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

The interoperability capabilities of today's acute care devices are not always able to address the future needs of clinicians and hospital IT systems. To enable an "Internet of Things", Dräger and other manufacturers have developed a new web services-based architecture that is designed to become a standard that will benefit patients, clinicians and the healthcare system.

INTRODUCTION

Manufacturers of medical devices are increasingly faced with having to deliver an interface for the Clinical Information System (CIS) used in hospitals. This is normally achieved either by using a specific gateway from the manufacturer that utilizes the HL7 standard for data exchange with the CIS or by appropriate middleware.

Developing these gateways and the corresponding middleware is time-consuming, requires constant adaptations, and causes considerable expenditures for manufacturers and hospitals. For this reason, hospitals are increasingly requiring medical device manufacturers to make their products compatible with each other, which includes the ability to integrate the data flow between the different medical devices and the CIS.

Current standards and profiles (e.g., HL7v2, IHE) are fulfilling today's basic requirements of interoperability and are continuing to be extended. However, standardized interfaces for safe interoperability between medical devices are still missing, even though they will be crucial for fulfilling future clinical requirements.

Within the framework of a German initiative (OR.NET), Dräger and several other manufacturers have created a web services-based architecture to allow interoperability between medical devices. The result of this collaboration is the development of the open source software "SDC" (open Smart Device Connect).

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Based on the related reference implementation, the solution was submitted to the IEEE 11073 Standards Committee to be adopted as a new standard in the IEEE 11073 series. The proposal was accepted by the IEEE General Committee in September 2014. A dedicated project team that is supported by the DKE STD 1000.8.03 working group will work to finalize the draft standard by 2017.

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.

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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 errors during workflow, due to the fact that the network software is developed according to a Failure Mode and Effects Analysis and takes the "human factor" into consideration

Advantages for the hospital administration:
- Creation of an automated surgery protocol with integrated recording of processes, events and newly generated data (e.g. image 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 medical care and aftercare by using innovative concepts and solutions for mobile and managed healthcare. Some examples of intelligent 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 (HTTP).

INNOVATIVE BUSINESS CONCEPTS

The integration of web services-based interfaces 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"[1] will become the "Internet of Things and Services". For example, the market for mobile applications in the health care sector alone is expected to grow from $1.2 billion in 2011 to $11.8 billion in 2018[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 installation, remote maintenance, and online system review
- Automated delivery of used materials and spare parts
- Innovative service concepts
- Pay-per-use concepts for new financing models
- Remote diagnosis of defective medical devices and systems
- Technical device management of cross-linked systems

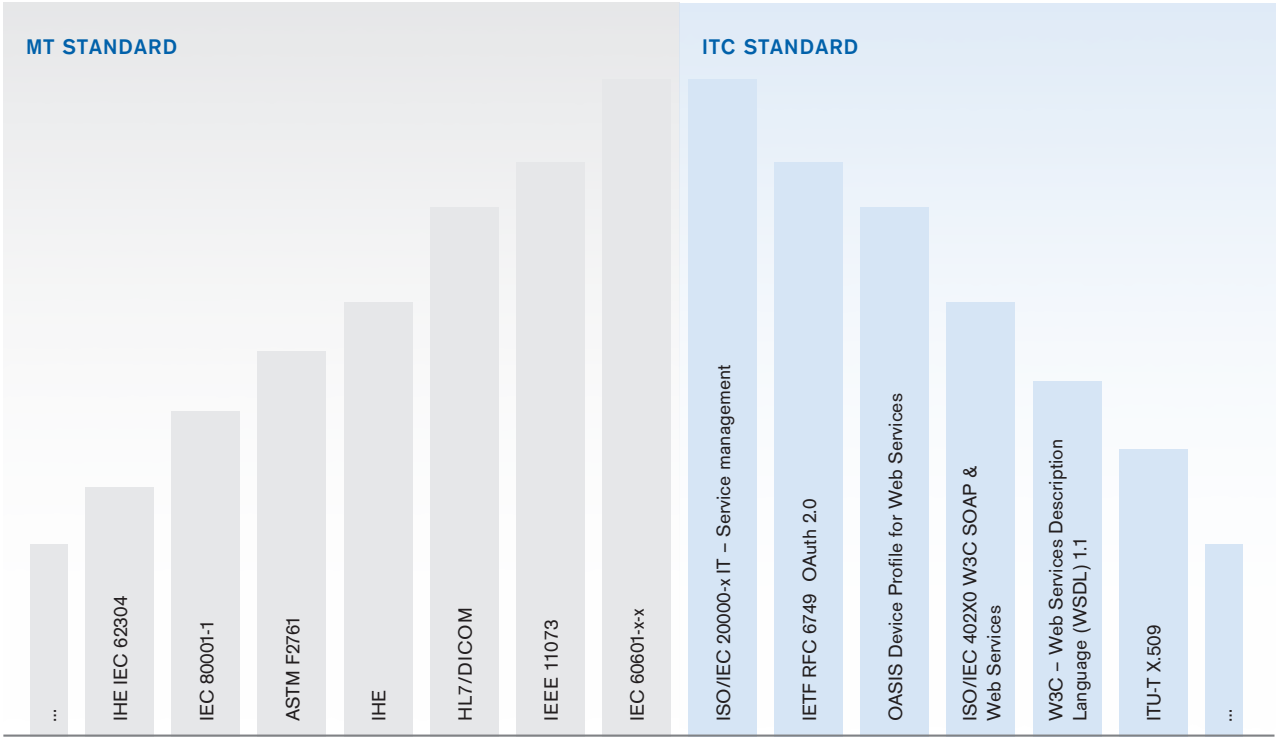

Figure 1: Relevant medical device and medical software standards and related IT and web (de facto) standards concerning the device-oriented open health web platform.[3, 4]

It can be expected that the pressure exerted by users, hospitals, the health system, and standardization committees will drive the change and innovation process in a target-oriented way.

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[5] and Underwriter Laboratories (UL)[6] are currently working to standardize and certify medical IT networks and their components and interfaces. The Association for the Advancement of Medical Instrumentation (AAMI)[7] and UL[8] 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[9]. With these “Technical Frameworks” and the “Connectathon” events (see also HIMSS showcase), organizations such as IHE[10] and Continua Health Alliance[11] offer a valuable step forward in the process of achieving conformity.

For all manufacturers that intend to have a web services interface, there is now a chance to participate in the design of the standardization process by starting the realization and aligning of technical approaches with relevant bodies.

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 SOMDA

Dräger wants to lead the process of conformity by being actively involved in driving the initiative for standardizing the innovative web services-based concept of SDC.

REQUIREMENTS

The new architecture of SDC 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.

PROPOSAL OF TECHNICAL SOLUTION

The proposed SDC architecture is built on the principles of clinical workplace Service-Oriented Medical Device Architecture (SOMDA). The newly introduced Medical Device Profile for Web Services (MDPWS), as well as the Basic Integrated Clinical Environment Protocol Specification (BICEPS) are recommended as technical specifications for the communication inside of the distributed system.

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 remote control that ensure patient safety.

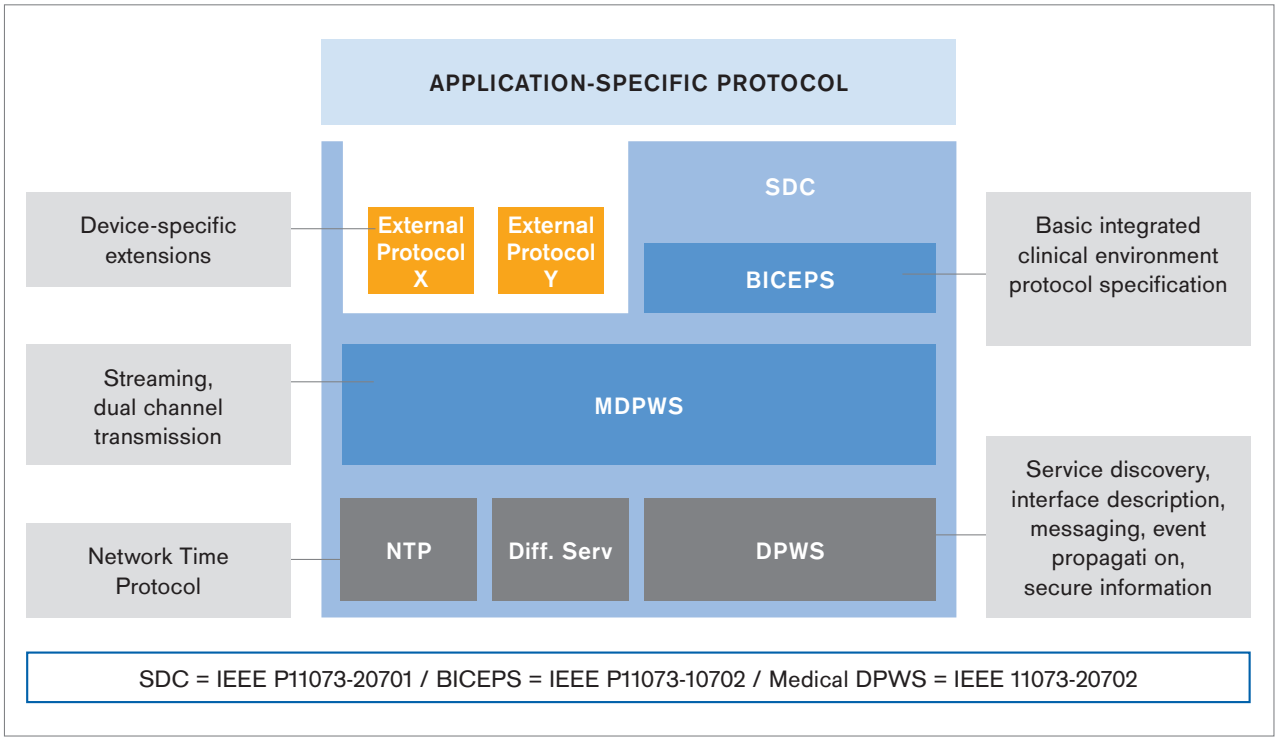

Figure 3: Proposed scope of artifacts for standardization

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

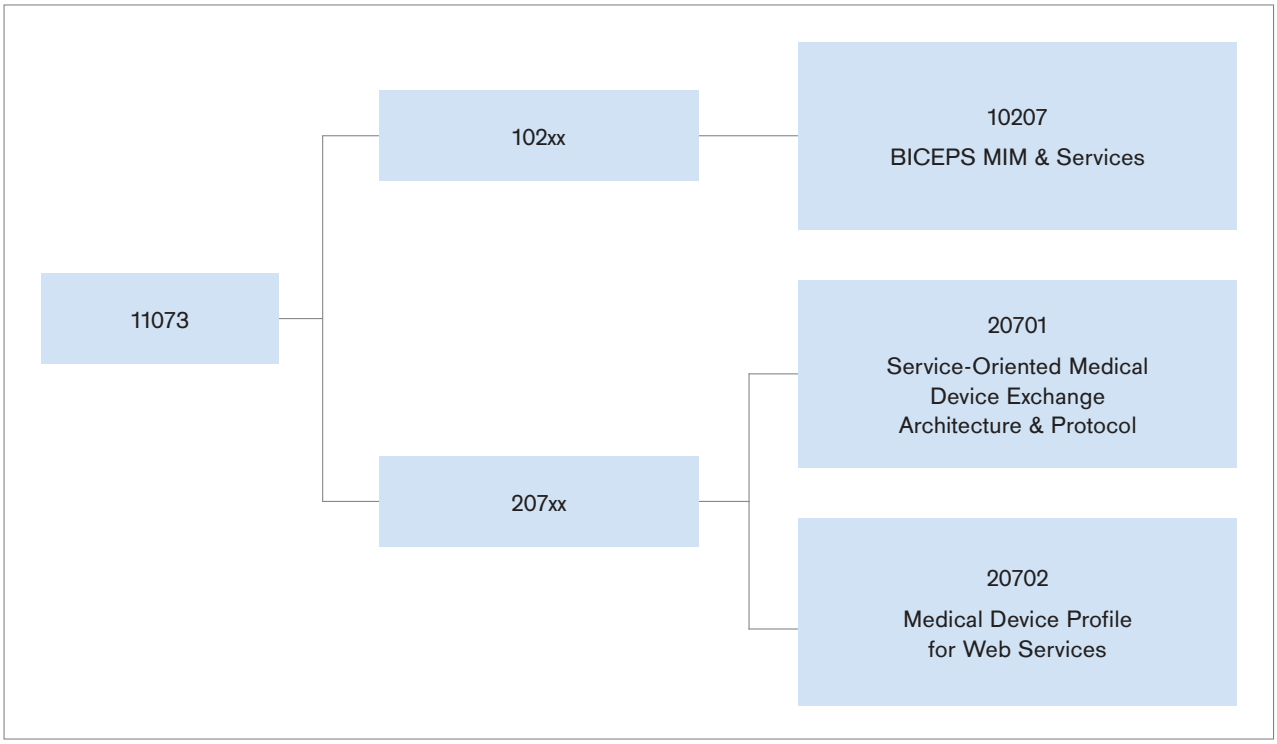

Figure 4: Structure of the scoped standardization related to artifacts

ROADMAP FOR 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. A dedicated project team that is supported by the DKE STD 1000.8.03 working group will work to finalize the draft standard by 2017. The first output of the work by the project team is that the MDPWS (IEEE 11073-20702) part of the standard series has been approved in 2016.

The project team appointed by the IEEE Commitee is instructed to prepare the following artifacts for standardization.

CONCLUSION

Future demands for an “Internet of Things and Services” in the hospital environment 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 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 a new web services-based approach by launching an open source solution (SDC) that allows for the ICE conform implementation according to the ASTM F2761-09 standard.

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2 www.alliedhealthworld.com/visuals/smartphone-healthcare.html
3 www.doop-projekt.de/tl_files/ebooks/business-kontext/index.html
4 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
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