An Introduction To Medical Regulations: Understanding The 60601 Standard

by Kevin Parmenter, Chair, and James Spangler, Co-chair, PSMA Safety and Compliance Committee

This article aims to give an initial introduction to the rules and regulations that govern safety and compliance in medical equipment. This basic information does not go into details of medical power supplies. Rather, an attempt is made to enlighten those not familiar with the medical regulations and standards, including designers and specifiers of medical power supplies. In particular, we aim to shed light on the importance of medical equipment immunity from radiated and conducted electromagnetic emissions.

Medical regulations are complex because they apply to the safety of both patients and medical practitioners, including nurses, doctors, anesthetists and others. The 60601 standard, which is the focus here, applies to most locations throughout the world, (see Appendix B in reference 7), and anywhere medical equipment is used: operating rooms, hospital rooms, intensive care units, nurseries, senior care facilities and even households. The IEC 60601 specific "end use" categories that cover the different facilities, which will be discussed later in the article.

In these discussions, we'll use 60601 as a shorthand to refer broadly to the different versions of the regulation, which include UL 60601, IEC 60601, and EN 60601. Each of these standards often has revisions such as Rev 3 or the latest Rev 4, which serve to update the standard to improve patient safety.

The fourth edition of IEC 60601 is now in force in the U.S., Canada, and Europe as of Jan. 1 2019. In the case of IEC 60601-1-x, there are eight collateral standards [1.2], in addition there are the IEC 60601-2-x, 47, particular standards [1.2]. The IEC/EN/UL 60601-1 has the leakage current specifications. The IEC/EN/UL 60601-2 has limits for electromagnetic magnetic interference (EMI), conducted and radiated radiation, susceptibility to power line transients and radio frequency interference. Please utilize the references given, to gain greater knowledge of the specific benefits needed.

There is a misconception that if a power supply has an IEC 60601, UL 60601, or EN 60601 approval that power supply can be used anywhere as a medical power supply. However, a power supply is considered a component that is used in a piece of equipment. Only if the power supply has passed the highest level of requirements can one make that assumption about its acceptability.

Most importantly, the equipment must be tested per the regulation that applies to it. The IEC/EN 60601 has various aspects. In the United States, the final approval is from the Food and Drug Administration (FDA) for a piece of equipment. The equipment includes a power supply and other electronic components that make up a medical system.

A recent conversation with Jack Black at the Chicago IEEE EMC Society's Mini Symposium, May 7, 2019 provided insight into this "complete system" issue.

Premarket Approval (PMA)

The FDA has a process of scientific and regulatory review to evaluate the safety of effectiveness of medical devices.[3] This process is called Premarket Approval (PMA). The FDA website (see reference 3) posts the following statement explaining that if the process is not followed, the application will not proceed. In that case, you must restart and reapply.

"If a PMA application lacks elements listed in the administrative checklist, FDA will refuse to file a PMA application and will not proceed with the in-depth review of scientific and clinical data. If a PMA application lacks valid clinical information and scientific analysis on sound scientific reasoning, it could impact FDA's review and approval. PMA applications that are incomplete, inaccurate, inconsistent, omit critical information, and poorly organized have resulted in delays in approval or denial of those applications. Manufacturers should perform a quality control audit of a PMA application before sending it to FDA to assure that it is scientifically sound and presented in a well-organized format."[3]

It is strongly recommended that a company work with a test house that has expertise in the 60601 medical standards area. For example, both Intertek and DLSEMC have this type of specific knowledge. Michael F. Murphy of Intertek presented a webinar [4] and slides [5] (EMC for Medical Electrical Equipment & Systems) in

which he discussed IEC/EN60601-1-2 and the need to create a Test Plan, and define Essential Performance. These are needed prior to submitting to the FDA.[3]

The Operating Room And Intensive Care

A hospital operating room incorporates a substantial number of complex pieces of equipment as shown in the figure. Among and in addition to such equipment, there are computers and smart phones. In his July 2014 presentation on IEC 60601-1-2, 4th Edition [6], Darryl Ray of EMC Consulting used this photo (originally produced by Keith Armstrong of Cherry Clough Consultants) to describe the possibilities of radiated emissions, and susceptibility to radiated and line-conducted emissions.

There are numerous pieces of equipment called out in this operating room photo. But one important item that's not shown is a patient grounding mat. Typically, a patient is connected to this grounding mat to prevent electrical shock and provide a return path for life support monitoring.

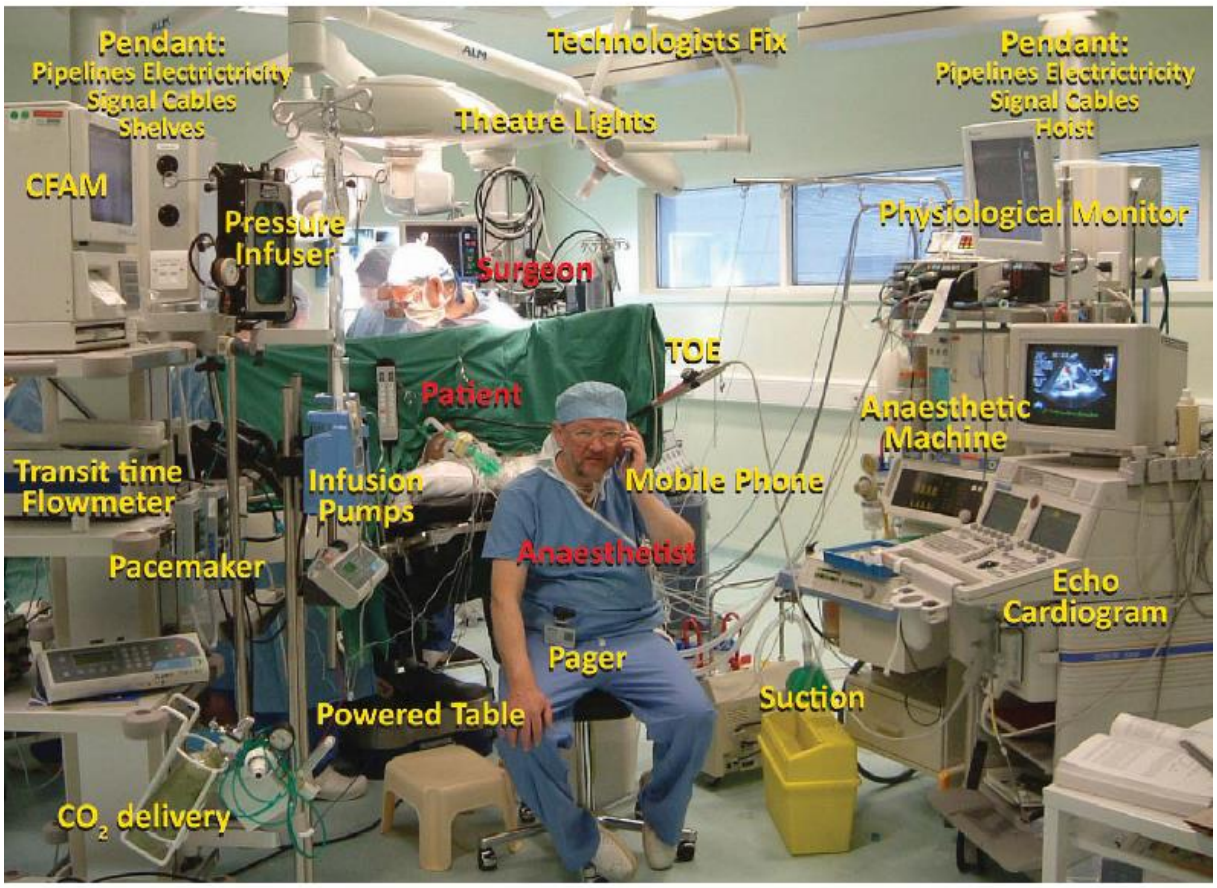

Figure. PESE in Orange County in July 2014, IEC 60601-1-2. (Reproduced with permission of Keith Armstrong of Cherry Clough Consultants).

Note that the operating room is not the only setting where this type of equipment is used and connected to a patient. A hospital's intensive care unit has similar equipment. There are pumps for fluids, EKG monitors, breathing tubes, blood oxygen sensors, blood transfusing equipment, etc. All of these instruments are often connected to a central station for constant monitoring. In the operating room the anesthetist is the main monitor of the patient.

But in general, all of this equipment has alarms to alert nurses and doctors in the event something is out of the normal range. Not surprisingly, the equipment has battery backup in case there is a power outage.

Intended Use [7]

The fourth edition of 60601 considers immunity in terms of the "intended use environment" and there are different classes of such environments. Basically, there are three classifications:

1. **Professional healthcare facilities** with attending medical staff, e.g. hospitals, intensive care units and dental offices.
2. **Home healthcare** as defined in collateral standard IEC 60601-11, as dwelling places where patients live or are present (excluding professional healthcare facilities). Here equipment will be used by non-specialist users and must also be tolerant of poor electrical supplies.
3. "**Special" environments** that could include locations with high levels of electromagnetic disturbance (e.g. due to industrial machinery), or where particularly high-power medical equipment might be used (e.g. radio-therapy equipment).

Patient focus [7]

The 60601 standard also calls out different classes of equipment relating to how the patient may or may not come into contact with that equipment. These terms have been around since the second edition.

1. Type B (body) equipment operates within the vicinity of the patient, but without patient contact. Examples of type B equipment include x-ray machines, hospital beds, LED operating lighting, and MRI scanners.
2. Type BF (body floating) equipment makes physical contact with the patient. Examples of type BF equipment include blood pressure monitors, ultrasound equipment, and thermometers.
3. Type CF (cardiac floating) makes physical contact with the heart. Examples of type CF equipment include defibrillators and dialysis machines.

Immunity Test Requirements [7]

The following is a short summary of Immunity Test Requirements. Only the fourth edition tests are listed here as these are currently in effect in the U.S., Canada, and Europe. However, in some of the references, they compare the requirements of the second, third, and fourth editions.

AC Test Voltage and Power Frequency

1. CISPR 11: AC emissions
2. CISPR 11: Radiated Emissions
3. IEC 61000-3-2 Harmonics
4. IEC 61000-3-3 Voltage Fluctuations and Flicker
5. IEC 61000-4-2 Electrostatic Discharge
6. IEC 61000-4-3 Radiated RF immunity
7. IEC 61000-4-4 Electrical Fast Transients/Burst
8. IEC 61000-4-5 Surge
9. IEC 61000-4-6 Conductive RF immunity
10. IEC 61000-4-8 Power Frequency Magnetic (ac power line frequency 50Hz or 60Hz)
11. IEC 61000-4-11 Voltage Dips, Dropouts & interruptions

Electrostatic Discharge

Note there are two types of discharge with three levels shown depending upon the "intended use environment". The first number being the lowest is for "Special" environment, the second is for Home Healthcare, and the highest is for Professional healthcare facilities.

Table. ESD withstand test levels.

	Special	Home health	Professional
Contact discharge	±2 kV	±4 kV	±8 kV
Air discharge	±2 kV	±4 kV	±15 kV

There are yet other tests too numerous to mention in this article. The most important thing to consider is patient safety. As illustrated in the figure, there are many components in an operating room or intensive care unit. In addition there are personal communication devices such as smart cell phones and pagers. All of these can interfere with patient monitoring and can cause equipment malfunctions.

Summary

This short article has provided just an introduction to medical equipment standards relevant to power supply designers and those applying them in medical equipment applications. The field however is very complex. It is not only about power supplies but about all the equipment and connections made when a patient is involved.

Many of the immunity tests are for the leads connecting the patient to the monitors. The radio frequencies being tested are to ensure there is immunity in the sensor leads between the patient and monitoring equipment and any interference does not cause an equipment malfunction. Among the potential sources of interference are smart phones and tablets, which use RF to communicate between the sender and receiver. These devices may be present even in operating rooms and intensive care units.

The final step in processing medical equipment to be listed and be approved, is to submit all the paper work to the Food and Drug Administration [3].

References

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About The Authors

Kevin Parmenter is an IEEE Senior Member and has over 20 years of experience in the electronics and semiconductor industry. Kevin is currently director of Field Applications Engineering North America for Taiwan Semiconductor. Previously he was vice president of applications engineering in the U.S.A. for Excelsys, an Advanced Energy company; director of Advanced Technical Marketing for Digital Power Products at Exar; and led global product applications engineering and new product definition for Freescale Semiconductors AMPD - Analog, Mixed Signal and Power Division.

Prior to that, Kevin worked for Fairchild Semiconductor in the Americas as senior director of field applications engineering and held various technical and management positions with increasing responsibility at ON Semiconductor and in the Motorola Semiconductor Products Sector. Kevin also led an applications engineering team for the start-up Primarion.

Kevin serves on he board of directors of the PSMA (Power Sources Manufacturers Association) and was the general chair of APEC 2009 (the IEEE Applied Power Electronics Conference.) Kevin has also had design engineering experience in the medical electronics and military electronics fields. He holds a BSEE and BS in Business Administration, is a member of the IEEE, and holds an Amateur Extra class FCC license (call sign KG5Q) as well as an FCC Commercial Radiotelephone License.

Jim Spangler is a Life Member of the IEEE with over 40 years of electronics design experience and is president of Spangler Prototype Inc. (SPI). His power electronics engineering consulting firm's priority is helping companies to place products into production, assisting them to pass government regulations and agency standards such as UL, FCC, ANSI, IES, and the IEC.

For many years, he worked as a field applications engineer (FAE) for Motorola Semiconductor, On Semiconductor, Cirrus Logic, and Active Semiconductor, assisting

customers in using semiconductors. He published numerous application notes and conference papers at a variety of conferences: APEC, ECCE, IAS, and PCIM. Topics included power factor correction, lighting, and automotive applications. As an FAE, he traveled internationally giving switch-mode power supply seminars in Australia, Hong Kong, Taiwan, Korea, Japan, Mexico, and Canada.

Jim has a Master's Degree from Northern Illinois University (NIU), and was a PhD candidate at Illinois Institute of Technology (IIT). He taught senior and first-level graduate student classes: Survey of Power Electronics, Fields and Waves, and Electronic Engineering at IIT and Midwest College of Engineering.

Jim is a member of the IEEE: IAS, PELS, PES; the Illuminating Engineering Society (IES), and the Power Sources Manufacturers Association (PSMA) where he is co-chair of the Safety and Compliance Committee.

For further reading on power supply-related safety and compliance issues, see How2Power's special section on Power Supply Safety and Compliance.