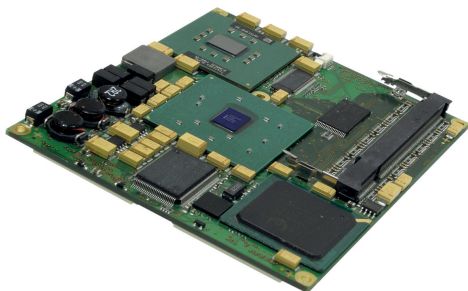# » Application Story «

Project Management in Medical

Kontron provides one-stop-shop for embedded medical computing technology

Medical technology from a single source

Medical professionals require highly reliable computing equipment that meets strict international requirements on safety and electromagnetic compatibility (EMC). To meet these demands cost-effectively, Kontron provides a single source for designing and producing medical computing equipment like the mobile computer for adjusting pacemakers for the Sorin Group.

Around 600,000 pacemakers are implanted every year worldwide1. When they are supplied from the manufacturer, the pacemakers come with default settings that need to be adjusted and fine tuned for each individual patient. This can only be done once the devices have been surgically implanted. To provide the best possible level of care, doctors use specially designed mobile computers, like the orchestra+ programmer for medical pacemakers from the Sorin Group, to adjust the settings of the implanted device. A special electrocardiogram sensor placed on the patient's chest and connected to the orchestra+ programmer enables doctors to obtain parameter information from the pacemaker and adjust the settings without the need for invasive surgery. The portable programmers are also used for regular patient check ups and responding to emergencies.

The challenge: Meeting international standards

One of the biggest challenges in developing medical equipment is meeting the strict international safety standards such as the EN 60601-1 (Europe) and UL 60601-1 (USA) that define the requirements concerning mechanical stability as well as electromagnetic compatibility (EMC) to ensure interference-free operation with other devices. Performance is also important. In urgent cases, the medical programmer needs to boot quickly and rapidly display graphically the information from the pacemaker.

Figure 1: The orchestra+ programmer for medical pacemakers offers optimal performance and ergonomics.

The solution: A single source

Companies like the Sorin Group that develop highly-specialized medical technology for use in cardiac surgery rely upon expert partners to design and develop medical computers. For the new orchestra+ programmer, the Sorin Group outsourced the entire development and production to Kontron who supplied not only the embedded computer technology consisting of a proven and highly reliable ETX® Computer-on-Module and custom designed carrier board, but the complete finished product including tested implementations of TFT touch screen, keyboard, hard disk, power supply and fan as well as the easy to handle light-weight plastic casing. Outsourcing the entire design and production to a single partner that can supply the complete value chain is the most cost-effective solution: On the one hand, the Sorin Group frees up the maximum amount of its own resources since there is no need to manage multiple suppliers, enabling the company to concentrate on its core competence of developing innovative technology for cardiac surgery. Additionally, working closely with a single partner who has experience in product life-cycle management for medical equipment designed in accordance with the relevant EN and UL standards reduces application development and evaluation resulting in quicker time-to-market.

Meeting international safety requirements

To minimize weight for easy handling, Kontron designed the portable orchestra+ with a tough plastic casing. To meet the EN 60601-1 and UL 60601-1 standards for human life related systems, the electronics and casing have been designed to ensure that the orchestra+ does not expose any live parts or cause a fire, electric shock, or mechanical hazard even in the event that it is dropped. The international standards also place strict requirements on product life management and traceability as well as other safety features such as leakage current limits and adequate shielding to ensure electromagnetic compatibility (EMC) with other devices. In order to meet the EMC requirements, Kontron used galvanic separation to electronically isolate boards and interconnects and applied an ultra-thin metal coating to the inside of the plastic casing as well as a difficult-to-apply 10m primer.

Control procedures are rigorous. Before delivery to the Sorin Group, each batch of orchestra+ programmers is controlled by an external test laboratory. This "proof of concept" procedure ensures that each orchestra+ meets the EU and US standards for electronic medical devices.

Optimal mix of standard and customized electronics

For the embedded computing technology, Kontron's dedicated medical technology team went for a design based on the Kontron ETX-PM Computer-on-Module with a customized carrier board. An ETX® Computer-on-Module was chosen because the ETX® specification is a de-facto industry standard (created by Kontron and adopted by many others) that defines a well-proven PCI and ISA-based module form factor for highly reliable and cost-effective processing performance for applications that do not require PCI Express. Based on the low power 1.6GHz Intel® Pentium M processor that has a TDP of just 24.5 watts and 512 MB of energy efficient DDR SDRAM, the Kontron ETX-PM Computer-on-Module provides exactly the right performance-per-watt values. Moreover, the fast boot time enables doctors

to provide treatment as fast as possible. Kontron's Boards & More carrier board design services delivered the custom carrier board with a special serial interface for the electrocardiogram sensor, as well as an interface for the TFT monitor, an IDE port for the internal hard drive and USB 2.0 and floppy interfaces. Using a design built around a customized carrier board paired with a standard Computer-on-Module reduces development costs since there is no need for a fully customized solution. Since the Kontron ETX-PM follows the ETX® standard, it is fully interchangeable with other ETX® compatible Computer-on-Modules for easy upgrades and maximum future security.
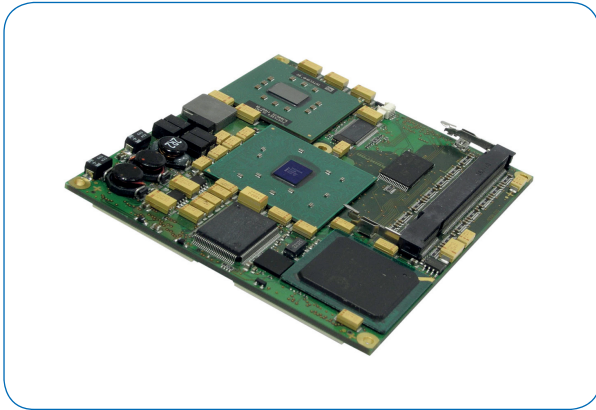

Figure 2: The Computer-on-Module Kontron ETX-PM

Project management made easy

The Kontron medical team also selected the TFT touchscreen, keyboard, hard disk, power supply and fan and carried out the entire development and validation as well as the required pretesting. After gaining the required certification, serial production is now underway at Kontron's own FDA (US Food and Drug Administration) registered manufacturing facilities. At this stage of the project, Sorin Group only has to tell Kontron how many units they need. Kontron takes care of everything else, including all that is needed for managing long-term availability of the orchestra+. For example, should a component be discontinued, Kontron intervenes immediately and resolves all necessary steps with the Sorin Group to ensure continuous product availability. Moreover, the availability of components used in the current configuration is guaranteed for at least 5 years. This is important because significant changes would require renewed certification to ensure continued adherence with the relevant standards. This would add extra costs. Should a component be discontinued within this time frame, Kontron issues a continuation of supply order that guarantees the continued availability of the component. If necessary, Kontron also selects and certifies alternative components.

"Working with Kontron makes project management easy", declares Dominique Grégoire, of the Sorin Group. "Kontron knows exactly which international requirements need to be met for medical equipment. We understood each other right from the beginning and were able to get started on the project straight away, enabling fast development of the first prototype

for validation. All of our communication with Kontron is dealt with professionally and efficiently, enabling us to free up our own resources and concentrate on our core competencies."
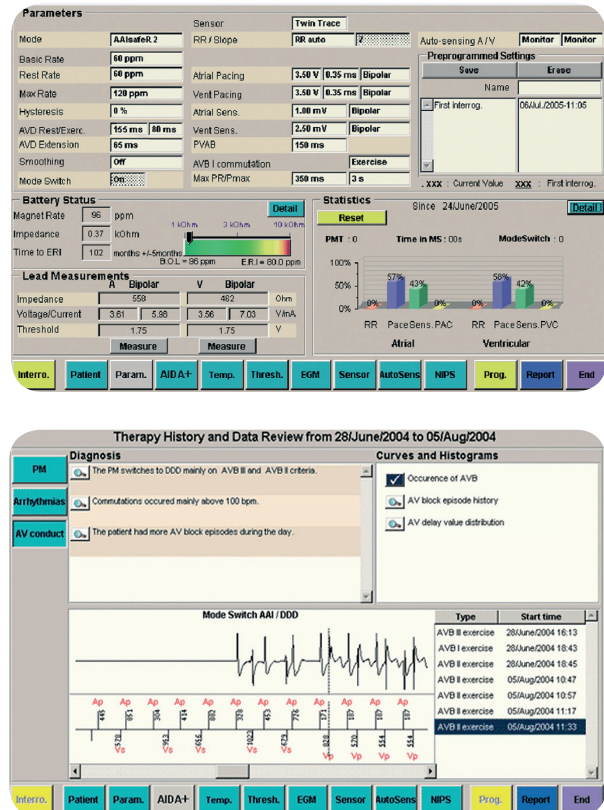

Figure 3: The orchestra+ is operated by keyboard and by touch screen.

Summary

The Sorin Group has found a supplier for its medical computer systems that is able to assume responsibility for the whole project - from selecting the right components including the Computer-on-Modules and customized carrier board to delivering the finished system with the required certifications. The system itself is an easy-to-handle and extremely reliable medical computer that not only meets international requirements for electronic medical equipment, but also offers maximum future security and lower total costs of ownership.

Ingrid Einsiedler

Marketing Managerin at Kontron

Kontron Project Management Services

Kontron's comprehensive customization, engineering and project management services are especially designed to enable OEMs, system integrators and designers achieve faster time to market for their applications in the medical, industrial automation, energy, telecommunication, defense/aerospace, transportation, POS/POI and infotainment markets. Kontron's dedicated global business units work closely with customers to design and manufacture tailor-made, application-ready OEM platforms ranging from industrial servers and medical PCs to pre-integrated and fully tested ATCA and MicroTCA platforms as well as rugged Modular Embedded Computers (MEC) amongst others. In developing a customized solution, Kontron draws upon its comprehensive portfolio of standard, off-theshelf products that includes Computer-on-Modules, boards and mezzanines, HMIs and Panel PCs as well as systems and platforms. Using standard, off-the-shelf components and platforms minimizes development costs and accelerates time-to-market. Production takes place at Kontron's advanced testing and manufacturing facilities that are ISO 9001 and ATEX-certified to ensure consistency and the highest level of quality in products and services on a global basis. Each Kontron business unit has specialist expertise in its respective vertical market to ensure that all OEM platforms are designed and produced in accordance with the highest international certifications and standards. Kontron also organizes and coordinates rigorous product testing of prototype and series products at independent testing laboratories. Long-term availability management and EOL management round off the project management services that cover the entire value-added chain, enabling customers to free up the maximum amount of internal resources in order to concentrate on their core competences, reduce total cost of ownership and ensure fastest time to market of their products.

About Kontron

Kontron is a global leader in embedded computing technology. With more than 40% of its employees in research and development, Kontron creates many of the standards that drive the world's embedded computing platforms. Kontron's product longevity, local engineering and support, and value-added services, helps create a sustainable and viable embedded solution for OEMs and system integrators.

Kontron works closely with its customers on their embedded application-ready platforms and custom solutions, enabling them to focus on their core competencies. The result is an accelerated time-to-market, reduced total-cost-of-ownership and an improved overall application with leading-edge, highly-reliable embedded technology.

Kontron is listed on the German TecDAX stock exchanges under the symbol "KBC". For more information, please visit: **www.kontron.com**

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