

Guidance for a resting 12-lead Electrocardiogram

All participants over 12 years and older, included in the ANTICOV study, must have a resting 12-lead electrocardiogram (ECG) performed before randomization into the study. The 12-lead ECG records the heart's electrical activity as waveforms. It gives a complete picture of the heart's electrical activity by recording information through 12 different perspectives. This is necessary to monitor the participant's cardiac rhythm and ensure his/her safety. An ECG is recorded at the following time points:

D0	D7	D14	D21	Unscheduled
x	x	x	x	x

ECG readings are due as per appendix 4, table 8, Master protocol version 5.0/9 July 2020.

Procedure

Please Note

- The ECG must be taken **before** venipuncture!
- Read the leaflet/manual of the device **first before** use and keep it at hand.
- Check if the calibration is performed by the manufacturer (written in leaflet/manual).
- Perform and document a weekly quality check: activate the ECG device (and if applicable your PC if the ECG is linked to a software). Check if everything is working well, run a dummy record reading. Verify if the cables are intact and if you do not run out of equipment (electrodes, paper tissue, hand sanitizer, etc.). Do this weekly check for all applicable ECG devices used in the study.
- Please note as well that any broken equipment must be documented on the weekly quality check form, this might not be the same day as the day of quality check. If necessary, replace the equipment and assign the new equipment with another identifier.

To measure the heart's electrical activity accurately, proper electrode placement is crucial. In a 12-lead ECG, there are 12 leads calculated using **10** electrodes.

1. Please ensure the participant is lying down (supine position). Allow the participant to lie quietly, relax with legs uncrossed **for at least 5 minutes before taking the ECG**. Remove all electronic devices, including mobile phones.
2. Inform the participant of the procedure and why you are doing it
3. Check the ECG machine is working well and has enough thermal paper
4. Program the machine with the required demographic data to allow identification during analysis. This is the trial name or number, participant number, visit, date and time, date of birth and gender.
5. Wash your hands according to universal precautions and start preparing participant's skin as per figure 1. Skin should be dry, hairless, and oil-free. You might need to shave to make sure the electrodes stick in place (type depending).

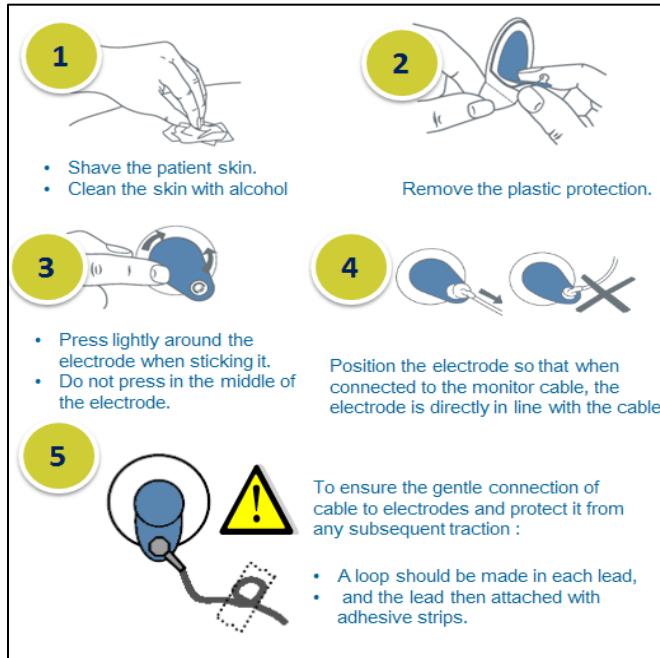


Figure 1: Skin and Electrode Preparation¹

Tips:

- Ensure electrode is moist
- Do not place electrodes on skin over bones, incisions, irritated skin
- Use electrodes of the same brand.

6. Place the electrodes as per diagram below:

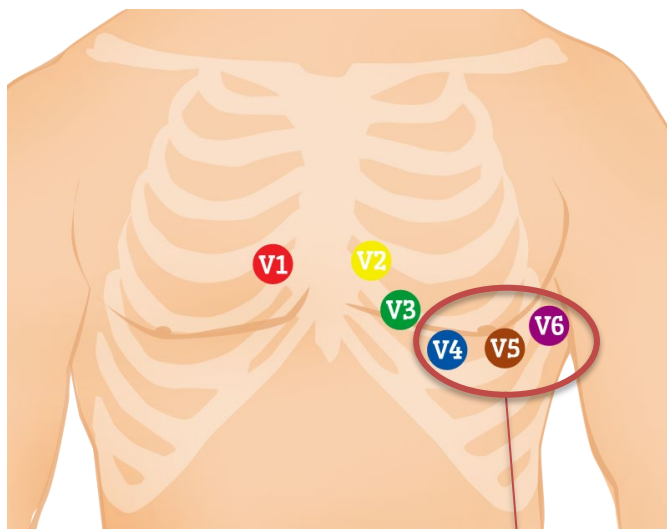
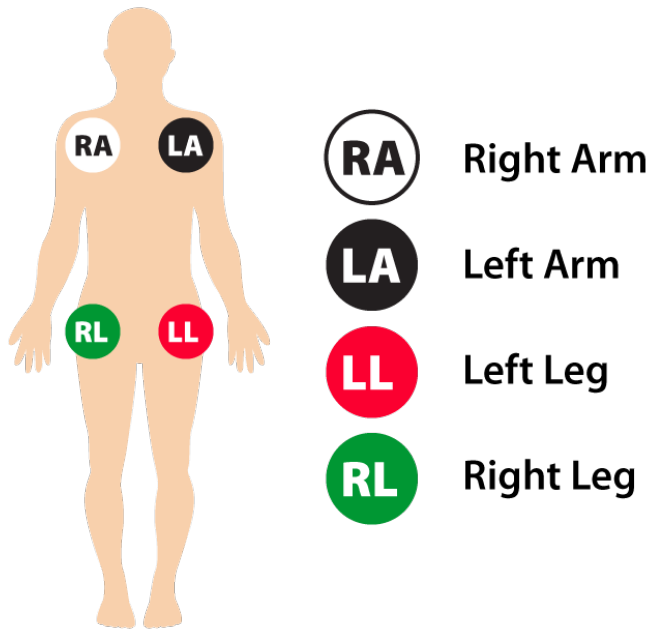


Figure 2: Chest electrodes placement ²

- **V1** Fourth intercostal space at the right border of the sternum
- **V2** Fourth intercostal space at the right border of the sternum
- **V3** Midway between placement of V2 and V4
- **V4** Fifth intercostal space at the midclavicular line
- **V5** Anterior axillary line on the same horizontal level as V4
- **V6** Mid-axillary line on the same horizontal level as V4 and V5

It is important to place V4 + V5 + V6 on the **same horizontal level!** Remember the chest is curvy and **NOT** the placement of the electrodes.



- **A (Right Arm)** - Anywhere between the right shoulder and right elbow
- **RL (Right Leg)** - Anywhere below the right torso and above the right ankle
- **LA (Left Arm)** - Anywhere between the left shoulder and the left elbow
- **LL (Left Leg)** - Anywhere below the left torso and above the left ankle

Figure 3: Limb electrodes placement ²

Please Note

- The limb leads can also be placed on the upper arms and thighs. However, there should be uniformity in your placement. For instance, do not attach an electrode on the right wrist and one on the left upper arm.
- For female patients, place leads V3-V6 under the left breast
- Do not use nipples as reference points in placing electrodes for both men and women as nipple locations vary from one person to another. **Use center of clavicle as referral point instead.**

7. Which system color are you using?

There are two color-coding standards. Please check which standard you are using and follow guidelines as per diagram below:

	AHA (American Heart Association)		IEC (International Electrotechnical Commission)	
Location	Inscription	Colour	Inscription	Colour
	RA	White	R	Red
	LA	Black	L	Yellow
	RL	Green	N	Black
	LL	Red	F	Green
	V1	Brown/Red	C1	White/Red
	V2	Brown/Yellow	C2	White/Yellow
	V3	Brown/Green	C3	White/Green
	V4	Brown/Blue	C4	White/Brown
	V5	Brown/Orange	C5	White/Black
	V6	Brown/Purple	C6	White/Purple

Figure 4: Color coding standards for 12-lead ECG ²

8. Perform ECG and record reading. Wait for at least 10 seconds and for two readings to have passed on the screen before capturing to get an accurate reading. Observe, check for quality and repeat if need be, labelling appropriately. Any issues and decisions should be recorded in the participant notes and CRF. The lead wires and electrodes are then removed using a warm wet cloth or alcohol wipes unless otherwise indicated.
9. Please record ECG reading and findings as per CRF and protocol dictates.
10. All performed ECGs must be shown to the doctor in charge.
11. The doctor may ask you to repeat the ECG.
Treat participant first as per instructions by the doctor, record all actions in the participant notes, CRF, and follow study protocol as indicated. All abnormalities must be described for each time point in the source notes and consequently entered into the CRF.
12. The ECG result is considered as source note. File the result in the participant's medical dossier. Please hand out a copy of the result to the participant, if requested. If your ECG is not connected to a PC/laptop, which allows automatically a copy on your server, in that case do a photocopy of the ECG result (thermal paper) or scan it and double check storage on your server.

References:

1. ANTICOV_01 COV_Master Protocol_v5.0_9 July 2020
2. IDDO Guidance_Collection of ECG data in Covid-19 trials V1.0_15Jun2020
3. Cables and Sensors (2020) 12-Lead ECG Placement Guide with Illustrations. Available at: <https://www.cablesandsensors.eu/pages/12-lead-ecg-placement-guide-with-illustrations> Accessed on 06.07.2020