Penn State New Kensington Biomedical Engineering Technology

Electrical Safety

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Classes of Medical Devices

- Class G General Areas
- Class H Critical Care Areas
- Class W Wet Locations





Electrical Safety

Leakage current – Where does it come from?

Impedance (Z) consists of three components

X_I - Inductance Reactance

X_C - Capacitance Reactance

R - Resistance

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Carr-Brown

$$Z = \sqrt{R^2 + (X_L - X_C)^2}$$





Electrical Safety

Leakage current

Micro & Macro Shock

Micro Shock or Cardiac Shock - is defined as a low value current (ua), which passes directly through the heart via a needle or catheter in an artery or a vein

- Less than 1ma of current.
- Current can still have effect on patients with invasive equipment, such as: pacemakers, swan-ganz catheters, invasive blood pressure lines, cardiac cath lines, etc.

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Carr-Brown







Electrical Safety

Leakage current

Micro & Macro Shock

Macro Shock – is defined as a high-value current (ma), which passes arm to arm through the body by (skin) contact with a voltage source. There must be two points of body contact. The resulting current eventually passes through the heart and may cause ventricular fibrillation of death.

- Body can sense shock.
- 1ma Threshold of Perception
 - 10-20ma Let go Current
 - 50ma Pain
 - 100-300ma Ventricular Fibrillation
 - 6A Total Myocardial Contraction
 - >6A Burns and Respiratory Paralysis

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Carr-Brown





Electrical Safety

Leakage current

High frequency currents – The primary concern of electrical shock is with 60 hz currents. Medical equipment today may produce leakage current at higher frequencies, due to harmonics, carrier frequencies and switching mode power supplies.

Frequencies above 100 khz have current limits increased 100 times that of low frequency currents

Frequencies from 1 khz to 100 khz have their limits increased on a linear scale up to 100 times that of the low frequencies.

As the frequency is increased, there is less effect of shock and increased effect of RF burns





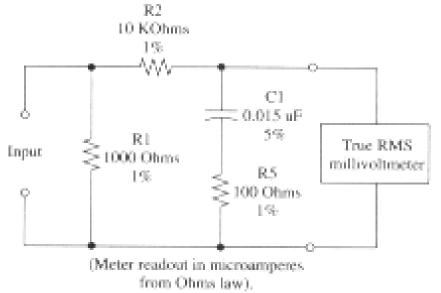


Electrical Safety

Leakage current

AAMI filter – Due to multiple frequencies that could exist in leakage current the AAMI filter is used to pass only the low frequencies of interest. High frequencies are shunted to ground, This filter provides a weighted risk current.

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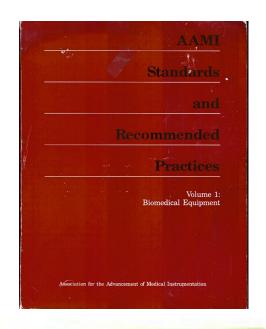


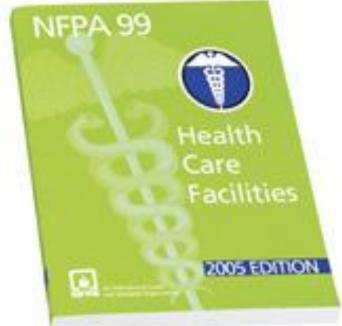


Electrical Safety Leakage current Standards

 AAMI – Association for the Advancement of Medical Instrumentation

NFPA 99 – National Fire
 Protection Agency – Health
 Care Facilities (2005 Edition)







Electrical Safety

Leakage current

Current limits – are the safe levels of currents produced by the medical equipment, including all cables.

Chassis current – current on the metal cabinet

Isolated Patient Current – current on any patient connection that has an isolated circuit

Non-Isolated Patient Current – current on any patient connections that is not isolated (older equipment)







Electrical Safety

Leakage current

Current limits – Below are the **AAMI** recommended leakage current limits.

- Chassis, Non-Patient Contact 500 ua
- Chassis, Patient Contact 100 ua
- Patient Leadwire, Isolated 10 ua
- Patient Leadwire, Sink Current 20 ua
- Patient Leadwire, Non-Isolated 50 ua

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1985 AAMI Stds.





BET 204W – Electrical Safety Electrical Safety

Leakage current

Current limits – Below are the **NFPA** recommended leakage current limits.

- Chassis, Fixed Equipment 5 ma
- Chassis, Patient Contact 300 ua
- Patient Leadwire (all to G), Isolated 100 ua
- Patient Leadwire (single to G, w/G), Isolated 10 ua
- Patient Leadwire (single to G, wo/G), Isolated 100 ua
- Patient Leadwire, Sink Current 50 ua
- Patient Leadwire, Non-Isolated 50 ua

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Electrical Safety

Leakage current

Current limits - are measued in the following configurations:

• Device ground OPEN CLOSED

Device power ON OFF

Device polarity (hot/nueutral) NORMAL REVERSE

Record the highest measured leakage current and the configuration (ON/Off, Ground OPEN/CLOSED and Polarity NOR/REV)





Electrical Safety

Leakage current

120 Volt Isolation test (sink current) – This is a test performed on the isolation of circuits of medical equipment, to verify that an external current can on pass from the patient back into the medical equipment.

A potential of 120 Volts rms, 60 hz, is applied through a 120 K ohm resistance, to each patient connection of the medical device. The sink current the is measured is the amount that passes back into the medical device.

The test is performed with the medical device powered on and off.

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Electrical Safety

Leakage current

120 Volt Isolation test (sink current)

page 98 1985 AAMI Stds.

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PBETMI.

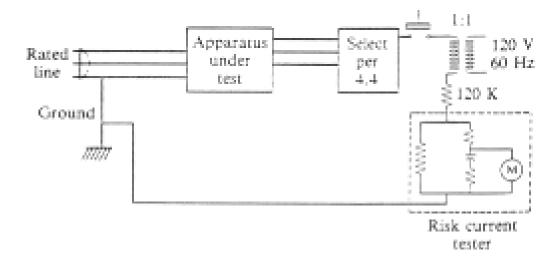


Figure 6. Patient sink current test circuit.

Note: The 120-kilohm resistance is intended to protect the test operator.







Electrical Safety

Grounding

Why it is necessary – Provides the least amount of resistance for leakage current to flow back to the power source.

Current will always take the least path of resistance.

Leakage current exists in all electrically powered devices, therefore a ground is required to remove the current.

Ground conductor is also required for faults or failures with the device so currents have a safe path to follow.







Electrical Safety

Grounding

Where it is measured – from the device chassis to the ground pin of the power plug.

If possible, the plug should be removed from the receptacle with the power off.

If the device is "hard wired," the ground can still be measured from the metal chassis to a ground on the electrical distribution system (power off).







Electrical Safety

Grounding

Measurement limits – the maximum grounding resistance should not be greater that 0.5 ohms.

While measuring, the power cord should be twisted and moved at the strain relief to the device and at the power plug to check for loose connections.

Redundant grounds should be removed if the device can not be unplugged.







Power Plugs & Outlets

- Hospital Grade Green Dot
- Cut Wires for hot/neutral shorter
- Ground Pin Longer first to make, last to break
- Wire Colors:
 - Ground Green (US) or Green-Yellow Stripe (Europe)
 - Hot Black (US) or Brown (Europe)
 - Neutral White (US) or Blue (Europe)



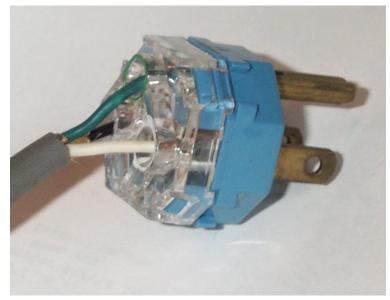


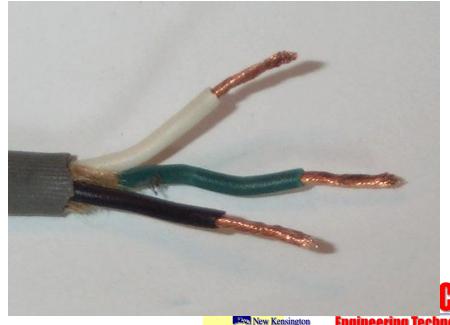
Wiring Devices

120 Volt Plugs 3 prong (15 and 20 amp)

Installation

Hot and Neutral wires cut shorter (1/4 inch)





Power Plugs & Outlets

- Normal Power Outlets Ivory/Brown
- Normal/Emergency Outlets Red
- Isolated Ground Outlets Orange
- Surge Protected Blue
- Tamper Proof Pediatric & Psychiatric
- Ground Fault Circuit Interrupters (GFCIs) Class
- Cover Plates & Circuit Identification
- Hospital Grade Rating

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Power Plugs & Outlets

- Ground Fault Circuit Interrupter (GFCI)
 Wet Locations, Shock Hazard Elimination, No Life Support Equipment, Trip Point 5-6 ma.
- Line Isolation Monitors (LIMS)

Shock Hazard Elimination, Trip Point 5-20 ma, Isolation Transformer

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Isolated Power and Line Isolation Monitors (LIMs) Why they are used

- For added protection to prevent electrical shock to the patient and the users of medical equipment
- Patients that have invasive procedures or catheters connected to their heart are at a greater risk of electrical shock
- Isolated power systems are simply "isolated ungrounded electrical distribution systems"
- They are not required by code for new installations, but any existing must be maintained, tested and calibrated

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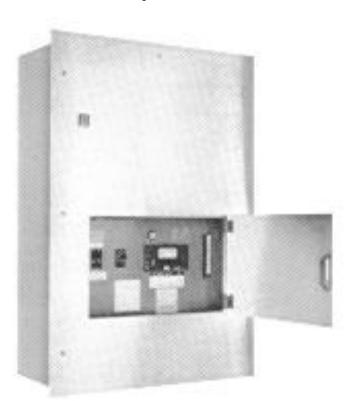






Isolated Power and Line Isolation Monitors (LIMs)

Photos of Systems





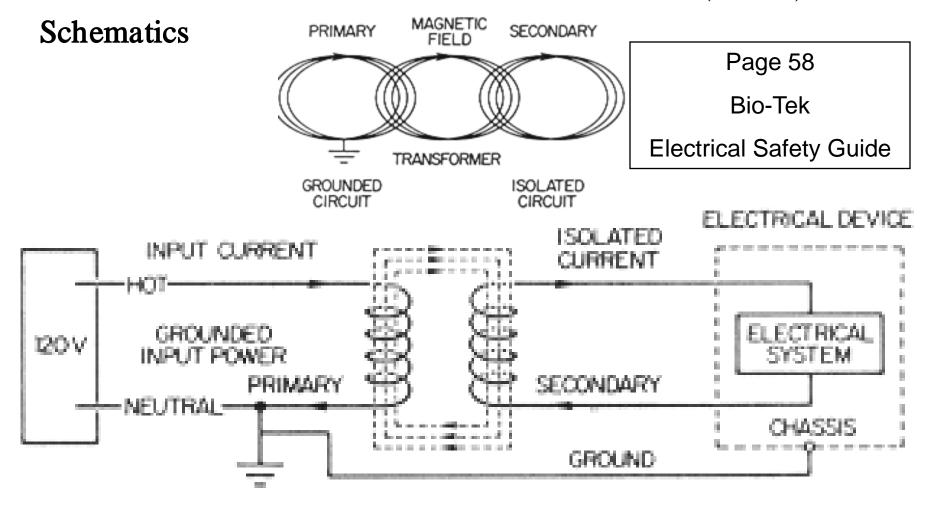








Isolated Power and Line Isolation Monitors (LIMs)



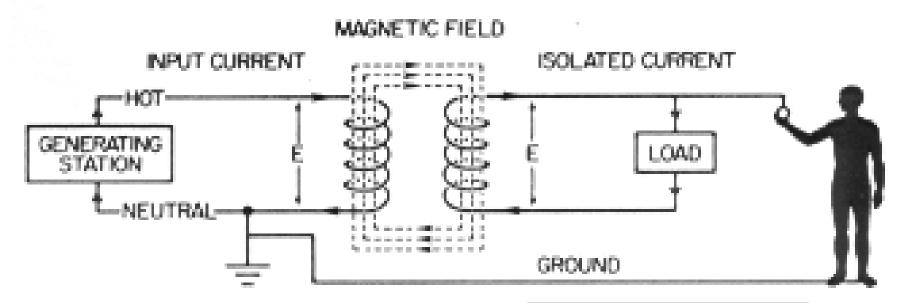
Isolated Power and Line Isolation Monitors (LIMs) Transformer ratings

- Typical transformer ratings for Isolated Power Systems are rated in KVA, with the most common being 5 and 7.5 KVA
- The transformer turns ratio is simply a 1:1 with 120 V input and 120 V secondary
- Most operate at 208 V input and 120 V secondary, which is a 1.73:1 turns ratio
- Power in must equal power out, so the KVA rating can be used to calculate current on the secondary, ie: 7.5 KVA @ 120 V single phase will provide 62.5 amps of current (7500/120)





Isolated Power and Line Isolation Monitors (LIMs) Current loops







Isolated Power and Line Isolation Monitors (LIMs)

Testing

Secondary voltage – measured from X1 to X2

120 V RMS is the expected, +/-5% (114 – 126 V)

60 Hz is the expected, +/-0.5% (59.7 – 60.3 Hz)

Macro current A & B

Simulated short circuit from X1 or X2 to ground and measuring the maximum current that would flow in the system

LIM trip point

Set point should be about 5-6 ma

Checked with variable resistor from X1 or X2 to ground

LIM accuracy

Verifying accuracy of gauge or digital display against calibrated analyzer

Alarms

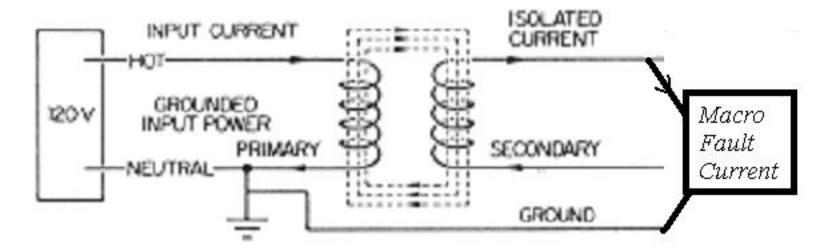




Isolated Power and Line Isolation Monitors (LIMs) Testing

Macro current A & B

Simulated short circuit from X1 or X2 to ground and measuring the maximum current that would flow in the system



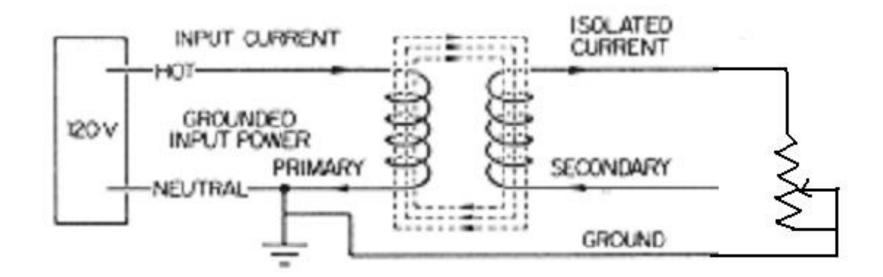






Isolated Power and Line Isolation Monitors (LIMs) Testing

LIM trip point







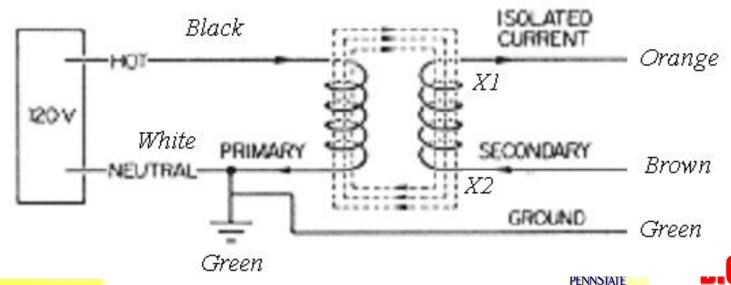
Isolated Power and Line Isolation Monitors (LIMs) Outlet wiring

X1 –Orange

X2 –Brown

Ground – Green

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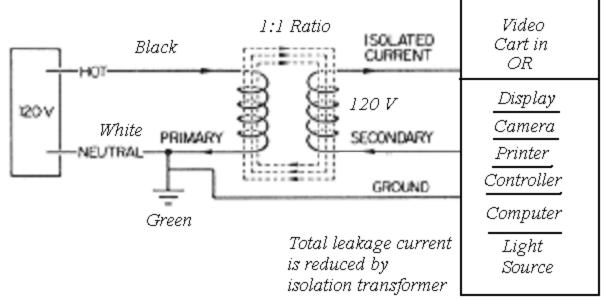
Portable Isolation Transformers

Used for multiple systems in single configuration

Surgical video systems

Portable video equipment

Computers, printers, video displays, network devices,...





Portable Isolation Transformers

Used to reduce leakage current levels

The isolation transformer creates a secondary voltage that is not referenced to ground

Current will not flow from the secondary winding to ground, therefore leakage currents are eliminated

Typical sizes

0.25 KVA - 5.0 KVA

Transformers can be purchased with systems or added on as needed







120 Volt Receptacle Testing

Voltage & Frequency

Measured from Neutral to Hot on receptacle

120 V RMS is the expected, +/-5% (114 – 126 V)

60 Hz is the expected, +/-0.5% (59.7 – 60.3 Hz)

Wiring Polarity

The Hot connection is connected to the hot on the electrical distribution system

The Neutral connection is connected to the neutral on the electrical distribution system, which is connected to the ground

Pin Tension

At least 4 ounces of pull on each blade

Ground to Ground resistance

Must be less than 0.1 ohms

Ground to Neutral resistance

Must be less than 0.1 ohms

Faceplate cracked/broken

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Electrical Distribution Systems

Hospitals have 2 primary feed circuits that must take the full load of the building

These are connected by tie breaker that works automatically or manual

Under normal conditions, ½ of the building is on one circuit and the other ½ is on the other circuit

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Emergency Generator Testing

Emergency generator must supply power if utility power is lost or if there is an internal distribution failure. Power must be supplied to: ICCU, CCU, Ors, ED, Neuro, L/D, and all critical care areas

Testing - Emergency generators must be tested by starting them once a week and then placing them under load once a month

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Emergency Generator Testing

Power must be supplied within 10 seconds from time of utility interruption



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Electrical Distribution Systems

Automatic Transfer Switches (ATS) switch critical loads from either utility or emergency power.

Open Transition – Switch opens from one source (utility) then closes other source (emergency). This creates an interruption of power for a fraction of a second, but long enough to cause computers to reset.

Closed Transition – The switch parallels the power from the utility with the emergency generator for several m sec, then opens one source. No interruption of power occurs to loads down stream

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Electrical Distribution Systems

Automatic Transfer Switches (ATS)





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