# Electrical Safety

## NANT – Las Vegas 2015

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# Why Electric Safety Standards

- **To protect patients and caregivers from electrical shock**
- **To prevent electrical interference between instrument sub-systems/circuits**
- **To prevent electrical interference between different instruments and equipment**
- **To protect electrical equipment from people (ESD) Electrostatic Discharge**

# A Person at Risk

- **Electrical Shock Hazard**
  - **Electricity passing through the body**
  - **Body resistance is about 1,000 ohms**
- **Risk = Probability x Severity**
- **Harm**
  - **Startle reaction – 0.5 mA, 50/60 Hz (hand)**
  - **Inability to let go – 10 mA, 15-100 Hz (arm)**
  - **Ventricular fibrillation –**
    - **35 mA, 15-100 Hz (hand-foot)**
    - **0.01 mA, 50/60 Hz (heart, direct)**

# A Patient at Risk

- **The needles are inserted into an electrolyte (blood plasma).**
- **The electrolyte path is directly to the heart.**
- **An IV of normal saline connected to a needle inserted into the blood stream has a resistance of about 30 ohms.**
- **A 1.5 volt battery creates a current of 0.05 ampere at a resistance of 30 ohms.**
- **The patient can make direct contact with the dialysis equipment.**

# Safety Standards History

- First guideline in United States was created by Underwriter's Laboratories,  May 1972 = UL – 544
- European Guidelines first edition was published in 1977 = IEC 601-1 entitled:
  - Safety of Medical Electrical Equipment
- IEC 606-1 second edition published in 1988.
  - Amendment 1 – 1991
  - Amendment 2 - 1995
- IEC 60601-1 third edition published in 2005
- IEC 60601-1-2 fourth edition published in 2014

# International Electrotechnical Commission (IEC)

- **Medical Equipment**
  - **IEC – 60601 – 1**
- **Electromagnetic Compatibility**
  - **IEC – 60601 – 1 - 2**
- **Hemodialysis Equipment**
  - **IEC – 60601 – 2 – 16**
- **Blood Pressure Equipment**
  - **IEC – 60601 – 2 – 30**
- **Peritoneal Dialysis Equipment**
  - **IEC – 60601 – 2 – 39**

# Scope of IEC 60601-1

- (1) – General (Terminology, Definitions, Regulations)
- (2) – Environmental Conditions
- (3) – Protection Against Electrical Shock Hazards
- (4) – Protection Against Mechanical Hazards
- (5) – Protection Against Hazards From Unwanted Or Excessive Radiation
- (6) - Protection Against Hazards Of Ignition Of Flammable Anesthetic Mixtures
- (7) – Protection Against Excessive Temperatures And Other Safety Hazards
- (8) – Accuracy Of Operating Data And Protection Against Hazardous Output
- (9) – Abnormal Operation And Fault Conditions; Environmental Tests
- (10) – Constructional Requirements

# AAMI Standards

- **ANSI/AAMI ES60601 –1**
  - **ANSI = American National Standards Institute**
  - **Joint venture of ANSI, AMMI, and UL**
- **Electric Safety Requirements**
  - **Non-isolated Patient Connection.**
    - **Chassis risk current = 100 microamperes.**
    - **Patient risk current = 50 microamperes.**
  - **Electrical Ground Required.**
  - **Metal/Components – Corrosion Resistant.**
  - **Instrument Outlets – Shielding from fluid spills**
  - **Electric circuits separate from hydraulics.**
  - **Supply mains electrical failure for system and components must create audible alarm.**

# Medical Electrical Equipment

- **Defined in IEC 60601 – 1 Section 2.2.15**
  - **One connection to a Supply Mains**
  - **Intended to diagnose, treat, or monitor the patient under medical supervision**
  - **Patient Interface:**
    - **Makes physical or electrical contact to patient**
    - **Transfers energy to or from the patient**
    - **Detects energy transfer to or from the patient**

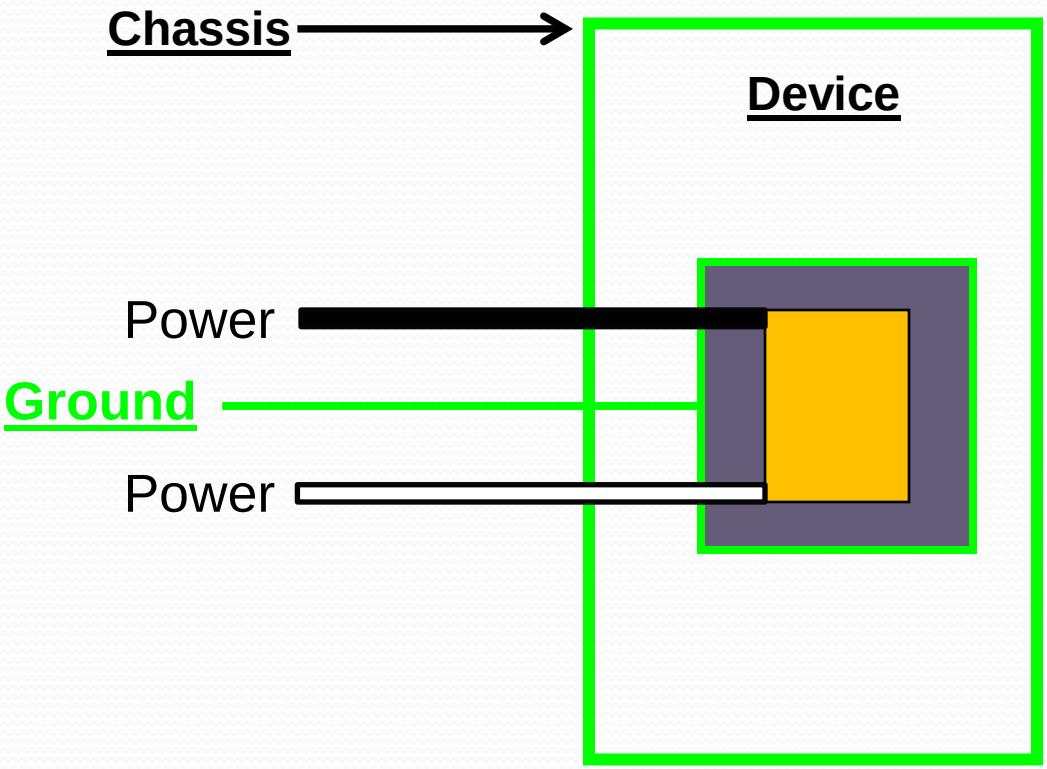
# Class I Equipment

- **Applies to Hemodialysis Equipment**
- **Protection from electrical shock does not rely on basic insulation only.**
  - **Protection = Insulation + Ground**
- **Means provided for connection to a protective earth conductor.**
  - **Uses fixed wiring through a/c power cord.**
  - **Accessible metal parts can't become "live" if basic insulation fails.**
  - **Power cord has 3 wires**

# Preventing Shock by Grounding

Component

Insulation



# Type B Equipment

- **Particular degree of protection against electric shock in regards to allowable leakage currents Type B**
  - **B = Earth ground**
  - **Hemodialysis equipment**
- **Blood pressure connections on hemodialysis equipment is Type BF**
  - **F = Floating**
  - **The pressure cuff is connected to the monitor by a piece of non-conductive tubing**

# Class II Equipment

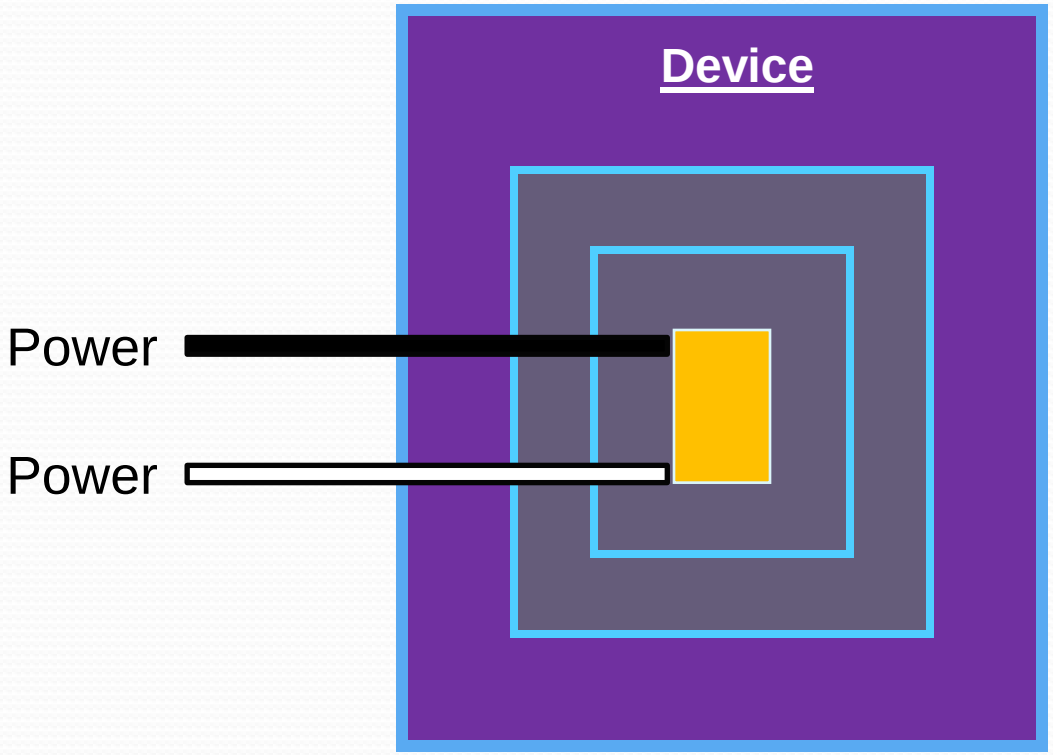
- It’s safer than class I
- It doesn’t need a ground wire
- Protection = Insulation + Insulation
  - Double Insulation
  - Reinforced insulation
- The power cord has only 2 wires
- Examples: Blow dryer, Iron, Drill

# Preventing Shock by Extra Insulation

Component

Insulation

Clearance



# Safety Tests

- **Earth leakage current.**
  - Current through the ground conductor
  - Max = 0.5 mA for Normal Condition
  - Max = 1.0 mA for Single Fault Condition
- **Enclosed leakage current.**
  - Current from an enclosure if touched
  - Max = 0.3 mA patient vicinity
  - Max = 0.5 mA non-patient area
- **Applied part leakage.**
  - Called patient lead leakage
  - Any flow from, between, or into an applied part.

# End User Electrical Safety Testing

- **Performed by a qualified individual.**
- **Completed every 12 months.**
- **Documented in equipment log.**
- **If leakage limits exceeded, then Equipment must be repaired.**

# End User Safety Check List

- **Inspect for mechanical and function damage.**
- **Inspect safety labels for legibility.**
- **Inspect fuses for rated current and breaking characteristics.**
- **Verify proper function per manufacturer's instructions for use.**
- **Perform functional safety tests per manufacturer's PM program.**

# End User Safety Check List

- **Test the earth ground resistance between the Mains ground pin and any accessible metal parts.**
  - **Resistance should be < 0.1 ohms.**
- **Test earth leakage current.**
  - **Normal condition < 500 microampere**
  - **Single fault condition < 1.0 milliampere**
- **Enclosure leakage current.**
  - **Normal condition < 100 microampere**
  - **Single fault condition < 500 microampere**

# Electrostatic Discharge - ESD

- **Medical Electrical Equipment ESD = IEC-801**
- **Damage can happen as fast as 1 nanosecond.**
- **Results can be immediate or dormant failure.**
- **Dormant failure is the worse.**
  - **Failure can occur months later.**
  - **Trace ability is almost impossible.**
  - **Major impact on warranties.**

# Developing Static Potentials

| Electrostatic Generator | Voltage |
|---|---|
| Taking off a sweater | 30,000 V |
| Combing your hair | 10,000 V |
| Walking on a carpet | 3,000 V |
| Putting on a coat | 1,000 V |
| Touching a doorknob | 400 V |

# Device Sensitivity to ESD

| Types of Devices | ESD Potential |
|---|---|
| VMOS | 30 to 1,800 V |
| EPROM | 100 V |
| MOSFET | 100 to 200 V |
| SAW | 150 to 500 V |
| CMOS | 250 to 2000 V |
| BIPOLAR | 380 to 7000 V |
| SCR | 680 to 1000 V |

# ESD Devices

| Catalog # | Item | Price |
|---|---|---|
| 19844 | Jewel Metal Expansion Wrist Strap with 6 ft. Cord | $29.72 |
| 09100 | Elastic Adjustable Wrist Strap with 6 ft. Cord | $23.91 |
| 09480 | Standard 6 ft. Extended Coil Cord | $14.25 |
| 16475 | 18” x 22” Field Service Kit | $76.73 |

**DESCO (www.desco.com)**

# Cell Phones

- **EMC – Electromagnetic Compatibility**
  - **Must continue to provide “essential Performance”**
- **Addressed under IEC – 60101-1-2 (2044)**
- **Signal limit = 3 V / meter**
- **Standard covers frequencies up to 1 GHz**
- **Standards information:**
  - **http://www.fcc.gov/oet/info/rules**

# Cell Phones vs. Dialysis Machines

- **Testing has shown that interference can occur.**
- **Failure modes:**
  - **Blood pump speed slows/stops**
  - **Blood pressure monitors fluctuate**
  - **Air detector alarms**
- **All malfunctions are fail safe.**
- **No failures occur outside a 50 cm distance from the dialysis machine to the cell phone.**