Advanced Energy

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TODAY'S CHANGING HEALTHCARE DEMANDS HAVE BIG IMPACT ON POWER SUPPLY DESIGN CONSIDERATIONS

It is clear that the medical electronics industry has entered an era of dramatic transitions that touch virtually every aspect of the business from design to marketing. As is often the case with such substantial "Big Picture" changes, it can be easy to overlook how these changes affect foundational technologies such as power supplies, which are a vital component in all medical electronics.

Key developments, triggered by general technological advances, an aging population worldwide, and even aspects of government healthcare reforms are driving these trends that include:

- Proliferation of wireless technologies,
- Proliferation of implantable medical devices,
- Push towards home healthcare options versus in-hospital or outpatient clinic visits
- Greater demand for cost containment in medical products and services.

For each of these trends, careful planning of the power design from the beginning can enhance end product feature sets while reducing costs, maximizing reliability, and accelerating time-to-market.

Choosing the right power supply design is imperative for an overall successful product. With ongoing goals of increased density, reliability, and efficiencies, power ratings need to be reviewed carefully. Of course, product life, thermal issues, input voltage, load, and cooling needs are also vital considerations. Other factors especially important for medical electronics vendors include demonstrated reliability and proven quality systems. These encompass control processes for design, purchasing, and production as well as product traceability and Corrective and Preventative Actions (CAPAs), which have been the consideration for power supplies. However, because of increased regulation, medical device designers must now consider closely their electromagnetic compatibility (EMC) performance. EMC compliance specifications are spelled out in various EN 61000 standards as listed in Table 1.

Table 1 – EMC Compliance standards by section.

Limits for Harmonic Current	IEC 61000-3-2
Limitation Voltage Fluctuation/Flicker	IEC 61000-3-3
High Current Voltage Fluctuation/Flicker	IEC 61000-3-5
Electrostatic Discharge Test	IEC 61000-4-2
Radiated RFI Immunity	IEC 61000-4-3
Electrical Fast Transients/Burst	IEC 61000-4-4
Mains Surges	IEC 61000-4-5
Conducted RFI	IEC 61000-4-6
Harmonics and Inter-Harmonics	IEC 61000-4-7
Mains Frequency Magnetic Field	IEC 61000-4-8
Pulsed Magnetic Field	IEC 61000-4-9
Damped Oscillatory Magnetic Field	IEC 61000-4-10
Supply Voltage Dips and Interruptions	IEC 61000-4-11
Oscillatory Waves Immunity	IEC 61000-4-12

EN 61000-3-x sets limits and measures methods for low frequency emissions on the AC mains, while EN 61000-4-xx sets limits on susceptibility or immunity of the equipment powered from AC mains. These standards require precise performance so the power supplies or other electronic devices do not affect the safety and effective functionality of other implantable or critical care medical devices.

The stricter standards are also needed to sustain full operation despite noisy and a somewhat less regulated power conditioning environment at home. For example, an infusion pump malfunctions when a cell phone is used in close proximity to the patient. Or perhaps, a home ventilator shuts down when the line voltage dips below the minimum operating limit

caused by a neighboring motor or generator use. Or, a remote patient monitoring device is zapped when touched by someone walking around the house and building electrostatic discharge.

Regulatory Environment

Once designers determine the basic power requirements, the final hurdle in power supply product selection involves meeting standards for safety, EMC, and regulatory environmental impact compliance.

Today's medical electronics must meet stringent safety requirements and performance testing adhering to various standards starting with IEC 60601-1 3rd Edition for medical devices. Depending on the end use of the product and its implementation, additional standards such as EN and IEC standards for EMI/EMC, RoHS compliance, and CE Mark may also apply.

When selecting an AC or DC power supply—either off the shelf or custom—designers must consider the specific performance criteria suitable for their application when defining these requirements. In addition, keep in mind that transition to the IEC 60601-1-2 4th Edition standard on electromagnetic disturbance started in 2014 (figure 1).

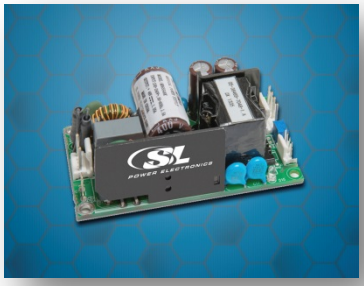

Figure 1. SL Power's MB65 65-Watt AC/DC power supply is approved to IEC60601-1, 3rd Edition 2MOPP and designed to meet 4th Edition EMC.

Regulatory vs. Market Needs

Generally, manufacturers are only required to have their medical device end products meet many of the standards, especially those relating to IEC 60601-1 family of technical standards for medical equipment. However, designers will find that starting out with power supplies designed from the ground up to meet those standards will greatly simplify achieving final compliance while accelerating time-to-market for their end product, particularly since power and safety issues are the basis for many key facets of the standards.

For example, internal type power supplies are meant to be handled only during the manufacturing process, as parts are installed in end equipment. There - fore, the assumption might be that the power supply should be designed for, and tested based on, that use. However, as internal power supplies are increasingly being designed into portable devices, such as home healthcare equipment, power supplies meeting the more stringent test parameters will provide the end system designer a more robust power supply, potentially allowing easier system compliance to more demanding certifications (figure 2).

Figure 2 – Portable devices are vital for home healthcare.

IEC 60601-1 General Standard

This key standard is a widely accepted benchmark for medical electrical equipment. Compliance has become a requirement for electrical medical equipment marketed in many regions globally. However, the standard functions on several levels and is not always well understood. While compliance may be a *de facto* requirement, it is not the same as device approval, only a recognized step in the approval process. The current 3rd Edition of the standard places emphasis on usability engineering, risk assessment, and use in home healthcare applications.

Collateral Standards

In addition to regional variations, the 60601-1 standard also encompasses Collateral Standards (numbered 60601-1-x) that define requirements for certain aspects of safety and performance. Requirements for the general standard may be overridden or bypassed by specific language in the collateral standards that are applicable to specific aspects of product design, such as:

- IEC 60601-1-2 – Electromagnetic Compatibility
- IEC 60601-1-3 – Radiation Protection for diagnostic use of X-rays
- IEC 60601-1-4 – Programmable electrical medical systems
- IEC 60601-1-8 – Alarm systems
- IEC 60601-1-11 – Home healthcare environments.

Particular Standards

A further set of Particular Standards (numbered 60601-2-x) provides supplementary definitions and requirements for specific product types such as defibrillators, MR scanners, electroencephalograms, and insulin pumps.

Means of Protection

Medical equipment is required to incorporate Means of Patient Protection (MOPP) or Means of Operator Protection (MOOP), with patient protection being the more stringent standard. Primary distinctions between MOPP and MOOP relate to allowable creepage distance, isolations, and insulation. Each Means of Protection has a basic level and a 2x level with 2 MOPP referring to the highest level of protection with 4000 Vac isolation, 8mm creepage distance, and double insulation.

On the surface, MOOP and MOPP may appear to address distinct markets; however, the increasing use of home healthcare devices is blurring the lines between these applications. For that reason, it can be advantageous to design to the more stringent 2 MOPP levels, as long as it is not cost prohibitive. Increasing volumes resulting from home healthcare demands can, in many cases, mitigate the cost of increased levels of protection.

As mentioned above, final product certification is not dependent upon whether the power supply manufacturer specifies MOOP or MOPP isolation compliance. However, if compliance is not specified, it will be the end product designer’s responsibility to ensure that the final product meets the overall requirements.

EMC Compliance Requirements

It is important for designers to review and specify their product’s performance acceptance criteria. It is not enough to just state the IEC standard. There are four levels for acceptance criteria, and designers need to be clear on the level that is acceptable for each application.

- Normal performance within the specification limits.
- Degradation or loss of function, which is not recoverable due to damage of equipment or software or loss of data. In all cases, equipment shall not become dangerous or unsafe as a result of the application of the tests. The performance acceptance criteria can be different for the various levels or the test.

Electrostatic Discharge

Medical device designers must pay particular attention to electrostatic discharge (ESD) issues. The IEC 61000-4-2 standard defines four standard levels of ESD protection, using two different testing methodologies shown in Table 2: contact discharge and air discharge for cases where contact discharge testing is not possible.

Table 2 – EN 61000-4-2 Test Levels

Level	Relative Humidity as low as	Antistatic Material	Synthetic Level Material	Contact Discharge Test Voltage	Air Discharge Test Voltage
1	35%	X		2kV	2kV
2	10%	X		4kV	4kV
3	50%		X	6kV	8kV
4	10%		X	8kV	15kV

Designers should perform an engineering analysis to ensure that there would not be a significant unit cost increase in order for the power supply design to be compliant with the more stringent standard.

From a power supply design perspective, designing a product to comply with the IEC 61000-4-2 ESD requirements can be a challenge at the higher discharge voltages. This becomes even more challenging with a Class II AC input (two wire, no-earth ground conductor). When the ESD discharge is applied to the output or signal pin, the voltage is developed across various isolating barriers and capacitors. This occurs because the AC mains are virtually grounded at some point, so applied ESD voltage appears between the point where the charge is applied and earth ground.

Without careful consideration of the various discharge paths within the power supply, unexpected arcing and damage to the power supply can occur. Testing to the standard and providing a test report is some assurance that the product will perform well within the confines of the specification.

Conclusion

The evolving market trends and regulatory climate for medical device design can present daunting challenges on many levels, just a few of which we've addressed here. Other important aspects include RFI and wireless considerations, risk management, and regional differences, as well as issues relating to various types of devices and where they will be used. In all of these cases, starting the design with a power supply that addresses known requirements will give any design an edge for speeding development and meeting overall regulatory goals. Choosing a vendor with a depth of medical regulatory experience can further simplify the design process and ensure the smoothest path to market.

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