

Guidance for measuring the vital signs

Within the ANTICOV study protocol, the vital signs to measure are:

- Blood pressure
- Heart rate
- Respiration rate
- Body temperature (see applicable working instruction/type of thermometer: digital, temporal, NCIT)

All participants over 12 years and older, included in the ANTICOV study, will have their vital signs measured at the following time points:

D0	D1	D7	D14	D21	Unscheduled
X	X	X	X	X	X

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

Procedure

The vital signs are measured in a sitting position.

The equipment you need is:

- A digital tensiometer (automated blood pressure monitoring device)
- Different cuff sizes (small, medium, large)
- A non-elastic measurement tape
- A chronometer (e.g., you can use your mobile phone or a stopwatch)



Please Note

- Read the leaflet/manual of your 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.
- 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.

1. Explain to the participant that you check his/her blood pressure, heart rate and respiration rate. Guide the participant through the steps, which will support you in obtaining accurate measurements.
2. Make sure your hands are washed or disinfected and your equipment is clean.
3. Ask the participant to find a comfortable sitting position with 2 feet on the floor and back against the chair. Ideally participant should have 5 minutes of relaxation time before measurement.
4. Make sure that all measurements linked to the blood pressure are done on a bare arm.
5. Measure greatest circumference of the participant's upper arm in order to select the right cuff size. Document arm circumference and indicate right or left side of arm in the source notes. Then ask the participant to place his/her arm on the table. The cuff is placed on the arm so that its bottom edge is 2-3 cm above the antecubital fossa.
6. Make sure that clothes do not restrict the measurement.
7. The device should be placed on the table in front of the measurer. The participant should not see the result.
8. Ask the participant to keep still during measurement, ask him/her not to talk and to focus on breathing. Agitation and talking can increase blood pressure. Do not talk to the participant during measurement.
=>Measure the respiration rate at the same time you are going to use the tensiometer. See next steps:
9. Press the "on" button, wait for symbols to display on the screen, then press the "start" button and wait for the blood pressure and pulse rate results.

10. **For the respiration rate:** DO NOT tell the participant that you are going to count his/her respiration rate. **During** the blood pressure measurement, look at participant's chest and count the number of times he/she **exhales during 30 seconds**, which you need to chronometer.
11. Document all recorded values of blood pressure and heart rate into the source notes, as well as the measured respiration rate and inform the participant. Precise also in the source notes on which arm that you have taken the measurements (e.g., right arm). All values must be reported to the doctor in charge.
12. It can happen that your device displays an "error" function. Document the error code into the source notes. Wait one minute (chronometer) before next measurement. Then check if the batteries are properly in place, check the position of the cuff and participant's sitting position and repeat the measurement.
13. Clean the equipment after use.

Reference:

1. ANTICOV_01 COV_Master Protocol_v5.0_09 July 2020
2. http://www.ehes.info/core_measurements.htm