

COMMUNICATION

Interoperable OR: the next step



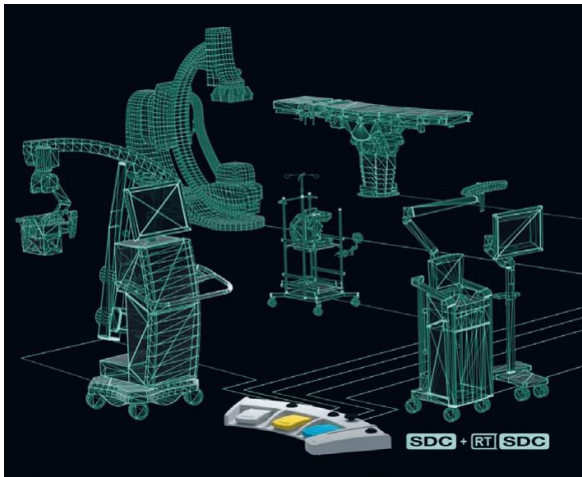
The OR is becoming digital and interoperable. RT-SDC provides a communication standard with real-time capability.

SDC now with real-time capability

The SDC family of standards oversees cross-manufacturer communication between medical devices. Now it is taking that communication to the next level: real-time capability with RT-SDC. SDC is unlocking new, time-critical applications and reinforcing its position as the universal standard for data exchange between medical devices and shared user interfaces in the interoperable OR.

Medical device integration is a key topic in the design of components for the (interoperable) OR of the future. The goal:

multiple medical devices can be operated using a single shared user interface. The surgeon then no longer has a separate control system (with e.g. a screen, a hand control and a foot switch) for each medical device – facilitating ergonomic and, ideally, intuitive operation. In addition, medical devices can also be connected via the user interface, bringing benefits during surgery involving e.g. navigation and/or medical imaging. Device integration also simplifies follow-up administrative steps – in other words documentation. Other advantages



Digital data flow between medical devices opens up new applications. For example, one device can request from other participants within the network the necessary data for a closed-loop control. The medical devices can be operated via a central user interface in the OR.

are shorter surgery duration, reduced risk of error and increased patient safety.

Goal: interoperability – standardisation, not stand-alone solutions

This development has been ongoing for twenty years, not least thanks to the OR.NET initiative (see side box In Brief: OR.NET e.V.). This long period has been partly due to the lack of any standardisation. Standards guaranteeing interoperability and safe operation first had to be created. To date, most medical devices in the OR are stand-alone solutions, or are only integrated via proprietary interfaces.

SDC family of standards

In the meantime, however, the IEEE 11073 SDC family of standards has been released, defining communication protocol, data model, nomenclature and responsibilities

(see side box In Brief: What are SDC and RT-SDC?).

This family of standards is continually being expanded and facilitates cross-manufacturer communication between medical devices. Core aspects include:

- Device profile for web services (DPWS) as the communication protocol
- Other communication protocols can also be used
- Self-descriptions of medical device functionalities (Medical Device Information Base: MDIB)
- Plug & play and plug & trust for medical devices
- Safeguarding of device communication through state-of-the-art encryption methods and certificates

In Brief: OR.NET e.V.

OR.NET e.V. was founded as a consequence of the BMBF-funded flagship project OR.NET (2012–2016, with over 50 project partners). Its goal was to drive forward the safe and dynamic integration of medical devices in the OR and hospitals, as well as to standardise this field – which IEEE 11073 has successfully accomplished.

The Association promotes open, cross-manufacturer integration of medical devices in operating theatres, intensive care units and other locations for acute medicine. Its focus is on safe device-to-device data exchange via plug & trust.

OR.NET unites industry, hospitals and research. It provides support in various ways, including standardisation, demonstration and test centres, as well as consulting during the development, approval and implementation of SDC interfaces.

www.ornet.org



RT-SDC in practice: a single universal foot switch from steute Meditec controls multiple medical devices.

"Classic" SDC: latencies not guaranteed

The IEEE 11037 SDC standard is based on standard internet protocols. They achieve reliability and interoperability, but not guaranteed latencies or deterministic transmissions. For medical device applications, this means: real-time capability is required when, for instance, foot switches and the devices they control have to be reliably switched and new target values set within milliseconds.

This clearly defines one development goal: an expansion of SDC is required to include real-time capability. It must also guarantee constant cycle times as are necessary with time-critical closed-loop controls, for example in navigation and medical imaging.

Important development step: RT-SDC for real-time applications

This development is advancing and will later be available as part of the IEEE 11073 family of standards.

It is not intended to replace the existing SDC standard, but to complement it, uniting both approaches within a coexistent architecture: while SDC guarantees safe, non-time-critical communication between

medical devices, RT-SDC will assume time-critical control tasks and facilitate precise, synchronised processes.

Real-time capability is based on three key technologies: Time-Sensitive Networking (TSN)/Quality of Service, Precision Time Protocol (PTP) and Data Distribution Service/RealTime Publish Subscribe (DDS/RTPS).

TSN ensures guaranteed latency

Time-Sensitive Networking (TSN) to IEEE 802.1Q ensures guaranteed latency, reserves bandwidth and prioritises safety-critical data streams, facilitating reliable and precise data transmission – as a further development based on Ethernet. For deployment in the OR, this means that important control information is prioritised and transmitted at precisely defined times. It is also possible to predetermine which data streams will always receive sufficient bandwidth and be transmitted with constant, predictable latency. This guarantees that devices in the OR function together smoothly and in perfect harmony. Device self-description in SDC/RTSDC enables the network to configure itself automatically.

Highly accurate synchronisation with Precision Time Protocol (PTP)

The Precision Time Protocol (PTP) to IEEE 1588 enables the synchronisation of device clocks to an accuracy of submicroseconds. In the OR, this permits precise and simultaneous triggering of multiple devices, which in turn simplifies the coordination of complex processes. In addition, PTP guarantees exact time-stamping of all relevant events, which is essential both for the regulatory

requirements and for uninterrupted traceability.

Data Distribution Service/Real-Time Publish Subscribe

Data Distribution Service/Real-Time Publish Subscribe (DDS/RTPS) is based on a Publish/Subscribe architecture which facilitates a fine-grained configuration of Quality-of-Service parameters. In the context of RT-SDC, DDS is deployed using the Real-Time Publish/Subscribe (RTPS) protocol in order to realise hard demands in real time. Benefits include flexible adaptation to different bandwidth and latency requirements, automatic detection of new devices and services, as well as the possibility of parallel operation with existing SDC implementations.

In Brief: What are SDC and RT-SDC?

SDC: IEEE 11073 Service-oriented Device Connectivity

- Family of standards for cross-manufacturer integration of medical devices in the OR and hospitals
- Service-oriented architecture
- Device self-description (MDIB)

RT-SDC: Expansion to enable use cases requiring real-time capability in milliseconds

- Combination of DDS/RTPS and TSN or QoS

Applications and practical benefits of RT-SDC

Which practical benefits does the new standard offer for OR routines – and which user interfaces will be equipped with it?

- **Wireless foot switches:** with RT-SDC, a single wireless foot switch can control multiple devices from different manufacturers in parallel. One example: an HF surgical device and a navigation system are controlled simultaneously. Deterministic communication guarantees that commands arrive exactly as planned – even with a high network load.
- **Universal hand control:** a remote hand control can be dynamically configured to control different devices, depending on the perioperative phase. Changes are executed during the intervention, without delays or manual replugging.
- **Closed-loop control:** in the future, diverse closed-loop controls will be realised interoperably on the basis of RT-SDC, for example between a ventilator and a C-arm to stop the ventilation briefly in order to create an image. Other possibilities exist in neurostimulation, ventilation and the administration of medication, e.g. to regulate blood pressure.

Benefits for the manufacturers

From the standpoint of the medical device manufacturers, one of the benefits of RT-SDC is that consistent support of interoperability facilitates the seamless integration of their devices in open, cross-manufacturer OR architectures. This not only opens up new market opportunities, but also simplifies collaboration with

hospitals reliant on modular and flexible system solutions.

Another crucial aspect is safety: guaranteed latencies in the communication increase functional safety and facilitate precise and reliable execution of time-critical commands – a factor which is highly relevant, especially in surgical applications.

Not only technical, but also strategic and commercial benefits

Moreover, both SDC and RT-SDC help to lower the costs by reducing the requirement for proprietary interfaces and considerably curtailing the effort needed to integrate new devices. Use of internationally recognised standards also supports manufacturers in the regulatory certification of their products because many requirements from existing standards and regulations are already met. Adhering to future-proof IEEE standards also protects investments: devices

equipped with RT-SDC today are prepared for future developments in OR integration and comply with further expansions to the family of standards in the long term.

Conclusion: the next logical step

It can be concluded that RT-SDC is the next logical step in the development of interoperable OR technologies – and that use or application of this standard will bring about considerable benefits for medical device manufacturers, hospitals, surgeons and also patients.

Device manufacturers profit from higher product compatibility, lower integration costs and the chance to realise innovative use cases. And they secure a competitive advantage when they trust in RT-SDC early on. In the long term, this standard will not only make surgical interventions safer and more efficient, but also open up new application fields like AR-based navigation or AI-based assist systems.

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