The Importance of Choosing the Right Interconnect Systems in Medical Device Design

Guideline for the selection of medical connectors

Medical devices such as patient monitors, imaging systems, electrophysiology catheters, and other diagnostic & therapeutic systems require dependable connectivity and accurate signal transmission. Designing equipment for the medical market requires care to eliminate the potential for failure or loss of functionality. Interconnects are especially vulnerable because they can be in the most exposed areas of the system, with the potential for damage due to environmental factors or poor usage. In the medical sphere, there are many factors to consider when selecting connectors to ensure maximum performance and reliability over the expected life of the device.

The potential of mating connectors that don't belong together is a safety risk in many medical applications. System developers can build in safeguards by using an appropriate form of color-coding, which provides a visual indication of a correct match between a plug and receptacle.

Often however, the system of color-coding has to be decided when the connectors are purchased from the supplier because the color will be an unchangeable feature of the plastic housing. However, some connectors offer greater flexibility. Interconnects, for example, can incorporate a mechanism for color-coding the connectors as required during assembly. The colors assigned to the receptacle and plug can be chosen through the use of interchangeable and differently colored silicone rings and strain reliefs, respectively.

Incorrect mating also can be avoided by using keyed connectors. These incorporate a mechanism that physically prevents the plug and receptacle from being mated if they are an unmatched pair.

There are various options to consider here. One is to use connectors that, while identical in every other respect, have fixed keys that are part of the connector body. However, it is also possible to purchase connectors with customizable keying, which can help lower the cost of inventory. For example, some designs allow users to alter the keying of the connector by changing the position of an insert.

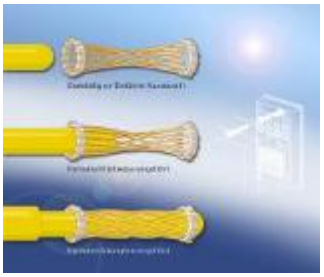
In one case, six different positions are possible, affording the developer the flexibility to alter the interconnect configuration as the system requirements evolve. Mismating is prevented by a plastic barrier between plug and receptacle, which is positioned in such a way that only compatible connectors will be able to mate. Such an approach reduces the possibility of contact damage compared to connectors where the contacts themselves provide the physical barrier that prevents mismating.

In medical applications, especially those with a safety-critical function, care must be taken to ensure that a plug and receptacle remain interconnected reliably. One consideration is to be sure that the connector has been specified for a sufficiently high number of mating cycles.

Some of the connectors used in patient monitoring equipment, for example, have to be mated and unmated many times a day over a lifetime of many years. Depending on the type of system, the connector may have to endure 10's of 1000's of mating cycles during its life. The typical high-quality medical, military, or industrial connector, which might be specified to perform reliably for 500 to 1000 mating cycles, is unsuitable for this application.

An additional consideration is the degree of shock and vibration present in the usage environment. For instance, if the equipment has to be used in an ambulance, care should be taken to choose connectors that are specified for this kind of use.

Many connectors are designed for applications that involve rough handling, but medical connectors also may have to be handled safely with surgical gloves, which could be torn or damaged if there are sharp edges, or if the connectors are awkward to handle. System developers mindful of this risk, which introduces an additional path for the spread of disease or infection, should choose connectors with these issues in mind.



The reliability of an interconnect—its ability to perform over a long life or in demanding situations—is largely determined by the contact design. A point of vulnerability is the cantilever-beam spring mechanism conventionally used in a connector's construction. The high normal-force required with these interconnects not only results in high mating forces but has a tendency to cause the spring to wear out.

System developers can eliminate this weakness by using a connector with an alternative contact design. For example, a hyperboloid contact system with a wire basket construction provides a reliable contact but doesn't require a high normal-force. As a result, connectors are inserted with smooth and low-force mating between pin and socket. This provides greatly increased longevity compared to many other contact technologies. Connectors with hyperboloid

contacts can withstand more than 20,000 mating cycles. Another benefit of the hyperboloid wire basket contact is the enhanced wiping action that cleans the contact mating surfaces as the pin pushes past the spring wires during mating.

Medical connectors can incorporate a variety of signal, power, high frequency coax and/or high-data rate fiber optic contacts to meet the specific needs of medical device developers. High density signal requirements could be addressed with spring probe contacts without the need to increase the size of the connector. Conversely, other contact technologies could be incorporated creating a hybrid connector that would enhance the functionality of the interconnect without the need to resort to multiple connectors.

In situations where one-half of a connector forms part of a disposable element, (such as an electronic catheter), but the other half must perform reliably for many thousands of mating cycles, it is tempting for developers to attempt to engineer the disposable half themselves to reduce costs. This practice should be avoided as it's easy to underestimate the engineering effort required to design high-reliability connectors. Electrical problems or damage to equipment can be prevented by ensuring that the connector supplier has designed both the plug and receptacle.

Medical appliances are increasingly incorporating plug-and-play functionality to simplify the process of connecting different pieces of equipment. To support such a capability, the design normally includes additional electronics or intelligence. For instance, some kind of "personality chip" is used to communicate with the host system, providing details of the identity or status of the appliance. This component may be located in the equipment itself or it may be incorporated, for electrical reasons, into the connector housing.

System developers can choose to implement this additional functionality themselves. However, if it's to be included in a connector, they should be careful to avoid compromising the connector design which could cause a significant degradation in performance. It is often worthwhile to specify this additional functionality directly from the connector manufacturer.

It may also be important to ensure that connectors withstand exposure to some of the cleaning and sterilization methods used in certain medical environments, as medical equipment often has to be cleaned or sterilized before use. Different approaches are used, ranging from a mild soap solution to harsher methods involving alcohol, ethylene oxide gas, and gamma radiation. In addition, high-temperature steam autoclaving is widely used for cables, tools, and other accessories.

Magnetic components positioned in close proximity to the RF coil in an MRI scanner tend to cast a shadow on the resulting image. As MRI systems have become more powerful, developers have

worked to eliminate magnetic components from the proximity of the imaging volume. Non-magnetic connectors are increasingly available to support this requirement. Some manufacturers have effectively addressed the performance requirements of MRI scanners with non-magnetic variants of high-reliability connectors, incorporating them into fully non-magnetic cable assemblies and interconnect subsystems.

Given the unusual requirements present when specifying medical connectors, it's important to pay attention to all elements of the design early in the development stage. Connectors frequently are considered after much of the design has taken shape. This can be problematic if the connectors used for the prototype do not support the requisite number of mating cycles or if the connectors are vulnerable to damage from medical cleaning protocols. Although connector suppliers can engineer a custom solution if such problems arise, designers can avoid this extra expense by considering interconnect requirements early in the design process.