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Fundamentals of Medical-Grade Power Supplies

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When sourcing a power supply for your device, begin by determining how and where the product will be used.

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Crunch time

The medical device development cycle is not what it used to be . . . literally. Not too long ago, the development process generally lasted 18 to 24 months from product inception to the beginning of production. In today's competitive environment, the timeline has been crunched down to a 12 to 18 month process. Similar to other markets—think cell phones and portable computers—the portable medical device sector has had to adapt to shorter product design cycles.

In this article, our goal is to simplify the process of sourcing a power supply for a new medical device. We will consider various options, define industry terminology, discuss regulatory requirements and, in the final analysis, help shave time from the development process.

It is important to note that this article will focus on 10–200 W Class I and Class II portable medical devices. We will look at the requirements needed to successfully design a single- or multiple-output switch mode power supply (SMPS) that meets medtech requirements.

Every quest begins with a few questions. Here are some that may come to mind when searching for the optimal power supply for a device:

- How will the device be used? Is it primarily an indoor application requiring a reliable ac power source, or is it intended for portable use and require both ac and dc voltage input? Will it be sold into a developing market, where the power source and reliability are in question?
- How critical is the overall size of the device to the medical application? Is space an issue? What trade-offs need to be made?
- In what regions of the world will the device be used? What are the target markets: Europe, North America, Asia, other areas of the world? What regulatory requirements must be met?
- How tight is the voltage requirement for the device it is supporting? How much efficiency should the power supply have? Is power factor correction (PFC) necessary and, if so, at what wattage?
- Which is better: an off-the-shelf or custom design? Let's take a look at all of these factors.

Device operation

Defining how a device will operate is an important first step and will help steer the sourcing process in the proper direction. If the device will be used mainly in a hospital, doctor's office or the patient's home, an ac power supply should be sufficient. Infusion pumps, patient monitors, cart-based ultrasound systems and respiratory devices fall into this category. Generally they are used in a set location and may be unplugged, moved to a new location and reconnected to the ac main.

If the product will be used in ambulatory or highly mobile applications—oxygen concentrators, defibrillators, negative pressure wound therapy (NPWT) systems, handheld ultrasound scanners and so forth—then ac/dc power technology should be considered.

Finally, how reliable is the power source where this device will be used? In developing countries, the power may be intermittent and subject to voltage fluctuations that vary from transient voltage spikes and surges to complete power interruptions. Battery backups in portable devices will help offset power interruptions. Designing a system that allows ac and dc power input is recommended.

Device size

A highly mobile and portable device will have strict requirements on weight, overall mechanical dimensions and industrial design. Because of size and weight limitations, these devices will probably use an external power supply. Several well-known power supply companies can provide a competitive, off-the-shelf ac power supply to satisfy most medical requirements.

This embedded power management system is designed for use with a respirator.

A few manufacturers offer a range of standard dc power supplies or adapters. It is advisable to use dc adapters that are designed specifically for the medical market, and not just a repackaged consumer product. It may be important to have a dc power supply with galvanic isolation, for example, to ensure patient safety.

The quest will become yet more challenging if your device needs to include an ac/dc power supply. There is no set medical standard for a combined or dual ac/dc power supply—manufacturers will need to contact a developer of medical power supplies to discuss options.

One choice is to develop a power supply that can be either embedded or external to the device and that can accept an ac or dc input (using the same connector). This will allow the greatest amount of design flexibility, requiring only that the correct input cord be supplied to the host device or power supply. This will involve a custom developed power supply that will require more time during the development process. Development of a custom solution may take up to six months or longer to complete.

A larger stationary device, such as a cart-based ultrasound system or medical computer workstation, typically will have the surface area and real estate to allow an embedded or open-frame power supply. There are many standard medical power solutions and established suppliers from which to choose. Make sure the vendor has extensive experience and is designing a power supply specifically for the medical market (versus modifying a commercial design). If a combination ac/dc supply is needed, consider the option of developing a custom power supply as discussed above.

Device use, regulatory terms

Determining where the device will be used geographically will help to define the testing that will be needed to achieve regulatory compliance. In most cases, only power supplies that comply with internationally accepted IEC 60601-1 (Third Edition), which ensures that medical electrical systems satisfy safety requirements, should be considered. The standard differentiates medical equipment, taking into account the direct electrical contact with patients that is required to perform diagnostics, monitoring and treatment. IEC 60601-1 has national variations in most major markets: EN 60601-1 (Europe); ANSI/AAMI ES 60601-1 (USA) and CAN/CSA C22.2 No. 601.1 (Canada). For specific country certification requirements in other markets around the world, this link from UL is very helpful [5]. To source a power supply manufacturer that understands the requirements and needs of the medical market, it is recommended to look for a vendor certified to ISO 13485.

Power supply specifications

For a better understanding of power supply specifications, it is important to be familiar with the following terms.

Earth leakage current: the unintentional current flowing to the earth conductor from a medical device.

Output voltage total regulation: depending on device requirements, a determination will need to be made regarding the tolerance. The typical power supply regulation is ±5%. To achieve a more tightly defined tolerance over varying load conditions, it may be necessary to develop a custom power supply.

Design engineers may decide to opt for a custom power supply to minimise EMI. A low-EMI embedded power system is pictured.

Patient leakage current: Unintentional current flowing from the medical device to the patient. These currents, which are electrically isolated, are either referred to as Type BF (<100 uA ac) or Type CF (<10 uA ac). Most reputable manufacturers of medical-grade power supplies should note the patient leakage current on their specification to help guide the customer during product selection.

Touch current: unintentional current flowing from the medical device (other than from patient-connected parts).

Short circuit protection: the power supply should automatically detect, recover and cycle on and off (the so-called hiccup mode).

Electromagnetic compatibility (EMC) and electromagnetic interference (EMI): EMC and EMI must be managed carefully, especially with sensitive medical products such as portable ultrasound equipment. The power supply needs to meet the more stringent Class B requirements (residential use) as opposed to Class A (industrial or commercial use). Given the advent of homecare applications, a Class B rating is mandatory. For medical devices, a collateral EMC standard exists: IEC 60601-1-2 includes the requirements of IEC 55011/CISPR11, IEC 55022/CISPR22, FCC 15 (conducted and radiated emissions), IEC 61000-3-2 (harmonic current emissions), IEC 61000-3-3 (voltage changes, variations and flicker), IEC 61000-4-2 (ESD immunity), IEC 61000-4-3 (radiated immunity), IEC 61000-4-4 (fast transient immunity), IEC 61000-4-5 (surge immunity), IEC 61000-4-6 (conducted disturbance immunity), IEC 61000-4-8 (immunity to power frequency magnetic field and IEC 61000-4-11 (immunity to voltage dips, interruptions and variations on the supply line).

Efficiency: power supply efficiency is driven by the marketplace to ensure that today's devices do not waste excessive power while in active or passive modes. Energy Star, which applies to external power supplies rated 250 W or less, is becoming the industry standard. It requires an average efficiency of about 87% in the active mode and sets the maximum amount of energy that can be consumed in passive or standby mode. Energy Star levels range from I to VI, with V the highest qualified efficiency level today. Level VI is achievable, of course, but it requires greater effort. Make it a goal for the future. For now, focus on power supplies that have 87% or greater efficiency.

Hold up time: the amount of time—measured in milliseconds—that a power supply will deliver its full output power within its specified voltage after loss of input power. A preferred minimum hold up time of 5 to 10 milliseconds is suggested, with longer hold up times for critical applications.

Power factor correction (PFC): This is required in power supplies above 75 W. In those cases, the device should have a power factor of 0.9 or greater. (IEC 60601-1-2 requires PFC for output power >75 W.)

Off-the-shelf or custom?

Based on the above guidelines, we can now address the important question of choosing a custom or an off-the-shelf design. The ultimate decision has a lot to do with the device in question.
Off-the-shelf power supplies may be considered if the device:

- has a highly portable design (external)
- lacks space for an embedded system
- is large and/or stationary (embedded)
- is primarily ac powered (but can also use a dc adapter)
- has a short design cycle
- must meet a low cost point.
- The products can use either an external or open-frame (embedded) design.
- A custom power supply may be preferred if the device:
- must manage both ac and dc input voltages, whether external or embedded.
- has specific power requirements, such as a minimal EMI signature, tight voltage requirements and so forth
- must conform rigorously to the space and power requirements of an application
- will require additional features such as battery charging or communications capabilities
- incorporates complete embedded systems.

This embedded power management system is designed for use with a respirator.

Regardless of the type of power supply that is selected, the following factors should always be front of mind:

- greater than 87% efficiency (Energy Star guidelines)
- IEC 60601-1 safety certification
- ISO 13485 manufacturing certification
- Class B EMC characteristics
- Low touch currents

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