

Technology Brief



How SDC maximizes your Medical Device Interoperability

For many years the number and complexity of medical devices in operating rooms, isolation units and other hospital departments have been increasing. Especially in the acute-care, there is a need for sharing information by enhanced communication, higher flexibility as well as access to critical parameters on demand.

Furthermore, to help reduce the workload on the overburdened healthcare staff, automation is becoming a critical factor to improve the safety, effectiveness and security.

However, today medical devices are mostly monolithic solutions, with very limited, one-way interoperability, and may be supported by vendor-locked proprietary integrated operating room systems. Sometimes only legacy interfaces are available, which are not always compatible with modern hospital networks.

Why do we need interoperability?

According to National Institute of Standards & Technology (NIST): "The lack of interoperability between medical devices can lead to preventable medical errors and potentially serious inefficiencies that would otherwise be avoided".

Delivering Solutions for a Connected World

Next to this the FDA issued a guidance report describing design considerations "to promote the development and availability of safe and effective interoperable medical devices"².

It is clear, that when actual lives are at stake it is crucial that medical devices in any (hospital) network have the ability to exchange data effectively and in an organized way.

This is where Service-oriented Device Connectivity (SDC) comes in.

Applications

- Patient monitors and medical sensors
- Ventilators
- Infusion pumps
- Endoscopes, controls, lights
- Foot control pedals
- and many more.

¹ Medical-Device-Fact-Sheet-09FEB11.pdf

² https://www.fda.gov/media/95636/download



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What is SDC?

Vendor-independent medical device networking has been standardized as the new IEEE 11073 SDC (Service-oriented Device Connectivity) family. Within an SDC-enabled network medical equipment can automatically discover other devices, share their services, provide access to medical sensor data, and allow remote alerting and control settings. All interactions are standardized and allow two-way interoperability among medical equipment from different suppliers. A critical design factor of SDC has been that all data transactions are secure and authenticated, using the latest technologies for message encryption and cybersecurity. This ensures that the medical devices can be connected to the hospital network or other networks while guaranteeing safe and secure communication.

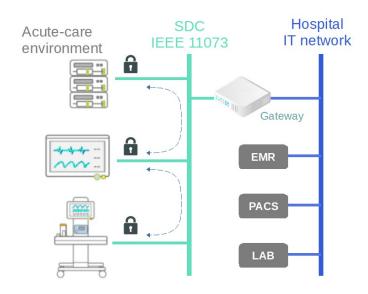


Figure 1: SDC enables secure and two-way communication between medical devices.

Benefits

Standardized communication

Medical systems from different suppliers transfer bidirectional data according to a standardized protocol.

Cybersecurity

Authentication guarantees that only approved devices and systems can interact; and all communication is encrypted to protect patient and hospital data records. Under the GDPR regulations it is mandatory that personal data is diligently protected, and proof is recorded on how this data is protected. SDC provides for both.

Flexible networking

Automatic detection of relevant medical devices on the network, creating ease of use, simplified maintenance, and offering scalability.

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The SDC protocol targets medical equipment in acute-care environments such as operating rooms (OR), intensive care units (ICU), emergency wards, or isolation rooms. Examples of medical devices that benefit from SDC support are patient monitors, ventilators, infusion pumps, endoscopes, foot control pedals, surgical tables, and lights. Furthermore, SDC supports medical sensors and actuators, nurse call systems, central ward remote control panels and alarm systems. In addition, SDC is considered the safe and secure network solution for remote care equipment, ambulances, and telehealth applications.



AimValley integration services for Medical Device Interoperability

Aimvalley provides development and integration services to medical device manufacturers that need to enhance their equipment and systems with an improved cybersecurity profile and networked interoperability, using protocols such as the IEEE 11073 SDC.

Examples of various solutions

- SDC protocol stack integration, definition of the logical interface to the medical middleware application.
- Definition, review and development of the Medical Device Information Based (MDIB) model.
- Risk management and definition of countermeasures related to SDC, specific to the medical device.
- Addition of new extensions to the SDC stack as the standards evolve, to include new functionality such as Alarm Handling and External Control.
- Embedded and secure software development, device drivers, supporting medical sensors or actuators.
- Integrated cybersecurity functionality such as certificate handling, certificate revocation, and support for Online Certificate Status Protocol (OCSP) management.
- Zero Trust cybersecure networking, using hardware enabled root of trust and Trusted Platform Module (TPM).
- License management, risk assessment of third party Software of Unknown Provenance (SOUP) components.
- Infrastructure for inventory management, and secure software updates.



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AimValley Expertise

- AimValley is a provider of embedded system solutions tailored to specific target platforms: from large, multiprocessor applications to small bare metal applications.
- Design and integration of medical embedded products and sub-systems, including the development of medical-grade device drivers on VxWorks and Linux.
- Quality management, risk assessment, software development, and documentation according to ISO 13485, ISO 14971, and IEC 62304 respectively; either under the QMS of our customers or our own AimValley QMS (pending certification).
- Embedded solutions for critical infrastructure systems, which require the highest reliability without downtime.
- Cybersecurity for Industrial Automation and Control Systems (IACS) according to IEC 62443.
- High quality, extensively tested, field grade, robust software components.

- Experience with a wide variety of interfaces and protocols for control and management of distributed and remote systems.
- Realizing a short time-to-market through re-use and portable code, and automatic code generation enhancing consistent behavior and simplifying maintenance
- AimValley has a huge experience with being a product owner for various types of products. A dedicated support and maintenance team takes responsibility and commitment to providing Field Application Engineering services from the early integration phase up until manufacturing, aftercare, and life-cycle support.
- AimValley has a proven track record of helping fix 'broken projects' by troubleshooting and fixing bugs in embedded devices that either malfunction under a heavy network load, have memory leaks, fails after a power cycle or any other complex rainy-day scenarios.
- Our products and solutions are extensively stress-tested before release to our customers.

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Why AimValley?

AimValley is a reliable provider of HealthTech designs for many years, delivering solutions for:

- High-speed data processing applications
- Complex FPGA-based accelerated systems
- Robust embedded software for HealthTech
- Early adopter of Acceleration Technology

Quality Focus

- Outstanding track record of on-time delivery
- Best in Class Designs Time, Budget & Quality
- ISO9001, ISO140001,
- Ecovadis 2% CSR rating since 2018

AimValley understands the full complexities as well as the subtle nuances of designing excellent edge solutions. We excel in building complex systems that are part of your product in the fields of Industry 4.0, Big Data, Healthcare, and Transportation markets. Our combined skills represent all the important aspects required for the development of end-to-end systems.

Our customers enjoy the benefits of working with a strong team with over 2000 years of engineering experience. AimValley is a trusted partner of Tier 1 customers in Telecom and HealthTech markets and has shipped more than 100 000 products.

Talk to one of our experts!