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Interfaces for the interoperable OR

With the dynamic integration of devices in the "interoperable OR", new interface generations are emerging

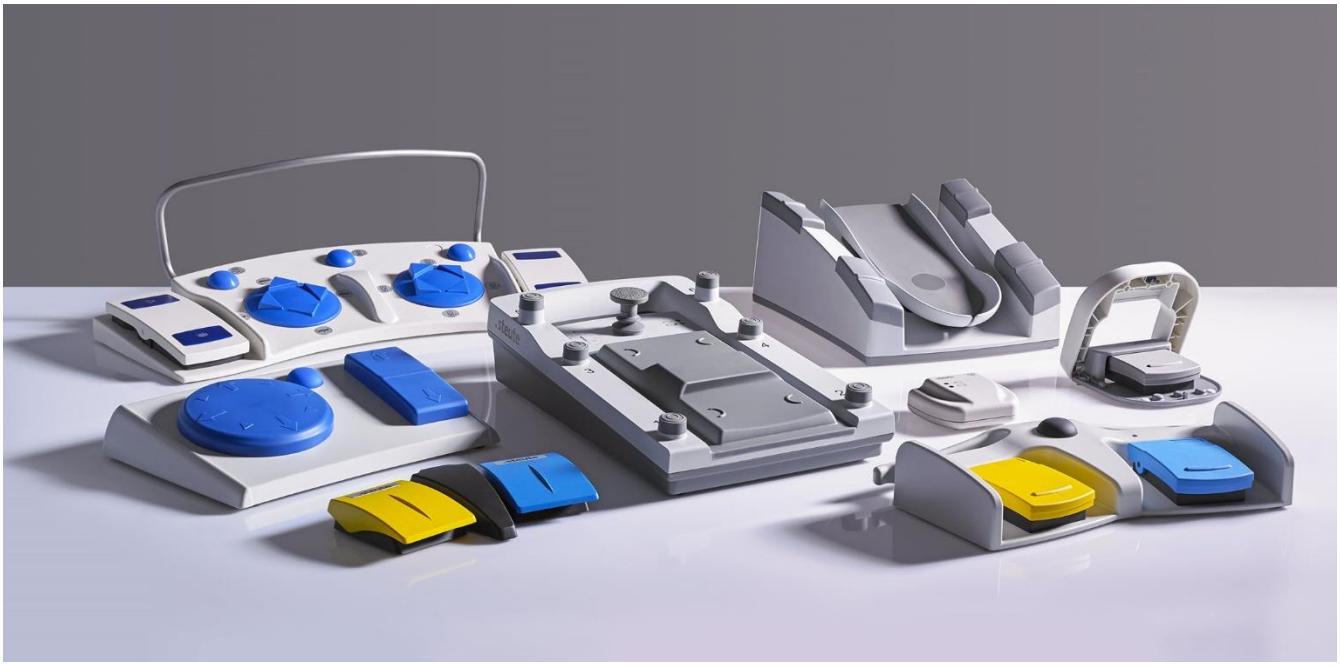

Fig. 1: User interfaces for medical devices are becoming increasingly complex

In edition 5/2018 of the meditronic journal, authors from the RWTH Aachen University (RWTH) and Aachen University Hospital report typical OR situations in which the existing controls for medical devices caused delays in surgical procedure. In one concrete case, a surgeon needed to adjust the operating table, but could not leave the sterile surgical zone for the non-sterile table adjustment zone, and all his colleagues in the non-sterile zone were otherwise occupied.

Current status: improvements needed

This is just one of many examples illustrating the benefits of the interoperable OR. Numerous experts believe that this is the way forward as an increasing number of devices find their way into the OR, all of which need to be controlled. Today a surgeon might have to handle eight or even ten different interfaces, often located as foot controls below the operating table. This in turn requires a high degree of concentration because the surgeon has to keep adjusting

steute Schaltgeräte GmbH & Co. KG
Brückenstr. 91
32584 Löhne, Germany
Phone: + 49 (0) 5731 745 0
Fax: + 49 (0) 5731 745 200
info@steute.com
www.steute.com

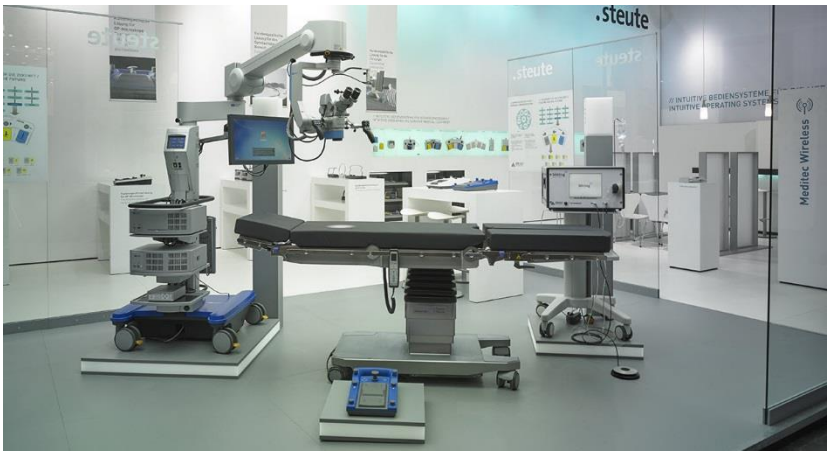

Fig. 2: Demonstrator for a user interface in the interoperable OR. The surgeon determines via a touchscreen or voice control which medical device should be controlled by the user interface.

from one design of foot control to the next. It would be far better if surgeons could just concentrate on their patients. The variety of controls also makes their intuitive handling - desirable for both safety and usability - difficult.

Research projects advance interoperability

On the basis of these findings, the authors of the article in Vol. 5/18 have set out the wishes of users and hospitals. These wishes revolve around "the direct possibility of accessing all relevant devices and functionalities, as well as integration and workflow support." This is precisely the goal of the lighthouse project OR.NET. Following completion of its funding by the German Ministry for Education and Research (BMBF), it is now being continued as a registered association alongside the projects ZiMT (certifiable integrated medical equipment) and MoVE (Modular Validation Environment for Medical Device Networks). RWTH Aachen is involved in all three projects, and so is steute Technologies GmbH & Co. KG. The steute business unit Meditec develops and produces user interfaces for medical equipment in different fields (e.g. electrosurgery, ophthalmology, imaging..., Fig. 1)

One user interface for multiple medical devices

Four years ago, steute Meditec – within the framework of OR.NET and in cooperation with manufacturers of medical equipment – developed a first multifunctional user interface enabling several different medical devices to be controlled (Fig. 2). On a touchscreen the surgeon selects the device to be used and then controls it via a single foot control from the steute Meditec standard range. Intuitive use of the touchscreen is sufficient, for example, to change from X-ray to ultrasound, from navigation to table adjustment, or from microscope to HF device, and immediately the central foot control assumes the corresponding functionality. The current pedal configuration is displayed at all times.

Such a user interface allows the controls to become interoperable. In addition – and that is another goal of the abovementioned projects – they can be integrated in superordinate communication systems. Following on from the funded research project, OR.NET e.V. coordinated the further management and development of the IEEE 11073 SDC (Service-oriented Device Connectivity) standards. These standards regulate open communication facilitating the integration of medical devices from as many different

steute Schaltgeräte GmbH & Co. KG
Brückenstr. 91
32584 Löhne, Germany
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Fax: + 49 (0) 5731 745 200
info@steute.com
www.steute.com

manufacturers as possible in the dynamic network.

Search for new control concepts

From the perspective of a leading manufacturer of user interfaces, besides dynamic networking there are additional research fields with future prospects for surgical practice. They include the evaluation of new types of interaction via voice or gesture control currently becoming established in consumer goods and electronics (gaming consoles, Apple Siri, Amazon Echo....) and the automotive sector (from the VW Golf to the BMW 7-series). The question is: can technologies such as voice or gesture control also make sense as an option for new human-machine interfaces in the OR?

steute Meditec investigated this question within a research project from the "Intelligent Technical Systems – it´s OWL" cluster of excellence. The project was called "OPtimal – multimodal and adaptive user interfaces for the OR", and in it steute collaborated with CITEC, from the University of Bielefeld, an institute which conducts top-level research into robotics and human-machine communication.

Voice, eye or gesture control in the OR?

The project focused on multimodal operation. In the very early stages, gesture and eye control could soon be discounted because they were too burdensome to the activity (countermovements) or concentration (eye strain) of the surgeon. Voice control, on the other hand, proved realistic and was tested on a prototype in three different actuation scenarios: the (virtual) medical devices were controlled by universal foot control, by voice control or

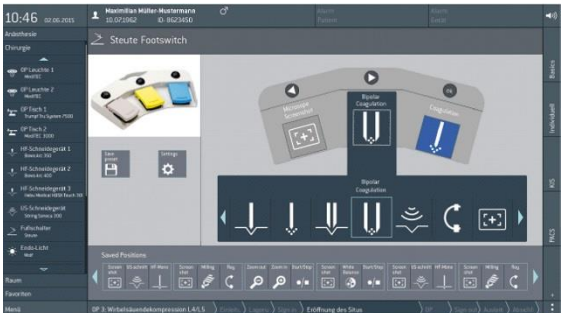

Fig. 3: The surgeon defines via touch screen or voice control which medical device is operated with the user interface

multimodally using a combination of foot and voice control (Fig. 3).

Evaluation: voice control of medical devices

Sixty test persons performed these scenarios within the context of (simulated) spine surgery. A comprehensive evaluation including not only performance but also cognitive strain on the user showed: the best results and the highest acceptance were both achieved when the tasks were "shared" by foot and voice control. The test persons predominantly (and increasingly over time, i.e. as their experience grew) used the foot control to trigger functions and commands. This has been the typical task for foot controls in the OR to date, confirming that this is an appropriate or even ideal use for them.

When selecting devices, on the other hand – which device should the foot control currently operate? – voice control proved to be the more practicable method. In applications and demonstrators realised for the interoperable OR to date, this task is usually assumed by touchscreens.

Dynamic integration as a development task

From the point of view of usability and user experience, there are thus many benefits of the concept "foot for functions, voice for

steute Schaltgeräte GmbH & Co. KG
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32584 Löhne, Germany
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info@steute.com
www.steute.com

devices". In the project there was a clear preference for innovative user interface design in the OR, which will be further pursued. In addition, steute Meditec will – in the three abovementioned initiatives and in its own research and development, as well as in cooperation with manufacturers of medical devices – continue to drive forward the dynamic integration of devices in the OR and to develop interoperable user interfaces.

These various focal points of research can be teamed up in practice. At the Medica 2018, steute Meditec presented an OR.NET project with an interoperable user interface using not only a central wireless foot control unit, but also a touchscreen and voice control.

Acknowledgements

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Increasing documentation required for user interfaces

Cabled controls are now only to be found in medical equipment in market segments which are very price-sensitive. All the user interfaces described in this article communicate with their corresponding medical devices by remote control. steute has developed a wireless standard specifically for this purpose, fulfilling all the requirements for medical equipment, including reliability and operational safety.

Fulfilment of these requirements increasingly needs to be documented with test results and approvals. For example, the EU "Radio Equipment Directive" (RED) and the EMC guideline for medical equipment applications (IEC 60601-1-2:2016) are both crucial. Equally important is the test of coexistence with other wireless networks or frequencies according to standards such as IEEE/ ANSI C63.27, or the FDA regulations and corresponding documentation that all test results meet their standards. Further documentation obligations include software validation according to EN 62304 and risk management to EN 14971.

steute Meditec can support the manufacturers of medical devices regarding testing and certification of user interfaces to these and additional standards, and can also optionally provide a "Certificate of Compliance", issued as the result of an independent test by the CSA. Moreover, steute can help manufacturers to gain a "CB certificate", in line with the "CB scheme" for electromedicine and recognised by international approval bodies.

steute Schaltgeräte GmbH & Co. KG
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32584 Löhne, Germany
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Fax: + 49 (0) 5731 745 200
info@steute.com
www.steute.com

Authors:

Guido Becker
Product Manager Meditec
steute Technologies

Julia Mönks
Product Manager MMI
steute Technologies

Images: steute Technologies GmbH & Co. KG / CiTEC, Bielefeld

steute Schaltgeräte
GmbH & Co. KG
Brückenstr. 91
32584 Löhne, Germany
Phone: + 49 (0) 5731 745 0
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