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Completely cable-free: approved user interfaces for the OR

The amount of documentation required in the development of medical equipment is steadily increasing. This is also true of wireless technologies for communication between medical devices and their controls. steute Meditec can assist customers with mandatory tests and documentation.

Wireless user interfaces are now standard in the OR – here a demo installation by steute Meditec at a fair for medical equipment.

Nearly all customised controls currently developed by steute Meditec in collaboration with medical equipment manufacturers communicate with their corresponding devices by remote control. And even standard HMI (human-machine interfaces), such as the steute Meditec "Classic" multi-pedal foot control, are increasingly cable-free.

There are good reasons driving this development. HMI which are not connected to their medical devices by cable can be positioned more freely, providing increased ergonomic comfort. Having no cables is also a very hygienic option. Moreover, the quality of the overall system increases considerably with a cable-free foot control because wireless technology is state-of-the-art, helping device manufacturers to stand out from the crowd.

Another reason behind intensive use of wireless technology is the fact that highly reliable wireless technologies are now available which have been developed especially for

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the medical field – such as SW2.4LE-MED from steute Meditec. This technology features high transmission reliability and low energy consumption with fast response times. Due to a very low residual error probability of < 1 x 10^{-9} 1/h, the transmission reliability is given. The wireless system thus complies with SIL 3 (Safety Integrity Level to IEC 61508).

And yet it should also be mentioned that the effort which needs to be put into testing and documenting wireless controls has increased considerably over the last few years. This is partly due to new or changed guidelines, such as the EU "Radio Equipment Directive" (RED), replacing the previous R&TTE guideline, or the altered EMV guideline for medical equipment (IEC 60601-1-2:2016), valid since April 2017. And country-specific regulations governing the use of wireless systems also need to be taken into account nationally.

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Classic or Custom? Also a question of documentation

As a medical device manufacturer, opting for a standardised or a customised user interface also influences documentation and the appro val process.

With regard to the user interfaces in the steute "Classic" range, the abovementioned written documentation is very easy for customers to produce. During their development, the standard wireless controls have all been tested to the relevant standards as a matter of course. The wireless module which is used has been approved for use in major markets such as North America (FCC), Canada (IC) and Japan (ARIB). The corresponding documen--tation is provided with the controls so that it can be integrated in the documentation for the overall medical device. With regard to the user interfaces in the "Custom" range, on the other hand, the abovementioned tests and documentation must be performed and created individually. Luckily, this too has become a routine task for the staff in the steute development centre.

Wireless transmission in the OR must be reliable

The stricter regulations are due, amongst other things, to the fact that there are now more and more wireless systems – also in the OR – and that very high safety standards are crucial in conjunction with medical equipment. Coexistence – the ability of different wireless systems to exist side by side without impacting each other – therefore also plays an important role in the guidelines. For example, manufacturers are required to test coexistence with different wireless networks and frequencies (Wi-Fi, Bluetooth, Zigbee, microwaves, etc.). Not only must the tests themselves comply with the relevant standards (to IEEE/ANSI C63.27), but also the documentation of their results. Manufacturers of medical equipment must also produce documented proof of coexistence with other wireless systems for the FDA.

The documents which steute Meditec provides with its wireless controls include certificates of compliance to e.g. FCC (USA), IC (Canada) and MIC (Japan). The test results reference the abovementioned guidelines (RED, EMV-RL etc.) and their required standards, documenting that the wireless system in question fulfils these regulations. Ultimately it is the task of the device manufacturer as the marketing authorisation holder to produce this proof. However, with the tests which steute has already performed and the corresponding documentation including the test reports, manufacturers only have to check the test results to see whether the values are still correct after integration of the user interface in the overall system. This procedure is called "delta analysis" or "gap analysis". It is easier to perform and therefore

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both faster and cheaper. This path is compliant and is known as a "simplified approval" for wireless products in the sense of the ETSI standard (ETSI EG 203 367). Following on from the testing and documentation of its wireless (customised) user interfaces, steute can optionally provide a "Certificate of Compliance", awarded by the CSA as the result of an independent inspection. Moreover – also overseen by steute – a "CB certificate" can be issued which follows the "CB schema" familiar from electromedicine and is accepted by international notified bodies.

That is not an end to the documentation, however. Since individual software is written for customised user interfaces, it is also subject to comprehensive testing and documentation. And: any risks for users and/or the environment have to be identified. The EN 14971 standards for risk management apply. Independently of this, a risk calculation must be performed for every control system – including those with cables. steute passes on the results of these calculations to medical device manufacturers as the basis for their risk analysis of the overall system. In fact, manufacturers receive comprehensive documentation complying to all the applicable standards and including all the relevant tests, reports, analyses and records. It is recognised all over the world.

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