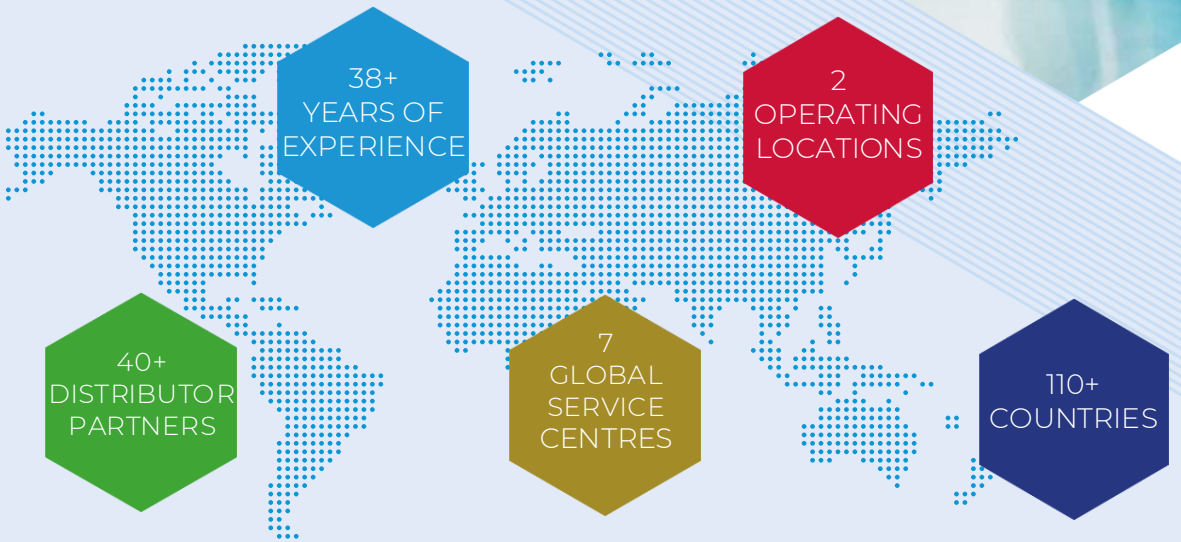
NFPA 99 Unplugged: Navigating Electrical Safety in Healthcare

Passionate about
patient safety.

Introducing **Rigel Medical**...
Making our world a safer place.
Every. Single. Day.

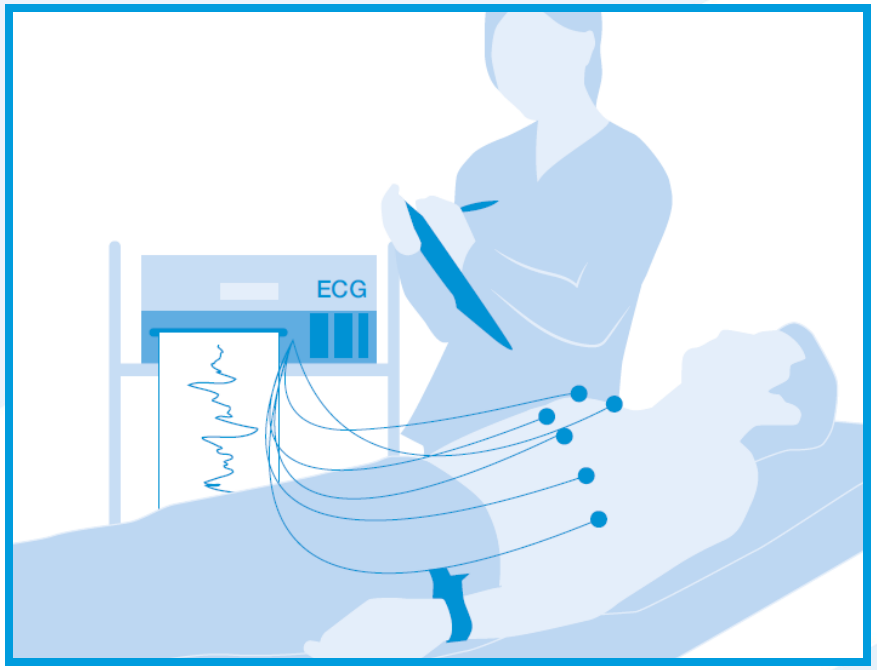


Rigel Medical are renowned globally as a designer and manufacturer of reliable, portable and compact biomedical test equipment.

Our products ensure that critical medical equipment is safe to use throughout the device's life-cycle. As metrology specialists, for almost four decades our innovative testing solutions have been mitigating risk worldwide in healthcare environments.

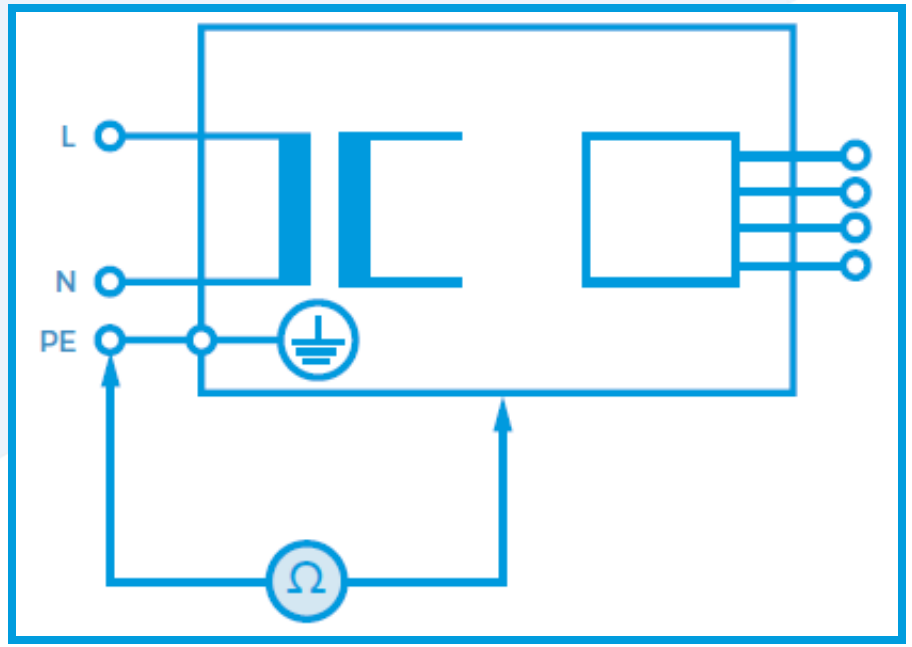
Introduction

- Substantial risk from electrocution in healthcare environments
- The human body is a good conductor of electrical currents
- Patients are also often in poor health, anaesthetized or unconscious.
- Applied parts connected close to the heart



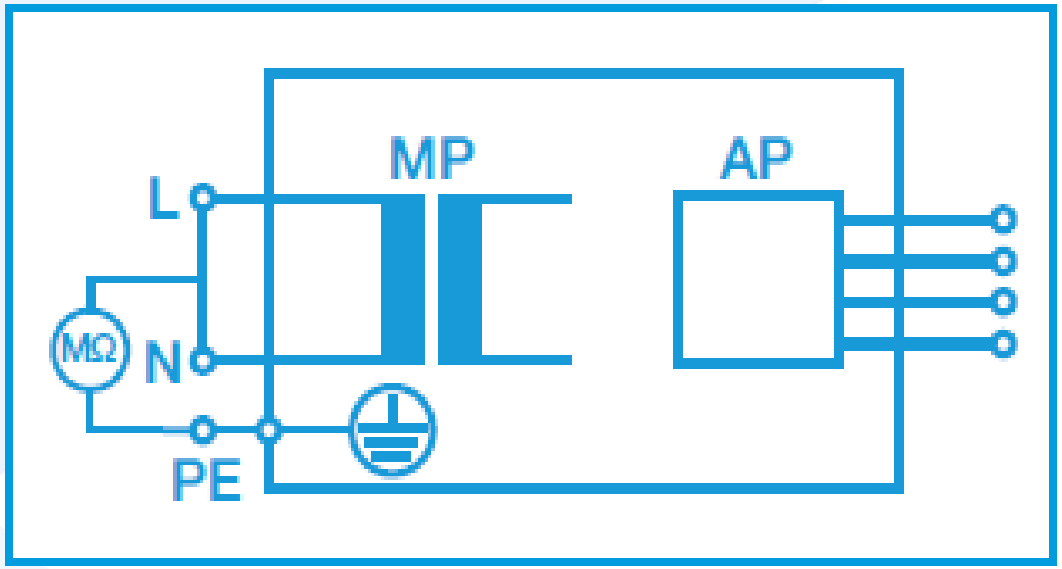
Ground Bonding

- Protective ground provides current path in case of fault currents
- Proves protective integrity
- Primary form of protection for Class I equipment
- Fault currents might trip the fuse / RCD/circuit breaker
- What are we measuring?



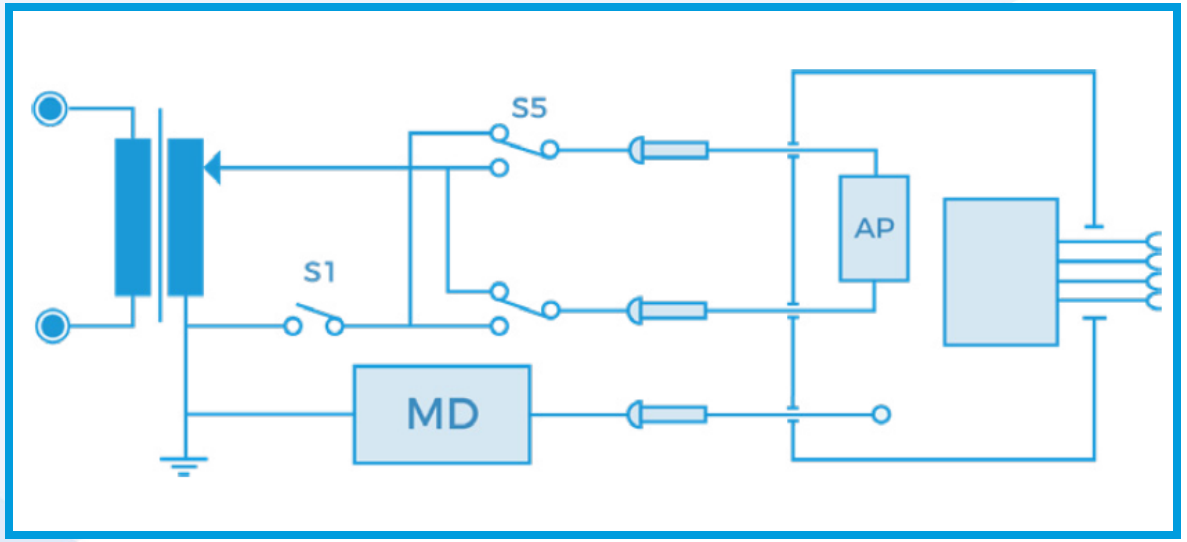
Insulation

- L-N shorted, equipment does not power-up
- 500V DC applied across the power supply to chassis / ground.
- The Rigel 288+ and 62353+ offer 50V to 500V options
- A high resistance (MΩs) is measured



What is Leakage Current?

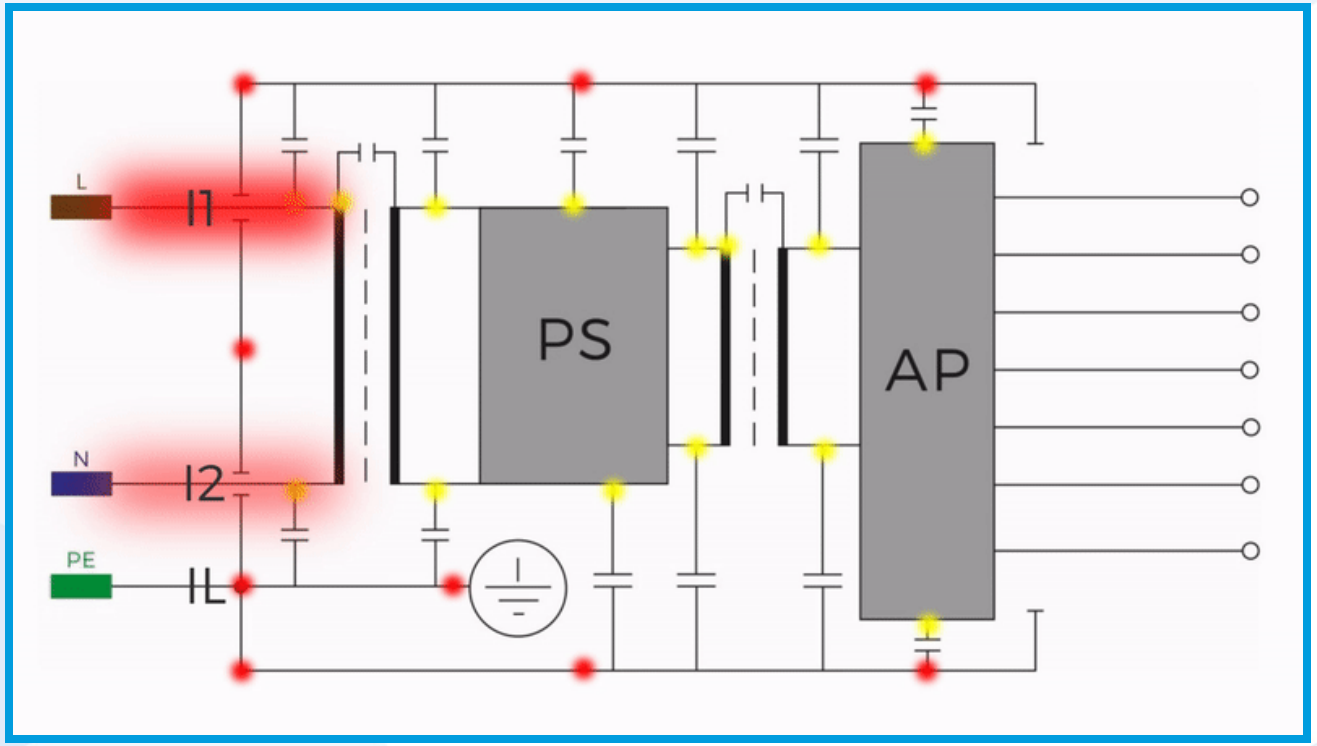
- “Current that is not functional”
- Unavoidable
- Current at commercial frequencies of 50Hz or 60 Hz
- Can be non-hazardous if within the limits of ANSI/AAMI ES60601
- Easily overlooked and subject to incorrect testing



Stray Capacitance?

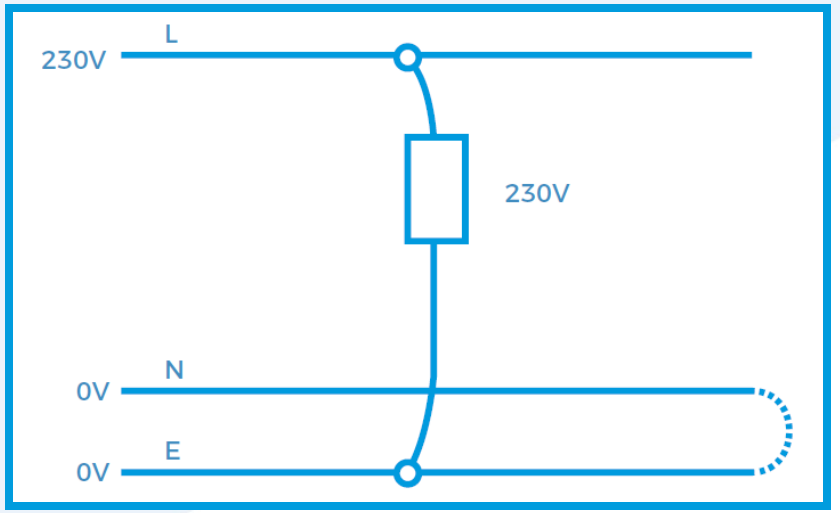
- Class I Ground Leakage travels down the earth path to ground within a medical device
- Earth leakage (IL) can be expressed as:

  I1 (L current) – I2 (N current)

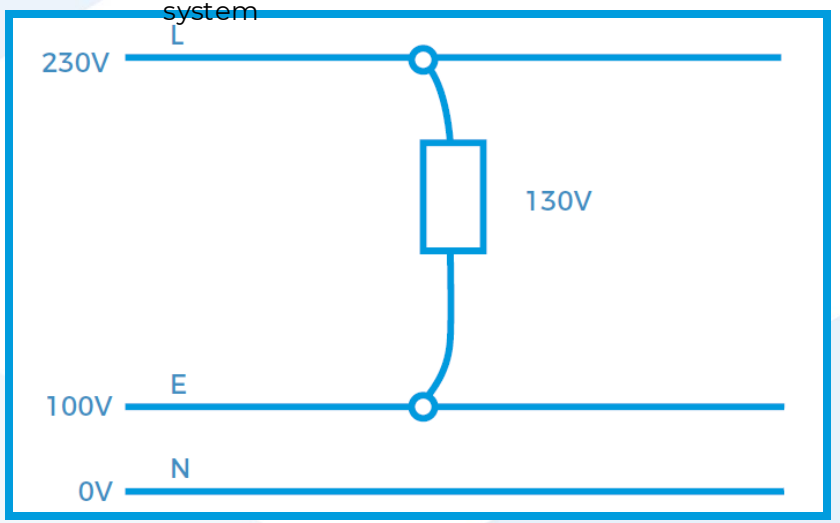


Test Conditions

- NFPA 99 does specify the configuration of the main for Electrical Safety Test as :
  - TN system (Terre Neutral = Neutral at same potential as Ground)
  - 120 Volt Hot
  - Leakage current is typically measured from a high potential to ground
  - Not from Hot to Neutral
  - To ensure highest possible leakage is measured



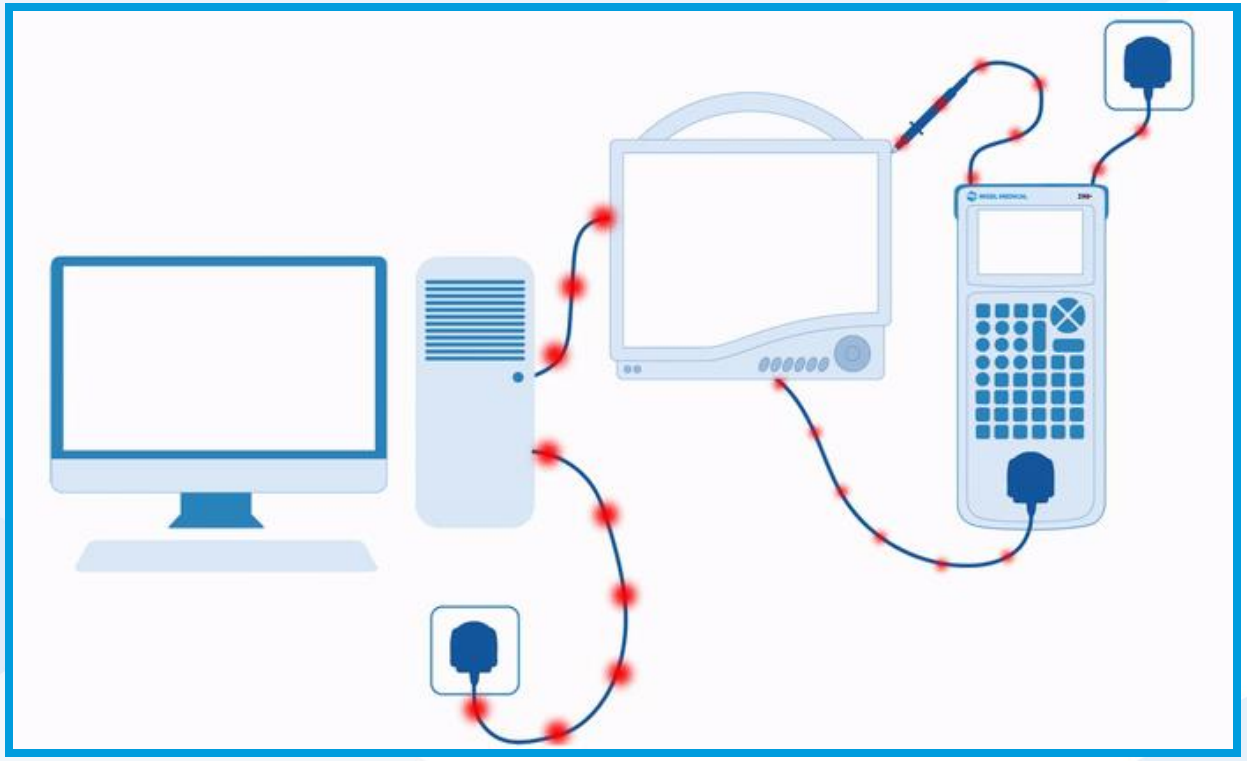
Leakage measurement on a TN system



Leakage measurement on a IT system

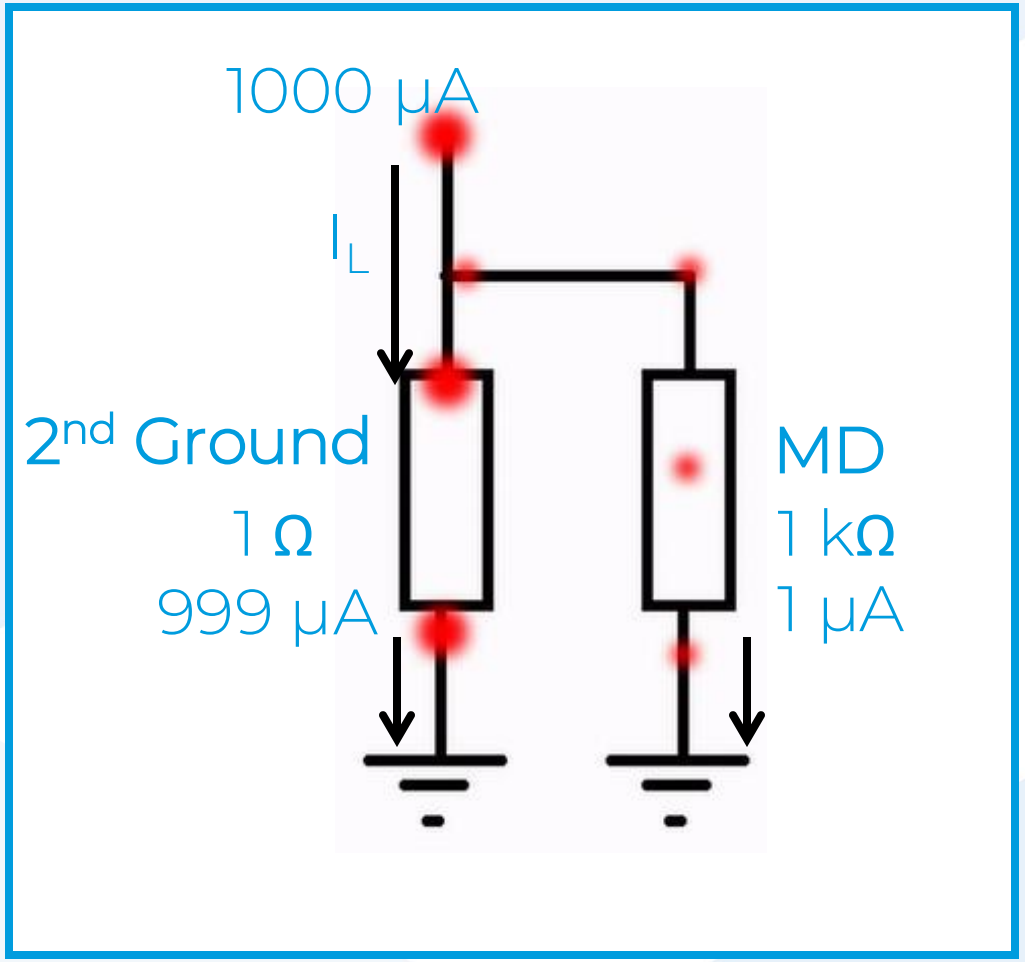
The Secondary Ground Path

- Common problem but often unnoticed
- Occurring when medical equipment is connected to other equipment, data lines, monitors, endoscopy or even water
- Provides a second low resistance path
- Leakage current takes path of least resistance



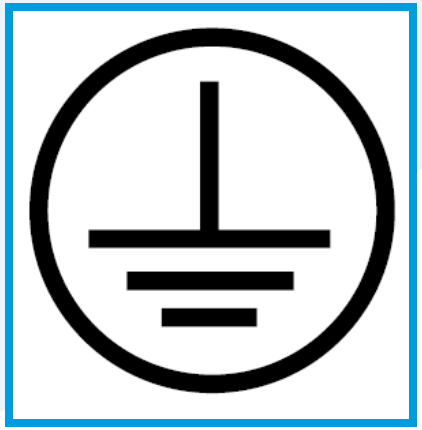
Alternative Ground Path

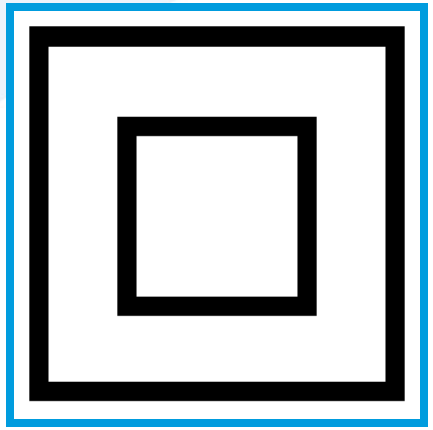
- Results in significantly less leakage current flowing through the analyzer
- The 1kΩ body model of the safety analyzer
- A value of 1Ω or less can be expected via an alternative ground, which means a 1000 times error or more!



Input Protection Classification

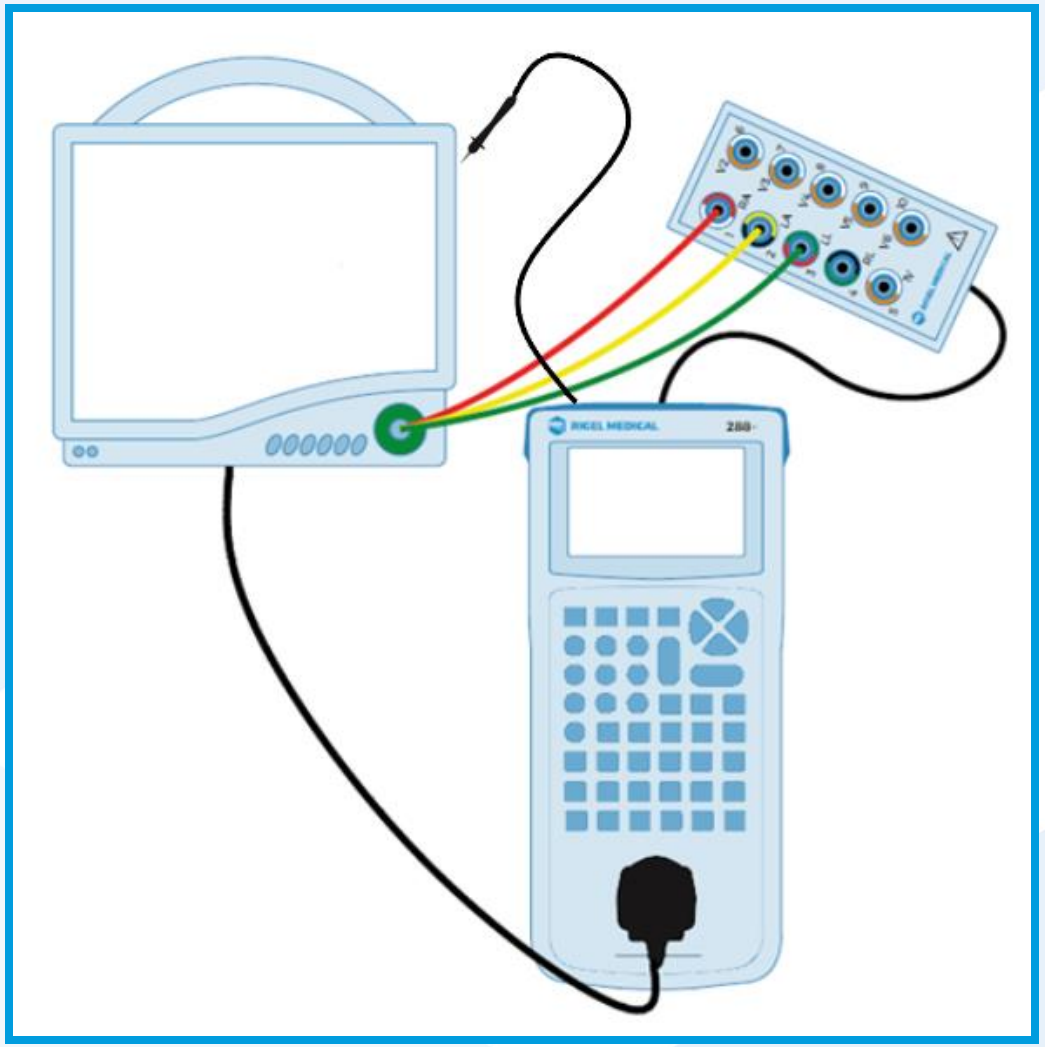
- All tests relating to the electrical safety of ME equipment and devices can be categorized into two categories:
- **Medical Equipment (ME) Class – Means Of Operator Protection (MOOP)**
  - ME class 1 (Protection relying on fault currents to Ground)
  - ME class 2 (Double Insulated, protection relying on additional insulation)





Medical devices

- What standard?
- Visual test
- Class I or Class 2?
- Connections?
  - Exposed Metal work
  - Applied Parts



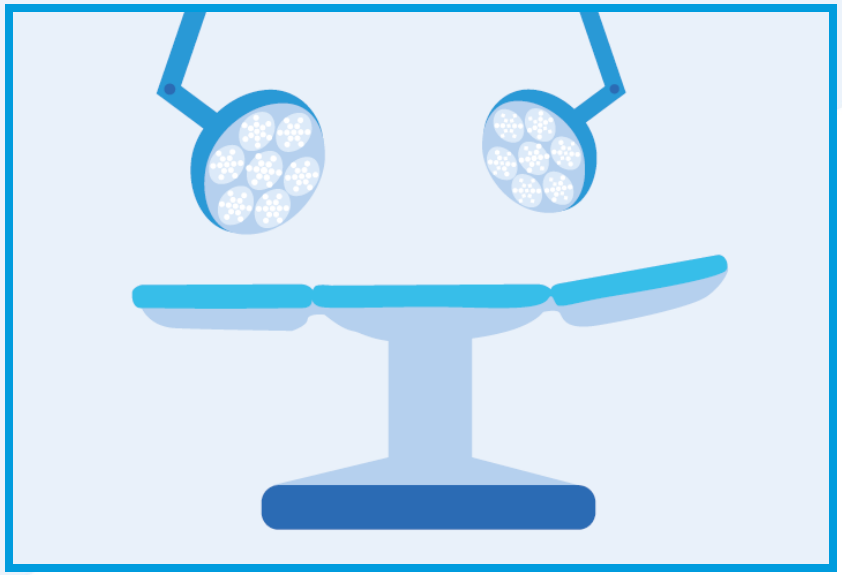
Standards and Codes

IEC 60601	NFPA 99	IEC 62353
Earth Bond	Ground Bond	Earth Bond
Earth leakage	Ground Wire Leakage	Equipment Leakage DIRECT / DIFFERENTIAL
Earth Leakage SFC Neutral open	Ground Wire Leakage SFC Neutral Open	Equipment Leakage ALTERNATIVE
Enclosure Leakage	Chassis Leakage	Equipment Leakage DIRECT / DIFFERENTIAL
Enclosure leakage SFC earth	Chassis Leakage SFC earth	Equipment Leakage DIRECT / DIFFERENTIAL
Patient Leakage	Lead to Ground Leakage	Equipment Leakage (enclosure probe disconnected)
Mains on Applied Parts	Isolation Leakage	Applied Part Leakage
Measured values	Measured values	Some are calculated
Only direct method	Only direct method	Direct/Differential/Alternative

NFPA 99

Categories

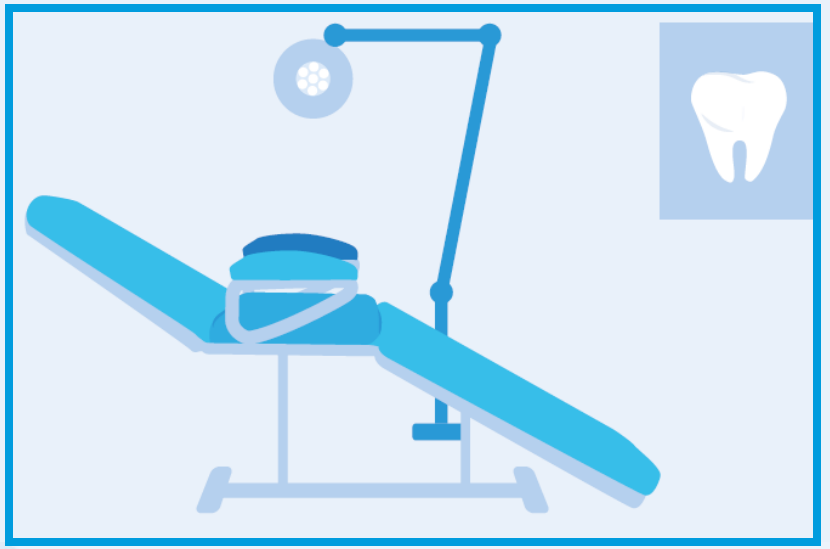
- NFPA 99 defines health care facilities as including hospitals, nursing homes, limited care facilities, clinics, medical and dental offices, and ambulatory health care centers
- There are four levels of system categories that need to be considered
- Each category is based on the risk to the patients and caregivers in a healthcare facility



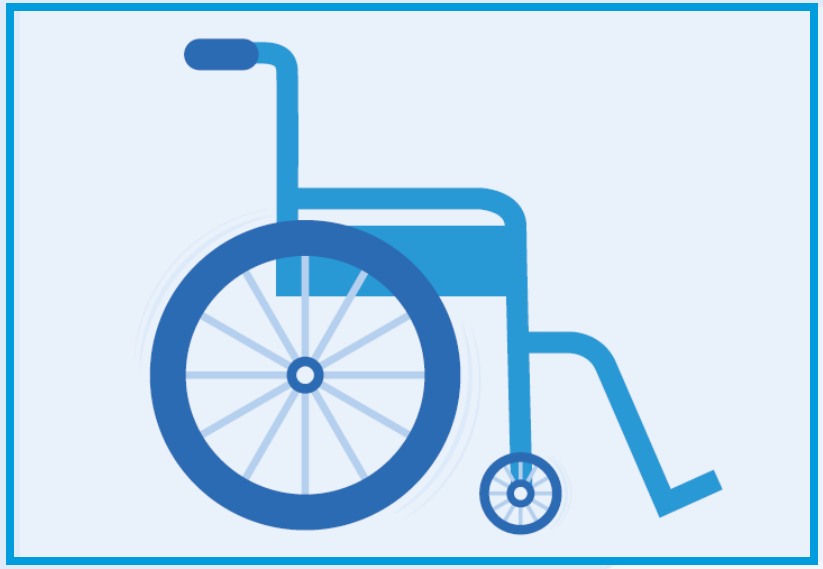
Category 1: Equipment failure for any duration is likely to cause serious injury or death, e.g. operating rooms

Categories

Category 2: Equipment failure is likely to cause minor injury. Short durations of downtime unlikely to cause problems, e.g. outpatient services



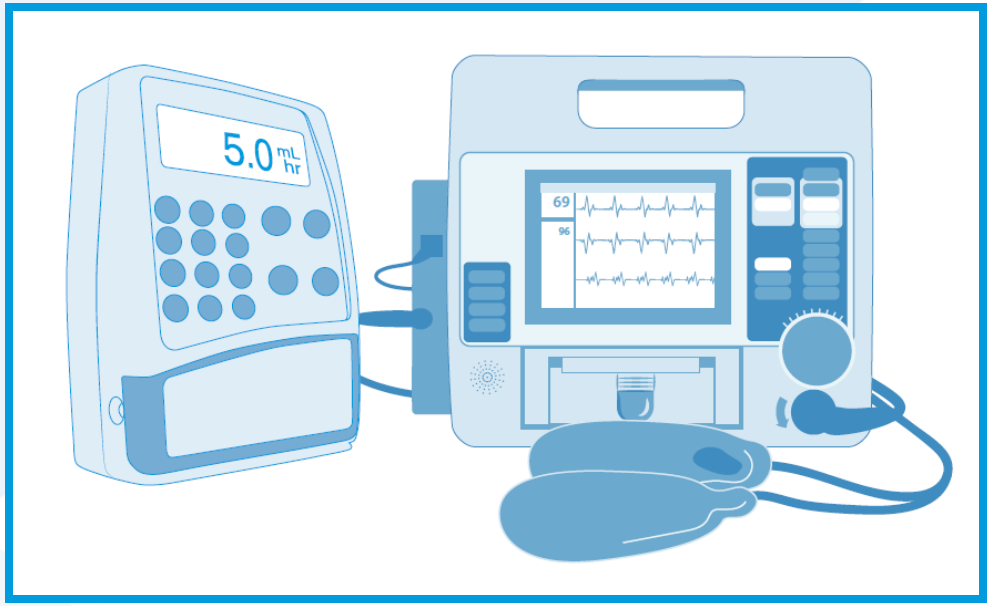
Category 4: Equipment failure will have no impact on patient care, e.g. exam room



Category 3: Equipment failure is unlikely to significantly affect patient care, e.g. dental room

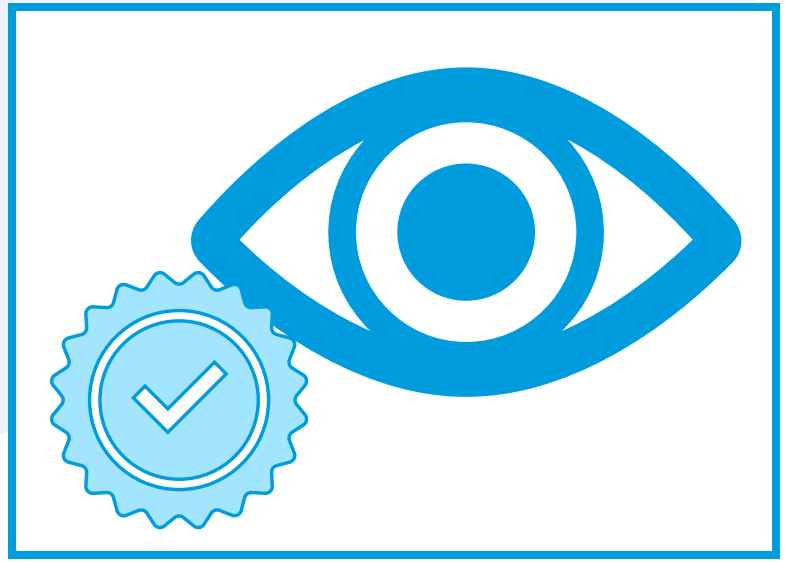
NFPA 99

- Aligned with ANSI/AAMI ES60601
- Includes performance and safety of medical appliances
- Defines when tests should be pefromed
- A manufacturer will also produce recommendations for intervals
- Ensures the device is free from hazardous current flowing though patient, operator or visitor



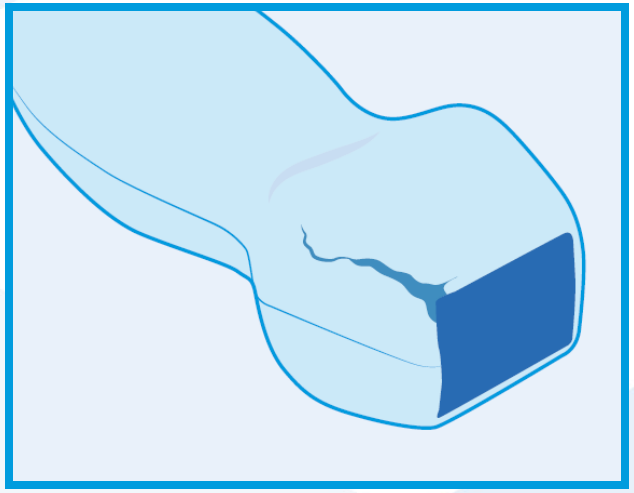
Visual Inspection

- Critical part of inspection – 70% of all faults detected
- Helps to quickly detect hazardous appliances
- Equipment to be removed and repaired if any defects identified
- Formal or documented visual inspections are not required
- Must still be carried out during all scheduled and unscheduled maintenance checks!



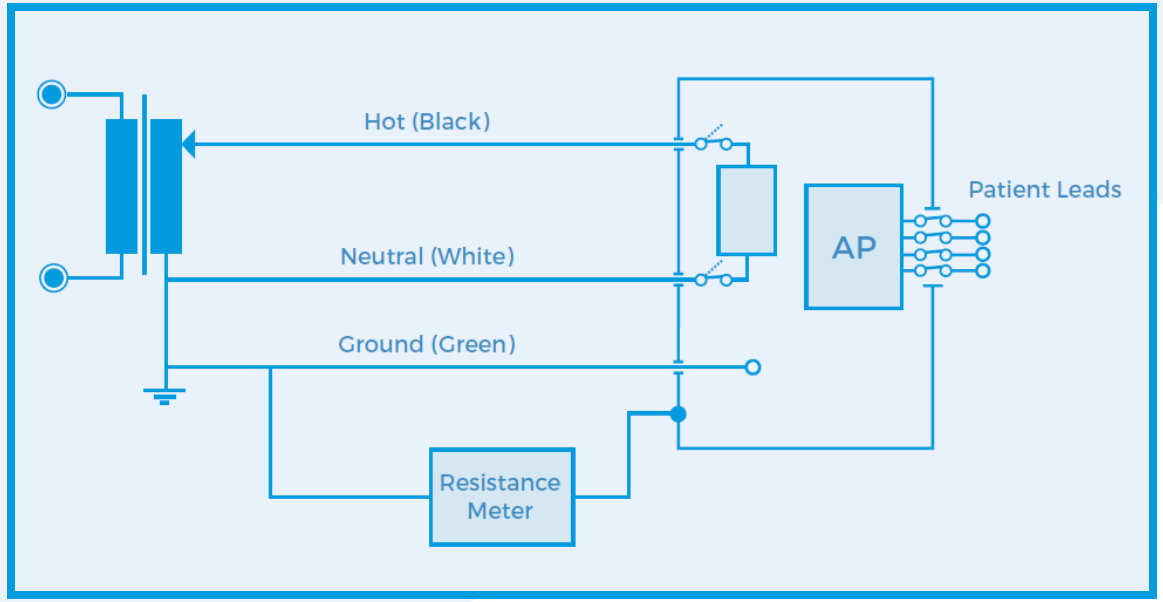
A Typical Inspection?

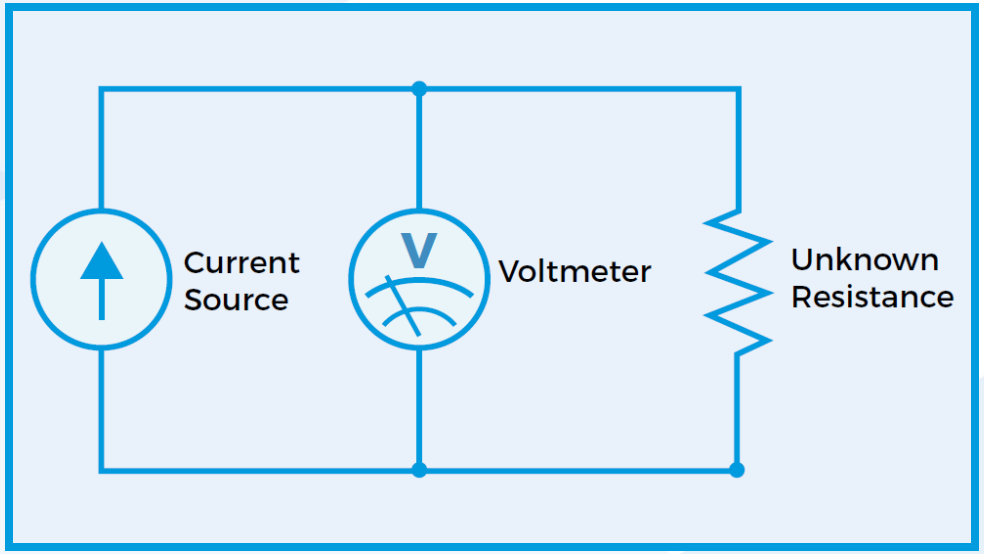
- Cases or chassis – damage or cracks
- Cords and plugs – stress relief, correct amperage, frayed wires, or damaged plugs
- Integrity – check mechanical parts for obstructions
- Multiple outlet connections – ensure receptacles are permanently attached, appliances ampacity does not exceed 75% of the cord rating
- Don’t forget nonpatient care related electrical equipment



Ground Bond Tests

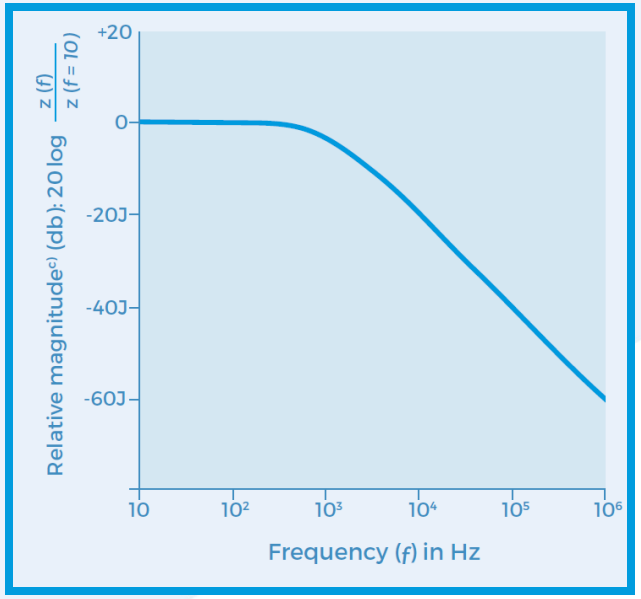
- Tests the integrity of the low resistance connection between the ground conductor and the exposed conductive parts of the appliance
- When the grounding conductor is below the threshold (0.5Ω) and a person is in contact with the chassis, almost all the touch current flows through the grounding conductor

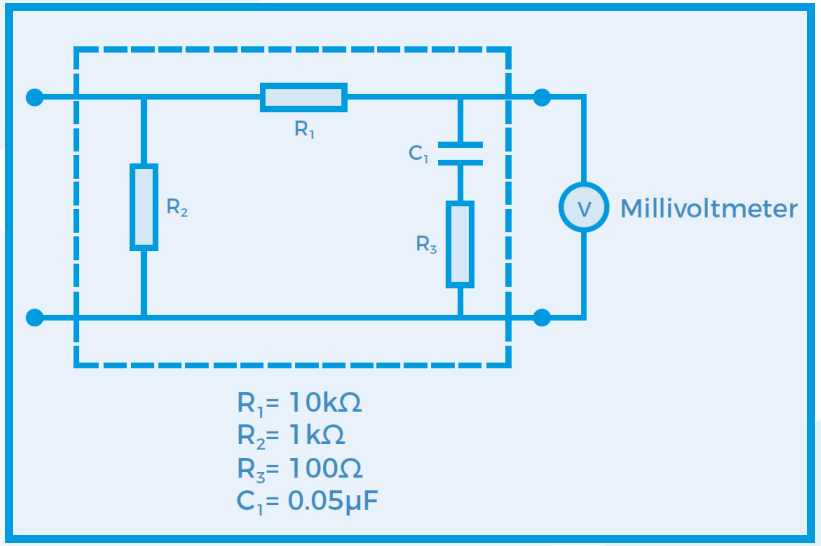




Leakage Current Tests

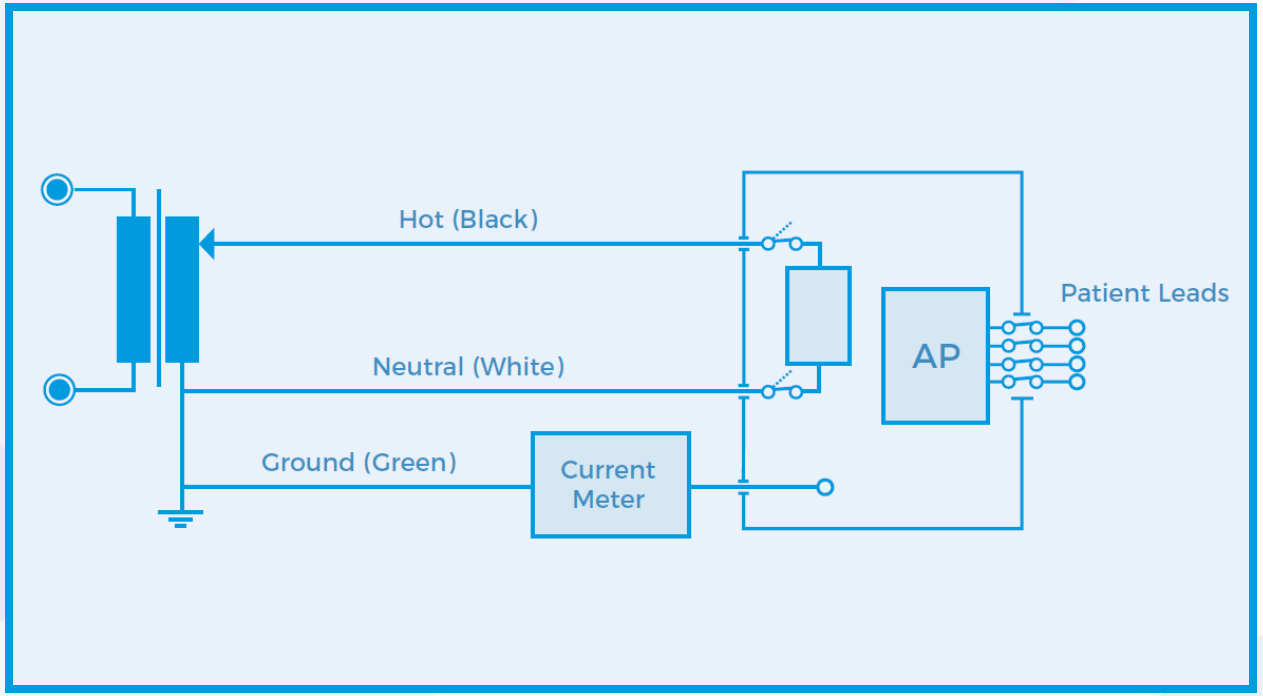
- Leakage measurements are broken down into:
  - Ground leakage,
  - Touch leakage
  - Patient lead leakage
- No body model is mentioned in NFPA-99, however, the frequency response characteristics must match the body model found in AAMI/ANSI ES60601





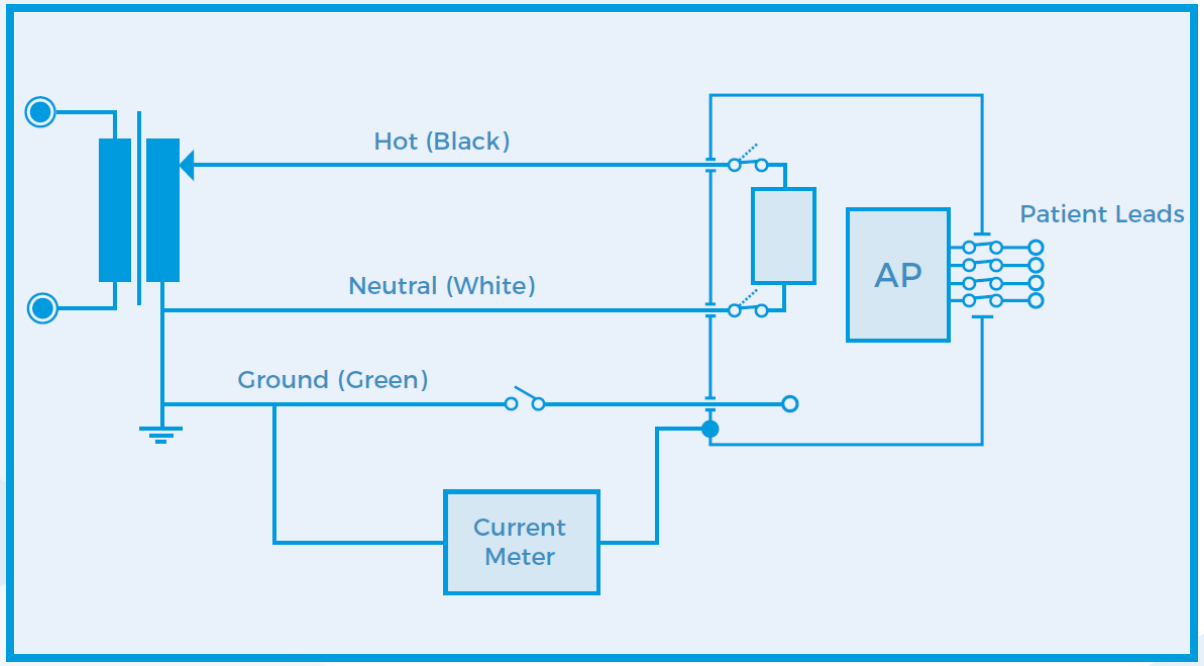
Ground Leakage Tests

- For fixed equipment in Category 1 and 2 spaces only
- Test is done before installation
- The leakage current is measured from the ground conductor of the power supply to the ground of the fixed appliance
- DUT needs to be tested with the power switch in both the ON and OFF positions



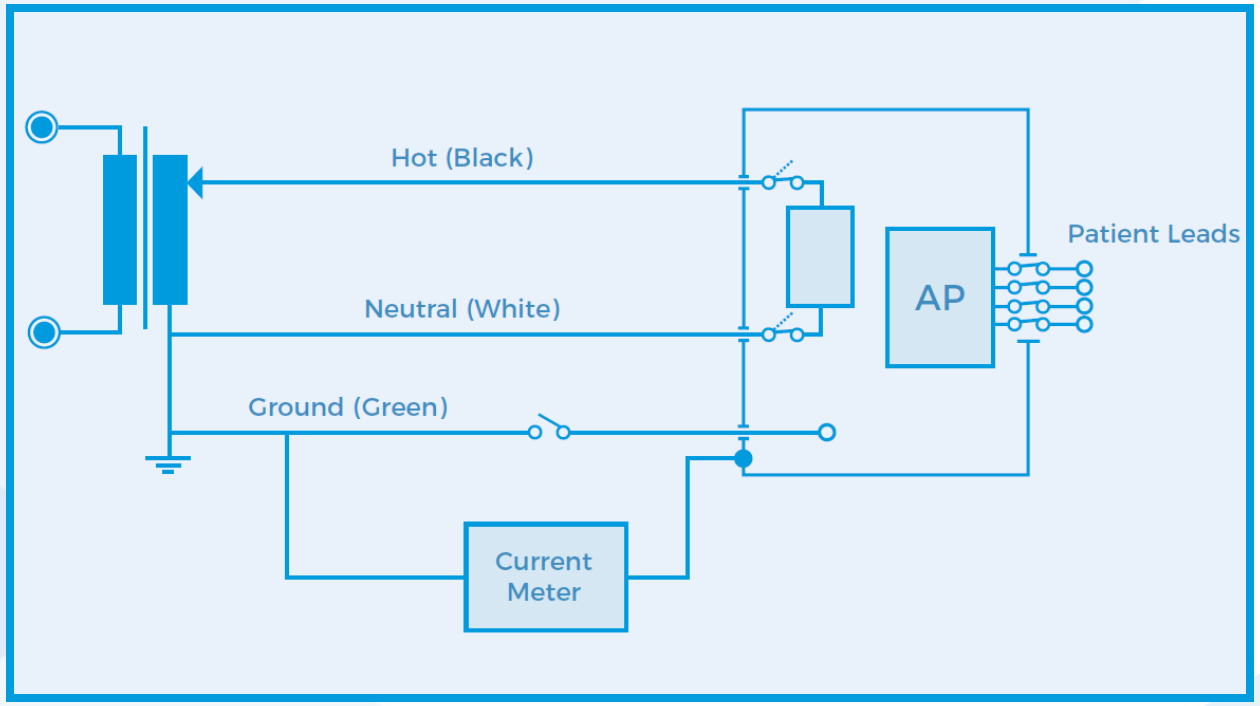
Touch Current Tests

- Touch current tests simulate a human body contacting different parts of the equipment
- Ground is switched to open
- Two measurements - power switched in both the ON and OFF positions
- If permanently fixed to ground, measured in situ without ground open
- Limit of 500uA



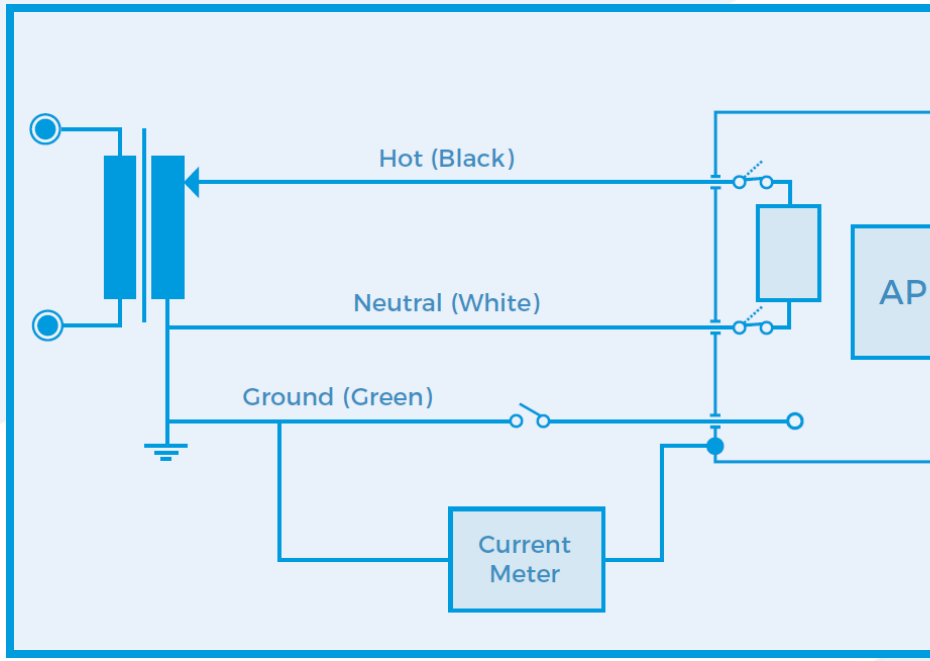
Touch Current Tests

- The current must be measured using power supplied directly from a standard grounded system
- Gives the highest possible leakage outcome!
- Current measured as a group if one power cord supplies the power to multiple devices – 500µA as normal
- What if there's no exposed conductive surface?



Lead Leakage Current Tests

- A patient lead is any lead that has direct conductive contact with the patient and is referred to as an applied part
- This includes non-invasive and invasive connections, e.g., ECGs and pacemakers
- Patient leads are grouped together for testing
- The leakage current limits are 100µA for ground wire closed and 500µA for ground wire open



Test Limits

Test	Single fault condition	Limit
Ground Bond	None	0.5Ω
Leakage Current (Fixed Equipment)	None	10mA AC/DC
Touch Current	Open Ground	500µA
Lead Leakage	None	100µA
Lead Leakage	Open Ground	500µA

Best Practises

- Facilities responsibility to identify which equipment requires regular checks.
- Must be tested at acceptance and during any maintenance that may affect the electrical integrity
- Periodic testing at least every 12 months
- The responsibility for the duration of retention for test records falls on the healthcare facilities record policy
- Appreciate that secondary ground connections and isolated systems will lead to invalid measurements

Best Practises

- Each record must define
  - What was tested (The unique identification of the equipment),
  - The test date
  - Pass or fail
- Test protocols should be developed to ensure consistency for each electrical safety check and record
- Service manuals often specify recommended additional safety checks, but the NFPA-99 code is law and must be followed first and foremost regarding electrical safety

Electrical Safety Analyzers

- The NFPA-99 handbook clearly states about the use of dedicated electrical safety analyzers
- How to choose?
  - An analyzer must simply produce the results you require accurately and repeatedly
  - The measuring device frequency response characteristic closely matches the body model in ANSI/AAMI 60601
  - Traceability of measurement results
  - Test convenience, including test duration, user interface, time efficiency

Alternative Testing Techniques

Ultrasound

- The ultrasound devices can have a variable number of probes (up to 6) and on some models, there is a 3 leads ECG option
- Electrical safety test in 2 parts :
  - 1) Test the ultrasound device alone (without the probes)
  - 2) Test the probes alone
- 1) Test the ultrasound device alone (without the probes)
- Connect the DUT to the R288 WITHOUT connecting the probes to the R288 and they are running NFPA 99 tests as normal
- Select semi auto mode and run a simple test, very easy

Ultrasound

- 2) Test the probes alone
- Ultrasound is connected to the analyser and power ON
- All the probes are placed into a plexi-glass container filled with 0.5 L of a saline solution
- The test is patient lead leakage. The duration of the test must be 30 seconds
- Up to 3 probes in the saline together at the same time
- If leakage limits out of spec, test each probe individually to identify fault