



Warren Grant Magnuson Clinical Center  
Materials Management Department  
10 Center Drive MSC 1070  
Bethesda, Maryland 20892

January 3, 2003

**SET LIMIT:**

Any EQUIPMENT Used for the care of patient that FALLS WITHIN three or more scope of the primary factors OF THE CRITERIA SHALL BE INCLUDED IN THE MEDICAL EQUIPMENT MANAGEMENT PROGRAM.

**PRIMARY FACTORS:**

a. **Equipment having Function such as:**

- \* life support
- \* Deliver energy to the patient
- \* Provide diagnostic information
- \* Monitor physiologic condition.

b. **Equipment with Clinical Application such as:**

- \* Invasive connections
- \* Control of body functions
- \* Delivery of drugs or nutrients

c. **Equipment Requiring Maintenance such as:**

- \* used in harsh environment
- \* used frequently
- \* typified by mechanical/pneumatic/electrical assembly

d. **Equipment having Incident History such as:**

- \* published hazard notice
- \* history of misuse
- \* high risk, such as radiation

**NOTE: Discretionary clause**

- e. **It is to Biomedical Engineering discretion when the piece of equipment contains debatable features that may or may not be considered clinical equipment.**

## Grounding resistance

**Grounding protects the patient and staff from electrical hazards in two ways: First, should a fault (short) to the chassis occur, the grounding conductor must pass sufficient current to trip a circuit breaker or blow a fuse quickly. Second, the ground must allow leakage currents to flow to ground, rather than through the patient or personnel. Both of these functions will be satisfactorily accomplished at grounding resistances of 0.5  $\Omega$  or less.**

This criterion is consistent with NFPA 99's requirements for healthcare facilities. However, a lower resistance of 0.15  $\Omega$  is readily achievable. (NFPA 99 calls for 0.15  $\Omega$  under *manufacturer* requirements.) Some ohmmeters may not have the accuracy or resolution to reliably measure this lower resistance, and poor contact between the ohmmeter leads and the device may result in increased readings. Thus, 0.5  $\Omega$  is a more convenient and acceptable criterion for healthcare facility inspections.

IEC 60601-1 calls for grounding resistance of 0.1 or 0.2  $\Omega$ , depending on whether it is measured from the ground pin of the chassis-mounted connector for a detachable power cord or from the ground pin on the plug of a nondetachable power cord. ECRI recommends that grounding resistance measurements during inspections always be made from the ground pin of the power cord, whether the power cord is detachable or not.

## Double insulation

Double-insulated or IEC 60601-1 Class II medical equipment can safely be used in healthcare facilities. We use the term double-insulated to include IEC 60601-1 Class II devices, which may use double or reinforced insulation; functionally, these are equivalent. Relevant codes and standards generally allow the use of double-insulated devices in any healthcare facility area, including special care units and anesthetizing locations. Preferably, a double-insulated device should be listed as such by a recognized testing organization (e.g., UL) or certified to meet IEC 60601-1 Class II requirements.

### ***Is grounding necessary?***

Grounding of a line-powered device is usually required if only one layer of basic insulation separates "live" internal parts from externally accessible metal (e.g., the housing). Should that layer of insulation fail, contact between the live part and the metal housing could cause a shock hazard. With the housing grounded, this fault current is diverted away from someone contacting the housing and will blow a fuse or trip a circuit breaker to provide shock protection (but will also cut power to the device and possibly the branch circuit). A double-insulated device uses a separate, additional layer of insulation (or a single reinforced layer of insulation) to provide protection from shock. With this additional insulation, grounding is usually not required.

Some plastic-encased ungrounded devices, although not double insulated or listed as such, offer a similar degree of safety by virtue of their design and construction. If marketed for healthcare facility use, such devices can be considered. The healthcare facility must weigh the device's clinical advantages and should thoroughly inspect the device for safety. The inspection should consider possible abuse (e.g., liquid spills, dropping) to which the device may be exposed. (Considering a device not marketed for healthcare facility use requires careful thought. If a similar device that is designed to withstand the demands of healthcare facility use is available, it should be given preference over a device intended for household use.)

### ***Which type of plug should be used?***

Some concerns have been expressed in U.S. facilities over which type of plug should be used on the power cord of double-insulated devices in healthcare facilities. In the United States, healthcare facility staff have become accustomed to requiring grounding and looking for Hospital Grade plugs; however, Hospital Grade two-prong plugs are not available. The primary benefit of these plugs is improved grounding security; this is not an issue with double-insulated devices. We agree with NFPA 99-1993 (paragraph 9-2.1.2.1), which permits either two-prong plugs (and two-wire cords) or three-prong plugs (if a grounding conductor is required in the power cord) on double-insulated equipment. IEC 60601-1 has a provision for use of a three-prong plug on a Class II device but calls for appropriate labeling (clause 18.1). In some countries (e.g., the United Kingdom), all mains plugs are grounded. The concept of Hospital Grade plugs does not exist outside the United States.

The greatest problem created by using two-prong plugs is providing a consistent policy for the clinical staff. While routine practice has been to train clinical staff to reject any equipment with a two-prong plug, a better practice is to instruct them to reject any device that does not have a healthcare facility control number tag signifying that it has been inspected by the clinical engineering personnel and found acceptable for use.

### ***Is chassis leakage current a concern?***

Chassis leakage current criteria for a double-insulated device are the same as those for grounded devices. (ECRI does not recommend routine chassis leakage current tests of double-insulated devices, although such testing can be conducted using metal foil in contact with the device [see **Error! Reference source not found.**, above].) However, in a well-designed, double-insulated unit, we would expect low leakage current and recommend further investigation if the chassis leakage current is greater than one-half the limit applied to grounded units.

**From: Electrical Safety chapter in the *Health Devices Inspection and Preventive Maintenance System***

**ECRI leakage current limits recommendations**

Healthcare facilities must comply with national and local codes and standards. Often, however, clinical engineering personnel require a simple summary of common requirements or assistance in determining what is safe. The ECRI recommendations listed below have been formulated following review of the various standards discussed in this section, with special emphasis on IEC 60601-1 and NFPA 99. The recommendations provide a practical guide for all healthcare facilities, regardless of which standard a healthcare facility applies. Specific criteria and test methods are specified in the General Devices procedures and in individual device procedures.

<b>Comparison of IEC 60601-1 and NFPA 99-1999 Requirements†</b>			
<b>IEC 60601-1</b>	<b>Limit, <math>\mu\text{A}^{**}</math></b>	<b>NFPA 99-1999</b>	<b>Limit, <math>\mu\text{A}^{**}</math></b>
Earth Leakage Current for General Devices	NC: 500 SFC: 1,000	NA	NA
Enclosure Leakage Current	NC: 100 SFC: 500	Chassis Leakage Current (7-5.1.3.5)	NC: 300 SFC: 300
Patient Leakage Current, AC <sup>+++</sup> (Type B [Nonisolated] and BF [Isolated])	NC: 100 SFC: 500	Lead to Ground (Nonisolated Input) (7-5.1.3.6(a))	NC: 100 SFC: 100
Patient Leakage Current, AC <sup>+++</sup> (Type CF)	NC: 10 SFC: 50	Lead to Ground (Isolated Input) (7-5.1.3.6(b))	NC: 10 SFC: 50
Patient Leakage Current, Mains Voltage on Applied Part (Type CF) <sup>++++</sup>	SFC: 50	Isolation Test (Isolated Input) (7-5.1.3.6(b))	NC: 50
Patient Auxiliary Current, AC <sup>+++</sup> (Type B [Nonisolated] and BF [Isolated])	NC: 100 SFC: 500	Between Leads (Nonisolated Input) (7-5.1.3.6(d))	NC: 50 SFC: 50
Patient Auxiliary Current, AC <sup>+++</sup> (Type CF)	NC: 10 SFC: 50	Between Leads (Isolated Input) (7-5.1.3.6(e))	NC: 10 SFC: 50
† This table is simplified; additional conditions and limits are specified in the standards.			
** Explanation of abbreviations: NA—Not applicable, NC—Normal condition, SFC—Single-fault condition. For tests listed here, SFC is open ground in NFPA 99. In IEC 60601-1, a number of SFCs are specified, including open ground.			
+++ Leakage values for the DC component of the current are specified separately in IEC 60601-1.			
++++ For Type BF equipment, the patient leakage current with mains voltage applied is 5,000 $\mu\text{A}$ . Also note that the SFC for this test is the application of mains voltage.			

### **Recommendations by device category**

To delineate risks and appropriate electrical safety criteria, we define our recommendations for the different categories of electrical equipment found in healthcare facilities. Our recommended criteria are summarized in the ECRI-Recommended Leakage Current Limits table, below.

**Equipment outside the patient vicinity**

Devices used outside the patient care vicinity<sup>1</sup> (including the nurses' station and clinical laboratory) should adequately ensure staff, employee, and visitor safety. Grounding or double insulation (IEC 60601-1 Class I or II) is preferred, but household, office, or maintenance appliances that are not commonly equipped with grounding or double insulation can be used. ECRI recommends that leakage currents not exceed 500  $\mu\text{A}$ . However, this is not always practical. Leakage currents up to 3,500  $\mu\text{A}$  may be considered appropriate where no special requirements or risks exist (e.g., contact with conductive surfaces likely to become energized is unlikely; the user is unlikely to be grounded). Although such high leakage currents may be felt, or even cause an involuntary reaction, they are allowed in some standards applicable to nonmedical products.<sup>2</sup>

**Non-patient-care equipment possibly used within patient vicinity**

Housekeeping and maintenance equipment that may be used in the patient care area should be grounded (or double insulated) and have leakage currents less than 500  $\mu\text{A}$ .

**Patient equipment without patient connections**

Patient care equipment intended for use in the patient vicinity, where patient contact is likely, should be grounded or double insulated, and chassis leakage current should not exceed 300  $\mu\text{A}$  (500  $\mu\text{A}$  for facilities following IEC 60601-1).

**Patient-contact equipment**

Equipment with parts that are intentionally applied to the patient (e.g., ECG electrodes) must meet additional criteria for leakage current from these applied parts.

Some patient-contact equipment is designated as having an isolated patient connection, commonly called an isolated input. In addition to having very low (source) leakage current, a device so labeled is designed to isolate any part (e.g., an electrode) deliberately applied to the patient from electrical continuity with ground. Such isolation prevents the part from serving as a return path (sink) for ground-seeking leakage current from another device that is also in contact with the patient.

An isolated patient connection (applied part) must meet leakage current criteria and also pass an isolation test from the patient connection (electrode). The isolation test consists of applying a line or mains voltage ground-referenced potential to each patient connection and measuring the resulting current.

<sup>1</sup> In NFPA 99 1999, the patient care vicinity is the space "within a location intended for the examination and treatment of patients, extending 6 ft (1.8 m) beyond the normal location of the bed, chair, table, treadmill, or other device that supports the patient during examination and treatment. A patient care vicinity extends vertically to 7 ft 6 in (2.3 m) above the floor." In IEC 60101-1-1 the patient environment encompasses any space "in which intentional or unintentional contact can occur between Patient and parts of the system or between Patient and other parts of the system." The referenced figure provides an example area extending 1.5 m from each side of the patient support and 2.5 m above the floor.

<sup>2</sup> For example, the UL standard *Safety of Information Technology Equipment, Including Electrical Business Equipment* (UL 60950 3<sup>rd</sup> edition) allows up to 750  $\mu\text{A}$  for handheld equipment and up to 3,500  $\mu\text{A}$  for portable and stationary equipment.

**CAUTION:** Device isolation testing poses some risks to personnel. See the General Devices Procedure for appropriate test methods.

Any device that is (or may be) attached to a conductive pathway to the heart or that is applied directly to or near the heart should be of isolated design or Type CF. The conductive path may be a fluid path within a nonconductive catheter that ends near or in the heart. An invasive blood pressure monitor (e.g., one that is monitoring pulmonary artery blood pressure) is an example of such a device.

<b>ECRI-Recommended Leakage Current Limits†</b>			
<b>Type of Equipment</b>	<b>Patient-Applied Parts or Leads</b>		<b>Chassis</b>
	<b>Leakage to Ground</b>	<b>Current with Line Voltage Applied to Lead</b>	
<b>Equipment Located outside Patient Vicinity</b>	NA	NA	500 $\mu$ A
<b>Non-patient-care Equipment Possibly Used within Patient Vicinity (not intended to contact patient)</b>	NA	NA	500 $\mu$ A
<b>Patient-Care Equipment without Patient Connections</b>	NA	NA	300 $\mu$ A††
<b>Patient-Contact Equipment</b>			
<b>With Nonisolated Patient Connections</b>	100 $\mu$ A with all leads together	NA	300 $\mu$ A††
<b>With Isolated††† Patient Connections</b>	50 $\mu$ A each lead (ground open); 10 $\mu$ A each lead (ground intact)	50 $\mu$ A, each lead (ground intact)	300 $\mu$ A††
†	For line-powered, cord-connected equipment for routine healthcare facility testing under single-fault conditions.		
††	500 $\mu$ A for healthcare facilities following IEC 60601-1 rather than NFPA 99.		
†††	Type CF for healthcare facilities following IEC 60601-1 rather than NFPA 99 (see discussion under Comparison of NFPA 99 and IEC 60601 in this section).		