Product Design Specifications

Client: Dr. Philip A. Bain
Advisor: Professor Thomas Yen

Team:

Carly Hildebrandt childebrandt@wisc.edu - Team Leader
Michal Adamski adamski2@wisc.edu - BWIG
Katherine Barlow kbarlow@wisc.edu - Communicator
Lazura Krasteva lkrasteva@wisc.edu - BSAC
Jeffrey Wu jwu69@wisc.edu - BPAG

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Function

Anemia affects many people worldwide and disproportionately affects those in developing countries due to a lack in medical infrastructure to properly diagnose the blood disorder. A portable, easy to use, and cost-effective device is needed to diagnose the condition in these countries at the time of initial medical care. Anemia can be diagnosed by evaluating red blood cell size using the mean corpuscular volume (MCV). The goal is to fabricate a microfluidic device that effectively measures the MCV of red blood cells to determine if a patient has normocytic, macrocytic, or microcytic anemia with results comparable to current cell counting techniques.

Client requirements

- Device should provide an accurate diagnosis of anemia and differentiate between microcytic, normocytic, and macrocytic anemia
- Device should be low-cost and adaptable to resource-limited environments
- A clinician should be able to use the device easily and reliably after proper training with an intuitive user interface
- The device should be able to diagnose anemia at the point of care

Design Requirements

1. Physical and Operational Characteristics

a. Performance requirements: The device should be able to diagnose anemia, by identifying patients' Red Blood Cell (RBC) count, Mean Corpuscular Volume (MCV), and hemoglobin (Hb) levels. Testing and diagnosis time should take less than 30 minutes.

b. Safety: Blood samples must be introduced to the device in a contained environment so that no contamination occurs between device uses and between the user. The device must be used with proper blood collection techniques.

c. Accuracy and Reliability: RBC, MCV, and/or Hb levels should be measured with at least 95% accuracy when compared to standard counting techniques (i.e. Coulter Counter) to allow for diagnosis of anemia. Diagnosis with 95% accuracy should take no longer than 30 minutes.

d. Life in Service: Device hardware should function for at least 5 years, and the blood collection platform will be reusable. Software should be able to be upgraded when necessary.

e. Shelf Life: Device and all attachments should have the ability to be stored for 5 years from the time of manufacture.

f. Operating Environment: The device will be primarily used in developing countries (i.e. countries in Africa, Southeast Asia and South America), so available resources should be taken into consideration. Generally access to most resources is limited so the device should be able to stand alone or run with minimal outside help (i.e. batteries or a small generator).

g. Ergonomics:The device should be easily transportable and usable by clinicians of varying experience and educational backgrounds.

h. Size: The device should be small enough to fit on a benchtop in a clinical setting while maintaining enough portability to transport to areas in need. The circuitry housing should be no larger than 4” x 6” x 10”. The microfluidic device should be no larger than 4” x 4”.

i. Weight:The device should weigh no more than five pounds (2.3 kg).

j. Materials: Materials should be low-cost and durable. They should also be biocompatible as to not disrupt cell structure as the blood is moving through the device (i.e. PDMS for the microchannels).

k. Aesthetics, Appearance, and Finish: Device should have an output screen to view RBC, MCV, Hb levels, and classification of anemia. Data should be easily interpreted by the user. Circuitry should be hidden from view.

2. Production Characteristics
a. Quantity: One prototype is needed for proof of concept.

b. Target Product Cost: Product should not cost more than $200.

3. Miscellaneous
a. Standards and Specifications: To be determined at a later time. Device will be used in developing countries, not covered by the FDA. FDA guidelines will be followed, but approval is not needed.

b. Customer: Clinicians of varying skill levels in developing countries.

c. Patient-related concerns: Should be able to give patient a diagnosis at point of care.

d. Competition: Existing devices include the following:

- Coulter Counter : A coulter counter measures the MCV, hemoglobin and the red blood cell distribution width. The coulter principle, which uses the direct current impedance method, governs the use of the device.

- HemoGlobe: HemoGlobe is a non-invasive device designed by students from Johns Hopkins University that measures the hemoglobin level of a blood sample. The device measures the parameter and then sends the data to a center for further data analysis.
- Microfluidic card for RBC analysis: Patent - US8034296 B2: The cartridge enables a complete blood count including red blood cell analysis of various parameters. The cartridge channel may also be subject to an electric or magnetic field during operation.