Editorial

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OR.NET - secure dynamic networks in the operating room and clinic

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For many years, the number and complexity of technical systems in the operating room (OR) and clinic has been increasing. Especially the latest advances in computer assisted diagnosis and therapy devices support the trend towards personalized medicine. This in turn induces the need for sharing information by enhanced communication, high flexibility and access to specific minimal invasive therapeutic options on demand. The borders between medical devices and clinical information technology (IT) are vanishing. The paradigm shift from isolated devices towards system interoperability requires a consideration of inter-device as well as human-technology interaction. In recent years, proprietary integrated operation room systems with a central user interface cockpit have been provided. However, these monolithic solutions limit the flexibility of the operators and users regarding the interoperability and integration of independent innovative devices in these integrated OR solutions.

Vendor-independent medical device and system interoperability goes beyond the mere physical networking of the systems. In addition to the technical, syntactic, and semantic interoperability, it has also the entire systems in view. Interoperability is a particularly important key technology.

This issue presents results on interoperability research in the field of clinics of the future with focus on operating room and intensive care unit. Interoperable medical devices in the operating room and the interplay of these systems with the clinic IT are an outstanding topic. It results in emerging requirements for highly complex risk management, the need of testability of composed subsystems from different vendors and high demands on certification of medical device systems. The research results presented here can contribute to the competitiveness of the research institutes and the applied industries and should serve the well-being of the patient in a sustainable way and improve clinical workflows.

The majority of contributions presented in this issue are based on results of the OR.NET project on safe dynamic networking in surgery and clinic. OR.NET was a flagship project funded by the German Federal Ministry of Education and Research (BMBF: funding ID: 16KT1203). The main objective of the project OR.NET was to develop the technological, legal, and operational basis for modular dynamic integration of medical devices and IT systems into the future operating room and its clinical environment. With the direct involvement of the end users, the project participants systematically dealt intensively with the manifold challenges. They researched new approaches and methods, as well as developed new standards, hardware and software systems, prototypes and comprehensive demonstrators. The OR.NET results currently carry forward to the international standard IEEE 11073-SDC, fostering the application in future medical devices. Authors from different OR.NET partner institutions [1, 3–6, 8, 9] provide a comprehensive overview on different aspects and results of the project as well as ongoing developments. Two research teams from Japan [7] and USA [2], working in the same field of research, contribute to this journal and give an insight into related developments in their countries.

The OR.NET project, coordinated by Prof. Klaus Radermacher (RWTH Aachen University, Aachen, Germany), finally incorporating more than 90 partner institutions from clinical operators and health personnel as well as academia, industry (more than 50%) and standardization committees, ended after a term of four years in 2016. Today, many of the partners continue their cooperation in the framework of the non-profit association OR.NET (www.ornet.org).

Companies, which are usually exposed to strong international competition, have seized the opportunity for intensive work on open networked systems, which also

enable them to offer completely new services and innovative functionalities and better flexibility to the medical staff, thereby potentially supporting an optimized therapy for each individual patient.
This journal covers the following topics in detail:

- Clinical requirements to connected medical devices and systems and the clinical IT
- Creation of completely new applications and perspectives for end users
- Networking of systems from different manufacturers
- Interoperability of medical devices, hard and software systems and services
- Adaptation of IT technologies and service-oriented architectures (SOA) to the needs in the operating room and clinic
- Integration of medical device systems in the operating room with clinic IT
- Development of open-source software
- Prototypical demonstration of the project results in complex, realistic surgical scenarios
- Enhancements to IT technologies to meet hard real-time requirements
- Interoperability concerns between established standards for the clinical IT and for the operating room and intensive care unit.
- Risk management and testability of open networked medical systems

OR.NET aimed to meet the needs of patients and clinicians. Thus, already with the start of the project, end users were involved in the research work. Developers and researchers presented the benefits of the envisioned solutions to the clinicians. In addition, project members have taken into account the requirements of the clinicians in the development process. Czaplik et al. [4] address the inclusion of clinicians and operators and bring together representatives from various medical disciplines, who present their views on the advantages of the implemented concepts of integration.
An essential starting point is the networking technology used in the project. The project was based on the concept of a service-oriented architecture (SOA), which was refined into the service-oriented medical device architecture (SOMDA) concept. The special requirements of medical technology in the area of the operating room were taken into account. Kasparick et al. [6] describe the basics of vendor-independent device networking, which are being standardized as the new IEEE 11073 SDC (service-oriented device connectivity) family.
In addition to the interoperability approach developed in the OR.NET project; this journal presents two additional approaches, SCOT and openICE. The concept introduced under the name "SCOT" (Smart Cyber Operating Theater) uses the communication standard ORiN originally developed for industrial automation and is described by Okamoto [7]. The work of Arney et al. [2] introduce the Integrated Clinical Environment (ICE) architecture and the open-source implementation openICE. OpenICE was developed as part of Medical Device Plug-and-Play Interoperability Program (MD PnP) at Massachusetts General Hospital. The authors describe important design decisions in the implementation of their third generation ICE platform. The ICE platform uses Data Distribution Service (DDS) from OMG as the basic middleware technology.
Based on the new IEEE 11073 SDC standard family, Besting et al. [3] implemented the open software library OSCLib (Open Surgical Communication Library). With this software library, developers are able to create IEEE 11073 SDC-compliant systems of networked medical device. Various demonstrators of the OR.NET project have used the library. The paper details the applied methods for the developed software, the software layers, and the implementation. OSCLib is interoperable with other available SDC-compatible frameworks (like openSDC).
Anderson et al. [1] describe ways to connect the operating room that is conform with IEEE 11073 SDC to already established medical standard technologies (HL7, IHE, DICOM) in clinical IT. The authors present how clinic IT and the surgical equipment exchange clinical and administrative data. The key challenge is to combine medical IT systems that is mainly centralized and closely coupled with loosely coupled device systems.
In the OR.NET project, participants developed demonstrators as realistic testbeds at five locations in order to evaluate the concepts of integration and to perform performance analyzes to better test the systems in interaction. The developers have used these functional demonstration systems to improve the various specialized use cases together with the end users and surgeons and to collect feedback from them. In [9] Rockstroh et al. give an overview of these demonstrators.

When transferring the SOA concept to medical real-time systems, adjustments and enhancements are necessary, because most SOA uses non-real-time capable IP networks. Pfeiffer et al. [8] examine in their article how medical device networks can ensure real-time properties. The authors introduce the implementation of a medical device network that provides hard real-time guarantees for control and sensor data. By means of two application examples, they combine the flexibility of SOA networks and the reliability of real-time networks to reach real-time behavior and introduce the surgical real-time bus (SRTB).

The modular and open networking based on the new IEEE 11073 SDC standards, which allows integration of systems from different manufacturers, requires new approaches to testing a newly created integrative operating room. Janß et al. [5]Fehler! Verweisquelle konnte nicht gefunden werden. describe the challenges of interoperability testing and modular risk management resulting from the application of the open, vendor-neutral communication standard IEEE 11073 SDC. The article presents a three-stage test methodology for open medical devices. This consists firstly of conformity tests, secondly of interoperability tests and thirdly of usability integration tests.

Finally, we hope that this special issue of the Journal for Biomedical Engineering provides an interesting insight into latest developments, trends, and needs for open standards and approaches for integrated medical-device-IT networks in the operating room and clinic. The OR.NET project was a major milestone on the way to the interoperability of medical technology. The developed communication standard SDC will be available for implementation after completing the standardization phase in 2018. We wish you enjoyable and interesting reading – as well as safe and secure medical technical systems whenever you need them.

References

[1] Andersen B, Kasparick M, Ulrich H, et al. Connecting the clinical IT infrastructure to a service-riented architecture of medical devices. Biomed Eng-Biomed Tech 2018; 63: 57–68.

[2] Arney D, Plourde J, Goldman JM. OpenICE medical device interoperability platform overview and requirement analysis. Biomed Eng-Biomed Tech 2018; 63: 39–47.

[3] Besting A, Bürger S, Kasparick M, Strathen B, Portheine F. Software design and implementation concepts for an interoperable medical communication framework. Biomed Eng-Biomed Tech 2018; 63: 49–56.

[4] Czaplik M, Voigt V, Kenngott H, Clusmann H, Hoffmann R, Will A. Why OR.NET? Requirements and perspectives from a medical user's, clinical operator's and device manufacturer's points of view. Biomed Eng-Biomed Tech 2018; 63: 5–10.

[5] Janß A, Thorn J, Schmitz M, et al. Extended device profiles and testing procedures for the approval process of integrated medical devices using the IEEE 11073 communication standard. Biomed Eng-Biomed Tech 2018; 63: 95–103.

[6] Kasparick M, Schmitz M, Andersen B, et al. OR.NET: a service-oriented architecture for safe and dynamic medical device interoperability. Biomed Eng-Biomed Tech 2018; 63: 11–30.

[7] Okamoto J, Masamune K, Iseki H, Muragaki Y. Development concepts of a smart cyber operating theater (SCOT) using ORiN technology. Biomed Eng-Biomed Tech 2018; 63: 31–37.

[8] Pfeiffer JH, Kasparick M, Strathen B, et al. OR.NET RT: how service-oriented medical device architecture meets real-time communication. Biomed Eng-Biomed Tech 2018; 63: 81–93.

[9] Rockstroh M, Franke S, Dees R, et al. From SOMDA to application – integration strategies in the OR.NET demonstration sites. Biomed Eng-Biomed Tech 2018; 63: 69–80.

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