Medical Intelligence

Protection of the "Electrically Susceptible Patient":

A Discussion of Systems and Methods

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In the late nineteenth and early twentieth centuries, Thomas Edison, George Westinghouse, and others were engaged in arguments concerning power-distribution systems. Westinghouse proposed that his alternating-current system could transmit electrical energy over far greater distances than could the direct-current system. His method involved "stepping up" the voltage to be transmitted, then reducing it just prior to delivery. The debates grew to hostile, emotional battles as Edison, the established distributor of direct-current electricity, insisted that the Westinghouse electricity was "absolutely lethal." "Just as certain as death," said Edison, "Westinghouse will kill a customer within six months after he puts in a system of any size. . . . It will never be free of danger." Lawyers, politicians, reporters, and an alarmed public became involved in a complicated, technical controversy, of which they had little understanding. As it turned out, outstanding technical contributions of Nikola Tesla, the perseverance of George Westinghouse, and the 184-foot torrent of Niagara Falls led to the gradual defeat of direct current.

Today, in hospitals, patients are connected to many devices supplied with the "Westinghouse electricity." While Edison and Westinghouse were involved with "dangerous" voltages ranging from 50 to perhaps 10,000 volts or more, we believe today that certain patients should not be exposed to more than five thousandths of one volt. The patient, therefore, must be nearly insulated from electricity, yet he is connected to many, often faulty or misused, sometimes antiquated, electrical and electronic devices.

A striking similarity to the Edison–Westinghouse debates is manifested in recent technical publications and meetings which concern the National Electric Code for Health Care Facilities. Factors of differential cost versus potential life-protecting gains are hotly debated. Administrators, politicians, lawyers, medical doctors, and firemen, who have little training in the technical, engineering areas of electricity, contribute to the decision-making mechanism. It is necessary, therefore, that technical information be provided to them so that decisions can be made with better understanding.

Electrical Terminology

An ideal insulator blocks the flow of electricity. A conductor allows the flow of electricity. Current is the flow of electricity and is measured in amperes or some part thereof (e.g., milli- or microamperes). Voltage or potential difference must be placed across a conductor to make current flow through the conductor. If identical voltage levels are applied or exist across a conductor, then no current will flow between the points of contact. If, however, the voltage levels differ in relative magnitude, then current must flow. Inversely, if current flows between two points of a conductor, there must be a voltage difference (potential difference) between the points. Voltage, or potential difference, is measured in volts or parts thereof (e.g., milli- or microvolts). Impedance, in general, represents the degree of "ease" with which a conductor allows the flow. Real "insulators" have very high impedances and hinder or limit the flow of current. Good conductors have low impedances and allow electricity to flow easily. Impedance is measured in ohms or parts thereof (e.g., milli- or microohms). Impedance, in general, represents how many volts are necessary to accom-
Protection of Electrically Susceptible Patient

Fig. 1. Simplified conventional neutral-grounded power-distribution system. Note the use of three conductors, hot, neutral, and ground. The grounding conductor is connected to the neutral at the electrical service entrance of the building. Therefore, both “hot” and “neutral” lines are referenced to ground. Although many devices constitute the load, only one is shown here, for simplicity.

pany one ampere of current flow through a conductor. Impedance is thus the ratio of voltage across a conductor to current passing through the same conductor (Ohm’s law).

An interesting, sometimes misunderstood, electrical property is leakage, the escape of electricity from one conductor to another via stray conductive paths of high or low impedance. For example, a conductive material in proximity to electrical conductors “receives” some of the available electricity for itself. The amount received depends on the impedance of the leakage pathway and the potential difference across the leakage impedance. It is generally independent of the level of current flow in the other conductors. An example of this is that metallic surfaces of electrical devices will sometimes contain voltages even though the equipment is turned off, yet plugged in.

The Electrical Environment

Wiring of the conventional, neutral-grounded electrical distribution system is shown in figure 1. For any electrical device (called the “load”) there must be at least two conductive paths for electricity to be delivered and returned to the source of generation. Electricity is delivered via the hot line (1) and returned via the neutral (2). However, not all electricity returns through the neutral conductor, because some has leaked through real (imperfect) insulators onto conductive surfaces which, for example, enclose equipment. An attempt is made to return this “lost” electricity to the service entrance neutral via grounding conductors (3). The neutral and ground conductor are connected together and “earthed” only at the service entrance of the building. Earth-ground is utilized as the master voltage reference point (zero volts) of the facility supplied with electricity.

As sea level is used as reference for measuring heights, any voltage level can be used as reference for measurement purposes. To measure his own height, one may use any reference level. Awkwardly he might say, “My feet are 3,600 feet above sea level and my head is 3,606 feet above sea level.” Rather, it is said that there is a difference of 6 feet or “I am 6 feet tall.” The identical techniques exist in speaking of voltage, or potential difference, for the measurement is invariably made between two points, one of which often is implicitly understood as the reference level for the measurement. Service entrance ground is building “sea level.”

If a grounding conductor on an electrical device breaks, then leakage electricity has no way to escape from the frame or chassis. Should a grounded patient come in contact with this device, then the leakage electricity, in seeking ground, will flow through the patient. An electrically susceptible patient might be one who is “being treated with an externalized electrical conductor, such as a probe, catheter* or other electrode connected to the

*The catheter referred to is the surface-insulated type which passes electricity only from end to end, providing a direct route to the heart.
heart." Ten microamperes of current could be lethal. The patient impedance is estimated at 500 ohms; therefore, Ohm’s law justifies the point that as little as 5 millivolts potential difference between chassis, patient, and ground could be dangerous.

If, however, the grounding conductor is not broken, the grounded patient will receive far less current, because the impedance of the wire conductor is much less than that of the patient. Current will “split” and now take two paths enroute to ground; mostly through the wire, and a little through the patient. The amount received by the patient then depends on how severe the overall leakage or fault happens to be and on the relative impedances of the grounding pathways (the patient and the ground wire).

It is not necessary that the patient be grounded for current to flow through him. For example, two “grounded” devices to which the patient is connected may be of different potentials relative to ground. Should this difference exceed 5 millivolts, then more than 10 microamperes could flow from device number one through the patient to device number two.

To minimize the possibility of such hazards, it has been widely suggested that all grounds within the patient location be connected to a single electrical reference point called the equipotential point (EPP). This may be accomplished, for example, through use of an equalizer ground bus (a large, low-impedance conductor) to which all smaller grounds are connected. All electricity at the location of the patient is then measured relative not to ground, but to this “EPP,” which is in turn connected to a grounding conductor, eventually returning to earth.

In addition to the establishment of the equipotential point, an attempt is made to maintain an equipotential environment such that there will never be more than 5 millivolts potential difference either between two devices or between any device and the equipotential point. Thus, in no way could an electrically susceptible (500-ohm) patient receive more than 10 microamperes. Ten microamperes is popularly considered, although not with certainty, to be the current minimum which, if applied directly to the heart, can induce ventricular fibrillation. In consideration of this 5-millivolt or 10-microamperes “criterion,” grounding systems must be carefully analyzed in light of maximum expected (or probable) leakage currents. Ground conductor dimensions, for example, should be adjusted to maintain the “equipotential environment” successfully in accord with the worst-case leakage probabilities. Unfortunately, worst-case probabilities really are not known yet; therefore, grounds might best be adjusted in accord with realistic, worst-case fault possibilities. This leads into the subject of grounding conductor impedance.

Electrical impedance is the vector sum of three components, namely resistance, capacitive reactance, and inductive reactance. The reactive components will, at this time, be ignored for two reasons. The first is that these most often play a minor role in the maintenance of the “equipotential environment.” Second, consideration of the reactive components would render the discussion needlessly complex. Resistance of grounding conductors must be discussed, for this component of impedance is most significant.

Four factors determine grounding conductor resistance. The first is the conductivity, a property of the particular metal or alloy used as material for the wire. Second and third are the cross-sectional area, and length of the conductor. Resistance decreases as cross-sectional area is increased and increases with conductor length. The fourth is temperature, which, over the ranges with which we are involved, has little effect.

Wire cross-sectional area is generally expressed in units of AWG, which stands for “American Wire Gauge.” The lower the AWG, the greater the cross-sectional area of the wire. The #18 AWG, annealed copper conductor (40.3-mil diameter), commonly used as equipment power cord ground, is rated at roughly 0.0064 ohm per foot. For purposes of the discussion a larger conductor, #10 AWG, 101.9 mil diameter, 0.001 ohm per foot, is introduced. The latter conductor has, although not commonly, been used for purposes of “better grounding.”

To investigate the effects of current through these conductors, let us assume conservative power-cord lengths of 6 feet from equipment to the equipotential point. It is easily calculated from the data of the above paragraph.
that the #18 AWG grounding conductor has a resistance of 0.0384 ohm; the #10 AWG, 0.006 ohm. From these resistance values it can be calculated, through Ohm's law, that the #18 and #10 conductors carrying currents in excess of 0.130 ampere and 0.833 ampere, respectively, create equipment chassis potentials greater than 5 millivolts. Since currents larger than the aforementioned values can indeed occur, it is clear that neither conductor can provide complete safety to the 500-ohm patient.

To demonstrate this point, let a device contain a 3-ampere fuse. The device is on "standby," ready for use. To represent a condition of deteriorated or damaged insulation, let 2.9 amperes flow through 6 feet of #18 grounding conductor. This realistic condition clearly provides an example where the fuse will not break the circuit, and there will be no warning that more than 200 microamperes can flow through a patient even though the equipment is "grounded."

To form another example, let the neutral line, because the insulation has deteriorated, contact the frame of a "grounded" device. Inspection of figure 1 will reveal that the total current supplying the particular load will then divide between neutral and the grounding conductor. In equipment which uses 6 amperes, about 3 would flow through the grounding conductor, yet no fuse or breaker would react to the fact that the "grounded" chassis had been raised many magnitudes beyond the voltage presently believed to be "dangerous." Table 1 serves to demonstrate possible results in the clinical environment of the "electrically susceptible patient."

Should a grounding conductor be broken prior to any fault condition, there will be no warning of a potential hazard, and the chassis can carry as much as 120 volts, fully capable of providing 240,000 microamperes through 500 ohms (full-scale macroshock).

One inexpensive way to provide a solution to problems of broken or resistive grounds might be to increase the cross-sectional areas of all grounding conductors. This would increase the strength of the conductors and resistance would be very much reduced. It would also, however, prescribe the use of power cords exceeding one inch in diameter.

The unfortunate fact is that there are realistic conditions where ground currents of the conventional distribution system can, without warning, exceed 20 amperes. More severe faults, in actuality, can manifest ground currents in excess of 100 amperes before circuit breakers react to break the circuit. Clearly, grounding conductors would have to be very large to protect against all faults, many of which are possible, but of unknown probability.

The Need for Safety Measures

Which locations or clinical situations should be considered to contain electrically susceptible patients and which should not? What are the chances that grounds will not be broken but will be of impedances greater than 0.1 ohms where leakage of 50 milliamperes will raise the chassis to more than 5 millivolts? How probable are ground currents of certain ranges such as 50, 130, or 830 milliamperes in health care facilities? Is 10 microamperes really the lowest current which, if allowed to "reach the heart," can endanger life? How many patients are subjected to these "hazards" and how many electrical accidents do really occur? The facts is that nobody knows the exact answer to any of these questions.

Due to lack of important information, one can only partially justify decisions to remove, not to install, or to take several routes in protecting against "hazards" of the conventional distribution system. Thus one can react only on levels of intuition, formulated through knowledge of a wide range of electrical, system-oriented conditions which can be shown to be truly possible and possibly dangerous.

Presently we do know the following: 1) Patients are placed in a grounded environment served by neutral-grounded power. 2) Patients are often casually or rapidly connected to electrical or electronic equipment which has not been subjected to the rigors of good quality control or reliability engineering. 3) Patients are often connected to devices, the proper operation and maintenance of which is unknown to those who use the equipment. 4) Patients are often connected or proximate to equipment which may be antiquated and which has often been mistreated. It has been rolled roughly from place to place; its power cords have been yanked from outlets and rolled.
over by heavy objects; the ground prong has been cut off or the plug inserted into a cheater adapter as the ground “pigtail wire” floats free of ground. 5) Schematic diagrams often are not supplied with the equipment, and even when they are, many hospitals have no one qualified to examine the schematics to find the electrical hazards.

In consequence of these and other factors, many have claimed that the major problem is not with the power-distribution system, but instead with the equipment which is plugged into it. No one disagrees about the equipment. However, certain safer distribution systems, properly installed, maintained, and respected, do help protect against hazardous equipment. This is not to imply that dangers inherent in equipment or the operation of equipment would be erased. There would be, in fact, little need for safer systems if the equipment were not inherently dangerous! In view of the “hazards” of 5 millivolts and 10 microamperes, it is difficult and, in some cases, impossible to obtain devices which are free of electrical danger, and the spectrum of this danger is widest when these devices are served by conventionally distributed “Westinghouse electricity.”

Some feel the overall problem is attenuated by incorporation of larger grounding conductors within the distribution system. In actuality, this is not where the great problem lies. The grounding conductors which present the major issue here are those of power cords between power outlets and equipment. True, the larger the power cord conductor is in cross-sectional area, the safer it is, but this is not a complete solution to the problem. No conductor known to man has an impedance of zero ohms. Thus, there will be, for a conductor of any size, a quantity of current above which the conductor end-to-end potential difference will exceed any level considered dangerous.

There are others who vigorously state that ground currents of the order of 833 mA or 130 mA are highly improbable. However, they do not consider the fact that the grounding conductor pathways may not necessarily break, but can deteriorate to the point where much smaller currents can be dangerous. If probabilities are going to be used, then both factors should be included, for it is the product of current and impedance which quantitates voltage.

One school, often welcomed with open arms, is that which states, “The chances of many patients being shocked or electrocuted are very slim.” Such intuition may well contain the truth. However, the certainty of such statements must be questioned until a thorough, widespread survey and study of probable electrical conditions and associated patient safety is completed and the results proven and formally documented. It would seem best that such activity be directed to replace the ongoing stalemate of whether or not 1,500 patients “really” are electrocuted per year. Included should be more about the actual “susceptibility” of electrically susceptible patients. Eventually, then, the popular term “cost-effectiveness” may be better related to electrical safety.

Safer Systems

There are many approaches to making the environment of the “electrically susceptible patient” safer. Let us first focus on some of the simpler approaches.

Although electrical hazards are not unique to devices which are intentionally connected to patients, manufacturers now are introducing electrical isolation units which place an electrical “buffer” between patient and device. Examples of these are the various ECG patient isolators. These have extremely high output impedances relative to the equipment and high input impedances relative to the patient. This is to say that very little current could possibly flow from machine to grounded patient or from “energized” patient to grounded machine. Isolators, in essence, block electrical hazard pathways of which they are a part, yet allow the physiologic signals through. Certain radiotelemetry and optically-coupled units present characteristics of good isolation.

Another approach, similar to the isolator, is that of current limiting. Devices of this category allow current to flow only up to a specific level, but current above this level is “blocked.” Again, minute physiologic currents are accepted, but dangerous levels are not.

Available also is the ground fault interrupter which, upon sensing excessive equipment leak-
age current, immediately removes power from one or more devices. This approach, of course, has serious shortcomings and inherent dangers with regard to essential life-support equipment.

A safer environment can be provided, with varying degrees of ease, by insulating equipment surrounding the patient. Nonconductive enclosures, for example wooden or plastic, can serve as relatively inexpensive protection. This provision rests within the category of so-called "double insulation." 

Several methods for delivering electricity can replace the neutral-grounded distribution system. One example is the use of battery-powered devices. This approach is gaining increased popularity, especially for cardioscope and blood pressure monitors. Trickle chargers which plug into the conventional power outlets are sometimes utilized to charge the batteries. Generally it is wise not to use the chargers while the equipment is in contact with the patient, for the safety provided by the battery supply is then apt to be defeated. This point is often ignored or misunderstood.

Another example is the utilization of motor-generator sets. Certainly, motors with nonconductive connections to generators could provide isolated ("neutral-floating") power. However, for each foot of distribution cable to the location of the electrically susceptible patient, there will be increased leakage, within the cable, to ground. Should the cable distance be made short, there probably would be mechanical noise undesirable for patient and medical staff.

Another method of providing safety consists of "tuning." Auxiliary impedances are adjusted within devices to tune ground current to zero amperes. Thus, should the ground conductor break, no current could flow from equipment through patient to ground. However, tuning does not appear to be practical for general application at this time. Proposers of the system say the technology needed to put it in general use economically has not yet been fully developed. Further, tuning will not work with the conventional, neutral-grounded system.

Due to the fact that broken grounds appear to be the most common failure within the hospital electrical complex, redundant grounding has been suggested. This step, along with routine ground inspections, indeed does make for a safer system. The unfortunate component of this approach is the fourth wire, which calls for new plugs and sockets or a separate, extra wire connected from each device to ground. Although hazards of the three-wire neutral-grounded distribution system perhaps would be reduced, there would be no guarantee of protection against large ground currents and/or excessive ground-contact impedances.

The Isolation Transformer

An additional technique of providing a safer, but still not absolutely safe, environment for the electrically susceptible patient is the isolation transformer. Isolation transformers can be included within each device or used as part of a patient power-distribution panel. This approach is more complex than all the earlier examples, has led to much controversy and confusion, is expensive, and is not the cure-all.

Isolated power distribution systems have been referred to as ungrounded systems. Owing to the use of the word “ungrounded,” some have been led to believe that equipment served with isolated power need not be grounded. This is truly a misconception which could lead to real danger. As the reader will recall, the neutral conductor (fig. 1) is grounded at the hospital service entrance. Consequently, the conventional distribution system is referred to as “neutral-grounded” or, simply, “grounded.” There are three conductors, a hot conductor, a neutral conductor, and a grounding conductor. Full line voltage exists from hot to neutral and from hot to ground.

In the isolated power system, there is no “hot” conductor and no “neutral.” Instead, the two power conductors may be referred to as “line 1” and “line 2,” both of which are “ungrounded” or “floating.” Between them is provided the potential difference of 120 volts. Line voltage, however, does not exist from either line to ground. This is accomplished through use of a transformer. A grounding

† The author has been informed that electrical interference on cardioscope monitors is significantly increased as double insulation is used with electric beds; however, he has made no investigation pertaining to this report.

† Voltage capable of supplying large amounts of energy to equipment and, inadvertently, to the patient (120-v source with low output impedance).
A transformer is, in general, a four-terminal input-output device which contains two adjacent, but separate, conductive pathways which are wound about an iron core. The input winding is called the primary; the output winding, the secondary. Alternating current, when applied to the primary, creates a magnetic "signal" called flux which is guided through the iron core. Elsewhere on the core is the secondary winding, which receives the magnetic flux. Upon this reception, a voltage which corresponds to that of the primary is induced as secondary output (fig. 2).

While the distribution system of figure 1 is used to supply current to the primary, ground does not contribute to the corresponding magnetic flux. Thus, the grounding conductor could be removed from neutral at the service entrance and little change would be seen if one were to measure secondary voltage, line to line or line to ground. The output is said to be floating relative to ground. This indicates the key advantage of isolation. Should a grounded patient or other grounded conductor come in contact with either secondary terminal, virtually zero current would flow through the conductor to ground. This would not be the case for contact with the hot, the neutral or, in some cases, the ground conductor of the conventional system.

Due to leakage, which does exist between the primary and the secondary, a little of the secondary output is not isolated from ground. The magnitude of this unavoidable leakage is one major factor which determines the quality of a transformer used for purposes of isolation (viz., an isolation transformer). Devices served by the secondary are grounded, therefore, to clear these currents (now small), but still referenced to ground. What really has been gained is nearly 100 per cent release from the built-in 100 per cent "leak" of the conventional distribution system, namely, neutral connected to ground at the service entrance.

In summary, the purpose of the isolation transformer is to serve grounded devices with two power lines, both of which have been "released," although not completely, from environmental ground. Therefore, these power lines do not have the capability of transmitting large currents through grounding conductors even should one line short, partially or completely, to the chassis. Consequently, the "less than 5 mV" criterion is much more easily achieved.

Since there is no such thing as perfect isolation from ground, and since power cords and equipment augment the total leakage to ground, it is necessary that some instrument measure and indicate the status of system isolation. One popular much-debated instrument which is meant to provide such a function is the dynamic ground-fault detector, or line-isolation monitor (LIM).

The Monitor

The major intent of the monitor is to predict the quantity of current which could flow to ground should either isolated (ungrounded) power conductor be inadvertently grounded. One fundamental need for ground-fault detectors is in the operating room, where sus-
ceptibility to electrically-induced combustion of anesthetic agents exists. Stiner reported that currents of less than 2 milliamperes are not capable of supplying enough energy to constitute an explosion hazard. In accord with this report, detectors are adjusted to warn of potential leakage currents equal to, or greater than, 2 milliamperes.

Currents displayed by the monitor are generally referred to as the “maximum total hazard index.” These can be used to foretell the highest current a grounded patient could receive if he were to be in “electrically susceptible” contact with a device (with broken ground) in which one power line was in direct contact with the chassis or metallic frame of the device. A detailed, technical discussion of ground-fault detector rationale and design has been presented by Kusters.

The Meter

A meter through which the line-isolation monitor displays data is shown in figure 3. The meter has two scales which serve to report the active status of isolation. The upper meter labeling represents leakage in terms of how direct a connection has been established between each power conductor and ground. The LIM “investigates,” alternately, line 1 and line 2. The “directness” of contact with ground is represented in units of impedance (kilohms). Note, on the far left, the symbol for infinity, on the far right, zero. These limits, respectively, indicate conditions of zero leakage and complete line-to-ground connection (100 percent leakage). All other degrees of contact fall between these two limits of “line-fault impedance.”

The lower scale, “Maximum Total Hazard Index” is represented in milliamperes. Should one “isolated” line be in contact of magnitude 416 kilohms with ground, as indicated (by arrow), a maximum of 1.5 milliamperes could flow through a good conductor inadvertently connected between the other “isolated” line and ground.

The range from the lowest reading to 2 mA is labeled “safe,” for upon contact of either power line with ground, not enough energy could be released to trigger an explosion in the operating room. The readings above 2 milliamperes fall within a range labeled “unsafe.” These range designations or zones are in keeping with standards of explosion prevention and must not be confused with the electrical-safety status of patients.

With or without line-isolation monitors, and regardless of zone, “electrically susceptible patients” would stand a meager chance of being safe, attached from either “isolated” power line to ground. Regardless of the quality of the isolation transformer, external leakage (10, 20, 100 microamperes, etc.) is unavoidably contributed by equipment and power cords. Thus, perfect isolation is impossible to attain. However, ground current is limited to levels very much lower than those characteristic of the conventional neutral-grounded system.

Broken Grounds

In predicting the maximum total hazard current, the line-isolation monitor utilizes a cumulative current which flows through continuous grounding conductors. This current flows alternately from line to line, through a pathway provided by the monitor, grounding conductors, and leakage impedances of equipment and power cords. The magnitude of this current, used in the “computation” of the maximum total hazard index, is a function of equipment and power-cord leakage impedance pathways to ground. Should a ground wire of a device break, then information concerning leakage of the device will not be included as a constituent of total monitor information; hence, the overall status could appear to be safer.
than it really is. The probability of correctness in the “readout” of maximum total hazard index is decreased in accordance with the probability of broken grounds.

The line-isolation monitor will not, and was not intended to, detect broken grounds. The major information the monitor does report is, “Should a ground wire break, an electrically susceptible patient could receive the electrical current indicated as ‘maximum total hazard index.’ This patient must contact ground and must, in some way, contact the more dangerous of two power lines.” Currents less than the maximum could flow and be dangerous should contact with ground or power line not be direct. The key weakness which provides the hazard is excessive grounding impedance. In view of this, one can see an important imperfection in the safety provided if this system is not accompanied by continuous or at least periodic ground continuity inspections, as indicated in NFPA 76BM.²

Not a Scanner

The line-isolation monitor generally is located in a distribution panel with the isolation transformer. All incoming equipment grounds are electrically joined within the panel to form an electrical point, connected to the monitor. Thus, the monitor “looks into” the entire equipment-grounding complex. Each power line, then, is investigated for leakage to this ground point. The line-isolation monitor is not a scanner which spot-checks individual devices for leakage. Rather, it warns of a future maximum total hazard current, although the current may be due to only one device. A full-scale warning on the LIM meter, for example, may warn that a certain faulty device served by the panel has just reverted the entire system to one which is neutral-grounded, with all the inherent dangers.

The Minimum, Maximum Total Hazard Index

Figure 3 reveals that the lowest maximum total hazard index of the monitor is not zero. The minimum which accompanies an infinite ground-fault impedance (no leakage) is, for purposes of the discussion, chosen to be 1 milliamperre.¶

The electronics of the monitor described by Kusters ⁶ mandates that some current for “computation” purposes be allowed to flow alternately from each line to ground, then onward, en route to the other line through leakage impedances under investigation. Should these impedances be infinite (no external leakage), then monitor and ground current will be zero. Should one line short to ground, current will flow from the other line through the monitor, through the ground point, and through the shorted line. The magnitude of this ground current would be 1 milliamperre, and the meter would read zero kilohms.

This current has more generally been called the “detector hazard index.” This current could constitute a hazard if the patient were grounded and if he were connected to or contacting either power line. More realistically, such a mishap would require four undesired events: 1) that ground on a device be broken; 2) that the patient be grounded; 3) that one power line directly contact the ungrounded chassis of the device; 4) that the patient contact said chassis.

In evaluating the hazard, however, one must consider that incomplete degrees of the preceding difficulties can still present some danger: 1) Ground need not be completely lost, but only of excessive impedance. 2) The patient need not be directly grounded, but only grounded through sufficiently low impedance. 3) The power line need not directly contact the device chassis, but merely leak through a sufficiently low impedance. 4) The electrically susceptible patient need not be in direct contact with the device, but only in contact through impedance sufficiently low that 10 microamperes of the possible 1 mA could pass through pathways of electrical susceptibility.

Micro-leakage

It should be clear that the LIM does not display leakage current. Instead, the device utilizes current capable of passing through given leakage pathways to foretell the maximum current which could, upon worst-case fault, travel through the grounding system. In providing this information, the monitor does help protect against microshock hazards which plying monitors with minimums less than 1 milliamperre, and the trend is to go much lower.

¶ One milliamperre represents certain monitors presently available. Manufacturers are now sup-
TABLE 1. Typical "Grounded" Equipment That Surrounds the Electrically Susceptible Patient*

<table>
<thead>
<tr>
<th>Device</th>
<th>Approximate Load (Amperes)</th>
<th>Neutral-Short Chassis Volts</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>#10 AWG (mV)</td>
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<tr>
<td>Hypo-hyperthermia unit</td>
<td>11</td>
<td>33</td>
</tr>
<tr>
<td>(Blanketrol)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MA-1 respirator</td>
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<td>9</td>
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<tr>
<td>(Puritan Bennett)</td>
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<td></td>
</tr>
<tr>
<td>Cardioscope</td>
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<td>0.75</td>
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<td>(American Optical)</td>
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<tr>
<td>Defibrillator</td>
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<td>12</td>
</tr>
<tr>
<td>(American Optical)</td>
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<td></td>
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<tr>
<td>Electric bed</td>
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<td>7.5</td>
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<tr>
<td>(Simmons)</td>
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<td></td>
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<tr>
<td>Bed scale</td>
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<td>1.5</td>
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<tr>
<td>(Brookline)</td>
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<td>Hemodialysis machine</td>
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<td>Dialysate delivery pumps</td>
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<td>6</td>
</tr>
<tr>
<td>(Emerson)</td>
<td></td>
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</tbody>
</table>

* If the neutral wire shorts to the chassis, the total load current will split between neutral and grounding conductors. More than half of the devices become dangerous with 6 feet of #10 AWG grounding conductor and nearly all are dangerous with 6 feet of #18. No fuse or breaker interrupts power in this situation, and there is no warning of failure. A one-to-one “split” has been assumed for purposes of this demonstration. The hazards are a function of load current, not necessarily representative of poor equipment design.

TABLE 2. Typical Grounded Equipment That Surrounds the Electrically Susceptible Patient*

<table>
<thead>
<tr>
<th>Device</th>
<th>Approximate Load (Amperes)</th>
<th>Line 1, 2-Short Chassis Volts</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>#10 AWG (mV)</td>
</tr>
<tr>
<td>Hypo-hyperthermia</td>
<td>11</td>
<td>0.012</td>
</tr>
<tr>
<td>(Blanketrol)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MA-1 respirator</td>
<td>3</td>
<td>0.012</td>
</tr>
<tr>
<td>(Puritan Bennett)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardioscope</td>
<td>0.250</td>
<td>0.012</td>
</tr>
<tr>
<td>(American Optical)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Defibrillator</td>
<td>4</td>
<td>0.012</td>
</tr>
<tr>
<td>(American Optical)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electric bed</td>
<td>2.5</td>
<td>0.012</td>
</tr>
<tr>
<td>(Simmons)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bed scale</td>
<td>0.5</td>
<td>0.012</td>
</tr>
<tr>
<td>(Brookline)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hemodialysis machine</td>
<td>11</td>
<td>0.012</td>
</tr>
<tr>
<td>(Travenol)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thermiotic suction pump</td>
<td>0.6</td>
<td>0.012</td>
</tr>
<tr>
<td>(Gomco)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dialysate delivery pumps</td>
<td>2</td>
<td>0.012</td>
</tr>
<tr>
<td>(Emerson)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Either “isolated” line shorts to the chassis. Ground current is limited to 2 milliamperes by the transformer and line-isolation monitor. None of the devices becomes dangerous with 6 feet of #10 AWG grounding conductor and none is dangerous with 6 feet of #18. Although no fuse or breaker interrupts the power, the line-isolation monitor WARNS audibly and visually of potentially hazardous current which could flow should contact between the opposite line and ground be made.

could accompany future line-to-ground faults and against macroshock which is the hazard that results from very poor isolation coexistent with insufficient grounding. The monitor certainly does not display microleakage currents already known to exist in old or new devices and power cords.

Certain monitors could be adjusted to alarm or read “unsafe” in correspondence with, for example, 5.0 microamperes. The existence of small leakage currents known to be present would then be verified as alarms and “unsafe” readings would occur frequently. The detection and verification of such highly probable and presently unavoidable leakage would seem to be more of academic value than of use.

Warning and Microshock Protection

The major advantage of the isolation transformer and line-isolation monitor is the warning provided when it has become possible for 2 milliamperes or more to flow directly from either power line through the grounding system to earth. Below this point of warning, neither power line is capable of “discharging” more than 2 milliamperes through grounding conductors. In contrast, neither warning nor such ground current limitation is provided in the conventional neutral-grounded system, where only one of many failures is necessary to constitute active danger. Comparison of table 2 with table 1 demonstrates the relative safety of systems.
The Operating Room

Those who fear the LIM and choose to supply grounded devices with individual isolation transformers in the operating room had better beware. Operating room distribution systems are, by code, supposed to be served by an isolation transformer and line-isolation monitor.

Should either terminal side of the secondary of an individual (second) isolation transformer leak beyond the 2-milliamperere point of impedance (60 kilohms), there will be no warning of an explosion hazard, for the second transformer limits ground current which would normally flow through the monitor. Hence, the monitor will not be supplied with proper information. Individual isolation transformers in combustible environments should be supplied with individual line-isolation monitors or their equivalent.

Summary of the Isolated Power Distribution System

In summary, the following can be said of the isolated power-distribution system which contains an isolation transformer and line-isolation monitor.

1. Line-isolation monitors were developed initially for use in the operating room. Meter zones “safe” and “unsafe” are labeled as such for purposes of explosion prevention.

2. The monitor, via a meter, provides information about the status of isolation. The alarm warns that 2 milliamperes or more could flow from line to ground.

3. The monitor was neither designed to, nor does it, detect broken grounds. The “report” of the monitor is weakened in accordance with the probability of broken grounds.

4. The monitor was neither designed to, nor does it, scan the leakage of individual devices. The monitor is utilized to examine the entire system.

5. The minimum maximum total hazard index is greater than zero, but does not exist in the form of current unless an external conductive pathway is inadvertently provided from either power line to ground.

6. The monitor does not confirm the fact that minute leakage currents do flow in grounding conductors. The monitor does confirm the fact that dangerous currents which grounding pathways may not adequately clear could occur upon future fault.

7. The monitor and transformer limit fault currents to levels easily cleared through grounding pathways. Alarm is provided and indication is given when larger ground currents are possible, pending a future, severe line-to-ground fault.

8. Individual isolation transformers, used as distribution subsystems without ground-fault detectors, defeat the master monitor and can “hide” impending explosion hazards in the operating room.

Relative Safety of Systems

The most important element common to both the conventional, neutral-grounded, and the isolated power-distribution systems is the grounding conductor. The desired function of the grounding conductor is to clear leakage (or fault) potentials from conductive frames and chassis of devices within the equipotential environment of the electrically susceptible patient. Any reasonable-sized grounding conductor, or redundant grounds, may fail to provide such protection upon certain, single, conventional-system failures. However, reasonable-sized grounds can indeed provide this protection when identical failures exist in the environs of isolated power-distribution systems.

Under the same fault situations, with ground broken, the conventional neutral-grounded system can neither warn of, nor prevent, hazards of micro- or macroshock. Poor grounding as well as large leakage currents must be considered as probable failures. Due to the microshock hazard which still can occur in the isolated system, although with significantly less possibility, the author has chosen to use for it the classification “safer system” rather than “safe system.” Upgrading of the isolated (or ungrounded) system toward a “safe system” in which only multiple, remotely possible failures could lead to hazardous situations depends, in large part, on the integrity of grounding pathways. The concepts of “tuning” and double insulation present interesting possibilities which,
in the future, may help decrease the hazards of broken grounds, poor grounds, and excessive leakage.

Power cords, plugs, and receptacles must be improved with several goals in mind. 1) Leakage in the cord should be minimized. 2) Reliability of good grounding should be increased. 3) Ground-continuity indicators which do not require two grounding conductors for operation should be developed. 4) Grounds should be inspected routinely with a frequency based on “ground-insufficient” statistics. 5) Grounding pathway impedance should be maintained such that probable single faults for which no prior warning has been given can be cleared to safe magnitudes.

The matter of providing safer systems for the electrically susceptible patient is obviously complex. Anyone without specialized training cannot, alone, be expected to make decisions regarding the design of safer systems. Complexity is compounded as the electrical and/or mechanical design engineer must make “safer systems” compatible with the environment of the health care facility.

Some General Precautions

The author believes that the following should be instituted in any health care facility, and especially in any area which contains electrically susceptible patients. These suggestions apply regardless of any “safe” systems or techniques planned or existent in the facility other than the complete abandonment of electricity.

1) Do not allow patient-owned, plug-in-type electrical devices in the hospital. These include radios, television sets, line-operated shavers, battery chargers, hair dryers, fish-tank heaters, fans, clocks, etc. At this institution such a policy has been in operation for three years. A notice is placed in every lobby and on patient floors, and also is distributed by our admitting department. It reads: “Important Notice. Out of concern for the safety of our patients, Memorial Hospital does not permit personal plug-in-type electrical appliances to be brought to or used in the hospital. Only totally battery-operated equipment is permissible.”

2) Institute a hazard-detection program directed to every employee who will enter patient locations or who is responsible for electrical equipment which will enter these locations. The program should be an ongoing one. We have prepared an internal publication, a manual which supplements a two-hour course. It contains three parts, “Basic Electricity,” “Electricity and the Heart,” “Hazard Detection.” Supplemented with problems and answers, the manual is quite fully illustrated, especially in the third part. Lectures are given in two parts, one hour each, and are ended with actual hazard setups in which the employee gains confidence in what we call “clearing up the mess.”

3) Do not accept or use two-wire devices; sockets or plugs. One two-wire device found in this hospital is used in the hazard detection course. The device is a simple, faultless-looking, perfectly operational, gooseneck lamp. Its frame is capable of lighting to full brilliance a 100-watt lamp bulb, one terminal of which is grounded, for example, to a grounded ECG machine. A nurse, upon lending the lamp to the author, advised, “Now, you be very, very careful with that lamp, because I got an awful shock from it last month.” She continued, “… and please do not forget to return it.”

4) Cheater adapters should be considered as dangerous as two-pronged ungrounded devices. Many staff members have believed that devices supplied with a three-pronged plug are grounded when used with two-pronged sockets so long as the cheater adapter is placed between the two. This is true only when the cover-plate of the socket is grounded; more specifically, when the cheater “pigtails” is connected to a grounded, conductive part of the cover-plate. These “pigtails,” however, are usually not connected. In addition, the pigtail is often ready to break or is broken; or the cheater is misplaced. Then, if the socket is two-pronged, the third prong of the plug is cut off or, if cutters are not available, bent until snapped off. Plugs and sockets should be three pronged (at least), and routine inspection of grounding pathways is a must. About three years ago roughly 240 ungrounded, two-

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f Some two-wire methods, associated with “double insulation,” may eventually be approved by code. The author’s personal belief is that this will cause confusion above the present confusion, which is already great.
pronged devices were detected in a 250-bed wing of this hospital. About 10 per cent of these included cheater adapters, most of which were supplied by outside vendors (rental televisions, respirators, suction devices, etc.). Some cheaters were used unnecessarily between three-pronged plugs and three-slotted outlets.

5) Institute routine electrical survey and maintenance programs. Equipment must be maintained by those properly trained to be aware of the type of clinical application, area of use, mobility, and hazard potential of the device. Institute a maintenance schedule for every device, including outlets and plugs. This overall task can be expensive, time-consuming, and conveniently forgotten because we have few reports of, and do not "know for sure," how many patients have been shocked or electrocuted.

6) Insist that all manufacturers supply complete instruction and maintenance manuals for electrical and electronic devices. Obtain MTBF (mean time between failure) reliability data where possible. Ask about quality control and failure-analysis departments or groups in the factor. Utilize qualified personnel to participate in or to control this area of incoming evaluation and analysis of "in-the-house" equipment. Ask whether improper operation of the device can, in any way, lead to electrical accidents, and especially, whether any single failure within the device can present an electrically hazardous condition. Include with every purchase order for electrical or electronic equipment a statement to the effect that the equipment must be supplied with a three-pronged plug and complete instructions and maintenance manuals.

7) Do not accept as an entire solution "safe," battery-operated, or low-voltage, direct-current devices. We have experienced two low-voltage direct-current incidents in which anesthetized patients were seriously burned. In both cases no schematic diagram had been investigated or was readily available. One of the devices was brand new, having been used only a few times. Voltages in each case were less than 15 volts, direct current. We have found that voltages as low as 3 volts direct current (two flashlight batteries) can cause burns. The burns are due neither to high current nor to heat, but to chemical byproducts of saline electrolysis. Recently, another institution reported a case of direct-current burns, and, although the probability is unknown, it may well be that these burns are occurring more frequently as low-voltage, direct-current (e.g., battery operated) devices enter the health care facility. Again, the need for good equipment evaluation and testing is emphasized.

8) Do not accept "safer" or "safe" systems as a substitute for any safety measure indicated in the above suggestions. True, "safer systems" can and do provide significant additional protection against the hazards of antiquated, under-maintained, or inherently dangerous equipment and certain systems are designed to, and can, warn of impending hazards. Safer systems, however, will not replace general precautions.

Evaluation

No one system or protocol can guard against all combinations of electrical failures, misuses and misapplications. The electrical safety armamentarium should include device-oriented and power-distribution safeguards.

Device- or equipment-oriented approaches fall within categories of a) equipment control structures, b) in-service equipment training programs, c) manufacturing and "in-the-house" changes, such as double insulation, tuning, and redesign. Each of these is complex and expensive, and none is accomplished rapidly. In the long run, however, hospitals may save money through these means. Accidents, on the other hand, will continue until action in each category is optimized. Improvement of the distribution system in key locations can help prevent accidents during developmental periods of device-oriented programs.

As for accidents, the major controversial issue is that of microshock. Although there has been much publicity, there really is no proof of the number of fatalities or incidents. A recent report by Bruner et al. stated "no support was found for anxiety about microshock," but all data used for the report were obtained from only one institution already "sensitized" to the need for electrical safety. Their findings may well be indicative of equipment control techniques and/or other facets of
PROTECTION OF ELECTRICALLY SUSCEPTIBLE PATIENT

a hospital electrical safety structure, but this is not at all commonplace. Some feel that a false premature sense of security against hazards of microshock may be derived from this report. Microshock is difficult to predict, is undefined in terms of voltage and current levels, leaves no trace to be found at postmortem examination, and could arise under transient conditions, not remaining after the "unexplained cardiac arrest."

Perhaps more representative of hospitals throughout the United States are the 20 recently surveyed by the Boston Patient Safety Committee and the Massachusetts Safety Council, an affiliate of the Massachusetts Hospital Association. If these hospitals are representative, and if the author interprets the data correctly, then we are confronted with the following statistics: 1) Forty per cent of the hospitals indicate they are doing virtually nothing along routes of electrical safety. 2) Fifty-five per cent have no engineer or electrical technician on their staff. 3) Fifty-five per cent have no device to measure or to check for excessive leakage levels. 4) Sixty per cent have no equipment control program, and only 40 per cent keep technical records of equipment. 5) Forty per cent do not keep check on the status of power outlets and other aspects of the distribution system. 6) Fifty per cent have no in-service training in the use of electrical equipment.

These figures, coupled with the fact that the "benefits" of electricity and medical electronic devices are not restricted to hospitals which are "sensitized" to the need for electrical safety, would seem to indicate need for not only "anxiety about microshock," but anxiety about macroshock and burns as well.

Until statistics become more encouraging and manufacturers provide superior devices to replace existing ones, it would appear best in the interest of safety that safeguards be provided through safer distribution systems and better cords, plugs and sockets.

"Good," maintained grounding can protect against many hazards of macroshock and burns, but cannot alone adequately protect against the levels considered to constitute microshock hazards. However, should the volt-ampere thresholds of microshock danger be found to be significantly higher than presently believed, then "good grounding" alone may suffice.

Decisions to mandate the use of safer systems or to exclude such systems by code cannot yet be supported by accurate data. However, engineering conclusions about safer systems are supported by basic laws of electricity. Common arguments that increased expense and added complexity give reason not to use these systems should not overstep the boundaries of these laws.

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