PATIENT SAFETY
This Patient Safety Application Note is a discussion of the technical, often subtle, factors involved in accidentally induced ventricular fibrillation. Safety design considerations in electronic equipment (particularly patient monitoring), power wiring systems, isolation transformers and new safe grounding procedures are discussed in this note, including Hewlett-Packard's engineering efforts in this discipline.

Efforts being made by professional organizations to improve safety through the development of a unified body of standards which will serve equipment users and manufacturers alike are briefly treated in the Foreword. The common goal among those involved is the greatest attainable protection for the patient.
FOREWORD

Recognition of the hazards of electrical shock to the catheterized patient has not paralleled the advances in medical electronic technology. It has become obvious that the prevention of electrical shock in today's patient care systems requires an aggressive assault on the barriers that prevent the hospital environment from being electrically safe. These barriers include a limited understanding by hospital personnel of the interaction of indwelling devices to appliances, patients and attendants; limited available data on patient safety; limited good maintenance routines; and the lack of a logical set of safety standards for both manufacturers and hospitals.

Several professional organizations within the medical instrumentation field have recognized the need for improved safety standards for medical equipment of all types. These groups have established safety committees with the intent of developing electrical standards on specific types of medical equipment. Their combined effort has been impressive, and a unified set of standards is beginning to evolve which should serve equipment users and manufacturers well in years to come. Purchasers and users will have assurance that their equipment will comply with the minimum performance requirements of the safety standard. Manufacturers will also benefit from having a definite set of safety goals from which to design equipment. Of course, as with any standards-setting activity, there are pitfalls. Standards must be written to define desired performance, not to define the methods by which such performance is to be achieved. Also, the standards must be realizable and reasonable from the standpoint of technology and cost.

Hewlett-Packard Medical Electronics Division has available three publications on electrical safety. The first, entitled "Using Electrically-Operated Equipment Safely With the Monitored Cardiac Patient," is written with the electrically uninformed person in mind. It contains practical information which the nurse or equipment technician will be able to use in their day-to-day activities. "Patient Safety Application Note AN-718" reviews the background of the electrical hazard, equipment faults, and safe practices to follow in building or remodeling a patient care area. Another booklet on "Maintaining the Safe Patient Environment" describes some important preventive measures and periodic checks hospitals should be aware of to maintain the electrically-safe patient environment. Finally, for those who desire further reading in the subject of patient safety, the papers in the References are recommended.
ELECTRICAL SHOCK . . .
A GROWING CONCERN
OF THE MEDICAL
COMMUNITY

There has been concern about shock hazard ever since electric power came into general use in the late nineteenth century. Probably the first electricians painfully discovered that there was more to electricity than running wires, installing generators and lights -- there was a potential hazard to themselves and others if they failed to observe certain "do's and don'ts". So electric companies got together to establish guide lines of safety to protect both their customers and workers. As a result much testing has been done through the years to establish safety standards by determining what amount of current makes one feel uncomfortable, what causes death, etc. The findings of these studies are summarized in Table 1.

### TABLE 1. Effects of 60 Hz Electric Shock * (Current) On An Average Human Through the Body Trunk

<table>
<thead>
<tr>
<th>CURRENT INTENSITY – 1 SECOND CONTACT</th>
<th>EFFECT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 MILLIAMPERE</td>
<td>THRESHOLD OF PERCEPTION</td>
</tr>
<tr>
<td>5 MILLIAMPERES</td>
<td>ACCEPTED AS MAXIMUM HARMLESS CURRENT INTENSITY</td>
</tr>
<tr>
<td>10 – 20 MILLIAMPERES</td>
<td>&quot;LET-GO&quot; CURRENT BEFORE SUSTAINED MUSCULAR CONTRACTION.</td>
</tr>
<tr>
<td>50 MILLIAMPERES</td>
<td>PAIN, POSSIBLE FAINTING, EXHAUSTION, MECHANICAL INJURY, HEART AND RESPIRATORY FUNCTIONS CONTINUE.</td>
</tr>
<tr>
<td>100 – 300 MILLIAMPERES</td>
<td>VENTRICULAR FIBRILLATION WILL START BUT RESPIRATORY CENTER REMAINS INTACT.</td>
</tr>
<tr>
<td>6 AMPERES</td>
<td>SUSTAINED MYOCARDIAL CONTRACTION FOLLOWED BY NORMAL HEART RHYTHM. TEMPORARY RESPIRATORY PARALYSIS. BURNS IF CURRENT DENSITY IS HIGH.</td>
</tr>
</tbody>
</table>

*Throughout the text the reference to "shock" is described in terms of electrical current.

Most accidental contact with electrical wiring occurs through intact skin surfaces. This is an important point to observe, since humans and animals are fortunate in having a skin that is a relatively good insulator surrounding their more susceptible internal organs.

Measurements made from one hand to the other have shown that resistance of the human body to electrical currents through intact skin surfaces can vary from 1000 ohms, if the skin is damp, to over 1,000,000 ohms, if the skin is dry. Probably all of us have experienced electric shock at one time or another. Although the threshold of perception of shock varies widely from person to person, it is about 1 milliamperes (one one-thousandth of an ampere). At this level, a faint tingling sensation is felt. At current levels of around 5 milliamperes, many sensory nerves are stimulated and the sensation becomes painful, usually to the point that the subject jumps away from the source of stimulation.

At current levels higher than 5 milliamperes, motor nerves are stimulated and the associated muscles contract. At the so-called “let-go” current level, (approximately 10 to 20 milliamperes) a person can just manage to release his grip on conductors supplying current. From 20 milliamperes to approximately 100 milliamperes, the subject has no ability to control his own muscle actions and he is unable to release his grip on the electrical conductor. The electrical current stimulation becomes increasingly painful and physical injury may result from the powerful contraction of the skeletal muscles. Despite pain and fatigue, the heart and respiratory functions usually continue since the current spreads uniformly through the trunk of the body and tends to bypass the heart as it makes up a relatively small part of the cross-sectional area of the human trunk.

At about 100 milliamperes, more life-threatening physiological phenomena can occur. One of the more common is ventricular fibrillation, a lack of coordinated action among the muscle fibers of the heart. To understand fibrillation we should discuss briefly the physiology of the heart.

The heart is one of the most sensitive organs to electric current. Since it depends for its function on periodic, highly organized muscle contractions controlled by internally generated electrical stimuli, small periodic external currents through the heart can derange the normally organized patterns. If the external current is of sufficient strength through an area of the heart, some of the muscle cells are captured by the unwanted stimuli and act out of the sequence which would normally cause an effective heart contraction to pump blood. One might think that a few cells acting out of sequence would not compromise the pumping ability of the heart. However, if a few cells become deranged, the effect propogates to neighboring cells which also become deranged and they in turn act on their neighbors in a similar manner (see Figure 1). This “chain reaction” can, in a relatively short time, result in most of the heart cells assuming random, chaotic activity instead of the synchronized action necessary for a useful, blood-pumping contraction. This random activity of the heart cells is referred to as “ventricular fibrillation”. Fibrillation defeats the heart’s ability to pump blood and is fatal unless corrected within minutes.

![Figure 1. The Heart In Ventricular Fibrillation](image-url)
If the electric shock to the body is as high as six amperes from accidental exposure to live conductors, the heart goes into sustained muscular contraction much as skeletal muscles do at above the "let-go" level referred to on Table 1, but if the current duration were only a few seconds, the heart can revert to normal coordinated muscular pumping. This phenomenon is used to restore fibrillating hearts to normal rhythm by applying a high current from a defibrillator for a few thousandths of a second.

Continuous high current levels of 6 amperes or more also cause temporary respiratory paralysis and may cause serious burns, if the current density is high. At current levels much above 6 amperes, massive damage is caused by the heating effect of the current flow. The voltages required to obtain these levels vary widely because impedance varies from person to person depending on skin type, contact area, and on other parameters such as whether or not the skin is moist or dry.

From the many investigations conducted over the years, 5 milliamperes has become accepted as the maximum current that should be allowed to pass through a human from external contact. Among the many tests that electrical equipment must pass to receive the Underwriter Laboratories listing is one specifying that "60 Hz leakage currents from the power line to the equipment case shall be less than 5 milliamperes." That is, if a person were to touch an electrical instrument or appliance while standing barefoot on wet earth, there should be no more than 5 milliamperes flowing through his body. The fact that accidental electrocutions are relatively rare is, at least in part, due to the adequacy of these standards.

In the early 1960's, the benefit of electronic monitoring equipment for some types of patients was widely recognized by the medical community. Relatively little attention was given to patient safety in this new environment where:

a. fluid electrolytes inside the body substantially reduce resistance to current flow (or electrodes in the body increase hazard to patient);

b. manufacturers differ in grounding systems and isolation techniques;

c. hospital power wiring is often inadequate;

d. hospital maintenance personnel do not thoroughly understand patient hazard, electrical grounding, leakage currents, etc.;

e. attendants and doctors have little knowledge of electricity and of their role in maintaining a safe electrical environment.

For example, a patient in a modern surgical intensive care unit may have as many as four direct connections to his heart to allow pressure measurements in the heart chambers. (This same patient could be on an electrically operated bed, with electrocardiographic electrodes, temperature probes, respiration sensors: be covered by a hypothermic blanket, and be connected
to a ventilator.) A patient in a coronary care unit often has pacemaker catheters running through a major vein directly into the heart muscle, ready to take over if the heart’s own pacemaker fails. A patient in a modern catheterization laboratory may require conductive catheters in the vicinity of the heart to measure intracardiac ECG’s and pressures within the heart chambers. All of these procedures have one thing in common: the electrodes and catheters are located inside the body and they bypass the protective electrical insulation of the skin.

Experimental work on dogs has shown that ventricular fibrillation could be produced by currents as small as 20 microamperes (20/1,000,000 of an ampere) at power frequencies of 50 or 60 Hz when the current is applied directly to the heart (see Figure 2). The reason for this increased sensitivity, which is 5000 times below the 100 milliampere level required for currents passing through the trunk, relates to the current density. Intracardiac electrodes are often in contact with less than one square centimeter of the heart muscle. This means that the 20 microamperes current is concentrated through relatively few heart muscle cells and the derangement of only these few cells is sufficient to cause ventricular fibrillation.

The actual value of current which is considered hazardous under these conditions is still under active investigation. Experiments on human subjects to determine the hazardous threshold have not been and are not likely to be performed. As a result, hazard limits must be based on extrapolation of animal experiment data. Based on this, several groups working on establishing safe levels of 60 Hz and 50 Hz current passing directly through the heart have established 10 microamperes as the upper limit.

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**FIGURE 2.** 20 Microamperes Can Produce Ventricular Fibrillation In Dogs

2 "Electrical Hazards Associated With Cardiac Pacemaking" Whalen, R.E.; Sturmer, C.H., and McIntosh, H.D.
Electrical hazards which arise in the hospital environment can be categorized into two types. The first and most obvious type of hazard is dangerous not only to the patient, but to the medical staff as well, and is caused by electrical wiring failures which allow personal contact with a live wire or surface at the full power line voltage. Such things as frayed power cords, broken plugs, faulty lamp sockets and wrongly wired outlets, all have the potential of allowing contact with electrically live parts and lethal voltages (see Figure 3). These hazards are usually well understood, and a good maintenance program can generally keep this kind of hazard under control. Such a maintenance program would require that a well-established hospital procedure be instituted to make sure that such hazards are immediately reported and corrected promptly.

The main intent of this note is to discuss an entirely different class of hazards — more subtle, but just as lethal to a catheterized patient as contact with a live power wire. The source of these subtle hazards usually involves the much discussed but poorly understood term “leakage current.” In essence, recent work on electrical safety has been primarily concerned with preventing leakage current passage through the patient.

A little time devoted to exploring how leakage current originates and how it can become a hazard to the patient will aid in an understanding of the requirements for a safe patient environment. The term “leakage current” is mentioned frequently in articles on patient safety. Unfortunately, the impression is often gained that a device with over 10 microamperes of leakage current is inherently unsafe. In reality, this is not the case, as leakage current over 10 microamperes is hazardous only when allowed to pass through internal catheters in the vicinity of the heart.
**LEAKAGE CURRENT**

The definition of leakage current for our purposes is the following.

"Leakage current" is an inherent flow of current from the live electrical parts of an appliance or instrument to the accessible metal casing or parts. This current normally flow through a third wire connection to ground.

Leakage current is an unfortunate name for this phenomenon, as it implies that something is faulty, when actually leakage current exists more or less in all power-line operated equipment.

Leakage current generally has two components — one capacitive and the other resistive. Capacitance leakage current develops because any two conductors separated in space have a certain amount of capacitance between them. If an alternating voltage is applied between them, a measurable amount of current will flow. Related to electronic equipment, these currents arise primarily from capacitive coupling in RF filters and between the primary winding, core, and case of the power transformer, as well as between power cord conductors and the third (ground) wire (see Figures 4 and 5).

The resistive component of leakage current arises similarly as the leakage current due to capacitance between primary wiring components and the instrument chassis, but now we're concerned with the insulation around conductors. Since no substance is a perfect insulator, some small amount of current will flow through it. However, insulation technology using modern thermo-plastic dielectrics is sufficiently advanced so that resistive leakage can usually be ignored. Our real concern, then, is dealing with capacitive leakage currents inherent in all line operated instruments.

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**FIGURE 4.** Origin of Leakage Current (Stray Capacitance)

**FIGURE 5.** RF Filters Increase Leakage Current
Because the leakage current is an inherent phenomenon in all power line operated equipment, a third or grounding wire is provided in the power cord which effectively drains leakage currents off. But what happens when this third wire becomes broken? The normally harmless currents become a hazard.

Let us consider a typical electrical instrument connected to the power line, where current flowing in the ground wire (the leakage current) is assumed to be 100 microamperes. If the chassis of this device were also connected to the patient who is grounded, very little of this current flows through him. If we assume the patient presents a 500-ohm resistance to ground and the ground connection from the instrument has 1 ohm of series resistance, then the current divides according to the relative size of the resistances (see Figure 6). Only 0.2 microampere flows through the patient. If the ground connection breaks for some reason, the full leakage current will flow through the patient (see Figure 7). This is a hazardous situation, particularly if the current goes through internal electrodes in the vicinity of the patient's heart.

![FIGURE 6. Normal Path of Leakage Current](image)

![FIGURE 7. Path of Leakage Current With Defective Grounding Wire](image)
Several measures could be taken to make sure that the leakage current does not present a hazard to the patient in the event of such a grounding failure:

a. The first, and seemingly most obvious solution, would be to reduce the leakage current from the instrument to below 10 microamperes, then even if the patient were connected to the instrument case and the power cord ground breaks, there would be no hazard. Practically, it is extremely difficult to obtain power transformers with low enough leakage capacitance or with primary wiring spacing which reduces leakage current to these levels. So this has not been a practical alternative.

b. A second solution might be to devise a warning device which continuously monitors the continuity of the ground connection. However, there are practical problems here such as the necessity of using four wire power cords, or additional ground wires. These facts do not make this approach feasible at present.

c. Third, an additional ground wire could be added, paralleling the ground wire in the power cord, to reduce the probability of failure. This requires the attention of the staff, however, to insure that this additional connection is made when the equipment is plugged in.

d. Fourth, the integrity of the ground connection could be checked on a routine basis by hospital electronic technicians or by the medical staff before the equipment is used.

e. Finally, it is possible to electrically isolate the patient input connections so that even if the ground wire did break, the current through the catheterized patient would be well below the hazardous point. This protection is referred to as isolated input circuitry and will be discussed in detail in succeeding sections.

Now, with a background in leakage currents and the physiological effect of small currents on the catheterized patient, let us consider some very plausible hazard situations in hospitals.

The first case illustrates the subtle electrical hazards which result from inadequate or non-existing grounds, but which does not produce sufficient hazardous current to be felt or seen by the staff members using the equipment:

CASE 1 Parameters: (1) the patient is lying on an electrically operated bed. (2) The ground connection from the wall plug is faulty. (3) The patient is equipped with a transvenous pacing catheter connected to a small, battery operated pacemaker. (4) The patient is connected to an ECG monitor. The right leg ECG electrode is connected to the hospital grounding system through the monitor.

Analysis: The faulty ground connection on the electric bed allows a voltage to exist on the bed frame due to capacitive coupling between the bed frame and the primary wiring in the bed. Normally this voltage produces a current which is conducted harmlessly to ground, but if this ground wire breaks the current can follow other paths. In this example, assume that a attendant comes to the bedside to adjust the pacing catheter connections and, without thinking, simultaneously touches the pacemaker terminals and the bedrail. Assume he supplies a 100,000-ohm connection between these two points, and that the resistance between catheter terminals and patient is 500 ohms.

We can see from the analysis that he completes the path between the power line and ground, with the path going directly through the heart. If we assume
the leakage impedance of the electrical bed is approximately 1 megohm (assuming 2500 pico farads of capacitance from power line to bed frame), then a simple calculation shows that over 100 microamperes pass through the patient's heart (200 microamperes if 240 volts is assumed).

\[
\frac{120 \text{ V}}{\sqrt{(1,000,000 \text{ OHMS})^2 + (100,500 \text{ OHMS})^2}} = \text{OVER 100 MICROAMPERES}
\]
This is almost certain to be a hazard to a catheterized patient. The medical staff probably would not have noticed that a hazard existed. If one of them were to touch the bed frame and ground simultaneously, only 100 microamperes would pass through them. This is below the threshold of perception of most adults for currents passing through the skin and would have gone unnoticed. A clue that something was wrong might have been an increase in the amount of line frequency interference on the ECG trace on the monitor. The natural reaction of the nurse would be to see if the electrode creme had dried out, requiring replacement. Since this procedure would fail to reduce the interference, she might then assume that something was wrong with the monitor, and call the monitoring equipment serviceman. During all this time the bed would continue to operate, so that a fault in it probably would not be suspected. Although the fault in this case was due to a faulty ground connection from the bed, the same kind of hazard would exist if the ground connection in this right leg grounded type of ECG monitor were broken instead.

Recommendations: (1) Periodic check of ground wire continuity of all equipment in vicinity of patient. (2) Isolated input circuits on ECG monitor, as described on Page 16. (3) Training staff to recognize potential shock hazards and remedies.

Summary
Fault: Broken ground wire in electric bed power cord.
Hazard: Leakage current from the bed that would normally be conducted to ground now can flow through the patient grounded through right leg electrode of ECG monitor.
Indications of Hazard: Possible increase in interference on ECG monitor.

CASE 2 Parameters: Same as Case 1 but with saline filled catheters and a two-wire cord appliance in the vicinity of patient.

Analysis: A similar situation could occur if saline filled catheters were used to monitor pressures or take blood samples in the vicinity of the heart. The saline column in the catheter is a sufficiently good conductor to provide a path for hazardous currents to reach the heart. Often these catheters are grounded through the pressure transducer to the monitoring instrument case. This presents a hazard because the patient or an intermediary could touch improperly grounded equipment. He would inadvertently provide a source of current which flows into the patient, through the catheter, and to ground via the pressure transducer and monitor.

The source of current could be any device with a two-wire power cord as well as improperly grounded equipment. Many such devices which connect to the power outlet with only a two-wire cord can present a hazard to the patient even though their power cords and insulation are in good condition. Sufficient capacitive coupling often exists in the power wires to allow leakage currents greater than 20 microamperes to flow if the patient just touches the outer case of some of these devices. In some equipment this current flow can be as high as 500 microamperes.

The leakage current available from ungrounded television sets, radios, electric shavers, and lamps is usually so feeble that it is not felt by the attending staff. But that feeble current is sufficient to be a hazard to the patient with electrodes in the vicinity of the heart, where 20 microampere currents are considered hazardous.
HAZARDS FROM EQUIPMENT THAT APPEARS TO BE PROPERLY GROUNDED

CASE 2

Recommendations: (1) Within 15 feet of patient, use only apparatus with 3-wire power cords and proper grounds. (2) Train staff in recognition of hazards. (3) Eliminate as many permanent ground paths from patient as possible through use of isolated input monitoring devices.

Summary
Fault: Devices with two-wire power cords.
Hazard: Leakage currents present on outer surface of bedside devices. Ground path through saline column in indwelling catheter.
Indications of Hazard: None, unless leakage current can be felt by attending staff.

In the situations discussed thus far, the sources of current have been due to leakage current from properly functioning equipment which was disconnected from ground. either through ground connection failure or because a 3-wire power cord was not used.

Unfortunately, a hazardous situation can still occur when equipment appears to be properly grounded. As an example, assume that a patient is being monitored in an ICU under the following conditions:

CASE 3 Parameters: (1) The patient is being monitored by an ECG monitor which grounds the right leg electrode. (2) The patient’s arterial pressure is being monitored using an intracardiac, saline-filled catheter connected to a pressure transducer, which in turn attaches to the pressure monitor case and then to ground. (3) These monitors are connected to separate, grounded 3-wire wall receptacles. (4) The grounds from these two outlets are not connected together except at a central power distribution panel many feet from the ICU area.
Analysis: Let us assume that a cleaning service person now plugs a vacuum cleaner into a wall outlet on the same circuit as the ECG monitor. The cleaner has a three-wire power cord with the third wire grounding its outer case. This is a necessary safety feature for vacuum cleaners, as they are notoriously hazardous devices from an electrical safety point of view.
The windings of the motor are continually exposed to dust, often damp, which provides a good path for an eventual “winding-to-outer-case” short. Because this kind of short makes the case rise to full line voltage, the case is grounded to protect the operator. In this example the vacuum cleaner hasn’t completely failed, but has developed a fault sufficient to allow 1 ampere to flow down the ground wire, back to the power distribution panel. If we assume that the power distribution panel is 50 feet away and that the power wiring is 12 gauge, the 50 feet of ground wire has 0.08 ohm of resistance.
The one ampere of current flowing in the ground wire common to the ECG monitor results in a voltage drop of 80 millivolts. Since a very small current is flowing in the ground wire from the pressure monitor, its case remains very close to ground. We see that this potential difference appears directly across the patient, between the ECG monitor and the pressure monitor.

If we assume that 10 microamperes is the maximum safe current, this amount of current will flow if the impedance through the patient between the ECG monitor and the pressure monitor drops to less than 8000 ohms. This might be considered a low resistance for this path, but the voltage could also have been higher due to longer ground wires or higher fault currents.

There are several important points to learn from this example, as it relates to an entire class of low voltage hazards which can be difficult to detect and the causes more difficult to find. In the example cited, the wiring would have met the provisions of most existing wiring codes. Such wiring could be in an older hospital, where additional power outlets and circuits were added as part of a modernization program without abandoning existing outlets and wiring.

These low voltage hazards would not be detected by the medical staff, since the resulting current through them would be too feeble to be felt. There is a remote possibility of an increase in the amount of interference on the ECG monitor trace, but if it occurs it may be interpreted as a fault in the monitor, not in the wiring. Also, the hazard may exist only for short periods of time, such as when the vacuum cleaner is in use, so that the staff may be unable to find the cause. If the voltage were sufficient to cause fibrillation in the patient in this example, it is unlikely that the medical staff would associate the patient’s difficulty with the cleaning service vacuum cleaner.

Summary
Fault: Two devices connected to patient are plugged into outlets with grounds connected together by excessively long wire.
Hazard: Faulty appliance causes difference in ground potential between two devices and allows current to flow through the patient.
Indication of Hazard: None likely, possible increase in ECG interference.

Recommendations:
(1) Place all power outlets in vicinity of patient on a common panel, with ground connections strongly bonded together. (2) Assign a power circuit to operate patient care equipment and prohibit its use for any other purpose. (3) Routinely check potential on ground terminal of outlets to be used for operating patient care equipment, with respect to all other conductive surfaces within 15 feet of the patient. (4) Provide isolated input monitoring equipment to eliminate possible paths for, and sources of, hazardous current. (5) Training staff to recognize potentially hazardous conditions and provide procedures for having them investigated and corrected promptly.

Since patient monitoring instruments are usually connected to the patient for relatively long and uninterrupted periods, it is true that the monitors could provide one link in the conductive pathway that results in hazardous current flow through the catheterized patient. Therefore, it is necessary to have an understanding of the development of various types of monitoring devices in relation to electrical shock hazard.
When the first amplified electrocardiographs appeared in the late 1940's an amplifier system was used called the "ground referenced differential amplifier" (see Figure 8). The right leg of the patient was wired with an electrode directly to ground to reduce power line interference on the amplified signal. The patient signal leads were connected to the input of a differential (ECG) amplifier. Since patients then did not usually have conductive contacts inside the heart (or body), patient protection from electrical shock was through a fuse, usually 5 milliamperes, in series with ground, or the right leg lead. This system had the advantage of low cost, simple design, and adequate safety as long as the electrodes were outside the body, on the patient's protective skin.

When continuous ECG monitors for Operating Room and ICU were first designed, electrical safety was not recognized as a major problem, so the same "grounded referenced differential amplifier" circuit was used in them as well. In fact, many ECG monitors on the market today use the same circuit, some without even a patient fuse to provide protection against gross shock hazard. These systems require a continuously connected ground contact on the patient for proper operation. From a safety point of view, this contact can serve as a path for hazardous current.

If equipment of this type is used for monitoring, it's not necessarily unsafe. However, it is mandatory that a stringent program be in effect, which will insure that all conductive surfaces in the vicinity of the patient are at the same potential, so that no source of hazardous voltage is present. Unfortunately, if a failure occurs in the ground wire, or an appliance in the patient environment fails, allowing large ground fault currents to flow, the patient can receive a potentially lethal shock. He is placed in a situation where a

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**1946**

Figures 8, 9, and 10 show evolution of Electrocardiograph Amplifier Circuit.

**1946**

FIGURE 8. Ground Referenced Differential Electrocardiograph Amplifier

**1962**

FIGURE 9. Driven Right Leg Electrocardiograph Amplifier

**1967**

FIGURE 10. Isolated Input Electrocardiograph Amplifier

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normally safe activity for himself or a safe procedure by the staff becomes a lethal one. Although some measures are available to detect such equipment failures, not all potential hazards can be detected. Constant vigilance of the staff and routine safety checks by electronic maintenance personnel are always required.

**DRIVEN RIGHT LEG ECG AMPLIFIER**

In 1962, with the emergence of the transistor, observers recognized that better circuit designs could be used to monitor and record an ECG while providing a worthwhile improvement in the safety of the patient. With the introduction of the Hewlett-Packard Model 500 Electrocardiograph and the first Hewlett-Packard 780 Series Patient Monitors, a new concept in ECG amplifiers was used. It is referred to as a “Driven Right Leg Electrocardiograph Amplifier” and is shown schematically in Figure 9.

The “Right Leg Amplifier” samples the interference in the ECG signal (usually 50 or 60 Hz) coming from the patient and delivers a signal back to the patient which cancels the interference signal already on the patient. This current feedback never exceeds the current already flowing through the patient due to capacitive coupling with the ac power line. The Right Leg Amplifier does not contribute to a hazard and results in a better, cleaner ECG record or trace. The right leg amplifier also is used to provide isolation of the patient from the chassis (hence ground) of the ECG amplifier. This isolation is sufficient so that the amount of current that can flow from the patient to the ECG monitor is limited to less than 40 microamperes if the patient is above ground by one volt or less from an external source.

Although this may not seem to be a significant amount of impedance, it does provide adequate protection against the whole class of low voltage hazards which are often the most difficult to detect. It provides considerably more protection than that offered by ECG amplifiers using a grounded right leg technique.

**ISOLATED PATIENT CIRCUITS**

It became apparent during the past few years that the patient in the typical ICU and CCU was being exposed to an ever-increasing danger of accidental electrical shock, due to the growing practice of using conductive internal electrodes or saline filled catheters in the vicinity of the heart. With improvements in transistor circuits, from an electronic engineer’s point of view, there was no reason why the ECG monitor, pressure monitor, or portable electrocardiograph had to have a direct ground path to the patient for proper operation. If it were possible to eliminate the direct ground path, which is continuously connected, a conductive pathway for hazardous currents through the patient could be removed.

Hewlett-Packard accomplished this by designing isolated input circuits into all of their electrocardiographic instruments which are normally connected to patients with indwelling electrodes. This circuit is shown in block diagram form in Figure 10.

The isolated circuits, which connect directly to the patient, are physically insulated from ground and other portions of the electrocardiograph or patient monitor. This isolated circuit receives its power through a small isolation transformer inside the instrument, operating at a high frequency, and transmits the ECG signal through another isolation transformer, operating also at the same high frequency, to the display and recording sections of the device. No conductive path is present between isolated and other sections of the instrument. If it were possible to make the circuit
infinitely small or separate it by an infinite distance from other portions of
the device, it would be possible to achieve perfect isolation. This is not
possible of course, so a small amount of capacitance remains between the
isolated and grounded sections of the circuits. It is an engineering objective
to reduce this capacitance as low as practical, and with present techniques
one can achieve over 10 megohms of isolation impedance at 50 Hz or 60 Hz
between input terminals and ground.

Portable electrocardiographs and ECG patient monitors currently manu-
factured by Hewlett-Packard which have isolated input amplifiers include the
1500A, 1511A, 1513A and 1514A 1515/16A electrocardiographs as well as
the 7807B and 7830A ECG monitors and the 8811A bio-electric amplifier
for operating room and catheterization laboratory use.

Other monitoring devices which are connected to the patient can also be
isolated. For example, transducers for arterial and venous pressure measure-
ment can be designed so that the saline column in the catheter is not
connected to the chassis of the pressure monitor through the shield in the
transducer cable. Such isolation is available in the Hewlett-Packard 1280B
and 1280C physiological pressure transducers. Sensors such as temperature
probes, heart sound microphones, and respiration transducers are also
available in isolated versions.

The value of isolating the ECG leads from a patient in an ICU can be further
emphasized by referring to Case 1 on Page 9. Recall that the patient was
being monitored by an ECG monitor which grounded his right leg. This
electrode became part of a hazardous current path when the attendant
touched the electric bed with its broken ground connection and the
pacemaker catheter terminals simultaneously. If we substitute a monitor
with isolated input circuits, such as HP 7807B with 25 megohm isolated
impedance, the amount of current flowing through the monitor shown in
Figure 11 will be less than 5 microamperes (a considerable reduction
compared to the 100 microamperes in Case 1). The actual current through
the patient in this example will be somewhat higher, as the isolation
impedance of the monitor is effectively shunted by patient cable and patient
body capacitance, which would allow approximately 5 to 10 microamperes
more to flow under the conditions described.

![FIGURE 11. Electrical Analysis of Case 1 Using HP 7807B Monitor](image-url)
The table shows the amount of power line frequency current which will flow into the input terminals of an ECG monitor from the patient for varying amounts of potential difference between patient and amplifier. Three different types of ECG amplifiers are compared: (1) Grounded input ECG amplifier with 1000 ohms patient impedance, (2) Typical ECG amplifier including driven right leg circuitry and 1000 ohm patient impedance, (3) ECG amplifier with isolated input circuit with an effective isolation impedance of 15 megohms made up of typical patient cable and stray capacitance, and the 25 megohm isolation impedance of instruments such as the HP 7807B and 7830A monitors and 1500A/1500A Electrocardiograph.

<table>
<thead>
<tr>
<th>VOLTAGE BETWEEN PATIENT AND MONITOR (60 Hz)</th>
<th>ECG MONITOR WITH GROUNDED INPUT (microamperes)</th>
<th>ECG MONITOR WITH DRIVEN RIGHT LEG CIRCUIT (microamperes)</th>
<th>ECG MONITOR WITH ISOLATED INPUT CIRCUIT (microamperes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2.5 mV</td>
<td>2.5</td>
<td>0.72</td>
<td>0.0002</td>
</tr>
<tr>
<td>5.0 mV</td>
<td>5.0</td>
<td>1.4</td>
<td>0.0003</td>
</tr>
<tr>
<td>80 mV</td>
<td>80</td>
<td>2.3</td>
<td>0.0054</td>
</tr>
<tr>
<td>150 mV</td>
<td>150</td>
<td>3.2</td>
<td>0.01</td>
</tr>
<tr>
<td>1.0 volt</td>
<td>1000</td>
<td>38</td>
<td>0.067</td>
</tr>
<tr>
<td>50 volts</td>
<td>50,000</td>
<td>1000</td>
<td>3.3</td>
</tr>
<tr>
<td>120 volts</td>
<td>120,000</td>
<td>2400</td>
<td>8.0</td>
</tr>
<tr>
<td>240 volts (50 Hz)</td>
<td>240,000</td>
<td>4800</td>
<td>16.0</td>
</tr>
</tbody>
</table>

Several important points should be apparent from Table 2.

(1) If grounded input ECG amplifiers are used on patient with indwelling electrodes, voltage differences in the vicinity of the patient should be no greater than 10 millivolts. When equipment using driven right leg circuits is used, considerably higher voltages can be tolerated in the vicinity of the patient (up to 1 volt maximum) with reasonable safety. This provides good patient protection from the usual voltages resulting from differences in ground potential, which rarely exceed 1 volt. (2) When equipment using isolated input circuits is used, the current through the amplifier under these conditions is almost not measurable at low voltages. (3) In the event of a ground wire break which exposed the patient to higher voltages, an isolated input monitor will provide protection against hazardous current flow.

Isolating the amplifier input circuit is not the complete answer to patient safety. No single element is. The entire patient environment must be considered:

a. Proper grounding of equipment.
b. Regular inspection to verify grounding integrity.
c. Instruments that isolate the patient from ground.
d. The value of power isolation transformer.
The power isolation transformer approach to a safe environment for the patient is conceptually based on eliminating low voltage hazards, in contrast to the isolated input or “patient isolation” approach, which eliminates possible current paths through the patient. Although the concepts are different, they are complementary, and the combination of both results in a safe patient environment.

Both concepts are based on achieving the same objective: the prevention of electric currents greater than 10 microamperes from passing through the heart muscle (myocardium) from indwelling electrodes.

The power isolation transformer concept assumes that the externally exposed end of the electrode or catheter will be grounded intentionally or by accident. Given this, and assuming that the resistance to current flow measured from the catheter terminals to a point on the patient’s skin surface can be as low as 500 ohms, it then becomes necessary to limit the potential difference between the catheter terminals and any other surface or instrument in the vicinity of the patient to less than 5 millivolts, if the current is to be below 10 microamperes.

Practically, achieving and maintaining such low levels of potential difference in a patient area is not an easy task. If the leakage current from an appliance near the patient exceeds 5 milliamperes, and the grounding connection to it exceeds one ohm, not improbable conditions, then the potential on the outer case of the device will exceed the 5 millivolts defined as hazardous. Furthermore, if an internal insulation failure occurs in the appliance, allowing a live power wire to touch a grounded part, the resulting fault current flow can reach many amperes before the fuse or circuit breaker in the branch circuit supplying power to the appliance opens. Larger fault currents will cause potential differences of several volts — obviously intolerable in the vicinity of a patient with a grounded indwelling catheter.

The power line isolation transformer has been proposed as a basic element in an electrical power system which will minimize voltages in the vicinity of the sensitive patient.

Isolation transformers and their associated accessories are relatively expensive, and can add $1000 to $2000 to the per bed cost of a monitoring installation. Because of this cost, it is important for hospital and building engineers to have a thorough understanding of isolated power systems in order to determine if the expense of such a system is justified in their situation.

The following is a brief discussion of the development and use of isolated power systems in hospitals.

Ether Fires and Static Electricity

The power line isolation transformer first came into use in hospitals several decades ago when the use of anesthetics in the operating room became widespread. One of the first anesthetic agents used was ether, which has excellent properties as an anesthetic, but which also has the unfortunate characteristic of being highly flammable. Ether vaporizes readily at room temperature, and its fumes are heavier than air. Explosive concentrations of a mixture of ether and air collect at the lowest level in the operating room, well below the level which could be detected by smell by the attending staff. After several tragic explosions involving ether fumes, it became obvious that stringent safety procedures were required to use ether safely.
The explosion problem was solved by the elimination of potential ignition sources. Studies revealed that static electrical discharges and fires or arcs from insulation breakdown in the power wiring to electrical devices in the operating room accounted for many of the fires.

Eliminating the build-up of static electricity was accomplished by providing a path to ground for any built-up static charge before the potential became large enough to cause an accidental spark. This was accomplished by grounding all metallic objects in the operating room. In addition, personnel in the room are required to wear clothing which does not tend to build up static charges. They are also required to wear shoes which make electrical contact between their bodies and the floor. The floor is treated with a special additive which makes it conductive to ground. These and other measures have resulted in almost complete elimination of ether fires in present day operating rooms due to static electricity discharges.

In the early 1900's electrical insulation was made of gum rubber, silk or cotton and was much more susceptible to breakdown (which causes arcing between the “hot” wires) than modern thermo-plastics and synthetic rubber dielectrics. The isolation transformer provided a solution to the arcing problem.

To understand the operation of isolation transformers, first consider the normal ac electrical supply in wall receptacles in the home, office or hospital. In modern wiring systems, the electrical supply is served by branch circuits containing three wires:

a. The “hot” or current carrying wire which is at approximately 120 volts above ground in the United States and Canada, and 240 volts in most of the rest of the world;

b. the neutral wire carrying the return load current, which is near ground potential; and

c. the grounding wire, which is at ground or zero potential. The grounding wire provides a safe return path for any leakage currents originating from the appliances or other devices supplied by the branch circuit. The assumption is that ground is connected to the outer case of these devices. This wire also serves to carry large “fault” currents if a current carrying part in the appliance comes in contact with the case, thus preventing the case from becoming “hot” with respect to ground. In this type of power circuit, the amount of current which would flow if the hot wire contacts a grounded part of an appliance is limited only by the branch circuit fuse or circuit breaker.

Thus, in many cases, a current of over 20 amperes is required before the fuse opens or the circuit is interrupted. If such a fault happened in an operating room, in the presence of ether fumes, the arc inside the appliance could cause an explosion.

Now if we add a power line isolation transformer, as shown schematically in Figure 12, note that both sides of the branch circuit are isolated from ground, and that either one (line A or B) can be short circuited to ground without a large current flowing through the connection. In fact, the current that will flow in a short circuit to ground is limited by the leakage capacitance in the transformer and associated wiring. It is usually no more
than a few milliamperes, not enough to cause an arc or fire if the short occurs inside an appliance in the presence of explosive fumes.

The isolation transformer also provides considerable protection against electrical shock to the operating room personnel. As mentioned earlier, the operating room staff and all conductive equipment are grounded to prevent static discharges. These measures (grounds) have the unfortunate side effect of increasing the possibility that if one of the staff were to contact a live power wire accidentally he would receive a serious shock. However, through the use of the isolation transformer, line-to-ground fault currents are limited to low milliampere values: accidental contact with the power line may result in a painful but not lethal shock.

**THE PROBLEMS**

Another important point about isolation transformers is worth discussing. If a fault or short circuit occurs from one side of the isolated power transformer to ground, the power supply of the monitor is no longer isolated. If a fault now occurs from the other side of the transformer to ground, the current which would now flow is limited only by the resistance of the two faults in series and/or the circuit breaker for the power supply to the transformer. Therefore, it is very important to have some indication as soon as the first fault occurs, so that corrective action can be taken immediately before a second and possibly catastrophic fault occurs.

**THE LINE ISOLATION MONITOR**

A device known as a Line Isolation Monitor (Figure 13) is now always included in isolated ac power systems. The Line Isolation Monitors operate by continuously monitoring the impedance of either isolated power line to ground. The detector is set to trigger an appropriate alarm if this impedance drops below a pre-determined level. For many years, Line isolation Monitors in operating rooms in the United States were set to alarm at 25,000 ohms. Stated another way, as long as the alarm had not been triggered, one could be relatively sure that each power line was at least 25,000 ohms above ground, and if either (but not both lines) were shorted to ground, not more than 5 milliampere would flow through the fault (assuming 120 volt 60 Hz system). Experience indicated that 5 milliampere currents were unlikely to start fires, and provide considerable safety to the medical staff if accidental contact to a live power wire happened.
In all practical wiring systems there is always some capacitance between the wiring on the secondary side of the isolation transformer and ground. The amount of capacitance depends on the length of wiring to receptacles, the receptacles themselves, and the type and thickness of insulation on the wires. Each equipment plugged into the isolated system adds more capacitance between the isolated power lines and ground. Even with no insulation failure in the system, it is conceivable that the total impedance of the isolated power wiring to ground may be on the order of several thousand ohms. In fact, on occasion, with poorly designed systems and with excessive capacitance between the building wiring and ground, it is almost impossible to plug in any equipment to the isolated power system without triggering the hazard alarm. Very often the result of this annoyance causes someone to turn off the hazard alarm which defeats this safeguard. In isolation transformer systems it is extremely important that the capacitance to ground on the secondary side be minimized by limiting the length of branch circuits and using low capacitance insulation.

Until recently, the line isolation monitors used in most operating room power systems were the “static” type. They depended on detecting an unbalance in impedance-to-ground of either isolated power line wire. They do not detect balanced faults. The increasing use of equipment with balanced radio interference filters on input power wiring has resulted in the increase of “balanced” faults.

For this reason a better isolation monitor has recently become available, appropriately called a “dynamic line isolation monitor.” The impedance of each isolated power line to ground in it is measured alternately several times per second. It can, therefore, detect balanced and unbalanced faults made up of any combination of resistive, inductive or capacitive elements, and is now recommended for use in new isolation transformer installations.

To understand how the isolation transformer can provide protection to the patient, consider the following situation. A patient is electrically connected between two devices (see Figure 14). Assume that intentionally or not, the
catheter leading to his heart is connected to the outer case of device A while another part of his body is connected to the case of device B. Further assume that devices A and B are connected to a common ground point with wires each having one ohm of resistance, and that the patient represents 500-1000 ohms of resistance (usually assumed for patient safety calculations). The power for each device is supplied from an isolation transformer, which under single fault conditions will limit the current flowing in the fault to less than one milliampere.

If a fault now occurs in device B (for example, an insulation breakdown in the power transformer which allows the live power line to touch the case), the isolation transformer limits the fault current flowing to one milliampere, and because of the 500 to 1 ratio between patient and ground wire impedances, 998 microamperes will flow in the ground wire and 2 microamperes will flow through the patient. The isolation monitor would have alarmed, of course, indicating an equipment failure, and the current through the patient is limited to a safe value.

Despite its obvious value in managing the fault current problem, one very important class of failures is not eliminated by the isolation transformer system. If a ground wire in a power cord breaks, it will not be recognized by the isolation monitor, and if the patient is in the situation shown in Figure 14, he can be in immediate danger. Therefore, it is necessary to consider the probability of an internal line-to-ground failure in a surrounding equipment (a hazard which is managed by an isolation transformer) and break in a ground wire (which is not managed by an isolation transformer, see Figure 15). A ground wire failure is more likely to occur than an internal line-to-case insulation failure. The ground wire in the power cord from the device is continually “exercised.” The cord is flexed, casters are rolled over it and the plug is yanked from the wall, so that the cord or plug is bound to fail in some manner eventually, if not replaced. If one of the power conductors...
FIGURE 15. Grounding Wire Failure in Isolation Transformer System

opens, the equipment will not operate, or if they short together, a circuit breaker or fuse usually "blows" so that the staff is alerted to these failures. However, a ground wire break would not be detected by the staff since the equipment would probably continue to function.

Consider again a patient connected to two devices, with the indwelling electrode attached to the case of device A, and another point on his body connected to device B. It is common practice for these devices to have radio frequency interference suppression filters connected from power line to case, indicated by \( C_A \) and \( C_B \) in Figure 15. In addition, stray capacitance between building power wires and ground play an important part in total capacitance and are indicated by \( C_S \). Now assume that the grounding connection to device B breaks. The leakage current that normally flows from B to ground can now go through the patient. If Figure 15 is redrawn (Figure 16) it will be seen that the patient becomes the "sensing element" in a four-arm bridge circuit. The amount of current flowing through the patient is determined by the relative size of the various capacitances, and if \( C_A \) and \( C_S \) are on the order of 3000 picofarads and the two capacitors labeled \( C_B \) differ by 1500 picofarads (all reasonable values), currents on the order of 50 microamperes will flow through the patient, clearly an intolerable condition.

CONCLUSIONS ABOUT ISOLATION TRANSFORMERS

Isolation transformers can help to protect the patient if devices that ground, or that are likely to ground, the indwelling electrode are used for monitoring patient. The patient is not protected if a grounding connection fails so that routine inspection and testing of the quality of these connections is a vital requirement for patient safety.
We now need to develop some general principles for designing a patient environment which is electrically safe, economical and takes into account the type of equipment used to treat and monitor the patient.

In previous sections of the application note we discussed the reasons why today's monitored patient is more susceptible to shock and presented some examples of how shock hazards can occur in typical hospital situations. We also described two methods of improving the safety of monitoring systems, i.e., (1) input isolation of the monitoring instrumentation and (2) isolation of the complete electrical power system. However, the initial guide line for the design and installation of an electrically-safe patient monitoring system starts with an adequate grounding system. All metallic, conductive surfaces within reach of the patient, and of anyone touching the patient should be at the same potential. Such a grounding system is referred to as an Equipotential Grounding System. It ties all metallic surfaces in the room, the electric power outlet ground connections, and the metal furniture to one common reference grounding point which is in turn connected to the normal hospital electrical grounding system.

One method of installing a grounding system is shown in Figure 17. The Reference Ground is a solid metal bar in the power distribution panel used for terminating ground wires from bedside furniture, plumbing, ducts, power outlet ground terminals, and the hospital power grounding system. This power distribution panel is for one patient (i.e., one bed) and must be located close to the bed. If it is not convenient to bring ground wires from all necessary points in the patient area to this one Reference Ground, the grounding system can be rearranged as shown in Figure 18. This system is particularly useful when the beds are remotely located from the power distribution panel, and when more than one patient is in the same room. Each bed location is equipped with a Patient Grounding Point. The ground terminals from electrical outlets for that bed and ground wires from furniture and the non-electric bed are connected to the respective Patient Grounding Point. The Room Ground serves to tie plumbing, partitions,
window frames and permanent metal building parts together electrically for the entire room. All Patient Grounding Points and the Room Ground are in turn connected to the Reference Ground in the power distribution panel.

The grounding system shown in Figures 17 and 18 provide the prime safeguard against accidental electrical shock to the patient and attending staff. To insure the safety of the patient in the event of failure with this kind of grounding system requires that all catheters and electrodes applied to the patient are connected only to isolated input equipment (see page 16). The hospital must establish procedures to insure that no equipment is brought into the patient area and connected to the patient which provides a direct path to ground. Furthermore, the hospital should insure that the external ends of catheter plumbing, and indwelling electrodes are insulated so that accidental contact by the staff will not result in a path to ground.

If the patient's indwelling electrodes and catheters can not be protected from accidental contact with grounded objects, or if the patient may be grounded by the design of the devices attached to him, power line isolation transformers are justified (see page 19). However, a ground wire break can still endanger the patient. Therefore the use of isolated input equipment, routine and thorough inspections, and power line isolation transformers can achieve a safer environment.

Figure 19 shows a single bed system with a power line isolation transformer. The illustration is very similar to Figure 17 since the same basic grounding system is used. A single isolation transformer may be used for more than one bed as shown in Figure 20. However, the total impedance from either floating power line to ground must be no lower than 120,000 ohms with all equipment on the isolation transformer operating, or the Line Isolation Monitor will alarm. In a practical sense, with present equipment, and wiring techniques, the total load on a single isolation transformer should not exceed 3 KVA. If larger capacity systems are installed, it is probable that the line-to-ground impedance of the load, and the larger diameter and longer wiring will result in line-to-ground impedances of less than 120,000 ohms. This will usually limit the maximum number of beds served from one transformer to four.

ACKNOWLEDGEMENT

Several groups concerned with electrical safety in the United States are presently working on standards for power wiring and equipment used in the hospital. It is expected that by the middle of 1971, the National Fire Protection Association, Underwriters Laboratories, and the American National Standards Institute will publish their respective standards and that appropriate changes will be made in the National Electrical Code. The methods described herein for the design of the safe patient environment are based on the principles outlined in preliminary documents of these various groups which were available at the date of writing this publication.
FIGURE 17. Wiring Installation for Grounded Line Outlet Cluster Near Bed

FIGURE 18. Wiring Installation for Grounded Line (Beds Remove from Distribution Panel)
FIGURE 19. Isolated Line Distribution Panel Located Near Patients' Beds

FIGURE 20. Wiring Installation for Isolated Line (Beds Remote from Distribution Panel)
REFERENCES


