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Selecting a Wireless Technology for “Medical-Grade” Foot Controls

Introduction

Historically medical device manufacturers, requiring a foot control as a human interface, have used a cabled unit that would plug-into the console of the device being operated. Typical applications include X-ray equipment, urology tables, cataract surgery systems, ultrasonic diagnostic systems, surgical microscopes, electrosurgical generators, shavers, dental chairs, examination tables, biopsy sampling systems, laser-based dental systems, laser-based dermatology systems, fluoroscopes, medical camera systems, ophthalmic surgery systems, MRI equipment, CT scanners, medical cameras, and surgical navigation systems.

Until recently, a “cabled” unit has been the only available option. While these “cabled” solutions proved to be acceptable, many OEMs recognized that the cable presented some limitations. These included:

- The cable posed a “tripping hazard” to personnel.
- The cable limited the location of the foot control relative to the location of its host medical device.
- The cable was typically the single most frequent point of failure … either from excessive stress at the strain relief, or due to damage to the cable (from being rolled-over by chairs, examination tables or equipment carts).
- The cable made it difficult to store and/or clean the foot control.

As a result of these issues, field experiences, and a proliferation of wireless equipment (e.g. cell phones, patient monitoring systems, computers, et al) many medical device OEMs asked if it was possible to eliminate the cable. Wireless operation became the most frequently requested feature.

Figure 1

Cataract Surgery System (Phaco) Foot Control

Major Selection Factors

The following are among the major factors to consider when selecting a wireless technology for a medical foot control:

Nature of the medical device ... and its related risk assessment:

As noted earlier the diverse potential use for wireless controls ranges from relatively low (patient) risk applications (such as medical camera systems capturing reference images) to relatively high-risk applications (such as X-ray equipment or laser-based systems). In this context, one must consider consequences of the loss of a desired signal, and/or the consequences of the equipment being activated by a random signal (noise) rather than through the purposeful actuation of the foot control.

These concerns are, of course, similar to those that one might assess with a cabled foot control – wherein control may be lost due to a cart or exam table cutting the cable. For example, while the loss of a signal in an image capturing system is an inconvenience, it has no serious consequence for a patient. Here the use of a unidirectional communications protocol (wherein the transmitter signals the receiver, but there is no communication from the receiver) may offer the user the benefits of less frequent battery servicing (recharging and/or replacement).

Alternatively, the integrity of communications between a foot control and a C-arm X-ray system or laser-based surgical instrument, may have more significant consequences for consideration. Here it may be more prudent to use a bidirectional communications system (capable of two-way communications between the foot control and the medical device receiver). Systems such as BlueTooth®, Zigbee®, or some other similar proprietary protocol may offer the benefits of noise immunity, greater encryption possibilities (for "pairing" the transmitter with its' receiver), and the ability to verify the integrity of the communications link in real-time.

Power consumption:

The choice of a wireless technology (together with the duration of a typical procedure, the number of procedures per day, the duty cycle, and required data transfer rates) will have an impact on the type (rechargeable vs. non-rechargeable), size and number of cells required to satisfy the power and battery service parameters of the application. Here the wireless technology's inherent power requirements, and the ability to minimize power consumption (e.g. through use of a sleep-mode), will gate the most practical battery candidates.

Ability to minimize or eliminate the potential for interference:

While the OEM medical device design engineer can control the generation and /or emission of random noise from their own equipment, they may have little control over the its presence in their user's environment.

For many medical applications, total elimination of potential interference is typically impractical. The possibility of "noise" (EMI signals from sources such as "like" systems … identical systems from the same manufacturer, patient monitoring systems and other wireless equipment, and other electrical/electronic equipment in proximity to the medical device) must always be considered.

For example:

- The need for use of two or more "like" systems in the same local environment may require a wireless protocol capable of "pairing" the foot control and its' controlled medical device in real- time. Such bidirectional communication assures that foot control "A" for device "A" will not operate device "B" (and vice versa).
- Infrared (IR) wireless systems are typically not recommended for use in the presence of plasma screens (due to their emission of light in the IR portion of the spectrum).
- Unless properly applied, ZIGBEE-based system signals may be masked by selected WLAN.

- The possibility of random noise (such as from electro-surgical generator) may, depending upon its frequency, dictate use of a wireless protocol unaffected by such an EMI presence (such as a frequency-hopping or similarly robust technology which is not compromised by such equipment).

Such issues can be addressed through judicious analysis of, and elimination of, the potential for such interference, programming of data frame formats in a specific form acceptable to the Receiver (e.g. such as identifying the medical device manufacturer, identifying the specific transmitter source, signal encoding, et al), and/or choosing a wireless protocol that is sufficiently robust to operate reliably in the environment.

Need for unidirectional vs. bidirectional communications:

As mentioned earlier, the need for unidirectional vs. bidirectional communications will be affected by the level of assessed risk inherent in the application/procedure, the number of “like” systems in a common environment, and/or the ability to tolerate potential interference from other wireless devices (such as patient monitoring equipment). For some medical device applications there may also be a need or desire to transmit and receive ancillary, non-control information/data. For example, medical device manufacturer’s identification, medical device identification, real-time state of battery condition (voltage,current, charge status, temperature, number of experienced recharge cycles, et al) may be important parameters as assessed risk increases and/or interruption of a procedure due to a power loss becomes unacceptable. If so, the selected wireless technology must be capable of supporting this need.

Desired transmission distance/potential signal barriers:

The desired transmission distance may affect both the power requirements of the wireless protocol, and the risk assessment (as the farther the transmission distance capability, the greater the risk of inadvertent actuation of the controlled medical device. In addition, one must be concerned about the possibility of signal loss due to “barriers” to signal path within the environment (e.g. carts, table drapes, stools, personnel, et al). For most medical devices operated via a foot control, the transmission distance is generally well-below 10 meters as the user is typically in close proximity to the medical device being controlled. Never-the-less, the wireless protocol chosen should be capable of reliable operation in the target environment/application.

Response Time/Transmission Delay

When called upon for control, the wireless protocols typically considered for medical foot controls have response times well within those required (e.g. less than 250ms). However, when using a sleep-mode to conserve power/extend useful battery life, system wake-up time must be considered. Here it is important that the system wake-up time does not exceed the desired control response time.

Cost:

Cost will typically be driven by the technical requirements of the application and/or the level of acceptable risk aversion. For example, applications having lower levels of assessed risk may be satisfied by typically lower overall cost (batteries, support circuitry, base technology) of unidirectional wireless protocols such a Infrared and single-frequency technologies. Where risk aversion is high, data density is high, or real-time "pairing" of the transmitter - receiver is desirable, or worldwide acceptance is desired, higher-cost wireless protocols may better address the needs of the application.

Some Possible Wireless Technologies

With the apparent need and potential benefits as drivers, a number of commercially-available "wireless" technologies can now be considered.

These include:

- Infrared (IR)
- 915 MHz (a frequency available in the ISM band for medical applications)
- DECT (Digitally Enhanced Cordless Telecommunications)
- WLAN 802.11
- ZigBee®
- BlueTooth®
- STEUTE “Wireless RF 2.4-MED”
- Other proprietary protocols

Each of these has its own unique attributes … some of which are summarized in Table I. These performance characteristics should, of course, be considered in the context of the risk assessment associated with the medical device function and application. Where the level of assessed risk is “low” almost any wireless technology may be suitable depending upon cost-performance requirements … e.g. response time, desire for signal confirmation, consequence of erroneous or lost signals, need for worldwide acceptance, etc. Where the level of assessed risk (e.g. patient vulnerability) is “high”, a technology that offers the highest degree of safety may be more suitable. Here one must also consider high noise immunity, bidirectional communications capability for signal reception confirmation, “pairing” of transmitter-receiver, etc.

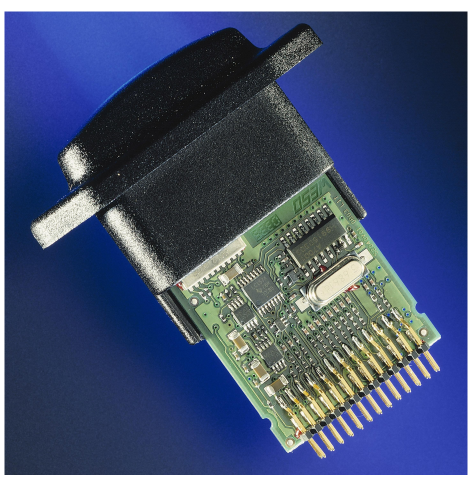
Table I.
Pros & Cons of Selected Wireless Technologies for Use in "Medical-Grade" Foot Controls

Wireless Technology	Pros	Cons
Infrared (IR)	• Accepted worldwide • Relatively low power consumption • Relatively lower in cost	• "Line-of-sight" technology • Potential of interference from plasma displays
915 MHz (European norm)	• North American in ISM Band • Relatively low cost	• Not accepted worldwide • Susceptible to interference
DECT	• Safe data transmission • Accepted worldwide	• High RF power (4 to 10 mW)
WLAN 802.11	• Accepted worldwide	• High RF power • Susceptible to interference
ZigBee®	• Accepted worldwide • Relatively low power consumption	• Potential of interference from WLAN • Typically higher cost than some other wireless alternatives
Bluetooth®	• Accepted worldwide • Relatively low RF power • Immune to EMI • Safe (bidirectional) data transmission	• Higher power consumption than some other technologies • Typically higher cost than some other wireless alternatives
STEUTE "Wireless RF 2.4-MED"	• Accepted worldwide • Relatively low RF power • Immune to EMI • Safe (bidirectional) data transmission • Low power consumption • Sleep-mode	• Typically higher cost than some other wireless alternatives

Generally Desired Features for Wireless Medical-Grade Foot Controls

In addition to the requirements for a conventional cabled foot control, the following are among the most common features medical device OEMs mention desiring when considering use of a wireless human interface:

- Ability to meet the functional control requirements.
- Compliance with all relevant radio-frequency Standards in the countries of use … e.g. USA (FCC Part 15.247/IC RSS-210 2.4 GHz), Europe (IEC 60601-1, IEC 60601-1-2, EN 60950 (2006), EN 50371 (2002), 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), and Japan (J60950).
- “Geographic” acceptance … here defined as acceptance in the countries in which the OEM wishes to market their equipment.
- Maximum operating time between battery recharging or battery replacement.
- Ease of periodic system maintenance … recharging, battery replacement, cleaning, “pairing” of transmitter and receiver.
- Robust construction … IP X6 to IP X8.
- Ability to monitor battery charge status in real-time.



RF Transmitter-Receiver Module With Integral Antenna

Figure 2

Frequently Asked Questions

As one would expect, medical device OEMs considering the use of wireless controls have many queries relevant to the choice of a technology for their application. The most frequently asked

- Safety/Reliability
- Power/Batteries
- Receiver Module.

Safety/Reliability:

While interest among both OEMs and their customers has been high, early adoption of the use of wireless foot controls has been slow due to concerns about safety and/or reliability. These concerns most often revolve around false signals (EMI), “crosstalk” between ‘like’ systems, and/or loss of signal.

Current technologies (especially bidirectional, frequency-hopping protocols such as BlueTooth® and STEUTE 2.4-MED) effectively address these issues. Their frequency-hopping characteristics have proven them to be highly immune to outside interference. With proper formatting of their data frames, they can eliminate the possibility of “crosstalk” with encryption for the manufacturer, serial number, type of device and device identity … such that the “pairing” of the transmitter (foot control) - receiver (medical device) eliminates communication with other ‘like’ systems or the interference from other wireless systems or stray EMI.

In addition with suitable programmed software, bidirectional communication permits constant confirmation of the married ”pair”, immediate safe actions in the event of signal loss, and real-time monitoring of the power supply status (to alert the user visually and/or audibly well-in-advance of the need for battery charging or replacement).

Other safety features that can readily been provided, if desired, include “floor sensors” which inhibit can cause intentional interruption of the communications link if the foot control is picked-up from the floor for more than some preset time period; monitoring of the number of experienced recharge cycles to allow signaling signal the need for battery replacement after a preset number of recharges, shut-down to a safe condition in the event of power loss or loss of communications, and periodic or permanent display of the battery charge status at all times.

If desired, wireless systems can also be designed as a "hybrid" … capable of also functioning (if desired or needed) as a conventional cabled device. Currently available technologies offer the OEM the opportunity to offer the benefits of wireless control without compromising patient safety or required systems reliability.

Power/Battery Issues:

Typically questions concerning the power supply (batteries) revolve around the interval needed between recharges and/or battery replacement battery monitoring battery charge status, and ease-of-replacement/recharging. Currently available battery chemistries/characteristics, coupled with today's wireless technologies, provide an array of combinations with which to address each specific application requirement. In addition, the use of sleep modes with acceptably fast wake-up times permits conserving battery power during periods of non-control activity. Such conservation can extend the interval between battery recharging and/or replacement to weeks and months (depending upon the application).

Foot control design can be such that recharging can be accomplished simply by plugging in a medical-grade wall recharger into a sealed recharging connector. Similarly, battery replacement can be made as fast and easy as one experiences with their digital camera … via a sealed battery compartment that is accessed without tools in a matter of seconds.

As previously mentioned, selected wireless technologies permit monitoring and transmitting battery charge status, number of experienced recharge, voltage, current, and/or temperature in real-time. Such monitoring permits safe, timely actions to be taken before a power supply (battery) and system operation has been compromised.

Receiver Module:

As one would expect, there are many questions resulting from the need to add a receiver module to the medical device to facilitate wireless operation. Typically these revolve around location, integration, interfacing and/or powering of the Receiver module.

Essentially there are two locations for the Receiver … integrated within the medical device console, or as an externally-mounted enclosure. Here the choice may be affected by whether the wireless control is offered as an upgrade or post-system sale add-on, the material of construction of the medical device console (for antenna consideration), and the wireless technology selected (line-of-sight such as Infrared or Omni-directional radio frequency systems such a BlueTooth®, ZIGBEE®, and STEUTE RF 2.4-MED.

Regardless of the location, the Receiver will require power … either from the host system power supply, a medical-grade plug-in power source (e.g. wall charger), or (if practical) from its own batteries. Where line-power is required, accommodation will need to be provided from the host power supply directly to the Receiver module hardware or (If externally mounted) via a pin on the female connector.

The outputs of the wireless Receiver can be formatted for interface compatibility to interface with the host system … whether this is discrete analog/digital signals, USB, RS232, RS485 or other requirement. Thus the Receiver outputs can mimic whatever has been provided previously via a cabled foot control such that the nature of the foot control (cabled or wireless) is seamless to the controlled medical device.

The questions that are paramount are, of course, a function of the application and the operating characteristics desired by the OEM's technical and marketing staff. However, the above are generally among those most frequently asked for making an informed decision and technology selection.

Benefits & Drawbacks to the Medical Device OEM

As with a conventional cabled foot control, there are benefits-to-use, as well as new issues to address for the OEMs choosing to offer a wireless solution. Among the benefits are:

Ability to expand increase revenues:

Depending upon the OEMs target market and competition, offering wireless controls presents the opportunity to expand their revenues by addressing customer wants and/or by providing an optional wireless upgrade for their installed base of devices.

Ability to enhance technical image:

With more and more end-users requesting the benefits of wireless control, OEMs who offer this feature (as standard or as an option) have the opportunity to be perceived as technical innovators or leaders.

Elimination of "issues" associated with cabled foot controls … such as the tripping hazard, cable damage, and cleaning/storage problems.

Among the new issues to address (different from a cabled foot control) are:

- Periodic recharging/replacement of batteries … this a function of the usage, battery energy density, number of batteries, use of a "sleep mode", et al.
- Need to maintain transmitter-receiver pairs … this is important for safety and where foot controls are collected in a group for cleaning or storage.
- Higher cost than a cabled unit … this is a given. The degree will be a function of the wireless technology selected, the number of discrete actuators, the type of controls signals required (analog and digital), and other desired design features.

Wireless Electro Surgical Generator Foot Control

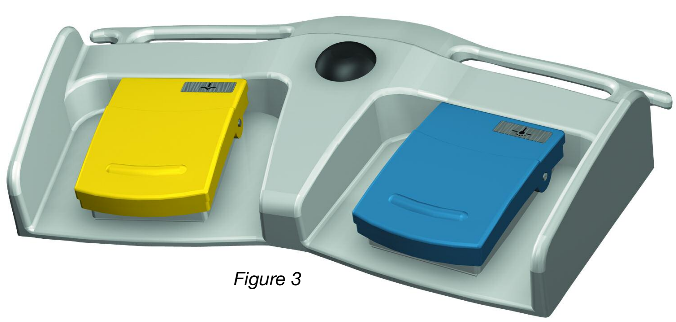


Figure 3

As wireless devices continue to proliferate, and users embrace wireless controllers, one can expect to see more medical device OEMs offering such foot controls as either their standard … or as an optional upgrade. Already a number of OEMs are offering such controls for X-ray systems, medical cameras, electro-surgical generators, fluoroscopy systems, orthopedic surgery systems and ophthalmic surgery equipment.

We trust that this overview is a helpful reference to those considering the use of wireless control as an addition or option to their medical device.