ESE 3400: Medical Devices Lab

Lec 7: September 26, 2022

Electrical Safety and Isolation

Lecture Outline

- Safety significance
- Perception thresholds
- Current pathway
  - Macroschocks and microshocks
- Sources of Leakage
- Solutions
  - Ground loops
  - Electrical isolation

Significance of Safety

- Thousands of 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.

Effects of Electricity

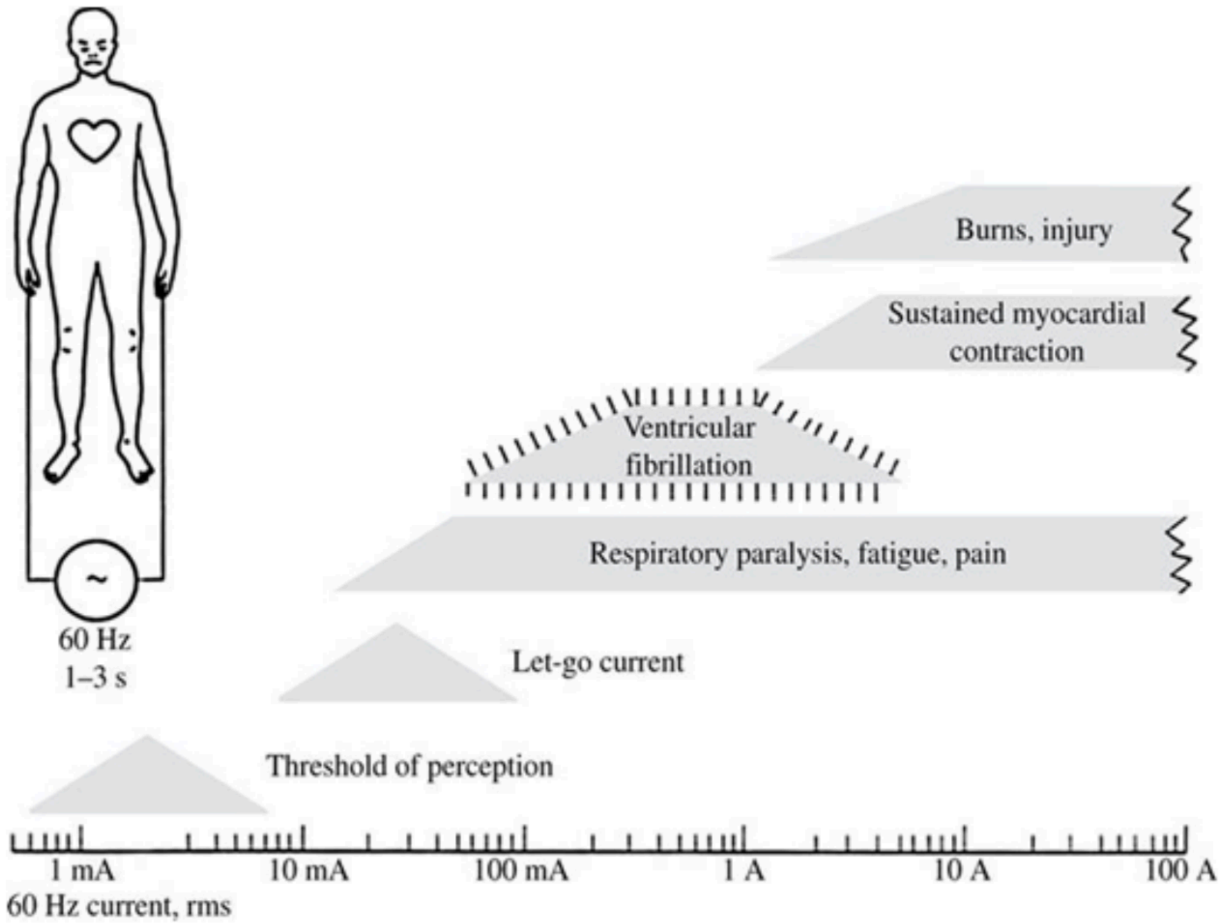
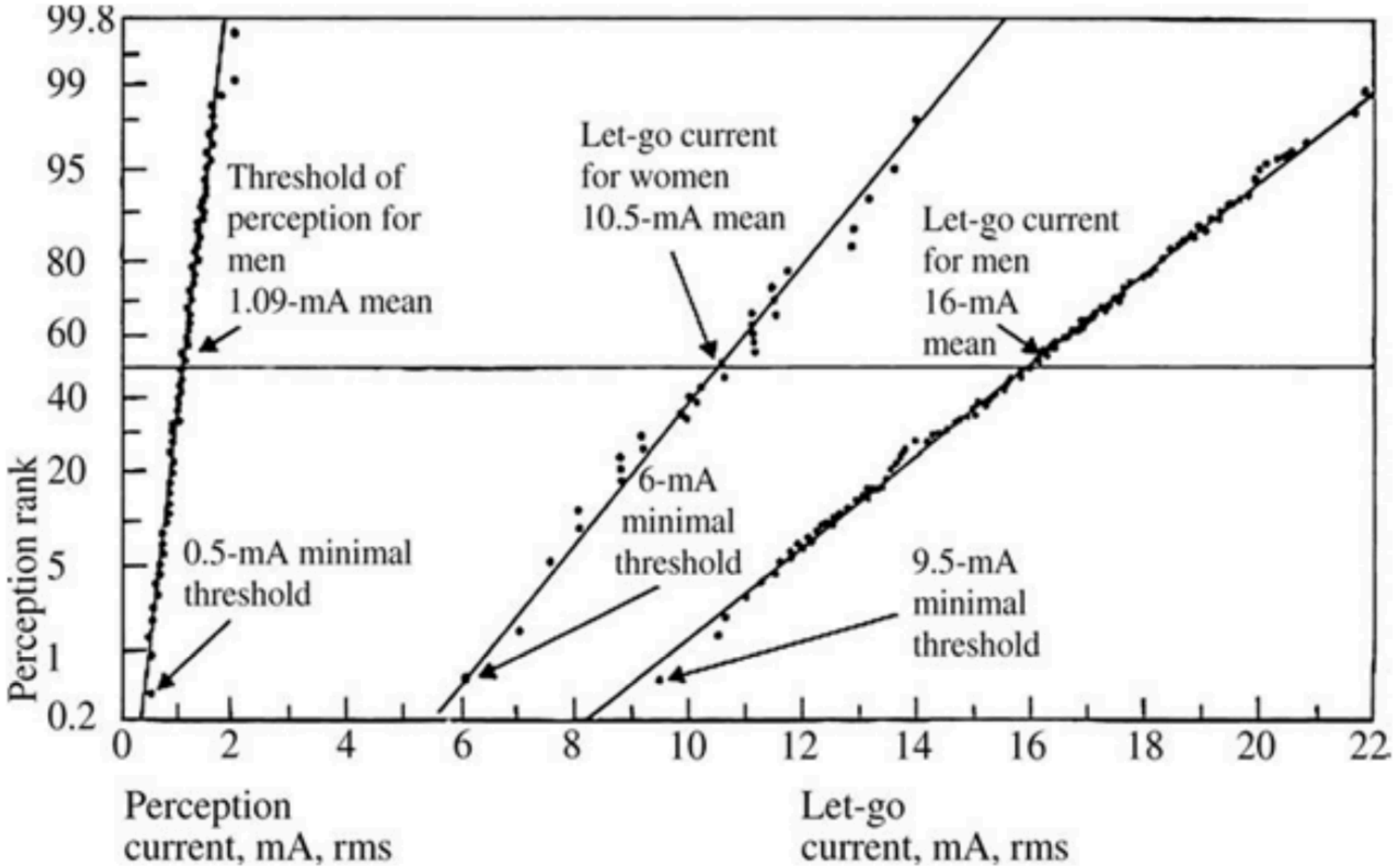
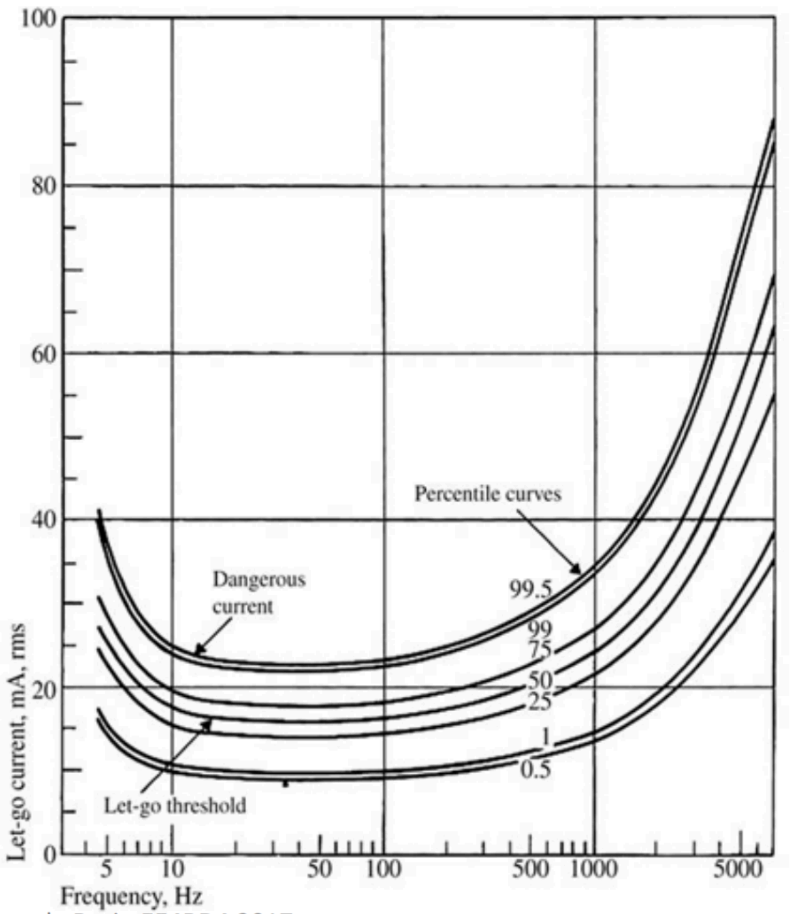


Figure 14.1 Physiological effects of electricity Threshold or estimated mean values are given for each effect in a 70 kg human for a 1 to 3 s exposure to 60 Hz current applied via copper wires grasped by the hands.

Variability of Threshold of Perception



Frequency Effect on the Let-Go Current



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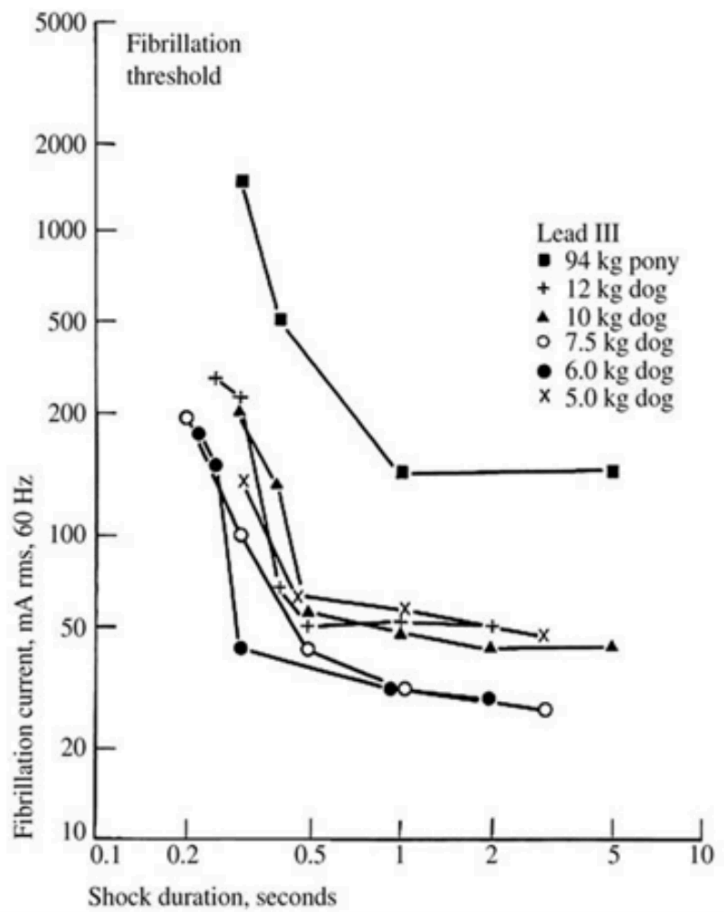
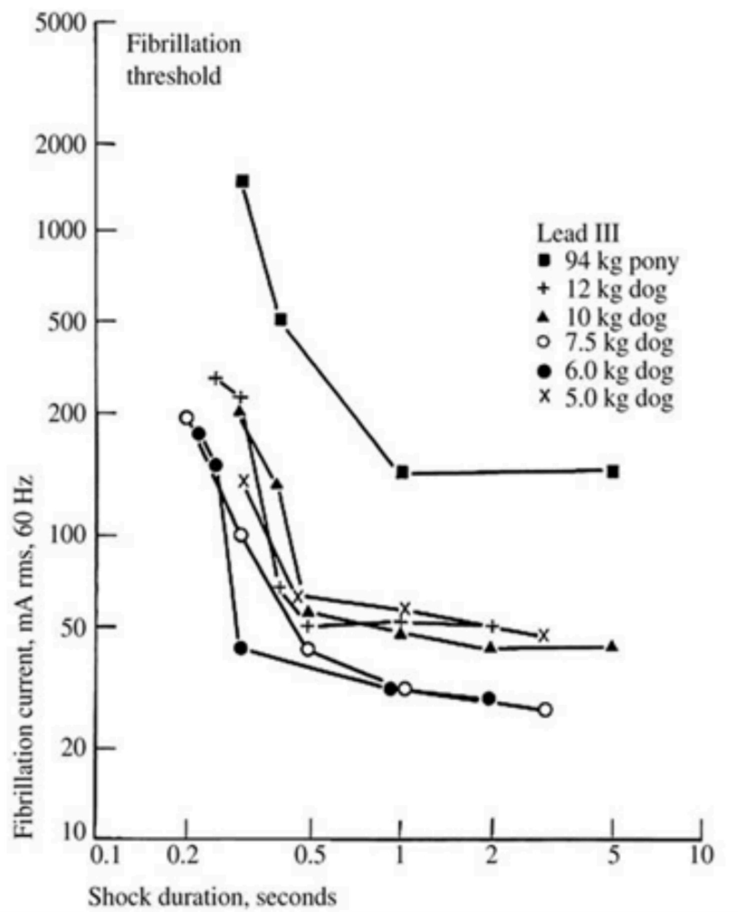
- Mean "**let-go current**"
  let-go current = max current where you can still release your grip
  - 16.5 mA for men
  - 10.5 mA for women
- Let-go current vs. frequency
  - Minimal let-go current occurs at commercial power-line frequencies of 50-60 Hz

Susceptibility Factors



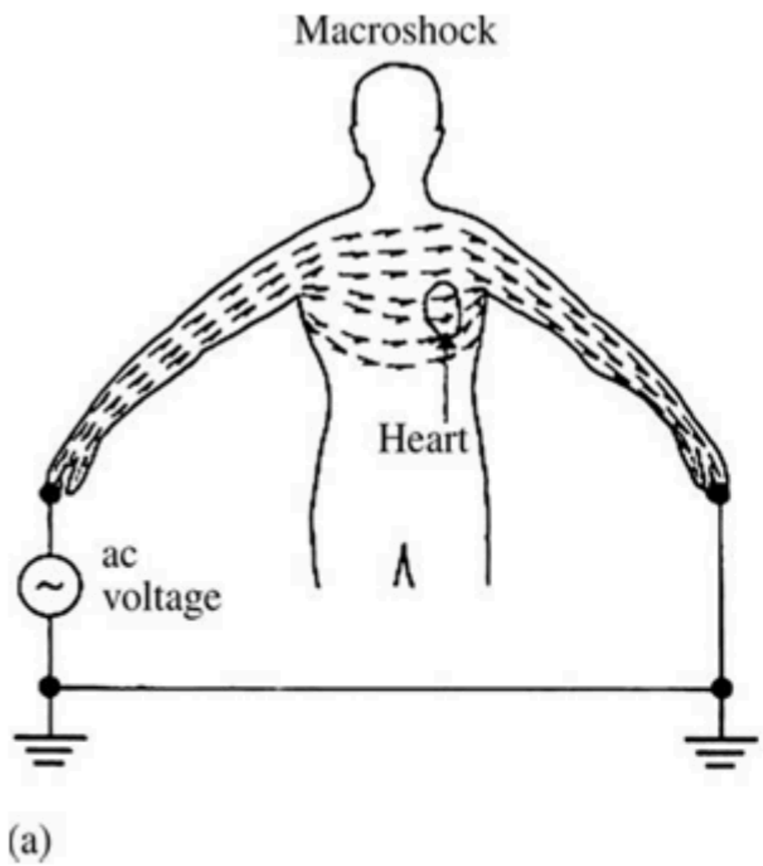
- Shock (stimulation) duration
  - Fibrillation current is inversely proportional to the shock pulse duration
  - Longer pulses → lower current does damage

Susceptibility Factors



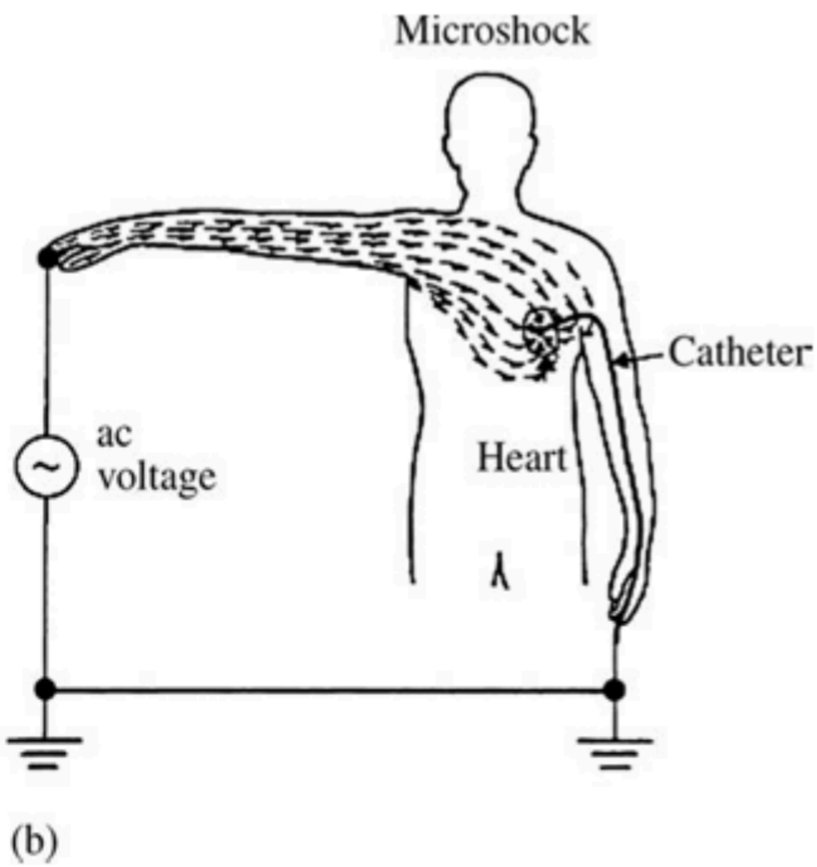
- Body weight
  - Fibrillation current increases with body weight
    - 50 mA RMS for 6 Kg dogs
    - 130 mA RMS for 24 Kg dogs
- Points of entry
  - Skin impedance varies: 15 kΩ to 1 MΩ
    - Resistive barrier that limits current flow
  - Tissue (beneath skin) has low impedance

Current Pathway



- Macroshock
  - Externally applied current
  - Spreads through the body and less concentrated

Current Pathway



- Microshock
  - Current concentrated at an invasive point
  - Accepted safety only 10uA
  - Generally only dangerous if current flows through heart

Controlled Stimulation

- Defibrillation
- Electrical muscle stimulation
- Electrosurgery
- Electroshock therapy
- Deep neural stimulation

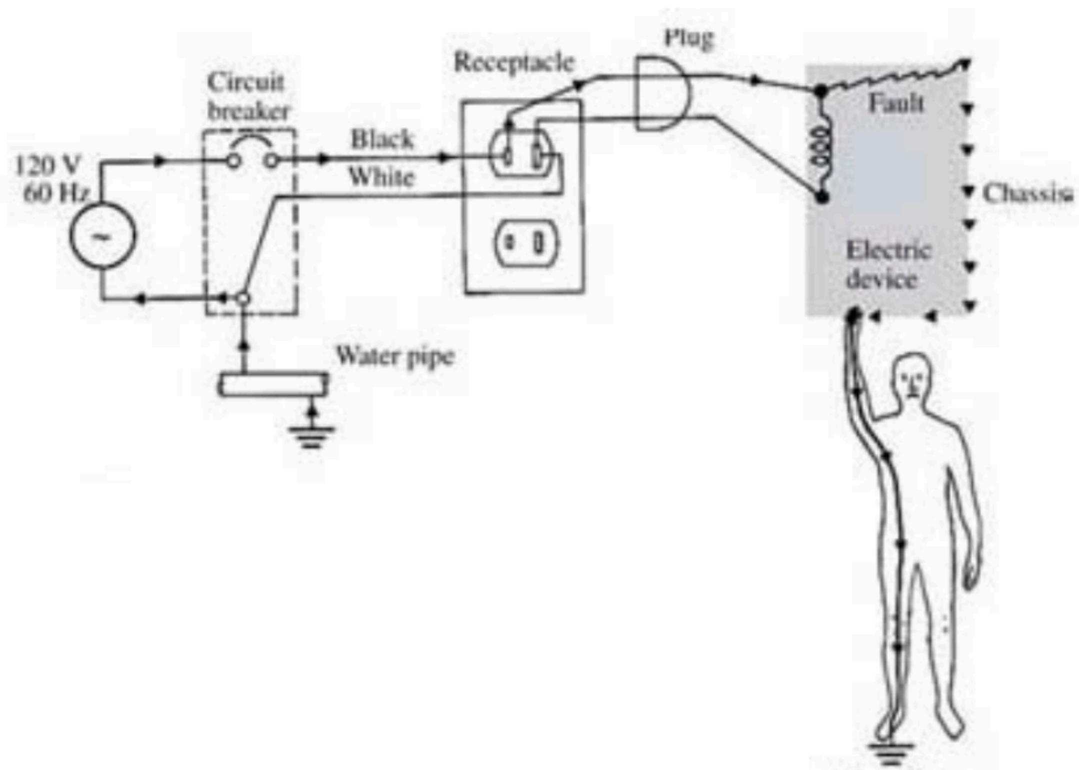
- …But it is very well controlled

Controlled Stimulation

- Electrical muscle stimulation
  - Low current & frequency... sort of
  - Not across heart
- Electrosurgery
  - high frequency (250 - 2000 kHz)
- Deep neural stimulation: very small current
- Defibrillation: as a last resort
- Electroshock therapy: last resort (if ever)

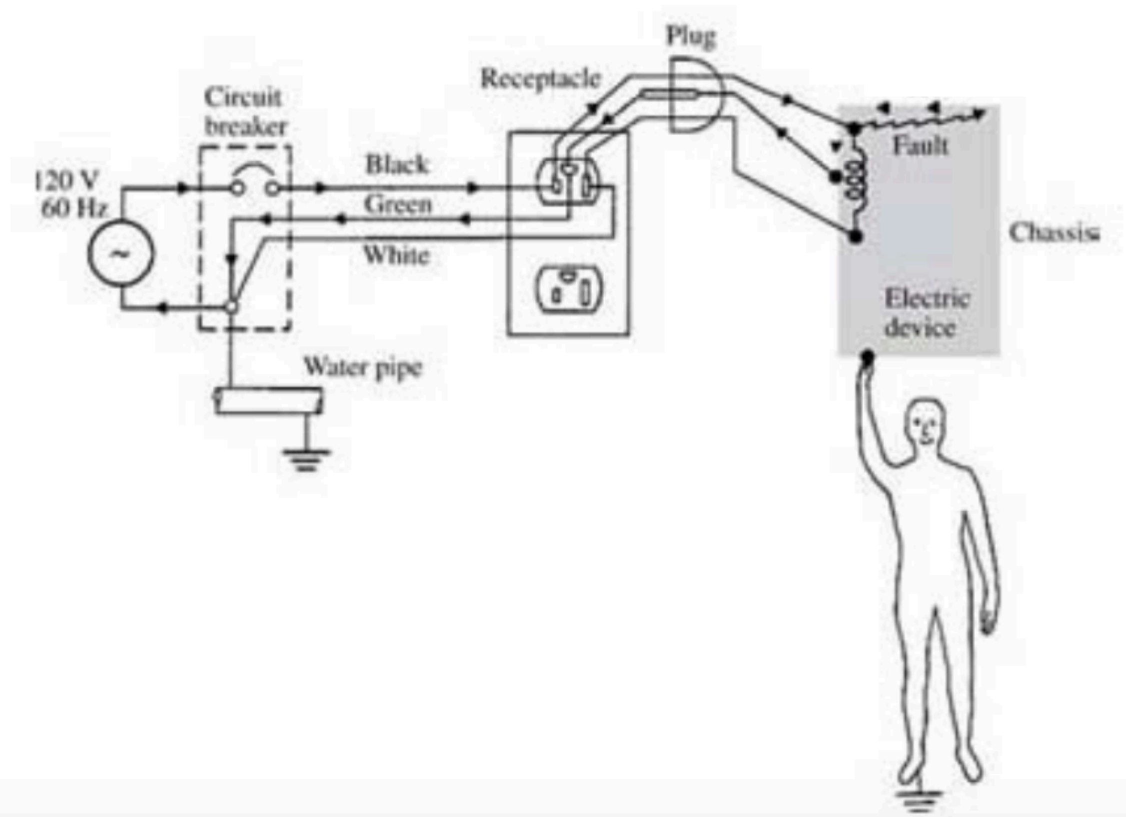
Macroshock

- Occur when equipment breaks down and the hot wire touches equipment case or other conductive pathway current flows through subject to ground but not enough to trip circuit breaker or breaker doesn’t trip in time



Macroshock

- Grounded circuits (case grounded) provides an almost direct short to ground which will trip breaker but not necessarily in time



Macroshock Hazards

- Most probable cause of death
  - Ventricular fibrillation
- Factors
  - Skin/body resistance
  - Design of electrical equipment
- Skin and body resistance
  - dry skin has high resistance (~15kΩ-1MΩ)
  - wet/broken skin has low resistance (~1% that of dry skin)
  - Internal body resistance: ~200Ω for each limb, ~100Ω for trunk of body, ~500Ω resistance between two limbs
- Procedures that bypass skin resistance can be dangerous
  - Example: gel electrodes, surgery, oral/rectal thermometers

Microshock

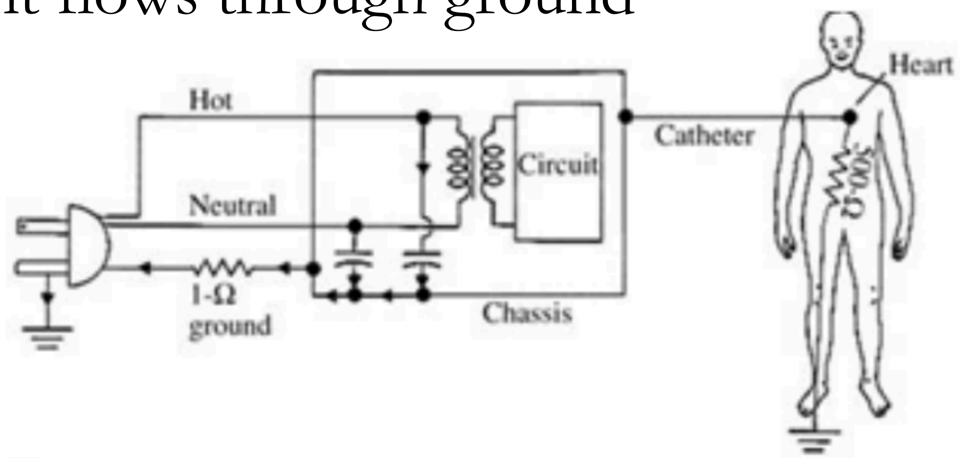
- Leakage currents are small currents (usually μA) that flow between insulated current carrying conductors during normal operation
- Due to coupling capacitance between conductors with AC currents
- Also could be due to resistive pathways established by moisture, dust or insufficient insulation
- Especially dangerous when there are patient applied parts

Microshock Hazards

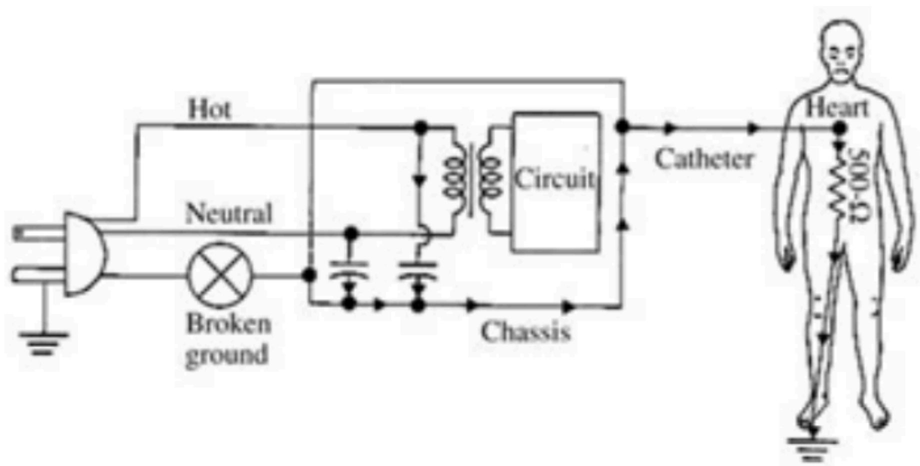
- Main causes
  - Leakage currents in line-operated equipment
    - Undesired currents go through insulated conductors at different potentials
  - Differences in voltage between grounded conductive surfaces

Microschock Hazards

- Leakage currents
  - If low resistance to ground is available → no problem, majority of current flows through ground



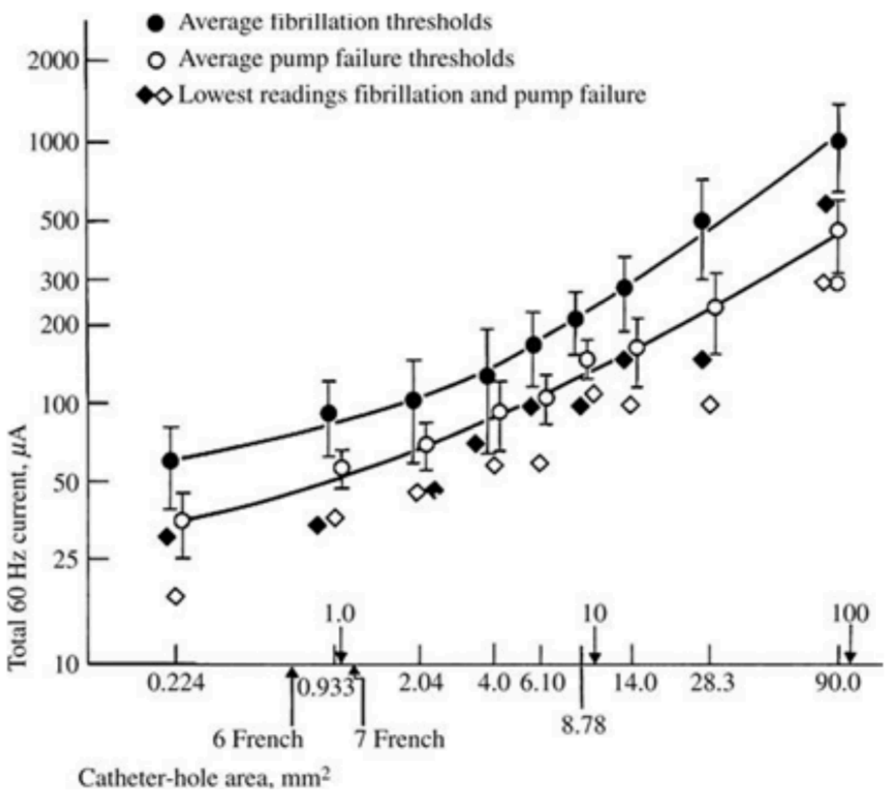
  - If ground is broken → all current flows through patient



Sources of Patient Leakage Currents

- All electrodes (and sensors with inputs to amplifiers) have leakage currents
- Any indwelling electrodes with pathways to or location close to heart are especially dangerous
  - epicardial or endocardial electrodes from an external cardiac pacemaker
- Liquid filled catheters for blood pressure, sampling or delivery of drugs (volumetric pumps which are line powered)
- Danger really only occurs when there is electrical connection to the heart

Electrode Current Density

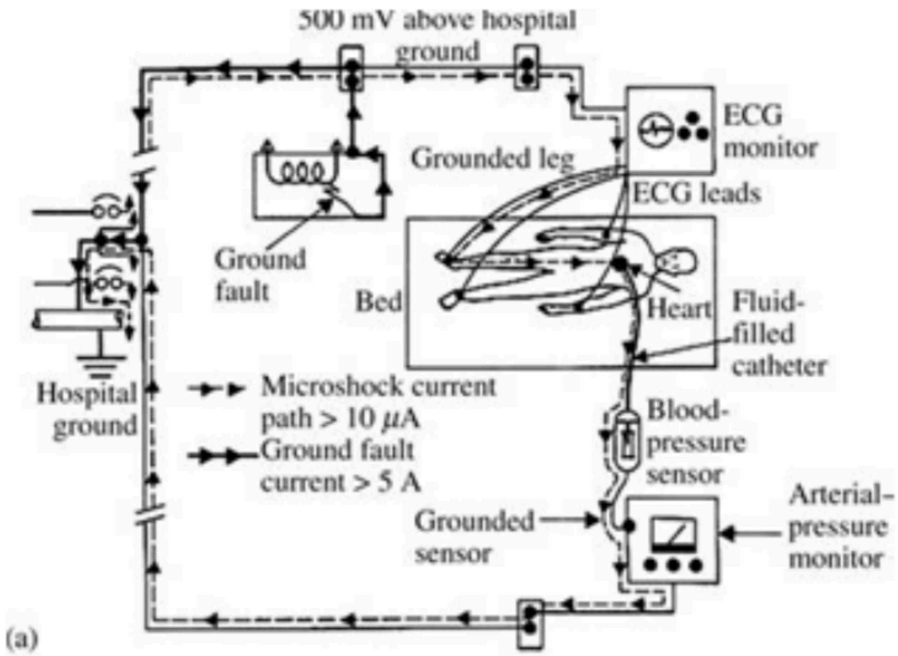


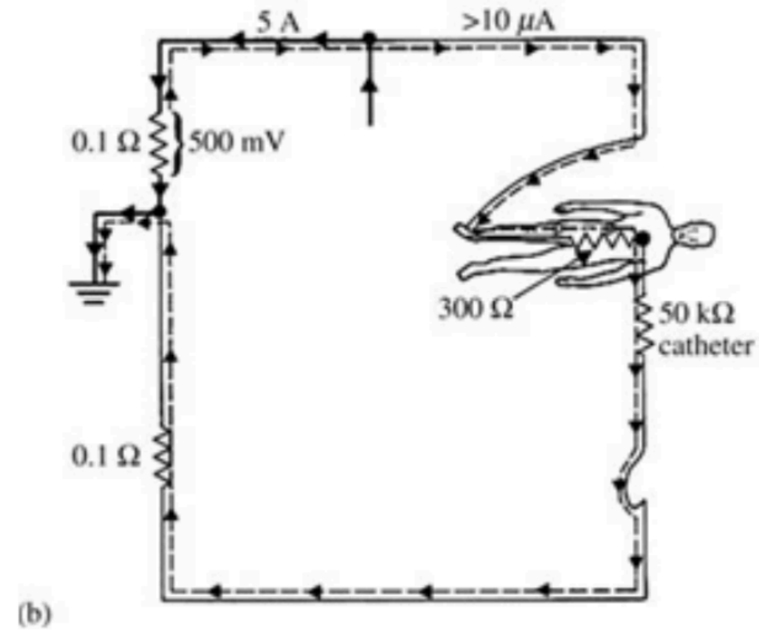
- Experiments suggest smaller electrodes (or catheters) are more dangerous

What if No Modern Standards?

- Patient in ICU with right leg electrode grounded to avoid noise and left ventricle pressure conductive diaphragm also grounded (unrealistic scenario)
- A defective floor polisher plugged into the ECG Power supply injects 5 A into the groundwire (in a modern system the circuits would be entirely different)
- With 0.1 Ω resistance in ground wire 500 mV is added to ground on ECG side
- Patient‘s body, ECG electrode, and catheter are <50 kΩ causing >10 μA through heart

Ground Loops





Patient's Electrical Environment

- Any two conductive surfaces near a patient cannot have more than
  - 500 mV potential difference for general care areas in a hospital
  - 40 mV in a critical care area (NEC 2006)
- In general care areas patients have only incidental contact with electrical devices
- In critical care areas all exposed conductive surfaces must be grounded at a single point
- Other regulations exist for numbers and connections of outlets in each patient care area

Single-point Grounding System

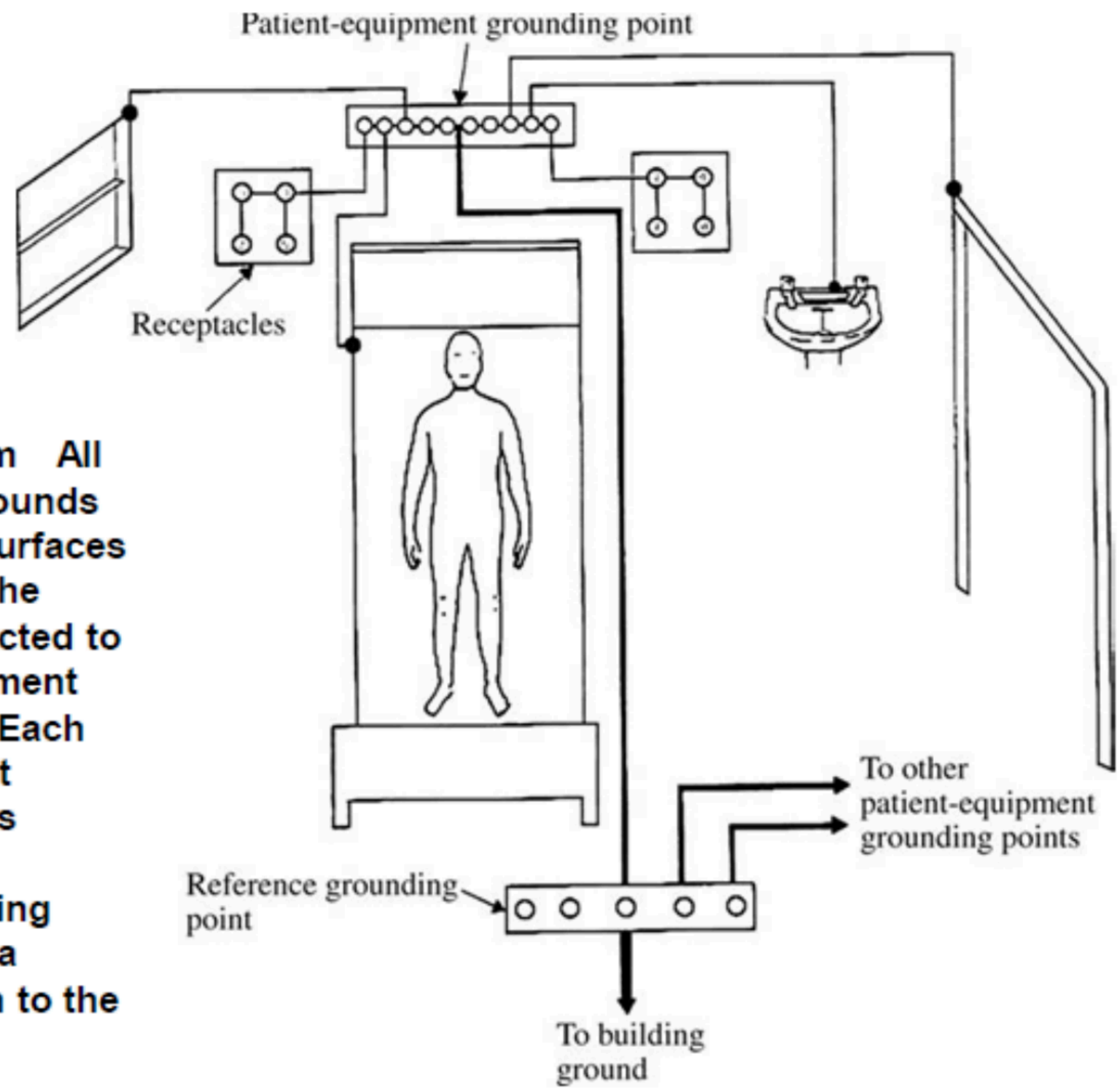
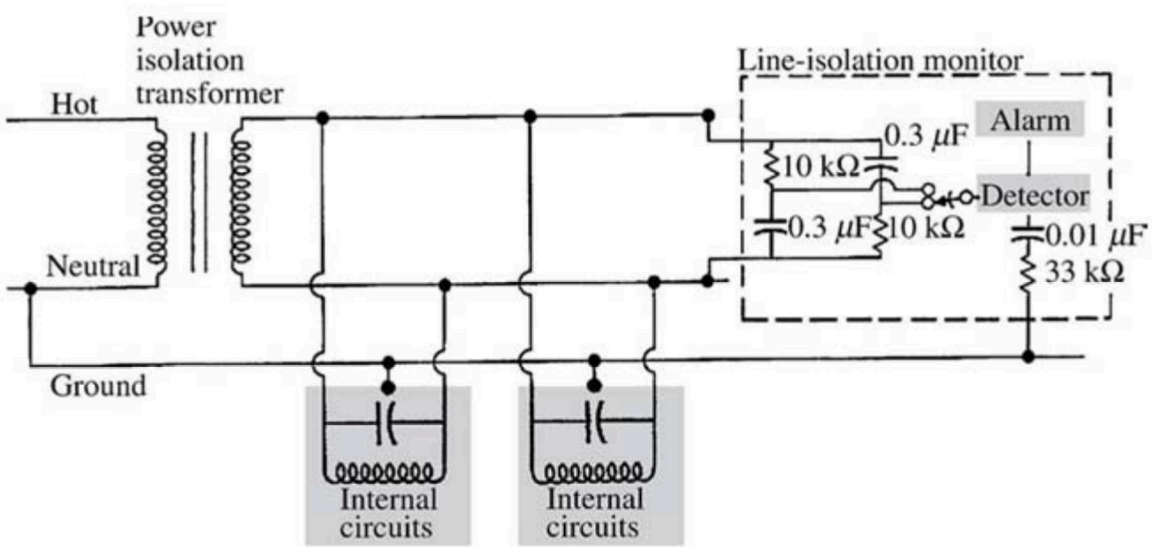


Figure 14.14
Grounding system All the receptacle grounds and conductive surfaces in the vicinity of the patient are connected to the patient-equipment grounding point. Each patient-equipment grounding point is connected to the reference grounding point that makes a single connection to the building ground.

Isolated Power Systems

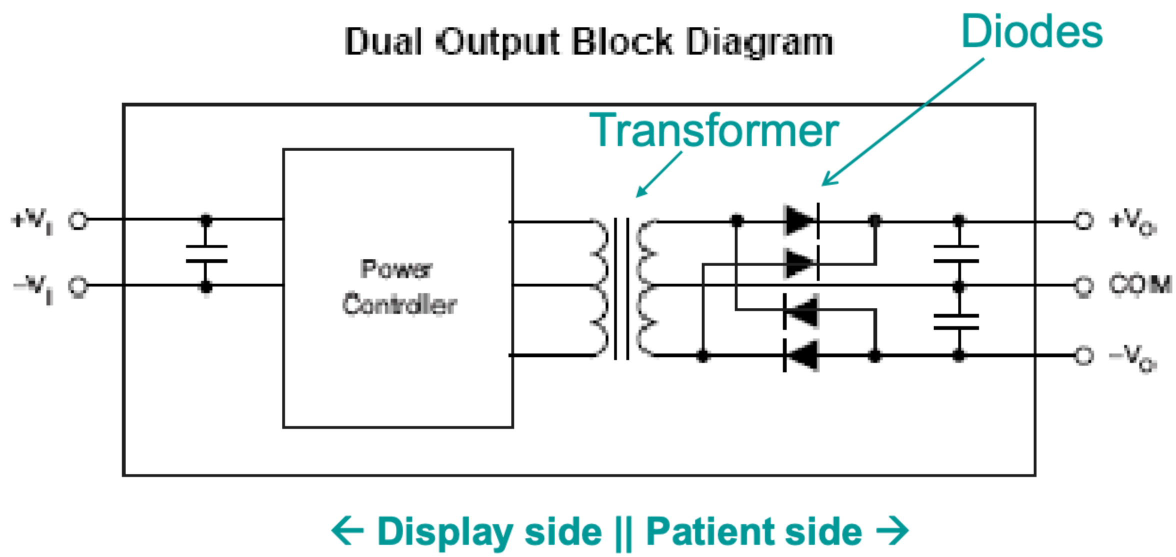
- Ground fault
  - Short circuit between hot conductor and ground
  - Injects large current into grounding system
  - Can create hazardous potentials on grounded surfaces
- Isolation transformer
  - Isolates conductors against ground faults
  - May include ground fault monitor/alarm



Electrical instruments

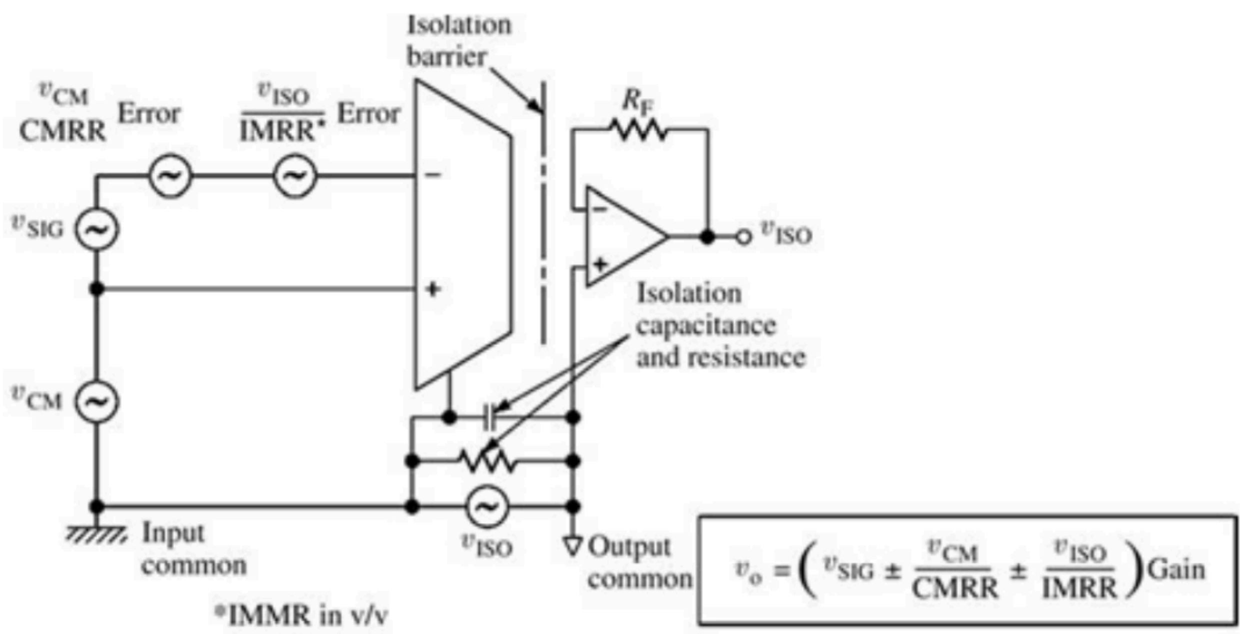
Isolated Power Supply

- DCH010505 Isolation Power Supply



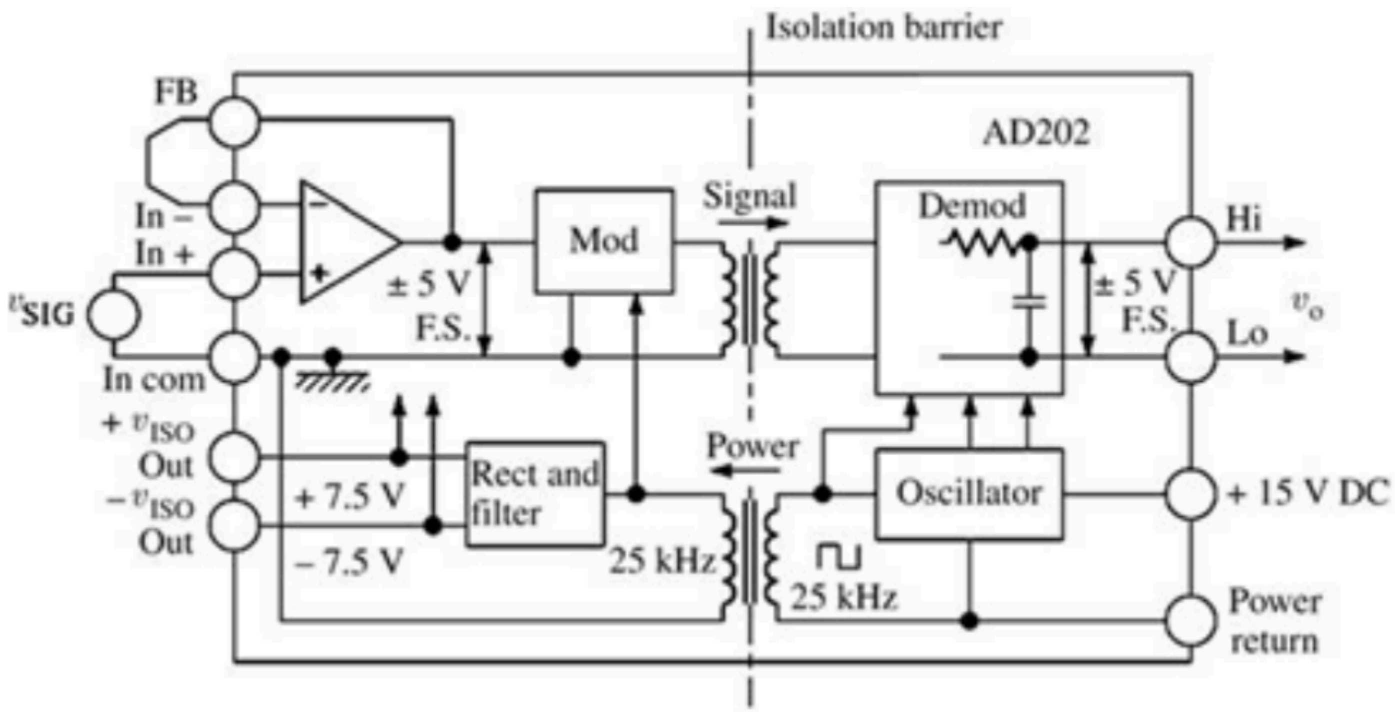
Isolation Amplifiers

- 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



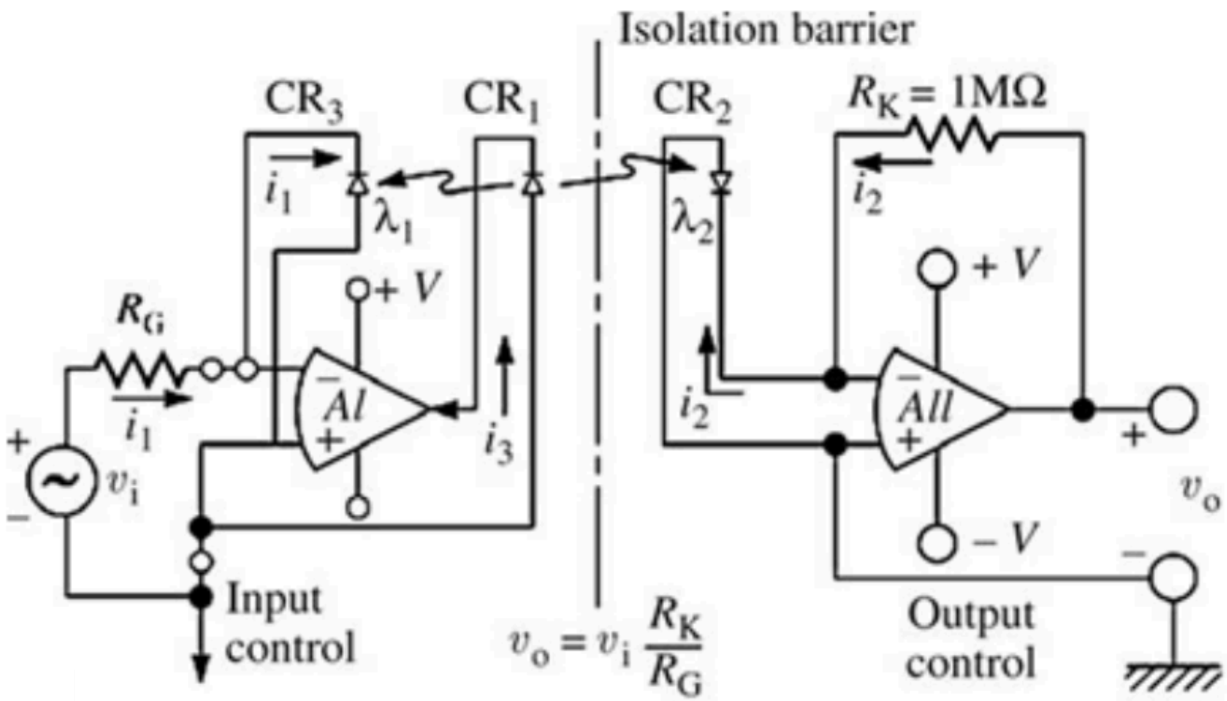
Isolation Amplifiers

- Transformer isolation
  - No current across barrier



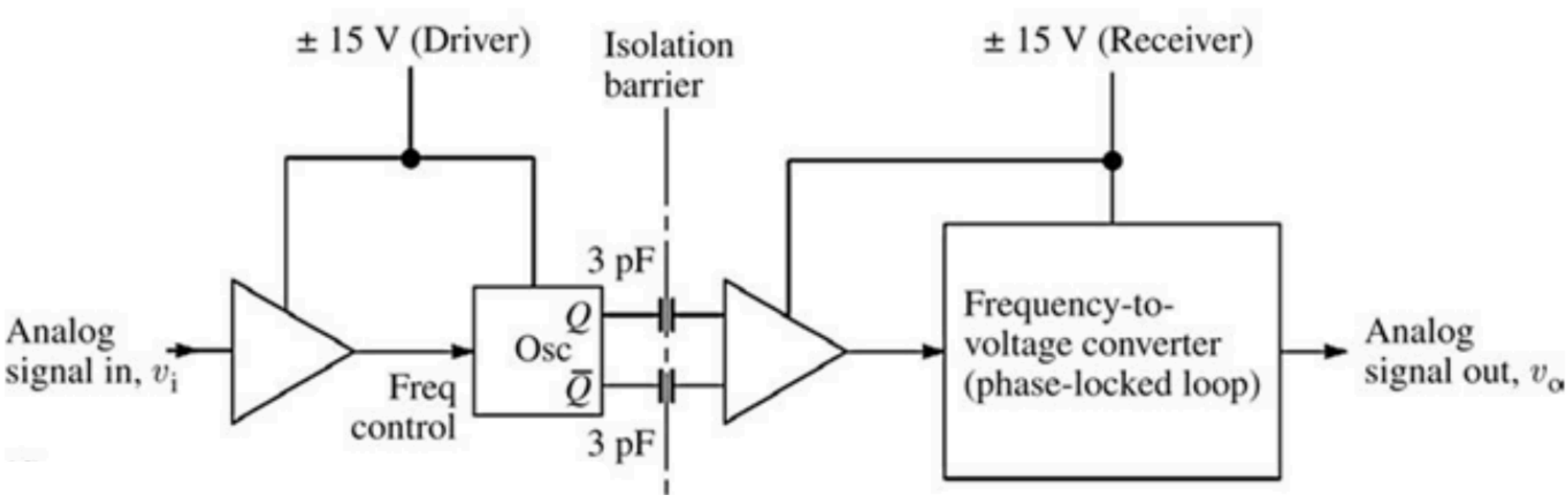
Isolation Amplifiers

- Optical isolation
  - No current across barrier



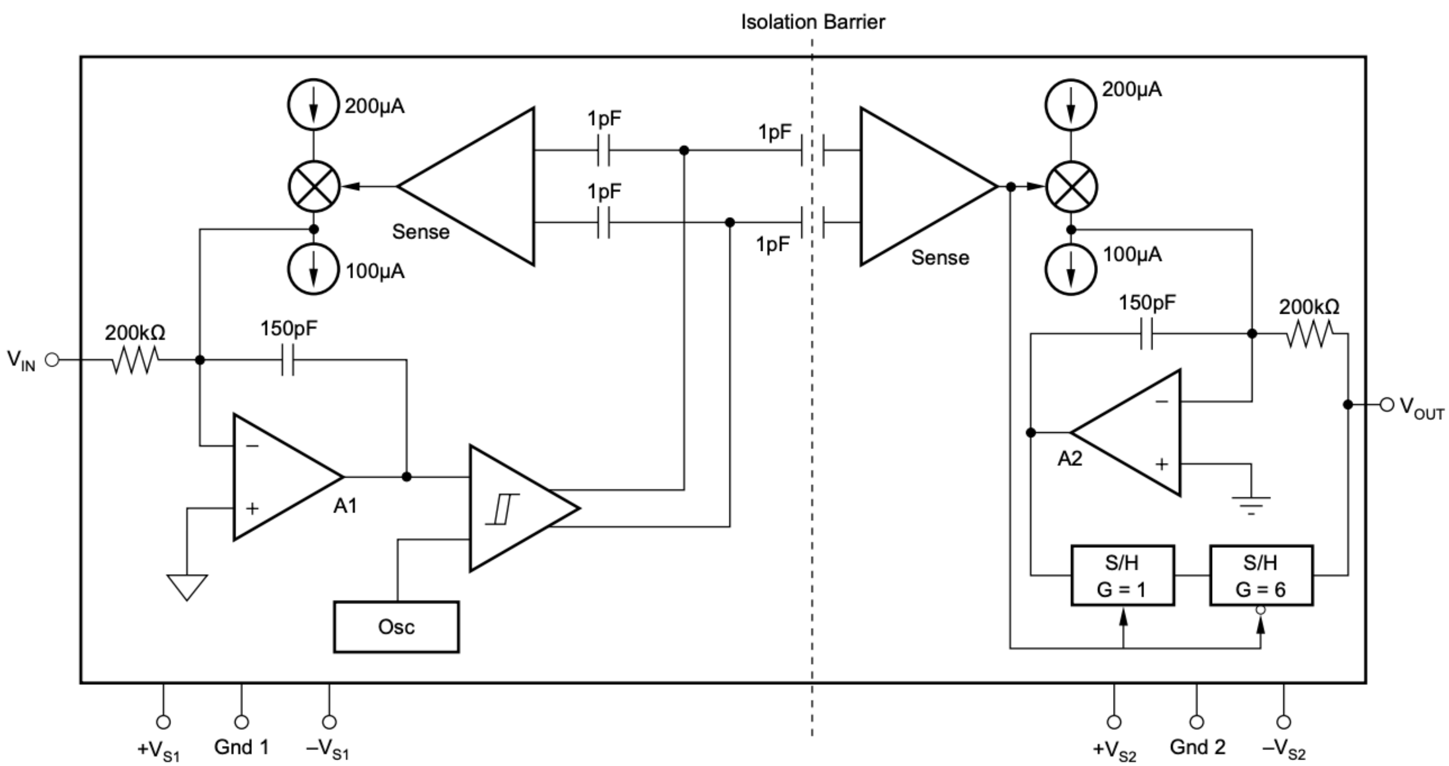
Isolation Amplifiers

- Capacitive isolation
  - No current across barrier
  - Functional diagram:



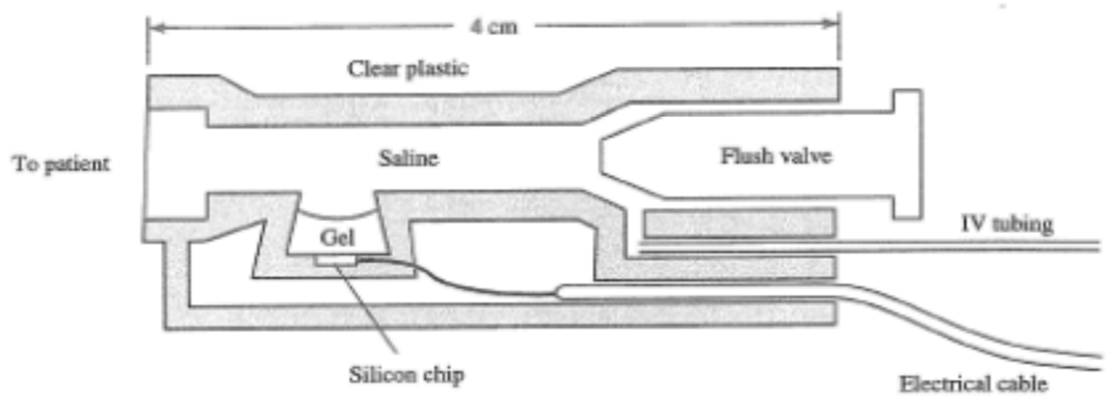
Isolation Amplifiers

- Capacitive isolation
  - ISO124

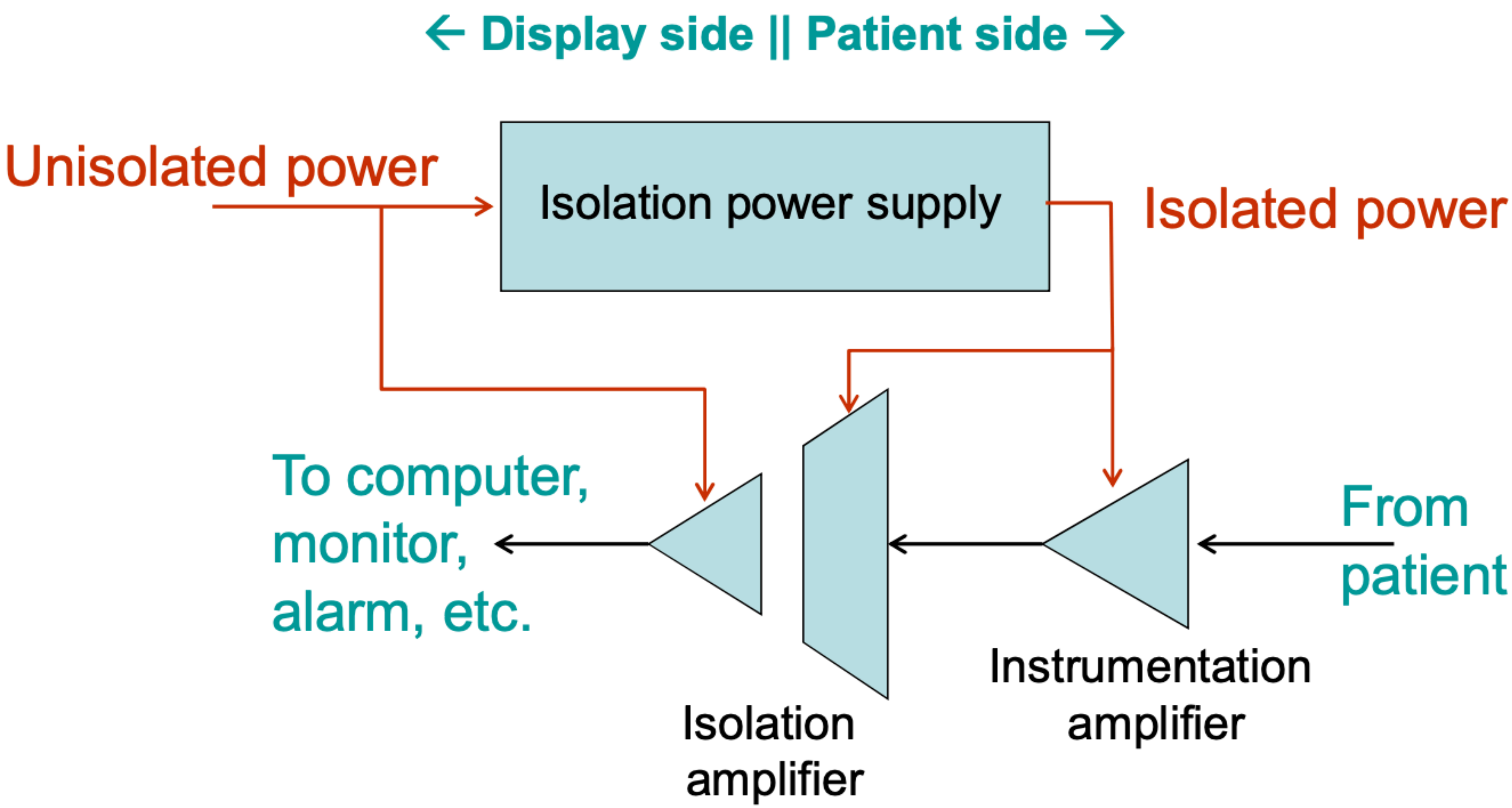


Implants

- Proper insulation required to prevent microschocks



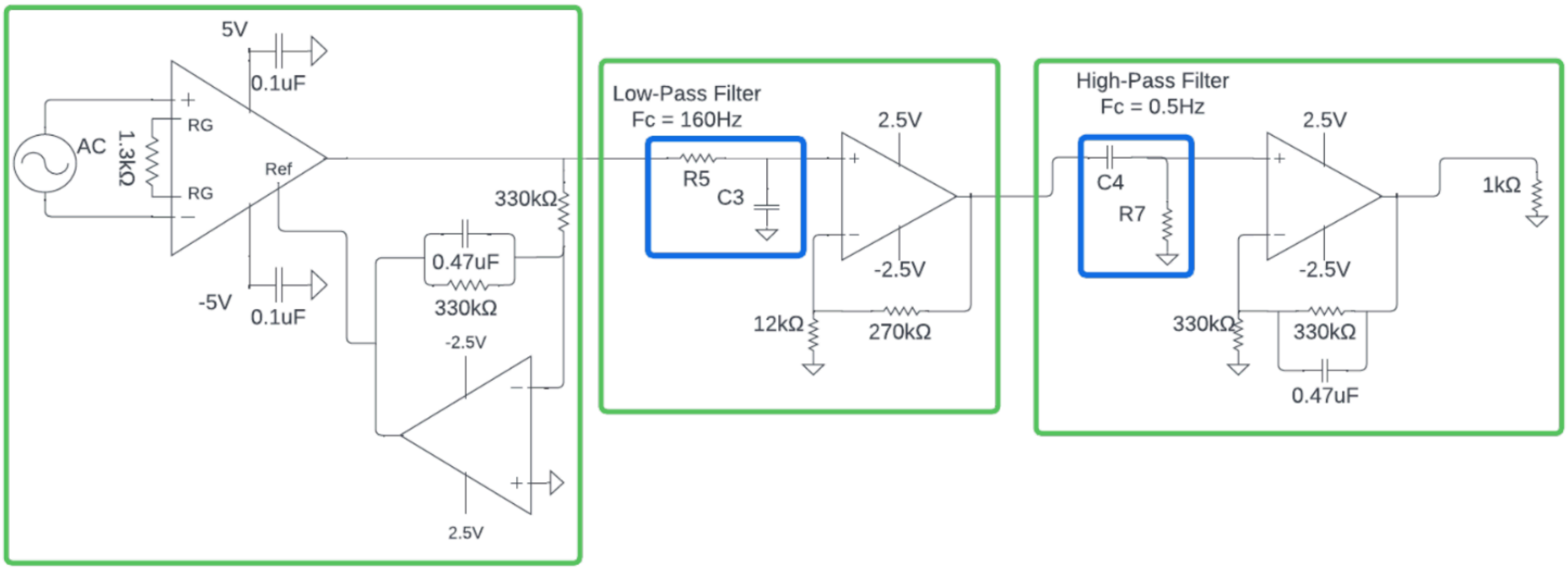
Basic Isolation System



Big Ideas

- Two main problems
  - Macroschocks and microshocks from leakage currents
  - Really only a problem if going through heart
- Solutions
  - Electrical isolation
    - Isolation amplifiers
    - Barrier isolation
  - Good grounding

Lab 4 - Breadboarding



Admin

- Finish Lab 3 and submit deliverables in Canvas by next lab day at midnight
  - New handout with SPICE tips