Berkeley Sensor and Actuator Center (BSAC)

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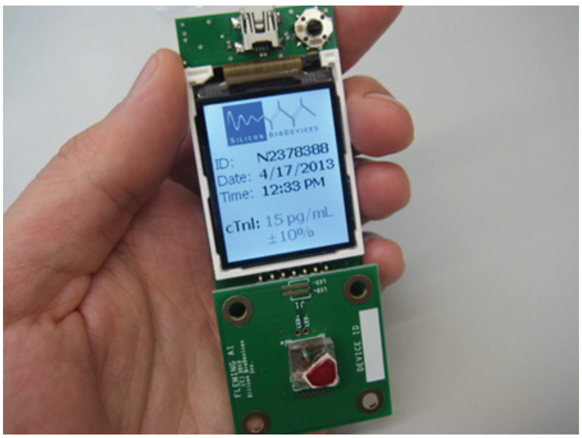
Disposable Blood Analyzer



Silicon BioDevices (SBD) has solved a key problem of point-of-care diagnostics - the trade-off of speed versus quality. Now clinicians can get rapid test results without sacrificing quality to make critical-care decisions for improved patient outcomes. SBD's state-of-the-art blood analyzer is as fast and easy to use as an over-the-counter pregnancy test, but with the sensitivity and accuracy of a central lab. In one self-contained system, the handheld device seamlessly integrates all of the assay functions of a point-of-care test directly onto the surface of a Complementary Metal Oxide Semiconductor (CMOS) chip.

Over 6 million people arrive at US hospital emergency departments annually with chest pain and nearly a third of them are admitted for a suspected heart attack. A diagnosis is made using a patient's symptoms, Electrocardiogram (ECG) readings, and biomarker blood tests. Symptoms and ECGs have long been the standard; however, around a 1/3 of patients having heart attacks have non-diagnostic ECGs, and 1/4 have atypical symptoms. Biomarker tests are the most reliable method of detecting heart attacks, with new high-sensitivity tests having diagnostic accuracy of roughly 95%. In 2000, the clinical definition of a heart attack was changed to reflect this. Unfortunately only about 50% of patients presenting with chest pain have biomarkers tested before being sent away or admitted. Currently, performing these tests can be disruptive and results typically take over an hour to return. Because of these difficulties in diagnosing chest pain physicians are caught in a balancing act between inaccurate Point-of-Care (POC) tests and slow laboratory tests.

Using magnetic biosensor technology spun out from BSAC, Silicon BioDevices (SBD) has developed the first single-use, handheld blood analyzer that can measure one or more biomarkers from a drop of whole blood with precision and accuracy equal to a clinical laboratory. Results can appear either on the device's integrated digital display or wirelessly on a secure smart phone or other remote display in less than 10 minutes.

The heart of the product is a microchip that contains a sensor array capable of detecting up to 100,000 single molecules directly from unprocessed samples - without the need for an external reader. In addition to overcoming the challenge of speed versus accuracy in point-of-care testing (POCT), the device's standalone design allows caregivers and patients to test anytime, anywhere.

With the potential to house up to 100,000 sensors, each about 100th the cross-sectional area of a human hair, the microchip-based device has the unrivaled ability to count single molecules one at a time. The microchip is mated to a passive sample-filtration system that takes a drop of human whole blood and delivers plasma onto the chip for analysis. Due to the advantages of CMOS digital technology, SBD can offer immunoassays, small molecules and DNA tests all in one handheld, single-use device.

An industry first, its on-chip integration of all analytical functions eliminates the need for an external reader, thus greatly simplifying the use of the device in any workflow environment and reducing its manufacturing cost. Exploiting microchip manufacturing, Silicon BioDevices estimates the devices can be produced at a cost of under $2 for production volumes in excess of 10 million a year.

Encryption and wireless transmission can be integrated so digitized data can be sent wirelessly to any remote display such as a smart phone, tablet, or computer-based electronic medical record. Since the device requires only one microchip, a battery and a digital display, it can be designed to conform to any form factor such as a thumb-drive or smart phone. Moreover, the single-use design is a key advantage that addresses the growing concern for infection control in hospital settings.

Silicon BioDevices' blood analyzer can be engineered to rapidly measure a wide range of single- or multi-target biomarkers that require highly sensitive quantitative detection in any setting - including ambulances and the home. These include biomarkers for heart failure, liver enzymes, inflammation, sepsis and a wide range of other infectious disease agents.

> **Economic Impact**: On the one hand, 2% or more of patients having heart attacks are sent home, representing the single largest source of medical malpractice costs. On the other hand, billions of dollars are wasted each year caring for patients unnecessarily admitted with benign chest pain. Accurate POC testing, which gives results in under 15 minutes, can substantially reduce both types of errors by providing results sooner, and for those patients admitted it can reduce the average total admission time by 30% and total charges per admission by 25%, resulting in millions of dollars of savings per emergency department per year.

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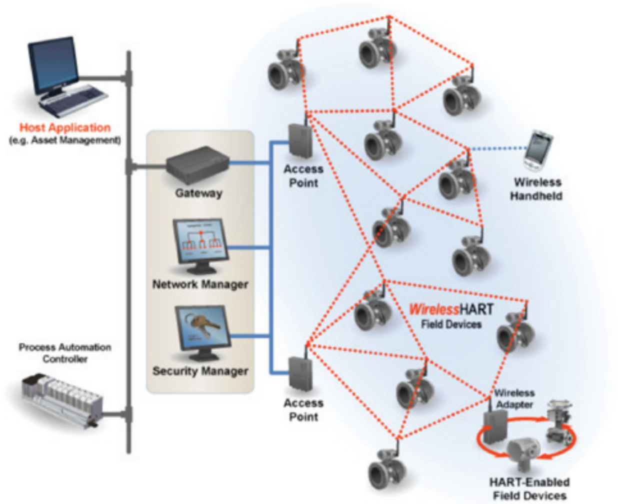
Wireless HART: Open Source Protocols for Wireless Sensor Networks

One of the first international wireless sensor standards to emerge, one that UC Berkeley professor Kris Pister helped draft, is known as Wireless Highway Addressable Remote Transducer or "Wireless HART." His previous work with "SmartDust" (see "Radio-Equipped Wireless Sensors called "Smart Dust"" on page 9) offered an advantage with an up to a 100:1 reduction in installation costs of new sensors. This is because installations do not require wiring to connect to the sensor networks. Quite simply, the "Wireless HART" protocol untethers a multitude of pre-existing industrial sensors previously connected and communicating locally over physical wires and globally via modems over the switched telephone network. It enables a pending swarm of up to a trillion connected sensors.



Wireless HART: Expands or Replaces Wired HART Networks with Economic & Reliable Wireless Devices in a MESH Network with no Change to Host Applications

Illustration courtesy Hart Communications Foundation

The work started as a modest effort involving an "Open Wireless Sensor Network" or OpenWSN by BSAC scientists at the University of California. This work helped foster and support industry standardizations by the International Institute of Electrical and Electronics Engineers (IEEE), the world's largest association for the advancement of technology, by the International Society of Automation, and soon by the Internet Engineering Task Force. BSAC Professor Kris Pister helped initiate efforts to fill this need with issuance of a series of software communications protocols "out in the open" (publicly available to all parties, without charge).

Cell phones are arguably one of the most important and impactful consumer product ever. These devices will soon be speaking wirelessly to local sensor networks using WSN radios and protocols. The smartphone, by accessing these emerging arrays of external sensor networks, will enhance healthcare and fitness as well as enable context awareness and control and a multitude of information-enabled applications that have not yet been conceived or invented. The synergies of the wireless sensory swarm and the smartphone are becoming truly transformative to the communications industry and to the personal lives of hundreds of millions. Smartphones already speak to a very small number of other electronic devices using wireless standards such as Bluetooth.

Economic Impact: More than a billion smartphones were shipped in 2012; many were so called "smartphones" with touch screens, cameras, compasses, navigation aids, even built-in projectors and significant computational capabilities. "Wireless HART" makes the previously wired networks wireless. This is accomplished with virtually no change to the (HART) language spoken by the sensors or to the massive hundred-billion dollar industrial control infrastructure of which these sensors are a part. Qualcomm has funded a new research laboratory at UC Berkeley called the "SWARM Lab" to stimulate amazing new WSN applications, testbeds and industry collaboration. Several BSAC faculty co-Directors are important contributors to the work underway in this laboratory, much of which might not exist without some of the pioneering work of Pister and other UC Berkeley researchers who with their technical leadership as well as scholarship, inspired new generations of engineers. Qualcomm continues to invest in wireless health and other connected applications.

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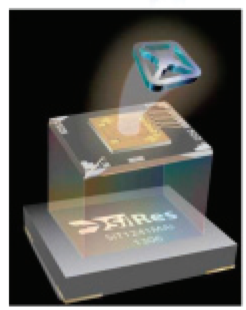
MEMS-Based Timing Components

Today (and for most of the past century), electronic systems depend upon or have depended upon quartz crystals for generation of basic timing signals. That is about to change. Microelectromechanical systems (MEMS) include an important class of devices that "resonate" at high frequencies and that can be used to create precise electronic timing and frequency-selective systems. These promise to change the way electronic systems derive their timing.

Several BSAC-inspired startup companies including SiTime (co-founder BSAC and co-Director Bernhard Boser), Harmonic Devices (acquired by Qualcomm), and Silicon Clocks founded by former BSAC co-Director Roger Howe and BSAC post-doctoral researcher Emmanuel Quevy (acquired by Silicon Labs), and current and former BSAC industrial member companies including Japanese NDK, and University of Michigan startup Discera Corporation (founder BSAC and co-Director Clark Nguyen) have been introducing quartz replacement technology based on these MEMS resonators.



MEMS resonator-based timing components (left) will likely be embedded in most computing and mobile devices (above).

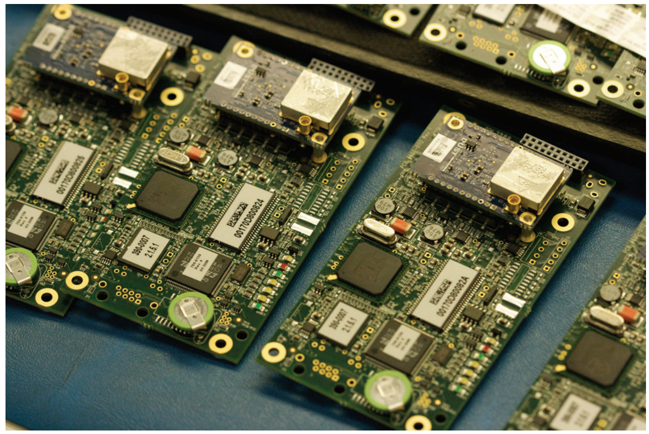
Image courtesy of SiTime Corporation.

Before end of this decade, it is nearly certain that high frequency filtering required for all mobile devices including cellular telephones and mobile computers as well as communications systems for wireless sensor networks, will depend upon integrated components with thousands of interconnected MEMS resonators. These will perform most of the radio frequency filtering functions currently done with external discrete surface acoustic wave (SAW) and discrete Film Bulk Acoustic Resonators (FBAR) devices. At that time, more than 2 billion portable computers and mobile (cellular) telephones will make use of this technology pioneered in large part at BSAC.

Economic Impact: The current US timing devices market of nearly \$2B/year represents only the initial target market for MEMS timing components (source: BCC Research Inc). In 2006, this market was 99% served by quartz crystal devices. Private estimates by both crystal and MEMS technology companies suggest a MEMS resonator penetration of approximately 5% in 2012 and 10% to 50% of a \$5B/year worldwide market by 2020.

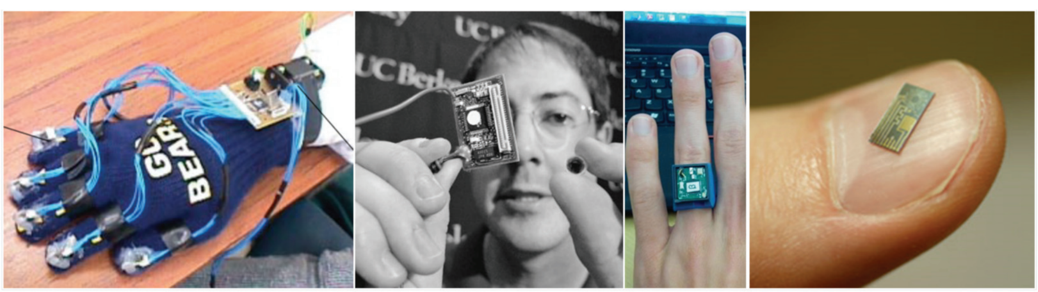
For more information, contact Bernhard Boser, 510. 643.8350, boser@eecs.berkeley.edu.

Radio-Equipped Wireless Sensors called "Smart Dust"



Kris Pister of the Berkeley Sensor and Actuator Center popularized the term "Smart Dust" to help visualize his goal of an autonomous network of highly miniaturized "motes" containing microradios and microsensors that can be deployed at random; that wake up; identify who and where their neighbor motes are; and form a dynamic ad hoc self-organized mesh data network over which sensor data such as location, motion, light, pressure, temperature, etc, is communicated wirelessly, reliably and without human intervention. In 2006, Professor Pister, professor of electrical engineering and computer science at UC Berkeley, was awarded the Alexander Schwarzkopf Prize for Technological Innovation from the I/UCRC Association.

This Smart Dust story is really a story of collaborative "stone soup" in which Pister contributed the stone from a $25,000 industrial award from I/UCRC member company Hughes and a $10,000 California (state) MICRO industrial matching grant that eventually led to a $1.7M DARPA Smart Dust program.



Smart Dust Evolution: inertial sensors + wireless communications

From Left: 1999 sensors & radio GLOVE..2004 BOARD…2013 RING …2016 GOAL

This work resulted in a groundswell of industrial and new venture capital investments in wireless sensor networks (WSN). UC Berkeley computer science collaborators developed an open source small footprint (4KROM, 256 bytes RAM) network operating system called Tiny OS for the little micromotes that were built from off-the-shelf components and later miniaturized. The micromotes were dropped from UC Berkeley unmanned aerial vehicles and installed at 1/100th the installation cost of wired sensors in a structure of a sister I/UCRC: "Center for the Built Environment (CBE)" on page 41. This inspired academic and industrial collaborations that haven't subsided today. This technology was awarded the Alexander Schwarzkopf Prize for Technological Innovation by the I/UCRC Association in 2006.

Economic Impact: Market forecasts of more than $8B/year made some 8 years ago by market analyst InStat* of overall wireless sensors and network components enabled in large part by the "Smart Dust revolution", were about 8 years too early; but these technology-enabled promises to revolutionize homeland security, environmental control, power management, and infrastructure monitoring are now materializing into the multi-billion dollar market envisioned. The global market for wireless sensor devices used in end vertical applications totaled $532 million in 2010 and $790 million in 2011. This market is expected to increase at a 43.1% compound annual growth rate and reach an estimated $4.7 billion by 2016.
*Source: InStat/MDR 11/2003 (Wireless); Wireless Data Research Group 2003; InStat/MDR 7/2004 (Handsets); www.MarketResearch.com. 2012.

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