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Chapter 12

ECG CORE LABORATORY

12.1 PURPOSE OF ECG CORE LABORATORY (ECL)

The purposes of the ECL are to record, database and analyze digital ECGs during the course of the LIFE trial. The information and methods used to acquire these ECGs must be uniform across sites to best ensure uniform analysis at the ECL. The focus will be high quality digital ECGs for rate, rhythm, interval and QRST analysis. A major emphasis will be identification of interval myocardial infarction not detected by usual clinical means, as well as changes in LVH, AV conduction and rhythm. This manual of operations concerns acquisition and submission procedures of resting ECGs to the ECL.

12.2 DATA COLLECTION INTERVALS

12.2.1. Scheduled Resting ECG Collection

Standard 12 lead resting ECGs using Phillips Pagewriter Trim III equipment and will be collected at Screen Visit 1, 18-month follow-up clinic visit, and the close-out clinic visit (if the measure was not completed at the scheduled follow-up visit or if the scheduled follow-up visit occurred more than one year to the close-out visit).

12.3 QUALITY, COMPLETENESS, AND ACQUISITION OF RESTING ECG DATA

12.3.1 Quality of Resting ECG Data

The following sections will review methods used to achieve good quality 12 lead resting ECGs. It is important that all clinical units adhere to uniform ECG electrode placement and acquisition procedures. The LIFE ECL monitors ECG quality within 48 hours of receipt at the ECL and reports inadequate ECG quality to the site and Coordinating Center (CC).

12.3.2. Completeness of Resting ECG Data

It is essential that all resting ECGs be obtained at their specified time points. The baseline resting ECG serves as the initial comparison with future ECGs. Omission of this ECG may invalidate serial ECG analysis because it is not possible to differentiate an abnormal ECG finding on a subsequent ECG from a pre-existing ECG abnormality. Omission of resting ECGs subsequent to baseline could miss development of new ECG abnormalities.

12.3.3. Resting ECG Acquisition

12.3.3.1. GENERAL GUIDELINES

Resting ECGs will be acquired with the following general guidelines:

- a. All resting ECGs will be 12 lead ECGs acquired using Philips digital recorders
- b. 25mm/sec paper speed
- c. Recorded calibration mark confirming calibration of 10 mm to 1 mV
- d. Resting ECGs should be raw data and not obtained in “average” mode
- e. Uniform procedures for lead placement, skin preparation, and quality control which follow will ensure comparability of resting ECG data.

12.3.3.2. SUPPLIES

- a) Electrocardiograph, Phillips Pagewriter Trim III
- b) ECG paper, disposable electrodes
- c) Isopropyl alcohol gauze pads and swabs
- d) Felt tip non-toxic washable markers
- e) Examining table disposable paper

12.3.3.3. RESTING ECG LEAD PLACEMENT

- a) The participant’s safety and comfort are of utmost importance
- b) Clean sheets/examination paper must be used at all times.
- c) The lead placement areas must be marked with non-toxic washable markers.
- d) 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.
- e) Introduce yourself. Ask the participant to relax and provide a brief explanation of the study.
- f) Patient must be supine with upper body exposed, shoulders straight, and arms relaxed.
- g) Ask patient to avoid movements that may cause errors in marking electrode locations or artifact in ECG recording.
- h) Mark each electrode site with a felt tip pen using anatomical landmarks to determine lead placement (see Attachment A):

Lead VI: Fourth ICS space at the right of the sternal border

Lead V2: Fourth ICS space at the left of the sternal border

Lead V3: Position equidistant between lead V2 and V 4

Lead V 4: Fifth ICS space in the midclavicular line

Lead V5: Fifth ICS space at the level of the anterior axillary line

Lead V6: Fifth ICS space at the level of the midaxillary line

Lead RL: Right lower leg above the inner ankle or as close as the electrode will reach

Lead LL: Left lower leg above the inner ankle or as close as the electrode will reach

Lead RA: Right inner right arm above the wrist
Lead LA: Left inner right arm above the wrist

Note: Electrode positioning for women is determined with respect to anatomical landmarks. In women with large breasts, place electrodes on top of the breast in their natural position when supine. Do not move the breast upwards or laterally to place electrodes under the breast.

12.3.3.4. RESTING ECG SKIN PREPARATION

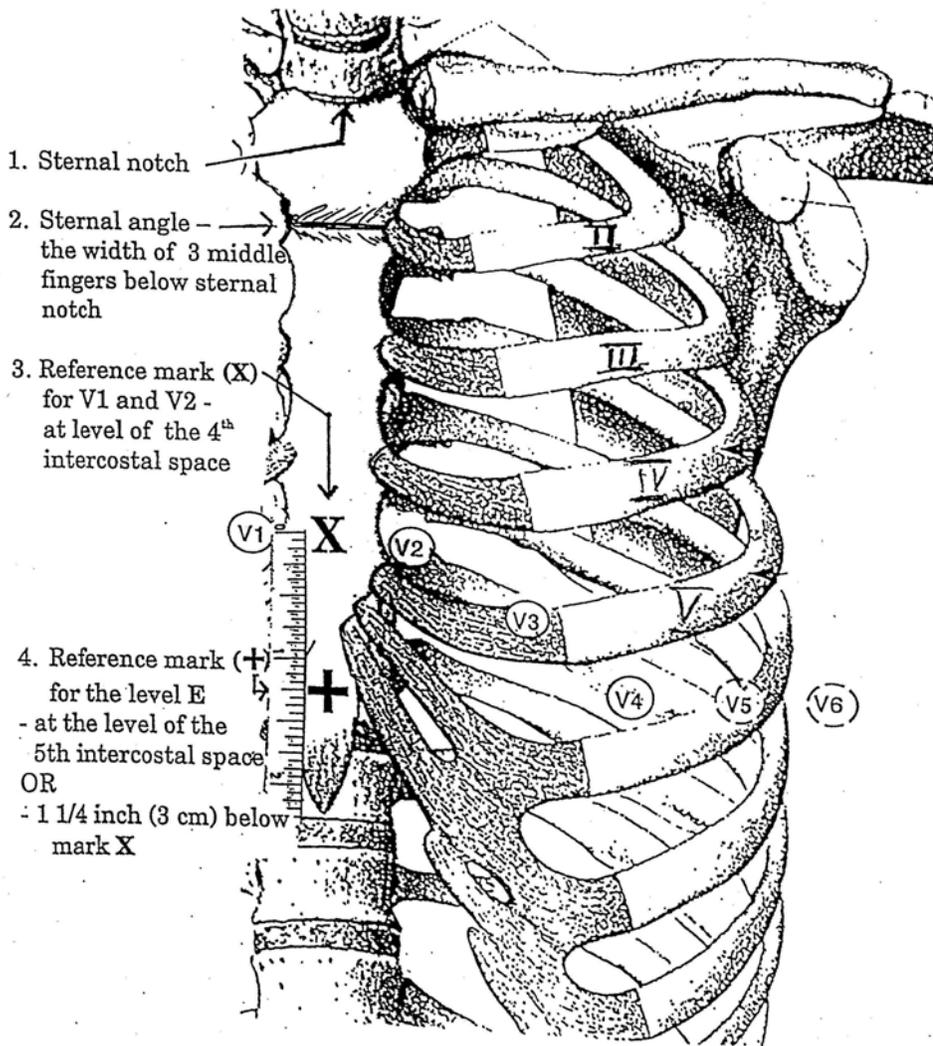
Skin must be prepared for electrode attachment:

- a. Shave hair from electrode sites to improve adhesion and conduction as well as electrode removal.
- b. Rub each electrode site with alcohol or acetone to remove skin oils.
- c. Rub in a single direction with gauze or a mildly abrasive pad to remove the epidermal layer at each site. This removes dead skin and oils to enhance conduction. The skin should appear slightly red.

12.3.3.5. RESTING ECG ELECTRODE ATTACHMENT

- a. Place an electrode at each prepared site.
- b. Apply pressure around perimeter of the electrode in a single motion if disposable electrodes are used. Do not press on the center gelled portion.
- d. Allow gel to penetrate for a minute or two to enhance conduction before recording the ECG.

Figure 1. Anatomic Landmarks for Locating Chest Electrodes 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.



12.3.3.6. RESTING ECG ELECTRODE CABLE ATTACHMENT

Risk of wrong connections (lead reversals) can be minimized if a uniform sequence of electrode attachment is followed. The following sequence of connecting electrode cables is recommended:

- a. Right Leg
- b. Left Leg
- c. Right Arm
- d. Left Arm
- e. V1
- f. V2
- g. V3
- h. V4
- i. V5
- j. V6

Straighten all electrode cable wires prior to attaching electrodes to decrease possible lead reversals. After attaching lead wires, verify one by one that connections to all electrode sites are correct.

12.3.4. Recording the Resting ECG

Patient must be in supine position. Ask patient to relax, breathe normally, and refrain from talking or moving while the ECG is recorded. Specific directives for recording ECGs with Philips electrocardiographic equipment are given in Attachment B. Record the 12 lead resting ECG and confirm good quality 12 lead printout using the post-recording quality check items listed below (Section 12.3.5.).

12.3.5. Post-recording Quality Check of Resting ECG

Inspect the resting ECG recording immediately for quality and repeat the recording if problems are identified. Check for the following:

1. EXCESSIVE BASELINE WANDER

Excessive Baseline Wander is defined as 1.0 mm difference between the PQ baseline in three consecutive ECG complexes. The source of this artifact is usually inadequate skin preparation.

2. MOTION ARTIFACT OR LOOSE ELECTRODE CONTACT

These may cause sudden jumps in some ECG leads.

3. EXCESSIVE MUSCLE NOISE

This is random noise in excess of 5 mm. The source of this artifact may be inadequate skin preparation or a patient that is shivering or trembling.

4. EXCESSIVE 60 HZ NOISE

60Hz noise is visible on the 12 lead resting ECG. This noise is usually associated with A-C and R-F interference from nearby machines picked up by the ECG cables, thus attention to the position of the cables is important. Another source may be poor skin contact.

5. VALID CALIBRATION DOCUMENTATION

The calibration standard should be recorded on each resting ECG. Invalid calibration exceeds ± 1.0 mm of the standard 10 mm pulse. Equipment should be calibrated if outside of the acceptable range.

6. MISSING LEADS

Ensure all 12 leads are recorded. A flat line in one or more of the lead groups is an indication that one or more leads is not attached.

7. CHECK FOR LEAD REVERSAL

The ECG should be inspected for possible lead reversals. Look for normal progression of chest lead patterns from V1 to V6. Inspect lead AVR for negativity, and lead I for mainly positive P, QRS, and T wave. If any condition is suggestive of lead reversal, re-check electrode cable attachment.

8. SOURCES OF ARTIFACT

Sources of artifact may include:

- a. Inadequate skin preparation (most common cause of artifact)
- b. Defective electrodes (check expiration dates, gel dries over time)
- c. Fractured lead wires
- d. Fractured wires in acquisition cord interface
- e. Patient not resting quietly and relaxed

12.3.6. Resting ECG Submission

The ECL is equipped to receive 12 lead resting ECGs electronically via a dedicated Philips Tracemaster VUE receiving unit. The unit has a validated noise reduction algorithm and can receive the ECG transmissions directly from the cart via Internet or the ECG can be

uploaded from a personal computer using some intermediate memory (USB drive) through the Tracemaster Vue client.

In order to transmit 12 lead ECG's from the Phillips Trim III, place the provided USB flash drive in the rear of the machine. Using larger than a 256 MB flash drive will lock up the machine. Select "Archive" from the bottom menu. Highlight the ECG's to be transferred. Select "Transfer" destination and select USB memory file and select OK. The highlighted ECG's will transfer to the USB drive. The drive can be removed and taken to a desk top computer and uploaded as outlined below to the Tracemaster VUE system. Each site will be responsible for making sure that site ECG's have been successfully transmitted. Do not delete files from the Trim III until successful transfer has been documented. Each Trim III can hold 150 ECGs. Additional USB drives are available to back up data if necessary.

To move ECGs from the jump drive to the Tracemaster system you will sign in to the TracemasterVue application.

1. Place the jump drive in a USB slot.
2. Click File on the menu bar, click Import and then find your drive and select the files you wish to import. (If there are only a few you can click the first one and, while holding down the CTRL key, you can select individual files. If you want to move all of the files then select the first file, press the SHIFT key and select the last file. All files between and including the first and last will be selected.)

The aim of standardizing ECG recording equipment and transmission capabilities is to provide the highest quality document for ECG analysis and provide a repository of digitized ECGs which can be easily stored and retrieved for subsequent data analysis. Detailed instructions are included in Attachment B for programming and transferring data via the Internet. It is imperative that electronic data be sent according to the parameters specified in Attachment B; resting ECGs that are not correctly identified will not be directed to reside in the LIFE ECG electronic folder and will not be logged in as received. A hard copy of the 12 lead ECG should be printed and provided to the physician investigator to read for safety purposes. These ECG's should be signed and dated by the investigator and placed in to the patients' study record.

Occasionally (ED visits, outside hospital admissions, etc.) a non digital ECG may have been recorded without opportunity for the Philips digital ECG. All non-electronic transferred resting ECGs will be original paper copies and will be mailed to the ECL where they will be logged in and assessed for quality. Each original paper copy resting ECG will be labeled using study labels. A template for these labels will be available on the LIFE website. These labels should be meticulously completed to provide all necessary information (patient ID, ECG date and time, ECG category, digitalis usage, procedure date and time, myocardial infarction/ ischemic event, etc.) to route the resting ECG to the appropriate study. Data should be submitted to the ECL with patient's name either deleted or blocked out to ensure confidentiality.

7. It should run the install with you taking any defaults. This may take a while since it will have to install Microsoft .NET Framework version 3.0 if your PC does not already have this. When it completes it should come up to the login screen and that means it is working.

You should also see on the desktop an icon for the TM ECGVue Application. Whenever you need to run TracemasterVue you will first have to login to the Shands VPN to create the secure “pipe”. To move ECGs from the jump drive to the Tracemaster system you will sign in to the TracemasterVue application. Place the jump drive in a USB slot. Click Eile on the menu bar, click Import and then find your drive and select the files you wish to import. (If there are only a few you can click the first one and, while holding down the CTRL key, you can select individual files. If you want to move all of the files then select the first file, press the SHIFT key and select the last file. All files between and including the first and last will be selected.)

ECL Contact:

ATTACHMENT A: PRECORDIAL RESTING ECG LEAD PLACEMENT

1 Electrode Placement for Standard Leads (I, II, III, aVR, aVL, aVF, V1...V6)

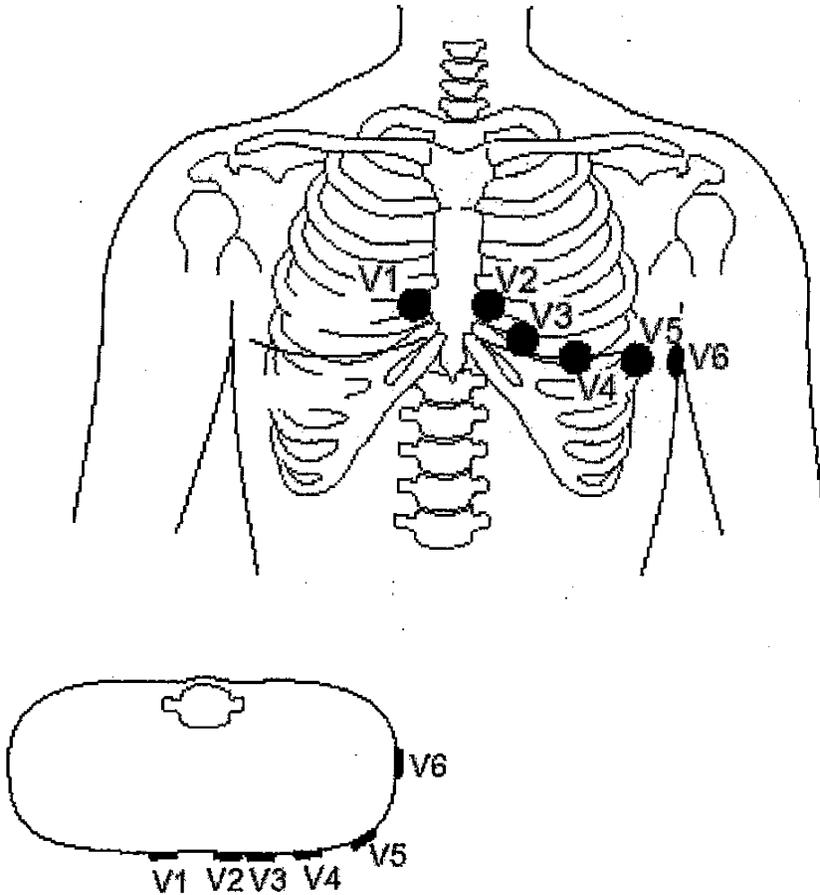


Figure 1-1. Chest electrode placement.

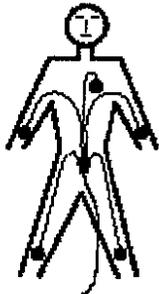
For acquisition of standard ECG leads, four electrodes must be applied on the limbs and six on the chest. Limb electrodes should be placed distally on the inner aspect of the wrists and ankles (Figure 1-2).

Figure 1-1 shows chest electrode application points.

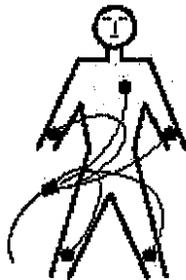
- V1 4th intercostal space at right sternal border
- V2 4th intercostal space at left sternal border
- V3 midway between locations V2 and V4
- V4 at the mid-clavicular line in 5th intercostal space

V5 at anterior axillary line on the same horizontal level as V4 and V6

V6 at mid-axillary line on same horizontal level as V4



correct



wrong

- Arrange lead wires and patient cable as shown in Figure 1-2.

ATTACHMENT B: RESTING ECG ACQUISITION: Phillips Pagewriter Trim III EQUIPMENT SET-UP PROCEDURES

1. Equipment Information

The present description refers to a Philip Pagewriter Trim III. The systems are similar with respect to setting up parameters specific to the study.

2. Equipment Support and Troubleshooting Information

The Philips Operator's Manual provides additional information and should be used in conjunction with information provided here. It is an excellent resource and contains detailed information for troubleshooting equipment problems.

3. Philips Equipment Set-up Procedures

The system set-up will be modified to the following specifications for the LIFE Study. The set-up will be stored for the duration of the study; only changes in time will need to be modified. (Refer to the Philips Operator's Manual: SETUP). Once these details are set, the system will retain them until they are manually modified. A configuration file will be sent to each site with specific site configuration information (site number etc) and this will be loaded into the LIFE ECG machine. Each site will download ECG's to the system and contact the ECL Core Lab for confirmation that transmission was successful.

Loading the Configuration Settings File

To ensure uniformity throughout the institutions participating in the study, we have decided to send a configuration file for the Life Study Pagewriter Trims. These are preconfigured with each individual institutions specific identifying information, such as department number. This will ensure that all uploaded ECGs will be deposited in the proper area of Tracemaster. Also, if the cardiograph loses all configured settings, you can upload the cardiograph configuration settings file again to the cardiograph using a USB memory stick. This procedure may also be used when loading cardiograph configuration settings onto multiple cardiographs.

NOTE: Network settings are not saved with the configuration settings file. It is recommended to print out a configuration settings report to capture a record of all network settings on the cardiograph.

To load the configuration settings file onto the cardiograph:

1. Save the Configuration file to the USB memory stick you will also use to load ECGs.
2. Insert the USB memory stick that contains the configuration settings file into the PC card slot or the USB port on the rear of the cardiograph.
3. From the R/T ECG screen, press the **Tab** key (key with arrows pointing left and right) or turn the Trim Knob to select the **Config** button on the Command Toolbar.
4. Press the space bar (on keyboard) or the Trim Knob to select the button. The Configuration screen appears.

5. Press and hold down the **Alt** key (**ALT**) on the keyboard.
6. Press the **S** key. The System screen appears.
7. Press the **Tab** key or turn the Trim Knob until the **Load Configuration File** button under **Configuration Management** is highlighted.
8. Press the space bar or the Trim Knob. The **Load Configuration File** window appears. The **Select Input Source** pull-down list is highlighted.
9. Press the up or down arrow key on the keyboard to select the input media. Press the space bar to select the input media. The configuration settings file(s) saved to the input media display under **Profiles List**.
10. Press the **Tab** key or turn the Trim Knob to highlight a profile under **Profiles List**. Press the space bar or the Trim Knob to select the configuration settings file.
11. Press the **Tab** key or turn the Trim Knob to highlight the **OK** button. Press the space bar or the Trim Knob to select the button.

The configuration settings file is loaded onto the cardiograph. The new settings are applied. All ECGs performed after this procedure will use this configuration.

4. Recording the 12 Lead Resting ECG

1. Ask patient to relax, breathe normally, and refrain from talking or moving while ECG is recorded. Record ECG by pressing the record ECG key at the top right corner of keyboard next to the numerical zero key.
2. A display will appear in the LCD window **** Acquiring Data ****, followed by **** ECG Acquisition Complete ****.
3. The Philips Unit will process the data (LCD screen: **** Analyzing ECG ****) and print reports (LCD screen: ****Printing reports****).
4. The LCD screen will prompt for number of extra copies (0-9). One copy of each resting ECG should be retained as hardcopy in the participant's study chart at the clinical unit. Enter the number of additional copies. If you do not want additional copies, press enter.
5. The LCD screen will display **** Processing ECG **** then **** ECG Storage complete****.
6. Press enter to return to the main menu.

Electronically Transmitting Resting ECGs- The TrimMaster III machine will store 150 12 lead ECG's in the machine. Each site has been sent a 256 MB Flash Drive which will be utilized to download the stored ECG's and then the flash drive will be taken to a desk top or lap top computer and transmitted/uploaded to the TraceMaster Vue system at the ECL.