Principles of Electrical Safety Testing of Medical Equipment

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American River College

Intro to Biomed Equipment Technology

Electrical Engineering 426

Why do we perform Electrical Safety Tests?

- Prevent harm to patients and staff.
- Comply with Joint Commission standards started in 1976 and NFPA 99 as adopted locally.

What type of current, voltages and frequencies produce harm or death to patients?

- D.C. or high frequency a.c. currents that pass through the body produce heat. Sometimes heat is a desired effect produced by medical instrumentation. Electrical Surgical units produce these effects to cut tissue and coagulate body fluids. Ultrasonic physical therapy equipment uses high frequency to heal damaged muscles.
- Low frequency a.c. signals inadvertently applied to human tissue can cause a tingling sensation, muscle spasms or even death. Sensitivity is frequency dependant and is high at 60 Hz, normal U.S. power line frequency

Patient safety is primarily concerned with eliminating or reducing low frequency a.c. signals entering the patient's body.

- The common frequency of North American power is 60 hertz. and 50 hertz in Europe. The heart beat bandwidth is .5 Hz to 240 Hz so these frequencies can disrupt normal cardiac rhythms.
- Frequency is not the only component of potentially harmful signals. Many students and Biomedical Technicians often guess that voltage is the next most important component. <u>IT IS NOT.</u> Skin resistance is a much larger component of the electrical safety picture.

Resistance in the body varies greatly upon many conditions.

- Dry, healthy skin has a resistance of 60k to 100k ohms. As resistance decreases, smaller and smaller voltages can result in higher and higher currents and thus can harm the patient.
- Many patients enter the hospital with diminished resistance because of illness or wound.
- Many medical procedures reduce the skin’s resistance.
- Many solutions used in medical treatment reduce this resistance. When solutions pool at or near a puncture or wound in the skin, the resistance drops significantly.
- When trocars are inserted into the body to allow instruments to be inserted for endoscopic procedures, the skin resistance is eliminated.

Items a, b, and d below are examples of macro shock. Item f is an example of micro shock. Both can harm, the difference is that people cannot feel micro shocks.

A. When an unintentional application of 120 v.a.c. occurs, such as a person touching an exposed conductor, approximately 1.2 milliamps flows from the conductor through the body and out to a pathway to ground. That person might feel a tingling sensation.

B. What if the resistance is lowered to 6k ohms and a 20 mA current path developed?

C. The person might experience muscle spasms and find it difficult to release their grip.

D. What if the resistance was lowered to 2.4k ohms and a 50 mA current path developed?

E. The person would feel pain and might faint or have an interruption in their breathing cycle.

F. Now suppose that a small current from arm to arm flows out through the thorax making the current density low, the allowable threshold is 100 -300 milliamps. Currents greater than this could produce ventricular fibrillation.

What specifically reduces the skin's resistance?

- Patient contact with conductive substances like water, saline, betadine, silver chloride gel because they are highly conductive.
- Wounds, punctures and indwelling catheters break the skin layer and greatly reduce the skin's resistance.
- Patient contact with leads, catheters, etc. from medical instrumentation reduces skin's resistance. All of these devices have direct patient contact and can be a conduit for dangerous low frequency a.c. signals.
  - EKG leads
  - Catheters inserted into the body
  - Probes
  - ESU devices
  - Defib paddles
  - Physical therapy equipment

What steps do we take to reduce potential harmful currents produced by or traveling through medical instrumentation?

- Measure the ground pin to chassis resistance (GPCR) and take steps to reduce it. The measurement should never be more than .5 ohms. In some cases the limit may be .3 ohms and new construction limits for manufacturers is .1 ohms.

My personal opinion

- is that I repair the grounding circuit to .3 ohm. If it cannot be reduced to .3 ohm, then I replace the power cord. This is because some medical equipment is only tested once a year. If the resistance is .35 ohm, it might degrade to higher than.5 ohm in the next year.

Why is achieving the lowest GPCR so important?

- The lower the resistance, the more likely those accidental, unintentional and harmful currents will have a harmless path to ground. Current divides inversely proportional to pathway impedance and the ground conductor is the safety outlet for harmful currents since it has very low resistance and will carry the largest proportion of current.

So the ground is good, are we done?

- No. We must test current flow
- If a good ground circuit prevents harmful currents flowing into patients and staff, why are chassis and lead leakage testing required?

Codes mandate that hospitals and manufacturers follow established safety programs.

- These guidelines are for maximum limits of risk currents produced by medical equipment.
- There are several codes and standards that a hospital can follow.
- NFPA 99, AAMI Standard for Safe Current Limits, UL-544, IEC 601.
- They are each slightly different.

What types of current are measured by the standards?

- Chassis source current
- Lead to ground current
- Lead to lead current
- Patient sink current (Isolation Test)