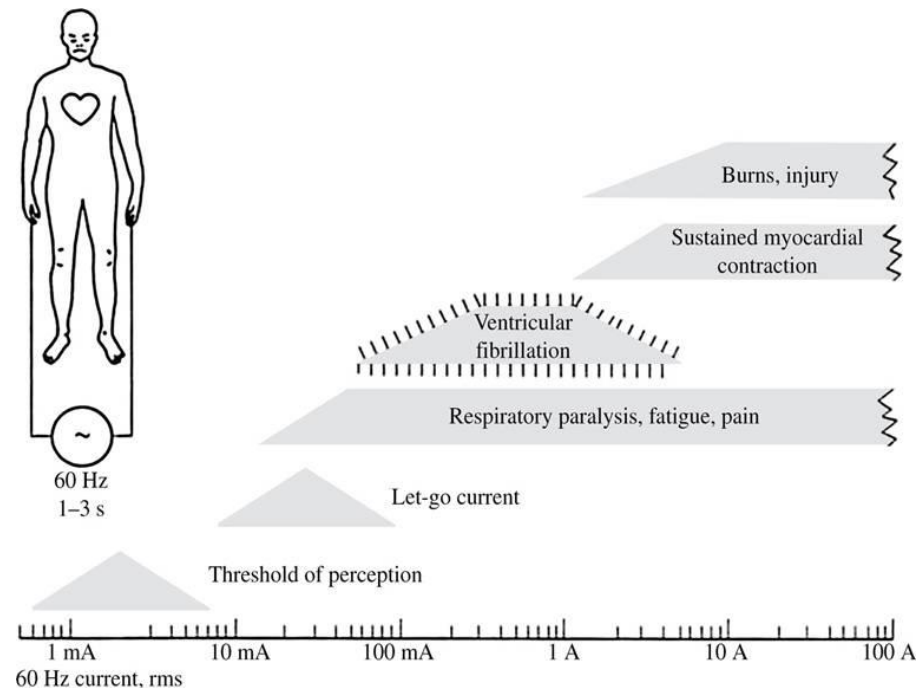


Electrical Safety

- **Advances in medical technology have greatly improved health care and decreased morbidity and mortality**
- **But the increased complexity of these devices and systems has led to 10,000+ device-related patient injuries each year**
 - **Most are related to improper use due to lack of training or experience**
 - **The rest can be attributed to device failure**

Effects of Electricity on Humans

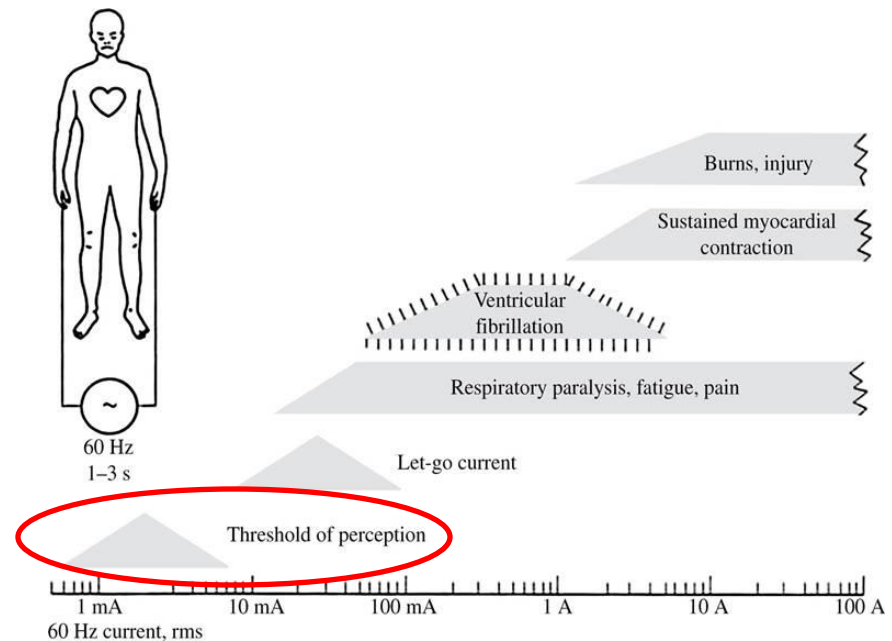
- Your body is a series of resistors
- It is easy for you to become part of an electrical circuit
- Current flowing through tissue causes 3 main effects:
 - Stimulation of excitable nerve and muscle tissue
 - Resistive heating of tissue
 - Electrochemical burns and tissue damage for DC and very high voltages



It's The Current That Kills!

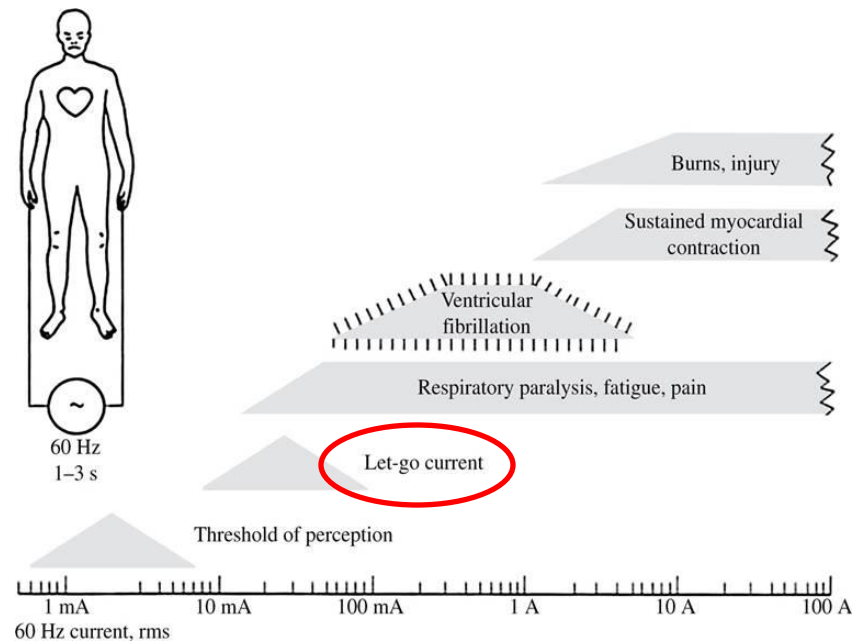
Electricity Effects

- **Threshold of perception**
- Tingling sensation due to stimulation of nerve endings in the skin
- Slight warming of skin
- 2-10mA DC
- As low as 0.5mA at 60Hz
- Wet skin lowers this threshold



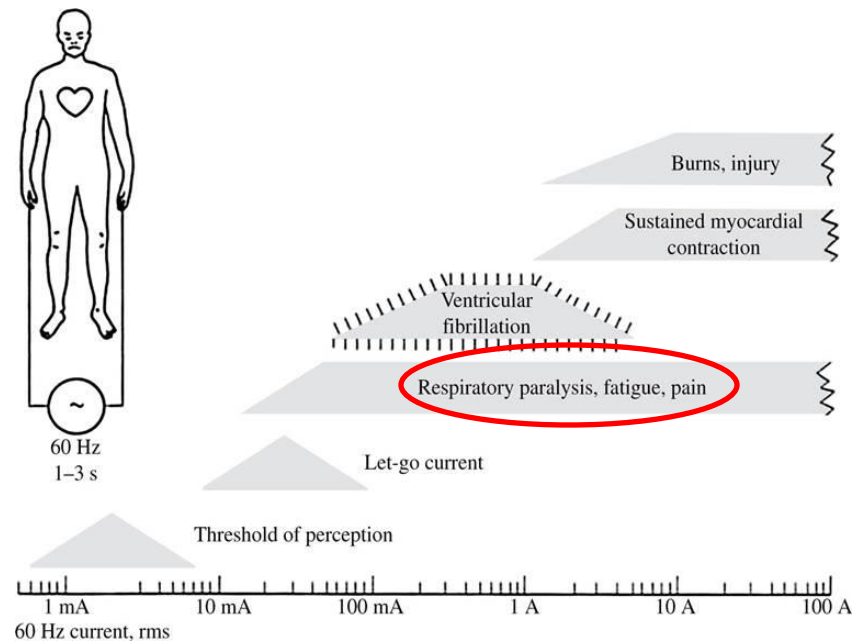
Electricity Effects (2)

- **Let-go current**
- Maximum current at which you can “let go”
- Vigorous stimulation of nerves and muscles
- Can cause involuntary muscle contractions or reflex withdrawals
- Occurs at currents as low as 6mA



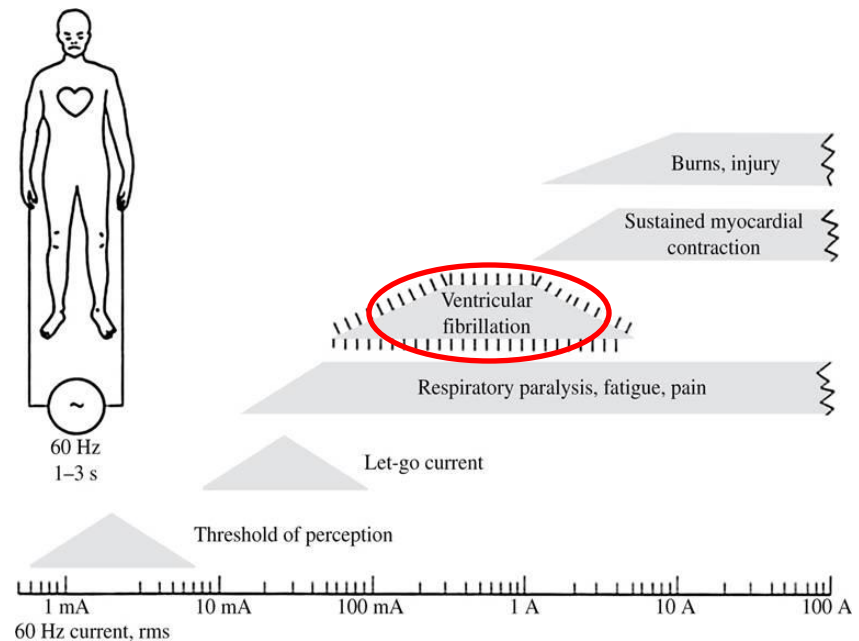
Electricity Effects (3)

- **Respiratory paralysis, pain and fatigue**
- **18-22mA**
- **Causes involuntary contraction of respiratory muscles, leading to asphyxiation**
- **Long exposure leads to pain and fatigue due to strong muscle contractions and nerve stimulation**



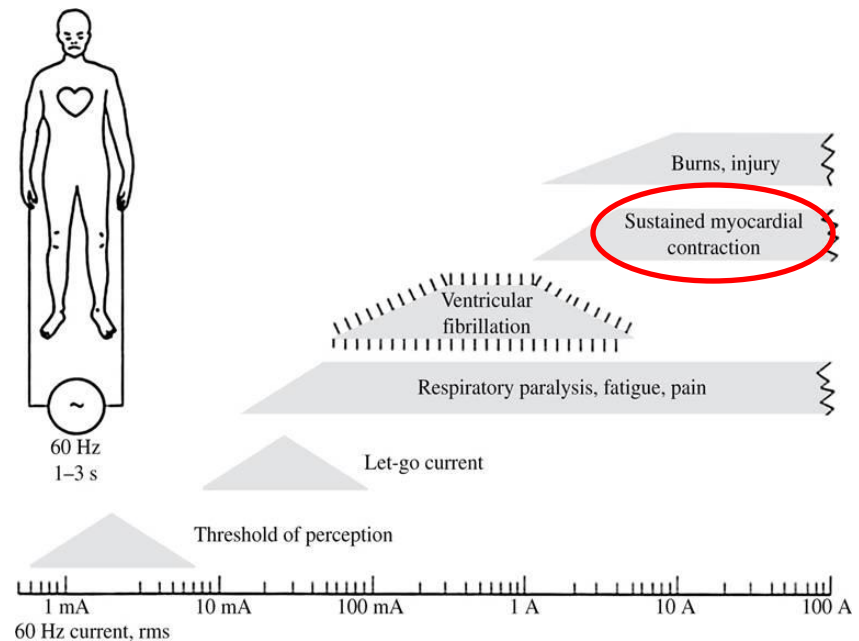
Electricity Effects (4)

- **Ventricular fibrillation**
- **75-400mA**
- **Disrupts the heart's normal electrical pathways**
- **Heart rate can skyrocket to 300 beats/min – death occurs within minutes**
- **Normal sinus rhythm does not return when current is removed (defibrillation required)**
- **~1000 deaths per year**



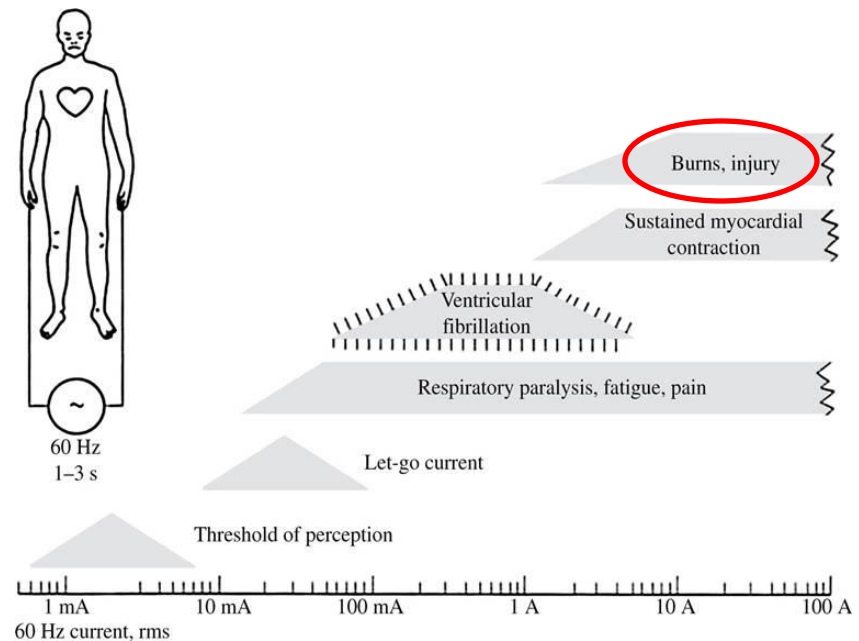
Electricity Effects (5)

- **Sustained myocardial contraction**
- **1-6A**
- **Entire heart muscle contracts**
- **And stops beating!**
- **Sinus rhythm returns when current is removed**
- **Similar to defibrillation**
- **No apparent damage to heart tissue after brief exposure**



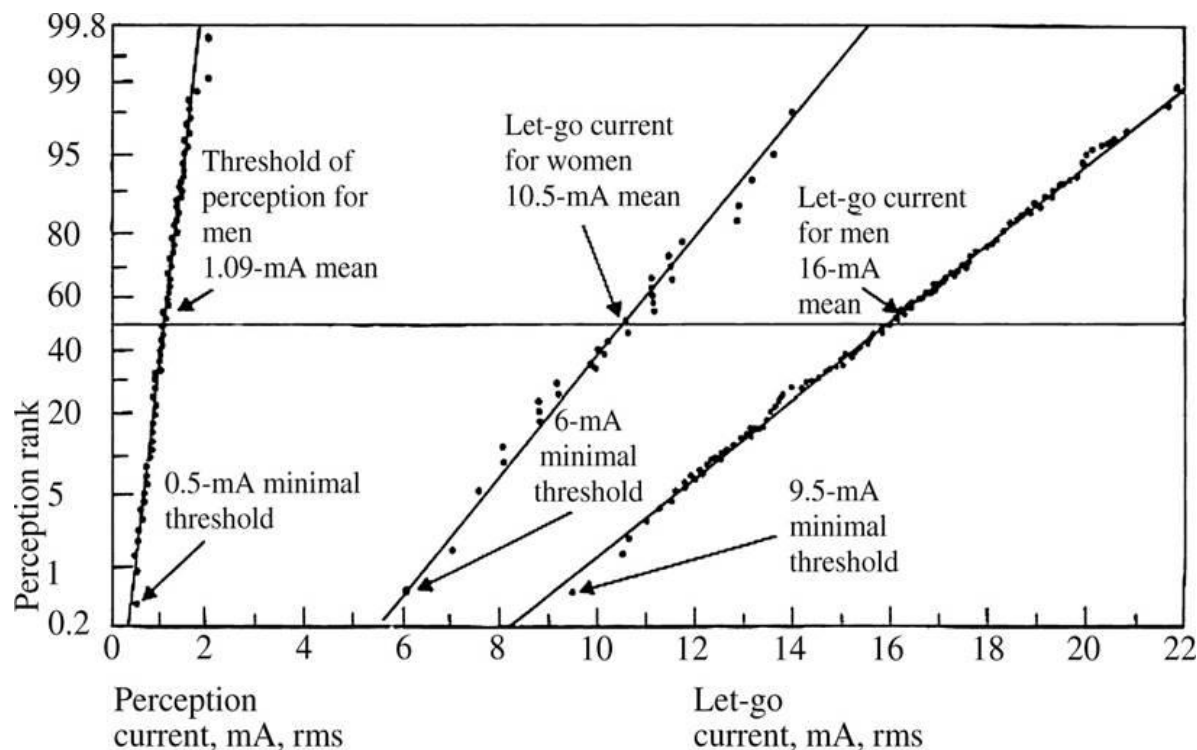
Electricity Effects (6)

- **Burns and physical injury**
- 10A and higher – little is known about the effects at this level
- Burns at current entry points
- Irreversible damage to brain and other nervous tissue
- Strong muscle contractions can detach muscle from bone



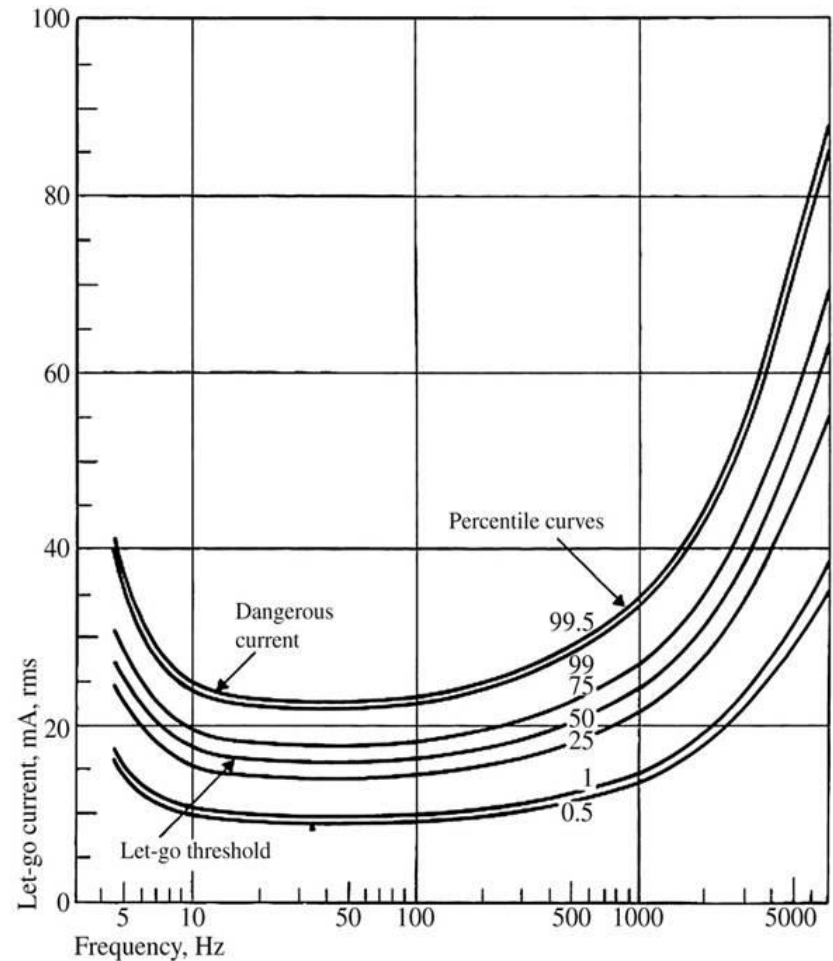
Threshold Variability

- Varies by body weight (e.g. fibrillation threshold increases with body weight on animals)
- Varies between men and women:



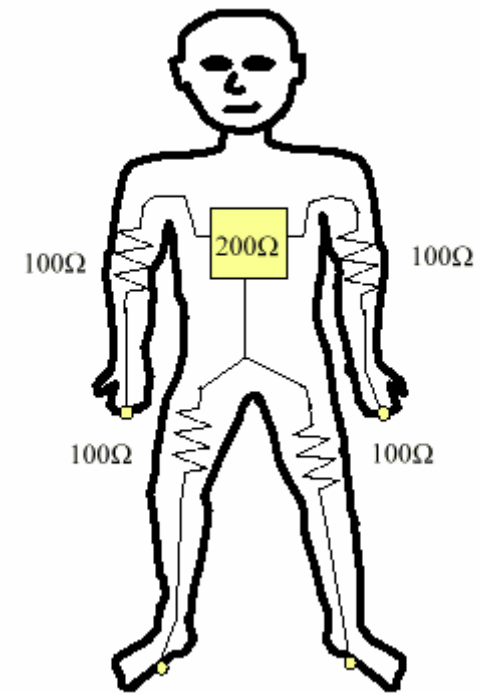
Let-go Current vs. Frequency

- Minimum (i.e., worst) let-go currents occur at 50-60Hz
- Unfortunate, since this is the most likely frequency we encounter
- Let-go current rises below 10Hz – muscles have time to partially relax
- Also rises for higher frequencies above 1kHz



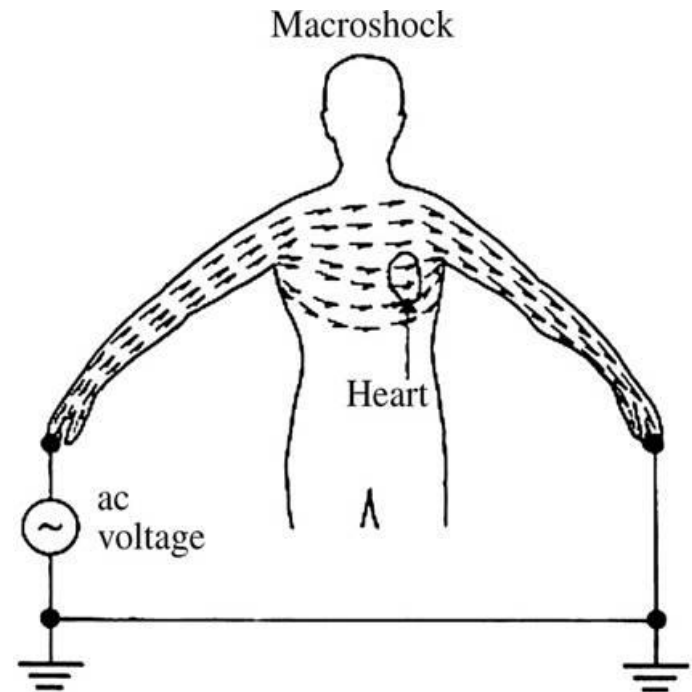
Resistive Model for Tissue

- Resistances in the body are generally small
- Skin adds much larger resistances:
 - Calloused skin $\rightarrow 2\text{-}3\text{M}\Omega/\text{cm}^2$
 - Normal skin $\rightarrow 20\text{-}30\text{K}\Omega/\text{cm}^2$
 - Moist skin $\rightarrow 500\Omega/\text{cm}^2$
 - Punctured skin $\rightarrow 200\text{-}300\Omega/\text{cm}^2$
- Notice the typical ECG Lead pathway is only 400-500 Ω excluding skin resistance



Macroshock

- A **macroshock** occurs when current is applied to two points on the surface of the body
- Only a small fraction of the current flows through the heart
- Very large currents needed to produce V-fib
- Entry points are key:
 - Both on the same extremity, the risk of V-fib is small
 - Across two limbs, risk of V-fib is higher

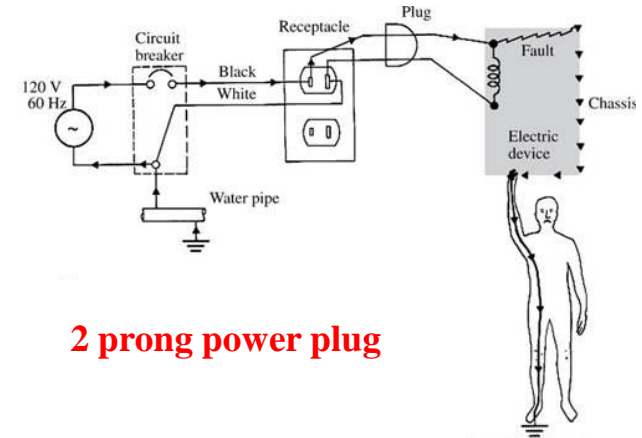


Macroshock Hazards

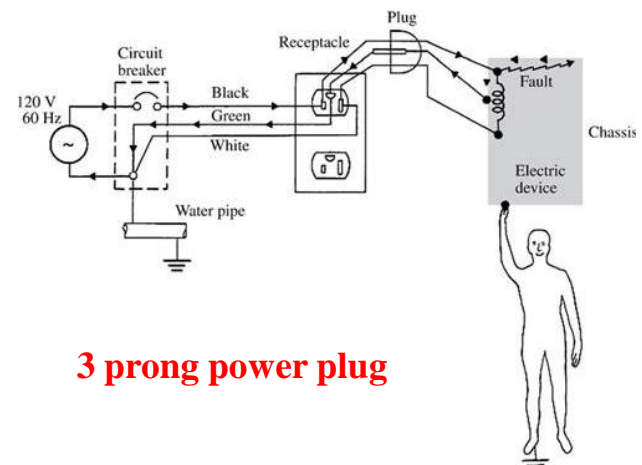
- **The additional protective resistance afforded by the skin is often bypassed:**
 - Natural openings
 - Skin incisions or abrasions
 - Electrode gel
 - Electronic thermometers inserted in the mouth or rectum
 - Intravenous catheters containing fluid, which acts as a conductor
- **For these reasons, patients in medical care facilities are at a much higher risk of macroshock**

Macroshock Hazards (2)

- The other source of macroshock is ungrounded or poorly grounded equipment
- If you are contacting the ground, you are grounded
- Without a good chassis ground, AC voltage during a fault (a short between conductors) can be passed from the equipment to you
- Proper grounding provides a lower resistance path to ground than you do, so the current flows through the green wire to ground (rather than through you!)



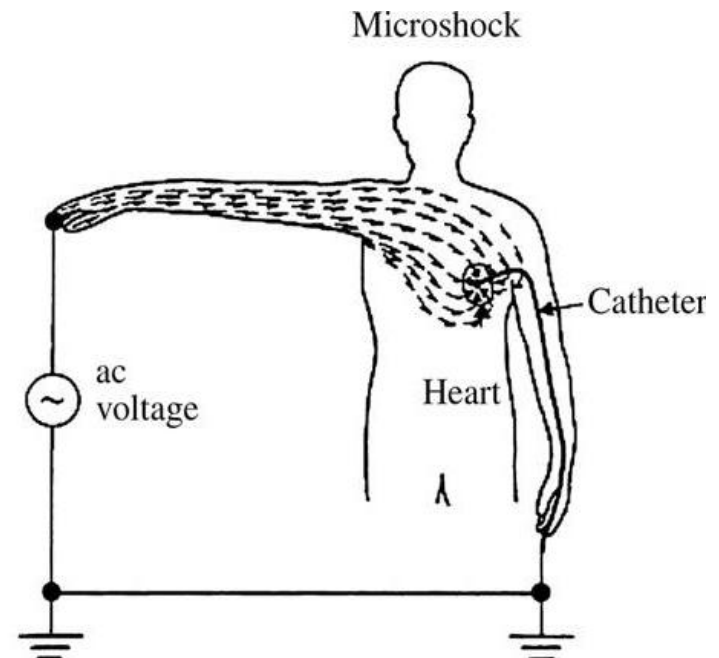
2 prong power plug



3 prong power plug

Microshock

- When an invasive device (such as a catheter) is placed in direct contact with the heart, a **microshock** can occur
- With one point of entry at the heart/catheter boundary, the other point can be anywhere
- V-fib can occur at very low currents $\rightarrow 50\mu\text{A}$
- For this reason, current safety limits are set at $10\mu\text{A}$ to prevent this



Electrical Standards

- **Several standards have been established for electrical systems used in patient care facilities**
- **NEC (National Electrical Code) 2006, Article 517**
 - **Covers all building power supply**
 - **Requirements vary for general-care, critical-care and wet areas**
- **NFPA (National Fire Protection Assn) 2005, Article 99**
 - **Covers electrical equipment for patient diagnostic, therapeutic and monitoring purposes**
 - **Covers gas, vacuum and environmental systems**
 - **Also covers high frequency equipment above 100kHz**

Electrical Standards (2)

- **AAMI (Assn for the Advancement of Medical Instrumentation) ESI-1993**
 - Provides chassis and patient lead leakage current limits for DC to 1 kHz; higher limits for 1 kHz to 100 kHz
 - For products sold in the US
- **IEC (International Electrotechnical Commission) 2006, standard 60601-1**
 - International version of AAMI
 - Widely supported by medical device manufacturers and their associations
 - Also supported by the FDA

Patient's Electrical Environment

- To reduce the possibility (and the effects) of shock hazards, the NEC 2006 standard set maximum potential differences between any two exposed conductive surfaces in the vicinity of a patient:
 - 500mV in general-care areas
 - 40mV in critical-care areas
- Only incidental contact in general-care areas; hence the higher limit
- Patients are intentionally exposed to electric devices in critical-care areas, so the limit is much lower
- Goal is to eliminate microshock potentials
- NEC 2006 also specifies circuit and grounding requirements for each patient bed location
- NEC 2006 also requires emergency power backup systems that activate within 10 seconds

Factors affecting the severity of a shock

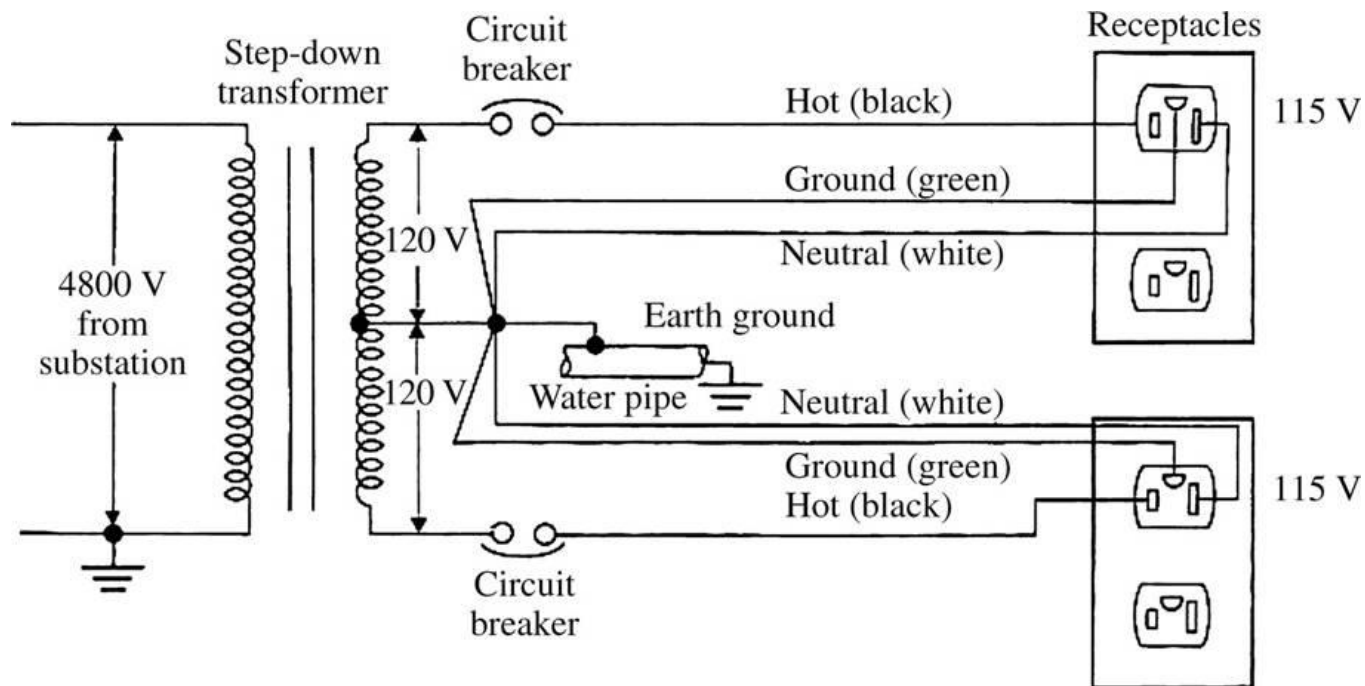
- Factors affecting the severity of the shock a person receives:
 - Amount of current flowing through the body
 - Path of the current through the body
 - Length of time the body is in the circuit
 - The voltage of the current
 - The presence of moisture in the environment
- Under dry conditions, human skin is very resistant. Wet skin dramatically drops the body's resistance.
 - **Dry Conditions: Current = Volts/Ohms = $120/100,000 = 1$ mA (barely perceptible)**
 - **Wet conditions: Current = Volts/Ohms = $120/1,000 = 120$ mA (sufficient to cause ventricular fibrillation)**

Factors affecting the severity of a shock (2)

- If the extensor muscles are excited by the shock, the person may be thrown away from the circuit
 - This can result in a fall from elevation that kills a victim even when electrocution does not!
- When muscular contraction caused by stimulation does not allow the victim to free himself from the circuit, even relatively low currents can be extremely dangerous
 - 100 mA for 3 seconds = 900 mA for .03 seconds : in causing fibrillation
- High voltage electrical energy greatly reduces the body's resistance by quickly breaking down human skin. Once the skin is punctured, the lowered resistance results in massive current flow.
 - At 120 volts, $\text{Current} = \text{Volts/Ohms} = 120/500 = 240 \text{ mA}$

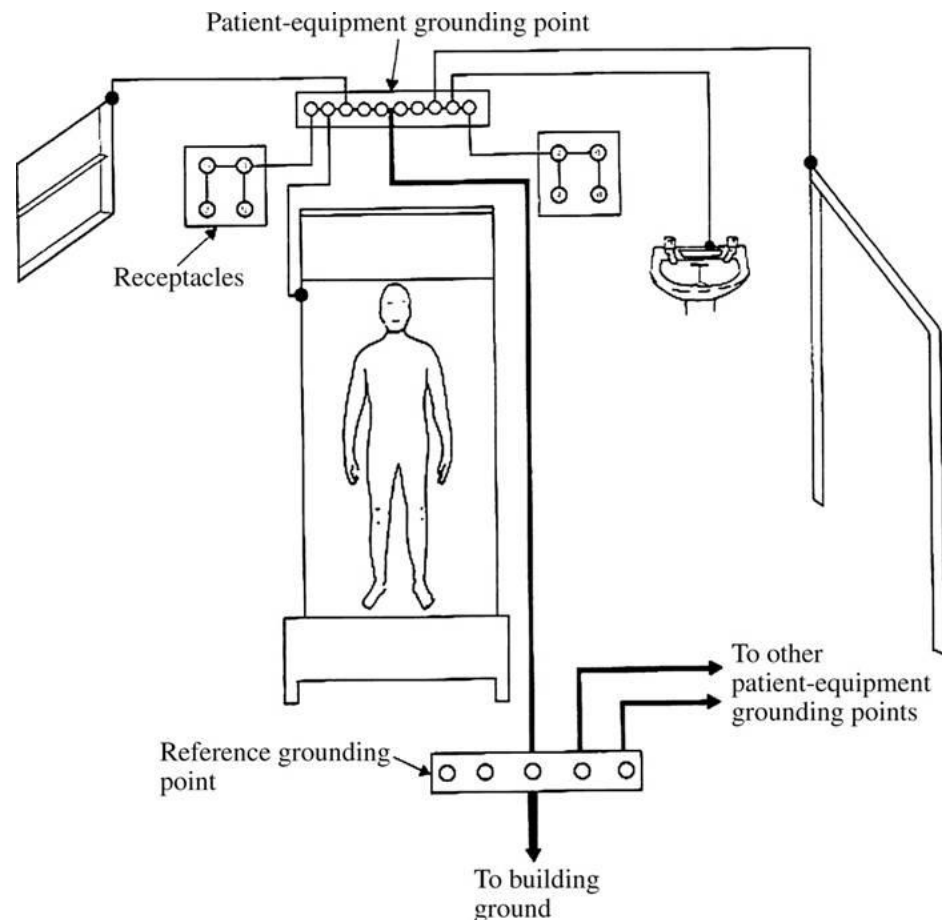
General Power Distribution

- Below is a simplified power distribution system
- Fine for most patient care locations



Grounding System

- Very important to keep all “grounds” at the same potential to protect against shock hazards
- This includes grounding all potential current carrying surfaces (windows, sink, etc.)
- Too much current: the fuse or normal breaker in the main panel will blow/trip
- Why not connect ground to neutral?
 - Differential breaker: senses change in current between neutral & hot
 - A separate earth ground provides an added layer of protection under severe fault conditions (if neutral is temporarily disconnected for some reason)

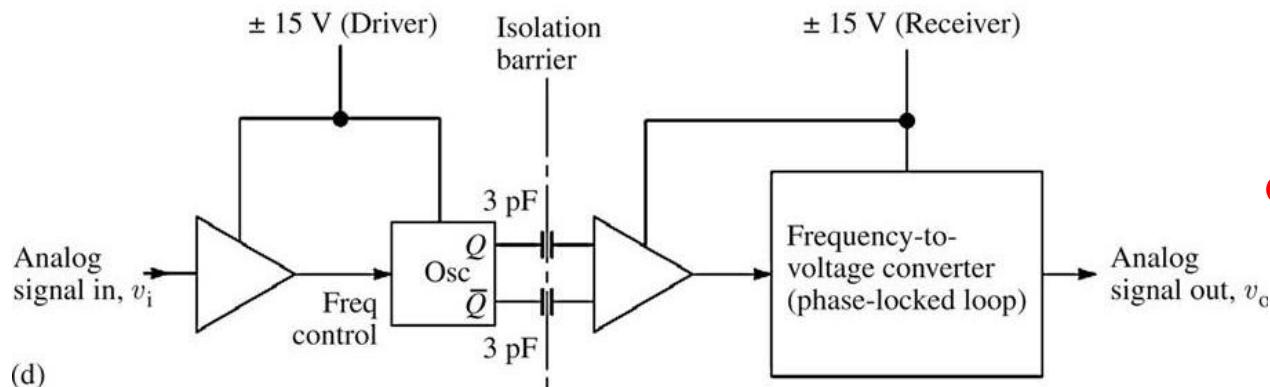


Equipment Design Techniques

- **Reliable grounding of equipment**
 - Strain relief on power cords
 - 3-prong power plug (with strong encouragement not to bypass it!)
- **Leakage current reduction**
 - Low leakage power cords
 - Proper layout and insulation to reduce/eliminate capacitance between conductors
 - Good circuit design to reduce leakage current from the circuit itself
- **Equipment insulation**
- **Low voltage operation**
 - Battery powered when possible
 - Or use low voltage isolation transformers
 - Less voltage, less possible current!

Equipment Design Techniques (2)

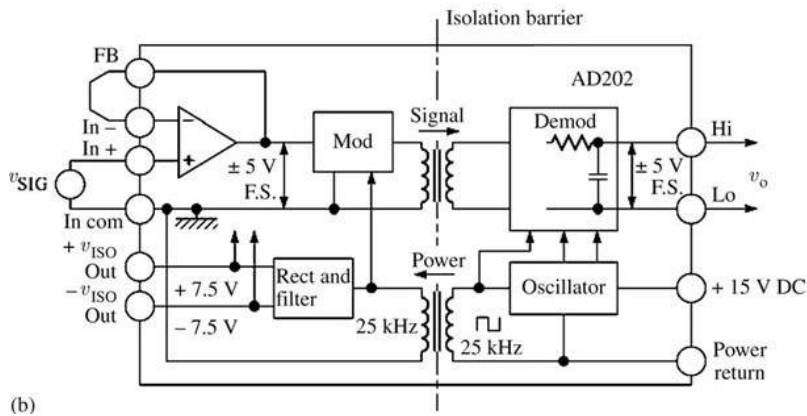
- **Electrical Isolation**
 - Provides a physical break in the electrical signal between the patient and the equipment:
 - Isolation transformer
 - Optical isolation
 - Capacitively coupled
 - Goal is to isolate current



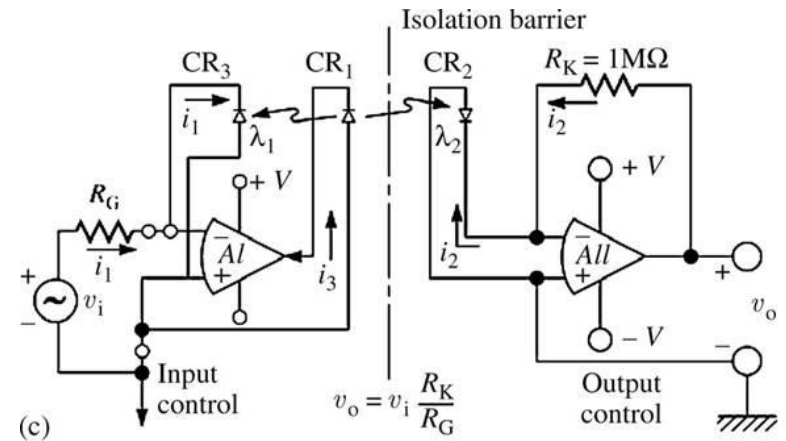
Capacitively Coupled

(d)

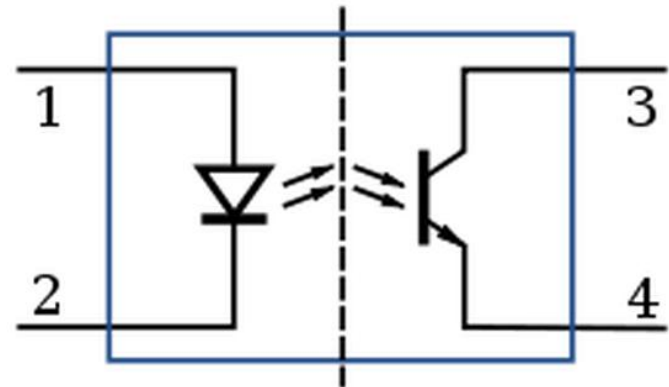
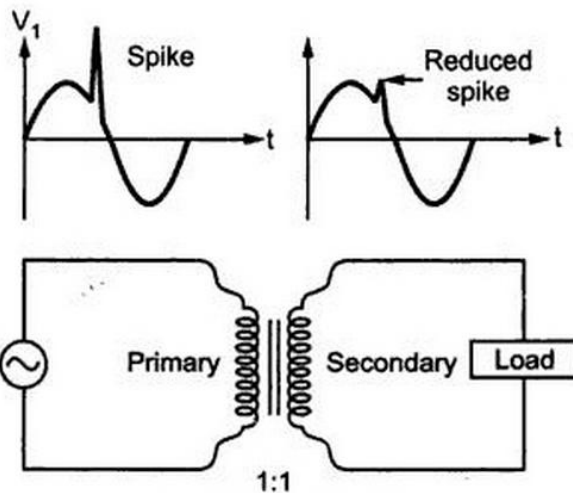
Electrical Isolation Techniques



Transformer Isolation



Optical Isolation



How Do We Design For Safety?

- **Be a pessimist**
 - Assume that issues will occur, both in the design and in its usage
- **Design failures do happen**
 - How does your design respond?
 - Does the device remain safe for the patient and care-giver?
- **Misuse will happen**
 - Untrained user not understanding how to use the device properly
 - **Anticipating how your device may be used** (properly or improperly) will allow you to add additional safety measures to keep users safe in the event of a malfunction