

.steute

Meditec

CERTIFIED USER INTERFACES



A BRIEF INTRODUCTION: STEUTE MEDITEC



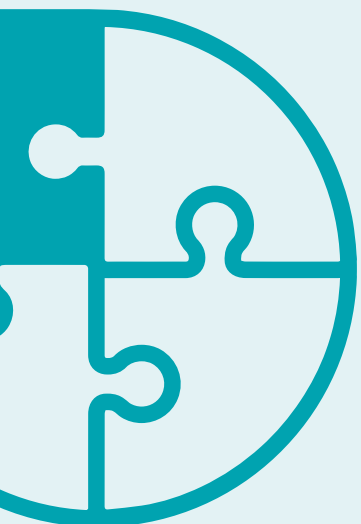
MORE THAN 40 YEARS OF INNOVATION, INDIVIDUALITY AND EXPERTISE IN USER INTERFACES FOR MEDICAL DEVICES



Certified user interfaces for medical devices

Our steute user interfaces for medical devices meet the highest standards of ergonomic comfort, intuitive operability and reliability, as well as the strictest regulatory requirements. On the basis of over 40 years of experience, we develop and manufacture controls for various medical fields, which in all cases are high-quality, durable, highly functional and designed especially for medical applications. We pride ourselves on our innovative approach, for example using a wireless technology we developed ourselves for this specific purpose. Collaborations in a variety of different research projects enable us to play an active role in shaping the interoperable OR of the future, which in turn enables us to offer you future-proof user interfaces.

The result: your customers – surgeons in the OR, clinical physicians, ambulatory physicians – are able to work responsibly and to the best of their ability, safe in the knowledge that their medical devices are in complete harmony with our controls.



APPROVALS AND DOCUMENTATION

For highly demanding customers in need of user interfaces for medical devices, we are the supplier of choice. Because we offer more: supporting those customers along their entire development chain and throughout their medical device life cycle.



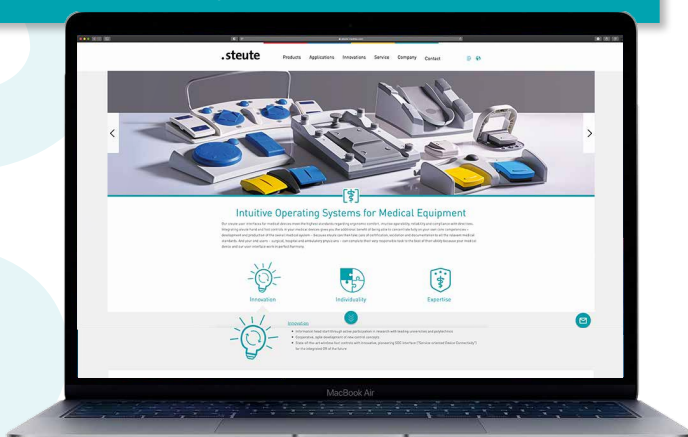
We often become involved in the device development process very early on, facilitating a perfect match between the customer's medical device and our steute user interface.

Should you choose to integrate our hand and foot controls in your medical devices, we are able to offer you the option of an additional benefit: we can take care of the certification, validation and documentation for the interface in accordance with all the relevant medical standards.

This leaves you free to concentrate on your core competence – the development and production of the medical system. We will provide you with MDR-compatible documentation for you to include within your overall device documentation. You then have the documents proving that the production and final inspection of the user interface meet the requirements of the MDR. This considerably simplifies the approval process for your overall system – including its user interfaces – in your name.

We can support approval of your device not only in Europe, but also in the American market. steute Meditec is registered with the FDA (FDA Establishment Registration) as a “contract manufacturer” (21 CFR 807). This permits us to offer you the option of FDA-compatible documentation and proof of manufacturing for your user interface. For device approvals in the US, this has the following advantage: when you apply for approval for a medical system equipped with one of our interfaces, you can link us as a contract manufacturer in the FDA listing for your medical device. We can thus help you to prove that your components or accessories were also manufactured at an FDA-registered site.

For more detailed information about our MDR and FDA expertise, please go to: www.mdr-ready.com



PRODUCTS

07 Wireless foot controls

With safe steute wireless SW2.4LE-MED technology

09 Cabled foot controls

User interfaces with cabled signal transmission

12 Wireless hand controls

Individually adaptable to different medical devices

14 Customised products

Complex user interfaces tailor-made to specific requirements

16 Foot controls for surgical microscopes

Customised foot controls for sensitive applications

18 Foot controls for ophthalmology

Precise and highly intuitive user interfaces

20 Configurable foot controls

User interfaces for applications with special requirements

APPLICATIONS

22 Innovations

Integrated medical devices and interoperable user interfaces

24 Research projects

Status quo

26 OR.NET

Comprehensive infrastructures for operating theatres and hospitals

28 Expertise

Exploit our expertise to your own ends

WIRELESS FOOT SWITCHES

steute Meditec

SW2.4LE-MED



6

»MAXIMUM EFFICIENCY, CHARGING UNNECESSARY«



MKF SW2.4LE-MED SK13



- Developed for the actuation of surgical or cosmetic laser devices to IEC 60601-2-22
- Power supply via 3 batteries type AA
- Typical battery life: 230 days
- Battery compartment can be opened by hand
- Latchable protective guard prevents unintended actuation of control unit
- Wireless signal transmission via steute wireless low energy

MKF 2 SW2.4LE-MED GP211



- Wireless signal transmission via steute wireless low energy
- Power supply via 3 batteries type C
- Typical battery life: 600 days
- Battery compartment can be opened by hand
- Collapsible carrying handle (optional)
- Additional push buttons for extra functionality (optional)

MKF 4 SW2.4LE-MED GP411



- Wireless signal transmission via steute wireless low energy
- Power supply via 3 batteries type AA
- Typical battery life: 230 days
- Battery compartment can be opened by hand
- Collapsible carrying handle (optional)
- Additional push buttons for extra functionality (optional)

MKF 3 SW2.4LE-MED GP311



- Wireless signal transmission via steute wireless low energy
- Power supply via 3 batteries type AA
- Typical battery life: 230 days
- Battery compartment can be opened by hand
- Collapsible carrying handle (optional)
- Additional push buttons for extra functionality (optional)



8

»DESPITE THE LOW POWER CONSUMPTION, RESPONSE TIMES ARE VERY SHORT: SIGNAL TRANSMISSION FROM AN ACTIVE FOOT CONTROL TAKES JUST 20 MILLISECONDS.«

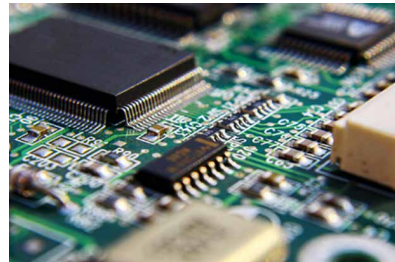


REC SW2.4LE-MED AG43



- Wireless receiver for medical applications
- 4 digital switching outputs (relays)
- 2 digital validate outputs (relays)
- 1 serial interface (RS 232)
- Rated voltage: 24VDC

REC SW2.4LE-MED AG43 PCB



- Wireless receiver for medical applications
- Circuit board for integration in medical device
- 4 digital switching outputs (relays)
- 2 digital validate outputs (relays)
- 1 serial interface (RS 232)
- Rated voltage: 24VDC

REC SW2.4LE-MED 5VDC PCB



- Wireless receiver for medical applications
- Circuit board for integration in medical device
- 1 digital validate output (relay)
- 1 serial interface (RS 232)
- Nominal voltage: 5VDC

CABLED FOOT SWITCHES

10

»WE MAY BE PIONEERS IN WIRELESS TECHNOLOGY FOR THE OR,
BUT WE STILL OFFER A WIDE RANGE OF USER INTERFACES WITH
CABLED SIGNAL TRANSMISSION.«



RF-MED 2G



- Robust die-cast aluminium foot control
- Operable from all sides
- Powder coating
- Waterproof: IPX8 (IEC 60529)
- Digital output signals
- Different RAL colours available

MKF 2-MED GP26



- Robust fibreglass-reinforced plastic foot control
- Powder-coated aluminium housing
- Waterproof: IPX8 (IEC 60529)
- Additional push button for extra functionality (optional)
- Collapsible carrying handle (optional)
- Digital or analogue output signals available

MKF 3-MED GP34



- Robust fibreglass-reinforced plastic foot control
- Angled aluminium housing
- Waterproof: IPX8 (IEC 60529)
- Wireless signal transmission via steute wireless SW2.4LE-MED (optional)
- Additional push buttons for extra functionality (optional)
- Carrying handle (optional)

MKF 4-MED GP47



- Robust fibreglass-reinforced plastic foot control
- Angled plastic housing
- High functionality at low cost
- Waterproof: IPX8 (IEC 60529)
- Digital or analogue output signals available

CABLED FOOT SWITCHES

MGF-MED



- Robust die-cast aluminium foot control
- Powder coating
- Waterproof: IPX8 (IEC 60529)
- Additional push button for extra functionality (optional)
- Carrying handle (optional)
- Digital or analogue output signals available

MKF-MED GP17



- Robust fibreglass-reinforced plastic foot control
- Plastic housing for high stability and low weight
- Waterproof: IPX8 (IEC 60529)
- Additional push buttons for extra functionality (optional)
- Collapsible carrying handle (optional)
- Digital or analogue output signals available

MGF2-MED



- Robust die-cast aluminium foot control
- Powder coating
- Waterproof: IPX8 (IEC 60529)
- Additional push buttons for extra functionality (optional)
- Carrying handle (optional)
- Digital or analogue output signals available

MKF 2-MED GP25



- Robust fibreglass-reinforced plastic foot control
- Fibreglass-reinforced plastic housing
- Waterproof: IPX8 (IEC 60529)
- Stainless steel carrying handle (optional)
- Digital or analogue output signals available
- Different RAL colours available

MKF-MED GP111



- Robust fibreglass-reinforced plastic foot control
- Plastic housing for high stability and low weight
- Waterproof: IPX8 (IEC 60529)
- Wireless signal transmission via steute wireless SW2.4LE-MED (optional)
- Additional push buttons for extra functionality (optional)
- Collapsible carrying handle (optional)

MKF-MED SK12



- Robust fibreglass-reinforced plastic foot control
- GRP protective flap provides maximum protection from unintended actuation (IEC 60601-2-22)
- Minimal design
- Waterproof: IPX8 (IEC 60529)
- Digital or analogue output signals available
- Different RAL colours available

MTF 3-MED



- Aluminium housing with flat design
- Ergonomic design
- Tactile switching points
- Waterproof: IPX8 (IEC 60529)
- Very easy to clean
- Digital output signals

WF 3-MED GP71



- Rocker switch for rapid switching between 2 functions
- Robust powder-coated die-cast zinc foot control
- Variable aluminium housing for additional functions
- Waterproof: IPX8 (IEC 60529)
- Carrying handle (optional)
- Digital or analogue output signals available



»USING WIRELESS HAND-HELD REMOTE CONTROLS WITH SW2.4LE-MED WIRELESS TECHNOLOGY IN THE OR OR THE MEDICAL PRACTICE HAS MANY BENEFITS.«

FFB SW2.4LE-MED



- Wireless hand-held remote control
- Wireless signal transmission via steute wireless low energy
- Power supply via 3 batteries type AA
- Membrane keypad with different functions
- Very easy to clean
- Various LEDs available

Customised solution



- Wireless hand-held remote control
- Wireless signal transmission
- Power supply via 3 batteries type AA
- Membrane keypad with different functions
- Very easy to clean



»DEVICES WITHIN THE VARIOUS MEDICAL DISCIPLINES ARE BECOMING INCREASINGLY COMPLEX, AND SO IS THEIR OPERATIONAL FUNCTIONALITY. THIS IS ONE REASON WHY THE TREND IS MOVING CLEARLY TOWARDS CUSTOMISED USER INTERFACES.«

Foot control for urology



Foot control for microscopes



Laser foot control



Foot control for diagnostics and interventions



Foot control for surgery



Foot control for hospital beds and examination tables



FOOT SWITCHES FOR SURGICAL MICROSCOPES



18

»THE FOOT CONTROLS WHICH WE DEVELOP FOR THIS SENSITIVE FIELD ARE TAILOR-MADE. ALL ACTUATOR ELEMENTS ARE ARRANGED WITH ERGONOMIC COMFORT IN MIND.«

MFS Microscope SW2.4LE-MED



- Wireless signal transmission via steute wireless low energy
- Power supply via 3 batteries type C
- Battery compartment can be opened by hand
- Zoom and focus functions with central foot rest
- Joystick for positioning of microscope
- 6 additional push buttons with programmable functions
- Very easy to clean

WF-MED GP14



- Rocker switch for rapid switching between 2 functions
- Robust powder-coated die-cast zinc foot control
- Aluminium housing for increased weight
- Waterproof: IPX8 (IEC 60529)
- Additional push button for extra functionality (optional)
- Digital or analogue output signals available

MFS-MED GP71



- Variable aluminium housing for additional functions
- Joypad with joystick function
- Additional push buttons for extra functionality (optional)
- Waterproof: IPX8 (IEC 60529)
- Stainless steel carrying handle (optional)

CONFIGURABLE USER INTERFACES

20 »THESE CONFIGURABLE FOOT CONTROLS ARE CUSTOM-DEVELOPED. CUSTOMERS RECEIVE USER INTERFACES DESIGNED TO THEIR OWN REQUIREMENTS AND ABLE TO TRIGGER MULTIPLE FUNCTIONS.«

.steute

MFS-MED GP712



- Robust plastic housing
- Joypad with joystick function, diagonal switching
- Rocker switches for rapid switching between 2 functions
- Additional push buttons for extra functionality (optional)
- Stainless steel carrying handle (optional)
- Very easy to clean

MFS-MED GP71



- Variable aluminium housing for additional functions
- Joypad with joystick function
- Rocker switches for rapid switching between 2 functions
- Additional push buttons for extra functionality (optional)
- Waterproof: IPX8 (IEC 60529)



»EYES ARE DELICATE. ACTUATORS OF OPHTHALMOLOGICAL DEVICES MUST THEREFORE BE EXTREMELY SENSITIVE AND PRECISE IN THEIR OPERATION. FOOT CONTROLS FROM STEUTE ARE DESIGNED WITH THIS IN MIND.«

MFS PHACO SW2.4LE-MED



- Wireless signal transmission via steute wireless low energy
- Power supply via rechargeable lithium-ion battery
- Socket for recharging of battery
- Pedal with proportional output signal (both vertical and horizontal)
- 4 rocker switches with 2 switching functions each
- Programmable braking points for tactile feedback
- Intuitive and extremely precise operation

WF-MED GP14



- Rocker switch for rapid switching between 2 functions
- Robust powder-coated die-cast zinc foot control
- Aluminium housing for increased weight
- Waterproof: IPX8 (IEC 60529)
- Additional push button for extra functionality (optional)
- Digital or analogue output signals available

MFS-MED GP71



- Variable aluminium housing for additional functions
- Joypad with joystick function
- Rocker switches for rapid switching between 2 functions
- Additional push buttons for extra functionality (optional)
- Waterproof: IPX8 (IEC 60529)

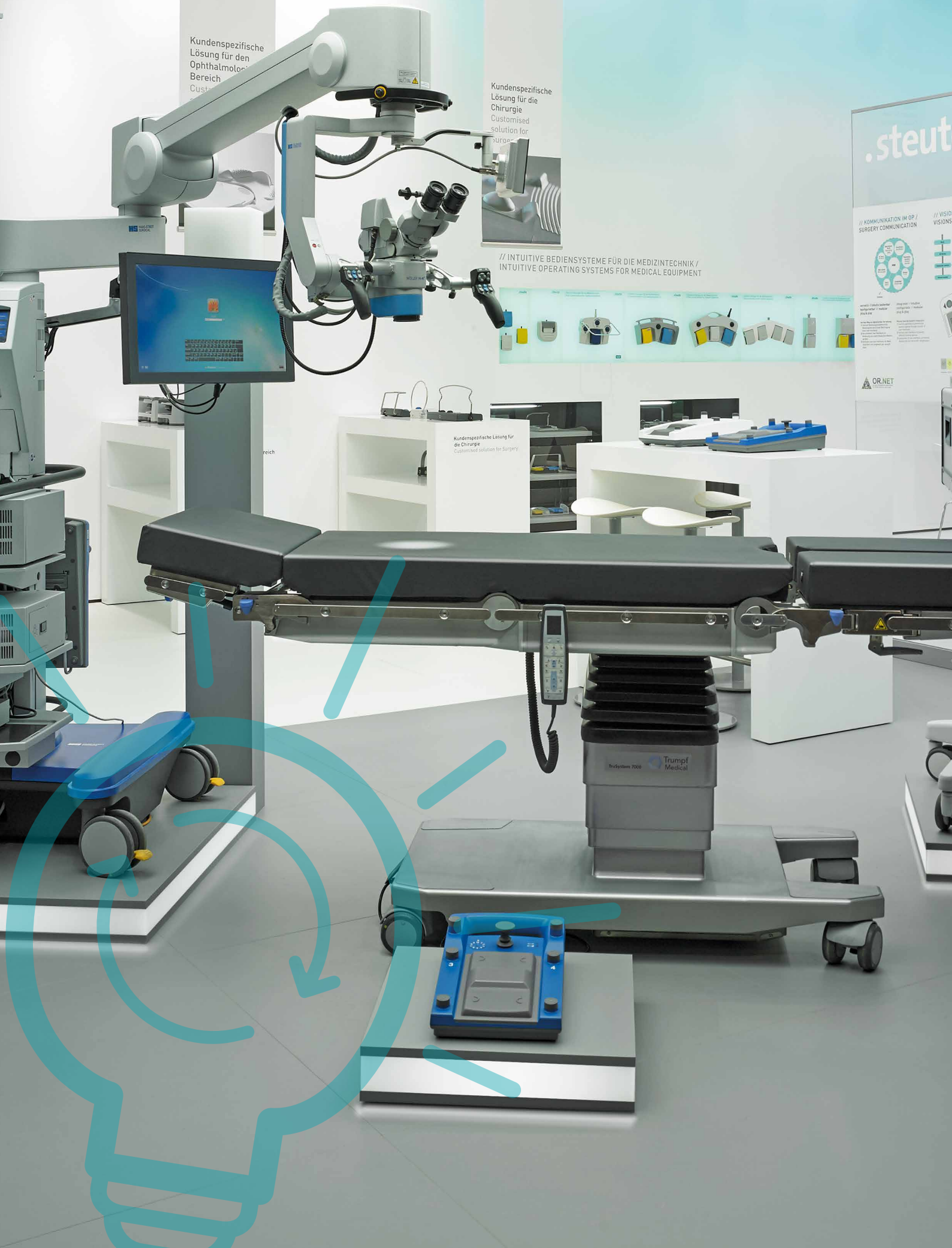
MFS Microscope SW2.4LE-MED



- Wireless signal transmission via steute wireless low energy
- Power supply via 3 batteries type C
- Battery compartment can be opened by hand
- Zoom and focus functions with central foot rest
- Joystick for positioning of microscope
- 6 additional push buttons with programmable functions
- Very easy to clean

INNOVATIONS

Integration of medical devices and interoperability of user interfaces



Kundenspezifische
Lösung für den
Ophthalmologie
Bereich
Cust

Kundenspezifische
Lösung für die
Chirurgie
Customised
solution for
surgery

// INTUITIVE BEDIENSYSTEME FÜR DIE MEDIZINTECHNIK /
INTUITIVE OPERATING SYSTEMS FOR MEDICAL EQUIPMENT

Kundenspezifische Lösung für
die Chirurgie
Customised solution for Surgery

.steu

// KOMMUNIKATION IM OP /
SURGERY COMMUNICATION

// VISIO
VISIONS

OR.NET

ProfSystem 2000
Trumpf
Medical

Looking towards the OR of the future

What will the OR of the future look like? What kinds of user interface will be needed? How will surgeons be able to operate the increasing number of different medical devices intuitively? These are questions we ask ourselves every day – in our own research and development, in cooperation projects and in dialogue with scientists.

The standards which we have set ourselves include not only adhering to state-of-the-art technology and developing user interfaces with the best possible features; our goal is also to be pioneering and to ask ourselves: which requirements will be made of user interfaces in the future?

One trend predominates here without a doubt: the number of medical devices required during surgery is increasing. Surgeons therefore face the challenge of concentrating increasingly on multiple user interfaces with differing usability concepts.

The pioneering OR

The solution is the interoperable OR: multiple medical devices are controlled via a joint user interface – consisting of one screen and one foot-controlled system. This is the solution which we are currently working on. Important foundation stones were laid in the OR.NET project, which we have been a part of since 2014.

The results of this application-oriented research include the SDC standard („Service-oriented Device Connectivity“), which defines an open communication protocol for the safe dynamic integration of medical devices. This standard has already been described in a family of standards (ISO/IEEE 11073). This provides an important basis for realisation of the interoperable OR.

Huge benefits all round

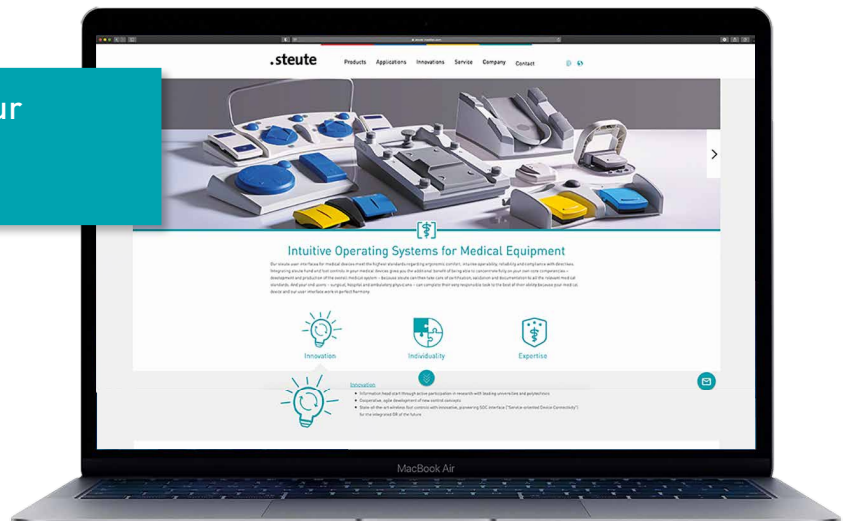
Integrating medical devices via a joint touchscreen and a single human-machine interface is a complex task, but one which is progressing well. One reason for this is that the benefits are obvious for everyone involved:

- Manufacturers of medical devices can realise future-oriented concepts for integrating their devices in networked OR environments.
- Surgeons can operate multiple devices intuitively and concentrate more fully on the surgery and the patient.
- Patients profit from precise and faultless operation of all medical devices used.

The integration of medical devices via a shared user interface also has other benefits. For example, the OR staff can call up patient data and images from the hospital archive on the screen if required. Hygiene is improved because the number of HMI (human-machine interfaces) in the OR is reduced. And operating the controls is additionally improved by the fact that surgeons can adapt the user interface, or rather the arrangement of functions offered, to the requirements of their surgical routines and to their own ergonomic comfort.

OR.NET is just one of several research and cooperation projects currently pursuing interoperability in the OR. We are active participants in the quest to develop user interfaces for the medical devices of tomorrow.

For more detailed information on our research projects, please go to: www.steute-meditec.com



EXPERTISE
Exploit our expertise to your own ends



We have been developing and manufacturing user interfaces for medical devices for decades. We work with global players in the medical device market, but also with highly specialised medium-sized businesses.

You can profit from this expertise by signing up to our comprehensive services. We can develop for you and with you customised user interfaces specific to your needs and applications. And we always take into account the requirements of the medical discipline and technology in question, as well as the latest research into ergonomic comfort and usability. Examples of customised user interfaces are available at www.steute-meditec.com.

And once our collaboration, in other words the design and functionality of your new user interface, has been completed, we will be happy to offer you additional services to simplify your work, e.g. the approval of your medical device. Our products fulfil all the regulatory requirements of the Medical Device Regulation (MDR) and are optionally FDA-compatible as well.

Nearly all customised user interfaces currently developed by steute Meditec, in collaboration with medical device manufacturers, communicate with the device in question by remote control. And even for our standard controls, such as the multi-pedal foot controls in our "Classic" range, wireless HMI (human-machine interfaces) are increasingly in demand. There are good reasons for this development. HMI which are not connected to the medical device by cable can be positioned more freely. This makes them more ergonomic and also less problematic with regard to hygiene. And it should not be underestimated how much a wireless foot control upgrades an overall system. Wireless technology is state-of-the-art and helps manufacturers to stand out from the crowd.

Another reason behind the intensive use of wireless technology is the fact that highly reliable wireless technologies are now available which have been developed specifically with medical equipment in mind – for example SW2.4LE-MED from steute Meditec. It features high transmission reliability and low power consumption in conjunction with fast reaction times. The transmission reliability is documented with a very low residual error probability of below 1×10^{-9} 1/h. This means that the wireless system fulfils the requirements of SIL 3 (Safety Integrity Level to IEC 61508).

It should not be forgotten that the effort required for testing wireless control systems and the corresponding documentation has risen considerably in the past few years.

One reason for this is new or changed guidelines, such as the EU "Radio Equipment Directive" (RED) replacing the previous directive R&TTE, as well as the amended EMC guideline, valid since April 2017, for applications involving medical equipment (IEC 60601-1-2:2016). In addition, some countries have their own stipulations for the use of wireless systems.



For more than 60 years steute has been a specialist in the development, production and marketing of switchgear and sensors. Besides a comprehensive standard range of products for »Wireless, Automation, Extreme and Meditec« applications, we also and increasingly develop customised switchgear and sensors for all four business fields. Some examples: emergency pull-wire switches for the mining industry, position switches for industrial automation and control panels for laser surgery. Our head office is in Löhne, Germany. Worldwide sales are conducted through steute's subsidiaries and trading partners.

If you would like further information or individual advice, please contact us. Please go to our website for more details: www.steute.com

steute Technologies GmbH & Co. KG

Brückenstraße 91
32584 Löhne, Germany
Tel + 49 57 31 7 45-0
Fax + 49 57 31 7 45-200
meditec@steute.com
www.steute-meditec.com

