CardioSecur
Knows Your Heart

CardioSecur

ECG system instructions

Version 4.0
Personal MedSystems GmbH

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1. Electrode system and diagnostic power

The CardioSecur (EASI) lead system has all the diagnostic capabilities of a conventional 12-lead ECG and allows professionals to work with 22 leads diagnostically beyond the gold standard. For instance, if a cardiac ischemia is suspected and the 12-lead ECG is inconclusive, the ESC guidelines recommend additional recording of the precordial and right ventricular leads (V7-V9, VR3-VR4). In practice, however, this is rarely the case as repositioning the conventional electrodes is awkward and the display of the ECG curves does not show the correct names of the then measured leads. CardioSecur is the only ECG system that meets this guideline in practice by optionally including leads V7-V9 and VR3-VR9 (22-lead ECG) in one synchronous reading, with only 4 electrodes and no need for repositioning.

Applying only 4 electrodes in more marked positions on the body compared to the conventional system with 10 electrodes, enables physicians to perform a reading more swiftly and mitigate the risk of lead misplacement across the various anatomies of patients.

The fact that the electrode positions of the conventional ECG with 10 electrodes and the EASI system with only 4 electrodes are different, inevitably conditions a different model for the ECG generation. The difference may show in a recorded ECG by means of certain characteristics. These characteristics mainly concern the absolute amplitude of e. g. the R-wave and the T-wave as well as the heart axis. The ECGs, however, speak the same “diagnostic language”, not bearing any effect on the diagnosis of an ECG. This has been proven repeatedly and unambiguously over decades in both third-party and internal clinical studies comparing both lead systems (see our document "Scientific Background"). In particular, none of the studies has shown a disadvantage in the diagnosis between the EASI derivation system and the 12-lead ECG.

There are mainly three characteristic differences regarding R-, T- and Q-wave which a physician needs to take into account when working with CardioSecur. They are explained in more detail below.

2. Characteristic differences vs. conventional 12-lead ECG

2.1 Amplitude R-waves and T-wave

With CardioSecur there are slight differences in amplitude of the R-wave and the T-wave, but these do not have any diagnostic impact. Furthermore, the R-wave progression is not affected.

The following depiction shows exemplary the differences that may occur with the R-wave and the T-wave.

2.2 Q-waves

With CardioSecur, the Q-waves in the leads of the inferior wall are commonly slightly deeper than in the conventional ECG. However, they are not wide, but have a characteristically very pointed course. This therefore has no diagnostic impact.

Following the guidelines of the European Society of Cardiology (ESC), a pathological Q-wave is present, if the Q-wave is wider than 40ms and higher than ¼ of the corresponding R-wave. At a writing speed of 25mm/s, 40ms corresponds to one

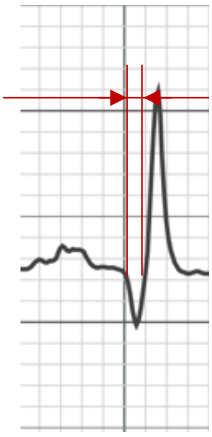
box on the millimetre grid. The following examples of CardioSecur ECGs are used to explain the diagnosis in accordance with the ESC guidelines:

Narrow Q-wave
<40ms

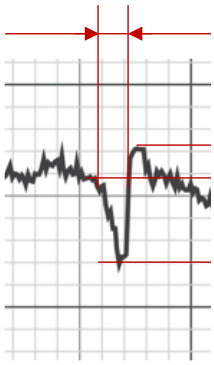
Wide Q-wave
>40ms and
>1/4 of R-wave height

Example 1

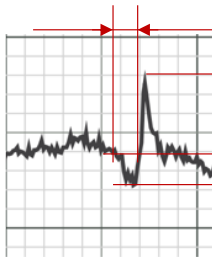
Example 2



Example 3



Example 4



Not pathological

Pathological

All example depictions at 25mm/s speed => one box corresponds to 40ms

When using the automatic interpretation feature, called the HES-algorithm, physicians need to be aware that this licensed generic algorithm is based on the conventional 12-lead system. Therefore, the characteristically deep, narrow Q-wave of CardioSecur is in some cases identified by the automatic interpretation false positively as “possible posterior wall infarction”. The physician should in such cases evaluate according to the ESC guidelines as given above.

3. Obese patients

With CardioSecur there are slight deviations in relation to the heart axis. However, this has no influence on the diagnosis of an ECG, especially not on the diagnosis of ischaemia.

4. Electrode choice

For optimum ECG signal quality, please use the recommended wet gel adhesive electrodes for CardioSecur. Wet gel reacts with the skin and quickly forms a good contact. The conductivity increases over the following minutes after the electrode has been applied.

Please note: For short-term measurements do not use electrodes for long-term measurements, neither with wet gel nor with dry gel. Dry gel electrodes should not be used, even in combination with other contact gels! We recommend the electrodes listed below for short-term measurements of the **BlueSensor** series from the manufacturer **Ambu®**:

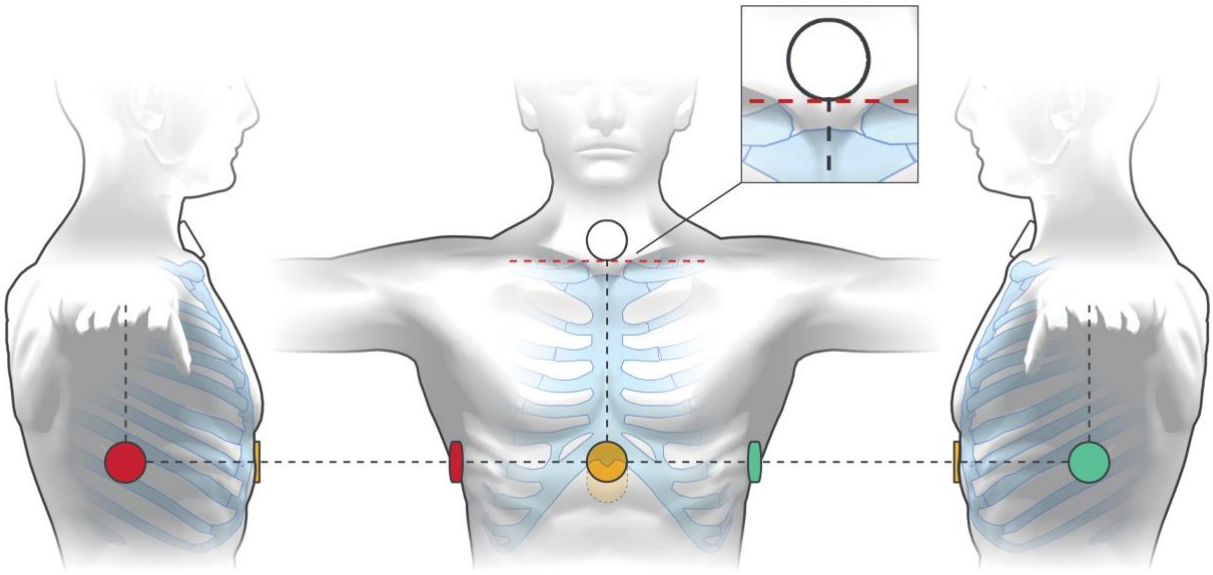
Electrode type	Conductivity - AC impedance acc. to manufacturer information (the lower the Ω value, the higher is the conductivity)
Ambu® BlueSensor P	700 Ω (Ohms)
Ambu® BlueSensor Q	650 Ω (Ohms)
Ambu® BlueSensor R	500 Ω (Ohms)

If you wish to use other wet gel electrodes, we can offer you the validation of your designated electrodes. Our customer support will be happy to assist you:
info@cardiosecur.com

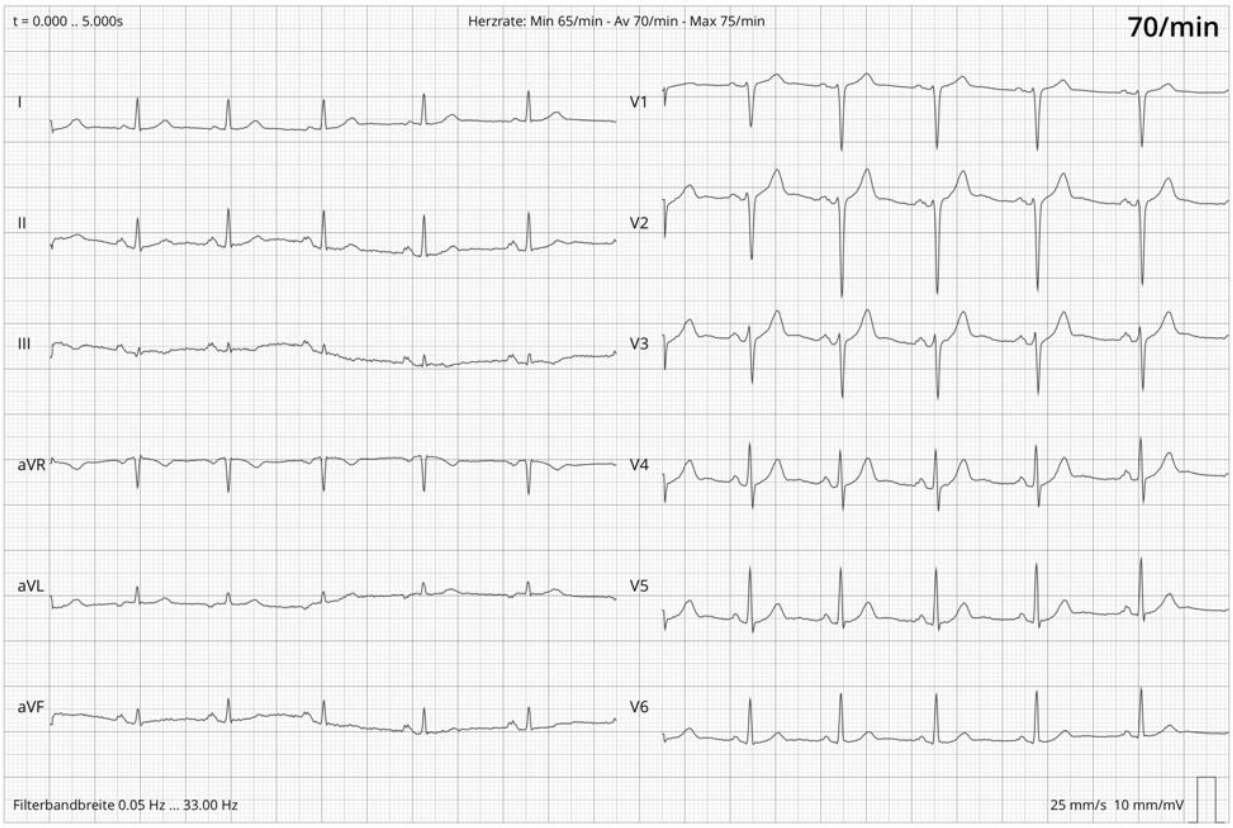
5. Electrode positioning

ECGs can only be displayed correctly, if all electrodes are positioned on the patient's thorax according to the following diagram:

White electrode: Precisely in the depression above the breastbone, never below the collarbone level.



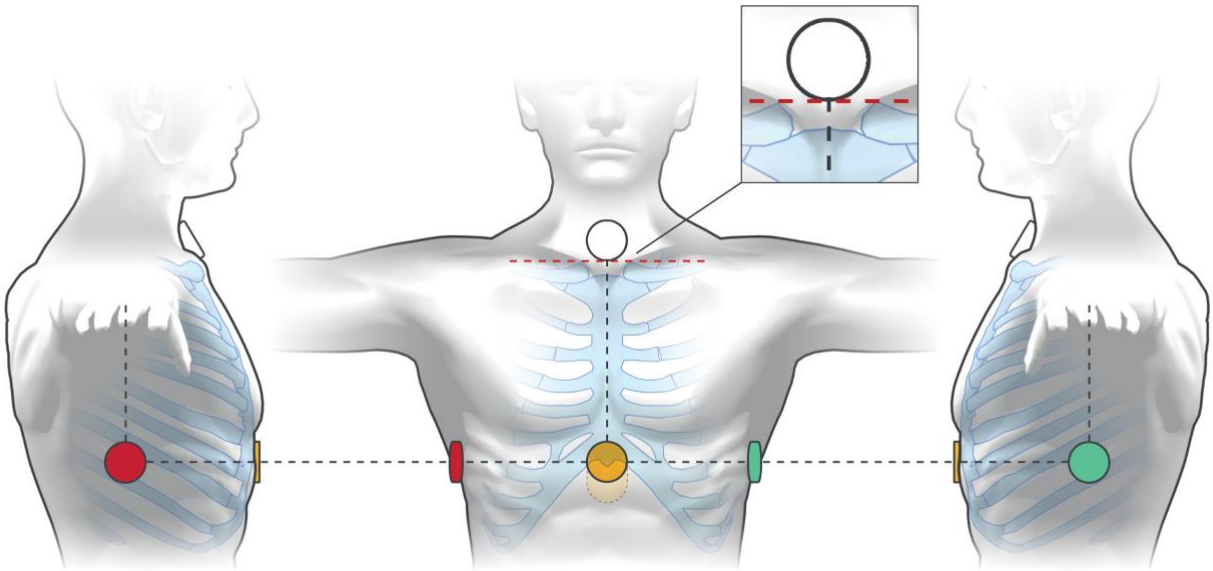
Yellow electrode: On the lower bony end of the sternum or slightly below.
Red electrode: Centered under the right arm, on the same level as the yellow electrode.
Green electrode: Centered under the left arm, on the same level as the yellow electrode.
Placing all electrodes correctly will provide a standard ECG (PQRST-wave) as shown below.



6. Preventing of misrepresented negative T-waves

If the white electrode of CardioSecur is placed too low, the T-wave may flip and show negative in the ECG, without a pathological background. This may already occur if the white electrode is placed 2 cm below the designated position.

To avoid misrepresented negative T-waves and attain a proper ECG it is imperative to place the white electrode correctly on the upper end of the sternum. More precisely, the wet gel centre of the electrode - not its adhesive edge - is decisive for positioning the electrode correctly and must be placed precisely in the depression above the breastbone, never below the collarbone level (see expansion below).



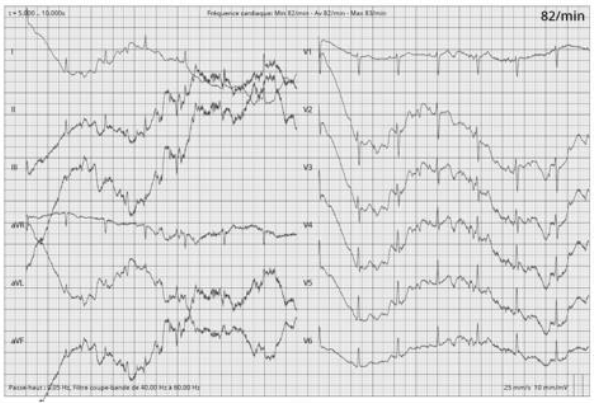
7. Signal quality

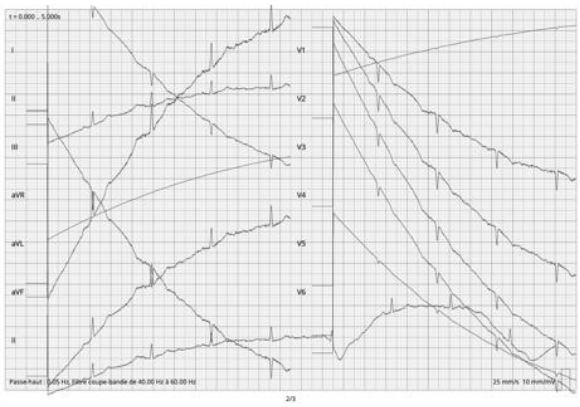
Signal quality is crucial for reliable results. The signal quality of the ECG is significantly influenced by the following factors:

- Type of electrode used
- Condition of electrodes used
- Positioning of the electrodes
- Condition of the skin
- Electromagnetic sources of interference in the environment
- Use of filters
- Physical activity of the patient
- Synthetic clothing
- Pressure exerted on the electrodes by clothing
- Training level personnel (changing personnel, rare ECG use)
- Time pressure in the measurement process

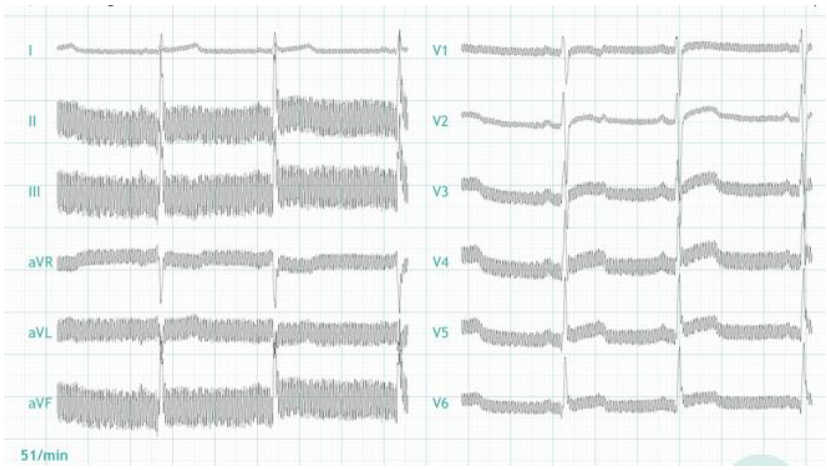
ECGs as shown in the following examples are caused by low signal quality:

Wandering of baseline





Interferences from disturbance sources



The following describes measures to ensure optimal signal quality with CardioSecur:

7.1 All around the electrodes:

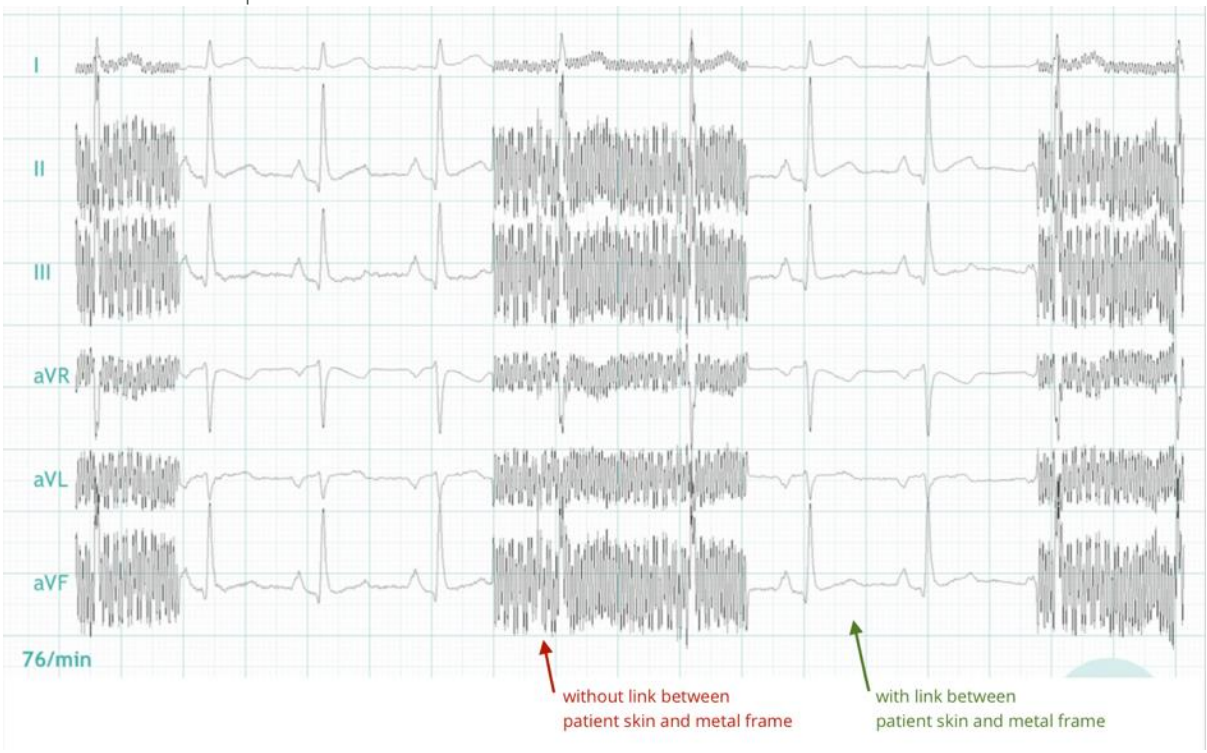
- Only use wet gel electrodes that have been validated for CardioSecur, e.g. the BlueSensor series from Ambu® (see chap. 4). If you want to use other wet gel electrodes, please contact our Customer Support. We can offer you the validation of your preferred electrodes.
- Never use dry gel electrodes, not even in combination with other contact gels!
- Consider the best before date of the electrodes
- Electrodes from an opened pouch may dry out quickly, depending on the ambient temperature and humidity. Please always use fresh electrodes.
- Always place the electrodes in the correct position (see chap. 5 and chap. 8).
- When applying electrodes to the body, please do not apply pressure to the gel centre of the electrode, as this may affect the adhesive surface and the gel film may become too thin for a good signal.
- Important: Wet gel electrodes need some time to develop their full conductivity. Always try to apply the electrodes to the skin as early as possible before an ECG reading, so that the wet gel renders the skin correspondingly more conductive. In case the ECG curves wander out of the baseline in the beginning of the measurement, please do not discontinue the process, but wait 1-2 minutes until the conductivity is established.
- Recommended skin preparation:
  - Clean skin only with mild cleanser and water and dry well.
  - If the signal quality is poor, wipe the skin with a dry compress.
  - When cleaning with alcohol, only use isopropyl alcohol >95%. Otherwise, the skin impedance may increase (signal quality becomes worse).
  - Do not use skin disinfectants as they are re-fattening.
- If you store electrodes, make sure to observe the recommended storage temperature and close opened pouches with a clip or store in a sealed storage box.

7.2 All around the patient:

- To ensure electrode adhesion, the patient's skin should be free of creams, water, oils or similar as well as strong hair growth at the electrode positions.
- Patients should take a calm position and not speak or cough.
- Patients should not wear synthetic clothing (e.g. bras, sports shirts, etc.) as this can charge the patient electrostatically. Electrostatics build up especially in dry air. Before an ECG measurement, patients should touch a grounded object to discharge any electrostatics from the body.
- No pressure should be applied to the electrodes, e.g. by clothing.

7.3 Measurement environment:

- Measurements should not be carried out near sources of electromagnetic interference (e.g. monitors, dimmers, refrigerators, electric beds, electric blankets, etc.).
- Use the filters provided in the CardioSecur App to reduce possible ECG artifacts and noise.
- Important: Noise can be further reduced by placing the metal frame of the recording iPhone/iPad in contact with the patient's skin (the body part is irrelevant in this respect). This minimises the antenna effect of the ECG cable. The same effect can be achieved if the recording person touches the metal frame of the iPhone/iPad with one hand and touches the patient's skin with the other hand. The following illustration shows, in the case of extreme noise, the difference direct or indirect contact with the patient's skin can make.



8. Identifying electrode permutation

Interchanging the position of electrodes (permutation) will affect the ECG and show a false ECG depiction. In fact, from the alterations observed in the PQRST waves, the mispositioning can be identified and should be corrected. The following cases illustrate mispositioning:

8.1 Interchanging the red and green electrode:

If the red and green electrodes only are interchanged, while the white and yellow electrodes are correctly placed, the R-wave of lead I is affected. The R-wave appears with a negative value (see fig. 1.2). The second consequence of falsely interchanging the red and green electrode is the missing R-wave progression in the chest leads.

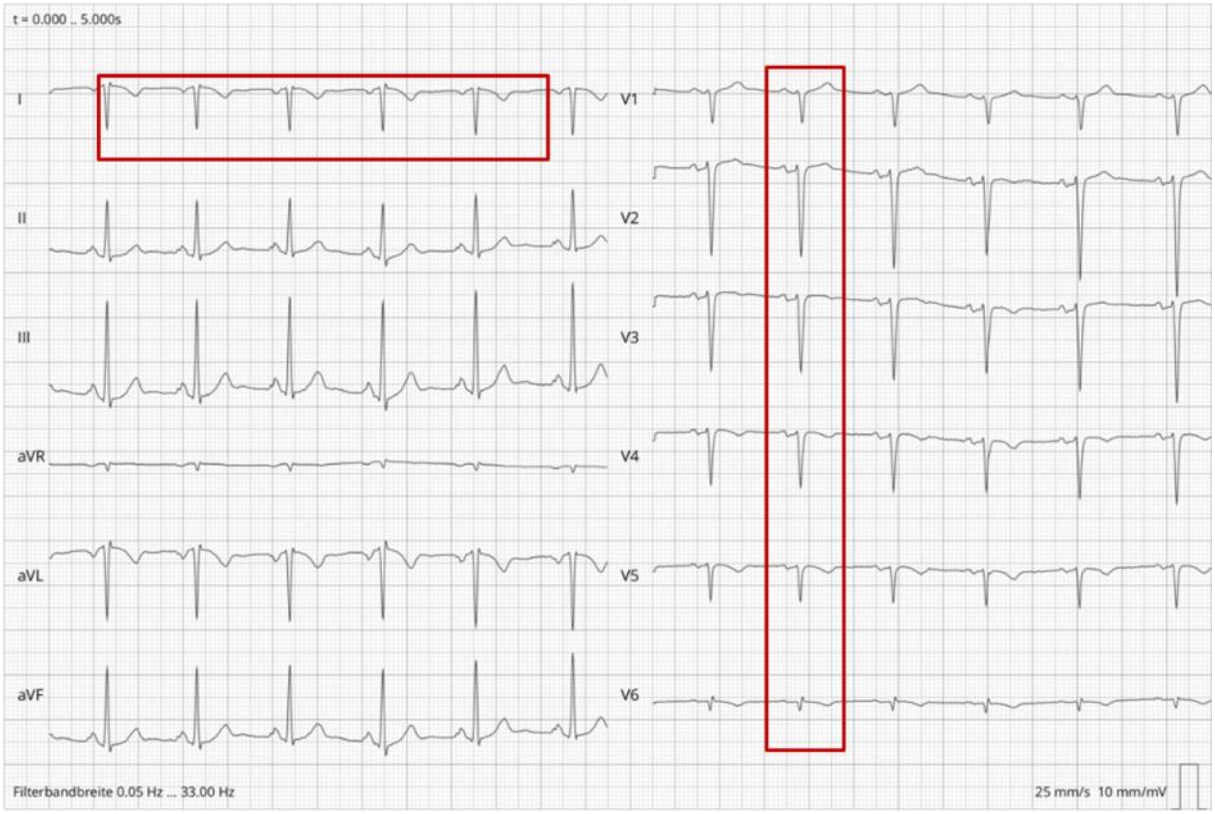


Fig. 1.2: ECG featuring negative R-wave in case of interchanging the red and green electrode

8.2 Interchanging the white and yellow electrode:

If the white and yellow electrodes only are interchanged, while the red and green electrodes are correctly placed, the T-wave of the ECG is affected. The T-wave appears as a negative wave in leads I, II and avF (see fig. 1.3), while no particular change occurs in the other leads.

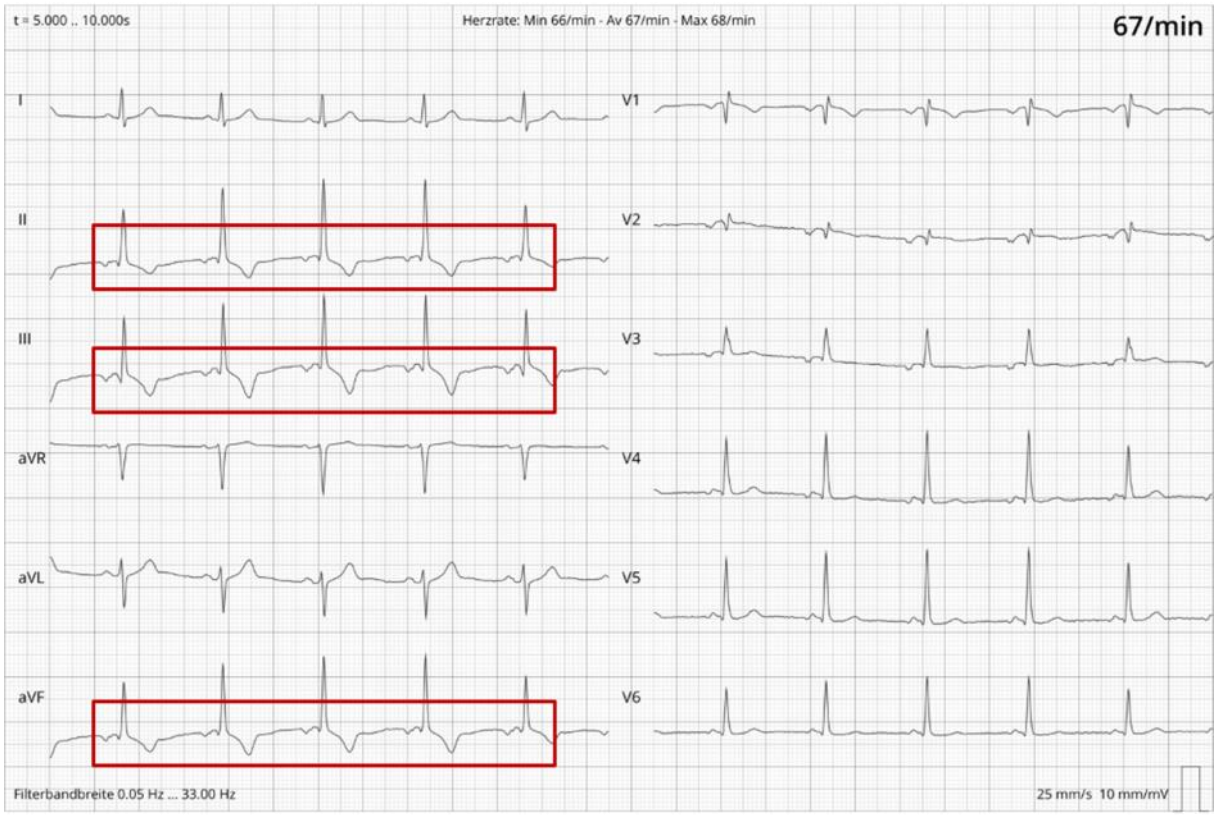


Fig. 1.3: ECG featuring negative T-wave in case of interchanging the white and yellow electrode

8.3 Interchanging all electrodes - red and green and white and yellow:

If all electrodes are interchanged (red and green AND white and yellow) the R-, T- and P-wave of the ECG are affected. The R-wave appears negative in lead I. In the chest leads the R-, T-and P-wave each appears negative (see fig. 1.4).

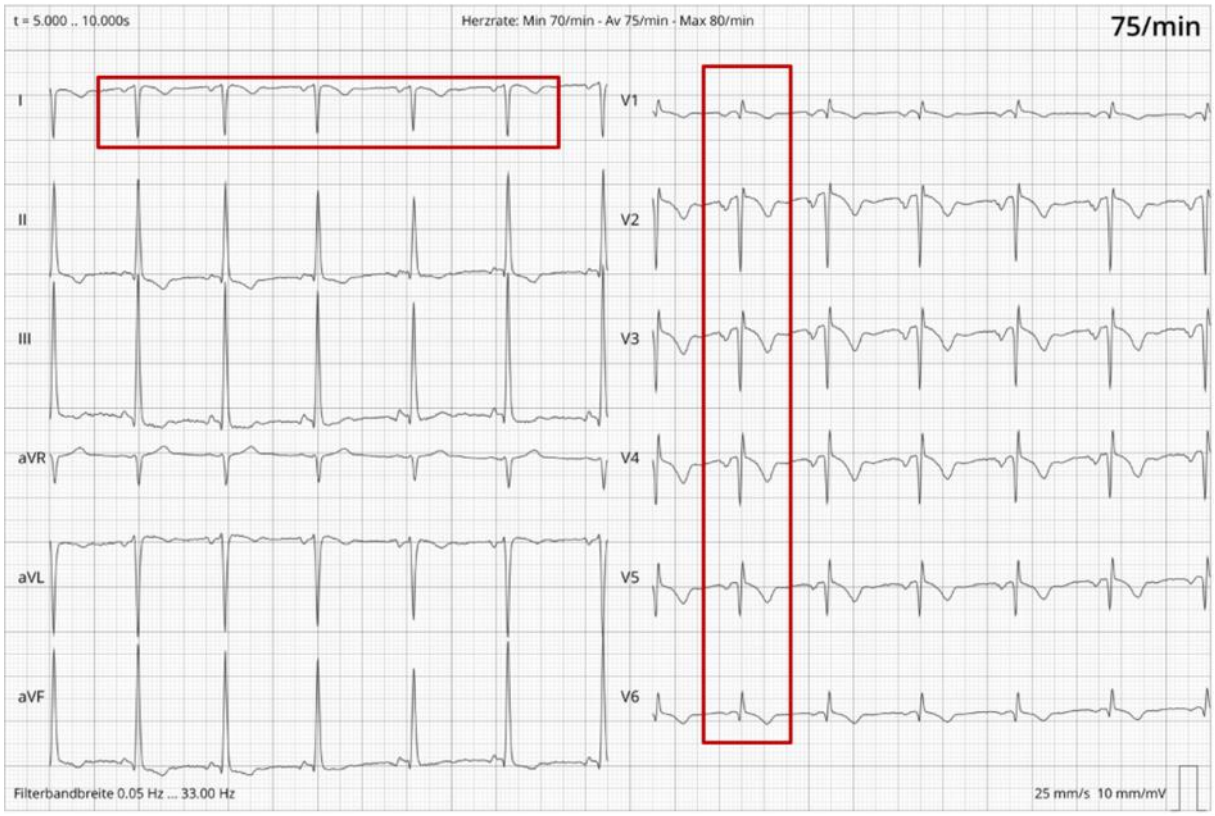


Fig. 1.4: ECG featuring negative R-, T- and P-wave in case of interchanging all electrodes

Please ensure at all times that electrodes are positioned correctly according to the CardioSecur instructions as given above, in the user manual or the CardioSecur app.
For optimal signal quality also ensure that only fresh wet gel electrodes are used as validated by CardioSecur.

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