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SECURE AND DYNAMIC NETWORKING
IN OPERATING ROOM AND HOSPITAL

Secure and dynamic networking in operating room and hospital

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Introduction

For many years, the number and complexity of technical systems in the operating room and clinic has been increasing. Especially the latest advances in computer assisted diagnosis and therapy devices support the trend towards personalised medicine, which 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 IT are vanishing. The paradigm shift from isolated devices towards system interoperability requires a consideration of interdevice as well as human-technology interaction. Therefore, proprietary integrated operation room systems with a central user interface cockpit have been provided in recent years.

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. Against this background, the main objective of the OR.NET project is to develop the technological as well as legal and operational basis for an open platform and standards for the modular dynamic integration of medical devices and IT systems into the future operating room and its clinical environment.

OR.NET – Secure Dynamic Networking in Surgery and Clinic – is a lighthouse project of the German Federal Ministry of Education and Research (BMBF). We started with 50 project partners from research, industry, clinics and standardisation in October 2012 with an overall budget of EUR 18.5 million (with M€15 funding by the BMBF). Our efforts focused on several interdependent topics: The development of a data model with open source libraries for standardised and open network communication was one of the major objectives of our work and could be brought into the international standardisation process. Another essential aspect of the project was the development of strategies and methods for the approval and risk management of modular integrated clinical system architectures with interacting modules including the consideration of related legal issues. Models for business partnerships between clinical operators and industrial providers had to be elaborated in order to define the roles, responsibilities and efficient pathways for the clinical integration. Last but not least, new concepts for safe and usable human machine interaction have been developed in close collaboration with our clinical partners in order to ensure that technical progress creates a real benefit for the clinic staff and patients without generating new risks. Several OR demonstrators at different partner institutions in Germany were installed, addressing different aspects of the project work and enabling the evaluation of the technical as well as clinical aspects of the OR.NET approach.

Today, the OR.NET consists of approx. 90 national and international partner institutions forming a network which provides an opportunity for first-hand experience and developmental partnerships as a solid basis for a sustainable dissemination and implementation of this new approach.

To assure the sustainability of the OR.NET platform and consortium activities beyond the BMBF funding period, the non-profit making OR.NET Association (OR.NET e.V.) has been founded by OR.NET partners in March 2016. The activities will be including, but not limited to, the continuing development of software libraries, tools and methods, the international standardisation and cooperation for education and training and the coordination of demonstrator and test labs. If you are interested in membership, please visit www.ornet.org or contact info@ornet.org for further information.

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Sub-Project SP 2: IT-integration/networking in the OR

Objectives and challenges

Sub-project SP 2 addresses the technical issues and challenges with respect to interoperability, safety, dynamics and networking of medical devices and adjacent IT systems. Particular attention is paid to the fact that the requirements for the communication technologies of IT systems are radically different to those of medical devices. Therefore, new approaches to integrating Medical Devices into IT infrastructure need to be developed.

A common knowledge base and the exchange of Information between all the work packages are key factors for an efficient cooperation in OR.NET. In addition to the conceptual solution, the high degree of complexity in the field of medical devices and information systems, as well as coordinating the many partners involved, pose challenges to the project.

Status quo and results

The sub-project is divided into eight work packages. Additionally, focus groups are used as an instrument to address specifically challenging tasks.

The basis for any viable technical solution is the requirements. These were obtained in a cooperative effort of clinicians and technical project partners. Additional requirements derived from the project application, the communication matrix and their underlying key indicators were also identified and documented.
Based on these requirements, an overall architecture, taking into account the relevant preparatory work of all project partners has been developed. To achieve this, the existing preparatory work originating from former research projects has been presented and compared. Based on the design principle of a Service-Oriented Architecture (SOA), a complete architecture comprising all the necessary components and technologies has been designed in numerous workshops. The essential features of this architecture are the separation of the medical information systems network and the OR network, the support for real-time communication and a common data model used to transmit data between the devices.

Medical devices are connected with each other and with the medical information systems by a middleware called Open Surgical Platform (OSP). OSP consists of multiple distributed software components containing all functions and data classes required for networking and integration. Its components communicate via the Open Surgical Communication Protocol (OSCP). Likewise, the communication between the devices and the transmission of essential data classes of information systems (such as patient and order data) use OSCP.

The operation of the OSCP protocol is based on methods for setting and retrieving values on a device. This was realised by using an implementation of the MDPWS layer (Medical Devices Profile for Web Services). A necessary prerequisite for adding more software components is the mentioned common data model. Protocol and data model both undergo an international standardization process (IEEE 11073-10207, 11073-20702 IEEE, IEEE-20701).

The protocol definition must consider security, safety and a consistent semantic data model. For this, the modelling of medical devices with respect to the data to be transmitted and the description of their functional characteristics is of great importance. The focus group security discussed the necessary safety and security concepts at different levels. Not only patient safety, but also data integrity and in the correct operation of all the devices at any time have to be guaranteed.

An essential aspect of the overall architecture is the communication between medical devices with hard real-time requirements. These requirements typically arise within the field of device control and sensor data transmission – in particular control of all active instruments that are indispensable for most surgical interventions. Hard real-time communication is achieved using an additional real-time capable infrastructure (Surgical Real Time Bus, SRTB) based on the Ethernet-Powerlink protocol. Synchronisation and data routing in SRTB is performed by a dedicated Master. The entire SRTB is integrated into the overall architecture via the SRTB-OSCP-Gateway – a subcomponent of the Master acting as OSCP-compliant device that provides OSCP-services without real-time requirements (device configuration, change of data

routing).

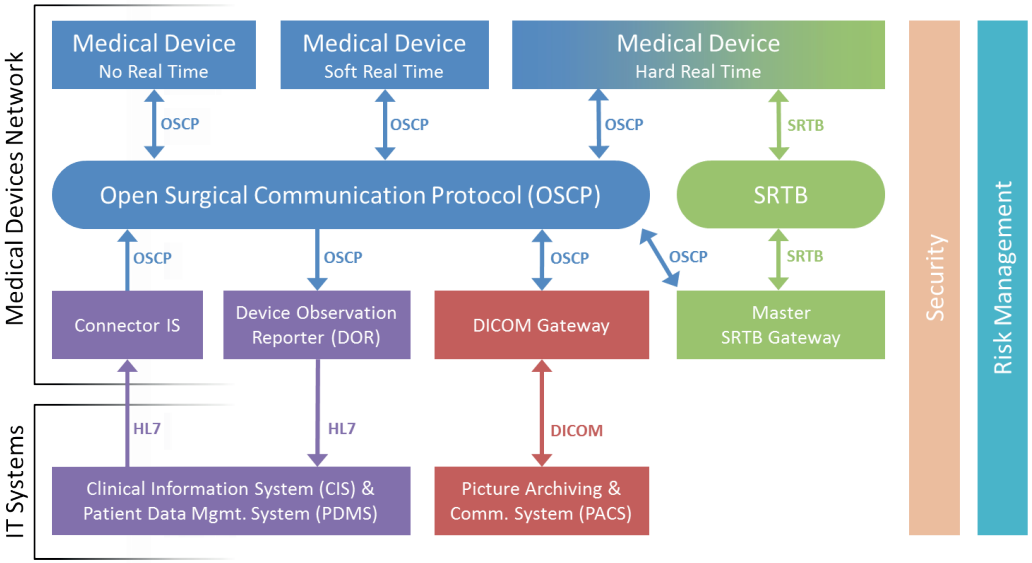
The integration of medical devices with medical IT systems is based on a stand-alone component, the Connector IS. In determining the functionality of the Connector IS, systems and data streams relevant to the project were analysed. Subsequently, a differentiated analysis of the types of messages was performed. The Connector IS translates and transmits patient and order data from the hospital-IT to the device in the OR's network. By means of an additional component called the Device Observation Reporter, readings and other device data can be transmitted to hospital information systems.

The need for the safe operation of groups of networked devices in the operating room is challenging since the user has to manage these networks: the availability of required devices and services must be determined, devices must be assigned to specific treatment situations and patients, failures and problems must be identified and communicated to the user. This task is performed by a separate component in OR.NET: the context manager.

Besides OSCP, OR.NET also allows the use of different communication protocols (e.g. DICOM and HL7 Version 2). OSCP explicitly does not try to replace these widespread protocols. Instead, dedicated gateways are specified that enable the operation of the DICOM and HL7 protocols despite the separation of OR network and the hospital network.

To facilitate interconnectivity with the OSCP protocol for manufacturers, a software library has been implemented. This allows the use of OSCP on medical devices by easy-to-use software interfaces. In the project, two different implementations are cur-

The OR.NET architecture



Sub-Project SP 2: IT-integration/networking in the OR

rently used. The implementations are interoperable and are adapted to the different software environments on the devices.

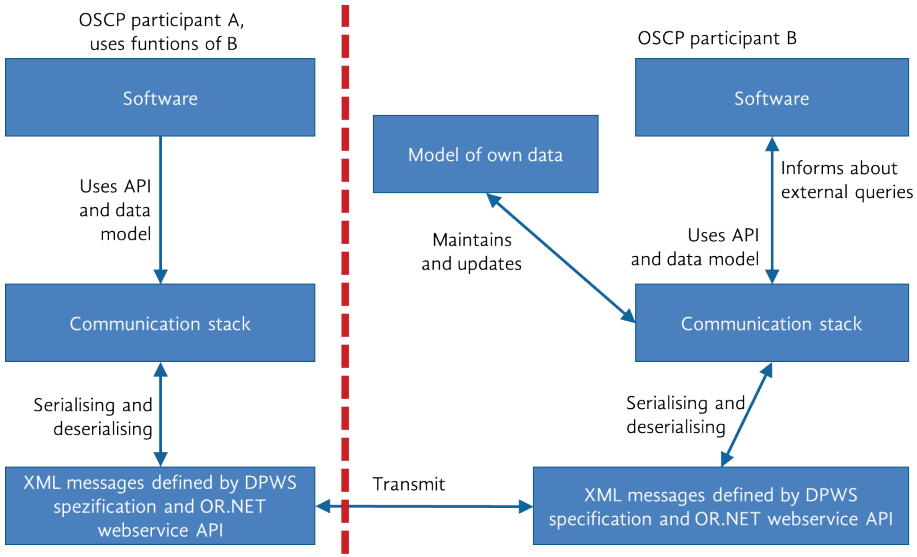
All development work and the resulting components are tested for consistency, functionality and interoperability in development and testing laboratories at different OR.NET partner institutions (see www.ornet.org for acutal information).

The operation of the entire system and of the individual devices takes place via a central control station. New concepts and policies in the field of human-machine interaction are developed and implemented. An important aspect is the screen layout to present information to the operator. In a first step, data from orthopaedic surgery and neurosurgery was collected to analyse it with respect to its kind and flow of information. One possible arrangement for presenting such data would be, for example, the subdivision of the display area into different areas, such as a status line with a list of devices (active/inactive), an indication of the patient's condition and the combination of views and the devices behind. Furthermore, concepts for intelligent alarms were developed.

Outlook

In sub-project SP 2, numerous development works take place in parallel with the completion of the concepts. By spring 2016, the core components of the OSP and the connectors MP and IS will be available. The OSCP interfaces are tested for compatibility, data integrity and interoperability within OR.NET. Towards the end of the project, integration profiles will be tested as part of internal project connectathons to ensure the interoperability of the participating devices and information systems.

Interaction of OR.NET participants



Sub-Project SP 3: Approval strategies for Open Integrated Medical Devices

Background

Nowadays proprietary integrated OR systems have to be approved by one manufacturer, which is solely responsible for the accomplishment of the risk management and usability engineering process. The dynamic cross-linking of various devices from different manufacturers represents a completely new situation and raises juridical questions regarding the approval process.

Especially, the usability engineering according to IEC 62366 and the risk management according to ISO 14971 (technical and human-centered) as well as the validation of software components, which communicate via network, have to be reconsidered and redesigned. The aim is to find a technically feasible and legally clarified approval strategy and system architecture. Furthermore, adequate methods and tools to support the approval process for manufacturers and the operating process for clinics have to be available and standardised.

Challenge

The challenge in this project is to consider and solve the problem of the approval of modular devices in an open networked OR system by defining application-specific scenarios, relevant device combinations and system configurations with interfaces based on an open communication standard. The interface of the device pairing has a major impact on the risk control as part of the risk management and the associated documentation regarding the intended use in the context of use and the complexity of the device function. Here, the risk management and the usability engineering process have to be conducted integrally.

In particular, the controlling and the visualisation of medical device functions by using input and output components of different manufacturers' devices have to be considered and assessed in detail regarding the approval process. Offering new functionality by cross-linking devices in the context of the approval process could implicate the fulfilment of new requirements regarding the conformity statement of medical devices, especially when a classification in a higher risk category is mandatory. According to the Medical Device Directive (MDD) and the classification rules for software application, particularly the control of external devices is considered as application interference (Annex 9 Rule 2.3 Directive 93/42). „Software, which controls a device or influences the use…" is classified within the same risk category as the controlled device.

In the framework of the risk management, manufacturers and operators must be able to use the risk and usability analysis of the individual components in the flexible integration via open interfaces for a comprehensive risk and usability analysis of the complete OR system. For this purpose, tools and standards must be developed. In particular, the human risk assessment has to take into account the additional risks, resulting from the combination of individual device solutions and the changes in the human-machine-interaction characteristics.

Status quo and results

Against this background the following aspects are in the focus of the development and evaluation:

- Approval strategies and legal aspects for open networked systems
- Service and device profiles for a modular technical risk analysis
- User interface profiles and human risk analysis
- Tools and methods for runtime verification
- Conformity, interoperability and usability testing on the basis of service and device profiles

Sub-Project SP 3: Approval strategies for Open Integrated Medical Devices

Table 1: Service and device profile	
Extension of the intended use, device functions	Which function is provided by the device or the service? May the function be controlled by a different input device or is it only allowed to display the function on another output device? How is the communication between device/service with users and other devices/services? What is the context of use for a defined use scenario?
Technical specifications	Protocol, Data model version, data types, function description: Medical Device System - MDS-descriptor (Model-No, Model name, Serial No, Manufacturer, friendly name, UDI), functions (1-n) are represented by channel and metric descriptors
User Interface Profiles	Characteristics of input and output devices as well as GUI interaction elements (size, position) and their dependencies, criticalities of functions, grouping and positioning information about interaction elements, etc., scenario-specific defined performance shaping factors inter alia environmental factors
Countermeasures against network risks	Which risks of an individual device/service function influence other devices/services in the context of the application scenario? Which risks occur especially in the framework of the network integration (requirements for the networked partner)? Which counter measures have been chosen by the networked partners? How do we inform the networked partner about the chosen counter measure (e.g. time stamp, 2-channel capability)?
Network requirements	Which risks occur at/through the network (requirements for the clinical operator)? Quality of service requirements (latency, jitter, packet loss rate, data transfer rate, bandwidth)?

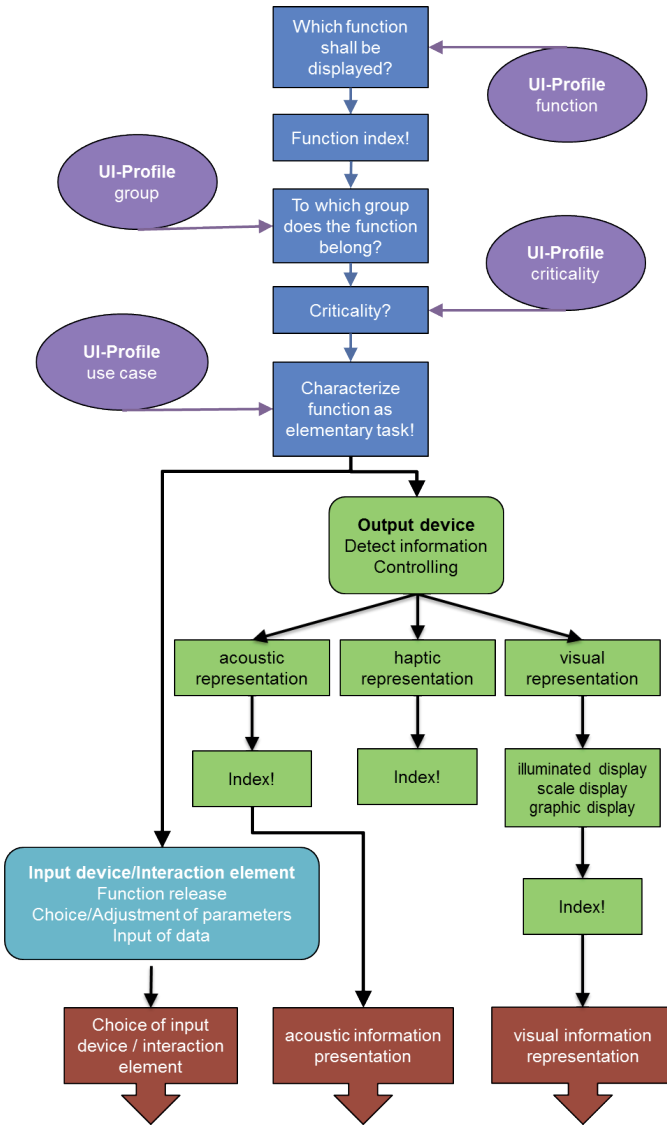
In order to enable an open and dynamic network approach (that does not mean unknown device functions), it is necessary to define non-proprietary standards, which are formally described and documented and which allow safety tests. The development of such standards is based on the definition of service- and device profiles (see Table 1). On the one hand, this allows for a vendor-independent communication between unknown devices and, on the other hand, a risk assessment for manufacturers and operators with respect to the application in an comprehensive integrated OR system.

The evaluation of the developed approval strategy in cooperation with the notified bodies confirms so far that the currently pursued approach seems promising and applicable according to valid law and actual approval practice. Initially, the development and evaluation of the approval strategies have been conducted for specific device pairings (OR-microscope, cutting device and footswitch) and functions (e.g. controlling the power of the cutting device) and are currently being applied for the demonstrator settings in close cooperation with the OR.NET standardisation working group.

User Interface Profiles extend the standard of ISO 24752 (Universal Remote Console) regarding HMI-specific device- and function-description especially with reference to safety-relevant aspects, which are mandatory for the development of reliable and usable medical devices.
The core of the UI Profiles are attributes (e.g. characteristics of input and output devices as well as characteristics of GUI interaction elements, human information processing factors, environmental and process factors, task-specific factors, criticality of device functions, grouping of interaction elements) and dependencies of the attributes in the corresponding UI method, which are described in inter alia in four matrices: Generation/selection of interaction element and input device, visual presentation of information, acoustic information presentation and visual grouping. Based on these matrices, an integrated user interface can be

Sub-Project SP 3: Approval strategies for Open Integrated Medical Devices

Procedure on the application of the UI Method



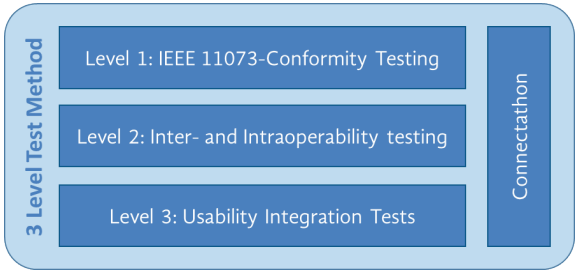
evaluated and furthermore designed. The UI profiles are defined as additional information in the technical device/service profile. With the help of a systematic modelling and human risk analysis technique, the way for standardised GUI development of integrated medical devices shall be paved.

The evaluation of the UI profiles and UI methodology has been conducted with different device pairings (e.g. an OR microscope and an ultrasonic cutting device) and additionally carried out successfully in a central surgical operating cockpit and the integration of multiple GUI panels of individual medical devices (e.g. US dissector, operating table, US bone knife, universal foot switch, RF unit, endoscopic light and camera as well as an insufflator).

For the future use of the OR.NET device-, risk- and service-profiles corresponding test procedures must be provided. In the framework of this part of the project, a 3-level test method has been developed in collaboration with a notified body and the VDE Testing and Certification Institute in Offenbach and sub-project SP 4 „Standardisation“.

In the first level, the medical device must be tested regarding standard conformity to IEEE 11073 by an independent testing laboratory (Figure 3). In the second level, the manufacturer guarantees that tests have been successfully carried out for intra- and interoperability (Figure 4).

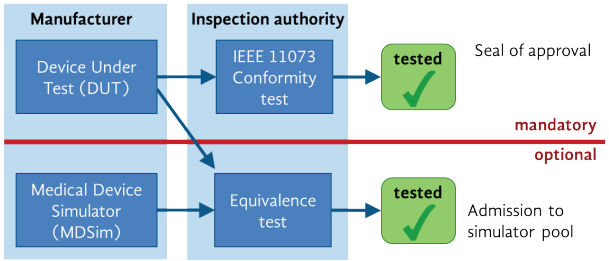
The accomplishment of OSCP Connectathons (also possible to perform in parallel to the other test levels) and usability evaluations in test laboratories represent the 3rd test level “integration assessment”.



Sub-Project SP 3: Approval strategies for Open Integrated Medical Devices

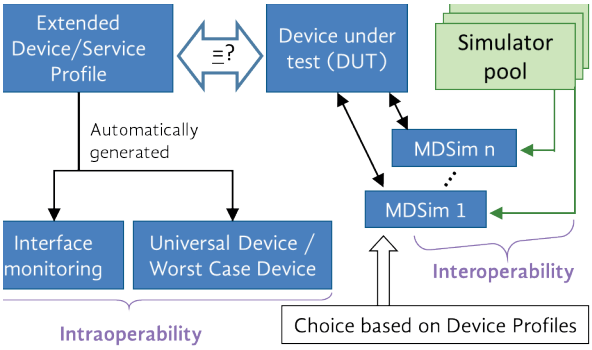
Level 1: IEEE 11073 Confomity testing

- SUT (System Under Test) will be tested by an independent inspection authority (e.g. VDE test and certification institute or certified OR.NET test labs)
- The simulator will be available in a central collection after passing the equivalence test. The administration can be enabled by an independent institution or association, which allows arbitrary access and the provision of the device profiles.



Level 2: Inter- and intraoperability testing:

- The manufacturer is testing its device against the simulators of foreign devices and functions, and thereby communication can be tested between the devices.
- The worst-case device may be tested automatically with the extended device profile.



Level 3: Usability integration testing

- Usability evaluation in test laboratories with members of a representative user group (e.g. surgeons, anesthesiologist, sterile and unsterile nurses)

Furthermore, a validation within OSCP Connectathons can be done. The review of the test results will be performed by a referee just as within IHE Connectathons.

The extended OR.NET device/service profile has been compared by various enterprises in the context of different application examples regarding the additional and required expansions for the technical documentation in the framework of the declaration of conformity.

Currently defined within the OR.NET community, clinical application scenarios and documentation are developed and discussed in german and international working groups. For future application, the project partners will be provided with the developed guidelines for the preparation of the approval documents for open integrated OR-systems.

Outlook

Within the realisation of the approval of open networked systems, the additional and required expansions regarding the documentation in the framework of the declaration of conformity have been identified. Finally, the results will be presented to a Notified Body.

Additionally, these concepts will be presented in terms of internationalisation in another workshop on regulatory strategies in the US. There, the results shall be coordinated with the Food and Drug Administration - FDA.

Moreover, the introduction of the latest results of the sub-project in the Notified Bodies Recommendation Group and in the NB-Med Certification Committee will also be an important and successful step towards international implementation and standardisation.

Challenges

The market for networked medical devices and integrated operating rooms is currently dominated by proprietary solutions from just a few vendors. A small number of manufacturers use their own communication protocols and vocabularies for data exchange, making these inaccessible for other interested manufacturers. For other competitors to network with the proprietary devices in the operating room and in the hospital setting, they have to purchase the corresponding interface. The complexity and high costs involved usually make competitors desist.

Consequently, when the user needs to procure new devices, they often face the dilemma of either having only a very limited choice or of having to manage without connectivity and integration. Such restrictions hinder an independent market.

There are two measures for dealing with this situation. Firstly, globally valid standards should be developed that offer service providers the interoperable use of products by different vendors in one and the same hospital. And secondly, simplified commissioning procedures should be introduced so that service providers can operate a heterogeneous network in the operating room or throughout the hospital. Measures of this kind would permit the evolution of a genuine market where the focus shifts to product quality.

Development work is currently in progress on the supplementary parts of the standards family IEEE 11073 respectively family DIN EN ISO 11073 which define the components of a system that constitutes a standardised architecture for the exchange of data between medical devices. They also give manufacturers the necessary scope so that they can distinguish themselves from other competitors on the market through additional functionalities, quality, and product design. Hence this standards family assumes an important role in promoting competition. Invitations to tender for products specified as per family DIN EN ISO 11073 thus help to save costs, for example in equipping operating theatres, without compromising the quality of medical care.

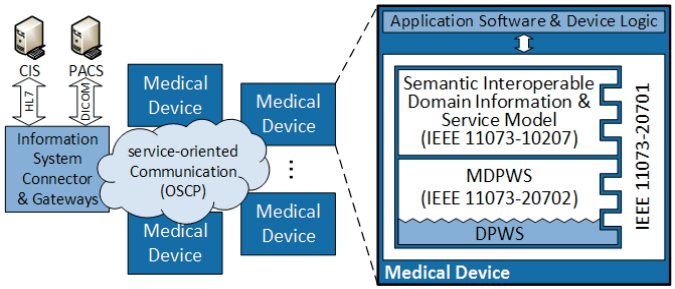
Status quo and results

Three of the draft standards for standardised communication between medical devices in operating rooms and hospitals, developed in OR.NET in cooperation with associated partners, have currently reached the status of authorised projects in the IEEE Point-of-Care Devices working group, with balloting due to take place in the course of the year.

These three draft standards elevate the established standards in the IEEE 11073 family „Health informatics – Personal/health device communication“, with its series of standards for point-of-care device communication, onto the state-of-the-art technology level of a service-oriented architecture for medical devices, thus closing an important gap.

The project name IEEE P11073-20702 refers to what is known as the Medical Devices Profile for Web Services (MDPWS). It expands the Devices Profile for Web Services (DPWS) to fulfil the requirements towards data transfer in network of medical devices. The domain information and service model (IEEE P11073-10207) permits semantically interoperable descriptions of medical device capabilities and the current status, as well as defining means of interaction, such as read or write access or messaging following the publish/subscribe pattern.

Interaction of the standards



Sub-Project SP 4: Standardisation

The third proposal IEEE P11073-20701 defines the overall architecture based on the paradigm of a service-oriented architecture (SOA) together with the protocol binding between the two standards described above. Further aspects include quality of service measures (QoS) and time synchronisation. The breakdown into three separate standards allows for these to be updated and developed independently of each other. It would be possible, for example, to replace the MDPWS transport with another technology without impacting the structure and semantics of device modelling.

These standards specific to medical devices are also joined by others relevant to the operating room context. In the hospital setting, the standard „Digital Imaging and Communications in Medicine“ (DICOM) is established on the global scale for the exchange of medical images, while Version 2.x of „Health Level Seven“ (HL7) is used for administrative data (e.g. patient master data or insurance data) and clinical findings. Both provide information that is also relevant in the operating room, with corresponding gateways permitting their use in the new architecture described above. Semantic interoperability is ensured by using standardised concepts and terminology in both domains connected by the gateways.

The global initiative „Integrating the Healthcare Enterprise“ (IHE) aims to improve the transfer of information between computer systems in the healthcare sector. Use cases refer to integration profiles to describe how various information systems and devices transfer certain data in defined transactions.

Data transfer in the transactions is specified on the basis of standards such as DICOM and HL7. OR.NET has identified various existing profiles that can be used for connecting the operating room to clinical IT infrastructure: *Device Enterprise Communication* for communicating device data to hospital information systems or to a database, *Retrospective Data Query* for querying data from a database, *Patient Demographics Query* for querying patient data and *Scheduled Workflow* for integrating DICOM devices. In the Patient Care Domain, two new work item proposals have been submitted, while a workflow profile has been postulated in the Surgery Domain. Drafts of not-yet existing integration profiles have been prepared.

Furthermore, requirements were identified for test scenarios to verify that the devices safely communicate with each other. This includes the validation of the standard conformity of the messages being transferred *and* of the way the systems behave on receiving regular messages or also in various exceptional situations, such as network problems, dealing with faulty data, or how to react when unauthorised users try to take over control.

Partners of the international standardization platform

HL7 INTERNATIONAL · ETSI · IEC · ISO International Organization for Standardization · CENELEC · IHE Integrating the Healthcare Enterprise · cen European Committee for Standardization Comité Européen de Normalisation Europäisches Kommitee für Normung · IEEE

Outlook

The standards family IEEE 11073 with its three novel parts

- 20701 Service-Oriented Medical Device Exchange Architecture & Protocol Binding
- 20702 Medical Devices Communication Profile for Web Services
- 10207 Domain Information & Service Model for Service-Oriented Point-of-Care Medical Device Communication

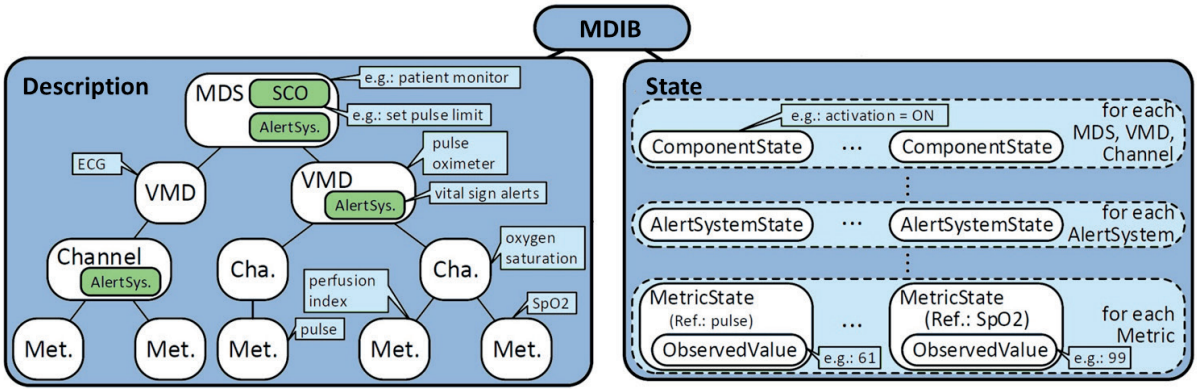
provides the key prerequisites for interoperable communication. The resulting IHE profiles also enhance interoperable communication with the hospital.

Furthermore, the resulting standard architecture has to safeguard access rights and data protection at all critical points, as is also the case in other parts of the hospital. The supplementary standards to the IEEE 11073 standards family already take account of corresponding concepts.

The new draft standards benefit the service providers, as the devices are ready for use via Plug&Play after initial commissioning and are registered accordingly. It is also possible to record and monitor device operating statuses, such as normal status, servicing, error, total operating hours, and availability. As a result, this will improve the transparency, effectiveness, and efficiency of medical processes in the operating room and hospital.

Detailed documentation of past, present, and future standardisation activities can be found in the white paper „Interoperability of devices and systems in operating rooms and hospitals“, issue 2015.

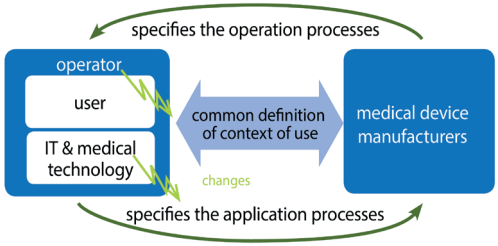
Domain information and service model for semantic interoperability - based on the IEEE 11073 standard



Sub-Project SP 5: Operation strategies

Background

When deploying medical devices, operators of health care facilities especially need to assure safety, reliability and performance. Furthermore, it is necessary to comply with prevailing regulations and standards. Especially when running networked medical devices in settings varying with the use case, operators of health care facilities likely have to implement measures and procedures which require dedicated technical information of and support by the medical device manufacturers. As these might consider such information to be dispensable or might reject the request due to market-strategic or other reasons, operators of health care facilities could run into trouble when trying to deploy and operate networked medical devices.



For example, the use of antivirus software is an established way to protect the entire IT-system against malicious software or malware. To ensure the effectiveness of such software, the database of the virus scanner containing specific code or behavioural pattern of known viruses needs to be up to date. To achieve this, manufacturers of antivirus software publish updates daily, some even several times a day. However, when looking at medical devices, refreshing virus patterns is not that easy. As activities of antivirus software might have a severe negative impact on performance, stability or reliability of the overall medical system, updates of antivirus software need to be evaluated for their impact on the system carefully. Accordingly, either automatic updates have to be deactivated, rendering the system to a higher risk of being compromised by malicious software. This might not only affect the medical device, however, but might also compromise systems all over the health care facility. Or updates are activated instantly, providing higher protection from malicious software, but increasing the chance of antivirus software impairing the functioning of the medical device. This conflict can only be solved in cooperation between the operator and manufacturer.

Challenges

Medical device manufacturers and operators together determine the context of use for a networked medical and information technology system. In this process, medical device manufacturers stipulate the operating processes, while the operators define the application processes.

The sub-project has examined the prerequisites and requirements for balancing interests between medical device manufacturers and operators of these devices, and how this might get implemented. This includes keeping manufacturers of medical devices in the process of risk management according to ISO 80001-1 after the integration of the device into the medical device network and first-time operation. In the scope of sub-project activities essential for operating networks of medical devices have been identified and documented in service level agreements. Additionally, different forms of organisations appropriate to run medical devices networks have been identified. This includes third party organisations as well as internal forms of organisation suitable to assure a safe, secure, and effective use of the medical devices connected. Identifying service level agreements, appropriate business models as well as technical requirements specific for delivering the services and accompanying measures for data protection need to be identified. Synagon is in charge of the project management of sub-project SP 5 for developing operating strategies for networked medical devices.

Status quo

In cooperation with the sub-projects SP 2 and SP 3 reference systems relevant for operation models and corresponding use cases have been identified. According to ISO 80001-1 medical device manufacturers/suppliers have to contribute to the overall risk-

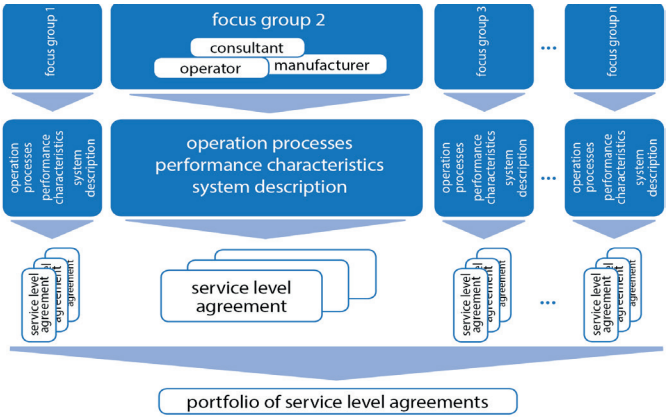
management implemented by the operator of networked medical devices. Building up focus groups focussing on specific use cases, based on these duties taken from ISO 80001 processes for the operation of the networked medical have been developed. Subsequently, these were grouped across the different focus groups into operation models, taking into account the different use cases tackled in OR.NET (spinal surgery, laparoscopic surgery and ear-nose-throat intervention), which had been identified in sub-project SP 2.

The specification of the operation processes includes, amongst others, a characterisation of the IT-network of the service provider as well as a description of the networked systems. Based on the intended use of the medical devices deployed in the medical IT-network, and taking into account the requirements on the IT-network, hazardous situations were identified by means of risk assessment. From this, risk control measures were identified and taken subsequently to derive the corresponding processes for the initial start-up and operation of the system.

Thereafter, the developed service operation processes were mapped and summed up into service level agreements. These service level agreements are the core part of an agreement between an MIT-service provider and its customer containing a specification of the quality and quantity of the service offered by the service provider. For the specification of these services, those activities were specifically focused upon which have to be carried out either on a regular basis triggered by events or periodically. Furthermore, in the context of quality assurance and service level reporting in order to improve the service provided, measurement procedures were defined consisting of indicators to be monitored and reported.

Corresponding to the service level agreements, master service agreements have been identified which are suitable to provide a framework for employment of the service provider. These master agreements were identified by analysing established and standardised prototypes of IT-service agreements, such as the German "supplementary conditions of contract for the procurement of IT services", which are applicable to the procurements of the public sector in Germany. Next to the scope and volume of activities as defined by the service level agreement, these master agreements specify the responsibilities and liability together with contract duration and contract termination. To facilitate the identification of the master contract which is most suitable for the service requested, an Excel-based tool was developed.

The development of the diverse topics and issues has been conducted by means of device and use case specific focus groups, which brought in their particular point of views. Basically, a focus group comprises a medical device operator and one or two medical device manufacturers. These focus groups were complemented by consultants from Synagon.



Outlook

By means of specific focus groups comprising different networked medical devices and corresponding use cases, a set of operational services necessary to run the medical devices integrated into the OR.NET medical device network has been identified. These services have been summed up into a portfolio of service level agreements and supplemented with a corresponding framework of contracts. Additionally, the service level agreements were discussed with an established MIT service provider to assure the generic, device independent applicability of the operational services.

Sub-Project SP 6: Demonstrators

Goals and challenges

The practicability of the OR integration concepts developed in the project has been proved at five demonstration sites throughout Germany, focusing on the different technical and clinical challenges which were constructed. A large set of clinical demands and use cases were technically implemented in close cooperation with sub-project SP 2. The experiences gained during the realisation of the demonstration ORs were directly reflected in the development of the middleware. Additionally, the applications provided valuable feedback and a sustainable reality checks for the standardisation of the novel set of IEEE standards in sub-project SP 5.

The demonstration ORs cover many different research topics which range from device integration based on a service-oriented architecture and real-time communication infrastructure to interoperability of devices and clinical IT systems. As part of sub-project SP 6, reference implementations of the key aspects of the overall integration architecture were developed and tested. The prototypes of medical devices and systems were implemented by the industrial partners. Hence, the demonstration ORs also served as a test field and supported the numerous vendors in the implementation of open, standardised interfaces. For interface development, two compatible reference implementations of the novel standard for medical device interoperability were implemented and successfully applied to a large variety of technical solutions.

The demonstration ORs will serve as a platform for technical and clinical evaluations. Additionally, further development of the standards and new devices will be continued at the demonstration sites in close cooperation with the industrial partners. Prototypes of assistance concepts and novel functionalities, which were enabled by the underlying open OR integration infrastructure, are already presented during public demonstration sessions.

In addition to the established demonstration sites, partners from academia and industry passionately contributed to public exhibitions, most importantly the annual conhIT in Berlin. Numerous visitors from industry, clinical routine and clinic operators have shown great interest in the results of the project.

Research areas on the demonstrator sites

Each of the demonstration sites focused on specific research areas. The solutions implemented in sub-project SP 6 cover a large variety of relevant topics for integrated operating rooms, emerging from the foundation of service-oriented architectures for medical device communication and real-time communication stacks.

The sub-project also demonstrates the developed framework for syntactic and semantic interoperability between the medical device domain and clinical information systems. This is essential for the distribution of patient demographics and order data from the Hospital Information System (HIS) to the medical devices, as well as the documentation of relevant data acquired during the intervention in return.

Besides the technical aspects, enormous efforts have been put into concepts for user interaction with distributed, dynamically integrated OR setups. The surgeons, the anaesthesiologists and OR staff need to interact with numerous medical devices and information sources during the surgical workflow. Thus, frameworks for centralised device interaction, alarms and notifications, as well as information provision were developed at the demonstration sites. This especially includes the sharing of information and control between anaesthesia and surgery as well as tele supervision.

Furthermore, academic prototypes of novel active assistance and workflow management strategies were also integrated into demonstrators to provide a glance at future developments enabled by a cross-vendor integration based on open standards.

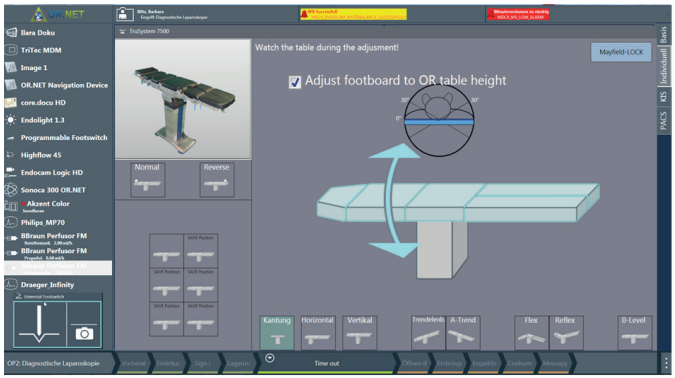
Selected applications of the demonstrator sites

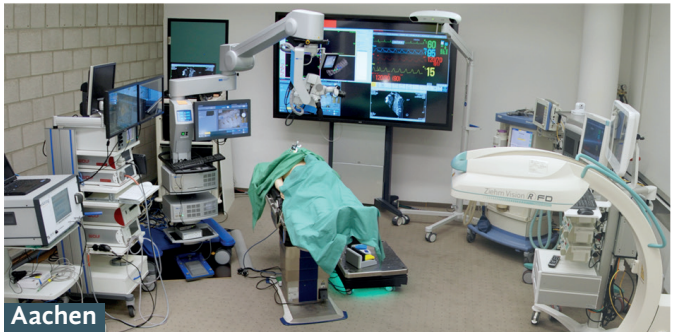
Aachen

Usability and interoperability are the main research areas of the demonstrator in Aachen. The addressed use cases have been de-

veloped in close collaboration with surgeons and anaesthesiologists. More than 30 technical use cases were embedded into a realistic surgical workflow, based on the neurosurgical intervention of a cervical decompression and spinal fusion surgery.

One major result was the development of a common framework for the user interfaces of the central workstations in the OR, which can be used by both, the surgical team and the anaesthesiologist. The concept is able to adapt its information presentation to the differing requirements of both disciplines, but retains a consistent user interface. Usability and interoperability are enhanced and information sharing between surgery and anaesthesiology is eased. The framework visualises information on all connected medical devices, the patient and the intervention, the workflow, as well as





physiological and technical alarms. In addition, it provides access to the Clinic Information System (HIS) and to the Picture Archiving Communication System (PACS).

Another highly relevant use case was addressed with a central Another highly relevant use case was addressed with a central programmable foot switch device for. The system provides a configuration panel for the surgical workstation, which shows the assignment of device functions to foot switch pedals and allows changing this assignment intraoperatively. Thus, the surgeon may use tailored combinations of device's functions.

The usability of the programmable footswitch was tested with 10 surgeons from different surgical disciplines. The preliminary results are promising and the surgeon's feedback indicated that such a system could be helpful in daily clinical routine. Furthermore, valuable suggestions will be considered in future prototypes.

The integration of the safety checklist into the clinical workflow was also considered. The safety check list is strongly recommended by the world health organization (WHO). It consists of three parts, handled by the anaesthesiologist and surgeon in different intervention stages. The safety checklist was integrated into the workflow digitally and the anaesthesiologist and the surgeon can efficiently manage it using the workstation.

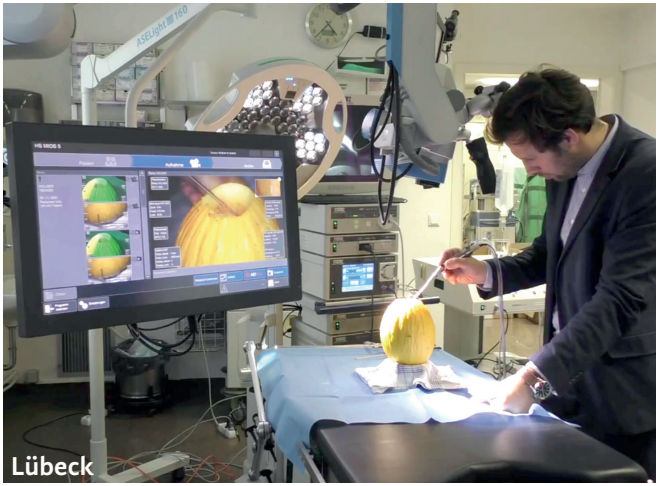
Lübeck

The demonstrator in Lübeck focuses on SOA-based communication and specifically on its technical aspects. It presents, for example, the establishment of a group of interconnected devices, the initialisation of interactions and verification of the systems at runtime. In addition, it allows for integrating existing networked systems, e.g. hospital information systems, into the overall OR.NET framework.

The first project-public demonstration took place in Lübeck in July 2015. The mentioned technical aspects had been integrated into a complex medical device setup, such that their SOA-based interaction and first clinical workflows could be demonstrated. Fur-

Sub-Project SP 6: Demonstrators

thermore, in October 2015 a presentation was given in front of head and senior physicians of several clinics of UKSH Campus Lübeck. The presentation included the networking demonstration of several medical devices including a microscope, an operating light and an endoscope which implemented several medical use cases. The physicians suggested some improvements and further use cases which were taken as an input for subsequent work.


Lübeck

As a proof of modularity of the SOA approach in general and specifically the components developed in Lübeck, several of these have been integrated, during the further course of the project, into other demonstrators such as the ones in Aachen and Leipzig.

Munich

The demonstrator located in Munich focusses on medical device communication with hard real time requirements. Real-time requirements arise whenever data needs to be processed within predefined time slots in order to ensure safe and intuitive operation of the respective device - especially when it comes to instrument control.

Various dedicated hardware modules have been implemented to connect devices of the operating room to standardised communication architecture - ranging from simple aspirators to complex stereo cameras used for surgical navigation.

Furthermore, functionalities such as e.g. sensor-based instrument control, navigation-based instrument control and data fusion of navigation cameras on the basis of the standardised data transferred over the network have been implemented.

Instrument control is possible in parallel with the web service-based communication. This allows the configuration of the devices via web-services and control via the real-time architecture. Furthermore, the real-time network as a whole is compliant with the OSCP protocol, thus allowing for the performance of network-related actions such as manipulating the communication paths via OSCP. The first experiments indicate that time requirements posed by clinicians can be fulfilled by the real-time architecture.

Munich

Heidelberg

The concluding demonstrator at the Heidelberg University Hospital will focus on the standard based integration of clinical IT systems with medical devices to address and satisfy the essential

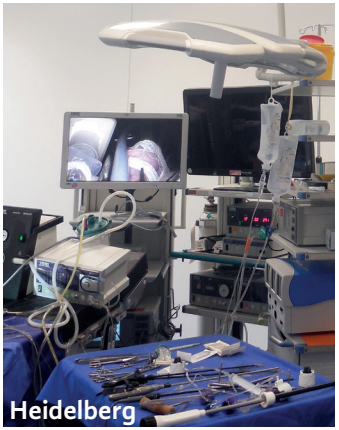
requirements of clinical users and operative responsible persons. This should ideally be achieved by conducting representative clinical workflows in a realistic operating room setting. Typical representative tasks would include e.g.: getting a patient or worklist on medical devices, sending measured data to either a display, an information system (anaesthesia, PACS) or a data warehouse. In order to make the tests as practical as possible, existing test instances of clinical information systems like the HIS Cerner i.s.h.med, the GE Centricity RIS/PACS, COPRA6 PDMS and operational communication servers will be used. For interoperability, established communication standards like DICOM and HL7 will be applied either in form of existing or future IHE profiles or as newly developed components within OR.NET.

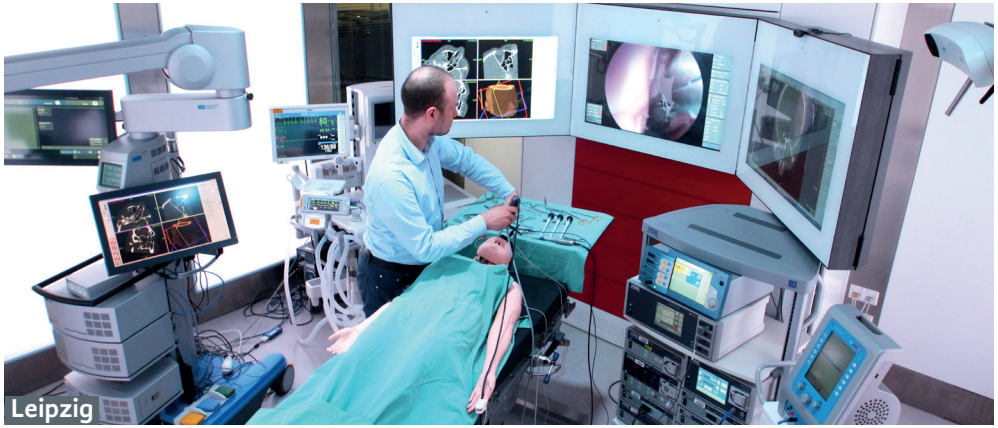
Leipzig

Clinical use cases from head and neck surgery were addressed in the demonstration OR established in Leipzig. The demonstration setups especially focused on rehabilitating middle ear surgery and transsphenoidal resection of pituitary adenoma. Thus, the setup includes a microscope-centric setting as well as endoscopic clinical use case. The surgical workflows, technical environment and user interaction were intensively analysed in close cooperation with experienced clinicians in both use cases. For the most realistic simulation of the surgical workflows, sophisticated patient phantoms are available which include all relevant anatomic structures and allow for drilling, suctioning and soft tissue treatment using the standard instruments and medical devices.

In general, the demonstration OR includes 15 devices and several IT systems from various vendors as well as academic prototypes. The setup also integrates technologies and developments from other demonstration sites, for example a centralised workstation (Aachen), a configurable real-time communication infrastructure for device activation (Munich), and a semantic interoperability engine (Lübeck).

The research and development focused on assistance functionalities and the support of the surgical workflow. A set of challenges and useful high-level services was identified in the conducted surgical workflow analysis. Example applications of workflow management strategies were integrated into the demonstration setting. These prototypes present opportunities enabled by the integration technology to support the surgeon and the OR staff in their routine, especially with tasks of information seeking and device maintenance. The applications include automatic pre-con-


Heidelberg


Leipzig

figuration of operational device parameters, such as revolution speed of the electric shaver, or irrigation. The provided configuration profiles could be applied according to the detected surgical situation. Additionally, a primary surgical display was managed automatically, i.e. the selection of the video source (endoscopy, PACS viewer, Navigation system).

Surgeons, anaesthesiologists, and scrub nurses will evaluate the various functionalities of the integrated demonstration OR. Their experiences and suggestions will be collected in structured interviews and analysed to identify promising directions for further development.

Technical and clinical evaluation

The technical as well as the clinical evaluation of the developed concepts is ongoing research at the demonstration sites. From a technical point of view, mainly the properties of a network of medical devices, latencies in data transmission, and stability are addressed. A careful evaluation of the technical infrastructure and architectural design decision from a technical perspective are crucial to a safe and reliable interoperability of integrated medical devices and IT system in clinics.

The clinical evaluation focused on the future users and stakeholders. Surgeons, anaesthesiologist and scrub nurses work with an operating room integrated based on open standards in different clinical use cases. The user experience is collected in interviews and reports. By means of that, insights are gained into the benefits of the technology and the challenges in future work. Besides the clinicians, clinic operators are important stakeholders in the development and dissemination of integrated operating room technologies.

Thus, public demonstrations and a survey are conducted as part of the "Frühjahrstagung des KH-IT" in Leipzig. A broad set of opinions, experiences, and suggestions will be an essential input for further developments of the integration standards and novel devices and systems within the area of integrated operating rooms.

The demonstration ORs established in the project will be perpetuated to allow for an ongoing development of technical solutions, the dissemination of the developed concepts, and a continuous extension and maintenance of the results of the OR.Net flagship project.

Picture: Swen Reichold

Partners and associated partners

Providers of integrated operating room systems
- Karl Storz GmbH & Co. KG
- Richard Wolf GmbH

Manufacturers of medical devices or device components
- SurgiTAIX AG
- Inomed Medizintechnik GmbH
- Localite GmbH
- KLS Martin Group
- Möller-Wedel GmbH
- Ziehm Imaging GmbH
- Söring GmbH

(IT-) service providers
- UTK - UniTransferKlinik GmbH
- Synagon GmbH
- MedPlan Engineering GmbH
- MT2IT GmbH & Co.

Providers of medical software
- VISUS Technology Transfer GmbH/ R & D

Providers of IT solutions for networking
- MEDNOVO Medical Software Solutions GmbH

Research institutes
- Fraunhofer institute MEVIS
- Fraunhofer institute FOKUS
- RWTH Aachen university - chair of medical engineering
- RWTH Aachen university - chair for medical information technology
- RWTH Aachen university - University hospital, department of integrated tele-anaesthesiology
- University Lübeck - Institute of telematics
- University Lübeck - Institute for software eng. and programming languages
- University of Lübeck - Institute of medical informatics
- University Leipzig - ICCAS
- OFFIS - Institute for informatics e.V.
- University Rostock - Institute for app. microelectronics and data technology
- TU Munich - Institute of micro technology and medical device technology
- TU Munich - Institute of automation and information systems
- TU Munich - Institute for robotics and embedded systems
- TU Munich - Minimally invasive interdisciplinary therapeutic intervention
- University Augsburg - Research center for medical product legislation

Clinical partners
- University hospital Tübingen - Urology
- University hospital Tübingen - Radiology
- University hospital Tübingen - Gynaecology
- University hospital Rostock - Anaesthesiology and intensive care
- University hospital Schleswig-Holstein - Surgery
- University hospital Leipzig - Cardiac surgery
- University hospital of the RWTH Aachen - Anaesthesiology
- University hospital of the RWTH Aachen - Orthopaedic Surgery
- University hospital of the RWTH Aachen - Neurosurgery

Clinic IT departments and clinical operators
- University hospital of Heidelberg - Center for information technology and medical engineering
- Rhön-Klinikum AG
- University hospital of Schleswig-Holstein - IT planning and strategies

Standardization/Approval
- VDE
- DIN- standards commitee medicine (NAMed)
- IHE Germany e. V.
- qcmed GmbH

Associated partners

steute Schaltgeräte Gmbh & Co.KG, GADV GmbH, Fritz Stephan GmbH Medizintechnik, BOWA – electronic GmbH Co. KG, HEBUmedical GmbH, Maquet GmbH & CO. KG, Infoteam Software AG, Synedra information technologies GmbH, Trumpf Medizin Systeme GmbH & CO. KG, Weber Instrumente GmbH & Co. KG, Healthcare IT Solutions GmbH, CeMPEG e.V., TEKNO-Medical-optik-Chirurgie GmbH, Docs in Clouds GmbH, Tritec Elektronic AG, Drägerwerke AG & Co. KGaA, Healthcare Consulting GmbH, HL7 Deutschland e.V., AKTORmed. GmbH, ICT AG, ESCTAIC e.V., Beger Design, UL International Germany GmbH, UK RWTH Aachen – Institut der Medizinischen Informatik, Storz Medical AG, Yacoub Automation GmbH, Ilara UG, Dr. Hornecker Softwareentwicklung und IT-Dienstleistungen, EIZO GmbH, G.punkt medical Services, DEKOM Engineering GmbH, HB Technologies AG, SemVox GmbH, Fraunhofer VVS, SMARTIT, UK Carl Gustav Carus an der TU Dresden, MT2IT, Open Connections GmbH, IT4process GmbH, Cerner Health Services Deutschland GmbH, Simeon Medical GmbH & Co.KG

Members of the steering commitee
- Dr.-Ing. Wolfgang Lauer, BfArM, head of research group for safety of medical devices
- Dr. Julian Goldman, CISE Advisory Committee at NSF
- Dr. Max Skorning, head of department for *patient safety*, MDS
- Hans-Peter Bursig, ZVEI – German Electrical and Electronic Manufacturers' Association, competence centre health management
- Stefan Vollmer, Federal office for security of information technology
- Dr. Maureen Baker CBE, Clinical Director for Patient Safety, NH, UK

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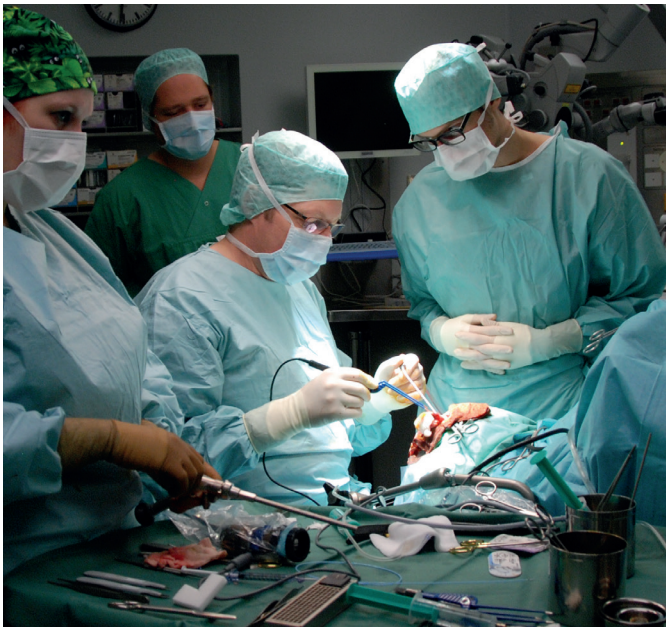
The OR.NET Non-Profit Association

What's next?

The dynamic interconnection of medical devices in the OR-network as well as the interaction of these devices with medically approved software is a particular challenge to information- and communication technologies in the medical field. The aim of the OR.NET non-profit association is to **continue the work** which has been done during the OR.NET project in 2012 - 2016.

Fundamental concepts for the secure and dynamic networking of components in operating room and hospital shall be further developed, evaluated and brought into standardization processes. For these concepts appropriate offers for training and further education and for services related to testing and approval have to be developed in order to ensure sustainability.



The OR.NET Association consists of several working groups, which build the operational base for cooperation and teamwork within the association:

- Industry
- Clinical users and operators
- Standardisation and Internationalisation
- Human-machine-interaction and Risk Management
- Regulatory affairs
- Software Stacks (Library)
- Test labs, simulators and data security
- Education and training
- Approval strategies
- Coordination of OR.NET test labs and demonstrator sites

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SECURE AND DYNAMIC NETWORKING IN OPERATING ROOM AND HOSPITAL

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