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Power supplies for medical devices

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Power for Good

Power supplies for medical devices

One of the most sensitive areas when it comes to the mains operation of a device is the power supply of a medical device. Here, special requirements are placed on the basic safety and the essential performance characteristics of electrical systems. That is: for the entire device. The careful design of the power supply or the careful selection of finished modules can be major steps towards a functional and standard-compliant medical device.

Do it yourself or buy ready?? Especially in medical technology, where safety is paramount, it is not a bad idea to use certified and tested power supplies. Nevertheless, even with this approach, you have to know what is important.
Guidelines for the assessment or selection of a power supply for use in the medical sector are the standards of the IEC 60601 series, which on the one hand specify the requirements for basic safety and on the other hand the essential performance characteristics of medical electronics with a connection to the power grid.

For whom or what?

A first orientation for the classification or assessment of a power supply can be the fixed classifications of the usage categories for the patient and operator environments:

- With **Type B (body)**, there is no direct physical contact with the patient. Examples of this are LED lighting in the operating room or medical laser devices.
- Class **BF (Body Float)** devices have physical contact with the patient and involve the risk of endangering the patient in the event of device failure. These can be ventilators, ultrasound devices or diagnostic equipment.
- Type **CF (Cardiac Float)** has direct contact with the patient's heart and carries a risk of injury or death in the event of equipment failure. Examples: defibrillator and heart-lung machine.

An essential part of the classification of the categories of use are the specifications for insulation and creepage distances as shown in Table 1.

Classification	Isolation	Creepage distances	Insulation
Type B	1500 VAC	2.5 mm	Simple
Type BF	3000 VAC	5 mm	Double
Type CF	4000 VAC	8 mm	Double

Table 1. IEC 60601-1 2nd edition "Protective agents" classifications

Three things a medical power supply needs: isolation, isolation and isolation

The latest edition of the IEC 60601-1 standard extends the classification of use categories and distinguishes between the operator and the patient by specifying MOOP (Means of Operator Protection) and MOPP (Means Of Patient Protection). For patients, MOPP has the stricter requirements (Table 2).

Classification	Isolation	Creepage Distance	Insulation
1 × MOOP	1500 VAC	2.5 mm	Simple
2 × MOOP	3000 VAC	5 mm	Double
1 × MOPP	1500 VAC	4 mm	Simple
2 × MOPP	4000 VAC	8 mm	Double

Table 2. The IEC 60601-1 3rd Edition Isolation Classifications

The main requirement of IEC 60601-1 is that of insulation between the mains input, internal high-voltage levels and the DC voltage output. Insulation is mainly based on the distance between conductors and electrical components. The standard defines minimum distances that are much higher than the requirements in the industrial sector.

Furthermore, protective insulation plays an important role. Many medical power supplies use double or reinforced protective insulation. Here, too, the requirements differ between medical and industrial power supplies. Reinforced or double insulation in power supplies at 240 VAC mains voltage must, for example, have a dielectric strength of 4 kVAC for medical applications.

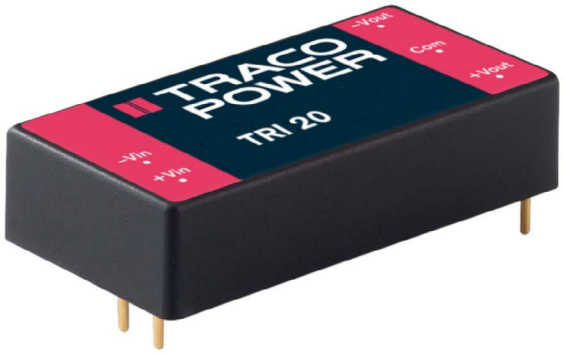

Figure 1. RS Components has the controlled DC/DC converter series TRI from Traco Power in its product range. The TRI series includes five power options: 3.5W, 6W, 10W, 15W and 20W. They offer 7,071VDC I/O isolation and peak isolation of 9000VDC up to one second duration. (Image: RS Components)

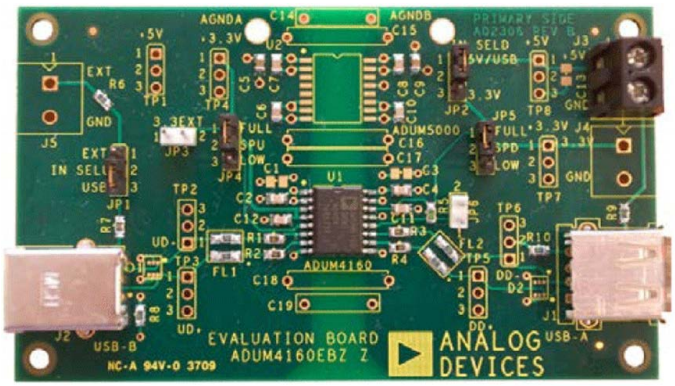

Figure 2. Development board for the IEC 60601-1 compliant ADuM4160 digital isolator iCoupler. It enables isolation of peripherals in USB applications.

Height - the “degrader” of insulation

With increasing altitude, the air becomes a much poorer insulator, which must be compensated with larger insulation distances. Table 3 contains corresponding correction factors (base: 8mm air distance at 2000m):

Height [m]	Air Pressure [kPa]	Air distance multiplier [mm]	Resulting air distance [mm]
2000	80	1.00	8.00
3000	70	1.14	9.12
4000	62	1.29	10.32
5000	54	1.48	11.84

Table 3. Correction factors for ensuring insulation sections at different heights

The table shows that a power supply for 5000m operating height must have 48% greater distances between traces and components than a comparable power supply for 2000m operating height.

There is another aspect to consider for the use of power supplies at high altitudes - the lower heat dissipation in thinner air. In order to ensure cooling despite lower heat dissipation, power supplies must either be operated with reduced power when used at high altitudes (derating) or additionally cooled by larger heat sinks or reinforced ventilation.

EMC standards

In the case of life-sustaining or life-saving devices, faults caused by electromagnetic or radio interference can lead to death for both the operator and the patient.

The 4th edition of the IEC standard on electromagnetic compatibility deals with the requirements for the electromagnetic immunity of the devices and thus also for the power supply. For example, devices must currently be immune to high-frequency fields up to 2.7GHz. In addition, the standard specifies threshold values to prevent damage caused by electrostatic discharges. A threshold of 8kV has been set for contact discharge. For air discharge, the voltage value is 15kV.

OEM Power Supply Selection Checklist

To simplify the compliance process for medical device designers, RS Components offers a range of medical power supplies certified to IEC 60601 Edition 3.1, to MOPP safety standards and 4th edition EMC standards. The following checklist can be a first basis for choosing a certified power supply for medical applications.

Electrical parameters:

Input/Output Conditions DC/DC or AC/DC	
Class I (3-phase AC input) or Class II (2-phase AC input)	
Number of outputs	
Voltage and current for each output	
Output power (W) for the individual outputs	
Calculate the total power supply power by adding all output power (W)	
EMC/EMI (radiated and conducted)	
Efficiency	
Control and monitoring functions	Remote On/Off, protection against short circuit, over current, over voltage, over temperature
Patient safety	MOP
Safety of operating personnel	MOOP
Usage Category	B, BF, CF

Mechanical requirements:

Physical size L x W x H, weight	
Installation requirements	internal / external
Cooling	None, forced ventilation, convection or drainage
Thermal aspects, airflow, temperature rise	possible derating
Electrical connections	Input and output, type of connector, wiring harness
Shock and vibration conditions	Aircraft, helicopter, ship, ambulance
Acoustics	especially in the case of noise-sensitive, applications e.g. sleep laboratory
Reliability	MTBF, lifetime, other quality assurance agreements
Environment / Safety / Legal Regulations	e.g. REACH requirements, RoHS2 (exclusion of hazardous substances), WEEE (recycling)
Location	Hospital / Clinic / Private apartment / Ambulance / Airplane / Ship / High altitude
Type of application	portable / permanently installed
Ambient temperature conditions	

According to documents from

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TDK
TDK Lambda
CUI Inc.
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