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ELECTRICAL SAFETY

Walter H. Olson

Medical technology has substantially improved health care in all medical specialties and has reduced morbidity and mortality for critically ill patients. Nevertheless, the increased complexity of medical devices and their utilization in more procedures result in about 10,000 device-related patient injuries in the United States each year. Most of these injuries are attributable to improper use of a device as a result of inadequate training and lack of experience. Medical personnel rarely read user manuals until a problem has occurred. Furthermore, medical devices eventually fail, so engineers must develop fail-safe designs.

The safe design and the safe use of medical instrumentation are broad subjects that involve nearly all medical procedures, every conceivable form of energy, and the familiar concept that everything that *can* go wrong eventually *will* go wrong. Medical procedures usually expose the patient to more hazards than the typical home or workplace, because in medical environments the skin and mucous membranes are frequently penetrated or altered, and because there are many sources of potentially hazardous substances and energy forms that could injure either the patient or the medical staff. These sources include fire, air, earth, water, chemicals, drugs, microorganisms, vermin, waste, sound, electricity, natural and unnatural disasters, surroundings, gravity, mechanical stress, and people responsible for acts of omission and commission, not to mention radiation from x rays, ultrasound, magnets, ultraviolet light, microwaves, and lasers (Dyro, 2006). Although this chapter focuses on electrical safety, it is important to recognize that there are also many other aspects of medical instrumentation safety (Charney *et al.*, 1990, Fagerhaugh *et al.*, 1987, Geddes, 1995).

In the 1980s, many minimum performance standards were written for most medical devices. Issues for the 1990s include inappropriate use of electrical connectors, sterilization efficacy, medical waste, and laser safety.

In this final chapter we focus on electrical safety and discuss the physiological effects of electric current, shock hazards, methods of protection, electrical safety standards, and electrical-safety testing procedures. Our objectives are to understand the possible hazards and to learn how safety features can be incorporated into the design of medical instruments we have studied in previous chapters.

14.1 PHYSIOLOGICAL EFFECTS OF ELECTRICITY

For a physiological effect to occur, the body must become part of an electric circuit. Current must enter the body at one point and leave at some other point. The magnitude of the current is equal to the applied voltage divided by the sum of the series impedances of the body tissues and the two interfaces at the entry points. The largest impedance is often the skin resistance at the contact surface. Three phenomena can occur when electric current flows through biological tissue: (1) electric stimulation of excitable tissue (nerve and muscle), (2) resistive heating of tissue, and (3) electrochemical burns and tissue damage for direct current and very high voltages.

Let us now discuss the psychophysical and physiological effects that occur in humans as the magnitude of applied electric current progressively increases. The chart in Figure 14.1 shows the approximate range of currents needed to produce each effect when 60 Hz current is applied for 1 to 3 s via AWG No. 8 copper wires that a 70 kg human holds in each hand. Then, in the section that follows, we will examine the effect of each of these conditions (weight of the individual and so on).

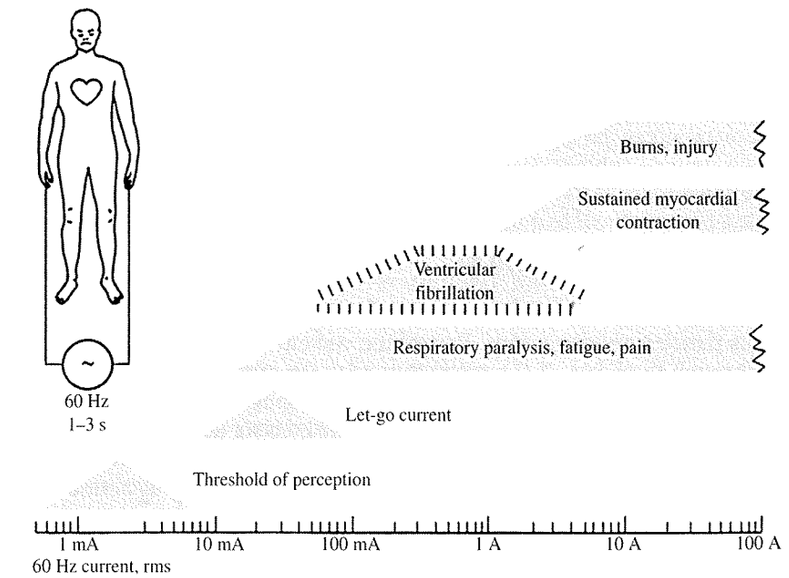


Figure 14.1 Physiological effects of electricity Threshold or estimated mean values are given for each effect in a 70 kg human for a 1 to 3 s exposure to 60 Hz current applied via copper wires grasped by the hands.

THRESHOLD OF PERCEPTION

For the conditions just stated, when the local current density is large enough to excite nerve endings in the skin, the subject feels a tingling sensation. Current at the *threshold of perception* is the minimal current that an individual can detect. This threshold varies considerably among individuals and with the measurement conditions. When someone with moistened hands grasps small copper wires, the lowest thresholds are about 0.5 mA at 60 Hz. Thresholds for dc current range from 2 to 10 mA, and slight warming of the skin is perceived.

LET-GO CURRENT

For higher levels of current, nerves and muscles are vigorously stimulated, and pain and fatigue eventually result. Involuntary contractions of muscles or reflex withdrawals by a subject experiencing any current above threshold may cause secondary physical injuries, such as might result from falling off a ladder. As the current increases further, the involuntary contractions of the muscles can prevent the subject from voluntarily withdrawing. The *let-go current* is defined as the maximal current at which the subject can withdraw voluntarily. The minimal threshold for the let-go current is 6 mA.

RESPIRATORY PARALYSIS, PAIN, AND FATIGUE

Still higher currents cause involuntary contraction of respiratory muscles severe enough to bring about asphyxiation if the current is not interrupted. During let-go experiments, respiratory arrest has been observed at 18 to 22 mA (Dalziel, 1973). Strong involuntary contractions of the muscles and stimulation of the nerves can be painful and cause fatigue if there is long exposure. (Today's human-subject-research committees probably would not approve these experiments.)

VENTRICULAR FIBRILLATION

The heart is susceptible to electric current in a special way that makes some currents particularly dangerous. Part of the current passing through the chest flows through the heart. If the magnitude of the current is sufficient to excite only part of the heart muscle, then the normal propagation of electric activity in the heart muscle is disrupted. If the cardiac electric activity is sufficiently disrupted, the heart rate can rise to 300 beats/min as re-entrant wave fronts of depolarization randomly sweep over the ventricles. The pumping action of the heart ceases and death occurs within minutes.

This rapid, disorganized cardiac rhythm is called *ventricular fibrillation*, and unfortunately, it does not stop when the current that triggered it is removed. Ventricular fibrillation is the major cause of death due to electric shock. The threshold for ventricular fibrillation for an average-sized human varies from about 75 to 400 mA. Normal rhythmic activity returns only if a brief high-current pulse from a defibrillator is applied to depolarize all the cells of the heart muscle simultaneously. After all the cells relax together, a normal rhythm usually returns. In the United States, approximately 1000 deaths per year occur in accidents that involve cord-connected appliances.

SUSTAINED MYOCARDIAL CONTRACTION

When the current is high enough, the entire heart muscle contracts. Although the heart stops beating while the current is applied, a normal rhythm ensues when the current is interrupted, just as in defibrillation. Data from ac-defibrillation experiments on animals show that minimal currents for complete myocardial contraction range from 1 to 6 A. No irreversible damage to the heart tissue is known to result from brief applications of these currents (Roy *et al.*, 1984).

BURNS AND PHYSICAL INJURY

Very little is known about the effects of currents in excess of 10 A, particularly for currents of short duration. Resistive heating causes burns, usually on the skin at the entry points, because skin resistance is high. Voltages greater than 240 V can puncture the skin. The brain and other nervous tissue lose all functional excitability when high currents pass through them. Furthermore, excessive currents may stimulate muscular contractions that are strong enough to pull the muscle attachment away from the bone (Lee *et al.*, 1992).

14.2 IMPORTANT SUSCEPTIBILITY PARAMETERS

The physiological effects previously described are for an average 70 kg human and for 60 Hz current applied for 1 to 3 s to moistened hands grasping a No. 8 copper wire. The current needed to produce each effect depends on all these conditions, as explained below. Safety considerations dictate thinking in terms of minimal rather than average values for each condition.

THRESHOLD AND LET-GO VARIABILITY

Figure 14.2 shows the variability of the threshold of perception and the let-go current for men and women (Dalziel, 1973). On this plot of percentile rank versus rms current in milliamperes, the data are close to the straight lines shown, so a Gaussian distribution may be assumed. For men, the mean value for the threshold of perception is 1.1 mA; for women, the estimated mean is 0.7 mA. The minimal threshold of perception is 500 μA. When the current was applied to ECG gel electrodes, the threshold of perception averages only 83 μA with a range of 30 to 200 μA (Tan and Johnson, 1990). Recent data for surface electrical stimulation of skeletal muscle showed that sensory threshold

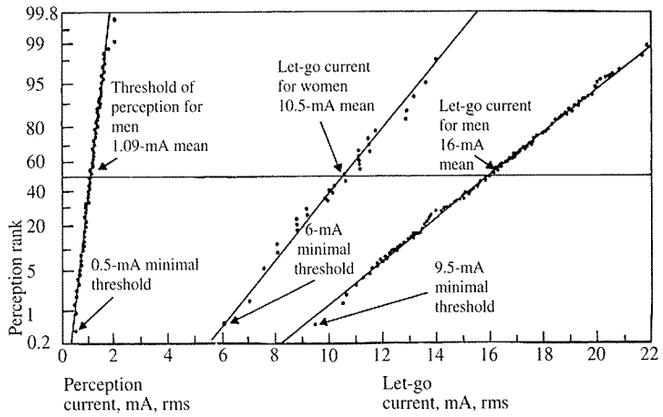


Figure 14.2 Distributions of perception thresholds and let-go currents These data depend on surface area of contact (moistened hand grasping AWG No. 8 copper wire). (Replotted from C. F. Dalziel, "Electric Shock," *Advances in Biomedical Engineering*, edited by J. H. U. Brown and J. F. Dickson III, 1973, 3, 223–248.)

was 43% ($p < 0.001$) lower in women and supramotor threshold was 17% ($p < 0.01$) less for women (Maffiuletti *et al.*, 2008).

Let-go currents also appear to follow Gaussian distributions, with mean let-go currents of 16 mA for men and 10.5 mA for women. The minimal threshold let-go current is 9.5 mA for men and 6 mA for women. Note that the range of variability for let-go current is much greater than the range for threshold-of-perception current.

FREQUENCY

Figure 14.3 shows a plot of let-go current versus frequency of the current. Unfortunately, the minimal let-go currents occur for commercial power-line frequencies of 50 to 60 Hz. For frequencies below 10 Hz, let-go currents rise, probably because the muscles can partially relax during part of each cycle. And at frequencies above several hundred hertz, the let-go currents rise again.

DURATION

To estimate the ventricular fibrillation (VF) risk of electromuscular incapacitation devices (EMDs), it is important to understand the excitation behavior of myocardial cells. Geddes and Baker (1989) presented the cell membrane excitation model by a lumped parallel *RC* circuit that represents the resistance and capacitance of the cell membrane. This model determines the cell excitation thresholds that exceed about 20 mV for varying rectangular pulse durations d by assigning the rheobase currents I_r (for very long pulse durations) and cell

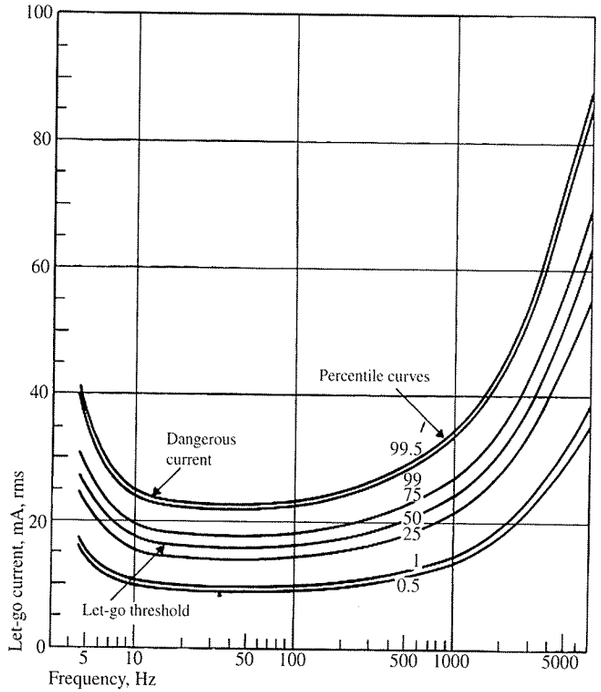


Figure 14.3 Let-go current versus frequency Percentile values indicate variability of let-go current among individuals. Let-go currents for women are about two-thirds the values for men. (Reproduced, with permission, from C. F. Dalziel, "Electric Shock," *Advances in Biomedical Engineering*, edited by J. H. U. Brown and J. F. Dickson III, 1973, 3, 223–248.)

membrane time constant $\tau = RC$. Figure 14.4 shows that for short durations the stimulation current threshold I_d is inversely related to the pulse duration d by the well-known strength–duration equation

$$I_d = \frac{I_r}{1 - e^{-d/\tau}} \tag{14.1}$$

EXAMPLE 14.1 A cardiac pacemaker company wants to minimize pacing duration d while keeping current at 3 times I_r. Assume cardiac membrane $\tau = 2$ ms, and calculate d.

ANSWER Use (14.1): $0.33 = 1 - e^{-d/0.002}$, $0.67 = e^{-d/0.002}$, $\ln 0.67 = -d/0.002 = -0.4$, $d = 0.8$ ms.

A single electric stimulus pulse can induce VF if it is delivered during the vulnerable period of cardiac repolarization that corresponds to the T wave on

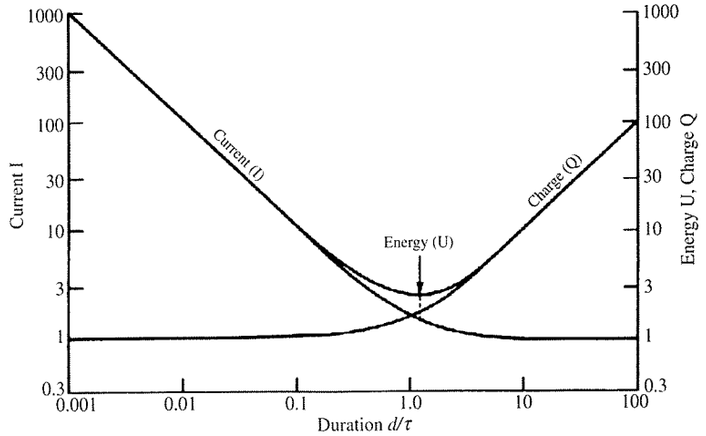


Figure 14.4 Normalized analytical strength–duration curve for current I, charge Q, and energy U. The x axis shows the normalized duration of d/τ. (From Geddes, L. A., and L. E. Baker, *Principles of Applied Biomedical Instrumentation*, 3rd ed. New York: John Wiley & Sons, 1989).

the ECG. For large-amplitude electric transients less than 100 μs in duration applied directly to the heart, the stimulation threshold approaches a constant charge transfer density of 3.5 $\mu C \cdot cm^{-2}$. For normal hearts, the ratio of the fibrillation stimulation threshold to the single-beat stimulation threshold is 20:1 to 30:1 for electrodes on the heart and 10:1 to 15:1 for chest surface electrodes (Geddes *et al.*, 1986). For 60 Hz current applied to the extremities, the fibrillation threshold increases sharply for shocks that last less than about 1 s, as shown in Figure 14.5. Shocks must last long enough to take place during the vulnerable period that occurs during the T wave in each cardiac cycle (Reilly, 1998). For the 100 μs pulses of electric fences (IEC, 2006) and Tasers, Figure 14.4 shows that much higher currents are required for excitation.

BODY WEIGHT

Several studies using animals of various sizes have shown that the fibrillation threshold increases with body weight. Fibrillating current increases from 50 mA rms for 6 kg dogs to 130 mA rms for 24 kg dogs. These findings deserve more study, because they are used to extrapolate fibrillating currents for humans.

POINTS OF ENTRY

When current is applied at two points on the surface of the body, only a small fraction of the total current flows through the heart, as shown in Figure 14.6(a). These large, externally applied currents are called *macroshocks*.

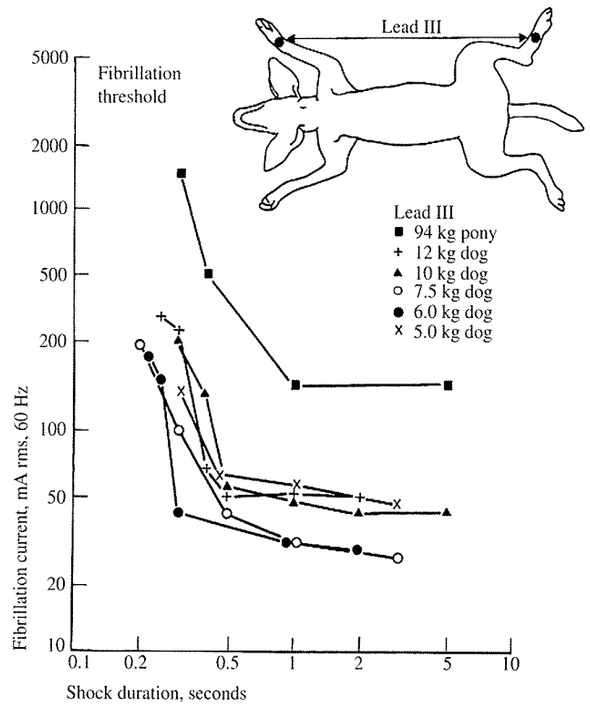


Figure 14.5 Fibrillation current versus shock duration. Thresholds for VF in animals for 60 Hz ac current. Duration of current (0.2 to 5 s) and weight of animal body were varied. (From L. A. Geddes, *IEEE Trans. Biomed. Eng.*, 1973, 20, 465–468. Copyright 1973 by the Institute of Electrical and Electronics Engineers. Reproduced with permission.)

The magnitude of current needed to fibrillate the heart is far greater when the current is applied on the surface of the body than it would be if the current were applied directly to the heart. The importance of the location of the two macroshock entry points is often overlooked. If the two points are both on the same extremity, the risk of fibrillation is small, even for high currents. For dogs, the current needed for fibrillation is greater for ECG lead I (LA–RA) electrodes than for ECG leads II and III (LL–RA and LL–LA) (Geddes, 1973). The protection afforded by the skin resistance (15 kΩ to 1 MΩ for 1 cm^2) is eliminated by many medical procedures that require insertion of conductive devices into natural openings, skin incisions, skin abrasion, or electrode gel.

If the skin resistance is bypassed, less voltage is required to produce sufficient current for each physiological effect.

Patients are particularly vulnerable to electric shock when invasive devices are placed in direct contact with cardiac muscle. If a device provides a conductive path to the heart that is insulated except at the heart, then very

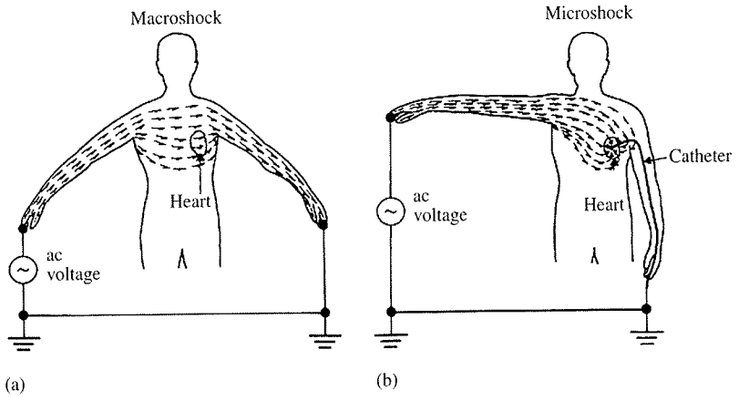


Figure 14.6 Effect of entry points on current distribution (a) *Macroshock:* Externally applied current spreads throughout the body. (b) *Microshock:* All the current applied through an intracardiac catheter flows through the heart. (From F. J. Weibell, "Electrical Safety in the Hospital," *Annals of Biomedical Engineering*, 1974, 2, 126–148.)

small currents called *microshocks* can induce VF. As Figure 14.6(b) shows, all the current flowing through such a conductive device flows through the heart. The current density at the point of contact can be quite high, and fibrillation in dogs can be induced by total currents as low as 20 μA. [See Roy (1980).] Application of 60 Hz ac for 5 s test periods to a ventricular pacing catheter during implantable cardioverter–defibrillator implant testing in 40 patients showed intermittent capture with a minimum current of 20 μA, continuous capture with hemodynamic collapse with a minimum current of 32 μA and VF persisting after ac termination with a minimum current of 49 μA (Figure 14.7) (Swerdlow *et al.*, 1999.) The other connection can be at any point on the body. The widely accepted safety limit to prevent microshocks is 10 μA.

14.3 DISTRIBUTION OF ELECTRIC POWER

Electric power is needed in health-care facilities not only for the operation of medical instruments but also for lighting, maintenance appliances, patient conveniences (such as television, hair curlers, and electric toothbrushes), clocks, nurse call buttons, and an endless list of other electric devices. A first step in providing electrical safety is to control the availability of electric power and the grounds in the patients' environment. This section is concerned with methods for safe distribution of power in health-care facilities. Then, in the sections that follow, we will discuss various macroshock and microshock hazards (Klein, 1996).

A simplified diagram of an electric-power-distribution system is shown in Figure 14.8. High voltage (4800 V) enters the building—usually via

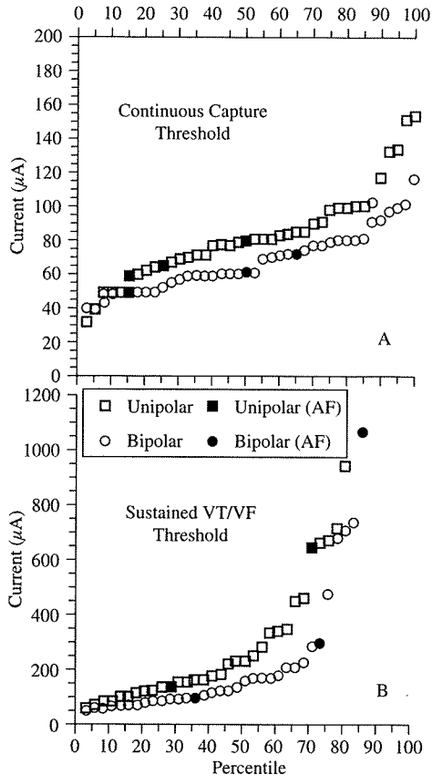


Figure 14.7 Percentile plot of thresholds for continuous capture and VF (or sustained VT). Cumulative percent of patients is shown on abscissa and root-mean-square ac current (in μA) on ordinate. Squares denote unipolar data; circles denote bipolar data. Solid symbols identify data from patients in whom the only clinical arrhythmia was atrial fibrillation (AF). (*Top*) Thresholds for continuous capture. Current strength of 50 μA caused continuous capture in five patients (12%) with unipolar ac and in nine (22%) with bipolar ($P = 0.49$). (*Bottom*) Thresholds for sustained VT/VF. These plots do not reach 100% because sustained-VT/VF thresholds exceeded maximum output of stimulator in six patients (15%) with bipolar ac and eight (20%) with unipolar ac. [From Swerdlow, C. D., W. H. Olson, M. E. O' Connor, D. M. Gallik, R. A. Malkin, M. Laks, "Cardiovascular collapse caused by electrocardiographically silent 60-Hz intracardiac leakage current – Implications for electrical safety."*Circulation.*, 1999, 99, 2559–2564.]

underground cables. The secondary of a step-down transformer develops 240 V. This secondary has a grounded center tap to provide two 120 V circuits between ground and each side of the secondary winding. Some heavy-duty devices (such as air conditioners, electric dryers, and x-ray machines) that require 240 V are placed

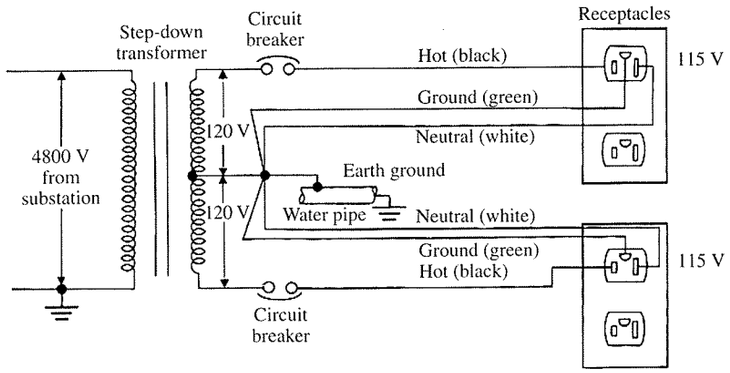


Figure 14.8 Simplified electric-power distribution for 115 V circuits. Power frequency is 60 Hz.

across the entire secondary winding; electricians do this by making connections to the two ungrounded terminals. Ordinary wall receptacles and lights operate on 120 V, obtained from either one of the ungrounded hot (black) transformer terminals and the neutral (white) grounded center tap. In addition, for health-care facilities, the National Electrical Code (NEC) for 2006 requires that all receptacles be "Hospital Grade" and be grounded by a separate insulated (green) copper conductor (Article 517-13). An additional redundant ground path through the metal raceway, conduit, or a separate cable is required for patient-care areas. Some older installations used metal conduit as the only ground conductor. Conduit grounds are generally unsatisfactory, because corrosion and loose conduit connections make them unreliable.

PATIENTS' ELECTRICAL ENVIRONMENT

Of course, a shock hazard exists between the two conductors supplying either a 240 V or a 120 V appliance. Because the neutral wire on a 120 V circuit is connected to ground, a connection between the hot conductor and *any* grounded object poses a shock hazard. Microshocks can occur if sufficient potentials exist between exposed conductive surfaces in the patients' environment. The following maximal potentials permitted between any two exposed conductive surfaces in the vicinity of the patient are specified by the 2006 NEC, Article 517-15:

1. General-care areas, 500 mV under normal operation
2. Critical-care areas, 40 mV under normal operation

In general-care areas, patients have only incidental contact with electric devices. For critical-care areas, hospital patients are intentionally exposed to electric devices, and insulation of externalized cardiac conductors from

conductive surfaces is required. In critical-care areas, all exposed conductive surfaces in the vicinity of the patient must be grounded at a single patient-grounding point (Section 14.8). Also, periodic testing for continuity between the patient ground and all grounded surfaces is required.

Each patient-bed location in general-care areas must have at least four single or two duplex receptacles. Each receptacle must be grounded. At least two branch circuits with separate automatic overcurrent devices must supply the location of each patient bed. For critical-care areas, at least six single or three duplex receptacles are required for each location of a patient bed. Two branch circuits are also required, at least one being an individual branch circuit from a single panelboard. A patient-equipment grounding point (Section 14.8) is permitted for critical-care areas. For details, see NEC 70–2006, Article 517-19.

ISOLATED-POWER SYSTEMS

Even installing a good separate grounding system for each patient cannot prevent possibly hazardous voltages that can result from ground faults. A *ground fault* is a short circuit between the hot conductor and ground that injects large currents into the grounding system. These high-current ground faults are rare, and usually the circuit breakers open quickly. If the center tap of the step-down transformer were not grounded, then very little current could flow, even if a short circuit to ground developed. So long as both power conductors are isolated from ground, a single ground fault will not allow the large currents that cause hazardous potentials between conductive surfaces.

Isolation of both conductors from ground is commonly achieved with an *isolation transformer*. A typical isolated-power system is shown in Figure 14.9. In an isolated system such as this, if a single ground fault from either conductor

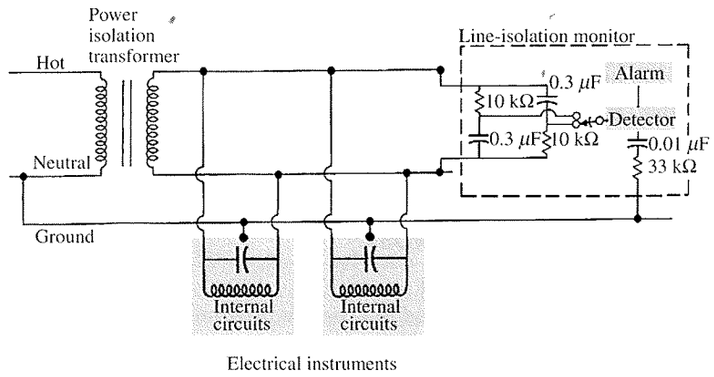


Figure 14.9 Power-isolation-transformer system with a line-isolation monitor to detect ground faults.

to ground occurs, the system simply reverts to a normal grounded system. A second fault from the other conductor to ground is then required to get large currents in the grounds.

A continually operating *line-isolation monitor* (LIM) (also called a *dynamic ground detector*) must be used with isolation transformers to detect the occurrence of the first fault from either conductor to ground. This monitor alternately measures the total possible resistive and capacitive leakage current *(total hazard current)* that would flow through a low impedance *if it were connected* between either isolated conductor and ground. When the total hazard current exceeds 3.7 to 5.0 mA for normal line voltage, a red light and an audible alarm are activated. The LIM itself has a monitor hazard current of 1 mA. This makes the allowed fault total hazard current for all appliances served by the transformer somewhat less than 5 mA.

The kinds of corrective action that should be taken when the alarm goes off must be explained to medical personnel so that they do not overreact. The periodic switching in some line-isolation monitors produces transients that can interfere with monitoring of low-level physiological signals (ECG and EEG) and give erroneous heart rates. Or it can trigger synchronized defibrillators and aortic-balloon assist pumps during the wrong phase of the patient's heart cycle. Some LIMs avoid these problems by using continuous two-channel circuitry instead of measuring the total hazard current by switching between each line and ground.

Isolated-power systems were originally introduced to prevent sparks from coming into contact with flammable anesthetics such as ether. The NEC requires isolated-power systems only in those operating rooms and other locations where flammable anesthetics are used or stored.

EMERGENCY-POWER SYSTEMS

Article 517 of the 2006 National Electrical Code specifies the emergency electric system required for heath-care facilities. An emergency system is required that automatically restores power to specified areas within 10 s after interruption of the normal source. The emergency system may consist of two parts: (1) the life-safety branch (illumination, alarm, and alerting equipment) and (2) the critical branch (lighting and receptacles in critical patient-care areas). For additional details, see Article 517-25, 30–35.

14.4 MACROSHOCK HAZARDS

The high resistance of dry skin and the spatial distribution of current throughout the body when a person receives an electric shock are two factors that reduce the danger of VF. Furthermore, electric equipment is designed to minimize the possibility of humans coming into contact with dangerous voltages.

SKIN AND BODY RESISTANCE

The resistance of the skin limits the current that can flow through a person's body when that person comes into contact with a source of voltage. The resistance of the skin varies widely with the amount of water and natural oil present. It is inversely proportional to the area of contact.

Most of the resistance of the skin is in the outer, horny layer of the epidermis. For 1 cm^2 of electric contact with dry, intact skin, resistance may range from 15 kΩ to almost 1 MΩ, depending on the part of the body and the moisture or sweat present. If skin is wet or broken, resistance drops to as low as 1% of the value for dry skin. By contrast, the internal resistance of the body is about 200 Ω for each limb and about 100 Ω for the trunk. Thus internal body resistance between any two limbs is about 500 Ω. These values are probably higher for obese patients, because the specific resistivity of fat is high. Actually, the distribution of current in various tissues in the body is poorly understood.

Any medical procedure that reduces or eliminates the resistance of the skin increases possible current flow and makes the patient more vulnerable to macroshocks. For example, biopotential electrode gel reduces skin resistance. Electronic thermometers placed in the mouth or rectum also bypass the skin resistance, as do intravenous catheters containing fluid that can act as a conductor. Thus patients in a medical-care facility are much more susceptible to macroshock than the general population.

ELECTRIC FAULTS IN EQUIPMENT

All electric devices are of course designed to minimize exposure of humans to hazardous voltages. However, many devices have a metal chassis and cabinet that medical personnel and patients may touch. If the chassis and cabinet are not grounded, as shown in Figure 14.10(a), then an insulation failure or shorted component between the black hot power lead and the chassis results in a 115 V potential between the chassis and any grounded object. If a person simultaneously touches the chassis and any grounded object, a macroshock results.

The chassis and cabinet can be grounded via a third green wire in the power cord and electric system, as shown in Figure 14.10(b). This ground wire is connected to the neutral wire and ground at the power-distribution panel. Then, when a fault occurs between the hot conductor and the chassis, the current flows safely to ground on the green conductor. If the ground-wire resistance is very low, the voltage between the chassis and other grounded objects is negligible. If enough current flows through the ground wire to open the circuit breaker, this will call people's attention to the fault.

Note that direct faults between the hot conductor (or any high voltage in the device) and ground are not common. Little or no current flows through the ground conductor during normal operation of electric devices. The ground conductor is not needed for protection against macroshock until a hazardous

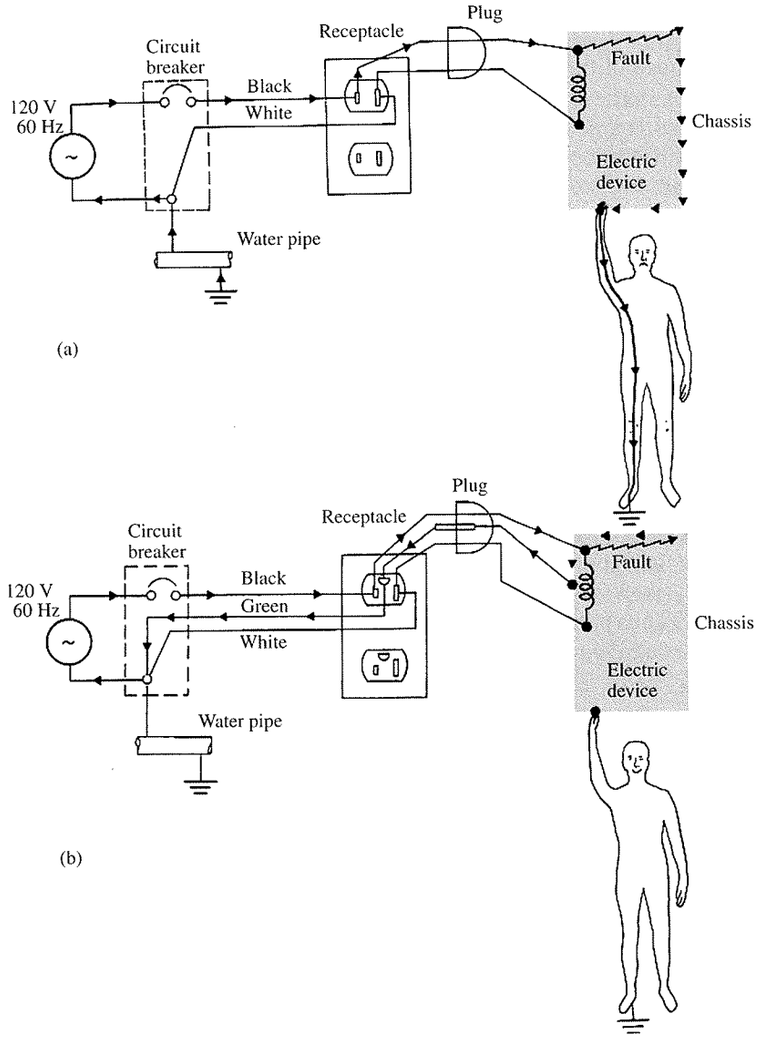


Figure 14.10 Macroshock due to a ground fault from hot line to equipment cases for (a) ungrounded cases and (b) grounded chassis.

fault develops. Thus a broken ground wire or a poor connection of a receptacle ground is not detected during normal operation of the device. For this reason, continuity of the ground wire in the device and the receptacle must be tested periodically.

Faults inside electric devices may result from failures of insulation, shorted components, or mechanical failures that cause shorts. Power cords are

particularly susceptible to strain and physical abuse, as are plugs and receptacles. Ironically, it is possible for a device's chassis and cabinet to become hot because a ground wire is in the power cord. If the ground wire is open anywhere between the power cord and ground, then a frayed cord could permit contact between the hot conductor and the broken ground wire leading to the chassis. Often, macroshock accidents result from carelessness and failure to correct known deficiencies in the power-distribution system and in electric devices.

Fluids—such as blood, urine, intravenous solutions, and even baby formulas—can conduct enough electricity to cause temporary short circuits if they are accidentally spilled into normally safe equipment. This hazard is particularly acute in hospital areas that are subject to wet conditions, such as hemodialysis and physical therapy areas. The cabinets of many electric devices have holes and vents for cooling that provide access for spilled conductive fluids. The mechanical design of devices should protect patient electric connections from this hazard.

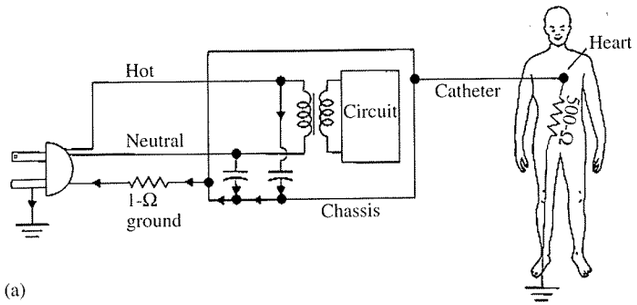
14.5 MICROSHOCK HAZARDS

Microshock accidents in patients who have direct electric connections to the heart are usually caused by circumstances unrelated to macroshock hazards. Microshocks generally result from *leakage currents* in line-operated equipment or from differences in voltage between grounded conductive surfaces due to large currents in the grounding system. The microshock current can flow either into or out of the electric connection to the heart.

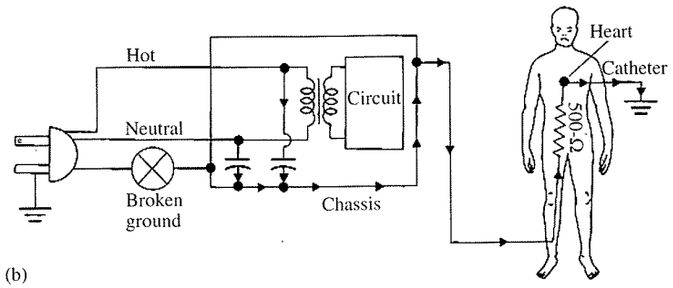
LEAKAGE CURRENTS

Small currents (usually on the order of microamperes) that inevitably flow between any adjacent insulated conductors that are at different potentials are called *leakage currents*. Although most of the leakage current in line-operated equipment flows through the stray capacitance between the two conductors, some resistive leakage current flows through insulation, dust, and moisture.

The most important source of leakage currents is the currents that flow from all conductors in the electric device to lead wires connected either to the chassis or to the patient. Leakage current flowing to the chassis flows safely to ground if a low-resistance ground wire is available, as shown in Figure 14.11(a). If the ground wire is broken, then the chassis potential rises above ground, and a patient who touches the chassis *and* has a grounded electric connection to the heart may receive a microshock [Figure 14.11(b)]. If there is a connection from the chassis to the patient's heart *and* a connection to ground anywhere on the body, this could also cause a microshock [Figure 14.11(c)].



(a)



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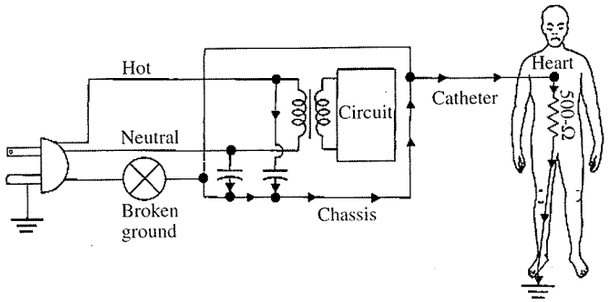


(c)

Figure 14.11 Microshock leakage-current pathways Assume 100 μA of leakage current from the power line to the instrument chassis, (a) intact ground; 99.8 μA flows through the ground, (b) broken ground; 100 μA flows through the heart, (c) broken ground; and 100 μA flows through the heart in the opposite direction.

CONDUCTIVE SURFACES

The source that produces the microshock current need not be leakage current from line-operated equipment. Small potentials between any two conductive surfaces near the patient can cause a microshock if either surface makes

contact with the heart and the other surface contacts any other part of the body. An example is given later in this section.

CONDUCTIVE PATHS TO THE HEART

Specific types of electric connections to the heart can be identified. The following clinical devices make patients susceptible to microshock.

1. Epicardial or endocardial electrodes of externalized temporary cardiac pacemakers
2. Electrodes for intracardiac electrogram (EGM) measuring and stimulation devices
3. Liquid-filled catheters placed in the heart to
   - **a.** Measure blood pressure
   - **b.** Withdraw blood samples
   - **c.** Inject substances such as dye or drugs into the heart

It should be emphasized that a patient is in danger of microshock only when there is some electric connection to the heart. The internal resistance of liquid-filled catheters is much greater (50 kΩ to 1 MΩ) than the resistance of metallic conductors in pacemaker and EGM electrode leads. Internal resistance of the body to microshock is about 300 Ω, and the resistance of the skin can be quite variable.

In dogs, the surface area of the intracardiac electrode is an important determinant of minimal fibrillating current (Roy *et al.*, 1980). Figure 14.12 shows that as catheter electrodes get smaller, so does the total current needed to fibrillate. This means that current density at the tip of the intracardiac electrode is the important microshock parameter. Smaller catheter electrodes may have larger internal resistance.

EXAMPLE 14.2 From Figure 14.1, find the current required for arm-to-arm VF. Assume that all this current passes through the area of the heart (about 10×10 cm). Calculate the current density through the heart. How does this compare with the lowest value current density from Figure 14.12?

ANSWER Figure 14.1 shows minimal current for VF by macroshock of 75 mA. For 10×10 cm cross-sectional area, the current density $J = 75{,}000\,\mu\text{A}/10{,}000\,\text{mm}^2 = 7.5\,\mu\text{A/mm}^2$. Figure 14.12 shows for 90 mm^2 a current for VF of 1000 μA, or $J = 1000\,\mu\text{A}/90\,\text{mm}^2 = 11.1\,\mu\text{A/mm}^2$. This comparison supports the view that macroshock and microshock cause VF by the same mechanism.

Microshock via Ground Potential Differences An example of microshock illustrates the need for a single reference ground point of each patient in

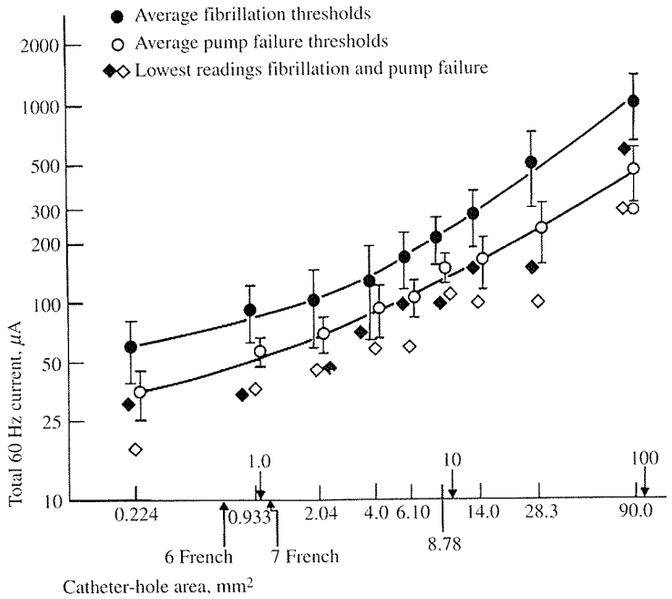
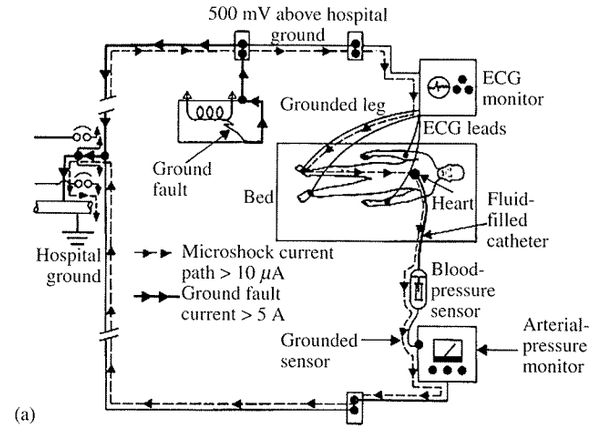


Figure 14.12 Thresholds of VF and pump failure versus catheter area in dogs. (From O. Z. Roy, J. R. Scott, and G. C. Park, "Ventricular Fibrillation and Pump Failure Thresholds Versus Electrode Area," *IEEE Transactions on Biomedical Engineering*, 1976, 23, 45–48. Reprinted with permission.)

critical-care areas and the need for a 40 mV limit on the difference in potential between conductive surfaces in these areas.

Figure 14.13 shows a patient in the intensive-care unit (ICU) who is connected to an ECG monitor that grounds the right-leg electrode to reduce 60 Hz interference. In addition, the patient's left-ventricular blood pressure is being monitored by an intracardiac saline-filled catheter connected to a metallic pressure sensor that is also grounded. Assume that these two monitors are connected to grounded three-wire wall receptacles on separate circuits that can come from a central power-distribution panel many meters away. A microshock can occur when any device with a ground fault that does not open the circuit breaker is operated on *either* circuit.

Figure 14.13(a) shows the scheme of this hazard; Figure 14.13(b) shows an equivalent circuit. Suppose that a faulty electric floor polisher, which is dusty and damp, allows 5 A to flow to the distribution panel on the ground wire. The floor polisher functions properly, so the fault is not noticed by the operator. The ground wire could easily have a 0.1 Ω resistance, so 500 mV could appear across the patient between the ECG-monitor ground and the pressure-monitor ground. If the resistance of the patient's body and of the liquid-filled catheter is less than 50 kΩ, a current in excess of the 10 μA safe limit could flow. Of course, more current would flow if the ground



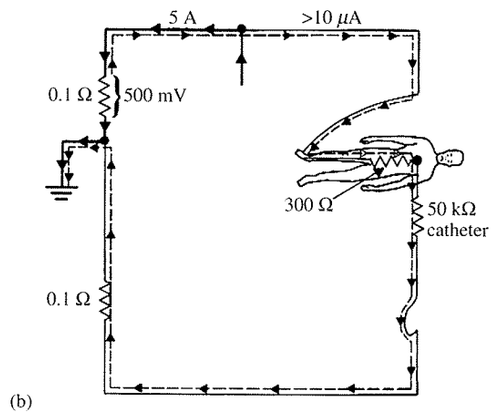


Figure 14.13 (a) Large ground-fault current raises the potential of *one* ground connection to the patient. The microshock current can then flow out through a catheter connected to a different ground. (b) Equivalent circuit. Only power-system grounds are shown.

resistance or fault current were higher or if the catheter resistance were lower. If a grounded pacing catheter were to be used instead of the liquid-filled catheter in this example, then much smaller differences in ground potential would exceed the safe limit.

Most low-voltage hazards can be avoided if the grounds of all devices used in the vicinity of each patient are connected to a single patient-grounding point. This also prevents faults at one patient's bedside from affecting the safety of other patients. Modern pressure sensors and ECG monitors provide electrical isolation for all patient leads.

14.6 ELECTRICAL-SAFETY CODES AND STANDARDS

A *code* is a document that contains only mandatory requirements. It uses the word *shall* and is cast in a form suitable for adoption into law by an authority that has jurisdiction. Explanations in a code must appear only in fine-print notes, footnotes, and appendices. A *standard* also contains only mandatory requirements, but compliance tends to be voluntary, and more detailed notes and explanations are given. A *manual* or *guide* is a document that is informative and tutorial but does not contain requirements (AAMI, 2008).

The development, adoption, and use of standards and codes for electrical safety in health-care facilities have had a particularly arduous history that continues to the present day (Bruner and Leonard, 1989, Chapter 9). The process began following tragic explosions and fires resulting from electric ignition of flammable anesthetics such as ether. In the early 1970s, the microshock electrical-safety scare resulted in some proposals that were not practical. Implicit requirements for isolated-power systems and very low-leakage current requirements were hotly debated for many years. Finally, the National Fire Protection Association NFPA 99-1984 and ANSI/AAMI ES1-1985 standards were adopted.

The NFPA 99—Standard for Health Care Facilities—2005 has evolved from 12 NFPA documents that were combined in 1984 and revised every 3 years. In addition to electric equipment, this standard also describes gas, vacuum, and environmental systems and materials. It is the primary document that describes the requirements for patient-care-related electric appliances used for diagnostic, therapeutic, or monitoring purposes in a patient-care area. Chapter 7 "covers the performance, maintenance, and testing of electrical equipment" by personnel in health-care facilities. More detailed manufacturer requirements are given in Chapter 9 for "the performance, maintenance, and testing with regard to safety, required of manufacturers of equipment used within health-care facilities." Annex 2 concerns "the safe use of high-frequency (100 kHz to microwave frequencies) electricity in health-care facilities.

The National Electrical Code—2006, Article 517—Health Care Facilities is published by the NFPA and is widely adopted and enforced by state, county, and municipal authorities having jurisdiction. Requirements vary for general-care areas, critical-care areas, and wet locations. The major sections are I. General; II. Wiring and Protection; III. Essential Electrical System; IV. Inhalation Anesthetizing Locations; V. X-Ray Installations; VI. Communications, Signaling Systems, Data Systems, Fire-Alarm Systems, and Systems Less than 120 Volts, Nominal; and VII. Isolated Power Systems.

The Association for the Advancement of Medical Instrumentation (AAMI) developed an American National Standard on "Safe Current Limits for Electromedical Apparatus," ANSI/AAMI ESI—1993. This standard concerns limits on chassis and patient-lead leakage currents, which are fixed from dc to 1 kHz and increase from 1 kHz to 100 kHz. For single-fault conditions

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 *nonisolated* patient leads	100	10
Appliances with *nonisolated* leads and single fault	300	100
Appliances with *isolated* patient leads	100	10
Appliances with *isolated* 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, particularly in areas subject to wet conditions. Isolated power systems are only necessary in locations where flammable anesthetics are used. The additional protection against microshocks provided by isolation transformers does not generally justify the high cost of these systems.

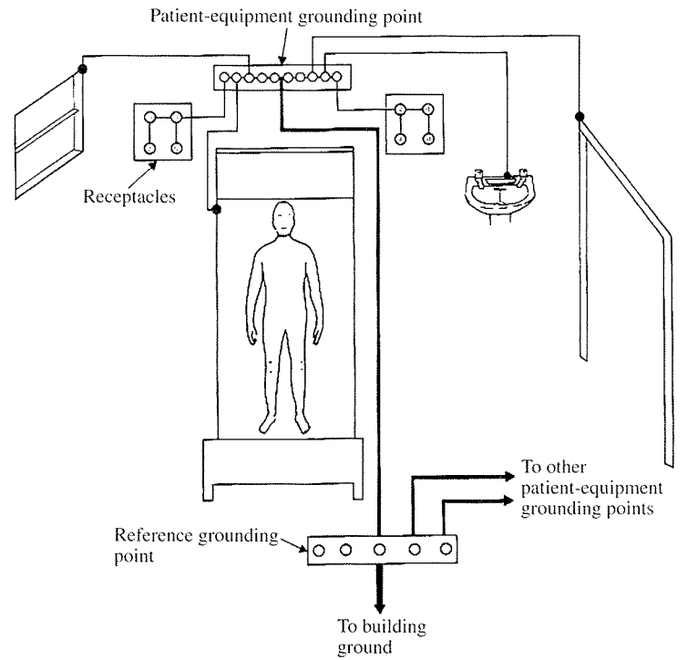
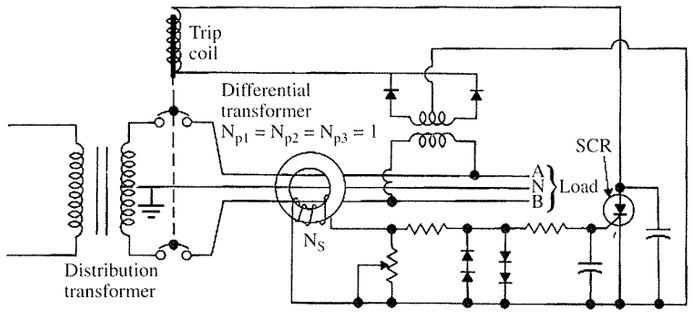


Figure 14.14 Grounding system All the receptacle grounds and conductive surfaces in the vicinity of the patient are connected to the patient-equipment grounding point. Each patient-equipment grounding point is connected to the reference grounding point that makes a single connection to the building ground.

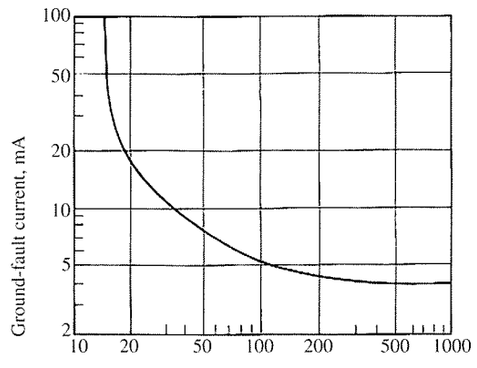
GROUND-FAULT CIRCUIT INTERRUPTERS (GFCI)

Ground-fault circuit interrupters disconnect the source of electric power when a ground fault greater than about 6 mA occurs. In electric equipment that has negligible leakage current, the current in the hot conductor is equal to the current in the neutral conductor. The GFCI senses the difference between these two currents and interrupts power when this difference, which must be flowing to ground somewhere, exceeds the fixed rating. The devices make no distinction among paths the current takes to ground: That path may be via the ground wire or through a person to ground (Figure 14.10).

Most GFCIs use a differential transformer and solid-state circuitry, as shown in Figure 14.15(a). The trip time for the GFCI varies inversely with the



(a)



(b)

Figure 14.15 Ground-fault circuit interrupters (a) Schematic diagram of a solid-state (three-wire, two-pole, 6 mA) GFCI. (b) Ground-fault current versus trip time for a GFCI. [Part (a) is from C. F. Dalziel, "Electric Shock," in *Advances in Biomedical Engineering*, edited by J. H. U. Brown and J. F. Dickson III, 1973, 3: 223–248.]

magnitude of the ground-fault current, as shown in Figure 14.15(b). The GFCI is used with conventional three-wire grounded power-distribution systems. When power is interrupted by a GFCI, the manual reset button on the GFCI must be pushed to restore power. Most GFCIs have a momentary pushbutton that creates a safe ground fault to test the interrupter.

EXAMPLE 14.3 Most GFCIs have a momentary push button that creates a safe ground fault to test the interrupter. On Figure 14.15, *design* the modifications to permit this test.

ANSWER Add from B to earth ground a resistor in series with a momentary push-button switch so current flows outside the magnetic core. $R = V/I = 120\,\text{V}/12\,\text{mA} = 10\,\text{k}\Omega$.

The 2006 National Electrical Code requires that there be GFCIs in circuits serving bathrooms, garages, outdoor receptacles, swimming pools, and construction sites (Articles 210-8,680-5). NFPA 99 requires the use of GFCIs in wet locations, particularly hydrotherapy areas, where continuity of power is not essential.

Ground-fault circuit interrupters are not sensitive enough to interrupt microshock levels of leakage current, so they are primarily macroshock-protection devices. They can, however, prevent some microshocks by interrupting the source of large ground-fault currents that cause differences in potential in grounding systems.

However, circuits in patient-care areas generally should not include GFCIs, because the loss of power to life-support equipment due to GFCIs is probably more hazardous to the patient than most small ground faults would be. Where brief power interruptions can be tolerated, the low cost of GFCIs ($10) make them an attractive alternative to isolated power-distribution systems ($2000).

14.9 PROTECTION: EQUIPMENT DESIGN

RELIABLE GROUNDING FOR EQUIPMENT

The importance of an effective grounding system for equipment has already been illustrated (Figure 14.10). Most failures of equipment grounds occur either at the ground contact of the receptacle or in the plug and cable leading to the line-powered equipment. Hospital-grade receptacles and plugs and "Hard Service" (SO, ST, or STO) or "Junior Hard Service" (SJO, SJT, or SJTO) power cords must be used in all patient areas. Molded plugs should be avoided, because surveys have shown that 40% to 85% of these plugs develop invisible breaks within 1 to 10 years of hospital service. Strain-relief devices are recommended both where the cord enters the equipment and at the connection between cord and plug. A convenient cord-storage compartment or device reduces cord damage. Equipment grounds are often deliberately interrupted by improper use of the common three-prong-to-two-prong adapter (*cheater adapter*).

REDUCTION OF LEAKAGE CURRENT

Reduction of leakage current in the chassis of equipment and in patient leads is an important goal for designers of all line-powered instruments. Special low-leakage power cords are available (<1.0 μA/m). Leakage current inside the chassis can be reduced by using layouts and insulating materials that minimize the capacitance between all hot conductors and the chassis. Particular attention must be given to maximizing the impedance from patient leads to hot conductors and from patient leads to chassis ground. Most modern equipment

meets the leakage-current limits given in Section 14.6. Old equipment with higher leakage should not be used with patients susceptible to microshocks unless proper grounding is ensured.

DOUBLE-INSULATED EQUIPMENT

The objective of grounding is to eliminate hazardous potentials by interconnecting all conductive surfaces. An equally effective approach is to use a separate layer of insulation to prevent contact of any person with the chassis or any exposed conductive surface. Primary insulation is the normal functional insulation between energized conductors and the chassis. A separate secondary layer of insulation between the chassis and the outer case protects personnel even if a ground fault to the chassis occurs. The outer case, if it is made of insulating material, may serve as the secondary insulation. All switch levers and control shafts must be double insulated (for example, plastic knobs may have recessed screws). Double insulation generally reduces leakage current. For medical instruments, both layers of insulation should remain effective, even when conductive fluid is spilled. Double insulation protects against both macroshock and microshock.

OPERATION AT LOW VOLTAGES

Most solid-state electronic diagnostic equipment can be powered by low-voltage batteries (<10 V) or low-voltage isolation transformers. Macroshock is avoided if the voltage is low enough to be safe even when the device is applied directly to wet skin. Low-voltage ac-powered equipment can still cause microshock if the current is applied directly to the heart. However, low-voltage ac equipment is generally safer than high-voltage ac equipment. See Section 164 in Article 517 of the 2006 National Electrical Code for requirements for low-voltage equipment used in inhalation-anesthetizing locations.

ELECTRICAL ISOLATION

Isolation amplifiers are devices that break the ohmic continuity of electric signals between the input and output of the amplifier. This isolation includes different supply-voltage sources and different grounds on each side of the isolation barrier. Isolation amplifiers usually consist of an instrumentation amplifier at the input followed by a unity-gain isolation stage. Figure 14.16(a) shows a general model for an isolation amplifier that has a triangular operational amplifier symbol split by a perfect isolation barrier (dashed line). The very high impedance across the barrier is modeled by the isolation capacitance and resistance. The isolation voltage v_{ISO} is the potential that can exist between the input common and the output common (note the different ground symbols) and is rated from 1 to 10 kV without breakdown. The rejection of this voltage by the amplifier is specified by the isolation-mode rejection ratio (IMRR). The desired input voltage v_{SIG}, the input common-mode voltage v_{CM},

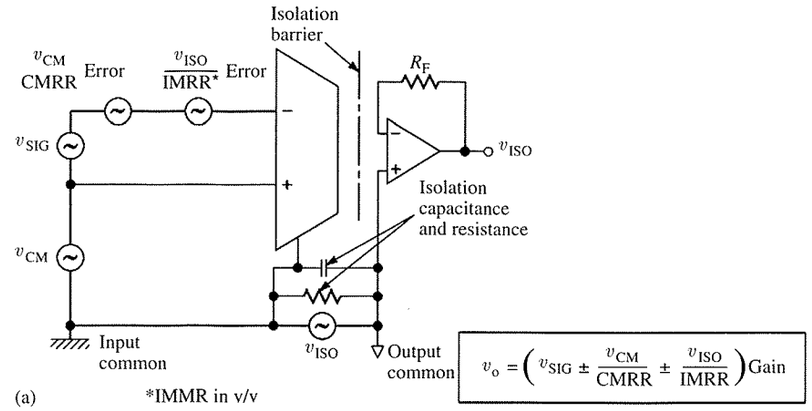
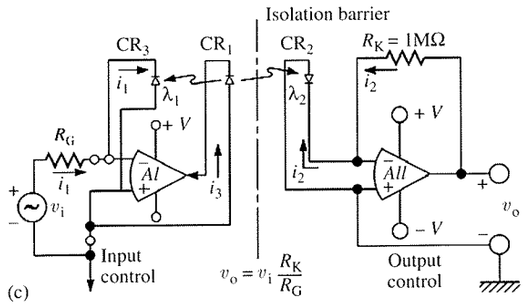


Figure 14.16 **Electrical isolation of patient leads to biopotential amplifiers** (a) General model for an isolation amplifier. (b) Transformer isolation amplifier (courtesy of Analog Devices, Inc., AD202). (c) Simplified equivalent circuit for an optical isolator (copyright 1989 Burr-Brown Corporation. Reprinted in whole or in part with the permission of Burr-Brown Corporation. Burr Brown ISO100). (d) Capacitively coupled isolation amplifier (Horowitz and Hill, *Art of Electronics*, Cambridge Univ. Press, 1989, Burr Brown ISO106).

and the common-mode rejection ratio (CMRR) are the same as for a non-isolated amplifier. Typical maximal ratings for v_{CM} are only ±10 V. The input common may be connected to the source in applications that break ground loops or may be floated to make possible simpler, two-wire connections to the source and reference of the common-mode signal across the isolation barrier to the output common. The three main features of an isolation amplifier are high ohmic isolation between input and output (>10 MΩ), high isolation-mode voltage (>1000 V), and high common-mode rejection (>100 dB).



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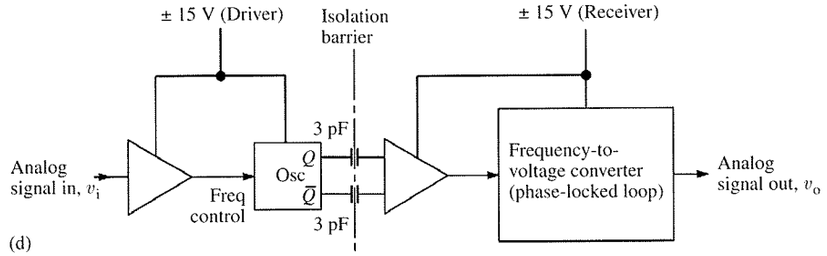


(d)

Figure 14.16 (*Continued*)

Three fundamental methods are used in the design of isolation amplifiers: transformer isolation, optical isolation, and capacitive isolation. The transformer approach illustrated in Figure 14.16(b) uses either a frequency-modulated or a pulse-width-modulated carrier signal with small signal bandwidths up to 30 kHz to carry the signal. It uses an internal dc-to-dc converter composed of a 25 kHz oscillator, transformer, rectifier, and filter to supply isolated power. The optical method uses an LED on the source side and a photodiode on the output side. No modulator–demodulator is needed, because the signal all the way to dc is transmitted optically. A matched photodiode on the source side is used with feedback to improve linearity. Increased light from the forward-biased LED CR_1 causes increased reverse leakage current through CR_2 and CR_3 (see Figure 2.22). The simplified circuit in Figure 14.16(c) operates only for one polarity of input signal. The capacitive method, shown in Figure 14.16(d), uses digital encoding of the input voltage and frequency modulation to send the signal across a differential ceramic capacitive barrier. There is no feedback, though a power supply is needed on both sides of the barrier. The peak isolation voltage can be as high as 8 kV, and bandwidth up to 70 kHz is available.

EXAMPLE 14.4 For the isolation barrier in Figure 14.16, calculate the capacitance to limit the 60 Hz, 120 V current to 10 μA.

ANSWER $Z = 120\,\text{V}/10\,\mu\text{A} = 12\,\text{M}\Omega$, $C = 1/(\omega|Z|) = 1/(2\pi 60 \times 12\,\text{M}\Omega) = 221\,\text{pF}$.

ISOLATED HEART CONNECTIONS

Undoubtedly the best way to minimize the hazards of microshock is to isolate or eliminate electric connections to the heart. Fully insulated connectors for external cardiac pacemakers powered by batteries have greatly reduced this hazard. Modern blood-pressure sensors are designed with triple insulation between the column of liquid, the sensor case, and the electric connections (Figure 2.5). Catheters with conductive walls have been developed that provide electric contact all along that part of the catheter that is inside the patient, so that microshock current is distributed throughout the body, not concentrated at the heart. Conductivity of the catheter wall does not affect measurements of pressure made with liquid-filled catheters. Catheters that contain sensors in the tip for measuring blood pressure and flow should have low leakage currents.

14.10 ELECTRICAL-SAFETY ANALYZERS

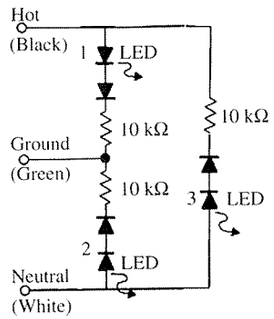
Commercially available instruments called *electrical-safety analyzers* are useful for testing both medical-facility power systems and medical appliances (Anonymous, 1988). These analyzers range in complexity from simple conversion boxes used with any volt–ohm meter to computerized automatic measurement systems with bar code readers that generate written reports of test results. The features to consider are accuracy, ease of use, testing time, and cost. The analyzers also reduce errors caused by incorrect test setups and reduce the risk of shock to the person performing tests such as applying line voltage to patient leads to test isolation. Automated methods for measuring leakage current for medical equipment have been developed (Hu *et al.*, 2005).

14.11 TESTING THE ELECTRIC SYSTEM

When we test systems of electric distribution and line-powered equipment, we must consider the safety of both the patients and the personnel conducting the tests. We shall briefly describe and comment on only the common tests.

TESTS OF RECEPTACLES

Receptacles should be tested for proper wiring, adequate line voltage, low ground resistance, and mechanical tension. The common three-light receptacle



Wiring Codes (∗ ≡ LED on)

	1	2	3
1. Hot open (or all hot!)	O	O	O
2. Neutral open	∗	O	O
3. No possible wiring	O	∗	O
4. Ground open	O	O	∗
5. Hot/ground reversed	∗	∗	O
6. Correct (or ground/neutral reversed)	∗	O	∗
7. Hot/neutral reversed	O	∗	∗
8. Hot open and neutral/hot	∗	∗	∗

Figure 14.17 Three-LED receptacle tester Ordinary silicon diodes prevent damaging reverse-LED currents, and resistors limit current. The LEDs are ON for line voltages from about 20 V rms to greater than 240 V rms, so these devices should not be used to measure line voltage.

testers shown in Figure 14.17 are deficient in several respects. These devices were designed to check only the wiring, but even so, they can indicate only 8 (2^3) of 64 (4^3) possible states for an outlet. The three lights have only two states (2^3), whereas each of the three outlet contacts has four states (4^3)—hot, neutral, ground, and open.

These testers give an OK reading when the ground and neutral wires are transposed and when the green and white wires are hot and the black wire is grounded. (Opening of the circuit breaker would probably call attention to the latter miswiring and to several others as well.)

Ground resistance can be measured by passing up to 1 A through the ground wire and measuring the voltage between ground and neutral. Anyone doing these ground-wire tests should take care not to incur the microshock hazards described in Section 14.5 (and shown in Figure 14.13). The resistance of neutral wiring can be tested similarly, by passing the current through the neutral conductor. Ground or neutral resistance should not exceed 0.2 Ω. The minimal mechanical retaining force for each of the three contacts is about 115 g (4 oz).

TESTS OF THE GROUNDING SYSTEM IN PATIENT-CARE AREAS

The NFPA 99 requires both voltage and impedance measurements with different limits for new and existing construction. The voltage between a reference grounding point (see Figure 14.14) and exposed conductive surfaces should not exceed 20 mV for new construction. For existing construction, the limit is 500 mV for general-care areas and 40 mV for critical-care areas. The impedance between the reference grounding point and receptacle grounding contacts must be less than 0.1 Ω for new construction and less than 0.2 Ω for existing construction.

TESTS OF ISOLATED-POWER SYSTEMS

Isolated-power systems should have equipotential grounding that is similar to that of unisolated systems (Figure 14.14). The line-isolation monitor (Figure 14.9) should trigger a visible (red) and an audible alarm when the total hazard current (resistive and capacitive leakage currents and LIM current) reaches a threshold of 5 mA under normal line-voltage conditions. The LIM should not trigger the alarm for a fault-hazard current of less than 3.7 mA. For complete specifications, see the latest NFPA 99 standard.

14.12 TESTS OF ELECTRIC APPLIANCES

GROUND-PIN-TO-CHASSIS RESISTANCE

The resistance between the ground pin of the plug and the equipment chassis and exposed metal objects should not exceed 0.15 Ω during the life of the appliance (Figure 14.18).

During the measurement of resistance, the power cord must be flexed at its connection to the attachment plug and at its strain relief where it enters the appliance.

CHASSIS LEAKAGE CURRENT

Leakage current emanating from the chassis, as measured in Figure 14.19(a), should not exceed 500 μA for appliances with single fault not intended to contact patients and should not exceed 300 μA for appliances that are intended for use in the patient care vicinity. These are limits on rms current for sinusoids from dc to 1 kHz, and they should be obtained with a current-measuring device of 1000 Ω or less. Figure 14.19(b) shows a suitable circuit. The limits on leakage current apply whether the polarity of the power line is correct or reversed,

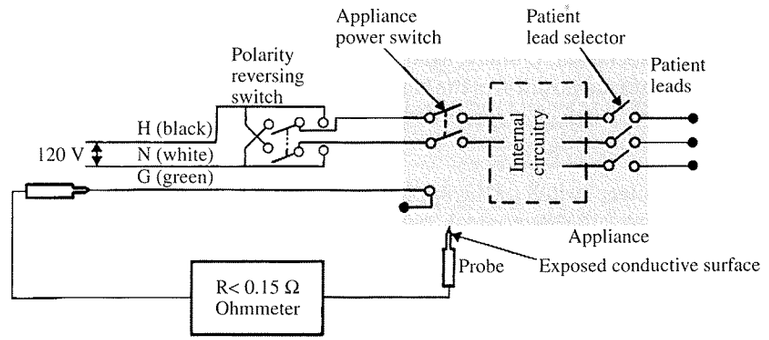


Figure 14.18 Ground-pin-to-chassis resistance test

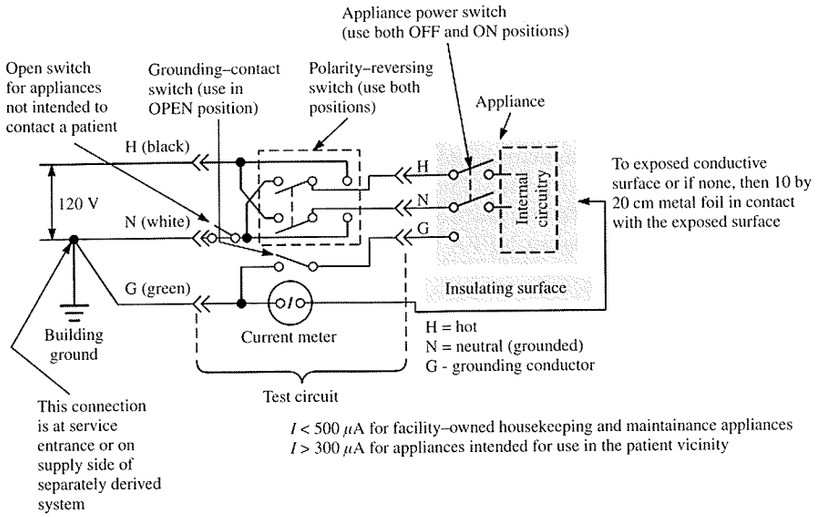


Figure 14.19 (a) Chassis leakage-current test. (b) Current-meter circuit to be used for measuring leakage current. It has an input impedance of 1 kΩ and a frequency characteristic that is flat to 1 kHz, drops at the rate of 20 dB/decade to 100 kHz, and then remains flat to 1 MHz or higher. (Reprinted with permission from NFPA 99-2005, "Health Care Facilities," Copyright ©2005, National Fire Protection Association, Quincy, MA 02269. This reprinted material is not the complete and official position of the National Fire Protection Association, on the referenced subject, which is represented only by the standard in its entirety.)

whether the power switch of the appliance is in the on or the off position, and whether or not all the control switches happen to be in the most disadvantageous position at the time of testing. The polarity-reversing switches in Figures 14.18 to 14.22 are required for equipment manufacturer testing but may be omitted for testing in health-care facilities. When several appliances are mounted together in one rack or cart, and all the appliances are supplied by one power cord, the complete rack or cart must be tested as one appliance.

LEAKAGE CURRENT IN PATIENT LEADS

Leakage current in patient leads is particularly important because these leads are the most common low-impedance patient contacts. Limits on leakage current in patient leads should be 50 μA. Isolated patient leads must have leakage current that is less than 10 μA. Only *isolated* patient leads should be connected to catheters or electrodes that make contact with the heart. Leakage current between individual or interconnected patient leads and ground should be measured with the patient leads active, as shown in Figure 14.20.

In addition, leakage current between any pair of leads or between any single lead and all the other patient leads should be measured, as indicated in Figure 14.21.

Finally, the leakage current that would flow through patient leads to ground if line voltage were to appear on the patient should be tested. This leakage current is called *isolation current* or *risk current*. Application of power-line voltage and frequency to the isolated patient leads should produce an isolation current to ground that is less than 50 μA (Figure 14.22).

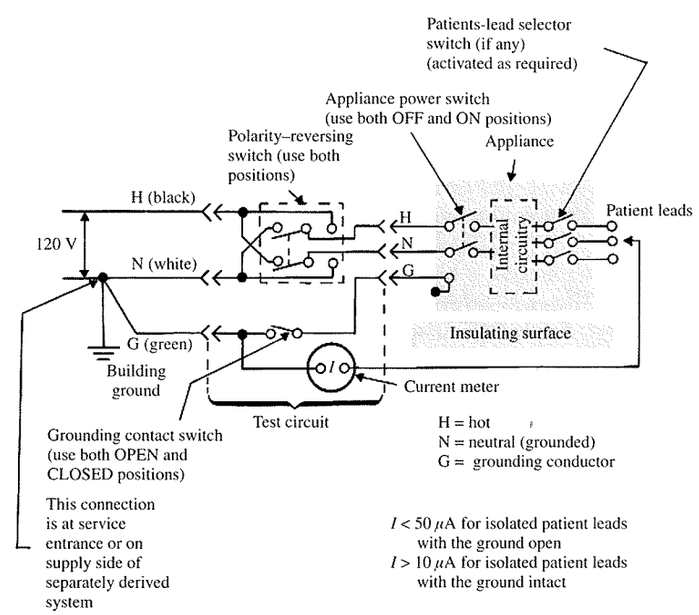


Figure 14.20 Test for leakage current from patient leads to ground. (Reprinted with permission from NFPA 99-2005, "Health Care Facilities," Copyright © 2005, National Fire Protection Association, Quincy, MA 02269. This reprinted material is not the complete and official position of the National Fire Protection Association, on the referenced subject, which is represented only by the standard in its entirety.)

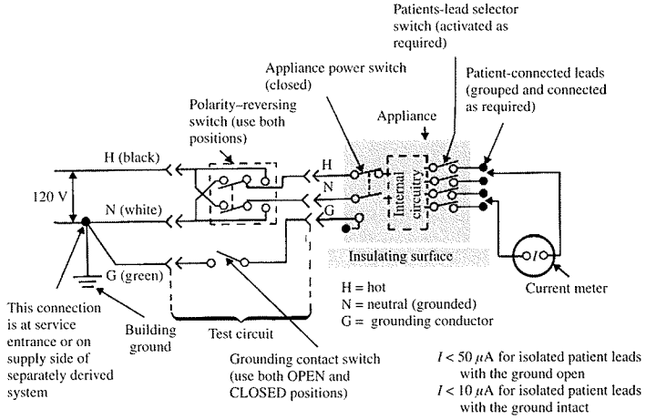


Figure 14.21 Test for leakage current between patient leads (Reprinted with permission from NFPA 99-2005, "Health Care Facilities," Copyright ©2005, National Fire Protection Association, Quincy, MA 02269. This reprinted material is not the complete and official position of the National Fire Protection Association, on the referenced subject, which is represented only by the standard in its entirety.)

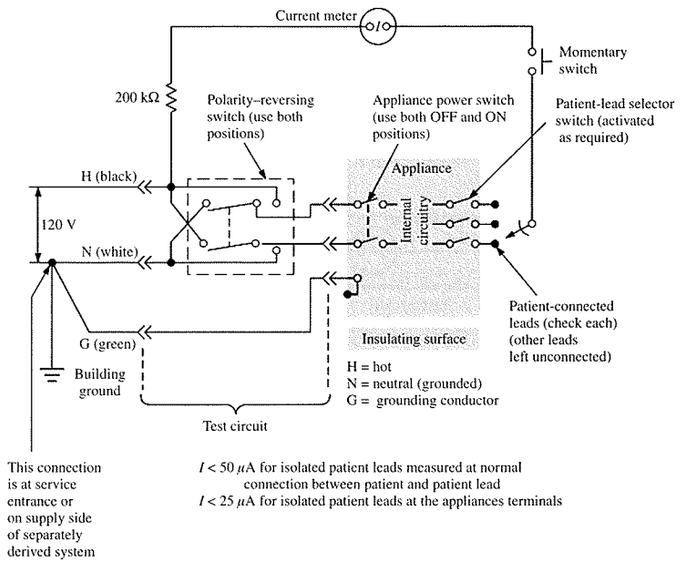


Figure 14.22 Test for ac isolation current. (Reprinted with permission from NFPA 99-2005, "Health Care Facilities," Copyright © 2005, National Fire Protection Association, Quincy, MA 02269. This reprinted material is not the complete and official position of the National Fire Protection Association, on the referenced subject, which is represented only by the standard in its entirety.)

CONCLUSION

Adequate electrical safety in health-care facilities can be achieved at moderate cost by combining a good power-distribution system, careful selection of well-designed equipment, periodic testing of power systems and equipment, and a modest training program for medical personnel. Fortunately, the electrical-safety scare of the early 1970s has led to increased knowledge and greater safety for both patients and medical personnel.

PROBLEMS

14.1 Assume that the cell membranes of a very large number of cells in parallel can be modeled by a 1 Ω resistor in parallel with a 100 μF capacitor. Determine the rms sinusoidal current versus frequency necessary to depolarize the cells. Assume that the peak potential of the cell membrane must be raised 20 mV above its resting potential to exceed threshold. Plot your results together with those shown in Figure 14.3, and compare.

14.2 From your knowledge of cardiac electrophysiology (Section 4.6), explain what rhythm would result from an intense 100 ms shock that occurred during (a) the P wave, (b) the R wave, (c) the T wave, and (d) diastole. From these results, explain the shape of the curves shown in Figure 14.5.

14.3 Resketch Figure 14.6(b) for the case in which a catheter made of conductive plastic is used.

14.4 If the secondary earth ground in Figure 14.8 were not connected, would this prevent electrocution under no-fault conditions? What would be the result in case of a primary-to-secondary fault in the transformer?

14.5 The LIM in Figure 14.9 has a monitor hazard current that is too high. Redesign it to achieve a lower monitor hazard current of 25 μA by changing the value of a *single* passive component shown and adjusting the detector threshold.

14.6 Design the simplest line-isolation monitor that would be capable of detecting a *single* fault from either line to ground.

14.7 Some authors hypothesize that it is current density flowing through the cell membrane that raises the resting potential of the cell to exceed threshold. Replot Figure 14.12 to show the average current density of the fibrillation threshold versus area of the catheter. Is the foregoing hypothesis correct? Explain any discrepancies.

14.8 Calculate the maximal safe capacitance between a liquid-filled catheter and dc-isolated pressure-sensor leads for a 120 V, 60 Hz fault in the sensor leads.

14.9 Compute the resistivity of the liquid necessary for safe operation of a liquid-filled catheter that is 1 m long and has a radius of 1.13 mm. Use the data

given in Roy *et al.* (1980) (shown in Figure 14.12). Assume that the patient is grounded and that a 120 V fault develops at the sensor.

14.10 Draw a complete equivalent circuit, and compute the rms current through the patient's heart for the following situation. The patient's hand touches a faulty metal lamp that is 120 V rms above ground. A saline-filled catheter ($R = 50\,\text{k}\Omega$) for measuring blood pressure is connected to the patient's heart. Some of the pressure-sensor strain-gage wiring is grounded, and the sensor is somewhat isolated electrically. However, there is 20 MΩ of leakage resistance in the insulation between the ground and the saline in the sensor. There is also 100 pF of capacitance between the ground and the saline. Assume that the skin resistance of the patient is 1 MΩ. Is there a microshock hazard?

14.11 Show how a single electric instrument can be the path for microshock current flowing both to and from the patient, at the same time. Use complete diagrams, and do a sample calculation.

14.12 Devise your own hospital-patient microshock situation. Give complete details, including a diagram and equivalent circuit. Describe all tests, and give the standards for test results necessary to ensure the safety of the patient.

14.13 Figure 14.15 is designed for two-phase operation. Redesign it (draw a circuit diagram) for one-phase operation.

14.14 Design a tester for an electric receptacle that will indicate as many states as possible, including those not detected by the common three-LED receptacle testers (Figure 14.17).

14.15 A power engineer receives a lethal macroshock while standing in water and simultaneously touching the ungrounded metal casing on a high-voltage, 60 Hz power transformer. Assume that the resistance of the skin on the engineer's hand is 100 kΩ and that the resistance of the skin on the engineer's feet is negligible. A capacitance of 25 nF is measured between the transformer casing and the high-voltage conductors. Find the minimal value of the high voltage, assuming that 75 mA is the minimal fibrillating macroshock. Draw an equivalent circuit.

14.16 In Figure 14.16(c), the diodes are forward-biased for only *one* polarity of v_i. Redesign the circuit such that it works for *both* polarities of v_i. Consider the op-amp summer as a possibility.

14.17 Figure 14.1 shows us that 60 Hz arm-to-arm current of 100 mA rms causes VF. Assume I_r in (14.1) is 60 Hz peak current of 141 mA and that $\tau = 3\,\text{ms}$. Calculate I_d for a Taser that has $d = 100\,\mu\text{s}$.

REFERENCES

AAMI, *AAMI Electrical Safety Manual, 2008, A Comprehensive Guide to Electrical Safety Standards for Healthcare Facilities*. Arlington, VA: Association for the Advancement of Medical Instrumentation, 2008.

AAMI, *American National Standard, Safe Current Limits for Electromedical Apparatus.* (ANSI/AAMIES1–1993). Arlington, VA: Association for the Advancement of Medical Instrumentation, 1993.

Anonymous, "Electrical safety analyzers." *Health Devices*, 1988, 17, 283–309; "Update." *Health Devices*, 1989, 18, 411–413.

Bruner, J. M. R., and P. F. Leonard, *Electrical Safety and the Patient.* Chicago: Year Book Medical Publishers, 1989.

Charney, and W., J. Schirmer, *Essentials of Modern Hospital Safety*. Chelsea, MI: Lewis Publishing, 1990.

Dalziel, C. F., "Electric shock." In J. H. U. Brown and J. F. Dickson III (eds.), *Advances in Biomedical Engineering*, 1973, 3, 223–248.

Dyro, J. F., "Safety program, hospital." In J. G. Webster (ed.), *Encyclopedia of Medical Devices and Instrumentation*, 2nd ed. New York: Wiley, 2006, Vol. 6, pp. 109–122.

The National Electrical Code 2006 Handbook, Quincy, MA: National Fire Protection Association, 2006.

Fagerhaugh, S. Y., A. Strauss, B. Suczek, and C. L. Wiener, *Hazards in Hospital Care: Ensuring Patient Safety*. San Francisco, CA: Jossey-Bass, 1987.

Geddes, L. A., *Handbook of Electrical Hazards and Accidents*. Boca Raton, FL: CRC Press, 1995.

Geddes, L. A., J. D. Bourland, and G. Ford, "The mechanism underlying sudden death from electric shock." *Med. Instrum.*, 1986, 20, 303–315.

Geddes, L. A., and L. E. Baker, *Principles of Applied Biomedical Instrumentation*, 3rd ed. New York: Wiley, 1989.

Hu, Y., L. Y. Pang, X. B. Xie, X. H. Li, and K. D. K. Luk, "Automated leakage current measurement for medical equipment safety." *Proceedings of IEEE Engineering in Medicine and Biology*, 2005, 440–442.

IEC 60601-1 2006 *Household and similar electrical appliances—Safety—Part 2-76: Particular requirements for electric fence energizers*, (IEC 60335-2-76, Edition 2.1).

Klein, B. R., *Health Care Facilities Handbook*, 5th ed. Quincy, MA: National Fire Protection Association, 1996.

Laks, M., R. Arzbaecher, J. Bailey, A. Berson, S. Briller, and D. Geselowitz, "Will relaxing safe current limits for electromedical equipment increase hazards to patients? " *Circulation*, 1994, 89, 909–910.

Laks, M., R. Arzbaecher, J. Bailey, D. Geselowitz, and A. Berson, "Recommendations for safe current limits for electrocardiographs." *Circulation*, 1996, 93, 837–839.

Lee, R. C., E. G. Cravalho, and J. F. Burke, *Electrical Trauma: The Pathophysiology, Manifestations and Clinical Management*. Cambridge, England: Cambridge University Press, 1992.

Maffiuletti, N. A., A. J. Herrero, M. Jubeau, F. M. Impellizzeri, M. Bizzini, "Differences in electrical stimulation thresholds between men and women." *Ann. Neurol.*, 2008, 63, 507–512.

NFPA No. 99-2005, *Standard for Health Care Facilities.* Quincy, MA: National Fire Protection Association, 2005.

Reilly, J. P., *Applied Bioelectricity: From Electrical Stimulation to Electropathology*. New York: Springer, 1998.

Roy, O. Z., "Summary of cardiac fibrillation thresholds for 60 Hz currents and voltages applied directly to the heart." *Med. Biol. Eng. Comput.*, 1980, 18, 657–659.

Roy, O. Z., A. J. Mortimer, B. J. Trollope, and E. J. Villeneuve, "Effects of short-duration transients on cardiac rhythm." *Med. Biol. Eng. Comput.*, 1984, 22, 225–228.

Roy, O. Z., J. R. Scott, and G. C. Park, "60 Hz ventricular fibrillation and pump failure thresholds versus electrode area." *IEEE Trans. Biomed. Eng.*, 1976, 23, 45–48.

Staewen, W. S., "Electrical safety reconsidered—the new AAMI electrical safety standard." *Biomed. Instrum. Tech.*, 1994, 28, 131–132.

Swerdlow, C. D., W. H. Olson, M. E. O'Connor, D. M. Gallik, R. A. Malkin, and M. Laks, "Cardiovascular collapse caused by electrocardiographically silent 60-Hz intracardiac leakage current—implications for electrical safety." *Circulation*, 1999, 99, 2559–2564.

Tan, K. S., and D. L. Johnson, "Threshold of sensation for 60 Hz leakage current: Results of a survey." *Biomed. Instrum. Tech.*, 1990, 24, 207–211.