

.steute

Meditec

english



// INTUITIVE OPERATING SYSTEMS FOR MEDICAL EQUIPMENT

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steute

// SAFE SWITCHGEAR FOR DEMANDING AND CRITICAL APPLICATIONS

Wireless



Automation



Extreme



Meditec



»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

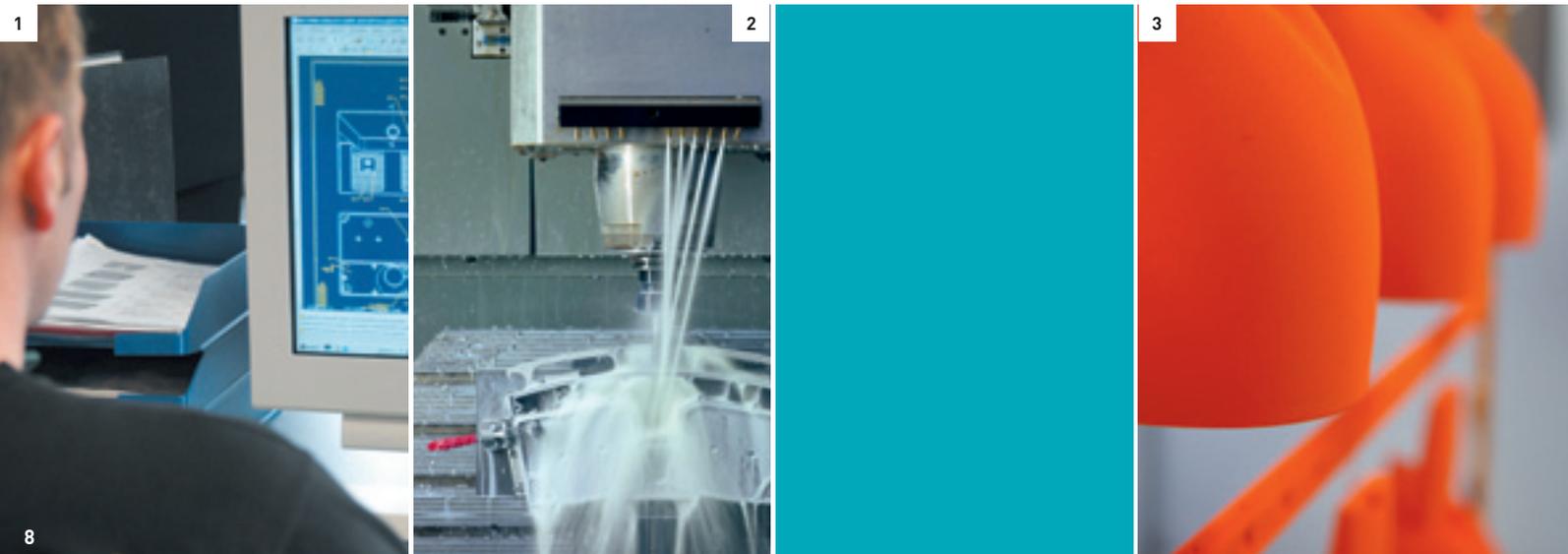
All steute control units for medical equipment fulfil very high standards in ergonomic comfort and availability. For many years now steute has been coming up with innovations to improve functionality and operational comfort, and this is a major reason why global leaders in medical technology choose man-machine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

// 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.



4

5

9

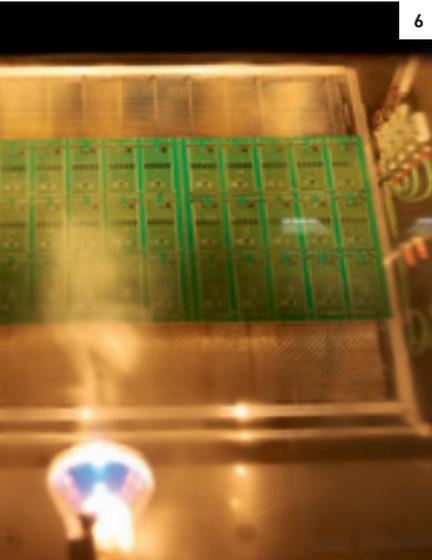
// WATER PRESSURE, COMPRESSED AIR AND IMPACT TEST

7



10

// 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 immersion) 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.

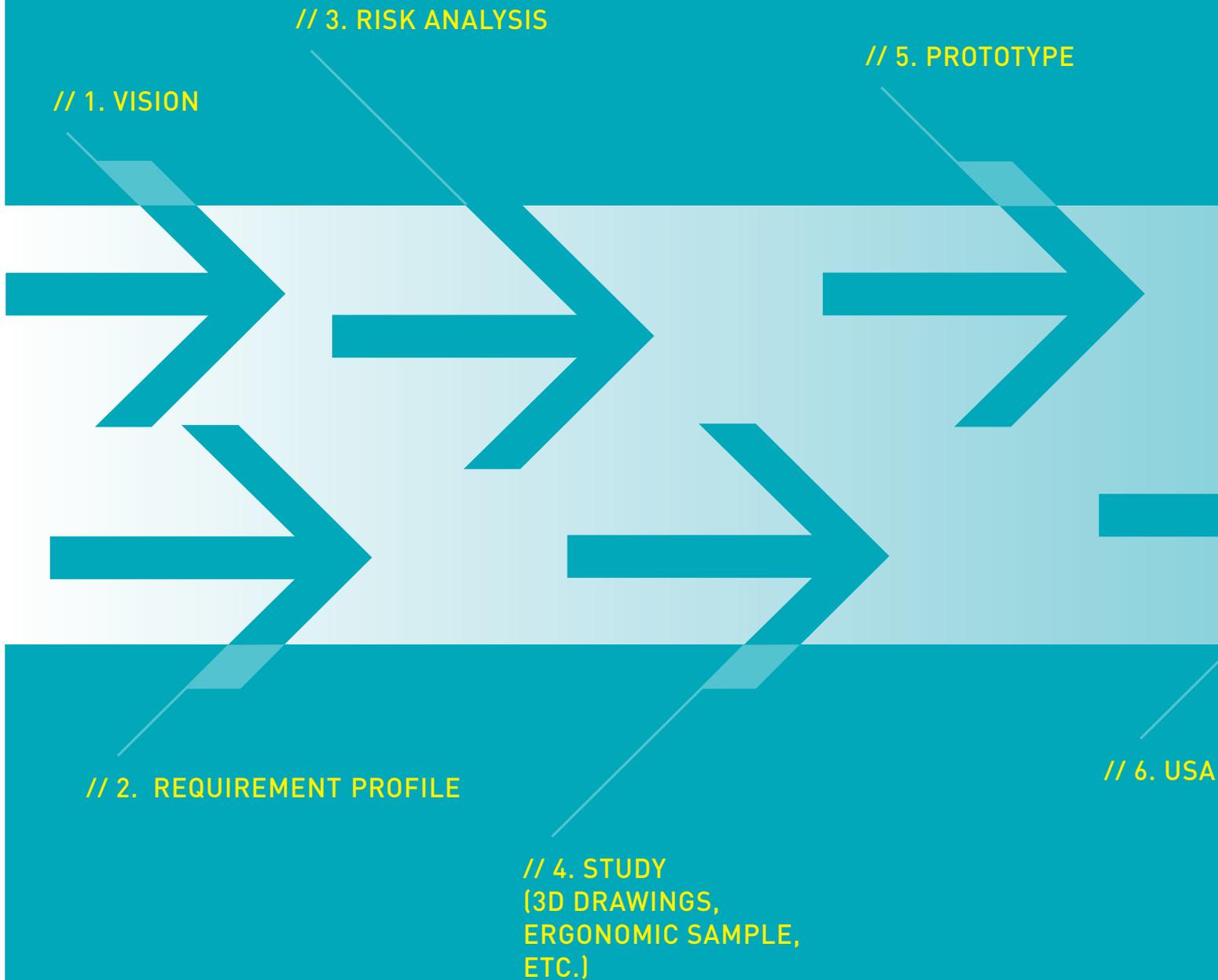
Water on!

For IP X6 tests (protection against powerful water jets) our newly installed test machine is used. The testing conditions are: impact with 100 l 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 electro-surgical devices.

// FROM THE IDEA TO YOUR PRODUCT
A WELL-PLANNED PROCESS-OPTIMISED SYSTEMATICAL
DESIGN PROCESS



12

If one follows the other

»Good planning is half the work«: This motto is also valid for the development and production of foot controls. We have optimised and structured the work processes in such a way that at a minimum of production time a maximum of flexibility and quality is achieved. Therefore you can expect from us a quick reaction, even if an individual solution for a complex task is requested.

// 7. FIRST SERIES

// 9. SERIES



BILITY

// 8. CLINICAL
TESTING



// WE OFFER MORE THAN THE VALID REGULATIONS DEMAND

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 specialists.

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 operating elements or safety equipment. To find out how we proceed, please read pages 6 to 13.



The approval per UL 60601.



The CE marking per Medical Device Directive 93/42/EEC.



The type test per IEC 60 601.



The GM mark: Approved medical device.



The AP mark for anaesthesia approved medical devices.



The Quality Management System per ISO 9001/EN ISO 13485.

What can we offer you?

- CE-conforming products per directive 93/42/EEC
- Products per standard series IEC 60601
- Approval per UL 60601
- Protection classes up to IPX8 per IEC 60529
- Customised developments
- Ergonomic samples
- Longtime experience in the cooperation with manufacturers of medical devices
- Application-related know-how
- Special switch inserts for low currents
- Gas-proof encapsulated switching elements for AP applications
- Exclusive designs
- Easy-to-clean features
- Special prewired cables and plug-in connectors
- Different thermoplastic and aluminium enclosures
- Wireless transmission technology





1-pedal medical foot controls

// Series MKF-MED

Shock-proof, glassfibre-reinforced
thermoplastic foot control
starting on page 18

// Series MGF-MED

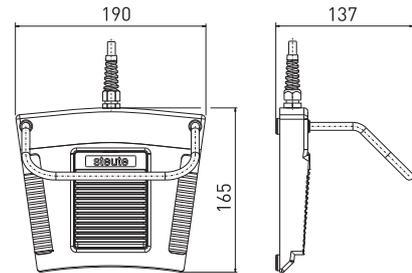
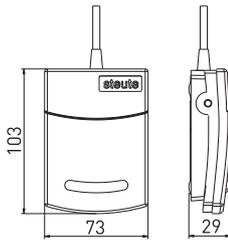
Easy-to-clean aluminium
die-cast foot control
starting on page 21

// Series RF-MED

All-side actuation aluminium
die-cast foot control
starting on page 23

1-pedal medical foot controls

// Series (M)KF-MED



// MKF-MED



// KF-MED GP11

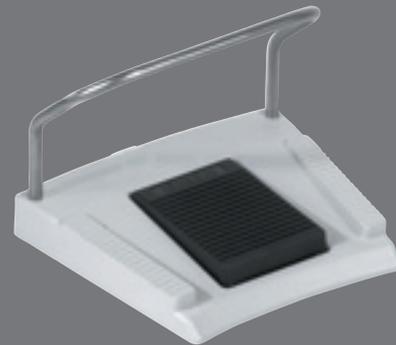
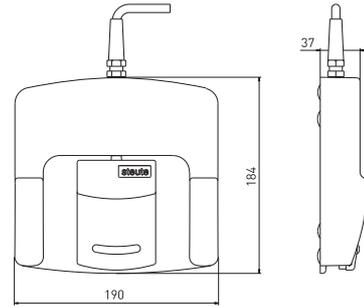
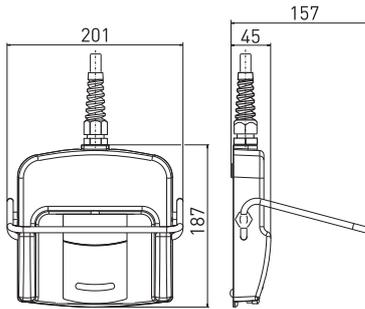


Photo shows optional accessories

Features/Options	<ul style="list-style-type: none"> - high mechanical stability - non-contact switching systems - reed contacts for small currents - digital or analogue output signals - class AP - GM (approved medical device, TÜV) - 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
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

Features/Options	<ul style="list-style-type: none"> - high mechanical stability - non-contact switching systems - reed contacts for small currents - digital or analogue output signals - additional push-buttons - LEDs - stainless steel protective bracket - wireless signal transmission - class AP - GM (approved medical device, TÜV) - 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 A



// MKF-MED GP12



Photo shows optional accessories

Features/Options	<ul style="list-style-type: none"> - high mechanical stability - non-contact switching systems - reed contacts for small currents - digital or analogue output signals - additional push-buttons - LEDs - protective bracket - class AP - GM (approved medical device, TÜV) - 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

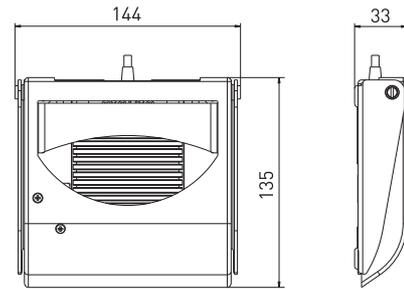
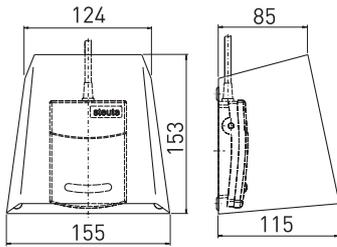
// MKF-MED GP 17



Features/Options	<ul style="list-style-type: none"> - Thermoplastic console ideal for intergration of steute Wireless - 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 - GM (approved medical device, TÜV) - 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
Protective shield	shock-proof thermoplastic, 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

1-pedal medical foot controls

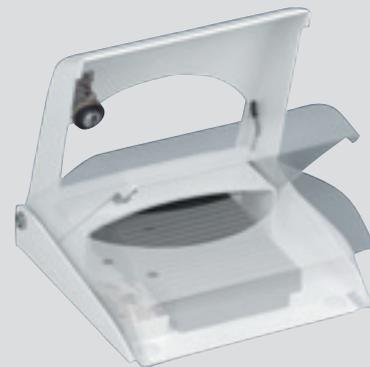
// Series (M)KF-MED



// MKFS-MED



// KF-MED SK11



- Features/Options**
- protection against unintentional actuation
 - high mechanical stability
 - non-contact switching systems
 - reed contacts for small currents
 - digital or analogue output signals
 - class AP
 - GM (approved medical device, TÜV)
 - plug-in connector
 - pressure point
 - special labels
 - different RAL colours

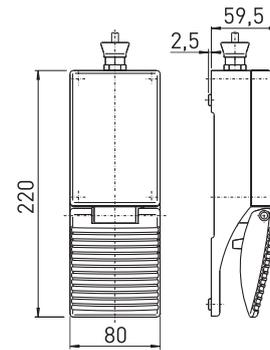
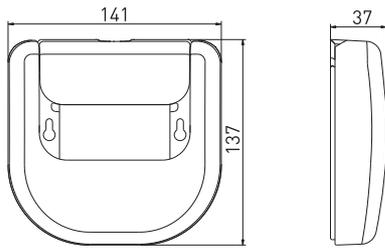
- Standards** IEC 60601-1; UL 60601-1; IEC 60529; MPG 93/42/EEC
- Pedal** shock-proof thermoplastic, UL 94-V0/-V2
- Protective shield** steel sheet, RAL 7035
- Protection class** IP X5 per IEC 60529, up to IP X8 as option
- Switching element** reed contact/micro switch/Hall sensor
- Switching system** 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** max. 30 VAC/max. 1250 VA
- Hall sensor** 15 ... 30 VDC/max. 25 mA

- 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
 - class AP
 - GM (approved medical device, TÜV)
 - 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
- Protective flap** stainless steel, 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** max. 30 VAC/max. 1250 VA
- Hall sensor** 15 ... 30 VDC/max. 25 mA

1-pedal medical foot controls

// Series (M)KF-MED / MGF-MED



// MKF-MED SK12



Photo shows optional accessories

// MGF-MED

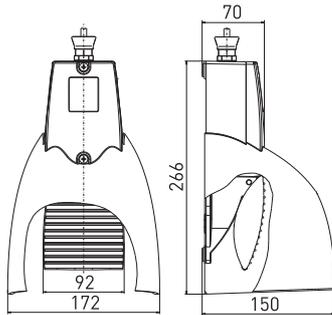


Features/Options	<ul style="list-style-type: none"> - maximum protection against unintentional actuation at minimum dimensions - high mechanical stability - non-contact switching systems - reed contacts for small currents - digital or analogue output signals - GM (approved medical device, TÜV) - class AP - plug-in connector - pressure point - special labels - different RAL colours
Standards	IEC 60601-1; UL 60601-1; IEC 60529; MDD 93/42/EEC
Pedal	shock-proof thermoplastic, UL 94-V0/-V2
Protective flap	shock-proof thermoplastic, RAL 7035
Baseplate	GD-Zn 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

Features/Options	<ul style="list-style-type: none"> - high mechanical stability - easy-to-clean - digital or analogue output signals - additional push-buttons - protective bracket - wireless signal transmission - class AP - GM (approved medical device, TÜV) - 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 Ω ... 1 kΩ ±3 %; 20 Ω ... 2 kΩ ±3 %; 50 Ω ... 5 kΩ ±3 %; 100 Ω ... 10 kΩ ±3 %; ±0,5 %
Linearity	
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

1-pedal medical foot controls

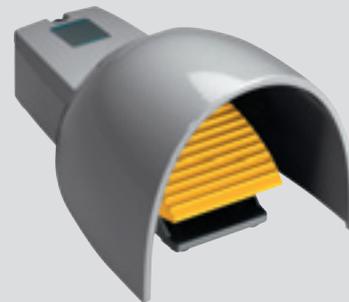
// Series MGF-MED



// MGF5-MED



// MGF5-MED



- Features/Options**
- protection against unintentional actuation
 - high mechanical stability
 - easy-to-clean
 - digital or analogue output signals
 - wireless signal transmission
 - class AP
 - GM (approved medical device, TÜV)
 - 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 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

Output value poti 0 ... 10 VDC, 0 ... 20 mA, 4 ... 20 mA
20 Ω ... 1 kΩ ±3 %; 20 Ω ... 2 kΩ ±3 %;
50 Ω ... 5 kΩ ±3 %; 100 Ω ... 10 kΩ ±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

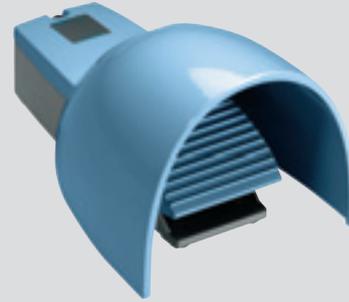
Supply voltage

Hall sensor 15 ... 30 VDC/max. 25 mA

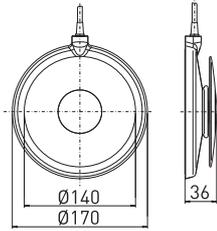
// MGF5-MED



// MGF5-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
- GM (approved medical device, TÜV)
- plug-in connector
- special labels
- different RAL colours

Standards

IEC 60601-1; UL 60601-1; IEC 60529;
 MPG 93/42/EEC

Switching plate

GK-Al alloy, RAL 7035

Enclosure

GD-Al alloy, RAL 7035

Protection class

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

Switching element

reed contact/micro switch

Switching system

1 – 2 NO contacts /1 change-over contact

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

// RF-MED







2-pedal medical foot controls

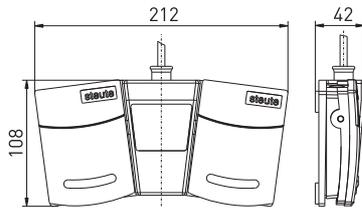
// Series MKF 2-MED

Foot control on thermoplastic/
aluminium console
starting on page 26

// Series MGF 2-MED

Aluminium die-cast foot control
starting on page 29

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



// MKF 2-MED GP25



// MKF 2-MED GP25



Features/Options

- high mechanical stability
- non-contact switching systems
- reed contacts for small currents
- digital or analogue output signals
- LEDs
- protective bracket
- class AP
- GM (approved medical device, TÜV)
- 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

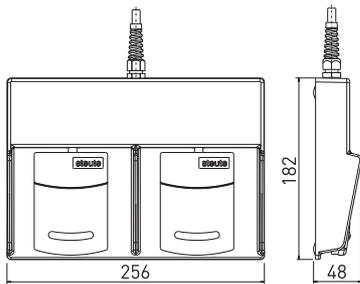


Photo shows optional accessories

// MKF 2-MED GP25



Photo shows optional accessories



// MKF 2-MED GP23



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
- GM (approved medical device, TÜV)
- 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
GK-Al alloy, RAL 7035

Console

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

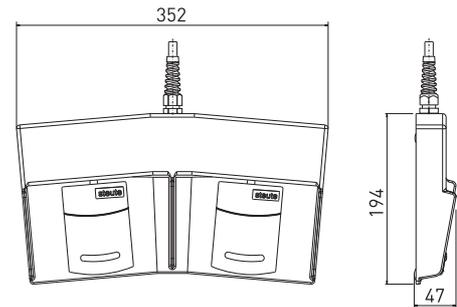
Switching power

max. 30 VA/max. 1250 VA

Supply voltage

Hall sensor

15 ... 30 VDC/max. 25 mA



// MKF 2-MED GP21



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
- GM (approved medical device, TÜV)
- 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
GK-Al alloy, RAL 7035

Console

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

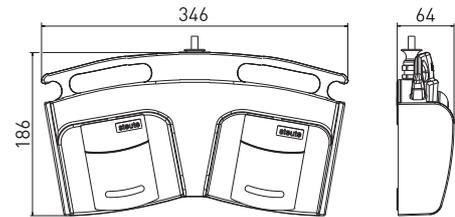
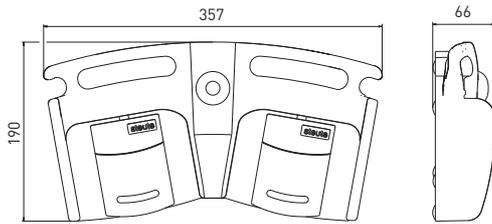
Supply voltage

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



Photo shows optional accessories

// MKF 2-MED GP26



Features/Options

- high mechanical stability
- Thermoplastic console ideal for steute
- Wireless integration
- 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
- GM (approved medical device, TÜV)
- 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, black RAL 9005

Console

shock-proof thermoplastic, 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

max. 30 VDC/max. 25 mA

Hall sensor

15 ... 30 VDC/max. 25 mA

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
- GM (approved medical device, TÜV)
- 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

GD-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

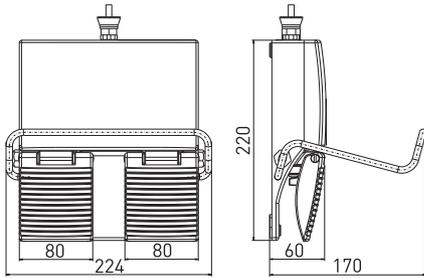
Supply voltage

max. 30 VDC/max. 25 mA

Hall sensor

15 ... 30 VDC/max. 25 mA

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



// MGF 2-MED



// MGF 2-MED



// MGF 2-MED



Photo shows optional accessories

29

Features/Options

- high mechanical stability
- easy-to-clean
- digital or analogue output signals
- additional push-buttons
- hinged stainless steel protective bracket
- wireless signal transmission
- class AP
- GM (approved medical device, TÜV)
- 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 Ω ... 1 kΩ ±3 %; 20 Ω ... 2 kΩ ±3 %;
50 Ω ... 5 kΩ ±3 %; 100 Ω ... 10 kΩ ±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

15 ... 30 VDC/max. 25 mA

// MGF 2-MED



Photo shows optional accessories

// MGF 2-MED



Photo shows optional accessories





3-pedal medical foot controls

// Series MKF 3-MED

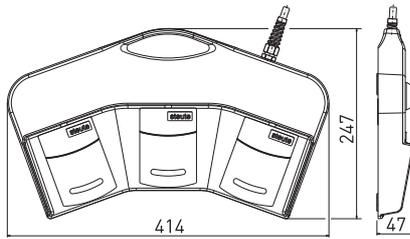
Foot control on aluminium console
starting on page 32

// Series MTF 3-MED

Foot control in ergonomic
aluminium die-cast enclosure
starting on page 34

3-pedal medical foot controls

// Series MKF 3-MED



// MKF 3-MED GP34



// MKF 3-MED GP34



Photo shows optional accessories

// MKF 3-MED GP34

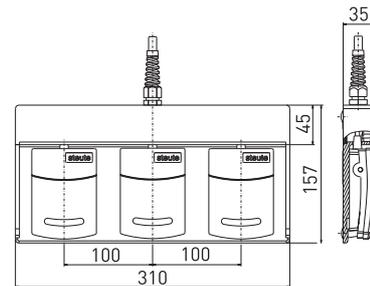
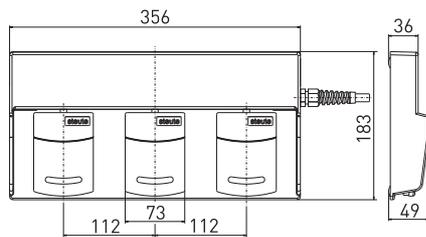


Photo shows optional accessories

// MKF 3-MED GP34



Features/Options	<ul style="list-style-type: none"> - 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 - GM (approved medical device, TÜV) - 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 GP33



Photo shows optional accessories

// MKF 3-MED GP31

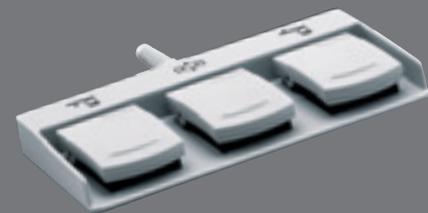


Photo shows optional accessories

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
- GM (approved medical device, TÜV)
- 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 GD-Al alloy, RAL 7035

Console

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

Protection class

reed contact/micro switch/Hall sensor

Switching element

1 – 2 NO contacts/1 change-over/analogue output 0 ... 10 VDC, 0 ... 20 mA, 4 ... 20 mA

Switching system

> 1 million operations

Mechanical life

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

15 ... 30 VDC/max. 25 mA

Hall sensor

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
- GM (approved medical device, TÜV)
- plug-in connector
- pressure point
- special labels
- different RAL colours
- 4- or 5-pedal type available

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

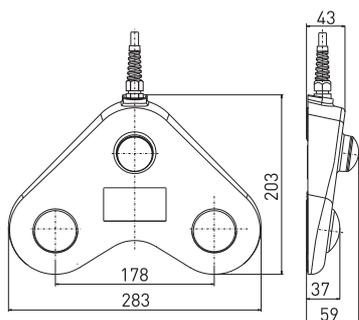
Supply voltage

15 ... 30 VDC/max. 25 mA

Hall sensor

15 ... 30 VDC/max. 25 mA

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



// MTF 3-MED



Photo shows optional accessories

// MTF 3-MED



Photo shows optional accessories

// MTF 3-MED



Photo shows optional accessories

Features/Options

- flat design
- ergonomic design
- easy-to-clean
- high mechanical stability
- tactile switching points
- reed contacts for small currents
- class AP
- approved medical device, TÜV
- 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
optionally available

Switching voltage

max. 25 VAC/60 VDC

Switch-on current

max. 1 A

Switching power

max. 30 VA

PRODUCTION PROCESS COATING LINE
MOUNTING FACILITY OF OUR MODERN COATING LINE





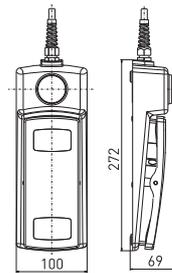
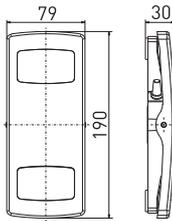


Medical rocker foot controls

// **Series WF-MED**
Rocker foot control,
zinc die-cast housing
starting on page 38

Medical rocker foot controls

// Series WF-MED



// WF-MED

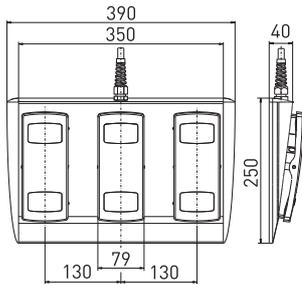


// WF-MED GP14

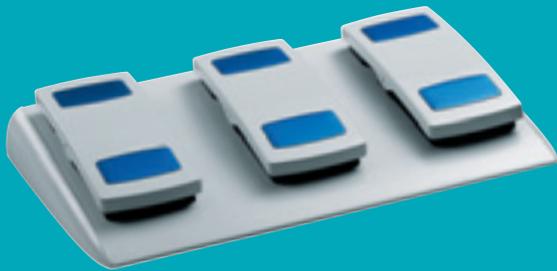


Features/Options	<ul style="list-style-type: none"> - rocker switch for fast change between two functions - high mechanical stability - non-contact switching systems - reed contacts for small currents - digital or analogue output signals - class AP - GM (approved medical device, TÜV) - plug-in connector - pressure point - special labels - different RAL colours
Standards	IEC 60601-1; UL 60601-1; IEC 60529; MPG 93/42/EEC
Pedal	GD-Zn alloy, RAL 7035
Enclosure	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

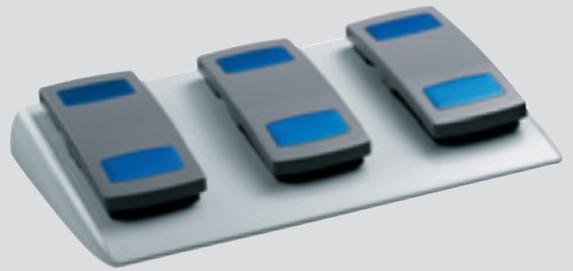
Features/Options	<ul style="list-style-type: none"> - rocker switch for fast change between two functions - high mechanical stability - non-contact switching systems - reed contacts for small currents - digital or analogue output signals - additional push-buttons - LEDs - class AP - GM (approved medical device, TÜV) - plug-in connector - pressure point - special labels - different RAL colours
Standards	IEC 60601-1; UL 60601-1; IEC 60529; MPG 93/42/EEC
Pedal	GD-Zn alloy, RAL 7035
Enclosure	shock-proof thermoplastic, UL 94-V0
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



// WF 3-MED GP71



// WF 3-MED GP71



Features/Options

- rocker switch for fast change between two functions
- 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
- GM (approved medical device, TÜV)
- plug-in connector
- pressure point
- special labels
- different RAL colours

Standards

IEC 60601-1; UL 60601-1; IEC 60529; MPG 93/42/EEC

Pedal

GD-Zn alloy, RAL 7035

Enclosure

shock-proof thermoplastic, UL 94-V0

Console

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

15 ... 30 VDC/max. 25 mA

Hall sensor

15 ... 30 VDC/max. 25 mA

// WF 3-MED GP71





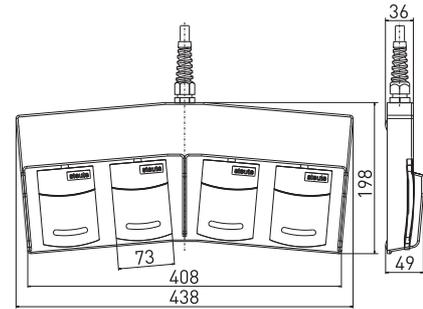
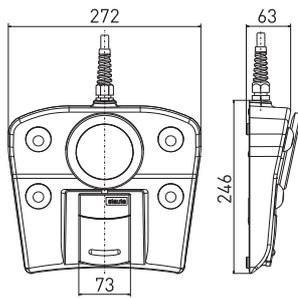


Medical multi-function foot controls

// **Series MFS-MED**
Multi-function foot control –
complex, flexible and modular
starting on page 42

Medical multi-function foot controls

// Series MFS-MED



// MKF-MED GP13



Photo shows optional accessories

// MKF 4-MED GP42



Photo shows optional accessories

Features/Options

- actuating plate with joystick function
- 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
- GM (approved medical device, TÜV)
- 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, UL94-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

15 ... 30 VDC/max. 25 mA

Hall sensor

15 ... 30 VDC/max. 25 mA

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
- GM (approved medical device, TÜV)
- 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

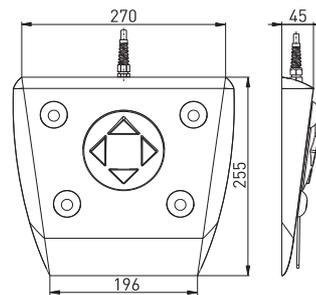
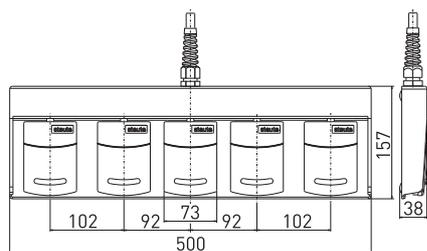
max. 30 VA/max. 1250 VA

Supply voltage

15 ... 30 VDC/max. 25 mA

Hall sensor

15 ... 30 VDC/max. 25 mA



// MKF 5-MED GP51



// MFS-MED GP71

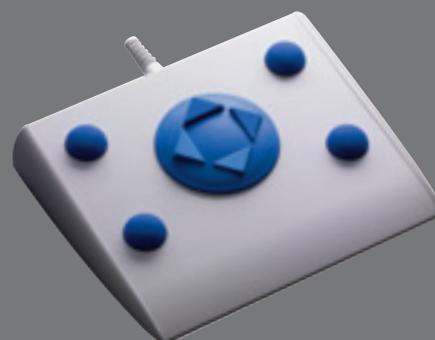


Photo shows optional accessories

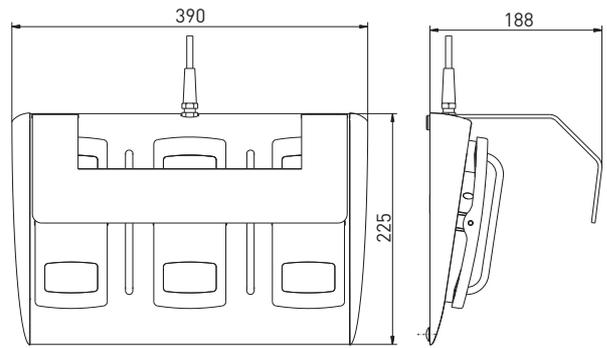
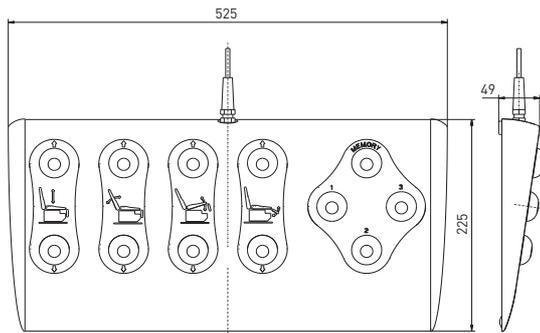
43

Features/Options	<ul style="list-style-type: none"> - 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 - GM (approved medical device, TÜV) - 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

Features/Options	<ul style="list-style-type: none"> - joystick with joystick function - high mechanical stability - ergonomic design - easy-to-clean - digital output signals - wireless signal transmission - steute Wireless - additional push-buttons - LEDs - protective bracket - class AP - plug-in connector - different RAL colours
Standards	IEC 60601-1; UL 60601-1; IEC 60529; MPG 93/42/EEC
Enclosure	Al alloy, RAL 7035
Actuator/joystick	robust, operating theatre approved silicon
Protection class	IP X5 per IEC 60529, up to IP X8 as option
Switching element	reed contact/micro switch
Switching system	1 – 2 NO contacts/analogue output
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

Medical multi-function foot controls

// Series MFS-MED



// MFS-MED GP71



Photo shows optional accessories

// WF3-MED GP71



Photo shows optional accessories

Features/Options

- high mechanical stability
- ergonomic design
- easy-to-clean
- digital output signals
- wireless signal transmission
- steute Wireless
- additional push-buttons
- LEDs
- protective bracket
- class AP
- plug-in connector
- 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 X5 per IEC 60529, up to IP X8 as option

Switching element

reed contact/micro switch/inductive sensor

Switching system

1 – 2 NO contact/analogue output

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

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
- GM (approved medical device, TÜV)
- 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

GD-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

15 ... 30 VDC/max. 25 mA

Hall sensor

15 ... 30 VDC/max. 25 mA

PRODUCTION PROCESS ASSEMBLY
Preassembly foot pedal type MGF 2-MED



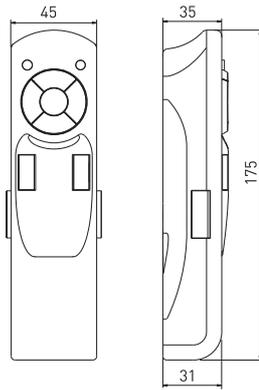


Medical wireless
hand-operated controls

// **Series FFB-MED**
Wireless hand-operated controls
starting on page 48

Medical wireless hand-operated controls

// Series FFB-MED



// FFB-MED



// FFB-MED



// FFB-MED



// FFB-MED



Features/Options

- wireless remote control
- steute Wireless
- Push-button with joystick function
- high mechanical stability
- ergonomic design
- additional push-buttons
- LEDs
- special labels
- different RAL colours

Standards

IEC 60601-1; IEC 60529;
MPG 93/42/EEC

Enclosure

shock-proof thermoplastic, RAL 7035

Actuator

shock-proof thermoplastic, RAL 5015

Protection class

IP X1 per IEC 60529

Switching element

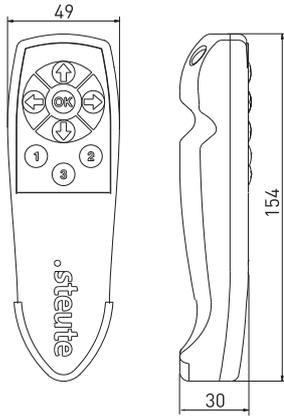
micro switch

Switching system

NO contact, change-over

Mechanical life

> 1 million operations



// FFB-MED



// FFB-MED



// FFB-MED



// FFB-MED



Features/Options

- wireless remote control
- steute Wireless
- keypad with different functions
- high mechanical stability
- ergonomic design
- easy-to-clean
- additional push-buttons
- LEDs
- special labels
- different RAL colours

Standards

IEC 60601-1; IEC 60529;
MPG 93/42/EEC

Enclosure

shock-proof thermoplastic, RAL 7035

Actuator

customised keypad

Protection class

IP X5 per IEC 60529

Switching element

keypad

Switching system

NO contact

Mechanical life

> 1 million operations





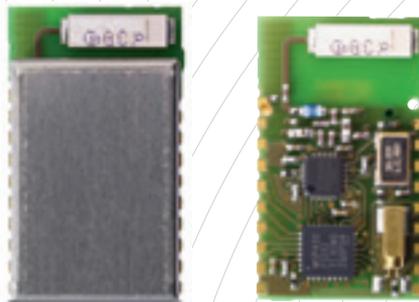
steute wireless

// Series RxT RF SW 2.4-MED
steute wireless module

Page 52

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// STEUTE WIRELESS HAS BEEN DESIGNED AS GLOBAL RADIO STANDARD ESPECIALLY DEVELOPED FOR THE PRACTICAL DEMANDS OF MEDICAL EQUIPMENT



More and more manufacturers of medical devices are now opting for wireless footswitches. There are good reasons for this. Wireless footswitches are more hygienic: their smooth surfaces can be cleaned easily. Safety and comfort are improved: there are no tripping hazards and the footswitches can be placed anywhere.

A new system with significant advantages

In order to provide users with reliable, manageable and practical radio technology, steute has developed the system "steute wireless" especially with medical equipment in mind. On the basis of experience gained with various radio technologies over many years, a new system has emerged boasting significant advantages: low power consumption, rapid connection times, low cost.

Significantly lower power consumption – shorter connection times

The system uses the internationally accessible 2.4 GHz frequency band and is split into 32 channels. At a maximum of 25mA, power consumption is as much as 60 % lower than with other radio standards. An added advantage of the steute wireless system is its »sleep mode«, with an electricity requirement of just 6 μ A. By actuating a switch, the system »wakes up« and the radio data link is established in under 200 ms (in most cases 50 to 100 ms). This goes unnoticed, but users profit from a significantly longer battery lifespan.

Fulfilment of all medical standards

This new radio standard was especially developed with the requirements of medical equipment in mind. It meets high safety standards, and signal transmission is reliable even in unfavourable ambient conditions.

// STEUTE WIRELESS THE COMPACT WIRELESS TECHNOLOGY



Left: Wireless module RF-RxT-SW2.4-MED
Top: steute rechargeable battery

Use of the free 2.4 GHz frequency band is low-cost and energy-efficient: steute wireless is becoming the standard wireless solution for the field of medical equipment.

// REDUCED COSTS, RELIABLE AND LOW POWER CONSUMPTION



Interference resistance

steute enables users to operate different devices in parallel, without any interference. The signal transmission is bi-directional within a time period of 20 ms. Thus a further wireless module is both transmitter and receiver at the same time. Besides numerous techniques for the automatic detection and correction of transmission errors, steute Wireless also provides additional safety by avoiding sources of interference using its frequency hopping technique.

Use with disposable or rechargeable batteries

Due to such a low power consumption, with high-performance lithium batteries extremely long running times can be realised. Alternatively, a lithium battery pack which can be recharged using a conventional battery charger is also available. This pack has an incorporated management system which displays the following parameters: battery voltage, amount of charge left, temperature, number of charge cycles, status information, serial number and date (programmable). The safety functions of the module include temperature monitoring, undervoltage monitoring and load current limitation.

Compact radio module

Nearly all foot controls made by steute Medical Equipment can be optionally equipped with the new steute wireless technology. This includes one- and two-pedal footswitches, dental control pedals, surgical microscopes, etc., as well as foot control systems for ophthalmology (phacoemulsification). In these cases, instead of a cable connection a compact module with an integrated antenna is installed which communicates with a receiver inside the device.

Also for hand controls

The steute wireless technology is also employed in a new generation of hand controls. Here too, the compact design of the wireless module has proved ideal, as well as the low power consumption facilitating use of a small and light battery.

// STEUTE WIRELESS IS A COMPACT SYSTEM WITH LOW POWER CONSUMPTION, RAPID CONNECTION TIMES, OPTIMISED PAIRING AND REDUCED COSTS

steute Wireless

- energy-saving
- extremely safe
- developed especially for medical equipment
- total hygienic protection
- costz-efficient solution
- internationally compatible

Features /options

- point-to-point connection
- pairing with interface RS 232
- frequency hopping: switching among 32 frequency channels (200 switches/s)
- transmission incl. frequency switch max. 20 ms
- synchronisation following sleep mode: max. 200 ms
- power consumption: 25 mA
- power consumption in sleep mode: approx. 6 μ A
- two transmitters can access one receiver
- transmission level 0 dBm (1 mW)

Radio specifications

Performance

- Distance 10 m (nominal)
- Radio output 1 mW (0 dBm)
- Internal ceramic antenna, external antenna optionally available

Radio technology

- Frequency range 2400 – 2483.5 MHz
- Certifications
 - FCC Part 15.247/ IC RSS-210 2.4 GHz
 - 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)

All steute Medizintechnik products conform with the relevant standards and directives for medical equipment:

- CE (93/42/EEC)
- IEC 60601-1
- UL 60601-1 (as option)
- IEC 60529 (Protection class up to IPX8)





Products with integrated interfaces

// Foot-operated controls
with USB interface
Page 58

// A TREND IN THESE APPLICATION FIELDS OF MEDICAL TECHNOLOGY IS THE DESIRE FOR SIMPLE, STANDARDISED INTERFACES



Foot controls with USB interface

In nearly all factories, laboratories and hospitals foot controls ensure that machines and devices can be operated reliably, even when users literally have their hands full. Originally these controls used to trigger simple switching procedures; nowadays users expect far more and the options have become far more sophisticated. For example, steute now develops and produces foot controls with integrated tilting switches and joypads which can be used to control far more complex procedures.

A further trend in this field of electrical technology is a desire for simple, standardised interfaces. For this requirement steute has already developed foot controls which can communicate with various devices totally without wires. Now another flexible connection option has been realised: foot controls can be equipped with a USB interface transmitting signals to conventional PCs. Up to eight digital and three analogue inputs can be read.

// USB IS STANDARD ON EACH MODERN PC



Problem-free integration

The new USB interface can be integrated within nearly all the foot controls in the steute range – even those with several switching systems for different operations.

Two versions for various applications

FTDI Chip set Different analogue and digital information can be read in and transmitted via USB to the medical system. The required FTDI chip set drivers can be provided by steute on request.

HID Interface (Human Interface Device) A further possibility is offered by connection via DHID-USB to PCs. This connection is of great advantage because standard input devices like keyboard, mouse, etc. can be simulated. The required drivers can be found »on board« the steute products and these are self-installing. With an appropriate software which is available from steute the HID commands can be modified afterwards by the operator.

The USB connection is advantageous when, for example, transmitted information needs to be visualised. The positioning of a pedal or a joystick can be displayed on a PC screen, for example, or the operating status of various actuators can be shown on overriding visualisation systems.

In this way transparency is increased and operators and staff are informed about activated device functions. This helps to avoid incorrect functioning and/or activation – an important factor for user safety. The USB interface has the added advantage of being a standardised feature within every state-of-the-art PC.





Typical Application Fields

// Laser devices

Page 62

// High frequency surgery

Page 64

// X-ray/MRI/CT

Page 66

// OP-beds/chairs

Page 68

// Ophthalmology

Page 70

// Dental equipment

Page 72

// 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 foot-operated 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



// MKF-MED SK12



// MGFS-MED



At work in the operating theatre and for the control of therapeutic 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 »coagulating«).



// MKF 2-MED GP26



Photo shows optional accessories

// MKF 2-MED GP25



Photo shows optional accessories

// MGF 2-MED



// MTF 3-MED



Photo shows optional accessories

// steute Wireless control device



Photo shows optional accessories



The HF surgery allows gentle operations in many fields.

// 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.

// KF 2-MED GP25



// MKF 3-MED GP33

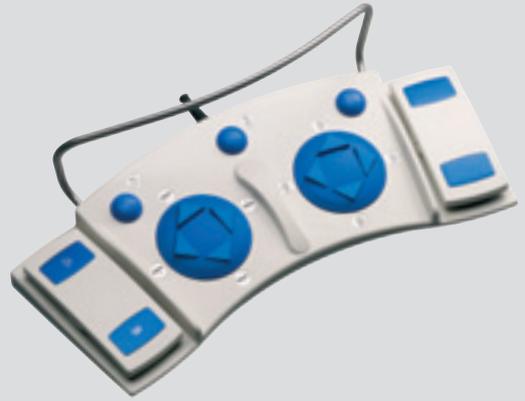


Photo shows optional accessories

// Customised solution



// Customised solution



// Customised solution



// Customised solution



// 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 switching elements; an integrated interface on request; use of multi-function elements.

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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

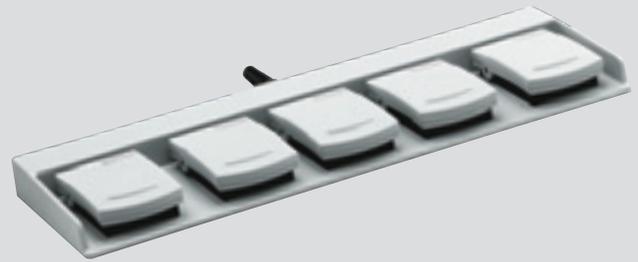
// WF 3-MED GP71



Photo shows optional accessories



// MKF 5-MED GP51



// MFS-MED GP71



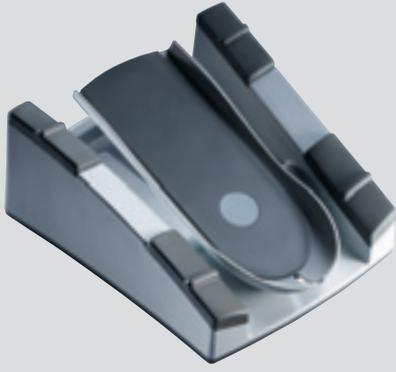
Photo shows optional accessories

// 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



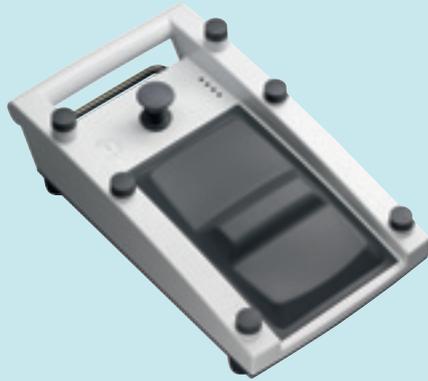
// WF-MED GP14



// MFS-MICROSCOPE-MED



// Customised solution



// MFS-MED GP71



Eyes are sensitive. Therefore the control devices of equipment for ophthalmology must be very sensitive 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 multi-function foot controls from steute.

// MFS-DENTAL-MED



Photo shows optional accessories

// MKF-MED GP16



Photo shows optional accessories

// MFS-MED GP71



Photo shows optional accessories

// MKF-MED GP13

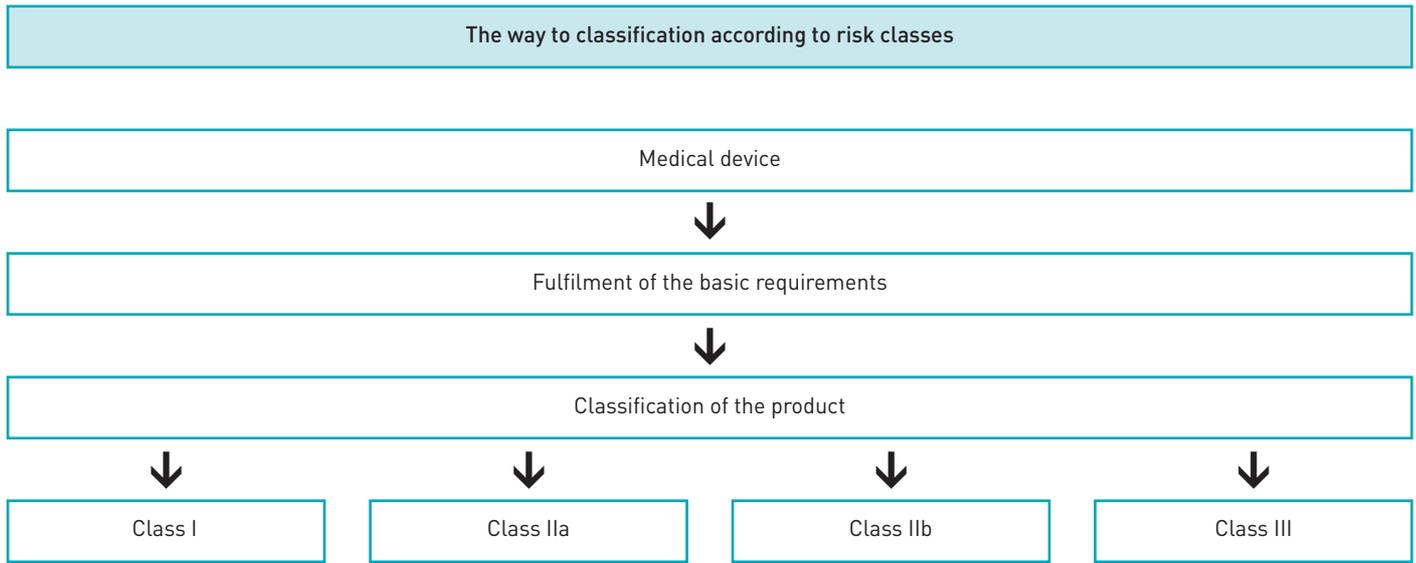


Photo shows optional accessories



// MKF-MED GP17





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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 60601 series 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.

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 performance 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 possibility 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



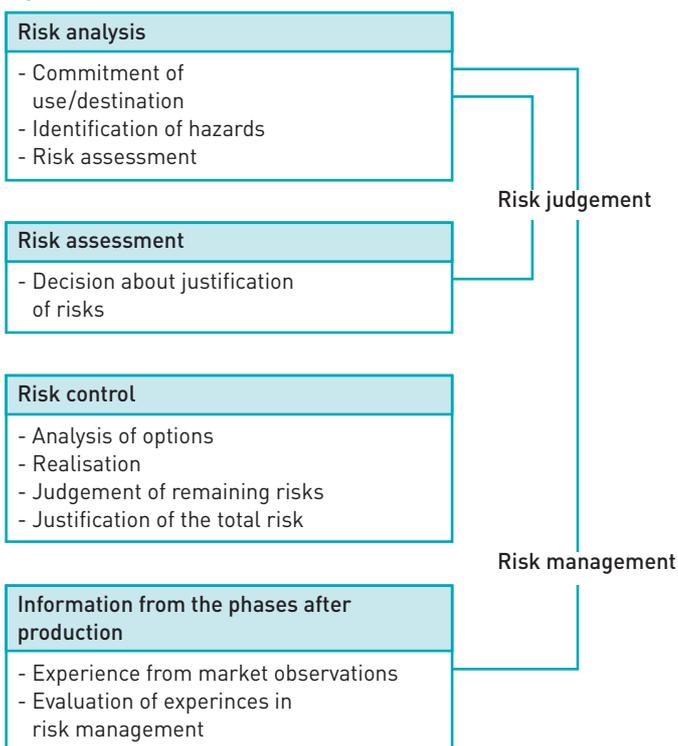
// MINIMIZE RISKS FOR USERS, PATIENTS OR OTHER TO AN ACCEPTABLE DEGREE

Risk analysis and/or product standard?

The manufacturer, meticulous to details, might question whether a risk analysis 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.

Fig. 2



Alignment with other areas of safety technology

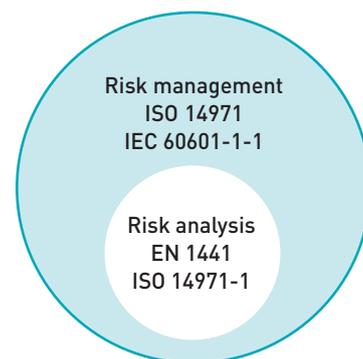
The revisions made to the IEC 60601-1 standard need to be viewed in a wider context. In other safety-relevant areas, e.g. machine safety, terms and procedures such as functional safety, risk analysis, hazard assessment, etc. also constitute part of the state-of-the-art technology.

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.

Fig. 3



Zertifikat

Prüfungsnorm **ISO 9001:2008**

Zertifikat-Registrier-Nr. 01 100 5554

TÜV Rheinland Cert GmbH bescheinigt:

Zertifikatinhaber:

.steute

steute Schaltgeräte GmbH & Co. KG
Brückenstraße 91
D - 32584 Löhne

Geltungsbereich:

Entwicklung, Fertigung und Vertrieb von Schaltgeräten und Steuerungssystemen für den allgemeinen Maschinen- und Anlagenbau, sowie für medizinische Geräte.

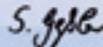
Durch ein Audit, Bericht Nr. 5554, wurde der Nachweis erbracht, dass die Forderungen der ISO 9001:2008 erfüllt sind.

Das Fälligkeitstermin für Folgeaudits ist der 27. November.

Gültigkeit:

Dieses Zertifikat ist gültig vom 26.11.2009 bis zum 27.11.2012.
Entzertifizierung 1995

Köln, 30.11.2009



TÜV Rheinland Cert GmbH
Am Grauen Stein 51105 Köln



TGA-25A-05-00

www.tuv.com



TÜVRheinland®
Genau. Richtig.



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**steute Schaltgeräte
GmbH & Co. KG**
Brückenstr. 91
32584 Löhne
Deutschland

has established and applies a quality management system for medical devices
for the following scope:

**Design and development, manufacture and distribution of
switchgear and control systems for medical equipment.**

Proof has been furnished that the requirements specified in

EN ISO 13485:2003 + AC:2009

are fulfilled. The quality management system is subject to yearly surveillance.

Certificate Registration No.: SX 6033353 0001

An audit was performed. Report No.: 21157448 001

This Certificate is valid until: 14.11.2015



Akkreditiert durch
Europäisches Komitee
für Normung
für Zertifizierung
und Kalibrierung
D,5-25-993,05.01-46

Certification Body



Dipl.-Ing. I. Munkler

Date: 15.11.2010

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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 pull-wire 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.