Electrical Hazards & Patient safety in Bio-medical equipment

Medical Electrical Equipment Safety and Regulation

- Medical equipment can expose patients and caregivers to potential electrical hazards. Several international standards exist to ensure adequate protection is incorporated into equipment designs.
- This article is the second in our series on advancements in medical isolation transformer design.

What Is Medical Electrical Equipment?

Medical electrical equipment is provided with no more than one connection to a particular mains supply and is intended to:

- diagnose the patient
- treat the patient
- monitor the patient under medical supervision
- make physical or electrical contact with the patient
- transfer energy to or from the patient and/or detect such energy transfer
- to or from the patient

- The use of electricity in medical equipment has potentially exposes patients and even caregivers to the risk of electrical shock, burns, internal organ damage, and cardiac arrhythmias directly due to leakage current resulting from improper grounding and electrical isolation.

- The electrical conductivity of body fluids and the presence of various conductive solutions and gels in the patient care system make this environment even more vulnerable.

- Several techniques commonly provide isolation when designing electronic equipment.

- Careful component placement and printed-circuit-board layout can provide adequate room for creepage and clearance of components in close proximity of high voltages.

- Meeting these two specifications can be a tedious, time-consuming task, and each component subject to them must meet the requirements called out in the applicable standards.

- Electrical safety in a hospital is a shared responsibility between several parties including:

- physicians
- nurses
- engineers (electrical, biomedical, facility, etc)
- manufacturers

- The increasing number of medical devices being used in hospitals creates several basic concerns, one of which is patient safety. An important electrical safety requirement is to measure the leakage current.

Safety Classifications in Medical Standards

- MOPP (Means of Patient Protection) — Electrical equipment with direct patient contact must fulfill the highest safety requirements.

- MOOP (Means of Operator Protection) — Electrical equipment without direct patient contact must fulfill high safety requirements.

Significance of Electrical Danger

- 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 - anaesthetics, 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 Effect of Electrical Current

- **For a physiological effect the body must become part of an electrical circuit**
- **Three phenomena occur when electrical current flows**
  - Electrical stimulation of excitable tissue (muscle, nerve)
  - Resistive heating of tissue
  - Electrochemical burns

- **Further consideration are based on the following parameters**
  - Human body with contact to el. circuit at left and right hand
  - Body weight: 70 kg
  - Applied current time: 1 s to 3 s
  - Current frequency: 60 Hz

Physiological Effect of Electrical Current

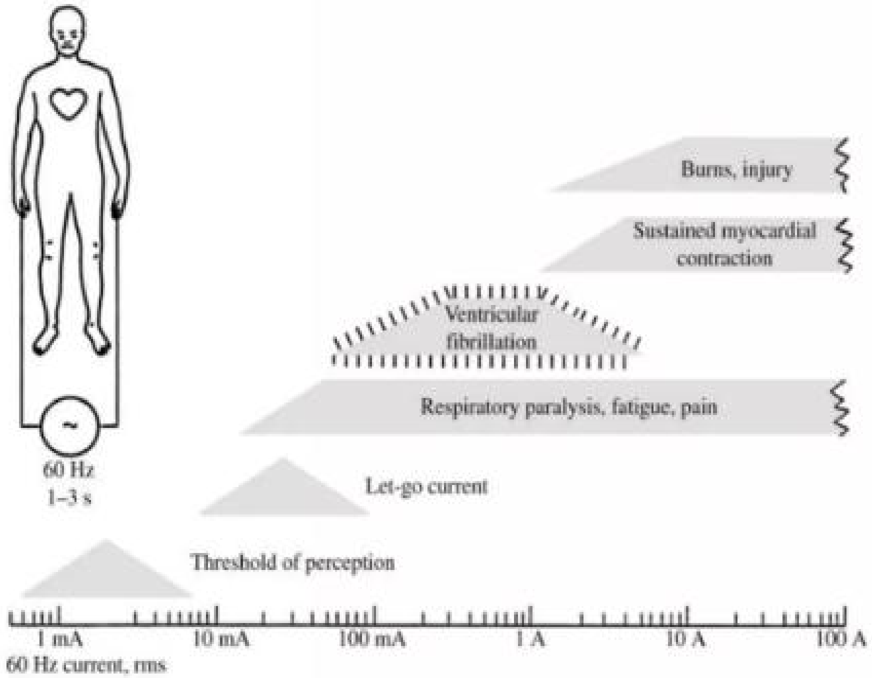
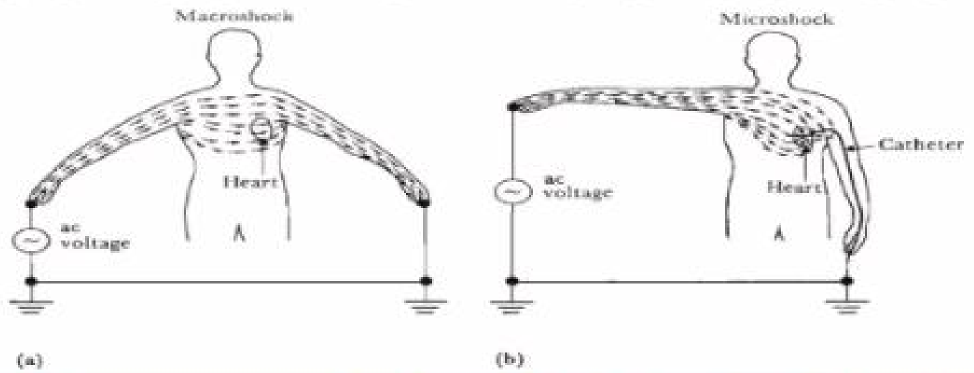


Fig.1: Physiological effects of electricity Threshold or estimated mean values are given for each effect in a 70 kg human for a 1 to 3 s exposure to 60 Hz current applied via copper wires grasped by the hands.

Microshock vs. macroshock



- Macroshock is caused by current passing through the body through the skin, and the current that can cause harmful effects is relatively high and significantly depends on the point of contact
- Microshock is caused by the passage of relatively low current, but the source of electricity was brought directly into contact with the heart, for example, during cardiac catheterization (catheter in the heart is a diagnostic procedure). Electricity sufficient to induce fibrillation is of n x 10μA. Another point of contact can be anywhere on the body (eg limbs). Current of 10 μA is considered safe limit to prevent microshock

Basic Approaches to Protection against Shock

- There are two fundamental methods of protecting patients against shock

1. Complete isolation and insulation from all grounded objects and all sources of electric current
2. Same potential of all conducting surfaces within reach of the patients

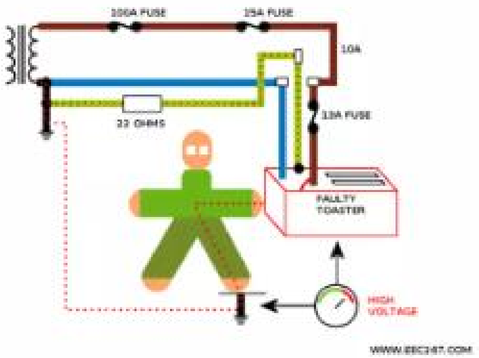
- Neither approach can be fully achieved in most practical environments, so some combination must usually suffice
- Protection must include patient, applicants and third party persons

Protection: Power Distribution Grounding System

- Low-resistance grounding system carry currents up to circuit-breaker ratings by keeping all conductive surfaces on the same potential
  - Patient-equipment grounding point
  - Reference grounding point
  - Connections for other patient-equipment

Protection: Equipment Design Introduction

- **Operation at low voltages (< 10 V)**
  - Reduction of risk of macroshock with reduced operation voltage
  - Risk of microshock still exists
- **Electrical isolation with isolation amplifiers**
  - Isolation amplifiers break the ohmic continuity of electric signals
  - Isolation amplifiers use different voltage sources and different grounds
  - Isolation voltage v_{iso} is rated from 1 kV to 10 kV without breakdown and described by the isolation-mode rejection ration (IMRR)



Protection: Equipment Design Introduction

- **Most failures of equipment ground occur at the ground contact or in the plug and cable**
  - Molded plugs should be avoided because of invisible breaks
  - Strain-relief devices are recommended
  - No use of three-prong-to-two-prong adapters (cheater adapters)
- **Reduction of leakage current**
  - Special use of low-leakage power cords
  - Capacitance-minimized design (special layout-design and usage of insulation)
  - Maximized impedance from patient leads to hot conductors and from patient leads to chassis ground
- **Double-Insulated equipment**
  - Interconnection of all conducting surfaces
  - Separate layer of insulation to prevent contact with conductive surfaces (e.g. non conductive chassis, switch levers, knobs, etc.)
- **Operation at low voltages**
- **Electrical isolation**

Protection: Equipment Design Electric Isolation

- Three fundamental design methods

1. Transformer isolation
   - Frequency-modulated or pulse-width-modulated carrier signal with small signal bandwidths
   - Possibility to transmit energy and/or information
2. Optical isolation
   - Uses LED on source-side and photodiode on output-side
   - Very fast signal transmission possible, but no energy
3. Capacitive isolation

Electrical safety analyzer

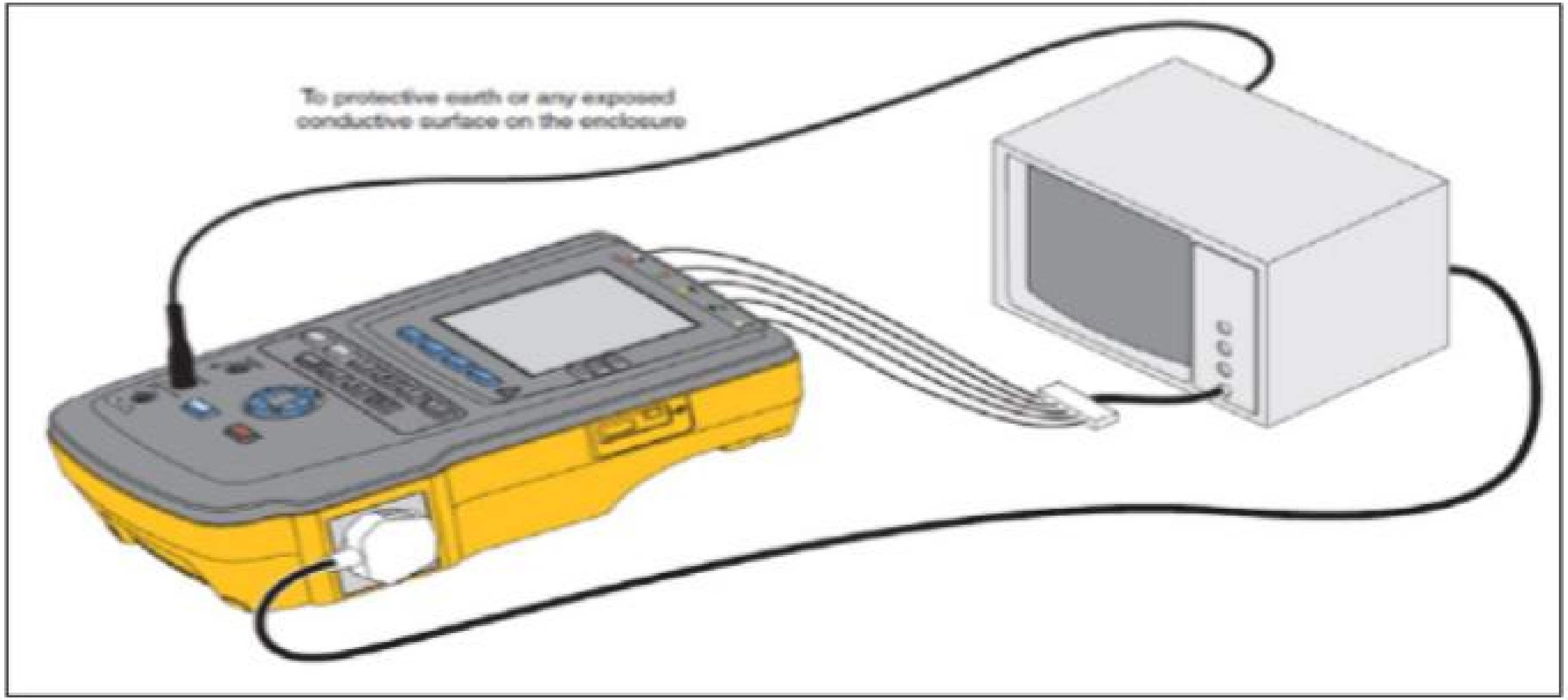


Figure 5. General connections to an electrical safety analyzer.

Methods of Protection Against El. Shock

- Over-current protection (indirect protection).
- Protective earthing (grounding).
- Double insulation.
- Low voltage power supply.
- Differential circuit breaker (Ground Fault Circuit Interrupter GFCI) .
- Isolated power system (IPS)

Protective Earthing

- Simple, efficient, and inexpensive, but it is not “fail-safe” (i.e. if it fails, equipment does not go in a safe mode (alarm, power interruption for example)).

Double insulation

- All surfaces which can be contacted are made of non- conductive materials, or all voltage carrying parts are double insulated. Equipment protected this way are referred to as class II, and need not to be earthed.

Methods of Protection Against El. Shock

Low Voltage Supply

- Supply voltage less than 50 Volt.
- Equipment need not to be earthed.
- For wet areas: voltage less than 25 Volt.
- If skin immersed in water: voltage less than 12 Volt.
- If supply is via transformer, then primary and secondary must be galvanically separated.

Rules for Med. Equipment Electrical Safety

1) Equipment connected to a patient to be powered from one socket, or a block of sockets having the same protective grounding point.
2) All metal subjects in the vicinity of the patient to be grounded one at a time with the same protective ground point.
3) Patient to be connected to the common ground through only one grounding pole.
4) Isolation amplifiers to be used for measurements if possible.
5) If possible, avoid using material which can be charged electro-statically .
6) Deal carefully with electric wires and sockets and let it be checked periodically. Do not use extension cables. Do not use faulty cables / plugs and ask for replacement.
7) If an equipment has a failure, which can cause electric shock, it has to be taken out of service immediately.
8) Do not use any medical equipment you do not know the basics of its operation and did not read its instruction manual carefully.

Why do biomedical signals need processing?

- Researches in biomedical signal processing projects are mainly increasing due to the rise in demand for its enhancement in the medical field throughout the world.
- Biomedical signal processing is the method used for the extraction of valuable data from biomedical signals.
- Most real-world signals include noise. Noise, in this case, is any unwanted signal that corrupts the signal of interest.

- In order to extract useful information from the signal, noise has to be eliminated.
- Filtering of signals is, therefore, one of the first steps in the processing of biomedical signals.

WHAT ARE COMMON SOURCES OF NOISE IN BIOMEDICAL ACQUISITION?

- Noise in biomedical signals is mainly due to the artifacts and interference factors acquired along with the physiological signals.
- Various sources of noise include the following:

- Heat in electronic implants
- Electrical signals in the environment
- Subject and sensor motion

- Consider an example to understand the noise factors in a BSP system.

- Electrical (man-made) sources are the reasons for noise in ECG.
- It is especially 50 to 60 Hz frequency power line that has to be removed completely
- For this purpose a filter (primarily a notch filter) is to be employed
- Also low pass filters are used for allowing only the signals of lower frequencies