Selecting the "Right" Embedded Computing Solutions Provider for Medical Applications

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Overview

Besides criteria such as sophisticated mechanics, complex chemical control processes and vital imaging detection algorithms, a medical device needs an embedded computing platform as the central engine to coordinate its various functions, power its performance, manage sensitive data and monitor and control the process flows. Embedded computing systems often play a significant part in medical devices for an ever-growing list of applications, including clinical diagnostics, surgical imaging, digital radiography, ultrasound, point of care, computer guided therapy and ophthalmology.

For medical devices designers, selecting the right embedded computer solution for their next generation design is only the first step. It is critically important to select the right solution provider with proven skills in supporting OEMs in this challenging market.

The following key criteria serve as a guideline in qualifying the "right" partner for the "right" embedded computing solutions to help bring the medical device competitively and timely to the market.

1. Broad Experience in Medical Applications

The medical device landscape is a fragmented market with a diverse range of applications in which the requirements can differ greatly. Whether it is a clinical diagnostic device or a healthcare self-service kiosk, the requirements of the device vary based on the feature set and performance required by its specific target market. Even within the same application, different sub categories can exist where handheld, portable and/or stationery medical devices demand completely different feature sets resulting in the need for a range of board form factors, dimension of the chassis and power supplies. Temperature fluctuation (moderate or wide) also dictates the design of a medical device for its intent deployment in the indoor or outdoor environments.

The right embedded computing partner needs to understand the application-specific requirements for this sensitive market and also have a proven track record of delivering innovative solutions capable of fulfilling those requirements. In other words, the right partner not only demonstrates the capabilities for delivering the functions and features required by a medical device design, but also has extensive experience of carrying out various medical design projects successfully. Nothing short of the success of projects can prove that this partner has the necessary know-how and resources to help medical device designers take on the fundamental challenges they face: performance, space, cost, safety and security.

2. Extensive Knowledge of Computing Technology

Depending on where and how they are used, medical devices within the same application could demand different computing or data processing power, memory size, hard disk or solid state disk (SSD) capacity, and number of I/Os – which could be either in high speed or low speed. For example, a low power Intel® Atom™ processor-based handheld or pocket-sized ultrasound device could be used as an solution for point-of-care applications; a more powerful Intel® Core™ processor-based portable ultrasound device could be on the desktop for clinical use; and an Intel® Xeon™ processor-based stationary ultrasound on a movable cart could be used in the radiology department of a hospital for heavy duty image diagnostics. Likewise, other applications from radiography imaging systems to in vitro analysis instruments could be available in the forms of handheld, mobile and stationary. A good partner should have extensive knowledge of computing technology to help their customers optimize a target system, providing the ideal configuration of form factors, CPU, memory, storage, and I/Os.

A qualified partner must not only be capable of recommending the right embedded computing solutions, but also should have strong ties with an innovative processor technology provider like Intel®, a recognized leader in its field. Intel's advanced architecture and technology help drive the innovation and the growth of its ecosystem partners, supporting both their hardware and software development. With strong, long-term partnership with Intel, qualified computing solution providers can access and utilize Intel's latest processor technologies to deliver the most ideal solutions for advanced medical projects.

3. Comprehensive Product Portfolio

The solution provider must not be limited just to CPU technologies and related peripherals, but must also be able to recommend how to partition the required computing functions based on the engineering trade-offs and assist in selecting the most appropriate solution for the targeted application. For many medical applications, designers will need to make their choice on the embedded computing solution between modular computers and off-the-shelf single board computers (SBCs).

A modular embedded computing solution such as a computer-on-module (COM) – COM Express or Qseven (Q7) module – is flexible and scalable, and allows for extensive customization. From the high level, this modular approach divides the computing platform in two major portions: a CPU module with memory and CPU, and a carrier board that hosts the rest of electronic functions. This modular

configuration enables the same system to have the capability of adopting various CPU modules to achieve the performance required by different system configurations, but keep the rest of computing system the same without any addition modifications. The major benefit of this approach is the ability to offer a system with exceptional scalability and flexibility in adjusting CPU power without any impact on re-design.

For medical device applications that require expandability to add on functions, such as capture cards, video cards, I/O cards and the like, a PICMG-based SBC or System Host Board (SHB) computing solution could be suggested. The combination of a PICMG-based SBC or SHB, where the CPU resides, and the backplane, which could be easily modified based on the number of PICMG expansion slots needed, could dramatically enhance the expandability and upgradability of the design.
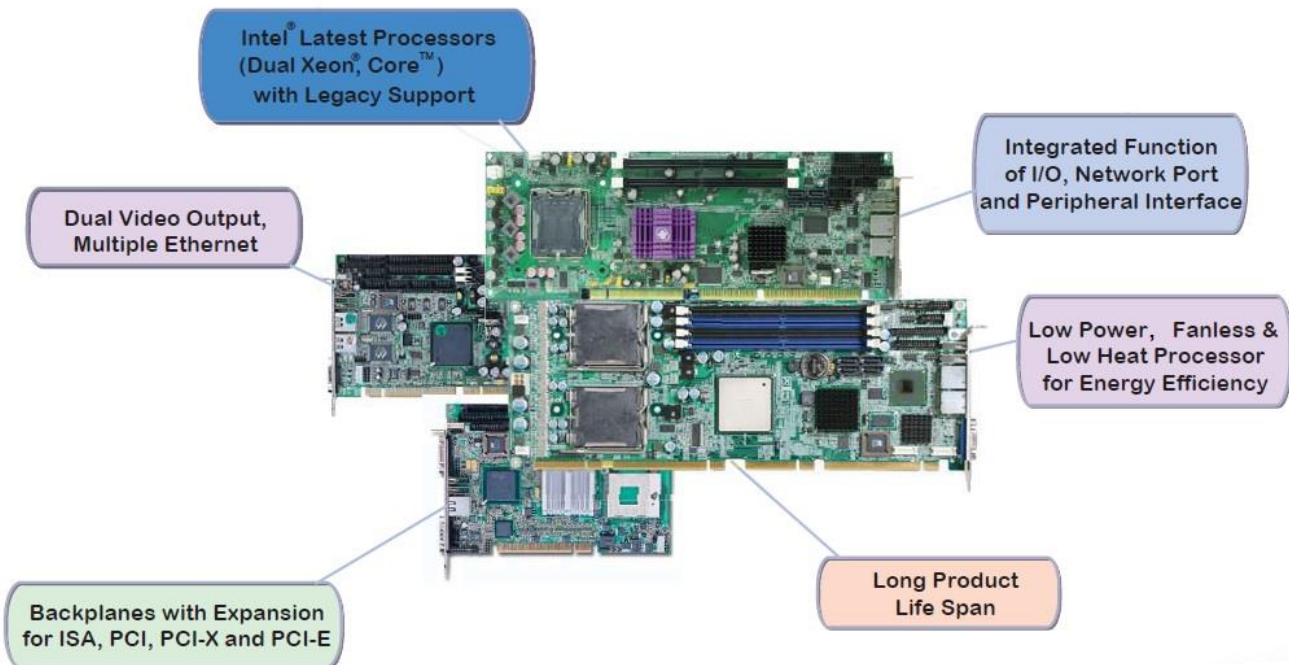
An experienced partner will go further with its engineering services in a number of areas: fan-less or ruggedized packaging for handheld or portable devices; smart cooling systems for environments where quietness is important; wireless connectivity for applications where cables are more than just an annoyance; wide-temperature support for systems operating in an extreme environment; and support of certain operating systems (OSs) based on the customer's application and desired software capability.

4. Long Lifecycle Support

In comparison to other vertical market applications, medical devices have very long product lifecycles. This is necessary because of the time it takes to gain FDA approval and the demand for instrument stability in critical operating environments related to human life. Most medical device manufacturers require that embedded computing solutions sustain the same long life span as the device itself (or

longer, when aftermarket support is considered). So, a computing solution provider who is able to support the longevity of its computing solution is not only necessary, but also crucial to medical device projects.

As a world leader in processor technology, Intel® is committed to members of the Intel® Internet of Things Solutions Alliance and provides longevity support for their embedded product roadmap. This enables an Alliance member to design their embedded computing solutions with seven-year lifecycle support. A thorough design and vendor approval approach in addition to regular reviews will remove unwanted surprises during the product life.

5. Customization Capabilities

When off-the-shelf computing solutions cannot address the specific needs of a medical device, a low-risk path of customization should be provided. The right provider should not only support customization for computing functions and chassis, but also provide a prudent way to deliver customization. An experienced vendor will base the discussion of customization around their available off-the-shelf products to determine what other functions the project needs. From this point they will look at customizing the solution with the minimum changes possible, in order to reduce the design risk and to shorten the time to market. Working with the right vendor guarantees that sustainable and viable medical solutions can be delivered within time and budget.
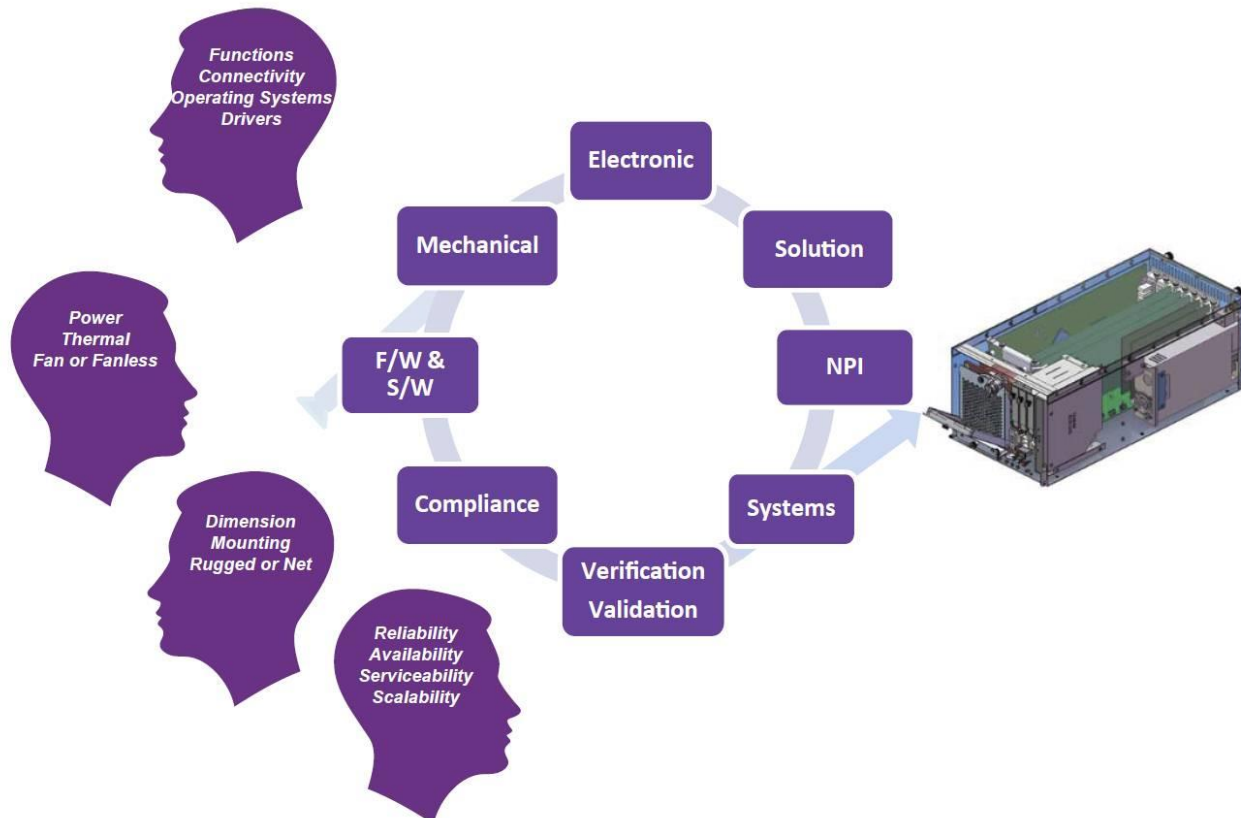
In addition to special compute form factors, the dimensions of the chassis, and particular color/logo on the chassis, there may be other customization requirements that need to be considered, such as a novel way to access the battery, which needs to be replaced every 3 years on average; a backplane with more USB or SATA ports than the standard model; or a unique BIOS (basic input/output system) with an intelligent power-up sequence.

Moreover, customization should not be limited to the product. The right partner should also be flexible enough to provide different ways to accommodate the customer's special needs in business operations. These operational needs could be: software and hardware integration, revision control, engineering change management, supply chain management, inventory control, End of Life (EOL) management and longevity support of product.

These customization features and capabilities that address the unique needs of the project should be well written in documents and carried out in every step of the design and operation cycles, with rigorous project management support from concept to final product.

6. Compliance with Medical Regulatory Requirements

Most medical devices need to meet certain regulatory compliance, like FDA clearances. The right embedded computing solution partner must work closely with the medical device development team to examine requirements and provide consulting, testing and other required services to ensure those products will meet those certifications and practices.

In addition, a computing solution provider should be certified to EN 60950/IEC 60950 at a minimum and preferably to EN 60601-1/IEC 60601-1. Manufacturing location should have ISO 9001 and ISO 14001 certifications. And, most importantly, a solution partner should be certified with ISO 13485, which confirms that the provider has a quality management system in place with abilities to provide related services that consistently meet medical devices and regulatory requirements.

Conclusion

They say "success breeds success." This is at its truest when working with the "right" embedded systems partner, from design cycle to lifecycle management. The right partner must have a proven track record of successfully delivering medical device projects; proven experience and expertise in the necessary engineering disciplines, including engineering support; and a proven ability to choose the "right" computing system. Such a track record and expertise will in turn facilitate a proven business model that will help medical device OEMs to fast-track the design and development of their medical devices and systems, and will help to ensure that aggressive time to market considerations are met so that one can stay one step ahead of the competition.

About American Portwell Technology

American Portwell Technology has more than 15 years of experience in providing embedded computing solutions and design consultation to the medical industry. Successfully completed projects include: Biomolecular Analyzer, Clinical Diagnostic Equipment, DICOM Web PACS, Digital Radiography, Image-Guided Radiation Therapy, Injection Control, Intravascular Ultrasound, Microplate Washer, Healthcare Information Management, Patient Care Dashboard, Ultrasound Imaging, Vascular Diagnosis and more. American Portwell is a Premier member of the Intel® Internet of Things Solutions Alliance, and is an ISO 13485, 9001 and 14001 and TL 9000 certified company.

For more information, visit http://www.portwell.com/solutions/medical.php.

About Intel® Internet of Things Solutions Alliance

From modular components to market-ready systems, Intel® and the 250+ global member companies of the Intel® Internet of Things Solutions Alliance provide scalable, interoperable solutions that accelerate deployment of intelligent devices and end-to-end analytics. Close collaboration with Intel and each other enables Alliance members to innovate with the latest technologies, helping developers deliver first-in-market solutions.

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