Team 4 Eva ECG: Low Cost ECG Tester

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1 Executive Summary

Developing nations have medical equipment such as ECG machines but do not have the equipment to test for their proper operation. These countries are characterized by low industrialization compared to population and have a low standard of living with countries like Pakistan making only \$2,100 per person[1]. For this reason, their test equipment needs to be cheap, however existing equipment such as the BioTek Lionheart II cost \$350 or roughly a sixth of what the average Pakistani makes in a year. To satisfy this need for an affordable ECG Tester, ECE2799 team 4 and *Engineering World Health* have teamed up to design such a device: *EvalECG*.

EvalECG uses direct digital synthesis to generate known test waveforms for ECG machine, such as a pulse train, a sine wave and a pulsed sine wave. The ECG's operating characteristics can then be inferred by comparing its characterization of the waveforms with what EvalECG is generating. EvalECG is also low cost, at \$3.50 each in production quantities. This represents a savings of \$346.50, or 99%, when compared with the Lionheart II that Engineering World Health is currently using. It also surpasses many other low cost ECG testers that are in development at this time in terms of features. For these reasons, we expect EvalECG to be the right product at the right time.

2 Introduction

Here at WPI, we cherish the ideals of humanism. This team in particular holds self evident that while matters of the soul are important, matters of the flesh are at least equally so, and that through technology we can make of stardust a better world. For that reason, when, six weeks ago, we were given the opportunity to improve the quality of health care for everyone, we attacked it vigorously. Low cost ECG equipment testing is the means, and EvalECG is the ends.

2.1 Problem Statement

Six weeks ago, we were given the following problem:

"You are to design a battery powered ECG Tester for verifying the operation of an ElectroCardioGram machine. Your design must include features that your market research deems necessary for a successful product. Although you may choose a domestic market, you are strongly encouraged to target the global marketplace and find application in the developing world. Your design must also be cost-effective.

Complete prototype cost not to exceed \$50."[3]

In addition, Engineering World Health, the organization that contracted this project, has their own problem statement:

"ECG Tester General Performance.

A device which generates a signal which can be fed into an ECG machine. A minimum performing ECG tester would produce a pulse at a fixed rate when connected to standard test leads from an ECG machine. A device which offers several rates is preferred. A superior design would allow flexibility in the strength of the delivered signal. The ability to switch to sine waves is note required, but would be considered a bonus.

Relevant Additional Specifications.

Cost: <\$4 in quantities of 500

Size: less than 4" x 4" x 1" when stored (can fold or unroll if desired)"[2]

2.2 Market Research

Our target market is developing nations, or most countries in Asia, Africa, South America, Central America, and the Caribbean, which have low industrialization compared to population and have a low standard of living[1]. Countries in this category have poor economies that cannot easily support expensive products for their limited and overwhelmed health care services. For example, in 1993, Pakistan had a GDP of \$50.8 billion, which translates to \$408 per person on average[4]. Since then, it has grown to \$318 billion, or \$2,100 per person. For comparison, existing ECG testers, such as the Dale ECG Patient Simulator[5], cost approximately \$300 so while the average Pakistani makes more than he did in 1993, the cost of a patient simulator is still an exorbitant percentage of what an average Pakistani is expected to make in a year. Appendix B contains information on other patient simulators in the domestic market, and they're all similarly expensive.

Despite the inability of developing nations to absorb the cost of high priced testing equipment, we believe that ensuring the reliability of medical devices such as ECG machines is a crucial step toward saving lives and diagnosing heart ailments in a timely and accurate manner. For this reason, *Engineering World Health* has chosen a price range of \$0-\$4 for our ECG test device, and that is the main constraint on our functionality. To determine which features

are absolutely necessary for a device within that constraint, we constructed a questionnaire for doctors in the Usenet newsgroup sci.med.cardiology in order to determine what they believe are the most important features, however the only response we received was the interest of a competitor: Les Schafer of Designspring, Inc., an engineering R&D corporation. We also scoured through Internet resources such as IEEE Xplore, InfoTrac, PubMed, competitors web sites, as well as the general web for prior art and information on ECG machines. Lastly, we communicated with Professor Mendelson of WPI and Professor Malkin of EWH to get a better understanding of what we needed to design.

Information gleaned from this research was primarily used for determining our product specifications. For example, through research we learned about how ECG machines function, their sampling rate and dynamic range[6], as well as how the ECG P, R, S, T, and Q waves are interpreted[7]. One extremely important non-obvious detail we have learned through research is that electrodes placed on the human body can act like capacitors and generate voltages large enough to saturate the ECG's front end input stage amplifier[8]. For that reason, it is beneficial to support simulating a DC offset in the test wave to determine the ECG machine's response to that condition. Additionally, we may not need to produce a human signal to test the machine because a 1mV pulse shares enough similarity with the RST wave to be a useful approximation.

During the course of doing market research, we had a few surprises as well. Researching the domestic market, we noticed a significant trend in consolidating disjoint systems into single electronic medical devices. Not only are these devices portable, but they also combine many features such as defibrillators, pacemakers, and ECGs[8]. These features result in life saving tools that can help patients outside of a hospital setting. Our expectation was that ECGs were built as independent devices in the domestic market, just as they are marketed within developing nations, however such is not the case. Perhaps this is the industry's safeguard against commoditization of ECG hardware.

Another surprise was that according to Suzanne Winter, a nurse at Brigham and Women's Hospital trained in using and interpreting ECGs, the ECG technicians that she is familiar with do not know anything besides administrating an ECG and interpreting the reading. She has never seen ECG equipment fail in her years of working with the hospital, however should that happen it would be handled by the biomedical department. "The hospital taught me how to perform ECGs and interpret them. They also take people off the street to perform them in the ECG department in hospitals. They are *not trained to test ECGs*. We do know how to troubleshoot problems, like checking lead wires for cracks and checking all connections, replacing electrodes if the signal is poor, changing cables if the problem persists, and repositioning leads if there is some kind of external interference," said Winter. This portrays the ECG equipment to be fairly reliable, and it also means that the users of our test device will likely be biomedical engineers rather than ECG technicians.

2.3 Customer Requirements

As contracted engineers, our first step to building our customer's product is to determine what our customers want. In a direct sense, this means itemizing the features our customer specifically requests. In addition, we have also spoken directly to them to further elicit information about their needs. Engineering World Health, our customer, dictated the following requirements[2, 3]:

- Prototype shall cost no more than \$50
- Costs no more than \$4 in bulk quantities of 500
- Consumes an area of less than 4"x4"x1" when stored. May fold or unroll.
- Produces a pulse at a fixed rate

- Connects to standard ECG leads
- Product can be constructed by a high school student
- Maintenance free
- Survives -10 degrees Celsius to 40 degrees Celsius
- Operates from 20 degrees Celsius to 40 degrees Celsius
- PCB-based circuit

Additionally, Engineering World Health specified the following additional features that would be nice to have:

- Variable frequency
- Variable voltage
- Sinusoidal test signal in addition to pulsed signal
- Perform tests outlined in EWH protocol for ECG and monitors
- Perform same tests as Lionheart II

While these initial requirements provide a baseline for what our customers expect, we performed market research to determine unspecified product requirements.

The market appeal of this product will primarily be its affordability for reasons discussed later. Affordability is attained by eliminating all but the most essential features that are necessary to test ECG equipment. In this context, the importance of a feature is primarily determined by market research and feature cost. In cases where there are multiple contending features with similar market value and cost, our own subjective analysis was the final judgment. This meant sacrificing ease of use, cosmetic appearance and aesthetic values which, while important in the domestic market, may not be as highly valued in the developing world. Instead, our design focus for this product was to create as thorough a test as possible for the right price.

2.4 Product Specifications

We derived the following product specifications from the customer requirements and product requirements:

- 1. LED status indicator
- 2. PCB design
- 3. Variable resistor for beats per minute
- 4. Variable resistor for output gain
- 5. 3 Alligator Clips
- 6. 1 9-volt battery holder
- 7. 1 Waveshaping circuit, either analog or digital, capable of creating a smooth signal between ± 1 millivolt. If digital, must be able to produce a signal accurate in time to at least 1 microsecond[6]

- All components can survive -10 degrees Celsius to 60 degrees Celsius, and all components can operate from 20 degrees Celsius to 60 degrees Celsius
- 9. Operational electrical characteristics shall not exceed 30 volts and 20mA
- 10. Either performs correctly or not at all

Sometimes customers do not always know what they want. For instance, although the customer asked for an operating temperature range of 20 degrees Celsius to 40 degrees Celsius, we've increased that to 60 degrees Celsius. In these sort of cases, we talk to the customer to produce better customer requirements, which can then support the necessary product requirements.

2.5 Project Plan

We completed the hardware design, prototype, and created working software for our ECG testing device in six weeks. Because of the fast pace of the project, the restrictive time constraints, and the changing project requirements, we knew that the ECE2799 design process would be inappropriate for our project, so we used an agile approach. Agile methods are known by many names in different fields, such as lean manufacturing in manufacturing engineering and concurrent engineering in electrical engineering. Following agile processes, we condensed the entire process of researching, designing, and testing into two week iterations. We then iteratively and incrementally improved our design. We researched and designed our product during the first iteration, or first two weeks of the term. We improved that design and ordered parts during the second iteration, two weeks before everyone else. We had a prototype by the third iteration, and we improved, debugged, and put it onto perfboard while creating software for it. While, currently, our software does not fully exploit the EvalECG's powerful hardware capabilities, the flash MCU can be reprogrammed in the field with a newer firmware.

The Gantt chart shown in Appendix D provides a rough sketch of the focus of our work during the course of this project. It's simplified nature does not capture the entire dynamic of the project for the reasons explained above.

3 Design Approach

We implemented EvalECG using a direct digital synthesis technique to generate the test waveforms for the ECG. We considered analog approaches as well as non-electronic approaches, however they each had fundamental limitations. For example, analog circuits are good at doing one job very well, however it is very difficult to adapt them to doing several jobs, such as producing different waveforms or different pulse rates. If we were to have both an analog sine wave generator and an analog pulse train generator, it would be difficult to have the frequency control work with both of them. From this, we reasoned that if we wanted anything more than a simple pulse train, then digital techniques are the way to go. We wanted something more than a simple pulse train.

The direct digital synthesis process involves three steps. First, the user enters the desired waveform information into a series of controls. Then, a microprocessor polls the state of the controls and generates the desired waveform in a digital format. Then, some form of digital to analog conversion generates the final analog signal output into the ECG. This entire process is shown in Figure 1.



Figure 1: Block Diagram of EvalECG

The battery and power supply power the electronics such as the stylus, which allows the user to enter the waveform they desire, as well as the waveshaping circuit, which actually generates the waveform. The waveshaper comprises of a PIC microcontroller that polls the user input, generates the LED output signal, and generates a pulse width modulated signal which is filtered by a low pass filter to create an output waveform for the ECG.

3.1 Design Options

Based on our product specifications, we determined that our device is made up of five subsystems. We did not know about EWH's use of bare PCBs, so we decided that some form of enclosure would protect the subsystems. In our block diagram, figure 1, there is a power source, power supply, wave shaper, and test leads.

The power source is either a 9-volt battery cell or AC wall power fed through an AC/DC converter. Batteries are

a very costly item, so we decided that our device must be capable of operating for at least 10 hours continuously on a single battery pack. Since the device will only be used for brief periods of time to test the electrocardiogram machine, we believe that this battery lifetime will be suitable for the application. In the case of power from an AC power system, we have decided that due to poor power distribution and the additional cost of an AC/DC converter, it may not be a wise decision to use AC power. Nevertheless, we considered it as a design option.

We determined five possible candidates for the power supply. Those possibilities are: a voltage divider, a zener diode configuration, a linear voltage regulator, a voltage reference, or a buck converter. The advantages and disadvantages of these implementations will be discussed below. Ultimately, we chose a power supply based on affordability, longevity, feasibility of implementation and performance.

Our team found several possibilities for implementing the wave shaping circuitry. We questioned why healthy human beings could not be used to test the ECG. The human heart is great for generating cardiac signals. However, since the goal of our project is to meet the EWH design requirements, we brainstormed a few circuit based approaches as well. We found that our options included a 555 timer circuit with or without filtering, PIC microcontroller based digital synthesis, or a function generator. We ruled out the idea of using function generator chips as soon as we discovered how expensive they were. We also considered some of the operational amplifier circuits offered on the course web page. A Wien bridge oscillator could be used to synthesize sine waves. The PIC microcontroller we considered (**PIC12F683**) was affordable and offered a pulse width modulator (PWM). The PWM could control a rudimentary DAC. As the duty cycle of the pulse width varies, the analog output could vary, which would allow the generation of various waveforms. We decided that only three different signals would be necessary to adequately assess the ECG machine's functionality. This could be achieved from a single frequency generator by dividing the primary frequency signal by two. Two frequency dividers would then be used to create different waveforms for the other two probes. Unfortunately, the tradeoff there is that frequency dividers are only trivial circuits for square wave signals.

3.1.1 Power Source Design Options

The power source must provide the circuitry with a stable consistent supply of power. Through brainstorming, we found two potential candidates for a power source. Value analysis, as shown in table 1 on the following page, was performed to find the power source that provided the best trade offs for the situations our product will be involved in.

Wall power was given a longevity score of 10 because it is normally a more plentiful, cheaper source of energy than other sources. This is because the existence of wall power implies an infrastructure to distribute large amounts of electricity for cheap, although not always consistently. For battery power, we chose a longevity score of 8 because our battery life is aimed at ten hours. Since the device will only be powered for brief periods of time to test the electrocardiogram, 10 hours is acceptable for product longevity. Battery power is simpler than wall power because the circuitry required to convert wall power to an appropriate form of electricity is more complex than just using a battery. We would need to have an AC-DC converter and a transformer to step down the wall voltage. Simplicity of battery power was given a rating of 7 because it is simple for us to implement and simple for the user to use.

The availability of wall power was a low score because there are many areas of developing nations that do not have a power distribution system available. The feasibility of implementation score is lower than battery power, because implementing AC power in our design is more difficult. For performance, we found that battery power was a tie with AC power if the AC power was stable and readily available. With proper signal conditioning, there is no difference in performance as far as the circuitry is concerned. Battery power was scored much higher in feasibility of implementation than wall power because we feel that it will be much easier for us to implement that battery powered system than the AC system. We also believe that battery power will be more accepted in the market.

For affordability, battery power was scored lower, with a score of 4, than wall power. The cost of batteries is expensive. However, our long life circuit will compensate for this issue. Availability of battery power was given a much higher score of 8 than the availability of wall power. Many products in developing nations are powered by batteries. The availability of AC power on the other hand is nonexistent in some areas.

From the value analysis, battery power seems like the most viable approach.

	Powe	r Source					
	Value Ar	nalysis					
	Market	Market Wall power			Battery Power		
Quality	Value point	Value point	Total	Value point	Total		
1 Longevity	90	6	540	8	720		
2 Simplicity	50	6	300	7	350		
Tota			840		1070		
	Market	Wall power		Battery Pow	Battery Power		
Convenience	Value point	Value point	Total	Value point	Total		
1 Availability	60	2	120	8	480		
2 Performance	50	6	300	6	300		
3 Feasibility of Implementation	80	4	320	8	640		
Tota			740		1420		
	Market	Wall power		Battery Pow	er		
Cost	Value point	Value point	Total	Value point	Total		
1 Affordabilitiy	90	7	630	4	360		
Tota			630		360		
Customer Value: (Quality*Convenience/Con	it)		986.7		4220.6		

Table 1: Value Analysis for Power Source

3.1.2 Power Supply Design Options

Converts 9 VDC from a battery cell into a voltage suitable for our circuitry. It must act as a stable, consistent source of power. Our goal is to achieve at least 10 hours of battery life from a 9 volt battery cell. For a 9-volt Duracell Ultra battery, which is rated at 550 milliampere-hours[9], our circuit must consume no more than 55 mA. Therefore, our power supply must not deliver much more than 55 mA.

For longevity, the power supplies were mostly tied with a score of 7, except buck converters with a score of 8. All of the systems basically last for the same amount of time. They do not require any maintenance and longevity of the components is not really an issue. For simplicity, the voltage divider scored highest because it is merely two resistors. Zener diodes, a linear voltage regulator, and voltage reference all tied with a score of 8 because they basically require the same amount of research and time to implement. The buck converter scored a low 6 because our team considered it to be non-trivial to implement. As far as availability, all products were tied except for the buck converter because its components are harder to locate. The performance of the supplies was varied. The voltage divider is very easy to implement, however, the voltage output will continue to decrease as the battery cell ages. Therefore, its performance score was only a 2. The zener diode scored a 5 because it can perform better than a voltage divider in that it will maintain a specific voltage. Unfortunately, it wastes unused power through a resister. The linear voltage regulator scored very well because it can maintain the same voltage even as the battery voltage is decreasing like the zener however is approximately 70% efficient. The voltage reference is like a linear regulator with far greater accuracy, however it scored lower because it may not be capable of supplying enough current for our need. The buck converter is the greatest performance wise, because it can charge pumps the battery and can be designed with an efficiency of over 90%. For feasibility of implementation, the voltage divider scored lowest because we realize that it is undesirable to have our circuit being supplied with a voltage that will be decreasing. If we choose to use a microcontroller, it may not like being provided with a decreasing voltage. Linear voltage regulator scored highest for feasibility of implementation because it will provide the necessary current as well as maintain the voltage. The feasibility of using the voltage reference is lower because it may not supply enough current or be rugged enough to act as a power supply. For affordability, voltage divider scored best (low scores mean cheaper), because it only consists of two resistors. Linear voltage regulators scored lower because they cost about \$1.20 from digikey, which is quite expensive. The buck converter is far too expensive for our project, so its affordability score was the worst.



Table 2: Value Analysis for Power Supply

3.1.3 Waveforming Circuit Design Options

The wave shaper circuitry must generate smooth (in steps of a millivolt), consistent waveforms. These waveforms may consist of varying frequency pulse waves and sine waves. The first option we considered was just using a healthy human test subject to test the ECG. For performance, we ranked the human subject lowest with a score of 3. Although humans can produce cardiac signals, we believe that it is advantageous to be able to produce several different signals to evaluate different situations the ECG may be exposed to. A person cannot easily control factors such as beats per minute or test the saturation level of the ECG amplifier. The 555 timer circuit was given a performance score of 5. A 555 timer by itself would allow us to meet the requirement of generating variable frequency pulses, but would not let us create sine waves without further filtering. A 555 timer combined with filtering scores a 6, because it has the capability of producing sine waves. PIC based synthesis was given a performance score of 7 because using its PWM and some additional circuitry, we could synthesize virtually any signal. The same is true for the AVR microcontroller, but there are memory limitation issues which would require tight coding on our part and limits the number of signals we can store in its memory. So the AVR synthesis scored a 6 for performance. The availability score for the human was the lowest because a person may not always be available to test the ECG device. For availability, we decided the PIC was slightly less available in the market because they are only produced by the company MicroChip. The same is true for the AVR microcontroller, but its score was lower because it is not as popular of a microcontroller. For feasibility of implementation, the human option scored 0 because using human subjects as signal sources have nothing to do with our design. We scored 555 timer, 555 timer with filtering, and PIC synthesis equally because we feel that they would all be equally usable implementations.

After the value analysis was conducted, the PIC based synthesis scored highest.

3.1.4 Test Lead Output Design Options

When we presented our design ideas to the other ECG groups on 3 November 2004, their questions and body language showed surprise about the possibility of using as little as three outputs to test an ECG machine. The concept therefore deserves a complete explanation. As shown in figure 2 on the next page, there are a total of 10 distinct leads for a typical ECG machine. Three additional "leads", known as the standard leads, take the difference of the signals at the physical augmented limb leads: aVR, aVL and aVF. Each of these augmented limb leads records a difference



Table 3: Value Analysis for Waveshaping Circuit

between the voltage at the lead and the average voltage of the other two leads. Lastly, the remaining leads, known as the precordial leads, record the voltage difference between themselves and the ground reference lead at the right leg.

aVR 오 a۷L 0 0 aVF 0 0 Т 0 0 П Ш • 0 • ٧, 0 000 ۷, ۷, 0 0 ٧4 ٧, 0 0 ۷. 0 • ground Ш н 0

Figure 2: Test Lead Placement on Human

The test leads are placed such that they can record the passage of electrical impulses across the heart. The three augmented limb leads, aVR, aVL, and aVF record the strength of the electrical impulses with respect to the three corners of the triangle. The three standard leads, I, II, and III each take the difference of a pair of augmented limb leads to determine the strength and direction of the electrical impulse being recorded in the direction of the sides of the triangle. Lastly, the precordial leads V_1 , V_2 , V_3 , V_4 , V_5 and V_6 all recorded the electrical activity under their locations, with respect to the ground reference on the right leg[?].

Measurements are therefore a function of more than one lead. This is why some groups may have believed that it

		Extern							
		Value Analysis	1						
	Market	Twelve Output	ts Three Outputs			Twelve Outputs with DeMux			
Quality	Value point	Value point	Total	Value point	Total	Value point	Total		
1 Longevity	90	8	720	8	720	8	720		
2 Simplicity	50	1	50	8	400	7	350		
Total			770		1120		1070		
	Market Twelve Outp			Three Outpu	rts.	Twelve Outputs with DeMux			
Convenience	Value point	Value point	Total	Value point	Total	Value point	Total		
1 Usability	50	8	400	8	400	8	400		
2 Feasibility of Implementation	80	2	160	8	640	5	400		
Total			560		1040		800		
	Market	Twelve Outputs		Three Outputs		Twelve Outputs with DeMux			
Cost	Value point	Value point	Total	Value point	Total	Value point	Total		
1 Affordabilitiy	90	9	810	3	270	4	360		
Total			810		270		360		
Customer Value: (Quality*Convenience/Cos	532.3		4314.1		2377.8				

Table 4: Value Analysis for External Leads

is necessary to have 10 outputs. In fact, the maximum number of leads that can affect a single measurement in this system is three. This happens when measuring the three augmented limb leads, which are all a function of each other. Since the standard leads are a function of the augmented limb leads, they too are completely defined by three leads. The remaining precordial leads are only dependent on the voltages at two leads: themselves and ground.

Providing a full 10 lead output system is convenient because it can test all ECG measurements at the same time. However, doing so is not possible with all of our design options. Since any given measurement can be completely defined by three leads, three leads is our lower bound for how many test connectors we offer. This tradeoff between cost and usability of our final product is one we're willing to make because EWH does not require the design to be easy to use.

Although the choice between a full 10 output system and a system with a reduced number of outputs is entirely dependent upon our choices for other modules, particularly the waveshaping circuit, the number of actual external connectors can still be analyzed.

3.1.5 Number of External Leads

Implementing a full 10 lead output system is very expensive and, as illustrated above, not necessary for an accurate evaluation of the ECG. Using this option would automatically cause us to exceed the EWH cost requirement in most cases. This option had the lowest feasibility of implementation score because we it is virtually impossible to implement and meet our customer requirements.

Implementing three leads externally is shown through value analysis as the optimal option for our design. The three lead configuration will not have restrictions on the type of signal we can use, and it is the most affordable, with a score of 3. It has the highest simplicity score because the circuitry involved with its implementation is much simpler than the other options. It holds the highest feasibility of implementation score because of cost and simplicity.

With the use of a de-multiplexer, the microcontroller can be used to automatically select which leads are being tested. However, choosing this approach creates a restriction as to which types of signals our waveshaper can generate. The de-multiplexer is based on logic gates, which would not allow sine waves to pass through. Therefore, we would only be able to use pulse waves for output. Furthermore, using a de-multiplexer adds to the cost of the design and costs us more pins on the microprocessor. Because of these restrictions, the feasibility of implementation score for the de-multiplexer option is only a 5.



Table 5: Value Analysis for Enclosure Design

3.1.6 Enclosure Design Options

Commercial-grade ABS plastic enclosures are readily available from numerous domestic electronics resellers such as Mouser or Digi-key. However, current market research has yielded that they are too costly for meeting our price target of \$4 in quantities of 500. Minimalist home-made ABS plastic enclosures appear to be the most cost effective solution. In terms of aesthetic value, it is probably the least attractive. ABS plastic sheets are available in dimensions of 12" x 12" at cost of \$5.36 / sheet from K-mac plastics [10]. Constructing a cardboard enclosure would be the most cost friendly approach. However, the durability of a card board enclosure is virtually non-existent, which will rule it out as a viable solution after value analysis. Ultimately, when we learned that EWH did not want an enclosure, it became a moot issue.

4 Final Design

As our design evolved over time, we made minute evolutionary changes based on what works and what doesn't work, however the basic "big picture" design is simple, sound, and thus has remained unchanged. This is the culmination of our efforts.

4.1 Power Supply

Although we initially used a zener diode, we eventually changed to a *linear regulator* because athough it costs \$0.40, it affords us one feature that we cannot compensate for in software: a stable reference voltage. The *linear regulator* that we use, the ZMR500CL, has a voltage drift of 0.700 $mV/^{\circ}C[1]$. That means if the operating voltage ranges from $20^{\circ}C$ to $40^{\circ}C$, the change in temperature, at worst, is $20^{\circ}C$ so

$$\Delta V_{linear} = (\Delta t)(\frac{\Delta V_{linear}}{\Delta t}) = (20^{\circ}C)(0.700\frac{mV}{\cdot \circ C}) = 14.0mV$$

Then factoring in the voltage division

$$\Delta V_{EvalECG} = \left(\frac{6mV}{5V}\right)(\Delta V_{linear}) = \left(\frac{6mV}{5V}\right)(14.0mV) = 0.0168mV$$

In other words, the output voltage drift is only 0.28% under the worst-case scenario. By comparison, a zener can drift 8.5% under the same circumstances. You'll note that we are not considering the variance caused by using 5% parts. This is because our instrument can be calibrated after production and those variances are cancelled out in software, leaving only the variance of individual components over time.

From our analysis of the EWH ECG diagnosis procedure, we've discovered that while an accurate ECG readout with a precise voltage reading is something they check for, they are more concerned with other properties such as: does the ECG beep when the person flatlines? In this case, what's being tested is the ECG's analysis circuitry, and for that, we need to be able to produce precisely timed pulses. For instance, one test is for whether the ECG can determine the heart rate to a precision of ± 1 bpm. The low variation in the linear regulator helps keep the PIC's internal RC clock from drifting, which helps us satisfy this demand.

4.2 Stylus System

Our stylus system tracks the position of a metal stylus across a conductive polypropylene plastic strip, shown in Figure 3 on the following page. The electrical details are further shown in Figure 4 on page 15. It is primarily concerned with three pieces of information:

- Where was the stylus placed onto the surface element?
- What is the stylus' displacement
- Where was the stylus removed from the surface element?



This diagram shows a breakaway view of the enclosure with the plastic surface for the stylus screwed into the case.

Figure 4: Electrical Schematic of Stylus System



The stylus system electrically functions as a potentiometer, with some differences detailed in the Design Changes section. A pulldown resistor forces the stylus to ground if it is removed from the surface. Additionally, the PIC periodically makes AN3 a low impedance output tied to ground to ensure that the stylus is not floating.

These three pieces of information allow our user interface to function. Placing the stylus onto the strip and then removing it without moving it across the strip is considered a "click" and selects a function. Placing the stylus on the strip and moving it to either the left or the right is interpreted as a drag.

First, the information from the A/D converter monitoring the stylus is pre-processed to adapt to the characteristics of the surface element. Noise is reduced or eliminated and the signal is re-normalized to account for discontinuities at either end of the linear region. This process is shown in Figure ?? on page ??. On-the-fly calibration relies on the user inadvertedly (or deliberately, in the case of initial calibration) dragging the stylus onto the screw energizing one end of the plastic stylus surface. When this happens, the software will detect the jump to ~5V. The size of the jump is then recorded as the calibration parameter and assumed to be the same for both the positive and negative end of the surface element. While this simplification is not perfect, it is good enough. We cannot use the jump to ground as part of calibration because that is used to detect when the stylus has been removed from the surface element.

During a drag operation, the displacement of the stylus between samples is multiplied by a weight and then integrated to give a weighted total displacement. This is weighted because slow drags are interpreted as small changes and allow the user to undercontrol, while large drags are interpreted as proportionally larger changes and allow the

user to overcontrol. This process is shown in Figure 5.



Figure 5: Stylus Drag Procedure

Once the stylus system detects that the user has moved the stylus beyond a certain threshold, the gesture is interpreted as a drag. First, the displacement of the drag since the last sample is calculated. Then, a weighting is chosen depending on whether the displacement is large or small. This weighting is multiplied with the displacement and then summed up with other displacements to produce a value change.

When the value being controlled reaches the maximum or minimum value and the stylus is being dragged, the LED on EvalECG will show full on. This indicates to the user that attempts to continue dragging in the same direction will have no effect.

4.3 PIC Microcontroller

The PIC microcontroller is responsible for handling the user interface defined by the stylus system above as well as producing waveforms through the low pass filter described below. Although, by default, it operates at 4MHz, we switch it to an 8MHz clock rate in software once the PIC turns on. The PIC performs one instruction every four clock cycles, so the effective instruction rate is 2MHz. If we generate a 1 kHz signal, that gives us 2000 instructions between each modification of the PWM register. Since most ECGs sample at 150 Hz at most, that gives us 13,0000 instructions between modifications of the PWM register. In either case, there is plenty of time for processing the user input and the waveform data, as can be demonstrated by Figure 6 on the following page.

Figure 6: Processing Input and Altering PWM



This series of photos demonstrates the PIC processing user input and adjusting the amplitude of the output signal. The oscilloscope is watching the output of the PIC's PWM module and so a high amplitude shows up as a 99% duty cycle and a low amplitude as a 1% duty cycle.



Same thing except now viewed after the RC filter and with a pulse delay.

The primary method for producing an arbitrary waveform pulse is through a lookup table. The waveform is described as a series of numbers, like in Table 6 on the next page, which are then placed into the PWM register sequentially, altering the PIC's PWM duty cycle over time. The control flow of the software for the PIC is further described in Appendix A.

Phase	PWM	Phase	PWM	Phase	PWM	Phase	PWM
0	50	10	99	20	50	30	0
1	57	11	98	21	42	31	1
2	65	12	97	22	34	32	2
3	72	13	94	23	27	33	5
4	79	14	90	24	20	34	10
5	85	15	85	25	14	35	14
6	90	16	79	26	10	36	20
7	94	17	72	27	5	37	27
8	97	18	65	28	2	38	34
9	98	19	57	29	1	39	42

Table 6: PWM Data for 40 Point Sine Wave

This table shows a lookup table we implemented in the PIC for a 40-point sine wave. The phase is a counter that decrements (more efficient in assembly) while the PWM data are numbers from 0 to 99 indicating full off to full on. There are far more efficient methods to produce a sine wave within the PIC, however this lookup table demonstrates how any arbitrary waveform can be generated.

4.4 Low-pass Filter

The low-pass filter, shown in Figure 7 on the following page, contains two pairs of resistors and capacitors. These are low pass RC filters designed to cutoff around 1 kHz. The cutoff frequency of an RC filter, in radians, is defined to be $\frac{1}{RC}$ so

$$1kHz = 2\pi x 10^3 \frac{rad}{s} = \frac{1}{RC}$$

therefore

$$RC = \frac{1}{2\pi x 10^3 \frac{rad}{s}} = 1.59x 10^{-4}$$

So if we use a $0.15\mu F$ capacitor in an RC pair, then we need

$$R = \frac{1}{2\pi C x 10^3} = 1061\Omega \approx 1k\Omega$$

Similarly, a 0.015μ capacitor is paired with a $10k\Omega$ resistor. The second RC filter has a resistance ten times the first to prevent one stage from loading down the other and forming a voltage divider.



Figure 7: Low-pass Filter System

The two resistor capacitor pairs are low-pass RC filters with a cutoff frequency of 1 kHz.

As a result, when the PIC generates PWM pulses from Table 6 on the page before, the output after the two stage RC filter is a sine wave shown in Figure 8 on the following page.

Figure 8: Sine Pulses



This sine pulse is generated using the 40-point sine data. Although this pulse shows a portion of a sine wave, it could just as easily be an PQRST wave.



Same thing, except the pulse delay has been set to zero. This is a 4 Hz sine wave. Higher frequencies can be attained by removing software delays.

4.5 Enclosure and Other Systems

Since EWH likes bare PCB's, that is what we intend to do. Although our demonstration prototype won't be a PCB, the design for a PCB is shown in Appendix C. We've generated a data file for PCBPro (http://www.PCBPro.com/). The boards from PCBPro.com cost \$0.99 in quantities of 500, or \$1.06 with silkscreening. We can then epoxy dip the boards for about \$0.10 to make them permanent and durable.

We've scaled back the current through our LED to approximately 7 mA as shown in Figure 9. This was originally to satisfy the current sourcing abilities of the zener diode, however with a *linear regulator*, our reason is simply to be low power. The LED still appears bright from the front even with 7 mA.





This circuit uses a 715 ohm resistor to cut the current to 7mA.

4.6 Manufacturability

As EWH requested, we have designed our circuit to work on a single 2" by 2" PCB. Production of these PCBs can be outsourced to PCBPro (http://www.PCBPro.com/). The components are all through hole components and can be mounted onto the PCB by a high school student with training in proper soldering techniques. The board can then be dipped into epoxy, and the conductive plastic can be screwed into the epoxy.

4.7 Bill of Materials and Cost Analysis

The bill of materials is shown in Appendix E. For cost analysis, we know that EWH uses volunteer labor. We assume that their shipping charges are ameliorated over the volume that they produce. Furthermore, since they are nonprofit, we assume no storage charges, rooming charges, equipment charges, and so on. We also assume that they are not trying to replace their Lionheart II's, that is, it is not a zero sum game whereby the replacement of a unit with a

new unit itself costs money. We also assume that they will not sell the EvalECG. In short, we model their cost function as the cost of the parts with no net gains. At \$3.75 per EvalECG in quantities of 500, that comes out to \$1875. Now compared to the cost of 500 Lionheart IIs, which while inconcievable does provide a basis for comparison: $500 \times 350 = 175,000$. Savings = \$173,125. This is a good deal.

4.8 Failure, Hazard Analysis

EvalECG performs its functions using a safe level of electrical power: at most 20mA of DC at five volts. Assuming a worst case body resistance of 100k, then

$$I_{body} = \frac{5V}{100k\Omega} = 0.05mA$$

This level of current is not dangerous or even above the threshold of human perception. However, while EvalECG cannot directly harm someone, it can fail. Luckily, it is fail safe in that it will not flag a bad ECG as good. This is because it's signal generation process is organic in the true sense of the word: if any essential component fails, the whole thing fails and there are no nonessential components that can make a bad ECG machine look good.

The main failure point of our ECG circuitry is the stylus system. Although we've designed it to be robust and work across a range of conductive surfaces, we have only tested it with one particular circuit. Further testing needs to be done to insure that the plastic always works. All other components are solid state and should last for a very long time. The first components to fail will probably be the electrolytic capacitor, within seven to ten years, due to electrolyte leakage. This will add some noise to the output however the device will still be usable. The rest of the components will probably outlive the user.

4.9 Legal Considerations

The two main legal issues our device may have is liability and patents. Although we have not found any relevant claims while searching the Patent and Trademark office archives, it is not inconceivable that the use of signal generators for the purpose of testing ECG equipment is covered by a patent. This problem is mitigated by several factors. First, since our equipment is used for nonprofit purposes, the benefits of litigation would not outweigh the costs and the bad press. For similar reasons, should such a lawsuit be successful, there would be no damages to recover. Since infringement is not "will-full," treble damages do not kick in. Lastly, these devices are marketed to developing nations, which do not all enforce patents. In the worst case, production of EvalECG can be offloaded offshore.

The other legal issue is that our device may fail. Although we believe the chance of device malfunction in the field is negligible, we also acknowledge the possibility that we may not have created a good ECG tester in the first place. For that reason, we disclaim all responsibilities. Use of the EvalECG design is provided as-is. It is not appropriate for any medical use, hobbyist use, or ingestion.

5 Prototype Results

As of the time this paper was written, our software is still *in fieri* and not all parts of it have been extensively tested. The waveforming software module is one of the heavily tested parts, and performs exceptionally on the EvalECG hardware as shown in Figure 6 on page 17, 8 on page 20 and Figure 10. The user interface code is still being improved. Despite the continued development, the current prototype fulfills all of the requirements of EWH.



Figure 10: Pulse Train on Low Noise Scope

This is the output of our non-breadboard prototype on a high precision analog oscilloscope. The human body has more noise than EvalECG, so we may need to inject our own noise into the output in future revisions of our software. This picture was taken using slow shutter speed motion capture in a dark room.

Our initial prototype, shown in Figure 11 on the next page, shows an initial prototype, which is nothing like how EvalECG will be constructed on production. As detailed earlier, the design of EvalECG was based on the assumption of a casing, however a case turned out not to be required.

On Tuesday, December 13th at 1600 hours, we will put our prototype hardware and software to the test on Professor

Figure 11: Prototype



This is the inside of our prototype. The board contains connectors to allow it to be removed from the casing. This is not how a production EvalECG will look.



The outside of the prototype shows off the stylus system and the three leads.

Bitar's home-made ECG machine.

6 Next Steps and Recommendations

At the moment, the programming for EvalECG is rudimentary. The large memory size and extensive capabilities of the EvalECG hardware should be exploited to create a more comprehensive testing device. Existing units can be reprogrammed with the new software as it becomes available.

Additionally, we are unsure about the performance of Velostat plastic under mass-production conditions. Although, in theory, it should work well, we would prefer to further test by producing a PCB based device with another Velostat strip and ensure that the software still works under those new conditions.

Furthermore, to more closely model the Lionheart II, we would like to find out the resistor divider configuration on it's output, so we can copy it. This would allow our tester to operate exactly like the Lionheart II, except better and cheaper.

Lastly, should we decide to send our design in to Engineering World Health, we need to produce detailed assembly instructions. This is so their assemblers can produce our product.

7 Ethics

As respectable engineers, the EvalECG team has held itself up to high ethical standards. Here is our evaluation of our performance with respect to the IEEE Code of Ethics[11].

"1. to accept responsibility in making engineering decisions consistent with the safety, health and welfare of the public, and to disclose promptly factors that might endanger the public or the environment;"

We have designed our product to be safe. Wherever possible, we have disclosed potentially harmful weaknesses in our product.

"2. to avoid real or perceived conflicts of interest whenever possible, and to disclose them to affected parties when they do exist;"

We have embraced a philosophy of openness to share information with our fellow engineers and prevent conflict of interest situations evolving from competitive environments.

"3. to be honest and realistic in stating claims or estimates based on available data;"

As students, we are times too optimistic about our designs, however to the best of our ability we have followed this.

"4. to reject bribery in all its forms;"

Thus far neither the professor nor anyone else has offered bonus points or other incentives that could constitute as bribery. Thus, we cannot judge ourselves on this code.

"5. to improve the understanding of technology, its appropriate application, and potential consequences;"

Done, done and done.

"6. to maintain and improve our technical competence and to undertake technological tasks for others only if qualified by training or experience, or after full disclosure of pertinent limitations;"

Since EWH expresses a desire for students to design these projects, while we may or may not be qualified, our level of training is fully disclosed.

"7. to seek, accept, and offer honest criticism of technical work, to acknowledge and correct errors, and to credit properly the contributions of others;"

We have attended every design review and contributed to the evolution of every ECG tester design. We have also cited all references that we've used.

"8. to treat fairly all persons regardless of such factors as race, religion, gender, disability, age, or national origin;"

What race, religion, gender, disability, age, or national origin? We have a hearing impaired team member? I didn't know that.

"9. to avoid injuring others, their property, reputation, or employment by false or malicious action;"

Thus far we have not resorted to sabotaging other people's ECG testers. Additionally, we have avoided being drawn into negative arguments during design reviews.

"10. to assist colleagues and co-workers in their professional development and to support them in following this code of ethics."

We have been supportive of other groups, offering ideas that were quickly adopted by them as well as providing support when asked for. Our openness policy has allowed all teams to benefit from the information we dug up.

8 Conclusions

Our design is finalized, our prototype is ready for testing, and we are preparing for the presentation. This last week has been extremely hard on the EvalECG team, but we persevered. Although the journey was its own reward, we do hope to see our creation leave the quiet shelter of a school that is WPI and enter the vast world where it must survive or perish. The pride of creators lives among us.

A Software Flowchart



Figure 12: PIC Software Flow

The PIC's software constantly updates the PWM module as well as handles user interface issues.

B Schematic



C PCB Layout



D Gantt Chart

ID	6	Taek Name	Leader	Start	Finish	TE	Oct 3	1, '04		N	ov 7, '04	TW	те	
1	2	Market Research	Bob D.	Fri 10/29/04	Thu 11/4/04		3 3				5 IVI	1 1		
2	2	Customer Requirements	Bob D.	Sat 10/30/04	Mon 11/1/04									
3	Product Specifications		Bob B.	Sat 10/30/04	Mon 11/1/04									
4	2	Brainstorming	Paul	Tue 11/2/04	Thu 11/4/04									
5	2	Design Ideas	Paul	Thu 11/4/04	Mon 11/8/04									
6	2	Value Analysis	Bob D.	Mon 11/8/04	Mon 11/15/04									
7	2	Order Parts	Bob B.	Thu 11/11/04	Mon 11/15/04									
8	2	Planning & Time Management	Bob B.	Thu 11/11/04	Mon 11/15/04									
9	2	Component Research	Bob B.	Thu 11/11/04	Thu 11/18/04									
10	2	Wait for Parts	Everyone	Tue 11/16/04	Fri 11/19/04									
11	2	Schematics	Paul	Tue 11/16/04	Mon 11/22/04									
12	2	PIC Programming	Paul	Mon 11/22/04	Tue 12/7/04									
13	2	Speak to Biomedical Professor	Paul	Wed 12/1/04	Fri 12/3/04									
14	1	Construct Circuit on Breadboard	Paul	Fri 12/3/04	Wed 12/8/04									
15	1	Test and Debug PIC	Paul	Tue 12/7/04	Fri 12/10/04									
16	~	Test and Debug Analog Circuit	Bob B.	Tue 12/7/04	Fri 12/10/04									
17	1	Build Prototype	Bob B.	Fri 12/10/04	Mon 12/13/04									
18	~	Write Final Paper	Bob D.	Fri 12/10/04	Mon 12/13/04									
19	m	Write Final Presentation	Bob	Sun 12/12/04	Tue 12/14/04									
20	.	Give Final Presentation	Bob D.	Wed 12/15/04	Wed 12/15/04									
Project	nantt de	Task		N	Vilestone	•		External Task	s					
Date: Si	un 12/12	/04 Split			Summary			External Miles	tone 🔶					
Progr			ss	F	Project Summary			Deadline	$\hat{\nabla}$					
	Page 1													



E Bill of Materials

Item	Qty	Value	Description	Dist.	Part No.	MFG	MFG Part No.	Unit	Sub	Min Qty
			Microchip PICmicro -							
1	1		PIC12Fxxx	Mouser	579-PIC12F683-	Microchip	PIC12F683-I/P	\$1.56	\$1.56	1
2	1	180 Ohm	Xicon 1/4W 5%	Mouser	30BJ250-180	Xicon	30BJ250-180	\$0.22	\$0.22	1
3	1	240 Ohm	KOA Speer 1/4V	Mouser	660-CF1/4L241.	KOA Speer	CF1/4L241J	\$0.05	\$0.05	1
4	2	100 Ohm	KOA Speer 1/4V	Mouser	660-CF1/4L101.	KOA Speer	CF1/4L101J	\$0.05	\$0.10	1
5	2	100K	Xicon 1/4W 5%	Mouser	30BJ250-100K	Xicon	30BJ250-100K	\$0.05	\$0.10	1
6	1	1K	Xicon 1/4W 5%	Mouser	30BJ250-1.0K	Xicon	30BJ250-1.0K	\$0.22	\$0.22	1
7	1	10K	Xicon 1/4W 5%	Mouser	30BJ250-1.0K	Xicon	30BJ250-10K	\$0.22	\$0.22	1
8	1	0.015 uF	AVX MonoCapa	Mouser	581-SR201C1	AVX	SR201C153KA	\$0.26	\$0.26	1
9	1	0.15 uF	Ceramic Capaci	Mouser	80-C320C154K5	Kemet	C320C154K5R5	\$0.28	\$0.26	1
10	1	10k Ohm	Carbon Resistor	Mouser	660-CF1/4L103.	KOA Speer	CF1/4L103J	\$0.05	\$0.05	1
11	1		LED Standard T	Mouser	604-L1503EC	KingBright	L1503EC	\$0.11	\$0.11	1
12	1	0.5" x 4"	Velostat Plastic					\$0.10	\$0.10	1
13	2		Screws	Hardware Store				\$0.10	\$0.20	1
14				Mouser					\$0.00	1
15				Mouser					\$0.00	1
16				Mouser					\$0.00	1
17				Mouser					\$0.00	1
								Total	\$3.45	

F PIC Assembly Code

Obtain the latest firmware from http://ecg.bluereboot.net/

G References

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