Designing battery operated medical equipment for IEC 60601-1 compliance

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The IEC 60601-1 standard establishes general safety requirements for all aspects of medical devices. It includes test requirements, documentation, protection from electrical hazards, protection from mechanical hazards, protection against excessive or unwanted radiation, protection against temperature, fire prevention, ingress of liquids, disinfection, biocompatibility etc.

As electrical designer you must be aware of the requirement pertaining to the protection from electrical hazards. The purpose of this article is list some general methods used for hazard prevention for battery operated medical devices.

Prevention from Reverse Battery Connection

If the medical equipment uses battery, there must be safeguard against reverse battery connection. There are two methods for reverse battery protection.

Series Diode Protection

![Figure 1: Series Diode Protection](image)

We can use simple diode in series with the positive side of the battery as shown in the figure 1. The power rating of the diode should be calculated so that it can handle at least double the amount of the required current.

Normal switching diodes have greater voltage drops in the range of 0.6V to 0.7V. So, if we the medical device working on two series AAA alkaline batteries (1.5V each), the voltage available to the circuit will be only 3.0V - 0.7V = 2.3V. This will lead to drop in the voltage available to the circuit. In addition, this scheme will be inefficient due to the power loss across the diode. We may use schotty diode for smaller voltage drop.

We can also use MOSFETs, with very low Rds ON resistance. These are ideal for providing reverse current protection with minimal loss. These are slightly more expensive.
Parallel Diode Protection with Polyfuse

The problem with the series Diode protection is the voltage drop and the power loss due to the IR drop. An alternate scheme to overcome this is shown in Figure 2. We use a polyfuse F1 for overcurrent protection. If a battery is connected in reverse fashion, the Fuse F1 blows, as huge current flows through the diode D1. The advantage of polyfuse F1 is that it recovers when the cause of the high current disappears.

The diode D1 should have a rating of at least twice the amount of the Fuse F1. Following are the steps required to find rating of the Fuse F1 and diode D1.

1. Find the maximum current requirement of the circuit.
2. Find the Fuse F1 with rating about 2 to 3 times the max current required by circuit.
3. Find Diode with current rating at least twice the Fuse F1 rating.

Overcurrent Protection

As part of the 60601-1 electrical hazard testing, the medical device will be tested for short at all the derived voltages. For example if the medical device uses voltage regulator that generates 2.5V and 3.0 from battery it will be tested for a hazard by shorting 2.5V and 3.0V.

If we are using a voltage regulator, we should preferably use the one that has ability to limit the current. Choose a voltage regulator that provides ability to set current limit using an external resistor. This will not only prevent hazard, it will make the system recoverable, once the short is removed.

For added safety we should add a polyfuse at the output of the regulators.

In addition we should use a polyfuse at the Input of the power supply.

Explore all possible Hazard conditions

The designer must consider all the possible hazard condition and list them out and test for safety. Here is a sample list.

1. Your system is designed for a chargeable battery. Check what happens if non rechargeable battery is inserted and user tries to charge it. Try different battery chemistries (Alkaline, NiCD, LiMH).
2. Check what happens if charger is placed without battery.
3. Check what happens if a deeply discharge battery is connected for charging. We should use an intelligent charger with built-in current limiting. We can use a polyfuse for additional safety.
4. Explore what happens if battery is placed reverse and it attempted for charging.