WHITEPAPER

Designing electronic medical diagnostic and monitoring devices for extended lifecycles using off-the-shelf single board computers

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Designing Electronic Medical Diagnostic and Monitoring Devices for Extended Lifecycles Using Off-the-Shelf Single Board Computers

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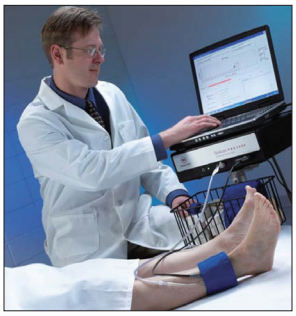

Due to the high costs and long lead time of product development and regulatory approval, profitability in the medical device industry is dependent upon the manufacturer's ability to design and develop superior products that have a long lifespan in the marketplace. Since population demographics and the rapid pace of technological change drive demand among both medical professionals and their patients, products with a long life expectancy are only desirable as long as they continue to assist medical professionals in providing superior patient care.

Electronic patient diagnostic and monitoring devices are complex systems consisting of a variety of discrete components. To design effectively for extended product life expectancy, medical OEMs need to gain assurances from equipment manufacturers that the components they are designing (or embedding) into their systems will continue to be available for the long term. Medical equipment manufacturers need vendors who understand that product longevity, process consistency, and responsive technical support are the most important services an embedded component vendor can provide.

When designing electronic medical equipment, OEMs must plan a strategy that mitigates problems caused by the obsolescence of critical components. This is especially true when designing and specifying the embedded single board computers (SBCs) that are at the heart of many critical diagnostic and monitoring systems. Such systems are often designed with two separate internal computers to provide redundancy and ensure equipment uptime. Since SBCs are designed as industrial-grade products, they are guaranteed to have long term availability. However, with some electronic components, the rapid pace of technological change coupled with the industry's long product development and regulatory approval cycle can result in a component becoming obsolete and no longer available well within the useful market life of an electronic patient diagnostic or monitoring device. Unfortunately, such obsolescence can not be avoided. This is why SBC manufacturers must practice effective component obsolescence planning.

Proper obsolescence planning is a highly specialized skill that requires not only an intimate knowledge of the market but also very close working relationships with component manufacturers. Single board computer manufacturers who have developed the infrastructure and processes designed to address component obsolescence can contribute greatly to the expected profitability of a given product with an extended lifespan. Today in this highly specialized industry there are a handful of industrial grade SBC manufacturers who have built solid reputations over the span of many years based on their consistent manufacturing processes, experienced supply chain management, and forward looking planning to support customers.

Industrial grade embedded computers come in various sizes and are based on a variety of architectures and manufacturer's "chip sets." Products based on the x86 architecture have a long history of reliable performance that consistently reinforces their staying-power in the marketplace. Of the products using the x-86 architecture, there are a variety of form factors and approved standards. These include EBX, EPIC, PC/104 and PC/104-*Plus*, COM modules, Micro TCA, and others. OEMs who design products that require higher levels of processing in a reduced footprint typically look to the x86 architecture because of its computing capabilities, longevity in the market, wide industry acceptance and solid backing from major industry players such as Intel®, AMD®, VIA®, among others. These low-profile, high-powered, industrial grade embedded form factors are supported by multiple vendors who continue to design chips for them. As the demand by medical OEMs for more robust, smaller, faster processing, and lower powered SBCs increases, x86 platforms will continue to provide a solid foundation as capable vendors continue to push the design envelope.

Suppliers working within the field of electronic medical equipment design and manufacture have a unique set of challenges and hurdles. Indeed, depending upon the type of product being designed, three to five years may be required during the product development process to allow time for required foreign and domestic regulatory

filings and approvals. Governmental agencies need assurance that regulations, guidelines and current Good Manufacturing Practice (cGMP) are met, and that the benefits and risks remain constant over the lifecycle of the product. Due to the regulatory-driven extended time to market and the consequently long period of time to recover development and regulatory costs, medical devices need to have long-term viability in the marketplace. This makes it increasingly important to have considered long term support and lifecycle management well ahead of time during the design phase. Again, this is where having the supplier relationships, the infrastructure, the facilities, and the commitment to supporting long term availability of product becomes very important. If all of these things are in place then customers can be protected from the impact of component obsolescence.

It is extremely important for the manufacturer of electronic patient diagnostic and monitoring devices to have a solid working relationship with their SBC supplier. The ever increasing density and functionality of today's commercial board-level products can compound the issue of product obsolescence. The number of parts that can become unavailable increases with the number of features, functions, and components that are designed into a single board computer. SBC manufacturers who maintain a close working relationship with their customers can alert them of any changes well ahead of time, work with them to secure components to meet estimated future demands, and/or develop a component obsolescence plan to help mitigate the customer's risk. During the partnership, the OEM and the SBC manufacturer will undergo long term planning and migration paths which will help equipment developers plan for the long term. In addition, responsible OEMs will qualify SBC manufacturers on whether they have multiple component suppliers. SBC manufacturers who make a point of multi-vendor component supply in the lifecycle management process are more likely to be able to reliably supply the embedded computer for the length of time required. If the SBC manufacturer focuses on service, quality and ongoing customer relationships, the working relationship can help alleviate component availability issues.

It is also important for an OEM to examine the fit between their company processes and philosophy, and their supplier's business model. Such criteria as financial stability, manufacturing process control, understanding of regulatory hurdles, manufacturing capacity to meet demand, product quality and reliability, and reputation for on-time delivery and quality of service and support are all important factors that can be considered in the selection of an SBC supplier. Selecting appropriate products requires the selection of appropriate vendors who will honor their commitments and agree to adapt, customize and upgrade their products to meet the needs of the OEM. Again, SBC manufacturers who put a focus on developing solid relationships with their own suppliers will be able to react and mitigate issues.

In some cases, an off-the-shelf solution may not meet OEM requirements for performance and/or ruggedization. In these cases the OEM will want to select an SBC vendor who has the experience and expertise at customizing their off-the-shelf products. Typical customizations include application of conformal coating for protection from humidity, installation of custom I/O connectors, custom BIOS development, battery removal, and others. Such a customized product can provide substantial cost savings to the OEM versus a fully custom solution. If, however, a fully custom solution is needed, many SBC manufacturers are also very experienced at designing products specifically for an OEM's particular application.

In order to deploy off the shelf products in a medical application that expects extended lifecycles, the areas that should be considered by the medical OEM include: proper selection of products, long term product availability guarantees, proactive component obsolescence planning, product quality and reliability, and overall fit and comfort with the embedded computer supplier's processes and business practices. With the right choice of SBC technologies and vendors who offer open standards and have the support of multiple vendors, the medical equipment designer can realize low cost of ownership, high-performance, extended deployment and maximum profitability.