The Product Design Specification (PDS) – Revised 12/12/12

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Title: Portable Diagnostic Device for Anemia in Developing Countries

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Project Need:

Anemia is one of the leading causes of preventable death worldwide, particularly in developing countries such as Ghana where screening is largely unavailable due to limited resources. Anemia is a condition that limits the uptake of oxygen by the body due to insufficient quantity of hemoglobin or improper bonding of oxygen to the hemoglobin. This lack in oxygen restricts cell function and respiration leaving an infected person with symptoms such as fatigue, headaches, and shortness of breath. If left untreated, palpitations and heart failure may occur. Yet, this can be easily prevented if a person is diagnosed and treated in timely manner. A portable and accurate diagnostic tool can help decrease undiagnosed and untreated anemia cases in Ghana.

Problem Statement:

To develop a cost effective, intuitive point of care solution for portable devices with magnification and resolution capabilities adequate to measure red blood cell size to determine mean corpuscular volume from a peripheral blood smear

CLIENT REQUIREMENTS

Design requirements: This device description should be followed by list of all relevant constraints, with the following list serving as a guideline.

1. Physical and Operational Characteristics

a. *Performance requirements*:

- Magnification: The magnification of this solution must produce results with low percent error when compared to results of a clinical coulter counter.
- Resolution: The resolution of this solution must produce results with low percent error when compared to results of a clinical coulter counter.
- Stability: The solution must safely and stability fit on a portable microscopic imaging device to reduce error during analysis.
    - Note: The type of imaging device has not been determined.
- Glass Slide Ready: The solution must allow a glass slide with a peripheral blood smear to be inserted. The solution must also allow the user to accurately position the slide for analysis by ImageJ. The solution must then have a feature that locks the slide in this position to avoid error.
    - ImageJ is a public domain, Java-based image-processing program developed at the National Institutes of Health (http://rsb.info.nih.gov/ij/docs/concepts.html). This program will be utilized by the developed application to count RBC and analyze RBC size based on neutrofils and lymphocytes found on the slide. These "landmarks" will also require analysis.

- Manufacturing: The solution must be easy to produce at a low cost but of durable, lightweight material in order to be easily transported.
    - Sterility: The solution must be easily disassembled for thorough cleaning if the device would come in contact with a contagious or dangerous substance or material in order to protect the user and patients (See *Safety*).
    - Overall Use: The primary focus of the designed diagnostic tool is that it must be easy to use to ensure an efficient workflow by users that may have different levels of medical experience. The purpose of this device is to screen as many people as possible for anemia in the functioning eight hours per day at clinics in developing countries. Because clinics in developing countries do not have the resources to support advanced medical equipment, the solution itself must be cost effective and it must be compatible with a cost effective, portable imaging device.

b. *Safety*: Due to it being very common for target populations to be misdiagnosed, safety concerns to keep in mind while using this tool include:

- Misdiagnosis: Failure to accurately position the slide may cause ImageJ to not receive an accurate analysis of RBC. This may lead to misdiagnosis.
- Water Exposure
    - To Slide: Water exposure to the slide may cause water to leak into the peripheral blood smear. This may cause lysis to occur destroying the RBC.
    - To Device: Water exposure to the device may cause the device and portable imaging device to become unusable. The user may be in danger of electrical shocks.
- Sterility: Many blood borne illnesses are prevalent in developing countries. It is important that the solution can be easily disassembled for thorough cleaning to protect the user from contracting bacteria/viruses that may be in blood smear.

c. *Accuracy and Reliability*:

- Peripheral Blood Smear Analysis: The solution must analyze a peripheral blood smear with a low percent error when compared to the analysis of a coulter counter.

d. *Life in Service*:

- Stability: The device should be able to withstand daily wear-and-tear and traveling including potential drops and bumps.

e. *Shelf Life*: Not Applicable

f. *Operating Environment*: Because this solution will be primarily used in a highly populated clinic in Africa, the operating environment consists of stresses from the natural environment and general usage including:

- Water Exposure
- Heat Exposure
- Dust Exposure
- Vibrations

- Dropping Hardware/Phone

g. *Ergonomics*:
- Magnification and Resolution: The magnification and resolution should be preset to avoid error.
- Hardware Dimensions: See *Size*.
- Hardware Implementation and Removal: The solution should be easy to connect to a portable imaging device and should maintain in place throughout the procedure. The solution should also be easy to remove from the imaging device.
- Slide Insertion: A glass slide should be easily inserted and removed from the hardware.
- Slide Lock: A glass slide should be easily locked into place inside the hardware for analysis.

h. *Size*:
- Hardware Dimension: The dimensions of this solution should be that of a specified diagnostic imaging device so the solution fits without movement to avoid error. The imaging device has not been determined.
- Hardware Maintenance: The solution should not have to be cleaned if used correctly and without exposure to bodily fluids. However, the solution should be easily disassembled if needed (See *Safety*).
- Portability: The solution should lightweight, stable, and safe for both during use and travel.

j. *Materials*:
- Material: High density polyethylene, polycarbonate, and aluminum

k. *Aesthetics, Appearance, and Finish*: TBD

2. Production Characteristics

a. *Quantity*:
- 1 portable imaging device

b. *Target Product Cost*:
- Testing Costs: $0
    - Testing costs were kept at $0 with the help of Dr. Bain and Dr. Eliceiri
- Hardware Manufacturing Costs: TBD
- Competitors Costs -
    - HemoGlobe: $10 - 20
- Final Cost of Hardware: TBD

3. Miscellaneous

a. *Standards and Specifications*:

- Cultural Acceptance: Because this solution is the first of its kind, it is important to educate the patients on how it is used and the results it can produce to establish trust in the device. This may lead to more patients requesting to have this procedure performed on them.
- Travel Requirements and Safety
    - Country Expectations
    - Device Protection: The device will require protection during traveling to prevent damage.

b. *Customer Expectations*:
- Easy to Use: The solution should be made so a user can logically inser the slide and lock the slide in place. The magnification and resolution should be pre-set to avoid unclear images and misdiagnosis.
- Easy to Clean: The solution should be easy to clean to avoid contamination and user or patient harm.

c. *Patient-related concerns*:
- Sterility: See *Safety.*

d. *Competition*:
- HemoGlobe
- Lifelens
- Hemocue