

Chapter 40. Electrocardiogram (ECG)

This manual chapter is intended to serve as both a training and a reference document for persons who perform the ECG for the PVDOMICS study using standardized procedures and techniques. This will aid in obtaining accurate test results and a safe testing environment.

The Cardiovascular Physiology Core (CPC) will review all PVDOMICS participants' ECG reports submitted to the core laboratory. The CPC is located at the Cleveland Clinic in Cleveland, Ohio and is under the direction of W. H. Wilson Tang, M.D.

40.1 Overview

An electrocardiogram is a routinely used, non-invasive procedure that allows physicians to monitor and assess the electrical activity in the heart. It is recognized as the gold standard for detecting heart arrhythmias and conduction delays¹.

All study participants will receive an ECG. The ECG must be done for the PVDOMICS study. Results from a prior ECG, even if recent, cannot be used.

40.2 Site and Technician Certification

Before ECG studies may be performed on subjects, each site will be required to complete the following list of requirements:

1. Establish two or three primary contact persons at their site who will be responsible for communication with and transmission of ECG data to the Study Coordinator. The Study Coordinator will be responsible for transferring ECGs to the Data Coordinating Center (DCC) through the secure portal.
 - 1.1. Each of these individuals must provide the PVDOMICS Study Coordinator with contact information for the PVDOMICS Cardiovascular Physiology Core (CPC) via a completed Form 10-Study Personnel. The Study Coordinator will be responsible for entering this information into the study database.
2. Review and become familiar with this MOP chapter and study procedures.
 - 2.1. Ensure that this chapter of the Manual of Operations (Chapter 40) and Form 245 (Center Electrocardiogram Data Transmittal Form) are available and easily accessible to all individuals who will perform an ECG for the PVDOMICS study.
 - 2.2. Each individual who will perform an ECG for the PVDOMICS study should review the ECG Study Training Webinar video and slides available on the PVDOMICS website.

3. Provide the name of the manufacturer(s) of the ECG cart(s) that will be used for PVDOMICS. This information must be added to Form 20 (Equipment for PVDOMICS Testing Registration Form) and entered into the database.
 - 3.1. Any change of equipment must be reported to the study coordinator so that they can update the database to reflect the most current information.
4. Submit two ECG printouts from a healthy adult subject as per the transfer protocol found below (Section 40.9). The two ECGs must be from different subjects on different days.
 - 4.1. Sites will be evaluated based on their ability to: (1) follow a site qualification protocol, (2) generate reproducible ECG data, and (3) transmit data to the CPC.
 - 4.2. Test results will be compared to data available on normal individuals from the CPC laboratory and the published literature.
 - 4.3. It is suggested that each local site limit the number of ECG technicians who will be performing ECGs for the PVDOMICS study. This will diminish variability in testing.
5. Receive approval from the CPC to proceed with testing of subjects.
 - 5.1. Sites should await feedback from the CPC laboratory confirming that their site has qualified prior to scheduling study patients for testing.

40.3 Participant Contraindications and Safety

ECG is a non-invasive procedure with little to no risk. If there is any question as to the suitability of the participant to receive an ECG, the site PI should be contacted.

Personnel performing the ECG for the PVDOMICS study should be trained in the appropriate placement of the electrode leads, competent at using the necessary equipment, and familiar with this MOP. They must also be certified in basic cardiac life support and able to recognize abnormal rhythms and ST segment changes indicative of acute myocardial infarction (MI) on an ECG.

40.4 Equipment and Supplies:

1. ECG system
 - 1.1. Instrumentation should meet the specifications set by the American Heart Association (AHA)¹⁻⁴, including a continuous display of a minimum of three leads.
 - 1.2. Instrumentation must have the capacity to print a copy of a 12-lead ECG.

1.3. System settings should be as follows for the 12-lead ECG:

Report Sequence	Standard
Rhythm Leads	I
Gain	10
Report Format	4x2.5R1
Number of copies	1
Delete ECG after transmission	NO
Autosave ECG	YES
Interpretation	YES
Print Interpretation	YES

2. Resuscitation cart ⁴

- 2.1. Airway management equipment
- 2.2. Defibrillator
- 2.3. Airway suction apparatus, tubing and disposable ends
- 2.4. Emergency medications (e.g., epinephrine, lidocaine, nitroglycerine)

40.5 Equipment Quality Control

The ECG machine should be regularly checked for quality control and maintained as per the manufacturer's recommendations.

40.6 Participant Preparation (Pre-Test Instructions):

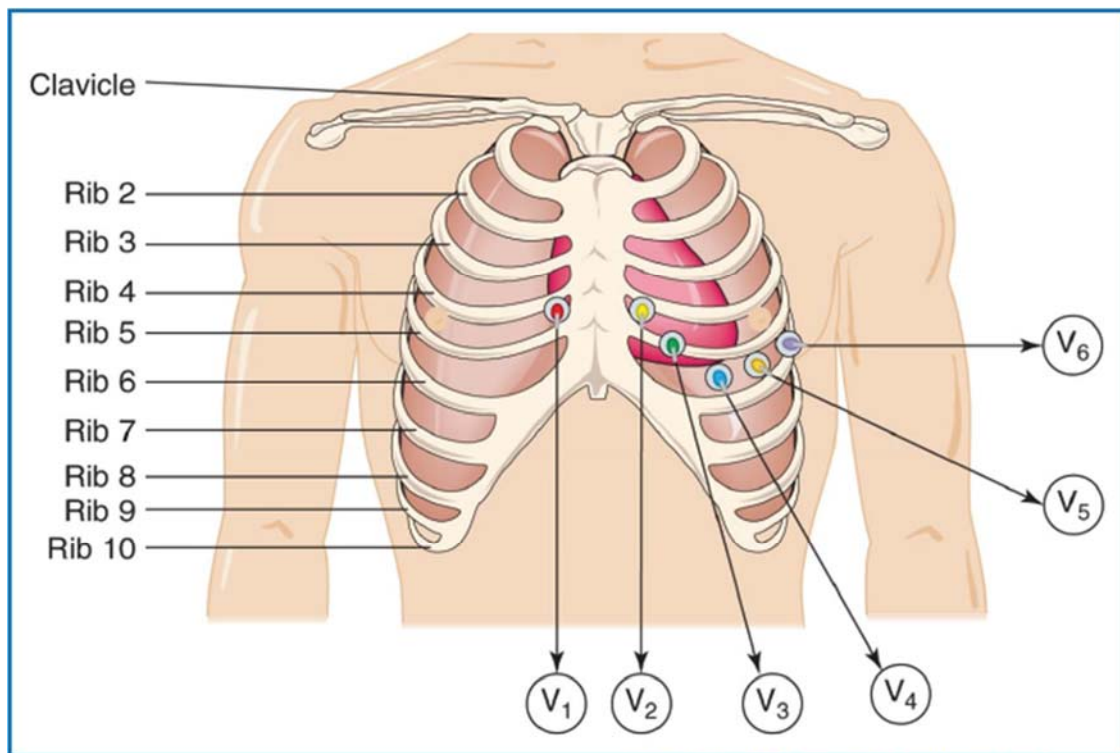
1. Identify participant using two separate identifiers.
2. Briefly explain the procedure and answer the participant's questions before the test.
 - 2.1. Explain that the test requires access to the chest wall as this may be uncomfortable for some participants.
3. Obtain informed consent (if applicable in your institution) by personnel who can accurately describe the test and potential risks.
4. Skin preparation is essential to reduce surface resistance and ensure a good ECG signal.^{2,3,4}
The following steps may be used at the discretion of the personnel performing the ECG.
 - 4.1. Use alcohol wipes to remove surface oils.

- 4.2. Shave hair, when applicable.
- 4.3. Abrade skin with fine emery cloth, 240 grit sandpaper or other appropriate mechanical skin preparation device.

40.7 ECG electrode placement:

1. Instruct the participant to lie flat on their back for the duration of the procedure.
 - 1.1. If the participant cannot lie flat because of orthopnea or other physical limitation, have the participant lay as flat as possible while still maintaining participant comfort.
2. Use a drape across the chest for participant comfort, both for modesty and to prevent the participant from becoming chilled during the test.
3. The standard 10-electrode configuration will be used for electrode placement when obtaining a 12-lead ECG.
 - 3.1. When placing electrodes on the chest of female participants, always place electrodes under the breast tissue rather than on the breast. This consideration supersedes other placement criteria. Take care to maintain participant comfort and avoiding “cupping” the breast tissue during electrode placement.
 - 3.2. The right arm (RA) and left arm (LA) electrodes should be placed on the ventral side of the arm, 2 to 3 inches above the wrist.
 - 3.3. The right leg (RL) and left leg (LL) electrodes should be placed on the anterior side of the leg, 2 to 3 inches above the ankle.
 - 3.4. The precordial leads (V1-V6) are placed as below (see Figure 40.7.1):
 - V1: 4th intercostal space at the right sternal border
 - V2: 4th intercostal space at the left sternal border
 - V3: midway between V2 and V4
 - V4: 5th intercostal space at the midclavicular line
 - V5: 5th intercostal space, midway between V4 and V6
 - V6: 5th intercostal space at the midaxillary line

Figure 40.7.1: Precordial Lead Placement for 12-lead ECG



12-Lead ECG for Acute and Critical Care Providers
2006, Pearson Education, Inc. Upper Saddle River, NJ

40.8 Procedure:

1. Enter participant data into the ECG machine as per the table below. If your specific machine does not list one of these fields, skip over it. If your specific machine has a field not listed below, leave it blank. DO NOT include any of the following in any field: first or last name, initials, medical record number, social security number or date of birth.

Field Listed on ECG Machine	Information Entered by the ECG Technician
New Patient?	YES
Last Name	PVDOMICS
First Name*	Enter 2 digit alphacode assigned to this participant. <i>(Obtain this ID from local site study coordinator.)</i>
Participant ID*	Enter 6 digit Identification Number assigned to this participant. <i>(Obtain this ID from local site study coordinator.)</i>
Secondary ID	Enter 2 digit alphacode assigned to this participant. <i>(Obtain this ID from local site study coordinator.)</i>
Pacemaker	Select YES or NO as appropriate
Gender	Select MALE or FEMALE as appropriate
Height	Enter Height in centimeters, rounded to the nearest whole number. <i>Note: if height measurement is recorded on Form 120 Study Visit Vital Signs (taken on day one), record that height rounded to the nearest whole number.</i>
Weight	Enter Weight in kilograms, rounded to the nearest whole number. <i>Note: if weight measurement is recorded on Form 120 Study Visit Vital Signs (taken on day one), record that weight rounded to the nearest whole number.</i>
Race	Select the appropriate predefined race category (as self-reported by the participant).
Age	Enter participant's age as a whole number.
Referring Physician	Enter the local site PVDOMICS Study PI.
Reason for Test	RESEARCH
Technician*	Select or enter the technician's PVDOMICS username or other ID.**
Location	Leave blank if system allows, or leave the default setting in place.

*Required fields

** If the technician has a PVDOMICS username, that should be used. If not, their normal identification should be selected. Be sure that the technician's name selected matches the technician actually performing the test and the technician name listed on Form 245.

2. Instruct participant to breathe normally but not to move their extremities.
3. Ensure that a good quality signal is being recorded.
4. Press the “Start/Stop” key on the ECG machine to initiate data collection. The machine will automatically print a copy of the ECG and store the data if another copy needs to be printed later.
5. Record extraneous movement or tremors, extreme obesity and any medications the participant is currently taking that may cause bradycardia on Form 245 (Center Electrocardiogram Data Transmittal Form) as these circumstances may explain abnormal results.
 - 5.1. Extreme obesity will be judged on a case-by-case basis by the local site PI or the technician performing the procedure and should be noted if the participant’s weight or excess body tissue may have interfered with the results of the test.

40.9 ECG Transmission to the Cardiovascular Physiology Core (CPC):

De-identified ECG reports will be sent to the CPC. The only identifiers on the ECGs submitted to the CPC will be the participant’s PVDOMICS ID and alphacode. Each report will be scanned/converted into Portable Document Format (PDF) and sent securely to the CPC.

1. Verify that the participant’s 6-digit PVDOMICS ID number, their 2-digit alphacode and the date of testing are included on the ECG printout.
 - 1.1. If one of these three components are missing, use a black pen to write the missing component on the ECG printout before converting it into a PDF file.
2. Verify that no other identifiers are included on the ECG printout.
 - 2.1. If any other identifiers exist (e.g. participant’s date of birth or medical record number), obscure that identifier using a black marker or other means before converting the ECG printout into a PDF file.
3. Send one PDF copy of the ECG printout to the CPC.
 - 3.1. Scan ECG printout into a secure computer and save as a PDF file.
 - 3.2. Name the PDF file according to the convention: **ECG_#####_ac_mmddyyyy.pdf**
Where “#####” is the participant’s unique 6-digit PVDOMICS ID#, “ac” is the participant’s unique alpha code, and “mmddyyyy” is the test date. Do not use any special characters in the file name.

For example: ECG_987654_AC_12102016.pdf
 - 3.3. Send PDF file to the DCC as outlined in Manual of Operations Chapter 6-Appendix 1: Securely Transferring Documents to PVDOMICS DCC Server

4. Complete and enter Form 245 Center Electrocardiogram (ECG) Data Transmittal Form into the PVDOMICS Study database or provide the local site study coordinator with the completed form for data entry.
 - 4.1. Form 245 must be entered into the database before the CPC can enter any results so it is important to get this form entered as soon as possible.
5. File paper copies of participant's ECG and completed Form 245 in their study record.

40.10 References

1. Kadish AH, Buxton AE, Kennedy HL, et al. ACC/AHA clinical competence statement on electrocardiography and ambulatory electrocardiography: A report of the ACC/AHA/ACP-ASIM task force on clinical competence (ACC/AHA Committee to develop a clinical competence statement on electrocardiography and ambulatory electrocardiography) endorsed by the International Society for Holter and noninvasive electrocardiography. *Circulation* 2001;104:3169-78.
2. Committee on Electrocardiography, American Heart Association. Recommendations for standardization of leads and of specifications for instruments in electrocardiography and vectorcardiography: *Circulation* 1967;35:583-602.
3. Bailey JJ, Berson AS, Garson A Jr, Horan LG, Mcfarlane PW, Mortara DW, Zywiets C. Recommendations for standardization and specifications in automated electrocardiography: bandwidth and digital signal processing. A report for health professionals by an ad hoc writing group of the Committee on Electrocardiography and Cardiac Electrophysiology of the Council on Clinical Cardiology, American Heart Association. *Circulation* 1990;81:730-739.
4. Kligfield P, Gettes LS, Bailey JJ, et al. Recommendations for the standardization and interpretation of the electrocardiogram: part I: The electrocardiogram and its technology: a scientific statement from the American Heart Association Electrocardiography and Arrhythmias Committee, Council on Clinical Cardiology; the American College of Cardiology Foundation; and the Heart Rhythm Society: endorsed by the International Society for Computerized Electrocardiology. *Circulation* 2007;115:1306-24.
5. Fletcher GF, Balady G, Froelicher VF, et al. Exercise Standards: A Statement for Healthcare Professionals From the American Heart Association. *Circulation* 1995;91:580-615.