

Wireless  
FAQs

Benefits  
For You



*The world leader in medical-grade foot switches*

**The Future Starts at Ground Level**

**.steuteMeditech**



*The next generation in medical device interfacing from the recognized world leader in medical-grade foot switches.*



MKF 2 SW2.4LE-MED GP211

Hello,

Thank you for your interest in Steute's medical-grade wireless foot switches. Over our many years supplying medical device manufacturers with wireless foot switches, we are often asked many great questions. As a result, I thought it would be useful to put together a list of the most frequently asked questions, as I believe it will be a valuable tool when considering adding a Steute wireless foot switch to your host medical system. As you will see in the following pages, we don't just answer those questions, we give you quantifiable benefits that reinforce why Steute has the right answers for you.

Steute has been making foot switches for over 55 years and has focused on medical-grade foot switches since the creation of the MDD in the early 1990s. The combination of sophisticated German engineering and advanced technologies makes Steute the clear choice for medical device manufacturers who want to upgrade the perceived value of their products and who want to provide their end-users with a suite of superior benefits, such as better performance, better energy-efficiency, and intuitive ergonomics.

I encourage you to read this short booklet. Not only will it answer the most commonly asked questions, it will also give you insights that will make for easy integration of a Steute foot switch, thus dramatically impacting your bottom line. Please feel free to contact me with any specific questions you may have or to discuss an application requiring a wireless foot switch for your own medical device.

Thank you very much for your attention!

Sincerely,

*Maurizio Lauria*

Maurizio Lauria

.steute

*Answers To Frequently Asked Questions  
and Quantifiable Benefits For You*

Steute Meditech



MKF 1 SW2.4LE-MED GP111

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# Steute's SW2.4LE Wireless Medical-Grade Foot Switch Line

Steute's revolutionary third generation of wireless foot switches delivers enhanced performance and increased energy efficiency.

Thanks to precision German engineering, Steute announces the biggest news in our industry in years. We're introducing the SW2.4LE wireless foot switch family with the perfect pedal configuration to suit most medical applications, from one pedal to four. Don't see a configuration that's right for your application, please call to discuss a custom development. Steute has been making custom foot switches for the world's leading medical device OEMs for decades. We can help!

### Our Wireless Line Offers Distinct Advantages

- Robust and secure wireless signal specially designed for medical applications. Industrial-grade and commercial-grade wireless are inadequate for most medical applications
- New series of ergonomically designed housing (from 1 to 4 pedals available)
- Extremely energy-efficient use of standard alkaline batteries... for a longer battery life
- Eliminates cabled foot switch risks: tripping hazards and damaged cables or strain reliefs
- Fast response time, low latency
- Custom receivers available for easy system integration
- Suitable for use in medical risk classification II(b)

*Please refer to page 15 for the complete wireless foot switch line.*



MKF 4 SW2.4LE-MED GP411



MKF SW2.4LE-MED SK13



MKF 3 SW2.4LE-MED GP311



# Steute's Foot Switch Receivers

Each medical system has its own set of receiver interfacing requirements. The most commonly requested specification is standard, relay-based contacts or serial communication (RS232). Knowing this, Steute developed two main receiver types, each offers standard, relay-based contacts and serial communication (RS232).

The REC SW2.4LE-MED AG43 is a receiver with an enclosure. The enclosure features a cable receptacle that mates to the host system. This packaged receiver type is commonly used when a medical device OEM is looking to offer a wireless foot switch as an option/alternative to a cabled foot switch, whether it's a new system sale or field upgrade.

The REC SW2.4LE-MED AG43 PCB Open Frame is a receiver without an enclosure... just a PCB. This PCB receiver is mounted inside the host system and interfaced via a short cable and JST connector. The PCB receiver type is most commonly used in newly designed medical systems where the wireless foot switch is a standard feature of the medical device.

If neither of these two options will work for your application, no problem, let Steute custom-tailor a receiver by either modifying our standard offering or creating a fully-custom solution. Call us, we can help!

REC SW2.4LE-MED AG43



REC SW2.4LE-MED AG43 PCB



General Wireless Protocol Specifications	
Frequency	2.4 GHz ISM-Band
Frequency Hopping	40 Channels
Security	Retransmission, CRC <sub>24</sub> , 128-bit AES
Average Latency	29ms
Latency Coming Out Of "Sleep Mode"	Less than 70ms
Data Transmission Interval	20ms
Protocol Length	Up to 23 Byte
Transmission Power	3 to 7dBm
Power Consumption (Transmitting @ 3 dBm)	11mA



## Answers To Frequently-Asked Questions and Quantifiable Benefits For You

### >> General Questions

What are the advantages of a wireless foot switch over a cabled foot switch?

**A:** Wireless foot switches reduce tripping hazards in the O.R., reduce clutter on the floor, and eliminate a common source of failure on a cabled foot switch, the cable itself. In addition, they afford the user greater freedom of foot switch location for comfort and convenience.

**We have virtually eliminated the risks associated with cabled foot switches.**

What types of medical applications are suitable for Steute's wireless foot switches?

**A:** Steute's wireless system is suitable for a variety of applications including imaging, laser-based, electro-surgery, CT, X-ray, Ophthalmic, saws and shavers, etc. (up to and including Risk Classification II(b)). **We can satisfy your needs.**

Which wireless protocol does Steute use?

**A:** Steute uses its own protocol based on spread-spectrum, frequency-hopping technology. Developed expressly for medical applications, it meets or exceeds all FDA guidelines, and has modular approval for use in North America, Europe and Japan. **Now system certification is much easier and less expensive.**

Why did Steute develop its own wireless protocol?

**A:** Steute developed its own wireless protocol specifically for medical applications and to address the safety, security, and usability issues that commercially available wireless protocols could not. **We deliver the signal robustness needed for the demands of the medical device market.**

What frequency does the system use?

**A:** It uses 2.4 GHz ISM-Band, operating on 40 channels and hopping on 1600 hops per second. **This fast frequency-hopping and robust security algorithm reduces the probability of signal interference.**

How many Steute wireless foot switch systems are currently in use in the market?

**A:** Steute has been making wireless foot switches for over two decades. Currently, there are more than 20,000 systems in the field used in various medical applications around the world. **You will directly benefit from our in-depth knowledge and experience.**

When a treating physician or surgeon has his hands full dealing with a patient, it makes sense, and it is also typical, for their foot to take control. Phacoemulsification (for cataract surgery) is a perfect example of a physician needing the aid of a multi-functional foot switch. These controls fulfil all the relevant regulatory requirements and enable the desired function to be performed effortlessly and comfortably.





## >> Foot Switch Questions

Does the foot switch offer signal and battery charge status?

**A:** Yes, multi-color LEDs indicate transmission status and battery charge status, in addition to aiding in the "pairing" process (see the "receiver" section for more on the "pairing" process").  
**End-users will never be caught off-guard.**

What is the foot switch latency (i.e., how long does it take for the receiver to respond once a pedal or other actuator is operated/pressed)?

**A:** Average latency is 29ms if foot switch is in "active mode." **This makes operation seamless for the user.**

What is the foot switch power consumption?

**A:** Approximately 11mA while in "active mode." **This helps ensure a long battery life.**

Can the foot switch be placed in "sleep-mode" to preserve battery life?

**A:** Yes, sleep-mode is a feature on all series types. While in sleep-mode, there is no communication between foot switch and receiver. **This reduces the power consumption from 12mA to 60-80uA.**

How long does it take for the foot switch to come out of sleep-mode and transmit the pedal/actuator signal?

**A:** Approximately 70ms. **The sleep-mode is undetectable by the user.**

What type of batteries are used to power the foot switch?

**A:** Depending on the series, either 3xC-size or 3xAA-size primary (alkaline cell). Additionally, Steute can offer a rechargeable Li-Ion cell. **This is a very important feature for applications requiring greater energy density.**

How long will the batteries last?

**A:** It's a function of usage and series type. For example, based on one hour of continuous use per day, 3xC-size batteries will need to be replaced after 600 days, 3xAA-size batteries will need to be replaced after 230 days, and the Li-Ion battery will need to be recharged after 190 days.  
**The longer a battery lasts, the less down-time and maintenance are required.**



Quarter-turn to remove battery compartment knob.





### Are tools required to open the battery compartment to replace the batteries?

**A:** With the exception of the GP212 and GP34 series, no tools are required. Simply remove the battery compartment cap by rotating a quarter turn. **End-users will really appreciate how easy battery replacement can be.**

### Can the foot switch be charged using an inductive charging system?

**A:** Yes, inductive charging is available as a custom option. Points to consider are: location of dock station, length of time required for full charge, and powering the inductive charging circuit when the host medical device is not plugged into an electrical socket. **This is one of the many customization advantages Steute offers you.**

### What is the transmission distance between the foot switch and receiver?

**A:** Approximately 10m (33 feet). This distance can be increased or decreased by factory adjustment of the power setting. **This degree of application and environmental versatility is and-yet another example of Steute's industry-leading customization benefits.**

### Can Steute produce fully customized design solutions?

**A:** Yes, we can offer fully customized designs or work with the medical device manufacturer's design concepts. **Sometimes, one size does not fit all. If this is the case, we can help.**

### How many foot pedals are available on a standard (fully-tooled) wireless unit?

**A:** We offer standard foot switches with one, two, three, or four pedals plus auxiliary pushbuttons. **This ensures that our wireless products will cover the needs for the majority of medical applications.**

### What is the IP rating for a wireless unit with batteries?

**A:** IPX6 and up to IPX8 gated by application requirements. **Wash-down is not a concern.**



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MKF 3 SW2.4LE-MED GP311



MKF 4 SW2.4LE-MED GP411



MKF 2 SW2.4LE-MED GP212



MKF 3 SW2.4LE-MED GP34



MKF SW2.4LE-MED SK13



MFS Microscope SW2.4LE-MED



MFS Phaco SW2.4LE-MED



## >> Receiver Questions

What types of outputs are available?

**A:** Various types are offered including normally-open relay contacts and serial communication such as RS232, USB, I2C for controlling “on/off” and analog functions. **We can design around your system requirements for ease of receiver integration.**

What types of receivers are offered?

**A:** Steute offers two basic receiver types, one with an enclosure for external system mounting and one as a PCB card for internal system mounting. **These options allow for integration within a new system/product design or as an addition to an existing system where there may not be space to accommodate a receiver PCB.**

Is it possible to build a custom receiver?

**A:** Yes, fully-custom receivers are possible. However, whenever a new PCB receiver is created, regulatory testing and certification will be required. **Let us handle that while you focus on the host system.**

Does the receiver offer signal and battery charge status?

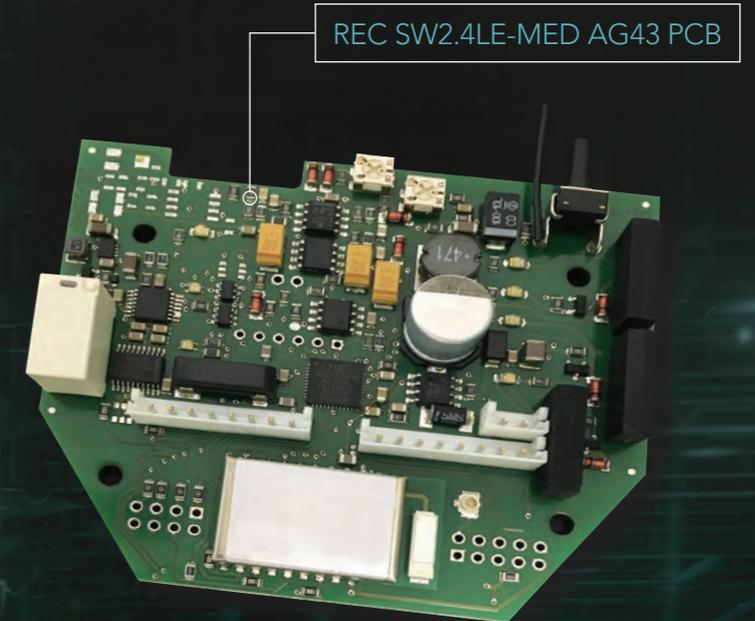
**A:** Yes, the externally-mounted packaged receiver offers multi-color LEDs to indicate transmission status and battery charge status, in addition to aiding in the pairing process. The same status information is offered via serial communication. The internally-mounted PCB receiver also offers transmission status and battery charge status via serial communication. **Serial communication allows for transmission status and battery charge status to be displayed on the host system’s GUI for easy monitoring of vital foot switch data.**

What other type of data can be transferred via serial communication?

**A:** In addition to battery charge status, serial communication can transfer the following data: foot switch serial number, software version, number of charging cycles experienced to date (for rechargeable Li-Ion batteries), and custom parameters required by the customer. **The data is vital to improving the system’s maintenance program.**

Where is the externally-mounted receiver mounted?

**A:** The preferred mounting location is on top of the medical system. However, other locations are possible assuming the receiver can be secured into position and properly protected from mechanical damage. **Versatile mounting options allow for easier after-market integration of the externally-mounted receiver.**





## How do you interface an externally-mounted receiver to the medical system?

**A:** A short length of cable and customer-specified connector will interface the receiver to the medical device. Often the same receptacle used to connect the cabled foot switches can be used to connect the receiver cable (this is especially true if the receiver power is available within the receptacle). **Easy interfacing means faster system integration and less cost!**

## Can the internally-mounted PCB receiver be customized?

**A:** Yes, we can customize per your requirements. We do offer a standard size PCB with dimensions of 3.6" x 2.6" with standard JST connectors. However, we can offer specific dimensions, mounting options, and interface types (i.e., RS232, I2C, etc.). **More proof of Steute's ability to customize.**

## Where is the recommended mounting location for the receiver and antenna?

**A:** In a location where the transmitted signals will be unimpeded by metal, large diameter cable harnesses, or metallic paint (e.g. metalized console skins). **Have doubts or concerns? Send drawings or images, we can help!**

## How do you "pair" the foot switch and receiver?

**A:** The receiver is put into "pairing" mode by either pressing a "pairing" pushbutton provided on the rear of the receiver housing or via serial communication. This is followed by a series of pedal actuations within a specific (customer-specified) time frame. **Custom "pairing" sequences or processes are possible based on system requirements and risk assessment.**

## Can "pairing" be performed in the field?

**A:** Yes, "pairing" can be performed in the field by the end user or service technician. **No need to return to the factory, thus saving time and cost.**



## >> Safety and Security

Can the wireless foot switch be used in a hospital and O.R.?

**A:** Yes, Steute's foot switches are specially designed and built for medical applications and medical environments such as the O.R. **Robustness and security of the transmitted signal is the main difference between a medical-grade foot switch and an industrial-grade foot switch.**

Are there any concerns over interference with other wireless protocols/signals?

**A:** No, Steute's wireless protocol is based on spread spectrum technology using low-power transmission. Signals are encrypted with a secure algorithm. This proprietary chip set has been fully-tested and has modular approval for use in North America, Europe and Japan. Steute can offer documentation to aid in the regulatory process in other nations such as Brazil and China, where modular approval is not recognized. **Our certifications and test reports help make system certification easier and less expensive.**

Is there a possibility of "cross talk" if more than one wireless foot switch is in the same room?

**A:** No, the receiver will only communicate with its "paired" foot switch, identified by its unique identification number. **Safety and security are critical design features for medical-grade foot switches.**

Do I need to select an operating frequency?

**A:** No, the wireless signal is transmitted automatically on 40 channels and hops 1600 times per second. No need to select frequencies based on available bandwidth. **This makes the wireless system easier to use and less likely to be interfered with or cause interference.**

Can my other Bluetooth-based equipment "pair" to the foot switch receiver?

**A:** No, Steute's software is based on the Bluetooth LE software stack, but additional software layers were added for the robustness and security required for medical applications. **Steute's receiver is designed specifically not to communicate with other Bluetooth devices, thus helping to ensure safety during operation.**





Is there any concern over other wireless protocols that may exist in a hospital or O.R.?

**A:** Other wireless protocols such as Wifi, commercial Bluetooth, or wireless telemetry will not interfere with the wireless foot switch. We have completed coexistence testing according to ANSI C63.27:2017. **We will be pleased to share this report to make your regulatory process easier.**

## >> Regulatory

Which countries will accept Steute's wireless system?

**A:** Steute has wireless module approvals for North America, Europe and Japan. Other countries are possible on request (assuming these countries accept modular approvals). **For countries that do not accept modular approvals (i.e., China, Brazil, etc.), we can provide certificates and test reports to make system certification easier and less costly.**

Is the wireless set IEC 60601 compliant?

**A:** Yes, it is! **Steute is 100% committed to the medical device industry, which requires us to keep up with the applicable regulations.**

What is the risk classification for the wireless system?

**A:** Steute's wireless foot switch can be used for systems with risk classification up to "Class II(b)". **This covers the vast majority of medical applications making the regulatory process faster and easier.**

Are there any other safety standards/certifications that differentiate a Steute wireless foot switch from others?

**A:** Yes, Steute's Software Risk Management meets "class C" according to the IEC 62304. In addition, we meet Safety Integrity Level 3 (SIL 3), according to IEC 61508. **As you can see, Steute is definitely in the business of producing wireless foot switches for medical applications. This is our core competence, let us handle the foot switches so you can focus on the host medical device.**

MKF 3 SW2.4LE-MED GP311 with Brace





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