CAPABILITY BRIEF SUPPLEMENT

Security Controls for Software Connectivity

NAVIGATING FDA REGULATORY GUIDANCE

The U.S. Food and Drug Administration (FDA) defines specific regulatory guidance for various Security Control Categories. To meet these requirements, RTI Connext® delivers many technical features that support best practices for scalable, secure communication architectures across the product lifecycle.

Here is a high-level mapping of these recommendations and how Connext features can help users achieve compliance.

SECURITY CONTROL CATEGORIES		
FDA Regulatory Guidance	**What This Means**	**How RTI Connext Delivers**
Authentication	As part of normal operations within a secure system, devices are expected to verify the authenticity of information from external entities, as well as prove the authenticity of information that they generate.	• PKI-based authentication • Distributed authentication with no central broker • Support for short-lived certificates • Support for dynamic certificate renewal and revocation
Authorization	Within an adequately designed authorization scheme, the principle of least privileges should be applied to users, system functions, and others, to only allow those entities the levels of system access necessary to perform a specific function.	• Fine-grained access control for data in motion and data at rest • Enables least privilege data access
Cryptography	Cryptographic algorithms and protocols are recommended to be implemented to achieve the secure by design objectives.	• Protected key distribution • Industry-standard cryptography algorithms • FIPS 140-2/3 compatible algorithms • Meets CNSSP-15 security requirements • Enables layered security
Data integrity	Validate and verify the integrity of all incoming data, ensuring that it is not modified in transit or at rest.	• Cryptographic operations to ensure message authentication and data integrity (based on GCM/GMAC)
Confidentiality	Manufacturers should ensure support for the confidentiality of any/all data whose disclosure could lead to patient harm.	• Cryptographic operations to ensure confidentiality (based on GCM) • Authenticated encryption of data flow
Event Detection and Logging	Event detection and logging are critical capabilities that should be present in a device and the larger system in which it operates in order to ensure that suspected and successful attempts to compromise a medical device may be identified and tracked.	• Distributed secure logging features for security events
Resilience/Recovery	Devices should be designed to be resilient to possible cybersecurity incident scenarios and maintain availability.	• High reliability and low-latency data connectivity architecture • QOS enables availability in the event of failure • Decentralized architecture — no single point of failure and high availability. • Supports redundant communication patterns

Regulatory expectations for medical device cybersecurity continue to evolve and become more rigorous. In addition, as cyber crimes become more sophisticated and the attack surface of complex and connected devices continues to grow, manufacturers need to stay ahead of the risks. Choosing a software communication framework that protects data in motion across applications, devices, and systems is a critical step. For more information on how RTI Connext can protect your system, contact us at **www.rti.com**.

Find the complementary capability brief here: **RTI Connext: Securing Connected Medical Devices**.

ABOUT RTI

Real-Time Innovations (RTI) is the infrastructure software company for smart-world systems. Across industries, RTI Connext® is the leading software framework for intelligent distributed systems. RTI runs a smarter world.

RTI is the market leader in products compliant with the Data Distribution Service (DDS™) standard. RTI is privately held and headquartered in Silicon Valley with regional offices in Colorado, Spain, and Singapore.

Your systems.
Working as one.

CORPORATE HEADQUARTERS

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