



Curso Académico:

Resumen

El presente trabajo aborda el diseño, cálculo e implementación de un electrocardiograma para aplicaciones médicas. El desarrollo de este TFG comienza con una introducción teórica de los pasos que harán falta debido a las características de la señal. Se continuará con el diseño teórico de las distintas etapas y más tarde se introducirá en Orcad Capture y en Orcad Layout.

Una vez finalizado todo el diseño, se fabricará la placa base, se taladraran los agujeros y se soldará los componentes. Durante el proceso, se irá comprobando que todas las etapas funcionan hasta tener todo el circuito operativo. Para finalizar, se realizaran las últimas pruebas de funcionamiento y se comprobaran partes de la normativa.

Palabras clave: Orcad, señales bioeléctricas, placa base, electrocardiograma.

Abstract

This project addresses the design, calculation and implementation of an electrocardiograph for medical applications. The development of this TFG begins with a theoretical introduction of the stages that will be required due to the characteristics of the signal. To continue with, the theoretical design of the different stages will be done and later all of this will be introduced into Orcad Capture and Orcad Layout.

Once the design has been completed, the baseplate is manufactured, holes are drilled and the components are welded. During this process, the different stages will be tested to check they work as they should until the whole circuit is working. Finally, the last few tests to check the circuit fulfills certain parts of the appropriate legislation are done.

Key words: Orcad, bioelectric signals, baseplate, electrocardiogram.

Resum

El present treball aborda el disseny, càlcul i implementació d'un electrocardiograma per a aplicacions mèdiques. El desenvolupament d'aquest TFG comença amb una introducció teòrica dels passos que caldran causa de les característiques del senyal. Es continuarà amb el disseny teòric de les diferents etapes i més tard s'introduirà en Orcad Capture i en Orcad Layout.

Finalitzat tot el disseny, es fabricarà la placa base, es taladraran els forats i es soldarà els components. Durant el procés, s'anirà comprovant que totes les etapes funcionen fins a tenir tot el circuit operatiu. Per finalitzar, es realitzaran les últimes proves de funcionament i es comprovaran parts de la normativa.

Paraules clau: Orcad, senyals bioel·lèctriques, placa base, electrocardiograma.

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2 Introduction

Since the first electrocardiogram was registered in 1903 it became essential for doctors as a way of diagnosis and analysis. Its use is widespread as it is a non-invasive method for measuring the hearts electrical activity. Due to this, this project will focus in designing, manufacturing and testing a circuit capable of measuring these potentials for medical applications, and its specifications will be the ones shown in Table 2-1. The reasons for these specifications are explained in this document.

Gain	High-pass filter cut-off frequency (Hz)	Low-pass filter cut-off frequency (Hz)	Band-stop filter stopband frequency (Hz)
1000	0.05	250	50

Table 2-1

3 Objectives

The main objective is to design and develop a working and safe electrocardiograph, but to do this, many secondary objectives had to be accomplished first. These secondary objectives where the steps taken to move from barely knowing anything about the functioning of an electrocardiograph to being able to design, manufacture and test one.

The first thing that had to be done was to understand how an electrocardiogram works and all the things it needed regarding the good functioning of itself and the security of the patient. This meant understanding the reason why they had to be included and the functioning of all the different filters, the third electrode and other things that will be analysed more deeply later.

Once the previous step had been accomplished, the next one was to draw the schematic of the circuit. To do this the specifications sheets of all the components that were going to be used had to be searched for and from them all the information relevant to the task. For example the pin diagrams of each component were needed so as to draw a reliable schematic that could be used for further steps. Lastly, all the calculations needed to know which values of capacitors and resistances were needed were done.

To continue with the design, two completely new programs for the designer had to be used, Orcad Capture to draw the schematic on the computer and then pass it to Orcad Layout to design the baseplate. Although this could seem quite simple the process of

learning how to use these programs, completing the task and correcting all the mistakes that were found involved much more time than any of the steps that had been done before.

Once all the previous stages had been completed the manufacturing of the baseplate started. To start with, the procedure that will be described later on in more detail had to be followed to have all the copper tracks on the baseplate. Once this had been done the holes were the pins of the components would be inserted had to be drilled and lastly the components were soldered and the circuit was tested stage by stage, so if any error was found it wasn't so difficult to track down where it was.

When all of the circuit was working the final tests were done. This stage consisted of 5 tests that the circuit had to accomplish, them being frequency response, common mode rejection ratio, noise, techniques to minimise noise and finally testing it on a person. The procedure followed and the results will be described and shown later on in this document, along with the appropriate legislation.

Once all the steps described previously had been completed the next thing to do was to search on the internet for the prices of all the components that had been used. To appreciate the difference between manufacturing one baseplate to manufacturing many two budgets were produced, one where the components were bought separately and another where they were bought in packs of a hundred.

With this being done, the project had been designed, manufactured and tested, while keeping in mind the legislation that had to be fulfilled. The electrocardiograph was finally finished.

4 ECG

This project focuses on the measurement of the potentials generated by the heart; this is the electrocardiogram, hereinafter referred to as ECG. To measure an ECG, electrodes have to be placed on the body of the patient and the signal measured will depend on the location of these electrodes.

Einthoven studied this relationship between the location of the electrodes and the signal measured and came up with Einthoven's triangle. This is an equilateral triangle with the heart in the centre of it. This triangle gave place to the standard leads I, II and III, shown in Figure 4-1.

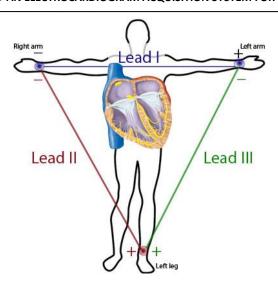


Figure 4-1. Standard leads. Source: http://www.medicine.mcgill.ca/physio/vlab/cardio/setup.htm

As it can be observed from the previous figure, lead I goes from right arm to left arm, lead II from right arm to left leg and lead III goes from left arm to left leg.

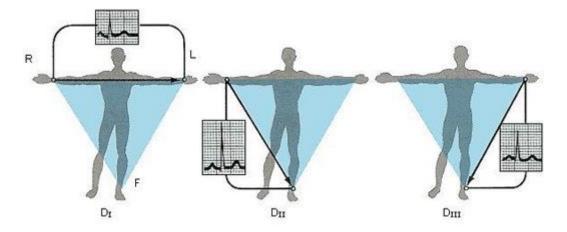


Figure 4-2. Waveforms for different leads. Source: http://www.electrocardiografia.es/derivaciones.html

In Figure 4-2 the different waveforms of the ECG depending on the lead can be seen. Later on, when testing the circuit on a real person, leads I and II will be measured and this difference in the waveform will be seen.

With all of this being said, the way of measuring an ECG, how locating the electrodes in different places affect the signal and the typical leads used have been described. This is the base needed to understand measurements that happen further on on this document and the characteristics of the signal measured can be now described.

5 Signal characteristics

It is vital to know the characteristics of the signal that is going to be measured as they will dictate the specifications that the circuit will have to fulfil in order to have a clear and filtered signal at the output of the circuit.

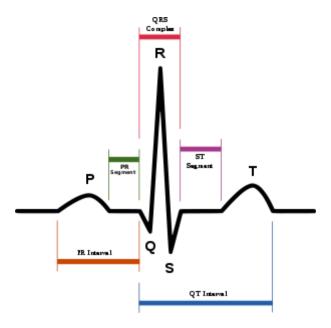


Figure 5-1. Complete cycle of a normal ECG corresponding to the first lead. Source: http://friamedicina.blogspot.com.es/2011/11/pruebas-diagnosticas-descifrando-el.html

Figure 5-1 shows the typical ECG waveform for a first lead reading. From this signal, the two most important things that have to be taken into consideration to know what specifications the circuit has to fulfil are the amplitude and the frequency.

The amplitude of the signal depends on the lead used, but this amplitude will be between 1 and 5 mV. These amplitudes are very small and they are difficult to read, so the circuit is designed to amplify the signal, making it have a gain of 1000. In UNE-EN 60601-2-47 clause 51.5.1 it is stated that the system must be able to visualize and bear with voltages of 6mV peak-to-valley.

The system designed in this project, having a gain of 1000, will have at the output a voltage of 6V which is less than the supply voltage of $\pm 9V$, meaning that the circuit will follow the legislation and show the signal wanted at the end of it.

The next factor that has to be analysed are the typical frequencies an ECG has, as this will be needed in order to design the filters of the system. To do this, the frequency spectrum of an ECG must be analysed. A standard spectrum of an ECG is shown in Figure 5-2.

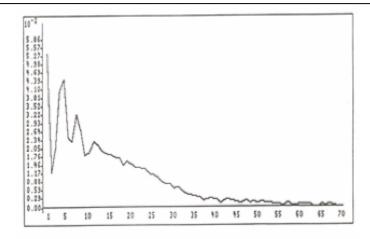


Figure 5-2. Frequency spectrum of a normal ECG, lead I. Frequencies in Hz.

From this frequency spectrum it can be observed that the fundamental frequency is around 1Hz. Also, it can be seen that as the frequency increases, the harmonics decrease until they are almost negligible beyond 60Hz. However, as the application of this circuit is for medical purposes, the cut-off frequency of the low-pass filter will be set at 250Hz. This is because some pathologies can be identified by a high frequency component in the signal read.

6 Design and development

6.1 Theoretical fundamentals

6.1.1 Design specifications and requirements

There are many design specifications that had to be accomplished so that the circuit worked as it had to, and these can be divided into two groups. The first group are the specifications that will ensure that the circuit accomplishes its requirements, them being to show an amplified and filtered signal. The second group contains the specifications that had to be met to make sure the patient was safe when using this equipment.

The first specifications that are going to be analysed are the ones regarding the correct functioning of the circuit, as although both groups are important this project concentrated more on this first group.

The first specification that had to be met was dealing with the direct voltage found at the entrance of the circuit due to when a metal is put in contact with a nonmetallic conductor, as a potential difference appears. This is exactly what happens when an electrode is put in contact with the patients' skin, this situation can be seen in Figure 6-1. If the electrodes are exactly the same this difference is 0, but in reality this is impossible to get due to impurities and other factors. Legislation is very clear about this and the equipment has to be able to bear with a direct voltage input of up to 300mV.



Figure 6-1. Electrode-skin.

$$E1 - E2 = Ep$$
$$Ep \le 300mV$$

This direct voltage has to be removed as it can saturate the amplifiers and to do so the signal will be attenuated at 0.05Hz.

The second specification is a source of interference and it is going to be analysed how this affects the design of the circuit. Regarding two typical situations, shown in Table 6-1, that can take place when taking measures of a patient.

Cr	Ст	Situation
0.2pF	520pF	Patient lying down in the bed. Bed with TT.
200pF	3300pF	Patient lying down in the bed, touching the bed. Bed without TT.

Table 6-1. Typical situations.

lf:

$$Vc - pp = Vmains * \frac{C_R}{C_T + C_R}$$
 (6.1)

With $Vmains = 2 * \sqrt{2} * 220$. Then for the first situation Vc - pp = 0.24V and for the second one Vc - pp = 35.5V .

Having these previous calculations done its time to analyse the interference that the circuit would have with a regular differential amplifier and with a good differential amplifier. With the regular one the circuit would have CMRR = $80 dB \ (*10^4)$ and with the good one CMRR = $120 dB \ (*10^6)$.

If:

$$Vinterference = \frac{Vc}{CMRR}$$
 (6.2)

and this equation is used with both amplifiers and both situations:

Regular amplifier, situation 1=24µV

Regular amplifier, situation 2=3.5mV

Good amplifier, situation 1=0.24µV

Good amplifier, situation 2=35µV

The criterion followed to know if the interference is acceptable or not is:

$$\frac{Level\ of\ noise(10\mu V)}{interference} \le 1\%\ signal \tag{6.3}$$

With the level of noise= $10\mu V$, the interference being the values calculated previously and knowing the signal will be approximately of 1mV it can be seen that the interference isn't acceptable. To reach a reasonable level of interference Vc has to be made equal to 0 and this can be done by connecting the patient to ground. To do this, another electrode is used; this electrode will have a certain impedance different from 0 as electrodes are not ideal. This impedance is called the impedance of the third electrode.

Although this third electrode has the major advantage that it makes Vc almost 0 it also has a big disadvantage regarding the safety of the patient. If the patient gets in contact with the mains supply the current would go through this third electrode as it has the lowest impedance and this would be very dangerous for the patient, this is shown in Figure 6-2.

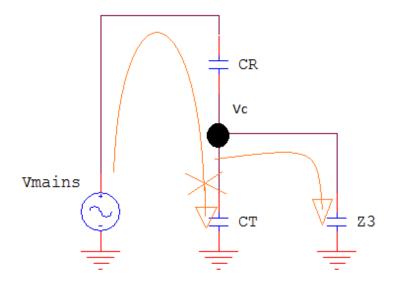


Figure 6-2. Problem of the third electrode.

From all of this it can be seen that the circuit will need this third electrode in order to have an acceptable level of interference.

The next specification takes into consideration the fact that the signal read from the patient is going to be very small (of the order of millivolts). Clearly this signal will have to be amplified so as not to lose the information due to noise or interference. The method used to accomplish this gain of 1000 needed will be described later on.

The circuit will need to have available an extra stage that the doctor may activate or not to reject the signal at 50Hz. This is required so as not to see the mains supply when reading the signal. This is effective because the frequency of the power supply is 50Hz and by doing this if it interferes with the signal this interference is attenuated.

There are various causes of internal interference that could contaminate the signal wanted to be measured making it useless so one of the most important things to do is to minimize the impact of these sources of interference. For example, the power source may have ripples, causing interference, and these have to be attenuated before supplying the components. Also, the components used in the circuit introduce noise to the signal read and to filter it the signal must be attenuated at 250Hz.

Due to the application of this equipment, the circuit may be subject to situations that normally it wouldn't. One of the most important is if when having the electrodes connected to a patient, a defibrillator is used. The circuit must be protected in such

circumstances against the high voltage that may occur and the method used involving diodes will be explained later on.

As the common mode is responsible for most of the interference it is vital to reduce it. This is done by increasing the common-mode-rejection ratio, hereinafter CMRR. One way of doing this is by choosing an appropriate amplifier, but there are other ways of increasing the CMRR. One of this ways consists in getting the common mode, amplifying and inverting it and feeding it back to the patient in order to cancel it.

Lastly, regarding the safety of the patient, it is necessary to have a way to stop unwanted currents to flow through the body of the patient. An electrical separation between the circuit and the patient will be needed, and this will be accomplished by introducing an isolated power supply.

In conclusion, the specifications needed are:

- Gain of 1000
- Filter to cut-off the frequency at 0.05Hz
- Filter to cut-off the frequency at 250Hz
- Attenuate the signal at 50Hz
- Isolated power supply
- Protection against high voltages due to a defibrillator
- Third electrode
- Dealing with the direct voltage present at the entrance
- Limit the impact of noise and interference

6.1.2 Accomplishing specifications

So that the circuit fulfils the specification that it has to bear with a direct voltage input of 300mV the gain of the first amplifier was designed taking into account this 0.3V. This will be shown after in the calculations done to get the values of the resistances at the entrance of the amplifier.

Later on this direct voltage has to be eliminated from the circuit so as to not saturate the rest of the circuit. To do so a high-pass filter with a cut-off frequency of 0.05Hz is included.

To amplify the signal two amplifiers have been put. The first one has been located as near as possible to the entry of the circuit so as to amplify it before the signal gets too contaminated with noise. In this amplifier there is still the direct voltage component of

the signal so it is necessary to consider the fact that the amplifier can saturate and this is taken into account later on when the gain of this amplifier is calculated. The value calculated will be reduced so that there is no risk of saturation or entering the nonlinear functioning of the amplifier.

The second stage of amplifying the signal is put just before the last filter and as here the direct voltage has been filtered already, the signal can amplified by a much larger amount. To know for how much it needs to amplify the gain of the previous amplifier is taken into consideration and knowing that both these gains multiplied have to be approximately 1000 the gain of this second amplifier can be calculated.

To reduce the impact of noise on the final signal the problems mentioned earlier had to be solved. To start with, the power source may have ripples and to stop this capacitors have been included in all the places were the power source supplies a component. Also, to filter the noise a low-pass filter with a cut-off frequency of 250Hz is put at the end of the circuit.

One of the phases that had to be added is the rejection of the signals at 50Hz, to reduce the interference of the mains supply. This is done by adding an extra filter that will reject this frequency and a switch so that the doctor includes this filter or not.

If a defibrillator is used on the patient connected to the circuit, the circuit could get damaged, as it was mentioned before. To solve this a set of diodes have been included and they will act as the protection of the circuit, burning up first if something like this happens and not letting it burn the rest of the circuit. These diodes will need some protection too as if not they could burn under other circumstances that aren't as critical, leaving the circuit unprotected and having to replace them very often. To protect them, resistances have been placed near the entrance of the circuit and before the diodes so as to limit the current going through them.

As it has been mentioned earlier, one way of increasing the CMRR is by feeding an amplified and inverted version of the common mode into the patient in order to cancel this common mode. This is done by a well-known method called driven-right-leg system that will be described in more depth later. This system also brings a further advantage regarding electrical safety as if a high voltage appears between the patient and ground the operational amplifier will saturate and unground the patient. Another method used to increase the CMRR is by choosing an AMPO2 operational amplifier, as it has a high CMRR. Another system used to increase CMRR is the common mode shield driver. The main source of interference is the mains supply, which introduces an interference signal of

50Hz. This is due to capacitive interferences between the different elements of the system (patient, cables, amplifier) and the mains supply. The way to minimize this is to reduce the currents flowing between them and to do this the common mode shield driver is introduced. By doing this, the currents that occur because of the mains supply get dissipated to the ground via the common mode shield driver, this way they don't interfere with the cables.

Lastly, to protect the patient from unwanted currents that are dangerous for their health an isolated system is used. This consists in an isolated power supply that will be created by various components that will be described further on.

6.2 Block diagram

From the previous part the specifications the design has to meet and how they are going to be met are known. The next step is to draw a block diagram to see in which order each part of the circuit is going to be put. This has to be done before starting the calculations and searching for the datasheets of all the components as first the type of filters and the order in which everything is going to be put has to be known.

Taking everything said earlier the block diagram can be started. This diagram will later be used as the base when drawing the schematic where the actual shape and pin location of the components will be included.

The start of the circuit will be the three electrodes connected to the patient, two of them being the normal ones from which the signal will be read and the last one being the third electrode. From these three electrodes the design will head to the four diodes and the two resistances that limit the current through the diodes that protect the circuit from burning up if the patient is defibrillated. To continue with the first amplifier will be placed as it's known that the first amplifier has to be the closest as possible to the entrance to minimise the effect of noise on the signal read, as it is very small and a minimal amount of noise may distortion it enough that no matter what is done after no useful information will be got from it.

To continue with, the DC/DC convertor, the ISO and the MAX are placed. These three components function is to have the two isolated grounds needed to protect the patient, the positive and negative power supply and the two isolated power supplies that are needed to supply each side of the circuit. The ISO will provide the two isolated grounds, the MAX the positive and negative voltages and the PWR will provide the two isolated power supplies needed for the two sides of the circuit.

Now that the entrance of the circuit and all the power supplies and grounds are sorted out the next step is to organise the filters and the other amplifier that will lead to the exit of the circuit with the clean and amplified signal.

Knowing that the direct voltage in the signal has to be eliminated as fast as possible it is decided to locate the high-pass filter just after the ISO to do so. The next step is to introduce the 50Hz rejection filter together with the switch needed so this stage can be turned on or off according to the need of it.

The last two things that need to be placed are the second amplifier and the low-pass filter. It is decided to put first the amplifier and then the filter because the filter is used to eliminate the noise in the signal and this way it is amplified and then cleaned, while the other way round the signal would be filtered and then amplified but as the amplifier also introduces noise there would still be noise at the exit of the circuit, making the low-pass filter useless.

Now that it has been decided how the circuit is going to be step by step it's time to draw the block diagram that will later be used as a reference to draw the schematic in Orcad. This block diagram is shown in Figure 6-3.

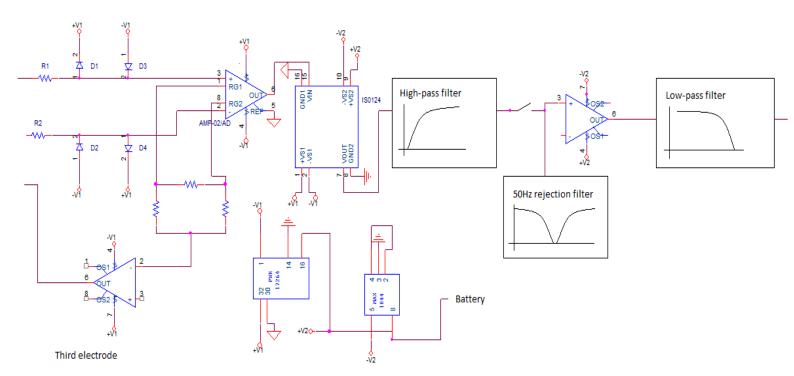


Figure 6-3. Block diagram.

6.3 Theoretical design

6.3.1 Entrance

As there are four diodes at the beginning of the circuit they will have to be protected with two resistances, one on each of the cables coming from the first two electrodes as shown in Figure 6-4. The diodes specifications are 0.5W and INDiode =20mA and therefore only the voltage remains to be determined. As the job of these diodes is to sacrifice themselves to protect the rest of the circuit in case a high voltage appears due to a defibrillator, the voltage has to be determined studying this same defibrillator. A defibrillator generally develops 150 Joules of power, and from this it can be assumed that around 200V get to the circuit. Therefore:

$$R = \frac{V}{I} = \frac{200}{0.02} = 10k\Omega \tag{6.4}$$

Component	Value	Quantity
Resistance	10kΩ	2
Diode	-	4
Terminal block, 3 plug-ins	-	1

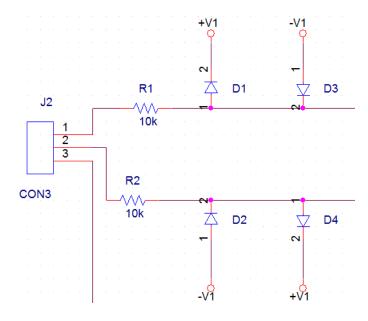


Figure 6-4. Entrance of the circuit.

6.3.2 Amplifiers

The first amplifier has a limit to how much it can amplify by the power supply of 9V and by taking into consideration the appropriate legislation; UNE-EN 60601-2-47:2001, clause 51.5.1, the entrance is set to a maximum of 300mV. With this the gain of the first amplifier can then be calculated:

$$G_1 = \frac{9}{0.3} = 30 \tag{6.5}$$

It is decided to leave the amplifier with a gain of 25 as it is not advisable to have it working nonlinearly.

The second amplifier doesn't have a limit as this first one as the direct voltage has been filtered of the signal so it's possible to amplify until the total gain of 1000 needed:

$$G_T = G_1 G_2 \; ; \quad G_2 = \frac{1000}{25} = 40$$
 (6.6)

With the gains of these two amplifiers the total gain of 1000 needed is achieved while respecting the specifications mentioned earlier.

Now the values of the resistances needed to achieve these gains have to be calculated.

For the first amplifier:

$$G_1 = \frac{50k\Omega}{R_G} + 1 = 25 \; ; \; R_G = 2083\Omega$$
 (6.7)

$$\frac{1}{R_G} = \frac{1}{R_1} + \frac{1}{R_2 + R_3} \tag{6.8}$$

$$R_2 = R_3 \tag{6.9}$$

$$\frac{1}{2}R_1 = R_2 = R_3 \tag{6.10}$$

Using equations 6.8, 6.9, 6.10 and operating:

$$\frac{1}{R_G} = \frac{1}{\frac{1}{2}R_1 + \frac{1}{2}R_1} + \frac{1}{R_1} \tag{6.11}$$

Then from 6.11 $R_1=4166\Omega$ and $R_2=R_3=2083\Omega$.

Normalizing these values: $R_1=3.9k\Omega$; $R_2=R_3=2k\Omega$. All of these results are shown in Figure 6-5.

With the normalised values of these resistances the final value of the gain:

$$\frac{1}{R_G} = \frac{1}{R_1} + \frac{1}{R_2 + R_3} = \frac{1}{3900} + \frac{1}{2000 + 2000} = \frac{79}{156000}$$
 (6.12)

From equation 6.12:

$$R_G = 1974.7\Omega$$

Calculating the new gain with equation 6.7:

$$G_1 = \frac{50k\Omega}{R_G} + 1 = \frac{50k\Omega}{1974.7} + 1 = 26.32$$

In conclusion the components needed for this first amplifier are:

Component	Value	Quantity
Resistance	3.9kΩ	1
Resistance	2kΩ	2
OP-27	-	1
Capacitor	10μF	2
Capacitor	10nF	2

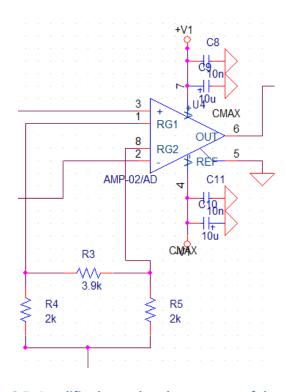


Figure 6-5. Amplifier located at the entrance of the circuit.

For the second amplifier, shown in Figure 6-6:

$$40 = G_2 = 1 + \frac{R_2}{R_1} \tag{6.13}$$

Setting $R_2=20k\Omega$, then $R_1=500\Omega$.

Normalizing these values $~R_1=470\Omega$; $~R_2=20k\Omega$.

With the normalised values of the resistances the new gain will be:

$$G_2 = 1 + \frac{R_2}{R_1} = 1 + \frac{20\ 000}{470} = 43.55$$

Therefore, the total gain of the circuit will be:

$$G_T = G_1 G_2 = 43.55 * 26.32 = 1146$$

In conclusion, the components needed for the second amplifier are:

Component	Value	Quantity
Resistance	470Ω	1
Resistance	20kΩ	1
OP-27	-	1
Capacitor	10μF	2
Capacitor	10nF	2

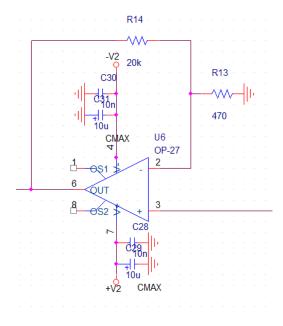


Figure 6-6. Second amplifier.

6.3.3 Third electrode

The amplifier next to the third electrode, which is the driven right leg system mentioned earlier, has a gain of -10 (the negative is put because this filter inverts the signal) so the value of the resistances needed to achieve this can be calculated:

$$G = -10 = -\frac{R_2}{R_1} \tag{6.14}$$

If the value of one of the resistances is set; $R_1=1k\Omega$ then $R_2=10k\Omega$ and these are the normalized values already. These values are shown in Figure 6-7.

In conclusion, the components needed for the driven right leg system are:

Component	Value	Quantity
Resistance	10kΩ	1
Resistance	1kΩ	1
OP-27	-	1
Capacitor	10μF	2
Capacitor	10nF	2

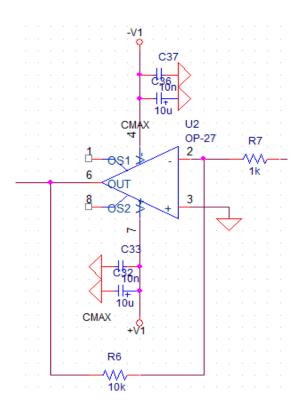


Figure 6-7. Driven right leg.

This part is the one in charge of amplifying, inverting and then feeding back to the patient the common mode signal so as to reduce the common mode effect.

In Figure 6-8 the way that the common mode shield driver was implemented can be seen. This stage is the link between the driven right leg and the instrumental amplifier. This stage has a unitary gain and at its output the common mode signal can be read.

The driven right leg and the common mode shield driver both reduce the interference due to the common mode and also provide an alternative path for the polarization currents, helping the system to stabilize.

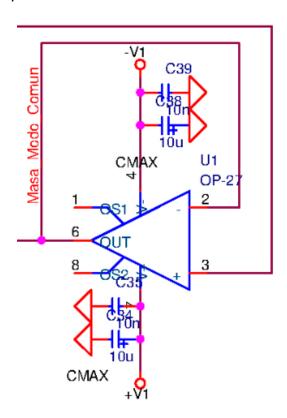


Figure 6-8. Common mode shield driver.

In Figure 6-9 it can be seen how the shielding of this common mode shield driver was accomplished, the two isolated grounds can be seen and the common mode shielding too (indicated this last part in the figure).

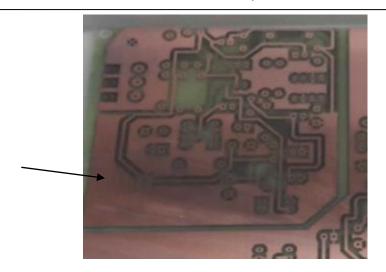


Figure 6-9. Common mode shield driver shown in the baseplate.

6.3.4 Isolated grounds

It is now needed to introduce the two isolated grounds with their respective isolated power supplies that are needed to protect the patient, together with a physical separation between both grounds. To do this the components ISO124 (Figure 6-10), the PWR17264 and the MAXIM1044 (Figure 6-11) are used. The physical separation was made of about 2-3mm so as to ensure the isolation.

Figure 6-11 shows the entrance (J3) of the battery that will give the +9V needed. This entrance is connected to the MAXIM1044, the component that gets a positive input supply voltage in its pin number 8 and then produces a negative output voltage in its pin number 5. In this stage the -/+9V needed to continue with the other stages is achieved. In the same figure it can be seen how this -/+9V are connected to the PWR. The objective of this component is to provide the circuit with the two isolated power supplies that will be used on the two isolated grounds. This can be seen as the PWR is supplied by the MAX with -9V in its pin number 14 and with +9V in its pin number 16 and at the exit (pins 1 and 32) there is the isolated power supply. In this same figure two polarized capacitors can be seen. These capacitors are used to attenuate any ripples that could come from the power supply.

Lastly, in Figure 6-10 the schematic of the ISO124 is shown. This component provides the circuit with the two isolated grounds needed as its pin number 16 gives the first ground and the pin number 8 gives the second isolated ground. This component has a gain of one so that the signal is not amplified when it passes through it. If the datasheet of this component is studied it can be seen that it has a maximum leakage current of $0.5\mu F$ and a barrier impedance of $10^{14}\Omega$ (all at 60Hz), which is enough to keep the patient safe. By

looking at the datasheet of the PWR it can be seen that this component has a maximum leakage current of $2\mu A$ and a high isolation voltage of 3500 V rms.

Once it's clear what is needed and why, by searching their datasheet the structure of each of these components is found and they can be connected as the next figures show.

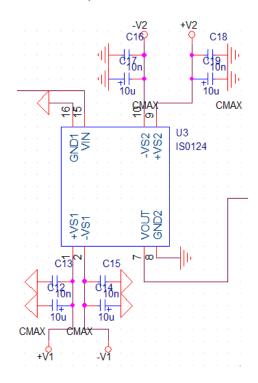


Figure 6-10. ISO124.

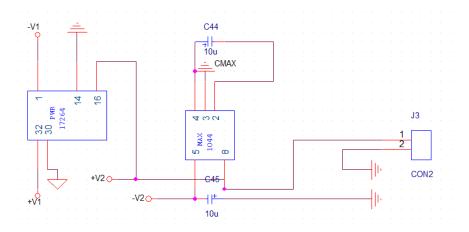


Figure 6-11. PWR17264 and MAX1044 and entrance of the battery.

Component	Value	Quantity
ISO124	-	1
PWR17264	-	1
MAX1044	-	1
Capacitor	10μF	6
Capacitor	10nF	4
Terminal block, 2 plug-ins	-	1

6.3.5 High-pass filter

The high-pass filter is the one in charge of attenuating the signal at 0.05Hz and eliminating the continuous part of the signal. It is very important that this is taken into consideration not only because it's needed for the correct functioning of the circuit but also because it's a requirement of the appropriate legislation, UNE-EN 60601-2-47:2001, clause 51.5.9.

The curve a high-pass filter looks like Figure 6-12, where $G(j\omega)$ is the transfer function of the filter and $\omega c = 2 * \pi * fc$, where fc is the cut-off frequency, in this case 0.05Hz.

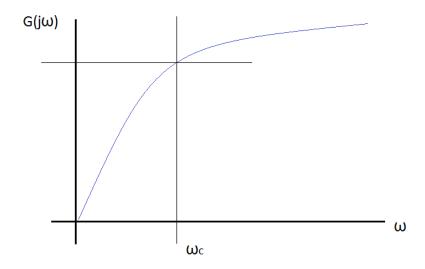


Figure 6-12. Curve high-pass filter.

For Figure 6-13, the transfer function would be:

$$G(p) = -\frac{p^2}{p^2 + K_1 p + K_2 p^2} \quad ; \quad p = j\omega$$
 (6.15)

Where
$$K_1 = \frac{1}{C} \frac{R_{1+}R_2}{R_1R_2}$$
 and $K_2 = \frac{1}{R_1R_2C^2}$

Proceeding as before with the structure of the transfer function of a second order filter it can be concluded that:

$$\omega = \frac{1}{RC} = 2\pi f$$

This way it is easy to now continue and calculate the values of the resistances and capacitors needed for this filter.

$$f_c = \frac{1}{2\pi RC} = 0.05Hz \tag{6.16}$$

The capacitors needed for this have to have a very low capacitance or the resistances will be too big for them to be available. Therefore the first step to start calculating is to set the value of the capacitors at $4.7\mu F$, which are accessible in the laboratory. With this the only unknown is the value of the resistance which can be easily got from the equation above. With this, $R=677~k\Omega$ and normalising this value $=680k\Omega$. Figure 6-13 shows the result of all these previous calculations.

In conclusion, the components needed for the high-pass are:

Component	Value	Quantity
Resistance	680kΩ	2
Capacitor	4.7μF	2
OP-27	-	1
Capacitor	10μF	2
Capacitor	10nF	2

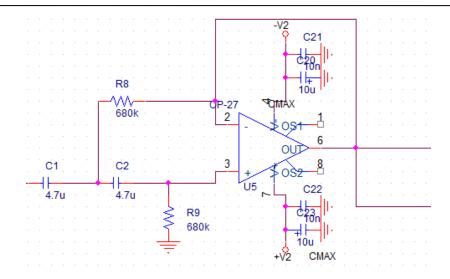


Figure 6-13. High-pass filter.

6.3.6 Low-pass filter

The low-pass filter is needed to filter the signal with a cut-off frequency of 250Hz, so the values of the resistances and capacitors must be calculated according to this.

The curve a low-pass filter follows looks like Figure 6-14, where $G(j\omega)$ is the transfer function of the filter and $\omega c = 2 * \pi * fc$, where fc is the cut-off frequency, in this case 250Hz.

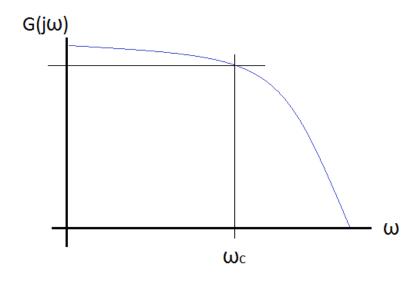


Figure 6-14. Curve low-pass filter.

For Figure 6-15, the transfer function would be:

$$G(p) = -\frac{1}{1 + K_1 p + K_2 p^2}$$
 ; $p = j\omega$ (6.17)

Where $K_1 = 3\alpha_2 R C_1$ and $K_2 = \alpha_1 \alpha_2 R^2 C_2^2$

If the general structure of a transfer function for a second order filter is:

$$G(p) = \frac{G_0}{\frac{p^2}{\omega_0^2} + 2 * \delta * \frac{p}{\omega_0} + 1}$$
 (6.18)

By comparing the part squared it can be concluded that

$$\omega = \frac{1}{\alpha RC} = 2\pi f$$

This way it is easy to now continue and calculate the values of the resistances and capacitors needed for this filter.

$$f_c = \frac{1}{2\pi R\alpha C} = 250Hz \tag{6.19}$$

This is one equation with two unknowns so it's decided to set the value of the resistance to $10 \mathrm{k}\Omega$. Being $\alpha_1=2.12$; $\alpha_2=0.47$ the value of the two capacitors needed can now be calculated: $\mathcal{C}_1=135~nF$; $\mathcal{C}_2=35~nF$. Normalising these values; $\mathcal{C}_1=100~nF$; $\mathcal{C}_2=27~nF$. This is shown in Figure 6-15.

In conclusion, the components needed for low-pass filter are:

Component	Value	Quantity
Resistance	10kΩ	3
Capacitor	100nF	1
Capacitor	27nF	1
OP-27	-	1
Capacitor	10μF	2
Capacitor	10nF	2

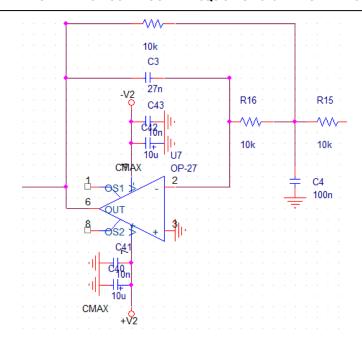


Figure 6-15. Low-pass filter.

6.3.7 50Hz rejection filter

This is the filter that the doctor can turn on or off depending if he needs it or not and its main mission is to protect the patient so it's very important it's designed correctly.

The curve a band-pass filter looks like Figure 6-16, where $G(j\omega)$ is the transfer function of the filter and $\omega c = 2 * \pi * fc$, where fc is the cut-off frequency, in this case 50Hz.

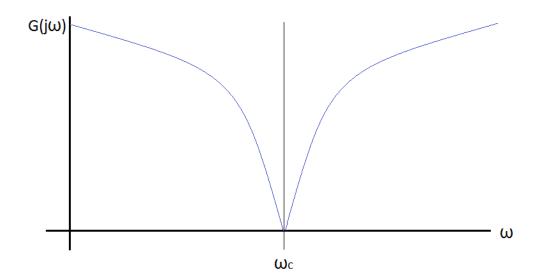


Figure 6-16. Curve 50Hz rejection filter.

For Figure 6-17 the transfer function is:

$$G(p) = \frac{1 + (\frac{p}{\omega_0})^2}{1 + 3\frac{p}{\omega_0} + (\frac{p}{\omega_0})^2} \quad ; \quad p = j\omega$$
 (6.20)

Where $\omega_0 = \frac{1}{RC}$. With this said, it is possible now to proceed with the calculation of the values of the resistances and capacitors needed.

Starting with:

$$f_c = \frac{1}{2\pi RC} = 50Hz \tag{6.21}$$

It is decided to set one of the values of the resistances to $R=82k\Omega$ and with this the value of one of the capacitors is C=39~nF (both normalised). So the value of the other resistances and capacitors ends up in C=82~nF; $R=39k\Omega$. With this done, Figure 6-17 is got.

In conclusion, the components needed for this filter are:

Component	Value	Quantity
Resistance	39kΩ	1
Resistance	82kΩ	2
Capacitor	39nF	2
Capacitor	82nF	1
OP-27	-	1
Capacitor	10μF	2
Capacitor	10nF	2

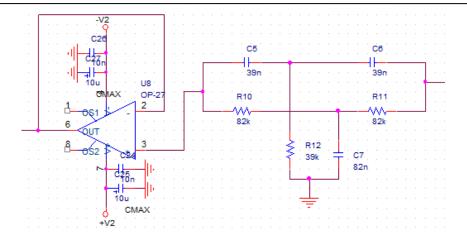


Figure 6-17. 50Hz rejection filter.

7 Circuit development

7.1 Design in Orcad

After designing all the stages of the circuit and calculating the value of all the resistances and capacitors that were going to be needed, the next step was to put all of this in Orcad, to have the schematic and then the design of the base plate to have all the copper tracks and pads for the components.

To start with Orcad Capture was used to draw the schematic of the circuit. Although this seemed simple to start with several problems were encountered as it was the first time this program was used by the designers. First all the components had to be searched for in the libraries of the program. Some of the components were very easy to find such as the resistances and the capacitors but soon it could be observed that some of the components weren't in the libraries.

The solution to place the components that weren't in the library was to create them on the same program. This had to be done with 3 components, the PWR1726 (Figure 7-1), the MAX1044 (Figure 7-2) and the switch (Figure 7-3).

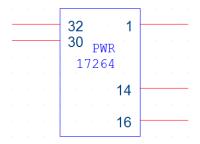


Figure 7-1. PWR17264

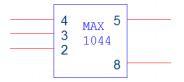


Figure 7-2. MAX1044.



Figure 7-3. Switch.

After creating these components, all the things needed to complete the shematic were available and the result can be seen in the document *Layouts*, in layout number 1.

With this done it was the moment to pass this schematic to Orcad Layout so the base plate could be designed. To do this the components that had been created in Orcad Capture had to be created in Orcad Layout too, as if not errors occurred and the component didn't appear in Layout. To create them as in Orcad Layout the components appear with their real shape and size the components had to be measured, together with the distances between the pinsand the location of these pins, and then introduce this in the program to create the component.

Having created the footpaths of these components it was time to edit all of the others as the pads that the program gives for default are very small as they are prepared for very specialized equipment that a real company whose service is manufacturing these circuits may have but that is not available in the laboratory. For this reason the pads had to be made larger as if not when drilling the holes all the copper of the pad would probably be removed.

With this previous step completed, all the components were finished and it was possible to continue with the task and start positioning them on the baseplate. Although the program has a tool that makes all the connections by itself in this case they hay to be done manually as the application of this baseplate is not the usual one. This is because the baseplate will be used on people so security has to be taken into account and to make sure all the specifications are met it has to be done manualy. This was quite difficult as the components had to be located so as the copper tracks were separated enough and wouldn't cross. Due to the large amount of connections, the quantity of components and the fact that it was the first time the designer used this progarm this step turned out to be the most time consuming.

The criteria followed to do the connections was to put the ones regarding the power supplies, the grounds and some of the ones going out from the plug-in sockets on top and the rest of connections between the components and the ones going out of the terminal blocks on the bottom. This was decided as it would be imposible to solder the connections of the terminal blocks and the plug-in sockets on the top due to their physical structure. Although this was the main criteria followed to place all the connections, when proceeding to do it due to lack of space and the obligation of leaving space between the connections it couldn't be followed always and some connections had to be done in the face where they theoretically shoudn't have been done.

With all of this said, all of the connections were finally done and they can be seen in layout number 2 in the document *Layouts*. In layout number 3 of this same document the arrangement of the components can be seen.

7.2 Manufacturing of the baseplate

Once the design in Orcad had been finished the template shown in Figure 7-4 was printed as it was going to be needed for the next stages of manufacturing the baseplate.

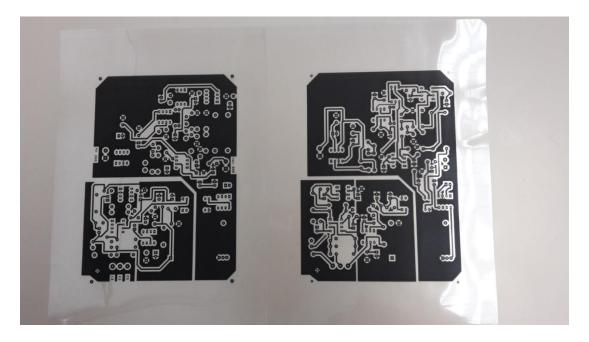


Figure 7-4. Printed template

The presensitized circuit board was taken out from its package taking into consideration that solar light couldn't fall directly on it as this could damage the baseplate and then it was put in between the template taking a lot of care that the two sides coincided as perfectly as possible. It was very important that the drill holes were perfectly aligned as if not they wouldn't be drilled properly.

With this being done the plate is put in the equipment shown in Figure 7-5 and in Figure 7-6 to insolate it, which meant having the plate exposed to UV light for around 100 seconds in the double layer contact printer shown in the image. This is done so that the photoresist the board is covered in decays and the copper underneath is exposed. This way, when the plate is passed through the next steps were the copper is removed, it won't be removed from all the plate but just in the places wanted.



Figure 7-5.



Figure 7-6.

Once the plate has been insolated, the template is removed and the plate is transferred to the next equipment, shown in Figure 7-7. This equipment consists in various stages, the first of them being a slot with developer liquid. After this the plate is changed to the next slot which contains iron chloride. All these steps eliminate the unwanted copper, leaving the connections desired. A drawback of this method is that the time must be controlled precisely as if not the copper from tracks or pads could be eliminated by mistake too.



Figure 7-7.

The result when the baseplate had finished all the previous steps is shown in Figure 7-8. To get the finished look it had to be cleaned with cotton wet with alcohol and that way the black that can be seen in the figure is removed.

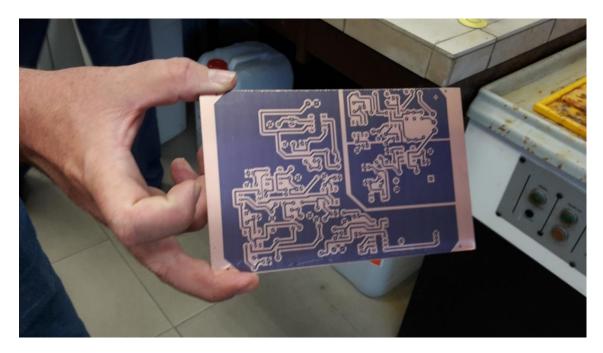


Figure 7-8. Finished board after chemical procedure.

Once the baseplate was ready the holes for the pins of the components had to be drilled. This had to be done with care so as to not remove the copper pads. Figure 7-9 shows an image taken during this procedure. During this step three different sizes of drills were used, one for the pads of the components, one for the four legs used to support the

baseplate and a last one for the holes in the plate whose job was to be a connection path between the top and the bottom.



Figure 7-9. Drilling.

7.3 Soldering of the components

The result of when the baseplate had passed through all the chemical processes, cleaned with alcohol and had all the holes drilled is shown in Figure 7-10. Once this had been achieved it was the moment to start soldering the components and start testing the baseplate to check that all had been done correctly.



Figure 7-10. Finished drilling and cleaning.

As the resources of the laboratory are finite some of the components weren't soldered directly on the baseplate. Usual components such as resistances and the capacitors used in the connections to the power supply were soldered directly but others weren't.

The more expensive and rare components couldn't be soldered as they were probably going to be reused and unsoldering them could have damaged them permanently. Therefore, instead of soldering them directly, a number of independent pins were soldered so that the component could be placed and removed easily from these pins.

The components that had to be placed like this were the PWR, the ISO, all the OP27, the AMP02, the switch and the capacitors of the high-pass filter. Even though only these parts mentioned had to be placed on pins it was decided to do the same with the capacitors and resistances that had been calculated for the different filters and amplifiers. This was done because although the values had been calculated they were all theoretical values and maybe when testing them the response that they gave wasn't the one desired and had to be changed. This could happen due to the normalisation of the values or the tolerances of the components. In Figure 7-13 most of the pins were these resistances and capacitors were going to be placed can be seen, together with how the PWR was placed on the pins prepared for it.

When soldering and testing it was decided to start with the power supply stage as this had to be working before any other part could. In Figure 7-11 it can be seen the entrance of the battery, the MAX and the pins were the PWR and the ISO were going to be located. Once this part was tested and it was checked that all the connections were correctly made and the appropriate results were got it was possible to continue with the next stages.

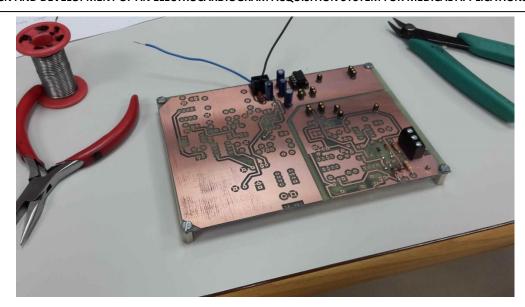


Figure 7-11. Power supply.

The next stage was to solder all the components regarding the entrance of the circuit, were the electrodes were going to come out from. This is shown in Figure 7-12. In this figure it can be seen the entrance of the electrodes, named E1, E2 and E3, the protection diodes, the first amplifier and the setup of the third electrode. This stage had to be functioning well before moving on to the next filters and although there were many continuity problems once these were solved it worked perfectly.

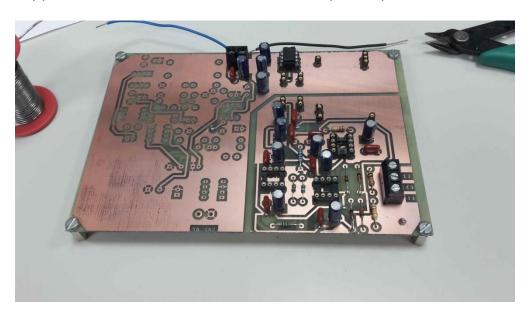


Figure 7-12. Power supply and first stages.

In Figure 7-13 it can be observed the mid-stage before everything was soldered as the pins for the resistances and capacitors of the low-pass filter haven't been placed yet. At this stage the high-pass filter had been checked and the 50Hz rejection filter was close to be tested. Once this was done there would only be one step left.

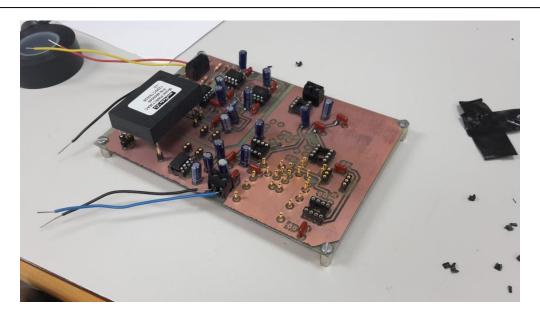


Figure 7-13.

On Figure 7-14 the completed baseplate can be seen. In this final stage all the filters and the supply had been tested and checked their functioning was correct.

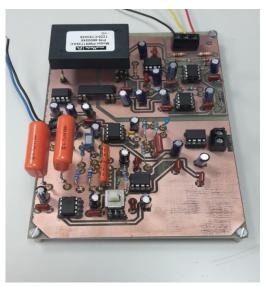


Figure 7-14. Finished baseplate.

7.4 Problems encountered

When developing the circuit many problems were encountered and a wide range of different solutions had to be thought of to find resolve them. The first of the problems has been mentioned earlier on. This problem was encountered when doing the schematic in Orcad Capture and some of the components couldn't be found in the libraries and it was solved by creating the three components manually.

When passing the schematic to Orcad Layout the components that had been created in Capture had to be created there too, but this time they had to be measured as Orcad Layout works with the real size and shape of the components.

When locating the components and making all the connections many changes had to be made as the equipment that was available in the laboratory had certain restrictions that had to be respected. To do this a larger spacing than when using specialized equipment had to be kept between tracks as the one in the laboratory had much less precision. Due to this the pads of the components had to be enlarged, as well as the tracks.

Once the design in Orcad Layout had been done the baseplate was manufactured and the holes drilled. The only complications in this step was measuring the time so that the plate wasn't too much time in the different phases and being careful when drilling so as to not remove the copper pads.

With all of these previous stages completed the soldering of the components and the testing of each part of the circuit started. This was a very complicated stage due mainly to inexperience. When testing the different parts of the circuit none of them worked the first time round due mainly to problems regarding the continuity between the top and bottom. This happened to be the most common problem and finding the place where the defective solder was turned out to be a very laborious and time-consuming task.

Even though the criteria described earlier on regarding the face where the tracks had to be located was followed some mistakes were made, for example a track was coming out of a terminal block on the top side and due to its physical shape it was impossible to solder this and a splice between two points had to be done on the bottom side. This is shown in Figure 7-15.

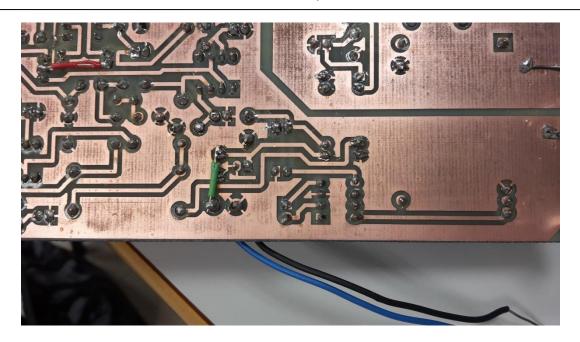


Figure 7-15. Correcting mistakes, splices.

Although the solution above had to be adopted only once other components had connections that were difficult to solder, for example a plug-in socket that had to be soldered on the top and bottom side due to a connection on this top side. This was a problem due to the shape and size of this component that made it difficult to solder on the top side.

Another problem encountered was that the low-pass filter was an inverter and another inversion wasn't arranged after it so that the wave at the exit of the circuit wasn't inverted. To resolve this problem it was decided to make one of the amplifiers (the one with a gain of 40) an inverting amplifier too, as this was considered easier than making the low-pass filter stop inverting. This is shown in Figure 7-16.

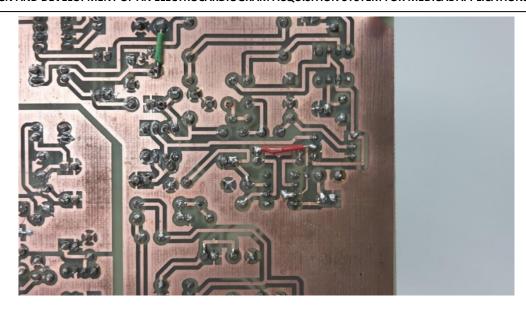


Figure 7-16. Correcting mistakes, inverting amplifier.

The last problem encountered was the response of the low-pass filter the first time it was tested, as it didn't give the values that were expected. This could have happened because although the resistances used have a tolerance of 1% and therefore their values are quite exact, the capacitors tolerance is 10%, and the variation in their value could have been the cause of the response obtained from the low-pass filter. To solve this problem the values of the capacitors and the resistances were recalculated.

Using again Equation (4.17) but this time with the value of the resistances set to $12k\Omega$ the value of the capacitors were recalculated and normalised, getting $C_1=124~nF$; $C_2=22~nF$. With these values the low-pass filter had the response that was expected and the baseplate worked as it should.

8 Tests on the base plate

The baseplate was now finished as all the components had been placed and all the errors had been identified and corrected. The circuit now amplified and filtered the signal it read at its entrance and when activated, the 50Hz rejection filter attenuated the signal as expected. Once everything was working as it should, it was the moment to test the baseplate to see how well it achieved the specifications that had to be met.

The first thing that had to be done before starting to test the circuit was to put an impedance divider. This had to be done because the arbitrary waveform generator produces a minimum signal of 20mV and as the circuit amplifies the signal by 1000 and the amplifiers are supplied with 9V they obviously saturate. As the amplifiers saturate if

the tests are done in these conditions the conclusions that will arise from this tests won't be reliable. To stop the amplifiers saturating an impedance divider is placed at the entrance of the circuit so as to get a signal of approximately 1mV and like this there won't be any more problems due to amplifiers saturating. The schematic of this impedance divider is shown in Figure 8-1.

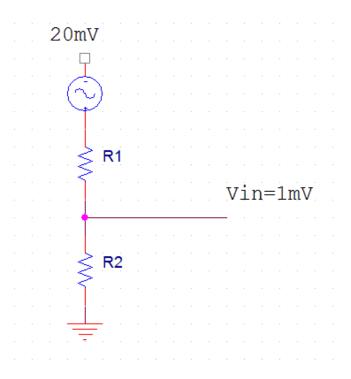


Figure 8-1. Schematic impedance divider.

The value of the resistances needed has to be calculated, so, knowing that the current that passes through both the resistances has to be the same:

$$I = \frac{V}{R} = \frac{19mV}{R1} = \frac{1mV}{R2} \tag{8.1}$$

Operating equation 6.1:

$$19 * R2 = 1 * R1$$

By doing R2 = 20Ω , then $R1=380\Omega$. Normalising these values $R1=390\Omega$; $R2=20\Omega$.

The physical appearance of the impedance divider used is shown in Figure 8-2.



Figure 8-2. Impedance divider.

8.1 Frequency response

The first test done on the baseplate was to see how it responded to all the range of frequencies it could be subject to, and this had to be done with the 50Hz filter and without it. Figure 8-3 shows how the baseplate was supplied with the 9V, how the impedance divider was placed so as to get a signal at the entrance of 1mV and how the exit of the circuit was measured with the oscilloscope.

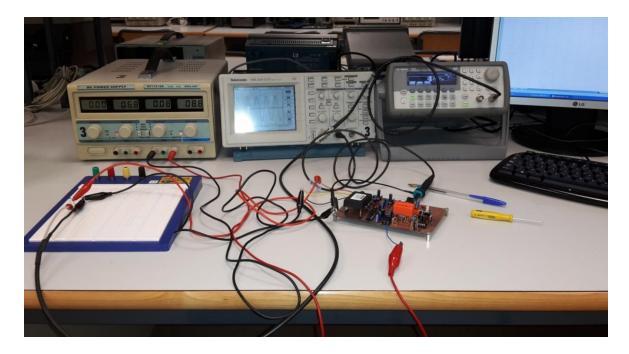


Figure 8-3. Set-up frequency response.

The first column in the next table shows the minimum voltage the pulse generator can give, the second one is the voltage got from the impedance divider and with which the entrance of the circuit is supplied. The next columns show the frequencies of the signal supplied, the voltage read at the exit of the circuit and lastly the gain of the baseplate and then this same gain but in dB.

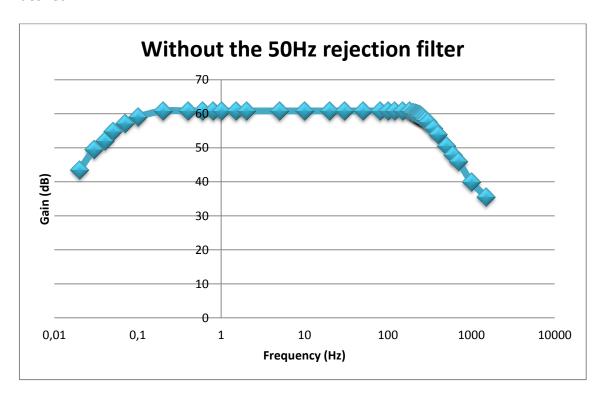
The first gain is calculated by doing:

$$Gain = \frac{Vout}{Vin (after impedance divider)}$$
 (8.2)

And the gain in dB is calculated with:

$$Gain(dB) = 20 * \log Gain$$
 (8.3)

Once these measurements had been taken, a graph was drawn to see clearly the response of the circuit to all these frequencies and then see if the curve had the shape desired.



Graph 8-1.

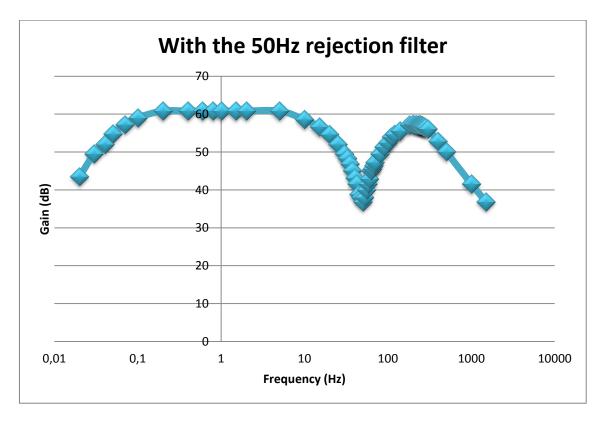
The graph got from excel (Graph 8-1) had to be represented with a logarithmic scale so that the Bode diagram could be seen. From this graph it can be seen that the Bode diagram got as a response of the circuit has the shape wanted, which means that the

circuit works as it was intended to. It can also be observed that the final gain was a bit higher that it should, as it haves a maximum gain of 60.82dB which is around 1100, while a gain of 1000 would be 60dB

The next step to continue testing the circuit is to do the same test but now with the 50Hz rejection filter to see if this filter works correctly and the patient would be safe if it came to the point where it had to be activated. The next table shows the results got from the test.

The equations used to calculate the gain and the gain in dB are the same ones as those mentioned before.

A new graph had to be plotted so as to analyse the Bode diagram of the circuit now that the 50Hz rejection filter has been activated. The procedure is the same as the one mentioned before, and again the scale has to be set to a logarithmic scale for the Bode to have the shape wanted.



Graph 8-2

In conclusion it can be seen that Graph 8-2 has the shape wanted, but it can also be observed that due to the slopes got when starting to reach the frequencies at which the filters had to attenuate (between the 50Hz and the 250Hz) the curve doesn't reach the previous gain of 1100 (or 60 dB). This is because it doesn't have enough time to do so

before the next filter starts attenuating. This happens because obviously the filters are not ideal and they don't attenuate in a vertical line at the frequency wanted but in slopes.

It can be observed how without the 50Hz rejection filter at 50Hz there was a gain of 60dB and when the filter is introduced this gain falls to 36dB, managing to get the attenuation wanted.

8.2 Common mode rejection ratio

The following image shows the arrangement done to test for the common mode rejection ratio. It can be seen how the entrance was short-circuited and supplied with 5V at 50Hz. The signal was chosen to have a frequency of 50Hz as this is the most troublesome. The amplitude from peak to peak was decided to be of 10V as the signal that is going to be read is going to be very small. This is because the AMP-02 ideally has a common mode gain of 0 and although in reality it isn't, it is also true that this value is very small. Due to this, unless the circuit is supplied with a high voltage at its entrance the signal at the exit will be too small to take any conclusions from it or even see it.

To test this, the signal at the entrance of the circuit and the one at the exit are going to be compared. This is done so as to use the 1100 gain directly in the calculations.

When doing this test it has to be taken into consideration that what is going to be read will be a fictitious measurement. This is so because when measuring this way if the electrodes are put on a patient the signal at the exit of the circuit will change. Also, if the electrodes are put on a different patient this signal will be different too. Due to this, although this test has to be done these factors have to be taken into consideration. In Figure 8-4 the setup to do this test can be seen.

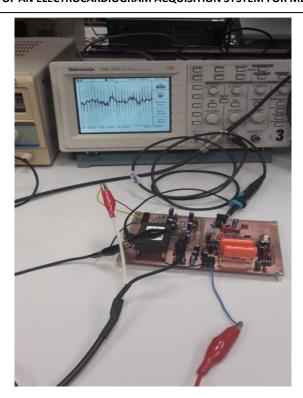


Figure 8-4. Set-up for measuring common mode rejection ratio.

This is the graph seen on the oscilloscope at the end of the circuit.

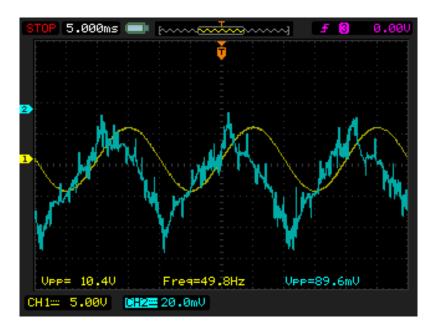


Figure 8-5

Once this is done the next step is to check if this result is acceptable or if it isn't. To do this it proceeds as:

$$G_{dif} = 1100$$

$$G_{mc} = \frac{50mV}{10400mV}$$

Being the 50mV the voltage peak-to-peak read from the oscilloscope in Figure 8-5, not taking into consideration the last peaks of the signal, which are ignored as they are not representative of the signal wanted. The 10400mV=10.4V, being the value of the signal at the entrance.

Now it has to be checked if this value is small enough for the circuit to work correctly.

$$CMRR = 20 * \log \frac{G_{dif}}{G_{mc}} = 107.2dB$$

From legislation; UNE-EN 60601-2-47:2001, clause 51.5.3 it can be seen that an acceptable value of CMRR is at least 60dB so the circuit clearly satisfies this condition.

The last thing remaining to say is that although in this case this test was done this way, in UNE-EN 60601-2-47:2001, clause 51.5.3 and Figure 105 of this same document the official test can be seen. This test was too complicated to do in the laboratory so this simpler one had to be done, but it's important to know that there is an official test regulated in legislation that should be done.

8.3 Noise

This test is done to check if the circuit has an acceptable level of noise or if, on the other hand, it distorts too much the signal making it useless. In Figure 8-6 a general view of the arrangement prepared to do this test can be seen. In Figure 8-7 closer look at the baseplate and the connections can be seen.

To test the baseplate for noise the entrance was short-circuited and connected to ground. With no signal at the entrance what is read at the exit will be the noise the components are introducing into the signal. This test has to check if this noise is small enough so as to not affect the signal this equipment has to read and show.

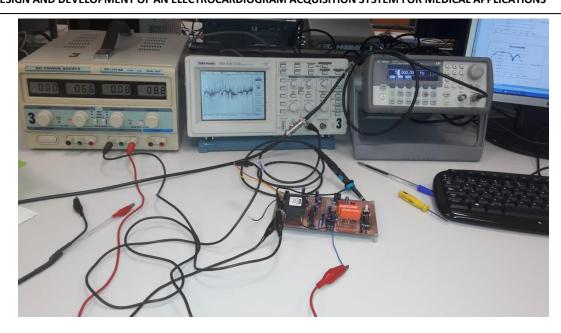


Figure 8-6. Set-up for measuring noise.

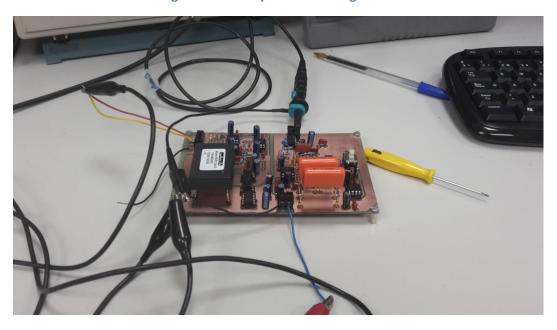


Figure 8-7. Closer look of the set-up.

Figure 8-8 shows what can be seen at the exit of the circuit when carrying out this test.



Figure 8-8

The next step is to check if this level of noise is acceptable or not. To do this the size of the noise measured and the size of the signal wanted to be measured in normal conditions have to be compared. To do this the noise has to be referred to the entrance and measured in Vrms:

Noise referred to the entrance
$$=\frac{Noise}{Gain} = \frac{39.9mV}{1100} = 0.0000363V$$

Comparing this to the signal at the entrance of the circuit when measuring a patient that will be around 1mV:

$$0.0000363V \ll 0.001V$$

Being the noise much smaller than the signal we are going to read we conclude that the amount of noise is acceptable and therefore the circuit has passed successfully this test.

8.4 Techniques to minimize noise

This test consisted in checking that everything related to the third electrode worked as it had to as this third electrode decreases the interference of the common mode. The way it does this was explained previously.

To do this the first thing that had to be checked was the exit of the follower, where the same signal as the one supplied at the entrance should be seen. Figure 8-9. shows the setup prepared for this test, how the entrance was short-circuited and supplied with 10V at 50Hz.

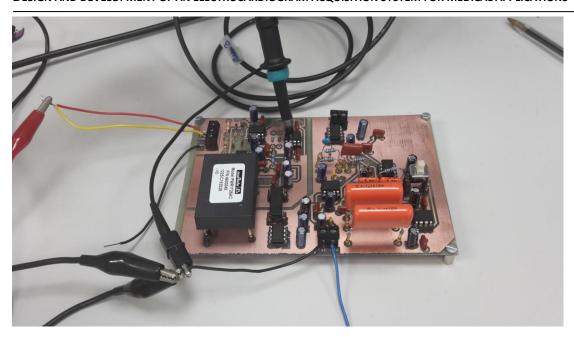


Figure 8-9. Set-up for measuring at the exit of the follower.

Figure 8-10. shows the signal that at the entrance of the circuit (channel 1) and the one at the exit of the follower (channel 2). It can be easily seen that both signals are exactly the same, meaning that this stage has been checked and it works as it has to.

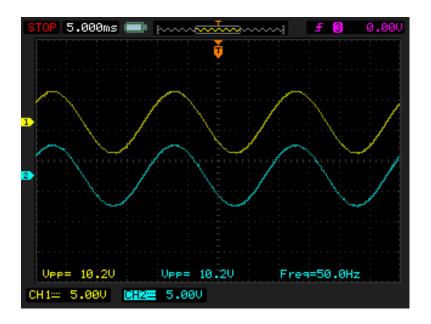


Figure 8-10.

The next step was to see the signal at the exit of the third electrode. The entrance of the baseplate was short-circuited again but now the signal supplied was of 50mV at 50Hz. The amplitude of the signal has been reduced because the third electrode has to amplify the signal by -10 and if the peak-to-peak value of the signal supplied at the entrance isn't

reduced the amplifier will saturate and whatever is read will be of no use as it will be impossible to tell if its amplifying by -10 or not.

Figure 8-11 shows the arrangement prepared to carry out this test and in Figure 8-12 a closer look of the baseplate itself can be seen, so it can easily be seen where the signal is being read.

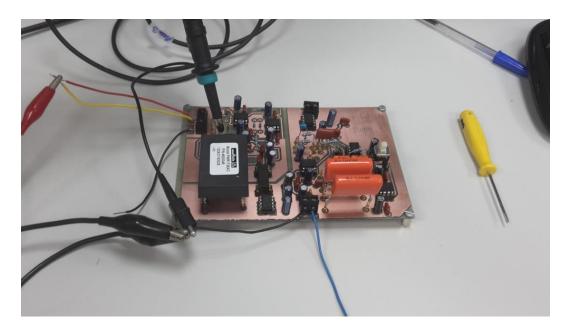


Figure 8-11. Set-up for measuring the exit of the third electrode.

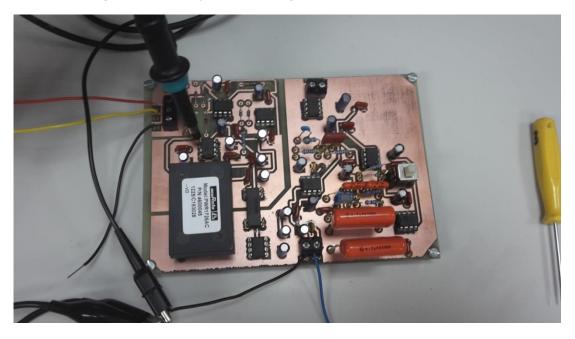


Figure 8-12. Closer look while measuring the exit of the third electrode.

Figure 8-13 shows the signal on the screen of the oscilloscope when this test was carried out. Channel 1 is the signal supplied to the circuit with the pulse generator and channel 2 is the signal read at the exit of the third electrode. It can be seen that the third electrode is amplifying by -10 as the signal at the exit is 10 times bigger than the one at the entrance (from 284mV to around 2.84V) and the wave at the exit is inverted to the one in the entrance. This being said, it has been checked that the third electrode works and it fulfils its objective.

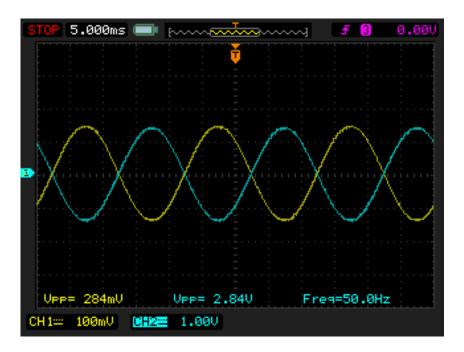


Figure 8-13

8.5 Testing the baseplate on a person.

After all the previous test and making sure all of the stages that protect the patient work correctly it's finally the moment to test the baseplate on a person. To do this the electrodes shown in Figure 8-14 were used.



Figure 8-14. Electrodes.

The measurements were taken with the patient lying down inside the space shown in Figure 8-15. This was prepared especially as it helps to minimise the interference of the mains with the readings of the oscilloscope.



Figure 8-15.

In Figure 8-16 it can be observed the first lead that was used to take measurements. This first lead consists on having the two normal electrodes each on each wrist and the third electrode on an ankle. The second lead that was used was with a normal electrode and the third electrode each on one ankle and the other normal electrode on the wrist. The measurements taken with these two leads are shown later on.



Figure 8-16. Lead 1.

In Figure 8-17 the signal shown on the oscilloscope when the first lead was used without the 50Hz filter can be seen.



Figure 8-17

In Figure 8-18 the same lead was used but this time the 50Hz rejection filter was being used. As a result of using this filter it can be observed that the signal was smaller as the interference with the mains had been attenuated due to this filter.



Figure 8-18

In Figure 8-19, the response when the second lead (one normal electrode on an ankle and the other one in the wrist and the third electrode on the other ankle) was used can be seen. This lead gives a stronger response than the first one, as it can be clearly seen on

the figure and considering that Vpp has changed from 960mV to 2.18V. It is compared with this value and not with 880mV because this measurement was taken without the 50Hz rejection filter too.



Figure 8-19. Lead II.

Figure 8-20 was done to see an example of how doing a certain movement can change the signal read in the oscilloscope. All the previous tests were done with the patient lying down without moving, but in this test the patient was asked to close his fist firmly. The point where the patient did this can be easily identified in the middle of the image.



Figure 8-20. Muscle interference.

9 Previous knowledge used

In the process of doing this project knowledge from previous experiences had to be used. To know how an ECG works and the bases to start designing one, a seminar from the Master en Ingeniería Biomédica had to be attended. To do all the calculations to get the values of the resistances and capacitors knowledge from previous subjects was used, for example from Sistemas Electrónicos and Teoría de Circuitos. Lastly, to prepare this document things learnt in the subject Proyectos was used.

10 Conclusions

In conclusion, to develop the final circuit many mistakes had to be corrected in all the stages and competences in Orcad Layout, Orcad Capture, manufacturing of baseplates and soldering were acquired. Lastly, learning how to use an oscilloscope in order to do all the tests was required. By learning step by step how to do all of this finally resulted in a working circuit that correctly measured and showed an ECG.

11 Bibliography and Figures

11.1 Bibliography

John G. Webster, Medical Instrumentation. Application and Design, 1998.

Jose Maria Ferrero Corral, Bioelectrónica. Señales Bioeléctricas, 1994.

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GRADO EN INGENIERÍA EN TECNOLOGÍAS INDUSTRIALES DESIGN AND DEVELOPMENT OF AN ELECTROCARDIOGRAM ACQUISITION SYSTEM FOR MEDICAL APPLICATIONS

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II. Scope Statement

GRADO EN INGENIERÍA EN TECNOLOGÍAS INDUSTRIALES DESIGN AND DEVELOPMENT OF AN ELECTROCARDIOGRAM ACQUISITION SYSTEM FOR MEDICAL APPLICATIONS

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1	INDEX	1
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2 COMPONENT LIST

Quantity	Description	Value and units
1	Terminal block, 3 plug-ins	-
3	Resistance	10kΩ
4	Diodes	-
1	AMP-02	-
2	Resistance	2kΩ
1	Resistance	3.9kΩ
6	OP-27	-
1	Resistance	1kΩ
1	ISO124	-
2	Capacitor	4.7uF
2	Resistance	680kΩ
1	Switch	-
1	Resistance	39kΩ
2	Resistance	82kΩ
1	Capacitor	82nF
2	Capacitor	39nF
1	Resistance	470Ω
1	Resistance	20kΩ
3	Resistance	12kΩ
1	Capacitor	124nF
1	Capacitor	22nF
2 Terminal block, 2 plug		-
1	MAX1044	-
1	PWR1726	-
1	Battery	9V
8	Plug-in socket	-

The resistances used were metal film resistances with a tolerance of 1%. The capacitors used had a tolerance of 10%. The difference in the tolerances between the resistances and the capacitors is due to the fact that capacitors with a tolerance of 1% are much more expensive so they weren't available for this project.

The resistances and the diodes used have a total power dissipation of 0.5W.

Regarding the choice of components, the AMP02 was chosen because a differential amplifier with high input impedance was needed. Also, this component has a high common-mode rejection, which is very useful due to the application of this circuit. The OP27 was chosen in the end, even though there are components that can do the same thing but are cheaper because the OP27 is a low-noise precision operational amplifier and the circuit needs introduce the least noise as possible.

To continue with, the first page of the datasheets of the components are shown. The whole datasheets are available in the cd attached.













ISO124

SBOS074D - SEPTEMBER 1997 - REVISED JANUARY 2015

ISO124 Precision Lowest-Cost Isolation Amplifier

1 Features

- · 100% Tested for High-Voltage Breakdown
- Rated 1500 Vrms
- High IMR: 140 dB at 60 Hz
- 0.010% Maximum Nonlinearity
- Bipolar Operation: V_O = ±10 V
- DIP-16 and SO-28
- Ease of Use: Fixed Unity Gain Configuration
- ±4.5-V to ±18-V Supply Range

2 Applications

- Industrial Process Control:
 - Transducer Isolator, Isolator for Thermocouples, RTDs, Pressure Bridges, and Flow Meters, 4-mA to 20-mA Loop Isolation
- · Ground Loop Elimination
- · Motor and SCR Control
- Power Monitoring
- PC-Based Data Acquisition
- Test Equipment

3 Description

The ISO124 is a precision isolation amplifier incorporating a novel duty cycle modulation-demodulation technique. The signal is transmitted digitally across a 2-pF differential capacitive barrier. With digital modulation, the barrier characteristics do not affect signal integrity, thus resulting in excellent reliability and good high-frequency transient immunity across the barrier. Both barrier capacitors are imbedded in the plastic body of the package.

The ISO124 is easy to use. No external components are required for operation. The key specifications are 0.010% maximum nonlinearity, 50-kHz signal bandwidth, and 200- μ V/°C V_{OS} drift. A power supply range of ±4.5 V to ±18 V and quiescent currents of ±5 mA on V_{S1} and ±5.5 mA on V_{S2} make the ISO124 ideal for a wide range of applications.

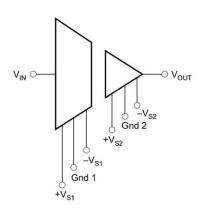
The ISO124 is available in PDIP-16 and SOIC-28 plastic surface-mount packages.

Device Information⁽¹⁾

PART NUMBER	PACKAGE	BODY SIZE (NOM)
100101	PDIP (16)	17.90 mm × 7.50 mm
ISO124	SOIC (28)	20.01 mm × 6.61 mm

 For all available packages, see the orderable addendum at the end of the data sheet.

4 Simplified Schematic



19-4667; Rev 1; 7/94



Switched-Capacitor Voltage Converters

General Description

The MAX1044 and ICL7660 are monolithic, CMOS switched-capacitor voltage converters that invert, double, divide, or multiply a positive input voltage. They are pin compatible with the industry-standard ICL7660 and LTC1044. Operation is guaranteed from 1.5V to 10V with no external diode over the full temperature range. They deliver 10mA with a 0.5V output drop. The MAX1044 has a BOOST pin that raises the oscillator frequency above the audio band and reduces external capacitor size requirements.

The MAX1044/ICL7660 combine low quiescent current and high efficiency. Oscillator control circuitry and four power MOSFET switches are included on-chip. Applications include generating a -5V supply from a +5V logic supply to power analog circuitry. For applications requiring more power, the MAX660 delivers up to 100mA with a voltage drop of less than 0.65V.

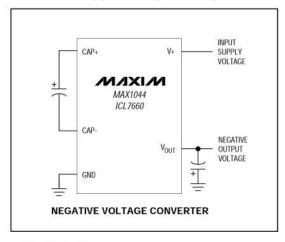
Applications

-5V Supply from +5V Logic Supply Personal Communications Equipment Portable Telephones Op-Amp Power Supplies EIA/TIA-232E and EIA/TIA-562 Power Supplies

Data-Acquisition Systems Hand-Held Instruments

Panel Meters

Typical Operating Circuit



Features

- © Miniature µMAX Package
- © 1.5V to 10.0V Operating Supply Voltage Range
- © 98% Typical Power-Conversion Efficiency
- © Invert, Double, Divide, or Multiply Input Voltages
- ® BOOST Pin Increases Switching Frequencies (MAX1044)
- © No-Load Supply Current: 200µA Max at 5V
- No External Diode Required for Higher-Voltage Operation

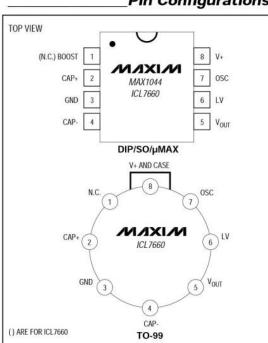
Ordering Information

PART	TEMP. RANGE	PIN-PACKAGE
MAX1044CPA	0°C to +70°C	8 Plastic DIP
MAX1044CSA	0°C to +70°C	8 SO
MAX1044C/D	0°C to +70°C	Dice*
MAX1044EPA	-40°C to +85°C	8 Plastic DIP

Ordering Information continued at end of data sheet.

* Contact factory for dice specifications.

Pin Configurations



MIXIM

Maxim Integrated Products 1

Call toll free 1-800-998-8800 for free samples or literature.



Product Data Sheet

1.5 WATT UNREGULATED DC/DC CONVERTER

PWR1726A/PWR1726A1



FEATURES

- 8000V ISOLATION TEST VOLTAGE
- NO EXTERNAL PARTS REQUIRED
- SYNCHRONIZABLE
- REMOTE ON/OFF
- LOW-BARRIER CAPACITANCE

APPLICATIONS

- BIOMEDICAL DATA ACQUISITION
- INDUSTRIAL PROCESS EQUIPMENT
- DATA ACQUISITION
- TEST EQUIPMENT
- PORTABLE EQUIPMENT

DESCRIPTION

The PWR1726A/PWR1726A1 is a single-channel, dualoutput DC/DC/ converter designed for those applications where high-isolation voltage and low-barrier capacitance are critical for system reliability and integrity.

Calculated mean-time-to-failure (MTTF) is in excess of 100 years at an ambient temperature of +25°C and at rated output power. The performance of the PWR1726A/PWR1726A1 is not derated over its entire specified temperature range of -25°C to +85°C.

Synchronization of the PWR1726A/PWR1726A1 may be

accomplished simply by connecting the sync pin of one unit to the sync pin of another unit. In this manner, up to eight converters may be ganged together.

The PWR1726A/PWR1726A1 provides a plus and minus output voltage that is approximately equal to the magnitude of the input voltage. The unit operates over an input voltage range of 7VDC to 16VDC.

Each PWR1726A/PWR1726A1 isolation barrier is tested per the method set forth by UL544, VDE750, and CSA C22.2.

Power Electronics Division, United States 3400 E Britannia Drive, Tucson, Arizona 85706 Phone: 800.547.2597 Fax: 520.770.9369 C&D Technologies, (NCL)
Tanners Drive Blakelands North
Milton Keynes MK14 5BU UK
Tel: +44 (0)1908 615232 Fax: +44 (0)1908 617545

Panasonic

Push Switches/ESB33

ESB33 Vertical Push Switches

Type: ESB33 (H=6.0 mm)

■ Features

- Low profile (H=6.0 mm)
- 3 N and 5 N operating force availables

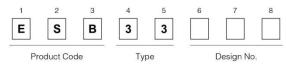
■ Recommended Applications

- Operation switches for automobiles (heater control switches etc.)
- Secondary power switches for lower voltage in consumer electronic equipment and different types of mode switches





■ Explanation of Part Numbers



■ Specifications

Rating	50 μA 3 Vdc to 0.2 A 14 Vdc (Resistive load)	
Travel	Lock travel=1.5 mm Full travel=2.3 mm	
Mounting Height	6.0 mm	
Poles and Throws	2-poles 2-throws	
Operating Mode	Self-lock, Non-lock	
Switching Mode	Non-shorting	
Minimum Quantity/Packing Unit	100 pcs. Polyethylene Bag (Bulk) / 300 pcs. Embossed Taping (Reel Pack)	
Quantity/Carton	2000 pcs. Polyethylene Bag (Bulk) / 1800 pcs. Embossed Taping (Reel Pack	

■ Standard Products

Operating Mode	Terminals	Packaging	Operating Force	Part Numbers	Lever Color
PP	Wave Soldering	Polyethylene Bag (Bulk)	3.0 N±1.0 N	ESB33133	Liebt Veller
NL				ESB33134	Light Yellow
PP	Surface Mount	Embossed Taping (Reel)	3.0 N±1.0 N	ESB33535	Light Yellow
NL				ESB33536	

Note: PP=Self-lock NL=Non-lock

Design and specifications are each subject to change without notice. Ask factory for the current technical specifications before purchase and/or use. Should a safety concern arise regarding this product, please be sure to contact us immediately.

00 Oct. 2012



Low-Noise, Precision Operational Amplifier

OP27

FEATURES

Low Noise: 80 nV p-p (0.1 Hz to 10 Hz), 3 nV/ $\sqrt{\text{Hz}}$

Low Drift: 0.2 μV/°C

High Speed: 2.8 V/µs Slew Rate, 8 MHz Gain

Bandwidth Low V_{os}: 10 μV

Excellent CMRR: 126 dB at V_{CM} of $\pm 11~V$ High Open-Loop Gain: 1.8 Million Fits 725, OP07, 5534A Sockets

Available in Die Form

GENERAL DESCRIPTION

The OP27 precision operational amplifier combines the low offset and drift of the OP07 with both high speed and low noise. Offsets down to 25 μV and maximum drift of 0.6 $\mu V/^{\circ}C$, makes the OP27 ideal for precision instrumentation applications. Exceptionally low noise, $e_n=3.5~nV/\sqrt{Hz},$ at 10 Hz, a low 1/f noise corner frequency of 2.7 Hz, and high gain (1.8 million), allow accurate high-gain amplification of low-level signals. A gain-bandwidth product of 8 MHz and a 2.8 V/µsec slew rate provides excellent dynamic accuracy in high-speed, data-acquisition systems.

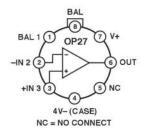
A low input bias current of $\pm\,10$ nA is achieved by use of a bias-current-cancellation circuit. Over the military temperature range, this circuit typically holds I_B and I_{OS} to $\pm\,20$ nA and 15 nA, respectively.

The output stage has good load driving capability. A guaranteed swing of ± 10 V into $600~\Omega$ and low output distortion make the OP27 an excellent choice for professional audio applications.

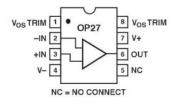
(Continued on page 7)

PIN CONNECTIONS

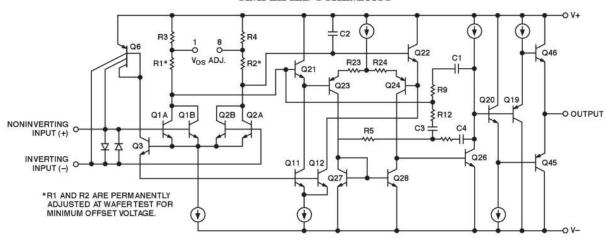
TO-99 (J-Suffix)



8-Pin Hermetic DIP (Z-Suffix) Epoxy Mini-DIP (P-Suffix) 8-Pin SO (S-Suffix)



SIMPLIFIED SCHEMATIC



REV. C



High Accuracy Instrumentation Amplifier

AMP02

FEATURES

Low Offset Voltage: 100 μ V max

Low Drift: 2 μV/°C max Wide Gain Range: 1 to 10,000

High Common-Mode Rejection: 115 dB min High Bandwidth (G = 1000): 200 kHz typ Gain Equation Accuracy: 0.5% max

Single Resistor Gain Set Input Overvoltage Protection

Low Cost

Available in Die Form

APPLICATIONS
Differential Amplifier
Strain Gage Amplifier
Thermocouple Amplifier
RTD Amplifier

Programmable Gain Instrumentation Amplifier

Medical Instrumentation Data Acquisition Systems

FUNCTIONAL BLOCK DIAGRAM

8-Lead PDIP and CERDIP 16-Lead SOIC RG₁ 8 RG₂ 16 NC 7 V+ -IN 2 15 RG₂ RG₁ 2 6 OUT 14 NC +IN 3 NC 3 5 REFERENCE -IN 4 13 V+ 12 SENSE +IN 5 11 OUT 10 REFERENCE 9 NC NC = NO CONNECT

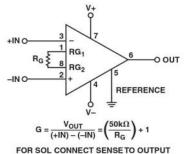


Figure 1. Basic Circuit Connections

GENERAL DESCRIPTION

The AMP02 is the first precision instrumentation amplifier available in an 8-lead package. Gain of the AMP02 is set by a single external resistor and can range from 1 to 10,000. No gain set resistor is required for unity gain. The AMP02 includes an input protection network that allows the inputs to be taken 60 V beyond either supply rail without damaging the device.

Laser trimming reduces the input offset voltage to under $100 \mu V$. Output offset voltage is below 4 mV, and gain accuracy is better than 0.5% for a gain of 1000. ADI's proprietary thin-film resistor process keeps the gain temperature coefficient under 50 ppm/°C.

Due to the AMP02's design, its bandwidth remains very high over a wide range of gain. Slew rate is over 4 V/μ s, making the AMP02 ideal for fast data acquisition systems.

A reference pin is provided to allow the output to be referenced to an external dc level. This pin may be used for offset correction or level shifting as required. In the 8-lead package, sense is internally connected to the output.

For an instrumentation amplifier with the highest precision, consult the AMP01 data sheet.

REV. E

The first page of the legislation used is shown now.

norma española

UNE-EN 60601-2-47

Junio 2002 TÍTULO Equipos electromédicos Parte 2-47: Requisitos particulares para la seguridad, incluyendo las características de funcionamiento esencial, de los sistemas de electrocardiografía ambulatoria Medical electrical equipment. Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems. Appareils électromédicaux. Partie 2-47: Règles particulières de sécurité et performances essentielles des Esta norma es la versión oficial, en español, de la Norma Europea EN 60601-2-47 de CORRESPONDENCIA octubre de 2001, que a su vez adopta la Norma Internacional CEI 60601-2-47:2001. **OBSERVACIONES** Esta norma ha sido elaborada por el comité técnico AEN/CTN 209 Equipos **ANTECEDENTES** Electrónicos cuya Secretaría desempeña ANIEL. Editada e impresa por AENOR Depósito legal: M 26717:2002 LAS OBSERVACIONES A ESTE DOCUMENTO HAN DE DIRIGIRSE A: Asociación Española de Normalización y Certificación AENOR 46 Páginas Teléfono © AENOR 2002 C Génova, 6 28004 MADRID-España 91 432 60 00 Grupo 28 Reproducción prohibida 91 310 40 32

DISCRETE SEMICONDUCTORS

DATA SHEET



1N4148; 1N4448 High-speed diodes

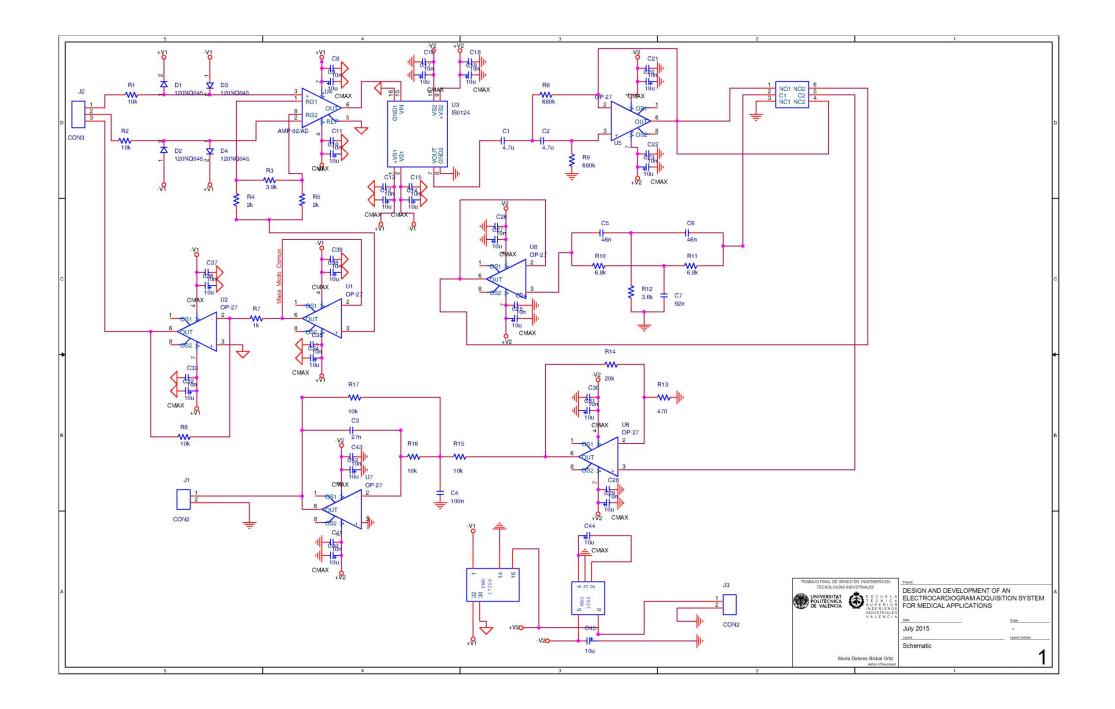
Product data sheet Supersedes data of 2002 Jan 23 2004 Aug 10

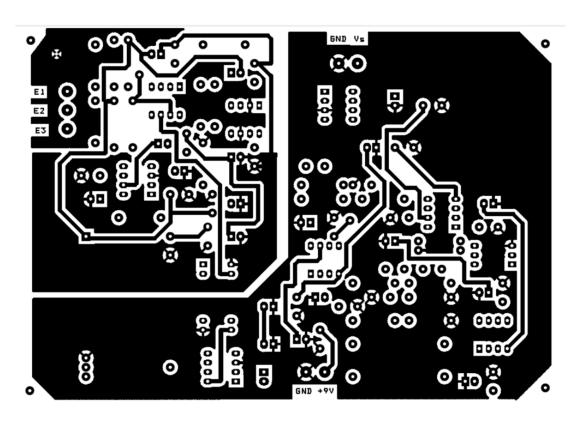


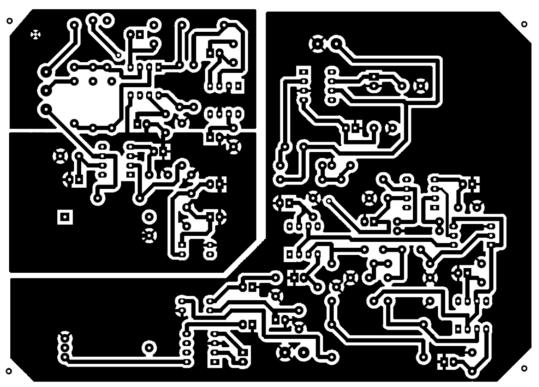
III. Layouts

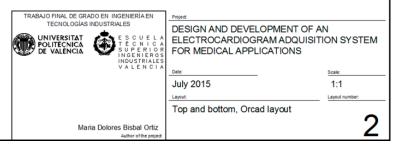
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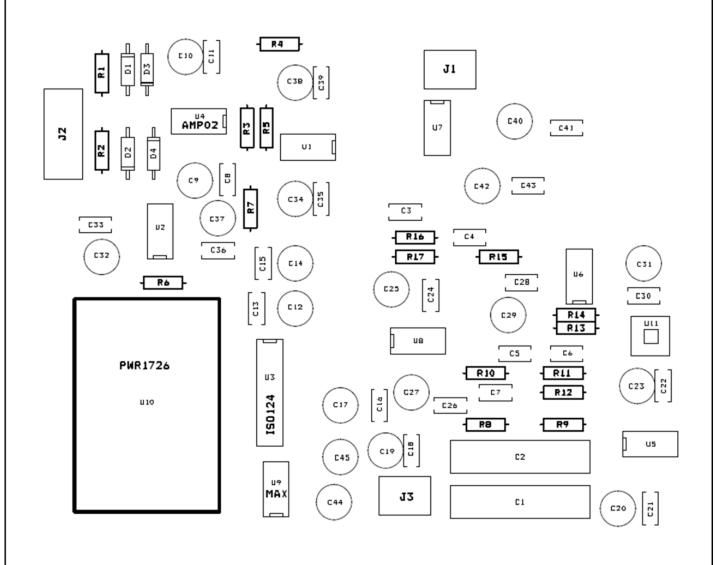
- 1. Layout 1. Schematic.
- 2. Layout 2. Top and bottom, Orcad Layout.
- 3. Layout 3. Component arrangement.

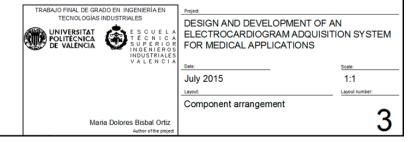












IV. BUDGET

GRADO EN INGENIERÍA EN TECNOLOGÍAS INDUSTRIALES DESIGN AND DEVELOPMENT OF AN ELECTROCARDIOGRAM ACQUISITION SYSTEM FOR MEDICAL APPLICATIONS

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2 INTRODUCTION

For this document two budgets have been prepared. It was decided to do it this way as this project could have been carried out by a company with the intention of selling this circuit. With this in mind, the first budget shows the price of the components if only one circuit was going to be done and the components were bought separately. The other budget assesses the change in price if a company had wanted to manufacture many of these circuits and the components had been bought in packs of 100. The prices shown in both budgets have been taken from www.mouser.es.

3 BUDGET FOR ONE CIRCUIT

The first budget would be the price of the whole baseplate if only one was to be manufactured, and therefore the prices of the components are the ones if they were to be bought in small packs or just one of them.

Quantity	Units	Description	Unitary Price	Row Total
17	Units	Resistances	0.489	8.313
4	Units	Diodes	0.097	0.388
1	Units	Switch	1.67	1.67
6	Units	OP-27	2.89	17.34
1	Units	MAXIM1044	2.74	2.74
1	Units	PWR1726	40.17	40.17
1	Units	AMP-02	11.39	11.39
1	Units	ISO124	17.11	17.11
50	Hours	Design by industrial engineer (social security included)	30	1500
3	Hours	Manufacturing by industrial engineer (social security included)	15	45
38		Capacitors	0.276	10.488
2	Units	Capacitors (4.6u)	2.21	4.42
10	Units	Plug-in socket	1.08	10.8
3	Units	Terminal block	0.389	1.167
			Total	1670 996

4 BUDGET FOR LARGE-SCALE MANUFACTURING OF THE CIRCUIT

This second budget shows the situation if a company wanted to manufacture this circuit in a larger scale, so for this budget the prices of the components have changed as it is the price if the components were bought in packs of 100.

Quantity	Units	Description	Unitary Price	Row Total
17	Units	Resistances	0.09	1.53
4	Units	Diodes	0.017	0.068
1	Units	Switch	1.18	1.18
6	Units	OP-27	2.11	12.66
1	Units	MAXIM1044	1.58	1.58
1	Units	PWR1726	32.51	32.51
1	Units	AMP-02	8.8	8.8
1	Units	ISO124	13.22	13.22
50	Hours	Design by industrial engineer (social security included)	30	1500
3	Hours	Manufacturingof the base plate (social security included)	15	45
38	Units	Capacitors	0.076	2.888
2	Units	Capacitors (4.6u)	1.37	2.74
10	Units	Plug-in socket	0.641	6.41
3	Units	Terminal block	0.35	1.05
			Total	1583.586

In conclusion, the second budget is around 100€ less expensive than the first one. This may not seem much but it has to be taken into consideration that the first budget is for just one circuit and the second one is for many, meaning that although this first circuit may be very expensive for the next ones there will be no 'design by industrial engineer' which is the most expensive factor. Therefore, the next baseplates manufactured will cost 83.586€ and now the real difference between the two scenarios described can be really appreciated.