

# **Finger Plethysmograph to Measure Blood Resistivity**

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## **Abstract**

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*Impedance plethysmography can be used to measure arterial volume change that occurs with propagation of the blood pressure pulse in a limb segment. For this measurement, we assume a constant value of blood resistivity. However, blood resistivity may change under both physiological and pathological conditions. Use of an impedance plethysmograph on a finger immersed in a saline filled beaker may yield a method for determining this change in blood resistivity. This may develop into a method that diabetics can use to measure glucose levels non-invasively. The goal of our project is to design a finger plethysmograph to measure blood resistivity.*

<b>Table of Contents</b>	<b>Page</b>
<b>Abstract</b>	<b>2</b>
<b>Table of Contents</b>	<b>3</b>
<b>Problem Statement</b>	<b>4</b>
<b>Background Information</b>	<b>4-8</b>
<b>Current Devices</b>	<b>8</b>
<b>Design Constraints</b>	<b>8-9</b>
<b>Design Alternatives</b>	<b>9-15</b>
<b>Final Design</b>	<b>15-18</b>
<b>Testing and Results</b>	<b>18-22</b>
<b>Future Work</b>	<b>22-23</b>
<b>Conclusion</b>	<b>24</b>
<b>References</b>	<b>25</b>
<b>Appendix A: Circuit</b>	<b>26</b>
<b>Appendix B: PDS</b>	<b>27-29</b>
<b>Appendix C: Project Expenditures</b>	<b>30</b>

## **Problem Statement**

Our goal is to design a finger plethysmograph to measure blood resistivity. In order to accomplish this, we will need to design and build a data acquisition device to acquire the signal from the finger. The device should mechanically immobilize the test subjects' finger such that motion artifacts are kept to a minimum. This device should be able to detect the electrical potential (voltage) change across the finger so that the change in resistance may be determined. It should be able to detect the velocity-dependent change in blood resistivity due to arterial blood pulsations.

In addition, we will need to build an electrical circuit to perform signal processing and analysis. This circuit should be capable of rectifying the alternating current (AC) signal from the finger data acquisition device and modulate it into a direct current (DC) signal to be analyzed. The circuit should be capable of discerning or visually displaying the voltage changes caused by correlated changes in blood resistivity. As an added feature, this circuit may contain an automatic reset function capable of adjusting one of the differential amplifier inputs to that of the output from the data acquisition (finger holder) device. This will allow the device to easily accommodate fingers having different electrical resistances and will prevent having to manually adjust voltages using a potentiometer to match independences with each new test subject or finger position.

## **Background Information**

### **Diabetes**

Diabetes is a disease characterized by the body's inability to manage glucose levels. It is a chronic condition caused by the pancreas's lack of ability to produce enough insulin or the

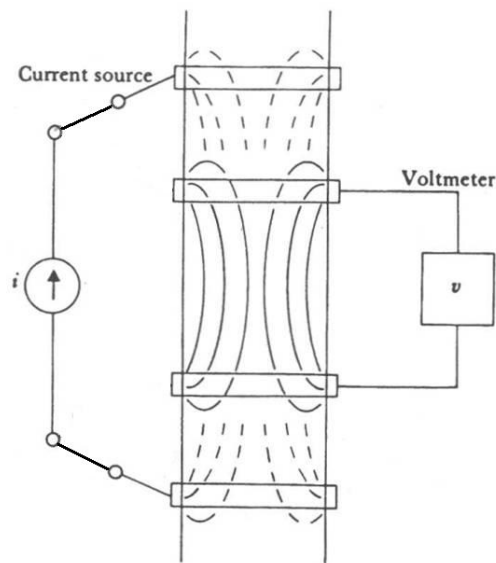
failure of the body to effectively use the insulin produced. Individuals with type 1 diabetes produce little to no insulin and as a result need to self-administer doses of insulin on a daily basis. People with type 2 diabetes cannot use insulin effectively. The condition is usually treated through lifestyle changes and if necessary, oral drugs [1] (WHO 2008). Regardless of type, however, it is important for all diabetics to closely monitor their blood glucose concentration.

The prevalence of diabetes is astounding. In the United States alone there are 17.9 million diagnosed cases of diabetes, and it is estimated that there are an additional 5.7 million undiagnosed individuals living with the disease [2]. The disease is also on the rise. Over the last three years, the number of diagnosed individuals has risen 13.5 percent. In addition, the American Diabetes Association projects 57 million people as pre-diabetic. Globally, occurrence rates of diabetes are even higher; at least 171 million people worldwide have diabetes [1].

As a result, the economic burdens of diabetes are substantial. In the US, the total estimated costs of diabetes in 2007 include \$116 billion in excess medical expenditures and an additional \$58 billion in reduced national productivity [3]. The indirect costs of diabetes that affect productivity include increased work absenteeism, reduced productivity while at work, unemployment from disease-related disability, and lost productive capacity due to early mortality. As highlighted by the large number of individuals living with the disease as well as the large associated economic burdens, there are exceptionally strong motivations (both moral and financial) to perform research in the area of diabetes treatment and monitoring. Thus, an improved method for diabetics to monitor their blood sugar is highly desired.

## **Electrical Theory**

Four electrode impedance plethysmography uses two electrodes to pass current through the finger and two electrodes to measure the voltage output across the finger. For this project, the finger will be inserted downward into a tube similar to that shown in **Figure 1**. The electrode at the top, near the base of the finger, is the current input. The electrode at the bottom acts as the ground where the current exits the system. The two center electrodes measure the voltage across the middle section of the finger. By passing current through the finger (which provides resistance), the resulting voltage drop can be measured across these electrodes [4].

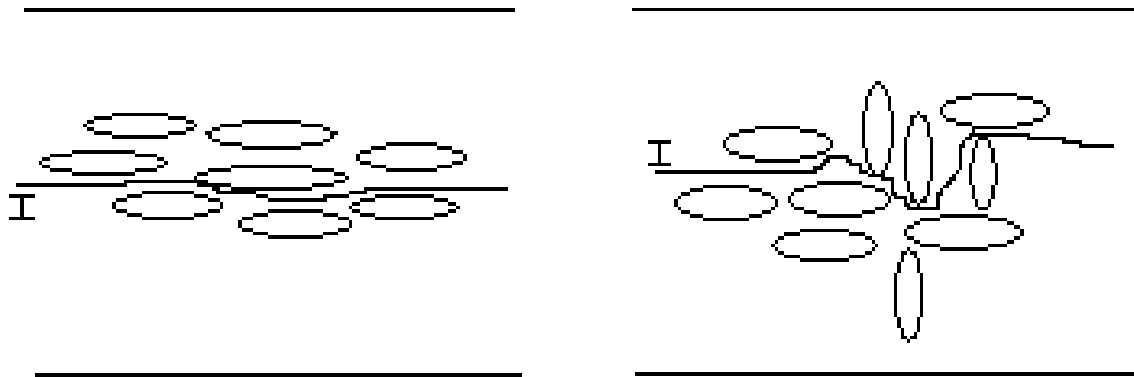


**Figure 1:** Four electrode impedance plethysmography [4]

The voltage measurements obtained will vary depending upon physiological changes in the blood and due to the blood pulse itself. It is expected that these measurements will be small. In order to observe and analyze the signal, the wires from the middle electrodes are connected to a circuit where the signal will be amplified and processed. Finally, the voltage output can be used to calculate the impedance and resistivity of the blood in the finger. It is thought that the resistivity can be correlated with different blood compositions.

## Biological Theory

During high blood flow, such as when the blood pulses through the finger, the red blood cells (RBCs) align as shown in **Figure 2**. When current passes through in this situation, it meets less resistance compared to when there is lower blood flow. During lower blood flow as shown on the right of **Figure 2**, the RBCs tend to clump together or misalign. In this situation, the current has a more difficult time passing through the blood and as a result the impedance increases. It is this electrical impedance and consequent resistivity change that is of interest to be quantified.



**Figure 2:** RBC alignment during high blood flow (left) and low blood flow (right)

It is hypothesized that the resistivity of blood will change with differing blood glucose levels. Higher levels of glucose in the blood would result in greater clumping of the RBCs and a higher resistivity. One of the goals is to be able to correlate these different impedance and resistivity measurements with varying glucose levels [5].

The arterial change in volume of the blood vessel during a pulse also has to be taken into account. If the finger is surrounded by isotonic saline (0.9% NaCl), the saline acts to cancel any signal generated by the volume change. During a pulse, an amount of saline equal to that of the pulse volume is displaced in the finger holder. The saline produces a signal that is equal and

opposite to that of the signal from the volume change of the blood vessel. Thus, the signal generated from the actual volume change of the vessel doesn't interfere with the small change in resistivity trying to be obtained [6].

## Current Devices

Current blood glucose monitors require a small sample of the patient's blood in order to determine glucose levels. This usually needs to be attained through a painful, self-induced finger prick using a lancet. The blood sample is then placed on a test strip where it interacts with chemicals. The strip is inserted into the blood glucose meter and provides an electronic pulse to the meter depending on the reaction. The meter then provides a digital readout of the amount of glucose in the blood. An



**Figure 3:** Accu-Chek kit with glucose meter, test strips, lancet, and carrying case [7]

example product is the Accu-Chek kit shown in **Figure 3**. Other test strips change color and come with corresponding indexes that give a range of glucose levels depending on the composition of the blood [8]. This method may not be as accurate as the digital readout, but both still require a blood sample. Because of the associated inconvenience and pain of these methods, a simpler, more user-friendly non-invasive method is desired.

## Design Constraints

Note: For a precise list of design constraints please see the attached PDS appendix

As with any biomedical device with a patient-electrical interface, the primary design constraint is safety. Electricity is only being applied across the finger, so there is no direct threat of current exposure to the heart. Extra precautions should still be taken, however, to ensure the patient is not exposed to excessive current. First, the electrical circuit going to and from the finger electrode device must be electrically isolated from the rest of the circuit, so any possibility of exposing the patient to 120V, 60Hz wall voltage is eliminated. Furthermore, the prototype must be completely electrically insulated. This will prevent another point of electrical contact being made with the patient, creating another route for current. The prototype must meet all Institutional Review Board (IRB) requirements so that it may be used in clinical studies.

Current home blood glucose meters' test results are considered 'accurate' if they fall within  $\pm 20\%$  of an accepted laboratory derived reference result [11]. Although this seems like a high margin of error, our design is by definition going to be less accurate than current invasive methods, so exceeding their accuracy is unlikely. Errors resulting from motion artifacts should be reduced by firmly restraining the finger and employing an automatic reset function.

The device is being designed for a clinical testing environment. Accordingly it should be easily operated by a trained medical professional. It must be designed ergonomically so the user does not experience any discomfort. Finally the device must be aesthetically pleasing with a professional and non-intimidating appearance.

## **Design Alternatives**

To meet the client's expectations and specifications, a receptacle will be made to secure the finger and hold a saline solution. The receptacle will also contain electrodes in the appropriate configuration to make a four electrode impedance plethysmograph. The receptacle

will be fed by a constant current and the voltage generated across the finger will be amplified and processed by analog and digital circuitry. Three different finger receptacle designs were brainstormed, with each connecting to the same circuit design. The finger receptacles differ by the methods of restraint. All three designs use a glass or plastic tube to hold the saline and provide a place to attach the electrodes. All three designs needed to leave a substantial amount of the finger surface area uncovered so that the finger can interact with the saline for volume canceling and current conduction.

### **Design 1: Inflatable Cuff**

The first design (**Figure 4A**) uses two inflatable cuffs to stabilize the proximal and distal ends of the finger. These cuffs can be inflated independent of each other to accommodate a wide range of finger tip and base sizes. The outer part of the cuff can be attached to the inner diameter of the tube and then inflated using either a hand or electric pump. This design allows for the ability to perfectly match the restraint size to the subject's finger size. The main drawbacks with this design are its difficulty to manufacture and also the complexity required to maintain appropriate pressures without occluding the finger blood vessels.

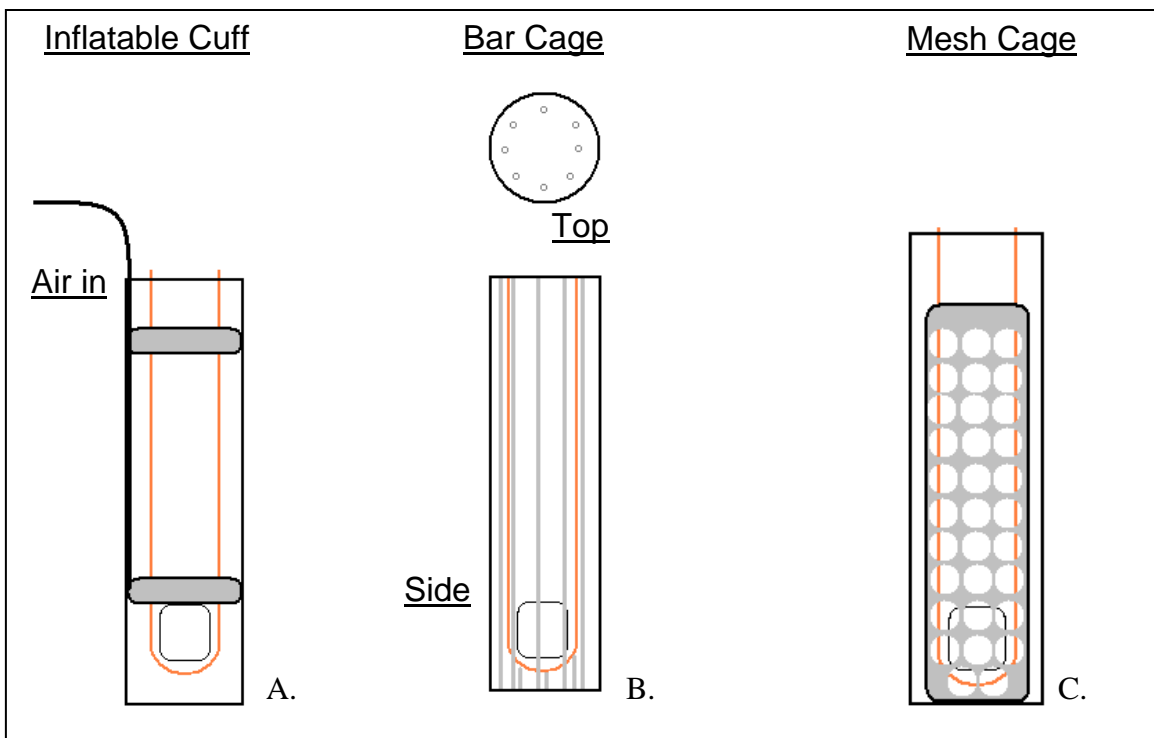
### **Design 2: Bar Cage**

The second design (**Figure 4B**) uses a cage with plastic rods running longitudinally down the length of the finger. The cage itself can be secured either to the sides or to the bottom of the tube. The plastic rods would be compliant enough to deform slightly to accommodate a range of finger sizes. The cage would form a circle around the finger and limit the fingers ability to flex at the two interphalangeal joints. This design would do an excellent job stabilizing the finger and also allow the electrodes to be placed anywhere on the inner tube surface. A major

drawback with this design is its complexity and inability to conform to a wide range of finger sizes.

### Design 3: Mesh Cage

The third design (**Figure 4C**) uses a mesh wrapping that is attached to the sides of the tube by a spacer, putting it closer to the center of the tube. The material is compliant enough to accommodate a range of finger sizes. The holes in the mesh are large, which allows for a large area of the finger to be in contact with the saline for maximum current flow and saline interaction. The mesh has the same advantage as the cage in that it inhibits finger movement in all directions by stabilizing the two interphalangeal joints. The major drawback with this design is its complexity in attaching to the tube while still allowing for a maximum ability to adequately accommodate a wide range of finger sizes. Large finger sizes would be most affected due to the loss of circulation from the tight fit.



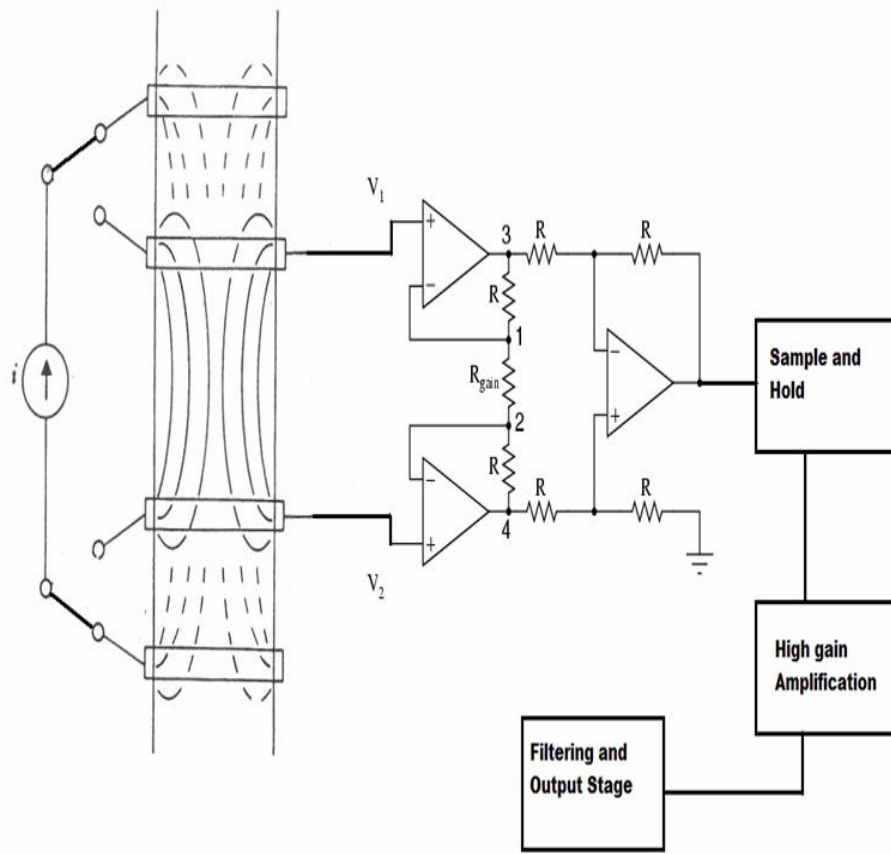
**Figure 4:** Finger restraint designs

## Circuitry

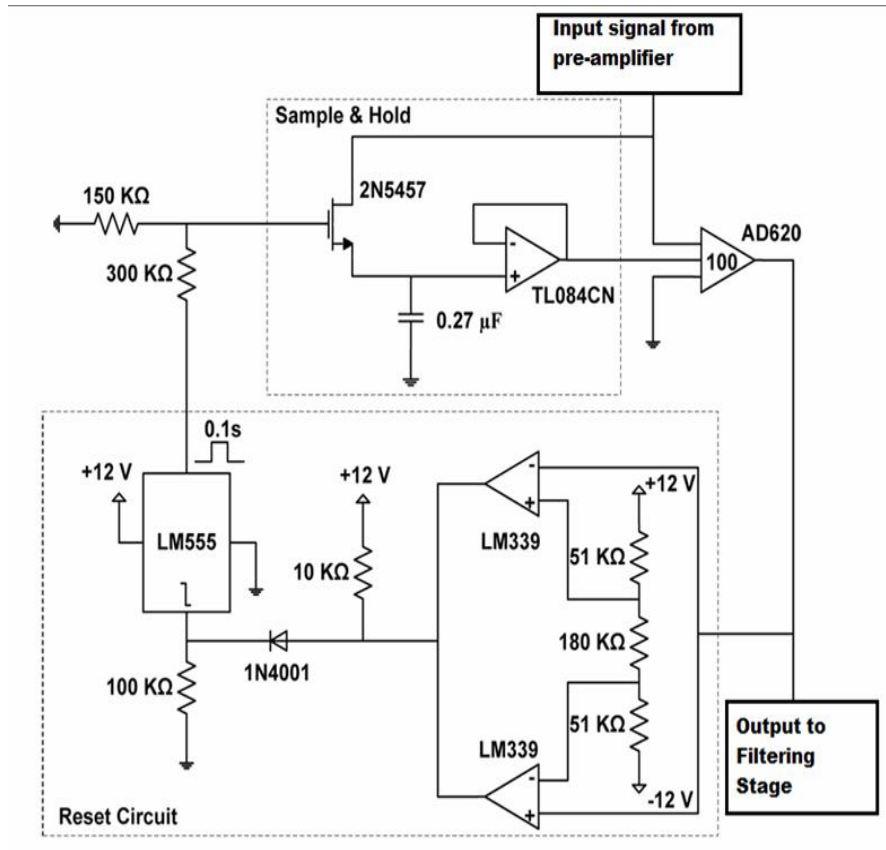
The voltage signals from across the finger are expected to be very small and could be buried within a substantial amount of noise. Because of this, a circuit must be designed that both amplifies the small voltage difference across the finger and filters out any noise that corrupts the signal. The extremely small nature of the signals being measured results in the need for high gain amplification. Because of this high gain, any movement of the finger would saturate the amplifiers. The sensitivity of the measurements requires the need for an automatic reset and sample and hold circuit. The signals being measured have a substantial amount of common interference that does not need to be amplified. To focus solely on the changing signal, a differential amplifier must be used.

All of these requirements were factored into the design of our circuit (**Figure 5**). The circuit has an instrumentation amplifier that acts as a preamp to amplify the changing voltage across the finger. This is then sent through a sample and hold circuit [9]. The sample and hold circuit automatically resets the output once it moves outside a preset voltage window (**Figure 6**). This allows for the circuit to reset once the high gain amplification stage saturates.

The exact requirements for the filter must be determined after data collection. It is necessary to assess the sources of noise and interference in order to be able to accurately design the filters. For this reason the filters are left unspecified.

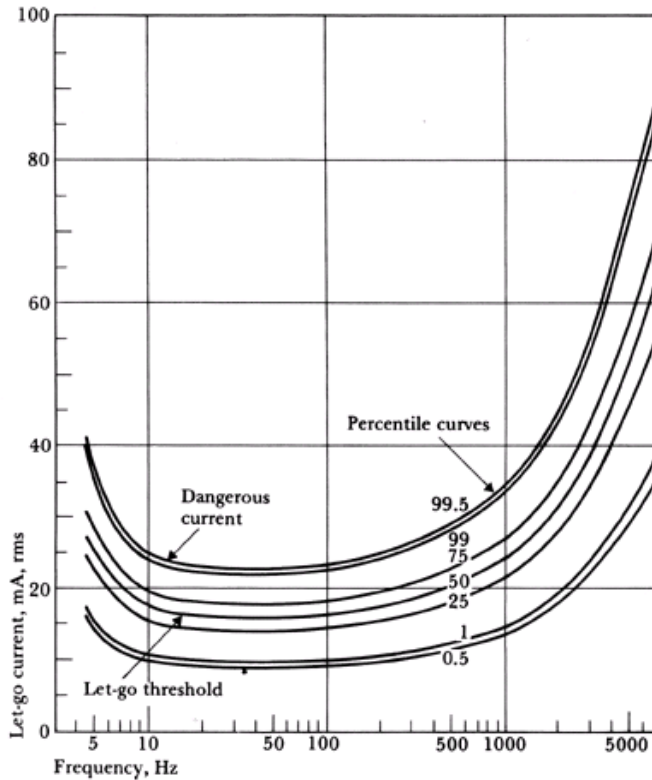


**Figure 5:** Block diagram showing instrumentation amplifier connections to the plethysmograph and signal cascade through the rest of the circuit [4]



**Figure 6:** Circuit diagram of the sample and hold circuit used to reset the circuit during saturation [9]

The current input into the receptacle must be chosen so that it can pass safely through the tissue without causing discomfort, but still encounter some resistance such that a potential difference can occur across the finger (**Figure 7**). A current ranging from 1-10 mA at 50-100 kHz [10] should provide a safe current that will not harm the test subject, yet still allow for an adequate voltage drop to appear across the finger. The exact current value will change between subjects due to variations in body resistance.



**Figure 7:** A plot of let go current versus frequency. As the current frequency is increased the affect it has on the muscles and tissues of the body decreases [4]

## **Final Design**

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Several changes were made to the preliminary design for both the finger receptacle and circuitry.

### **Finger Stabilizer**

The final design for the finger holder is most similar to the air cuff design. However, air cuffs were not used. Instead, elastomeric foam was chosen as an easy to use substitute. The foam came as a 6' cylinder with 5/8'' inner diameter and a 1/2'' wall. Three cylinder sections were attached to the tube: one section at the bottom to stabilize the finger tip, one stabilizing the proximal interphalangeal joint, and the other at the top opening of the tube to stabilize the proximal phalange. The proximal phalange tubing inner diameter was increased to 3/4'' because of the gradual thickening of the finger.

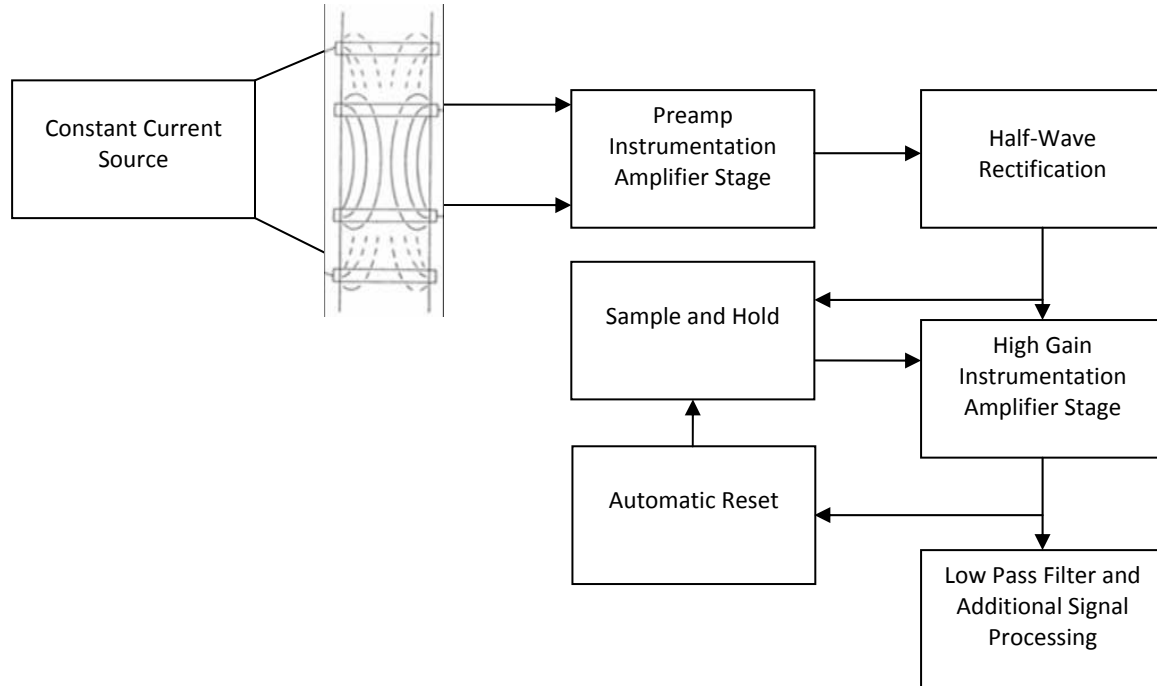
The outer shell of the finger stabilizer was cut to be 4.5'' long and constructed out of 1.5'' Sch. 40 PVC. The length of the tube was overestimated due to the fact that most anthropometric data used measurements from the metacarpophalangeal joint to the tip of the index finger. This data does not help determine an acceptable length due to the interference of the interdigit webbing when the finger is inserted. The foam stabilization at the finger tip also took this variation into account, being 1'' long and placed 2.5'' from the top of the receptacle. This ensured that a finger of length 3.5'' and greater, measured from the metacarpophalangeal joint, would contact all three foam inserts.

The electrodes were made from tin defibrillator electrodes. Each electrode was .5'' wide and 5'' long, enough to completely wrap the inner circumference of the tube. The electrodes were spaced in the tube such that the current ground electrode was at the bottom of the tube and the current input electrode was directly underneath the first foam stabilizer. The top voltage electrode was placed directly below the current input electrode. The bottom voltage electrode was placed immediately under the proximal interphalangeal joint-stabilizing foam. The ground electrode was modified from the original ring to a circular plate measuring 1'' in diameter and attached perpendicularly to the long axis of the tube. Each electrode had a wire soldered to it, which was run up the inner wall of the tube to exit out the top. The bottom of the tube was sealed with a 1.5'' Sch. 40 PVC end cap.

### **Circuitry**

The final circuit design differs slightly from the preliminary design. The circuit consists of six modules that have been designed specifically to measure the signals from the finger restraint. These six modules are differential pre-amplification, rectification, sample and hold,

automatic reset, high gain differential amplification, and filtering and signal processing (**Figure 8**).



**Figure 8:** Block diagram showing the constant current source, electrode configuration and signal pathway

Both differential amplifiers are AD620 instrumentation amplifiers. These amplifiers were chosen due to the fact that the gain could be altered with a single resistor. The gain of the preamp was set at 10 while the high gain amp was set for a gain of 100. The preamp gain was set high so that the incoming signal would be amplified enough to exceed the forward voltage requirement of the rectifying diode.

The rectifying stage uses a 1N4001 diode to create a half-wave rectifier with a ripple voltage to peak voltage ratio of 0.01. The rectification stage was added to strip the envelope off the high frequency input signal. The resulting DC signal would contain the low frequency changes in voltage that are to be amplified further.

The sample and hold circuit consists of a 2N5457 n-type enhancement MOSFET and a TL084CN op-amp. The MOSFET operated as a voltage controlled switch which would close when the output exceeded  $\pm 9$  volts. This would cause an electrolytic capacitor to charge to the voltage sampled from the rectifier output. This capacitor would then hold this voltage at the high gain amplifiers inverting input. This allowed for the high gain amplifier output to be reset back to zero. The TL084CN op-amp acted as a buffer with very high input impedance to slow down the capacitors rate of discharge.

The reset circuit consisted of a window comparator with a window set at  $\pm 9$  volts. LM339 comparators were used to construct the window. When the output voltage exceeds +9 volts or drops below -9 volts the comparator output is -12 volts. This causes the 555 timer to output a voltage pulse with amplitude of 8 volts and duration 0.1 seconds. This pulse turns on the MOSFET and enables it to sample the rectifier output. Once the MOSFET samples, the output is returned to within the comparator window.

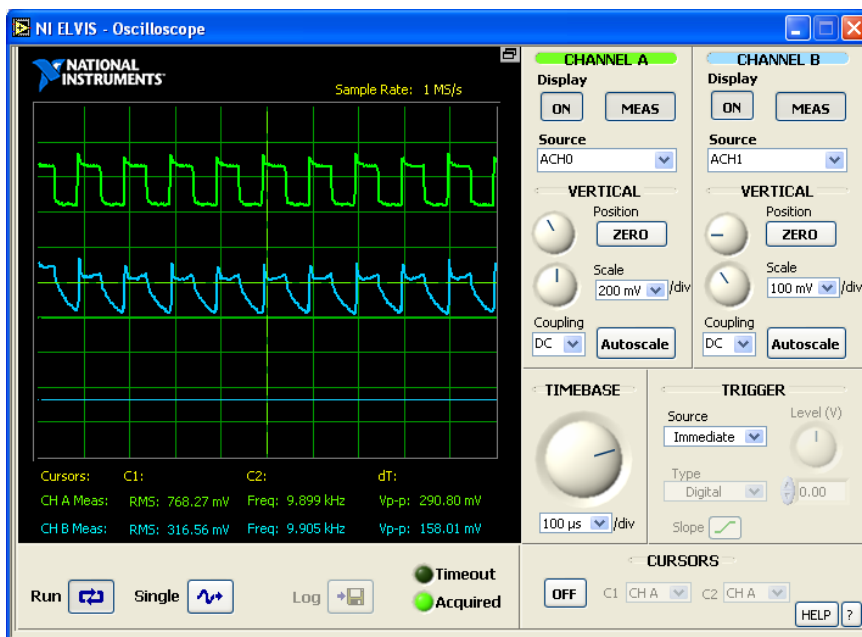
The filtering and data processing stages have not been completely designed at this time. Further research and testing is needed to determine what filtering needs to be done to the signal. As of now a low pass filter is the only filter in the circuit. This low pass filter has a 10 Hz cutoff so that it attenuates any high frequency noise. This cutoff was also chosen because the voltage pulses are expected to be at a frequency of 1-2 Hz, so anything above this is not wanted. Additional filtering and signal processing will need to be determined at a later date. (see **Appendix A** for circuit schematic)

## **Testing and Results**

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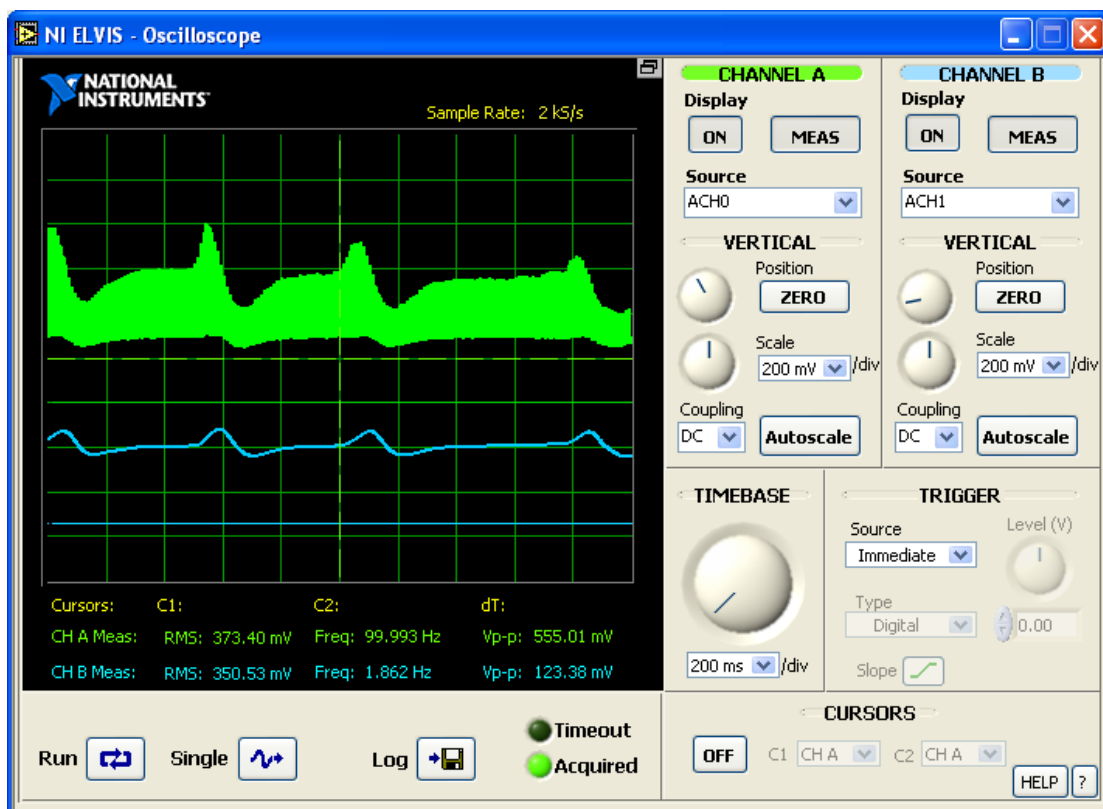
### **Testing of Circuit**

Using a finger plethysmograph to measure blood impedance as it correlates to glucose concentration is a complicated and largely unproven technology. Accordingly, it is important that we have tested each stage of the device to find the source of any error in the final output. First, the voltage across the two current input electrodes and the two voltage output electrodes was observed (**Figure 9**) to ensure that the finger electrode device was working. A Pulsar 6i signal generator was used to input a 10 kHz, 0.9 mA square wave signal to the outer electrodes of the finger device. The signal output was recorded using a NI ELVIS digital acquisition system. A single 21 year-old male was used as a test subject in each of the following tests. As shown in **Figure 9**, the voltage output of the finger device to the circuit showed an attenuated and sloped signal with respect to the generated square wave input. The attenuation was caused by the inner electrodes only measuring a fraction of the total voltage drop across the finger as supplied by the outer two electrodes. Sloping of the input square wave may be caused by the capacitance of the finger holding and then leaking some charge.

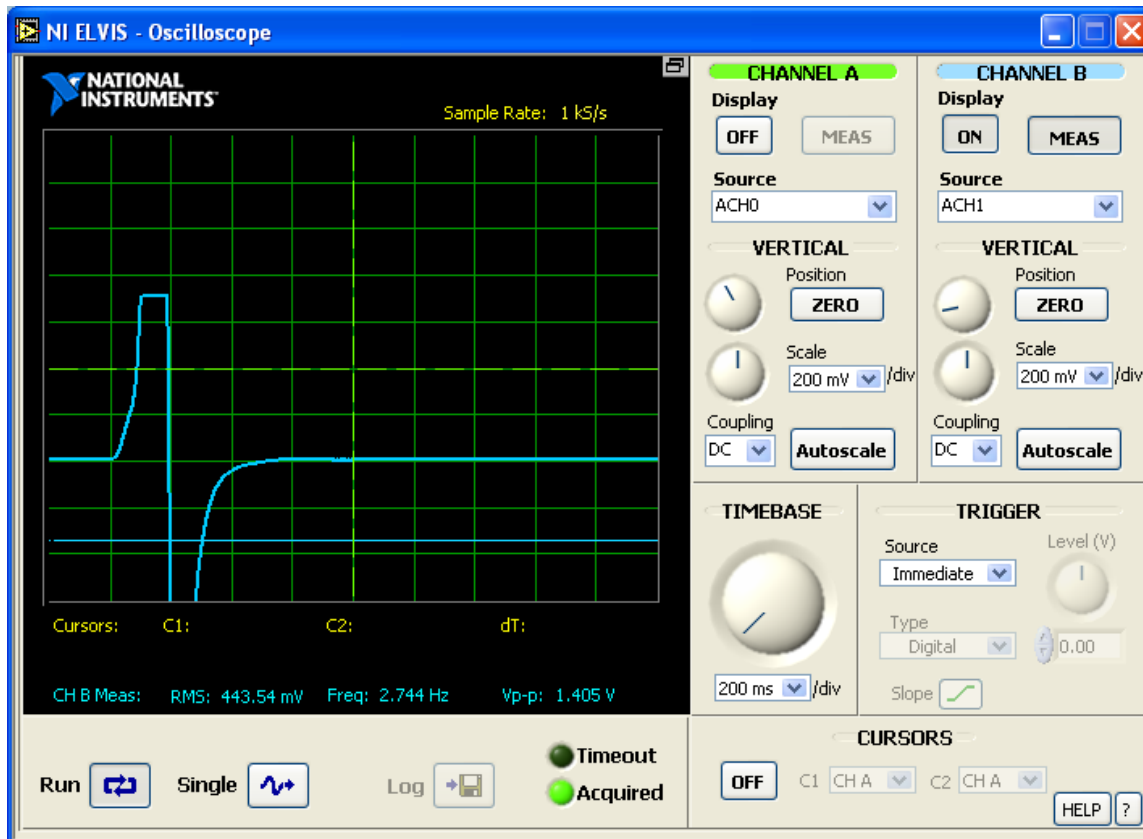


**Figure 9:** Voltage across the outer electrodes supplying the current (green) and across the inner voltage electrodes (blue) show the input and output signals to the finger electrode device

The final filtering stage of the circuit was tested by measuring the signal before and after the filter with a 10 kHz, 0.9 mA input signal (**Figure 10**). A small motion artifact was induced at ~1 Hz to show that signals at relevant frequencies are retained. The auto-reset function was tested by inducing a vigorous motion artifact (tapping against the electrode). As Show in **Figure 11**, once the output of the amplifier is saturated, the sample and hold circuit will reset the circuit back to the baseline value.



**Figure 10:** Graph shows effect of low pass filter (LPF), comparing signal before LPF (green) and after LPF (blue)

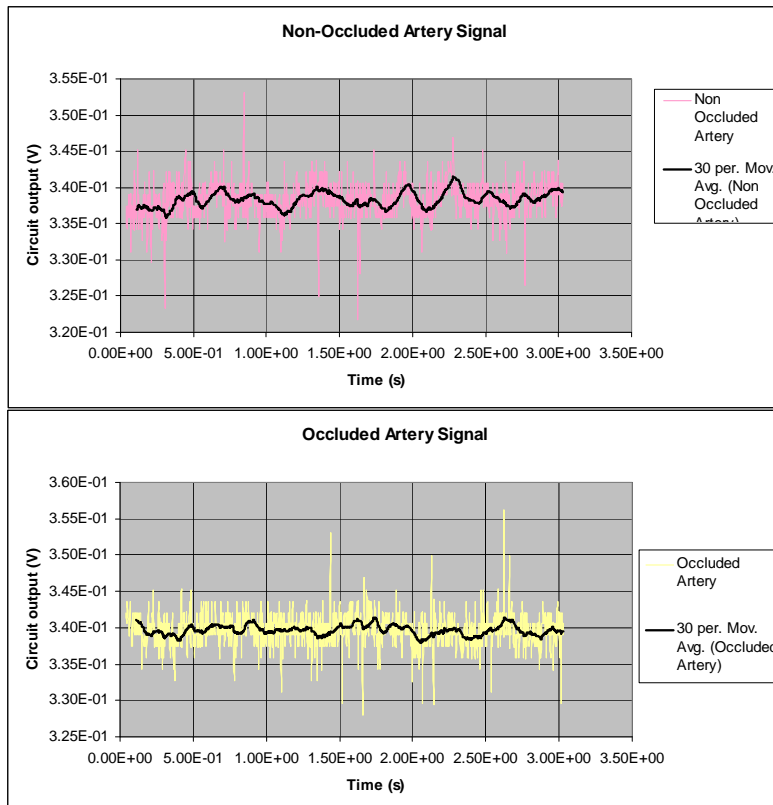


**Figure 11:** Graph shows effect of sample and hold circuit after a large motion artifact is induced

## Results

Upon testing of the device, a pulsatile waveform from the heartbeat was not immediately apparent. As previously stated, the pulsatile waveform from blood flow in the arteries will be very small with respect to the total impedance value of the finger. Further data analysis will be required therefore, to isolate the signal of interest. The output of the system was tested with and without the presence of pulsatile blood flow (**Figure 12**). Blood flow was stopped by occluding the brachial artery of the subject for a short period of time. As before, a Pulsar 6i signal generator was used to input a 10 kHz, 0.9 mA square wave signal to the outer electrodes of the finger device. An oscilloscope was used to sample the data and record it to a disk for transfer onto a computer. To make the signal more legible, the line averaging function of Excel was used

(averaged across 30 lines). Although the non-occluded graph seems slightly more pulsatile, there appears to be little significant difference between the two graphs. If the heart is approximated to pulse at a frequency of around 1 Hz, the space between pulses should be around 1 second. As originally expected, further signal analysis is required to isolate the signal of interest.



**Figure 12:** Graph shows output plethysmograph with artery occluded (bottom) and not occluded (top). Occluding artery will eliminate the change in impedance caused by blood flow. Black line shows line averaging over 30 time points

## Future Work

Several areas of improvement are required on the prototype to make it an effective testing tool as a plethysmograph for blood resistivity. Once optimized, the device can begin clinical trials to determine whether a correlation between glucose levels and blood resistivity exists. To verify the science behind this device, phantom testing units could be constructed and tested in the plethysmograph device.

First and foremost, to turn this design into a functional device, signal processing must be used to identify the pulsatile signal of interest. Occluding the artery can be used as a negative control, to compare a signal with no pulsatile component. Next, a LabVIEW program can be written to process the signal in real time for easier data acquisition. Ensuring a reliable signal will also involve increasing the mechanical restraints of the device to reduce motion artifacts. This can be done in part, by adding an arm rest that will relax the forearm and therefore reduce movement in the finger.

Once a reliable prototype is built and tested, capable of observing the change in impedance from pulsatile blood flow, the device can be used in a clinical study. This will involve getting IRB approval, so the device must be proven to be reliable and safe. At the end of this study, it will hopefully be determined whether there is a correlation between glucose levels and blood resistivity. Further testing may also be conducted to determine whether other physiological factors of blood resistivity (such as protein composition) can also be measured with this device.

To further test this device, and the theories behind it, a phantom could be constructed which pulses blood (or an electrically similar substitute) through an electrically conductive capillary tubing. This phantom could be inserted into the plethysmograph prototype to see if streaming blood cells indeed have a lower impedance than static blood cells. Furthermore this could also be used to test whether increased glucose levels affect how blood cells align statically or when streaming, and if this affects electrical impedance.

## **Conclusion**

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In the United States, over 17.9 million are afflicted with diabetes, with over \$116 billion dollars being spent annually in diabetes related treatment. The development of a non-invasive system to measure glucose could improve the life of diabetic patients by allowing them to comfortably and painlessly measure their blood sugar. Impedance plethysmography of the finger can be used to measure blood resistivity, which may correlate to blood glucose levels and other physiological metrics. The prototype described in this report is capable of measuring the impedance of a finger at relevant frequencies with limited motion artifacts. Further prototype development should allow measurement of the change in impedance from pulsatile blood flow, and clinical studies will be required to correlate blood resistivity with glucose levels.

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# Appendix A - Circuit



## **A Finger Plethysmograph to Measure Blood Resistivity**

**Team Members: Tim Balgemann, Tyler Lark, Nick Harrison, Lucas Vitzthum**

**Function:** Our goal is to design a finger plethysmograph to measure blood resistivity. Impedance plethysmography may be used to measure arterial flow change that occurs with propagation of the blood pressure pulse in a limb segment. For this measurement, we assume a constant value of blood resistivity that will change under dynamic and static conditions. However, blood resistivity and flow conditions may change under both physiological and pathological conditions. Use of an impedance plethysmograph on a finger immersed in a salt-filled beaker may yield a simple method for determining blood resistivity. This may develop into a method that diabetics can use to measure glucose level noninvasively.

**Client requirements:** (itemize what you have learned from the client about his / her needs): Briefly describe, in bullet form, the client needs and responses to your questions.

- The device must observe the change in impedance caused by pulsatile blood flow
- The device must meet all Institutional Review Board (IRB) requirements, so that it may be used in a clinical trial.
- The device should employ an automatic reset function to compensate for motion artifacts.

**Design requirements:** This device description should be followed by list of all relevant constraints, with the following list serving as a guideline. (Note: include only those relevant to your project):

### **1. Physical and Operational Characteristics**

a. *Performance requirements:* Initially, this device is intended to be used in a clinical research setting. Accordingly, it must be intuitive and easy to use for a trained medical professional. The data output must be reliable, and easy to read with a user friendly interface.

b. *Safety:* The device will be designed so that the electricity used will not cause any harm to the user. Electrical exposure is limited to the finger, so no current should ever flow through the heart. The American Heart Association recommends that no more than 10  $\mu$ A RMS current be applied

across the chest. Because our device exceeds this limit, it is important that the device is thoroughly electrically insulated such that no alternative current route is made through the body. ([www.americanheart.org](http://www.americanheart.org)) . Proper labeling must be used to ensure the patients and clinicians are aware of the dangers involved with applying an electrical current to the body. The safety standards employed in this device should meet Institutional Review Board's regulations.

c. *Accuracy and Reliability:* Current home blood glucose meters' test results are considered 'accurate' if they falls within  $\pm 20\%$  of an accepted reference result, usually a lab test<sup>1</sup>. Although this seems like a high margin of error, our design is by definition going to be less accurate than current blood drawing methods, so exceeding their accuracy is unlikely. To compensate for motion artifacts, the device should use an automatic reset function.

d. *Life in Service:* The device should be operable for a period of up to 6 months or until the completion of the necessary testing and evaluation of the prototype can be completed. The device should be able to provide consistent results over an entire research trial with run times of up to 5 consecutive hours. The device should be able to withstand minor physical impact such as being dropped from a height of 1 meter.

e. *Shelf Life:* The device should be able to withstand a shelf life of up to 3 years if kept in a 10-35° C low humidity environment. The saline solution should be made fresh daily to prevent changes in salinity from evaporation.

f. *Operating Environment:* This device will be used in a clinical and laboratory setting. It will likely be in a controlled temperature, humidity and light environment. The lab will most likely have other instrumentation instruments, so the device will likely be subjected to electrical interference. This device should employ some means of reducing electromagnetic interference to the signal.

g. *Ergonomics:* The device must be able to accept a wide range of finger sizes, while minimizing finger mobility. The user must be able to easily insert their finger into the device with their finger and fore arm comfortably yet firmly restrained.

h. *Size:* The devices size must be such so that it doesn't interfere with the positioning of the finger and it can't hinder the data collection, but size is not a critical design constraint in this clinical setting

i. *Weight*: The prototype designed for clinical setting does not need to be overly light. It must be under 25 pounds so any personal can move it without assistance.

j. *Materials*: Materials must be corrosion resistant, as they will be exposed to a saline solution for an extend period of time. All non electrical components must be insulating, so that no other points of electrical contact are made with the body.

k. *Aesthetics*,: Color, shape, form, texture of finish should look professional yet non intimidating to ensure both physicians and patients feel comfortable with the device.

## 2. Production Characteristics

a. *Quantity*: We will initially construct 2-3 devices to be used in research.

b. *Target Product Cost*: The current device is being designed for a research environment where low cost is not a high priority.

## 3. Miscellaneous

a. *Standards and Specifications*: Must meet all Institutional Review Board Requirements for clinical trials. Exact specifications can be found at <http://www.grad.wisc.edu/research/hrpp/hsirbs/hs.ForIRBMembers.html> .

## References:

1. Defined by the error-grid analysis method of Clarke WI., et al. In "Evaluating Clinical Accuracy of Systems for Self-Monitoring of Blood Glucose," *Diabetes Care*, Vol. 10, No. 5 (1987), 622-628.

### Appendix C – Project Expenditures

Source	Item	Part Number	Quantity	Total Price	
DigiKey.com	IC Timer CMOS 8-DIP	LMC555CN-ND	2	\$3.46	
	IC Comparator Quad Lo PWR 14-DIP	LM339NNS-ND	2	\$2.40	
	Rectifier Diode 50V 1A DO-41	1N4001DICT-ND	5	\$1.50	
	JFET N-CH GP 10MA TO-92	2N5457FS-ND	2	\$0.62	
	IC QUAD JFET-INPUT OPAMP 14-DIP	296-1784-5-ND	2	\$1.10	
	IC AMP INSTRUMENTATION LP 8-DIP	AD620ANZ-ND	2	\$20.34	
				<b>TOTAL</b>	\$29.42
The Home Depot	Elastomeric Pipe Insulation	803014116206	1	\$5.89	
	1.5" PVC cap	12871628368	2	\$1.66	
	1.5" PVC fitting	12871559389	1	\$0.51	
	1.5" PVC fitting	12871559228	1	\$0.72	
	PVC Plug	54211143162	1	\$0.89	
	PVC Bushing	12871627439	1	\$1.27	
	DMV P-trap	12871552144	1	\$2.69	
	1.5" PVC fitting	12871558221	1	\$1.68	
	1.5" X 8' PVC Pipe	754826203441	1	\$3.89	
	1.5" PVC fitting	12871559334	1	\$0.43	
	PVC Adhesive Handy Pack	38753302478	1	\$4.10	
				tax	\$1.79
				<b>TOTAL</b>	\$25.52
Radioshack	4CKT MALE MOLEX	2740224	1	\$2.39	
	4CKT FEMALE MOLEX	2740234	1	\$2.39	
	6CKT MALE MOLEX	2740236	1	\$2.59	
	6CKT FEMALE MOLEX	2740226	1	\$2.59	
				tax	\$0.55
			<b>TOTAL</b>	\$10.51	
Helen C. White	56"x42" Poster	N/A	1	\$49.00	
			<b>TOTAL</b>	\$49.00	
			<b>Grand Total</b>	\$114.45	