WHITEPAPER

Applying DDS to Medical Robots for Minimally Invasive Microsurgery

SOLVING THE TOUGH SYSTEM DESIGN CHALLENGES OF THROUGHPUT, INTEROPERABILITY, RELIABILITY AND SECURITY

OVERVIEW

Medical robotics, a technology once thought of as science fiction, is now becoming a reality. Medical professionals use robots for everything from surgery and rehabilitation, to non-invasive general hospital and pharmacy applications. This trend shows no signs of slowing down. The medical robotics market has increased almost sevenfold since 2012[1] and the market is predicted to an annual growth of over 20 percent through 2022, largely driven by medical robots for minimally invasive surgery, which represent roughly 70 percent of the market.

This whitepaper focuses on the design challenges for this specific application within the overall medical robotics category. It covers the trends that are driving innovation in this space and introduces new concepts like data centricity that diverge from traditional approaches. In particular, it discusses the benefits of an open connectivity standard called Data Distribution Service (DDS) and how it is enabling developers to meet the complex and rigorous requirements of medical robotics. It concludes with a discussion on how RTI Connext DDS works to expedite time to market for these breakthrough medical machines while reducing development and maintenance costs.

TECHNOLOGY DRIVERS FOR MEDICAL ROBOTICS

The smart machine era has disrupted industries across the board, particularly in healthcare. Imagine a world where robotic drone ambulances, robotic caregivers, robotic laboratory equipment, and robotic assisted surgeons deliver precise, high-quality care and improved patient outcomes. Some of these intelligent machines are available today, with many more in development. The past few years have provided significant advances in technologies and processes that have provided the catalyst for innovation in medical robotics.

These technology enablers are:

- An increase in CPU/GPU processing via new technology nodes and multicore architectures
- Increased availability and capability of artificial intelligence and machine learning
- Pervasive connectivity and standards-based technology, making communication from smart machines to the enterprise network much easier, safer, and more secure
- Increased availability and capability of safe and secure medical-grade, modular off-the-shelf hardware and software solutions

Combined, all of these technology enablers are having a major impact on the rapid growth of robotics in healthcare. For example, machine learning and artificial intelligence provide the foundation for autonomy, which, in turn, is enabling command and control applications like medical robotics.

The adoption of modular project methodologies is also highly relevant for medical robotics, where there are a significant number of subsystems that are independently designed but need to work together as a single unit. However, these systems have a degree of complexity that presents additional design challenges.

Another trend is the availability of high-quality commercial off-the-shelf software (OTS). There is still some apprehension in the engineering community about using commercial off-the-shelf software. Designers want to know the origin of the code. They want lifecycle data. And they want to know that the software is verified and validated. In general, the overall build quality of off-the-shelf software has increased significantly. Developers can get verified, validated and tested software that comes with artifacts and lifecycle data. They can put together these components, embed them in the system and know that the system will pass regulatory requirements, will not fail in the field and will scale for future requirements.

DESIGN CHALLENGES FOR MEDICAL ROBOTS

Before discussing design and development challenges, it is important to define the parameters of the application. Since 70 percent of medical robotics applications are surgical in nature and contain some of the most difficult design challenges, this paper will focus on this application. However, much of the information contained in this paper applies to all healthcare robotics applications.

System-Level Communications and Interoperability

In a medical robotic application, many subsystems need to communicate and interoperate. One system developer described a medical robot as "a modular system consisting of many inter-linked robots."

Some of these subsystems need to be accurate down to a very tight specification. Further, when these modules are put together, the entire system must function with this same level

of accuracy. The ability to achieve this system-wide accuracy depends on how the subsystems communicate. For example, if there are latency requirements of haptic feedback loops running between 1-4 kHz, the communication protocols between all subsystems must be fast enough for the whole system to meet this latency requirement.

Throughput and Low Latency

High-resolution cameras are the eyes of the surgeon. The higher image resolution, the more likely it is that the surgeon can identify disease states and improve surgical precision. At the same time, these high-resolution cameras are pushing the envelope for latency and through-put requirements.

Reliability

One of the drivers for medical robotics is to improve patient outcomes. Clearly, failures of any kind are unacceptable. This means that the system must have fail-safe precautions. One such precaution is building in redundancy for control systems (which will be found on several components in the system). Because of this imperative, medical robotics for minimally invasive surgery must be classified as mission-critical systems.

Security

As the robotic system connects to other devices and to clinical information and enterprise systems, it is at greater risk for security breaches, putting patient data and potentially patient lives at risk. To address this, the application must meet or exceed current regulatory requirements.

Interoperability and Scalability

The lack of interoperability in medical systems costs upwards of $30 billion annually.[2] A modular system requires an architectural approach to communication and connectivity that allows for scalability and provides a ready-to-grow foundation for connecting to the enterprise and overall healthcare IoT system.

In this application, it is required to connect the robotic surgical device to other medical devices used in the procedure, such as infusion pumps and patient monitors. In addition to the security discussed above, designers want to be able to connect to other systems in a plug-and-play manner. Having all of these devices communicate can reduce some of the costs associated with a lack of interoperability.

Product scalability is the ability to design new components for the medical robot and add them seamlessly – meaning that the new subsystem is easily discoverable by the rest of the system.

SOLVING DESIGN, DELIVERY AND COST CHALLENGES

Choosing a Data-Centric Architecture

Data centricity is the foundation for exceptionally low latency, high throughput, redundancy and security. In fact, it solves most of the design challenges described above. Data centricity requires a different way of thinking about communications. Data-centric technology connects appli-cations to the data, not to each other – unlike other models, such as message-centric, client/server, remote objects, SOA, and non-data-centric publish/subscribe. With data centricity, the data is the interface between devices but isn't stored anywhere. Messages do not need to be sent through brokers to access that data.

A data-centric architecture has the following characteristics:

- The interface is the data
- The infrastructure understands that data
- The system manages the data and imposes rules on how applications exchange data

The Benefits of a Software Databus

A data-centric communication architecture is based on a software databus. Think of the software databus as a shared application space where all of the data lives. It is an excellent tool for distributing and managing real-time data. It is what allows these applications and devices to work together as one integrated system.

The software databus is designed for exceptionally complex systems, like robots for minimally invasive surgery. It also provides the foundation for connecting to larger systems like the enterprise, or specifically to healthcare IoT.

Note: It's important to distinguish between a database and a software databus. A database implements data-centric storage and saves old information that can be searched at a later time by relating properties of the stored data. A databus implements data-centric interaction. It manages future information by filtering properties of the incoming data. Databases and databuses are complementary, but they have very different functions. In a data-centric architecture, there are plenty of places for databases to live and perform their functions for storing and retrieving data.

DDS Technology Defines the Software Databus

DDS is an open connectivity middleware standard specifically designed to handle complex, mission-critical, distributed computing applications. The DDS specification provides the technical requirements and defines the software databus. Managed by the Object Management Group® (OMG®), DDS has been adopted by several technical and industry groups including the Industrial Internet Consortium (IIC), AutoSAR and ROS2.

Another way to think about DDS is as a data everywhere abstraction (Figure 1). The subsystems of medical robots have data that they need to send. In the standard, each data piece is called a topic. Each topic can be individually tuned for attributes like Quality of Service (QoS) and security settings. Devices in the system can then subscribe to that data. There are devices that continuously publish data at a certain rate and there are devices that can subscribe to that data. The result is that all of the devices in this shared global data space get the data they need, when they need it.

Security and DDS. The DDS standard includes a plug-in security architecture that connects to the DDS library. It is customizable via any standard API and runs over any transport and provides complete protection through:

- Discovery authentication
- Data-centric access control
- Cryptography
- Data tagging and logging
- Non-repudiation
- Secure multicast

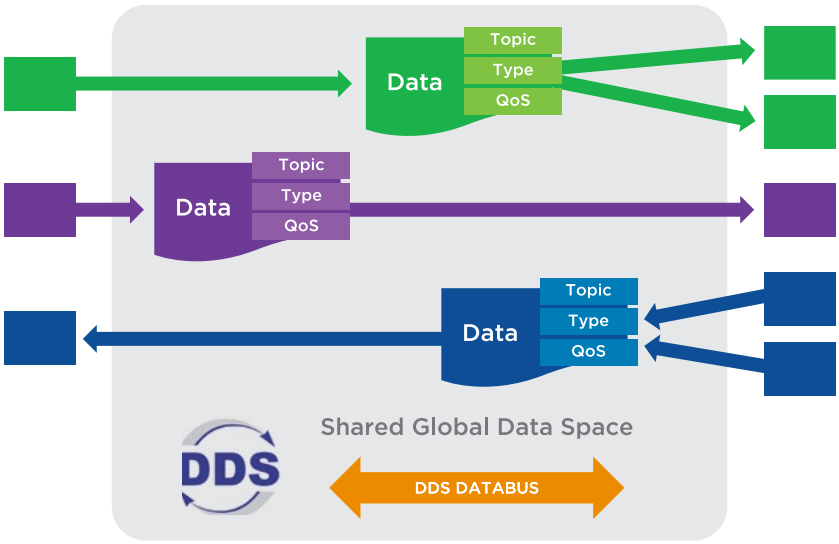

Figure 1: DDS is a data distribution system that enables a "data everywhere" abstraction

In the U.S., the Food & Drug Administration (FDA) provides guidance on security, but it does not provide a checklist of requirements. [Note: the FDA recently published new guidelines for pre-market submission management for cyber security in medical devices.[3]] It is recommended that medical robotics manufacturers meet the FIPS 140-2 cyber security standard published by the U.S. government. This standard is widely used for mission critical systems across many industries, including healthcare.

Some system designs are not designed to work within this level of security, which can be heavyweight to apply across robotics devices. However, security policies and access privileges can be scripted in DDS on a per topic basis, enabling implementation of FIPS 140-2-level security where it makes sense and lightening the security load in other areas.

For example, patient data is confidential, so it needs to be encrypted, authenticated, and checked for data integrity. But for diagnostics data and remote commands, the system only needs to authenticate the data and ensure data integrity. This data type may not need to be confidential. In the case of remote commands, non-repudiation alone can be added (Table 1).

Additional security recommendations are:

- Hardening devices
- Device components with multi-factor authentication
- Secure boot process to validate any firmware, OS and application
- Secure and cryptographically-signed firmware updates
- Integrating hardware and software based on secure roots of trust (e.g., SGX trust zone architectures)

Latency and DDS. Earlier in this paper, latency requirements as demanding as 1-3 kHz for control loops were discussed. DDS is a peer-to-peer architecture that works without a message broker. The standard was designed for applications that absolutely depend on low latency. In other words, DDS is constructed from the ground up for real-time control of a cyber physical system over a network.

Throughput and DDS. With DDS, developers can shape network traffic by balancing throughput for different types of data. This allows the system to use bandwidth more efficiently. For example, traffic can be limited to only necessary or critical data using data filtering and QoS.

Reliability and DDS. With DDS, the data is distributed across the system. Essentially, DDS creates building blocks that make it easy to build redundant systems and paths with failover anywhere in the system.

Interoperability and DDS. The DDS standard wire protocol provides syntactic interoperability, which provides a common communication protocol across subsystems. In combination with a consistent data model, which provides semantic interoperability, there is the foundation for a plug-and-play modular architecture. This allows system architects to move forward with a modular design that is key to these complex medical robotics systems. There can be data exchange between the devices across different programming languages without any application-level effort, significantly reducing the

DATA ITEM	AUTHENTICATION	ACCESS CONTROL	INTEGRITY	NON-REPUDIATION	CONFIDENTIALITY
Device diagnostic data	✔		✔		
Remote commands	✔	✔	✔	✔	
Patient data	✔	✔	✔		✔

Table 1: Recommended Security Architecture for Robotics

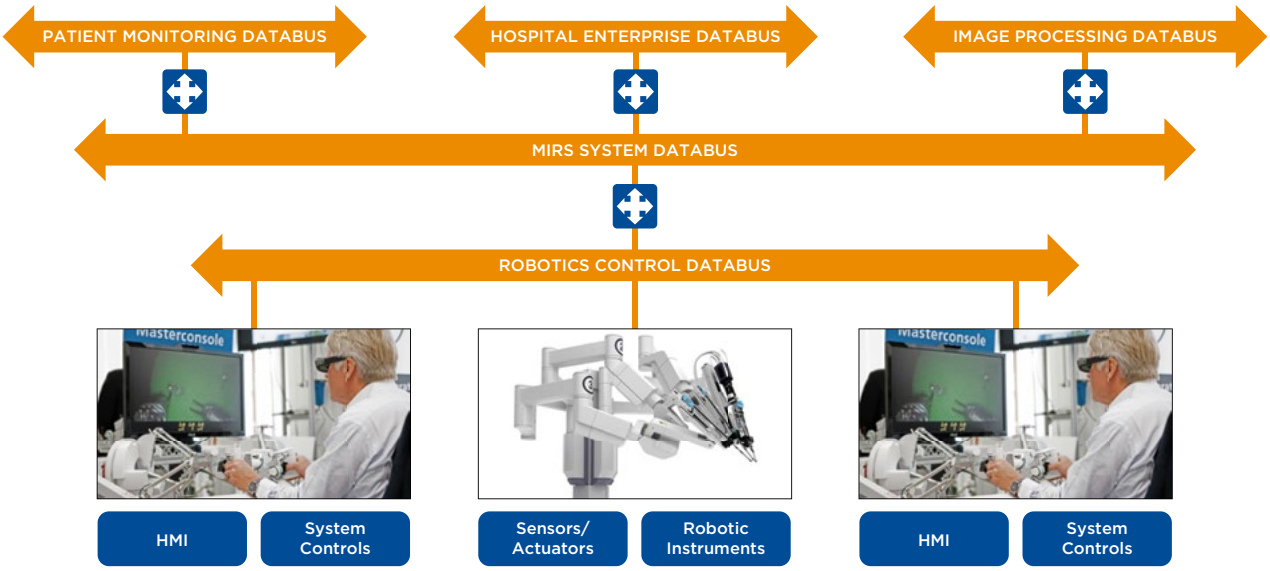

Figure 2: The software databus is highly scalable. It provides a foundation to connect to a larger group of systems, including clinical devices and information systems and enterprise systems and databases.

lines of code at the application level. Note: There's another feature in DDS called XTypes, which allows expansion of the data model while maintaining interoperability.

Scalability and DDS. The software databus decouples software, providing data anywhere, over any network and any transport. The decoupled subsystems work independently, and data-centric sharing enables them to function as one system. That same decoupling makes it easy to add future components to the medical device. A software databus also makes it easier to integrate the device into other IIoT devices and enterprise systems (Figure 2).

THE SOFTWARE DATABUS FOR MEDICAL ROBOTICS SYSTEMS

This section looks more closely at a software databus for a medical robot performing minimally invasive surgery. Note that this is a linear databus architecture. It is not a single databus that connects the entire system; there's a routing service that allows the databuses to communicate efficiently, so they're working together as a single system.

In this application, there is a robotics control databus, where the robotic arm would live, in addition to one or two surgeons' consoles. The system controls are connected to the same databus as that of the robotic arm and all of its sensors, actuators and robotic instruments.

This databus connects to a minimally invasive robotic surgery databus. Through this databus, the system can connect to an imaging processing databus. Beyond that, it can be connected to other clinical devices and the enterprise databus.

RTI CONNEXT DDS

RTI Connext™ DDS is an off-the-shelf medical-grade connectivity framework based on the DDS standard. Connext DDS allows all of the subsystems to work as a single integrated system by providing data between systems reliably, securely, and in real time (<ms and deterministic). Connext DDS Professional is the full featured connectivity software that comes with all the messaging libraries, developer tools, and runtime services to scale the system. It also comes with plug-in security architecture.

RTI can accelerate the time to market with a tested, validated, production-ready offering. This also reduces the system maintenance costs, which, according to market studies, can exceed 60 percent of the total cost of ownership.[4] The following ROI metrics are based on actual RTI customer projects:

- Approximately 50 percent reduction in initial development costs
- Approximately 70 percent reduction in annual maintenance cost

A CASE STUDY: DLR MIROSURGE

RTI worked with the Institute of Robotics and Mechatronics DLR to develop MiroSurge (Figure 3). This device pushes the limits of minimally invasive robotic surgery technology by using a robotic device to enable a surgeon to operate on a beating heart. In order for a surgeon to do this, the heart cannot look like it is beating. This means the robotic surgical device needs to move in sync with the beating heart so the heart appears to be still throughout the surgery. This is absolutely revolutionary technology in minimally invasive surgery and the use of robotics.

RTI Connext DDS provides the communications infrastructure between the three MIRO robots, the endoscope, the surgeon's robot controllers, and the surgeon's and technician's user interfaces, facilitating synchronization and coordination between them.

DLR's MIRO Lab adopted RTI Connext DDS because it delivered high performance distributed communications with

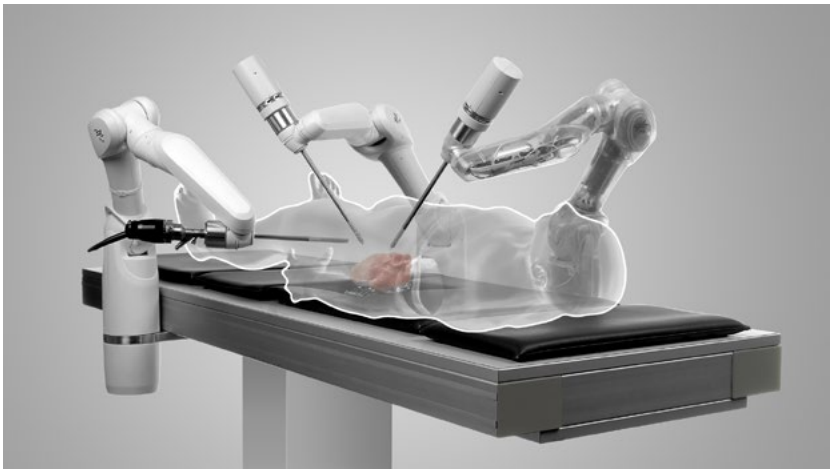

Figure 3. Three MIRO Lab robots coordinated through RTI Connext DDS software; image courtesy of DLR.

decoupled systems architecture. With Connext DDS, they could implement a deterministic solution functioning at rates between 1KHz and 3KHz, thus enabling the development of the distributed haptic closed control loops. The availability of RTI Connext Micro also means that systems can be developed today with an understanding of the medical certification route in the future.

CONCLUSION

In the near future, robots will be a prevalent and welcome part of healthcare delivery. They will play a key role in reducing costs and improving patient outcomes. Specifically, medical robotics for minimally invasive surgery will continue to expand their capability and begin to address a critical need in rural medicine, where communities have limited or no access to specialized surgeons, by offering remote surgery with industry leading surgeons. DDS is the key enabling technology that provides the real-time connectivity for high-stakes medical robotics.

[1] Crystal Market Research
[2] West Health Institute
[3] https://www.fda.gov/MedicalDevices/DigitalHealth/ucm373213.htm
[4] Galorath Incorporated

ABOUT RTI

Real-Time Innovations (RTI) is the largest software framework provider for smart machines and real-world systems. The company's RTI Connext® product enables intelligent architecture by sharing information in real time, making large applications work together as one.

With over 1,500 deployments, RTI software runs the largest power plants in North America, connects perception to control in vehicles, coordinates combat management on US Navy ships, drives a new generation of medical robotics, controls hyperloop and flying cars, and provides 24/7 medical intelligence for hospital patients and emergency victims.

RTI is the best in the world at connecting intelligent, distributed systems. These systems improve medical care, make our roads safer, improve energy use, and protect our freedom.

RTI is the leading vendor of products compliant with the Object Management Group® (OMG) Data Distribution Service™ (DDS) standard. RTI is privately held and headquartered in Sunnyvale, California with regional headquarters in Spain and Singapore.

Download a free 30-day trial of the latest, fully-functional Connext DDS software today: https://www.rti.com/downloads.

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Your systems. Working as one.

CORPORATE HEADQUARTERS
232 E. Java Drive, Sunnyvale, CA 94089
Telephone: +1 (408) 990-7400
Fax: +1 (408) 990-7402
info@rti.com

rti.com
rti_software
rtisoftware
company/rti
connextpodcast
rti_software