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Wireless benefits

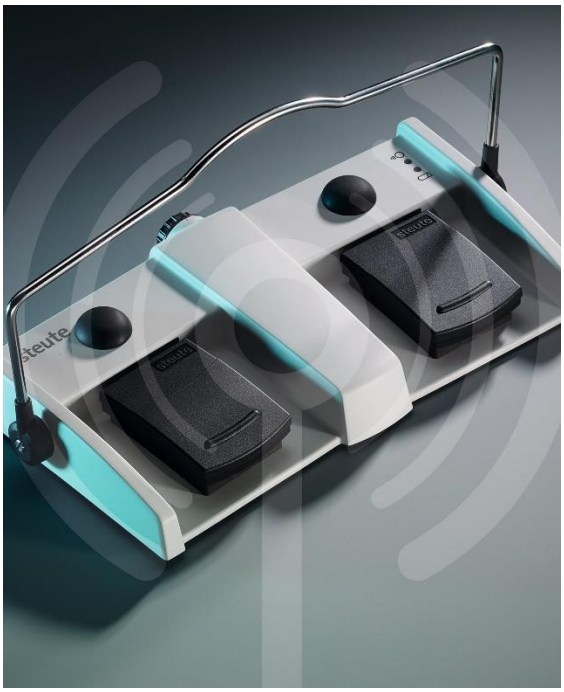
Nearly all customised user interfaces developed by steute Meditec in cooperation with medical device manufacturers communicate with the device in question via remote control. And wireless command devices are also becoming increasingly popular as standard user interfaces – with good reason.

In the early days of wireless technology, only extremely expensive medical devices communicated with their user interfaces – predominantly foot switches – by remote control. Today, this technology can often be found in »middle of the range« medical equipment – and there are good reasons for this. Wireless controls can be positioned far more flexibly, permitting increased ergonomic comfort. The »missing« cables and cable glands make the controls more hygienic, and a single user interface can now even be used to control multiple medical devices. In order to facilitate this new feature, special wireless technology has been developed specifically for the OR. When wireless user interfaces are optionally available with complete documentation complying with the MDR (Medical Device Regulation) and FDA (Food and Drug Administration), the (extra) effort of providing »compatible documentation« for the wireless technology is not a valid argument against it.

Another reason for the intensive use of remote control is the availability of highly reliable wireless technologies developed especially for the requirements of medical equipment, for example the SW2.4LE-MED protocol developed by steute Meditec. Its features include a low power consumption in conjunction with high transmission reliability (residual error probability below 1 x 10^{-9} 1/h), fulfilling the requirements of SIL 3 to IEC 61508.

Not to be underestimated: the effort of providing documentation

The effort required to test wireless user interfaces for the OR and to produce the



Example of a wireless standard foot control for medical devices. The compact receiver unit is installed inside the device.

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corresponding documentation should not be underestimated, however. Amongst others, the »Radio Equipment Directive« (RED), the EMC Directive for Medical Electrical Equipment (IEC 60601-1-2:2016) and where relevant also country-specific directives for wireless systems all need to be taken into account.

The elevated requirements are justified, not least because more and more wireless systems are being used in the OR. For this reason, the coexistence of different wireless networks and frequencies (WLAN, Bluetooth, Zigbee, microwaves...) must be tested, proven and documented to IEEE/ANSI C63.27. The FDA stipulates that medical device manufacturers must provide evidence of coexistence for wireless systems.

For user interfaces in the steute Classic range, it is very easy for device manufacturers to provide the aforementioned evidence. The standard wireless controls have been tested to all relevant directives, and their radio module is approved for major markets such as North America (FCC), Europe (RED), Canada (IC) and Japan (ARIB). The corresponding certificates and test reports are included in delivery, enabling them to be integrated in the documentation of the overall system.

For tailor-made user interfaces in the steute Custom range, however, these tests must be performed and documented individually. Here the manufacturer of controls for the OR aspires to assist its customers with all the mandatory tests and documents as comprehensively as possible and in accordance with the aforementioned directives.

The SW2.4LE-MED wireless technology is nearly always deployed in customised user interface developments. Shown here: a control system for a surgical microscope.

Simplified procedure: gap analysis

Nevertheless, it is ultimately the responsibility of the medical device manufacturer as the marketing authorisation holder to provide the 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).

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.

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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).

Test and documentation obligations actually extend even further because the risks for users and/or the environment also need to be ascertained. The EN 14971 requirements for risk management (also obligatory and also requiring documentation) apply. In addition, all user interfaces – including those with cables – must undergo a risk assessment. The device manuacturers then receive the results from steute for inclusion as input data in the risk analysis of their overall system.

All-inclusive: documentation to MDR and FDA

It goes without saying that customers can be optionally provided with certification, validation and documentation of the user interface in accordance with the medical device regulations (MDR). The device manufacturers can then simply include this documentation in their overall device documentation, proving that the user interfaces comply with the requirements of the MDR.

This service is offered by steute not only for Europe, but also for the American market if required. The company is registered as a contract manufacturer with the FDA within the framework of the FDA Establishment Registration (21 CFR 807) and, as such, can link as a contract manufacturer to the device listing of the medical system manufactured by the customer. From the point of view of the medical device manufacturer, this also simplifies the approval process.

Following all tests, test reports, analyses and paperwork, the medical device manufacturer receives documentation which is comprehensive, compliant with the standards, recognised worldwide and which eliminates a good deal of time and effort. At the same time, this documentation – independently of the regulations – is evidence of the high standards of development and safety for both the user interface and the overall medical device.

With a view to Medicine 4.0, the trend towards wireless user interfaces also makes sense as they become increasingly significant in ongoing projects surrounding the interoperable OR.

Outlook: interoperable OR

In the future, a single user interface (for example a combination of monitor and foot control) will be able to operate multiple devices, including medical imaging devices. This will facilitate intuitive operation by the entire surgical team and improve workflow in the operating theatre.

This research project – in which steute Meditec is participating – is driven by the OR.NET e.V. association. Communication protocols for the mutual integration of medical devices already exist, familiar as SDC (Service-oriented Device Connectivity). Standards have already been developed (in particular the IEEE 11073 standards family). And practical applications of SDC can already be found in hospitals.

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