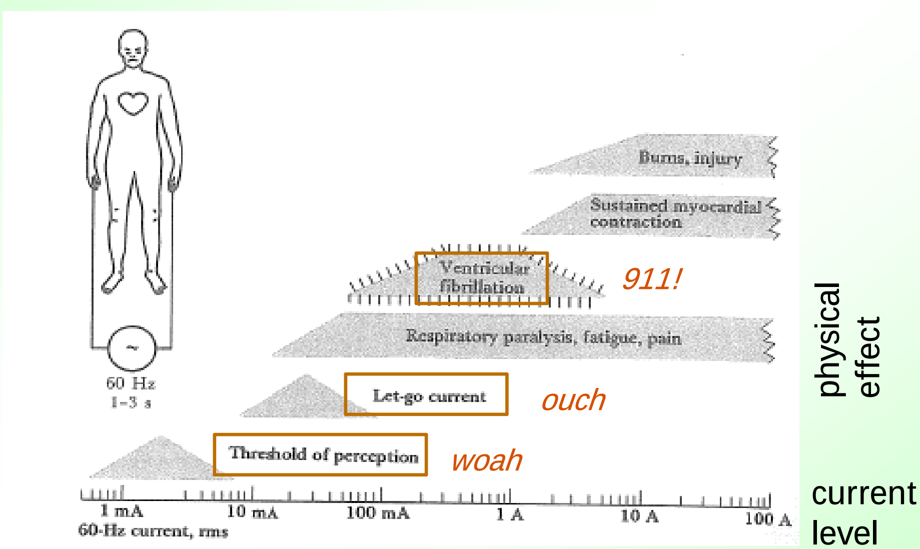
Medical Instrument Electrical Safety

- Significance of safety
  - 10s of thousands device related patient injuries in U.S every year.
  - Even a single harmful event can lead to significant damage in terms of reputation and legal action.
  - Different level of protection required as compared to household equipment.
  - Minimum performance standards introduced in 1980s –relatively new practice.

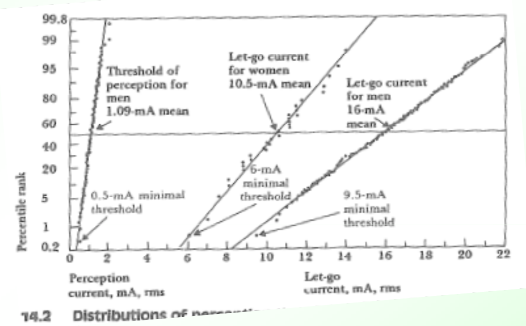
Physiological Effects of Electricity

- Physical effect vs. current level
  - Experiments from 160lb human with 60Hz current



Susceptibility Parameters

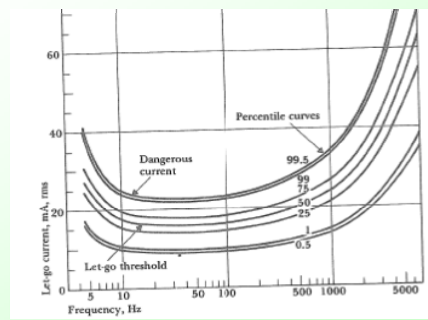
- Mean "**threshold of perception**"
  - 1.1mA for men
  - 0.7mA for women
- Minimum threshold of perception
  - 500 µA
  - 80 µA with gel electrodes
    (reduces skin impedance)



- Mean "**let-go current**"

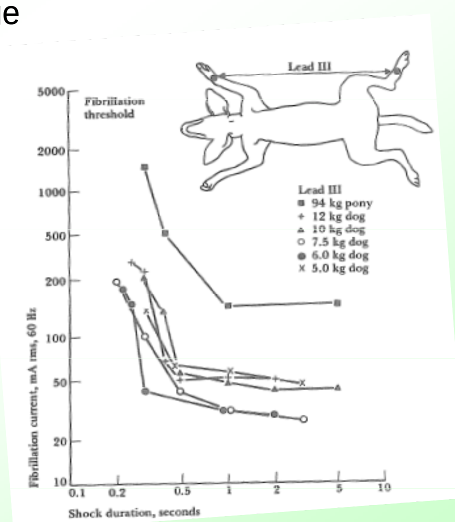
let-go current = max current where you can still release your grip

  - 16.5 mA for men
  - 10.5 mA for women
- Let-go current vs. frequency
  - Minimal let-go current occurs at commercial power-line frequencies of 50-60 Hz



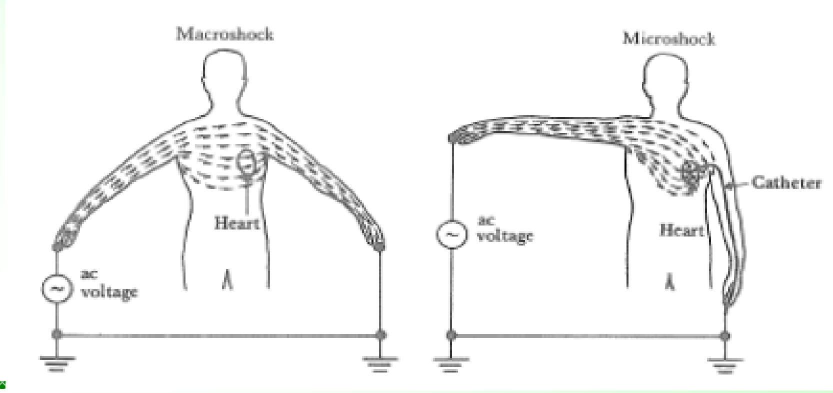
Susceptibility Factors

- Shock (stimulation) duration
  - Fibrillation current is inversely proportional to the shock pulse duration
  - longer pulses → lower current does damage
- Body weight
  - Fibrillation current increases with body weight
    - 50 mA RMS for 6 Kg dogs
    - 130 mA RMS for 24 Kg dogs
- Points of entry
  - Skin impedance varies: 15 kΩ to 1 MΩ
    - Resistive barrier that limits current flow
  - Tissue (beneath skin) has low impedance



Macro vs. Micro Shock

- Macroshock
  - externally applied current
  - spreads through the body so less concentrated
- Microshock
  - applied current is concentrated at an invasive point
  - accepted safety limit is only **10 μA**
  - generally only dangerous if current flows through the heart

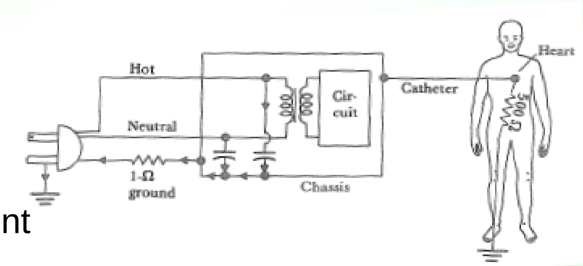


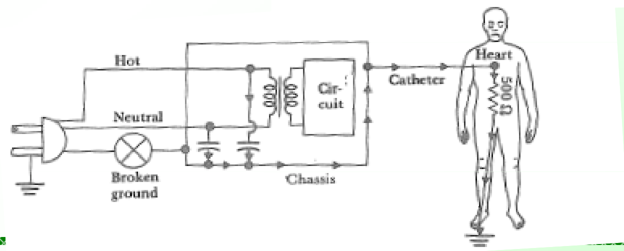
Macroshock Hazards

- Most probable cause of death due to macroshock
  - ventricular fibrillation
- Factors
  - skin/body resistance
  - design of electrical equipment
- Skin and body resistance
  - dry skin has high resistance (~15k-1M ohm)
    - limits current through body
  - wet/broken skin has low resistance (~1% that of dry skin)
  - internal body resistance
    - ~200 ohm for each limb
    - ~100 ohm for trunk of body
    - resistance between two limbs = ~500 ohm
  - procedures that bypass skin resistance can be dangerous
    - example: gel electrodes, surgery, oral/rectal thermometers

Microshock Hazards

- Main causes
  - leakage currents in line-operated equipment
    - undesired currents through insolated conductors at different potentials
  - differences in voltage between grounded conductive surfaces
- Leakage currents
  - if low resistance ground is available → no problem
  - if ground is broken → current flows through patient





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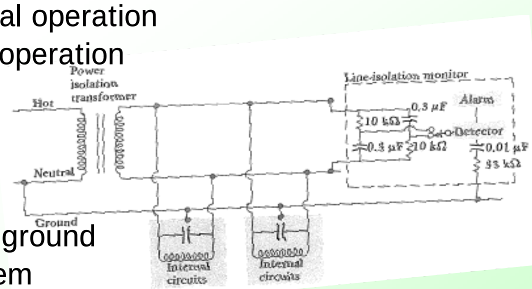
Conductive Paths

- Direct connection to an internal organ (during measurement or surgery) makes patients susceptible to mircoshock
  - External electrodes of temporary cardiac pacemakers
  - Electrodes for intracardiac measuring devices
  - Liquid filled catheters placed in the heart
    - liquid filled catheters have much greater resistance than electrodes
- Worst !danger!
  - currents flowing through the heart
- Electrode current density
  - experiments suggest smaller electrode are more dangerous

Power Distribution

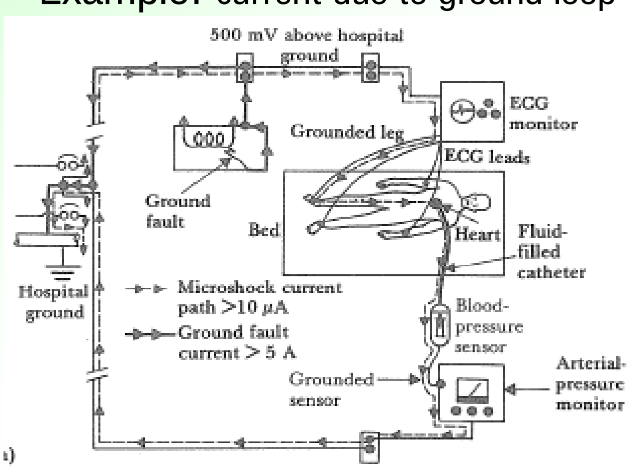
- Electrical power system in Healthcare Facility
  - must control available power (fuse/breaker to set max current)
  - must provide good ground
- Patient's Electrical Environment -Grounding
  - NEC code: max potential between two surfaces
    - general care areas: **500mV** under normal operation
    - critical care areas: **40mV** under normal operation

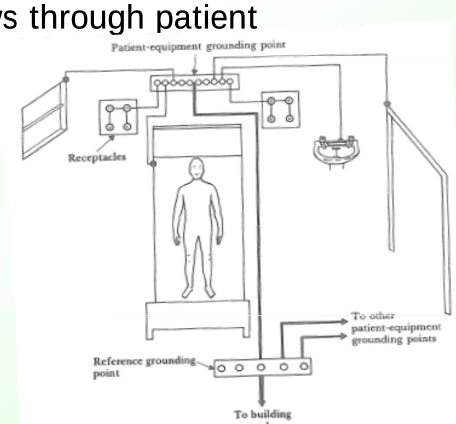


- Isolated Power Systems
  - Ground fault
    - short circuit between hot conductor and ground
    - injects large current into grounding system
    - can create hazardous potentials on grounded surfaces
  - Isolation transformer
    - isolates conductors against ground faults
    - may include ground fault monitor/alarm

Ground Loops

- Differences in ground potential: major source of microshock
  - all intensive care units must have single ground for each patient
    - isolated from hospital ground
  - 40mV limit on potential of any conductive surfaces
- Example: current due to ground loop flows through patient

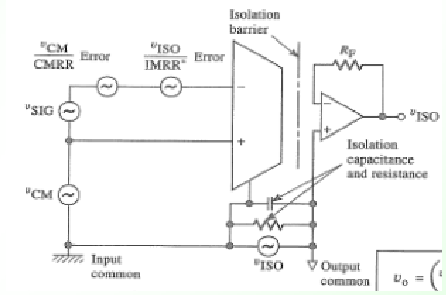




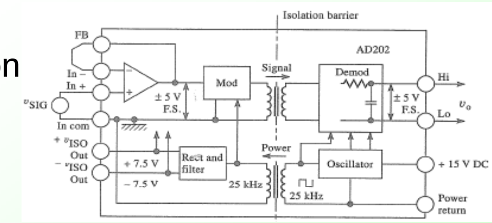
Good grounding: all conductive surfaces & receptacle grounds at same potential

Electrical Isolation

- Isolation amplifiers
  - devices that break ohmic continuity of electric signals between input and output of the amplifier
  - different supply voltage sources and different grounds on each side of the barrier



- Barrier isolation
  - transformer, optical or capacitive isolation
    - no current across barrier



- Implants
  - proper insulation required to prevent microshocks