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The Design Differences of a "Medical-Grade" Foot Control

Introduction

As medical device OEMs know, a product designed for the medical market is fundamentally different from one intended for industrial use. This is also true for a foot control.

From the bottom pads to the mating connector, the design requirements for a medical-grade foot control are significantly different from those of an “industrial-grade” unit.

Important design factors for medical use, many of which are often less-critically considered when designing for an industrial application, include:

- Weight
- Cleaning/storage requirements
- Mobility
- Stability
- Sealing
- Drainage
- Compliance with Medical Standards
- Actuator operating forces
- Actuator style/location
- Ergonomics and user comfort
- Patient safety
- User characteristics

Consideration of each of these parameters during the design of the foot control results in significant benefits to both the OEM and to the user of their Medical Device. A number of these considerations, and their implications, are discussed below.

Industrial-Grade Foot Controls are “Heavy Weight”
Medical-Grade Foot Controls are “Welter Weight”

Generally, foot controls used in an industrial application are installed once (sometimes bolted in-place) and seldom, if ever, moved. Because of this permanent installation, and the mechanical abuse expected in an industrial environment, such foot controls are typically designed of materials selected for their brutish robustness. The result often is a “heavy weight” unit … typically a weight that is not necessarily optimal for use in a medical application.

On the other hand; foot controls for medical applications will often be moved during the medical procedure, moved between procedures (perhaps from one operating theater to another), and/or moved to be cleaned or placed in storage. Recognizing the need for such mobility requires a foot control that is “welter weight” … a unit whose weight will assure stability during the procedure, yet will not be excessive for those responsible for its’ movement.

Consequently, the design objective for a medical-grade foot control is a weight that is not too light … nor too heavy. Optimal weight assures stability; ease-of-movement (often desirable and achievable without lifting the unit off the floor); and a tolerable weight for routine relocation, cleaning, and/or storage.

Industrial-Grade Foot Controls are “Dirty”
Medical-Grade Foot Controls are “Clean”

For most foot controls used in an industrial applications, a certain amount of dirt, dust, grease, oil and other environmental substances is expected, and of little consequence during the life of the product. The presence of and/or residual amounts of these contaminants is no cause-for-action. They can get “dirty”, and often stay dirty, without concern.

In medical applications, foot controls will be subjected to biohazards, disinfectants, and/or routine cosmetic cleaning. For cleaning to be effective and easy-to-accomplish, the foot control design must consider:

- The shape and contours of the unit.
- The clearance spacing between the actuators and between the actuators and their host console.
- The drainage of the surfaces.
- The level of sealing integrity (e.g. IP ratings typically of IP X6 to IP X8).
- The surface "texture" of the various elements of the unit (e.g. console, pedal covers, base plate, other actuators).
- The availability of special surface coatings (e.g. coatings that facilitate cleaning or discourage bacterial growth).
- The use of powder-coating and molded-in colors instead of painted surfaces that can crack, peel, or flake.
- The use of stainless steel hardware.

Only with careful consideration of each of the above will the final design effectively address the necessary cleanliness requirements.

Surface texture, actuator spacing, rounded corners and carrying handle facilitate cleaning and handling

Industrial-Grade Foot Controls are “Stationary”
Medical-Grade Foot Controls are “Mobile”

The typical industrial application requires a foot control that will be installed near a piece of machinery (e.g. wire winding, punch press, bending brake, assembly station, et al) where it will generally stay until it needs to be replaced. In many applications the unit is “bolted” to the floor … perhaps with the cable protected by conduit similarly secured.

Therefore, the need for relocation/repositioning of the foot control is seldom a design criterion.

Medical applications are quite the contrary. As already mentioned in the above discussion of “weight”, foot controls are frequently moved during, between, and after a procedure … if for no other reason than the preference of the operator.

In addition to weight, such mobility requires careful consideration of a number of design attributes including:

- Integrity of the strain relief … to insure tolerance to the foot control inappropriately being carried by its cable; to the tight winding of the cable around the foot control for storage; and to the use of the cable as a “tether” to pull the foot control to a new location.
- Characteristics of the foot pads … to optimize the balance between the need for the unit to remain stationery during use, yet allow it to be moved during the procedure without lifting it from the floor.
- The option of a fixed or collapsible “handle” which would allow lifting without undue strain/damage at the cable gland. This handle could also serve as a means of the user picking the unit up using their instep for repositioning during a procedure.
- Overall dimensions for storage considerations (e.g. in a docking station, on an equipment cart, et al).

Consideration of these, and other more subtle (but important) parameters, can optimize the medical-grade foot control design to best satisfy mobility requirements.

Industrial-Grade Foot Controls are “Dry”
Medical-Grade Foot Controls are “Wet”

With some special exceptions (e.g. outdoor installation), the environment for most industrial applications is “dry”. Therefore drainage and/or sealing characteristics are relatively unimportant compared to electrical rating, ruggedness, low-cost, etc. Due to their low cost, submersibility (when required) can be achieved by “potting/encapsulating” the electrical connections … to the exclusion of serviceability.

With the presence of liquids common in many medical applications (either during the procedure or for cleaning), drainage considerations and sealing integrity are important design factors which affect reliability and serviceability. Ingress protection ratings of IP X6 to IP X8 are typically required. Where the cost of the foot control is significant (e.g. a multifunction unit for urology tables, cataract surgery, or orthopedic surgery), meeting the sealing requirements - while still allowing servicing/repair - requires critical consideration of subassembly dimensional tolerances, gasket design/material integrity, and servicing requirements.

Industrial-Grade Foot Controls are “Control-Compliant”
Medical-Grade Foot Controls are “Medically-Compliant”

The typical industrial-grade foot control need only meet UL and CSA Control Standards such as UL 508 and CSA 22.2. The consequence of failure of an industrial foot control is generally nothing more than lost production due to downtime.

Quite differently, patient vulnerability and other assessed risks inherent in medical applications call for compliance with considerably more stringent industry Directives and Standards. Among these is the Medical Device Directive 93/42/EEC, IEC 60601,

UL 601, CSA 22.2-601, TUV “GM” requirements, EMC Directive, Low Voltage Directive, and FCC requirements (for wireless devices). With specific IEC application requirements (e.g. conductive foot pads for electrosurgical generator applications; protection against inadvertent operation for laser-based medical devices; IP X8 submersibility requirements … some while the unit is under power); “medical-grade” design requirements are considerably more demanding. Meeting these requirements by initial design provides the OEM and their customer with the safety, reliability, and conformance essential to securing the required certification for their device.

Ergonomic considerations result in user comfort and an aesthetically attractive design

Industrial-Grade Foot Controls are “Macho” Medical-Grade Foot Controls are “Coed”

Within the context of their desired ‘robustness’, most industrial-grade foot switches are designed with a generous amount of force required for operator actuation. Strong return springs provide tactile feedback, instill confidence regarding durability, and are compatible with the typical materials of construction (e.g. metal). While operable by both male and female users, their typical actuating forces can cause fatigue or discomfort in a medical application.

Actuating forces in medical applications must respect the IEC requirements, recognize the size and gender of the user, account for the variety of foot wear worn by the operator (e.g. surgical booties), and be consistent with the operator's position during use (e.g. standing or sitting). These requirements greatly affect the design ergonomics, the maximum/minimum actuating forces, and user acceptability.

Industrial-Grade Foot Controls are "Electrical" Medical-Grade Foot Controls are "Electronic"

Foot controls for industrial applications typically require switching of electrical loads of 1A to 10A at 120 or 240 VAC. Such requirements are typically handled by electromechanical switches and (for analog control) electromechanical potentiometers.

Both do an adequate job of providing the electrical signals to directly control relays, contactors, and other control components.

Medical applications are more often characterized by foot control signals of less than 100mA … generally at 5 to 30 VDC. While these loads can be addressed with electromechanical switches and potentiometers, they present the opportunity to use other longer-life, higher-reliability signal sources such as magnetic reed switches, Hall-effect sensors, and foil sensors. In addition, depending upon the OEM's device design, medical foot controls may be required to interface via USB, RS232, RS 485 or some other protocol. If so, this requirement can be efficiently and effectively addressed as part of the initial foot control design.

Industrial-Grade Foot Controls are "Single-Function" Medical-Grade Foot Controls are "Multi-Function"

The majority of the foot controls required for industrial applications are single-function (e.g. on-off or speed control). Even in those applications where two or more control functions are needed, they can generally be satisfied with "like" actuators – two pedals, three pedals, etc.

The diversity of medical applications, and the growing number of features offered by medical device OEMs, often requires multi-function foot controls. For example, electrosurgical generators typically require two or three functions; positioning systems may need two to eight functions - plus “memory’ recall actuators; and surgical microscopes often require up to eight functions. While the standard “foot pedal” (equipped with reed switches, micro switches, potentiometers, Hall-effect transducers, et al) could be used for each function, practicality demands the use of other actuator styles.

For reasons of overall foot control size, ergonomics, ease-of-use, and cost; an effective design can benefit from use of a diversity of actuator styles … such as rocker switches, pushbuttons, joy sticks, sliding switches, actuators, joy pads, and customized actuators designed for the needs of the specific application. Each of these must be designed and efficiently located …with careful attention to actuating force, sealing, frequency of use, protection against simultaneous operation, and labeling.

Diversity of actuator styles optimize functionality, minimize overall size, and facilitate easy, efficient operation

Industrial-Grade Foot Controls are “Drab”
Medical-Grade Foot Controls are “Attractive”

The typical industrial-grade foot control is designed primarily for functionality and robustness. Cosmetics are relatively unimportant. This is evident in their materials of construction, colors, and overall “industrial-design”.

The functional, ergonomic and aesthetic requirements for a medical application dictate an entirely different design philosophy. Multiple functions, ease-of-use, safety, user fatigue, cleaning requirements, and the desire for the foot control to aesthetically-complement the medical device it is controlling precipitate a different set of design parameters. If addressed early, each of these objectives can be optimized … rather than compromised.

Actuator layout and graphics facilitate efficient, easy worldwide use

Summary

With the foot control as a major human interface for a medical device; its’ design plays an important role in both functionality and market appeal. Because of the characteristics demanded of a medical application, it is easy to see the significant benefits that can be realized from a foot control that is “medical-grade” by initial design. The above differences, if addressed early in the design cycle, can result in a foot control that is optimized for functionality, performance, reliability, comfort, ease-of-use, and aesthetic-compatibility with the medical device it is controlling.

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