An Innovative Web Services-Based Architecture for Distributed Systems of Medical Devices

Today's medical devices for the acute point of care are not always capable of addressing the future needs of clinicians and hospital IT systems with respect to interoperability.

To enable an "Internet of Medical Things", several medical device manufacturers have developed a new web services-based architecture that in 2018 became an IEEE standard that will benefit patients, clinicians and the healthcare system.

INTRODUCTION

A main focus of medical device connectivity in past years has been the improvement of interfaces for data transfer to the Clinical Information System (CIS) added by further profiles defined by IHE. In most cases, this is achieved by using gateways or protocol converters working with patient monitoring that translate the different device protocols into the HL7 standard for data exchange with IT solutions.

For this purpose, current standards and profiles (e.g., HL7v2, IHE) are fulfilling today's basic requirements of interoperability on the hospital IT side and are expected to remain relevant. However, standardized protocols for integration of medical devices at the point of care such as IV-Pumps, Ventilators, patient monitors, etc. (Intelligent System Integration), are still missing, even though they will be crucial for fulfilling future clinical requirements.[1]

Certain important capabilities to achieve intelligent system integration are missing from today's technologies:

- bidirectional data transfer
- remote control
- standardized communication
- cybersecurity
- medical-grade data quality

As existing standards were regarded to be not adequate within the framework of a German initiative (OR.NET), a team of delegates from medical technology producers, including Dräger, created a new web services-based architecture that enables interoperability between medical devices and data exchange between point-of-care devices and clinical and hospital information systems. The result of this collaboration is the development of the open source reference software implementation for Interoperability.

Furthermore, based on that reference implementation, the solution was submitted to the IEEE 11073 Standards Committee for consideration to be adopted as a new standard in the IEEE 11073 series. The proposal was accepted by the IEEE General Committee in September 2014. The dedicated project team finalized the now-called SDC (Service-oriented Device Connectivity) standards family on September 27th, 2018.

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ADVANTAGES OF INTELLIGENT SYSTEM INTEGRATION

Many advantages of intelligent system integration in a clinical environment can be achieved by taking into account workflow observations, as well as interactions of surgical and intensive care staff among each other and with medical devices, instruments and infrastructures.

Advantages for the clinical staff:
- Availability of operating controls and information at any computer or mobile device, with which users can fulfill their roles and duties in a defined workflow
- The targeted availability of operating controls according to organized workflows, which facilitates the management of increasingly complex and numerous workflows for the participants
- Helping to increase patient safety by reducing the likelihood of workflow errors.

Advantages for the hospital administration:
- Creation of an automated surgery protocol with integrated recording of processes, events and newly generated data (e.g., imaging data)
- Increased efficiency due to coordinated procedures and integrated monitoring of the linked processes
- Automated quality certificate for diagnosis and therapy – efficient operation of cross-linked interoperable systems

Advantages for manufacturers of medical devices:
- Reduction of the development effort by using modular web services-based medical device interfaces and their embedded functions
- Modular interconnectivity with clinical information systems and other medical systems
- Innovative product and business concepts

BUSINESS DRIVERS OF INNOVATIVE PRODUCTS AND SYSTEM SOLUTIONS

In the healthcare sector, innovative products and services develop from “market pull” and “technology push”. “Market pull” results from efforts to avoid bottlenecks and inefficiency in hospital-based medical care and aftercare by using innovative concepts and solutions for mobile and managed healthcare. Some examples of innovative care concepts are the monitoring of vital parameters of patients for remote surveillance of their health condition, the remote control of therapy devices such as ventilators for isolated patients (e.g., Ebola) to improve staff safety, the management of chronic diseases by using appropriate combinations of self-management and specialized medical care, as well as IT-based and mobile aftercare of patients for secondary prevention of events such as strokes.

“Technology push” is provided by the Internet, cost-effective mobile devices with affordable Internet access, and attractive computer apps that use the web as a communication medium.

Web services make up an innovative network-based form of communication that allows interoperable interaction between different application programs on different platforms and/or frameworks. On the Internet or on their domain, web services can be called up selectively when a uniform resource identifier (URI) is used, in order to exchange data with other devices or information systems via standardized Internet protocols (e.g., HTTP).

INNOVATIVE BUSINESS CONCEPTS

The integration of web services-based networks with open and interoperable interfaces is only feasible for manufacturers of medical products if there is economic value and if customers require interoperable system components for their medical IT networks. This is an opportunity for manufacturers and hospital administration to create new business models. The “Internet of Things” will become the “Internet of Things and Services”. For example the global mobile health (mHealth) app market is projected to be valued at $28.320 billion (U.S.) in the year 2018 and is expected to reach $102.350 billion (U.S.) by 2023, growing at a CAGR of 29.30% during the period.[2]

For manufacturers of medical devices, the technical opportunities mentioned above result in innovative or enhanced business concepts that could not be implemented without the Internet. Possible business opportunities include:
- Remote software installation, remote maintenance and online system review
- Innovative service concepts based on artificial intelligence or augmented reality
- Pay-per-use concepts such as new financing models
- Remote diagnosis of defective medical devices and systems
- Technical device management of cross-linked systems

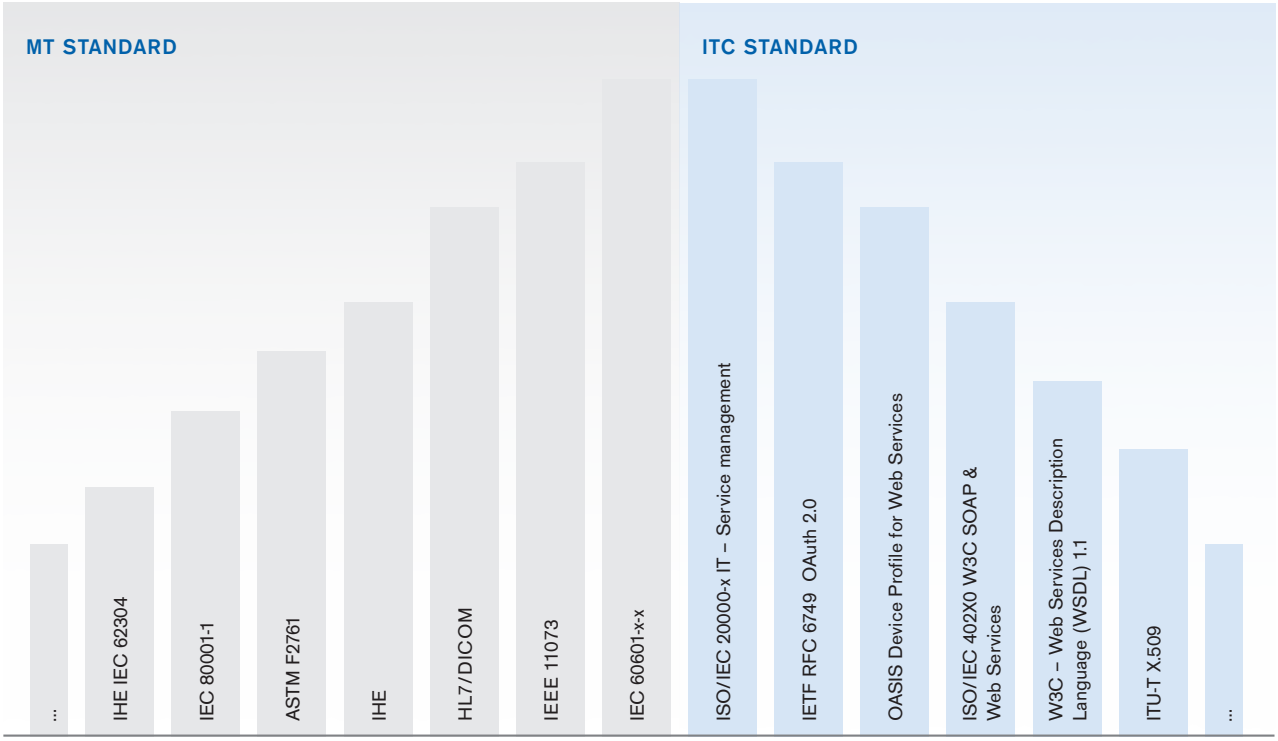

Figure 1: Relevant medical device and medical software standards and related IT and web (de facto) standards concerning the device-oriented open health web platform.[3]

A CHANCE FOR EVIDENCE OF CONFORMITY

Clear specifications for the regulatory boundary conditions are a major prerequisite for the successful market launch of medical devices and medical information systems with open interoperable interfaces. In addition, the establishment of standardized test environments will be required to provide evidence of interoperability and a safe and reliable implementation. The figure above shows a selection of standards that are relevant for the conformity of systems in the medical IT network and for the medical IT network itself.

Organizations such as VDE MedTech (www.vde.com/en) are currently working to standardize and certify medical IT networks and their components and interfaces. The Association for the Advancement of Medical Instrumentation (AAMI - www.aami.org/interoperability/Materials/MDI_1203.pdf) and UL (www.ul.com) are working together on advancements in interoperability of medical devices. UL plans to develop its own safety standard UL 2800 for interoperable medical device interfaces[4]. With these “Technical Frameworks”, “Connectathon” events as well as the HIMSS Interoperability Showcase, organizations such as IHE (www.ihe.net) offer a valuable step forward in the process of achieving conformity.

For manufacturers intending to employ open system integration in their technologies by utilizing the standardized SDC communication protocol, we suggest partnering with others to jointly devise creative solutions that advance clinical and economic value for customers. From the beginning Dräger actively supported the SDC concept and its subsequent submission to the IEEE. Now that SDC is an approved component of the IEEE 11073 standards family, Dräger will drive its implementation with SDC partners when portfolio synergies exist.

FUNCTIONAL	NON-FUNCTIONAL
Plug-and-play – Discovery and binding – Device capability description runtime – Extensibility and openness **Communication (1-1, 1-n, n-n)** – Event notification – Data reporting – External control	**Risk Management** – Safe communication – Access control – Trust establishment between participants – Privacy of patient-related data **Performance** – Latency in milliseconds range

Figure 2: Main requirements for SOMDS

REQUIREMENTS

The new architecture of the IEEE SDC standards family is optimized to the dedicated advanced requirements of high acuity environments such as the OR, ICU and NICU. The integration of all relevant devices, applications and the hospital IT has to be ensured. The web services-based architecture ensures a reliable multi-directional data exchange including remote control of medical devices. Because the system requirements for SDC are minimal, it allows for implementation into most existing hospital IT infrastructures. This reduces the operating and management effort and enables scalability simply by selecting powerful standard components.

DESCRIPTION OF TECHNICAL SOLUTION

The architecture defined in the SDC standard (IEEE 11073 standards family) is built on the principles of clinical workplace Service-Oriented Medical Device Architecture (SOMDS). The Medical Device Profile for Web Services (MDPWS), as well as the Basic Integrated Clinical Environment Protocol Specification (BICEPS) are IEEE 11073 standards for the communication inside of a SOMDS system. The numbers of the IEEE SDC Standards family are listed in Fig. 3.

MDPWS is based on the Device Profile for Web Services (DPWS). DPWS is the foundation of the communication protocol stack and provides a means for service discovery, including a service description at runtime as well as messaging and event propagation over an IP-based network. MDPWS adds additional means that are needed to fulfill specific requirements for a clinical workplace, such as waveform streaming or ensure patient safety.

Aside from these web services profiles, BICEPS provides a basic message information model, as well as medical device services to communicate within a clinical workplace context that is based on the ideas of the ISO/IEEE 11073 standards family.

The existing standard ASTM F2761-09 describes a functional concept for a safe, patient-oriented clinical workplace (Integrated Clinical Environment, ICE). According to this standard, a clinical workplace may be an intensive care bed in an ICU or an operating room. ICE supervisor apps will support the clinical staff by utilizing integrated data obtained from the ICE equipment interfaces.

From a technical point of view, ICE is not defined in every detail. This is why the BICEPS protocol layer was developed. Both BICEPS and the MDPWS allow for an efficient and modular implementation of the functional ICE concept based on web services. In addition to a reliable data exchange, the protocols enable the remote control of medical devices in accordance with requirements for

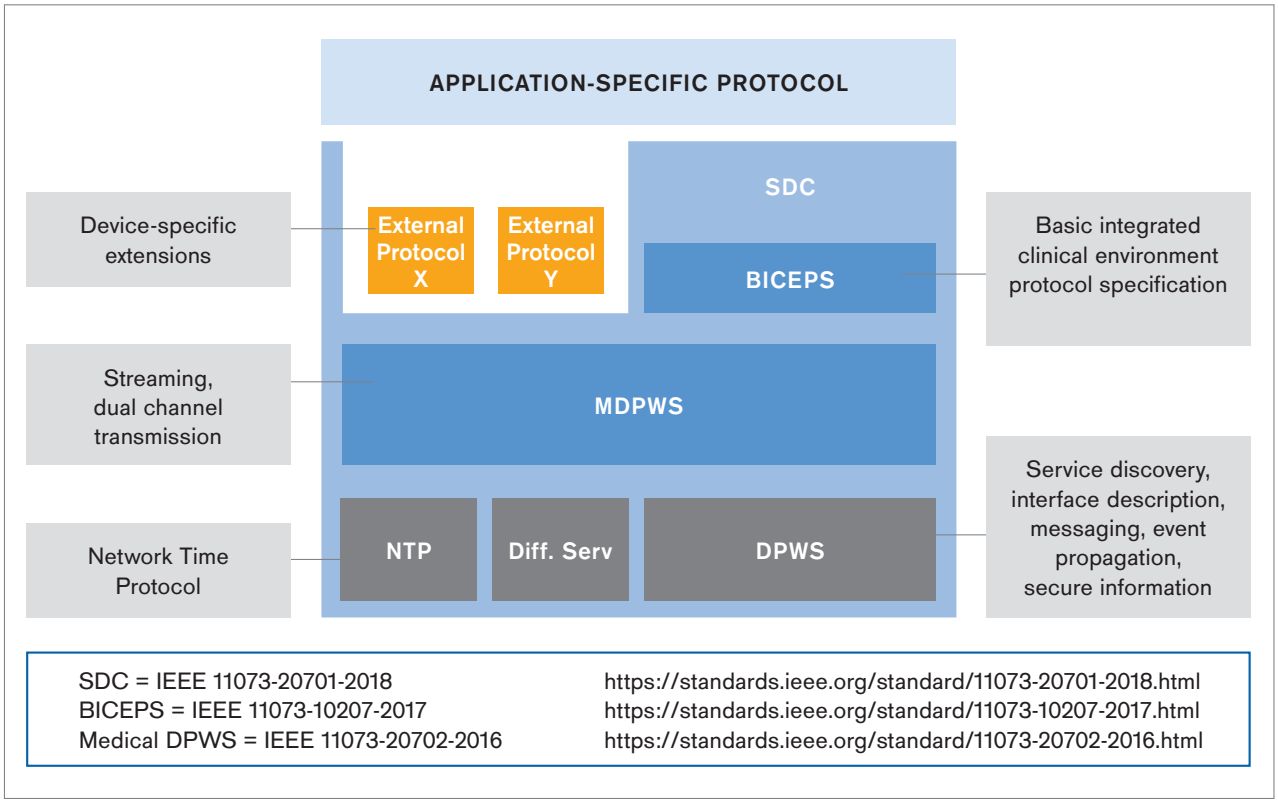

Figure 3: Diagram and parts of the IEEE SDC standards family

patient safety, without limitations related to the run-time environment.

STEPS TOWARDS IMPLEMENTATION

A joint research project consisting of users, hospitals and manufacturers was initiated in 2004 based on this idea and approach. A demonstration of data exchange and system function took place in December 2013 (DOOP Demonstrator). The software reference implementation of the protocols has been available on the “SourceForge” for testing and evaluation purposes since January 2014 (http://goo.gl/BncZQx). Dräger is happy to provide support to anyone interested in obtaining more information.

The actual implementation was evaluated by the MD PnP Interoperability Lab in Boston. An Ebola use case with the remote control of a ventilator was showcased at the White House by Julian Goldman on November 7, 2014. The concept of SDC was submitted to the IEEE 11073 Standards Committee to be adopted as a new standard in the IEEE 11073 series. The proposal was recommended as a new project by IEEE in December 2014. The first output of the work by the project team was the approval of MDPWS (IEEE 11073-20702-2016) specification and the BICEPS (IEEE 11073-10207-2017) specification as IEEE 11073 standards in 2016 resp. 2017. A dedicated project team that was supported by a DKE working group has now finalized the concept and the IEEE working group approved the SDC IEEE 11073-20701-2018) specification in September 2018.

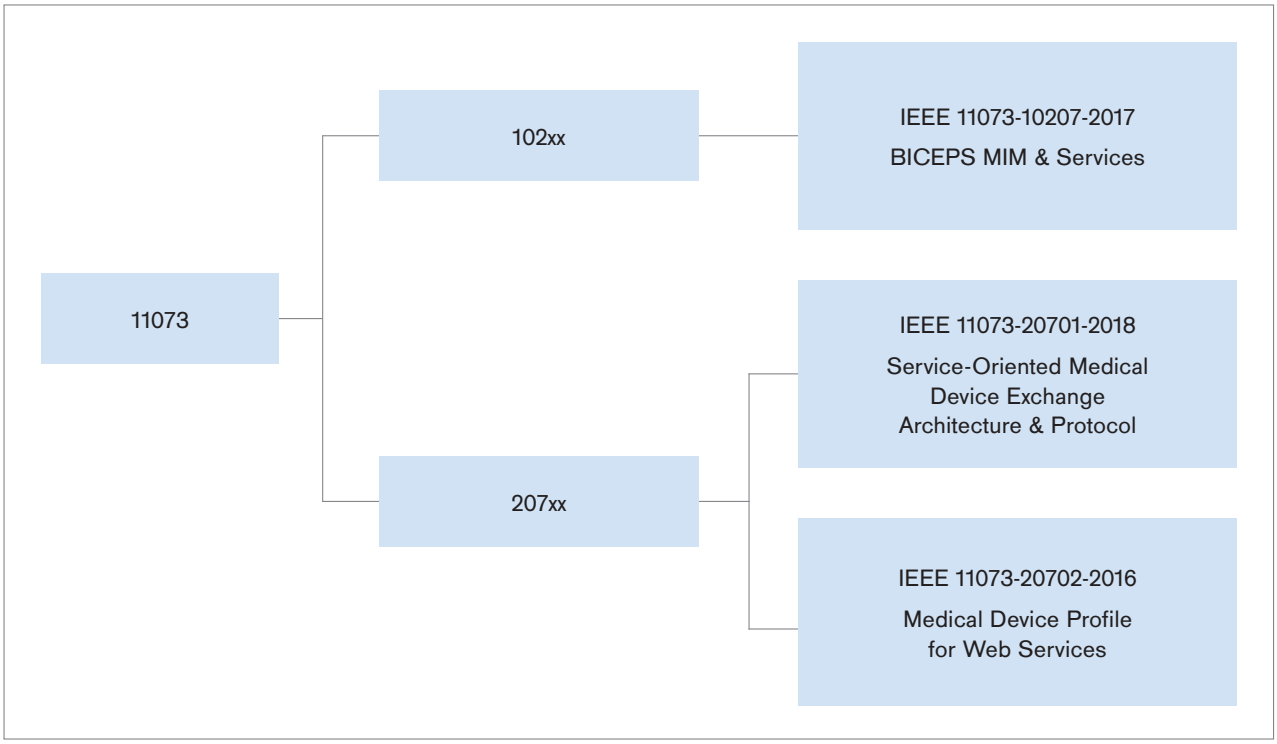

Figure 4: Structure of the IEEE Standards family

SUMMARY AND OUTLOOK

Future demands for an “Internet of Things and Services” at the acute point of care require innovation and cannot be fulfilled by today’s connectivity approaches. A web services-based architecture, coordinated and published under the guidance of international standards committees, will be required and is available since 2018 to prevent silo solutions that lead to additional costs for both the device manufacturers and care providers.

Furthermore, enhanced opportunities for improving clinical care and outcomes can be expected. Dräger is actively supporting the new web services-based approach (SDC) that allows for the ICE conform implementation according to the ASTM F2761-09 standard.

OR.NET together with IEEE are intending to continue working on the adoption of the SDC standards family to procure interoperability.

1 Pronovost, P., M. M. E. Johns, S. Palmer, R. C. Bono, D. B. Fridsma, A. Gettinger, J.Goldman, W. Johnson, M. Karney, C. Samitt, R. D. Sriram, A. Zenooz, and Y. C. Wang, Editors. 2018. Procuring Interoperability: Achieving High-Quality, Connected, and Person-Centered Care. Washington, DC: National Academy of Medicine.

2 https://www.businesswire.com/news/home/20171215005299/en/Mobile-Health-mHealth-App-Market-Industry-Trends

3 J .-U. Meyer, Open SOA Health Web Platform for Mobile Medical Apps 8th International Workshop on Service-Oriented Cyber-Physical Systems in Converging Networked Environments (SOCNE) in conjunction with ETFA 2014, Barcelona, Spain, September 16, 2014

4 https://ulstandards.ul.com/wp-content/uploads/2015/07/prop-2800_scope.html www.aami.org/interoperability/index.html

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