

Table 14.1 Limits on Leakage Current for Electric Appliances

Electric Appliance	Chassis Leakage, μA	Patient-Lead Leakage, μA
Appliances not intended to contact patients	100	Not applicable
Appliances not intended to contact patients and single fault	500	Not applicable
Appliances with <i>nonisolated</i> patient leads	100	10
Appliances with <i>nonisolated</i> leads and single fault	300	100
Appliances with <i>isolated</i> patient leads	100	10
Appliances with <i>isolated</i> leads and single fault	300	50

See Section 14.12 for specific test conditions and requirements.

only the patient-lead leakage current was relaxed from 10 μA to 50 μA and the chassis leakage current was relaxed from 100 μA to 300 μA . These changes were hotly challenged by the American Heart Association committee on electrocardiography (Laks *et al.*, 1994; Laks *et al.*, 1996). Laks said this change “constitutes experimentation on humans without their consent to determine the safe range of such currents.”

The International Electrotechnical Commission (IEC) 60601-1 (2006) standard has been adopted by all other standards organizations, including the limit on leakage current for medical electric devices. This conformity to a widely supported international standard is endorsed by the Health Industry Manufacturers Association (HEMA), the National Electrical Manufacturers Association (NEMA), and the U.S. Food and Drug Administration (FDA). The IEC 60601-1 standard allows a “patient auxiliary current” up to 100 μA at not less than 0.1 Hz to permit amplifier bias currents and impedance plethysmography if the current is not intended to produce a physiological effect.

The present limits on leakage currents for the IEC 60601-1 2005 standard are shown in Table 14.1.

14.7 BASIC APPROACHES TO PROTECTION AGAINST SHOCK

There are two fundamental methods of protecting patients against shock. First, the patient can be completely isolated and insulated from all grounded objects and all sources of electric current. Second, all conductive surfaces within reach of the patient can be maintained at the same potential, which is not necessarily ground potential. Neither of these approaches can be fully achieved in most practical environments, so some combination of the two methods must usually suffice.

Not only must all hospital patients be protected from macroshocks, but all visitors and staff must be protected as well. Patients with reduced skin resistance (perhaps coupled to electrodes), invasive connections (such as intravenous catheters), or exposure to wet conditions (as happens during dialysis) need extra protection. The small numbers of patients with accessible electric connections to the heart need additional protection from microshock currents. Many of the specific methods of protection described here can be used in combination to provide redundant safeguards. It is also necessary to consider cost-benefit ratios with respect to both the purchase cost of safety equipment and the periodic maintenance costs of such equipment.

14.8 PROTECTION: POWER DISTRIBUTION

GROUNDING SYSTEM

Low-resistance grounds that can carry currents up to circuit-breaker ratings are clearly essential for protecting patients against both macroshock and microshock, even when an isolated-power system is used. Figure 14.10 shows the importance of adequate grounds for protection against macroshock. Grounding is equally significant in preventing microshock (see Figure 14.11). A grounding system protects patients by keeping all conductive surfaces and receptacle grounds in the patient's environment at the same potential. It also protects the patient from ground faults at other locations.

The grounding system has a *patient-equipment grounding point*, a *reference grounding point*, and connections, as shown in Figure 14.14. The patient-equipment grounding point is connected individually to all receptacle grounds, metal beds, metal door and window frames, water pipes, and any other conductive surface. These connections should not exceed 0.15 Ω . The difference in potential between receptacle grounds and conductive surfaces should not exceed 40 mV. Each patient-equipment grounding point must be connected individually to a reference grounding point that is in turn connected to the building service ground.

ISOLATED POWER-DISTRIBUTION SYSTEM

Unfortunately, even a good equipotential grounding system cannot eliminate voltages produced between grounds by large ground faults that cause large ground currents. However, these ground faults are rare in high-quality and properly maintained equipment. The isolation transformers discussed in Section 14.3 and shown in Figure 14.9 prevent this unlikely hazard. The isolated power system also reduces leakage current somewhat, but not below the 10 μA safe limit. There is usually enough capacitance between the transformer secondary circuit and ground to preclude protection against microshocks with isolation transformers. Isolated power systems provide considerable protection against macroshocks,