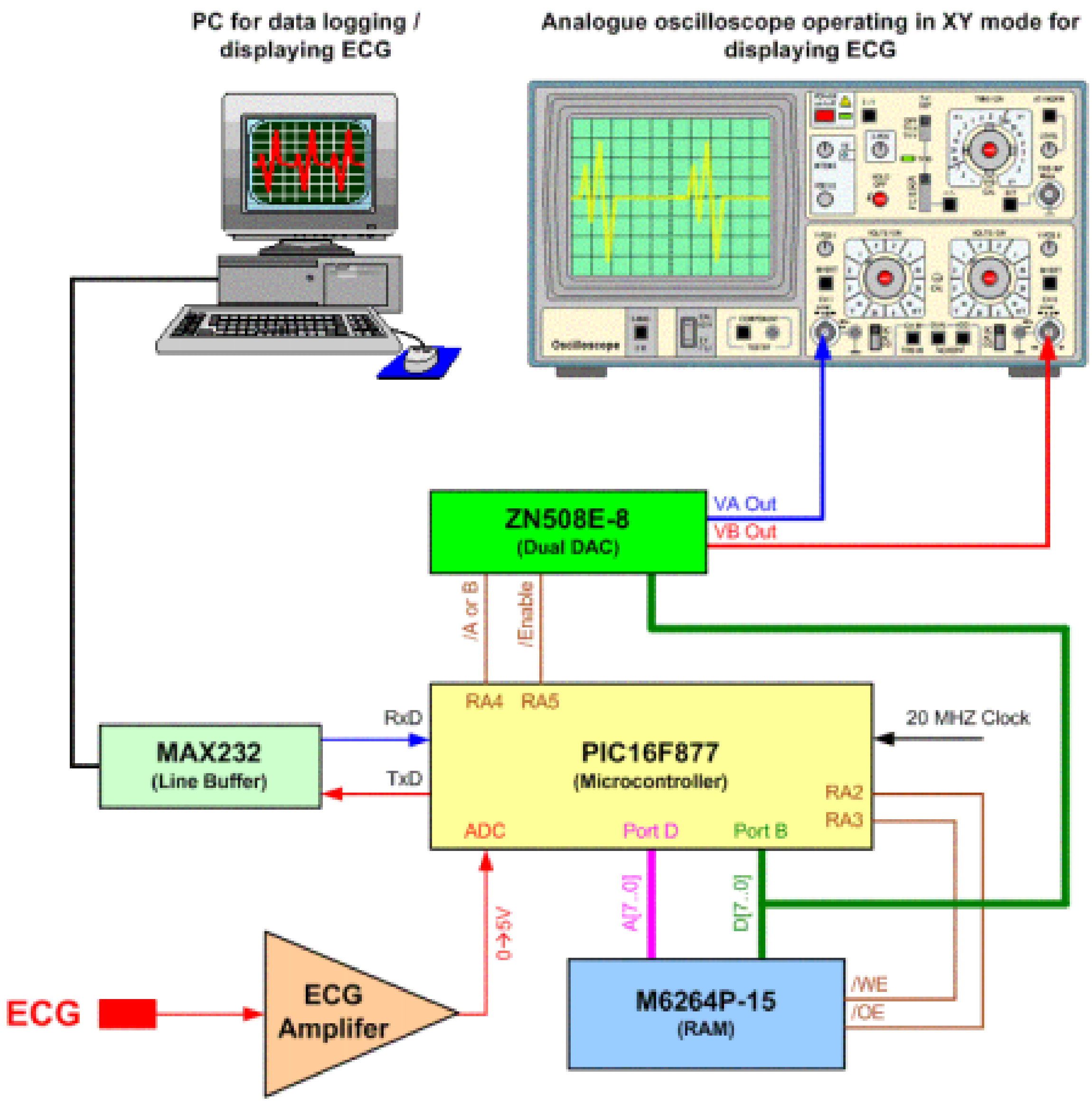
MiniProject

Real-Time Microcontroller Based ECG Monitor

Report A: Design Aspects



UNIVERSITY of ULSTER
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COURSE: BEng (HONS) Electronic Systems
MODULE: EEE512J2 - Electronic Product Design
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1.0 INTRODUCTION

The heart's strong pumping action is driven by powerful waves of electrical activity in which the muscle fibres contract and relax in an orchestrated sequence. These waves cause weak currents to flow in the body, changing the relative electric potential between different points on the skin. An electrocardiogram is a biophysical instrumentation device that is used to view/record the electrical activity of the heart for various diagnostic purposes.

The electrocardiogram (or ECG) has been used extensively in medicine sine its invention in the early 1900's, and has since proven to be invaluable in various diagnostic applications, such as the detection of irregular heartbeat patterns (i.e. fibrillation or arrhythmia), heart murmurs (or other abnormal heart sounds), tissue/structural damage (such as valve malfunction) and coronary artery blockage. Other applications of the ECG are very effective in areas of sports medicine, or sports therapy, in tracking the heartbeat through various levels of physical activity to assist the patient in attaining a desired, optimum heart rate.

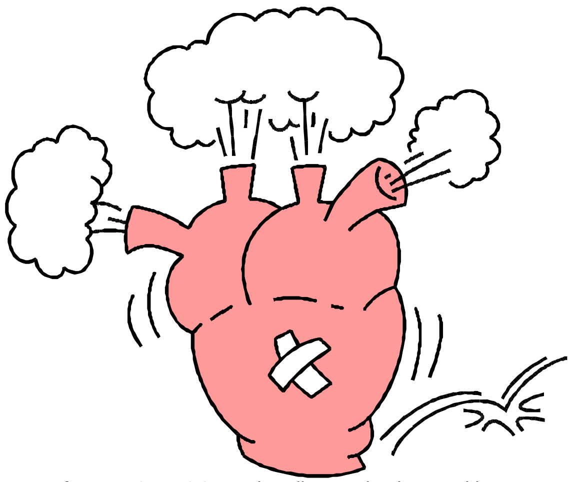


Figure 1.0a. ECG used to diagnostic abnormal heart

Figure 1.0b. ECG for sports therapy

Therefore, while the concept of an ECG is not a novel one, the attraction of this project lay in the challenge to build a simple, compact, operational medical device at a low cost. The basic design theory is as follows: -

- The electrical activity of the heart is detected using electrodes placed on the surface of the chest cavity. These electrodes act as bio-transducers to convert the signal from its existing form in the body (ionic) into electrical current in the wires.

- The generated signal is put through an amplifier to allow for observations, measurements, and recordings to be made. This stage is extremely important, as the cardiac signal is *very small*, i.e. on the order of mili-volts, thus a large amplification is necessary for any use to be made of the signal.

- The amplified signal is then sent to the PIC for Analogue-to-Digital conversion, signal manipulation, calculation of beats per minute (displayed using 3, 7-segment LED displays), data logging (RS232 communications) and analogue signal output (DAC) for a visual display of the ECG. Note that an oscilloscope can be used to provide a visual output.

This report will demonstrate how to design and plan the innovation of a new medical device, from the feasibility study through to physical realisation / manufacture of the product.

2.0. FUNDAMENTALS

2.1. Electrocardiography (ECG, EKG)

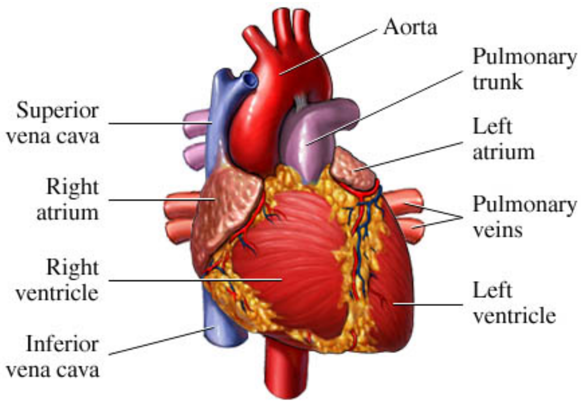


Figure 2.1a. Heart Anatomy [W1]

The heart is a muscular pump made up of four chambers. The two upper chambers are called atria, and the two lower chambers are called ventricles.

The purpose of the atria is to act as 'filling chambers' for the ventricles; the right side of the heart is the pulmonary pump, i.e. it pumps blood between the heart and the lungs, and the left side of the heart is the systemic pump, i.e. it pumps blood between the heart and the entire body.

The heart beats as a result of 'commands' passed in the form of bioelectric impulses and action potentials. These action potentials result in a series of rapid and successive patterns of depolarization and re-polarization across the cardiac muscle, generating an electric signal. The electrical activity of the heart can be detected through the skin by small metal discs called electrodes. The electrodes are attached to the skin on the chest, arms, and legs.

The cardiac cycle begins at the Sino-Atria node, located in the right atrium at the superior cava. The beginning of the cycle corresponds to the contraction of the atria. Following this is a 100ms delay until the activation of the Atria-ventricular node. This delay is important because it allows time for the ventricles to fill, increasing the efficiency of the heart. The signal is then propagated down the ventricular septum resulting in ventricular contraction. The signal generated over one period of the cardiac cycle is depicted in figure 2.1b (P-Wave: Atria Depolarization, QRS-Complex: Ventricular Depolarization, T-Wave: Ventricular Re-polarization).

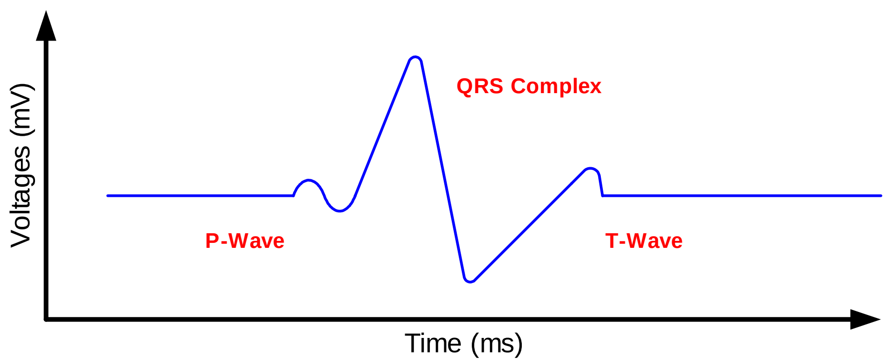


Figure 2.1b. One period of the cardiac cycle

Note that the signal generated from the heart is extremely small (about 2mV's in amplitude), and at a very low frequency, having a bandwidth of about 150Hz.

The heart can be considered as an electric dipole, repetitively changing both in magnitude and direction as it goes through the cardiac cycle. The magnitude of the dipole will be at a maximum during ventricular contraction. This is important note, as it is quite likely that the smaller P and T waves will be lost in the effects of noise. Therefore the theory behind detecting the cardiac signal is to place electrodes on the surface of the body, and simply measure the different differences in potential that arise as the dipole moves through its cycle.

The measured differences in potential are referred to as 'leads'. Note that it is always a difference in potential between at least two electrodes that is being measured, as there is no absolute zero reference voltage in the body, only a dipole changing in both space and time. According to cardiac theory, in order to detect the strongest difference in potential (the peak signal); the optimum electrode placement is to have one on the right shoulder, and one on the left hip. This is what is usually referred to as “Lead II”, a convention that arises from the work of Willem Einthoven, a pioneer in ECG development, who observed the differences in signal strength as he took measurements between two electrodes with placement on the left shoulder, the right shoulder and the left hip (Einthoven’s Triangle). See reference [W3] for an overview of the different standard electrode placements.

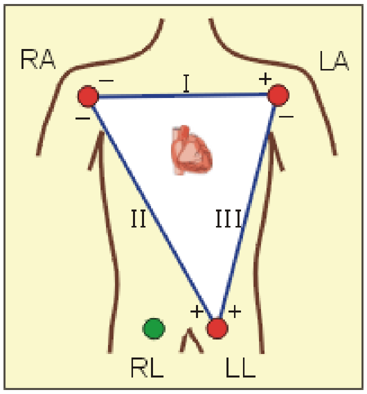


Figure 2.1c. Limb leads (Bipolar) [W3]

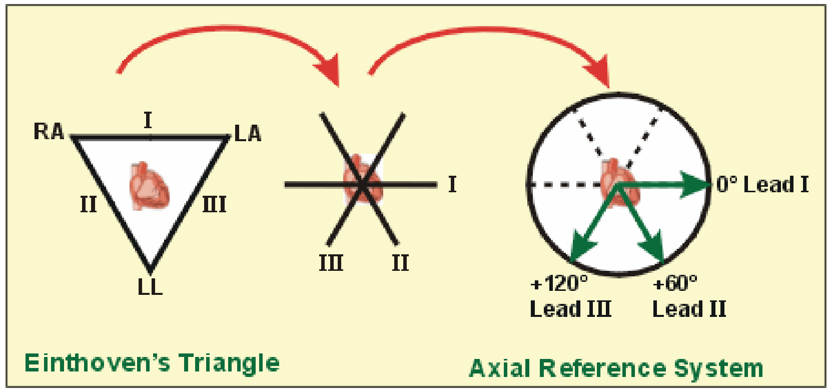


Figure 2.1d. Einthoven's triangle / axial reference system [W3]

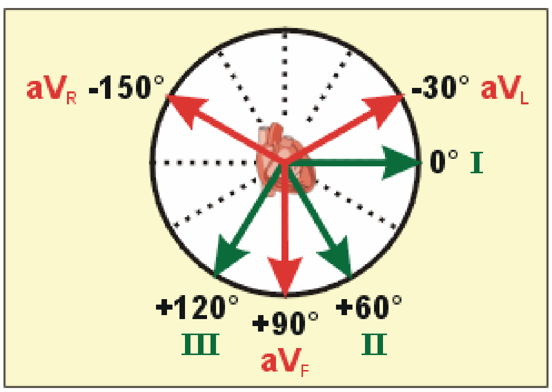


Figure 2.1e. Augmented limb leads (Unipolar) [W3]

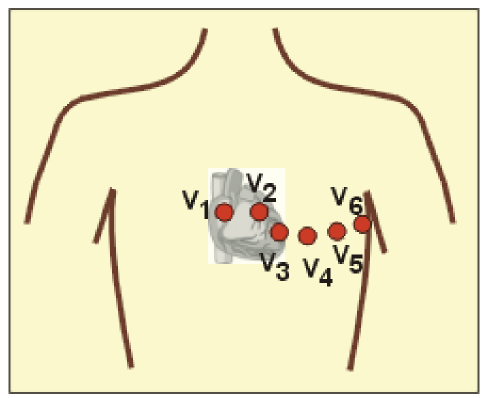


Figure 2.1f. Chest leads (unipolar) [W3]

The electrocardiogram (ECG) is a simple, non-invasive technique for detecting abnormalities and diagnosing heart defects, merely by noting the presence of irregularities in the PQRST waveform. For example an electrocardiogram may show: -

- Signs of insufficient blood flow to the heart.
- Signs of a new or previous injury to the heart (heart attack).
- Evidence of heart enlargement.
- Heart rhythm problems (arrhythmias).
- Signs of inflammation of the sac surrounding the heart.
- Changes in the electrical activity of the heart caused by a chemical (electrolyte) imbalance in the body.

Note: Electrocardiography cannot predict whether a person will have a heart attack.

2.2. Electrodes

The role of the electrodes is to act as bio-electric transducers at the interface between the body and the ECG. Inside the body, electricity exists in the form of ions. Thus, the purpose of the electrodes is to convert electricity from its ionic form in the body into an electric current in the wires.

Ag-AgCl electrodes are the current standard for use in medical applications related to biophysical instrumentation and measurements. The gel provides impedance matching at the interface between the electrode and the surface of the skin, which means that noise effects are reduced, increasing the signal-to-noise ratio, allowing for a clear signal to be detected. They are non-polarisable, meaning that the differences in potential that are measured do not depend on current variations in the wires. They are stable, easy to use, and inexpensive. See reference [W5] for detailed information on the Ag-AgCI electrode.

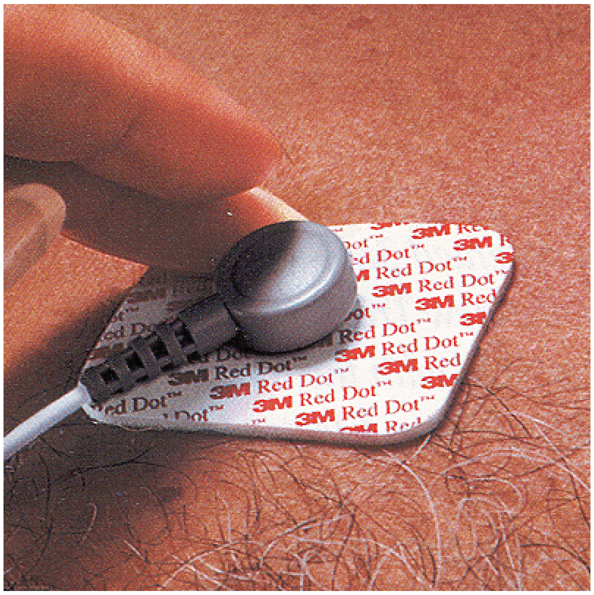


Figure 2.2b. 3M red dot electrodes cost $14.94 from [W7]

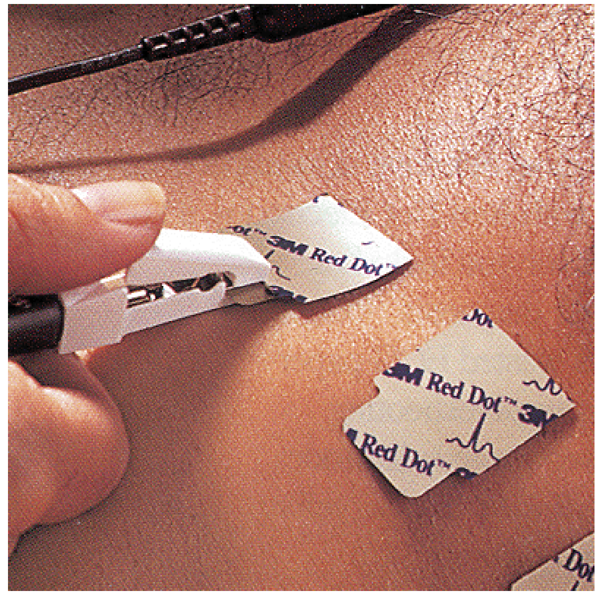


Figure 2.2c. 3M red dot resting electrodes cost $9.94 from [W7]

2.3. ECG Amplifier

The heart's strong pumping action is driven by powerful waves of electrical activity in which the muscle fibres contract and relax in an orchestrated sequence. These waves cause weak currents to flow in the body, changing the relative electric potential between different points on the skin by about 1mV. The signals can change sharply in as little as one fiftieth of a second. So boosting this signal to an easily measured one-volt level requires an amplifier with a gain of about 1,000 and a frequency response of at least 50 hertz.

At first it appears that an operational amplifier could be used. But two vexing subtleties make most op-amps unsuitable. First, when two electrodes are placed at widely separated locations on the skin, the epidermis acts like a crude battery, generating a continuously shifting potential difference that can exceed 2V. The cardiac signal is small in comparison. Second, the body and the wires in the device make good radio antennas, which readily pick up the 50Hz hum that emanates from every power cable connected to the mains supply. This adds a sinusoidal voltage that further swamps the tiny pulse from the heart and because these oscillations lie so close to the frequency range needed to rack the heart's action, this unwanted signal is difficult to filter out.

Both problems generate equal swells of voltage at the amplifier's two inputs. Unfortunately, op-amps usually can't reject these signals. To ensure that this "common-mode" garbage (whose amplitude, can be over 1,000 time greater than the cardiac signal) adds no more than a 1 percent error, a CMRR (Common-Mode Rejection Ratio) of at least 100,000 to one (100 decibels) is required. This precision eludes most op-amps.

When an application calls for both high gain and a CMRR of 80 dB or greater special devices known as "instrumentation amplifiers" are required. The AD624AD from Analog Devices (see [W12]) when set to a gain of 1,000 has a CMRR exceeding 110 dB. It is available from Farnell (order code 102-076) for £22.50. Clearly at bit expensive, hence another option is the AD620AN available from Farnell (order code 527-567) for £6.14.

Figure 2.3a shows a simple ECG amplifier using the AD624AD instrumentation amplifier. A gain of 1,000 is selected by shorting certain pins together as shown. The two-stage RC filter weeds out frequencies higher than about 50 hertz. A 3 lead cable connects the circuit to the electrodes and two wires are required to connect the output to an ADC for sampling.

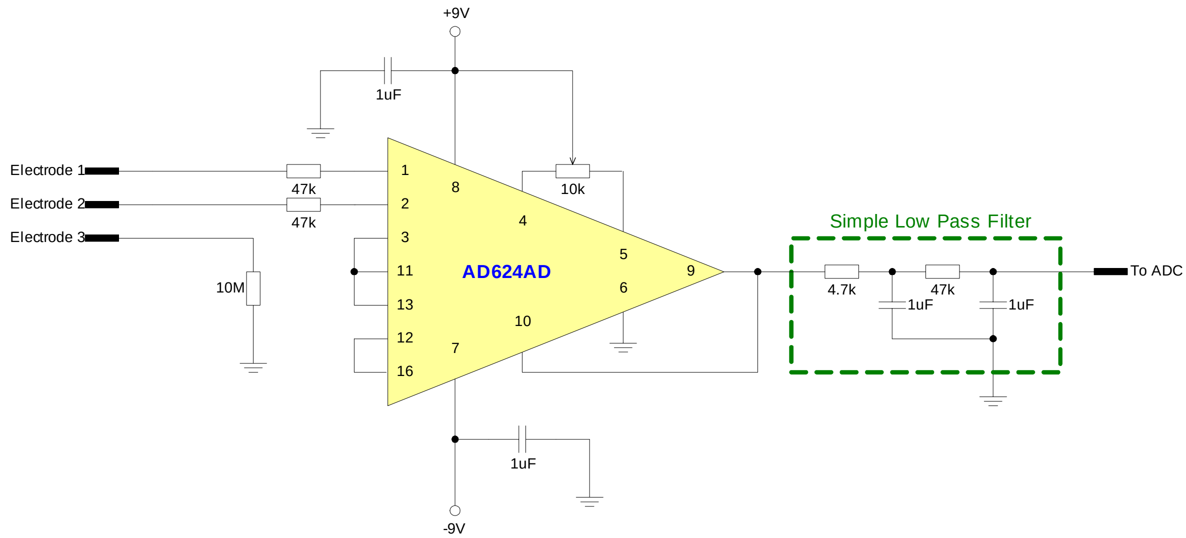


Figure 2.3a. Simple ECG Amplifier

2.4. The Cathode Ray Tube (CRT)

"The CRT is a glass bulb which has had the air removed and then been sealed with a vacuum inside. At the front is a flat glass screen which is coated inside with a phosphor material. This phosphor will glow when struck by the fast moving electronics and produce light, emitted from the front and forming the spot and hence the trace. The rear of the CRT contains the electron 'gun' assembly. A small heater element is contained within a cylinder of metal called the cathode. When the heater is activated by applying a voltage across it, the cathode temperature rises and it then emits a stream of electrons." [B2].

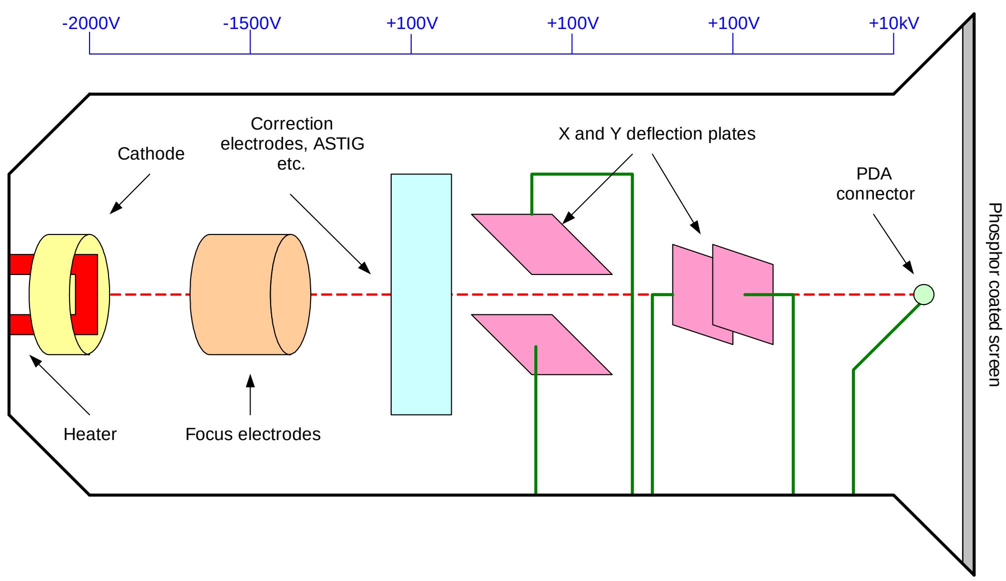


Figure 2.4a. Diagram of a typical Cathode-ray tube (CRT) construction.

A traditional analogue oscilloscope / analogue ECG machine draws its trace with a spot of light (produced by a deflectable beam of electrons) moving across the screen of its CRT (see Figure 2.4b). Basically an oscilloscope / ECG consists of the CRT, a 'time base' circuit to move the spot steadily from left to right across the screen at the appropriate time and speed, and some means (usually a 'Y' deflection amplifier) of enabling the signal to deflect the spot in the vertical or Y direction.

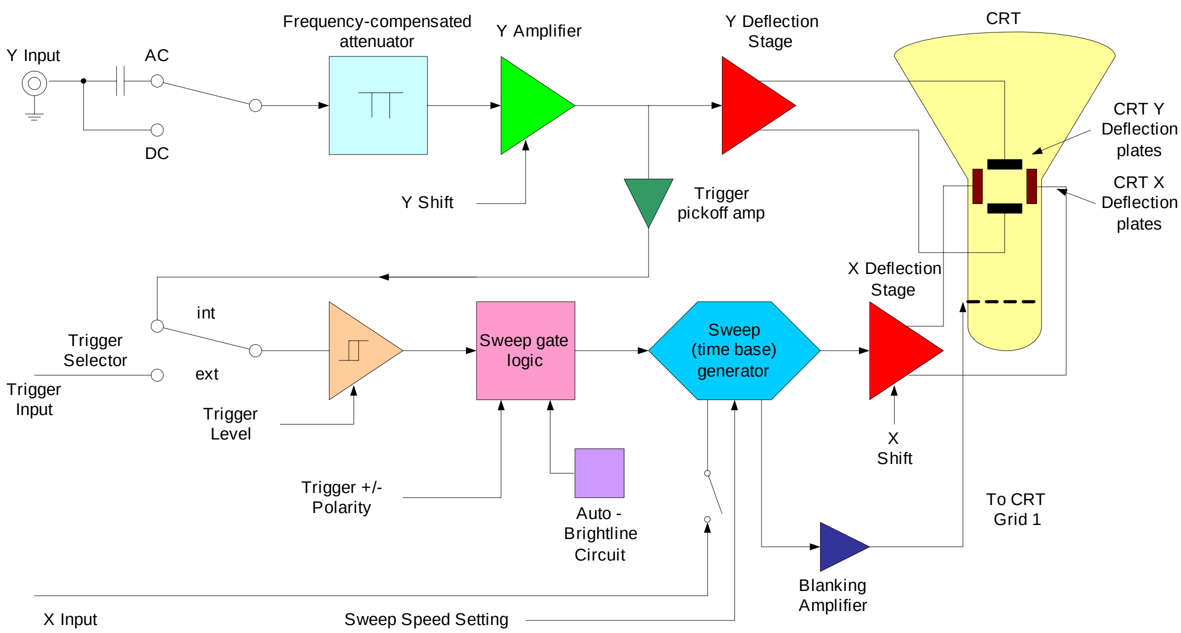


Figure 2.4b. Block diagram of a basic CRT oscilloscope; similar to a traditional analogue ECG display

2.5. Digital Sampling

Digital sampling requires an ADC (analogue-to-digital converter) to converter analogue voltages to binary representation. The sampling rate specifies the number of samples taken per second. Figure 2.5a demonstrates clearly how an analogue waveform is digitally sampled and displayed onto the screen (LCD, Computer Monitor, or a CRT using a DAC etc…).

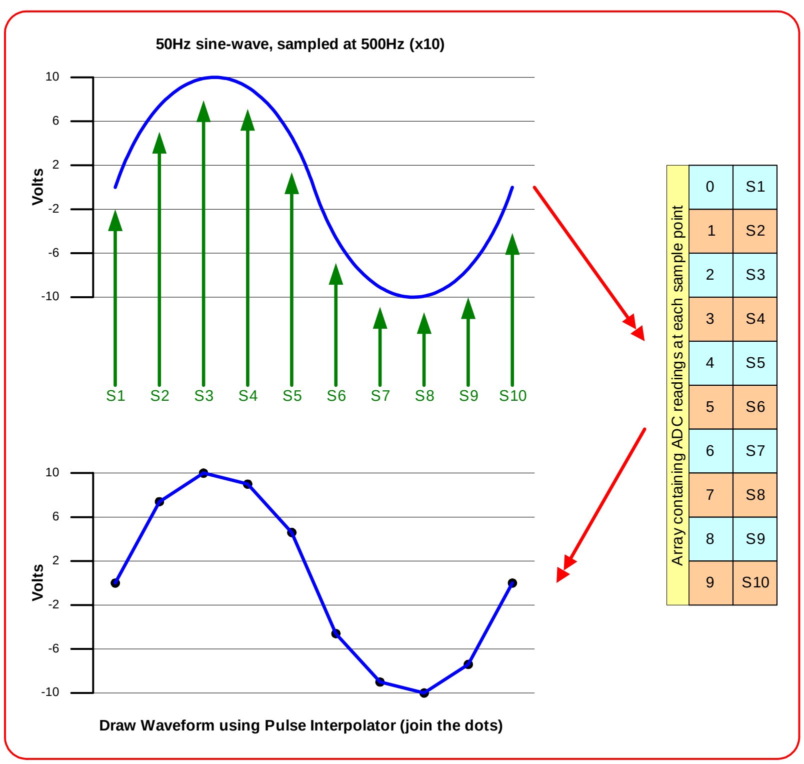


Figure 2.5a. Example showing how a sine-wave is digitally sampled

2.6. Aliasing

Aliasing is an undesirable effect that can occur when digital sampling analogue voltages. This is the display of an apparent signal which does not actually exist, usually caused by under-sampling.

Many samples should be taken per cycle (Nyquist theorem states that *"to define a sine wave, a sampling system must take more than two samples per cycle".*) to ensure an accurate representation of an analogue signal in a digital memory. If only one sample is taken per cycle, or one sample per several cycles, then aliasing occurs. For example say a waveform is being sampled every three cycles, these samples may form together, particularly when using pulse interpolation (join the dots), to look like a valid waveform.

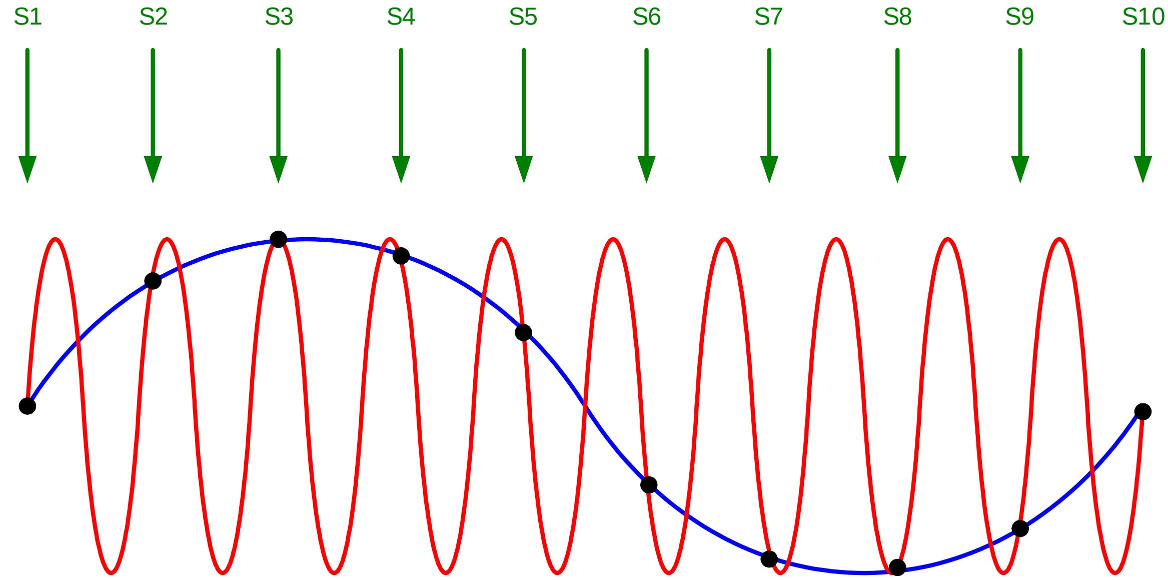


Figure 2.6a. Demonstrating aliasing, red is the real waveform, while blue is an alias.

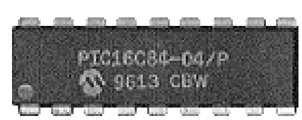
Figure 2.6a clearly demonstrates how false signals (aliasing) are created. The red waveform is the real waveform, notice that the waveform is under sampled (see green arrows for sample points). The black dots shows were the real waveform (red) has been sampled, by joining the dots, it is clear that a perfect sine-wave is created (blue), which is an alias of the original signal. Note that it is impossible to tell that the blue signal is an alias.

There is nothing that can be done after sampling to correct aliasing; hence the solution is to filter out high frequencies by sending the input signal through a low-pass filter. Ideally all frequencies above half the sample rate should be filtered out.

2.7. The PIC Microcontroller

A PIC (**P**eripheral **I**nterface **C**ontroller) microcontroller is an IC manufactured by Microchip.

MICROCHIP



These ICs are complete computers in a single package. The only external components necessary are whatever is required by the I/O devices that are connected to the PIC.

The traditional Von-Neumann Architecture (Used in: 80X86, 8051, 6800, 68000, etc…) is illustrated in Figure 2.7a. Data and program memory share the same memory and must be the same width.

"All the elements of the von Neumann computer are wired together with the one common data highway or bus. With the CPU acting as the master controller, all information flow is back and forward along these shared wires. Although this is efficient, it does mean that only one thing can happen at any time. This phenomenon is sometimes known as the von Neumann bottleneck." [B3]

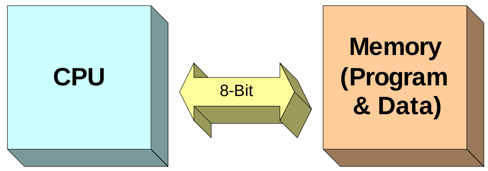


Figure 2.7a. Simplified illustration of the von Neumann architecture

PICs use the Harvard architecture. The Harvard architecture (Figure 2.7b) is an adaptation of the standard von Neumann structure with separate program and data memory: data memory is made up by a small number of 8-bit registers and program memory is 12 to 16-bits wide EPROM, FLASH or ROM.

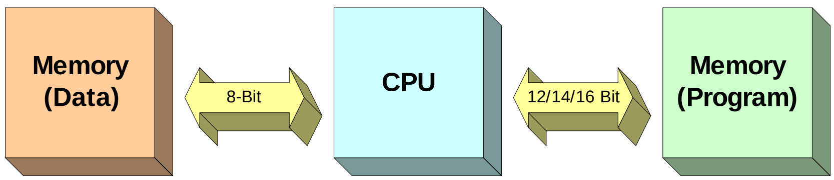


Figure 2.7b. Simplified illustration of the Harvard architecture

Traditional CISC (**C**omplex **I**nstruction **S**et **C**omputer) machines (Used in: 80X86, 8051, 6800, 68000, etc…) have many instructions (usually > 100), many addressing modes and it usually takes more than 1 internal clock cycle to execute. PIC microcontrollers are RISC (**R**educed **I**nstruction **S**et **C**omputer) machines, which have 33 (12-bit) to 58 (15-bit) instructions, reduced addressing modes (PICs have only direct and indirect), each instruction does less, but usually executes in one internal clock.

"The combination of single-word instructions, the simplified instruction decoder implicit with the RISC paradigm and the Harvard separate program and data buses gives a fast, efficient and cost effective processor implementation." [B3]

2.7.1. Summary of the PICs Built-in Peripherals

SPI (**S**erial **P**eripheral **I**nterface) uses 3 wires (data in, data out, clock), Master/Slave (can have multiple masters), very high speed (1.6 Mbps), and full speed simultaneous send and receive (full duplex).

I^2C (**I**nter **IC**) uses 2 wires (data and clock), Master/Slave. There are lots of cheap I^2C chips available; typically < 100kbps.

UART (**U**niversal **A**synchronous **R**eceiver/**T**ransmitter) with baud rates of 300bps to 115kbps, 8 or 9 bits, parity, start and stop bits, etc. Outputs 5V hence an RS232 level converter (e.g. MAX232) is required.

Timers, both 8 and 16 bits, many have prescalers and some have postscalers. In 14 bit cores they generate interrupts. External pins (clock in/clock out) can be used for counting events.

Ports have two control registers: TRIS sets whether each pin is an input or an output and PORT sets their output bit levels. Note: Other peripherals may steal pins, so in this respect peripheral registers control ports as well. Most pints have 25mA source/sink (LED enabled), but not all pins, it is important to look up the datasheet. Floating input pints must be tied off (or set to outputs).

ADCs (**A**nalogue to **D**igital **C**onverter) are currently slow, less than 54 KHz sampling rate (8, 10 or 12 bits), theoretically higher accuracy when PIC is in sleep mode (less digital noise) once the sample is complete the ADC sends an interrupt waking the PIC. Note that the PIC must wait until the sampling capacitor is charged; see datasheets.

2.8. RS232 Serial Interface

RS232 is simple, universal, well understood and supported, but it has some serious shortcomings as a data interface. Its origins predate modern computers and it contains many features that are not relevant to the modern user. It can control very old primitive modems and has many control signals to do this in hardware, but often it is used without these old control and status lines.

Its major feature is that it does not require the transmission of a clock, the reception of a 'start bit' is enough to cause the receiver to time all its actions from this one edge. This is called asynchronous transmission. RS232 allows a 5% difference in transmitted timings and receiver chip timings. This is important if using a PIC as the datasheet specifies the % error of the baud rate generator at certain baud rates (the higher the baud rate, the higher the % error), as long as this error is less than 5% the RS232 standard is capable of coping.

Electronic data communications between elements will generally fall into two broad categories: single-ended and differential. RS232 (single-ended) was introduced in 1962, and despite rumours for its early demise, has remained widely used.

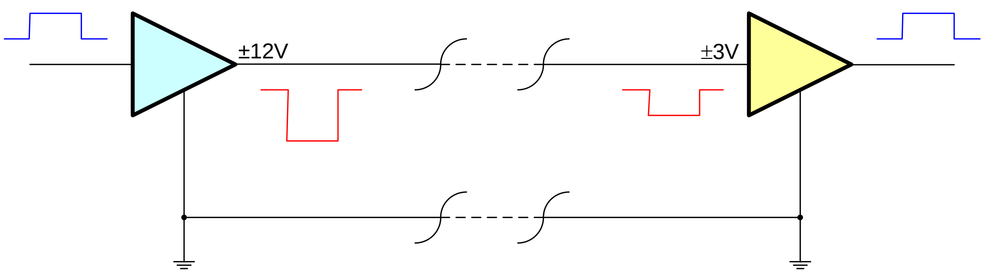


Figure 2.8a. Illustration of RS232, 1 driver and 1 receiver

"Both RS232 and RS423 are unbalanced (or single-ended) standards, where the receiver measures the potential between signal line and ground reference. Even though the transmitter and receiver grounds are usually connected though the transmission line return, the impedance over a long distance may support a significant difference in the two ground potentials, which will degrade noise immunity. Furthermore, any noise induced from the outside will affect signal lines differently from the ground return due to their dissimilar electrical characteristics – hence the name unbalanced." [B3]

RS232 data is bi-polar, e.g. a +3 to +12 volt indicates an SPACE (ON) while a -3 to -12 volt indicates an MARK (OFF). Modern computer equipment ignores the negative level and accepts a zero voltage level as the MARK (OFF) state. This means circuits powered by 5 VDC are capable of driving RS232 circuits directly; however, the overall range that the RS232 signal may be transmitted/received is dramatically reduced.

The output signal level usually swings between +12V and -12V. The 'dead area' between +3v and -3v is designed to absorb line noise. This dead area can vary for various RS232 like definitions, for example the definition for V.10 has a noise margin from +0.3V to -0.3V. Many receivers designed for RS232 are sensitive to differentials of 1v or less.

Pin	Signal	Pin	Signal
1	Data Carrier Detect	6	Data Set Ready
2	Receive Data	7	Request to Send
3	Transmit Data	8	Clear to Send
4	Data Terminal Ready	9	Ring Indicator
5	Signal Ground		

Figure 2.8b. 9-pin RS232 D-connector, pin signal description

Typical line drivers / receivers chips for RS232 are the Maxim MAX232 or MAX233 chips (see http://www.maxim-ic.com) the original specification states that RS232 should drive 50 feet, but modern line driver/receivers can manage much better than this.

Baud Rate	Max Distance Shielded Cable	Max Distance Unshielded Cable
110 bps	5000 feet	3000 feet
300 bps	5000 feet	3000 feet
1200 bps	3000 feet	3000 feet
2400 bps	1000 feet	500 feet
4800 bps	1000 feet	250 feet
9600 bps	250 feet	250 feet

Figure 2.8c. Typical maximum distance modern line driver/receivers can manage before errors occur.

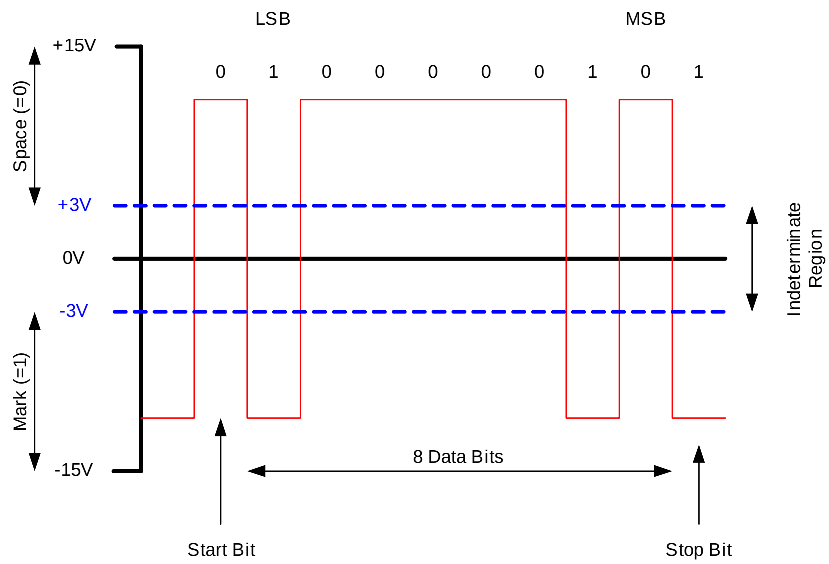


Figure 2.8d. Illustration of how data is transmitted over RS232

3.0. FEASIBILITY / INITIAL DESIGN APPROACH

The NHS (National Health Service) is in crisis, mainly due to years of severe under-funding, but partly because of the extremely high cost of modern medical equipment, drugs and overpaid doctors. Medical electronic equipment is expensive because they are low volume products that must be guaranteed to work at all times as peoples lives depend on them. The ECG monitor is one of the most widely used electronic medical device, if it is possible to produce a simple low cost product that works as well (or better) than the expensive machines in use today, organisations like the NHS could save a lot of money. Clearly there is a potential market, for a low-cost solution.

The ECG monitor proposed in this design brief must be low-cost, compact, accurate, reliable and comply with all of the associated international standards. The product must be designed for use by the medical community, allows attempts should be made to attract the use of the product by non-medical personnel (e.g. sports related), hence increasing the potential market.

The low cost of the product should not be the only aspect to attract customers, the shape, form, aesthetics, styling, tactile qualities / human interaction surfaces, visual interaction should be also considered. As research shows that most humans buy on impulses (Looks, feel of the product) rather than the technical aspect of the product because all products are expected to be technically perfect. Note most electronic engineers don't care what the product looks like, just the operation, hence they would be happy placing the product in a standard square box, drilling a couple of holes for switches and knobs. It makes since for the packaging to be design by a provisional designer and not an engineer.

3.1. Market Research and Information Analysis

Before detailed design, it is important to carry out market research on existing products. The researcher can than analysis the information discovering if it's realistic to produce a product that can complete with the existing products. The following brief list of commercial products should be studied in detail: -

Biolog 3000i 12 Lead ECG System, [W13]

- 12 Lead ECG Solution
- Biolog is a Small, lightweight
- ECG Software
- Accurate, Reliable and Rugged
- Backlit LCD screen with 2,000 pixels/cm2

£1,639.13

Pocket-sized 12 lead ECG machine, [W13]

- Light weight and compact
- Stores Multiple ECG's
- Infra red print option.
- Mains independent operation
- E-mail ECG's.
- User selectable display.

£2,344.13

12 lead ECG Acquisition Patient Cable, [W13]

- ABS Plastic.
- Dependant on PC (supplied by user).
- Complies with: AAMI EC11; IEC 601-1; IEC 601-1-1; IEC 601-1-2; IEC 601-2-25.

£1,586.25

ECG Machine (i) with LCD Display, [W13]

- Simple to Use
- Single button operation
- Accurate and reliable
- Dual Power supply
- ECG Interpretation software.

£3,172.50

ECG-120B, [W6]

- 1 Channel ECG
- Thermal array printer
- Compact design
- Audible alarm sound
- LCD message
- Digital filter

£798.263

ECG-310B, [W6]

- 3 Channel ECG
- Thermal array printer
- Compact design
- Audible alarm sound
- LCD message
- Digital filter

£1,093.27

Cardio Perfect LITE Resting ECG, [W6]

- Digital ECG using PC for display ECG.
- Automatic ECG Storage
- 5 second Pretrigger

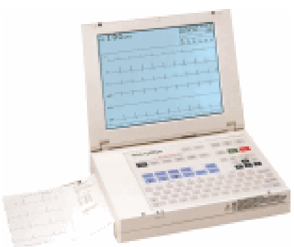
£971.09

IQMark (Brentwood by Midmark) Digital ECG, [W14]

- Digital ECG using PC for display ECG
- 12-lead ECG machine
- Digital filters

£2,255.92

Welch Allyn AT-5, [W14]



- small, notebook size system
- large 10" screen
- Built-in battery & printer
- RS-232 port

£2,950.05

Welch Allyn AT-10, [W14]

- Notebook size
- Large 10” screen
- Battery & printer
- Meets ATS, NIOSH, OSHA, and Social Security standards.
- RS-232 port

£4,494.40

Elite II and EK-10 Electrocardiographs, [W14]

- 12 lead ECG in a single or 3-channel format
- Battery operation
- simultaneous acquisition
- ECG transmission and fax option and storage for 30 ECGs

£1,093.23

Eclipse 850 Electrocardiograph, [W14]

- Three-channel backlit preview display
- Easy-to-use interface
- Automatic ECG measurements
- FAA compatibility
- Battery

£2,463.86

Welch Allyn AT-2 PLUS Combo, [W14]

- switch between ECG and spirometry with push-button ease
- Print full-size reports
- store test results for up to 60 patients
- RS-232 interface
- Rechargeable battery

£3,036.08

Eclipse 4 and 400 Electrocardiographs, [W14]

- Compact package
- Three-channel preview display
- Automatic ECG measurements
- Fax option with internal modem
- FAA compatibility
- Long life battery

£2,425.40

Clearly there are many compact portable ECG products on the market; most are easy-to-use with pleasing shape, form, aesthetics, and styling. The key aspect to note is the price (very expensive), if a low-cost solution is possible, there is a good change of commercial success as long as the product is technically suitable of medical use (e.g. must comply with all the relative international standards).

3.2. Concept Designs

The first design concept shown in figure 3.2a is very simple, basically the electronic signal of the heart is detected by electrodes, which is amplified by the differential amplifier and inputted into the micro-board. The micro-board converts the analogue ECG signal to digital and transmits the data to the PC (via RS232, USB, etc…) which then visually displays the ECG.

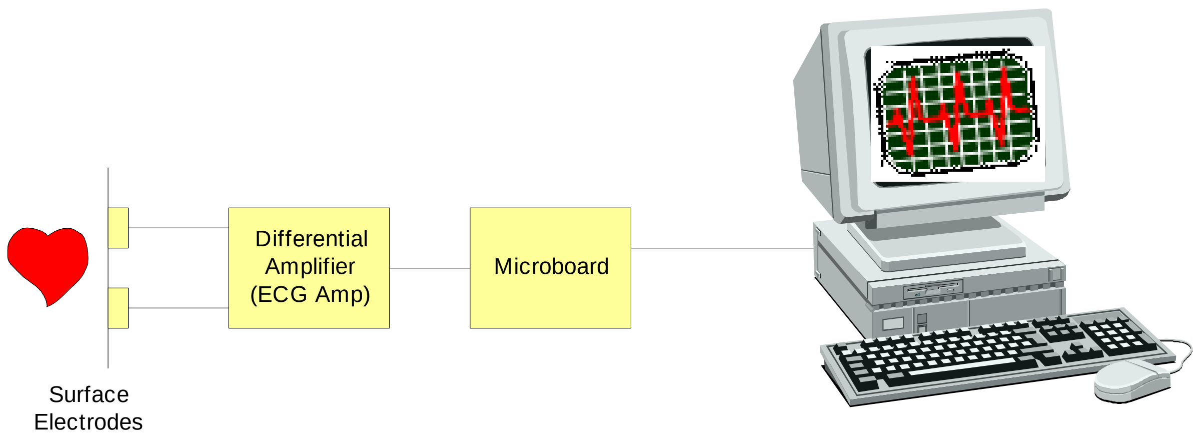


Figure 3.2a. Concept design 1, using a PC to display ECG.

Design concept 2 shown in figure 3.2b is also simple, basically the electronic signal of the heart is detected by electrodes, which is amplified by the differential amplifier and inputted into the micro-board. The micro-board converts the analogue ECG signal to digital, and generates an analogue signal to control the CRT (use oscilloscope in XY mode). The amplified ECG signal is also send through an audio amplifier to drive a speaker.

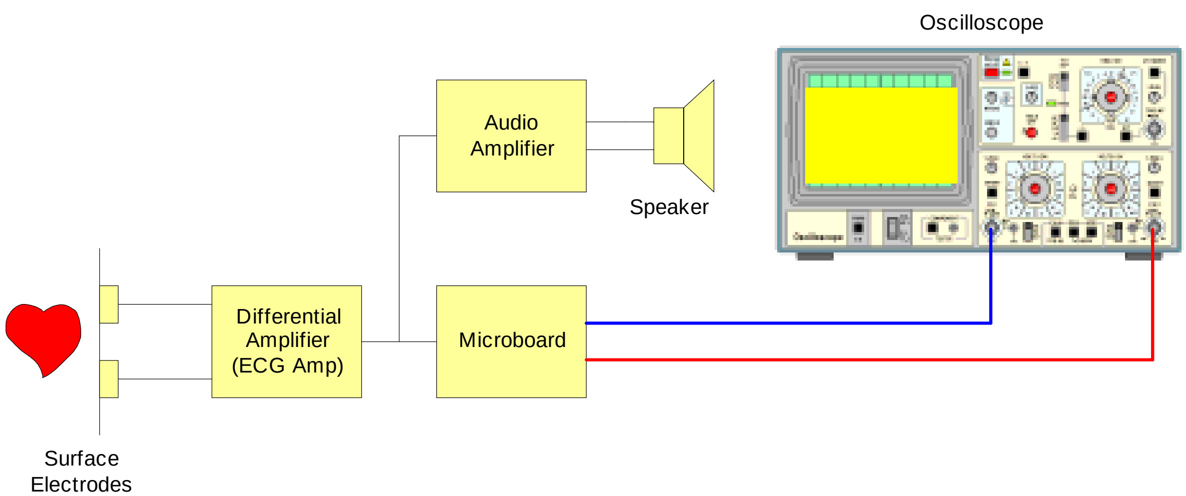


Figure 3.2b. Concept design 2, using a CRT / oscilloscope to display ECG.

Design concept 3 shown in figure 3.3b is simple, basically the electronic signal of the heart is detected by electrodes, which is amplified by the differential amplifier and inputted into the micro-board. The micro-board converts the analogue ECG signal to digital, and generates an analogue signal to control the CRT (use oscilloscope in XY mode). ECG data is also transmitted to the PC (via RS232, USB, etc…) which then visually displays the ECG. 7-segment displays display the beats per minute of the ECG, and a buzzer is used to beep for each heart beat.

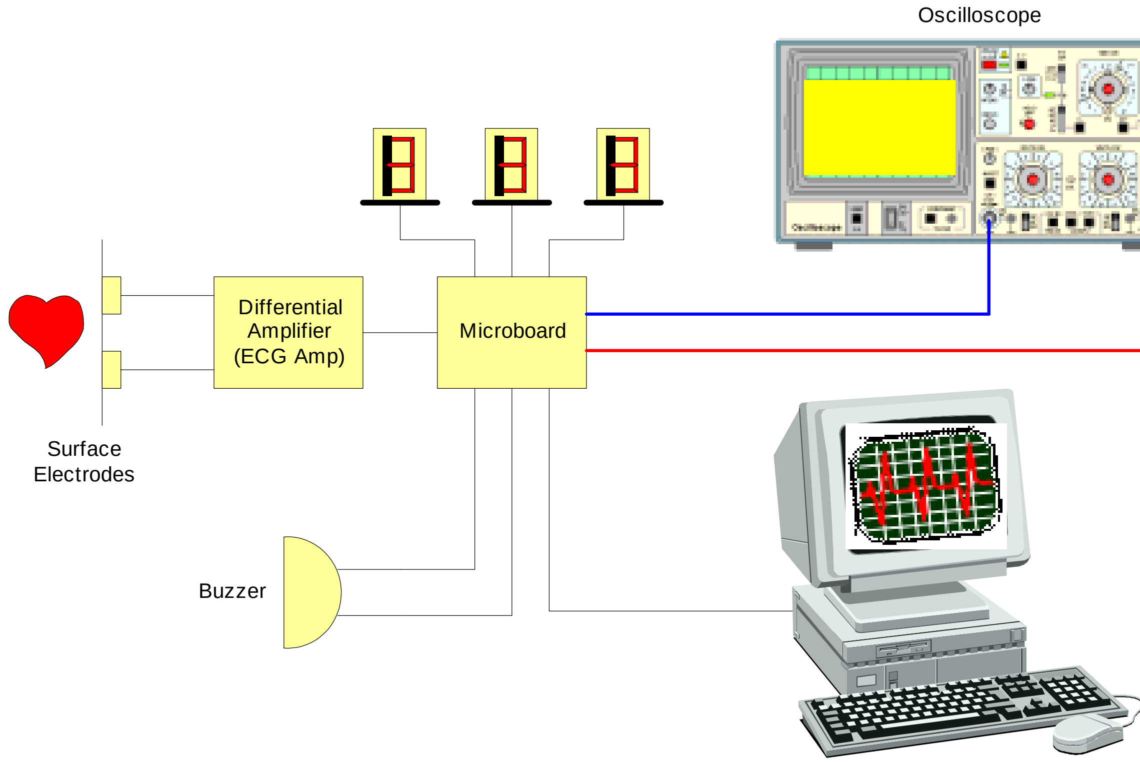


Figure 3.2c. Concept design 3, using a CRT and/or a PC to display ECG.

It was decide to developed concept 3, because it offered more features than 1&2, with only a small increase in product cost. Allow it maybe useful to have a volume control on the beeper, using a buzzer this is difficult to achieve as buzzers are either ON or OFF (some buzzers may drop in volume, if there input voltage is decreased, but this is not ideal), hence the idea from concept 2 (audio amplifier with speaker) is still an option because a volume control is easy to achieved (vary audio amplifier gain).

3.3. Initial Product Design Specification

ECG Display: Non fade with hold facility. Screen width – 50mm. Moving trace speed – 25 mm/sec Anti-glare treated screen for high contrast.

Heart Rate Display: 3 digit 7-segment numeric readout LED displays 10 seconds average rate, updated every 4 seconds. 30-240 bpm.

ECG Signal: 3 lead cable with AAMI standard 6-pin connector. Electrically isolated and fully protected from overload.

QRS Bleeper: 0-240 bpm with rear panel volume adjustment.

Surgical Diathermy: A highly effective diathermy filter will be fitted as standard. Permits continuous monitoring during electro-surgery.

Delayed Output: Operation of HOLD control stores the 3.3 seconds of ECG waveform on screen for write-out to recorder from delayed output jack after release of HOLD.

Real-time Output: Allows real-time recording of ECG from real-time output jack at a fixed gain of 1V/mW. Buffered output for driving long, high capacitance cable.

RS232 Output: Allows for transmission of ECG to PC via the RS232 serial interface.

Battery Operation: Four hours monitoring with fully charged battery pack. Four hours of recharge required for each hour of use.

Power Module: Compact convenient and independent unit with cable connection to AC outlet and monitor rear panel. Recharges batteries and permits continuous AC operation. Monitor automatically reverts to battery operation during AC power failure.
Size: 76mm x 50 mm x 152 mm
Weight: 0.7 kg

Heart Rate Limits: Upper and lower, heart rate alarms settings. Infinitely variable with audio alarms.

Power Supply: Separate mains pack to be provided this will have the ability to physically replace the battery pack.

Separate units available, suitable for either
(a) 110VAC @ 60Hz, or
(b) 220VAC @ 50Hz, or
(c) 100VAX @ 50Hz.

Weight: 3.5kg including battery pack, without separate power/charger module.

Power Switch: Front panel push-button with ON indicator light.

Low Battery: ON indicator light flashes when 15 minutes of battery operating time remains.

Lead Selection: Full lead selection under micro control.

Size: Push-button selection of 0.5, 1.0, 2.0 c/mv gain and momentary 1 mv calibration pulse.

Hold: Momentarily freezes trace on screen. Information on “hold” can be recorded from delayed output jack.

Volume: Rear panel slide control varies volume of QRS bleeper. Range includes zero volume.

Brightness: Rear panel slide control to optimise sweep displayed brightness according to ambient lighting conditions.

Bandwidth: 30 Hz or screen.

AC Power Light: Amber Neon on C power module.

Packaging: The unit should be ergonomically efficient and packaged in ABC-type plastic. As this is a low volume product a vacuum mode solution would be the most viable.

3.4. Applicable Standards

The ECG monitor should be designed and manufactured to fulfil the requirements of the Medical Device Directive 93/42/EEC of the European Community. The following standards are applicable: -

Standard	Title	Issued
EN 60601-1:1988 Amendment 1: 1991 Amendment 2: 1995	Medical Electrical Equipment Part 1: General requirements for safety.	1988 1991 1995

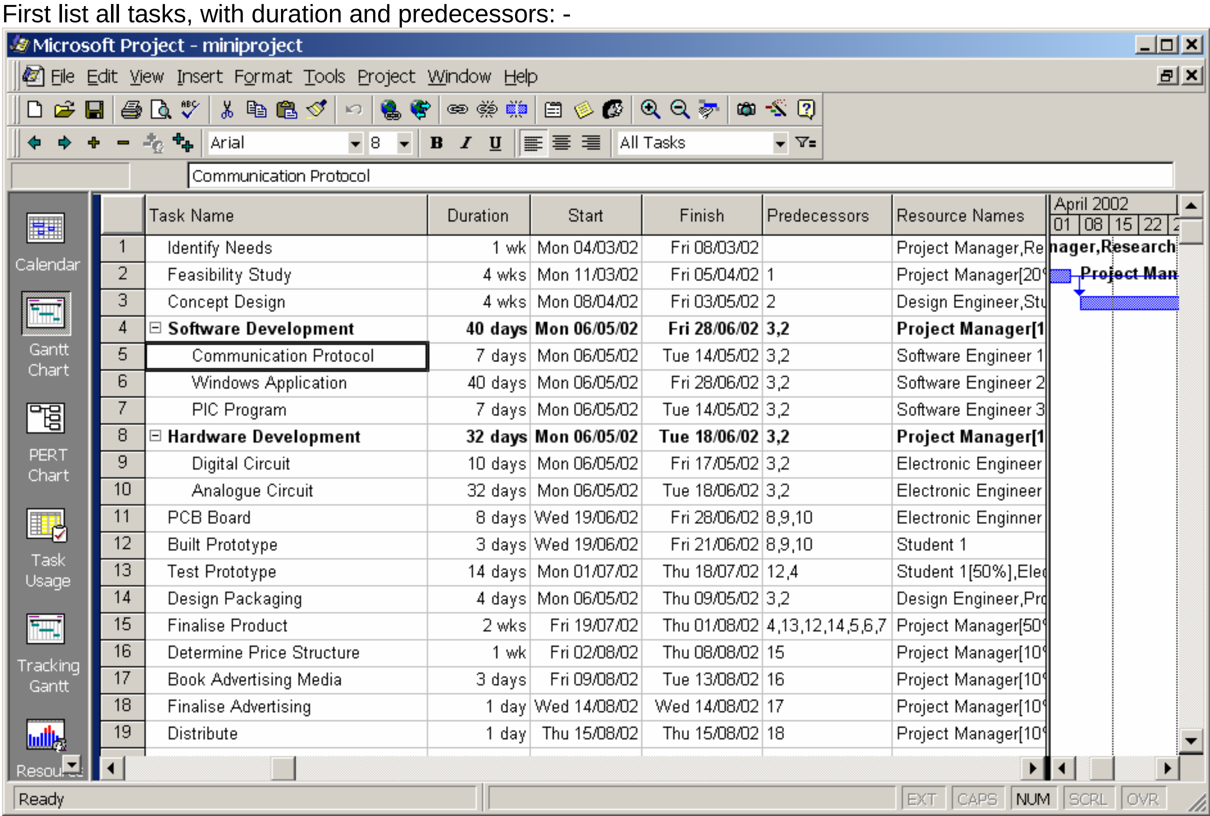
Amendment 11: 1995 Amendment 12: 1996 Amendment 13: 1996		1995 1996 1996
EN 60601-1-2:1993	<u>Medical Electrical Equipment</u> Part 1: General requirements for safety. Section 2: Collateral standard: Electromagnetic compatibility-requirements and tests.	1993
EN 60601-2-26:1995	<u>Medical Electrical Equipment</u> Part 2: Particular requirements for safety of electroencephalographs	1995
EN-ISO 9001: 1994	<u>Quality Systems</u> Model for quality assurance in design, development, production, installation and servicing.	1994
NEN-EN 46001: 1996	<u>Quality Systems</u> Particular requirements for the application of EN-ISO 9001	1996
EN 55011: 1991	Limits and methods of measurement of radio disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency equipment	1991
EN 61000-4-2	<u>Electromagnetic Compatibility</u> Part 4: Testing and measuring techniques. Section 2: Electrostatic discharge requirements.	1995
EN 61000-4-3	<u>Electromagnetic Compatibility</u> Part 4: Testing and measuring techniques. Section 3: Radiated, radio-frequency, electromagnetic field immunity test.	1996
DIN 42802: 1989	Stechverbinder Berührungsschutz für die Elektromedizin (contact protection for the electromedicine)	1998

4.0. PROJECT PLANNING AND MANAGEMENT

4.1. Planning / Development Costs

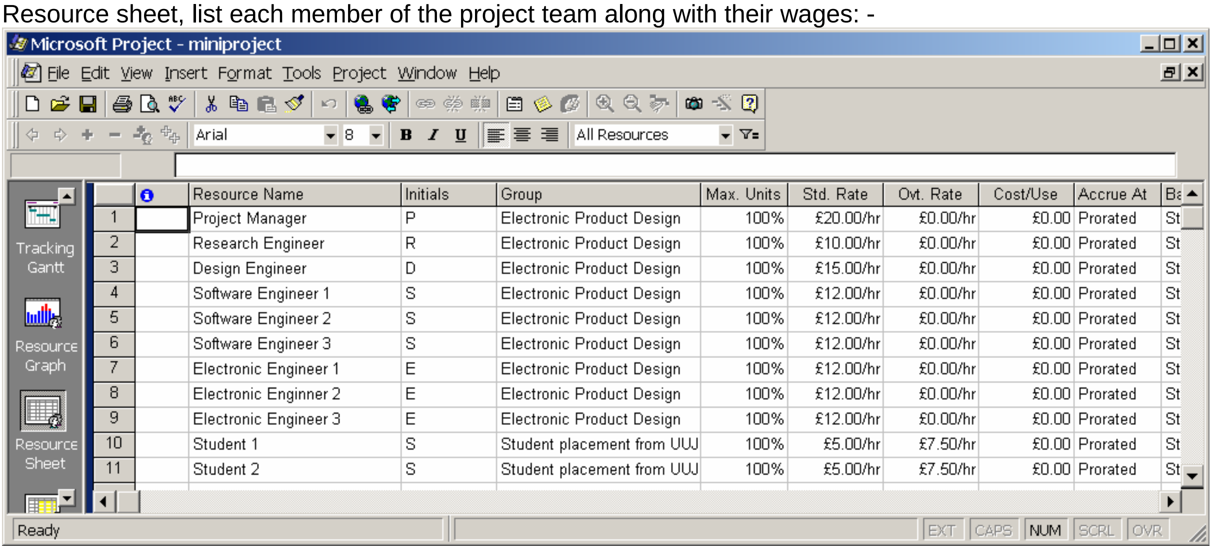
A detailed plan addressing all aspects of the project from initial brief through to manufacture, sales and distribution was made. The Microsoft Project software application was used: network, Gantt chart, resources, castings, timescale, financial planning and management planning. A selection of printouts produced by the Microsoft Project software application is attached to the end of this report (appendixes).

First list all tasks, with duration and predecessors: -



	Task Name	Duration	Start	Finish	Predecessors	Resource Names
1	Identify Needs	1 wk	Mon 04/03/02	Fri 08/03/02		Project Manager,Re
2	Feasibility Study	4 wks	Mon 11/03/02	Fri 05/04/02	1	Project Manager[20
3	Concept Design	4 wks	Mon 08/04/02	Fri 03/05/02	2	Design Engineer,Stu
4	**Software Development**	**40 days**	**Mon 06/05/02**	**Fri 28/06/02**	**3,2**	**Project Manager[1**
5	Communication Protocol	7 days	Mon 06/05/02	Tue 14/05/02	3,2	Software Engineer 1
6	Windows Application	40 days	Mon 06/05/02	Fri 28/06/02	3,2	Software Engineer 2
7	PIC Program	7 days	Mon 06/05/02	Tue 14/05/02	3,2	Software Engineer 3
8	**Hardware Development**	**32 days**	**Mon 06/05/02**	**Tue 18/06/02**	**3,2**	**Project Manager[1**
9	Digital Circuit	10 days	Mon 06/05/02	Fri 17/05/02	3,2	Electronic Engineer
10	Analogue Circuit	32 days	Mon 06/05/02	Tue 18/06/02	3,2	Electronic Engineer
11	PCB Board	8 days	Wed 19/06/02	Fri 28/06/02	8,9,10	Electronic Enginner
12	Built Prototype	3 days	Wed 19/06/02	Fri 21/06/02	8,9,10	Student 1
13	Test Prototype	14 days	Mon 01/07/02	Thu 18/07/02	12,4	Student 1[50%],Ele
14	Design Packaging	4 days	Mon 06/05/02	Thu 09/05/02	3,2	Design Engineer,Pr
15	Finalise Product	2 wks	Fri 19/07/02	Thu 01/08/02	4,13,12,14,5,6,7	Project Manager[50
16	Determine Price Structure	1 wk	Fri 02/08/02	Thu 08/08/02	15	Project Manager[10
17	Book Advertising Media	3 days	Fri 09/08/02	Tue 13/08/02	16	Project Manager[10
18	Finalise Advertising	1 day	Wed 14/08/02	Wed 14/08/02	17	Project Manager[10
19	Distribute	1 day	Thu 15/08/02	Thu 15/08/02	18	Project Manager[10

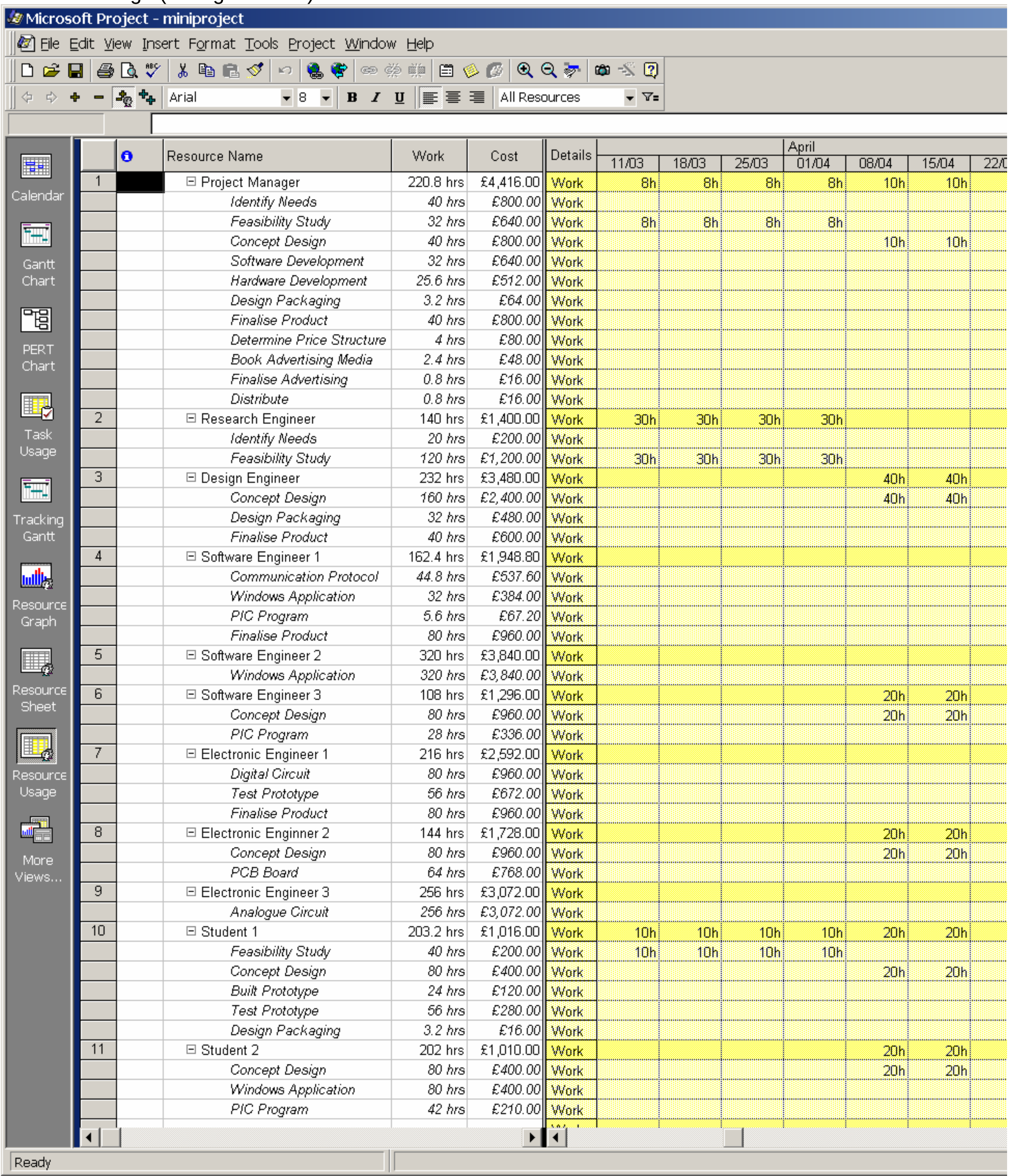
Resource sheet, list each member of the project team along with their wages: -



	Resource Name	Initials	Group	Max. Units	Std. Rate	Ovt. Rate	Cost/Use	Accrue At	Ba
1	Project Manager	P	Electronic Product Design	100%	£20.00/hr	£0.00/hr	£0.00	Prorated	St
2	Research Engineer	R	Electronic Product Design	100%	£10.00/hr	£0.00/hr	£0.00	Prorated	St
3	Design Engineer	D	Electronic Product Design	100%	£15.00/hr	£0.00/hr	£0.00	Prorated	St
4	Software Engineer 1	S	Electronic Product Design	100%	£12.00/hr	£0.00/hr	£0.00	Prorated	St
5	Software Engineer 2	S	Electronic Product Design	100%	£12.00/hr	£0.00/hr	£0.00	Prorated	St
6	Software Engineer 3	S	Electronic Product Design	100%	£12.00/hr	£0.00/hr	£0.00	Prorated	St
7	Electronic Engineer 1	E	Electronic Product Design	100%	£12.00/hr	£0.00/hr	£0.00	Prorated	St
8	Electronic Enginner 2	E	Electronic Product Design	100%	£12.00/hr	£0.00/hr	£0.00	Prorated	St
9	Electronic Engineer 3	E	Electronic Product Design	100%	£12.00/hr	£0.00/hr	£0.00	Prorated	St
10	Student 1	S	Student placement from UUJ	100%	£5.00/hr	£7.50/hr	£0.00	Prorated	St
11	Student 2	S	Student placement from UUJ	100%	£5.00/hr	£7.50/hr	£0.00	Prorated	St

The resource sheet is important as it allows Microsoft Project to calculate development costs; this is achieved by selecting who is working on each task and what percentage of their time is spent on the task.

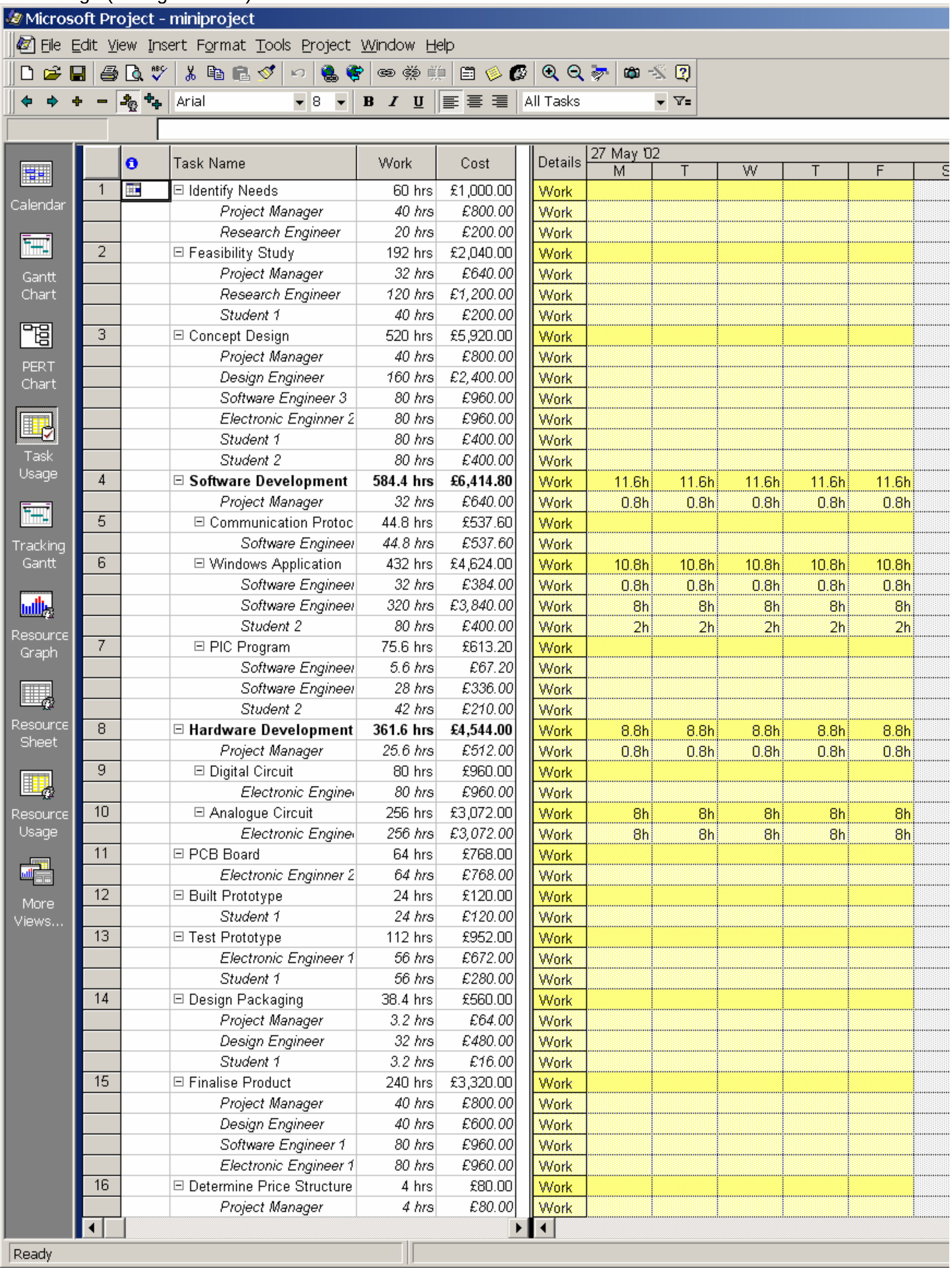
Resource usage (auto generated): -



	Resource Name	Work	Cost	Details	11/03	18/03	25/03	April 01/04	08/04	15/04	22/0
1	⊟ Project Manager	220.8 hrs	£4,416.00	Work	8h	8h	8h	8h	10h	10h	
	Identify Needs	40 hrs	£800.00	Work							
	Feasibility Study	32 hrs	£640.00	Work	8h	8h	8h	8h			
	Concept Design	40 hrs	£800.00	Work					10h	10h	
	Software Development	32 hrs	£640.00	Work							
	Hardware Development	25.6 hrs	£512.00	Work							
	Design Packaging	3.2 hrs	£64.00	Work							
	Finalise Product	40 hrs	£800.00	Work							
	Determine Price Structure	4 hrs	£80.00	Work							
	Book Advertising Media	2.4 hrs	£48.00	Work							
	Finalise Advertising	0.8 hrs	£16.00	Work							
	Distribute	0.8 hrs	£16.00	Work							
2	⊟ Research Engineer	140 hrs	£1,400.00	Work	30h	30h	30h	30h			
	Identify Needs	20 hrs	£200.00	Work							
	Feasibility Study	120 hrs	£1,200.00	Work	30h	30h	30h	30h			
3	⊟ Design Engineer	232 hrs	£3,480.00	Work					40h	40h	
	Concept Design	160 hrs	£2,400.00	Work					40h	40h	
	Design Packaging	32 hrs	£480.00	Work							
	Finalise Product	40 hrs	£600.00	Work							
4	⊟ Software Engineer 1	162.4 hrs	£1,948.80	Work							
	Communication Protocol	44.8 hrs	£537.60	Work							
	Windows Application	32 hrs	£384.00	Work							
	PIC Program	5.6 hrs	£67.20	Work							
	Finalise Product	80 hrs	£960.00	Work							
5	⊟ Software Engineer 2	320 hrs	£3,840.00	Work							
	Windows Application	320 hrs	£3,840.00	Work							
6	⊟ Software Engineer 3	108 hrs	£1,296.00	Work					20h	20h	
	Concept Design	80 hrs	£960.00	Work					20h	20h	
	PIC Program	28 hrs	£336.00	Work							
7	⊟ Electronic Engineer 1	216 hrs	£2,592.00	Work							
	Digital Circuit	80 hrs	£960.00	Work							
	Test Prototype	56 hrs	£672.00	Work							
	Finalise Product	80 hrs	£960.00	Work							
8	⊟ Electronic Enginner 2	144 hrs	£1,728.00	Work					20h	20h	
	Concept Design	80 hrs	£960.00	Work					20h	20h	
	PCB Board	64 hrs	£768.00	Work							
9	⊟ Electronic Engineer 3	256 hrs	£3,072.00	Work							
	Analogue Circuit	256 hrs	£3,072.00	Work							
10	⊟ Student 1	203.2 hrs	£1,016.00	Work	10h	10h	10h	10h	20h	20h	
	Feasibility Study	40 hrs	£200.00	Work	10h	10h	10h	10h			
	Concept Design	80 hrs	£400.00	Work					20h	20h	
	Built Prototype	24 hrs	£120.00	Work							
	Test Prototype	56 hrs	£280.00	Work							
	Design Packaging	3.2 hrs	£16.00	Work							
11	⊟ Student 2	202 hrs	£1,010.00	Work					20h	20h	
	Concept Design	80 hrs	£400.00	Work					20h	20h	
	Windows Application	80 hrs	£400.00	Work							
	PIC Program	42 hrs	£210.00	Work							

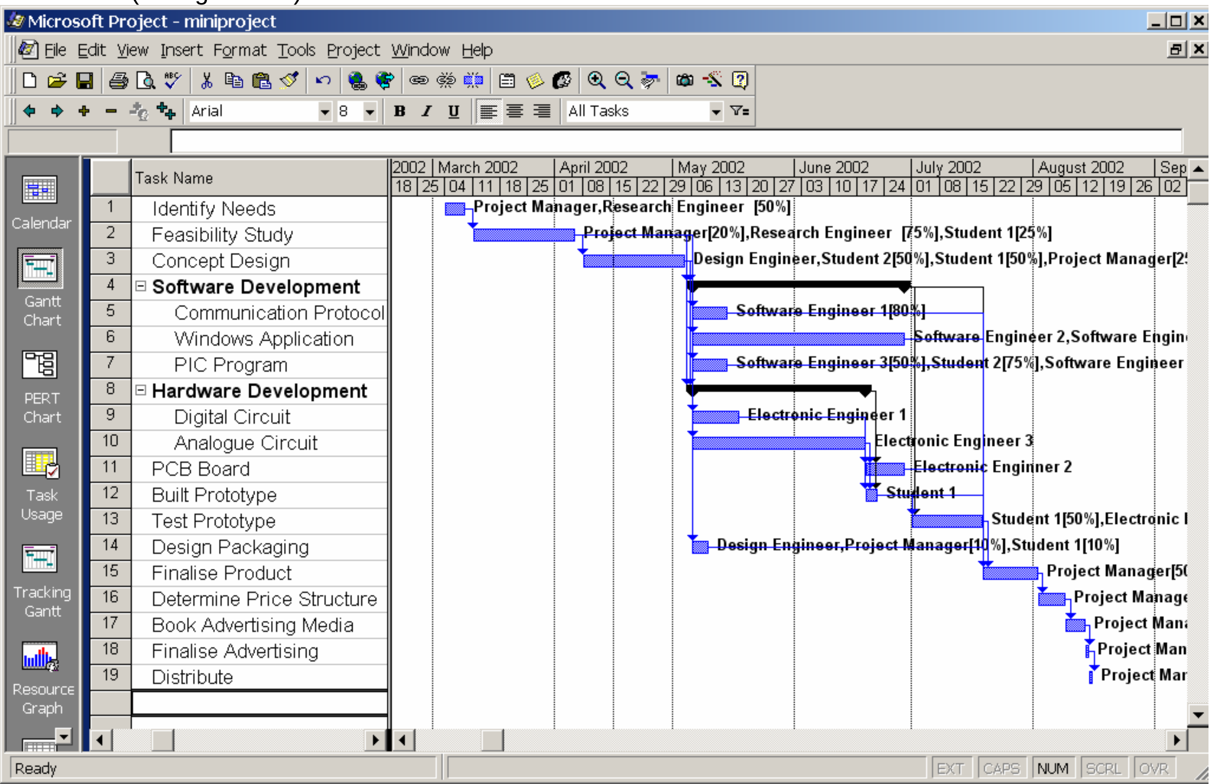
The resource usage section in MS Project summarises how many hours each employee is working on each task and the cost for their services. Notice that it is very economical to make wide use of students.

Task usage (auto generated): -

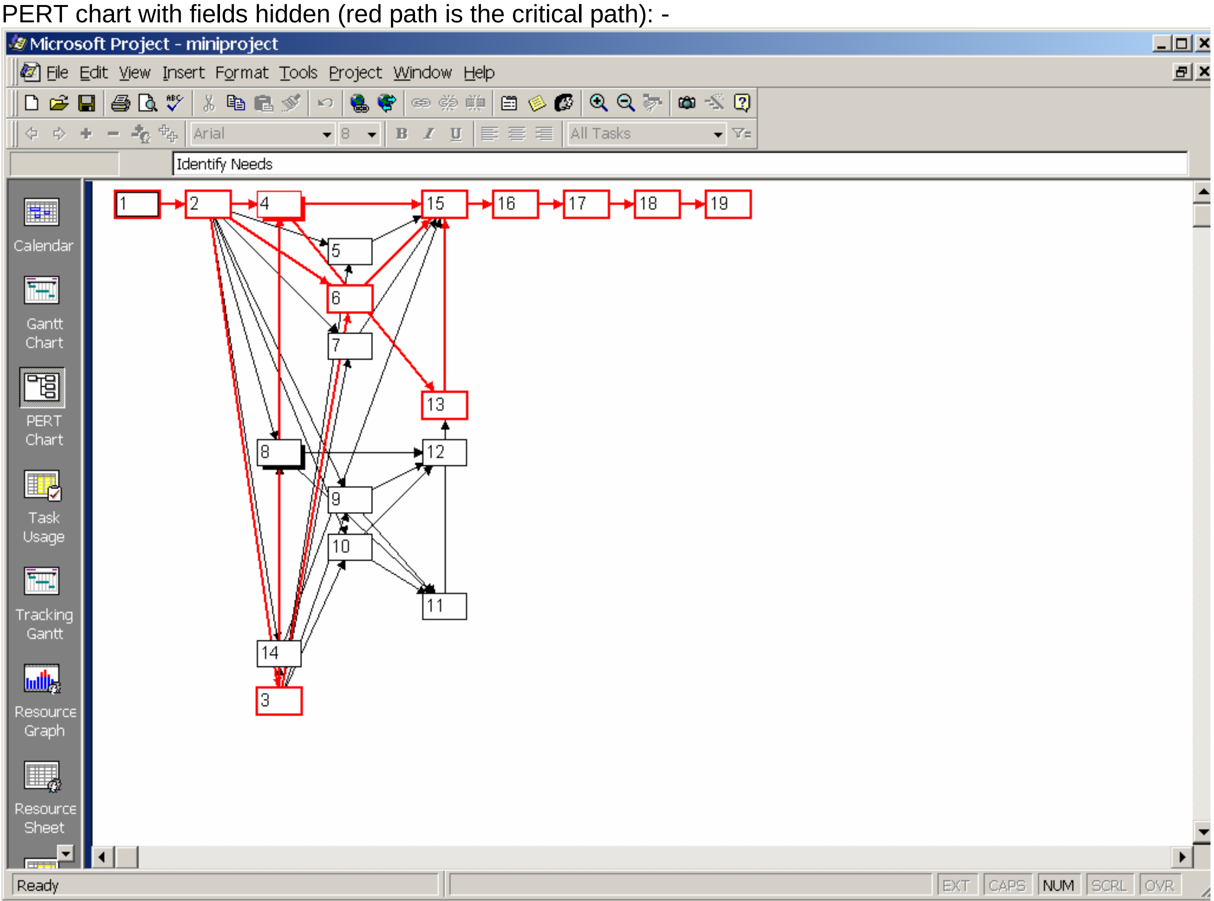


	Task Name	Work	Cost	Details	27 May '02 M	T	W	T	F	S
1	Identify Needs	60 hrs	£1,000.00	Work						
	Project Manager	*40 hrs*	*£800.00*	Work						
	Research Engineer	*20 hrs*	*£200.00*	Work						
2	Feasibility Study	192 hrs	£2,040.00	Work						
	Project Manager	*32 hrs*	*£640.00*	Work						
	Research Engineer	*120 hrs*	*£1,200.00*	Work						
	Student 1	*40 hrs*	*£200.00*	Work						
3	Concept Design	520 hrs	£5,920.00	Work						
	Project Manager	*40 hrs*	*£800.00*	Work						
	Design Engineer	*160 hrs*	*£2,400.00*	Work						
	Software Engineer 3	*80 hrs*	*£960.00*	Work						
	Electronic Enginner 2	*80 hrs*	*£960.00*	Work						
	Student 1	*80 hrs*	*£400.00*	Work						
	Student 2	*80 hrs*	*£400.00*	Work						
4	**Software Development**	**584.4 hrs**	**£6,414.80**	Work	11.6h	11.6h	11.6h	11.6h	11.6h	
	Project Manager	*32 hrs*	*£640.00*	Work	0.8h	0.8h	0.8h	0.8h	0.8h	
5	Communication Protoc	44.8 hrs	£537.60	Work						
	Software Engineei	*44.8 hrs*	*£537.60*	Work						
6	Windows Application	432 hrs	£4,624.00	Work	10.8h	10.8h	10.8h	10.8h	10.8h	
	Software Engineei	*32 hrs*	*£384.00*	Work	0.8h	0.8h	0.8h	0.8h	0.8h	
	Software Engineei	*320 hrs*	*£3,840.00*	Work	8h	8h	8h	8h	8h	
	Student 2	*80 hrs*	*£400.00*	Work	2h	2h	2h	2h	2h	
7	PIC Program	75.6 hrs	£613.20	Work						
	Software Engineei	*5.6 hrs*	*£67.20*	Work						
	Software Engineei	*28 hrs*	*£336.00*	Work						
	Student 2	*42 hrs*	*£210.00*	Work						
8	**Hardware Development**	**361.6 hrs**	**£4,544.00**	Work	8.8h	8.8h	8.8h	8.8h	8.8h	
	Project Manager	*25.6 hrs*	*£512.00*	Work	0.8h	0.8h	0.8h	0.8h	0.8h	
9	Digital Circuit	80 hrs	£960.00	Work						
	Electronic Engine	*80 hrs*	*£960.00*	Work						
10	Analogue Circuit	256 hrs	£3,072.00	Work	8h	8h	8h	8h	8h	
	Electronic Engine	*256 hrs*	*£3,072.00*	Work	8h	8h	8h	8h	8h	
11	PCB Board	64 hrs	£768.00	Work						
	Electronic Enginner 2	*64 hrs*	*£768.00*	Work						
12	Built Prototype	24 hrs	£120.00	Work						
	Student 1	*24 hrs*	*£120.00*	Work						
13	Test Prototype	112 hrs	£952.00	Work						
	Electronic Engineer 1	*56 hrs*	*£672.00*	Work						
	Student 1	*56 hrs*	*£280.00*	Work						
14	Design Packaging	38.4 hrs	£560.00	Work						
	Project Manager	*3.2 hrs*	*£64.00*	Work						
	Design Engineer	*32 hrs*	*£480.00*	Work						
	Student 1	*3.2 hrs*	*£16.00*	Work						
15	Finalise Product	240 hrs	£3,320.00	Work						
	Project Manager	*40 hrs*	*£800.00*	Work						
	Design Engineer	*40 hrs*	*£600.00*	Work						
	Software Engineer 1	*80 hrs*	*£960.00*	Work						
	Electronic Engineer 1	*80 hrs*	*£960.00*	Work						
16	Determine Price Structure	4 hrs	£80.00	Work						
	Project Manager	*4 hrs*	*£80.00*	Work						

Gantt chart (auto generate): -



PERT chart with fields hidden (red path is the critical path): -



Development costs: -

ID	Task Name	Fixed Cost	Fixed Cost Accrual	Total Cost	Baseline	Variance	Actual
3	Concept Design	£0.00	Prorated	£5,920.00	£0.00	£5,920.00	£0.00
6	Windows Application	£0.00	Prorated	£4,624.00	£0.00	£4,624.00	£0.00
15	Finalise Product	£0.00	Prorated	£3,320.00	£0.00	£3,320.00	£0.00
10	Analogue Circuit	£0.00	Prorated	£3,072.00	£0.00	£3,072.00	£0.00
2	Feasibility Study	£0.00	Prorated	£2,040.00	£0.00	£2,040.00	£0.00
1	Identify Needs	£0.00	Prorated	£1,000.00	£0.00	£1,000.00	£0.00
9	Digital Circuit	£0.00	Prorated	£960.00	£0.00	£960.00	£0.00
13	Test Prototype	£0.00	Prorated	£952.00	£0.00	£952.00	£0.00
11	PCB Board	£0.00	Prorated	£768.00	£0.00	£768.00	£0.00
7	PIC Program	£0.00	Prorated	£613.20	£0.00	£613.20	£0.00
14	Design Packaging	£0.00	Prorated	£560.00	£0.00	£560.00	£0.00
5	Communication Protocol	£0.00	Prorated	£537.60	£0.00	£537.60	£0.00
12	Built Prototype	£0.00	Prorated	£120.00	£0.00	£120.00	£0.00
16	Determine Price Structure	£0.00	Prorated	£80.00	£0.00	£80.00	£0.00
17	Book Advertising Media	£0.00	Prorated	£48.00	£0.00	£48.00	£0.00
18	Finalise Advertising	£0.00	Prorated	£16.00	£0.00	£16.00	£0.00
19	Distribute	£0.00	Prorated	£16.00	£0.00	£16.00	£0.00
		£0.00		**£24,646.80**	**£0.00**	**£24,646.80**	**£0.00**

4.2. Pareto Concept

The Pareto principle states that there are a ‘critical few and trivial many.’ This concept can be applied to inventory management using ABC analysis and cost estimating (a small number of elements have a large effect on the total cost of project).

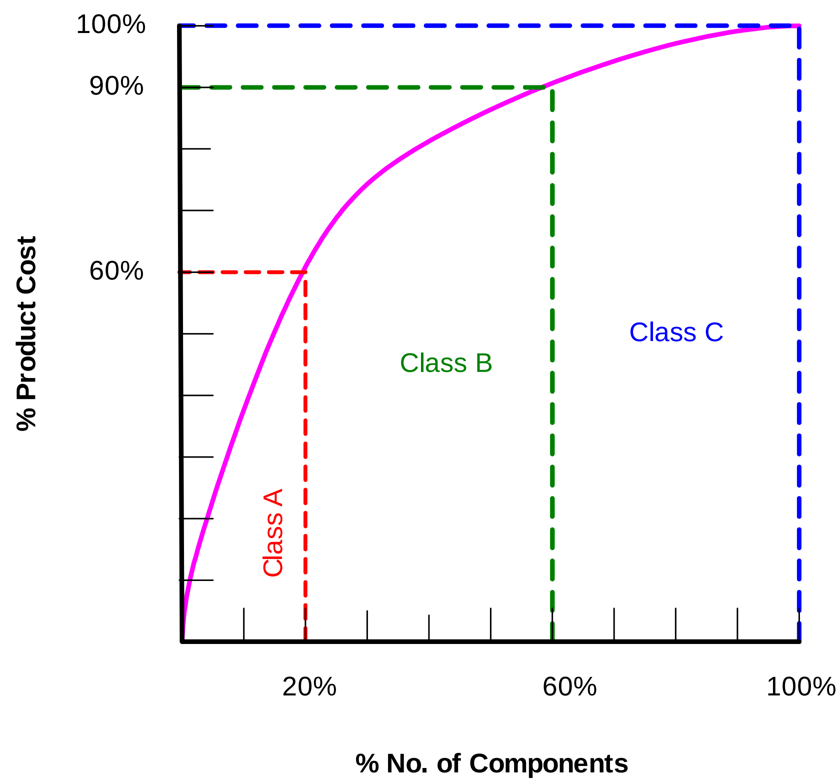


Figure 4.2a. Pareto Curve

ABC Analysis divides on-hand inventory into 3 classes, A class, B class and C class. Basis is usually annual £ volume (**£ volume = Annual demand x Unit cost**).

Class A (say 20% of items): -

- Develop class A suppliers more.

- Give tighter physical control of A items.
- Forecast A items more carefully.

Class B (say the next 40% of items): -

- A reorder cycle system could control this class.

Class C (Next 40% of items): -

- A two-bin or annual demand system could manage the final 40%.

The analysis requires items to be listed with their unit costs and annual volume. Judgment is needed on critical items or security matter that Pareto analysis in itself does not reveal. Remember in assembly situations where items from A, B and C are combined in an assembly, a C item out of stock can delay production just as much as an A or B item.

4.3. Predicted Product Cost (Ball Park Assessment)

PARETO			COMPONENTS OF COST						COST OF COMP
			MATERIAL			LABOUR			
GEN	**DET**	**ITEM**	**RAW**	**S/C**	**PROP**	**M/C**	**INSP**	**ASSY**	
0.6	0.2	ECG Amplifier	£1	-	£30	£3	£3	£3	£40.00
	0.15	Battery pack and charger	-	-	£22	-	£8	-	£30.00
	0.13	Diathermy filter	-	-	£22	-	£4	-	£26.00
	0.12	$12V_{DC}$ power supply	-	-	£20	-	£4	-	£24.00
0.3	0.11	Printed circuit board	-	-	£10	-	£6	£6	£22.00
	0.065	ABS plastic outer casing	-	-	£13	-	-	-	£13.00
	0.05	RS232 null modem cable	-	-	£10	-	-	-	£10.00
	0.04	3 lead ECG cable	-	-	£8	-	-	-	£8.00
	0.035	Microcontroller (PIC16F877)	-	-	£7	-	-	-	£7.00
0.1	0.03	Other PCB components	-	-	£6	-	-	-	£6.00
	0.02	8k RAM Chip (M6264P)	-	-	£4	-	-	-	£4.00
	0.01	Dual DAC (ZN508E)	-	-	£2	-	-	-	£2.00
	0.01	Piezo alarm	-	-	£2	-	-	-	£2.00
	0.008	7-segment LED Display X3	-	-	£1.60	-	-	-	£1.60
	0.006	X38-bit latch (74LS377) X3	-	-	£1.20	-	-	-	£1.20
	0.005	RS232 line buffer (max232)	-	-	£1	-	-	-	£1.00
	0.005	330R Resistor Network X3	-	-	£1	-	-	-	£1.00
	0.003	AAMI standard 6-pin plug	-	-	£0.60	-	-	-	£0.60
	0.003	9-way PCB D-type plug	-	-	£0.60	-	-	-	£0.60
-	-	**FINAL ASSEMBLY**	-	-	-	-	-	£5	£5.00
-	-	**FINAL INSPECTION**	-	-	-	-	£5	-	£5.00
		SUB TOTALS	£1	£0	£162	£3	£30	£14	£210
		GROSS TOTALS	£163			£47			£210
		MANUFACTURING CONTINGENCY							£105
		MAXIMUM MANUFACTURING COST							£315

Ball Park Assessment Method: -

1. List all components/assemblies in the product.

2. Assess most expensive and least expensive items and determine probable cost order.
   E.g. ECG Amplifier = 0.2, Batter pack and charger = 0.15, etc…

3. Rearrange components / assemblies in descending order of cost.
   E.g. ECG Amplifier (0.2) most expensive, 9-way PCB D-type plug (0.003) least expensive

4. Apply Pareto rating, first general then detailed.
   E.g. split items into three groups 60% (class A), 30% (class B) and 10% (class C) of total cost.

5. Estimate or otherwise determine the cost of one component / assembly.
   E.g. ECG Amplifier estimated at £40.

6. Divide this cost by its Pareto rating for total component / assembly (product) ball park cost.
   E.g. 40/.20 = £200

7. Add a generous contingency for Ball Park manufacturing cost.
   E.g. Say 50% of gross cost: £210 + 50% = £315.

8. Determine Individual costs of component.
   E.g. Microcontroller (PIC16F877) = 0.035*200= £7.00.

9. Determine the operative components of costs' areas involved.

10. Assess components of cost.

11. Add final inspection, final assembly, final test etc.

12. Determine manufacturing cost including estimating contingency.

13. Add PISC + sales / admin + profit to get factory selling price.
    E.g. Say 20%, hence factory selling price is £378.

14. Allow for retail mark-up (20-25%)
    E.g. Say 20%, hence **retail selling price is £453.60.**

Note: This entire costing exercise is accomplished without any design work, this is a pre-emptive technique.

19 items were included in the costing sheet: -

- 4 items (21% of items) contributed to 60% of the total component cost.
- 5 items (26% of items) contributed to 30% of the total component cost.
- 10 items (52% of items) contributed to 10% of the total component cost.

4.4. Line Balancing

A balanced line is one where each work station is allocated a package of work which will take an equal amount of time to complete as every other work station on the line. In practise this is difficult to achieve, allow there are a couple standard manual methods (largest candidate rule, Kilbridge and Wester's method, ranked positional weights method) that managers can use to obtain a good solution (computational software also exists). All methods provide a good solution approaching the true optimum and focus management attention on problem areas.

Precedence constraints describe a situation where an operation must be carried out before another operation can start. Positive zoning means that particular work element should be placed near to each other, and negative zoning means that particular work elements should not be placed near to each other. Position constraint (physical size) means that workers come to the product to perform their work. A precedence diagram is a diagrammatical representation of the sequence of work elements as defined by the precedence constraints.

The following list of work elements could describe the production of the ECG monitor for a line with a production rate of 60 units/hr. At a line efficiency of 100%, the value of the cycle rate is 1.0 min (i.e. the ideal cycle time is 1 min). Note: this is an example of line-balancing, values are crude approximations designed to demonstrate the method; in the real-world it is important to carry out work measured (timing of each element) and know exactly how many items need to be produced per hour.

Work Element	Element Description	T_e	Predecessors
1	Check PCB board (e.g. broken tracks, etc…)	0.2	…
2	Assemble plug to power cord	0.4	…
3	Populate PCB board	0.7	1
4	Test PCB board	0.1	1,3
5	Assemble PCB board to ABS plastic case	0.3	4
6	Wire power cord to transformer (via power switch and mains lamp)	0.11	2,5
7	Assemble metal cage for electrostatic protection	0.4	…
8	Insert rechargeable battery	0.11	7
9	Assemble the rear panel slide control	0.3	4
10	Attach cover	0.38	6,8,9
11	Testing	0.5	10
12	Place in bay for packing.	0.12	11

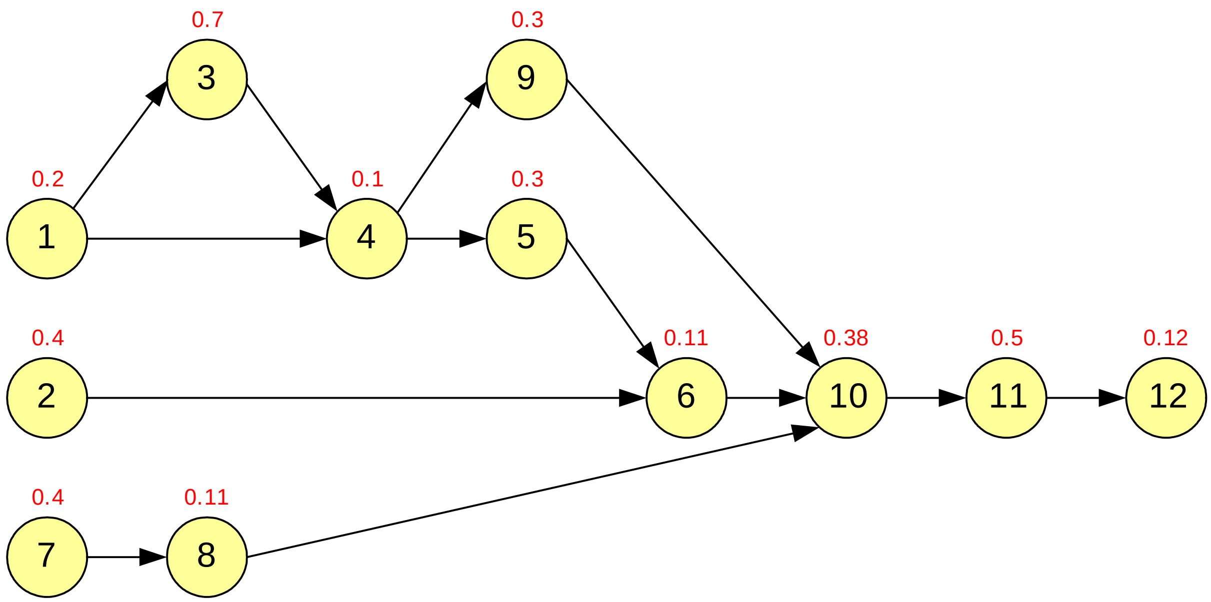


Figure 4.4a. Precedence Diagram

Note: T_C = Ideal cycle time = theoretical cycle time.
T_e = time associated with a work element.
n = No of work stations on assembly line.
d = Balancing loss $\cong$ Balancing delay.

Step 1: Calculate ranked positional weight (RPN) for each work element by summing the elements T_e with all T_e's of elements that follow it in the precedence diagram.

W_e	RPM	T_e	RPM Calculation
1	2.71	0.2	0.2 + 0.7 + 0.1 + 0.3 + 0.3 + 0.11 + 0.38 + 0.5 + 0.12
2	1.51	0.4	0.4 + 0.11 + 0.38 + 0.5 + 0.12
3	2.51	0.7	0.7 + 0.1 + 0.3 + 0.3 + 0.11 + 0.38 + 0.5 + 0.12
4	1.81	0.1	0.1 + 0.3 + 0.3 + 0.11 + 0.38 + 0.5 + 0.12

5	1.41	0.3	0.3 + 0.11 + 0.38 + 0.5 + 0.12
6	1.11	0.11	0.11 + 0.38 + 0.5 + 0.12
7	1.51	0.4	0.4 + 0.11 + 0.38 + 0.5 + 0.12
8	1.11	0.11	0.11 + 0.38 + 0.5 + 0.12
9	1.3	0.3	0.3 + 0.38 + 0.5 + 0.12
10	1	0.38	0.38 + 0.5 + 0.12
11	0.62	0.5	0.5 + 0.12
12	0.12	0.12	0.12

Step 2: Make a table with the largest RPN at the top.

W_e	RPM	T_e
1	2.71	0.2
3	2.51	0.7
4	1.81	0.1
2	1.51	0.4
7	1.51	0,4
5	1.41	0.3
9	1.4	0.3
6	1.11	0.11
8	1.11	0.11
10	1	0.38
11	0.62	0.5
12	0.12	0.12

Step 3: Assign each W_e to a work station according to precedence's and time constraint.

Work Station No.	Element (W_e)	T_e	Sum of T_e @ W.Station
1	1 3 4	0.2 0.7 0.1	1.0
2	2 7 6	0.4 0.4 0.11	0.91
3	5 9 8 12	0.3 0.3 0.11 0.12	0.83
4	10 11	0.38 0.5	0.88
		$\sum w_e$	3.64

Balancing delay $d = \frac{nT_C - \sum w_e}{nT_C} \times 100 = \frac{4(1) - 3.64}{4(1)} \times 100 = \frac{0.36}{4} \times 100 = 9\%$

5.0. SYSTEM ARCHITECTURE

5.1. System Block Diagram

The proposed design is shown in block diagram form in figure 5.1a, it is clear that there are two main features: displaying the ECG on a CRT display (e.g. use an oscilloscope) and transmitting the data to a PC in real-time to display and log ECG data.

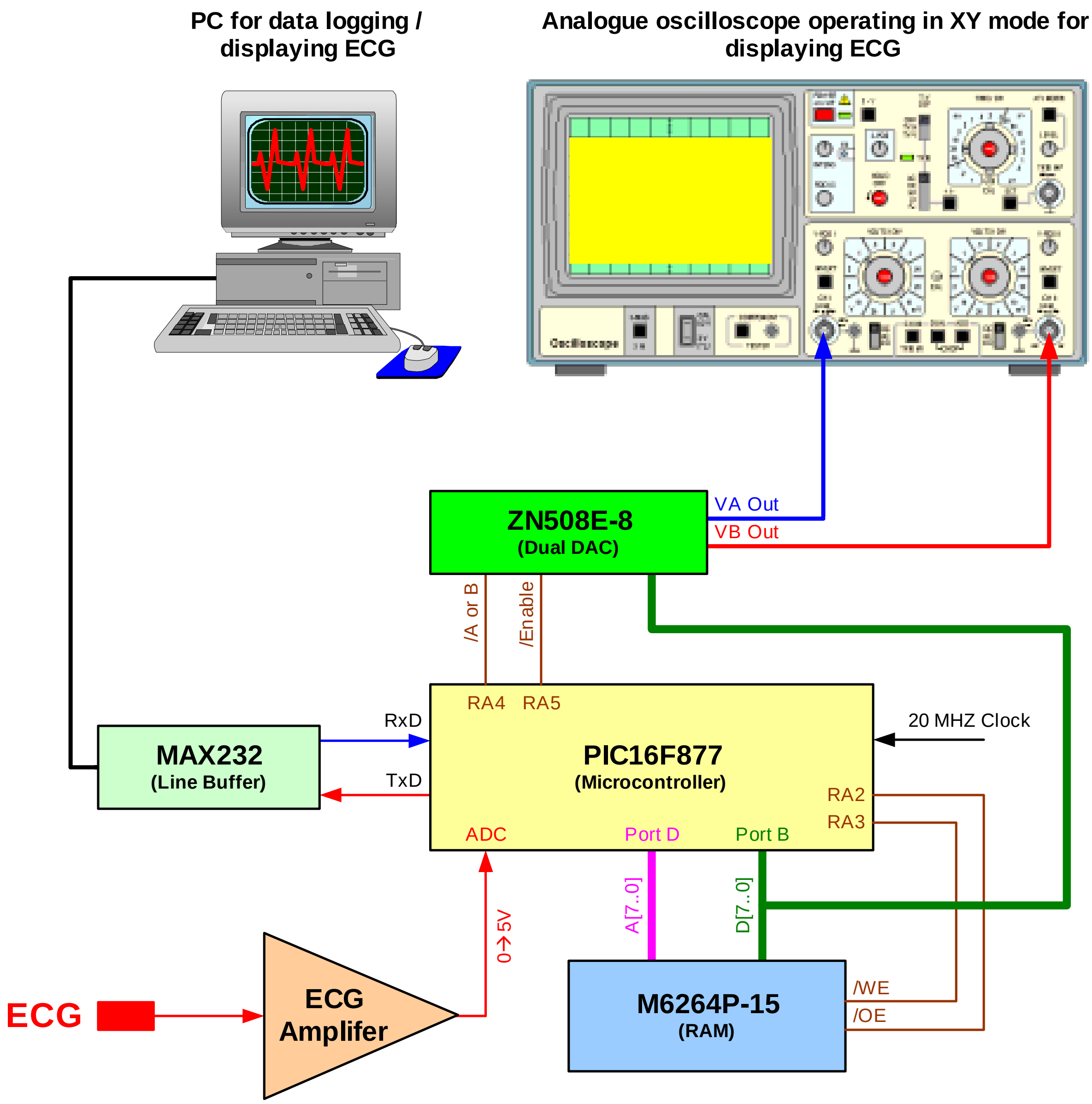


Figure 5.1a. Simplified block diagram of the system

Obviously the design of a Windows based software application is required to log and display ECG signals directly from the serial port. This application should be user-friendly, i.e. easy-to-use using standard Windows interface dialog controls (users are familiar with these controls). Clearly since serial communication is used a simple but effective communication protocol is required.

The heart of the system is the PIC16F877 microcontroller: *"The PIC16F877 is a high-performance FLASH microcontroller that provides engineers with the highest design flexibility possible. In addition to 8192x14* *words of FLASH program memory, 256 data memory bytes, and 368 bytes of user RAM, PIC16F877 also features an integrated 8-channel 10-bit Analogue-to-Digital converter. Peripherals include two 8-bit timers, one 16-bit timer, a Watchdog timer, Brown-Out-Reset (BOR), In-Circuit-Serial Programming™, RS-485 type UART for multi-drop data acquisition applications, and I2C™ or SPI™ communications capability for peripheral expansion. Precision timing interfaces are accommodated through two CCP modules and two PWM modules."* [W15]

The ECG signal (form electrodes place on the chest, arms and legs) is inputted into the ECG amplifier. The propose of the amplifier is to amplify the signal to a level that the PICs Analogue-to-Digital Converter (ADC) can sample (e.g. a common mode gain of 1000, hence the 1mV ECG signal is amplified to 1V).

The design specification specifies that there should be at least 2 seconds of data on the CRT display at any one time. Since time-compressed memory is used to obtain a flicker free trace, and it is known that the size of the memory is 256 bytes, the sample rate must be 128 Hz, e.g. the RAM will take 2 seconds to fill.

Notice that the block diagram shows an external RAM chip, this chip is optional because the chosen PIC has more than enough internal RAM. The external RAM chip is for flexibility, as the time-compressed memory uses 75% of the PICs internal RAM and if complex software processing (automatic diagnostic) of the signal is required (sometime in the future after the product is released, e.g. software upgrade) there may not be enough free internal RAM.

A dual digital-to-analogue converter (DAC) is used to convert digital data into analogue voltage. This chip is controlled by the PIC to manipulate the CRT trace, e.g. X (DAC A) and Y (DAC B) specifies the position of the spot, this spot moves faster than 50Hz across the screen hence it appears as a solid waveform to the human eye.

The MAX232 line buzzer converts PIC TTL logic (0V for logic 0, 5V for logic 1) into RS232 logic (12V for logic 0, -12V for logic 1).

5.2. Partitioning Decisions

Figure 5.2a splits software development into 3 main areas; simultaneous development of all three areas is possible. Figure 5.2b splits hardware development into 4 main areas: simultaneous development is possible for 3 of the 4 areas, as PCB design cannot start until the digital and analogue circuit has been designed.

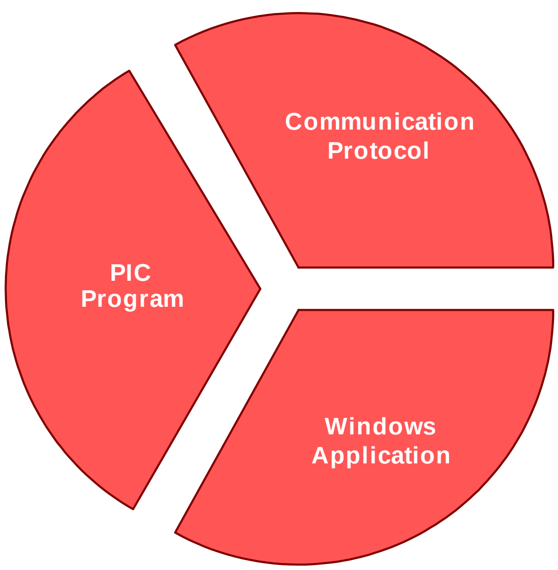


Figure 5.2a. Software Partitioning

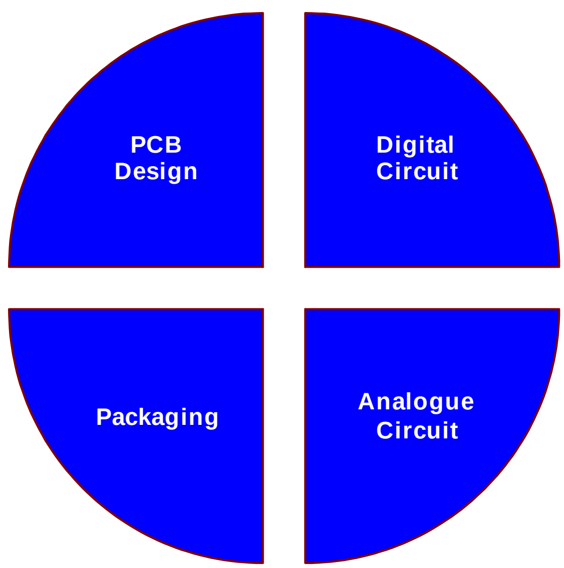


Figure 5.2b. Hardware Partitioning

Each partition could be given to a different engineer, with many partitions being developed simultaneously, allow there will be some overlap between partitions (e.g. 7-segment displays mounted on the PCB board must line up with holes in plastic case). Each partition can be split into sub-partitions, for example: -

Communication Protocol
- Concept design.
- Design of frame structure.
- Error checking, e.g. CRC.
- Test Program.
- Functional Testing.

Windows Application
- RS232 object.
- ECG Graphical Display.
- User Interface.
- Internet communications.
- Streaming ECG to disk (data logging).

PIC Program
- Time compressed memory.
- RS232 communications.
- Calculation of BPM for 7-segment displays.

PCB Design
- Top layer.
- Bottom layer.
- Ground plane.
- Separation of analogue and digital circuit to reduce noise.

Digital Circuit
- 7-seqment LED display circuit.
- Beeper circuit.
- RAM circuit
- DAC circuit.
- MAX232 circuit.

Analogue Circuit
- Power supply.
- ECG amplifier.
- Low pass filter.
- Diathermy filter.
- Noise reduction.

Packaging
- Size and shape of ABC plastic case.
- Colour, symbols, position of ports and controls.

This partitioning technique is extremely useful, as even the most complex of tasks can be split into a number of small simple tasks. The design of something as large as a plane for example would be impossible without the use of this partitioning method as the design is far too complex for one person to fully understand all aspects of design, hence it is split into partitions (e.g. engine, landing gear, etc…) then sub-partitions and partitions of the sub-partitions etc… until the partitions are small enough to be manageable tasks.

Besides the obvious (simplify design) this partitioning technique has many advantages, the main one is system flexibility. For example the software program for the PIC can be written in one large block, this will work, but it is not flexible as changes cannot be easily made, e.g. calculation of ECG bpm may be spread throughout the code, hence it would be difficult to debug/change, a change to this code could effect other parts of the program as the whole program is intertwined. It is common practice to partition software into blocks known as functions, e.g. a function is written to calculate bpm, this function can be tested independently of other program code, and can easily be modified in the future. Hardware partitioning has the same benefit, e.g. the 7-segment display circuit can be changed without affecting any other part of the circuit.

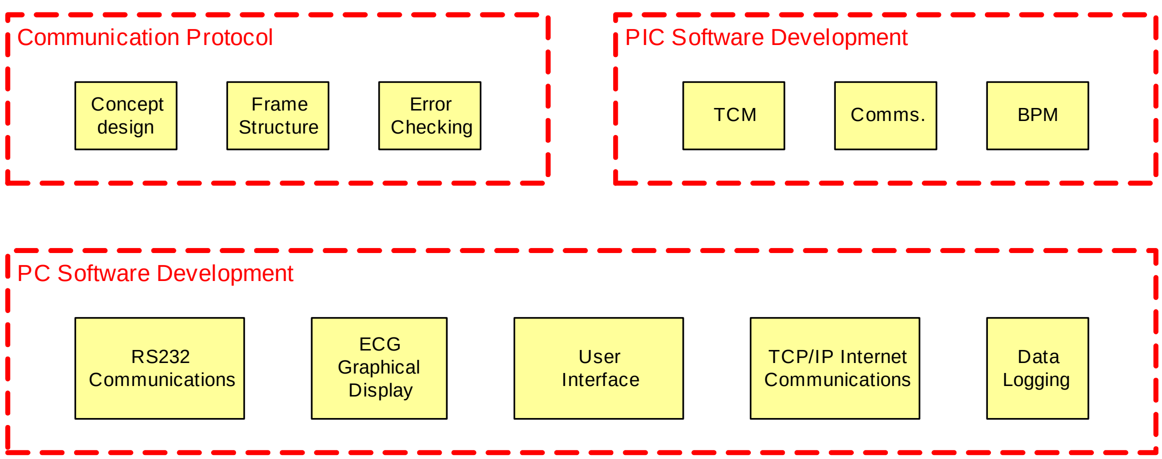


Figure 5.2c. Software development architecture

Figure 5.2c clearly shows how the software development could be partitioned. The communication protocol and PIC software development blocks are small enough for a software engineer to work on each block. But clearly the PC software development block is large and a group of software engineers could work on various aspects of this block, for example an engineer on the graphical display, another on the user interface, another on RS232 & TCP/IP internet and another on data logging.

Figure 5.3d clearly shows how the hardware development could be partitioned. An engineer could work on the power supply circuit while another works on the ECG amplifier and another on the low-pass / anti-aliasing filter. One engineer will design the PCB, a design engineer will design the packaging after some feedback from the electronic engineers, and an engineer will work on the digital circuit.

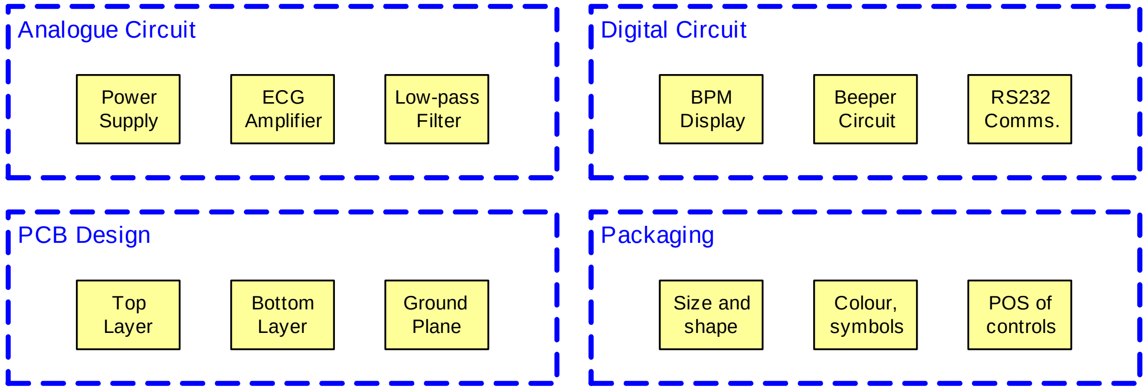


Figure 5.2d. Hardware development architecture

6.0. PHYSICAL DESIGN

The shape, form, aesthetics, styling, tactile qualities / human interaction surfaces and visual interaction of the ECG monitor could determine if the product is a commercial success or a failure.

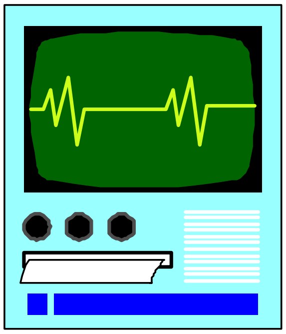


Figure 6.0a. ECG Monitor

Figure 6.0a shows the shape of traditional ECG monitor; clearly it's a square box. If engineers had their way everything would simply be put into a square box, but in terms of attracting customers the dull old square has no chance. The attraction of the design could be improved by simply rounding the edges.

The controls, display, and sockets should be layouted in a logical and neat manor. Styling of the product is extremely important, it should have unique style that sets it apart form any other product on the market, and colour should be chosen wisely for example bright colours may attract someone's attention.

Human interaction surfaces and tactile qualities, must be right, as certain textures feel bad (e.g. cheap plastic feel), while others give the impression of quality.

Plastics are characterised by high strength-to-density ratios, excellent thermal and electrical insulation properties, and good resistance to acids, alkalis, and solvents. The giant molecules of which they consist may be linear, branched, or cross-linked, depending on the plastic. Linear and branched molecules are *thermoplastic* (soften when heated), whereas cross-linked molecules are *thermosetting* (harden when heated).

The ECG monitor should be ergonomically efficient and packaged in ABS-type plastic. As this is a low volume product a vacuum mode solution would be the most viable. ABS-type plastic was chosen because it is a tough, heat-resistant thermoplastic making it ideal for this project.

The manufacture of the plastic case will be carried by a plastic specialist company charging an agreed price for each case. Generally the larger the quality to be manufactured the lower the production cost, but there are high tooling costs involved with the large production method of manufacture which are no viable for low volume products (like this ECG monitor).

6.1. ABS Plastic (Acrylonitrile Butadiene Styrene)

ABS is a graft copolymer made by dissolving styrene-butadiene copolymer in a mixture of acrylonitrile and styrene monomers, then polymerizing the monomers with free-radical initiators in an emulsion process. Grafting of acrylonitrile and styrene onto the copolymer chains occurs by chain-transfer reactions. ABS was patented in 1948 and introduced to commercial markets by the Borg-Warner Corporation in 1954.

ABS is a tough, heat-resistant thermoplastic. The three structural units provide a balance of properties, the butadiene groups (predominantly trans-1,4) imparting good impact strength, the acrylonitrile affording heat resistance, and the styrene units giving rigidity. ABS is widely used for appliance and telephone housings, luggage, sporting helmets, pipe fittings, and automotive parts.

6.2. Manufacture of Plastics

The manufacture of plastic and plastic products involves procuring the raw materials, synthesising the basic polymer, compounding the polymer into a material useful for fabrication, and moulding or shaping the plastic into its final form.

Most plastics today are derived from petrochemicals. These oil-based raw materials are more widely available and less expensive than other raw materials. However, because the world supply of oil is limited, other sources of raw materials, such as coal gasification, are being explored.

The first stage in manufacturing plastic is polymerisation. The two basic polymerisation methods are condensation and addition reactions. These methods may be carried out in various ways. In bulk polymerisation, the pure monomer alone is polymerised, generally either in gaseous or liquid phase, although a few solid-state polymerisation's are also used. In solution polymerisation, an emulsion is formed and then coagulated. In interfacial polymerisation, the monomers are dissolved in two immiscible liquids, and the polymerisation occurs at the interface of the two liquids.

Chemical additives are often used in plastics to produce some desired characteristic. For instance, antioxidants protect a polymer from chemical degradation by oxygen or ozone; similarly, ultraviolet stabilisers protect against weathering. Plasticizers make a polymer more flexible, lubricants reduce problems with friction, and pigments add colour. Among other additives are flame retardant and antistatic.

6.3. Shaping of Plastic

Plastic products are made from plastic resins, which melt into a syrupy liquid when heated. There are several standard manufacturing techniques for shaping plastics (see figure 6.3a for illustrations), many of which could be used in manufacture of the ABS plastic case of the ECG monitor.

Figure 6.3a. Illustrations of manufacturing techniques for shaping plastics, source [MS Encarta Encyclopaedia 96]

Compression moulding uses heat and pressure to shape plastics. The process is commonly used to mould thermosetting plastics.

Injection moulding shoots molten plastic material under pressure into a mould. It is the most widely used method of moulding thermoplastics.

Blow moulding produces hollow objects. It uses air or steam to expand a tube of molten resin, forcing the material against a mould's walls.

Casting does not depend on any external pressure to shape the plastics. In the casting process, melted resin is simply poured into a mould. Manufacturers use casting to produce thick, solid objects.

Extrusion is used to produce such continuous forms as pipe, rods, fibbers, wire coatings and supermarket plastic bags. Rotating screw force the plastics through a heated barrel, in which they melt, then force them out through a specially shaped die.

Calendering produces plastic sheets by pressing molten plastic material between two rollers. Manufacturers also feed fabric, paper, or other materials through the rollers to produce such items as tablecloths and playing cards.

Laminating involves coating sheets of such materials as wood, paper, or metal foil with plastics. The sheets are then stacked and pressed together to make such products as plywood, electronic circuit boards, and tabletops.

Foaming is any of several methods that produce solid plastics filled with air spaces. To make Styrofoam, for example, manufacturers use beads of thermoplastic resin containing a chemical that forms a gas when heated during moulding.

Thermoforming is used to mould items from sheets of plastics. A sheet is clamped over a mould and heated until it becomes soft. A vacuum pump sucks air out through tiny holes in the mould, drawing the sheet into the mould.

6.4. Health and Environmental Hazards of Plastics

Because plastics are relatively inert, they do not normally present health hazards to the maker or user. However, some monomers used in the manufacture of plastics have been shown to cause cancer. Similarly, benzene, which is an important raw material for the synthesis of nylon, is a carcinogen. The problems involved in the manufacture of plastics parallel those of the chemical industry in general.

Most synthetic plastics are not environmentally degradable; unlike wood, paper, natural fibres, or even metal and glass, they do not rot or otherwise break down over time. (Some degradable plastics have been developed, but none has proven compatible with the conditions required for most sanitary landfills.) Thus, there is an environmental problem associated with the disposal of plastics.

7.0. ELECTRONIC / SOFTWARE DESIGN

7.1. Design Considerations

Accuracy, dependability, and precision are an absolute must if the device were to be used for diagnostic, or other medical purposes. Any small fluctuation in the waveform generated could carry critical diagnostic value, thus it is extremely important that the clinician can confidently and fully rely on the equipment. This means that the ECG must faithfully display the cardiac signal exactly as it exists in reality, such that any irregularity detected did in fact arise from an unhealthy cardiac cycle, *not* from the equipment that was used. Therefore, there were many special considerations that had to be taken into account when designing the ECG Monitor.

Noise:
First and foremost in these considerations is the effect of *noise*. Noise interference in the signal detection process would be detrimental to the experiment, as the ECG signal is at such small amplitudes it could easily be masked by noise related fluctuations. Therefore in order to detect the signal accurately, there must be strict limitations on the acceptable level of noise allowed, and every possible attempt must be made to minimise this level and reduce the effects of noise on the data acquisition process.

Signal Amplitude:
Another consideration that strongly influenced the design of the ECG is the fact that the cardiac signal generated has a very small peak amplitude. (As stated above, this is the very signal attribute that makes noise control so vital). Considerable amplification is necessary if there is any use to be made from the cardiac signal in terms of analysis and output. Also, the small size of the signal plays a very influential role in the approach to creating a system of visual output. Caution has to be taken to effectively differentiate between actual changes in the signal amplitude as opposed to a random variation in noise amplitude.

Low frequency:
Because the signal that is generated from the cardiac muscle has such a low bandwidth, it is very important that the ECG have a good low frequency response. This is because any shifts in the frequency of the detected signal, especially the S-T portion of the waveform, carry critical diagnostic value.

7.2. System Powering

Figure 7.2a shows the circuit diagram; clearly a 5V regulator is used to generate a 5 volt DC output to power the circuit. The 0.1µF capacitors absorb line noise, while the 100µF capacitors are used for storage in the event of a minor drop in power (milliseconds) the circuit operation will not be affected.

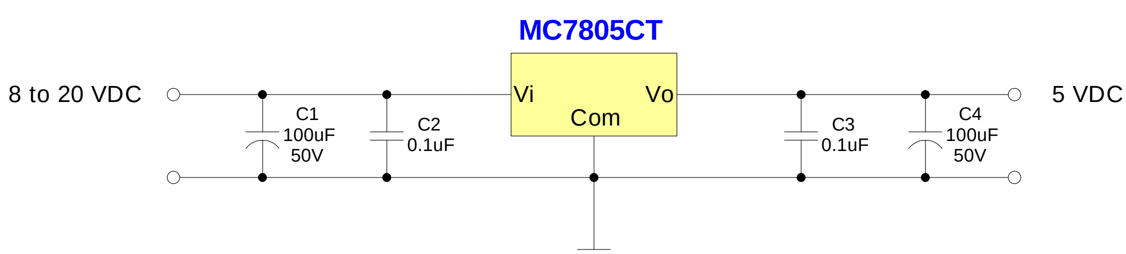


Figure 7.2a. System powering circuit

This means that the circuit has now got a wide operating voltage range as 8 to 20 volts DC will power the circuit. Note there are higher spec 7805 chips available that can operate up to 30 volts DC, if there is a need for a higher voltage range.

The system can be powered from a battery source (e.g. PP3 9V), or a DC power supply (e.g. 12V). It has been decided, not to design a complete power supply unit from scratch, but to use commercially available units. It is important to remember that voltage regulators are not efficient and as the input voltage increases the least efficient they become, energy is lost in the form of heat. A heat sink is normally required to keep the chip within its maximum operational temperature.

7.3. Digital Circuitry

Figure 7.3a shows the circuit diagram; it is important to note that this is a first draft (prototype) designed to test the concept of an ECG monitor, this version is not a valid commercial medial product as it does not comply with all the relative medial standards, for example RS232 communications is not isolated (A isolated DC to DC converter could be used for this task) and the design has no noise immunity. Allow this design could be released as a non-medical version (e.g. sports usage) for less than £100 (A lot less than the predicted retail cost of £453.60 for a fully complied medial product).

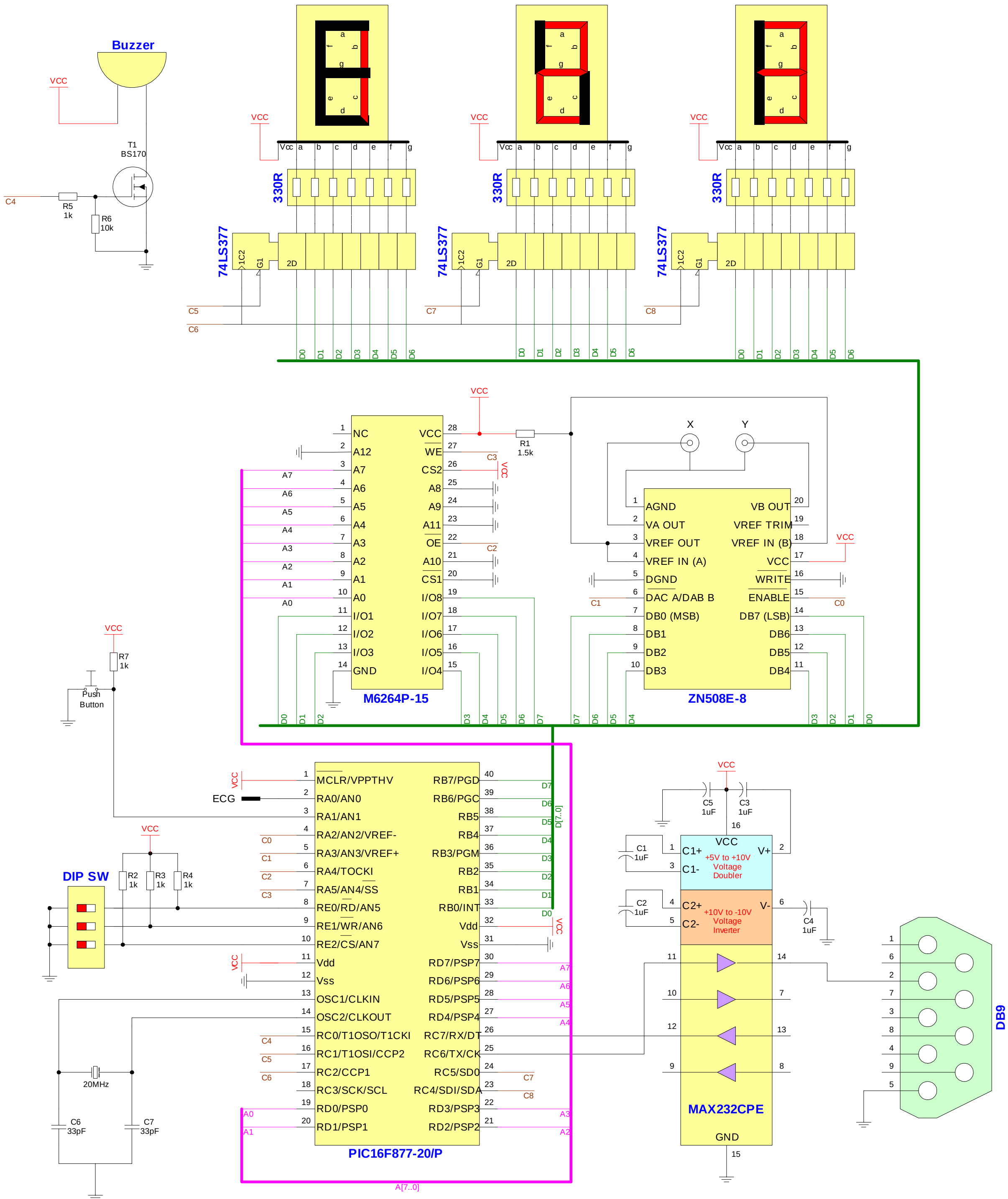


Figure 7.3a. Digital circuit diagram

S2	S1	S0	Baud Rate
0	0	0	115,200 bps
0	0	1	57,600 bps
0	1	0	38,400 bps
0	1	1	32,768 bps
1	0	0	19,200 bps
1	0	1	14,400 bps
1	1	0	9,600 bps
1	1	1	4,800 bps

The dip-switches are used to select RS232 baud rate, table shown on the left. The push button has three functions, if the user holds down the button during power up, it will put the ECG into test mode, e.g. 7-segment, RS232, RAM chip, DAC, ADC, will run through a simple diagnostics program. If the push button is pressed during normal operation, this will pause the ECG display, which resumes when the button is pressed again. The final operation of the push button is to mute the buzzer when a patient has “flat lined” (e.g. heart beat stopped).

Port D is used for an 8-bit address bus, the only component that requires an address is the RAM chip (M6264P-15). This RAM has 8k of memory, but because the address bus is only 8-bits wide, hence it is only possible to access 256 bytes of memory (This is OK). If it is decided that more RAM is required at a later stage of the design process, it is possible to use all 8k of RAM even though it appears that there are not enough free ports on the PIC. The trick is to use two 8-bit latches (as used for the 7-seg displays), were one latch sets the MSB of the address and the other sets the LSB of the address. Since both of these latches should not be enabled at the same time, the one free pin (RC3) can be used to select between the latches (e.g. use a not gate to one latch, and connect the pin directly to the other). But these increases chip count, therefore product cost, hence there would need to be a good reason of the usage of the entire RAM chip.

Port B is used for the shared data bus, the RAM (M6264P-15), the DAC (ZN508E-8), and the 8-bit latches for the 7-segment displays (74LS377) are all connected to this bus. Note that only one item can be enabled at any one time, for example if writing to the RAM chip all other devices on the data bus must be disabled. This is the classic microprocessor method of interfacing with devices, but it was not the only option it is possible to use a serial RAM chip, serial DAC and serial latches, this would reduce the number of pins required on the PIC (no need for data bus or address bus) hence a 28-pin device could be used, reducing product cost. But the disadvantage of this is speed: time compressed memory is used to display the ECG on a CRT; it requires a refresh rate of at least 50Hz (flicker free), since 256 bytes of data is displayed on the screen, this means that the DAC must be updated 12,800 (50 x 256) times per second. If a serial DAC was used each bit is clocked in one at a time, hence a serial baud rate of 102,400kbps (12,800 x 8) would have been required, the PIC can achieve this, but there may not be enough processor power left to carry out other critical operations.

The reason why the MAX232CPE (RS232 line buffer) was chosen was because it can be powered from a single 5V power supply. Recall that RS232 requires +3 to +12 volts for a logic ‘0’ and -3 to -12 volts for a logic ‘1’, the MAX232CPE has a built-in (external capacitors required) voltage doubler circuit (+10V) and a voltage inverter circuit (-10V). This reduces product cost as the other option is to using a switch mode DC to DC converter (cost about £5) to generate required power supply. Allow a +9 and -9 supply (could use -10, +10) is required for the ECG amplifier circuit, hence a DC to DC converter is required anyway. Allow the max232 data sheet states that the +10 and -10 voltage pins could be used to drive other circuits, but it is not recommended, plus its good design practice to keep analogue and digital circuits separate (problems with noise).

Notice that only the transmit wire is connected to the RS232 cable, the ECG monitor does receive any feedback from the PC, just transmits ECG data continuously. Perhaps it is a good idea to connect the receive wire, as this increases the possibilities for future product enhancement. For example the chosen PIC can protect blocks of program memory, hence a bootstrap program can be written to check the serial interface before calling the main program. If a certain block of characters are received during boot strap, it moves into program mode, using a bidirectional communications protocol (RTS, ACK, NAG, etc…) a new program can be download from the PC directly into program memory, when download is complete the new program is called. This offers greater product flexible as software updates (bug fixes, new features) can be downloaded free of charge and download directly into the product using the same serial interface and software used to display the ECG.

7.4. Analogue Circuitry

Figure 7.4a shows the circuit diagram; it is important to note that this is a first draft (prototype) designed to test the concept of an ECG amplifier, this version is not a valid commercial medial product as it does not comply with all the relative medial standards. This design is extremely simple, but the chosen amplifier is analogue devices AD624AD, this amplifier is an "Instrumentation amplifier" with a CMRR (Common Mode Rejection Ration) of 110dB and a gain of 1,000. Note the AD624AD chip is the most expensive chip in the design, costing £22.50 (retail price); hence perhaps a lower cost solution is possible. The reason why this expensive chip was chosen was because of its good CMRR (At least 80dB was required) and high precision.

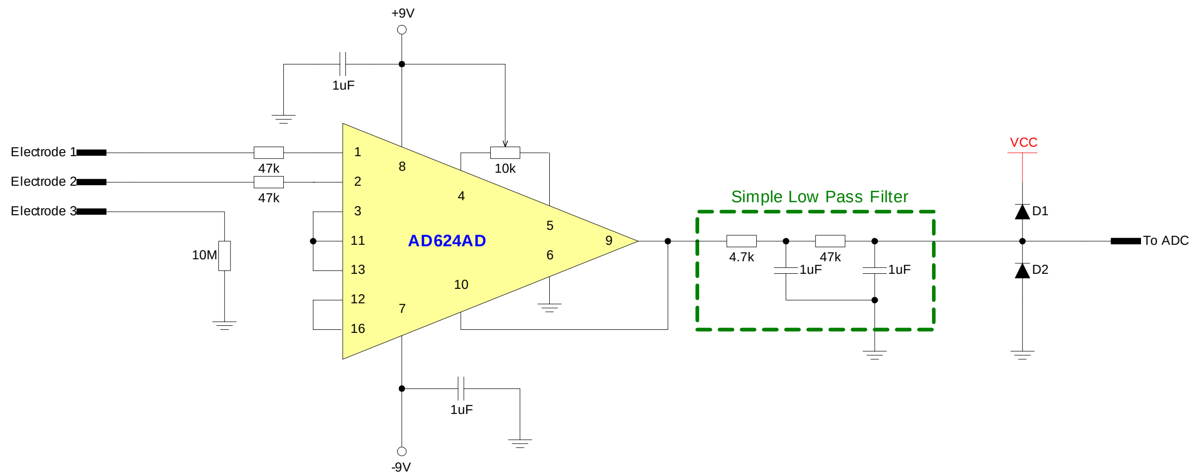


Figure 7.4a. ECG Amplifier circuit

A simple CR second order low pass filter was used to filter high frequencies (anti-aliasing) and the two diodes ensure that the PIC is not damage in the event of over voltage or negative voltages.

7.5. PIC Program

The philosophy that should be used during the development of the PIC code is to keep it simple, straightforward, comprehensible, and to a minimum. It was decided to write the program in C, C is a high – level programming language which allows for programs to be written quickly without any knowledge on how the CPU works.

The other option is to program at the assembly level, this has the advantage of producing more efficient code (runs extremely fast), but this code is not transparent to the chosen chip, hence if it was decided to change the microcontroller, the program may have to be completely rewritten, allow Microchip's range of microcontrollers seems to have good backward compatibly, hence maybe only manor chargers are required. The main draw back for assembly level program is the time it takes to develop the program, writing the program in a high-level language like C is easier and takes less time, hence reducing development costs.

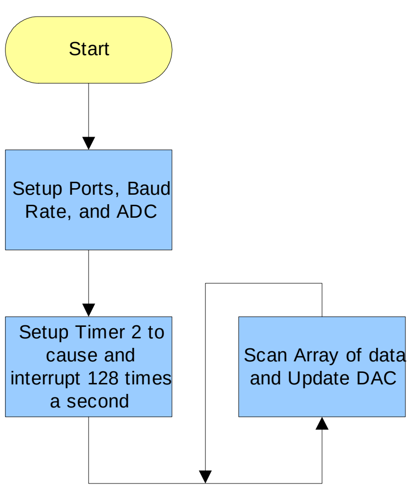


Figure 7.5a. Simplified Main routine

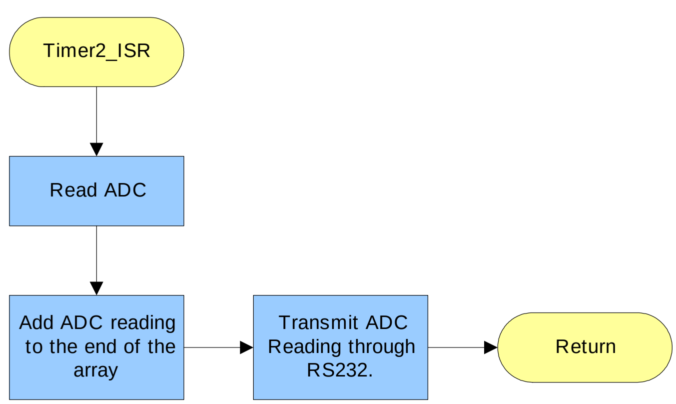


Figure 7.5b. Simplified Interrupt routine

Figure 7.5a shows a simplified block diagram of the main routine, this routines first setups the ports (configure as input / output), sets the baud rate as specified by the DIP switches, and the ADC. Timer 2 is setup to interrupt the main routine 128-times a second, and then the main routine is stuck in a loop forever contentiously scanning through the array refreshing the CRT display.

Figure 7.5b shows a simplified block diagram of the interrupt routine, this routine interrupts the main routine 128 times a second and returns back to the main routine after it has been successfully executed. Basically it reads the ADC, stores the reading at the end of the array, and transmits the reading through RS232 so the PC can display / log the ECG data.

It was decided to use interrupts, this allows for the CRT display and the sampling of the ECG to be completely separated and allow the PIC to do two things at once (time slicing). It did not have to be written this way as it is possible to write the entire program in the main routine, but the code would be intertwined and difficult to debug.

Obviously calculation of the ECG bpm and sounding of the buzzer has not been included yet as its good software design practice to build the code up step-by-step (e.g. get part A programmed before moving to part B, etc…). This code could be placed in the main program or another interrupt routine (using timer 0 or 1 to cause the interrupt).

8.0. CONCLUSIONS

Clearly the heart's strong pumping action is driven by powerful waves of electrical activity, which are detected by attaching electrodes to the skin. It is clear that these electrical signals are extremely small and must be amplified considerably (about 1000 times) to be of any use. Evidently an ECG monitor displays these electrical signals graphically just like an oscilloscope displays voltage variations; expect that the trace on an ECG monitor scrolls across the screen. The concept of an ECG is not novel one; the attraction of this project lay in the challenge to build a simple, compact, operational medical device at a low cost.

It is clear that the electrocardiogram (ECG) is a simple, non-invasive technique for detecting abnormalities and diagnosing heart defects, merely by noting the presence of irregularities in the PQRST waveform. Clearly other applications are very effective in areas of sports medicine, or sports therapy, in tracking the heartbeat through various levels of physical activity to assist the patient in attaining a desired, optimum heart rate.

The CRT display (Cathode Ray Tube) is one of the common display types in use today (TVs, monitors, oscilloscopes, etc...), clearly this technology is coming to the end of its life as new compact low power technologies like TFT and LCD are becoming more widely used. The main disadvantage of the CRT (besides it high power consumption) is the way it draws the image, the spot is moved across the screen at 50 Hz, even at 50 Hz some people will still see the display flickering badly (modern computer monitors have a refresh rate of over 100Hz), and most people experience problems when an CRT display is within their peripheral vision, causing headaches, dizziness, and eye strain when exposed for long periods of time. The use of a TFT or LCD display instead of a CRT display is clearly a better option, as the screen does not flicker, the reason why it does not flicker is because the screen is split up into pixels, each pixels can modified independently of each other, hence only the changes made to the display are refreshed.

Undoubtedly it is important for a product designer to first produce a couple of simple concept designs (see figures 3.3a to 3.3c) before starting detailed design. These design can be completely “of the wall” (not practical), but aspects of which could have contributed to the design of the finished product. After market research and the concept design stage, it is time for a designer to make some decisions and come up with a detailed product design specification that engineers can use to carry out detailed design of the product. Obviously this product design specification should be flexible, as engineers working on the product may have thought of a better way of going about a certain problem, new ideas, or certain aspects of the specification are not practical and have to be changed.

One of the main problems with the design of any product is compliance with international standards, and because the ECG monitor is designed for medial usage these standards are extremely high. Clearly international standards are a must, as this ensures the technical operation of the product over varying conditions and ensures the product is completely safe. Without these standards there would be a lot more low cost electrical goods on the market, which maybe unsafe, hence the reason why electronic products without ISO compliance should not be purchased. Allow this does not necessary mean that the product is unsafe, but with compliance a product is practically guaranteed to operate correctly and safely. The ECG monitor must fulfil the requirements of the medical device directive 93/42/EEC of the European community in order to be used as a medial instrument. Note international standards are updated regularly, hence it is important to keep an eye on them throughout the development of the product.

Powerful software applications like “Microsoft Project” are extremely useful for manning projects. A detailed plan addressing all aspects of the project from initial brief though to manufacture, sales and distribution was easily made. The software application automatically calculates development costs by calculating how long each employee spends of each task and multiplying it by their hourly wage. Gantt charts, PERT charts, and various forms (e.g. development costs) are easily generated by the system. The total development cost for the ECG monitor was estimated at £24,646, taking into account only personal wages, never mind overhead costs (power, telephone, etc…) and prototyping costs.

Clearly commercial ECG monitors are over priced; the main goal of this project is that the cost should be as low as practically possible, the total manufacturing cost is predicted to be £315 (£450 retail price) and this figure is being used as guild when selecting hardware components. The predicted retail price of £450 is a little higher than originally planed (due to compliance with international medial standards), allow the real cost of the project is likely to be lower (over estimated), clearly it is still much cheaper than existing portable commercial ECG monitors as the cheapest was £798 and it only had a printer for ECG output, no visual display, no PC communications, very basic.

Clearly line balancing is very important, as this ensures that the production line is almost optimal, keeping production costs to a minimum. There are powerful software applications designed specially for this task, and there are many good manual methods that managers can use. Evidently a balanced production line for ECG monitor can be achieved using 4 work stations with a balancing delay of only 9%.

The RS232 transport medium was chosen to transmit the ECG to a PC in real-time, the main reasons why it was chosen is because it is easy to program, reliable and every PC has at least one RS232 port. The main disadvantage of RS232 is that it is slow (max speed 115kbps) when compared to other mediums (e.g. USB 12Mbps). Because the ECG monitor is only sampling at 128Hz, the speed of the RS232 port is more than enough.

Unmistakably the partitioning of work is extremely useful, as even the most complex of task can be split into a number of small simple tasks. The design of a plane for example is clearly too complex for one person to fully understand all aspects of design and must be partitioned many times over, until the partitions are small enough to be manageable tasks. Besides the obvious (simplify design) the partitioning technique has many advantages, the main one being system flexibility, e.g. modules can be modified without the need to redesign the entire product. But it is important to note that a well designed non-partitioned design (difficult to achieve) will likely be cheaper and operate more efficiently, clearly this is not commercially viable as the product would not be flexible (difficult to change) as all aspects of the product are intertwined and rely on each other, and difficult to service (repair, upgrade).

It is clear that the ECG monitor should not rely totally on the low-cost of the product to attract customers, the shape, form, aesthetics, styling, tactile qualities / human interaction surfaces, visual interaction should be designed carefully. Research shows that most humans buy on impulses (Looks fell of the product) rather than the technical aspects of the product (with the exception of engineers, who are obsessed with technical details). Note most electronic engineers would be happy to place the product in a standard square box, drilling a couple of holes for switches and knobs. Clearly a design engineer should design the packaging, but their must be a close relationship between the design engineer and the electronic engineer as the PCB board must fit the case with switches and indicators lining up with holes in the case (no point having a cool case if the electronic circuit does not fit, or does not offer adequate cooling).

Obviously accuracy, dependability, and precision are an absolute must for the ECG monitor as the device is to be used for diagnostic, and other medical purposes. Clearly any small fluctuation in the waveform generated could carry critical diagnostic value. It is obvious that noise is the main design consideration, as the ECG is extremely small and can easily be masked by noise related fluctuations. The ECG amplifier must amplify the ECG single (1000 times) and not the noise, hence the need for an expensive “instrumentation amplifier” with a high CMRR. This explains why the ECG amplifier is the single most expensive module within the ECG amplifier.

Clearly the designed digital circuitry is low cost (under £20), if the same function was designed using analogue circuitry the cost and chip count would be extremely high. The design shown in 7.3a includes every that this required to produce a working prototype, but clearly development is required to comply with international standards, i.e. RS232 communications must be isolated.

This report clearly demonstrated how to design and plan the innovation of a new medical device, from the feasibility study through to physical realisation / manufacture of the product. Evidently there is a market for a low cost ECG solution, which is commercially viable to produce.

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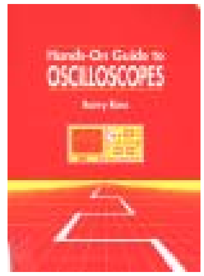
[B2] 

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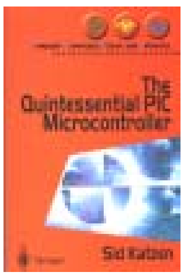
[B3] 

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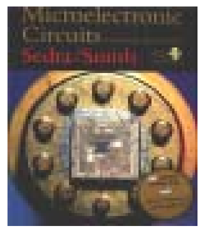
[B4] 

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