The risks involved in being a medical product user

Part of the reason for the 4th Amendment of the Medical Products Act (MPG) is the fact that medical technology has become very IT-dominated. This applies equally to hospitals, the place where such technology is put to use. But to avoid risks from the point of fulfilling their intended purpose as defined by MPG, medical products may only be operated as part of an overall system.

An ever-increasing variety of medical products and other devices are connected to one and the same IT network. This involves risks which require careful monitoring. After all, each individual device has to be safeguarded against any negative interaction with the network, so to speak.
Hospitals which reflect the high status of IT and medical technology in their decision-making structures are not only able to meet the demands imposed on them as operators, they also operate more cost-effectively. "The technology architecture of a network and all its components has to be conceived on a long-term basis," explains Timo Baumann, Divisional Head of MIO (Medical Technology, IT and Organization) of the hospitals of the District of Göppingen.

One of the cornerstones of running medical products in a network is risk management

"This is the only way to run such a complex landscape of equipment and applications in a sustainable way – and manufacturers have to do their bit, too," says Baumann. What he means here is that manufacturers should not produce their medical devices to be used in a vacuum, but for incorporation in existing networks. This ought to include practical instructions on network integration.

Stefan Josef Welte, an IT consultant with Human Internet Consult, which has an insight into the level of technological equipment in various sectors, was often surprised to see how low the ratio of devices to IT support staff is in some hospitals. "If you were to compare an automotive supplier and a hospital, you would think that an IT network supporting patients would have better or at least the same staffing levels as one where the worst case scenario would be 'merely' a production standstill." But this is not the case in some hospitals, especially smaller ones.

Low staffing levels, different departments, a lack of clearly defined responsibilities and interfaces – this is not necessarily the way of coping with fast-growing demands. Medical products not authorized for network operation have to be operated by hospitals based on improvised adjustments – and therefore at the hospitals' own risk. Would it be correct to refer to such instances as an in-house products or custom-made designs? Many IT coordinators say no. Johann Steinhauser, Head of the Medical Technology Service Center at Tübingen University Clinic – and responsible for over 38,500 active medical products – thinks otherwise. "The manufacturer of a medical product ought at least to define the interface, software and software requirements. If this information is not available and we hook up the medical product to the network, it is

virtually always an in-house product. Modifying the medical product – and turning into an in-house model – happens when you install software, for example a virus scanner, and patches, e.g. updates for a virus scanner, operating system and the like, which have not been expressly authorized by the manufacturer. In this case a comprehensive risk analysis has to be carried out prior to start-up." Clearly, one the cornerstones of running medical products in a network is risk management. And manufacturers do not exactly make life easy since they prefer to offer various proprietary solutions rather than revealing the existing interfaces, either partially or wholly. The idea of plug and play is still a dream.

There may be a vague shimmer of hope on the standardization horizon, such as DICOM in radiology as an open standard which virtually all manufacturers of imaging and image-processing systems adhere to, but a field like cardiology still appears to be a long way away from achieving this level of sophistication. One method of handling this and other difficulties and taking account of risks – even unforeseen ones – is IEC 80001-1. It contains safety instructions for the operation of medical devices in networks. According to Dr. Stefan Heusinger, Head of Standardization on the DKE German Commission for Electrical, Electronic & Information Technologies of DIN and VDE, publication can be expected by December 2010. Of course, this is a standard - not a law. "Nonetheless, if there is an incident after this standard has been issued, operators will be called to account as to why they did not adhere to it," says Heusinger. So the standard will safeguard operators if it is read and applied with the necessary expertise.

Ramona Riesterer ←

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"The times of 'Hey Joe' are over"

meditec INTERNATIONAL spoke to Joachim Hiller, Deputy Divisional Head of Medical Technology, IT and Organization (MIO) for the hospitals of the District of Göppingen

Mr. Hiller, your organization is especially keen on long-term planning. What does this mean in concrete terms?
It means we no longer operate on the 'Hey Joe' principle. 'Hey Joe' means that IT isn't called in until the new piece of machinery arrives.
This kind of thing happens when a sales rep recommends a piece of equipment to a doctor, and then it's question of: Hey Joe, come here, hook this thing up to the network and get it going!
This type of approach simply doesn't take into account the responsibility of the operator. This project-based approach has to stop. IT and medical technology coordinators have to collaborate constructively with users throughout the entire process of planning, procurement and operation – right through to the decision to take a machine offline and dispose of it.

Where do hospitals have catching up to do?
Growing demands from the MPG and the operator ordinance are forcing hospitals in the right direction. Firstly, they have to get expert personnel on board - you can't have the janitor being responsible for running medical equipment.
Secondly, IT and medical product coordinators can no longer avoid sitting down together, defining responsibilities and strategies and ensuring that one knows what the other is doing and vice versa.

Joachim Hiller: "IT and medical product coordinators can no longer avoid sitting down together."

How can this be implemented effectively?
Apart from the fact that we have set up an MIO department, i.e. Medical Technology, Information Technology and Organization, we are also currently introducing additional structures:
there will be a sponsorship concept. We are teaming up IT and medical technology staff members who work in pairs to run risk assessments and formulate standard operation procedures stipulating what has to be done in the case of a server failure, for example.