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User interfaces: from manufacturer to service provider

– Comprehensive documentation all-inclusive –

Wireless user interfaces are now standard in the OR – here a demonstration installation from steute Meditec at a medical equipment fair

Wireless user interfaces have multiple benefits, making them a popular choice in many medical disciplines. However, they also involve a higher level of effort for device manufacturers with regard to testing and documentation than cabled controls – unless the supplier is MDR-ready and able to provide the user interface with all the relevant documentation.

The documentation effort involved in medical equipment development is increasing palpably as a consequence of new directives and standards. The Medical Device Regulation (MDR) is probably 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

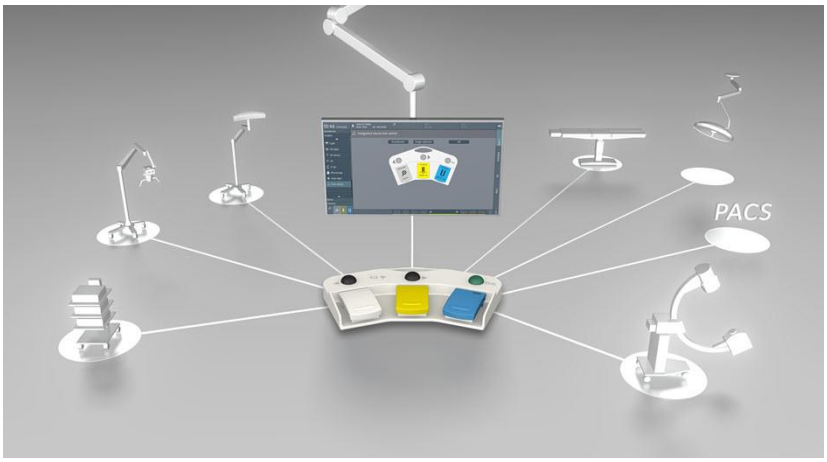
best known, but by no means the only example here. However plausible the meticulous documentation, tests and proofs required for medical equipment may be: they make using new technologies, which have considerable practical benefits in the OR, more complex and more time-intensive – at a time when new directives and requirements are increasing the necessary documentation effort even for medical equipment at the "status quo" level.

From the point of view of suppliers of subsystems for medical devices, the complex documentation has long ceased to be only about coexistence and can now be an obstacle to the wider deployment of innovations. That is also and especially true of wireless technologies used to communicate between medical devices and their user interfaces.

Wireless systems increasingly popular in the OR

In this case, the increased requirements are justified because wireless systems are increasingly popular in the OR, a direct result of the benefits of remote communication. Coexistence of the envisaged wireless standard alongside multiple other wireless networks or frequencies (Wi-Fi, Bluetooth, Zigbee, microwaves...) therefore needs to be tested, proven and documented to IEEE/ANSI C63.27. Medical device manufacturers must also prove the coexistence of their wireless systems to the FDA.

Other regulations to be taken into account when deploying wireless systems in the OR include the "Radio Equipment Directive" (RED), the EMC directive for medical electrical equipment (IEC 60601-1-2:2016) and, where appropriate, country-specific directives for wireless systems.



Benefits of remote control in the OR

There are good reasons for this trend towards user interfaces which communicate remotely. Foot switches can be positioned more freely – making them more ergonomic. In addition, there are no hygiene-related problems because they require neither cables nor cable glands. With a view to the (near) future, another benefit is coming into focus: soon multiple medical devices will be operated using a single wireless user interface. The principles behind this are currently – with the participation of steute Meditec – being developed and incorporated in standards (in particular the IEEE 11073 standards family). This ongoing process is known as SDC (Service-oriented Device Connectivity). First practical applications already exist.

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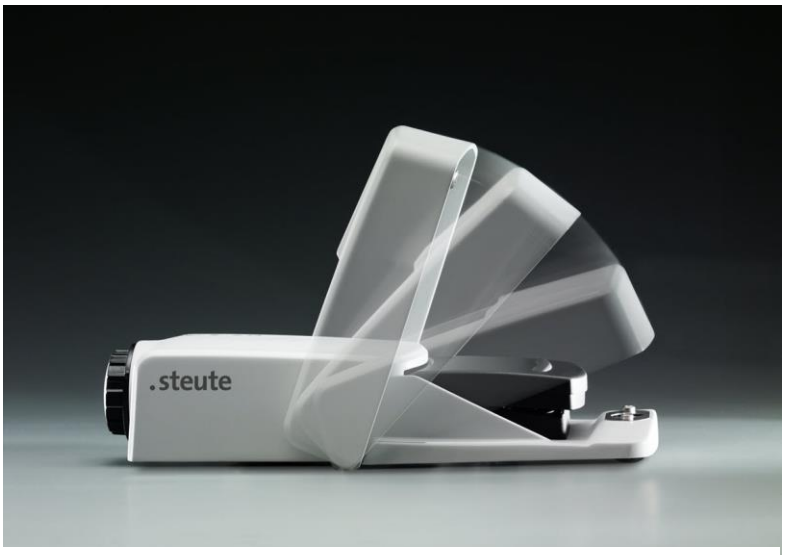
Standard wireless controls: documentation available

Manufacturers of medical devices who order wireless user interfaces from the steute Meditec standard range (Fig. 1) do not need to worry about extra documentation despite these additional requirements. These standard wireless controls have already been tested in line with all the relevant standards, while their radio module is approved for important markets such as North America (FCC), Europe (RED), Canada (IC) and Japan (ARIB). Corresponding proof, together with all test reports, is included in the delivery and is easy to incorporate in the documentation of the overall system.



Example of a wireless standard foot switch for medical devices; the compact receiver unit is installed on the device

Documentation also for customised user interfaces

For the customised user interfaces in our "Custom" range, in contrast, all tests must be individually conducted and documented. In order to make it as easy as possible for device manufacturers to integrate these interfaces, steute Meditec can optionally conduct most of the mandatory testing and documentation in accordance with the abovementioned directives. From the point of view of the device manufacturer, this saves (development) time. Since steute Meditec has comprehensive experience regarding the relevant documentation, the required proof is of high quality and fulfils the appropriate requirements completely.

Simplified documentation procedure: "gap analysis"

Nevertheless, it is ultimately the responsibility of the medical device manufacturer as the marketing authorisation holder to provide proof of conformity. With the conducted 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 in accordance with the ETSI standard (ETSI EG 203 367) as a simplified approval for wireless products.

Certificate for global 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)

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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 here, too, 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 testing and documentation can be provided by steute Meditec.

Additional requirements: risk assessment and risk analysis

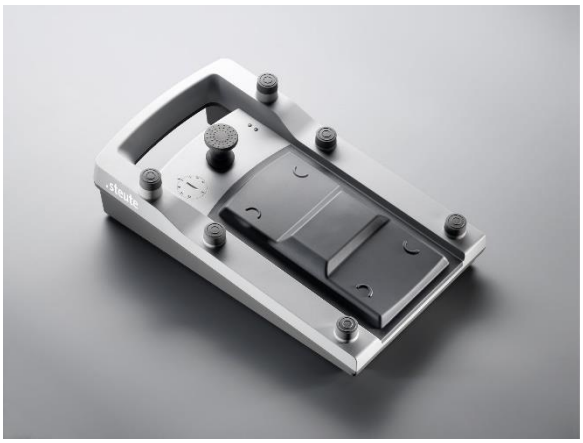
Testing and documentation actually extend even further because it is also obligatory to ascertain the risks to users and/or the environment. The EN 14971 requirements for risk management (also obligatory and also requiring documentation) apply. Moreover, all user interfaces – including those with cables – 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.

"MDR-ready": documentation to MDR and FDA

For some, the requirements of the Medical Device Regulation are still a matter of heated debate. User interfaces from steute are MDR-ready, meaning that steute Meditec can optionally provide customers with specifications, process information, risk analyses and certificates. The device manufacturers can then simply incorporate this documentation in their overall device documentation, proving that the user interfaces comply with the MDR requirements.

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

Joystick in action



Customised user interface developments from steute Meditec nearly always use the SW2.4LE-MED wireless technology. Shown here: foot control for surgical microscopes

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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 proof that the components used comply with the requirements of the FDA.

Tried-and-tested wireless system for the OR

In all cases, the wireless system used is the SW2.4LE-MED protocol developed by steute Meditec, featuring a low power consumption in conjunction with high transmission reliability. The transmission reliability is documented by a very low residual error probability of below 1 x 10^{-9} 1/h; the wireless system thus fulfils the requirements of SIL 3 (Safety Integrity Level to IEC 61508).

From manufacturer to service provider

Providing a documentation service for customised products and systems involves a considerable effort and requires multiple tests (which steute can predominantly conduct in its own well-equipped R&D centre). For a manufacturer of user interfaces, the production of such documentation is not just a matter of course. From the perspective of the medical device manufacturers, this documentation package saves a great deal of work. And they can also be sure that there will be no unexpected surprises when the national or international notified bodies conduct their own tests. From the perspective of steute Meditec, this service also has an added value because it represents a valuable step on the path from manufacturer to comprehensive service provider.

Author:

Guido Becker
Division Manager Meditec
steute Technologies

Images: steute Technologies GmbH & Co. KG

steute Technologies GmbH & Co. KG
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