



# The Building Blocks for Life-Critical Medical Devices

# The Evolution of Healthcare

Medical device manufacturers operate in a challenging environment filled with stringent regulatory requirements, connectivity and interoperability considerations, security threats and time to market pressures. In the face of these challenges medical device manufacturers must develop increasingly complex devices in timelines that are more typical of consumer-grade electronics, but difficult to meet in a regulated industry.

As a trusted industry leader for almost four decades, BlackBerry QNX is committed to providing operating systems and software that meet the unique and constantly evolving challenges facing medical device manufacturers today. We provide the building blocks that make innovations come to life and get to market faster, while fully complying with the strict safety, security, and connectivity requirements of medical applications.

## Safe. Secure. Reliable.

The world's largest medical device manufacturers trust BlackBerry QNX to help run their blood diagnostics, ultrasound imaging, infusion delivery, heart monitoring and resuscitation, robotic surgery, and numerous other applications.

Learn what they have already discovered.

# Technology

## BlackBerry QNX Medical Overview

What differentiates the BlackBerry QNX medical offering from other options is the peace of mind it provides. Medical device manufacturers that use BlackBerry QNX will benefit from pre-assessed software and professional services that ease the process of meeting safety, compliance, security and connectivity requirements.

BlackBerry QNX offers a comprehensive modular software approach that supports reliable, multi-core, safety-critical embedded medical systems with an IEC 62304 compliant RTOS, field-proven performance, feature-rich middleware, HMI, connectivity, security, clean IP, and professional support.

These components spearheaded by the foundational QNX® OS for Medical form the building blocks that will aid medical device manufacturers in translating their innovations from concept to reality.

What makes the QNX OS for Medical unique, and perfectly suited for medical devices, is the microkernel architecture where each and every component is protected and each component can recover without a system reset.

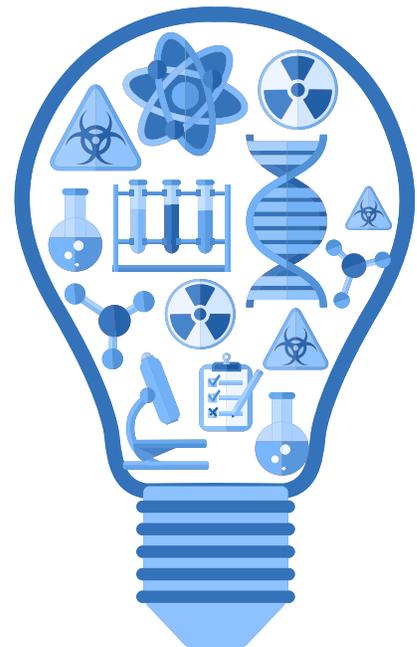
**HMI**  
HTML5, QT

**SECURITY**  
FIPS 140-2, PKI

**CONNECTIVITY**  
USB, BLUETOOTH, WI-FI, CELLULAR

## QNX REALTIME OS

- The QNX OS for Medical is fail-safe, providing service separation, so if one service fails, others continue to work reliably. That service can then be restarted without system interruption.
- The QNX OS for Medical allows seamless over-the-air updates to in-use medical devices drivers and networking stacks, without requiring reboot.
- Easy and fast integration. The microkernel architecture allows new processes to be added with very little re-design or coding.
- The QNX OS for Medical is IEC 62304 compliant, which greatly aids in software maintenance. IEC 62304 software aligns well with the FDA's post-market requirements for managing cybersecurity in medical devices.



# IEC 62304 Compliance

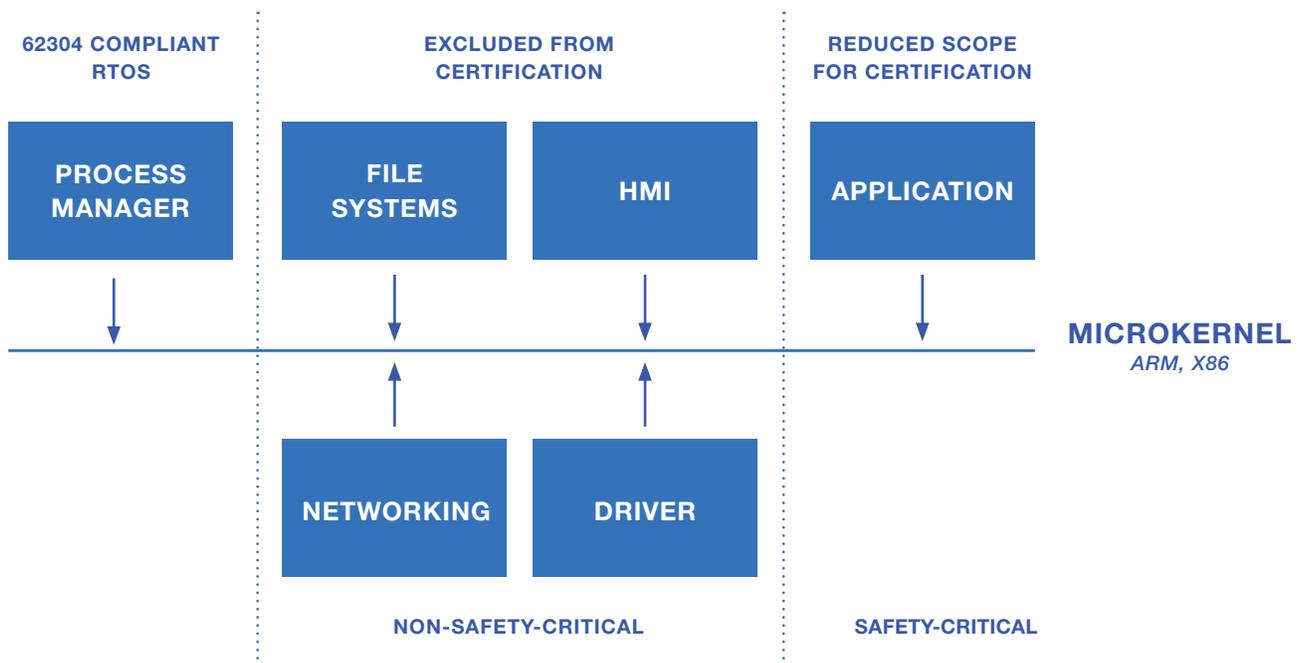
The QNX OS for Medical is compliant for use in applications requiring up to Class C IEC 62304 compliance, a standard for “Medical device software – Software life cycle processes”. It has been assessed by a reputable auditing body, TÜV Rheinland, thereby helping medical device manufacturers solve the 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 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., providing a framework for manufacturers to follow in developing high-quality software for medical applications.

## When the ultimate goal is to get a medical device certified, QNX OS for Medical offers the best path of least resistance.

The microkernel architecture of the QNX OS for Medical reduces certification costs, time, and effort. Monolithic kernels, which have drivers and BSP directly in the kernel, require the entire kernel included in scope for certification. As a result of the microkernel architecture of the QNX OS for Medical components that are not related to the safe operation of the device can be excluded from certification.



## Patient security and safety are critical concerns to medical device manufacturers

Connected medical devices are potentially vulnerable because they can be targets of attack in a hospital network. Devices are visible, vulnerable, and the hardest endpoints to remediate. Any software, beyond a patch provided by the manufacturer, might negatively impact FDA approval. Cybersecurity spans beyond just a single medical device—it encompasses boundary-access control safeguards within each device's operating system, network, and network access points.

When discussing cybersecurity, an important term to consider is "attack surface," which is the total of all possible entry points for a security breach or hack. When it comes to code, smaller is better, where QNX OS for Medical far outperforms monolithic, general purpose operating systems (GPOS) in terms of safety and security. The OS microkernel architecture of QNX presents a reduced attack surface that is approximately 200 times smaller than that of Linux. It goes without saying that is a huge security advantage.

QNX OS for Medical provides a more fine-grained control of system privilege levels control settings that govern and protect the operations a process can

perform. With granularity that goes down to the system-call level, it is no longer necessary to give processes root access to the entire system.

When it comes to robust security, QNX and BlackBerry Certicom offer Elliptic Curve Cryptography (ECC) algorithms validated to government-grade FIPS 140-2 Level 1 which is required to sell into Veteran's Administration (VA) hospitals and other federal establishments.

Certicom's validated ECC cryptographic solutions make it easy to add cryptographic algorithms to medical systems, providing confidentiality, data integrity, and authenticity, without having to become a crypto expert. Our managed public key infrastructure (MPKI) service to issue, manage, renew, and revoke digital certificates, serves to ensure the authenticity of medical devices.

Given all the prevalent wired and wireless communication in the medical and healthcare space, cybersecurity should be first to mind. Why start with an inferior and vulnerable platform?

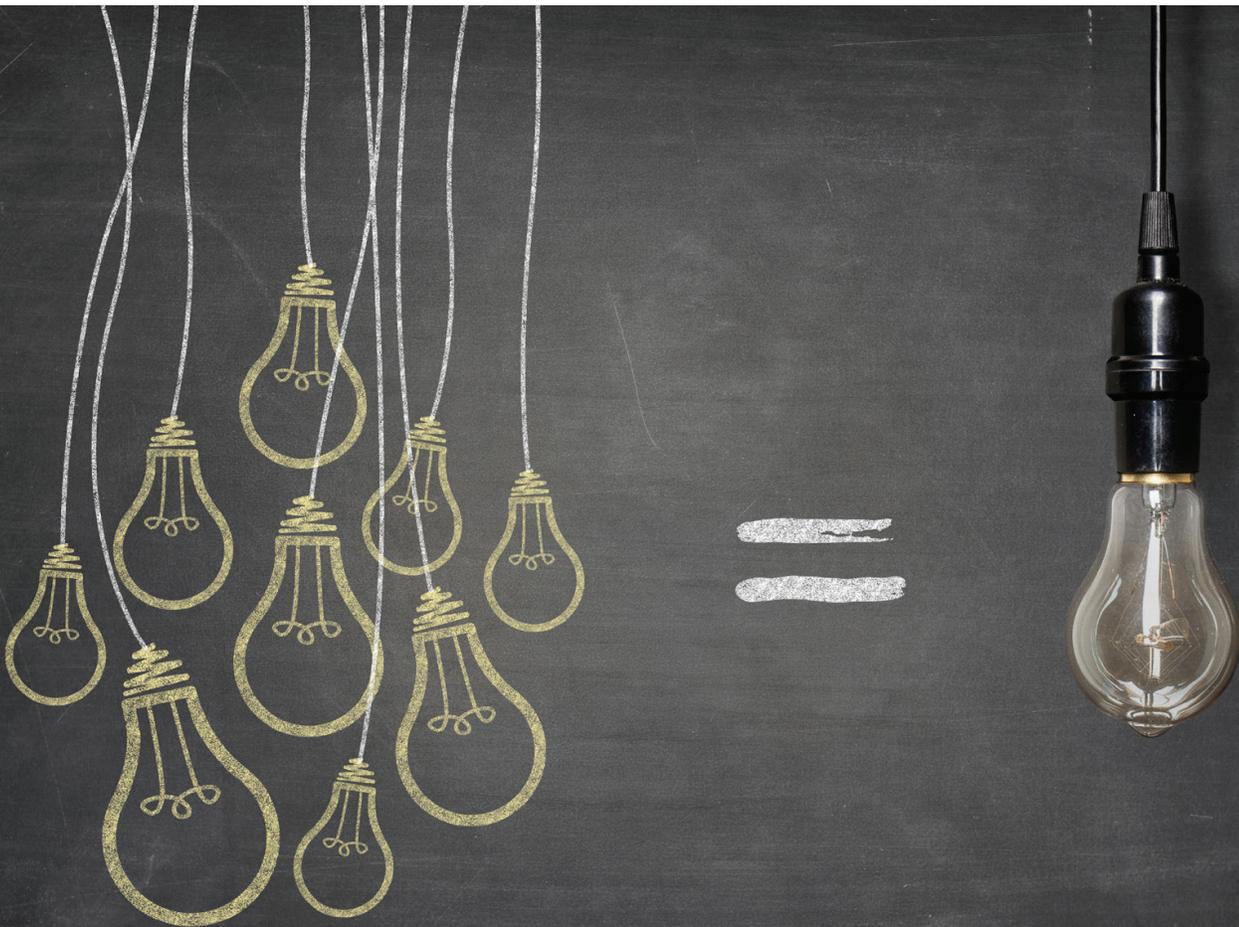
# Time to Market and Innovation Curve

Accelerate your new product introduction and allow your experts to develop and fully leverage your IP while allowing BlackBerry QNX to do the heavy lifting of supporting the operating system. You can forget about the need for finding, sourcing, configuring, and compiling your open source software by leveraging QNX OS for Medical; BlackBerry QNX lets medical device manufacturers jump start development and eliminate risks.

As a POSIX-compliant OS, QNX OS for Medical offers the capability to port Linux source code. Developers can ramp up quickly because QNX OS for Medical looks and feels like Unix and provides a familiar open

standards-based development environment. This greatly simplifies the migration from a Linux-based prototype to a certified production system.

Further downstream, unlike open-source operating systems, there is no need to worry about managing asynchronous patches that can affect a majority of your source base. Patching takes time, incurs real costs, and consumes real resources. Let BlackBerry QNX ease your burden of software maintenance with our products and professional services.



# Total Cost of Ownership

The total cost of ownership for a project consists of many factors that may not be immediately apparent. A simple decision based on a limited analysis of the cost of obtaining and licensing the source code is insufficient. When evaluating an OS for a medical device it is critical to compare the cost of such big-ticket items as in-house development resources, maintenance cost, support cost, and opportunity cost.

The Linux operating system provides open access to its source code, which has led companies to consider Linux as a viable development platform, based upon the impression that it costs less than commercial alternatives. But further examination reveals hidden costs associated with development, maintenance, and certification, usually coupled with

a growing software team to support the effort. A big differentiator that the QNX operating system offers is clean intellectual property (IP). The origin of the entire OS is known and transparent, unlike open source software where the lack of traceability can bring sublicensing and liability issues to the forefront. The lack of traceability with Linux is in direct contrast with IEC 62304 where traceability lies at the heart of the standard.

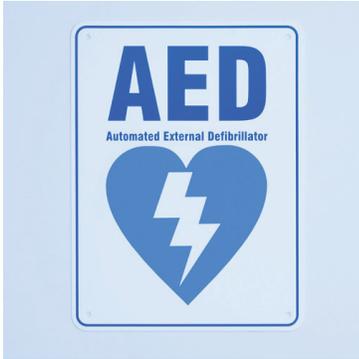
BlackBerry QNX offers the means to support customer issues, custom engineering, open-source integration and license compliance to help you get back to what you do best—your own application software.

	CERTIFICATION	RELIABILITY	COST
  <b>VS.</b>	Microkernel: only safety-critical components must be certified  Medical IEC 62304 compliant	Each and every component is protected and each component can recover without a system reset	Lower total cost of ownership
<b>Linux</b>	Monolithic kernel: all OS components must be certified  Lack of traceability creates huge burden to 62304 compliance	If one component crashes, the entire kernel and OS itself will crash and require a reboot of the device	“Free” software, no upfront license costs, higher costs for development, maintenance, support, and certification
<b>COMPARING COMMERCIAL OFF-THE-SHELF VERSUS OPEN SOURCE SOFTWARE</b>			

# Medical Devices

BlackBerry QNX Medical Overview

BlackBerry QNX already powers a wide range of medical applications, including those noted below, among others.



**AED/DEFIBRILLATOR**

- ECG / EKG
- Nurse Call Stations
- Nurse monitoring stations
- Anaesthesia equipment
- Patient monitor
- Dialysis Machines
- Peritoneal Dialysis
- Artificial Heart
- Hemodialysis
- Medical Ventilators
- Respiratory Care



**ROBOTIC SURGERY**

- CT / MRI
- PET / XRay
- X-Ray / C-Arm
- DR / Ultrasound
- Multi-spectral imaging devices
- Fluoroscopy Systems
- Angioplasty
- Nuclear Medicine
- Point-of-Care Testing or POC
- Pulse Oximetry equipment



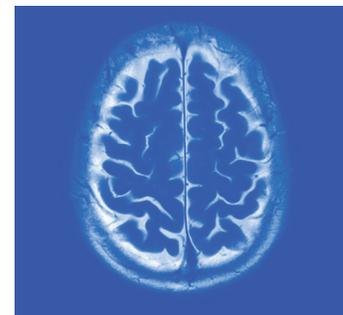
**INFUSION PUMPS**

- Multi-parameter Patient Monitors
- Medical Lasers / Eye lasers
- Pacemakers
- LVAD (Left Ventricular Assist Device)
- CPAP Machines
- Cataract surgery equipment
- Sterilizer / Laboratory Equipment
- Blood Analyzer
- Plasma Collection systems
- Organ Transportation devices
- Medical Gateways



**ARTIFICIAL HEART**

- Neurological Monitor
- Neurological programmer
- Cardiac Monitor / Exoskeleton
- Electrical Stimulation Rehab devices
- Biological Warfare Detection
- Blood diagnostics
- Laboratory diagnostics
- Tissue scanner
- Vacuum wound management
- Bone Densometer
- Sedation equipment



**MRI**

## About BlackBerry QNX

BlackBerry QNX is a leading supplier of safe, secure, and trusted operating systems, development tools, and professional services for connected embedded systems. Global leaders such as Ford, Audi, Cisco, General Electric, Lockheed Martin, and Siemens depend on BlackBerry QNX technologies for their next generation of secure vehicle software platforms, network routers, medical devices, industrial automation systems, security and defense systems, and other mission and/or life-critical applications. BlackBerry QNX is headquartered in Ottawa, Canada, with its products distributed in over 100 countries worldwide.

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