Exercises
Session 1 (chapter 3)

1 Safety protections for ECG device

Let us consider the device shown in Figure 1. The device intended use is the measurement of ECG for diagnostics. The standard IEC 60601-2-25 defines the requirements for such device. In this exercise, we will consider a device powered by its own 3.7 V battery (and therefore not connected to the mains) with BLE connectivity (Bluetooth low energy). The device shall have DEFIBRILLATION-PROOF APPLIED PART of TYPE CF. In addition to the insulation of the device and its cables, the MOPs (MEANS OF PROTECTION) will be resistors *R* inserted along the leads.

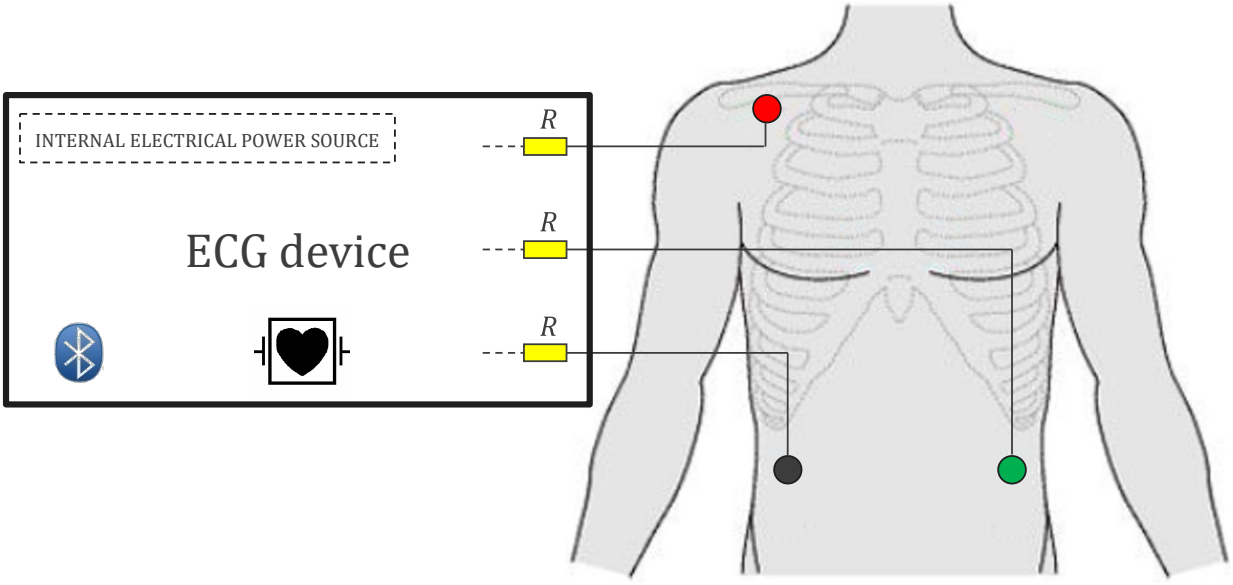

Figure 1: ECG device protected by resistors *R*

1.1 Enclosure and applied part

Exercise statement

Identify the APPLIED PART, ENCLOSURE, and PATIENT CONNECTIONS. Determine the MOPs required for the ENCLOSURE and APPLIED PART (except for PATIENT CONNECTIONS).

1.2 Auxiliary current

The auxiliary current is the current that flows between two PATIENT CONNECTIONS.

Exercise statement

Calculate the minimum resistance *R* (in yellow in Figure 1) to be added to an electrode to guarantee that the maximum auxiliary current is not exceeded in NC and SFC (normal and single fault conditions), assuming that the amplifier inputs are at the maximum battery voltage (3.7 V).

1.3 Energy reduction

When the defibrillator paddles are applied on the patient, some current can flow via the electrodes, cables, and device. To avoid that this current is too big, the standard (IEC 60601-2-25) makes sure that the amount of this current does not significantly decrease the defibrillation energy (which is supposed to be used to stop ventricular defibrillation of the heart).

Exercise statement

Calculate the minimum resistance R to be added to an electrode to pass the energy reduction test.

1.4 Thermal noise

From the previous sections, we now know that we must have R greater than a certain value to fulfil all safety conditions. The power dissipation of a resistor is $P = u^2/R$ and the more power a resistor must dissipate, the bigger it is. For wearable devices, the size is important. Therefore, one may want to take the largest resistance to have the smallest resistor. However, a too high resistance will result in a too large thermal noise (see section 2.1.7 in textbook).

Exercise statement

Calculate the maximum resistance R that can be added to an electrode and still limit the thermal noise of the ECG lead to less than 3 µV rms (root mean square), assuming a first-order low-pass filter at 150 Hz and a temperature of 20 °C.