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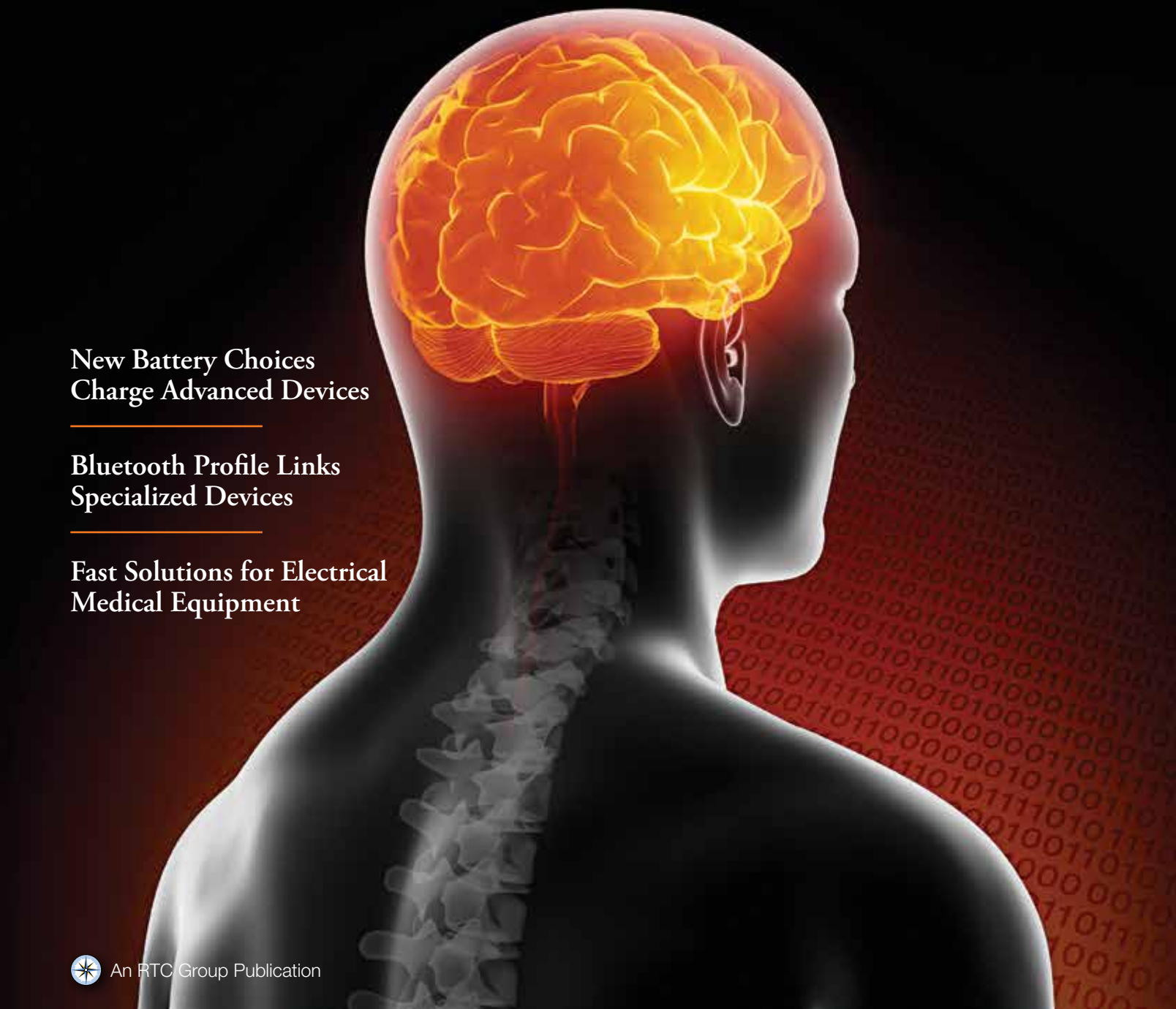

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NOVEMBER 2013

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PULSE

Medical Electronic Device Solutions (MEDS) uncovers how embedded technology will bring the biggest breakthroughs in electronic medical devices design. Whether large or small—*MEDS* is the most influential source of information for engineers, designers and integrators developing the newest generation of complex and connected medical devices. *MEDS* is currently a supplement of *RTC* magazine, distributed in print to 18,000 engineers, and electronically to 10,000 in the embedded computing market. Learn more about *MEDS* at **www.medsmag.com**.

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Making Good on the Promise of Implanted Devices

JOHN KOON
Publisher

A recent TV interview with Dick Cheney, former vice president of the United States, revealed the vulnerability of wireless implantable devices. In 2007 Dr. Jonathan Reiner installed an implanted defibrillator in the vice president. However, Dr. Reiner had to turn off the wireless feature. The reason? So that terrorists could not attack the vice president's device.

The possibility of such an attack is a very real concern. For instance, a terrorist could send a message to the device, instructing it to shock the heart in an uncontrollable manner. Another option might be to alter the parameters of the device to affect the heart's function. In the case of Vice President Cheney, the risk of an attack outweighed the benefit of an external controller that could send vital data wirelessly. However, foregoing this benefit increased the possibility for future surgeries. This concern is not isolated to implanted defibrillators. Not long ago I had the opportunity to discuss this issue with a security expert. His concern was about a certain diabetic device. Thanks to advancements in electronics, this modern device can provide an insulin injection via a handheld wireless controller. This expert speculated, what is to prevent a terrorist from sending a potentially hazardous signal to the device and causing an overdose?

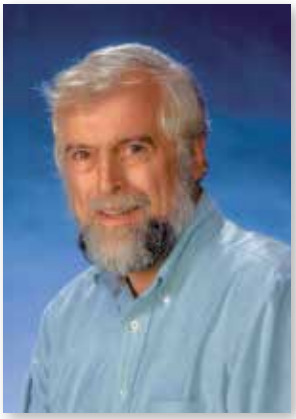
Of course the threat of a terrorist attack is not the only concern surrounding implantable devices. Another implantable defibrillator problem, albeit an uncommon one, is a "misfire." A friend of mine shared his personal story with me in which his device incorrectly calculated that his heart needed a shock and so misfired. He said it felt as though someone had kicked him in the chest, sending him flying backward. He went to the hospital where his doctor gave him a quick check, said everything seemed to be functioning properly, and sent him on his way. But on his way back to his car, my friend's device misfired again!

The solution? According to Greg Brown, VP and CTO, Cloud and Internet of Things at McAfee, "The three aspects of security are software configuration, only an authorized source can add software enhancement to the device and constant monitoring of the safe status of the device; doing all three is important."

Ultimately we need medical devices that are safe, private and secure from those that would cause us harm. We also need them to work reliably and seamlessly with other devices. Obviously, this is much easier said than done. The good news is that progress is being made. Today I see many organizations working together to solve these and other concerns. On a recent visit to the lab of the Cambridge-based non-profit Medical Device Plug-and-Play organization (MD PnP), I was very encouraged. I saw devices of varying functions working seamlessly together. Someday soon we will see devices such as these in hospitals and even our homes. Another cause for optimism is that today, countries such as the UK, Denmark and Singapore are adopting Continua's design guidelines. This organization is establishing a certification process that addresses many of the interoperability concerns shared by many practitioners. This seal of approval will give health personnel some level of comfort, much like a consumer product receiving a CE mark or a UL listing.

So there is hope! Let's work together to overcome the design defects and challenges soon. Remember: those who solve these problems first will reap the biggest profits!

Big Data and Genetics Promise a Path to Individual Treatment



TOM WILLIAMS
Editor-in-Chief

Remember when mapping the human genome was a tremendous accomplishment? It was also surrounded by all sorts of controversy over who "owned" the human genome and what that might imply in terms of patents, intellectual property, new drugs and other treatments. As far as I recall, that particular mapping was of a fairly general nature. Now we're starting to talk about sequencing full genetic maps of individual human beings. The concept is mind-boggling but the results could be nothing less than revolutionary.

At the Intel Developers Forum recently held in San Francisco, Intel discussed efforts to use high-performance computing (HPC) to not only map individual genetic data, but also to use that data to enable more personalized use of a person's genetic makeup as a guide for which drugs to apply and how to apply them in cancer treatment. HPC is essential to such efforts because the data involved grows into the petabyte range, which definitely qualifies as Big Data. Obviously, the time, computing power, storage and cost could present daunting challenges.

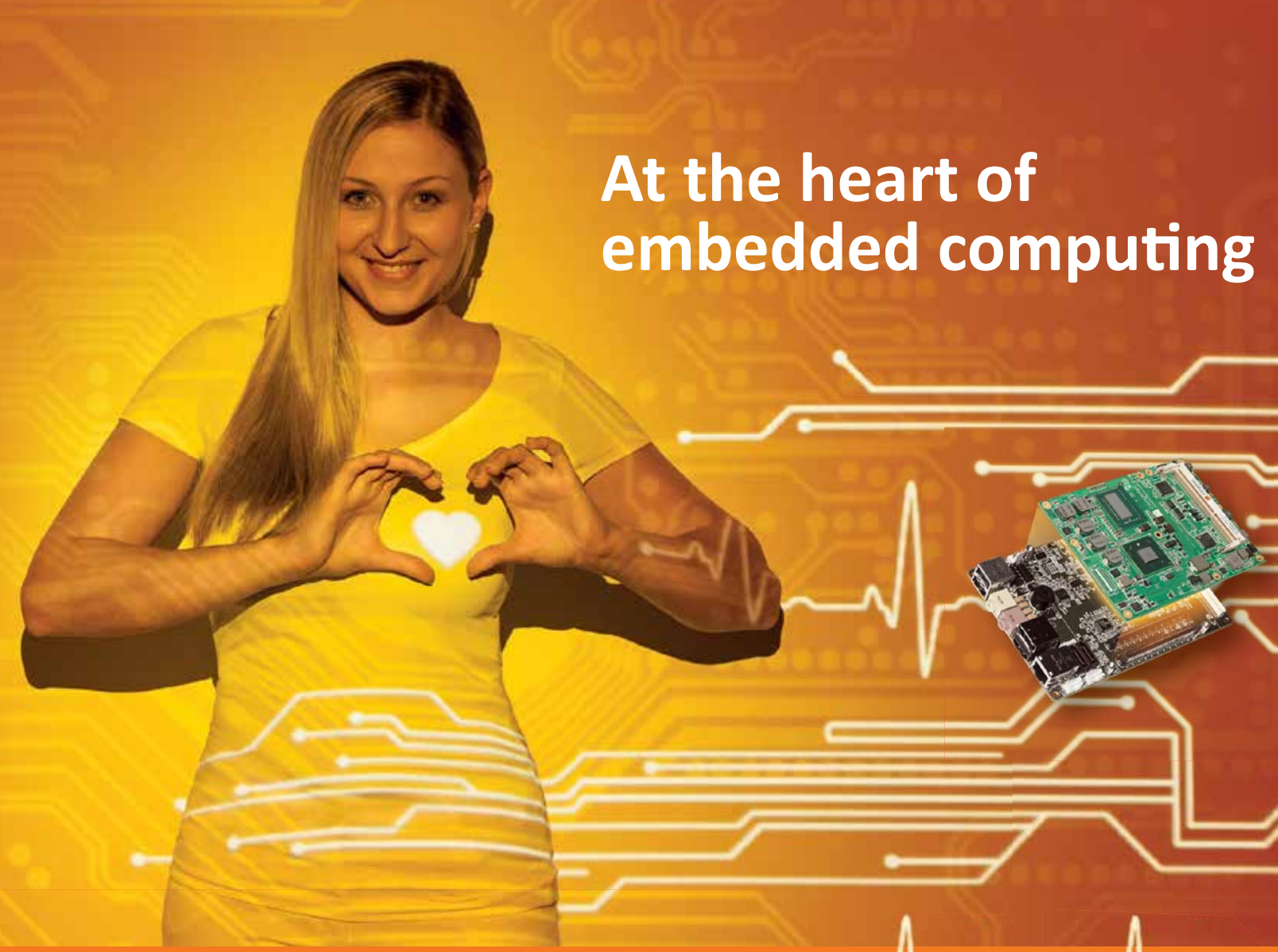
However, Intel now says it is aiming to get the sequencing down to a matter of hours and the costs into the thousand dollar range. This is a very ambitious goal, but they say they are closing in on it. As a moving example, there is an Intel employee who was a cancer patient and who had been on chemotherapy for a number of years. When he heard of these efforts, the young man volunteered to participate in the genome mapping effort. Using the data obtained on the patient's genetic map and the information on the cancer genomes, doctors were able to analyze the application of the medicine, determine where it was not being effective, and correct the application of the chemo. The results are that this young man is cancer free today. Not even Bones McCoy could have imagined such a thing.

Of course, simply mapping the genetic data is only the start. Once you've done that, you've got the Big Data. Now the task is to apply downstream analytics to get at the insights we are seeking, which involves all the tasks of data storage and movement, capturing data in structured form, normalizing it for analysis, and caring for privacy and security. Genetic data can yield both general insights into the nature of the organism as well as vital information that pertains to the individual patient.

Privacy and security also become issues when we want to analyze multiple sets derived from Big Data, such as centralizing data to analyze a population for possible characteristics, for example, correlating genetic characteristics with regional disorders and possible relationships to external factors such as environment or diet. All these aspects beg for analysis as we venture further onto the spiral staircase of chromosome and gene.

The challenge is to be able to handle Big Data so that we can zero in on those focal points of little data that can represent the key to treatment, and from these successes build bases of knowledge and technique. And from these we can further develop strategies and refine the treatments to get to the individual under care.

This will require enormous computing power, and it is exactly that level of computational raw force that is coming into our hands to combine with the human knowledge gained in the experience of finding real cures that will continue to light the way forward.



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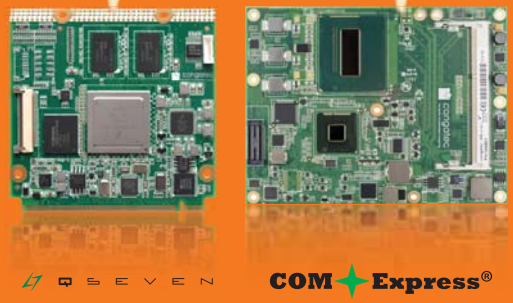

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MEDICAL TECHNOLOGY NEWS

A COLLECTION OF WHAT'S NEW, WHAT'S NOW AND WHAT'S NEXT

FDA Releases Guidelines on Mobile Medical Apps

The Food and Drug Administration (FDA) has released guidance on mobile medical apps. "The FDA has chosen wisely to target its strict regulatory efforts on mobile applications that could pose a significant risk to consumers if used improperly," said Jonathan Linkous, chief executive officer of the American Telemedicne Association. "Their regulation will help reassure patients and consumers that mobile health applications are not only convenient, but safe."

The FDA has tailored their risk-based oversight to regulate mobile medical apps that are intended to be used as an accessory to a regulated medical device—such as an application that would allow practitioners to diagnose a patient via images viewed through picture archiving systems or mobile devices. The oversight also applies to apps that have the ability to transform a mobile device into a regulated medical device—such as an application that turns a smartphone into an electrocardiography machine to detect abnormal heart rhythms or a heart attack.

"This regulation is critical to the growth in the use of wireless devices and software. Providing the FDA's stamp of approval will provide needed assurance to providers and consumers that telemedicine can help improve quality, access and affordability of care," said Linkous.

The FDA issued a first draft of the mobile medical application guidance in July 2011 and received over 130 comments. ATA submitted comments and suggestions to the agency on the draft, and is pleased that the final regulation supports risk-based oversight that will not hinder market growth and consumer adoption.

Improving U.S. Health Care with Remote Access

It is little known that today every state has a telemedicine program, ranging from stroke diagnosis to psychiatric evaluations to prenatal care. This is, of course, predicted to expand with the greater demand brought on by the increased number of insured patients under the Affordable Care Act (ACA). Proponents of telehealth believe its widespread implementation can have a positive impact on the future of the health care system.

One major effect is predicted to be a shortage of primary-care physicians and specialists, and a need to keep costs in control. This can be alleviated by the ability of communities with and without specialists and highly skilled practitioners to use technology to work together to provide access to care.

Some outcomes have already begun to prove that there is some benefit in adopting telemedicine: The Partners HealthCare system in Boston was able to reduce readmission of 1,200 heart-failure patients by 50% through a home telemonitoring program. Under the Affordable Care Act, Medicare is required to reduce payments to hospitals that have excessive readmissions rates by as much as 2% in 2014. New advancements in telemedicine such as in-home care products, proponents say, allow doctors to follow up with patients from outside the hospital via a computer or mobile device, which can help hospitals reduce readmission rates and avoid penalties.

BridgePoint to Provide Managed Services for Symphony Clinical Research

BridgePoint Technologies has entered into an exclusive partnership with Symphony Clinical Research, a provider of in-home and alternate-site clinical services to patients in all phases of clinical trials. Symphony Clinical Research has selected BridgePoint's Managed Services to improve overall operational efficiency, ensure maximum uptime and drive business growth.

As part of its Managed Service offering, BridgePoint Technologies is providing Symphony Clinical Research with remote Help Desk support as well as on-site technical maintenance, monitoring and administration of the company's mission-critical IT infrastructure, including servers, desktops, network and mission-critical business applications. BridgePoint also currently serves as the company's dedicated technology partner for the planning and deployment of various highly technical initiatives that provide an enhanced approach to Symphony's remote employment, critical uptime and Disaster Recovery processes.

BridgePoint provides Symphony Clinical Research with the right-sized solution to support its international customer base and 24x7 availability requirements, as well as the flexibility to work within the company's strict regulatory guidelines, auditing parameters and internal processes. The firm's knowledgeable Help Desk professionals provide expert technical troubleshooting and support, while its team of experienced engineers proactively identifies and remediates potential threats to Symphony Clinical Research's critical applications and infrastructure, resulting in improved operational efficiency, availability and customer service.

MEDICAL TECHNOLOGY NEWS

A COLLECTION OF WHAT'S NEW, WHAT'S NOW AND WHAT'S NEXT

How Telemedicine Could Change Medicare

The Medicare program, and the 49 million elderly and disabled Americans who rely on it, is facing an uphill battle when it comes to quality and cost. Some 10,000 baby boomers sign up for Medicare each day. This first wave will push total program enrollment from 50.7 million in 2012 to 81 million in 2030. Considering that adults age 65 and over account for the highest level of health care spending among all age cohorts, an increasingly larger share of taxpayer dollars will flow to Medicare services.

The majority of Medicare's costs come from the treatment of chronic illnesses such as heart disease and diabetes. In fact, about 82 percent of Medicare beneficiaries have one or more chronic conditions.

Fortunately, there are proven solutions to help patients better manage chronic diseases and access primary care providers that are already reducing costs and addressing the shortage issue. Currently, however, the Medicare law constrains most seniors and the disabled from access to these solutions.

Telemedicine is transforming the delivery of care by bringing health care providers and patients together virtually. Often, because of disease, transportation or mobility issues, Medicare beneficiaries are not able to travel long distances to receive the treatment they need. For this group, telemedicine has the potential to increase access to care, improve patient outcomes and combat rising health care costs. By remotely monitoring or consulting with a patient, providers are able to be involved proactively with their care, anywhere and at any time.

The potential benefits of telemedicine are currently blocked by a system of licensure laws that bind providers to state boundaries and rations care because of accidents of geography. Health care providers are required to obtain multiple state licenses and adhere to multiple state rules to provide telemedicine services to their patients across state lines.

However, the federal government has effectively implemented a national telemedicine framework, working in conjunction with state medical boards, to expand telemedicine opportunities to members of the Department of Defense and Veterans Affairs.

The Servicemembers' Telemedicine and E-Health Portability Act, passed in 2011, expands the current DoD state licensure exemption to allow credentialed health care professionals to work across state borders without having to obtain a new state license. It also expands the definition of an exempt health care professional to include qualified DoD civilians and contractors, while removing the current service location requirement to allow for care regardless of where the health care professional or patient is located.

At the VA, only one active, unrestricted state license is required to practice in every VA facility across all 50 states, a policy that has proved to be successful for improved patient outcomes and reduced costs.

Formtek Delivers First Phase of a Content Management and Workflow Solution

Formtek, a provider of document and content management solutions, has announced that it has delivered the first phase of a content management system for use by the Ohio Center for Autism and Low Incidence (OCALI). OCALI serves families, educators and professionals working with students with autism and low-incidence disabilities, including multiple disabilities, orthopedic impairments, other health impairments and traumatic brain injuries. OCALI's mission is to build state- and system-wide capacity to improve outcomes for individuals with autism and low-incidence disabilities through leadership, training and professional development, technical assistance, collaboration and technology.

OCALI resources are widely used by parents, groups and institutions from across all of the U.S. and in 101 different countries. Formtek was retained to provide a technology solution, based on the Alfresco One content platform, to help with the management of OCALI's large collection of educational and training documents and videos, and to automate processes associated with these resources.

After analyzing OCALI's requirements, Formtek installed, configured and tuned Alfresco, and developed a number of customizations, highlighted by a rigorous workflow process. The workflow automates the Integrated Systems Task (IST) Request process, beginning with a request for a video, through all steps of approval, scripting, production and uploading of the video to the web. Optimizing the video request and production process required customizations to the content model and forms, automatic folder creation during the workflow, and custom dashlets, dashboards and data lists. As a key part of this engagement, Formtek implemented methods to record the time spent per workflow task (using data lists) and to associate in-process and completed requests with their workflow history, including a record of all documents used in the process. Planned enhancements to the solution will include automation of other OCALI workflow processes within Alfresco.

INNOVATION HIGHLIGHTS

A COLLECTION OF WHAT'S NEW, WHAT'S NOW AND WHAT'S NEXT

New Version of the OmniPod Insulin Pump for Use with Humulin R U-500

Insulet has announced it has entered into an agreement with Eli Lilly and Company in which Insulet will develop a new version of the OmniPod insulin pump specifically designed to deliver Humulin R U-500 insulin, (regular U-500 [Concentrated] insulin human injection, USP [rDNA origin]), a concentrated form of insulin used by people with highly insulin-resistant type 2 diabetes. Insulet is partnering with Eli Lilly and Company on the clinical development program to evaluate the safety and efficacy of the combined delivery system.

As the incidence of severe insulin resistance continues to rise, more and more people with type 2 diabetes are requiring significantly higher doses of insulin in order to control their blood glucose. This new version of the OmniPod System would be the first insulin pump designed with specific feature modifications to deliver Humulin R U-500 insulin. Given the rapid increases in rates of obesity and corresponding increases in daily insulin requirements, the new delivery system, if approved, would represents a significant and growing opportunity for people with highly insulin resistant type 2 diabetes to potentially better manage their disease with such a product.

The OmniPod Insulin Management System is a tubeless insulin pump. The OmniPod offers people living with insulin-requiring diabetes all the benefits of insulin pump therapy, with freedom and ease. The tubing-free OmniPod insulin pump has just two easy-to-use parts: the discreet, waterproof Pod, which automatically inserts and can be worn on many parts of the body to hold and deliver insulin; and the Personal Diabetes Manager (PDM), a handheld device that wirelessly programs the Pod, calculates suggested doses and has a built-in blood glucose meter.

Insulet, Bedford, MA. (781) 457-5000. [www.myomnipod.com].

MAP System Benefits in the Prevention of Pressure Ulcers

Two studies have demonstrated improvement in the prevention of pressure ulcers with the use of Wellsense's MAP System, a continuous bedside pressure mapping system. The results of the first study showed a significant reduction in pressure ulcer occurrence when using the MAP System over a six month period in 2012. During this period, zero hospital acquired pressure ulcers occurred, in comparison to 16 pressure ulcers in the same timeframe in 2011.

The MAP System is a clinically proven, continuous bedside monitoring system that detects and depicts the variations in pressure across a patient's body, to aid in the prevention of hospital acquired pressure ulcers. Used on any existing bed, the MAP System enables caregivers to visualize real-time pressure distribution data to guide effective patient repositioning. The MAP System's live, color feedback empowers caregivers to easily identify early warning signs of risk to patient safety and has a demonstrated ability to improve upon a facility's pressure ulcer prevention program efforts.

The MAP System's pressure sensing mat is made of an intelligent textile, which constantly measures pressure from thousands of discrete points. The variations in pressure across a patient's body are depicted on a monitor, using a color scheme to help caregivers visualize high (red) to low (blue) pressure points, which enables them to easily identify and minimize areas of high pressure. The MAP System serves as a supportive tool for caregivers by providing live, visual feedback as they reposition patients.

Wellsense, Nashville, TN. (888) 335-0995. [www.themapsystem.com].

XRV Subsystems Can Provide up to 450 kV and 6 kW

The XRV X-Ray subsystem from Spellman High Voltage Electronics, is a high voltage power conversion product that features XRV high voltage generators, available in unipolar and bipolar, 160 to 450 kV, 1.8 to 6 kW. By combining the robust XRV generator with industry-leading Metal Ceramic X-Ray tubes, tube coolers/chillers and HV cables, Spellman provides a flexible, cost-effective solution for many applications.

Customers select cable lengths and standard or spring loaded connectors to integrate the generator, X-Ray tube, digital touch screen controller, I/O box, cooler and all other accessories, providing a "plug and play" X-Ray subsystem.

Spellman's XRV generators, used by OEMs and X-Ray integrators around the world, are the most compact and lightest available in the market. Featuring superior stability, low ripple, integrated dual filament supplies, digital interface, comprehensive fault diagnostics and protection circuitry, the XRV series has become the generator of choice in CR, DR and Industrial CT applications.

Spellman High Voltage Electronics, Hauppauge, NY. (631) 630-3000. [www.spellmanhv.com].

INNOVATION HIGHLIGHTS

A COLLECTION OF WHAT'S NEW, WHAT'S NOW AND WHAT'S NEXT

Blood Pressure Meter with Accurate Digital Measurement

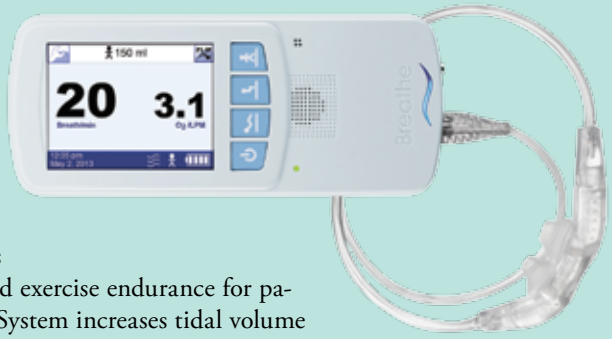
State-of-the-art measurement technology is now applied to monitoring blood pressure at the wrist with the push of a single button. The UB-521 Digital Wrist blood wrist monitor from A&D Medical is smaller, lighter and more compact than other wrist monitors and is ideal for travel. Unlike other monitors that measure blood pressure during deflation of the cuff, the UB-521 Digital Wrist blood monitor measures blood pressure during cuff inflation for a faster, more comfortable reading. The automatic memory keeps your last 90 blood pressure measurements for effective tracking.

The average reading feature automatically calculates the "average" of the total readings stored in memory. The UB-521 also has the Irregular Heartbeat feature. This feature provides blood pressure and pulse rate measurements even when an Irregular Heartbeat occurs and alerts the user. A rigid carrying case is included to protect the monitor when not in use. Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method within the limits prescribed by the American National Standards Institute (ANSI/AAMI SP10) for electronic sphygmomanometers.

Other features include one button operation with simultaneous readout of systolic/diastolic pressure and pulse rate. The monitor comes with a bilingual Instruction Manual with Blood Pressure Log Sheets (English and Spanish) along with the included rigid carrying case and two "AAA" batteries. The Digital Wrist blood pressure monitor fits easily and comfortably on one's wrist to provide an accurate reading. This compact and portable unit gives fast measurements and provides convenience to those looking for an easy way to monitor their blood pressure away from home.

A&D Medical, San Jose, CA. (800) 726-3364. [www.andmedical.com].

Non-invasive Open Ventilation System Improves over Standard Care



The NIOV System from Breathe Technologies is a 1 lb, wearable, ambulatory ventilation system for the treatment of symptoms associated with variety of respiratory insufficiency diseases. Presentations coming on the heels of a recent publication in the *American Journal of Respiratory Critical Care Medicine (AJRCCM),* have demonstrated the NIOV System's effectiveness in providing dramatic improvements in shortness of breath and exercise endurance for patients with Chronic Obstructive Pulmonary Disease (COPD). The NIOV System increases tidal volume by providing positive pressure ventilation that has been shown to significantly:

- Improve ventilation
- Reduce dyspnea
- Increase oxygenation
- Significantly enhance exercise endurance
- Unload respiratory muscle activity

The NIOV System is designed for applications such as supporting activities of daily living, patient ambulation, physical therapy and pulmonary rehabilitation in either home or institutional environments.

Patients living with COPD may be limited in their ability to participate in activities of daily living and exercise due to the symptoms associated with their disease. The NIOV System was designed to address these symptoms and facilitate ambulation. Research, such as the recent study in the AJRCCM, demonstrates the clinical efficacy of the NIOV System in reducing dyspnea, unloading respiratory muscles and improving exercise endurance.

Breathe Technologies, Irvine, CA. (949) 988-7700. [www.breathetechnologies.com].

Bluetooth Health Device Profile: Compatible Communication for Specialized Devices – Part 2

In the previous issue we introduced the Health Device Profile along with the IEEE 11073 protocol, which is enabling a number of specific medical devices to communicate data via multiple logical channels carried by a single master radio channel for compatible device communication. Here we continue with further details on implementation.

by Florian Herrmann, and Karsten Aalders, Stollman E+V

A Health Device Profile (HDP) implementation consists of several protocol layers, each of which are quite complex taken on their own. The attempt to map such a complex system in a single state machine or a few state machines is doomed to failure from the outset. Our experience shows that the opposite approach involving a variety of individually straightforward state machines is much more likely to succeed. Attention must be paid in this approach that the state machines are allowed to act autonomously to the extent possible, and that interactions between the individual state machines are minimized. This then leads to a design, for example, where there are individual state machines for establishing and disconnecting the eL2CAP data channel, for handling the signaling of an established data channel for eL2CAP SAR, and for the flow control, the MCAP protocol handler, and an IEEE 20601 state machine (Figure 1).

In addition to this HDP-specific part, thought must also be given to the portion of the implementation that is specific to security and inquiry/service discovery, so that these often neglected functions can also be mapped in a comprehensible way for the user.

For many of these state machines, there are examples in the relevant specifications as well as white papers that should serve as guidelines. This applies in particular to the naming of states, events and state transitions, because this is the best way to ensure that the implementation will match the specification. As a rule, all states and their transitions should be adopted from the specification since shortcuts will in all likelihood turn out to be dead ends later on.

It must also be noted that several instances of these state machines can, or possibly must, be active in parallel. An example of this is the above-mentioned state machine for eL2CAP SAR and flow control, because HDP connections must always support at least two data channels, e.g., the MCAP control channel and IEEE data channel, in parallel. Incidentally, the interaction of the MCAP state machine and the state machine for establishing and disconnecting the data channel is particularly complex because on closer analysis the establishing and disconnecting of a data channel turns out to be as fast as the asynchronous portion of the MCAP signaling.

Aggravating this situation is the fact that the state machine for security handling must also be able to act in parallel with all other state machines because the opposite side can initiate any security procedure at any time, which the implementation must then follow.

Last but not least, it must be noted that a radio connection can of course go down at

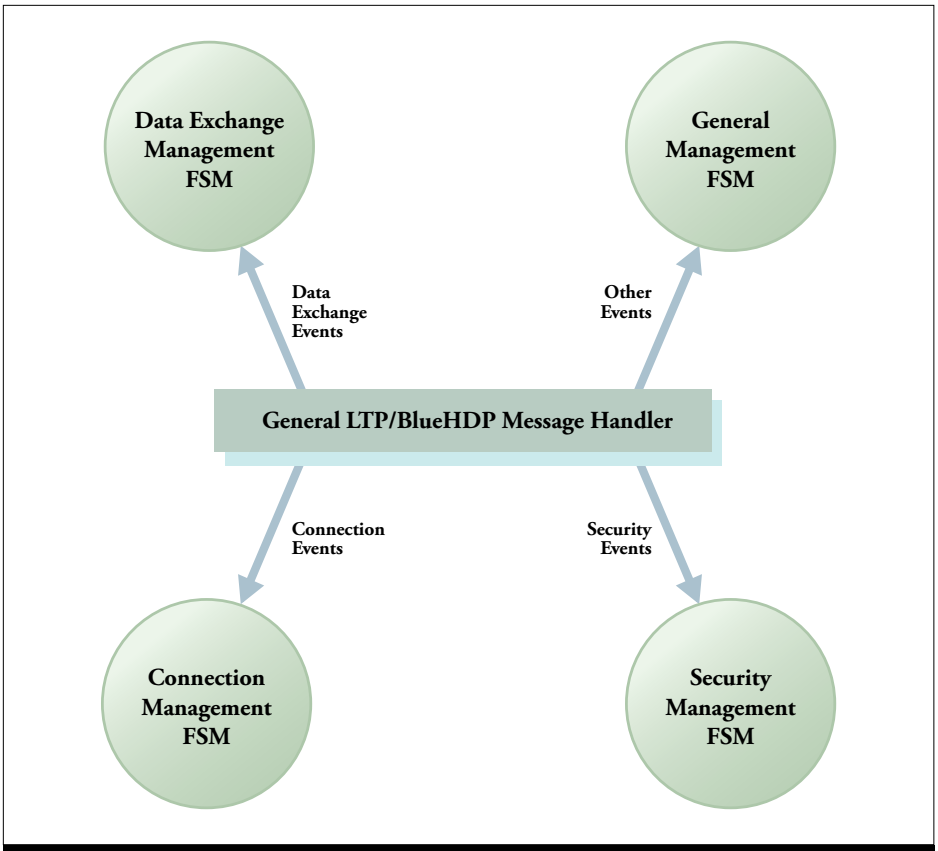


Figure 1: Structure of an individual state machine for establishing and disconnecting data channels.

any time, in which case it can take up to 20 seconds, based on the specified supervision timeout period, until the Bluetooth stack on the user side signals the corresponding event. During this 20 seconds, however, multiple events may have accumulated in the system and will have to be processed by the system after a disconnection of this type.

If one considers all this, it is clear that a shotgun approach of system-internal signaling will quickly bring a system to its capacity limits. A particular problem in this case is the risk of race conditions, i.e., non-deterministic time-related dependencies. Without a proper software design, it is easy to end up with a system that functions immediately 90% of the time, but that constantly trips up the remaining 10% of time involving "unlikely special cases"—an unsatisfactory situation for medical products.

Parties wanting to integrate Bluetooth HDP and IEEE 11073 as the future standards in their device but not wanting to take on the efforts required themselves, have a variety of options for using finished components. Several architectures are available for this.

Integrated Stack

With the integrated stack, all software components run on a single CPU. This architecture is used mostly for small and simple measuring devices that act as IEEE 11073 agents, and it requires a Bluetooth chip with a user-programmable CPU. Such chips are currently hard to obtain and are generally developed only for high volumes (several million chips).

For an integrated chip, the software parts are usually strongly optimized in order to minimize manufacturing costs. This effort is only worth it for products involving large quantities. If a corresponding market is identified, however, a very cost-effective solution can be developed in close collaboration between the chip manufacturer, protocol stack manufacturer, and software integrator and the device manufacturer.

Hosted Stack

With the hosted stack, Bluetooth HDP and IEEE 11073 run together with the application on the application processor, while the Bluetooth chip merely manages the functions of the base band (Figure 2).

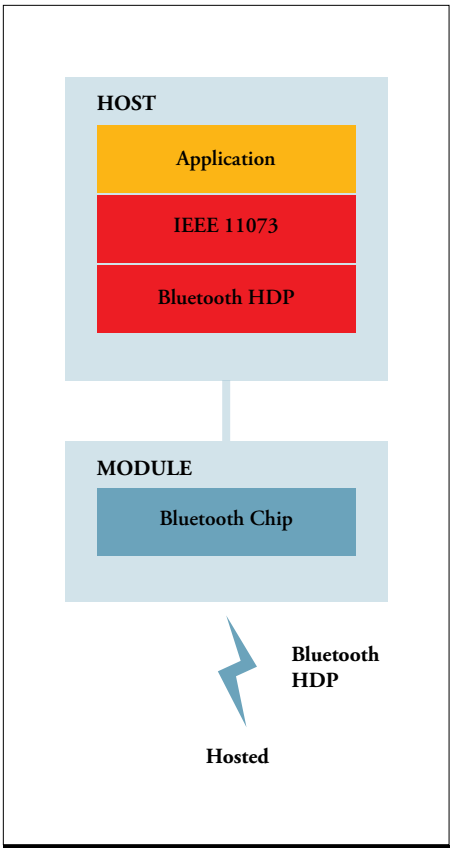


Figure 2: Hosted stack architecture.

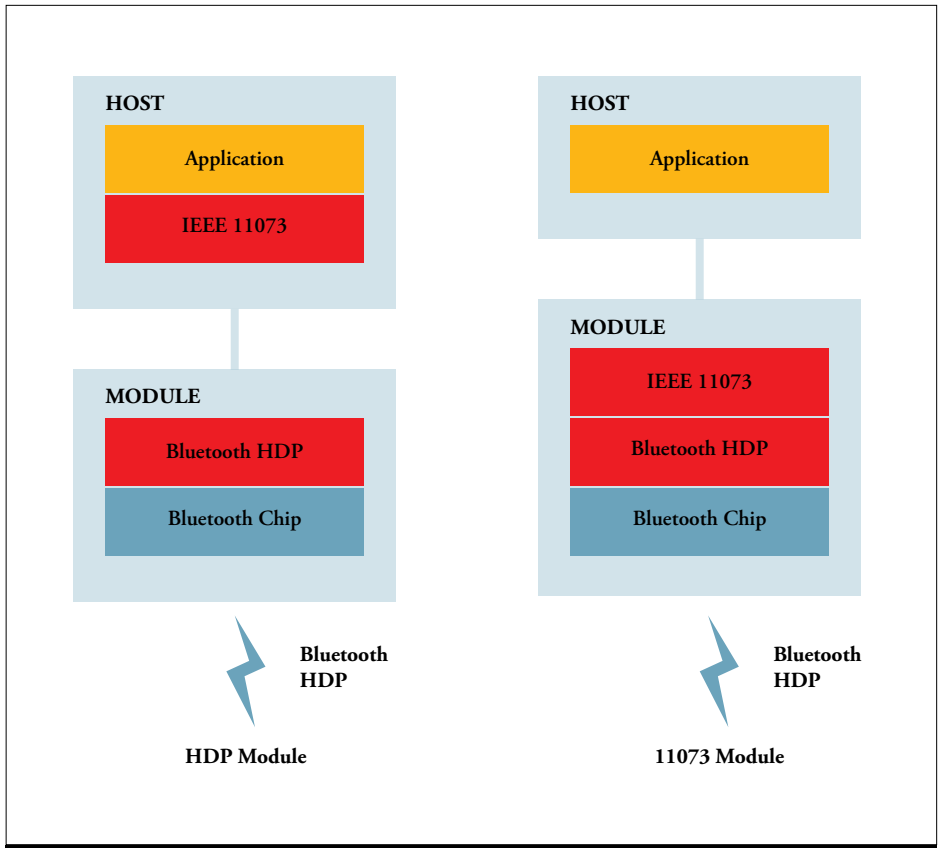


Figure 3: Module architecture.

In this case, simple Bluetooth chips can be used, but the Bluetooth HDP profile and the IEEE 11073 stack must be ported to the application processor and integrated with the application software.

The advantage of this architecture is that standard chips for Bluetooth can be purchased cost-effectively from various manufacturers. However, the host system with the application processor must be able to extend the stack software and have sufficient resources for this. The extension pertains mainly to the integration of the protocol stack into the operating system. Portable protocol stacks are therefore written—e.g., in "C" programming language—to allow them to be compiled for practically any new system. The adaptation to the operating system can be prepared for by providing special interfaces in the protocol stack for the mapping to operating system functions. As a result, they can be quickly and reliably adapted to new operating systems. The protocol stacks provide the application software with an API via which the protocol stacks are controlled and data are transmitted. Example code is generally available for operating the API and can be integrated into the application software, making development easier. If the development effort for the hosted stack architecture can be justified, it can produce economical, high-performance devices.

Modules

With the module architecture (Figure 3), at least the Bluetooth HDP stack runs on the Bluetooth module, which also contains the Bluetooth radio chip. In certain cases, the IEEE 10073 stack can also be integrated there so that the application processor is relieved of all communication tasks. This architecture is recommended in particular when an existing device is expanded to include Bluetooth HDP and IEEE 11073 and the application processor is already fully utilized by the application. Because the porting is eliminated, the integration effort is relatively small. However, the hardware costs are generally higher and the realization of complex functions is more difficult than for the other architectures.

The protocol stacks are already integrated on the module by the manufacturer. As a result, no additional development costs are normally incurred for the module, unless special requirements for the module are placed by the integrator. In this case, the module manufacturer can modify the module independently, which simplifies the collaboration. When the module fulfills the desired functions, it is integrated into the hardware and software of the target system. For this the assembly must be adapted to the type of construction of the module. The software integration consists generally of a simple modification of the application software already present on the target device. This is expanded to include commands for controlling the module and for transmitting data. A true software integration like that for the hosted architecture is not required. This reduces the development effort significantly and enables faster product maturity. For this reason, most medical products with Bluetooth today are using modules.

Depending on the manufacturer and performance capability, modules can also accommodate complex protocol stacks for HDP and IEEE 11073. As a result, they can contribute toward integrating these protocols into medical devices without significant development effort.

Bluetooth Low Energy

For battery-operated devices requiring very high energy efficiency, conventional Bluetooth radio technology (BR/EDR) uses too much energy. To enable radio connection of these devices, the Bluetooth Low Energy (BLE) standard has been developed that makes do—including in many medical applications—with a fraction of the power needed by conventional radio technologies. At the same time, however, a wide range of mobile gateways, such as cell phones and PCs, are available for BLE, because the new Bluetooth chips that are installed in these gateways are compatible with both standards without additional costs. BLE will therefore be available everywhere in the market very quickly. BLE was already integrated as early as the Apple iPhone 4S. BLE will likely be the radio technology with the highest growth rates ever achieved. It is therefore especially appropriate for manufacturers of medical devices to incorporate BLE in their product planning.

BLE achieves its low current consumption mainly through optimized radio protocols that reduce the overhead dramatically, especially for the small data packets that are typical for measurement values. Also very important is the extremely short time needed for connection preparation and disconnection. In many cases, this can even be eliminated entirely and practically only the user data will be transmitted. Because the power consumption depends directly on the activity duration of the radio interface, significant energy savings are possible.

To achieve these benefits, BLE is limited to point-to-point connections. No provision was made in BLE for scatternet connections, as are possible with conventional Bluetooth BR/EDR. In addition, the channel structure and the frequency hopping was simplified without jeopardizing the integration of conventional Bluetooth BR/EDR on a chip. Other functions such as encryption were adopted from conventional Bluetooth BR/EDR.

BLE is therefore optimally suited for integrating battery-operated devices into a Bluetooth radio network or for connecting them to a cell phone or PC. In contrast to most other low power radio technologies, BLE is a vendor-neutral standard. As a result, you can expect a fully developed specification, a broad range of receivers and long-term availability of chips from different manufacturers. BLE therefore represents an optimum enhancement for medical device manufacturers.

Bluetooth HDP and IEEE 11073 are complex protocol stacks that were developed for use in medical and other types of devices. The generous functionality and the well-devised specification make implementation expensive, however. It is generally not worth it for a medical device manufacturer to take on the development itself. Protocol stack manufacturers that have specialized in the development of such protocols and the modules for their integration can apportion the development cost among numerous customers and thus offer these protocol stacks more cost-effectively. In addition, the quality of such protocol stacks can only be guaranteed when they are subjected to further development and testing over a long time period.

Another consideration for standardized protocol stacks is the need to conduct many tests against reference systems and devices of other manufacturers, which requires a great deal of effort. However, this ensures a high degree of robustness and short, easy-to-estimate development times. Manufacturers of medical devices are well advised to weigh the different alternatives carefully before starting an integration project to ensure that Bluetooth communication can be integrated quickly and smoothly. The new Bluetooth Low Energy standard, which is quickly becoming established in the market via cell phones and PCs through integration into conventional Bluetooth BR/EDR chips, represents an additional solution for battery-operated devices that reduces current consumption drastically, thereby opening up new fields of application.

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Cutting-Edge Technology for a Cognitive Load Performance Assessment System

An embedded cognitive load performance assessment system collects neurological and physiological data unobtrusively and seamlessly during training sessions, classroom engagements, or outdoor activities for contextual analysis of performance, cognitive loads and psychological assessments.

by Dr. Bashir I. Morshed and Anthony Massa, Nexis Labs

For the modern information-intensive and demanding workloads, it is frequently necessary to have quantitative metrics for individual and collective engagement assessment in multiple tasks simultaneously. Usually personnel with higher cognitive abilities would have distinct advantages or abilities in real-life practical scenarios where safety-critical decisions need to be made within a short span of time, such as combat fields, first responders, or medical emergencies. With the advent of newer technologies and the ability to non-invasively monitor cognitive activities, there exists every possibility that our ability to identify and distinguish various levels of cognitive ability quantitatively with a high degree of confidence will be realized in the near future. Access to such technology in various practical settings such as classroom, training session, testing facility and other safety-critical situations, could deliver a significant leap in identifying competent leaders and high performers for real-life stressful activities including those associated with emergency, medical and other crisis.

Among various technologies that can non-invasively monitor brain signals and thus cognitive abilities, electroencephalography (EEG), magnetoencephalography (MEG) and functional magnetic resonance (fMRI) are prominent. Among all of these non-invasive sensing techniques, EEG and MEG have excellent temporal resolution, while MEG and fMRI have higher spatial resolution, as magnetic signals are less distorted by the skull, scalp and other fluids surrounding the cerebral cortex. MEG in particular primarily records activity of sulcus, in comparison to gyrus. On the other hand, fMRI is an indirect measurement of brain activities as it records increased blood flow in the cortex that represents increased brain activities. Both MEG and fMRI require highly sensitive magnetic sensors (such as SQUID) and a magnetically shielded room (MSR), and hence require relatively heavy components. MEG or fMRI sensors are rarely usable in the daily routines at home or outdoor settings. In contrast, EEG sensors are miniature and lightweight for convenient ambulatory wearing and continuous sensing while unobtrusive and convenient to the users. Such a system can be built with new cutting-edge embedded technology consisting of an onboard microcontroller with dedicated input and output ports with specific functionalities within a larger system and would operate within specified real-time computing constraints.

We conceptualize a performance assessment system that is comprised of an EEG and other co-sensed data and compactly contains an embedded system platform, which can be routinely worn for long periods, and collects, stores and wirelessly communicates such biometric (neurological and physiological) information in an autonomous fashion. The system would incorporate ultra-low-power embedded technology, smart wireless communication and power management algorithms for extended battery life yet powerful processing capabilities. The onboard real-time computing ability comes with high capacity

storage capabilities and ubiquitous connectivity for data extraction, analysis and assessment.

System Description

The system is comprised of embedded hardware nodes wirelessly communicating with each other and the central communication unit (CCU). A number of embedded wearable hardware nodes would need to be located at various strategic locations on the user's body, which are wirelessly communicating among themselves through a body area network (BAN) and transmitting their data to a CCU within a personal area network (PAN).

The two major elements of the each wearable performance assessment node in the system are the embedded wearable hardware and the data collection sensors. The embedded wearable hardware platform gathers the sensor data and stores it locally. Once each node is configured in the network, its data is communicated to the CCU for post processing, storage and re-transmission to a remote computing system as required. A system block diagram designed to perform assessment of cognitive loads of multiple individuals in a group setting is shown in Figure 1.

The wearable hardware node components are shown in Figure 2. Without a solid hardware platform to process and accurately capture the sensor data, the performance assessment algorithm will produce imprecise results and, hence, lead to errors in data analysis. Therefore, keys for the embedded platform in each node are:

- Concurrent processing of multiple physiological data while keeping power consumption low to enable data collection over many hours
- Real-time processing algorithm to compute the key metrics, packaging of multimodal data with timestamps

The main processing is performed by a high-performance, low-power 32-bit ARM-based microcontroller. The processor includes onboard analog-to-digital converters (ADCs) with 16-bit resolution and at least one synchronous serial module, commonly Serial Peripheral Interconnect (SPI) for connection to various outside peripherals.

The system includes additional interfaces (analog & digital) to accommodate other sensors. In addition, the system incorporates a wireless (Bluetooth low energy) module for communication with other sensor systems, remote units and the CCU. The data storage capabilities allow the embedded system

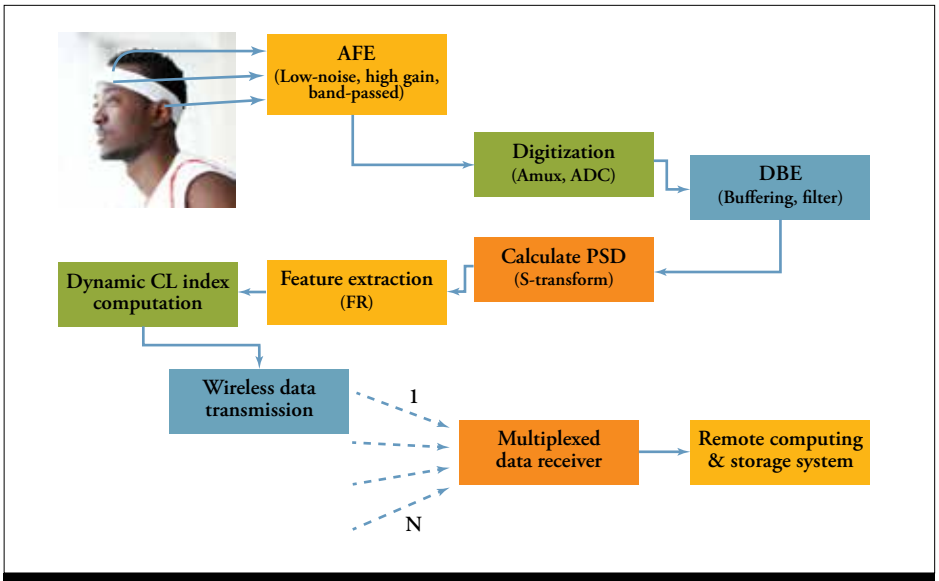

Figure 1. A block diagram depicting various elements of the system and corresponding computational functionalities.

to store the collected sensor data locally and transmit the data wirelessly with a smart algorithm when the computation constraint is less and power consumption is lowered. Figure 3 shows some early prototypes of such embedded wearable hardware platforms.

The main support system is power management. As with most battery-powered consumer devices, each node must perform under a wide range of rough environments. Factors such as temperature have significant effect on battery endurance. Power for recharging batteries is not always available or convenient.

The sensor node packaging must be designed to minimally affect the user and ensure that performance is not altered by outside disturbances. The shape of the housing is a key factor to overall performance and is designed to not interfere with garments worn over it. The optimal form factor for such a device is a disc shape (low aspect cylinder) with soft transition edges (fillets) from the sides to the top. Figure 4 shows an example of the sensor node unit mounted to the hand.

The CCU is responsible for collecting the individual sensor node data, storing it, and communicating the data to a remote computing system. The remote computing system records the wirelessly transmitted data, and computes individual or collective physiological states in real time or at a later time with contextual and time markers from the data. Transmission of computed data (such as cognitive load) instead of raw EEG data drastically reduces data-load and allows co-monitoring of many users with a simple wireless receiving unit.

The system is comprised of a number of sensors to capture physiological conditions. These sensors include transducers from EEG sensors, 3-axis orientation sensor, 3-axis gyroscope and 3-axis compass (e.g., MEMS-based ICs), heart rate variability (HRV) or Electrocardiogram (ECG) measurement, humidity sensor and temperature sensors. The low amplitude EEG signals must be conditioned carefully to remove noise and artifacts, then sufficiently amplified (70 - 80 dB) before digitization. The filtration of EEG data must have a second or higher order band-pass filter with range of 0.5 to 100 Hz. A notch filter at 60 Hz allows reduction of utility line noise—the most severe noise of the system. A sigma-delta ADC samples the amplified and biased analog data with low-quantization noise.

Among various onboard processing capabilities, the requirement to include an onboard real-time artifact removal algorithm is critical for EEG data processing. Useful metrics, such as cognitive load index (CLi), are computed from the processed data with the following expression:

$$CLi = \frac{P_{\alpha}^{R}}{P_{\alpha}^{M}} \times \frac{P_{\beta}^{M}}{P_{\beta}^{R}}$$

where P_{α}^{b} denotes the power spectral density (PSD) within the brain rhythms α (where α is α or β, two rhythms with frequency range of 8 to 13 Hz and 13 to 25 Hz, respectively), and b represents baseline relaxed state (R) or monitor stage (M).

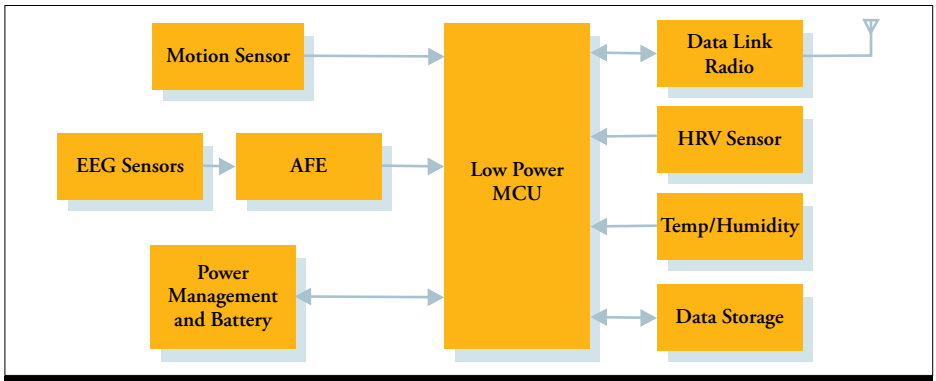

Figure 2. The cognitive load assessment embedded hardware block diagram.

The remote computing system records the wirelessly transmitted data as well as processing individual or collective physiological states in terms of CLi and other cognitive ability in real time or at a later time with contextual analysis. The time-stamped data packets are also co-analyzed with data fusion technique for a complete analysis of individual or collective cognitive performance.

Performance Assessment

The power consumption (P_{Total}) of the system can be divided into four classes:

$$P_{Total} = P_{AFE} + P_{Digitization} + P_{DBE} + P_{St/Trans}$$

where P_{AFE} is the power consumption of the analog front end, $P_{Digitization}$ is for the ISR (interrupt service routine) along with ADC and analog multiplexor, P_{DBE} is the power consumed by the microcontroller-based digital back end, and $P_{St/Trans}$ is the power consumption related to the storage element (micro SD card) or wirelessly transmitted data. The power consumption of the system is approximately 10 mW, which allows each node in the performance assessment system to operate for extended periods of time before needing to be recharged.

Among the system components, the EEG sensor requires about 70 to 80 dB gain with low-noise amplifier (such as an instrument amplifier). The EEG sensor also requires signals to be filtered for low (0.5 Hz) and high (100 Hz) frequencies using second or higher order active filters. In addition, power line interferences are removed with a high order notch filter. For stability reasons and continuous periodic sampling, the analog front end might be required to be continuously in active mode. If the time required for the signals to become stable is T_{Samp}, and the sampling period is $T_{AnaTran}$, then the analog front end can only be power cycled when the following constraint is met:

$$T_{Samp} > T_{AnaTran}$$

For EEG sampling at 256 samples per second, such a constraint will not be met, hence the analog front end must use the lowest power consuming circuitry and be left operating while the data is being collected. The $P_{Digitization}$ usually can be shut down between sampling. The required setup time, hold time and active time is usually in µs range—much smaller than T_{Samp}. This stage is optimized with switching to active and standby (or shutoff) modes even during data collection. The digital back end and storage/transmission sections can also be optimized with a similar approach using dynamic clocking and microcontroller low power modes.

The collected physiological data can be assessed for cognitive load calculation (from EEG and HRV data), attentiveness/drowsiness (from eye blinks, motion and orientation sensors with data fusion), and many other cognitive and psychological assessments for individual as well as collective performance. The use of multiple sensors with real-time clock synchronization allows the potential for automated contextual computation, unsupervised verification of events, and synchronization for team dynamics and workload assessment. The performance assessment system would operate autonomously without human intervention; hence, it would not increase the task load or add any additional burden to the instructor, while providing quantitative information seamlessly on the cognitive activities of individuals and collective performance metrics in real-life practical settings such as in classrooms, training sessions, or other stressful, safety-critical activities.

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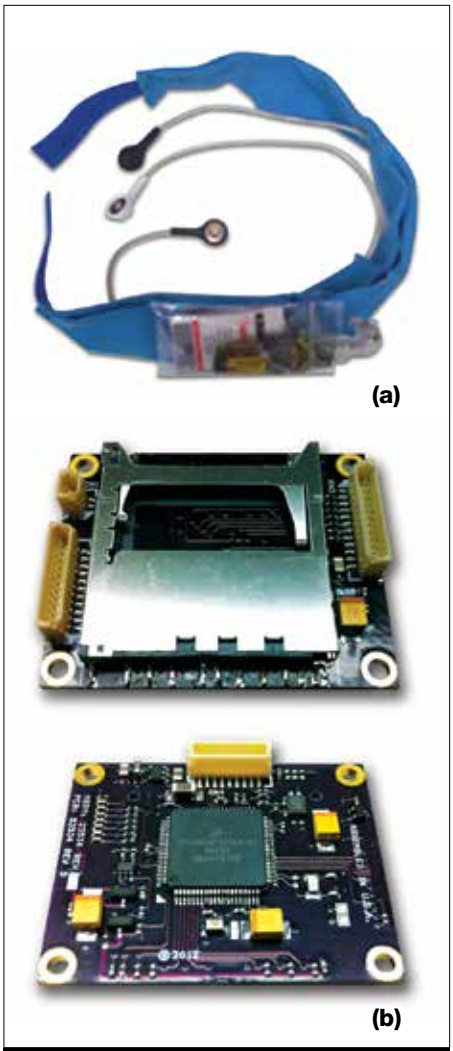

Figure 3. Various prototypes of the embedded wearable hardware platforms including ambulatory EEG device (a) and onboard data logger (b).

Figure 4. The small nature of the embedded wearable sensor node allows for a variety of mounting options.

Achieve Success with European Medical Device Commercialization

Getting a medical device certified in either the U.S. or Europe is never simple. However, the European route can be more straightforward and therefore attractive as a first step in gaining overall product certification in both realms.

by Russ King, MethodSense

Given the complexity of the FDA's regulatory pathway, many medical device companies are asking whether a Europe-first strategy for bringing their medical devices to market makes sense. The regulatory path in Europe has a reputation for being a quicker, less expensive path when compared to U.S. FDA clearance projects. Whether you are a U.S. company bringing your medical device to market in the European Union, or an EU company commercializing a new product, the regulatory route for medical device approval in the European Union is very manageable—given the right knowledge and tools. Our goal here is to outline the EU regulatory path and get you thinking about how your device might be successfully commercialized in the European medical device market.

Beginning the EU Commercialization Process

The EU compliance path begins with the Medical Device Directive (MDD), which consists of a framework of three Directives (Directive 90/385/EEC, Directive 93/42/EEC and Directive 98/79/EC) and rules for manufacturers, called Annexes (Annex I through XII). A detailed discussion about this regulatory framework is a topic for a different article. The important point for now is that the rules and regulations for medical device manufacturers are available in these Directives, just as U.S. medical device regulations can be found in 21 CFR Part 820, GxPs and other FDA regulations. A company implementing this regulatory framework would greatly benefit from contributions of experienced regulatory professionals who can properly interpret the requirements, ensuring the expectations of EU regulators are met. An overview of the EU regulatory process is shown in Figure 2.

Meeting the requirements of the MDD in the broadest sense has two parts: a company part and a product part. Usually, each part is respectively satisfied with an ISO 13485 certification (the ISO quality standard for medical device companies) and CE mark (a mandatory medical device product conformance). The EU approval process typically sees your company audited by a Notified Body to qualify your company for ISO 13485 certification, and which subsequently audits your company annually to maintain your certification. Depending on the classification of your product, your Notified Body may audit your product Technical File to qualify your product for CE mark.

Types of Medical Device Classification

To ensure conformity under the MDD, manufacturers should determine their product's classification as soon as possible. Early product classification sets the stage for the correct compliance path by enabling the opportunity for early implementation of corporate quality requirements for EU product commercialization as well as product conformity requirements for CE Mark.

We should note that EU medical device classification, like U.S. FDA device classification, is risk-based, where Class I products pose the least risk with their use, and Class III products the greatest risk. The EU and U.S medical device classification structure differs regarding how they treat medium risk products. While the EU designates medium-low risk products as Class IIa and medium-high risk products as Class IIb, the FDA does not make this classification distinction, designating all medium risk products as Class II products. Figure 1 offers a more detailed summary of EU Medical Device Classifications.

Regardless of your device classification, most routes to compliance require the involvement of a Notified Body, which is an organization appointed by the national accreditation authorities and "notified" to the European Commission to approve products covered by the Medical Device Directive. An exception to the general rule are Class I products that are "non-measuring" or "non-sterile."

There are many different Notified Bodies, including Underwriters Laboratories, BSI, Intertek, TÜV Süd and TÜV Rheinland to name a few. All Notified Bodies are accredited and required to follow the same regulatory standards. There may be reasons, however, to choose one Notified Body rather than another. For example, some of these bodies understand certain medical devices better than others while some have different approaches to satisfying areas of compliance that might subtly impact the cost of compliance. Others may have a backlog of commitments that may impact your commercialization timeline. And of course, some will have varying reputations for the quality of their work

Also, a medical device company's relationship with a Notified Body tends to be different

than the relationship they might have with the FDA. A relationship with a Notified Body can last years and may be characterized as more of a "business relationship" than you will experience with the FDA. Your choice of Notified Body should be reasoned and deliberate. If you are having difficulty making your selection, a regulatory professional experienced with EU product approval processes should be able to help you make your selection.

Quality Management Systems Are Mandatory

EU Quality Management Systems regulations, outlined in Annex II, V or VI of the MDD, are mandatory and establish the "company" part of meeting EU device regulations. The most common means for meeting EU Quality Management System regulations is through ISO 13485 certification. While this route is not necessary, alternative routes tend to be more difficult and more expensive. Consequently, the ISO 13485 certification path for demonstrating that a company complies with EU quality regulations has more or less become the *de facto* standard. Again, though some Class I product manufacturers can escape the necessity of ISO 13485 certification (see above), all medical device manufacturers selling products in the EU must comply with EU quality regulations.

ISO 13485 sets the requirements for a comprehensive Quality Management System for the design and manufacture of your medical device. Compliance with ISO 13485 will establish a risk-based approach to product development and realization and will complete the validation of processes. It will ensure compliance with regulatory requirements as well as implement effective product traceability and recall systems.

One final note for those unfamiliar with ISO certifications: they are renewed annually with an audit. Not only does this create a line item in your annual budget, but it also creates an interesting impetus for maintaining your Quality Management System throughout the year. If an annual audit by a Notified Body results in major observations, then the Notified Body could force a stop to your EU sales until the observations are resolved. In contrast, unless special reasons exist for regular inspections, it is very difficult to predict when—or even if—the FDA will inspect your company.

Class I stethoscopes & wheel chairs	Class IIa hearing aids & ultrasonic diagnostic equipment	Class IIb surgical lasers and ventilators	Class III balloon catheters and prosthetic heart valves
• Simple in design: either sterile and measuring or non-sterile and non-measuring • Pose little to no potential risk • Manufacturers of sterile products or those with a measuring function must apply to a Notified Body for certification	• More complicated in design • Pose medium-low risk • A conformity assessment must be carried out by a Notified Body via: • examination and testing of each product or homogenous batch of products, or • an audit of the full quality assurance process	• More complicated in design • Pose medium-low risk • A conformity assessment must be carried out by a Notified Body via: • examination and testing of each product or homogenous batch of products, or • an audit of the full quality assurance process • Type Examination is required unless the route (EN 46001), where Type Approval is not necessary, is taken	• Intricate in design • Pose the greatest risk • Audit of the full quality assurance system and examination of the design dossier by the Notified Body is required • Type Examination of the product is required • Examination and testing of each product or homogenous batch of products or an audit of the production quality assurance system is conducted (ISO 13485, excluding design)

Figure 1: Medical device classification in the European Union.

Preparing the Necessary Documentation

Technical Files, also known as technical dossiers, are required for all medical devices sold in the EU. A Technical File is a comprehensive collection of information and documents detailing everything about your medical device and is used to justify the Declaration of Conformity and CE mark. That is, the product Technical File is a core component of the "product" part of EU medical device commercialization. The Technical File must demonstrate compliance of the device with the MDD's essential requirements and must be maintained for five years after the last product placement.

The Technical File is similar to the Design History File required by the FDA. The high level common elements of a Technical File include:

- Cover page
- Index
- Declaration of conformity and classification
- Name and address of the Manufacturer/ European Representative and Manufacturing Plants
- Detailed Product description
- Product specifications
- Product verification

The Technical File is key for CE marking because it contains the most important information about the device, how it works, how it is manufactured, etc., thereby demonstrating how the device conforms to the requirements of the MDD. An incomplete, inconsistent or improperly completed CE Technical File may result in unexpected delays or even prevent market entry.

Risk Management

Like the FDA, the EU has embraced a risk-based approach to medical device design and approval, so risk management is an essential component to successful medical device commercialization. Not only is risk management required by ISO 13485 and for product approval in the EU, but the best risk management systems proactively cultivate extensive benefits, including the mitigation of liability, a deep understanding and knowledge of the product, and information that can drive product improvements.

The EU risk management standard for medical devices is ISO 14971. This standard specifies a process for identifying hazards associated with medical devices including:

- Risk analysis
- Risk evaluation
- Risk control
- Residual risk acceptability
- Report and documentation

Safety Testing Is Critical

Medical devices incorporating electrical components require testing to establish the safety of the device. The IEC 60601-1 standard is globally recognized for electro-medical

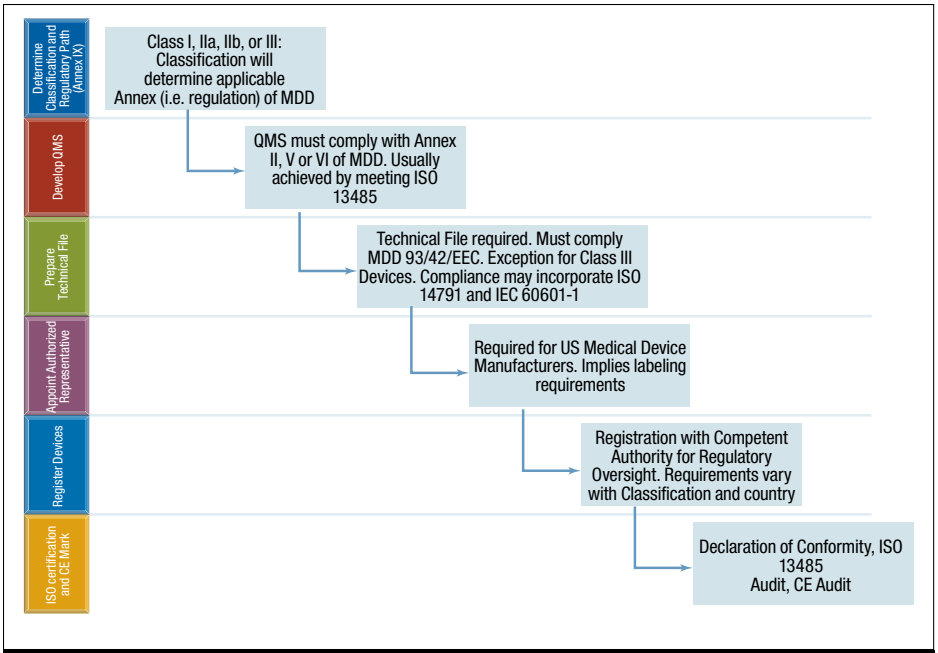

Figure 2: EU regulatory process overview.

equipment safety, and a parent standard to 60 particular device standards (also known as collateral standards).

Until recently, the standard was designed to ensure the safety of medical electrical devices exclusively through testing by a test lab, such as Underwriters Laboratories, Medical Equipment Compliance Associates (MECA) and TÜV. With the transition of 60601-1 2nd Edition to *3rd Edition*—in effect in the EU as of June 30, 2012, soon to be in effect in the U.S.—several changes occurred that have forced electrical medical device manufacturers to rethink how they manage safety testing. For example, 3rd Edition has adopted compliance with ISO 14971 as a key component. Now in addition to product testing, the manufacturer is responsible for demonstrating with documented evidence that their medical device is free from unacceptable risk during its entire product life cycle. From the practical planning perspective, medical device manufacturers must not only plan for safety testing by a test lab, but they also must plan for the development of a lot more risk-based and product life cycle documentation as part of a safety program.

IEC 60601-1, 3rd Edition has several other changes, including updates regarding device identification, marking and providing accompanying documents, hazards (electrical, mechanical, radiation, temperature and fire, accuracy, software, etc.), and the assessment of hazardous situations and fault conditions.

Meeting the documentation requirements of 60601-1 can be complex and, without planning, difficult. In our experience, the difficulties of meeting its rigorous requirements have caught the largest best-resourced manufacturers, as well as small manufacturers, off guard. Making IEC 60601-1 3rd Edition compliance part of your regulatory planning can trump this kind of disruption to your business. If you have questions about how to shepherd your product through IEC 60601-1, your test lab or a regulatory professional with 60601-1 experience can help you.

Working with a European Authorized Representative

Non-European manufacturers are required to have a European Authorized Representative (EAR), a neutral party who acts as a liaison with the national Competent Authorities. The EAR is the primary contact with the EU on behalf of the manufacturer and maintains technical files available to EU authorities, while maintaining the manufacturer's product confidentiality. The EAR has their contact information on all products and must notify EU authorities of all major product incidents. It is also the EAR's responsibility to ensure Class I registration requirements are met and to observe manufacturer's compliance with the conformity assessment procedure of applicable EU directives

Class I devices must be registered with the Competent Authority where the EAR is based. The Competent Authority is the national Ministries of Health, which are responsible for ensuring compliance with the directive in their national market.

Registration of Class IIa, IIb and III devices is not required by most EU countries, however, some countries require registration of all devices, regardless of classification. Alternatively, there are some countries that require registration of high risk devices only. Answering such registration questions can be addressed by contacting the Competent Authority in the region you are targeting in your commercialization effort or with the assistance of a regulatory professional.

The Final Step: ISO Certification and CE Mark

Once you have developed the quality systems for satisfying the quality requirements of ISO 13485 and completed your product documentation, you should be prepared for an audit by your Notified Body. The Notified Body will audit your quality system for compliance with ISO 13485 to certify that you operate to specific medical device quality standards. They, or an alternatively chosen Notified Body, will also review (though not necessarily at the same time) your technical file for conformity with the MDD (some Class I devices are exempt from this process as identified above).

In the event either audit results in major observations or deficiencies, ISO 13485 certification and CE Certificate can be withheld until the observations or deficiencies are addressed. But once awarded, you can issue a product Declaration of Conformity. This is a legally binding declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation. The CE mark may then be affixed to the product.

Many U.S. companies are turning to the European Union for the initial launch of their medical devices. Recognizing the subtle differences between U.S. and European markets, learning the requirements of European commercialization and implementing a successful launch strategy are necessary considerations. Working with a team who knows the intricacies of how to plan and manage a business from thousands of miles away will help you launch and grow your business overseas.

MethodSense, Research Triangle Park, NC. (919) 313-3962. [www.methodsense.com].

NFC-Enabled Sensors Provide Promise for Diabetics and Others

Taking clinical readings with sensors is a challenge both for accuracy and frequency as well as for being as nonintrusive and painless as possible. Near-field communications offers promise on a number of fronts.

by Oluf Alminde, ams AG

With more than 350 million children and adults afflicted with diabetes globally, both healthcare professionals and patients welcome ways to make the treatment process easier and less painful. Today, patients typically self-administer blood glucose-level testing through a painful procedure of puncturing the skin and drawing blood. But near-field communications (NFC) solutions may be changing all that.

Radio-frequency technology offers a means of ending the need to draw blood. NFC is a radio frequency (RF) protocol for exchanging data between devices that are close or touching (<10 cm apart). With the Android operating system's support for NFC in tablets and smartphones, NFC is quickly growing in popularity.

Applying NFC in medical applications is now becoming a real probability. For diabetic patients, medical equipment manufacturers see real potential in implanting a tiny NFC-enabled blood glucose sensor immediately beneath the patient's skin. Using an Android phone or tablet running a dedicated app in close proximity to the sensor implant location, the patient could quickly and easily monitor blood glucose levels without the need to draw blood. The host device could upload the reading automatically to the patient's medical practitioner. It could also be programmed to remind the patient to take regular readings, and to alert medical staff if the patient failed to take a scheduled reading.

An NFC-enabled sensor is suitable for this application because:

- it requires no external power source, since the sensor interface operates on energy harvested from the NFC reader's incoming RF emissions;
- it is quick and convenient, because the sensor pairs instantly and automatically with the host device;
- it is tiny; and
- it is low-cost.

Implantable medical devices show the promise of NFC-enabled sensors, but its promise extends to nearly any market sector.

NFC-Enabled Sensors: What Are They?

An NFC-enabled sensor is an RFID tag that incorporates a sensor interface (for conditioning and digitizing a sensor's input signal). Like any other RFID tag, it has a unique ID that allows the user to validate the origin of an object. The sensor also can verify the environmental conditions to which the object has been exposed, or provide other kinds of measurements, such as biological data from implanted sensors.

Adding sensor-acquired data to the tag does not alter the basic method of communication. The unique ID and sensor data may be read when the tag comes into proximity with an RFID reader or an NFC-enabled phone with a dedicated app.

Other methods of implementing wireless sensors include attaching a sensor to an object, interfacing it to a microcontroller and RF transceiver to set up wireless communication between an intelligent sensor and a reader.

Implementing this function with an NFC-enabled sensor makes the system design simpler, and offers more flexibility for power management. For relatively low-data-rate and short-range applications, NFC is a very attractive technology:

- NFC enables intuitive, simple interaction between two devices, since they simply need to be touched together.
- It takes just a fraction of a second to establish an NFC link, whereas other systems typically require several seconds.

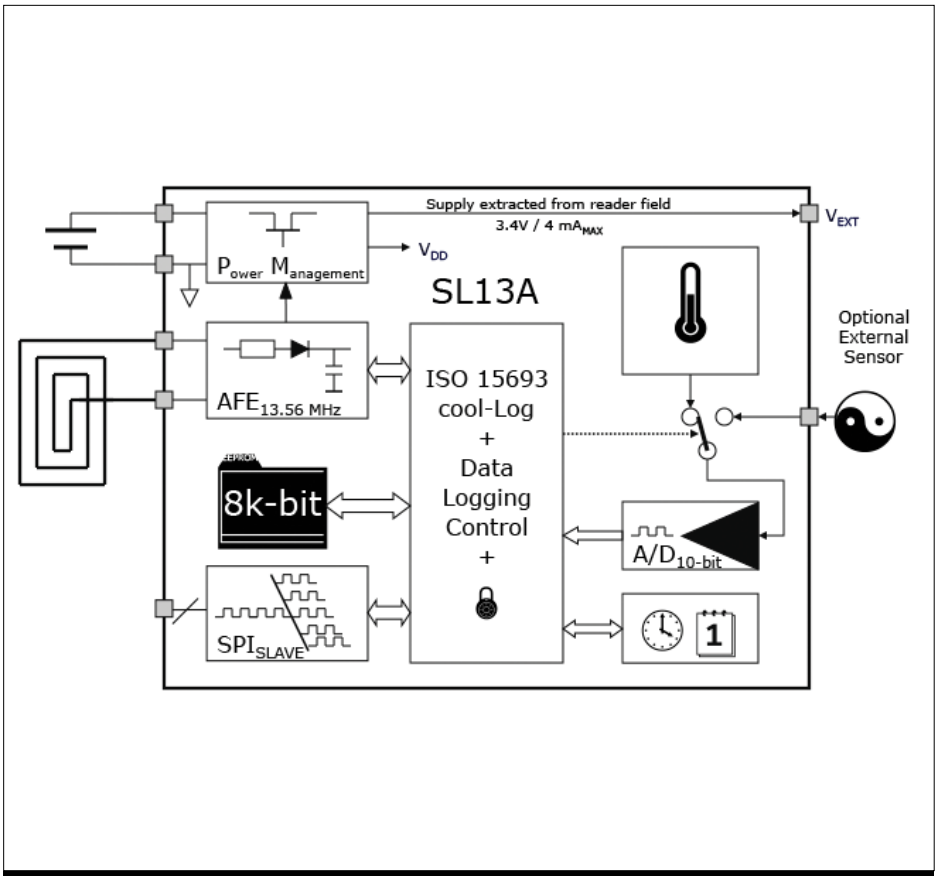

Figure 1: A block diagram of an SL13A NFC-enabled sensor from ams.

- NFC has a low power requirement, supporting very long battery lifetimes and implementations with no battery at all.
- The system cost of an NFC application is lower since the technology is less complex than competing technologies used for wireless sensing, such as ZigBee or Bluetooth Low Energy.
- Because NFC operates through near-field coupling, it is invulnerable to eavesdropping and interference.
- NFC systems can piggyback on existing infrastructure—often, a system implementation only requires the creation of an app for a host device.

In fully passive (batteryless) mode, an NFC-enabled sensor harvests energy from incoming RF emissions (from a reader) to power the sensor interface and RF transmissions. In semi-passive (battery-assisted) mode, the sensor can operate stand-alone in applications requiring autonomous and long-term monitoring. Alternatively, it may provide a user-controlled, onboard power source for a sensor.

Sensory tags might include operation in multiple modes: semi-passive until the battery is exhausted, and thereafter in passive mode. (Data is stored in non-volatile memory and is retained when the device is not powered.)

Fully Passive Promise

In RFID systems, the tag gets all the energy it requires from the field generated by the reader. In an NFC-enabled sensor, this harvested power (typically around 4 mA at 3.3V) can also be used to power a sensor. Even if the harvested energy is not sufficient for the sensor—for instance, if the tag has a small antenna or is a long distance from the reader—it is possible to add a small supplemental power supply in the form of a capacitor that is charged before the measurement, and from which power is drawn during the measurement.

Operating an NFC-enabled sensor in fully passive mode lets design engineers explore myriad possibilities. Because the lifetime of the tag is theoretically unlimited and requires no wired connection, the sensory tags can be embedded, for instance, inside structures such as walls and hermetically sealed products. For example, a builder might embed a new class of NFC-enabled humidity sensor into the walls

or flooring of a house adjacent to water supply pipes or waste water drains, allowing for early detection of leaks that might damage the structure.

Semi-Passive Mode Potential

Semi-passive tags include an onboard power source, usually a battery that supports the tag and sensor operation. Data transmission operates in the same way as in a normal passive tag, using backscattered power emitted by a reader.

User-controlled semi-passive sensory tags spend most of their time in a quiescent state, in which the current drawn from the battery is negligible. Sensor functions and measurement are activated by the user, typically when the device is woken on detection of RF emissions from a reader or NFC device.

Stand-alone semi-passive sensory tags used in autonomous long-term monitoring applications (so-called data loggers) can be activated by external events, or periodically triggered by an integrated real-time clock (RTC). Such applications would require a continuous current of typically 2 µA from the battery to support the RTC or event-triggered wake-up. The condition-monitoring NFC sensory tags could be fitted on goods that require special care during transport. At the end of the supply chain, an NFC-enabled reader device checks the sensory tag and raises an alert if non-approved conditions have occurred in transit. In addition, the sensor data are time stamped, allowing for detailed event monitoring.

NFC-Enabled Sensing Uses

The applications of NFC-enabled sensing require energy-harvesting capability, a sensor interface, power management circuitry and a real-time clock (RTC). These functions are now provided in the SL13A, a single-chip NFC sensory transponder from ams (Figure 1). The chip complies with the NFC-V (ISO15693) standard, and incorporates an onboard temperature sensor.

The sensory tag works in fully passive as well as semi-passive mode; a battery is used to support autonomous data logging when the on-chip RTC is required. In passive mode, a reader or NFC-enabled phone provides the time stamp instead, and the energy to support operation of the sensor is harvested from the reader's field.

Logged sensor data are stored in the on-chip electrically erasable programmable read-only memory (EEPROM) and protected with passwords to preclude manipulation and unauthorized usage of the data.

The ams SL13A can support a very wide variety of applications in which sensor data acquisition and wireless data transmission are required. These include:

Supply chain with shelf-life alert – The condition of goods in transit and storage, as well as environmental conditions, can be monitored and recorded by the SL13A. Perishable items such as food, beverages and medicines are subject to a temperature-dependent chemical reaction, which determines their shelf life. Some sensory tags include an algorithm for dynamically calculating the shelf life and provide an alert when the expiration date has been reached.

Building monitoring – An SL13A and appropriate sensors embedded inside structures such as buildings, bridges and viaducts can record conditions including temperature, humidity, pressure and vibration, and transmit the data when triggered by an NFC reader.

Medication programs – Dispensers and blister packs with integrated sensory tags can record and time-stamp the consumption of pills. This allows medical staff to monitor whether a patient has adhered to his or her prescription.

Process control – In factory automation, sensory tags may control processes and their quality at each step of the process.

Remote metering – SL13A sensory tags may be integrated into equipment with a wireless connection, such as WLAN or GSM, to extend the ability to track and monitor objects or environments in remote locations.

Implementing a proven communication protocol and providing an accurate and precise sensor interface, the SL13A demonstrates the new possibilities enabled by the integration of multiple electronic functions into a single device. The full range of application of such a flexible device is, however, yet to be discovered—the imaginations of system designers will provide the best guide to the potential uses of this new class of sensory RFID tag.

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The Fast Solutions for Electrical Medical Equipment

For decreased time-to-market, today's small, powerful processor modules offer excellent opportunities. It is, however, important to select a processor that will not only offer a path to the future, but will also allow consistency in software development

by Wolfgang Heinz-Fischer, TQ Group

Developments and trends in the electronics market are generally quickly reflected in the electrical medical equipment market. Cost pressure and time constraints are also heightened here, forcing companies to focus on their core competencies. This does not usually include processor cores, which are today generally "common" technology that can be purchased more easily and cheaply. In the past, there were many arguments in favor of using an embedded module, but today it is becoming increasingly important to use the same module in different devices, as was the case previously for processors. In real applications, this platform concept is becoming more important than the ability to scale a system. Which factors play a role when selecting a platform, and what does the market offer?

Electrical medical equipment has a wide range of requirements for the processor used. This starts with computing power and includes the necessary interfaces. Almost every device today has a display and therefore needs graphics, communicated via LAN or WLAN, and the interfaces for a series of sensors. Depending on whether it is a mobile battery-operated device or a stationary device, power dissipation is a crucial criterion. As the focus of costs and development time today is all about software, it is important to consistently find the same software environment. It is, however, not always easy to find the right processor for a number of devices, which is why it is sometimes necessary to select several platforms.

There are many reasons to employ a platform solution. Technology is becoming increasingly complex, increasing development times and the need for development resources. And this is precisely what conflicts with the market requirements. In some cases, the technical requirements for implementation are simply lacking: The use of a module with complex technology, e.g. a processor with 1.2 GHz clocking and DDR3 memory, requires a layer structure with Microvia and at least 10 or 12 layers. If the processor were to be integrated, the entire application board would have to have this layered structure. In cases of normal use, the additional costs often incurred for the module's plug are calculated based on the layers saved for the application board.

The average price of a PCB with dimensions of 175 mm x 120 mm and 12 layers is around $25 to $35 for medium-sized quantities. The layered structure can be reduced to 8 or less layers by using one module. For 8 layers, the PCB price is around $20 to $25 for the same quantities. A module's counterplug set is around $6 or $8 in higher quantities, meaning no additional material costs are incurred by using a module.

Along with this, all the known arguments in favor of using a module of course also apply. Time is clearly saved for users during development due to the fact that the processor module already exists as ready-made hardware. As the application board has a much simpler structure, it can be developed quicker and produced later on. Software development can begin immediately, as the reference platform is already available, usually with the relevant BSPs and drivers. Initial performance tests can thus commence very early on. One clear advantage for users is the fact that the "time-to-market" is significantly shortened. Still, risk minimization is also crucial. And risk means time and money. As the application board's design is much simpler, the risk of any redesign is

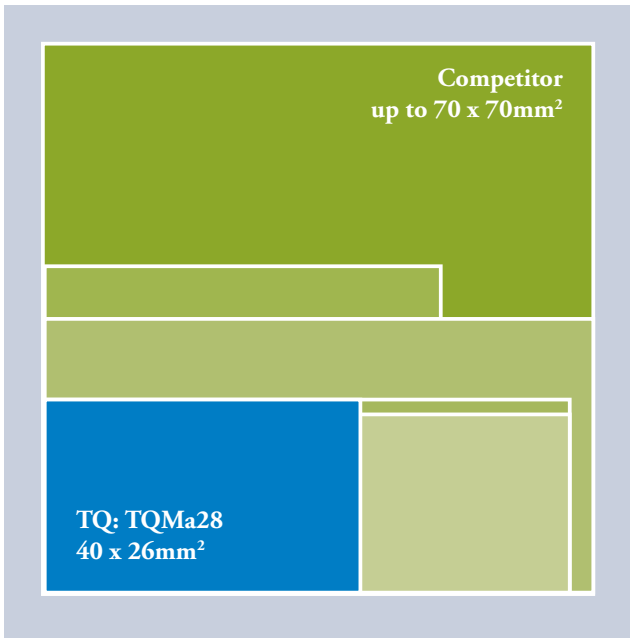

Figure 1: A sample of the board size options for a given processor. Similar comparisons should be carefully considered for other processor choices.

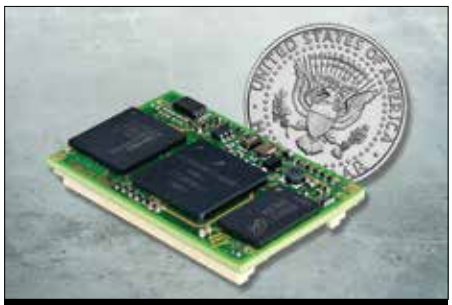

Figure 2: The trend for processor modules is to become ever smaller and ever more efficient thus bringing down development time and costs.

greatly reduced. During the product's lifecycle, a redesign is generally only necessary for the embedded module. Lower risk and prompt completion of development can significantly contribute to a product's market success.

Attempts have previously been made to always use the same processor wherever possible in order to utilize the infrastructural investments made, e.g. for development tools, software drivers, BSPs, test tools etc., including for new developments. But the vast number of processors and relevant embedded modules lead people to always select the optimum processor for each development and device. As the software portion of an overall development and in a device's added value is constantly increasing, further considerations have been deemed more beneficial to focus on a processor or platform in the form of an embedded module.

So once the right processor has been found, we have to also find the right module to use as a platform. The first question is, of course, whether or not the module provides the necessary output and interfaces, not just for current use but also for further planned applications for which the processor would be suitable. If the module does not possess all the processor's functions, there is a risk that, although the processor may be suitable for the application, it may not provide the necessary signals.

The same applies for board size (Figure 1). The smaller a module, the more likely it is to mechanically fit into all devices for which the processor is suitable. When it comes to electrical medical devices, long-term availability is also important, since they must be supplied over a long period of time. As already mentioned, software is playing an increasingly important role, so the relevant drivers should be provided for the platform(s). In doing so, the application software should be able to run on as many platforms as possible. Choosing the right module that will be successful over the long term is thus always a question of whether or not the module restricts the processor in any way.

Thus in most cases the use of modules constitutes a significant advantage for the developer. They allow him to fully concentrate on his core competency thus saving design resources and enabling several devices to be developed within a short space of time. The probability of developing a device within the prescribed time limit also increases since the device's complex parts are already available as a tested and ready-to-use solution. And time-to-market, i.e., the possibility of being the first on the market, may provide a decisive competitive advantage. Even lifecycle management becomes simpler since the probability of a redesign lies predominantly on the module side, and thus is not a problem for the developer but must be carried out by the module provider.

The use of a module is also advantageous with regard to costs. The development and production costs are considerably lower and easier to calculate. The entire investment for a product development may be up to $260,000 lower than the cost of a fully integrated development. And these lower investment costs also imply lower interest costs since the development, as a rule, must be pre-financed. The strong points of a platform concept become evident in any case upon deployment in a second device. Here, the savings are even higher since the developer is able to draw on many pre-existing elements. An example of this is the optimum use of investments that have already been made on one occasion. In addition, the higher number of units of the module deployed arising from several projects also offers the buyer the possibility of benefiting from quantity discounts. Thus as a rule, the successful route to the fast development of electro-medical devices passes through a processor platform (Figure 2).

All TQ modules consistently provide these requirements as an optimum platform module: compact design, all processor signals available, robust, suitable for industrial applications and available for at least 10 years.

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