

SDC: Operate multiple medical devices using a single control



New tasks and new technologies for user interfaces

When, in the near future, Service-oriented Device Connectivity (SDC) becomes reality and medical devices in the operating theatre become "interoperable", the impact on the user interface will be considerable. Manufacturers are already prepared for this – and are busy with further developments. Current projects include real-time communication between the interoperable user

interface and the corresponding medical devices, utilisation of 5G-based network infrastructures and simple integration of antennas in the surfaces of interface enclosures.

First developments towards the "interoperable OR" were within various funded projects nearly twenty years ago. Since then, things have moved beyond the normative. First



Wireless user interfaces are now standard in the OR – and enable multiple medical devices to be controlled by a single user interface.

products are nearly ready for launching, the SDC family of standards is developing and growing step by step, and there are first demonstrators and trials, as well as exciting projects surrounding further practical development of the SDC concept.

Multiple medical devices – one user interface

From the point of view of a manufacturer of controls for the operating theatre, i.e. for medical devices from a range of disciplines (electromedicine, diagnostics, medical imaging, ophthalmology), interoperability is a true transformation. In the ideal case, one central user interface consisting of e.g. a screen/keypad unit and a foot switch will be sufficient to operate all the medical devices in the room. This means new tasks for the user interface – true to the motto "and one for all".

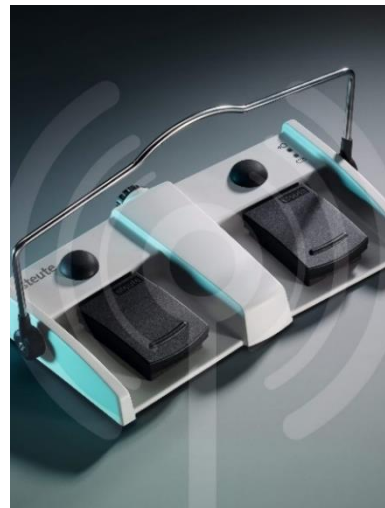
A central user interface is important because in the operating theatre an ever-growing amount of equipment is required for each operation. Multiple devices are required for anaesthesia alone (anaesthetic apparatus, patient monitor, syringe driver...), and the same is true of the surgery itself (HF device, endoscopic device, 3D navigation...). Integration of imaging techniques in the OR

(surgical microscopes, mobile X-ray units...) increases the complexity further.

Two prerequisites for device integration

Two conditions must be fulfilled if the prospect of simplified device operation in the OR is to become reality. Firstly, communication between medical devices and their user interface must be standardised, i.e. be generally compatible with different device classes and manufacturers. This is facilitated by the ISO/IEEE 11073 ("Service-oriented Device Connectivity/ SDC") family of standards. The standards committees expect to have completed processing of all basic standards currently in preparation by 2025. Standards are also being developed for individual medical device types.

Secondly, the central user interface must include new functions – in particular a way of switching between devices and/or visualisation of multiple devices or functions on one screen. Multiple demonstrators, co-developed by the steute division Meditec, show how this function can be (simply and ergonomically) realised.



A state-of-the-art example of standard wireless foot switches for medical devices. The compact receiver unit is installed in the device.

The future: communication via integrated SDC connectors

At the hardware level, the SDC concept in the OR is realised in a first step by connecting all medical devices via integrated SDC connectors. The development and implementation effort required is smaller due to the incorporation of standards within these connectors, meaning that devices can be linked more easily to other devices, e.g. of larger manufacturers. In particular for small and medium-sized enterprises (SME), market entry will then be more viable.



A state-of-the-art OR.NET demonstrator for the interoperable OR.

First pilot projects and practical experience

Both the hospitals and the manufacturers of medical devices are placing their trust in standardised communication according to the SDC concept as the way forward, illustrated by their keen participation in relevant standardisation efforts and pilot projects. No approved SDC devices are available to date, but there are first pilot applications in hospitals, for example at the Charité in Berlin. And work is also underway on standardisation projects for the interoperable OR in both Asia (Japan) and North America (USA).

Wireless technology as the basis for SDC

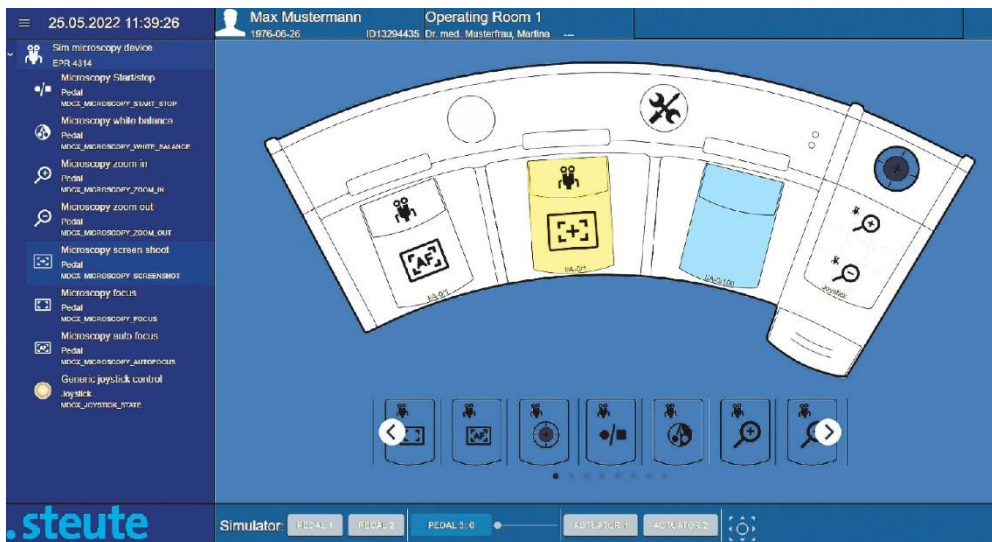
Since wireless controls, and in particular wireless foot switches, are widespread in operating theatres today, it is an obvious choice that communication in the interoperable OR of the future will also be wireless. As a manufacturer of user interfaces, steute Meditec has developed a wireless system which is designed especially for the requirements of medical devices. It facilitates very reliable wireless signal transmission and

can fundamentally also be used for SDC. However, some further developments are partly necessary and partly desirable.

Further development: real-time SDC

For the inclusion of user interfaces such as foot switches in the integrated OR, SDC must work in real time: surgeons have to be able to operate the medical devices, and most importantly switch them off safely, without any noticeable delay. Real-time operability is also absolutely crucial for inter-device communication, for example in closed loops.

In its basic version, however, SDC is not yet able to work in real time. Together with research partners, steute Meditec is therefore driving forward the improvement of this feature – to arrive at real-time SDC (RT-SDC). Communication will then be possible via the ethernet-based time sensitive network (TSN) family of standards to IEEE 802.1. It will be this development from steute Meditec which will enable SDC to control critical functions of medical devices in hospitals and operating theatres. At the hardware level, an SDC



Multiple medical devices can be selected and operated via a central user interface (foot switch combined with monitor/ keypad).

connector will facilitate the integration of user interfaces in the RT-SDC network.

5G campus network for the OR

Reliable localisation of both the user interfaces and the corresponding medical devices is an important prerequisite for communication in the SDC-compatible OR. For this reason, the research project KliNet5G, in which steute Meditec is a partner, is evaluating the realisability of an open 5G-based network infrastructure in hospitals.

One goal is to realise a safe and time-critical triggering of medical devices using a universal foot switch, as well as the localisation of medical equipment within the grounds of the hospital in question. Here 5G and low-energy sensors come into play, as well as an SDC connector developed by steute Meditec. In the further course, device functions are to be planned prototypically using 5G mobile and network technology.

Simplified antenna integration

In a project initiated by the "it's OWL" (Intelligent Technical Systems OWL) cluster of experts, steute Meditec and partners are working on new ways of simplifying integration – particularly of the antenna – in the user

interface, and where required also in the medical device. The "Merlin" project has developed so-called "mechatronic integrated devices" (MID), which can be manufactured using additive production techniques. This enables antennas, but also circuit paths and sensors, to be printed in the same process.

Data security is paramount

As with every project involving networks and data exchange, SDC networks must address the issue of security and data security – not least because sensitive patient and medical data are at risk. Here, too, an R&D project with steute Meditec participation has just reached completion.

The Mittelstand 4.0 Centre of Excellence in Kiel (M4KK), together with the approval expertise of the UniTransferKlinik Lübeck GmbH (UTK), has analysed the cybersecurity aspects of steute foot switches currently used in the OR. The aim is to fulfil the requirements of the FDA "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices". On this basis, steute is currently establishing new methods in order to increase the reliability of its data security and to protect its foot switches, including their wireless interfaces, from cyber attacks.

The next steps

Even though it now seems certain that SDC will be market-ready in the foreseeable future, there are still some fundamental questions and many smaller details which require clarification. The abovementioned projects are working to achieve this. The ultimate goal is for

as many manufacturers as possible to equip their devices with SDC-compatible interfaces in the near future – in order to enable the interoperable OR, with all its benefits and after more than twenty years of intensive preparation, to become reality. New generations of appropriate user interfaces are ready and waiting.

Author:



Julia Mönks
Product Manager MMI
steute Technologies

Images: steute Technologies GmbH & Co. KG