

Key Elements of a Medical Grade Wireless Foot Switch

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Wireless foot switch technology can be a preferred control mechanism for a variety of medical devices. However, there are a number of considerations designers need to consider before looking to use this technology. This article serves as a primer for many of those considerations while also providing an overview of the technology.

Wireless foot switches that control medical devices have been in use for several years. They primarily use radio frequency (RF) technology to send control signals from the foot switch to the receiver.

The communications protocol must be designed with safety and security as the most important specification. The protocol governs how well a wireless system performs in the presence of external forces acting upon it, such as:

- Other hand/foot controls
- Medical instruments
- Arcing from a surgical generator
- The motor from a bone shaver
- Video displays
- Wi-Fi systems
- Microwave ovens



Revere-101A receiver

To achieve a safe and secure protocol, three key elements must be incorporated

into the design.

1. Virtual wired paradigm for fail-safe operation. A virtual wire connects two ends of a controlled system using an RF medium. The transmitting end is hard-wired to the physical source control(s) (e.g., foot pedal). The receiving end is hard-wired to the device(s) being controlled (e.g., electro-surgical generator).

On activation of the source controls, the transmitter sends a continuous stream of data packets to the receiver. Each data packet indicates the current state of the source controls. The receiver actuates the associated device(s) as directed by control information in the data packets. If the stream of data packets ceases, for any reason, then the receiver must turn off all devices being controlled (i.e., enter a fail-safe state).

The key element of the virtual wire paradigm is to provide a fail-safe mechanism based on a loss-of-signal (LOS) condition. LOS at the receiver end is defined as the absence of the transmitters continuous data packet stream. If the receiver detects a LOS, it enters a fail-safe state that typically results in deactivation of all devices being controlled.

A virtual-wired system is analogous to a hard-wired system, in that a switched electrical current flow gates the activation of a device; if the electric current flow ceases, for any reason, then the controlled device deactivates.

2. Signal identification coding to ensure that a transmitted signal is only interpreted by the intended receiver. The transmitted signal or data packet should contain:

- Media Access Control (MAC) addressing indicating both “from” and “to” addresses
- Original Equipment Manufacturer code
- Device or model number

Before a receiver-transmitter pair can communicate a joining (also called pairing, linking, mating, or bonding) process must occur. The joining of one transmitter and one receiver together ensures that they will only communicate with each other and no other transmitter or receiver. This process basically entails exchanging of MAC addresses for use during normal operation. Some linking is done at the manufacturer’s location, while others can be linked in the field. Field linking is preferred since foot switches can be gathered from different locations and brought to a central place for cleaning. When they are returned, there’s no guarantee that the same foot switch will be returned to its original location.

3. Frequency hopping technology to minimize RF interference. Single channel systems (operate at one fixed frequency) should only be used to control devices that do not require the highest degree of security and safety, such as a camera or microscope. This is because of possible interference caused by various other RF devices that hospitals typically use. The following RF systems may raise the risk of interfering with a single channel system:

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- High power Wi-Fi systems
- Bluetooth wireless systems
- Patient worn telemetry on cardiac and obstetrical units

Frequency hopping multi-channel systems do not transmit on a single channel but rather change frequency ten or more times per second during the course of the transmission to maintain the highest security and safety level possible.

The foot switch (transmitter) is powered with batteries. Generally speaking, a longer battery life allows a more carefree usage of the foot switch. Both primary (consumer batteries available at retail stores) and rechargeable batteries are used throughout the industry. The advantage of primary batteries is the easy access to supply and thus, can be changed quickly, whereas rechargeable batteries require an extended time to charge or a charged spare must be kept on hand.

Battery life is different depending on the manufacturer and varies from a few hours to years. Some are specified at a 50% duty cycle (on half the time, off half the time) until the batteries are exhausted, or at a specific number of hours used a day. The longest term battery life is specified at greater than 3,000 hours at a 50% duty cycle or approximately two years at one hour usage per day.

A battery replacement warning is necessary to ensure that a medical procedure does not commence when the batteries have insufficient power. Typically, an LED on the receiver warns that the transmitter batteries are approaching their end-of-life and should be replaced. More advanced proactive warning or indicators include audio speech stating the condition and/or a color video screen having a battery-life fuel gauge, bar graph, or numeric display.



Wireless foot pedal controller

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Pedal identification prior to function activation is used to guard against inappropriate or mistaken action on behalf of the user. Two common passive methods are pedal color coding and relative pedal placement, as in the case of Cut (yellow, left) and Coagulate (blue, right) functions. These passive methods require the user to look at the foot pedals which can be difficult and distracting because the pedals may be located under the edge of a table.

Typically, an LED on the receiver lights up to indicate that an output function is active; it is not a warning that an output is about to become active. An advanced active method of pedal ID is called Near-On Awareness Technology. Near-On systems alert an operator which device is about to become active using audio and/or visual indicators. Near-On systems are designed to inform a user that he is about to perform an action. The user can decide if indeed it was the action he intended to perform. When an actuator is partially engaged, it will trigger a voice enunciation and the connected device will not activate until an "on" threshold value is reached on the actuator. For example, a surgeon is using a foot switch to control a laser scalpel. If he depresses the foot switch half way down, a computer voice will tell him that he is about to activate the laser scalpel. If he continues to depress the foot switch past the threshold point (half-way or 3/4 way), the scalpel activates.

Chattering of the receiver outputs should be mitigated. In the case of poor RF link quality, the receiver outputs can chatter caused by intermittent reception (i.e., the outputs can change state from "on-off-on"). This condition is not desirable and should be mitigated. When an intermittent signal or loss-of-signal is detected, the receiver should turn off all outputs. To exit the defunct session, the transmitter switches must be released. Reactivating the transmitter switches will commence a new session and, in-turn, reactivate the receiver output. This method avoids an "on-off-on" action that could occur when link quality is very poor.

Latency is defined as the time difference from when a foot switch is activated or deactivated to the time the receiver affects the associated output. The generally accepted maximum time is 250 milliseconds (1/4 second) or less. However, it is desirable to keep this time as short as possible (30 to 50 ms is optimal).

Locating the receiver is imperative to avoid inappropriate activation of an output at the receiver. In the case of multiple transmitters and/or receivers, a locate mode allows the user to determine the transmitter-receiver pairing without activating the outputs at a receiver. When the locate mode is activated at the foot switch, its paired receiver will announce pairing using an audio and/or a visual prompt.

Antenna type is important to ensure proper communication ability. External antennas (also called a rubber ducky) typically have a higher gain than internal antennas; however, external ones have a high chance of being damaged and also pose a problem when the foot switch is being cleaned. Therefore, a high gain internal antenna is the best choice. A signal quality indicator may be displayed or may be announced during locate mode activation.

Storing the foot switch must place the transmitter in a safe mode. During an extended storage period, a switch may inadvertently get depressed. This

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unintentional depressed switch must not activate an output at the receiver. Storage mode should put the foot switch to sleep in order to save battery power and inhibit communication with the receiver.

Linear outputs provide control for devices that require a varying output voltage proportional to the foot pedal displacement. A typical application would be a bone shaver that uses a variable speed motor to perform its function. More advanced systems allow an adjustable output voltage range to meet the needs of a variety of linear devices.

Industrial wireless controls are robust foot-switches usually constructed of cast iron or cast aluminum. Internal antennas are always preferred; however, the signal cannot get through the metal so the manufacturer must find a way of getting the signal out of the foot switch while still maintaining mechanical integrity. Other attributes are:

- Relay outputs at the receiver capable of switching high currents (20 to 30 amps @ 250 V) and high inrush currents of 80 to 100 amps
- An emergency stop located at the foot-switch. This can be a stage on the foot switch where the operator would have to push past a stiffer than normal condition to activate the emergency stop or an additional push-button switch on the foot pedal housing.
- Capable of operating single or three phase motors
- An independent relay to activate an external emergency stop module (loud horn and red light) or to activate the E-Stop of the machine under control

Gary Argraves and Charles Reynolds are with [Near-On Controls](#) [1].

Source URL (retrieved on 03/12/2014 - 5:50am):

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