

IT'S ELECTRIC!

Discussing Electrical Safety in Healthcare

Ensuring electrical safety is a key responsibility of healthcare technology management personnel. ECRI Institute regularly provides guidance to members who ask us how best to manage the challenges of protecting patients and staff from electrical hazards. This article covers topics related to how leakage current limits are established and how they should be applied in special cases.

TOUCH AND LEAKAGE CURRENT LIMITS

The term leakage current refers to currents, not intended to be applied to the patient, that flow from exposed conductive portions of a device to ground (earth). These currents normally flow harmlessly through the power cord grounding conductor. However, if there is a break in the grounding path or some other failure, these currents can flow through a person in contact with the device, possibly causing injury. Leakage currents may flow from the chassis or enclosure of a device, from patient probes and electrodes to ground, or from a part of a device through the patient or operator to another part of the device.

To help protect patients and staff, standards organizations have established leakage current limits for electrically powered equipment used in the healthcare environment. These limits are designed to ensure that leakage current from such devices will not harm individuals who come into contact with them, even in the event of a grounding failure or other reasonably likely failure.

The leakage current limits established in the primary standards that apply to equipment used in healthcare facilities — the National Fire Protection Association's NFPA 99 and the International Electrotechnical Commission's IEC 60601-1 — are based on limited experimentation in humans and the results of similar tests on animals. These studies examine the level of current flowing through the heart required to cause

ventricular fibrillation. The greatest risk exists with conductive intracardiac catheters. The allowable limit for leakage current through an intracardiac connector is 10 μ A, which is considered acceptably safe by NFPA and IEC.

Higher currents are allowed under certain fault conditions, such as when the line cord grounding conductor is open. Although exposure to these currents may pose greater risk to the patient, there is a lower risk that they will be applied to the patient in such cases. Therefore, the overall risk of ventricular fibrillation is kept low.

The widely accepted limit for touch current — the term newer standards use for leakage currents from the equipment case or enclosure of patient care medical equipment — is 500 μ A. Because these currents are unlikely to flow directly through the heart, they do not pose a significant risk to patients or users — though some patients or users may feel a small shock or tingle when these currents flow through their skin.

Perhaps the most important thing for healthcare facilities to understand when assessing leakage currents is that leakage current limits are based on very limited data and risk approximations. Therefore, small deviations above acceptable limits do not suddenly make a device unsafe.

In addition to leakage currents, patients are exposed to other nontherapeutic currents from devices. In most cases, these intentional currents pose less risk to the patient than leakage currents: Whereas



leakage currents often have frequencies of 50 or 60, intentional nontherapeutic currents have higher frequencies, to which the heart is less susceptible. The standards account for reduced concern at higher frequencies by allowing higher currents at these frequencies.

APPLYING LEAKAGE CURRENT LIMITS IN SPECIAL CASES

PERMANENTLY WIRED EQUIPMENT

For both patient-contact and non-patient-contact hardwired equipment, leakage current, before any grounds are connected, should not exceed 10 mA (10,000 μ A) measured with power conductors connected with correct polarity. Before 2012, 5 mA was required in U.S. standards. The high reliability of a hardwired ground justifies the higher limit. According to IEC 62353, if protective measures have been taken and regular testing performed in compliance with IEC 60364-7-710:2002, periodic leakage current measurements are not necessary.

EQUIPMENT IN CLINICAL LABS AND OTHER LOCATIONS OUTSIDE THE PATIENT VICINITY

ECRI Institute recommends that leakage currents up to 3,500 μA (with the ground open) be considered appropriate for equipment that will not be used in the patient care vicinity. Although such high leakage currents may be felt by an individual exposed to them, or may even cause an involuntary reaction, they are allowed in some standards that apply to nonmedical products or to clinical laboratory equipment or other products not used in the patient care vicinity; we base our recommended limit, in part, on these standards. The 3,500 μA limit would apply to devices such as centrifuges and laboratory analyzers as well as equipment in diagnostic imaging workstations, nurses' workstations, and monitoring central stations. However, if the device may be brought into the patient care vicinity, its leakage current (with the ground open) should be 500 μA or less.

The IEC 60601-1 and IEC 62353 standards do not apply to devices outside the patient environment.

DEVICES WITH REDUNDANT GROUNDING

Some devices have redundant grounding when they are installed; examples include bedside monitors connected to central station displays and whirlpool bath turbines grounded through the associated plumbing. Verify that these devices meet appropriate touch current requirements before installation or connection to ground during acceptance inspection.

MULTIPLE DEVICES ON ONE POWER CORD

In some instances, multiple devices may be powered through a single line cord, because, for example, accessory outlets of one device are used or because multiple devices are plugged into a relocatable power tap (RPT). The touch current of such an assembly of devices will depend on all the devices that are powered by the single line cord plugged into the wall power outlet. If these devices are

normally used in this configuration, touch current measurements should be made using the single line cord, and the entire assembly of devices should meet the appropriate limit (i.e., 500 μA).

Alternatively, the assembly can be powered by an isolation transformer to limit total touch current regardless of which devices are plugged in.

DEVICES WITH NO EXPOSED CONDUCTIVE SURFACES

ECRI Institute does not recommend making touch current measurements of devices with no exposed conductive surfaces. Such devices should ideally be listed as double insulated. If it is necessary to verify touch current from such a device, do so by placing a 10×20 cm (3.9×7.8 inch) piece of bare metal foil in contact with the device and then measuring "chassis" current from the foil as it is moved along the surface of the enclosure.

DEVICES WITH HIGH TOUCH CURRENT

While most medical devices on the market meet appropriate electrical safety standards, some older devices or specialized equipment may fail to meet healthcare facility touch current criteria. When there is no equivalent alternative, or when such a device offers unique, highly desirable features, the device should not be rejected simply because of high touch current. Failure to meet leakage current limits does not necessitate discontinuing use of older equipment, provided that the equipment is otherwise still functional and reliable. The resulting small increase in safety achieved by newer equipment would not justify the substantial cost of replacement. In fact, by requiring the diversion of funds slated for other areas and newer technologies, replacing such equipment may even prove counterproductive to the delivery of quality healthcare.

Consider each piece of equipment on its own merits, keeping in mind the extent to which the device exceeds the touch current limit and the steps that can be taken to minimize the possibility that leakage current will flow through patients or personnel. Remember that touch current

does not normally contact patients or personnel — it drains off harmlessly through grounding. Touch current limits are a backup or redundant protective measure. These limits were established so that if the grounding of a device should fail (such a failure is usually not evident), injury would be unlikely if a person touched the chassis of that device while in contact with grounded metal. Safety is primarily based on having good grounding (or double insulation).

If a device has always had a touch current just slightly above the limit but performs as designed, it should be used without hesitation. ECRI Institute recommends that equipment that exceeds the touch current requirements by just 10 percent or 20 percent be used without hesitation or modification. This will not pose a hazard to patients or staff. Be sure that it has a good-quality plug and that users are aware of the need for grounding. Consider whether periodic testing of grounding resistance should be performed.

Consistent with NFPA 99, Annex A, when a device has excessive leakage current, use of a small isolation transformer to bring device leakage current to an acceptable level or use of redundant grounding of the device (most practical for equipment that is kept in one spot) is permissible. If installing an isolation transformer, use one with an adequate current capacity for the intended purpose. Relatively inexpensive 1:1 transformers are available and will meet most facilities' needs; some transformers offer a greater degree of isolation than is necessary and are very expensive and heavy. ⚡

THIS ARTICLE is an excerpt from a Health Devices article posted on ECRI Institute's membership websites on November 5, 2014. The full article includes more guidance on double insulation, ground-fault circuit interrupters, and isolation. For guidance related to hospital electrical safety issues, to purchase the full article, or to learn more about membership programs, visit www.ecri.org, contact clientservices@ecri.org, or call (610) 825-6000, ext. 5891.