

CASE STUDY:

MEETING CF LEAKAGE REQUIREMENTS IN EMERGENCY MEDICAL DEVICES

APPLICATION

*Healthcare Emergency
Medical Services*



SOLUTION

*AC-DC External Adapter
with CF Leakage*



OPTIMIZATION

*CF Leakage Isolation and
Improved Efficiency*



OVERVIEW

EMS devices must adhere to strict regulations, similar to medical home use devices, such as IEC 60601-1-12, Class B EMC, and Class II input requirements. An example application of EMS devices necessitating CF leakage compliance is fluid and blood

warmers. These devices play a crucial role in preventing hypothermia during fluid administration over extended transport durations. They are available in portable options, powered by either batteries or an AC adapter to ensure continuous warming capabilities. The ability to seamlessly switch between battery and AC power enhances device usability by extending operation time and providing warm fluids during EMS transport.

POWER CHALLENGES

Cardiac Floating (CF) isolation is a crucial requirement for medical devices to prevent AC power from potentially coming into contact with a patient's heart or bloodstream. While traditional fluid and blood-warming devices have relied on battery power, the growing demand for extended operation times has sparked the need for a CF-compliant AC connection. Enhancing power run times without significant changes to the device's form factor has become a valuable asset in the medical electronics industry. Various methods exist to boost power duration in medical devices while meeting industry standards, yet manufacturers must be cautious of potential form factor adjustments.



Implementing a transformer for longer power durations, for instance, can lead to increased size and weight, requiring more space. Alternatively, using AC-DC power supplies with isolation circuitry might fulfill isolation requirements but can introduce drawbacks like added cost and size. In this evolving landscape, finding solutions that balance efficiency, reliability, and adherence to industry standards is paramount. With Astrodyne TDI's expertise in designing CF-compliant AC-DC power supplies, medical device manufacturers can enhance power efficiency without compromising on safety or incurring unexpected testing costs. Their commitment to providing reliable power solutions ensures that manufacturers can focus on product design without the burden of additional expenses.

The objective of the design project was to:

- ✓ *Prevent the necessity for substantial alterations to the device's dimensions, weight, or overall size*
- ✓ *Ensure adherence to industry regulations such as IEC 60601-1-12, Class B EMC, and Class II input standards without incurring unforeseen expenses for safety and EMC testing*
- ✓ *Enhance both the reliability and safety of patients while optimizing operational run times*
- ✓ *Minimize the reliance on in-house engineering resources to expedite product launch timelines*



ASTRODYNE TDI'S SOLUTION

Furthermore, the Astrodyne TDI team goes beyond developing BF-compliant AC-DC power supplies with downstream isolation circuits. They also specialize in designing and manufacturing power supplies that prioritize enhanced efficiency and heightened reliability to meet the rigorous standards of the medical industry, including IEC60601-1-11 for home use and IEC60601-1-12 for EMS devices. Astrodyne TDI's AC-DC power supplies feature CF isolation with internal components, ensuring top-notch safety measures. The WSZ8 and EDP400 series boast a non-grounded input and comply with EMC requirements, specifically Class B EMC. With a focus on innovation, Astrodyne TDI incorporates transformers and additional components into their power solutions, eliminating the need for medical device manufacturers to worry about additional costs while they concentrate on perfecting their product designs.