



STANDARD OPERATING PROCEDURE

Sheffield Clinical Research Facility

**Standard 12 Lead ECG Recording -
Using the MAC 1200**

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<i>Approved by</i>	Theresa Ledger

**Standard Operating Procedure: Sheffield Clinical Research Facility
Standard 12 Lead ECG Recording - Using the MAC 1200**

This SOP has been written to give general guidance to study personnel on how to obtain a participant electrocardiogram, using the MAC 1200. There are no GCP Guidelines concerning obtaining a standard 12 lead ECG recording.

Background

It is important that all clinical staff working in the Clinical Research Facility use the same procedure to obtain a standard 12 lead ECG reading as specified in the trial protocol, to ensure continuity and consistency in recordings.

Definition

A 12 lead ECG is a non-invasive procedure that is used to ascertain information about the electrophysiology of the heart.

Procedure

1. The investigator is responsible for ensuring the standard 12 lead ECG is recorded according to protocol. This duty can be delegated to other appropriately qualified members of the research team as recorded on the Project Delegation Log.
2. The investigator or delegated person will refer to the protocol to ensure specific requirements for obtaining a 12 lead ECG reading are identified. This may include the use of a specific machine solely for individual study use. In this case the ECG procedure will be dictated by the sponsor. If nothing is specified in the protocol then the investigator or delegated person should follow the procedure below.
3. The investigator or delegated person will explain the procedure to the participant to gain consent.
4. The investigator or delegated person must assemble all equipment required and ensure it is clean and appears to be in good working order. The equipment required to perform an ECG is:
 - MAC1200 ECG machine and leads
 - ECG Electrodes
 - Alcohol swabs
 - Razor
5. The investigator or delegated person will ask the participant to remove any clothing that may restrict access to the upper body or limbs, and ask them lay down in a comfortable position.
6. The investigator or delegated person must switch on the MAC1200 and wait for the self test to be performed.
7. The investigator or delegated person will enter the patient details, initials or name, subject number, date of birth and gender into the MAC1200 or enter study specific data as outlined in the study protocol.
8. The investigator or delegated person must wash their hands according to STHFT Hand Hygiene Policy.

9. The investigator or delegated person should attach the ECG electrodes to the chest and limbs; if necessary the skin should be prepared by cleaning with an alcohol wipe or shaving to ensure good contact.
10. The investigator or delegated person will attach the ECG cables to the electrodes in the correct order. If using snap on electrodes these must be attached to the limb leads before being placed on the patient. If the tab electrodes are to be used they should be placed on to the patient and the limb leads then connected.
11. The investigator or delegated person must instruct the participant to relax and remain as still as possible for the ECG recording to take place.
12. The investigator or delegated person must wait 10 seconds and observe the tracing displayed in the MAC1200 display screen to ensure good electrode contact identified by a good tracing. The screen should also be observed for any error messages that may be displayed.
13. Once the investigator or delegated person has confirmed a good tracing is shown and no error messages are present they must press the ECG record button to initiate the recording of the ECG.
14. The investigator or delegated person should review the recording and if it is satisfactory remove the ECG electrodes from the participant and ask them to get dressed.
15. The investigator or delegated person must ask the appropriate person to review the recording if they are not qualified to do so themselves.
16. The investigator or delegated person must document that the ECG recording has been performed on the relevant study source data, the case report form and in the participant's medical notes.
17. The investigator or delegated person must dispose of the used electrodes in to a yellow clinical waste bin and any razor used into a yellow sharps container if used in accordance with STHFT Waste Strategy & Policy.
18. The investigator or delegated person must wash their hands according to STHFT Hand Hygiene Policy.
19. Calibration will be performed annually by Clinical Engineering. For study specific ECG machines it is the responsibility of the investigator to ensure this is performed annually.
20. Study specific ECG machines used in the CRF must adhere to STH Policy for the Decontamination of Hospital Equipment & Medical Devices. The decontamination policy folder is located in the Clinical Research Facility (CRF) at the nurses station of the bedded bay. This folder contains decontamination evaluation forms which give specific instructions of how to clean the ECG machine, and is the responsibility of the investigator to complete.
21. The machine should be returned to its appropriate place of storage, which is the locked equipment room in the CRF.

Reference: http://sthweb/marsden/marsden/rm_28.htm#chapter28_402

Related Documentation¹

Document Name	Author
Project Delegation Log	CRF
STH Hand Hygiene Policy	STH Infection Control Team
Sheffield Infection Control Guidelines	STH Infection Control Team
STHFT Policy for the Decontamination of Hospital Equipment and Medical Devices	STH Foundation Trust

¹ The location(s) of any related document(s) are listed in the CRF SOP Referenced Documents Directory.

The CRF SOP Referenced Document Directory and any Related SOPs, listed on page 1 of this SOP, can be accessed electronically at <http://www.crf.dept.shef.ac.uk/downloads/sops.html> or can be requested by contacting Sheffield Clinical Research Facility, 0 Floor, Royal Hallamshire Hospital, Glossop Road, Sheffield, S10 2JF, 0114 2713339.