Importance of 60601 Certification

What is 60601-1 Certification for Medical Devices?

60601-1 ratings are given to devices that pass a rigorous screening process for potentially harmful radiation. This type of radiation refers to electromagnetic interference that could harm sensitive and often, life-sustaining medical appliances.

Medical device compliance has been mandated for years by the US Food and Drug Administration. These devices must comply with the 60601 standards required for near-patient safety.

Why the FDA?

The US FDA is not merely an organization enforcing nutritional guidelines but is primarily charged with improving and protecting the health of the public. These protective guidelines can include drugs, alcohol, tobacco, and even medical devices. There is a dedicated branch of the FDA that deals specifically with medical devices, medical computer systems, and electromagnetic emissions from other devices. This safety assurance took a larger precedence when the FDA, after restructuring, started The Center for Devices and Radiological Health in 1982.

Medical devices are required to pass rigorous testing and screening, outlined by the FDA and CDRH before it can be used anywhere near a clinical setting.

Know the Facts

Knowledge of the degrees of certification is critical in understanding the importance of the certification process. An "IEC 60601-1" or "EN 60601-1" certification are only versions of the 60601-1 standard. Although the basic concept in the certification is the same everywhere there are sight variances in the standards based on the laws, concerns, and regulations of different nations. These standards are most easily identified by the small tag in front of "60601-1", like UL (United States), EN (Europe), JS (Japan), CAN (Canada), KS (Korea) and AS.NZ (Australia/New Zealand).

Typically, these standards involve adding *more* safety features (or acknowledging differences: example - the United States and Europe use differing electrical systems with vastly difference voltage thresholds. The UL code for the United States has many more provisions protecting the patient, facility, and equipment from fire hazards, while the European code (EN)) is more concerned with the danger of electric shock.

Tangent Tests for you

Tangent spends detailed hours and finances on the research, testing, development, and certification of our Medical Devices. Our Engineers oversee the thorough testing, not only covering the device itself, but the separate and specific testing performed on the computer that powers the device, to every component in our system.

Choosing a Tangent Medical Computer, Medical Tablet, or Medical Monitor ensures that these purpose-built devices are already certified 60601-1, are safe and ready for use in your clinical setting.