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 flows 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.
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

**FIGURE 7.** Path of Leakage Current With Defective Grounding Wire
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 an 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 picofarads 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).

\[
I_L = \frac{120 \text{ V}}{\sqrt{(1,000,000 \text{ OHMS})^2 + (100,500 \text{ OHMS})^2}} = \text{OVER 100 MICROAMPERES}
\]
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 cream 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.
Recommendations: (1) Within 15 feet of patient, use only apparatus with 3-wire power cords and proper ground. (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.

**1962**

**1967**

**FIGURE 8.** Ground Referenced Differential Electrocardiograph Amplifier

**FIGURE 9.** Driven Right Leg Electrocardiograph Amplifier

**FIGURE 10.** Isolated Input Electrocardiograph Amplifier
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.

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.

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
Portability of the device is not possible. Electrically, 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 manufactured by Hewlett-Packard which have isolated input amplifiers include the 1500A, 1511A, 1513A and 1514B, 1515A/B, 1516A electrocardiographs as well as the 7807B and 7830A ECG monitors, the 8020A cardiocographe 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 measurement 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.
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>
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<tr>
<td>5.0 mV</td>
<td>5.0</td>
<td>1.4</td>
<td>0.0003</td>
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<td>80 mV</td>
<td>80</td>
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<td>0.0054</td>
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<td>150 mV</td>
<td>150</td>
<td>3.2</td>
<td>0.01</td>
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<td>1.0 volt</td>
<td>1000</td>
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<td>0.067</td>
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<tr>
<td>50 volts</td>
<td>50,000</td>
<td>1000</td>
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</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.