Chapter 12

Electrocardiogram

Study Documents Referred to in this Chapter

- Electrocardiogram

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12.1. Background and Purpose

The purpose of the baseline ECG in LIFE is to determine trial eligibility. Temporary exclusion criteria are the presence of (1) 3rd degree block, (2) any uncontrolled arrhythmia and (3) marked ST segment depression (more than 3 mm) in any lead. The study physician decides what is "uncontrolled arrhythmia."

12.2. ECG Acquisition Procedures

12.2.1. Electrocardiograph

Any clinically approved multi-channel ECG machine can be used to acquire the 12-lead ECG. The devices used at each site are listed below.

Cooper Institute-	Quinton Q-Stress
Stanford University -	Marquette MAC PC
Wake Forest University-	Marquette MAC VU or Med Graphic
Pittsburgh University-	Marquette MAC PC

12.2.2. Equipment and Supplies Needed for Recording ECGs

1. Electrocardiograph, 10 lead Acquisition Module
2. ECG paper, disposable silver chloride electrodes
3. Isopropyl alcohol gauze pads and swabs
4. Scissors
5. Cotton surgical tape
6. Felt tip non-toxic washable markers
7. 4 strips of narrow velcro [helpful in stabilizing the limb lead wires during recording]
8. Examining table disposable paper
9. Baby oil: used only after ECG recording if the participant's skin appears irritated or red

12.4. Recording ECGs

ECGs are recorded in a supine or semi-recumbent position.

12.4.1. Preparation of Participant for ECG Recording

- The participant's safety and comfort are of utmost importance.
- Clean sheets/examination paper must be used at all times.
- The lead placement areas must be marked with non-toxic washable markers.
- The bed must be wide enough to avoid falls. A bed which is too narrow may also lead to poor quality recordings. The left arm must be properly supported. If the bed is too narrow, a portable ironing board can be attached to the left side of the bed so that the left arm may rest on it in order to provide less tension in the muscles.
- Introduce yourself. Ask the participant to relax and provide a brief explanation of the study.

12.4.2. Electrode Lead Placement

- Stand on the left side of the participant at the level of the chest electrodes.
- Participant should be in a supine/semi recumbent position with chest bared. With female participants, cover the areas of the chest not used for ECG recording.
- Always follow the same procedure to ensure efficiency and quality of ECG.
- Attach a green ribbon on the Right Leg Electrode lead wire.
- Mark areas for electrode placement with non–toxic washable markers.
- Prepare the skin by rubbing areas marked (a gauze pad will abrade the skin best after using an alcohol wipe). {See Figure 1: Skin Preparation}
- Apply electrodes on the limbs as shown in Figure 2. Ensure that the Right Leg, Left Leg electrodes show the silver chloride end facing upwards towards the torso. The arm electrodes may face either way depending on

the height of the participant. The lead wires must show no tension or looping. Shave any excessive hair.

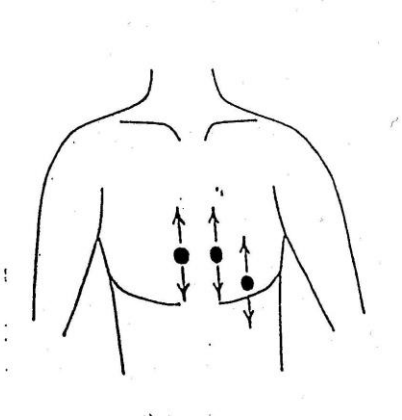


Figure 1. Skin Preparation

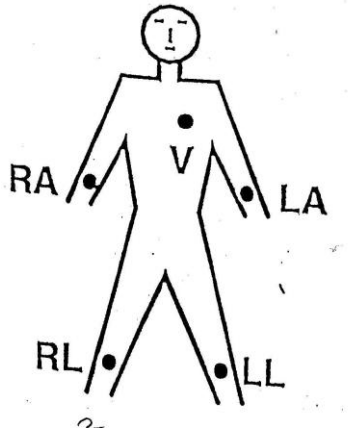


Figure 2. Limb Lead Locations
Adapted from GE/Marquette Mac1200 Manual of Operations

12.4.3. The Unipolar Chest Leads:

For the tracing of the unipolar and bipolar limb leads it is not important where the electrode is placed on the limbs, because the limbs work as extensions of the electrode. With the unipolar chest leads the placing of the electrode is of the utmost importance. These leads are placed in well defined points on the chest according to international standards:

- V1 in the fourth intercostal space, at the right side of the sternum

- V2 in the fourth intercostal space, at the left side of the sternum
- V3 halfwaybetween V2 and V4
- V4 in the fifth intercostal space, left mid-clavicular
- V5 in the same horizontal plane as V4, halfway between V4and V6 (anterior axillary.
- V6 in the same horizontal plane as V4, left mid-axillary

Figure 3. Anatomy of Sternum
Note: Sternal notch at the upper midpoint of the Sternum and the sternal angle where the Manubrium joins the main body of the sternum at the level of the second intercostal space.

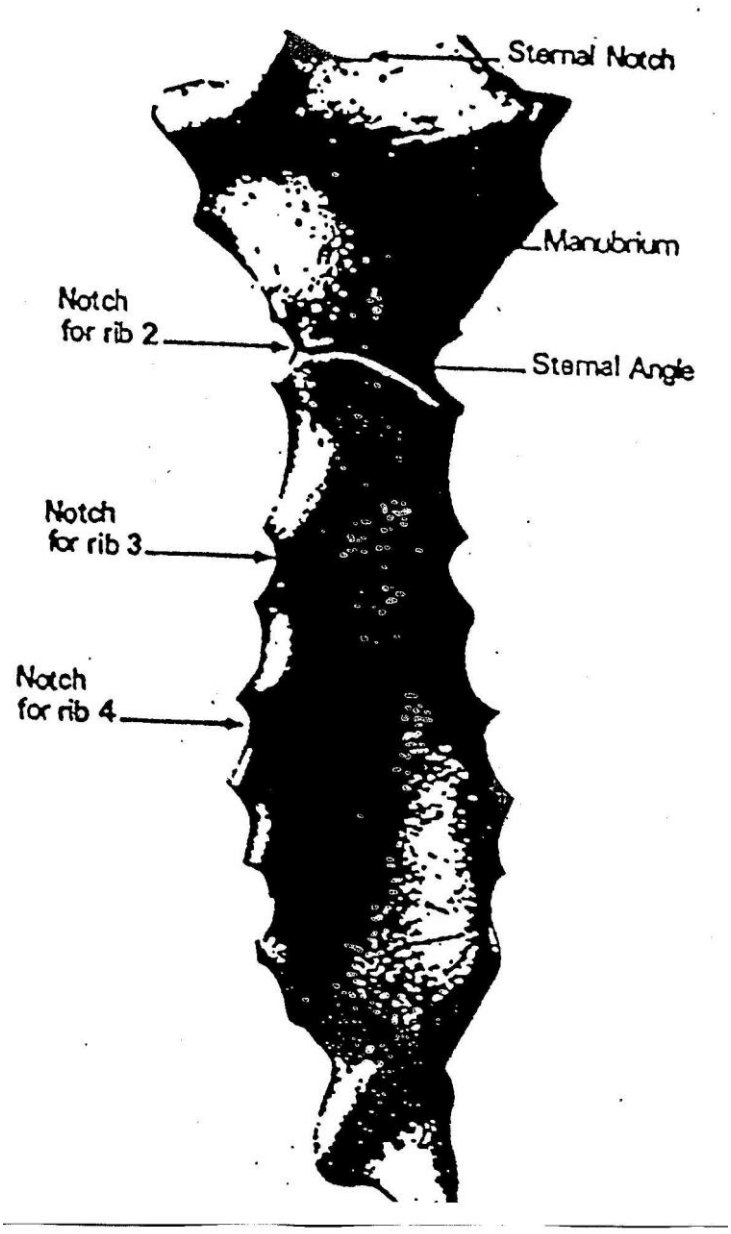
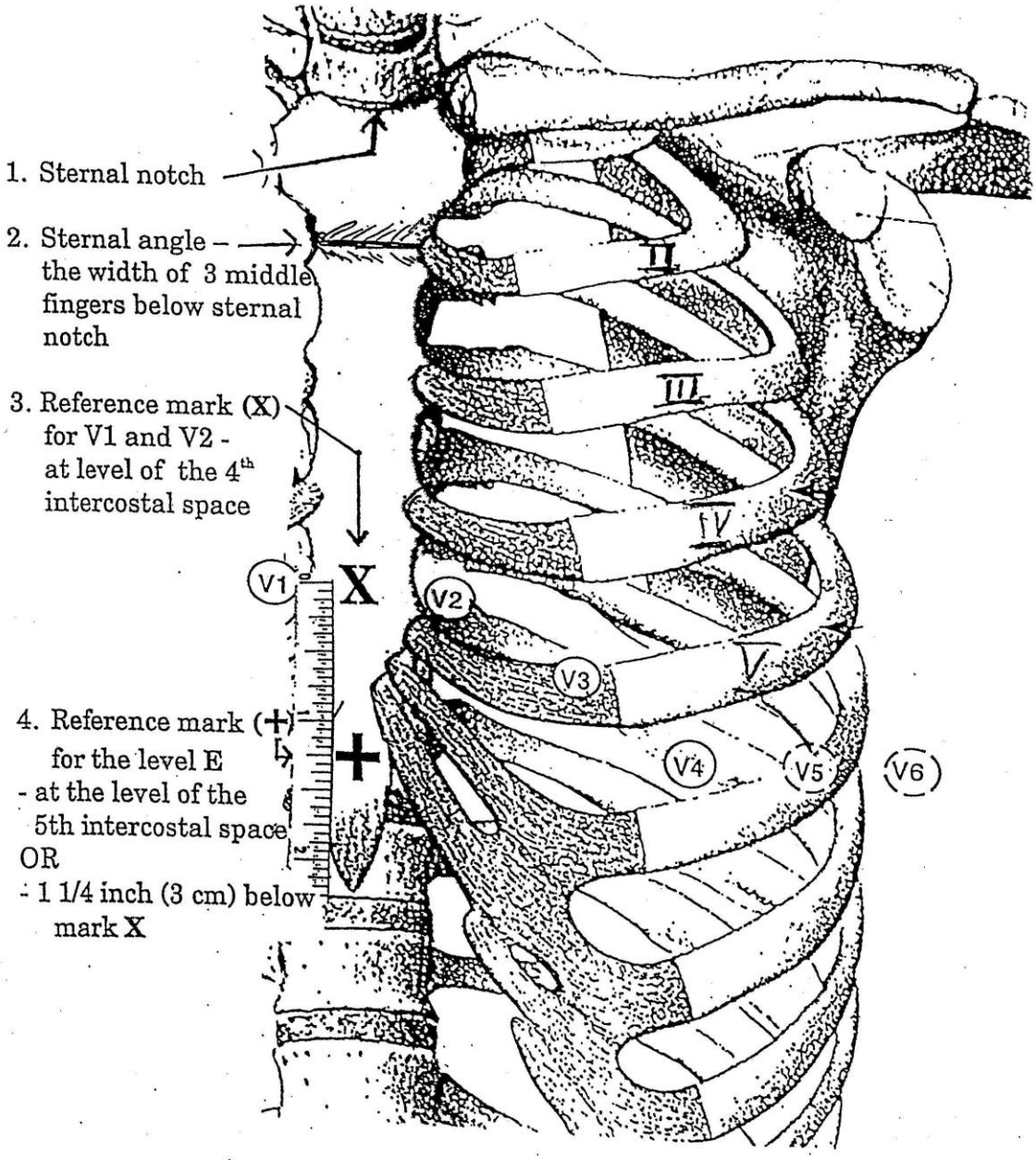


Figure 4. Anatomic Landmarks for Locating Chest Electrodes



12.4.4. Recording the ECG

- Ask the participant to relax, breathe normally and remain still.
- Record the ECG
- Inspect the record immediately for quality. Repeat the recording if you see any quality problems.

Examples of Technical Problems with ECG Recordings

Excessive Baseline Drift : This occurs if the participant is moving around or there is tension on the lead wires. Ask participant to lie still for a few seconds. Drift in excess of 1 mm between baseline points (QRS onset) of any two successive complexes is a sign of excessive drift.

Excessive Muscle Noise; Electrodes Falling Off : Participant is tense or may be cold. Use a blanket to cover the participant. Check the Acquisition Module to ensure that the wires are not pulling. Be sure to establish a good electrode connection. Lay a towel across the wires, if necessary. Adjusting the angle of the clip at the electrode often helps. You may need to tape down the chest leads; use only hypoallergenic medical tape to prevent allergic reactions. Use a U loop (not a cross loop) with the electrode wires, i.e., the wire should not cross but remain open like a U; never cross over wires.

Motion Artefacts : This indicates loose electrodes. This may cause sudden jumps in some ECG leads. Check each electrode to ensure that it is secure. Periodic 60 HZ noise is sometimes visible in the record. This may be caused by poor electrode contact, faulty grounding, or AC interference from a nearby machine. Make a visual check of this before recording the ECG. *Note:* Jewelry does not cause 60 HZ noise.

12.5. Local ECG Readings

The baseline 12-lead ECGs should be read by a local physician. Complete the requested measurements and interpret the ECG. Enter the information on the LIFE Electrocardiogram form.

Print two copies of the strip – one for the study physician and another to give to the participant to share with his/her primary care provider if desired. The auto interpretation should be suppressed on the participant's copy.