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THE DIGITAL OPERATING THEATRE

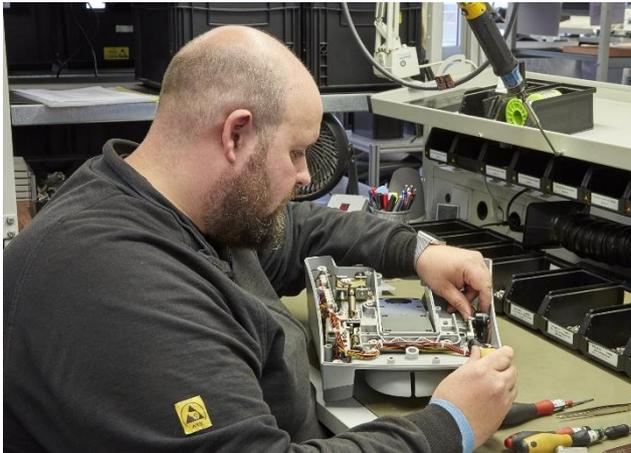
In Löhne, situated in East Westphalia, the operating theatre of the future is already reality: foot switch specialist steute Technologies GmbH & Co. KG has developed a multi-purpose foot control which enables surgeons to operate different medical devices from different manufacturers.

The first impression of the steute exterior is a warm, pleasing burgundy. Inside, the foyer of the long, two-storey building has a surprise in store: large works of art on all the walls, with additional photos and paintings accompanying visi-

tors as they move through the various corridors and staircases.

In contrast, the design of the conference room on the first floor is sober and functional. Only the unusual V-shaped table hints at a way of thinking beyond the con-

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In the final assembly, mechatronic technician Christian Tilker unites the switch housing with its interior.



Heads of Development Dr. Christof Gerhardy (left) and Marc Schmidt work closely together at all times.

ventional. This was all back in 2012, when in this very room a revolutionary idea was born: the development of a wireless multi-purpose foot control enabling surgeons to operate different medical devices from different manufacturers.

"Until now, surgeons have been used to having an entire pedalboard of foot controls under the table", says Managing Director Marc Stanesby as he pulls a screen mounted on a swivel arm into the room: it shows a footwell below an operating table which screams "cable spaghetti" and confusion. "This surgeon has to feel around blindly for the correct foot control or ask the surgical nurse to push the correct switch towards his foot", Stanesby explains.

Stanesby is unmistakably British and has been managing the operative side of business at steute since 2008. He remembers well that sense of excitement eight years ago when, at the very same conference table, the idea was mooted of a user interface to control multiple medical devices in the operating theatre. That same year, steute presented its idea at the

Medica in Dusseldorf, the largest medical fair worldwide.

Universal foot controls

Approximately 40 years ago, steute began producing foot and hand controls for medical devices and other types of machine. The surgical field usually requires foot controls, leaving the hands of the surgeon free and sterile to perform the surgery. A medium-sized company, steute quickly grew to become a European market leader for medical foot controls. Shortly before the turn of the millennium, it was the first manufacturer worldwide to equip its foot controls with wireless technology. Overnight, "cable spaghetti" became a thing of the past. What remained, however, was the confusion of different foot switches below the operating table.

The idea of a universal foot control for multiple medical devices was well received at the Medica 2012. "The time had come for an integrated OR", Stanesby remembers. "The medical devices from the various manufacturers had all been digital for quite

some time, and yet they were not speaking the same language."



"The Medical Devices Directive is both a blessing and a curse."

MARC STANESBY

The missing link was a universal human-machine interface, a single element enabling surgeons to control and operate every medical device in the operating theatre, whether that be a C-arm for X-raying, an HF device for cutting and cauterising, or a bone saw. In collaboration with 24 manufacturers, universities, physicians and hospitals, steute founded OR.NET e. V., a registered association with the aim of realising a digitalised operating theatre with an open communication network.

Open communication network

As the supplier of this interface, steute was the spider at the centre of the web, where all the threads met. Its multi-purpose foot control is, after all, the hardware which connects everything else. No less important is the software, the universal machine language with which the foot switch can control all manner of medical devices in the OR. "Thanks to our many years of experience developing human-machine interfaces, we were in

demand as a partner able to develop digital communication between the various devices", Stanesby stresses. He is a member of the OR.NET board and heavily involved in the VDMA as Deputy Chairman of the Workgroup for Medical Equipment, as well as a member of the research and innovation committee.

The lingua franca or the communication interface between the medical devices is the SDC standard IEEE 11073, published by the International Standards Organisation ISO. Now any manufacturers who are interested can configure their medical devices to speak the new machine language. "This has the huge advantage that hospitals can choose the devices best suited to their applications and budgets from a large pool of different brands", says Guido Becker, steute Product Manager for the medical field.

Over **50 %**
of foot controls
used in medical devices in
Europe are made by steute.

The standard is in place, the devices have learnt the new language, and the single wireless foot control for multiple medical devices has been developed. And yet it will still be years before the first surgeon can operate on patients using the new interface below the operating table: the European Medical Device Regulation (MDR) from 2017 stipulates an extremely thorough and therefore lengthy approval process for all medical equipment.



Product Manager Guido Becker demonstrates a foot control with a joystick for surgical microscopes.

"This is both a blessing and a curse", says MD Stanesby: "The Medical Devices Directive demands extremely complex documentation and testing, which is taking longer and longer." This is of course to rule out the possibility of a surgeon activating the wrong device by mistake, or a drill or saw not stopping immediately. "But when we do eventually have the approval, our customers will know that our foot controls meet the very highest of standards."

In the conference room, the digitalised operating theatre is already up and running. Marc Schmidt, Head of Software/Electronics Development at steute, places the universal foot control on the floor and actuates its three pedals and three push buttons, moving between them with the skill of a virtuoso. On the monitor at the end of the swivel arm he can observe what his right foot is doing: opening menus, selecting items and confirming those selections. Additional screens mounted on the walls light up and go dark to symbolise

the different medical devices in the virtual OR as they are activated and deactivated.

Schmidt's product design partner Dr. Christof Gerhardy, Head of Medical Hardware Development, stresses: "Our foot controls have to be able to withstand extreme mechanical loads, such as the weight of a surgeon" and demonstrates by balancing his body on one of the three pedals. A famous line by German singer Herbert Grönemeyer translates as "hard on the outside, but inside really sensitive" – he was referring to men when he wrote the line, but could also have been describing

these foot controls. An infinitely variable pedal has to react reliably and extremely sensitively despite its robust exterior – to ensure that, for example, a neurosurgeon does not drill one millimeter too deeply into the cervical spine.

QUICK FACTS

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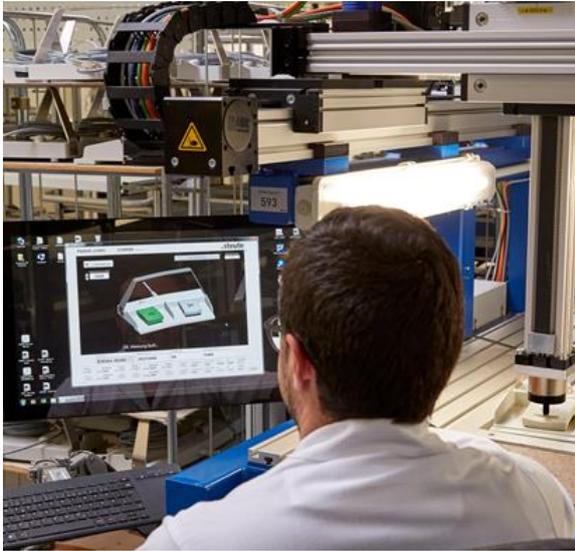
staff are currently employed by steute.

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steute production sites are in operation worldwide: in Löhne (Germany), in Shanghai (China) and in Vinhedo (Brazil).

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research projects for medical devices are currently carried out in which steute plays an active role



In the final inspection, Ümit Köker tests the function of every single foot switch.

"Depending on which medical devices they have in their operating theatres, customers will be able to configure their universal foot controls individually", says Product Manager Guido Becker. In its showroom, steute has a display of all its individual foot controls long established in the marketplace: some are on-off buttons, others like accelerator pedals which the user can either depress gradually or in predefined steps. Some foot switches turn, others tilt to one side. "As soon as the approval has been awarded, we will be able to take these individual foot controls and combine them in all manner of different ways to produce universal foot controls for different groups of medical devices", says Site Manager Andreas Bruns as we head to the factory.

In the mechanical production area, the mood is one of calm concentration. Above the background noise of the ventilation system, we can hear the irregular clacking of robots cutting holes and threads into housing blanks purchased from an external

supplier. From there employees push trolleys containing the processed housings into the paintshop, which is also quiet. Soon the housings are hanging from drying racks in a variety of bright colours as they give off that unmistakable smell of paint.

One floor above, in a protected ESD area, long glass walls separate the corridors from individual work zones. Here machines buzz like busy bees, mounting printed circuit boards with resistors, capacitors, etc. The final assembly is the only area where everything is done by hand: highly specialised mechatronic and electronic technicians fit the delicate and complex parts inside the robust outer housings.

In the corridor on the way back to the foyer, Stanesby remarks that steute had



Site Manager Andreas Bruns (left) in discussion with Thomas Klocke, Head of Final Assembly.

been growing steadily for years – right up until the start of the pandemic: "Covid-19 is of course impacting our business." Because many surgical operations have been postponed, hospitals have delayed the purchase of new medical devices and thus

also their foot controls. "This is, however, not a structural problem, merely a turnover blip", the MD assures us, takes his leave from the reporters in casual business attire and with an elbow bump.

Author:Hans Wille

Images: Ulrich Helweg Fotodesign (www.helweg-fotodesign.de)