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FOUNDATIONAL SOFTWARE SOLUTIONS

MEDICAL DEVICES

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FOUNDATIONAL SOFTWARE SOLUTIONS MEDICAL DEVICES

Medical device manufacturers operate in an environment filled with intense market pressures, stringent safety regulations and concerns about cyberthreats. These manufacturers must also meet costly and difficult safety goals and create complex and connected software-defined designs. To ensure that medical devices are safe, reliable, secure and safety-certifiable, manufacturers need to use a software foundation specifically designed for safety, cybersecurity and secure connectivity.

BlackBerry[®] QNX[®] embedded software solutions help medical device manufacturers innovate and rapidly deliver safe, secure medical applications to market. Our solutions scale to meet the requirements of medical applications that range from small-footprint, real-time applications such as ventilators and infusion pumps to full-featured applications such as robotic surgery, imaging and monitoring systems. BlackBerry QNX provides a clear path from Linux-based prototypes to medical devices ready for Class C certification.

At BlackBerry QNX, we provide solutions that are trusted by leading medical device manufacturers. We also work closely with silicon partners such as the ARM[®] vendor ecosystem, Intel[™] and major board vendors globally to deliver safe, secure and reliable software solutions.

300+ million

mission-critical systems

40+ years building trusted embedded software

100% success rate achieving safety certification



WHY LEADING MEDICAL DEVICE COMPANIES CHOOSE BLACKBERRY QNX

The same BlackBerry QNX software foundation that enables companies to build safety and cybersecurity into their products also simplifies safety certification, supports the reuse of legacy software, helps to improve reliability and enables innovation. BlackBerry QNX helps medical device manufacturers overcome many challenges at once.

We provide the confidence you need in building safety-critical software. BlackBerry QNX solutions are based on standards and offer proven software development tools classified to T3 and TCL3. The QNX® OS for Safety is pre-certified to IEC 62304 Class C. QNX® Hypervisor for Safety offers the same trusted functionality and performance as QNX® Neutrino® real-time operating system (RTOS), plus virtualization support. BlackBerry QNX also offers solutions for safe communications, graphics, system libraries and middleware. And all our software is backed by decades of experience in providing trusted professional services.

At the heart of BlackBerry QNX is the microkernel QNX Neutrino RTOS. The microkernel architecture minimizes downtime and cyberattack surfaces through isolation and separation mechanisms. Device drivers and system services run alongside applications, separated from one another and the kernel. Running all OS services outside of kernel space enables highly available, fault-tolerant designs—the failure of one application or service will not crash the kernel, other services or other applications. Building on the QNX Neutrino RTOS can help you to develop more resilient and reliable systems.

A microkernel RTOS also improves scalability and design flexibility. The QNX Neutrino RTOS scales from single-core to multicore to high-performance computing platforms seamlessly. For a system with limited capability and functionality, a microkernel can jettison excess services to fit in a small footprint with little memory. Developers can add drivers and services as needed. With virtualization support, the system can simultaneously run both new and legacy applications on multiple OSs.

ACCELERATE SAFETY CERTIFICATION

Certifying a system to an industry safety standard such as IEC 62304 is time consuming and costly. The use of a safety-certified OS dramatically simplifies development and testing efforts and shortens overall system certification processes. The QNX OS for Safety is pre-certified to IEC 62304; and both the QNX OS for Safety and the QNX Hypervisor for Safety are certified for use in applications requiring IEC 61508 SIL 3. In addition, the QNX OS for Safety includes toolchains qualified to ISO 26262 and IEC 61508 TCL3 and T3 requirements. Safety-certified C and C++ libraries are also available.

Safe data communication is essential for many medical devices. The Black Channel approach, defined in the IEC 61508 standard, constrains functional safety development to the safety layer and streamlines certification. QNX® Black Channel Communications Technology provides safe communication between endpoints even through an unsafe communication stack, which avoids the need to have a safety-certified network stack.

ESTABLISH RELIABILITY AND PERFORMANCE

Highly available, robust software systems for medical applications require a fail-proof foundation that enables them to boot quickly, run as specified and expected, avoid system crashes and ensure that the highest-priority tasks run first. The QNX Neutrino RTOS's deterministic microkernel architecture provides such a foundation. Because drivers and services run outside the kernel space, the microkernel also enables the software components to be added and upgraded with minimal impact on the overall system.

PORT SOFTWARE EASILY

When you design a prototype using Linux[®], you can easily port your system into a production environment based on BlackBerry QNX. BlackBerry QNX products are POSIX compliant, so developers can easily port software from Linux[®] or another OS to the QNX[®] Software Development Platform (SDP) with minimal redesign or recoding. In addition, developers ramp up quickly on QNX software because it looks and feels like Linux and uses familiar tools, such as the Eclipse-based QNX[®] Momentics[®] IDE and the GNU compiler collection (GCC).

With the QNX® Hypervisor and the QNX Hypervisor for Safety, you can contain entire systems with their OSs as guests in hypervisor virtual machines. This, in turn, allows you to port legacy code onto new SoCs and run them concurrently with your latest product. You can also implement new features or upgrade entire systems in virtual machines, confident that the new code won't affect other systems—including safety-critical systems running on the SoC.

STRENGTHEN CYBERSECURITY

Connected medical devices are targets of cyberattacks, and the breach of a medical device or device communications can put patients, customers and your company at risk. Such devices may need to operate successfully on an IEC 80001-conformant healthcare IT network. Building and maintaining a secure system requires, at a minimum, a reliable and secure OS, secure over-the-air (OTA) software updates, a secure supply chain, and managed public key infrastructure (PKI) authentication. BlackBerry QNX solutions provide a layered approach to security that won't hamper functionality or performance.

- The QNX Neutrino RTOS reduces attack surfaces by running services outside of the kernel space. It provides granular control of system privilege levels, secure boot and an AES-256 encrypted and self-verifying filesystem.
- QNX Black Channel Communications Technology helps to ensure safe data communication over unsafe links (e.g., UDP, TCP, UART).
- BlackBerry[®] Jarvis[®], our software composition analysis solution, can help you uncover and remediate software vulnerabilities in components from across your complex supply chain.
- BlackBerry[®] Certicom[®] solutions make it easy to add cryptographic algorithms to medical devices, providing confidentiality, data integrity and authenticity without requiring cryptographic expertise. This solution includes managed PKI (Public Key Infrastructure) authentication and algorithms validated to FIPS (Federal Information Processing Standards), which is required to sell into U.S. Veterans Administration (VA) hospitals and other U.S. federal agencies.
- BlackBerry QNX also provides a secure over-the-air (OTA) software update solution.

REDUCE THE COST OF OWNERSHIP

The reuse of application and driver code across devices and product lines helps you deliver new medical devices faster and drive more revenue with less risk of non-compliance. In contrast to the costly commitment of your resources to develop and maintain an open-source OS, such as Linux, BlackBerry QNX manages all OS maintenance and updates for you and frees your team to focus on innovative engineering of application software.

When you use the QNX Neutrino microkernel RTOS and QNX software stack across product lines, you can offload OS maintenance to BlackBerry QNX, while sharing drivers and applications throughout your organization for a lower total cost of ownership. Plus, with POSIX compliance, switching from Linux or another OS to QNX is not a big lift. The result can be more efficient and more scalable engineering operation.

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SILICON AND BOARD SUPPORT

QNX® Board Support Packages (BSPs) provide an abstraction layer of hardware-specific software that facilitates the implementation of the QNX Neutrino RTOS on your board. Our extensive BSP library includes BSPs for SoCs manufactured by leading hardware manufacturers. In addition, our professional services can develop customized solutions for you and support your safety and security requirements.

Learn more about our library of BSPs

SOFTWARE SOLUTIONS FOR MEDICAL DEVICES

Medical device companies globally trust BlackBerry QNX software for a broad range of life-critical and graphics-rich medical applications.

BlackBerry QNX provides time-tested and trusted foundation software, including the QNX Neutrino RTOS, a deterministic microkernel real-time operating system; a safety-certified OS for Safety and Hypervisor for Safety, and cybersecurity solutions like BlackBerry Jarvis for software composition analysis—all of which are purpose-built for embedded systems. We also have experts who can provide the software, support and services you need to build better medical devices and get them certified and approved for market. We partner with you at every step, from the inception to the launch of your embedded system. We believe we are successful only when you are successful.



SOLUTIONS BUILT FOR EMBEDDED SYSTEM SECURITY

Recent trends around consolidation of functions on a single system on a chip (SoC) and, increased connectivity and device complexity call for a new approach to security. For this reason, BlackBerry QNX delivers solutions that can help you secure your end products across the software development lifecycle and provide continued security measures once your products are in the field.

BlackBerry Jarvis is a software composition analysis solution designed for complex and critical embedded systems like those within today's medical devices. It enables you to safeguard your products from cyberthreats by helping you uncover and mitigate vulnerabilities that may exist within third-party software. It also provides cutting-edge system exploration to examine your embedded software product for security vulnerabilities and software craftsmanship so you can continuously track and improve the quality of your software components.

BlackBerry Certicom Asset Management System (AMS) helps medical device manufacturers to securely provision cryptographic keys, trust anchors and unique device identifiers and debug passwords, with visibility and governance over the manufacturing process. Its flexibility eliminates the need for ad hoc approaches to device provisioning and helps ensure a secure, traceable process throughout the supply chain.

- Anesthesia
- Angioplasty
- Artificial Hearts
- Biological Warfare Detection
- Blood Analyzers
- Blood Diagnostics
- Bone Densitometers
- Cardiac Monitors
- C-Arm DR & Ultrasound
- Cataract Surgery
- CPAP Machines
- CTs and MRIs
- ECG and EKG
- Electrical Stimulation
- Eye Lasers
- Fluoroscopy

- · Hemodialysis
- Infusion pumps
- Laboratory Diagnostics
- LVAD (Left Ventricular Assist Devices)
- Medical Exoskeleton Suits
- Medical Gateways
- Medical Lasers
- Medical Ventilators
- Multi-Parameter Patient Monitors
- Multi-Spectral Imaging
- Neurological Monitors
- Nuclear Medicine
- Nurse Call
- Nurse Monitoring

- Organ Transportation Devices
- Pacemakers
- Patient Monitors
- Peritoneal Dialysis
- PET & X-Rays
- Plasma Collection
- · Point-of-Care (POC) Testing
- Pulse Oximetry
- Rehab
- Respiratory Care
- Robotic Surgery Equipment
- Sedation
- Sterilizers and Laboratory Equipment
- Tissue Scanners
- Vacuum Wound Management

BLACKBERRY QNX SOLUTIONS ARE USED IN MORE THAN 50 TYPES OF MEDICAL DEVICES

SUPPORT AND SERVICES

BlackBerry QNX is your partner through your product lifecycle. We offer a range of services to help you reach your goals faster. The BlackBerry QNX professional services teams have deep knowledge of embedded systems, functional safety and cybersecurity and a 100-percent success rate in helping our customers achieve safety certifications.

We back our products with top-quality support, best-in-class documentation and expertise from the developers and engineers who built the QNX products you use. Whether you want help with staff augmentation, kickstarting a project or certifying products, our embedded systems development and OS experts can provide the proper knowledge and experience at the right time.



PROVEN EXPERIENCE

Thousands of person-years in development, support, integration



GLOBAL FOOTPRINT

Regional experienced teams in North America, EMEA, APAC



INTEGRATION & OPTIMIZATION

High-performance software for custom hardware, delivered when you need it



SERVICE EXCELLENCE

100% success at meeting start of production (SOP) deadlines



DEEP EXPERTISE

Experts in all areas of medical device software



COMMITMENT

Dedicated, dependable, trusted staff

SAFETY AND SECURITY SERVICES

The BlackBerry QNX safety and security services teams possess deep knowledge of functional safety and security. With a legacy in cybersecurity, BlackBerry has the expertise you need to secure both systems and supply chains.

PROFESSIONAL SERVICES

The BlackBerry QNX global professional services teams help companies bring safe, secure and reliable products to market on time and within budget. We closely fit our expertise to your needs, including custom development.

TRAINING

BlackBerry QNX offers project-customized courses on best practices in functional safety and embedded design, all of which are hands-on, instructor-led and use real-world examples.

SUPPORT AND MAINTENANCE

BlackBerry QNX provides unmatched support packages and services that span the entire lifecycle of systems built with BlackBerry QNX solutions, including regular updates, fixes and technical advice from developers, engineers and architects.



SOFTWARE AT-A-GLANCE

FOUNDATION PRODUCTS	
QNX Neutrino Real-Time Operating System	This deterministic, flexible foundation for your next-generation products has a unique microkernel architecture that provides scalability, dependability and layered security features.
<u>QNX Hypervisor</u>	This embedded virtualization solution with a microkernel architecture enables multiple OSs (e.g., QNX, Linux, Android™) to operate safely on the same system-on-a-chip (SoC).
QNX Software Development Platform	The power of QNX Neutrino RTOS plus the QNX® Momentics® Tool Suite provides a POSIX-compliant, Eclipse-based development platform.
SAFETY-CERTIFIED PRODUCTS	
<u>QNX OS for Safety</u>	Built on the same microkernel architecture as the QNX Neutrino RTOS, the QNX OS for Safety is pre-certified to IEC 62304 Class C. The QNX OS for Safety enables you to easily port Linux-based prototypes to the QNX Neutrino RTOS and get all the documentation and support you need to help you achieve certification.
<u>QNX Hypervisor for Safety</u>	This real-time microkernel hypervisor provides the reliability and performance of the QNX Neutrino RTOS. It enables multiple OSs to operate safely in isolation and in parallel on the same SoC.
<u>QNX Black Channel Communications</u> <u>Technology</u>	QNX Black Channel Communications Technology helps provide safe and verified data communications for embedded systems. The technology is based on the safe data communication requirements identified in IEC 61508.

SECURITY SOLUTIONS

BlackBerry Jarvis	This cloud-based software composition analysis solution blends system exploration technology and expert services to provide powerful capabilities for examining a complete software product for security vulnerabilities and software craftsmanship.
BlackBerry QNX [®] Over the Air	This customized remote software update solution addresses the complex requirements of embedded system manufacturers. It can be tailored to seamlessly and securely update and manage endpoints on a variety of embedded systems.
BlackBerry Certicom Solutions	These cybersecurity solutions provide device security, anti- counterfeiting and product authentication to deliver end-to-end security with managed public key infrastructure, code signing and other applied cryptography and key management solutions.
ADDITIONAL SOFTWARE	
<u>QNX[®] Multimedia Suite</u>	This product suite enables developers to easily implement media capabilities including playback and recording of rich audio and video content in embedded systems.
QNX® Sensor Framework	This framework enables developers to integrate feeds from diverse sensors into safety-critical embedded systems. It collects this data and maintains reliable, real-time response and decision-making in the face of critical events.

for UI development.

QNX® Graphics Framework

QNX® Speech Framework

Designed to ease and accelerate the development of voicecontrolled embedded systems, this framework abstracts the complexities of speech recognizers and natural-language processing engines from the OS platform and applications.

This mature and advanced graphics framework simplifies the creation of interactive user experiences by providing developers all the functionality required to work with industry standards

ABOUT Blackberry QNX

BlackBerry QNX is a trusted supplier of safe and secure operating systems, hypervisors, frameworks and development tools and provides expert support and services for building the world's most critical embedded systems. The company's technology is trusted in more than 195 million vehicles and is deployed in embedded systems around the world across a range of industries including automotive, medical devices, industrial controls, transportation, heavy machinery and robotics. Founded in 1980, BlackBerry QNX is headquartered in Ottawa, Canada, and was acquired by BlackBerry in 2010.

BlackBerry QNX software and development tools are standards-based and enable companies to adopt a scalable software platform strategy across product lines and business units. The BlackBerry QNX software portfolio, including safety pre-certified products, is purpose built for embedded systems and scales from single-purpose devices to highly complex systems of mixed criticality. Because we are successful only when you are, you can rely on our support and professional services teams to provide the expertise you need, when you need it—throughout the entire product development lifecycle.

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