STANDARD OPERATING PROCEDURE

NIHR Sheffield Clinical Research Facility

Standard 12 lead ECG Recording
Using the MAC 5500

*SOP CRF.C137 Version 1.1
Standard 12 lead ECG Recording – Using the MAC 5500
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Standard Operating Procedure: NIHR Sheffield Clinical Research Facility
Standard 12 Lead ECG Recording using the MAC 5500

This SOP has been written to give general guidance to study personnel on how to obtain a participant electrocardiogram, using the MAC 5500. 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.

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:
   - MAC5500 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 to lay down in a comfortable position.

6. The investigator or delegated person must switch on the MAC5500, and continue as below.

7. The investigator or delegated person will enter the patient details, initials or name, subject number, date of birth and gender into the MAC5500. To type in details use the right or down arrow to highlight the field, type in the details and then press the middle of the pad or the return key to enter the information, the cursor then goes to the next data field. To select data from a list press the right arrow to highlight for example Gender, press the middle of the pad to lock the list in place, then press the down arrow to highlight Male or Female, press the middle of the arrow pad to confirm selection.
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, using the tab electrodes which should be placed on to the patient first and the limb leads then connected.

11. The investigator or delegated person will ask the participant to relax and remain as still as possible for the ECG recording to take place. The MAC 5500 has a three circle indicator system to advise on the quality of the ECG. Red indicates a lead fail condition or extreme baseline shift, yellow indicates muscle artefact, power line interference, baseline wander or electrode noise. Green indicates generally an acceptable signal quality. The red or yellow signal will also have an accompanying message on screen to indicate the lead problem or status. The investigator or delegated person should remedy the problem as required, Please wait will be displayed until a full ten second period free from lead quality problems has been achieved. Once the green light is on, a recording can be made by pressing the ECG button; if a copy is required the Copy button can be pressed.

12. 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.

13. The investigator or delegated person must ask the appropriate person to review the recording if they are not qualified to do so themselves if possible whilst the patient is still in the department.

14. 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.

15. 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.

16. The investigator or delegated person must wash their hands according to STHFT Hand Hygiene Policy.
17. Calibration will be performed annually by Bio Medical Engineering who can be contacted on extension 12833. For study specific ECG machines it is the responsibility of the investigator to ensure this is performed annually.

18. The investigator or delegated person must clean the ECG machines used in the CRF in accordance to STH Policy for the Decontamination of Hospital Equipment & Medical Devices.

19. The machine should be returned to its appropriate place of storage, which is for the CVBRU MAC 5500 store room 10/1 and for the CRF MAC 5500 store room 10/1 NGH CRF.

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

Related Documentation

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1 Where a referenced document is unavailable electronically a hard copy may be requested from the document’s author or by contacting Sheffield Clinical Research Facility, O Floor, Royal Hallamshire Hospital, Glossop Road, Sheffield, S10 2JF, Tel: 0114 2713339.