Semiconductors for Wearable Medical Devices

How developing medical sensor interfaces using a semi-customisable System-in-Package (SiP) approach can result in smaller devices for the wearable age. By Jakob Nielsen, Sr. Manager, Consumer Health Product Line, ON Semiconductor

The medical market is very broad and includes devices used for monitoring and treatment at clinical healthcare facilities, and home healthcare devices. These devices include hearing aids used by people with hearing impairments, activity monitors used as part of weight reduction management by people suffering from obesity, medicinal monitors for people requiring ongoing treatment, and transdermal drug distribution patches used as part of a pain management regime.

Though clinical and portable devices serve an important purpose, the medical industry has recently shifted towards home healthcare options with the segment expanding at a growth rate typically above 9% per year (Databeans, 2014). As the ‘baby boomer’ generation ages and generally requires more medical care, the industry is becoming more reliant on alternative measures to treat patients. This, along with an increased interest in fitness and wellness, has necessitated more affordable, portable options. By using portable options instead of devices at traditional point-of-care facilities (hospitals, clinics), patients can be monitored and treated without the inconvenience of having to frequently visit a doctor. This improves quality of life for those dependent on treatment, and optimises industry costs for insurance companies and other facilities.

ON Semiconductor focuses its research and development efforts within four key health care categories: hearing health, patient monitoring, fitness, and therapies (e.g. pain management). These are characterised by a need for small, wearable, battery-powered devices which include two to three key technological features: ultra-low-level signal sensing; signal processing and control, and; interoperability.

Ultra-low-level signal sensing is required to capture small, physiological signals originating from sensors placed on the outside of the skin or from minimally-invasive sensors which break through the skin. An example of an outside-skin sensor is an electrocardiogram (ECG) electrode. ECG electrodes capture the small electrical changes on the skin that are caused when the heart muscles depolarize from each other during each heartbeat. Likewise, an example of a minimally-invasive sensor is a continuous glucose monitor (CGM), which uses sensors that gently pierce through the skin and measure the glucose level of interstitial fluid.

Maintaining balance

Most medical semiconductor companies address sensor-interfacing needs by providing separate discrete components like amplifiers, A/D converters, power management, or by providing system-on-chip (SoC) solutions that include microcontrollers in combination with basic analog circuitry and power management. In order to optimise both size and performance for the end-application, neither of these solutions is ideal for the medical industry.

Medical device manufacturers often spend years developing and refining their sensors in order to capture key physiological signals at continuously lower levels, while pursuing lower overall product costs and broadening adoption for an optimal range of customers.

Discrete solutions can typically be designed to convert the sensed signal into voltages or currents suitable for A/D conversion. However, they are often costly in terms of space required on the printed circuit board (PCB) and ultimately impact the size of the end-device. A key factor in ensuring adoption of wearable technology is minimising size and optimising comfort for the user, which makes discrete solutions problematic to implement.

Additionally, discrete solutions may suffer from aggregated variation stemming from tolerances. Variations in bias currents, dynamic range, and leakage currents can negatively impact the device's performance.

In comparison, System-on-Chip solutions are typically smaller and offer improved integration with both analog circuitry and microcontrollers. However, designers of SoCs are often constrained in terms of what analog performance can be achieved due to limitations in most SoC semiconductor processes. These processes are often dominated by a desire to achieve very high levels of digital integration (eg. the more memory and the more digital functionality per square millimeter of the chip the better). This implies that trade-offs such as higher leakage current and more noise for the analog portion of the SoC must be made, which is typically not acceptable for optimal medical device sensor performance.

In late 2014, ON Semiconductor launched Struix, a new product concept. Meaning "stacked" in Latin, Struix combines a custom ASIC and an application specific standard product (ASSP) microcontroller together in a miniature, high-performance system-on-chip (SoC) solution. The concept offers medical device manufacturers the best of both worlds: the ability to address specific, proprietary sensor-interface needs with a custom chip, while typically lowering design risks and associated costs by using an industry-standard product. Figure 1 below shows a typical Struix-based product.

Semi-custom SiP

In Figure 1, the upper chip is an example of a proprietary sensor interface and the lower chip is an industry-standard ARM Cortex- M3 controller-based microprocessor; the ULPMC10, which was designed specifically with low power and chip stacking in mind. In this example, the two components are stacked in a 6x6mm QFN package, but other packaging options are available. A Struix-based product begins with the development of a proprietary sensor interface. The development process takes advantage of ON Semiconductor's intellectual property (IP) within low-power, low-noise signal conditioning, amplification, and conversion. Some examples of available key IP blocks include 24-bit converters operating at less than 2.4pJ per conversion level and low-noise, differential amplifiers operating at only tens of micro amperes.

A proprietary sensor-interface development flow typically originates in the customer's proprietary sensor interface specification, and is followed by design, implementation, test, and qualification phases. In parallel with these phases, the

customer's application development team is able to develop the necessary end-application code on the ULPMC10 microcontroller. ON Semiconductor offers a small development board which is suitable for standalone operation as well as with a prototype of the proprietary sensor interface once available. This enables the customer to evaluate the performance of the end-application prior to full production.

Most medical devices operate in a duty-cycled manner (eg. The devices spend more time in sleep mode than in active mode). The ULPMC10 microcontroller targets such operation by offering a very low sleep mode current of 200nA with real-time clock circuitry always running. Active modes consume less than 200µA/MHz when fully loading the ARM Cortex-M3 processor and executing application code directly out of on-chip flash memory. This allows for extended battery life, which, combined with the usage of smaller batteries, leads to a smaller, more attractive medical device.

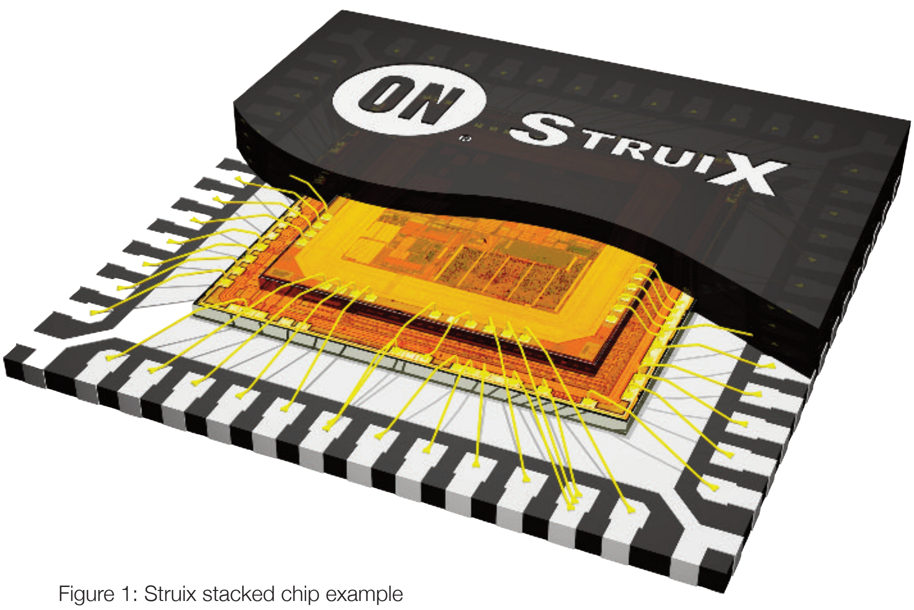

Figure 1: Struix stacked chip example