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

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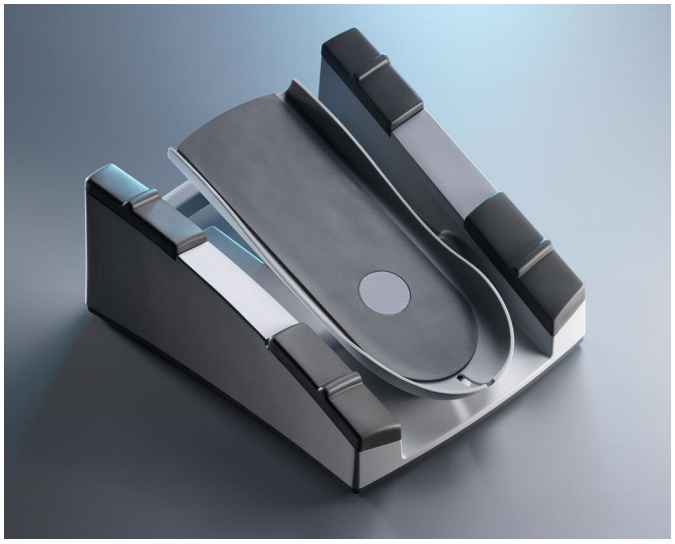
Introduction

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. 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.



Cataract Surgery 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.

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)
- 868 MHz (a European norm for medical applications)
- ENOCEAN™
- DECT (Digitally Enhanced Cordless Telecommunications)
- WLAN (Wireless LAN)
- ZigBee®
- BlueTooth®
- STEUTE "Wireless 2.4-MED"

Each of these has its own unique attributes … some of which are summarized in Table I (*see page 3*). 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.

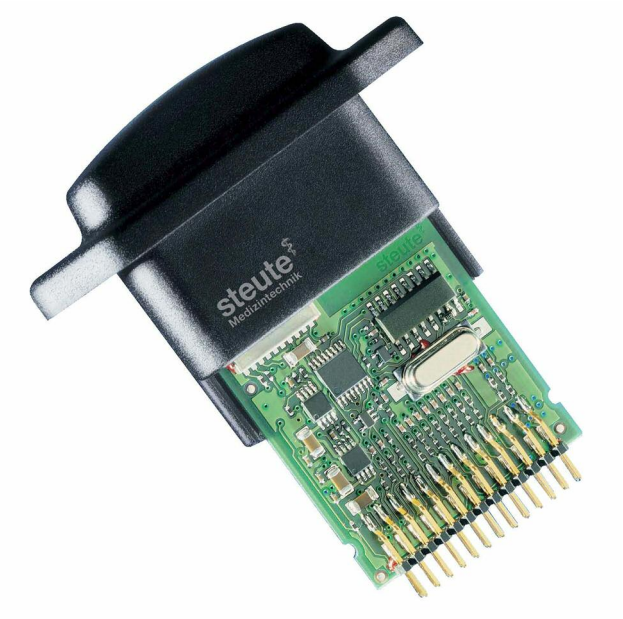
Table I.
Pros & Cons of Selected Wireless Technologies for Use in“Medical-Grade” Foot Controls

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
868 MHz (European norm)	• European Norm accepted for medical applications • Relatively low cost	• Not accepted worldwide • Often used frequency in North America • Susceptible to interference
ENOCEAN™	• Lower in cost than some other wireless alternatives • Self-generated power (no battery required)	• Available frequency (868 MHz) not accepted worldwide • Susceptible to interference
DECT	• Safe data transmission • Accepted worldwide	• High RF power (4 to 10 mW)
WLAN	• 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“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

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 Standards… IEC 60601, CE (93/42/EEC), UL 1950, CSA,
- FCC Part 15, J60950.
- “Worldwide” acceptance.
- 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.



Wireless Transmitter-Receiver Module

Frequently Asked Questions

The following are among the technical questions frequently asked by OEMs considering wireless foot controls:

- How safe is the technology?
- What safeguards are available to insure the system is not compromised due to corrupted or erroneous signals?
- What safeguards are available to insure 'reception of signal' confirmation?
- What safeguards are available to insure acceptance of signals from the appropriate/proper transmitter (where more than one transmitter is in the same environment)?
- What safeguards are available to prevent "crosstalk" from other 'like systems' in proximity?
- What other safety features (if any) should I be considering?
- How do I interface the wireless receiver with my medical device?
- Can the receiver be integrated into my medical device?
- Can the wireless foot control be designed such that I can offer it as a post-medical device purchase option?
- How do I power the receiver?
- What is the battery life (e.g. time between required battery recharging, time between battery replacement)?
- What types of batteries are used?
- What is their availability?
- How easy is it to charge and/or replace the batteries (e.g. time required, tools required)?
- Can I monitor the battery charge status to alert for the need for battery recharging or replacement?

The questions and factors that must be considered are, of course, a function of the application. 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

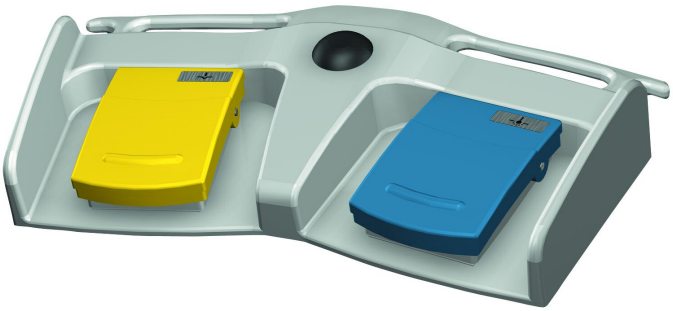
As with a conventional cabled foot control, there are benefits-to-use, as well as new issues to address for the OEMs choosing to offer a wireless solution. Among the benefits are:

- Ability to expand market potential
- Ability to enhance technical image
- Ability to increase revenues
- Elimination of "issues" associated with cabled foot controls (e.g. trip hazard, cable damage, cleaning/storage).

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 design features.

Electro Surgical Generator Foot Control



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. One can already see such controls being offered by manufacturers of 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.

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