Technical article, published in: medizin&technik (01/2025)

WHY IT MAKES SENSE TO INTEGRATE DEVICES VIA SDC

Internet of Medical Things | In the future, medical devices in the OR or ICU could communicate and exchange measurements with each other, and also forward data to the hospital information system (HIS). Practicians are in favour. First devices are already entering the marketplace with this option – and service providers can help by equipping other devices in the same way.

A cross-manufacturer standard for integrating medical devices is gradually gaining in relevance for the industry worldwide: "We can already see explicit inclusion of the SDC standard in hospital tenders", says Julia Mönks, Research and Innovation Manager at user interface expert, steute Technologies GmbH & Co. KG in Löhne.

Hospitals are not yet stipulating that devices must be SDC-ready "now", but the direction is clear – products purchased for the OR or ICU must be future-proof. There are only a few medical devices ready for the marketplace today which can already communicate via the SDC standard in practice.

01 Digital data flow between medical devices facilitates new applications: for example, a device can request the necessary values for a closed-loop control from other participants within the network.

KEY TAKEAWAYS

- Integrated medical devices
- Cross-manufacturer standard
- Standard provides framework for SDC
- Additional standards in preparation
- Users want SDC-ready devices

They include a patient monitor and a ventilator for the ICU, marketed in 2025 with MDR certification by Lübeck company Drägerwerk AG & Co. KGaA. "We are a step ahead in this field because we made it our concern to address development of this standard early on", says Michael Wilkening, Vice President of Strategy and Business Development Medical Technology at Dräger. This involved a certain level of risk, requiring resources to make it happen. "But we were convinced that cross-manufacturer integration was an emerging topic, and we decided to commit to it."

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

SDC standard is the future

Julia Mönks agrees: "We know it is the future." This topic is attractive for politicians, while the industry and hospitals have stopped asking what SDC is and started calling for it.

The cross-manufacturer integration of medical devices which the standard should facilitate can considerably simplify work routines, not only in the OR. "Communication is, of course, already possible", Dräger expert Wilkening concedes. But it is limited. The only device currently integrated in the hospital IT network is the central monitor – which can come from different manufacturers. All data from the installed medical devices are sent to this monitor via individually designed interfaces. The monitor then translates the information, filtering it if necessary and forwarding it.

This approach has two consequences. Firstly, forwarding information runs the risk of error, and not all data are passed on to the HIS. "Sometimes values such as blood pressure or oxygen saturation are not made available, and they could have been useful." Secondly, this method of data transfer means that the monitor manufacturer must be notified of any technical modifications to a medical device sending data via the monitor. The manufacturer then has to adapt the monitor to ensure that data transfer remains possible. As Wilkening stresses, this is a complex issue because there is more than one monitor manufacturer, and there are many different medical device manufacturers.

When all devices communicate with each other directly

Rather than repeatedly having to adapt proprietary systems to each other, the SDC standard facilitates exchange more or less immediately between devices which have only been set up once. This enables medical staff to access available patient data quickly and easily. "Sometimes it is a really small thing they need – such as the time", Wilkening reports. As long as every device in the OR works at its own pace – as is currently the case – it can happen that notifications about a necessary patient intervention are logged in the overall system with a time preceding the event which triggered the need for the intervention in the first place. "This is different with the SDC network because here all devices communicate with each other directly and synchronise their clocks", says Wilkening.

The foundations for the standard were laid years ago in the research project OR.NET. An

From OR.NET to SDC standard

Easy integration of medical devices from different manufacturers in the OR or ICU: this was the original idea which the OR.NET research project wished to realise years ago. Anaesthesia devices, monitors, surgical equipment, switches and other products should all be able to exchange data with each other, as well as with the HIS, via open interfaces.

The required SDC (Service-oriented Device Connectivity) standard has since been developed. It has been an interoperability standard globally recognised by IEEE/ISO since 2019.

It is compatible with the stipulations of the HL7 and FHIR standards. The nomenclature for data, units and numbers, for example for blood pressure measurements, already existed in these standards and was adopted for the SDC standard. This should help to avoid errors when translating data to the HIS.

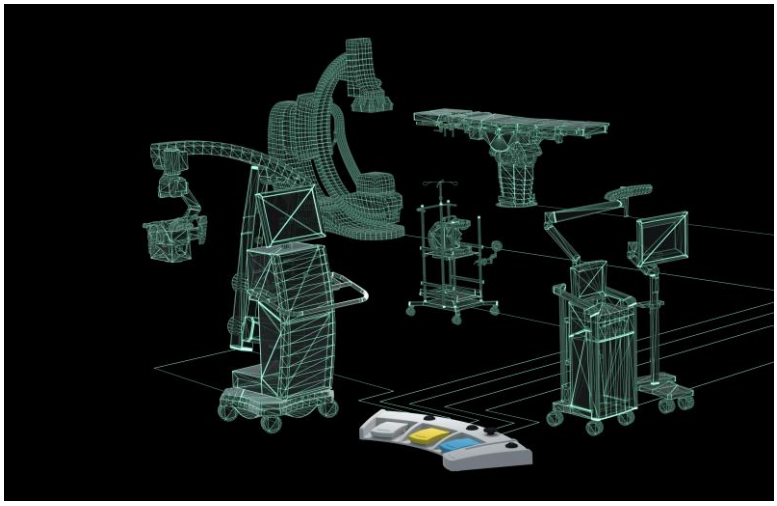
If a parameter needs to be filtered out of the transmitted data set, this task is assumed by the HIS – and not, as previously, by a monitor in the OR collecting all bundled data.

This work is being continued today by numerous companies within the OR.NET Association. International hospital studies are currently commencing as part of the Sasicu project.

https://ornet.org/; www.sasicu.eu

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

association with the same name was then established in 2016, enabling the researchers to continue their work. Members include research institutes, such as the Innovation Centre for Computer-Assisted Surgery – Iccas – in Leipzig, as well as hospitals and medical device manufacturers, such as Aesculap, B. Braun, Dräger, Erbe Elektromedizin, Fresenius Vial, Philips Medizin Systeme Böblingen and Richard Wolf, the specialists from steute Technologies or the software experts from Vector Informatik.



02 In the future, medical devices can exchange data via SDC, both with each other and with the HIS. The foot switches controlling the devices can also be integrated in the network and pass on their messages directly.

The collaboration has already resulted in the 11073 IEEE-SDC family of standards, the basis for the main standard. Complementary standards are in preparation and should, for example, facilitate the forwarding and processing of alarms, harmonise the External Control, as well as describe solutions for real-time communication.

Interoperability between medical devices, as provided by SDC, is important and "a prerequisite for efficient and safe digital processes in the OR". This at least is how Apl. Prof. Michael Czaplik sees it, Professor of Anaesthesiology at the University Hospital of the RWTH Aachen and also on the Board of the OR.NET Association.

But how should the number of medical devices integrated via SDC grow in the future? Devices in the past often had a serial interface, whereas new generations are now generally equipped with a network connection. Michael Wilkening: "This is necessary so that devices can communicate bidirectionally, as wished for by users. "A ventilator needing to adjust parameters within pre-determined limits, for example, can then query the current oxygen saturation value of the patient from the patient monitor via the network. "This of course also requires appropriate software, as well as sufficient computing power in the device."

The parameters which may be adjusted by medics and nurses are determined by the External (or remote) Control standard. "Medical staff will only be allowed to make certain adjustments to a life-support ventilator, for example, when they can actually see the patient", Wilkening reports. And the SDC standards must also include many different risks and appropriate behaviours. One example: how should the integrated devices react if a required value is not available?

In such a network, many functions can be organised differently and better than today. For example, instead of an alarm going off in the ICU directly next to the patient's bed, which is both disturbing and distressing for the patient unable to do anything, an alarm notification within a safe network could be sent directly to a responsible person outside the room, together with vital data and values measured by various devices. The alerted nurse can then go to the patient and intervene. "We call such an application the Silent ICU", Wilkening says. In collaboration with other medical device manufacturers, Dräger is

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

currently conducting tests to prove that this principle works.

Since hardly any SDC-ready medical products exist yet, the involved parties are using external converters to translate the signals between the devices "into SDC", so to speak. Retrofitting existing devices with this converter, plus the software, the computing capacity and a network connection, is not so easy, however. That is why, according to Wilkening, many manufacturers are favouring "inclusion of SDC-compatibility in the development of their next-generation devices from the outset".

This part of the development process is accompanied by service providers who can support medical device manufacturers, for example software programmers. They, too, are organised within the OR.NET Association. Retrofitting of existing devices nevertheless remains a fundamental option.

Companies who take this step in their own product development and – like Dräger – opt for a modular solution are able to integrate this solution in subsequent or additional devices with only moderate effort. "We plan to have our entire current portfolio SDC-ready within three or four years", Wilkening states.

steute Meditec is already designing foot switches which communicate with integrated medical devices via SDC, and has also developed a modular concept to this end. Modular because not every device has to be network-compatible, Julia Mönks explains. Some medical devices are stand-alone, for example in a medical practice, "so they do not need to be SDC-ready". It therefore makes sense to give foot switch users the option.

SDC at the DMEA

At the DMEA fair, which will be taking place in Berlin from 8th to 10th April 2025, the OR.NET Association will be exhibiting in Hall 6.2 Booth D-101.

www.dmea.de

According to Mönks, the general level of interest in SDC among medical device manufacturers is reflected in the rising membership of the OR.NET Association. Of course, a new standard like this will not be able to bring about a change in hospitals overnight. Numerous devices which have been available in the marketplace for years and which were never designed for networking will still be used in hospitals for a long time. Proprietary devices will also remain in use in order to integrate selected products – but still we may assume that all protagonists are following the SDC developments very closely and are preparing to react to an altered market situation.

Notified bodies contacted regarding SDC-ready devices

The advocates of medical devices with SDC integration are also addressing the issue of approvals. "We are already in negotiation with notified bodies", reports Mönks. Contact had been made previously, but the notified bodies were at full capacity due to the introduction of MDR, making progress impossible. But that is now changing.

Safety and cybersecurity are, of course, also issues which need to be tackled for device integration based on the SDC standard. "Proof that a system is safe is nothing new, independently of the details of the network – in other words, procedures and measures to guarantee this are already in place", says Mönks. She does not envisage any new risks arising specifically with the SDC standard.

Future-proofing integrated medical devices also means that any new standard must be compatible with technologies such as 5G or 6G. According to Mönks, the SDC standard has already been tested within the KliNet5G project, headed by the Leipzig centre Iccas. To date, there are no 5G applications or products in hospitals; everything is still at the research stage. But the tests have shown that the SDC standard functions not only in a Wi-Fi or Ethernet environment, but also with 5G or 6G.

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

Is there an alternative to SDC? No. "From the outset, this standard has been designed to close a gap in the international market", says Mönks. Its cross-manufacturer application is its unique selling point. It is neither able nor intended to replace standards such as HL7, FIHR or Dicom for medical imaging.

It is relevant that advocates of this project always intended it to be international. "Large numbers of medical device manufacturers are active in the global marketplace. A German or European standard would not have made any sense." Michael Wilkening adds that solidarity among European companies in this matter could also benefit the German medical device industry, strengthening its position in the global market.

Author:

Dr. Birgit Oppermann
birgit.oppermann@konradin.de

Images:

steute Technologies GmbH & Co. KG
(Image 01 is different to the original German article)

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