

A Finger Plethysmograph to Measure Blood Resistivity

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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 μ 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) . 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 test¹. 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.