Technical article, published in: NET (5/2022)

The benefits of remote control

Trends in user interfaces for medical devices

Medical devices in the OR are now usually connected to their corresponding user interfaces by remote control. This makes additional documentation necessary, but the advantages still far outweigh any disadvantages, and device manufacturers can purchase the systems with all the necessary approvals in place. Furthermore, radio technology is a prerequisite for interoperability in the OR: in the future, multiple medical devices will be operable via a single (wireless) user interface. First applications using this technology, known as SDC (Service-oriented Device Connectivity), are already available.

Fig. 1: Wireless user interfaces in the OR – demonstrated here by steute Meditec at a medical equipment fair – are now standard

Initially, only top-of-the-range medical devices communicated with their user interfaces (mostly foot controls) using radio technology. Meanwhile, however, remote control has also become the norm for "mid-range" medical equipment (Fig. 1).

There are good reasons for this, some of which, e.g. more flexible positioning of foot controls, are familiar from other application fields. More specific to medicine are two further benefits: eliminating cables improves hygiene, and wireless technology facilitates the operation of multiple medical devices using a single user interface. This functionality is known as interoperability and is an important (future) trend in the medical field, not least because the

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

number of devices used in the OR is steadily increasing, with six or seven different foot controls no longer unusual. Here there is most definitely room for improvement.

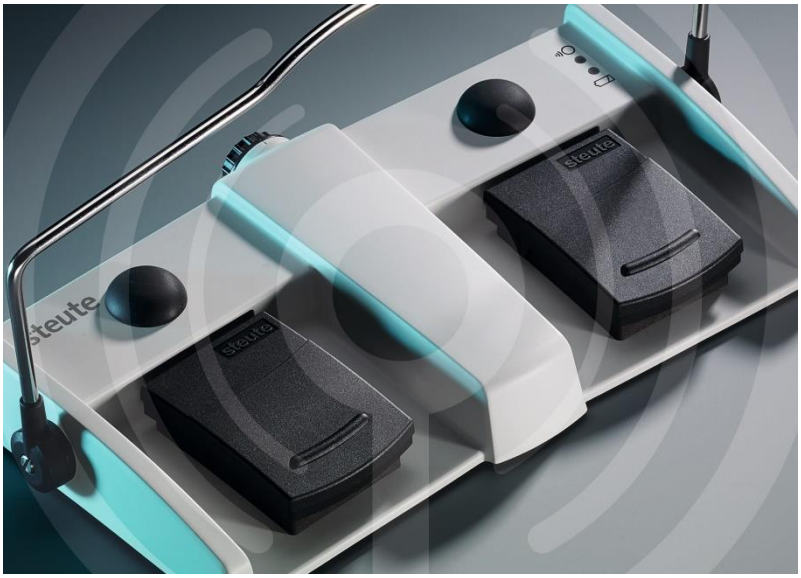

Fig. 2: One example of a wireless standard foot switch for medical devices. The compact remote control receiver unit is installed and connected directly in the device

Special wireless protocols

An additional reason for the intensive use of remote control in the OR is highly reliable wireless technologies, e.g. the SW2.4LE-MED protocol from steute Meditec based on Bluetooth LE, which have been developed specifically for the requirements of medical equipment. The features of this protocol include low energy consumption with a fast response time, as well as high transmission reliability (residual error probability below 10^{-9} 1/h), fulfilling the requirements of SIL 3 to IEC 61508.

For these reasons, nearly all the customised user interfaces developed by steute Meditec with medical devices manufacturers from different disciplines (electromedicine, laser surgery, ophthalmology, imaging techniques such as CT and MRI...) communicate with the medical device in question via remote control. Wireless user interfaces are also becoming the norm for standard user interfaces, e.g. the CSA-certified foot controls in the steute Classic range (Fig. 2).

Wireless-specific documentation

In general terms, the normative requirements and the effort of producing documentation for medical equipment are high. The same is true of the wireless technology to be used in the OR, requiring adherence to, for example, the Radio Equipment Directive (RED), the EMC directive for medical devices (IEC 60601-1-2:2016) and where appropriate also country-specific regulations for wireless systems.

The higher requirements are justified, not least because increasing numbers of wireless systems are being used in the OR. For this reason, for example, coexistence in conjunction with diverse radio networks and frequencies (WLAN, Bluetooth, Zigbee, microwaves ...) must be tested, proven and documented to IEEE/ANSI C63.27. The FDA also demands from medical device manufacturers proof of coexistence of wireless systems.

Customised user interfaces

For user interfaces in the steute Classic range, the above-mentioned proof is easy for customers to produce. These standard wireless controls have been tested to all relevant standards, and their radio module

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Fax: + 49 5731 745-200
info@steute.com
www.steute.com

is approved for use in major markets such as North America (FCC), Europe (RED), Canada (IC) and Japan (ARIB). The corresponding certificates including test reports are included in the delivery, so that they can easily be integrated in the documentation of the overall system, i.e. the medical device (Fig. 3).

Simplified documentation

In contrast, for customised user interfaces in the steute Custom range, these tests must all be performed and documented individually. Here steute Meditec aspires to assist its customers with all the mandatory tests and documents as comprehensively as possible and in accordance with the aforementioned directives.

Nevertheless, it is ultimately the responsibility of the medical device manufacturer as the marketing authorisation holder to provide proof of conformity. With the tests and corresponding documentation including all test reports, however, the device manufacturer only has to check the test results for applicability of the values following integration of the user interface in the overall system. This procedure is known as delta or gap analysis. It is compliant as a simplified approval for wireless products in accordance with the ETSI standard (ETSI EG 203 367).

Certificate for worldwide approval

Following on from the documented tests of its wireless user interfaces, steute can optionally provide a »Certificate of Compliance«, awarded by the CSA (Canadian Standards Association). Moreover, a CB (Certification Body) certificate can be issued which follows the CB schema familiar from electromedicine and accepted by international approval bodies.

Comprehensive software testing

But this is by no means an end to the total documentation required. Since customised user interfaces also require individual software, additional and comprehensive testing and documentation regulations apply, taking into account all phases of the life cycle process to EN 62304. This is also true for cabled user interfaces if they use individual software (for example, connection to a bus system). Both types of test or proof can be handled by steute Meditec. In addition, for all user interfaces – including cabled ones – a risk assessment must be conducted. The results are made available to the medical device manufacturer by steute as basic data for the risk analysis of the overall system.

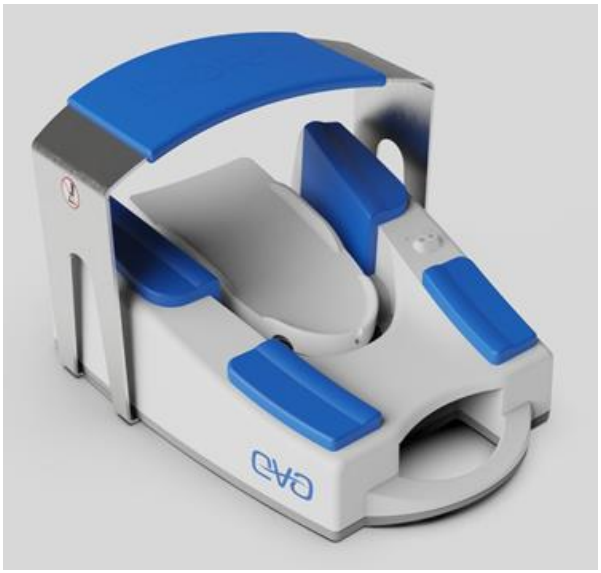

Fig. 3: For customer-specific user interface developments, SW2.4LE-MED wireless technology is used almost without exception. Shown here is a foot control for an ophthalmological device

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Documentation according to MDR and FDA

Following on from all inspections, test reports, analyses and documents, the medical device manufacturer receives documentation which is as comprehensive as it is compliant with the relevant standards – globally recognised and saving the manufacturer much time and effort. This service offer is not only for Europe, but also for the USA, where FDA regulations are in force.

It is certainly true to say that the extra documentation required for radio technology is not a hurdle, especially when it is performed for the manufacturer as part of an all-round service. And in return, surgeons have clear advantages when using wireless user interfaces, which is why radio technology has become the gold standard in the OR.

Medicine 4.0

The trend towards wireless user interfaces also makes perfect sense when viewed from the aspect Medicine 4.0, with these controls having become immensely important in current projects on the so-called interoperable OR (see Fig. 1).

In the healthcare sector, interoperability generally means the uninterrupted use of health-related and patient-related data. A practical consequence in the OR is that pre-existing data (e.g. from medical imaging) can be used and compared with current data (e.g. from surgical cameras).

At the medical device level, interoperability means: a single user interface (e.g. a combination of monitor and foot control, Fig. 4) will in the future be capable of operating multiple devices, including medical imaging devices. This facilitates intuitive use by surgeons and surgical staff, and will improve workflow in the OR.

Wireless as an "enabler"

An important prerequisite for realisation of the integrated OR is use of (flexible) wireless technology for communication between the central user interface and the various medical devices. In order to make this happen, standards must be created across devices and across manufacturers. In Germany this goal is being driven

Fig. 4: Wireless enables: via a central user interface (foot switch and monitor/ key-board), multiple medical devices can be selected and operated

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forward – with the participation of steute Meditec – by groups like the registered association OR.NET e. V.

Communication protocols for the mutual integration of medical devices already exist, familiar as SDC (Service-oriented Device Connectivity). Standards have already been developed on the basis of these protocols and published as the IEEE 11073 standards family. The benefits of standardisation are obvious: when all medical devices in the OR can be connected via a standardised basic network interface, this saves developer capacity. In the medium term, devices will be connected via integrated radio modules and a directly implemented SDS interface.

This wireless-based technology will be extremely advantageous to both hospitals and medical device manufacturers, as indicated by the active participation of companies in moves towards standardisation and pilot projects. Practical SDC applications already exist in some hospitals, including the Charité in Berlin. The wireless technology developed specifically for this application is an important "enabler" for interoperability in the OR.

Author:

Guido Becker
Division Manager Meditec
steute Technologies

Images: steute Technologies GmbH & Co. KG

steute Technologies GmbH & Co. KG
Brückenstr. 91
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