

Category: Handling and maintenance of equipment of Phase I unit

Title: Procedure to use ECG machine

SOP No.: DCP/Ph1/005

Date first effective: 01 Jan 2024

Review date: 31 Dec 2024

Department of Clinical Pharmacology, 1st Floor, New MS Building,
Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012

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1. Purpose

The purpose of this SOP is to describe the procedure for handling and maintaining the ECG machine in Phase I unit of Department of Clinical Pharmacology.

2. Scope

This SOP applies to handling and maintaining ECG machine in Phase I unit.

3. Responsibilities

Principal investigator, Co-Investigator(s), any other medically qualified member or nursing staff will be responsible for handling and maintaining ECG machine.

4. Detailed Instructions

- Written informed consent should be taken from the potential participant before taking ECG for any study related procedures
- Prior assessment of the participant should be done including his/her vital signs
- Any electronics in close contact with the participant (e.g mobile phone) would be kept aside till the ECG is complete.
- The medical officer must ensure the privacy and comfortable temperature for the participant and for female participant, a medical officer must be accompanied by a female staff.
- The medical officer must ensure that the ECG machine is functioning properly and attached to the printer prior to electrocardiography
- Medical officer should ensure that the ECG machine is adequately charged or plugged in to electricity source
- Medical officer should attach all the leads to the participant in the following fashion:
 - a. The electro-conductor jelly to be applied on the leads before attachment of the leads
 - b. Limb leads should be attached as following:
 - i. Red – Right forearm
 - ii. Yellow – Left forearm

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iii. Black – Right leg

iv. Green – Left leg

c. Chest leads should be attached as following:

i. V1 (red) and V2 (yellow) on the right and left fourth intercostal space (ICS) space respectively, adjacent to sternum

ii. V4 (brown) in left 4th ICS on mid clavicular line

iii. V3 (green) between V2 and V4

iv. V5 (black) on 5th ICS on anterior axillary line

v. V6 (violet) on 5th ICS on mid-axillary line

- After connecting the leads, the medical officer should switch on the ECG machine by pressing the power button (dark blue color) on button console
- The LED screen of the device will show the participant details on the top bar and tracings of the 12 leads of ECG
- The speed of the ECG should be set to 25mm/sec with the help of “MODE” button (green) on left-side of the button console
- The medical officer should wait for 30 seconds (for normalization of heart rate) and press “Print/Stop” button (green color) on right-side bottom of button console to start printing the ECG tracings.
- The device will prompt for providing participant ID and details (participant initial, screening ID, gender, age). The medical officer should press the “Menu” button (blue color) on right side of button console for entering participant ID and details
- The medical officer should use right navigation button “>” or “Tab” key for editing details, “Menu” button for selecting OK, “Recall” button for deleting, and up and down navigation buttons for navigating in between different fields of details
- After entering the participant ID and details, the medical officer should press “Menu” button to set the entered details
- After seeing the ECG record and finding it satisfactorily one should first “Freeze” and then Print.
- The medical officer should press “Print/Stop” button to start printing the ECG tracings

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- The lead/leads can be selected by navigating with the “Lead” button on bottom of button console
- The ECG machine should be switched off and the leads should be removed from participant
- The participant should be provided tissue paper to clean himself/herself
- The medical officer should clean all the leads of the device
- The details of the participant on the ECG should be verified and the printout must be handed over to the study coordinator
- The ECG machine should always be placed on a clean surface
- Food and beverages should be kept away from the area around the device
- The device should be charged at regular intervals
- The electro-conductor jelly should be replaced at regular time intervals
- A tissue roll should be available near the device
- Care must be taken while cleaning the device. The display screen should not be wiped with any harsh chemicals as it may permanently deface the screen

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