

Achieving Medical Device Compliance with the CF Rated Low Leakage Adapter

INDUSTRY**Medical****SOLUTION****SL Power 65 W External Power Supply****APPLICATION****Heart Pumps****CHALLENGE**

A manufacturing company in the medical sector approached Advanced Energy to find a solution for their heart pump system that can be used in a home care environment. The primary challenge faced by the customer was achieving a combination of low leakage current (less than 10uA) with Class B EMI compliance. And a longer cable added complexity to maintaining EMI compliance, efficiency, and output voltage regulation. Additionally, the customer required the adapter to meet stringent biocompatibility standards, mechanical robustness for portability, and operate efficiently at altitudes ranging from -500 to 5000 meters. Another emerging challenge was managing a surface temperature of 60°C, which is still under discussion and development.



SOLUTION

To address these challenges, the SL Power 65 W external adapter was leveraged and modified to meet the customer's critical requirements. The adapter was designed to have less than 10uA leakage current under normal conditions and less than 50uA under abnormal conditions. It featured a 3-meter output cable, Energy Star Level VI compliance, and an average efficiency of 88% at the cable end. The adapter also included 2 MOPP, CF rating, 8mm creepage, 5mm clearance, a custom-defined proprietary connector, and biocompatibility. The design improvements, particularly in magnetics, ensured that both the low leakage and EMI compliance requirements were met.

The biocompatibility standards for the CF rated adapter were critical to ensure the safety and effectiveness of the device when used in medical applications. The adapter was designed to meet the ISO standards, which include a series of tests to assess the potential for adverse biological reactions resulting from contact with the device. The tests cover various aspects such as cytotoxicity, sensitization, irritation, and systemic toxicity. By adhering to these standards, the 65 W adapter ensured that it is safe for use in medical environments, particularly in applications involving direct or indirect contact with patients.

RESULT / CONCLUSION

The customized adapter successfully met the customer's stringent requirements, providing a reliable and efficient solution for heart pump applications in home care environments. The modifications ensured low leakage current and EMI compliance, while also addressing biocompatibility and mechanical robustness. Although the surface temperature challenge is still under development, the CF rated adapter has proven to be a valuable solution for the customers' needs.



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