WHITE PAPER

Jerome Schang
MSP430 Strategic Marketing
Texas Instruments Incorporated

TEXAS INSTRUMENTS

Enabling secure portable medical devices with TI's MSP430™ MCU and wireless technologies

Introduction

Developers and users of portable medical devices today continue to demand more connectivity and longer battery lifetimes. For example, IMS Research's press release in June 2012 projects that Bluetooth® Smart used in medical devices powered by coin-cell batteries will gain tremendous momentum over other wireless technologies. Supporting this trend, Texas Instruments (TI) introduced the first semiconductor products based on its game changing "Wolverine" technology platform - MSP430FR59xx microcontrollers - which provides a mix of unique features enabling secure connectivity in personal portable and connected health care devices. This paper will introduce TI's embedded solutions leveragingMSP430FR59xx microcontrollers and the CC2541 Bluetooth low energy series for use in medical devices that support the secured-telehealth ecosystem.

The portable medical market has constantly evolved over the past two decades. As the world becomes increasingly connected, connected health, or telehealth, has become a prevalent trend in medical device technology. Below are a few key industry trends:

- More than 10.3 million consumer medical *Bluetooth* Smart devices will ship worldwide between 2012 and 2016, and more than 4.7 million in 2016 alone, according to IMS Research.
- IMS Research revealed that with its low-power consumption, *Bluetooth* Smart will be the dominant wireless technology on consumer medical devices by 2016 despite the fact that only 5 percent of medical devices have any wireless connectivity capability in 2012.
- In the report "Wireless Opportunities in Health and Wellness Monitoring 2012 Edition," IMS Research found that more than 35 percent of all wireless-enabled consumer medical devices shipping in 2016 will feature *Bluetooth* Smart technology.

In these portable medical devices, the *Bluetooth* Smart technology enables the device to collect vital data and then transfer that information to a *Bluetooth* Smart Ready device, such as a laptop, smartphone or tablet. These consumer devices can then transfer the data using cellular networks or Wi-Fi® to a cloud platform so doctors can monitor a patient's condition. While this may seem simple enough, electronically storing and transmitting medical data requires careful consideration of patient privacy regulations. The Health Insurance Portability and Accountability Act (HIPAA) enacted in 1996 aims to streamline electronic health record systems and impose strict electronic security regulations. As the trend toward electronic enabled medical records and telemedicine continues, medical practitioners have the same duty to safeguard a patient's medical records and keep their treatments confidential as was required with traditional paper records. In fact, because electronic documents can more easily be duplicated and transmitted, storage of electronic files, images, audio and video needs to be done with an even higher level of security. As a result, digital security needs to be carefully considered in the development of any portable medical device.

Enabling low-power security with TI's MSP430FR59xx microcontrollers

TI's MSP430FR59xx microcontrollers enable the design of medical devices with secure connectivity and storage for remote devices with displays such as smart phones, tablets or medical aggregation devices to help ensure that the chain of confidentiality remains intact. In conjunction with wireless products from TI, this FRAM-based product series can provide wired and wireless connectivity to healthcare devices, including blood pressure monitors, blood glucose meters, weight scales, pulse oximeters and more via ZigBee®, sub-1 GHz, *Bluetooth*, *Bluetooth* low energy and USB utilizing the personal healthcare device class (PHDC) protocol.

To help ensure that data remains confidential, *Bluetooth* low energy inherits the encryption, authentication and authorization security from "classic" *Bluetooth* technology. The encryption technique uses the advanced encryption standard (AES), which was a technique adopted as a standard by the U.S. government.

The AES technology is featured inside of MSP430FR59xx microcontrollers, which, combined with the MSP430FR59xx microcontrollers' advanced memory protection unit, enables a high level of security for portable medical devices.

Based on TI's ultra-low power "Wolverine" technology platform, MSP430FR59xx microcontrollers offer the following features, enabling security, long-battery life and high levels of integration for any portable medical device:

- Wireless sensing enabled with:
  - Lowest power 12-bit analog-to-digital converter (ADC)
    - 75µA at 200ksps
    - Up to 8 differential inputs from 16 channels
    - Window comparator on every input
    - 1.8-3.6V operation with auto power down
  - FRAM memory
    - Save 12-15% of battery life on wireless firmware updates
    - Fast response for time-sensitive data storage
    - Nearly infinite write endurance allows elimination of external EEPROMs
    - Inherently tamper resistant
  - Ultra-low power system-on-chip (SoC)
    - 7 low power modes
    - Fast wakeup <6 µs
- Secure applications enabled by
  - 256-bit AES
    - Low-power advanced encryption
    - On-the-fly key expansion
    - Supports 128-, 196- and 256-bit key sizes
    - DMA support for ECB, CBC, OFB and CFB cipher modes
  - Lockable memory segments
    - IP protection, device ID, tamper detection and secure data logging

About health device profile supported by CC2541

The *Bluetooth* Special Interest Group (SIG) has developed "Health Device Profile" (HDP) software to optimize performance of classic *Bluetooth* for health applications and deliver data in a standard format requested by the medical practitioners. Similarly, the SIG is developing HDP software for *Bluetooth* low energy.

Classic *Bluetooth* technology's HDP is a "one-size-fits-all" solution that caters to all types of medical products. Consequently, classic *Bluetooth* technology's HDP is a large program requiring a lot of memory and battery power. Bluetooth low energy has a number of HDPs customized to a given application. A medical product designer can select one or several profiles to suit their specific application, reducing the memory and power overheads. A *Bluetooth* low energy-equipped end product will be simpler, cheaper and more power efficient than would be possible with an equivalent classic *Bluetooth*-equipped device.

The current version of *Bluetooth* low energy includes HDPs for medical and fitness applications such as body temperature, blood pressure, weight scale, glucose, pulse oximetry, heart rate, pedometer, speed, distance, cycle cadence, simple remote control and battery status.

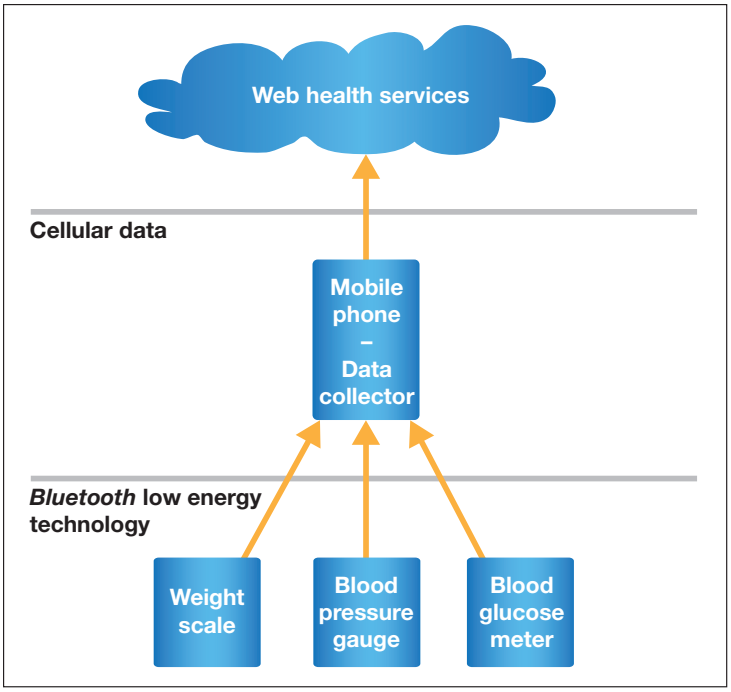

Figure 1: Data flow using BLE in medical and fitness applications

In addition to security protection, *Bluetooth* low energy also employs privacy protection in order to stop "tracking" by unauthorized receivers. This is done by limiting the ability to track a transmitting device through the use of a random device address that is frequently changed.

To support demanding applications requiring low-power and upgradable stacks, TI introduced its CC2541 *Bluetooth* low energy solution with the following key benefits:

- Early realization of low-power, single-mode *Bluetooth* low energy sensor applications
  - Full system solution: 2.4 GHz CC2541 SoC, profile software, sample applications, development kits, technical documents and support
  - Royalty-free BLE-Stack™ firmware that enables over-the-air downloads from any central device for simplified user experiences
- Simplified design with integration on one chip and a flexible solution
  - Controller, host and application on one 6mm x 6mm device
  - Applications can be written directly onto the CC2541, which supports both analog and digital peripherals
  - Flash-based: firmware can be updated in the field and persistent data can be stored on-chip
  - Pin-for-pin compatible with TI's CC2540 *Bluetooth* low energy SoC and CC253x ZigBee RF4CE solutions
  - Support for *Bluetooth* v4.0 and proprietary modes at 250Kbps, 500Kbps, 1Mbps and 2Mbps
  - Robust, proven *Bluetooth* technology that builds on success of the CC2540
- Enables design of low-power sensor devices that can operate for >1 year on a coin cell battery
  - 18.5 mA transmit current at 0 dBm
  - As low as 14mA current drawn from the battery (a 20% reduction) when using TI's TPS62730 step down converter
- Robust RF performance
  - Up to 99 dB link budget
  - Best-in-class coexistence with other 2.4 GHz devices

Wide adoption of wireless technologies and its effect on the telehealth industry

In June 2009, the Continua Health Alliance—an open industry coalition of 190 companies collaborating to improve the quality of personal health care—selected two wireless technology standards for inclusion in the next version of its interoperability design guidelines. The guidelines provide information for electronics product manufacturers on how to design their products to meet Continua's agreed interoperability standards and receive the Alliance's certification logo.

After consideration of required power levels, cell phone ubiquity, required range and anticipated market penetration, the Alliance chose *Bluetooth* low energy (pending finalization of the specification) for medical wireless monitoring of a user's health and fitness levels.

The benefits of this decision aid companies like the S3 Group, a leading provider of telehealth consultancy services. The S3 Group operates a patient portal, which has optimized software for MSP430 products. This portal enables the flow and sharing of medical information and telehealth data between patients and doctors outside of clinical settings. Through its flexible and interoperable architecture, the portal facilitates data exchange with multiple telehealth systems or electronic health records (EHRs).

The platform enables telehealth vendors or service providers to deliver more effective chronic disease management and information exchange toolsets across the entire telehealth ecosystem. Moreover, with the easy-to-use portal, patients can actively manage their long term condition by making informed decisions about their health, accessing educational materials, following recommendations from their providers, or engaging in local community activities. In addition, the portal allows authorized friends and relatives to track the progress of a patient and to provide motivation and support as necessary.

An example application: Blood glucose monitoring

Rates of type 2 diabetes are increasing in developed countries due to an aging and increasingly overweight population. In the United States, for example, according to the Centers for Disease Control, approximately 23.6 million people, or 8% of the current population, have diabetes of which 95% suffer from type 2 of this disease.

Uncontrolled diabetes can cause severe long-term health problems such as renal failure, blindness and arterial disease. These problems are expensive to treat, and as the number of those afflicted climbs, the costs continue to climb.

Proactive management of diabetes is one way to mitigate the cost of treatment, because such management delays may even prevent the onset of related health complications. Diabetes management depends on frequent and accurate measurement of blood glucose to maintain normal levels (a fasting range of 4 to 6 mmol/liter).

Patients are advised to record blood glucose levels several times a day – more frequent measurements result in better control, since diet, exercise or insulin injections can be adjusted quickly to stabilize high or low levels. To gauge blood glucose levels, a blood glucose meter measures samples deposited on a test strip. As an example of how microcontrollers enable this technology, an MSP430FR59xx MCUs used in such a blood glucose meter can store information in its integrated FRAM memory then later recall it at a regular health check-up. The FRAM technology provides continuous data logging options through its endurance (10^15 writing cycles). *Bluetooth* low energy built into a blood glucose meter offers several advantages in the management of diabetes. Data from the blood glucose meter could be uploaded frequently to the patient's cell phone then sent to the physician's computer for review via a patient portal, such as the S3 portal. An analysis of blood glucose measurement trends would allow the physician to spot persistent out-of-normal-range episodes much earlier than the typical quarterly reviews, enabling the physician to alter the patient's diet on a weekly basis.

Bluetooth low energy is capable of communicating with a web-based application without using a cell phone or PC by using a *Bluetooth* router - a device that acts as a "gateway" between the *Bluetooth* low energy device and the Internet. The web-based application can also send messages back to the Bluetooth low energy device.

To enable further diabetic control, continuous glucose monitoring offers patients and physicians real-time data to proactively manage the condition. Continuous glucose monitoring relies on frequent measurement (for example, 288 glucose measurements every 24h) of blood glucose. One FDA-approved continuous glucose monitoring device uses a tiny glucose-sensor inserted under the skin of the abdomen. The system automatically records an average glucose value every five minutes for up to 72 hours.

Continuous glucose monitoring with wireless capability also has major benefits to type 1 diabetes sufferers. Since they are more prone to short-term complications, such as low blood glucose levels (hypoglycemia) which can occur between routine finger prick measurements leading to a coma if not treated rapidly, BLE-capable devices could save lives. With frequent measurements, the provider or patient is able to set thresholds that warn the patient of dangerous levels enabling real-time treatment.

Both the traditional blood glucose monitoring methods and the more recent movement toward continuous glucose monitoring require regular storage of glucose measurements and protection of patient data during storage and transmission. TI's ultra-low power MSP430FR59xx microcontrollers offer the necessary features – integrated FRAM for glucose measurement storage as well as integrated security acceleration for encryption of sensitive patient information – to help medical device manufacturers design products that keeps patient data secure during storage or wireless transmission.

Furthermore, the ultra-low power performance enables the capability for some applications to operate from harvested energy, such as body heat, enabling true continuous monitoring independent of batteries or other power sources. The combination of MSP430FR59xx microcontrollers, TI connectivity solutions and high performance analog front ends (AFEs) enable medical device manufacturers to use such TI products to design a variety of implementations that include data logging.

Summary

As discussed throughout this paper, the trends of wireless communication and security for medical and fitness applications are becoming more important. Patients can share medical information and telehealth data with stakeholders outside of a clinical setting. Data exchange with multiple telehealth systems with security enabled by MSP430FR59xx microcontrollers is instrumental.

These platforms will further enable telehealth vendors or service providers to deliver more effective chronic disease management and information exchange toolsets across the entire telehealth ecosystem. Patients can actively manage their long term condition by making informed decisions about their health, accessing educational materials, following recommendations from their providers or engaging in local community activities. TI plays an active role in enabling the market and will keep developers informed about its investments and commitments to deliver leading edge solutions.

For more information, visit: **www.ti.com/MSP430**

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