

// IINTUITIVE OPERATING SYSTEMS FOR MEDICAL EQUIPMENT

Catalogue



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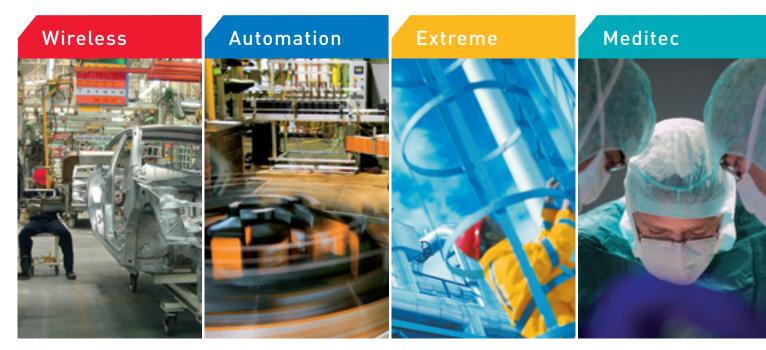
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// SAFE SWITCHGEAR FOR DEMANDING AND CRITICAL APPLICATIONS



»Safe switchgear for demanding and critical applications«. True to this motto, steute has been providing its customers with innovative, practical and durable switchgear solutions – for over 50 years.

When our customers are successful, so are we. Because we always focus on our customers, our company has grown steadily and sustainably over the last decades. Steute is committed to continuing this growth - in close cooperation with our customers.

We are situated in East Westphalia, a key region for machine building and electrical goods manufacturing. It is home to qualified specialists committed to developing and manufacturing innovative products. It is also the location of renowned universities, research and educational institutions to which we maintain healthy contacts.

Markets are no longer restricted by national borders. This is why our products are developed and tested for extreme conditions all over the world. We take care to ensure that our products are always certified according to the latest international standards. In every industrial or emerging nation in the world, steute has access to qualified specialists who can guarantee competent support and a quick service.

As a medium-sized company we are able to react with speed to customer wishes and market trends. We are continually developing innovative products and using new technologies as we consistently open up new fields of application for our switchgear.

steute is currently active in four different business fields, producing switchgear, sensors and control units for use in industry and in medical equipment:

Wireless

Cable free switchgear and sensors for use in machinery and process plants. These industrial-strength wireless switches communicate with higher level control systems via reliable radio transmission. »Energy harvesting« can play a major role in these products.

Automation

Standard and customised switchgear for machinery and process plants. Tried and tested electromechanical and non-contact technologies for classical applications in industrial automation and process control – always with a view to the latest global requirements.

Extreme

Switchgear and sensors for use in extreme environments or under extreme conditions. Certified products for use in hazardous areas worldwide (e.g. ATEX, IECEX, GOST).

Meditec

A comprehensive range of standard and customised foot and hand controls for medical devices, meeting the highest ergonomic and availability requirements. Produced in accordance with the certified EN ISO 13485 quality management system for medical products.

The following information provides an overview of our standard range of switchgear for complex and demanding applications. We will be happy to provide you with any additional information you require. If you cannot find the solution for your application: just get in touch. We have already helped numerous customers by developing "tailor-made" switchgear for their individual needs.

Marc Stanesby Managing Director steute Schaltgeräte GmbH & Co. KG

// STEUTE MEDITEC – INTUITIVE OPERATING SYSTEMS FOR MEDICAL EQUIPMENT





Whether in the operating theatre, the diagnostics lab or the doctor's surgery, medical equipment needs to be able to be operated intuitively so that physicians and medical staff can concentrate fully on the patient and/or operation.

The field of application: extremely demanding

In this extremely demanding field of application for man-machine interfaces, steute already has comprehensive expertise. The steute business field Meditec not only produces a standard range of foot and hand controls for medical equipment, but also a large number of customised actuators for highly complex and, increasingly frequently, wireless applications.

The development: to the highest standards

During the development of new generations of control units, steute always focuses on the individual application – and our goal of guaranteeing the highest degree of ergonomic and operational comfort, an area in which we have acquired more than 20 years' experience. We also collaborate with universities and scientific institutes evaluating the serviceability of medical devices and their man-machine interfaces. We employ the latest development tools and highest-quality testing apparatus and are continually expanding our R&D capacity.

The production: certified in accordance with EN ISO 13485: 2003 + AC: 2009 and ISO 9001: 2008

steute Meditec control units are produced on the basis of a quality management system certified in accordance with EN ISO 13485 and ISO 9001. Production is designed to achieve the highest quality and at the same time the greatest possible flexibility, meaning that we can manufacture both major product series and small piece numbers economically and fast.

The technology: innovative

All steute control units for medical equipment fulfil very high standards in ergonomic comfort and availability. For many years now steute has been coming up with innovations to improve functionality and operational comfort, and this is a major reason why global leaders in medical technology choose man-machine interfaces from steute Meditec.

A very good example is our wireless control units. steute has been addressing this complex topic for a long time and has developed a wireless standard designed especially for the safety and reliability standards expected of medical equipment.

The collaboration: cooperative

With our work and our products we are making just one small contribution to the overall »medical device« complex. And yet our contribution has a special impact because it constitutes the interface to the user. Our customers rightly expect a great deal. And they would like not only their own concept, but also their own »spirit« to be reflected in their actuators. This is why we closely involve our customers from the development phase onwards, while pursuing the goal of providing them with the optimum control unit for their individual application.

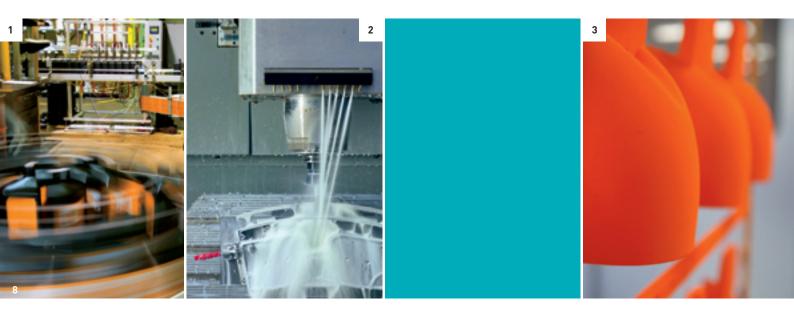
Meditec Basic

steute's basic product range is based on the broad spectrum of standard steute components. Customised solutions are developed from tried and tested components, avoiding initial costs and achieving very short »time to market« intervals.

Meditec Exclusive

steute's exclusive product range comprises all the complex devices which have been developed with a high level of effort in order to provide tailor-made user interfaces for particular medical devices. Contact us for your tailor-made solution.

// STEUTE MEDITEC MEANS: FLEXIBLE FROM THE DEVELOPMENT STAGE THROUGH TO INTEGRATED MANUFACTURING



From the idea to the finished product

steute Meditec demands extremely high quality from the manufacturing process – and that means every single step of the way. On the following two double pages the production process is illustrated using the example of a customised foot control for medical equipment.

Short paths between development and production (1)

At steute the paths are short. This is true of the spatial proximity between our development and production departments, but also of the close working relationship between our development and production experts. This closeness guarantees that good ideas can be put into practice while remaining both economic and high-quality.

»Make or buy?« (2)

Not everything has to be done by us. Diecast and plastic enclosures, for example, are manufactured especially for us by well established, specialised suppliers. But as soon as the enclosures are ready for further processing, we prefer to take over ourselves. This also enables us to keep delivery times for small series or customised special editions short.

Colour: as you like it (3)

Using a state-of-the-art powder coating machine, the diecast enclosures for our foot controls receive a finish of the highest quality. The flexibility of this machine means that we are able to provide switchgear in all the colours of the rainbow – to match the corporate identity of each individual customer.

Switches which stay shut (4)

The high hygiene requirements found in operating theatres, for example, impact the construction of a man-machine interface: neither water nor cleansing agents must be allowed to penetrate the foot control, even when cleaning has to be extremely thorough. For this reason we seal our enclosures using a fully automatic sealing-foaming machine. This sealing technique is a prerequisite for low maintenance. Even after opening, maintaining and reclosing the foot control, reliable impermeability is still guaranteed.

Fast mounting, 100% control (5)

The electronics inside state-of-the-art foot controls make a considerable contribution to their operational comfort and flexibility. In the electronics section of the steute Meditec production department, the latest surface mounting devices with integrated image processing for quality control are used

Flexible automation

Since, in addition to large standard series, we also manufacture many small and medium-sized series, as well as customised solutions, our motto when investing in new production technology is always: automation yes – but it has to be flexible. Only in this way can we continue to grant ourselves and our customers the advantage of highest quality in combination with short flow path and delivery times.





// WATER PRESSURE, COMPRESSED AIR AND IMPACT TEST



// TRIED AND TESTED BY STEUTE MEDITEC





Connecting well - with an environmental conscience (6)

We use sustainable, environmentally-friendly production methods, a fact aptly demonstrated by our soldering machine: the soldering bath in which the electronic components are set and attached to the circuit boards works at a temperature of just 230 °C. This saves energy and protects components by subjecting them to a lower level of heat.

Assembly (7)

The assembly at steute Meditec meets all the requirements of medical equipment production. It is completely ESD-protected, i.e. it reliably excludes the risk of electrostatic charge (which could damage the sensitive electronic components). The quality management of our production has been certified in accordance with EN ISO 13485 standards.

»Tried and tested« (8)

In order to be sure that our foot controls work reliably, even under unfavourable environmental conditions or with extreme wear and tear, we subject them to the toughest of tests, including the impact test required by IEC 60601

Compressed air replaces water

Devices in protection class IP X8 (protection against permanent immersal) are tested during the production procedure using a »dry« procedure. Instead of looking for bubble formation by immersing an enclosure in water, we fill it with compressed air to a defined pressure using a test hose, independently of the enclosure volume, and then measure any difference in pressure over a fixed period of time. If the pressure remains constant, the switch is perfectly sealed and fulfils IP X8.

Water on!

For IP X6 tests (protection against powerful water jets) our newly installed test machine is used. The testing conditions are: impact with 100 I of water per minute, with a jet diameter of 12.5 mm, from a distance of 2.5 to 3.0 m, for at least 3 minutes.

Finished.

Now just the packaging is missing – and the foot control can be sent off to the customer in order to fulfil its important task in the operating theatre: e.g. controlling the functions of microscopes, ophthalmological devices, lasers, X-ray devices or electrosurgical devices.



// WE OFFER MORE THAN THE VALID **REGULATIONS DEMAND**

The CE marking per Medical Device Directive 93 /42 / EEC. The approval per UL 60601 and IEC 60601

The AP mark for anaesthesia approved medical devices.



Everything is easy

Our extensive program of foot-operated control devices for medical equipment shows our competence in this field: You can expect a lot from us. And even exotic requirements cannot shock our spe-

If you think finding the optimum foot control is hard, we will convince you of the opposite! On pages 16 to 56 we introduce our standard program that we, of course, can adapt to your customised requirements.

As a middle-size company with short decision paths and a flexible production we also like to develop and produce your »desired switch« - in an exclusive design, with individual housing, with special operat-ing elements or safety equipment. To find out how we proceed, please read pages 6 to 13.

What can we offer you?

- CE-conforming products per directive 93/42/EEC

- Approval per UL 60601
 Protection classes up to IPX8 per IEC 60529
 Customised developments

- Longtime experience in the cooperation with manufacturers of

- Gas-proof encapsulated switching elements for AP applications Exclusive designs Easy-to-clean features





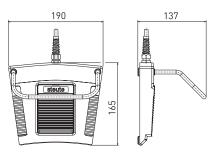
1-pedal medical foot controls

// Series MKF-MED
Shock-proof, glassfibre-reinforced
thermoplastic foot control
starting on page 16
// Series MGF-MED
Easy-to-clean aluminium
die-cast foot control
starting on page 19
// Series RF-MED
All-side actuation aluminium
die-cast foot control
starting on page 21

1-pedal medical foot controls // Series (M)KF-MED

16



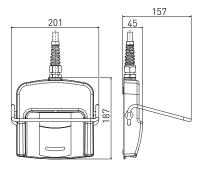


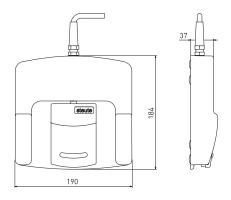
// MKF-MED // KF-MED GP11 Features /Options - high mechanical stability Features /Options - high mechanical stability - non-contact switching systems - non-contact switching systems - reed contacts for small currents - reed contacts for small currents - digital or analogue output signals - digital or analogue output signals - class AP - additional push-buttons - plug-in connector - LEDs - pressure point - stainless steel protective bracket - special labels - wireless signal transmission - different RAL colours - class AP - plug-in connector Standards IEC 60601-1; UL 60601-1; IEC 60529; - pressure point MPG 93/42/EEC - special labels Pedal shock-proof thermoplastic, - different RAL colours UL 94-V0/-V2 IP X5 per IEC 60529, up to IP X8 as option Standards IEC 60601-1; UL 60601-1; IEC 60529; **Protection class** reed contact/micro switch/Hall sensor MPG 93/42/EEC Switching element Switching system 1 – 2 NO contacts/1 change-over/analogue Pedal shock-proof thermoplastic, UL 94-V0/-V2 output 0 ... 10 VDC, 0 ... 20 mA, 4 ... 20 mA Console GK-Al alloy, RAL 7035 Mechanical life > 1 million operations **Protection class** IP X5 per IEC 60529, up to IP X8 as option 2 m cable, other lengths Switching element reed contact/micro switch/Hall sensor Connection optionally available Switching system 1 - 2 NO contacts/1 change-over/analogue output 0 ... 10 VDC, 0 ... 20 mA, 4 ... 20 mA Switching voltage max. 25 VAC/60 VDC Switch-on current max. 1 A/max. 5 A Mechanical life > 1 million operations 2 m cable, other lengths Switching power max. 30 VA/max. 1250 VA Connection Supply voltage optionally available 15 ... 30 VDC/max. 25 mA max. 25 VAC/60 VDC Hall sensor Switching voltage Switch-on current max. 1 A/max. 5 A Switching power max. 30 VA/max. 1250 VA

Supply voltage

Hall sensor

15 ... 30 VDC/max. 25 A



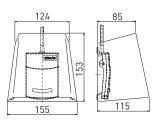


// MKF-MED GP12

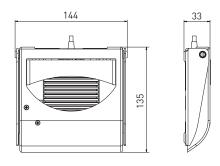


	Photo shows optional accessories		Photo shows optional accessories
Features /Options	 high mechanical stability non-contact switching systems reed contacts for small currents digital or analogue output signals additional push-buttons LEDs hinged stainless steel protective bracket class AP plug-in connector pressure point special labels different RAL colours 	Features /Options of steute Wireless	 Thermoplastic console ideal for intergation high mechanical stability non-contact switching systems reed contacts for small currents digital or analogue output signals additional push-buttons LEDs hinged stainless steel protective bracket wireless signal transmission class AP plug-in connector pressure point
Standards	IEC 60601-1; UL 60601-1; IEC 60529; MPG 93/42/EEC		- special labels - different RAL colours
Pedal	shock-proof thermoplastic, UL 94-V0/-V2	Standards	IEC 60601-1; UL 60601-1; IEC 60529;
Console	GK-Al alloy, RAL 7035		MPG 93/42/EEC
Protection class	IP X5 per IEC 60529, up to IP X8 as option	Pedal	shock-proof thermoplastic, UL 94-V0/-V2
Switching element	reed contact/micro switch/Hall sensor	Console	shock-proof thermoplastic, RAL 7035
Switching system	1 – 2 NO contacts/1 change-over/analogue output 0 10 VDC, 0 20 mA, 4 20 mA	Protection class Switching element	IP X5 per IEC 60529, up to IP X8 as option reed contact/micro switch/Hall sensor
Mechanical life	> 1 million operations	Switching system	1 – 2 NO contacts/1 change-over/analogue
Connection	2 m cable, other lengths optionally available	Mechanical life	output 0 10 VDC, 0 20 mA, 4 20 mA > 1 million operations
Switching voltage	max. 25 VAC/60 VDC	Connection	2 m cable, other lengths
Switch-on current	max. 1 A/max. 5 A		optionally available
Switching power	max. 30 VA/max. 1250 VA	Switching voltage	max. 25 VAC/60 VDC
Supply voltage		Switch-on current	max. 1 A/max. 5 A
Hall sensor	15 30 VDC/max. 25 mA	Switching power Supply voltage Hall sensor	max. 30 VA/max. 1250 VA 15 30 VDC/max. 25 mA

1-pedal medical foot controls // Series (M)KF-MED



// MKFS-MED





1	0
	O.

Features /Options	 protection against unintentional actuation high mechanical stability 	Features /Options actuation at minimun	- maximum protection ag n dimensions
	- non-contact switching systems		- high mechanical stabili
	- reed contacts for small currents		- non-contact switching s
	- digital or analogue output signals		 reed contacts for small
	- class AP		- digital or analogue outp
	- plug-in connector		- class AP
	- pressure point		- plug-in connector
	- special labels		- pressure point
	 different RAL colours 		- special labels
			 different RAL colours
Standards	IEC 60601-1; UL 60601-1; IEC 60529;		
	MPG 93/42/EEC	Standards	IEC 60601-1; UL 60601-1;
Pedal	shock-proof thermoplastic, UL 94-V0/-V2		MPG 93/42/EEC
Protective shield	steel sheet, RAL 7035	Pedal	shock-proof thermoplast
Protection class	IP X5 per IEC 60529, up to IP X8 as option	Protective flap	stainless steel, RAL 7035
Switching element	reed contact/micro switch/Hall sensor	Protection class	IP X5 per IEC 60529, up to
Switching system	1 – 2 NO contacts/1 change-over/analogue	Switching element	reed contact/micro switch
	output 0 10 VDC, 0 20 mA, 4 20 mA	Switching system	1 – 2 NO contacts/1 chang
Mechanical life	> 1 million operations		output 0 10 VDC, 0 20
Connection	2 m cable, other lengths	Mechanical life	> 1 million operations
	optionally available	Connection	2 m cable, other lengths
Switching voltage	max. 25 VAC/60 VDC		optionally available
Switch-on current	max. 1 A/max. 5 A	Switching voltage	max. 25 VAC/60 VDC
Switching power	max. 30 VA/max. 1250 VA	Switch-on current	max. 1 A/max. 5 A
Supply voltage		Switching power	max. 30 VA/max. 1250 VA
Hall sensor	15 30 VDC/max. 25 mA	Supply voltage	
		Hall sensor	15 30 VDC/max. 25 mA

against unintentional

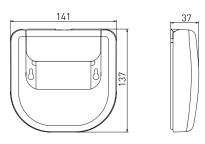
lity

- systems
- ll currents
- tput signals

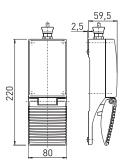
1; IEC 60529; stic, UL 94-V0/-V2 35 to IP X8 as option nge-over/analogue 20 mA, 4 ... 20 mA /Α

mΑ 15 ... 30 VDC/max. 25

1-pedal medical foot controls // Series (M)KF-MED / MGF-MED



// MKF-MED SK12



// MGF-MED

Features /Options

Standards

Enclosure

Protection class

Switching element

Switching system

Output value poti

Mechanical life

Switching voltage

Switch-on current

Switching power

Supply voltage

Hall sensor

Linearity

Connection

Pedal



Photo shows optional accessories

Features /Options - maximum protection against unintentional actuation at minimum dimensions

- high mechanical stability
- non-contact switching systems
- reed contacts for small currents
- digital or analogue output signals

IEC 60601-1; UL 60601-1; IEC 60529;

- class AP
- plug-in connector
- pressure point
- special labels
- different RAL colours

Standards

Pedal Protective flap Baseplate Protection class Switching element Switching system

Mechanical life Connection

Switching voltage Switch-on current Switching power Supply voltage Hall sensor MDD 93/42/EEC shock-proof thermoplastic, UL 94-V0/-V2 shock-proof thermoplastic, RAL 7035 GD-Zn alloy, RAL 7035 IP X5 per IEC 60529, up to IP X8 as option reed contact/micro switch/Hall sensor 1 - 2 NO contacts/1 change-over/analogue output 0 ... 10 VDC, 0 ... 20 mA, 4 ... 20 mA > 1 million operations 2 m cable, other lengths optionally available max. 25 VAC/60 VDC max. 1 A/max. 5 A max. 30 VA/max. 1250 VA

15 ... 30 VDC/max. 25 mA



- high mechanical sta	bility
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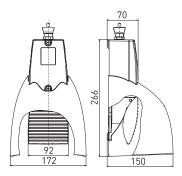
- easy-to-clean

- digital or analogue output signals
- additional push-buttons
- protective bracket
- wireless signal transmission
- class AP
- plug-in connector
- pressure point
- special labels
- different RAL colours

IEC 60601-1; UL 60601-1; IEC 60529; MPG 93/42/EEC GD-Al alloy, enamel finish RAL 7035 GD-Al alloy, enamel finish RAL 7035 IP X5 per IEC 60529, up to IP X8 as option switch insert, positive break, gold contacts/ Hall sensor/potentiometer slow action: 1 NC/1 NO contact or 2 NC/2 NO contacts/analogue output 0 ... 10 VDC, 0 ... 20 mA, 4 ... 20 mA $20 \ \Omega \ ... \ 1 \ k\Omega \ \pm 3 \ \%; \ 20 \ \Omega \ ... \ 2 \ k\Omega \ \pm 3 \ \%;$ 50 Ω ... 5 k Ω ±3 %; 100 Ω ... 10 k Ω ±3 %; ±0,5 % > 1 million operations 2 m cable, other lengths optionally available max. 25 VAC/60 VDC max. 5 A max. 1250 VA

15 ... 30 VDC/max. 25 mA

1-pedal medical foot controls // Series MGF-MED

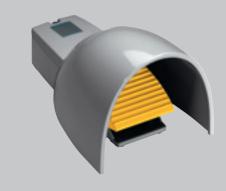


// MGFS-MED

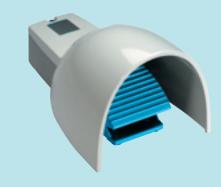


20		
	Features /Options	 protection against unintentional actuation high mechanical stability easy-to-clean digital or analogue output signals wireless signal transmission class AP plug-in connector pressure point special labels different RAL colours
	Standards	IEC 60601-1; UL 60601-1; IEC 60529; MPG 93/42/EEC
	Enclosure/Protective shield Pedal Protection class Switching element Switching system	GD-Al alloy, enamel finish RAL 7035 GD-Al alloy, enamel finish RAL 7035 IP X5 per IEC 60529, up to IP X8 as option switch insert, positive break, gold contacts/ Hall sensor/potentiometer slow action: 1 NC/1 NO contact or 2 NC/2 NO contacts/analogue output 0 10 VDC, 0 20 mA, 4 20 mA
	Output value poti	$\begin{array}{c} 20 \ \Omega & \dots & 10 \ \text{VDC}, 0 \ \dots & 20 \ \text{InA}, 4 \ \dots & 20 \ \text{InA} \\ 20 \ \Omega & \dots & 1 \ \text{k}\Omega \ \pm 3 \ \text{\%}; 20 \ \Omega \ \dots & 2 \ \text{k}\Omega \ \pm 3 \ \text{\%}; \\ 50 \ \Omega \ \dots & 5 \ \text{k}\Omega \ \pm 3 \ \text{\%}; 100 \ \Omega \ \dots & 10 \ \text{k}\Omega \ \pm 3 \ \text{\%}; \end{array}$
	Linearity Mechanical life Connection	±0,5 % > 1 million operations 2 m cable, other lengths optionally available
	Switching voltage Switch-on current Switching power Supply voltage Hall sensor	max. 25 VAC/60 VDC max. 5 A max. 1250 VA 15 30 VDC/max. 25 mA

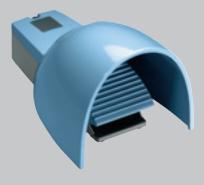
// MGFS-MED



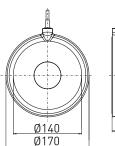
// MGFS-MED



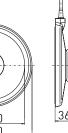
// MGFS-MED



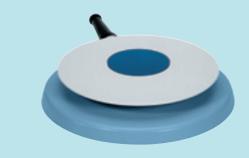
1-pedal medical foot controls // Series RF-MED



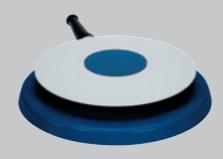
// RF-MED



// RF-MED



// RF-MED





Features /Options

- all side actuation
 - high mechanical stability
 - non-contact switching systems
 - reed contacts for small currents
 - class AP
 - plug-in connector
 - special labels
 - different RAL colours

Standards

Switching plate Enclosure Protection class Switching element Switching system Mechanical life Connection

Switching voltage Switch-on current Switching power

IEC 60601-1; UL 60601-1; IEC 60529; MPG 93/42/EEC GK-Al alloy, RAL 7035 GD-Al alloy, RAL 7035 IP X5 per IEC 60529, up to IP X8 as option reed contact/micro switch 1 – 2 NO contacts /1 change-over contact > 1 million operations 2 m cable, other lengths optionally available max. 25 VAC/60 VDC max. 1 A/max. 5 A max. 30 VA/max. 1250 VA

// RF-MED





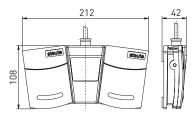
2-pedal medical foot controls



// Series MKF 2-MED
Foot control on thermoplastic/
aluminium console
starting on page 24
// Series MGF 2-MED
Foot control on thermoplastic/
aluminium console
starting on page 27

23

2-pedal medical foot controls // Series MKF 2-MED



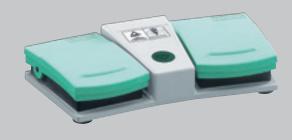
// MKF 2-MED GP25



2	1
/	4

Features /Options	 high mechanical stability non-contact switching systems reed contacts for small currents digital or analogue output signals LEDs protective bracket class AP plug-in connector pressure point special labels different RAL colours
Standards	IEC 60601-1; UL 60601-1; IEC 60529; MPG 93/42/EEC
Pedal	shock-proof thermoplastic, UL 94-V0/-V2
Console	shock-proof thermoplastic, UL 94-V0
Protection class	IP X5 per IEC 60529, up to IP X8 as option
Switching element	reed contact/micro switch/Hall sensor
Switching system	1 – 2 NO contacts/1 change-over/analogue output 0 10 VDC, 0 20 mA, 4 20 mA
Mechanical life	> 1 million operations
Connection	2 m cable, other lengths
	optionally available
Switching voltage	max. 25 VAC/60 VDC
Switch-on current	max. 1 A/max. 5 A
Switching power	max. 30 VA/max. 1250 VA
Supply voltage	
Hall sensor	15 30 VDC/max. 25 mA

// MKF 2-MED GP25



// MKF 2-MED GP25

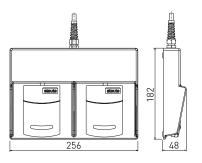


Photo shows optional accessories

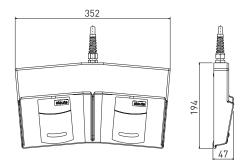
// MKF 2-MED GP25



Photo shows optional accessories



// MKF 2-MED GP23



// MKF 2-MED GP21

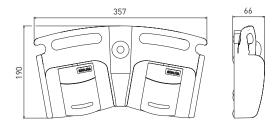


25

Features /Options	 high mechanical stability non-contact switching systems reed contacts for small currents digital or analogue output signals additional push-buttons LEDs protective bracket wireless signal transmission class AP plug-in connector pressure point special labels different RAL colours 	Features /Options	 high mechanical stability non-contact switching systems reed contacts for small currents digital or analogue output signals additional push-buttons LEDs protective bracket wireless signal transmission class AP plug-in connector pressure point special labels different RAL colours
Standards	IEC 60601-1; UL 60601-1; IEC 60529; MPG 93/42/EEC	Standards	IEC 60601-1; UL 60601-1; IEC 60529; MPG 93/42/EEC
Pedal	shock-proof thermoplastic, UL 94-V0/-V2	Pedal	shock-proof thermoplastic, UL 94-V0/-V2
Console	GK-Al alloy, RAL 7035	Console	GK-Al alloy, RAL 7035
Protection class	IP X5 per IEC 60529, up to IP X8 as option	Protection class	IP X5 per IEC 60529, up to IP X8 as option
Switching element	reed contact/micro switch/Hall sensor	Switching element	reed contact/micro switch/Hall sensor
Switching system	1 – 2 NO contacts/1 change-over/analogue output 0 10 VDC, 0 20 mA, 4 20 mA	Switching system	1 – 2 NO contacts/1 change-over/analogue out put 0 10 VDC, 0 20 mA, 4 20 mA
Mechanical life	> 1 million operations	Mechanical life	> 1 million operations
Connection	2 m cable, other lengths	Connection	2 m cable, other lengths
	optionally available		optionally available
Switching voltage	max. 25 VAC/60 VDC	Switching voltage	max. 25 VAC/60 VDC
Switch-on current	max. 1 A/max. 5 A	Switch-on current	max. 1 A/max. 5 A
Switching power Supply voltage	max. 30 VA/max. 1250 VA	Switching power Supply voltage	max. 30 VA/max. 1250 VA
Hall sensor	15 30 VDC/max. 25 mA	Hall sensor	15 30 VDC/max. 25 mA

2-pedal medical foot controls // Series MKF 2-MED

// MKF 2-MED GP212



// MKF 2-MED GP26

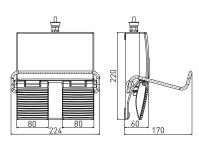


26

Photo shows optional accessories

			Photo shows optional accessories
Features /Options	- high mechanical stability - Thermoplastic console ideal for steute	Features /Options	- high mechanical stability - non-contact switching systems
Wireless integration			- reed contacts for small currents
	 non-contact switching systems 		- digital or analogue output signals
	 reed contacts for small currents 		- additional push-buttons
	 digital or analogue output signals 		- LEDs
	 additional push-buttons 		- protective bracket
	- LEDs		- wireless signal transmission
	- protective bracket		- class AP
	- wireless signal transmission		- plug-in connector
	- class AP		- pressure point
	- plug-in connector - pressure point		- special labels - different RAL colours
	- special labels		- unierent NAL colours
	- different RAL colours	Standards	IEC 60601-1; UL 60601-1; IEC 60529; MPG 93/42/EEC
Standards	IEC 60601-1; UL 60601-1; IEC 60529;	Pedal	shock-proof thermoplastic, UL 94-V0/-V2
	MPG 93/42/EEC	Console	GD-Al alloy, RAL 7035
Pedal	shock-proof thermoplastic, UL 94-V0/-V2,	Protection class	IP X5 per IEC 60529, up to IP X8 as option
	black RAL 9005	Switching element	reed contact/micro switch/Hall sensor
Console	shock-proof thermoplastic, RAL 7035	Switching system	1 – 2 NO contacts/1 change-over/analogue
Protection class	IP X5 per IEC 60529, up to IP X8 as option		output 0 10 VDC, 0 20 mA, 4 20 mA
Switching element	reed contact/micro switch/Hall sensor	Mechanical life	> 1 million operations
Switching system	1 – 2 NO contacts/1 change-over/analogue	Connection	2 m cable, other lengths
Mechanical life	output 0 10 VDC, 0 20 mA, 4 20 mA	Curitabing valtage	optionally available max. 25 VAC/60 VDC
Connection	> 1 million operations 2 m cable, other lengths	Switching voltage Switch-on current	max. 1 A/max. 5 A
Connection	optionally available	Switching power	max. 30 VA/max. 1250 VA
Switching voltage	max. 25 VAC/60 VDC	Supply voltage	
Switch-on current	max. 1 A/max. 5 A	Hall sensor	15 30 VDC/max. 25 mA
Switching power	max. 30 VA/max. 1250 VA		
Supply voltage			
Hall sensor	15 30 VDC/max. 25 mA		

2-pedal medical foot controls // Series MGF 2-MED



// MGF 2-MED

Features /Options



- high mechanical stability

reatures / options	 - easy-to-clean - digital or analogue output signals - additional push-buttons - hinged stainless steel protective bracket - wireless signal transmission - class AP - plug-in connector - pressure point - special labels - different RAL colours
Standards	IEC 60601-1; UL 60601-1; IEC 60529; MPG 93/42/EEC
Enclosure	GD-Al alloy, enamel finish RAL 7035
Pedal	GD-Al alloy, enamel finish RAL 7035
Protection class	IP X5 per IEC 60529, up to IP X8 as option
Switching element	switch insert, positive break, gold contacts/ Hall sensor/potentiometer
Switching system	slow action: 1 NC/1 NO contact or 2 NC/2 NO contacts/analogue output 0 10 VDC, 0 20 mA, 4 20 mA
Output value poti	$20 \ \Omega \ \dots \ 1 \ k\Omega \ \pm 3 \ \%; 20 \ \Omega \ \dots \ 2 \ k\Omega \ \pm 3 \ \%; 50 \ \Omega \ \dots \ 5 \ k\Omega \ \pm 3 \ \%; 100 \ \Omega \ \dots \ 10 \ k\Omega \ \pm 3 \ \%;$
Linearity	±0,5 %
Mechanical life	> 1 million operations
Connection	2 m cable, other lengths
	optionally available
Switching voltage	max. 25 VAC/60 VDC
Switch-on current	max. 5 A
Switching power	max. 1250 VA
Supply voltage	
Hall sensor	15 30 VDC/max. 25 mA

// MGF 2-MED



// MGF 2-MED



Photo shows optional accessories

// MGF 2-MED



Photo shows optional accessories

// MGF 2-MED



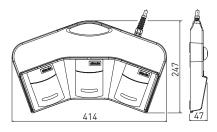


3-pedal medical foot controls



// Series MKF 3-MED
Foot control on aluminium console
starting on page 30
// Series MTF 3-MED
Foot control in ergonomic
aluminium die-cast enclosure
starting on page 32

3-pedal medical foot controls // Series MKF 3-MED



// MKF 3-MED GP34



Features /Options	 high mechanical stability non-contact switching systems reed contacts for small currents digital or analogue output signals additional push-buttons LEDs protective bracket wireless signal transmission class AP plug-in connector pressure point special labels different RAL colours
Standards	IEC 60601-1; UL 60601-1; IEC 60529; MPG 93/42/EEC
Pedal	shock-proof thermoplastic, UL 94-V0/-V2
Console	GK-Al alloy, RAL 7035
Protection class	IP X5 per IEC 60529, up to IP X8 as option
Switching element	reed contact/micro switch/Hall sensor
Switching system	1 – 2 NO contacts/1 change-over/analogue output 0 10 VDC, 0 20 mA, 4 20 mA
Mechanical life	> 1 million operations
Connection	2 m cable, other lengths
	optionally available
Switching voltage	max. 25 VAC/60 VDC
Switch-on current	max. 1 A/max. 5 A
Switching power	max. 30 VA/max. 1250 VA
Supply voltage	
Hall sensor	15 30 VDC/max. 25 mA

// MKF 3-MED GP34



Photo shows optional accessories

// MKF 3-MED GP34

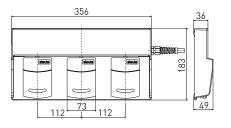


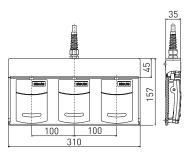
Photo shows optional accessories

// MKF 3-MED GP34



Photo shows optional accessories





// MKF 3-MED GP31

// MKF 3-MED GP33



Photo shows optional accessories

Features /Options

- high mechanical stability
 non-contact switching systems
- reed contacts for small currents
- digital or analogue output signals
- additional push-buttons
- LEDs
- protective bracket
- wireless signal transmission
- class AP
- plug-in connector
- pressure point
- special labels
- different RAL colours

Standards

Pedal Console Protection class Switching element Switching system

Mechanical life Connection

Switching voltage Switch-on current Switching power Supply voltage Hall sensor

IEC 60601-1; UL 60601-1; IEC 60529; MPG 93/42/EEC shock-proof thermoplastic, UL 94-V0/-V2 GD-Al alloy, RAL 7035 IP X5 per IEC 60529, up to IP X8 as option reed contact/micro switch/Hall sensor 1 – 2 N0 contacts/1 change-over/analogue output 0 ... 10 VDC, 0 ... 20 mA, 4 ... 20 mA > 1 million operations 2 m cable, other lengths optionally available max. 25 VAC/60 VDC max. 1 A/max. 5 A max. 30 VA/max. 1250 VA

15 ... 30 VDC/max. 25 mA

Standards

Pedal Console Protection class Switching element Switching system

Features /Options

Mechanical life Connection

Switching voltage Switch-on current Switching power Supply voltage Hall sensor max. 25 VAC/60 VDC max. 1 A/max. 5 A

max. 30 VA/max. 1250 VA

- high mechanical stability

- additional push-buttons

- wireless signal transmission

- protective bracket

- plug-in connector

different RAL colours4- or 5-pedal type available

GK-Al alloy, RAL 7035

> 1 million operations

optionally available

2 m cable, other lengths

- pressure point

- special labels

MPG 93/42/EEC

- LEDs

- class AP

- non-contact switching systems

- reed contacts for small currents

- digital or analogue output signals

IEC 60601-1; UL 60601-1; IEC 60529;

shock-proof thermoplastic, UL 94-V0/-V2

IP X5 per IEC 60529, up to IP X8 as option

1 - 2 NO contacts/1 change-over/analogue out

reed contact/micro switch/Hall sensor

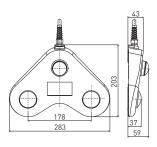
put 0 ... 10 VDC, 0 ... 20 mA, 4 ... 20 mA

15 ... 30 VDC/max. 25 mA

Photo shows optional accessor

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3-pedal medical foot controls // Series MTF 3-MED



// MTF 3-MED

// MTF 3-MED



Photo shows optional accessories

// MTF 3-MED



Photo shows optional accessories



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Features /Options	 flat design ergonomic design easy-to-clean high mechanical stability tactile switching points reed contacts for small currents class AP plug-in connector special labels different RAL colours
Standards	IEC 60601-1; UL 60601-1; IEC 60529; MPG 93/42/EEC
Enclosure	GD-Al alloy, RAL 7035
Actuator	robust, operating theatre approved silicon
Protection class	IP X8 per IEC 60529
Switching system	reed contact
Switching element	1-2 NO contacts per actuator
Mechanical life	> 1 million operations
Connection	2 m cable, other lengths
	and an all share the later

Switching voltage Switch-on current Switching power

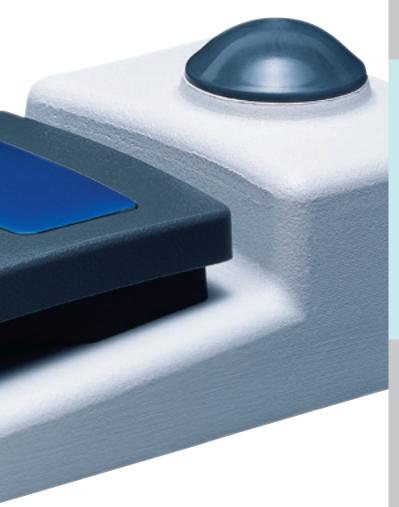
optionally available max. 25 VAC/60 VDC max. 1 A max. 30 VA

PRODUCTION PROCESS COATING LINE MOUNTING FACILITY OF OUR MODERN COATING LINE





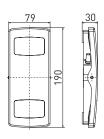
Medical rocker foot controls



// Series WF-MED
Rocker foot control,
zinc die-cast housing
starting on page 36

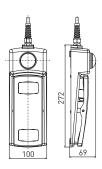
35

Medical rocker foot controls // Series WF-MED



// WF-MED

36



// WF-MED GP14

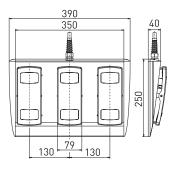


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1			
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Features /Options between two functions	 rocker switch for fast change high mechanical stability non-contact switching systems reed contacts for small currents digital or analogue output signals class AP plug-in connector pressure point special labels different RAL colours 	Features /Options between two functions	 rocker switch for fast change high mechanical stability non-contact switching systems reed contacts for small currents digital or analogue output signals additional push-buttons LEDs class AP plug-in connector pressure point special labels
Standards	IEC 60601-1; UL 60601-1; IEC 60529; MPG 93/42/EEC		- different RAL colours
Pedal Enclosure	GD-Zn alloy, RAL 7035 shock-proof thermoplastic, UL 94-V0	Standards	IEC 60601-1; UL 60601-1; IEC 60529; MPG 93/42/EEC
Protection class	IP X5 per IEC 60529, up to IP X8 as option	Pedal	GD-Zn alloy, RAL 7035
Switching element	reed contact/micro switch/Hall sensor	Enclosure	shock-proof thermoplastic, UL 94-V0
Switching system	1 – 2 NO contacts/1 change-over/analogue	Console	GK-Al alloy, RAL 7035
	output 0 10 VDC, 0 20 mA, 4 20 mA	Protection class	IP X5 per IEC 60529, up to IP X8 as option
Mechanical life	> 1 million operations	Switching element	reed contact/micro switch/Hall sensor
Connection	2 m cable, other lengths optionally available	Switching system	1 – 2 NO contacts/1 change-over/analogue output 0 10 VDC, 0 20 mA, 4 20 mA
Switching voltage	max. 25 VAC/60 VDC	Mechanical life	> 1 million operations
Switch-on current	max. 1 A/max. 5 A	Connection	2 m cable, other lengths
Switching power	max. 30 VA/max. 1250 VA		optionally available
Supply voltage		Switching voltage	max. 25 VAC/60 VDC
Hall sensor	15 30 VDC/max. 25 mA	Switch-on current	max. 1 A/max. 5 A

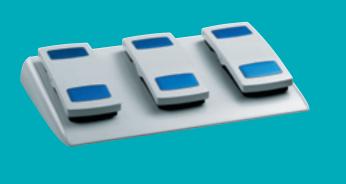
Switching power Supply voltage Hall sensor max. 1 A/max. 5 A max. 30 VA/max. 1250 VA

15 ... 30 VDC/max. 25 mA



// WF 3-MED GP71

// WF 3-MED GP71



Features /Options between two functions

- rocker switch for fast change

- high mechanical stability
- non-contact switching systems
- reed contacts for small currentsdigital or analogue output signals
- additional push-buttons
- LEDs
- protective bracket
- wireless signal transmission
- class AP
- plug-in connector
- pressure point
- special labels
- different RAL colours

Standards

Pedal Enclosure Console Protection class Switching element Switching system

Mechanical life Connection

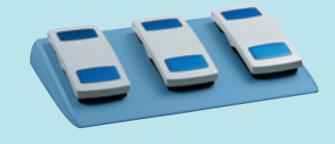
Switching voltage Switch-on current Switching power Supply voltage Hall sensor

IEC 60601-1; UL 60601-1; IEC 60529; MPG 93/42/EEC GD-Zn alloy, RAL 7035 shock-proof thermoplastic, UL 94-V0 Al alloy, RAL 7035 IP X5 per IEC 60529, up to IP X8 as option reed contact/micro switch/Hall sensor 1 – 2 NO contacts/1 change-over/analogue output 0 ... 10 VDC, 0 ... 20 mA, 4 ... 20 mA > 1 million operations 2 m cable, other lengths optionally available max. 25 VAC/60 VDC max. 1 A/max. 5 A max. 30 VA/max. 1250 VA

15 ... 30 VDC/max. 25 mA



// WF 3-MED GP71

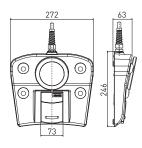




Medical multi-function foot controls

// Series MFS-MED Multi-function foot control – complex, flexible and modular starting on page 40

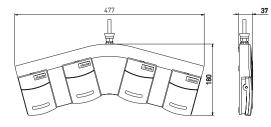
Medical multi-function foot controls // Series MFS-MED



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36 36 36 49 36 49

// MKF-MED GP13 // MKF 4-MED GP42 Features /Options - actuating plate with joystick function Features /Options - high mechanical stability - high mechanical stability - non-contact switching systems - non-contact switching systems - reed contacts for small currents - reed contacts for small currents - digital or analogue output signals - digital or analogue output signals - additional push-buttons - additional push-buttons - LEDs - LEDs - protective bracket - protective bracket - wireless signal transmission - wireless signal transmission - class AP - class AP - plug-in connector - plug-in connector - pressure point - pressure point - special labels - special labels - different RAL colours - different RAL colours IEC 60601-1; UL 60601-1; IEC 60529; Standards IEC 60601-1; UL 60601-1; IEC 60529; MPG 93/42/EEC Standards MPG 93/42/EEC Pedal shock-proof thermoplastic, UL 94-V0/-V2 shock-proof thermoplastic, UL94-V0/-V2 Console Pedal GK-Al alloy, RAL 7035 **Protection class** GK-Al alloy, RAL 7035 IP X5 per IEC 60529, up to IP X8 as option Console IP X5 per IEC 60529, up to IP X8 as option Switching element reed contact/micro switch/Hall sensor **Protection class** Switching element reed contact/micro switch/Hall sensor Switching system 1 - 2 NO contacts/1 change-over/analogue output 0 ... 10 VDC, 0 ... 20 mA, 4 ... 20 mA Switching system 1 - 2 NO contacts/1 change-over/analogue output 0 ... 10 VDC, 0 ... 20 mA, 4 ... 20 mA Mechanical life > 1 million operations 2 m cable, other lengths Mechanical life > 1 million operations Connection Connection 2 m cable, other lengths optionally available max. 25 VAC/60 VDC optionally available Switching voltage max. 25 VAC/60 VDC Switching voltage Switch-on current max. 1 A/max. 5 A Switch-on current max. 1 A/max. 5 A Switching power max. 30 VA/max. 1250 VA max. 30 VA/max. 1250 VA Switching power Supply voltage 15 ... 30 VDC/max. 25 mA Supply voltage Hall sensor Hall sensor 15 ... 30 VDC/max. 25 mA



// MKF 4-MED GP47

// MFS-MED GP71



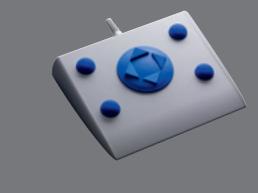


Photo shows optional accessories
41

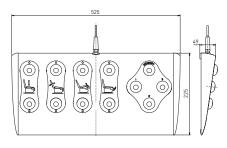
Features /Options	- high mechanical stability	Features /Options	 joypad with joystick function
	 non-contact switching systems 		- high mechanical stability
	 reed contacts for small currents 		- ergonomic design
	- digital or analogue output signals		- easy-to-clean
	- additional push-buttons		- digital output signals
	- LEDs		- wireless signal transmission
	- protective bracket		- steute Wireless
	- wireless signal transmission		- additional push-buttons
	- class AP		- LEDs
	- pressure point		- protective bracket
	- special labels		- class AP
	- different RAL colours		- plug-in connector
			- different RAL colours
Standards	IEC 60601-1; UL 60601-1; IEC 60529;		
	MPG 93/42/EEC	Standards	IEC 60601-1; UL 60601-1; IEC 60529;
Pedal	shock-proof thermoplastic, UL 94-V0/-V2		MPG 93/42/EEC
Console	GK-Al alloy, RAL 7035	Enclosure	Al alloy, RAL 7035
Protection class	IP X5 per IEC 60529, up to IP X8 as option	Actuator/joypad	robust, operating theatre approved silicon
Switching element	reed contact/micro switch/Hall sensor	Protection class	IP X5 per IEC 60529, up to IP X8 as option
Switching system	1 – 2 NO contacts/1 change-over/analogue	Switching element	reed contact/micro switch
	output 0 10 VDC, 0 20 mA, 4 20 mA	Switching system	1 – 2 NO contacts/analogue output
Mechanical life	> 1 million operations	Mechanical life	> 1 million operations
Connection	2 m cable, other lengths	Connection	2 m cable, other lengths
	optionally available		optionally available
Switching voltage	max. 25 VAC/60 VDC	Switching voltage	max. 25 VAC/60 VDC
Switch-on current	max. 1 A/max. 5 A	Switch-on current	max. 1 A/max. 5 A
Switching power	max. 30 VA/max. 1250 VA	Switching power	max. 30 VA/max. 1250 VA
Cumply voltage			

15 ... 30 VDC/max. 25 mA

Supply voltage

Hall sensor

Medical multi-function foot controls // Series MFS-MED



// MFS-MED GP71

// WF3-MED GP7'

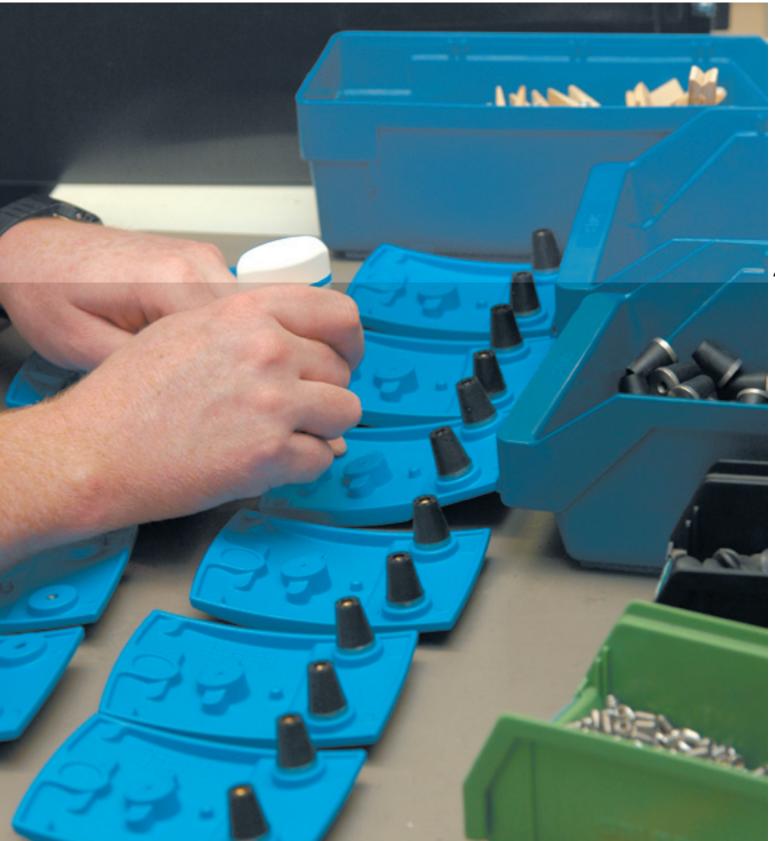


42

Photo shows optional accessories

Features /Options - high mechanical stability Features /Options - high mechanical stability - ergonomic design - non-contact switching systems - reed contacts for small currents - easy-to-clean - digital output signals - digital or analogue output signals - wireless signal transmission - additional push-buttons - LEDs - steute Wireless - additional push-buttons - protective bracket - LEDs - wireless signal transmission - protective bracket - class AP - class AP - plug-in connector - plug-in connector - pressure point - different RAL colours - special labels - different RAL colours IEC 60601-1; UL 60601-1; IEC 60529; **Standards** MPG 93/42/EEC Standards IEC 60601-1; UL 60601-1; IEC 60529; GD-Al alloy, RAL 7035 MPG 93/42/EEC Enclosure Actuator robust, operating theatre approved silicon Pedal shock-proof thermoplastic, UL 94-V0/-V2 **Protection class** IP X5 per IEC 60529, up to IP X8 as option Console GD-Al alloy, RAL 7035 reed contact/micro switch/inductive sensor **Protection class** IP X5 per IEC 60529, up to IP X8 as option Switching element Switching system 1 – 2 NO contacts/analogue output Switching element reed contact/micro switch/Hall sensor Mechanical life > 1 million operations Switching system 1 – 2 NO contacts/1 change-over/analogue output 0 ... 10 VDC, 0 ... 20 mA, 4 ... 20 mA 2 m cable, other lengths Connection optionally available Mechanical life > 1 million operations 2 m cable, other lengths Switching voltage max. 25 VAC/60 VDC Connection Switch-on current max. 1 A/max. 5 A optionally available max. 30 VA/max. 1250 VA max. 25 VAC/60 VDC Switching power Switching voltage Switch-on current max. 1 A/max. 5 A Switching power max. 30 VA/max. 1250 VA Supply voltage 15 ... 30 VDC/max. 25 mA Hall sensor

PRODUCTION PROCESS ASSEMBLY Preassembly foot pedal type MGF 2-MED





Medical wireless hand-operated controls

// Series FFB-MED Wireless hand-operated controls starting on page 46

FFB-MED

-0

// FFB-MED SERIES A VERY HANDY CONTROL



THE NEW GOLD STANDARD FOR WIRELESS HAND CONTROLS IN MEDICAL EQUIPMENT: THE FFB-MED SERIES.

Users of medical equipment should be able to concentrate fully on their patients. This presupposes that the device in question can be intuitively operated and that all required functions are directly to hand - literally. For this task steute Meditec has developed a new wireless hand control.







Comfortable, reliable, flexible

The FFB-MED provides seven digital functions which can be individually adapted to suit the desired functionality of the device. Doublelayer, redundant membrane keys are optionally available. This means that the control can even be used when very high standards of reliability are required.

The control is comfortable to hold and has a membrane keypad, making it easy to clean and giving it a high protection class (IP 65). The membrane keypad is always adapted to suit customer requirements.

Energy-saving wireless technology

Not only the shape of the FFB-MED is designed with ergonomic requirements in mind; the light weight of the hand control is also pleasing to users. A long battery life and a light weight used to be incompatible, but steute has managed to solve this conflict, firstly through the use of industrial alkaline batteries, and secondly through its energy-saving wireless technology RF SW2.4-MED.

When it is not in use, the wireless hand control is in sleep mode, requiring just 6 μ A of electricity. When a switching function is actuated, the control is reactivated and the wireless data connection built up in less than 200ms.



Tailored solutions for complex applications

// Foot-operated controls for surgical microscopes starting on page 50 // Foot-operated controls for ophthalmology starting on page 51 // Foot-operated controls for operating beds / chairs starting on page 52 // Foot-operated controls for X-RAY / MRI / CT starting on page 54

// FOOT-OPERATED CONTROLS FOR SURGICAL MICROSCOPES

// MFS-MICROSCOPE-SW2.4-MED

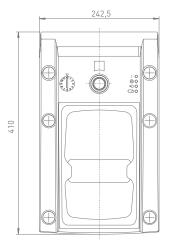


50

Features / options

- high mechanical strength
- plastic console ideal for steute Wireless integration
- zoom and focus function with central foot $\ensuremath{\mathsf{rest}}$
- joystick for positioning microscope
 6 additional buttons with programmable functions
 protection class IP X8 (IEC 60529)
 easy to clean

- wireless signal transmission
- LEDs
- customised labelling
- choice of RAL colours







// FOOT-OPERATED CONTROLS FOR OPHTHALMOLOGY

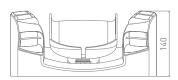
// MFS-PHACO-SW2.4-MED

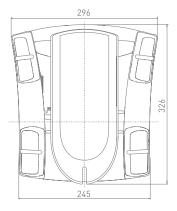


Features / options

- high mechanical strength
- plastic console ideal for steute Wireless integration
- pedal with proportional output signal both vertically and horizontally
- programmable braking points for tactile feedback
 intuitive and highly precise operability
 protection class IP X8 (IEC 60529)

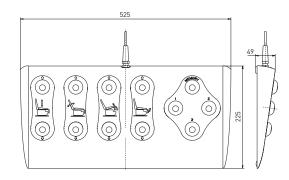
- easy to clean
- wireless signal transmission
- LEDs
- customised labelling- choice of RAL colours







// FOOT-OPERATED CONTROLS FOR **OPERATING BEDS / CHAIRS**



// MFS-MED GP71



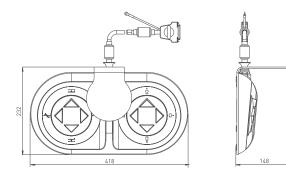
Features / options

- high mechanical strength
- ergonomic design
- easy-to-clean
- digital or analogue output signals
 choice of RAL colours
 steute Wireless

- additional push-buttons
- LEDs
- protective bracket
- class AP
- Stecker
- choice of RAL colours



// FOOT-OPERATED CONTROLS FOR X-RAY / MRI / CT



// MKF 2-SW2.4-MED GP212



Features / options

- high mechanical strength
- plastic console ideal for steute Wireless integration
- non-contact switching systems
- reed contacts for small currents
- digital or analogue output signalsadditional push-buttons
- LEDs
- protective bracket
- choice of RAL colours
- protection class IP X8 (IEC 60529)

- pressure point
 choice of RAL colours
 choice of RAL colours

Note

Photo shows optional accessories





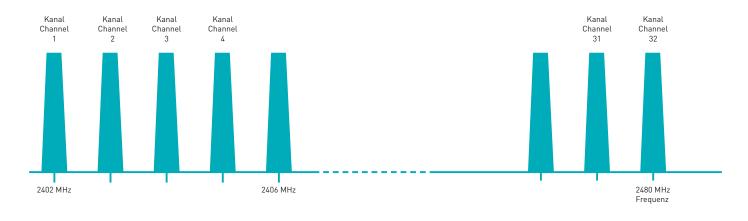
steute Wireless

// RF SW 2.4-MED

Wireless standard for medical equipment starting on page 58 // Using new technologies could not be easier starting on page 60

// RF SW2.4-MED THE WIRELESS STANDARD FOR MEDICAL EQUIPMENT

Low energy consumption, rapid connection times, high availability: these are the key advantages of RF SW2.4-MED »steute Wireless« technology.



The frequency band is subdivided into 32 channels.

Significantly lower power consumption – shorter connection times The system is subdivided into 32 channels and works on the globally accessible 2.4 GHz waveband. Signal transmission is bidirectional and takes less than 20 ms. At max. 25 mA its power consumption is up to 60 % lower than for other radio standards. In »sleep mode« the system has a power consumption of just 6 μ A. It is activated by a switching function, and the radio data connection is built up in less than 200 ms (a typical time is 70 to 100 ms). Users do not notice any difference, but profit from a significantly longer battery life.

As a result of the low power consumption very long battery lifespans can be reached by using merchantable alkaline batteries. As an alternative a rechargeable battery pack is also available.

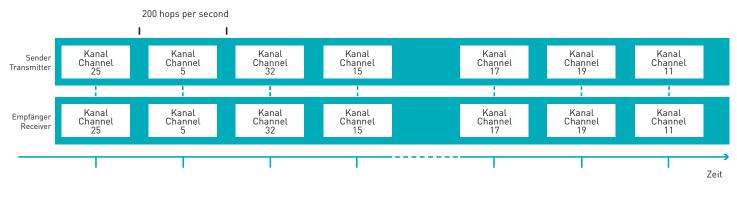
For foot and hand controls

Nearly all foot and hand controls from steute Meditec can be optionally equipped with steute's wireless technology. Instead of a cable connection, a compact radio module with integrated antenna is fitted inside the switch, which then communicates with a corresponding receiver belonging to the medical device. The receiver can be designed either as a printed circuit board for complete integration inside the medical device or as a unit in a separate external enclosure. In both cases the receiver interface is adapted to suit the requirements of the customer.

The RF SW2.4-MED radio standard, as well as all the switching devices and modules which use it, conform to the relevant directives for medical equipment as a matter of course.



Transmitter and receiver change channels synchronously.







steute rechargeable battery pack (1) Radio module RF RxT SW2.4-MED (2) The 2.4 GHz waveband facilitates global use of wireless actuators. steute Wireless is the gold standard for wireless solutions in medical equipment.

RF SW2.4-MED module approvals Europe, in accordance with: EN 300 440 -1 V1.3.1 (2001-09) EN 300 440 -2 V1.1.2 (2004-07) EN 301 489 -1 V1.6.1 (2005-09) EN 301 489 -3 V1.4.1 (2002-08) EN 60950 (2006) EN 50371 (2002) **Japan, in accordance with:** ARIB Standard T66 **North America, in accordance with:** FCC Part 15.247/ IC RSS-210; 2,4 GHz

// USING NEW TECHNOLOGIES COULD NOT BE EASIER

Our offer to the developers of medical equipment:

Use our wireless set with RF SW2.4-MED technology for your medical device. Both the reliability of the radio technology and the advantages provided by wireless foot and hand controls will convince you straightaway, of that we are sure.



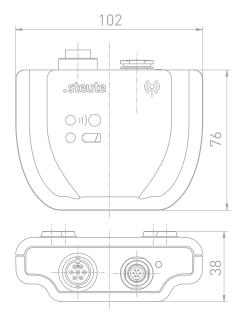
// REC RF SW2.4 USB-MED



Features

58

- wireless receiver for medical applications
- 3 digital switching outputs (relay)
- 1 digital validate output (relay)
- 3 analogue output signals (0-10V)
- 1 serial interface (RS 232)
- 1 connector cable for connection to medical device
- 1 status LED (battery charge indicator)
- 1 status LED (radio connection)



Features

- wireless USB stick receiver
- communicates by serial interface via USB port (serial COM port)
- compatible with all RF SW2.4-MED hand and foot controls

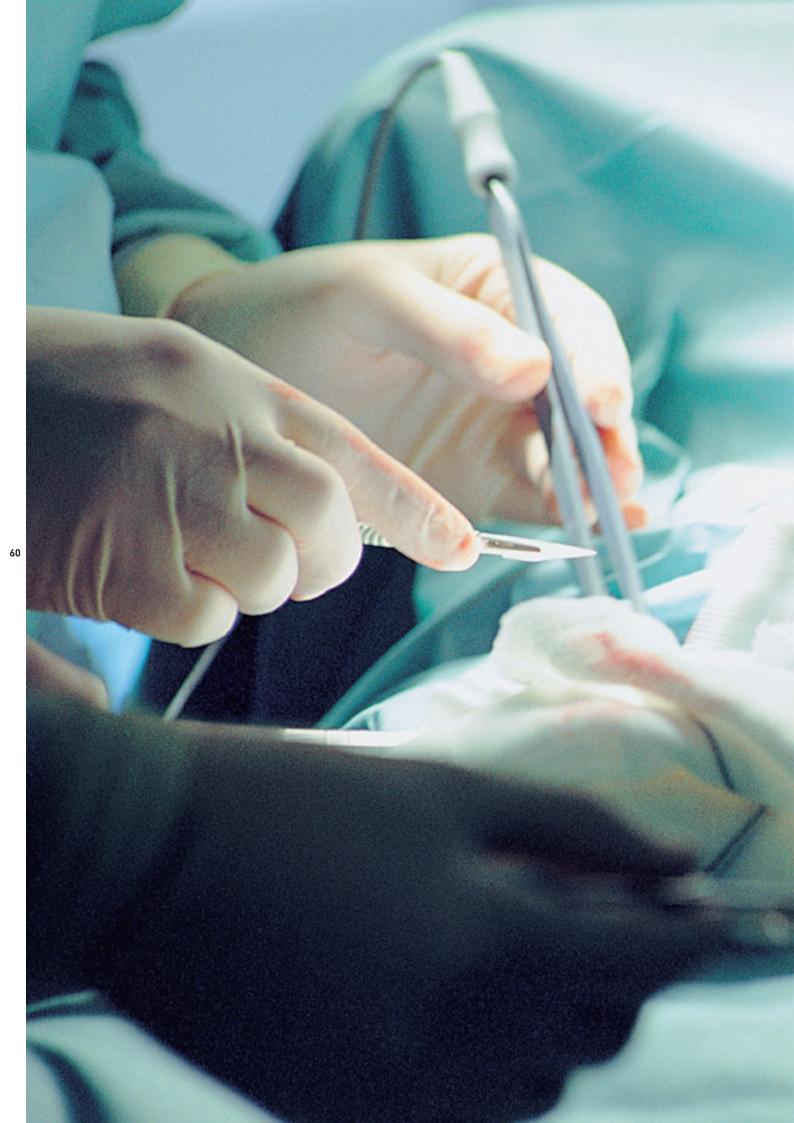
Receiver units

Options are also available for how the wireless receiver units are connected to the medical device. The standard solution is a compact AG43 receiver which permits the transmission of three digital and three analogue functions, while additionally providing a validate relay and an RS 232 interface. This universal receiver unit can be combined with all RF SW2.4-MED hand- and foot controls of steute Meditec.

As an alternative, a receiver unit is available which is integrated in a USB stick. The receiver communicates by serial interface (RS 232) via the USB port. This USB system is also universally applicable and can be combined with all steute Meditec wireless foot controls.

WIRELESS COMMUNICATION TYPICALLY INVOLVES A VARIETY OF POTENTIAL TRANSMITTER AND RECEIVER UNITS.







Typical Applications

// Control devices for laser systems
starting on page 62
// Control devices for high frequency
surgery
starting on page 64
// Control devices for x-ray/MRI/CT
starting on page age 66
// Control devices for operating beds/
chairs
starting on page 68
// Control devices for ophthalmology
starting on page 70
// Control devices for dental applications
starting on page 72

61

// CONTROL DEVICES FOR LASER SYSTEMS

Besides the IEC 60601-1 the IEC 60601-2-22 must also be observed for foot-operated control devices for diagnostic and therapeutical laser devices . This standard demands, for example, high requirements for mechanical stability. It requires protection against unintentional actuation and prescribes specific actuating forces. Besides this, certain protection classes – depending on the appropriate application – are determined according to IEC 60529. A mainly redundant design of the switching elements, as well as details concerning the cable and its entry at the footoperated control device, also belong to the requirements.

// KF-MED GP11



Photo shows optional accessories



// MKFS-MED



// MKF-MED GP12



Photo shows optional accessories

// KF-MED SK11







// MGFS-MED



At work in the oper-ating theatre and for the control of therapeutical and diagnostic laser devices, a non-tiring work situation is very important.

// CONTROL DEVICES FOR HIGH FREQUENCY SURGERY

For the actuation of high frequency surgery devices, foot-operated control devices are applied. The requirements for these control devices are prescribed in EN 60601-1, as well as in EN 60601-2-2. Foot controls for this application field are characterised by defined requirements for the protection class, as well as mechanical stability. Electrostatic charging must be avoided. The requirements for class AP (anaesthesia approved) might also be relevant. In this case the foot controls are gas-proof encapsulated (zone M). The main actuating elements are a yellow pedal (activation »cutting«) and a blue pedal (activation »co-agulating«).



// MKF 2-MED GP26



Photo shows optional accessories

// MKF 2-MED GP25

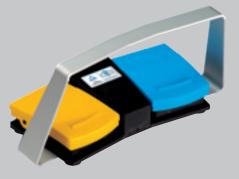


Photo shows optional accessories

// MTF 3-MED



Photo shows optional accessories



The HF surgery allows for gentle operations in many fields.

// MGF 2-MED



// MKF 2-MED GP212



// CONTROL DEVICES FOR X-RAY / MRI / CT

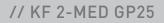
For the application field X-ray/MRI/CT multi-function foot controls developed especially by steute are mainly applied. In most cases complex positioning movements must be carried out, therefore »standard« foot controls can only rarely be applied.

Observed standards are, for example, IEC 60601-1, that refers to the general regulations for safety aspects, as well as the appropriate product standards, e.g. IEC 60601-2-43, considering the specific specialities of X-ray equipment.

The main features of foot controls for this application field: A defined minimum requirement for mechanical stability; defined requirements for the protection class; partly redundant design of switching elements; an integrated interface on request; use of multi-function elements.



View inside: Beside X-ray equipment, MRI- and CT-devices are therefore used, that can be operated via steute foot controls.





// MKF 3-MED GP33



Photo shows optional accessories

// Customised solution



// Customised solution





// Customised solution



// MKF 4-MED GP47



// CONTROL DEVICES FOR **OPERATING BEDS / CHAIRS**

The general requirements for control devices for operating beds and chairs are described in the standard IEC 60601-1. As far as published, the appropriate product standards must be considered. The main features of foot controls for this application field: A defined minimum requirement for mechanical stability; defined requirements for protection class; partly redundant design of switch-ing elements; an integrated interface on request; use of multi-function elements.



When the personnel have got their hands full with things to do, the patient on the operating bed can be brought comfortably into the optimum position using a foot control.



// MKF 4-MED GP42





Photo shows optional accessories



// WF 3-MED GP71



Photo shows optional accessories

// MKF 5-MED GP51



Photo shows optional accessories

// MFS-MED GP71



Photo shows optional accessories

// CONTROL DEVICES FOR OPHTHALMOLOGY

In Ophthalmology absolute precision is required – also for the operation of control devices. Because doctors and operating personnel often need both hands in order to carry out operations, foot controls are used for the operation of medical equipment.

Therefore an extremely high operating safety must be secured, as well as a high degree of precision. Control devices from steute are equivalently designed – whether it comes to standard devices or customised foot controls.

The program for this application field includes among others rocker foot controls that allow for fast change between two functions, foot controls with wireless signal transmission and multi-function foot controls with pedal and joystick.



// MFS-PHACO-MED

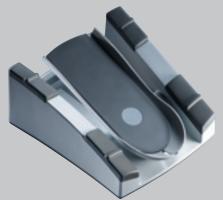






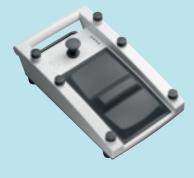
Photo shows optional accessories

// MFS-MICROSCOPE-MED





// Customised solution



// MFS-MED GP71





Eyes are sensitive. Therefore the control devices of equipment for ophthalmology must be very sensi-tive and precise in operation. Foot controls from steute are adapted accordingly.

// CONTROL DEVICES FOR DENTAL APPLICATIONS

The IEC 60601-1 describes the general safety requirements for foot controls for dental applications. The special features of foot controls for these applications: Use of multi-function elements, »joypad« for adjustment of the chair position; revolution control via lever or foot pedal; protective/carrying handle with emergency-stop function; protection class up to IP X8 for operating applications (class AP); actuating elements in different variations.



The main functions of chair and instruments can be controlled via multifunction foot controls from steute.

// Customised solution



Photo shows optional accessories

// MFS-MED GP17



Photo shows optional accessories

// Customised solution

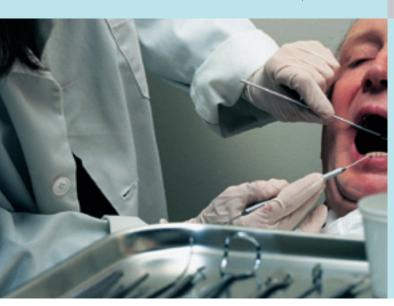


Photo shows optional accessories

// MKF-MED GP13



Photo shows optional accessories

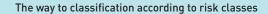


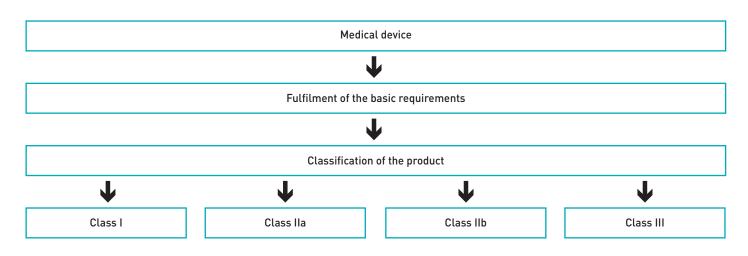
// MKF-MED GP17



Photo shows optional accessories

// STANDARDS AND DIRECTIVES





The CE mark and the classification

All medical devices are subject to certain rules of classification. The actuators which we develop and produce for manufacturers of electrical medical equipment are hand and foot-controlled actuators which are classed as accessories under the German Medical Devices Act (MPG). As such, they are also subject to the Medical Devices Directive (93/42/EEC).

The EC directive for medical devices (93/42/EEC) distinguishes four classes (I, IIa, IIb, and III), referring to the risk potential of each product, whereby class I represents the lowest risk potential and class III the highest. Manufacturers are obliged to distinguish their products using these classes. Our actuators for electromedical devices have been classified accordingly.

The steute Meditec developers and product managers have long been paying careful attention to the standards and directives applicable to our products. How we need to proceed in this respect, which standards we have to observe and which developments in this fairly obscure field could emerge in the future, are summarised in the following pages.

All normative requirements fulfilled

Because the intended purpose of our switching devices – in combination with the downstreamed control unit of the system marketer – is to actuate medical devices, hence they count as accessories and have to be equipped with a CE conformity marking in accordance with the MDD.

All steute Meditec series fulfil the conditions stipulated by the directive for medical products (93/42/EEC), by the IEC 60601 series of standards and by the class of AP (anaesthesia proof). They also fulfil the criteria for protection classes up to IP X8 in accordance with IEC 60529.

Testing by a notified body

As a manufacturer of medical devices we also, in order to meet the high standards of quality and safety expected of medical equipment, subject our products to an additional and voluntary safety check by a competent testing authority (notified body).

This safety check comprises a prototype test of the product on the basis of harmonised European standards, a plausibility test for the conformity procedure which is necessary for the CE marking, including technical documentation in accordance with the EC directive, and an inspection of the factory with repeat production controls.

We document this additional voluntary safety check on our foot switches with the TÜV seal of approval »GM« (tested medical device).

// THE INTERNATIONAL VALID STANDARD IEC 60601

Which regulations exist for medical handheld and foot operated controls in Europe?

The EC directive for medical devices (MDD) or in Germany the MPG, appendix I, names fundamental requirements for medical devices: »Products must be designed and manufactured in a manner which ensures that ... the safety of patients and users ... is not put at risk.«

The solutions chosen by manufacturers during the design and manufacture of devices must obey the principles of integrated safety, not forgetting adherence to state-of-the-art technology.

»When choosing suitable solutions, manufacturers must apply the following principles, proceeding in the order set out below:

1. Elimination or minimisation of risk (integration of safety concept in product development and construction).

2. Where appropriate, adoption of suitable protection measures, including alarms, to warn of non-eliminable dangers.

3. Instruction of users regarding residual risks for which no suitable protection measures can be found.«

This three-step procedure has been tried and tested and is well established in other areas of safety engineering, e.g. machine safety.

The international level: IEC 60601

The IEC 60601 series of standards directs safety concepts for electrical medical equipment worldwide. IEC 60601-1 (medical electrical equipment) states (1st section 3.1): »In their normal state and on first error, devices ... must not be hazardous ... «.

The 2nd section 2.10.11 defines the criteria for a first error: »state when in the device a single protective measure has failed to prevent a hazard...«. 3rd section 52.1 »Devices must be constructed and manufactured in such a way that they are not hazardous on first error «.

The additional standards in series IEC 60601 describe the demands made of individual equipment classes (e.g.: IEC 60601-2-22 for laser devices and IEC 60601-2-43 for X-ray devices).

Functional safety

The third, revised edition of the IEC 60601series of standards, which appeared in 2006, accommodates the fact that medical devices are found increasingly frequently in integrated systems. Since then, this standard has covered the basic safety and functional safety of devices and systems. This means that the requirements of the additional standard IEC 60601-1-1 are now included within the basic standard.

The basic ideas behind the revised standard address two very important points: safety in use (usability) and risk management.

// RISK MANAGEMENT

Usability (IEC 60601-1-6): Minimisation of risks for patients and users

The new standard IEC 60601-1-6 refers to medical electric devices and their combinations. It describes the process of ergonomic design and gives instructions, as to how this process shall be organised,

carried out and documented. The usability of the concerned medical equipment shall be so good that the fundamental safety, as well as its essential perfomance are secured. The standard refers explicitly to use errors and how these can be reduced to an acceptable value. Though the consequences of faults as result of the irresponsible conduct lie beyond the focus of the standard.

For many years now, steute Meditec has been adhering to the guiding principle of usability, as well as working closely with development partners and institutes with recognised expertise in the ergonomic comfort and usability of medical equipment.

Risk analysis / risk management for medical equipment

The idea of risk management known by the introduction of the ISO 14971 has characterised the basic concept of the third edition of IEC 60601-1. With it the product standard, as well as the process standard, are considered.

Basically the degree of risk is determined by two factors: degree of damage and possibilty of occurrence.

The risk analysis is in the meantime for designing engineers and safety engineers a usual method. The risk management per ISO 14971 and IEC 60601-1-1 goes beyond this. Beside the pure analysis and determination of risk classes, it contains decisions about the acceptability of the planned safety measurements, as well as the definition, implementation and verification of countermeasures and market observation.

Fig. 1



// MINIMIZE RISKS FOR USERS, PATIENTS OR OTHER TO AN ACCEPTABLE DEGREE

Risk analysis and/or product standard?

The manufacturer, meticulous to details, might question whether a risk anylysis is obligatory in the case of an existing product standard. The answer is: In principle yes, because the product standards also aim to define the necessary measurements, in order to reduce the risk to an acceptable degree. But the standards are often not state-of the-art. Thus the manufacturer should verify if the current technology is still covered by the standard.

Moreover the product standards assume standard realisations. »Exotic« concepts are often not considered. In these cases the more basic EN 1441, describing the risk analysis, is a lot more helpful.

Furthermore the product standards (partly implicitly) are based on the assumption that certain application fields and principles are present. Thus it must be verified if the product is covered by it. Finally the product standards do not consider the optional components.

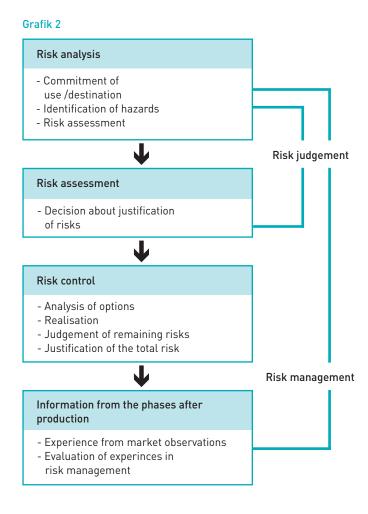
Therefore it should be checked if all functions or components of the product are covered by the standard.

Alignment with other areas of safety technology

The revisions made to the IEC 60601-1 standard need to be viewed in a wider context. In other safety-relevant areas, e.g. machine safety, terms and procedures such as functional safety, risk analysis, hazard assessment, etc. also constitute part of the state-of-the-art technology. Different systems of standards are thus gradually becoming aligned. Since we are also one of the branch leaders for safety switchgear used in machine and plant engineering, as well as for safety switchgear used in explosive environments, steute is able to benefit from considerable synergies in this respect.

International harmonisation of standards

A further key trend in conjunction with the standards and directives for medical equipment is harmonisation at a European and international level. And even when EN or IEC rules and standards are not adopted 1:1, they still serve as the basis for various national standards. In the USA, for example, the product standard UL 60601 must be observed. It correlates closely with IEC 60601, while taking into account typically American realities. All standard series made by steute are checked for compliance by the CSA.





Risk analysis EN 1441 ISO 14971-1

// TESTS, APPROVALS, CERTIFICATES





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steute develops and manufactures safe switchgear for demanding and critical application. Besides a comprehensive standard range of products for »Wireless, Automation, Extreme and Meditec« applications, we also and increasingly develop customised switchgear for extreme conditions in all four business fields. Some examples: emergency pullwire switches for the mining industry, position switches for industrial automation and control panels for laser surgery. Our head office is in Löhne, Westphalia, Germany; worldwide sales are conducted through steute's subsidiaries and trading partners.

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