



PVDOMICS: ECG Training Module

Cardiovascular Physiology Core
Cleveland Clinic, Cleveland OH
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NHLBI Pulmonary Vascular Disease Phenomics Program

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Electrocardiogram (ECG)

A routinely used, non-invasive procedure to monitor and assess the electrical activity in the heart.

Recognized as the gold standard for detecting heart arrhythmias and conduction delays.

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

It is expected that all personnel performing ECGs for the PVDOMICS study are:

- Trained in the appropriate placement of the electrode leads
- Competent at using the necessary equipment
- Certified in basic cardiac life support
- Able to recognize abnormal rhythms and ST segment changes indicative of acute myocardial infarction (MI) on an ECG

40.2 Site and Technician Certification

Before ECG studies may be performed on participants, each site will need to:

1. Review and become familiar with the PVDOMICS study-specific procedures.
2. Establish a primary contact person at their site who will be responsible for communication with and transmission of data to the data coordinating center (DCC).
3. Provide the name of the manufacturer(s) of the ECG cart(s) that will be used for the PVDOMICS study
 - ECG Equipment information should be added to Form 20 (PVDOMICS Equipment Form)
 - Any change of equipment must be reported to the study coordinator so the database reflects the most current information.

40.2 Site and Technician Certification

4. Submit two ECG printouts from a healthy adult subject. The two ECGs must be from *different* subjects on *different* days.
 - Sites will be evaluated based on their ability to: (1) follow the site qualification protocol, (2) generate reproducible ECG data, and (3) transmit data to the CPC.
 - Test results will be compared to data available on normal individuals from the CPC laboratory and the published literature.
 - 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 participants.

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 be 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

- Should meet the specifications set by the American Heart Association (AHA), including a continuous display of a minimum of three leads
- Must have the capacity to print a copy of a 12-lead ECG
- Correct system settings can be found on the next slide

2. Resuscitation cart with:

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

40.4 Equipment and Supplies

ECG Cart System Settings

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



40.5 Equipment Quality Control

- The ECG machine should be regularly checked for quality control and maintained as per the manufacturer's recommendations.
- Follow your normal site protocols.

40.6 Participant Preparation: Pre-Test Instructions

- Identify participant using two separate identifiers.
- Briefly explain the procedure and answer the participant's questions before the test.
 - Explain that the test requires access to the chest wall as this may be uncomfortable for some participants.
- Obtain informed consent (if applicable in your institution) by personnel who can accurately describe the test and potential risks.

40.6 Participant Preparation: Pre-Test Instructions

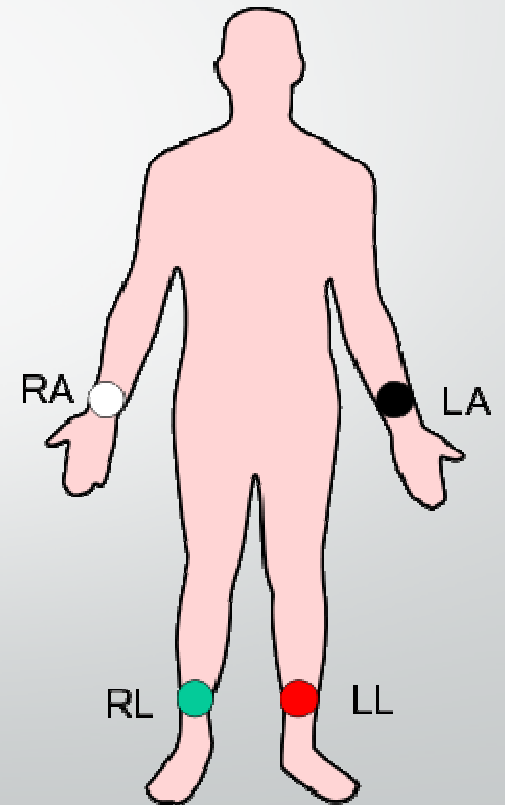
- Instruct the participant to lie flat on their back for the duration of the procedure.
 - If the participant cannot lie flat because of orthopnea or other physical limitation, have the participant lay as flat as possible while still maintaining participant comfort.
- Use a drape across the chest for participant comfort, both for modesty and to prevent the participant from becoming chilled during the test.

40.7 ECG electrode placement

- The standard 10-electrode configuration will be used for electrode placement when obtaining a 12-lead ECG.
- 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.

40.7 ECG electrode placement: Limb Leads

- 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.
- 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.



40.7 ECG electrode placement: Precordial Leads

- The precordial leads (V₁-V₆) should be placed as follows:

V₁: 4th intercostal space at the right sternal border

V₂: 4th intercostal space at the left sternal border

V₃: midway between V₂ and V₄

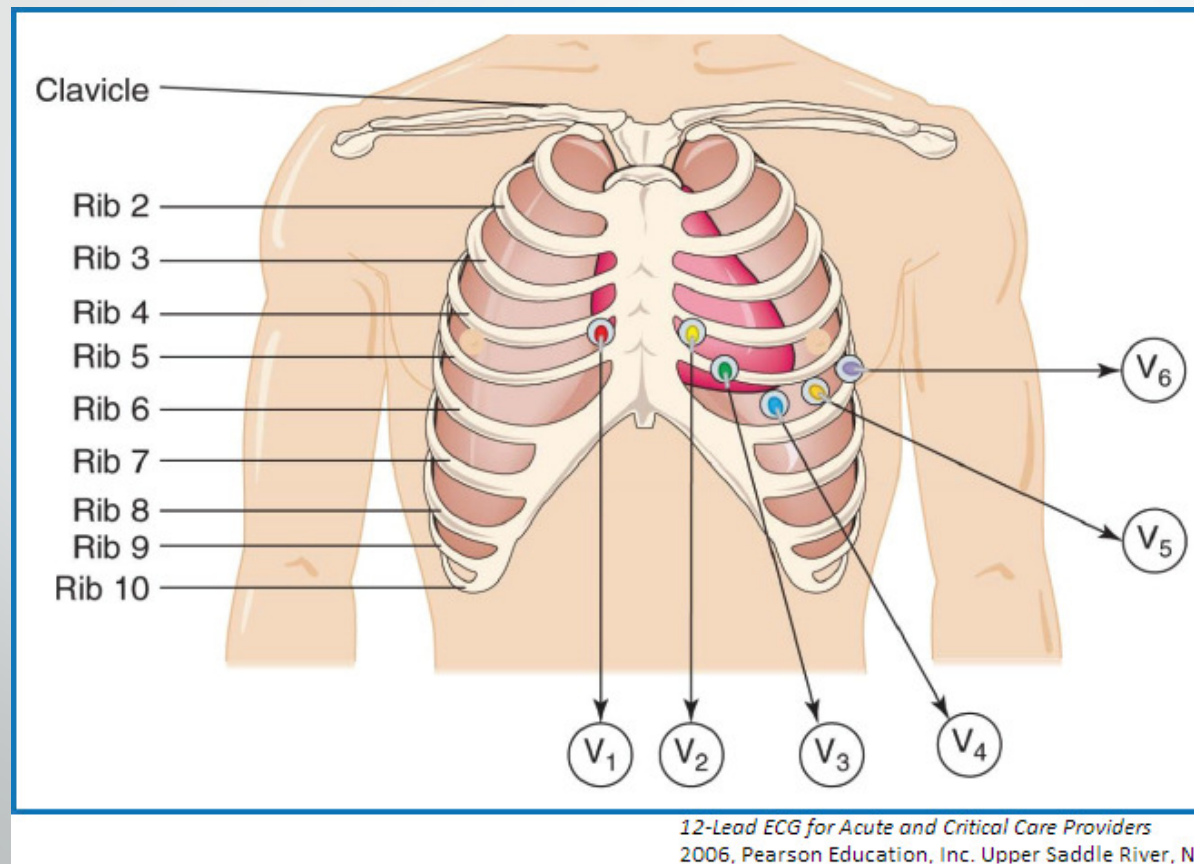
V₄: 5th intercostal space at the midclavicular line

V₅: 5th intercostal space, midway between V₄ and V₆

V₆: 5th intercostal space at the midaxillary line

40.7 ECG electrode placement: Precordial Leads

Figure 40.7.1: Precordial Lead Placement for 12-lead ECG



40.7 ECG electrode placement: Skin Preparation

- Skin preparation is essential to reduce surface resistance and ensure a good ECG signal.
- The following steps may be used at the discretion of the person performing the ECG:
 - Use alcohol wipes to remove surface oils
 - Shave hair (if applicable)
 - Abrade skin with fine emery cloth, 240 grit sandpaper or other appropriate mechanical skin preparation device

40.8 Procedure

- Enter participant data into the ECG machine as per the table on page 5 of the MOP (reproduced below)

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. (Obtain this ID from local site study coordinator.)
Participant ID	Enter 6 digit Identification Number assigned to this participant. (Obtain this ID from local site study coordinator.)
Secondary ID	Enter 2 digit alphacode assigned to this participant. (Obtain this ID from local site study coordinator.)

40.8 Procedure

Field Listed on ECG Machine	Information Entered by the ECG Technician
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. 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.
Weight	Enter Weight in kilograms, rounded to the nearest whole number. 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.
Race	Select the appropriate predefined race category (as self-reported by the participant).
Age	Enter participant's age as a whole number.

40.8 Procedure

Field Listed on ECG Machine	Information Entered by the ECG Technician
Referring Physician	Enter the local site PVDOMICS Study PI.
Reason for Test	RESEARCH
Technician	Select or enter the technician's PVDOMICS username. (PVDOMICS username is first 6 digits of last name followed by first initial.)
Location	Leave blank if system allows, or leave the default setting in place.

- Be sure that the technician's name selected matches the technician actually performing the test and the technician name listed on Form 245!

40.8 Procedure

- Instruct participant to breathe normally and to not move their extremities.
- Ensure that a good quality signal is being recorded.
- Press the “Start/Stop” key on the ECG machine to initiate data collection.
 - The machine should automatically print a copy of the ECG and store the data if another copy needs to be printed later.

40.8 Procedure

- Record any circumstances that may explain abnormal results on Form 245 (Center Electrocardiogram Data Transmittal Form) questions 5-7
 - Extraneous movements/tremors, extreme obesity and medications known to cause bradycardia
 - 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 CPC

- Each report will be scanned/converted into Portable Document Format (PDF) and sent securely to the CPC.
- Transmit one PDF copy of ECG report per participant to the Cardiovascular Physiology Core (CPC)
- Reports must be de-identified!!!
- The only identifiers on the ECGs submitted to the CPC will be the PVDOMICS ID and alphacode.

40.9 ECG Transmission to the CPC

1. De-identify the ECG printout

- a) Verify that each ECG printout has the participant's 6 digit ID #, participant's alphacode and the date of ECG test indicated on it somewhere
- b) If one of the 3 elements mentioned above is missing, hand write the missing element on the ECG printout
- c) Verify that no identifying information exists on the ECG printout
- d) Cross off or obscure any identifying information that does exist on the printout (e.g. name, date of birth, SSN, MRN, initials)

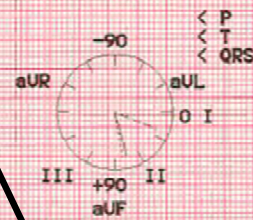
GEMS IT MAC1200 XY PUDOMICS 0000990002, CR CLEVELAND
Male, Caucasian, 191 cm, 95.0 kg

PVDOMICS 6-digit ID#

HR 82 bpm

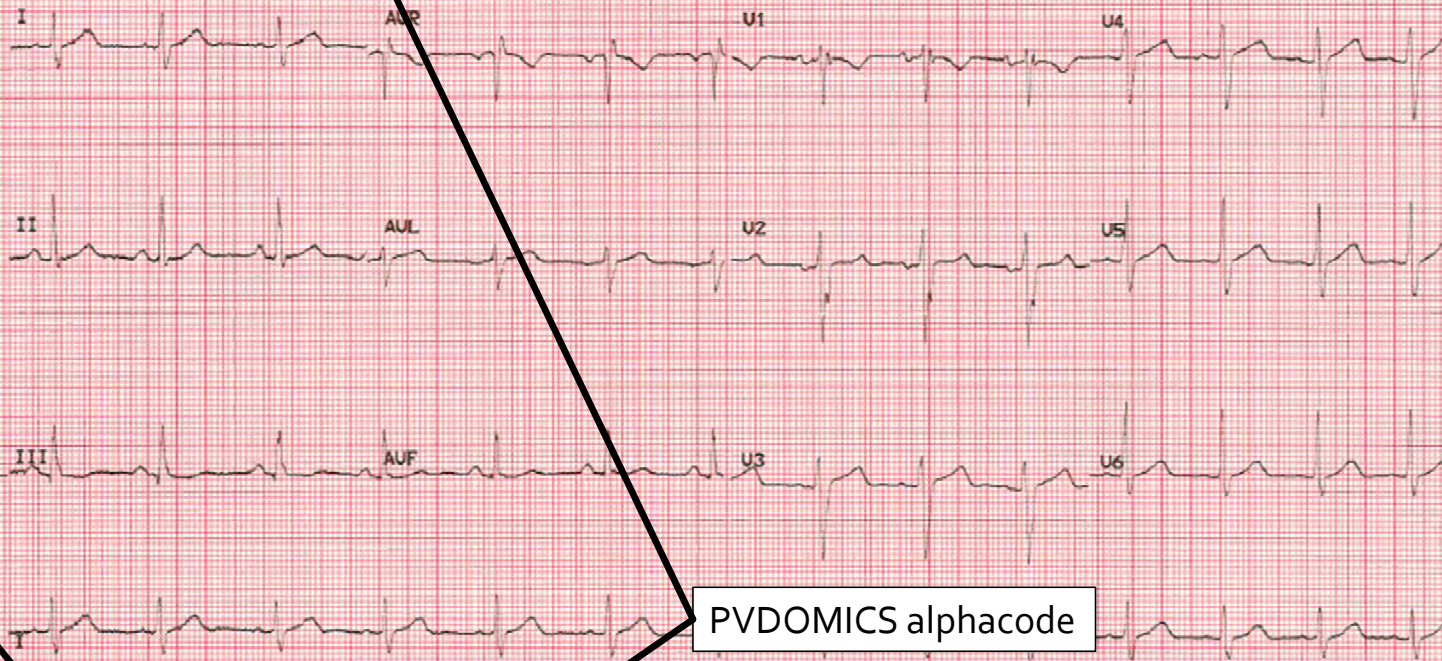
Measurements Results:
QRS 114 ms
QT/QTcB 380 / 443 ms
PR 140 ms
P 102 ms
RR/PP 734 / 730 ms
P/QRS/T 80/ 74/ 23 degrees

Refer. Physician : PUDOMICS PI
Technician : KIRSOPJ



Interpretation:
Sinus rhythm with sinus arrhythmia
Normal ECG

Unconfirmed report.



Date of Test

PVDOMICS alphacode

Birth 305
Aug. 26, 2016

Site# 108
11:58:21

Secondary ID XY

25mm/s 10mm/mV ADS 60Hz 0.08 - 150Hz 4x2.5R1 12 Lead U5.21 M121 (2) 12SLBv231

40.9 ECG Transmission to the CPC

2. Scan the de-identified ECG printout into a secure computer and save it as a PDF file.
3. Name the PDF file according to the following convention:

ECG_#####_ac_mmddyyyy.pdf

↑ ↑ ↑ ↑ ↑
Type of Test PVDOMICS ID# Alphacode Date of Test File Type

40.9 ECG Transmission to the CPC

4. Submit ECG to the CPC.

- Log in to SSH with your assigned account name and password
- Drag and drop the PDF file into SSH home directory for PVDOMICS on DCC server
- DCC will then move the file out of the home directory for processing

5. Document the date you uploaded the ECG on Form 245 (Q9).



PVDOMICS STUDY
Center Electrocardiogram (ECG)
Data Transmittal Form #245

Instructions: The ECG must be done specifically for the PVDOMICS Study. Form 245 is completed by the local technician or study coordinator and entered into the database once for each participant who consents to the PVDOMICS Study. Data will be reviewed by the Cardiovascular Physiology Core (CPC) at the DCC.

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1. Identification Number

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2. Alphacode

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3. Date of most recent ECG (mm/dd/yyyy)

4. Was a 12-lead ECG performed? (0=No, complete 4a; 1=Yes, skip to Q5)

a. Primary reason ECG was not done

1=Participant refused

2=Participant has other medical condition that makes completing ECG difficult

3=Equipment malfunction or lack of supplies

5. Were there extraneous movement/tremors present during this ECG? (0=No, 1=Yes)

6. Is the participant extremely obese? (0=No, 1=Yes)

7. Is the participant on any medications that may cause bradycardia (0=No, 1=Yes)

(Medications may include but are not limited to: beta-blockers [propranolol, atenolol, metoprolol], verapamil, diltiazem, digoxin (toxicity), opiates [opium, morphine and codeine])

8. Cart/Equipment number of ECG machine used for this test

(Cart/Equipment number assigned by DCC following completion of Equipment Form 20)

9. Date PDF of rhythm strip transmitted to Core? (mm/dd/yyyy)

200. Date form completed (mm/dd/yyyy)

201. Username of person completing/reviewing completeness of this form

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy)

Username of person entering this form

40.9 ECG Transmission to the CPC

6. Complete Form 245 and enter it into the PVDOMICS Study database or provide the local site study coordinator with the completed form for data entry.
 - CPC results cannot be entered into the database until Form 245 has been entered!
7. File the original paper copies of participant's ECG and completed Form 245 in their study record.



For Questions Please Contact

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