

Leakage Current Abstract

Leakage current is the current that flows from the unit through the grounding conductor into a household ground. Leakage current could shock an individual if the household grounding is not sufficient or there is an intentional or unintentional interruption of grounding connection.

Leakage current of 3 milliamps through the heart would create a mild shock and some pain; 8 milliamps would cause an interruption in heart function (cardiac arrhythmia), which could eventually kill a healthy person in seconds.

Note: the requirement for medical equipment however is more stringent; a fatal shock could result if the patient is in a weak or unconscious condition.

CLASS I EQUIPMENT: Products use basic Insulation in combination with Protective Earth. These products will have a three-prong power cord and the ground blade will be attached to any accessible metal on the product

CLASS II EQUIPMENT: Products that have a two-prong power cord are Class II products. Class II products rely not only on basic insulation but also supplemental insulation or reinforced insulation. These products are often referred to as double insulated products as protection against shock relies on two layers of insulation.

CLASS III EQUIPMENT: Equipment in which protection relies upon supply source from SELV circuits and in which hazardous voltages are not generated.

PATIENT AUXILIARY CURRENT: Current flowing between patient connections and that is not intended to be there to produce an effect in the patient.

PATIENT LEAKAGE CURRENT: Current flowing from the applied part via the patient to the ground or flowing from the patient via an F-type applied partially to the ground, originating for the unintended appearance of a voltage from an external source on the patient.

Medical Requirements

Current	Normal Condition	Single Fault Condition
Earth Leakage Current	0.5mA	1mA

Other than the medical leakage current requirement mentioned above, there are other leakage current requirements in IEC 601-1(Medical), such as patient leakage current, patient auxiliary current and enclosure leakage current.

For Class 2 Equipment

Type of Equipment	Maximum Leakage Current
Portable Unit	0.5mA
Stationary Unit	0.75mA

The U.S. leakage current deviation is based on the values and requirements of NFPA 99, "Health Care Facilities" and the ANSI/AAMI "Safe Current Limits for Electromedical Apparatus" standards. The differences from IEC 60601-1 modify the acceptable passing limits for the earth and enclosure leakage tests, and maintain the same values for the patient leakage tests.

The base IEC 60601-1 standard does not directly differentiate between inside and outside the patient environment. IEC 60601-1-1, "Medical Electrical Systems," which addresses a combination of several pieces of equipment, does make a distinction between inside the patient environment and outside it with respect to leakage current testing. UL 60601-1 differentiates between patient-care equipment (6 ft around and 7.5 ft above the patient) and non-patient-care equipment for these leakage current tests.

These values are given as:

- Class I product (typical value) = 300 μ A patient-care area
- Class I product (typical value) = 500 μ A non-patient-care area.

UL 60601-1 allows opening of the ground conductor and one of the supply connections simultaneously for non-patient-care equipment. In most cases, the following is true: The earth leakage current test per UL 60601-1 provides the worst-case conditions within the patient area, whereas the enclosure leakage current test per IEC 60601-1 is the worst-case test in the normal condition.

Definitions

Patient Auxiliary Current: Current flowing between patient connections and that is not intended to be there to produce an effect in the patient.

Patient Leakage Current: The current flowing from every individual part of the applied part back to earth or the current flowing from an unintended appearance of a voltage on the patient back to an F-Type Applied Part. Protective

Earth: Conductor that connects between any protectively earthed parts of a Class I product and an external protective earth connection.

Reinforced Insulation: A single system of insulation that provides two levels of protection against electrical shock.

Signal Input/Output Part: (SIP/SOP) Part of the medical product that is not an Applied Part but is intended to send or receive signals from other external equipment.

Single Fault Condition: Condition in which a single means of electrical safety protection is defective or an abnormal condition is present. Examples of a single fault condition would be interruption of the ground conductor on a Class I product or opening of the neutral supply conductor to the product.

Supplemental Insulation: Independent insulation applied in addition to Basic Insulation in order to provide protection against electrical shock in the event of a failure of Basic Insulation.

Touch/Chassis Leakage: Leakage Current from the enclosure or other parts, excluding applied parts that are not connected to a protective earth conductor.