Medical power supplies meeting IEC 60601-1-2 4th Edition voltage dips and interruptions

Customers call TDK-Lambda wanting their medical product to meet the strict IEC 60601-1-2:2015 4th edition immunity standard, and ask us if our medically certified power supplies fully comply. In particular, concerns are raised about meeting the section dealing with voltage dips and short interruptions to the AC supply.

IEC 60601-1-2 is derived from the IEC 61000-4 standard, which covers Electromagnetic compatibility (EMC). The testing and measurement methods are very similar, but some of the test levels for dips and interruptions in the section based on IEC 61000-4-11 are much tougher. The interruption test of removing the AC supply for 5 seconds, without the loss of the output, is almost impossible without a custom solution with some form of battery back-up. One may well question why are standard medical power-supplies being sold if they do not meet that standard.

Firstly, power supplies are not classified as medical devices, it is the customer's product or system that is the medical device.

Secondly the term "essential performance" used in the standard has to be examined. In the 3rd edition of IEC 60601-1 it is defined as "the performance necessary to achieve freedom from unacceptable risk". To clarify, the designer/manufacturer has to determine if a loss of performance or functionality of their medical device product or system will result in an acceptable risk or an unacceptable risk. That risk is the potential to harm a patient, operator or the environment. Analysis must be made of the probability or the frequency of an event happening compared to the severity of that event.

Let's give a simple example. Diabetics check their blood glucose level on a regular basis and most use a handheld battery-operated meter that accepts disposable test strips. If that meter was to stop working, say due to a faulty display, it would be classified as an acceptable risk. Replacement meters are readily available from supermarkets and pharmacies and a short delay in testing would not normally cause harm. An unacceptable risk would be if the internal sensor measuring the blood glucose level was to produce incorrect readings and the diabetic administered too much or too little insulin.

Power supplies, although not classified as medical devices, can have an impact on the IEC 60601-1-2 immunity performance of the device they are powering. For the voltage dips and interruptions section of the standard, there are five tests performed. Table 1 below shows the input voltage dip and the duration. 100Vac input and 50Hz conditions are shown as they could represent the worst case.

Test results are judged against four performance criteria levels:

Performance Criteria A – 'Performance within specification limits'

> This is the best result. A very slight drop in output of a few milli-volts (within the regulation limits) should not cause the end device to malfunction.

Performance Criteria B – 'Temporary degradation which is self-recoverable'

> Criteria B is usually acceptable in the majority of cases.

Performance Criteria C – 'Temporary degradation which requires operator intervention'

This would be classified as unacceptable from a user point of view, without even considering a risk analysis. If the AC power was interrupted and the power supply had to be reset by a patient or operator, it would be much too inconvenient.

Performance Criteria D – 'Loss of function which is not recoverable'

Criteria D is really a "fail" test result. If a power supply is damaged and needs replacing after the test, it is very unlikely that a product with this performance level would be placed on the market.

AC Input Voltage	Actual Voltage Dip for 100Vac nominal	Voltage Dip by AC Input Cycle (50/60Hz)	Voltage Dip Time Period for 50Hz	Suggested Performance Criteria Level
Dip down to 0%	0Vac	0.5 of a cycle	10ms	A
Dip down to 0%	0Vac	1 cycle	20ms	A
Dip down to 40%	40Vac	10/12 cycles	200ms	B
Dip down to 70%	70Vac	25/30 cycles	500ms	A
Dip down to 0%	0Vac	250/300 cycles	5000ms (5s)	B

Table 1: Test Levels

Referring to Table 1, most power supplies will pass the first two tests with a Performance Criteria level A with some output derating to increase the hold-up time.

The third and fourth tests requires the power supply to continue to operate for 200ms when the input drops to 40% of nominal or for 500ms at 70% of nominal. Criteria A could be achieved by having the power supply's low voltage input protection circuitry modified to allow the power supply to operate at the lower input voltage for a short time. As the AC input current will be higher, it is best to ensure that the power supply is not operated at full load. As hold-up time is related to the actual output power drawn, operating the power supply at 50% load will result in a significant "ride through" capability during the interruption.

The fifth test of a 5 second interruption to the AC supply is usually met with the installation of battery back-up or a UPS (Uninterruptible Power Supply). Adding sufficiently large energy storage inside the power supply would result in a significant increase in size.

In summary, the medical device designer/manufacturer must decide which performance criteria is needed, based on their risk analysis to meet IEC 60601-1. Unless continuous performance is critical, most manufacturers will opt for the criteria in Table 1.