

tech tips

TECHNICAL INFORMATION AND PRODUCT SOLUTIONS

ONEAC® Products for Special Medical & Dental Facilities Requirements

Medical facilities often have unique electrical specifications for such parameters as earth leakage current and input over-current protection for devices connected to their AC electrical distribution system. They may also need to comply with the international standard for electrically safe medical equipment: IEC60601-1. This tech tip reviews these applications/compliance and also discusses how ONEAC's medically-approved products may be used to satisfy them.

IEC60601-1 Compliance: A "global harmonization" is underway for the new IEC60601-1 safety standard. The deadline to comply with the regional derivative is outlined below:

Europe	EN60601-1	June 13, 1998
U.S.A.	UL60601-1 (UL2601-1)	December 31, 2004
Canada	CAN/CSA-22.2 No. 601.1-M90	January 01, 2000

Earth Leakage Current: Recognizing that patients may be in a weakened condition, special efforts are made in medical facilities to eliminate the possibility of electrical shock. Leakage current is defined as any current which is not intended to be applied to a patient but which may be conveyed by touching parts of medical equipment. IEC 60601-1 has established limits on exposed leakage current for equipment used in specific medical environments.

ONEAC products that feature a built-in isolation transformer as an integral part of the power conditioning system, ensure all secondary loads (i.e. equipment plugged into the UPS) are confined to the output section. Therefore, all leakage current from the connected equipment is confined to the secondary winding of the transformer. In normal operation, ONEAC transformer-based products will reduce earth leakage current to the AC supply to 500 microamps or less. The total leakage (including load) to the AC supply earth/ground would be the same as the transformer's earth leakage, regardless of the load or number of loads plugged into the transformer. Power protection product designs that do not incorporate an isolation transformer as part of the design will add their characteristic earth leakage current with that of the loads connected to it, resulting in a total system leakage current that may be too high for certain medical facilities.

Input Over-Current Protection:

Two-pole input over-current protection is standard on the IEC60601-1 compliant PCm Series Power Conditioners and the ON Series® m UPSs.

Single-pole input over-current protection is standard on all other ONEAC Power Conditioners and UPSs (model designators I, A and J). Two-pole input over-current protection, which some authorities may require for specific applications, is available by special order on these products.

PCm Series Power Conditioner and ON Series m UPS for IEC60601-1 Compliance

The PCm Series Power Conditioners and the ON Series m UPS models are listed for UL 60601-1 and CSA-C22.2, No. 601.1 compliance and carry the CE Mark for testing to the EN60601-1 standard for Medical Electrical Equipment. Designs are compliant with all specification parameters for Class I, Type B equipment (such as earth leakage and enclosure leakage currents). Units are available in 120 V and 230 V, 50/60 Hz with IEC connectors to facilitate country-specific connector compatibility. The ON Series m UPS also features an optically isolated communications interface and battery back-up capability.

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Typical applications include use in the "patient vicinity," providing both power conditioning and backup power to support attached loads (i.e. systems running under WindowsNT and Unix operating systems), while fully conforming to appropriate IEC60601-1 specifications. Additional applications may include manufacturer integration with new or existing medical systems as part of an IEC60601-1 test and compliance program, or use with installed equipment to improve compliance with certain safety parameters. Use of ONEAC listed product in itself does not create full IEC60601-1 standard compliance for the attached equipment, but may be an important element in a manufacturer's overall system solution.

Application Recommendations:

When installed in medical facilities that require limited earth leakage current, the PCm Series Power Conditioners and ON Series m UPSs are uniquely suitable as a power conditioning interface and limited-time emergency power source (i.e. for such uses as clinical chemistry analysis systems and clinical information systems). ONEAC transformer-based products are not, however, promoted or sold for use in life support or other life-critical applications. Please read the full disclaimer that follows for application in life-critical applications.

USE OF ONEAC PRODUCTS IN LIFE-CRITICAL APPLICATIONS

While ONEAC believes it designs and manufactures very reliable products, many of the vendors that ONEAC sources components from do not recommend or endorse the use of their products in life-critical applications. By extension, ONEAC must adhere to the same business policy and does not recommend the use of our products in life-critical applications.

DISCLAIMER

ONEAC PRODUCTS ARE NOT DESIGNED, INTENDED, OR AUTHORIZED FOR USE IN SYSTEMS INTENDED TO SUPPORT OR SUSTAIN LIFE, OR FOR ANY OTHER APPLICATION IN WHICH THE FAILURE OF THE ONEAC PRODUCT COULD CREATE A SITUATION WHERE PERSONAL INJURY OR DEATH MAY OCCUR. SHOULD BUYER PURCHASE OR USE ONEAC PRODUCT FOR ANY SUCH UNINTENDED OR UNAUTHORIZED APPLICATION, BUYER SHALL INDEMNIFY AND HOLD ONEAC AND ITS OFFICERS, EMPLOYEES, SUBSIDIARIES, AFFILIATES AND DISTRIBUTORS HARMLESS AGAINST ALL CLAIMS, COSTS, DAMAGES AND EXPENSES, AND REASONABLE ATTORNEY FEES ARISING OUT OF, DIRECTLY OR INDIRECTLY, ANY CLAIM OR PERSONAL INJURY OR DEATH ASSOCIATED WITH SUCH UNINTENDED OR UNAUTHORIZED USE, EVEN IF SUCH CLAIM ALLEGES THAT ONEAC WAS NEGLIGENT REGARDING THE DESIGN OR MANUFACTURE OF THE PART.