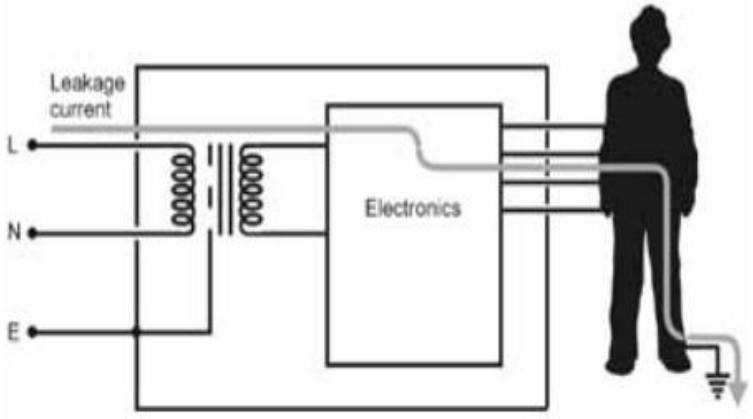
ADVANCED BIO MEDICAL INSTRUMENTATION

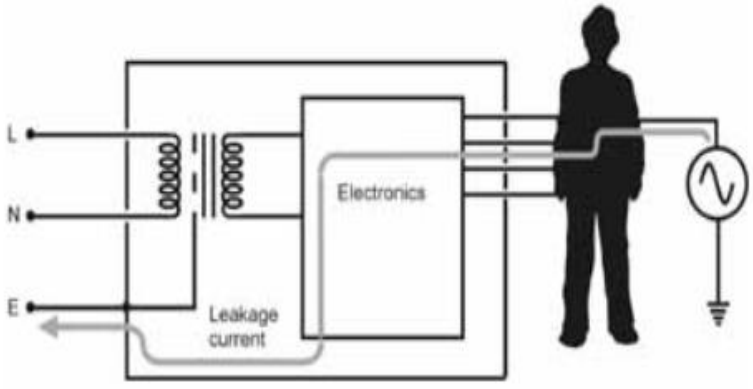
LECTURE 12: SAFETY MEASUREMENTS (for equipment in lessons 10 and 11)

1. Earth leakage current

Earth leakage current is the current that normally flows in the earth conductor of a protectively earthed piece of equipment. In medical electrical equipment, very often, the mains is connected to a transformer having an earthed screen.



Patient leakage current path from equipment



Patient leakage current path to equipment

Testing of Biomedical Equipments

1. Chassis leakage current measurement
2. Leakage current in patient leads
3. Ground continuity test

Danger to patients

In a clinical environment patient is exposed to various risks, more than a typical workplace or at home

- frequent invasive (blood) operations - penetration through skin or mucous membranes
- presence of potentially hazardous chemicals and substances - anesthetics, medicines, medical gases
- sources of infection - particularly "hospital infection"
- various sources of energy that penetrate into or through the patient: current, voltage, ionizing and non-ionizing radiation, sound and ultrasound, electric and magnetic field, UV radiation, lasers, microwave radiation, mechanical stress, etc.

Physiological effects of electricity

- Body (tissue) becoming a part of an electrical circuit
- The amount (amplitude) of electricity often depends on the ratio of voltage present and the sum of all (serially connected) impedance
- Usually, the highest impedance is the impedance of the skin
- The consequence of current flow:
  - nerve and/or muscle tissue stimulation
  - heating of tissues (a result of tissue resistance)
  - burns

Protective grounding

- Generally, patients are only occasionally and accidentally exposed to risk of getting in touching with devices whose conductive parts may be energized
- In hospitals, especially in intensive care units, patients are deliberately connected to the diagnostic and/or therapeutic electrical devices/equipment
  - particularly careful with the isolation of any conductive parts connected to the heart or its vicinity from all other conductive parts
  - all conductive parts in the vicinity of the patient must be connected to a single point grounding (eg, metal bed, cupboard, etc.)
  - periodic testing of the grounding impedance must be provided
- Tolerable difference in potential between the grounded conductive parts in clinical areas:
  - in the general - of 500 mV
  - intensive care and other critical cases- of 40 mV

Regulations, standards and recommendations

- Regulations are subordinate legislation which are obligatory and are related to the characteristics of devices and equipment that must be assured
- Standards stipulate features that must be assured , but their appliance is voluntary. Contain instructions on how to accomplish / verify compliance with the standard
- Recommendations (usually manufacturers) stipulate how to ensure the safety and prescribe manner and frequency of testing safety of devices

Design Recommendations for Safety

- Reliable grounding for equipment
- Reduction of leakage current
- Double – insulated equipment

- Operation at low voltages
- Driven right leg circuit
- Current limiters
- Electrical isolationisolated heart connectors