USER MANUAL

Contents

Introduction

ECG SmartApp is a low cost device to record, process and store ECG signals. The device is battery powered and consists of a front-end circuit to acquire the ECG signals (limb leads only) through common electrodes and an Arduino board to digitalize the analog signal and transmit it to an Android smartphone via Bluetooth protocol. The related App visualizes the ECG signal in real time and gives the possibility to filter and store the signal in a file.

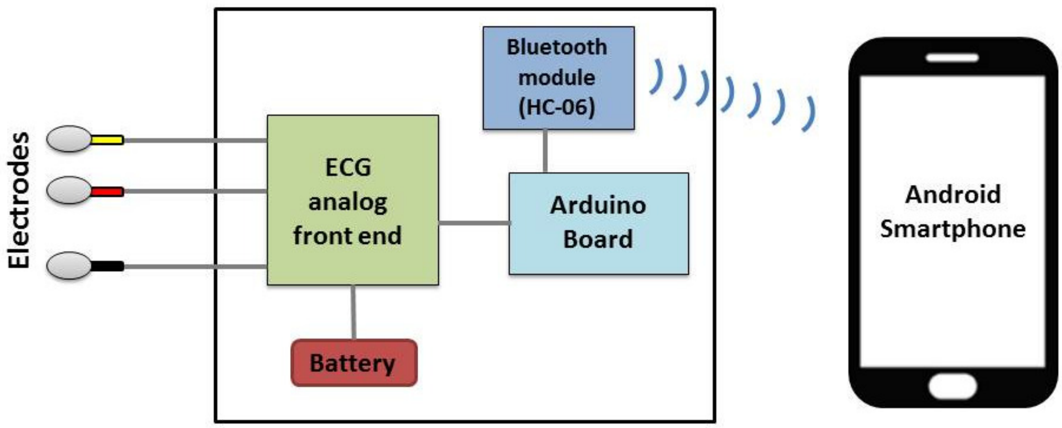


Figure 1: ECG device scheme

The ECG device can be built easily by following the assembly manual and only a basic knowledge of electronics is needed to realize the hardware circuit. No software programming knowledge is required since all you need is to install the App by opening the apk file from an Android smartphone and to upload the provided Arduino sketch on the Arduino board (this can be done easily by using the Arduino Software IDE and one of the many tutorials available on the web). However, source files are available to modify or personalize the App (in this case, Android programming skills are needed) and/or Arduino program.

The simple circuit design and layout are a good compromise for having both a low cost (few components) and good performance.
By excluding the Smartphone and disposable parts (electrodes and batteries), the device whole cost is around 43 US dollars (40 Euros).

<u>The ECG device is intended only as a design research project and it is NOT a medical device, so please read the Warnings and safety issues before going on.</u>

Warnings and safety issues

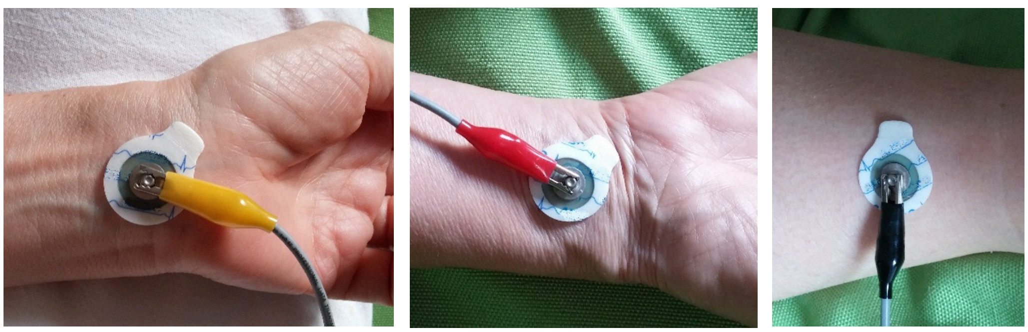
The ECG device is intended only as a design research project and it is NOT a medical device.
Use ONLY battery (max voltage supply: 9V).
DO NOT use any AC power supply, any transformer or any other voltage supply to avoid serious injury and electrical shock to yourself or others. Do not connect any AC-line powered instrumentation or device to the ECG device here proposed.
The ECG device is electrically connected to a person and only low voltage batteries (max 9V) must be used for safety precautions and to prevent damage to the device.
Placement of the electrodes on the body provides an excellent path for current flow. When the body is connected to any electronic device, you must be very careful since it can cause a serious and even fatal electric shock.
The authors cannot be responsible for any harm caused by using any of the circuits or procedures described in this manual. The authors do not claim any of the circuits or procedures are safe. Use at your own risk. It is imperative that anyone who wants to build this device has a good understanding of using electricity in a safe and controlled manner.

Start with ECG SmartApp

- Be sure that the battery (max voltage supply: 9V) connected to the device is charged
- Clean the skin before placing electrodes [1]
- Place the electrodes [2] according to the table below:

ECG Lead (limb leads)	Red electrode	Yellow electrode	Black electrode [3]
LI	Right Arm	Left Arm	Right Leg
LII	Right Arm	Left Leg	Right Leg
LIII	Left Arm	Left Leg	Right Leg

Table 1: Leads and electrodes positions



a) b) c)

Figure 2: electrodes connection: left arm (a), right arm (b), optional reference electrode on right leg (c)

[1] Dry dead skin layer (usually present on the surface of our body) and possible air gaps between the skin and the electrodes do not facilitate the ECG signal transmission to the electrodes. So a moist condition between the electrode and the skin is needed. The skin needs to be cleaned (tissue cloth soaked with alcohol or at least water) before placing the electrode gel pads (disposable).

[2] In case of a non-disposable electrode, electrode conductive gel (available commercially) should be used between the skin and the metal electrode or at least a pad of cloth tissue soaked in tap water or in saline solution.

[3] The device allows to record the ECG (LI, LII or LIII) also by using only 2 electrodes; the reference electrode (black) is optional and can be excluded by using a switch or removing the jumper J1 (see Assembly Manual file). However, the reference electrode should be used to have a better signal quality (lower noise).

- Power on the ECG device by using the switch (red led turns on)

- Run the App on the smartphone

- Press the button “ON” to connect the smartphone to the ECG device (the App will ask you the permission to turn on Bluetooth: press “Yes”) and wait for the discovery of the HC-06 (or HC-05) Bluetooth Module of the ECG device. Pairing code or password may be asked in case of the first Bluetooth connection with the module: enter “1234”. If the App does not find the Bluetooth Module, try to pair the smartphone with the HC-06 (or HC-05) Bluetooth Module by using the smartphone Bluetooth Setting (pairing code “1234”); this operation is needed only once (first connection)

- When the connection is established, the ECG signal will appear on the screen; in case of LI (default lead is LI, to change lead please go to the “Setting” paragraph) the heart rate (HR) will be estimated in real time. The signal will be updated every 3 seconds

- To apply a digital filter, press “Filter” button and choose a filter from the list. By default, a low pass filter @ 40 Hz and a notch filter (according to the preferences saved in the Setting) are applied.

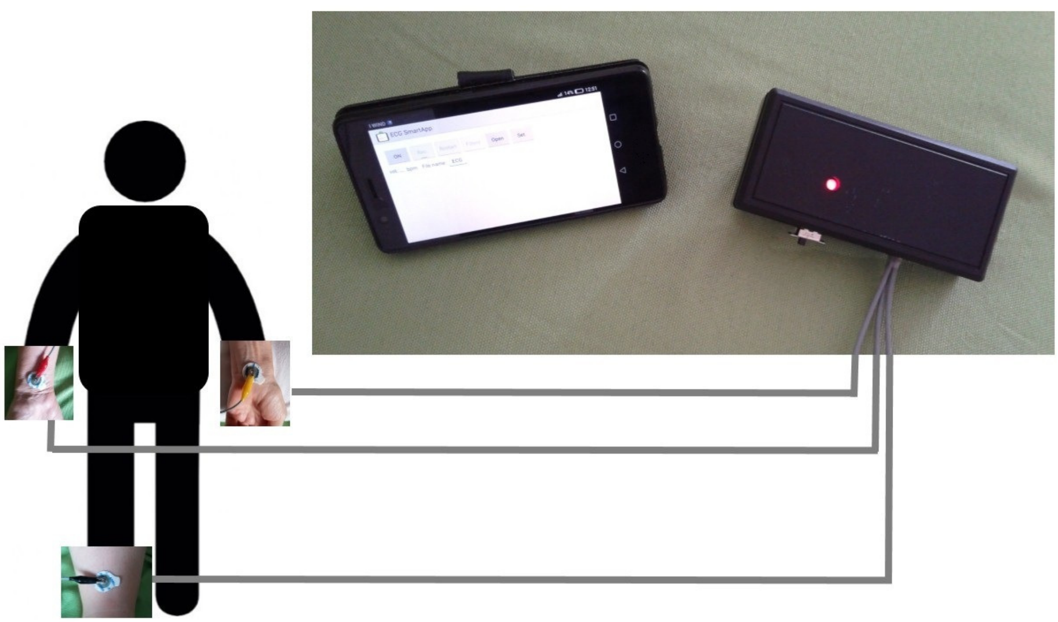


Figure 3: ECG device working

Settings

- Press the button "Set." to open the setting/preferences page
- Press "User Manual (help.pdf)" to open this document
- Select the ECG lead (LI is default)
- Select the notch filter frequency (according to the interference frequency: 50 or 60 Hz)
- Select the file saving option to save the ECG signal filtered or unfiltered on the file
- Press the button "Save settings" to save the preferences

Gain value can be changed in case of hardware modification or personalization of the ECG device.

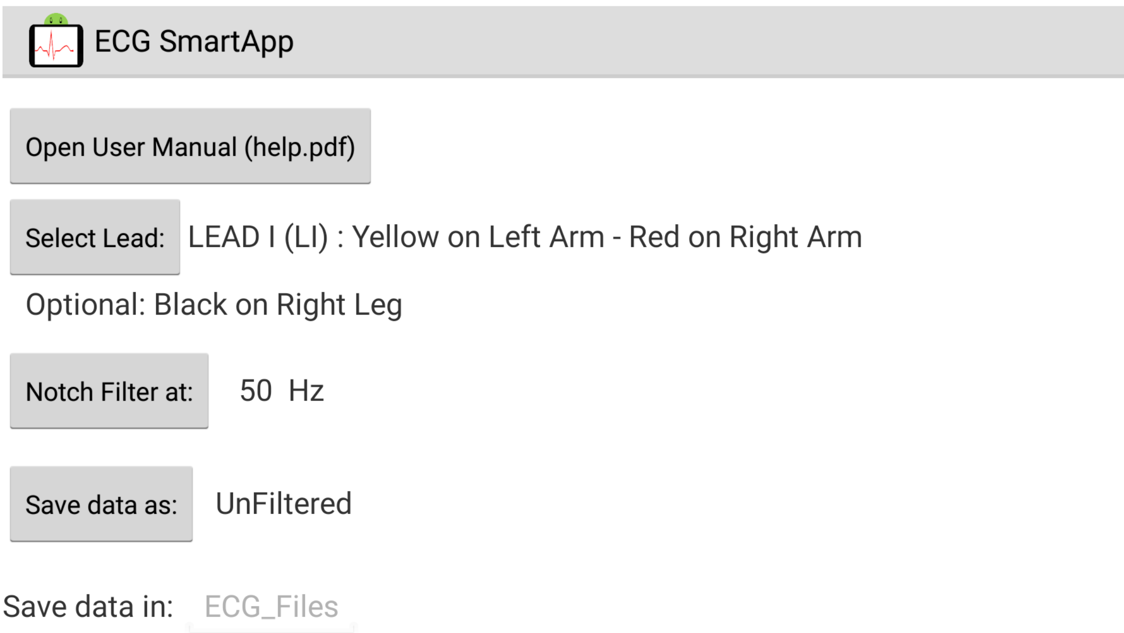


Figure 4: "Settings" screenshot

Recording ECG signal

- Insert the file name (if the user records more ECG signals in the same session without changing the file name, a progressive index is added at the end of the file name to avoid overwriting the previous recording)
- Press “Rec.” button to start recording the ECG signal
- Press “Stop” button to stop the recording
- Each ECG signal will be stored in a txt file inside the folder “ECG_Files” placed in the main root of the smartphone memory. ECG signal can be stored filtered or unfiltered according to the preferences saved in the setting
- Press “Restart” button to visualize again the ECG signal acquired in run time
- To record a new ECG signal, repeat the previous points

An ECG file contain the series of the samples (sampling frequency: 600 Hz) of the ECG signal amplitude in mV.

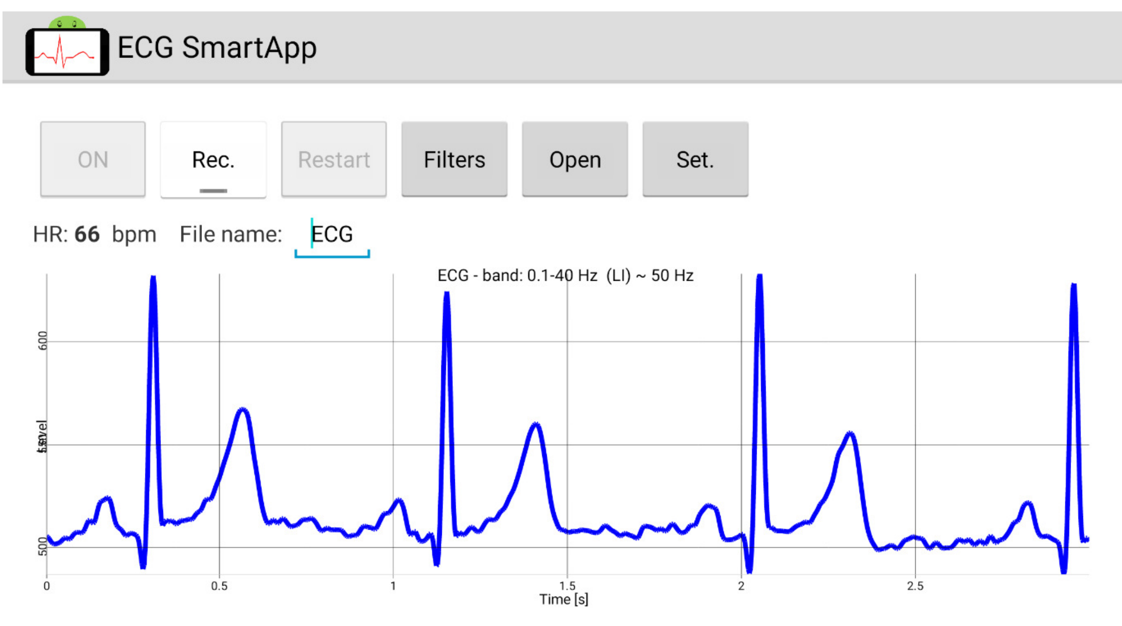


Figure 5: Main activity screenshot with ECG device connected

Opening and analyze an ECG file

- Press “Open” button: a list of the files stored in the “ECG_Files” folder will appear

- Choose the ECG file to be visualized

The first part of the ECG file will be displayed (10 seconds) with no grid.

The user can scroll manually on the display to visualize any time interval of the ECG signal. To zoom in or zoom out the user can press on the magnifying glass icons (right corner at the bottom of the graph) or use the pinch zoom directly on the smartphone display.

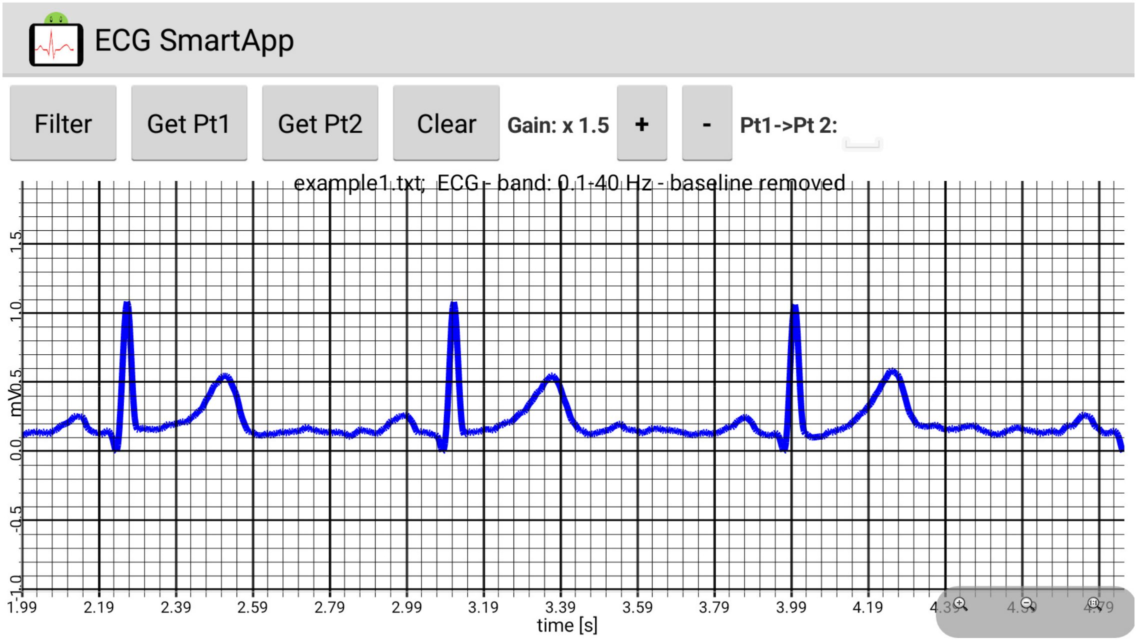
Time axis, voltage axis and the standard ECG grid will automatically appear when a time interval lower than 5 seconds will be visualized (by zooming in). Voltage axis (y-axis) values are in mV while time-axis (x-axis) values are in seconds.

To apply a digital filter, press “Filter” button and choose a filter from the list. By default a low pass filter @ 40 Hz, a filter to remove the wandering line and a notch filter (according to the preferences saved in the setting) are applied. The graph title displays:

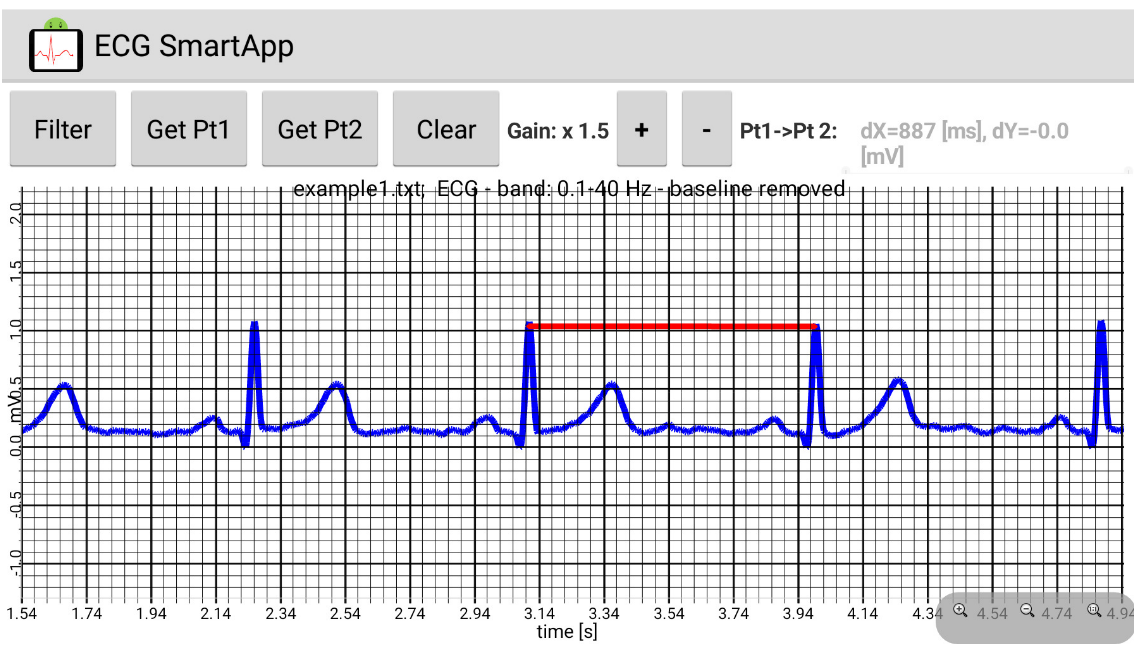
- the file name
- the ECG frequency band according to the applied filters
- the label “wandering baseline removed” if the wandering baseline filter is applied
- the label “~ 50” or “~ 60” according to the applied notch filter

The user can make measurements (time interval or amplitude) between two points of the graph by using the “Get Pt1” and “Get Pt2” buttons. To choose the first point (Pt1) the user can press “Get Pt1” and select manually a point of the ECG signal by clicking directly on the graph: a red point will appear on the ECG blue signal; if the user misses the ECG curve, no point will be selected and the “no point selected” string will appear: the user has to repeat the selection. The same procedure is needed to choose the second point (Pt2). In this way, the differences (Pt2 – Pt1) of the time values in ms (dX) and the amplitude values in mV (dY) will be displayed. The “Clear” button clears the selected points.

The user can adjust the ECG signal gain by using the “+” button (to enlarge) and “-“ button (to reduce); maximum gain: 5.0 and minimum gain: 0.5



a)



b)

Figure 6: visualizing an ECG example (a) and an example of measurements by means of "Get Pt1" and "Get Pt2" buttons (b)

Filters menu

- NO digital Filter: remove all applied digital filters

- Remove wandering baseline: apply a particular processing to remove the wandering of the baseline. In case of a signal very noisy, the processing may fail

- High pass 'x' Hz: apply an IIR high pass filter according to the specified cut off frequency 'x'

- Low pass 'x' Hz: apply an IIR low pass filter according to the specified cut off frequency 'x'

- 50 Hz removal ON (notch+LowPass 25 Hz): apply a particular very stable FIR filter that is both a notch at 50 Hz and a Low Pass at around 25 Hz

- 60 Hz removal ON (notch+LowPass 25 Hz): apply a particular very stable FIR filter that is both a notch at 60 Hz and a Low Pass at around 25 Hz

- 50 Hz removal ON: apply a recursive notch filter at 50 Hz

- 60 Hz removal ON: apply a recursive notch filter at 60 Hz

- 50/60 Hz removal OFF: remove the applied notch filter

Note:

- ✓ only one notch filter can be used at a time; only the last selected one will be applied

- ✓ only one low pass filter can be used at a time; only the last selected one will be applied

- ✓ only one high filter can be used at a time; only the last selected one will be applied

- ✓ "50 Hz removal ON (notch+LowPass 25 Hz)" gives better results (than "50 Hz removal ON") since it is used a filter more stable and with a higher attenuation of the interference frequency; however it has also a low pass behavior that may be unwanted (the upper frequency of the band could be too low)

- ✓ "60 Hz removal ON (notch+LowPass 25 Hz)" gives better results (than "60 Hz removal ON") since it is used a filter more stable and with a higher attenuation of the interference frequency; however it has also a low pass behavior that may be unwanted (the upper frequency of the band could be too low)

SPECIFICATIONS

Hardware Specifications

- Max Input signal amplitude (peak-to-peak): 3.6 mV [4]
- Voltage supply: USE ONLY BATTERIES (both rechargeable and not rechargeable)
- Min Voltage supply: 6V (e.g. 4 x 1.5V batteries) [5]
- Max Voltage supply: 9V (e.g. 6 x 1.5V or 1 x 9V batteries)
- Sampling frequency: 600 Hz
- Frequency Bandwidth @ - 3dB (Hardware): 0.1 Hz - 40 Hz [6]

---

[4] Max Input signal amplitude depends on the hardware gain according to the formula:
" 3618 mV / Hardware_Gain " ; for Hardware_Gain of 1005, the value is 3.6 mV.

[5] Input voltage limit of Arduino Board is 6V while recommended input voltage is at least 7V; however the ECG device seems to work with no problem with a voltage supply of 6V.

[6] For a simple monitoring ECG device, frequency bandwidth can be 0.1 - 40 Hz in order to have better (lower noise) ECG signal; the cut off frequency values can be changed according to the formula:

$$f = 1/(2*\pi*C*R)$$

For low pass filters @ 40 Hz , RC components values are:

R8 = 120 kΩ
C8 = 33 nF
R9 = 39 kΩ
C9 = 100 nF

The upper band limit of the low pass filter can be increased by changing R8 or C8 and R9 or C9. For a Frequency Bandwidth @ - 3dB (Hardware) = 0.1 Hz - 150 Hz , RC filter components must be changed according to the following values:

R8 = 47000 Ω
C8 = 22 nF
R9 = 47000 Ω
C9 = 22 nF

In this case, ECG SmartApp version for bandwidth at 150 Hz should be used since further digital low pass filters (at 100 Hz and 150 Hz) are available (this is the only difference between the App software versions at bandwidth 40 Hz and bandwidth 150 Hz).

- CMRR: min 1209 dB [7]
- Amplification (Hardware_Gain): 1005 [8]
- Resolution: 5V / (1024 x Hardware_Gain)
- Bias Current max 10 nA [9]
- Number of ECG channels: 1
- ECG Leads: limb leads LI, LII and LIII
- Number of electrodes: 2 or 3 [10]
- Smartphone connection : via Bluetooth
- Theoretical Supply Current: < 50 mA [11]
- Measured Supply Current : < 60 mA [12]

If a fault occurs inside the device and the low voltage dc power (9 V) comes directly to the patient leads accidentally, protection resistors (R3, R4, R13) limit the current flowing into the patient at a theoretical value lower than 50 µA [13]

---

[7] From INA128 datasheet

[8] Hardware_Gain can be changed by replacing Rp with another resistor (or a potentiometer) according to the formula:

0.797*(1+(50000/R5))*(1+(R8/(Rp+R6)))

If R5 = 2200 Ω , R8=120000 Ω, R6=100 Ω, Rp=2200 Ω then Hardware_Gain = 1005.
In case of the ECG SmartApp version for bandwidth at 150 Hz, R5 = 2200 Ω , R8=47000 Ω, R6=220 Ω, Rp=680 Ω and then Hardware_Gain is 1006.

[9] From INA128 datasheet

[10] The device allows to record the ECG (LI, LII or LIII) also by using only 2 electrodes; the reference electrode (black) is optional and can be excluded by removing the jumper J1 (or the switch S2, see Assembly Manual file). However, the reference electrode should be used to have a better signal quality (lower noise).

[11] Based on the datasheet info of the different components (Arduino Nano, HC-06 Module, INA128, TL062) and the current flowing into the Led (supposing a 9V voltage supply).

[12] With a 9V voltage supply and Arduino Nano (with other board such as Arduino UNO or Micro the consumption can be higher).

[13] The value is calculated under the hypothesis of a patient directly connected to the ground (-Vcc) and the maximum voltage (9V) applied before the resistor equivalent to the parallel of all the three protection resistor (560 kΩ) : 9V / (560kΩ / 3).

Software Specifications

- ECG visualization during the recording (time window: 3 seconds)
- Heart Rate estimation (only for LI)
- Sampling frequency: 600 Hz
- ECG signal recording and saving into a txt file (filtered or unfiltered signals can be saved in the txt file according to the setting) on the smartphone internal memory (folder: "ECG_Files" placed in the main root)
- Data (samples) are saved as values in mV at 600 Hz (value of 16 digits)
- Saved file visualization with zoom option, grid, gain adjusting (from "x 0.5" to "x 5") and two points selection (to measure time distance and amplitude difference)
- Smartphone display: the App layout adjusts for different display size; however for a better visualization, it is recommended minimum a 3.7'' display with a resolution of 480 x 800 pixels

Digital filtering:

- High pass filtering @ 0.1 , 0.15 , 0.25 , 0.5, 1 Hz [14]
- Low pass filtering @ 25, 35, 40 Hz [15] (@ 100 and 150 Hz are available in the ECG SmartApp version for bandwidth at 150 Hz)
- Notch filtering to remove the powerline interference @ 50 or 60 Hz [16]
- Wandering baseline removal [17]

---

[14] Apply a IIR high pass filter according to the specified cut off frequency (Direct Form II Second-Order-Section; Order: 4; Sections: 2; Design Method: Butterworth; cut off frequency attenuation: - 3dB)

[15] Apply a IIR low pass filter according to the specified cut off frequency (Direct Form II Second-Order-Section; Order: 4; Sections: 2; Design Method: Butterworth; cut off frequency attenuation: - 3dB)

[16] "50 Hz removal ON (notch+LowPass 25 Hz)" apply a moving average filter (FIR Low Pass; order: 12th) that has a zero at 50 Hz (attenuation: < -70 dB) and a cut of frequency at 23 Hz (attenuation: - 3dB); "60 Hz removal ON (notch+LowPass 25 Hz): apply a moving average filter (FIR Low Pass; order: 10th) that has a zero at 60 Hz (attenuation: < -70 dB) and a cut of frequency at 27 Hz (attenuation: - 3dB)" ; "50 Hz removal ON: apply a recursive notch filter at 50 Hz (IIR filter; order: 2nd)" ; "60 Hz removal ON: apply a recursive notch filter at 60 Hz (IIR filter; order: 2nd)"

[17] A digital signal processing is applied to detect the series of Q points of the ECG waves; a linear interpolation is made between two consecutive Q points to have an estimation of the wandering baseline that is subtracted from the ECG signal (before any high pass filtering action).