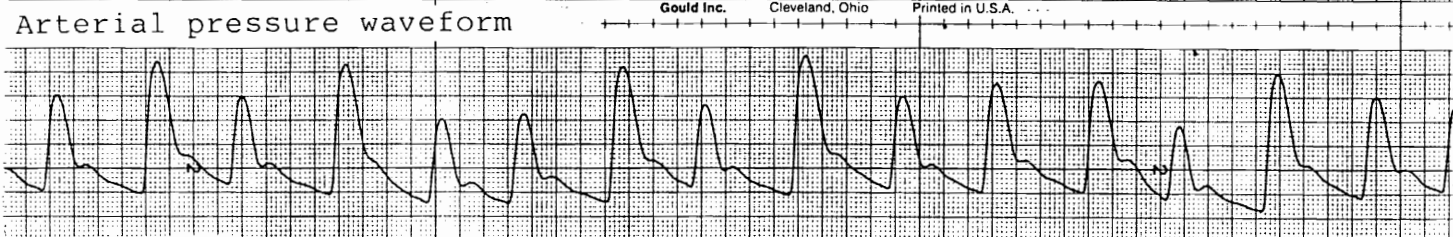
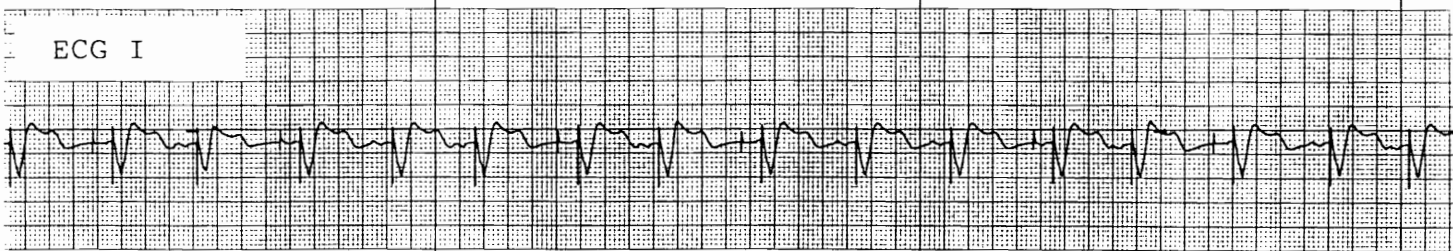


Figure 22. CCU-5. Normal rhythm -- paced. Paper speed  
25 mm/sec.



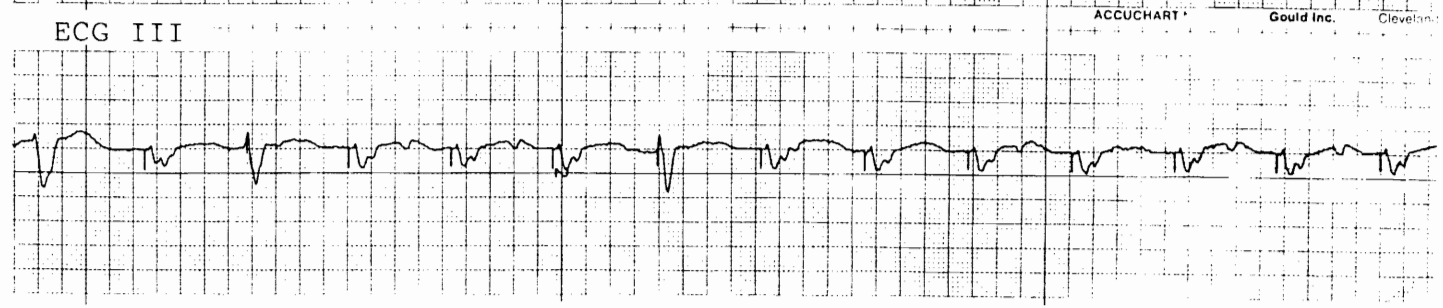
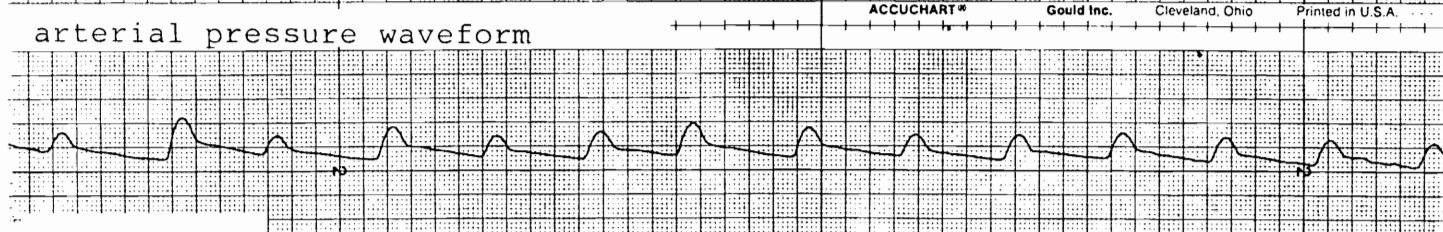
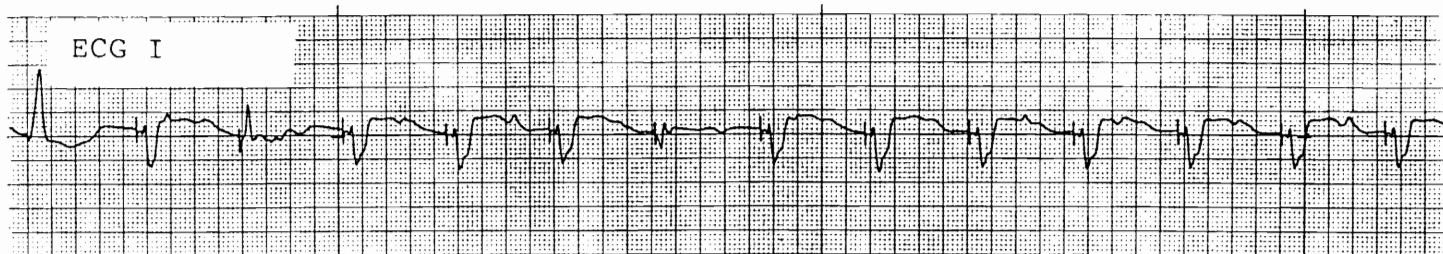


Figure 23. CCU-3. Normal rhythm. Paper speed 25 mm/  
sec.

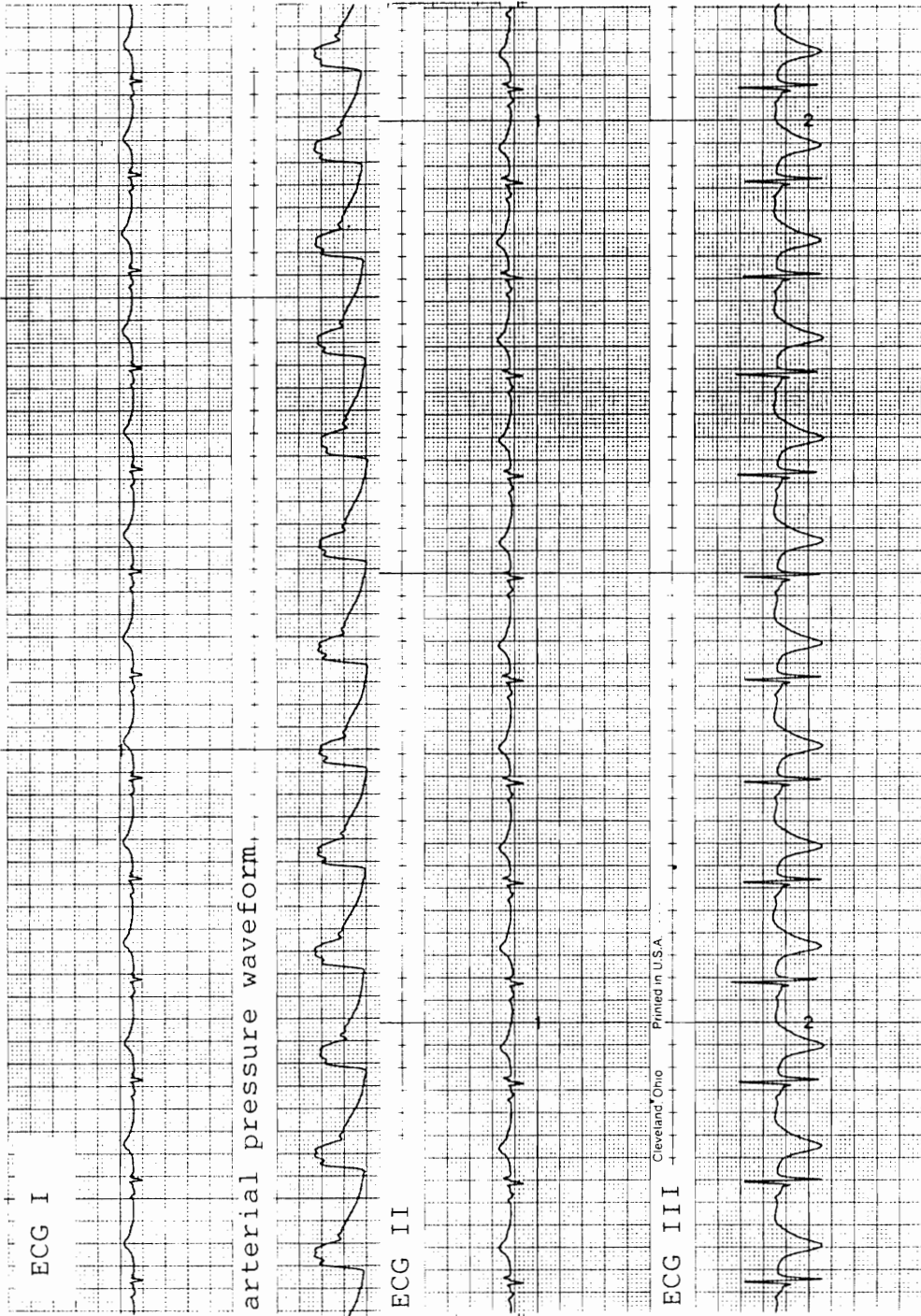
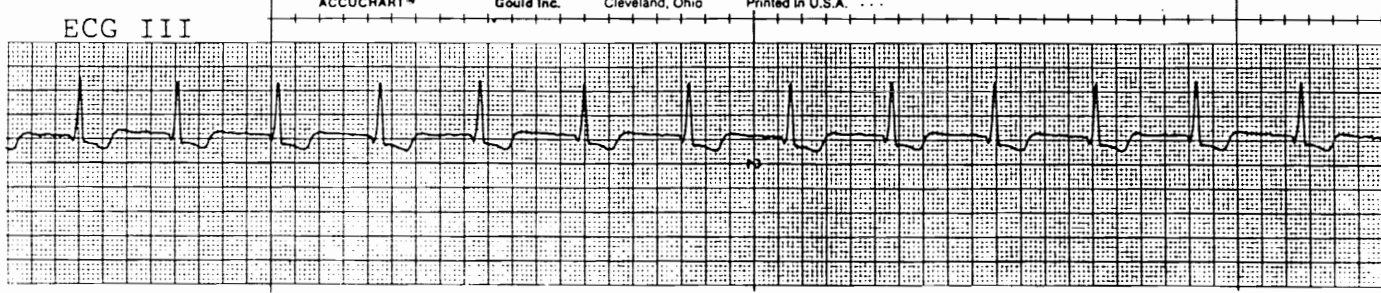
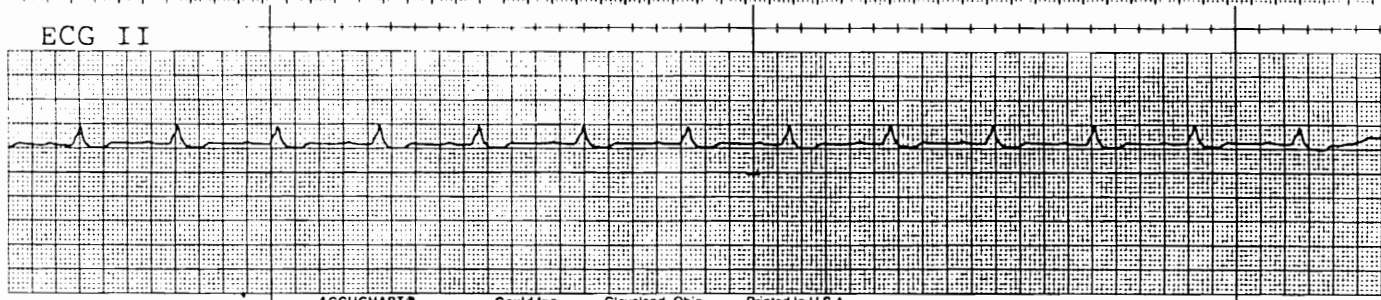
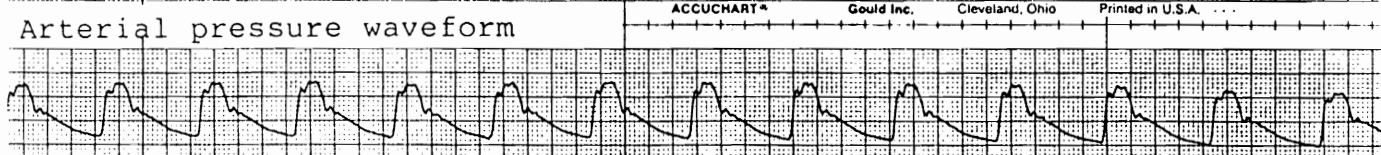
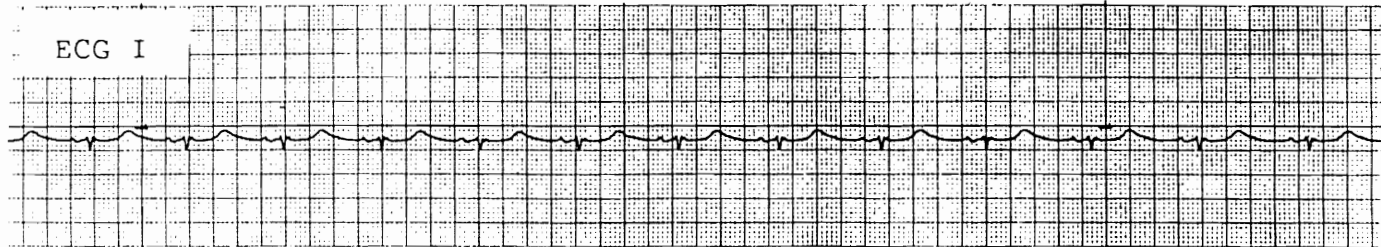


Figure 24. CCU-2. Normal rhythm. Paper speed: 25  
mm/sec.



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