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Design Considerations for Challenging Medical Environments

Today's medical devices rely on compliance with electrical, mechanical, and environmental design considerations, which ensure their safe and effective use.

Even though worldwide population growth has slowed from approximately 3% to less than 1% per year due to the pandemic, there are still over 7.9 billion people worldwide, of which the USA accounts for more than 331 million people. The pandemic has created heightened global awareness and need for medical device, drug delivery and other healthcare products, which diagnose, treat, save lives, and/or improve patient outcomes. These medical devices must function safely and flawlessly for challenging applications, procedures, and within highly regulated environments.

It's critical that medical products are designed to safely and effectively transmit signal, power, data, optics, pneumatics, and fluidics to meet the needs of the medical application and the environment where used. Medical devices are primarily designed for diagnostic, monitoring, or therapeutic purposes. The usage model for each application requires thorough evaluation of the expected product performance characteristics in order to develop technical specifications, product validation, verification, and qualification (VVQ) testing protocols, which prove product safety and efficacy for its intended use.

Medical Electronic Requirements in Harsh Environments

For years, patients and hospitals have been concerned about cross-contamination and hospital acquired infections (HAIs), but the pandemic has made the environmental usage challenge an even more critical design consideration than ever before. These concerns present mechanical sealing, cleaning, disinfection, and reprocessing challenges, which must be built into new product designs.

Today's modern medical devices also incorporate advanced electronics, connectivity, and power requirements, which have added complexity to design choices for electronic connectors, switches, power modules, EMI filters, cables, sensors, and other electronic components. As more features are packaged into smaller geometries, miniaturization and ergonomics become another usage factor. It's essential that medical designs can meet all the electrical, mechanical, and environmental requirements.

Safety & Effectiveness is of Paramount Importance

The medical application, procedure, and usage model impacts the specification requirements that influence medical device design decisions. Understanding the application, its electrical, mechanical, and environmental usage characteristics, including cleaning, disinfecting, and processing influences design selection of standard (off-the-shelf), an iteration (hybrid), or if a custom (application-specific) solution is required. The most important criteria for developing interconnect solution specifications are those which enable their safe and effective use for patients and medical personnel, followed by ease of use.

Mating systems and cabling used “inside-the-box” of a medical device are normally selected based on functionality and size, and have less scrutiny, because they are integrated within the device and do not come in contact with the patient or medical professional. Since the end-user is not coming in contact with inside-the-box electrical connectors and wire harnesses, concerns about mating cycles, IPxx ratings, cleaning, disinfection and sterilization are non-existent. There is also less concern about flexibility, mating cycles, and mating features. As such, most of these applications utilize standard, off-the-shelf (OTS) interconnects.

Interconnect solutions used “outside-the-box” carry signal and/or power in the diagnostic, monitoring, or therapeutic path of the patient. As such, these products typically come in direct contact with the patient or healthcare professional, where cleaning, disinfecting, and sterilizing between patients becomes of paramount importance. Mating systems which combine functionality with ease of use (visual recognition, audible click, tactile feel, and other features) are critical user considerations. In addition, mating cycles and other product performance testing requirements are more stringent. Iterations and application-specific customization is more common among interconnect solutions in the therapy path of the patient.

Reusable medical devices must be able to withstand various medical cleaning, disinfection, sterilization, and reprocessing guidelines such as CIDEX®, STERIS, STERRAD®, Ethylene Oxide (EtO), autoclave (steam), gamma, and other cleaning and sterilization methods. As such, reusables must be sealed from moisture ingress, dust and other potentially hazardous substances that might otherwise inhibit the safe and effective use and/or reuse of the device.

Reusable medical interconnect solutions are normally validated to an IPxx rating that meets the design requirements for the specific application when mated to its intended receptacle. The first “x” indicates resistance against dust intrusion (levels 1-6), and the second “x” indicates resistance against liquids (levels 1-9). For example, an IP67 rating has the highest level of protection against dust (6) and can withstand immersion up to 1 meter of water for up to 30 minutes (7). Medical connector IPxx ratings typically range from IP50 to IP68, with IP67 being most widely accepted for medical applications.

Disposable (single-patient-use) devices normally have fully integrated connectorized cables that are delivered in sealed and sterilized packaging. This is common for disposable patient monitoring lead-wires, surgical, and electrosurgical devices. Product usage models factor into actual product design specification choices, such as: materials (plastic or metal), contact types, and mating system desired.

Risk of Failure is Not an Option

When designing and developing electronic medical devices, it is imperative to not only understand the intended use and benefits of the device, but to also understand the potential risks to bodily harm, product recall, and compliance to regulatory requirements – because failure is not an option! Incidents resulting in bodily harm or loss of life are reported to the FDA or other regulatory notified bodies and can trigger costly product recalls, which can be devastating to your company’s reputation.

The typical “continuum of care” follows diagnosis, therapeutic treatment, followed by post treatment monitoring. There are many types of diagnostic equipment (such as MRI, CT, Ultrasound, Dental x-ray, etc.), therapeutic equipment (life-saving defibrillators, infusion pumps, ventilators and other respiratory systems, surgical and electrosurgical systems), patient vital signs monitoring (Temp, ECG, SpO2, BP, NIBP, etc.), and many other new emerging portable and wearable devices. Ensuring that your new device can withstand potential worst-case use scenarios will mitigate health risks, including loss of life, and ensure safe and effective functionality.

Diagnostic equipment enables doctors to obtain digital images of structures inside the body in a non-invasive procedure, which identifies potential abnormalities behind skin, tissue, and bones to guide treatment decisions. For example, magnetic resonance imaging (MRI) produces 3D anatomical images by detecting the change in the direction of the rotational axis of protons found in

the water inside living body tissues and requires high power, signal integrity, and EMI protection. Diagnostic imaging devices, such as CT and Ultrasound systems are becoming increasingly smaller and more portable.
Therapeutic defibrillators treat life-threatening cardiac dysrhythmias, ventricular fibrillation, and non-perfusing ventricular tachycardia. As such, functionality is a matter of life and death, because defibrillators deliver a controlled dose of high-voltage (360 joules) electric current to the heart to save the life of a patient in cardiac arrest.

Patient monitoring devices have become smaller, more compact, with increasing wearable and/or wireless solutions enhancing patient mobility and enabling the collection of vital signs data for patients and healthcare providers via the Internet of Medical Things (IoMT). For example, wearable wireless electrocardiogram (ECG) devices can record, analyze, and interpret patient diagnosis and assist cardiologists with treatment plans.

Waterproof and steam (autoclavable) interconnect solutions that can withstand extreme high temperatures are ideal for challenging reusable medical cleaning and disinfection environments, including: therapeutic, surgical, dental, emergency medical services, and other medical equipment.

Navigating Regulatory Requirements

The US Food & Drug Administration (FDA) classifies medical devices based on the risks associated with the use of the device. Devices are classified: Class I (lowest risk), Class II (higher risk), and Class III (highest risk). The European Union, Canada, and other countries have similar regulations. The FDA also documents medical manufacturing quality expectations in the FDA 21 CFR 820 to ensure medical standards of quality. Medical devices require regulatory approval proving its safe and effective use prior to marketing and sale of the device.

The medical industry does not have a unified global interconnect standard. However, the Association for the Advancement of Instrumentation (AAMI) published the ANSI/AAMI 53 (2013) standard, which specifies minimum safety and performance specifications for ECG monitoring cable and leads. This standard establishes baseline electrical, mechanical, and environmental requirements and test protocols as a guidance document to validate compliance to safety and effectiveness performance specifications.

IEC 60601 is a series of technical standards for the safety and effectiveness of medical electrical equipment. Compliance with IEC 60601-1 is a requirement for FDA approval of new devices. Most medical device companies have formal regulatory risk management strategies that are an integral part of the design process and consider the risks of every component and material used in their devices to document potential DFMEA risks in preparation for an audit or inspection.

In May of 2020, the Medical Device Regulation (MDR) No. 2017/745, became the regulatory authority for the safety, effectiveness, and marketing of medical devices in the European Union. European Union requirements include determining the appropriate medical device classification to obtain CE approval under the guidance of a selected Notified Body, which classifies medical devices in four risk classification categories: 1. Non-invasive devices, 2. Invasive medical devices, 3. Active medical devices, and 4. Special Rules. CE marking is then carried out by EU-accredited private organizations known as notifying bodies.

Simplification of Environmental & Electrical Complexity

Medical devices are getting smaller, incorporate more electronics, serve more purposes, and must withstand harsh cleaning and disinfection protocols. Interconnect solutions are required to meet these electrical, mechanical and environmental challenges given the worst-case scenarios without failure. Ensuring global healthcare infrastructures are met safely and effectively is vital for the health of business and society as a whole.

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