The complexity of medical devices continues to increase at an astounding rate. From high-precision robotic surgery to 3D printing of artificial organs, the possibilities seem limitless. As a trusted operating system provider for medical devices, BlackBerry QNX has had a front row seat at this amazing evolution in medical device technology.

BlackBerry’s QNX OS for Medical 2.0 is a reliable, multi-core, real-time operating system (RTOS) that is POSIX compliant for building safety-critical embedded systems for the medical market, supported by field-proven development tools, feature-rich middleware, and professional services.

**Overview**

QNX OS for Medical is a full-featured, multi-core operating system that meets the most demanding needs of today’s medical devices. With hundreds of millions of field usage hours in mission-critical applications, including devices and equipment for blood diagnostics, ultrasound imaging, infusion delivery, heart monitoring and resuscitation and robotic surgery, the microkernel-based RTOS has a proven record of reliability and pre-assessment to IEC 62304 compliance, which helps reduce the effort in regulatory approval activities. Comprehensive OS services, including graphics technologies based on the latest hardware, enables quick development of medical devices. POSIX compliance facilitates easy migration from prototypes on Linux to production quality software.

QNX® Neutrino® RTOS, the core of QNX OS for Medical, has been successfully deployed in hundreds of safety-critical applications across many different fields, including nuclear power plants, high-speed rail, industrial automation, and surgical equipment. The Neutrino® RTOS derives its reliability from the unique microkernel architecture and carefully-designed separation mechanisms such as Adaptive Partitioning. It is also designed to help reduce the effort involved in building safety-critical products that must pass regulatory approvals. Choosing components that are already compliant, and have a credible pedigree, can significantly speed up the device certification process.

**Benefits**

**Safety standards compliance to reduce risk, development time, and certification cost**

The QNX OS for Medical is compliant for use in applications requiring up to Class C IEC 62304 compliance, a standard for “Medical device software – Software life cycle processes”. It has been assessed by a reputable auditing body, TÜV Rheinland, thereby helping medical device manufacturers solve the problem of qualifying “SOUP” (Software of Unknown Provenance).

Since the first edition of the IEC 62304 standard was created, safety certification requirements in medical devices have become more prevalent and are driving the need for IEC 62304 compliant software. By supporting the needs of medical device manufacturers, BlackBerry QNX helps reduce program cost and risk, and shortens the time-to-market for medical device developers. The product is assessed by an independent third-party auditing firm to IEC 62304 Class C, the highest class for applications where death or serious injury is possible. IEC 62304 is a standard that has been endorsed under medical device-related directives by the FDA in the U.S. and by the Directorate-General for Health and Consumers in the E.U., enabling manufacturers to follow good development practices and to produce high-quality software for medical applications.
The innovative, trusted, secure, and reliable QNX OS is tailor-made for medical device applications.

Beyond the pre-assessed microkernel core, the QNX OS for Medical also delivers a full range of OS services that are needed in building medical applications.

1. Networking services provide native distributed processing to support complex distributed systems in which multiple devices seamlessly share resources and communicate without custom protocols;

2. A wide range of block and flash filesystem formats are supported along with a power-safe disk file system for data integrity and reliable storage;

3. For applications with a user interface, the screen framework enables developers to build graphically rich, compelling user interfaces using built-in, high performance, OpenGL ES-based transitions. It supports multi-touch displays and gestures, and renders images from multiple graphics engines through a single compositing windowing system, which integrates multiple graphics and UI technologies into a single scene.

**POSIX-compliant OS**

QNX® Neutrino® RTOS is a POSIX-compliant operating system. This greatly simplifies the migration from a Linux-based prototype to a production system. The Linux-API compatibility resulting from POSIX compliance can increase code re-use and eliminate the learning curve that often accompanies the adoption of a commercial RTOS.

**Services**

To complement QNX OS for Medical, QNX Professional Services provide cost-effective assistance and expertise to medical device manufacturers for developing highly reliable embedded software and meeting regulatory agency requirements. Examples of services include:

- Training
- Architectural reviews
- Custom engineering

**Diagram 1:** Pre-assessed microkernel helps reduce certification effort

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**About BlackBerry QNX**

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