

Clinical S.O.P. No.: 9
Version 1.0

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S.O.P. No. 9 Version 1.0

DOCUMENT HISTORY

Version number	Detail of purpose / change	Author / edited by	Date edited
1.0	New SOP	Shona Brearley	

S.O.P. No. 9 Version 1.0

1. Introduction

The Electrocardiograph obtains a tracing or measurement of electrical conduction which controls contraction of the myocardium (heart muscle). It can aid in diagnosis of a number of cardiac conditions including ischemia, hypertrophy, previous or current infarction and rhythm abnormalities.

2. Objectives

To describe the procedure for obtaining an electrocardiograph on patients and promote uniformity within the SDRN in accordance with ICH GCP guidelines.

3. Responsibilities

Research nurses trained in the measurement of ECG using equipment supplied and in accordance with ICH GCP guidelines. The Research Nurse should consider if a chaperone is required for this procedure.

4. Equipment

- 12 lead ECG machine
- Disposable ECG electrodes
- Alcohol wipes
- Disposable razors

5. Method

Preparation of subject

- Inform patient of need for test and obtain verbal consent.
- Ask if the patient has had an ECG before and if not explain the procedure in terms that they
 will understand. In particular ensure they are aware that the ECG takes a tracing of the
 heart and does not involve the use of electricity. If the patient has previously had one
 performed then ask if he/she would like a reminder. Keep the explanation short.
- If appropriate at this point ask female participants if they prefer a female member of staff to carry out the procedure.
- Ask the patient to loosen or remove shirts or blouses to allow access to the chest. Women
 may keep their bra on if they prefer. They should also remove shoes socks tights or
 stockings. They should lie comfortably on the bed/couch at an angle of approximately 45°
 (or head on two pillows).
- Clean relevant areas of chest and limbs (see figure 1) with alcohol wipes.
- Ask patient to relax with arms by their sides and legs extended.



S.O.P. No. 9 Version 1.0

Procedure

- Plug in and check that the ECG machine s working as per manufacturer's instructions.
- There are 6 chest leads and 4 limb leads that are attached to the patient using electrodes.
- Apply disposable electrodes first then attach appropriate leads. The limb leads may either have a strap to wrap around the wrists and ankles or they may be attached with adhesive electrodes.

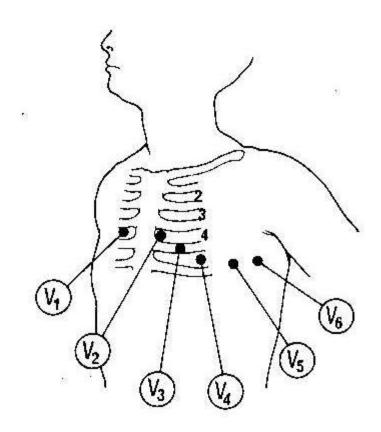
Chest leads

It may be necessary to shave some hair off the chest for two reasons.

- It can reduce the contact between chest and the electrode and therefore prevent conduction of the electrical wave from the heart.
- It would be painful for the participant when the electrodes were removed, as hair would be pulled out.

If shaving is required, permission must be sought from the patient first.

(See Appendix 1 to apply chest leads accurately)



Appendix 1

Attach 6 electrodes and leads to patient's chest as follows;

C1 Chest right of sternum in 4th intercostal space

C2 Chest left of sternum in 4th intercostal space

C3 Chest midway between C2 and C4 on left side

C4 Chest fifth intercostals space at midclavicular line on left side

C5 Chest same level as C4 on anterior axillary line on left side

C6 Chest same level as C4 on midaxillary line on left side

Attach 4 limb leads as follows;

RL (right leg inner ankle)
LL (left leg inner ankle)
RA (right arm inner aspect of right wrist)
RED LEAD
LA (left arm inner aspect of left wrist)
RED LEAD
YELLOW LEAD

It is vitally important that electrodes and leads are positioned correctly or inaccurate information will be obtained.

S.O.P. No. 9 Version 1.0

Recording of ECG

- Make sure the individual has relaxed for 5 to 10 minutes before recording. Ask them not to move or talk while the ECG is taking place but to breathe normally. This is generally for about 20 seconds.
- There will be 12 different recordings, 6 from the chest marked V1 to V6 and 6 from the limb leads marked VR, VL, VF, I, 11, and III. (Although there are only 4 limb leads there are 6 recordings)
- Check the ECG is complete and that there are no problems
- Repeat reading if there are any problems.
- Common problems are caused by poor contact of electrodes and patient movement.
- Document clearly in the CRF whether or not the ECG was completed successfully.
- Once ECG completed remove electrodes and leads and allow participant privacy to dress.
- It is usually necessary to either print 2 copies of the ECG or to photocopy original so that 1 copy given to study sponsor and 1 copy kept at site.