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Open system provides opportunities for hospital operators and SME

Project OR.Net: white paper and demonstrators for networked equipment

Numerous partners have been working together in the OR.Net project to create standards which will enable medical equipment from different manufacturers to be networked in all manner of combinations. The project has already come a long way – international standards and clinical studies are expected soon.

Anything and everything? In just a few years' time, this should be the reality in operating theatres containing medical devices from different manufacturers. Even today, anaesthesia devices, monitors, surgical equipment, switchgear and some other products are able via open interfaces to exchange data with each other, as well as with the hospital information system – in an operating theatre at the Innovation Centre for Computer-Assisted Surgery (ICCAS) in Leipzig, where a demonstrator has been set up.

The demonstrator shows results from the joint interoperability project OR.Net, funded by the German Ministry for Education and Research (BMBF) and presented for the first time in December. „Networking according to the open-source model is especially interesting for small and medium-sized manufacturers of medical equipment“, said Dr. Frank Portheine, MD of Surgitax GmbH in Aachen, at the Medica 2015 in Dusseldorf. His company has been part of the OR.Net project since 2012.



The operating theatre of the future. According to the VDE, in about five years the first theatres will be up and running with medical equipment networked via the open standard developed within the OR.Net project.

As soon as an open standard has become established, Portheine stressed, there will be new chances for niche providers to enter the market. „Hospital operators will then have more choice: they will no longer have to opt for a single system developed by one consortium, in which every device type is only represented by the products from one manufacturer.

Single-system solutions with a proprietary interface certainly function, but they do not offer users a choice if at some juncture or other they would prefer to opt for a different device with additional functions than that laid down by the consortium. „Companies whose devices were incorporated in such systems were previously at an advantage. An open standard would change the competition“, said Portheine. More money would not be spent within the healthcare system than before, but maybe it would be distributed differently.

Whether or not an integrated system with open interfaces can establish itself in the market strongly depends on whether or not hospital operators are prepared to specify easy networking in their tenders over the coming years. According to the partners within the OR.Net project, there are many reasons to favour this solution: with the help of the intelligence integrated within the operating theatre, surgical staff could concentrate on their core tasks. Modern assistance tools would support them in this. For example, all patient data and parameters would be transferred to all devices automatically and would no longer have to be entered manually. All networked devices could additionally be controlled from one central point. With a single, dynamically integrated foot control, different instruments could be actuated. And patient data, vital parameters, current images and monitoring functions would all be transferred to a central monitor in full view of the surgeon. Further ideas include integration of the Surgical Safety Checklist recommended by the WHO, as well as diverse standard operating procedures specific to the hospital in question. This

should ensure a high adherence to guidelines, as well as high-quality patient care. Several demonstrators should soon be able to show that this can indeed all function as envisaged.

The project managers continue to work on standardisation for the interface and approvals for all devices which work with it. At the Medica 2015, the German Association for Electrical, Electronic & Information Technologies (VDE) presented the latest version of its white paper „Interoperability of devices and systems in the operating theatre and hospitals“. It summarises the recommendations of manufacturers – based on experience to date – who would like to equip their devices with open interfaces.

The white paper analyses the current situation regarding standards for networking medical devices in the operating theatre and their connection to hospital information systems. In addition, it provides an overview of legal requirements and the international standards landscape, including risk management and safety. These analyses form the basis for recommendations concerning the direction standardisation should take, and how fast it should move, in order to guarantee the interoperability of devices in theatres and hospitals. The VDE expects innovations with open standards and secure interfaces within the next five years.

Spurred on by the OR.Net project, standards have already been submitted to the appropriate organisations for international comment. Here the Open Surgical Communication Protocol (OSCP), which was submitted internationally to the

Institute of Electrical and Electronics Engineers (IEEE) and which is the foundation for the declaration of conformity for networked medical equipment, plays a special role. On an initiative of the VDE, the responsible German inter-trade organisations have already committed themselves to the OCSP. At the Medica, the VDE announced that „on this basis it would become an international standard in 2016“.

Standardisation could also have a positive effect on conformity to guidelines. „Product combinations would then no longer be approved as a pair of devices; instead, application would be submitted for approval of a pair of types“, Portheine explained. And once such an approval was in place, the application process would not have to be repeated for each additional operating theatre.

Complete equipment of a hospital with numerous brand new and mutually compatible devices will certainly not be typical, however. „The reality is that many devices we use are older – and that they will not be disappearing any time soon“, said Dr. Micheal Czaplik, Section Leader for Medical Equipment at the Clinic for Anaesthesiology, University Hospital of the RWTH Aachen, and Spokesman of the Medical Board in the OR.Net project. Nevertheless, older devices can be fitted with an additional box quasi enabling its signals to be translated for the open standard.

In Europe, no initiatives comparable with OR.Net exist to date. In Japan, as well as in the US, groups are already working on open networking for medical equipment, but their approaches are different. „However, there is a chance that these approaches might later be combined to form a globally applicable standard“, said Julia Benzko, former member of the project and today Product Manager at steute Schaltgeräte GmbH & Co. KG in Löhne. At steute, actuators capable of controlling several different devices are undergoing further development beyond the OR.Net project.

According to the experts, the future of the open IEEE Standards (11073-20701, 11073-10207, 11073-20702) developed within the VDE strongly depends on the hospital operators: the market will only develop further in this direction once they begin to demand interoperability.

Further information

The running time of the OR.Net project has been extended by eight months until 30th April 2016 in order to complete work on the demonstrators and to achieve some additional subgoals. www.ornet.de
A full demonstrator integrating a maximum number of products will be on show at the Conhit 2016 congress and fair in Berlin in April: www.conhit.de

Demonstrating interoperability in practice

At the end of the OR.Net project a whole number of demonstrators will be available across Germany, giving interested parties the chance to inform themselves about all the possibilities available.

Partial demonstrators have been created in Aachen, Leipzig, Lübeck and Munich. Their main task is to support the development work of participating manufacturers. Each partial demonstrator has been specialised in accordance with the areas of competence of these project partners.

In Aachen, some of the questions being addressed are in the area of approvals for integrated OR systems, as well as usability analyses. In Lübeck, the main focus is on IT-related details, for example different solutions enabling existing networked systems to be connected to the OR.Net system. The demonstrator in Munich is showing how data from dynamically networked, existing devices can be brought together and used in real time in order to

be able to realise new functions reliably including those which are time-sensitive. The integration demonstrator in Leipzig permits simulation of all the components and functions necessary for an operating theatre and a network. In this environment, manufacturers can test the extent to which their medical devices can be integrated within a networked OR infrastructure and how it is then possible for them to work together with other systems.

In Heidelberg, all concepts and components developed within the project are tested in an integrated operating theatre acting as a full demonstrator to see whether or not they are practicable within a realistic clinical environment. In the future, surgery will also be simulated here, using real theatre staff. Just how well the OR.Net systems can be integrated within the existing IT infrastructure of a hospital will also be tested.

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Images: steute Schaltgeräte GmbH & Co. KG