

Creepage Requirements for Medical Applications

The international standard for medical safety equipment, IEC 60601, covers electrical aspects of isolation components and differs from other standards in several respects, including creepage and clearance requirements and defibrillation tolerance testing. The creepage requirements under many other standards allow the relationship between creepage and working voltage to be interpolated smoothly between the values listed in the specification tables. For example, if the creepage is slightly below the table values, the working voltage can be scaled down proportionately, and the part will retain most of its operating range. The IEC 60601 standard, in contrast, explicitly disallows interpolation of creepage and working voltages. 125 V rms working voltage requires greater than 6 mm of creepage, and 250 V rms working voltage requires greater than 8 mm of creepage for insulation that provides two means of patient protection—there are no exceptions to this for piece parts.

A common package for reinforced isolator components is the JEDEC standard SOIC16-W that is 7.4 mm wide and 2 mm thick. The shortest path along the surface of this package is usually around the end and is typically only 7.6 mm. This is shorter than what one might expect because, similar to most leaded devices, it includes metal tabs along the creepage path, which must be deducted from the creepage distance according to the rules for measuring creepage.

These metal tabs are tie bars that hold the package lead frame during the lead forming step in manufacturing. These tie bars are usually not connected to the internal lead frame but are exposed as floating metal at each end of the package. Even so, the creepage measurement must account for the tie bars, resulting in 7.6 mm* which, for medical applications, fails to meet the 8 mm creepage requirements. As a result, JEDEC standard SOIC-16W packages may be used only up to a working voltage of 125 V rms. Because the world primarily works on 220 V rms to 240 V rms, this package is not adequate for medical applications in most of the world.

Fortunately, there are a number of ways to meet 8 mm creepage requirements for worldwide medical applications. With specialty packaging, however, it is desirable to keep such packages close to JEDEC standard dimensions to reduce cost and risk for designers. An oddly shaped package incurs high costs because assembly lines must be retooled to handle them, and they create high risk because custom assembly equipment creates a single source bottleneck if broken down, as it becomes more difficult to maintain or replace, resulting in production downtime. Keeping compliance to JEDEC standard packaging allows part cost to be minimized through use of standard tooling and does not lock assembly into specific locations in case of facility problems. ADI's challenge was to make a package that matches JEDEC standards.

The *iCoupler*[®] solution is to change the creepage path for the isolator by extending the end of the package. When the package is extended from the end pin to the end of the package, the shortest distance moves from around-the-end of the package to over-the-top. This removes the tie bars from the creepage path and allows the full thickness of the molding compound to be counted in the creepage. This value is 8.3 mm (minimum) for a JEDEC standard wide-body SOIC. To achieve this, ADI has introduced a package that uses the body of a 20-lead SOIC package with the lead frame of a 16-lead package. This increases the distance around the end of the package by 2.54 mm to about 10 mm and changes the creepage path to over-the-top of the device. Because the package dimensions are the same as JEDEC standard packaging, production tooling is compatible with the new package, keeping costs and infrastructure in line with current products. This new package is rated for 250 V rms working voltage under IEC 60601.

*Some suppliers specify creepage based on their own measurements that do not consider tie bars. It is recommended that designers refer to the certified creepage as measured by UL, CSA, VDE, TUV, and other certifying agencies.

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