	Title:	Electrocardiogram (ECG)		
	Version Date:	2017-FEB-15	Document Number:	SOP_DCS_0009
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Data Collection Site (DCS)	Version:	2.4	Number of Pages:	5

1.0 Purpose:

The purpose of this document is to describe the standardized procedure for performing the Electrocardiogram (ECG) measurement.

2.0 Scope:

This document is to be used by the DCS staff when conducting the ECG measurement of a study participant.

3.0 Responsibilities:

It is the responsibility of the DCS staff to perform the procedures as described in the current and approved version of the standard operating procedure.

4.0 Related Documents:

- **SOP_DCS_0040** – GE MAC 1600 ECG SOP – Maintenance

5.0 Definitions:

Not applicable

6.0 Equipment:

- GE MAC 1600 ECG Analysis System; and,
- 10 Silver Mactrode ECG Electrode.

7.0 Supplies:

- Mild dishwashing detergent;
- Two clean, soft, lint-free cloths;
- Water; and,
- Spray bottle.

8.0 Procedure Steps:

Contraindications:

- Participant unable to stand unassisted.

Participant must rest for approximately 5 minutes before measurement is taken. While the participant is resting the preparation for the test should be done.

Step 1: At the *Interview Tab* in Onyx, look for “ECG” in the list of stages. Then select **Start** in that row.

Step 2: **Scan** the participant ID barcode then click on **Continue**.

NOTE: If you prefer you could do **Step 20-21** here.

Step 3: The participant will need to remove or open their shirt so that you can access their chest. The wrists and ankles also need to be accessible for lead placement. You may need to ask the participant to change into a gown. To be discrete, it is possible to do the ECG on women if they undo their bra only.

NOTE: Some female participants may prefer to have a female technician placing the electrodes. Wherever possible, male technicians should ask female participants if they would prefer a female to place the electrodes.

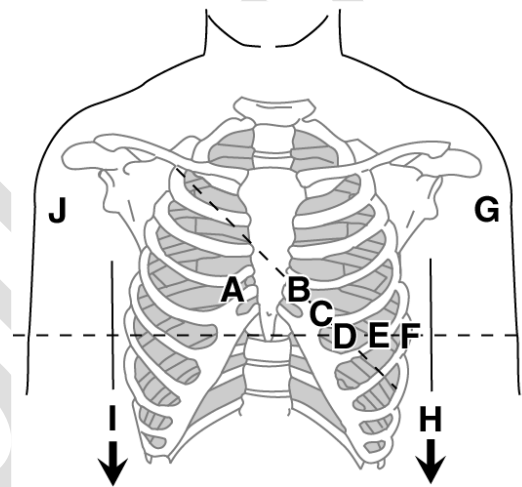
Step 4: Ask the participant to lie down, arms lying by their side, with the participant's palm facing upward and legs in an open relaxed position.

Step 5: Remind the participant to relax and to breathe normally. Assure them that an ECG does not hurt and they are not going to feel anything with this test.

Step 6: If the participant has oily or extremely sweaty skin, cleanse the skin areas where electrodes will be placed with an alcohol pad.

Step 7: For males with a lot of chest hair, move the hair as best possible to expose an area of skin where the electrode patch will be placed. For females, with discretion locate the area to place the electrode patch. It is important to have good contact with the gel filled area of the electrode patch to the skin.

Step 8: **Electrode patch placement is very important.** Place the electrodes on the participant as indicated in the diagram below.



Electrode Label	Lead Label	Electrode Placement
A	V1 red	Count the ribs, down from the clavical. Place the electrode on the fourth intercostal space at the right sternal border. (Typically in line with the nipple)
B	V2 yellow	Count the ribs, down from the clavical. Place the electrode on the fourth intercostal space at the left sternal border. (At the same height as A).
D	V4 blue	Place this electrode next, on the mid-clavicular line in the fifth intercostal space. (Typically, under the breast in line with and below the nipple).

Electrode Label	Lead Label	Electrode Placement
C	V3 green	Place this electrode midway between location B & D in a straight line.
E	V5 orange	Anterior axillary line on the same horizontal level as D to the left of D (toward the arm).
F	V6 purple	Mid-axillary line on the same horizontal level as D and E.
G	LA black Background	Left deltoid (Anywhere on the arm is fine).
H	LL red background	Above left ankle. (Alternate placement, upper leg as close to torso as possible)
I	RL green background	Above right ankle (alternate placement, upper leg as close to torso as possible)
J	RA white background	Right deltoid (Anywhere on the arm is fine)

NOTE: In the case of a participant with uncontrollable trembling, suggest that they place their hands under their buttocks to support them and reduce trembling.

- Step 9:** Connect the leads to the chest and limbs as shown in the image and table above. Be sure the leads are on the correct electrode. Colour coding is indicated. The green tab is lifted to fit the lead over the electrode and then snapped shut over the electrode button. Be sure it is secure.
- Step 10:** Verify the leads are all connected and working properly.
- Step 11:** Turn the ECG machine on.
- Step 12:** Verify the system is in *Resting* ECG mode. This is indicated in the top left corner of the screen on the ECG machine.
- Step 13:** Press **F1** and enter the participant ID number or **Scan** (if you have a barcode scanner attached to your ECG). Press **F6** to **Save** the ID number. It will be displayed in the upper left corner of the screen, above resting ECG.
- Step 14:** When the participant is resting and the waveforms are uniform, check the **Hookup Advisor Module**, located in the upper right corner of the screen, to the left of the heart rate. It will indicate the quality of the lead signals. Monitoring it can help reduce or eliminate poor quality ECGs. The following table describes each of the indicator's conditions.

Indicator	Description
Red	Indicates a lead-fail condition or extreme baseline shifts. A corresponding message is displayed.
Yellow	Indicates muscle artifact, power line interference, baseline wander, or electrode noise. A corresponding message is displayed
Green	Indicates acceptable signal quality.

When a red or yellow indicator is lit, identify and correct the error before proceeding with the ECG.

- Step 15:** When a green light is indicated press **ECG** key to begin the acquisition.

Step 16: While reviewing the preview, do one of the following;

To discard the reading and begin over:

- Press F3 (Cancel) and repeat from **Step 10**.
- To accept the reading, press F4 (Continue).

Step 17: Plug the cable from the back of the desktop into the port labeled B on the back of the ECG machine.

Step 18: Press the **F6 – More** and **F6 – More**, then **F5** to go to the **Main Menu**. Press the **F4 File Manager** button. This will allow you to see which ECG's have not been sent to Onyx.

NOTE: The following steps can be done right after the participant test is complete or at the end of the day.

Step 19: Press **F1** to **Select Participant ID** number of interest. Use the **▲▼** arrows to move to the correct participant ID. Then press the round button in the centre of the arrows to highlight this acquisition.

Step 20: On the Cardiosoft Software, choose **System Configuration** on the right side of the screen. In the System Configuration Screen, choose **Receive Data from ECG Device**. Check Baud rate=19200 and Port (is as per your site): COM4 (for example). Click **OK**. In Cardiosoft, the Receive Data from ECG Device screen pops up.

Step 21: Press **F4** to **Transmit** to Cardiosoft on the ECG machine.

Step 22: **Wait** until the number of transferred records changes from 0 to 1. Then the transfer is complete. Press **End**. Exit Cardiosoft by clicking the 'door' symbol on the right hand side. A window will appear, "Do you really wish to quit the program?" Click **Yes** to close the Cardiosoft window. In Onyx, press **Next** and verify that ECG results have been transferred successfully.

Step 23: Click **Finish**. The "ECG: Finish" window will pop up.

Step 24: Indicate in the **comment** field in Onyx if there was anything that may have affected or influenced the measurement. Ensure that comments do not contain any personally identifying information.

Step 25: Click **Continue** to return to the status page.

Clean up Procedure

Step 26: Remove the leads from the electrodes, and carefully drape them over the ECG machine. Ask the participant to remove the electrodes and offer them a Kleenex to remove any gel from their skin. Dispose of used electrodes in the garbage.

Step 27: Dampen one soft, clean cloth using the spray bottle containing the pre-mixed mild dish detergent cleaner.

Step 28: Wipe the leads moistened soft, clean cloth.

Step 29: Dry the leads with the second soft, clean cloth.

Step 30: Hang the cables and leadwires vertically. **Do not** coil cables or leadwires around the device.

Safe Participant Alighting

If the participant will be having the Carotid ultrasound or the DXA scan next, then recommend that they do not change at this point.

Step 31: Assist the participant to a sitting position and help them to a standing position when they feel ready to get off the bed.

9.0 Documentation and Forms:

Not applicable

10.0 References:

- GE Healthcare - MAC 1600 ECG Analysis System – Operator’s Manual

F1 Revision History:

New Version #	Revision Date	Revision Author	Content Approval
2.4	2017-FEB-15	Lorraine Moss	Mark Oremus
Summary of Revisions			
Updated section 9.0			
Updated contraindication sentence to clarify.			
Added “Participant must rest for approximately 5 minutes before measurement is taken. While the participant is resting the preparation for the test should be done.”			
New Version #	Revision Date	Revision Author	Content Approval
2.3	2015-APR-09	Lorraine Moss	Mark Oremus
Summary of Revisions			
Updated list of supplies and cleaning instructions from Steps 28-30.			