Electrical Safety of Medical Equipment

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Are you aware…

- Electrocutions are the 5th leading cause of accidental death in the U.S.
- More than 700 people lose their lives every year because of accidents associated with electricity and electrical products.
- 40,000 residential electrical fires occur annually.
- More than $2 billion is lost on property damage.

National Electrical Safety Foundation, http://www.nesf.org/beacon.html

Electrical Safety

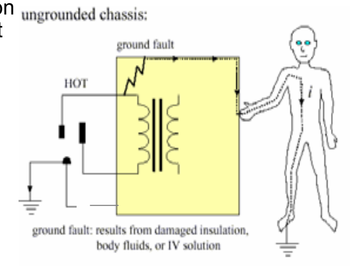
- The increased use and complexity of medical systems result in 10,000 device related injuries in the USA each year.
- Hazardous sources include electricity, fire, water, chemicals, drugs, germs, x-rays, EM fields, …etc.
- There are now performance standards that were written for medical devices.
- Our main objectives are to understand the possible electrical hazards and fault scenarios and learn how to improve deigns of medical instruments.

Outline

- Physiological Effects of Electricity.
- Electrical Macroshock.
- Codes and Standards.
- General Design Recommendations
- Equipment Safety Practices
- Safety Testing

Physiological Effects of Electricity

- People are usually standing on the ground when they contact a **"live" wire**, so the person touching a single wire is actually making contact between two points in the circuit (the **wire** and **earth**).



- **Muscle cramps**
- **Respiratory arrest**
- **Ventricular fibrillation**
- **Burns**
- **Electrolysis**

Physiological Effects of Electricity

Current must enter the body at one point and leave at some other point. Typical biological effects: stimulation of excitable nerves and muscle tissues, heating and electrochemical burns.

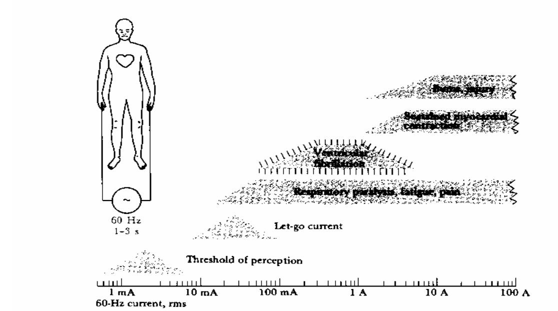
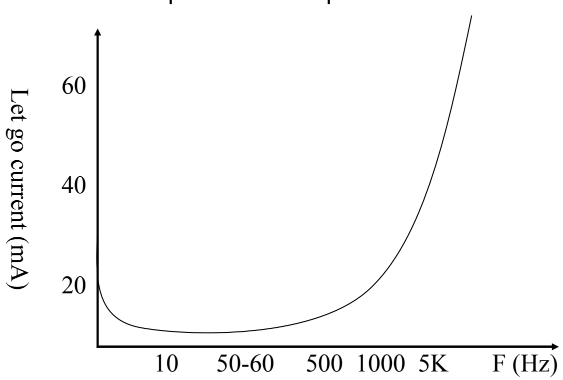


Figure 14.1 Physiological effects of electricity Threshold or estimated mean values are given for each effect in a 70-kg human for a 1- to 3-s exposure to 60-Hz current applied via copper wires grasped by the hands.

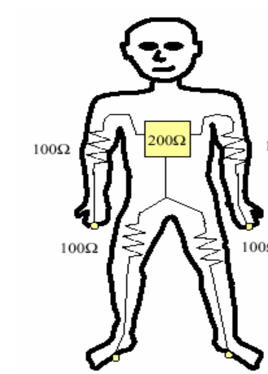
Frequency

- Research shows that minimal let go current occurs for commercial power line frequencies: 50 and 60Hz.

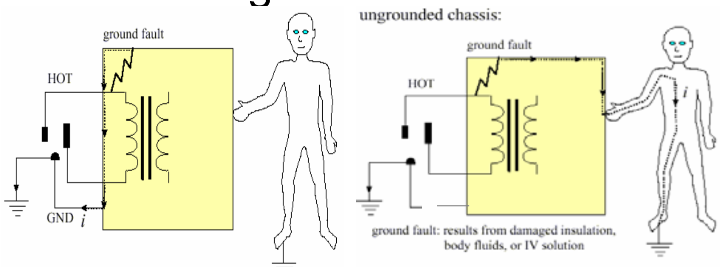


Body and Skin Resistances

- The skin resistance is the outer horny layer of epidermis. Z
- Z_{skin}=10K – 1MΩ (on cm^2 area).
- If skin is wet or broken, Z_{skin} may drop to 1% of its original value.



Earthing and Macroshock

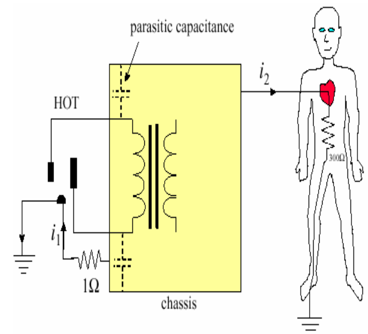


- If system becomes live for any reason, and chassis is ***grounded***, heavy current would still flow through the 1 Ω earth resistance, which would trip the circuit breaker.
- If system becomes live for any reason, and chassis is ***not grounded***, heavy current would flow through the patient. This current can cause difficulty in breathing or even ventricular fibrillation.

$$I_{zskin} = \frac{240}{5500} = 44mA$$

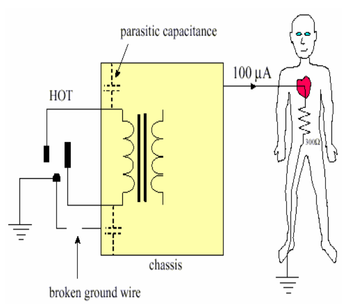
Leakage Currents

- Due to parasitic capacitive and poor-quality insulation resistive parts between L,N and earth (E), leakage current (100 μ A-range) flows through the earth 1Ω resistance rather than the Z_{skin}.
- Some current would still flow through patients having direct electrical connections to the heart.

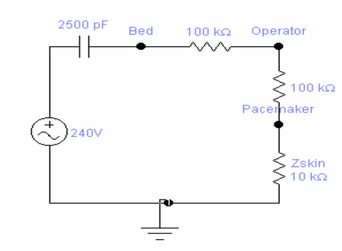


Microshock

- However, if for any reason, the safety ground connection is broken, all current would flow through the patient.
- This current value can cause difficulty in breathing or even ventricular fibrillation.



Microshock due to Operators



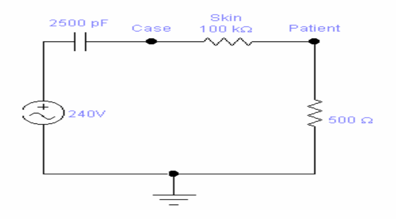
$$I = \frac{V}{R - jX_c}$$

$$I = \frac{240}{\sqrt{R^2 + X_c^2}}$$

$$= \frac{240}{\sqrt{(210k)^2 + \left(\frac{(1)}{(2\pi.50.2500x10^{-12})}\right)^2}} = 185\mu A$$

- Blood pressure catheter and an ECG systems are connected to a patient laying on an electric bed.
- Ground connection of bed is broken
- No problem!
- An operator comes in contact with bed and touches the catheter at the same time.
- Current flows through stray capacitance to bed, through operator, through patient to ecg systems.
- This current cases cardiac fibrillation. A due to this problem is the increase in 50 hz interference in ecg signal.

Microshock due to Surrounding Equipment



$$I = \frac{240}{\sqrt{(100k)^2 + \left(\frac{1}{2\pi.50.2500x10^{-12}}\right)^2}}$$
$$= 189\mu A$$

- Two wire table lamp is next to the patient bed.
- Saline filled catheter is used to measure BP and pressure monitor is grounded.
- Saline is good conductor.
- Patient touches lamp case.
- Fibrillation may occur.

Codes and Standards

- A **code** is a document that contains mandatory requirements. It uses the word shall. is generally adopted into *law* by authority that has jurisdiction.
- A **standard** is a document that contains mandatory requirements, but compliance tends to be voluntary.
- **FDA**: U.S. Food and Drug Administration
- **IEC: International Electrotechnical Committee**
- **NFPA**: National Fire Protection Association
- **ANSI**: American National Standards Institute
- **AAMI**: Advancement of Medical Instrumentation
- **BSI**: British Standards Institute
- **ISO**: International Organization for Standardization
- **ECRI**: Emergency Care Research Institute
- **HEMA**: Health Industry Manufacturers Association
- **NEMA**: National Electrical Manufacturers Association
- **NEC**: National Electrical Code

Important Codes and Standards

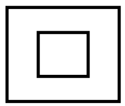
- IEC: International Electrotechnical Committee
- NFPA 99: Standards for Health Care Facilities.
- ANSI/AAMI ES1-1993: Safe Current Limits for Electromedical Apparatus.
- BS 5724: Electrical Safety of Medical Equipment.

Classification of Medical Equipment

- **Class I**[No Symbol]:- equipment in which protection against electric shock does not rely solely on basic insulation but also provided by connecting all accessible conductive parts to the protective earth conductor of the mains wiring. So, these parts cannot become live in the case of failure of basic insulation.
- Protective earth conductor is that conductor to be connected between the protective earth terminal and external protective earthing system. For flexible detachable supply cables, R< 0.1Ω [yellow, green, Y/ G sheets].
- Max resistance between protective earth plug pin and protective conductive parts is 0.2 Ω.

Classification of Medical Equipment

- Class II:- The protection provided by Class II equipment depends on the provision of additional insulation. One form of this protection is double insulation where there are two layers on insulation between any live part and accessible parts of the equipment. Another is to rely on only one layer of reinforced insulation.
- Double insulated or Class II equipment often bears the identification symbol of a square within a square.



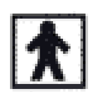
Classification of Medical Equipment

- Class III:- Classes I and II relate to equipment operating at mains voltage. A third category of equipment exists in which protection against electric shock relies on supply at safe extra-low voltage (SELV) and in which voltages higher than those of SELV are not generated. SELV is a voltage which does not exceed (25V ac or 60V dc) between conductors or, between any conductor and earth in a circuit which is isolated from the supply mains by means such as a safety isolating transformer.

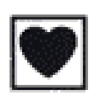
Types of Medical Equipment

- **Type B equipment**: Class I, II or III. Adequate protection against electric shock with regards to leakage current and reliability. Suitable for external use and internal applications except catheterization.

- **BF equipment**: Floating isolated applied part. It is only intended for connection to patient's skin but has floating input circuits. No connections between patient and earth.



- **CF equipment:** Class I, II or III providing a higher protection against shock intended for direct cardiac applications. Minimum required resistance between mains lead and earth = 20 M Ω and 70M Ω between mains leads and applied parts connected to patient.



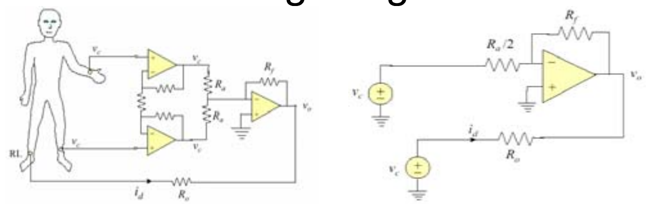
Equipment Design

- Reliable grounding of equipment
- Reduction of leakage current
- Operation at low voltage
- Driven- right-leg circuit
- Use of current limiters
- Electric isolation of patient circuits
- Equipotential grounding
- Ground faults interrupters
- Proper wiring distribution and grounding
- Line isolation system and monitors

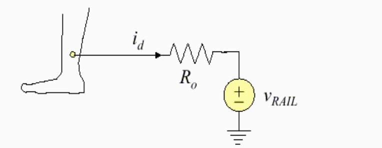
Equipment Design

- **Reliable ground of equipment:** From previous examples, it is clear that grounding of equipment is essential. A low resistance ground wire should be connected between case and receptacle. Stair relief devices are recommended. Avoid 3-2 adapters.
- **Reduction of leakage current:** Special low-leakage power cords are available (<1 μA). Inside case, leakage current is reduced using insulation materials which minimize capacitance between the live wires and case (chassis)
- **Operation of low voltage:** Since almost all electronic circuits are operated at low DC voltages, Macroshocks can be avoided if supply voltage is low. However, Microshock is still possible but still safer.
- **Driven right leg circuit:** Refer to ECG system design. This circuit plays a further role in isolating patients from earth by a very large resistor (5 MΩ) , thereby limiting current to very small valves. (1 μA).

Driven right leg circuit



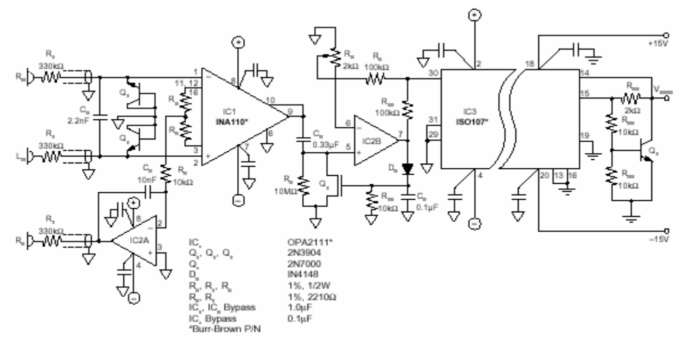
if patient touches HOT conductor, OP Amp saturates, $v_o = v_{RAIL}$ = +/-14.7V, get:



$$i_d = \frac{240-15}{5\times 10^6} = 45\mu A$$

Electrical Isolation

These isolation amplifiers provide patient isolation from ground while still faithfully transmitting signals across the isolation barriers.



Equipotential grounding

Low resistance ground that any currents up to circuit breaker. Keep all conductors & surfaces & receptacles grounds at the same potenti

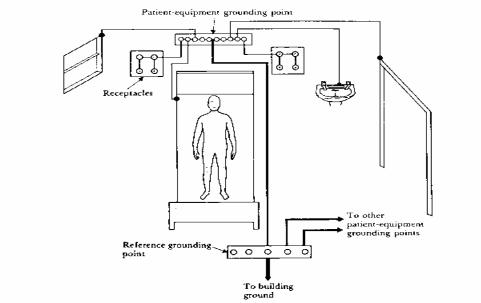
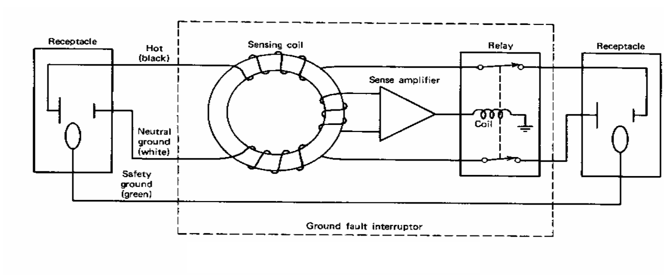


Figure 14.12 Grounding system All the receptacle grounds and conductive surfaces in the vicinity of the patient are connected to the patient-equipment grounding point. Each patient-equipment grounding point is connected to the reference grounding point that makes a single connection to the building ground.

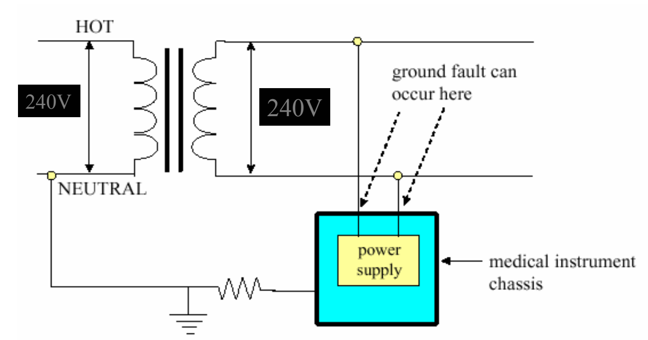
Ground Fault Interrupters

Automatic circuits which disconnects power supply if leakage current $>I_{max}$. When I_L & I_N are equal, no net mag flux is present. When they are equal, i.e. excessive leakage current, and open circuit. Typical currents = 5mA of leakage current.

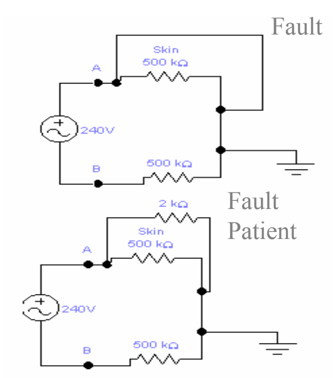


Isolated Power System

If a ground fault develops at *one* of the two sites, no dangerous potentials will develop on chassis



Isolated Power System

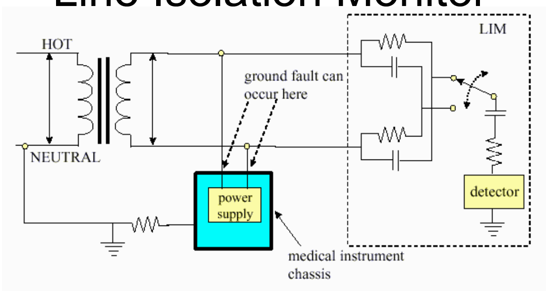


- A 1:1 transformer. Coupling capacitance between primary and secondary, between A and earth, and between B and earth cause leakage current.
- To minimize leakage between primary and secondary, shielded primary can be used.
- Now, If there is a single fault condition between either A&B and earth, a single fault condition develops.
- With no faults, I=240 μA.
- With single fault, I= 480 μA
- Now, if the single fault condition is a patient between A and the earth, I=480 μA.

Isolated Power System

- Advantages if isolated power systems are:
  - No macroshock hazards for a single fault condition.
  - No sparks with single fault condition
  - Single fault does not affect performance
- Disadvantages are :
  - If there is a single fault condition, problems may last for a very long time before being detected.
  - With single fault condition, system becomes unisolated, and if there is another fault, heavy current will flow.
- To solve this problem, line isolation monitors are used. It monitors impedance between either lines (A&B) and earth. If current through impedance goes >2mA, an alarm (Audio or visual) is given (don't over react).

Line Isolation Monitor



- switch sets up artificial ground fault. If other line has a ground fault, get large current flow to ground, alarm goes off.
- LIM can also monitor low-level leakage currents from either of the two isolated lines to ground.
- Sources of leakage current: parasitic capacitance, poor quality insulation between isolated lines and ground.

Leakage currents

- Earth leakage current is the current which normally flows in the earth conductor of a protectively earthed piece of equipment.
- Enclosure leakage current is described as the current that flows from an exposed conductive part of the conductor to earth through a conductor other than the protective earth conductor.
- Patient leakage current is the leakage current that flows through a patient connected to an applied part or parts.
- The patient auxiliary current is defined as the current which normally flows between parts of the applied part through the patient which is not intended to produce a physiological effect.

http://www.ebme.co.uk/arts/safety1.htm

IEC 601 Test Standards

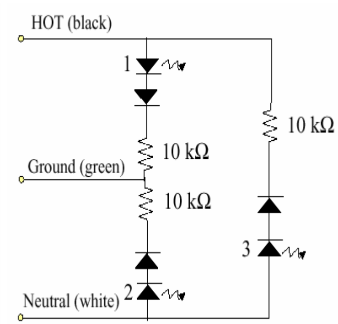
			Class I			Class II		
Description	**Pola-rity**	**Circ-uit**	**B**	**BF**	**CF**	**B**	**BF**	**CF**
Protective Earth Continuity Ω	**N/A**	**OFF**	**0.2**	**0.2**	**0.2**	**NT**	**NT**	**NT**
Insulation Resistance L1-L2-Case M Ω	**N/A**	**OFF**	**2**	**2**	**20**	**NT**	**NT**	**NT**
Enclosure Leakage μ A	**Norm**	**Norm**	**100**	**100**	**100**	**100**	**100**	**100**
Enclosure Leakage μA	**Norm**	**No L2**	**500**	**500**	**500**	**500**	**500**	**500**
Patient Leakage Current μA	**Norm**	**Norm**	**100**	**100**	**10**	**100**	**100**	**10**
Patient Leakage Current μA	**Norm**	**No L2**	**500**	**500**	**50**	**500**	**500**	**50**
Earth Leakage μA	**Norm**	**No E**	**500**	**500**	**500**	**NT**	**NT**	**NT**
Earth Leakage μA	**Norm**	**No E No L2**	**1000**	**1000**	**1000**	**NT**	**NT**	**NT**

NT: No Test is available for this particular class/type. NL: No Limit

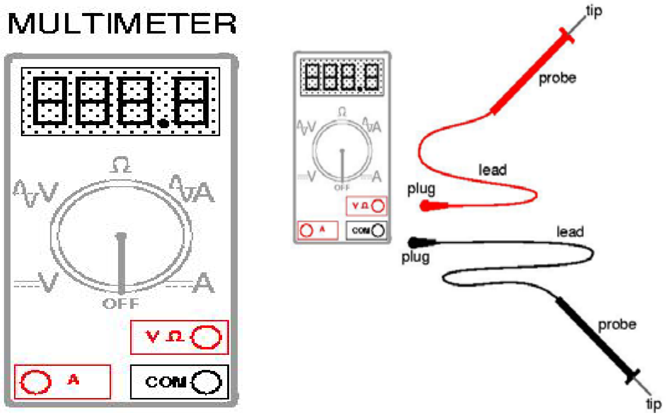
Safety Testing: Receptacle Test

	LED 1	LED 2	LED 3
Hot open	0	0	0
Neutral open	1	0	0
N/A	0	1	0
Ground open	0	0	1
Hot/ground reversed	1	1	0
Correct (or ground/neutral reversed)	1	0	1
Hot/neutral reversed	0	1	1
Hot open and neutral hot	1	1	1

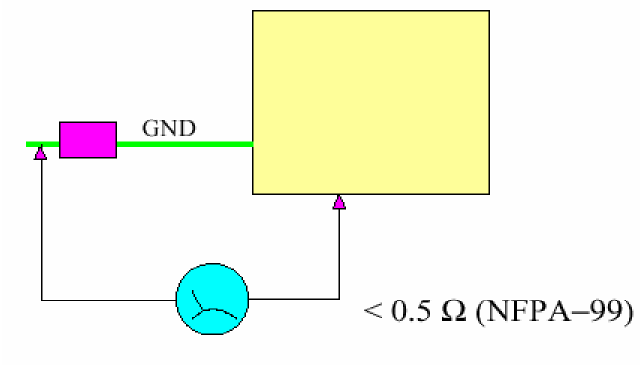
1 = LED on
0 = LED off



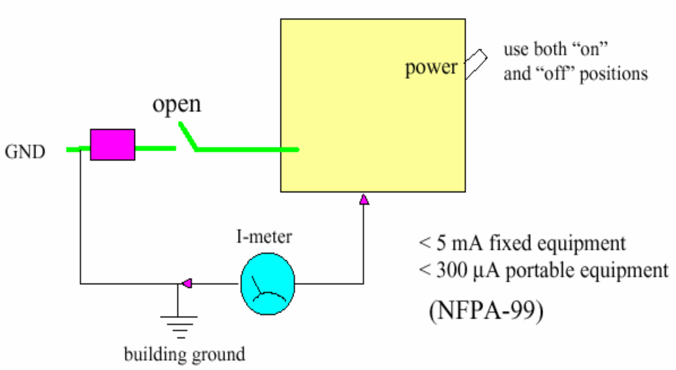
You can use the *multimeter* to measure voltage, current, and resistance



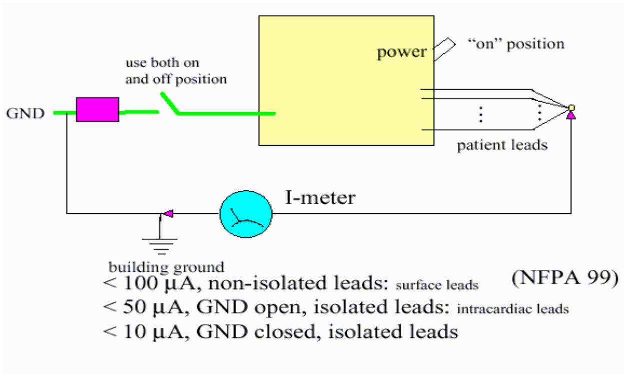
Ground Pin-to-Chassis Resistance



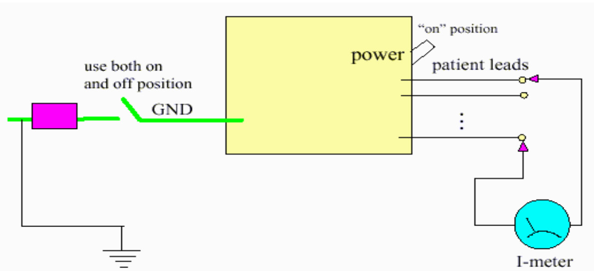
Chassis Leakage Current



Lead-to-Ground Leakage Current

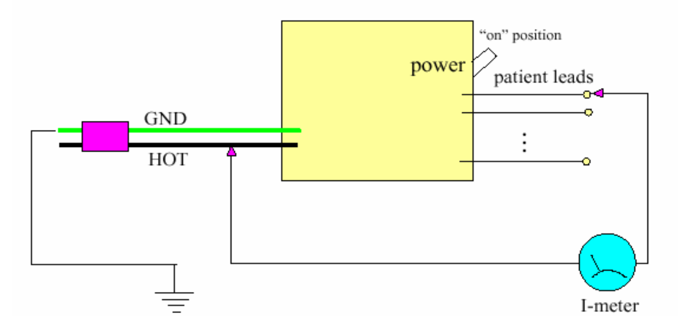


Lead-to-Lead Leakage Current



non-isolated leads: < 50 µA, GND open and closed
isolated leads: < 10 µA, GND closed
< 50 µA, GND open (NFPA 99)

Lead Isolation



only for isolated leads: < 20 µA, for each lead (NFPA-99)

Safety Testers

- Resistance Range: 0-5.000 Ohms, 10 mA
- Leakage Range: 0 - 5000 µA
- Patient Lead Isolation or Mains on Applied Part: YES, Limited to 1 mA @ 110v
- Leakage current: Range: 0-500µA, 450-5000µA true RMS
- ANSI/AAMI ES1-1993 or IEC 601.1 1995
- Frequency response: DC-1 MHz per AAMI

Medical Equipment Management

- **Safety Management**: The purpose of equipment management is to ensure that the right equipment is available when required, in a safe and serviceable condition and at a reasonable if not minimum cost.
- **Management factors :**
  - Selection of equipment
  - Acceptance procedure
  - Training
  - Servicing (maintenance, repair and modification)
  - Replacement

References

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Thank You