medical

industrial

consumer

ULTRACRIT™

An innovative application of ultrasound technology brought lab-grade accuracy to a hand held device.

Awards:
2007 MDEA Winner
2007 NIH Tibbetts Award
2004 Maryland Daily Record Innovator of the Year

The Reason:
Hematocrit is a relative volumetric measure of red blood cells that make up the total blood fluid. This index (directly related to hemoglobin) provides an indication of general patient health. Physicians and health care professionals use this as an adjunct to other clinical assessments to monitor cancer patients, anemia, acute blood loss, and dehydration, among others. Drawing on their expertise in ultrasonic fluid property measurement, the engineers at Key Tech developed a method for measuring hematocrit that could provide lab-grade accuracy in a portable hand held device with only a drop of blood.

The Challenges:
Ultrasound has a long track record of applications in the medical industry. But until this product, it had never been used to try to interrogate and distinguish properties of blood. Over the course of several years, several thousand man-hours of testing and many design iterations, the technology evolved to using less than one drop of blood, a custom miniaturized transducer, and a measurement process that takes 30 seconds or

Medical Design Excellence Awards® 2007 WINNER

Tibbetts Award
Innovator of the Year

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Product Development Cycle

Research & Development	Market Research	Concept Development	Prototyping	Clinical Trials	Design Transfer	Production Support

less. Another design challenge was developing a simple, effective way to collect the drop and to focus the ultrasonic beam on it.

The Work:
Having worked extensively with ultrasonic fluid property measurement in other fields, the engineers at Key Tech hypothesized they could measure the properties of blood using similar techniques. Large, crude, proof-of-concept tests were used to explore the general theory that ultrasound could be used to interrogate blood. The team explored different types of ultrasonic techniques (e.g., attenuation, backscatter and speed-of-sound), as well as issues like beam focus, red blood cell (RBC) settling, potential interferences and a host of others. New algorithms, processing techniques, blood collection and handling methods were developed, which revealed a technology that was incredibly precise and repeatable.

In parallel with the technology development, the engineers were also pursuing development of the actual device and consumable. There were issues of designing the consumable to meet performance and cost targets, as well as concerns related to packaging, data collection, power consumption and processing speeds. With regard to the consumable, the solution was a one-time-use cuvette, designed with two unique regions: a holding chamber and an ultrasonic window area. The blood sample is initially collected into the holding chamber of the cuvette, and is later moved into the window area for testing. The UltraCrit literally takes hundreds of millions of ultrasonic measurements per second, which are collected, filtered and analyzed by signal processing algorithms. To handle all these tasks, the electrical engineers developed a 12 layer circuit board, with all of the data collection, processing, and error checking capability self-contained, and they did it for about 2% of the cost of existing ultrasonic data collection systems.

To give the user a visual indication that a specific test was done, the team created a door that is spring loaded and hydraulically damped to provide a smooth motion. A latch automatically engages and auto-locks on the door, ensuring that the cuvette cannot be bumped or prematurely removed. When the test is complete, the device automatically un-latches the door, which then springs open. The motive force for un-latching the door is a shape memory alloy wire which provides significant load and displacement with very low power consumption. The door of the device was also designed to facilitate cleaning, and act as a redundant safety feature, by containing and catching any small blood residual that might fall off of the cuvette.

The Value:
In blood banking, accuracy means improved patient safety and a better supply of blood products. The UltraCrit uses ultrasound and technology to try to maximize both, ensuring the utmost safety and the maximum number of acceptable donors. For the manufacturer, the UltraCrit will be used to enhance existing product offerings and open new market segments. And, although initially developed for blood banks, the accuracy and speed of this device also has great value in other point-of-care applications such as acute care (emergency rooms), physician offices, natal care, and the military. The device is currently CLIA waived and FDA cleared.