



NFPA 99 and the SafeTest 60+

Passionate about
patient safety.



RIGEL MEDICAL
GMC-INSTRUMENTS GROUP



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.



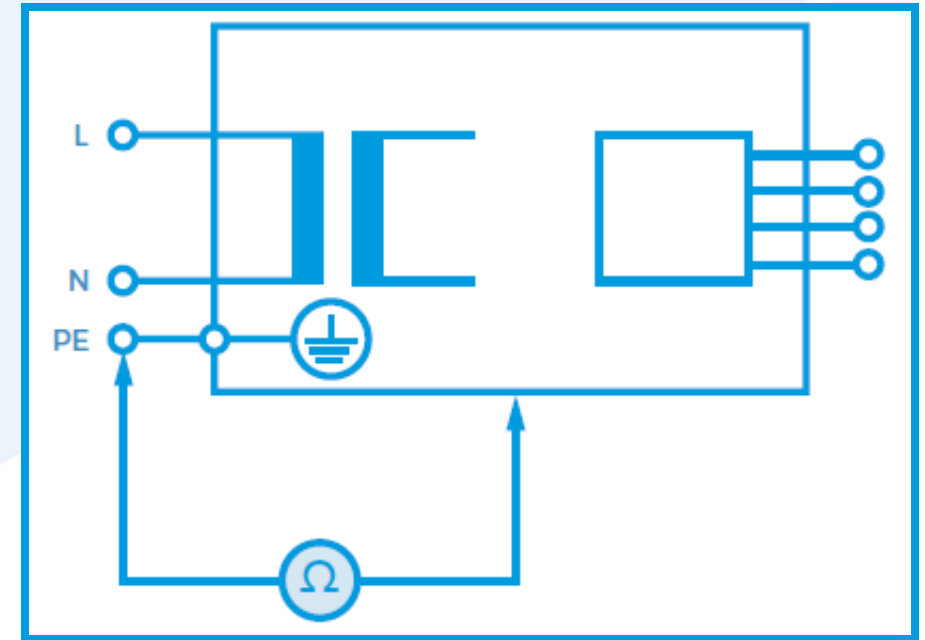
Introduction

- Substantial risk from electrocution in healthcare environments due to direct patient contact with medical electrical equipment
- The human body (Composed of water, ions and minerals) is a good conductor of electrical currents
- Patients are also often in poor health, anaesthetized or unconscious. Possibly unaware of an electric shock occurring
- Applied parts connected close to the heart – Cardiac muscles are sensitive to tiny currents



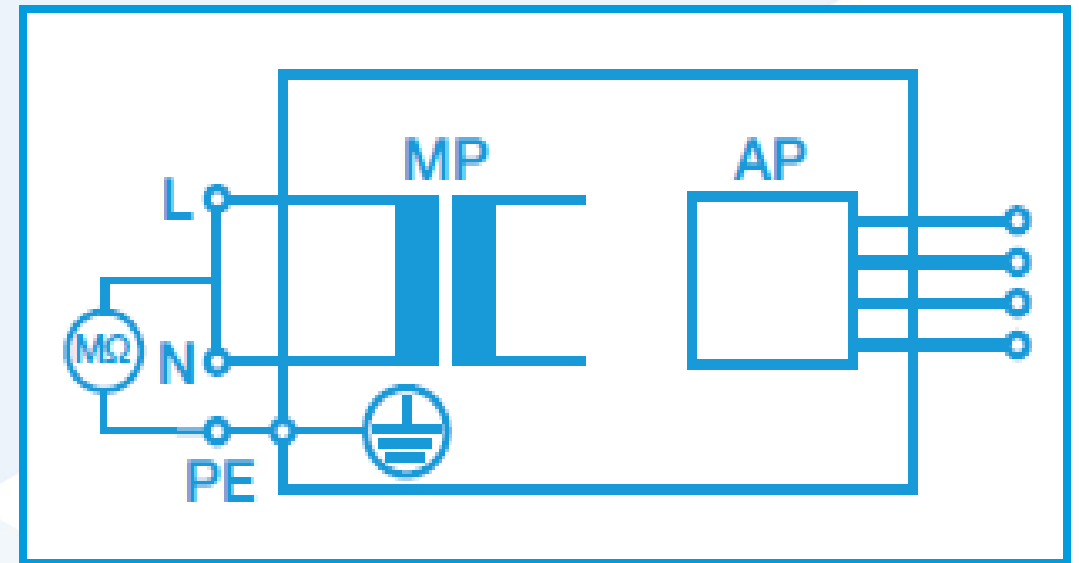
Ground Bonding

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



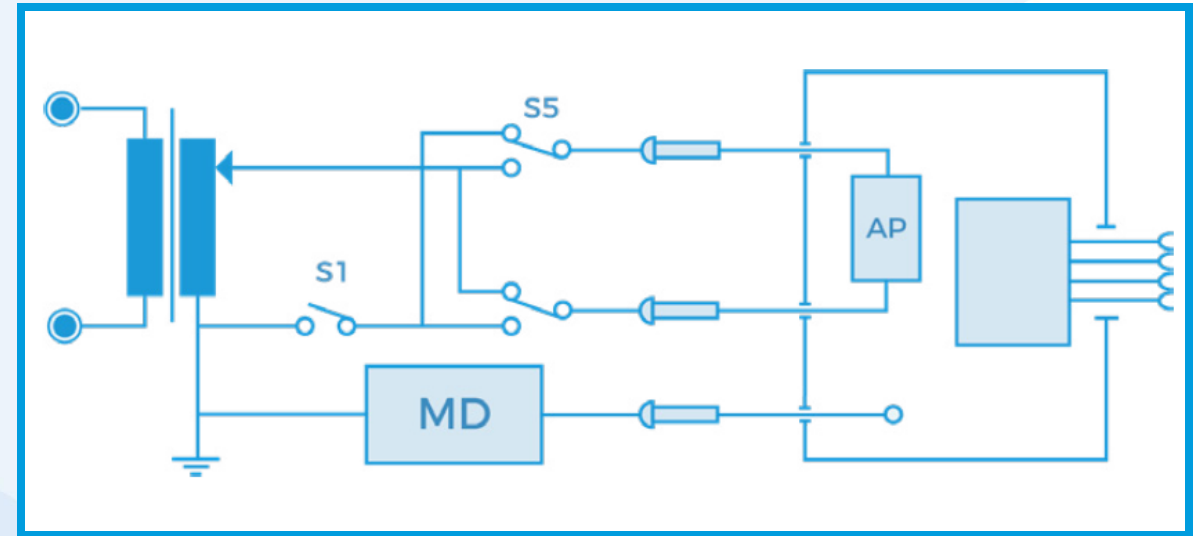
Insulation

- Not a mandatory part of standard testing
- L-N shorted, equipment does not power-up
- 500V DC applied across the power supply to chassis / ground. Why 500V?
- The Rigel 288+ and 62353+ offer 50V to 500V options
- A high resistance (M Ω s) is measured
- Limits vary with class and output



What is Leakage Current?

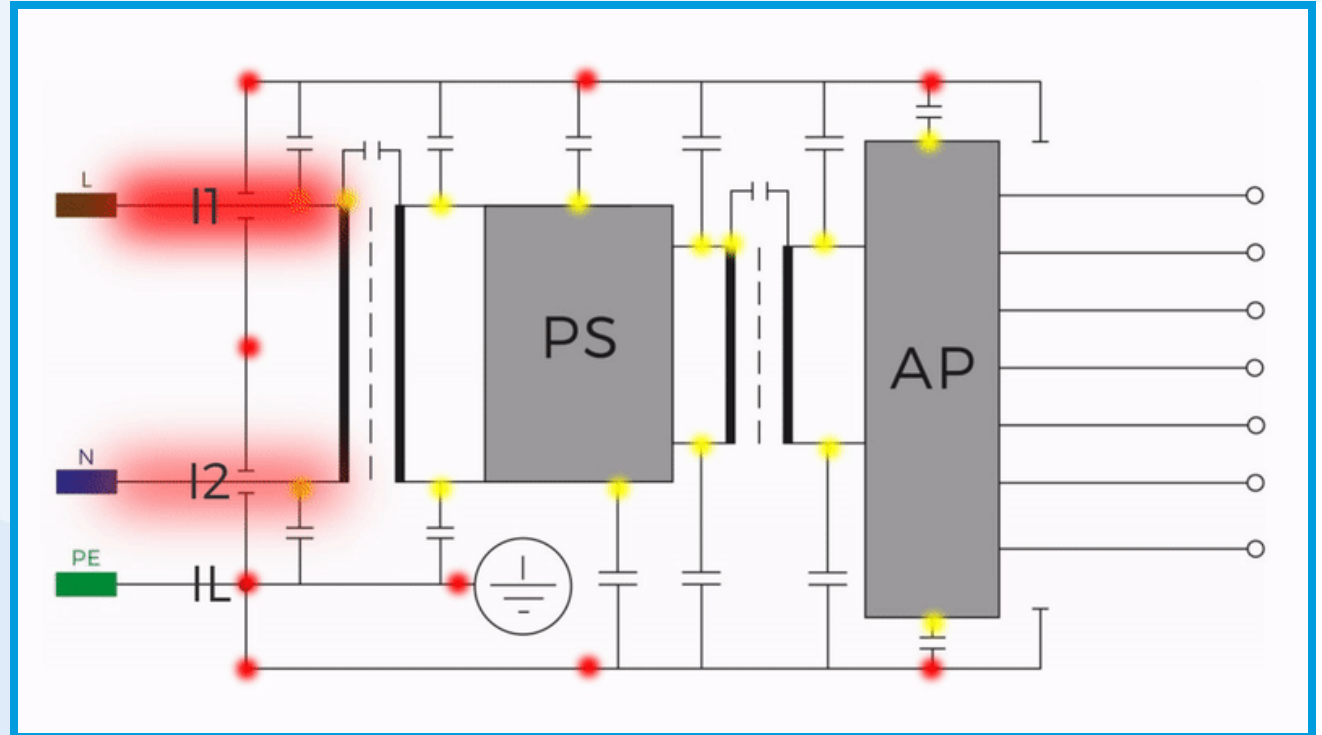
- “Current that is not functional”
 - *ANSI/AAMI ES60601-1:2016*
- Unavoidable - a result of stray capacitive and resistive dielectrics
- Current at commercial frequencies of 50Hz or 60 Hz flows from hot to ground
- Can be non-hazardous if within the limits of ANSI/AAMI ES60601 design criteria
- Easily overlooked and subject to incorrect testing



Stray Capacitance?

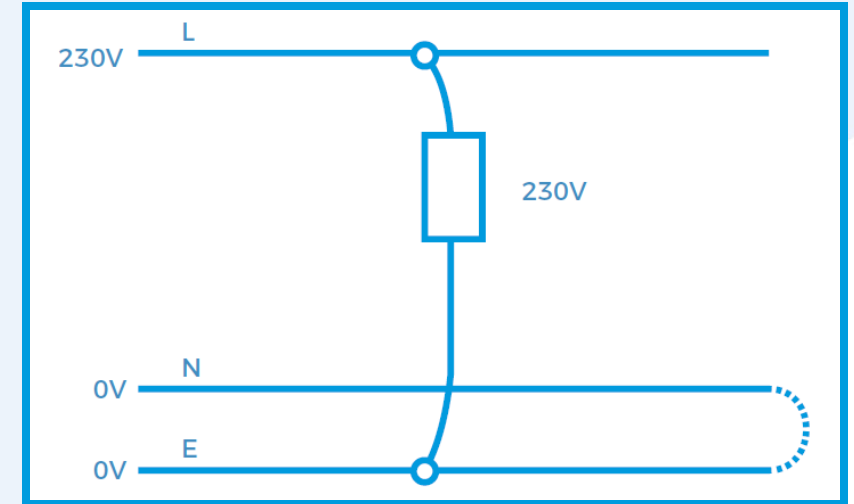
- Class I Ground Leakage travels down the earth path to ground within a medical device
- In a standard TN system, current in the hot wire carries both the functional current and leakage current, whereas the neutral wire contains only the functional current
- Earth leakage (IL) can be expressed as:

$$I_1 \text{ (L current)} - I_2 \text{ (N current)}$$

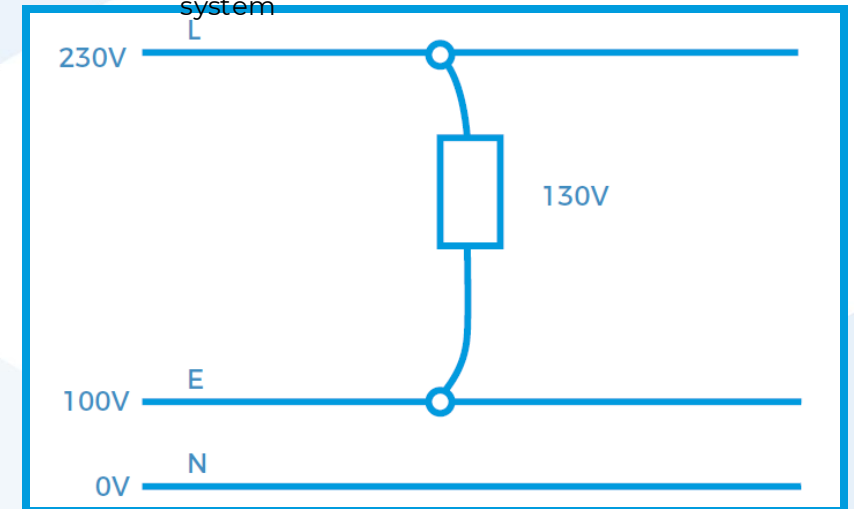


Test Conditions

- 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



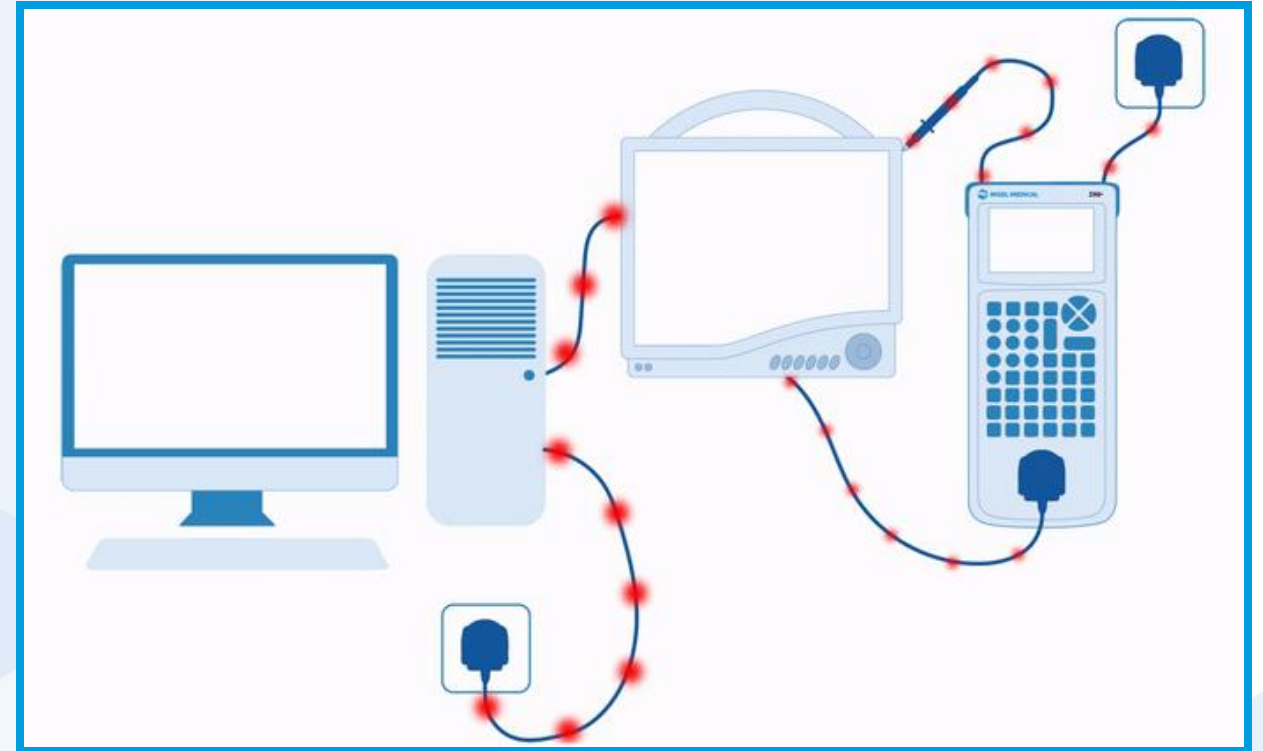
Leakage measurement on a TN system



Leakage measurement on a IT system

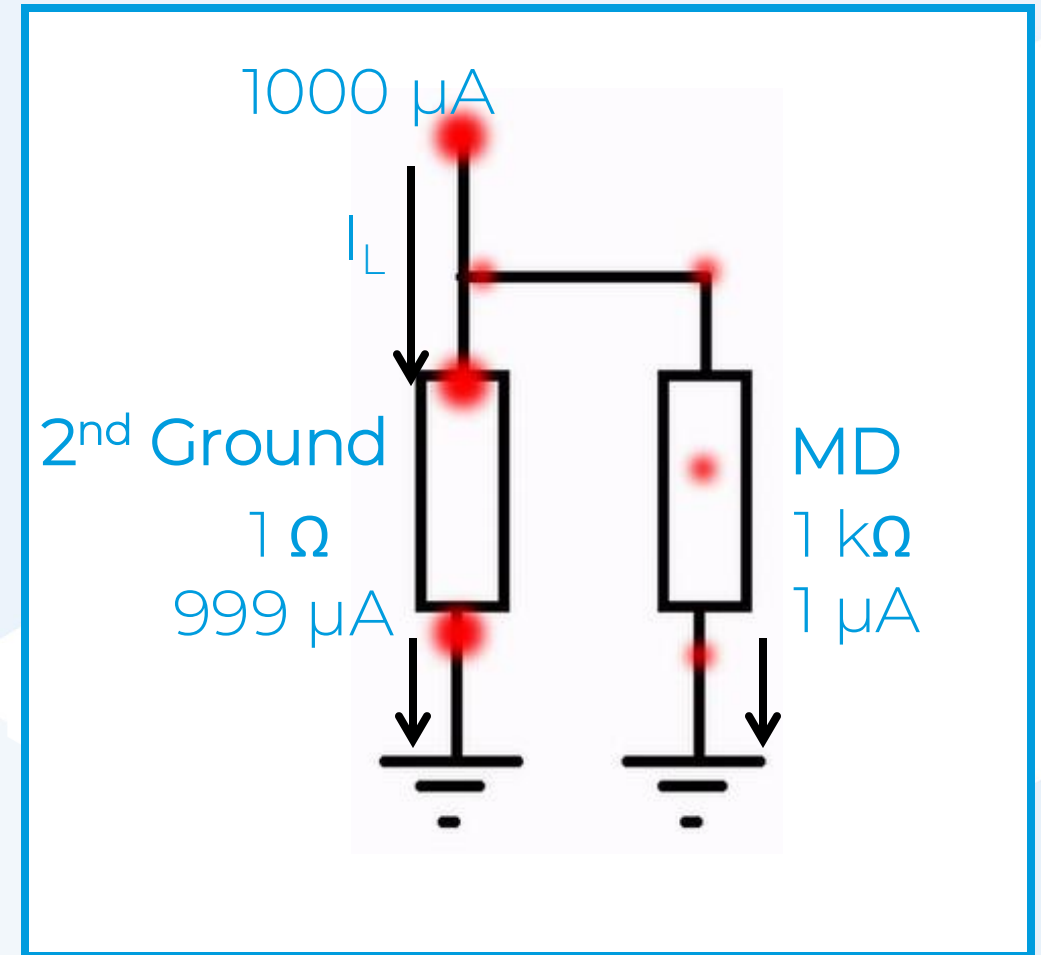
The Secondary Ground Path

- 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



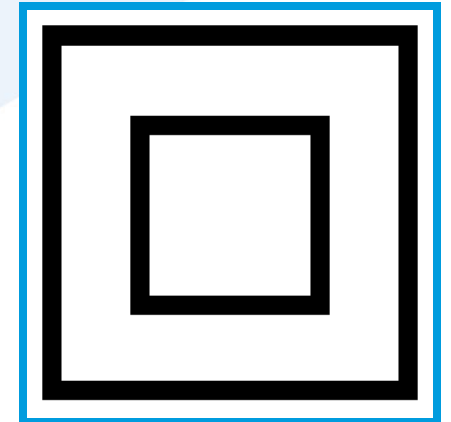
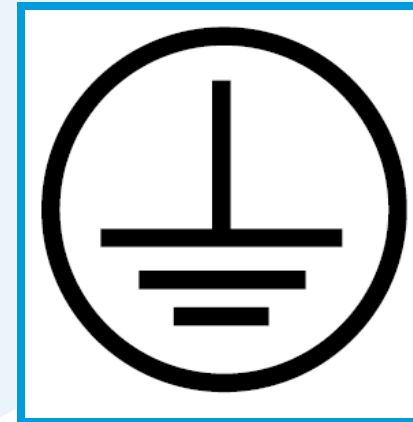
Alternative Ground Path

- Results in significantly less leakage current flowing through the analyzer
- The $1\text{k}\Omega$ body model of the safety analyzer means that most of the current flow is via the alternative ground path
- A value of 1Ω or less can be expected via an alternative ground, which means a 1000 times error or more!



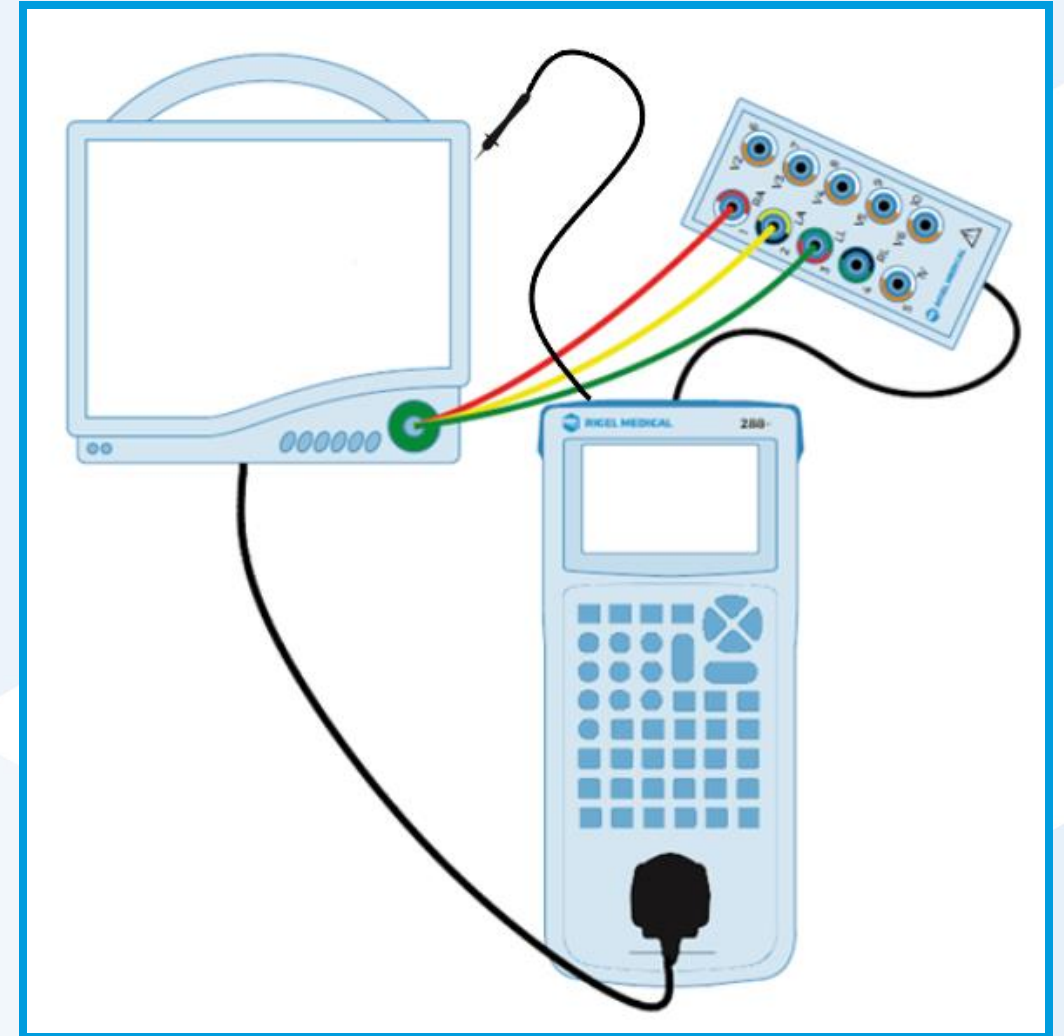
Input Protection Classification

- 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

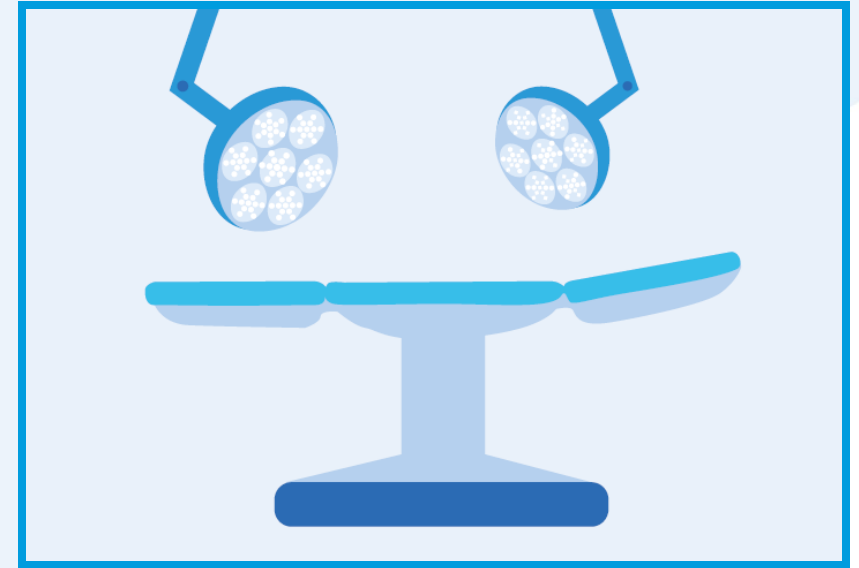




NFPA 99

Categories

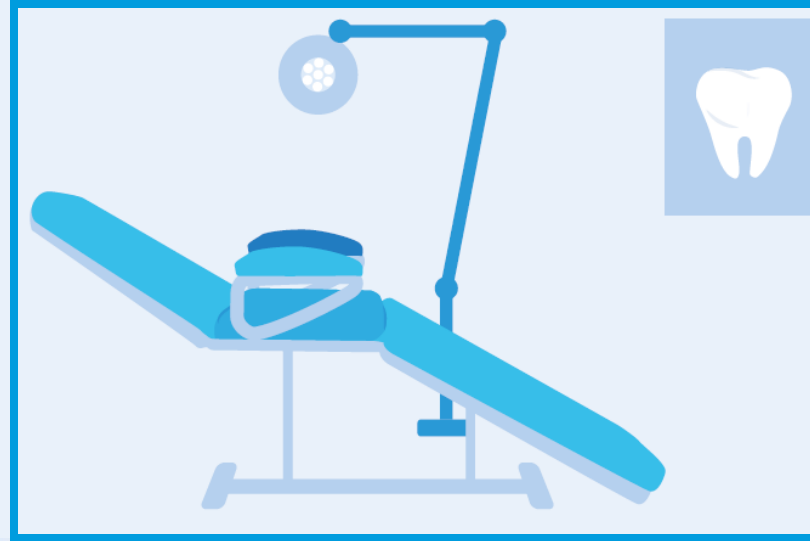
- NFPA 99 defines health care facilities as including hospitals, nursing homes, limited care facilities, clinics, medical and dental offices, and ambulatory health care centers
- There are four levels of system categories that need to be considered
- Each category is based on the risk to the patients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

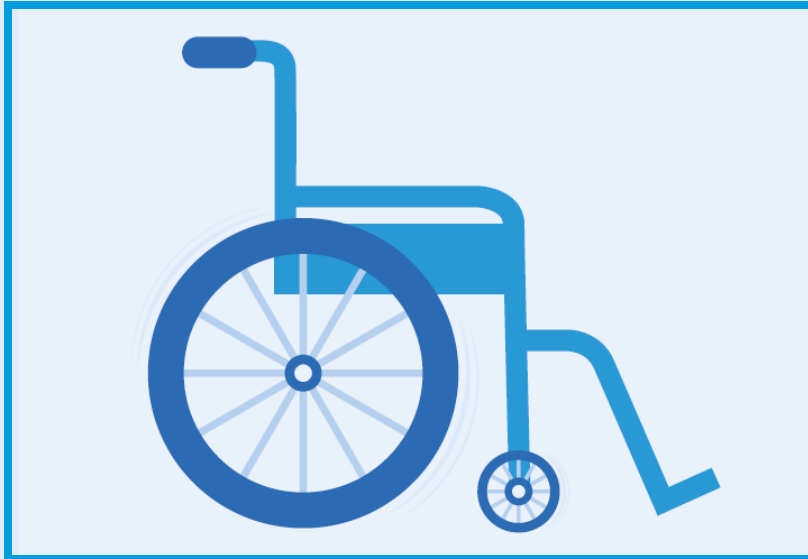
Categories

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



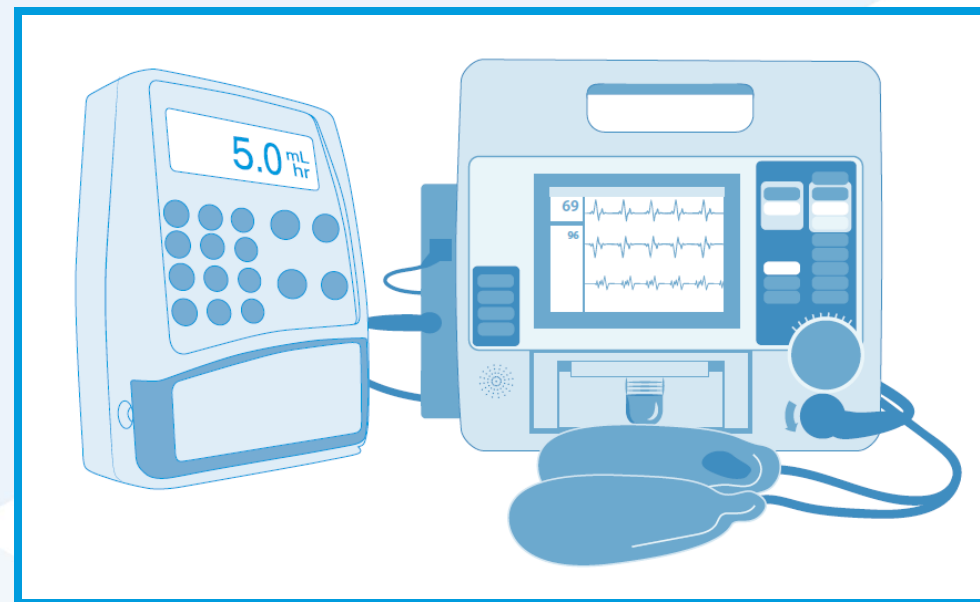
Category 4: Equipment failure will have no impact on patient care, e.g. exam room

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 performed
- A manufacturer will also produce recommendations for intervals
- Ensures the device is free from hazardous current flowing through patient, operator or visitor



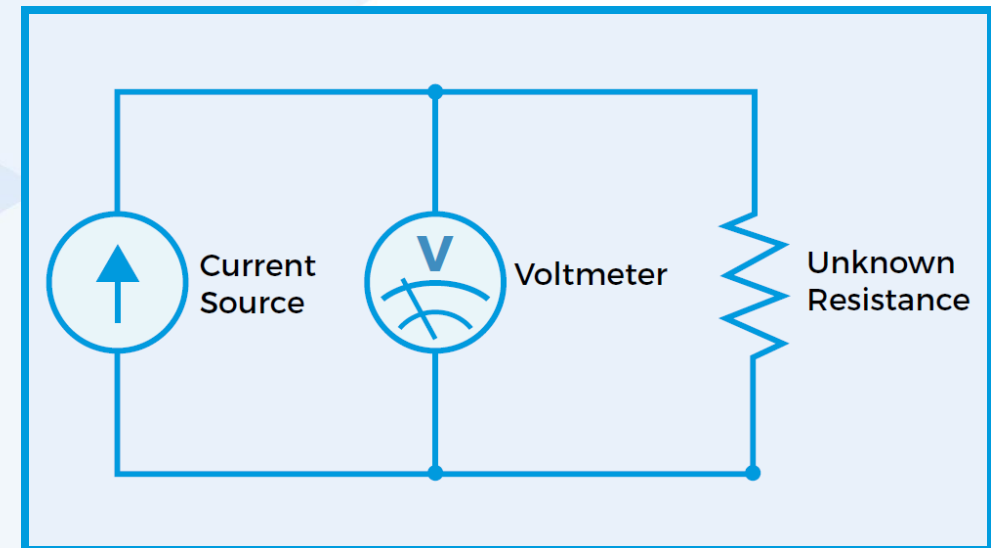
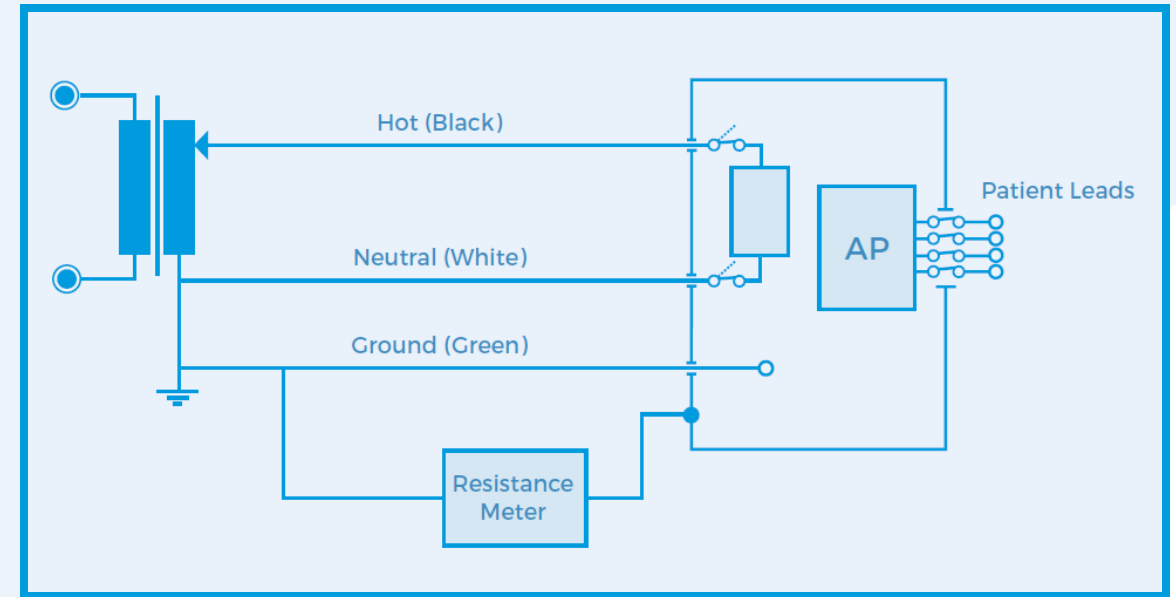
Visual Inspection

- 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 by the individual
- Must still be carried out during all scheduled and unscheduled maintenance checks!



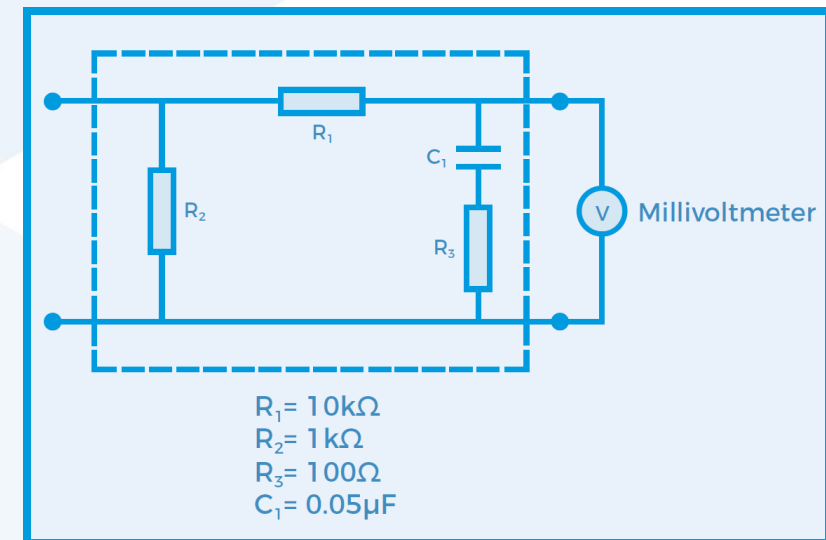
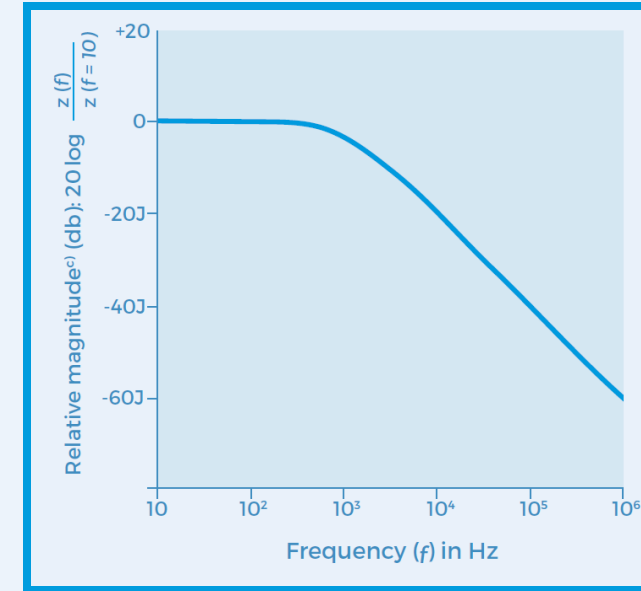
Ground Bond Tests

- 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



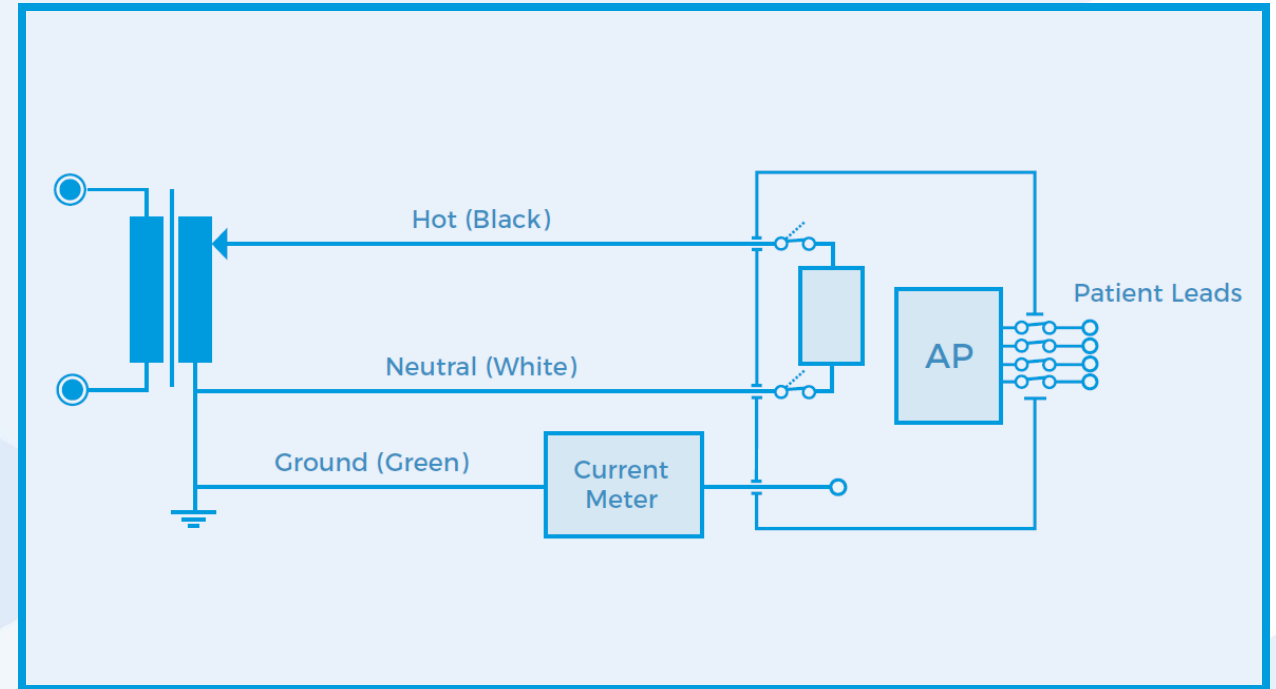
Leakage Current Tests

- 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 ES6060



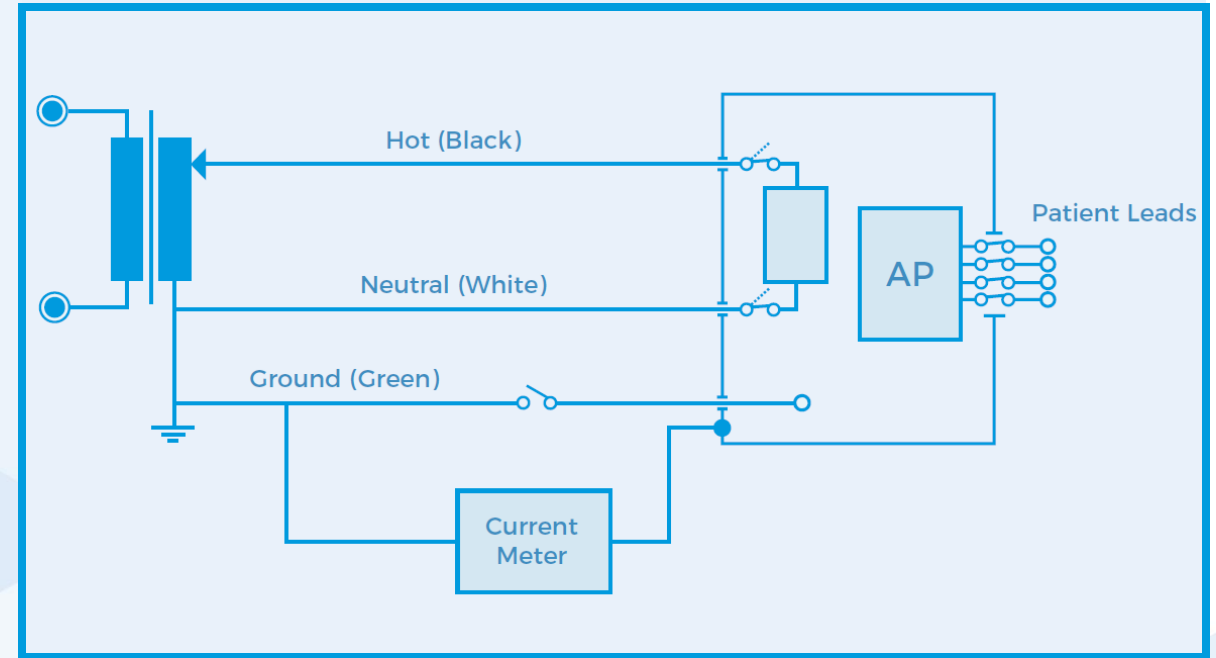
Ground Leakage Tests

- 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



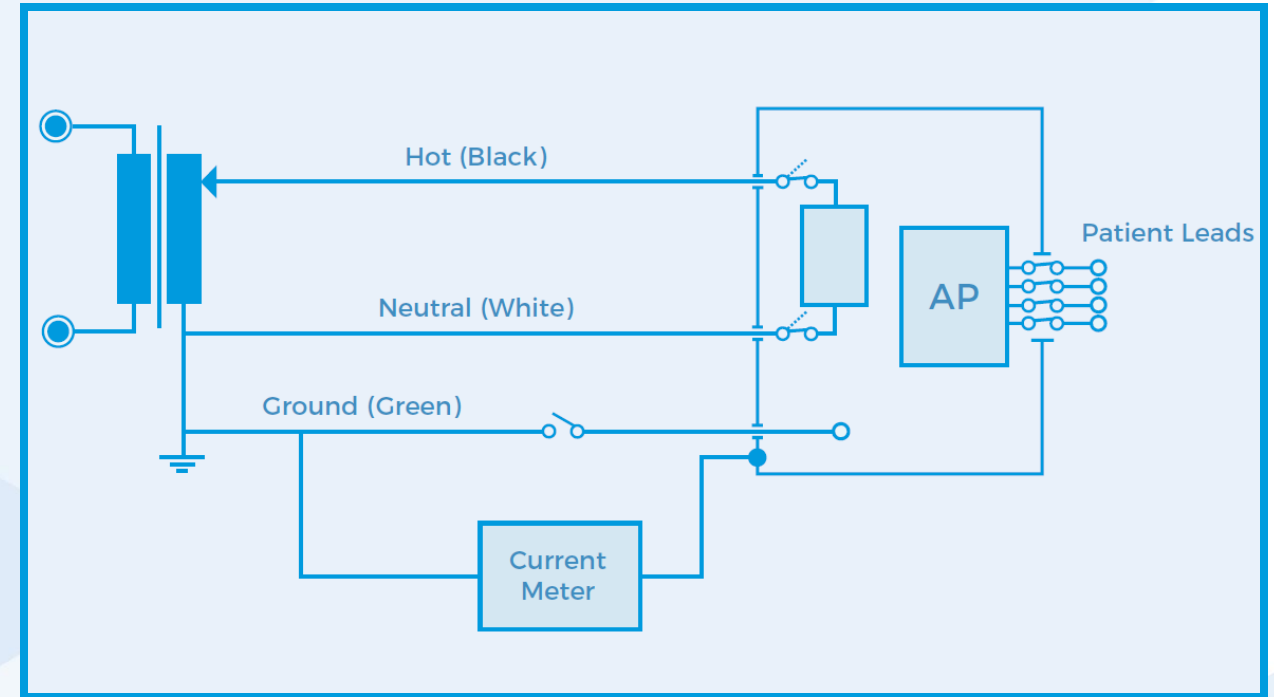
Touch Current Tests

- 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 500 μ A



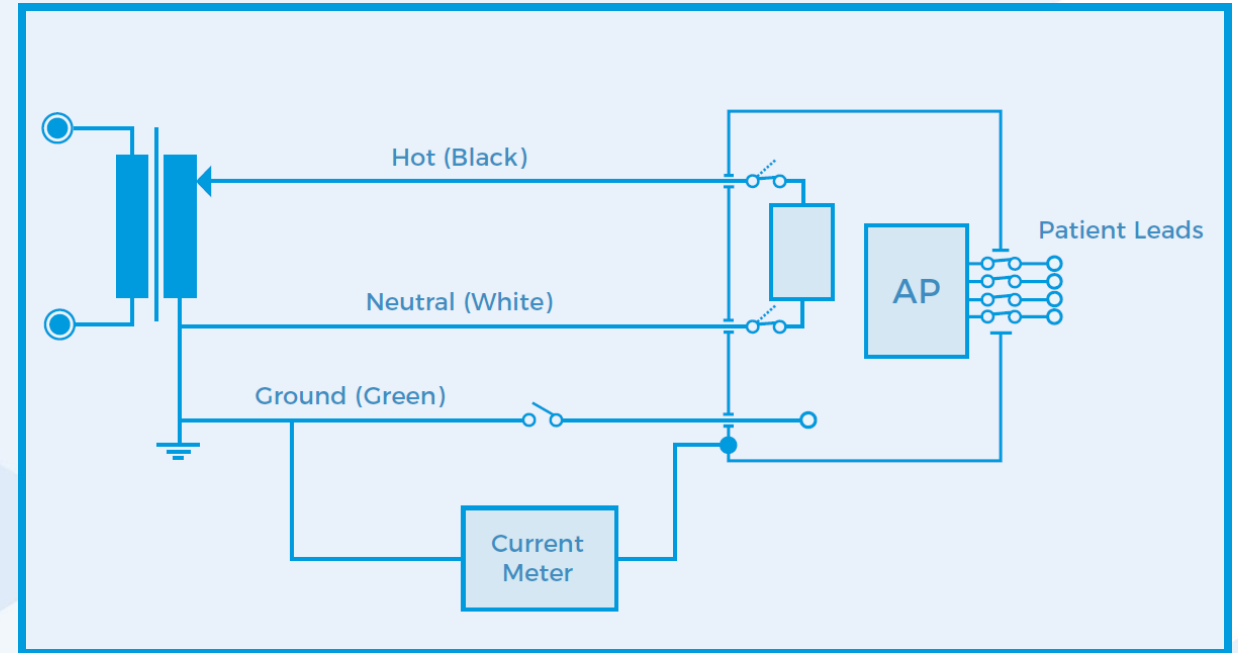
Touch Current Tests

- 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 – 500 μ A 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 $100\mu\text{A}$ for ground wire closed and $500\mu\text{A}$ 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





SafeTest 60+

Introduction

- The **SafeTest 60+** is an entry-level electrical safety analyser aimed at customers that test electrical equipment used in the healthcare industry
- Every hospital should own at least one!!
- It's our latest development and uniquely complements the range of existing safety analysers from Rigel Medical



Insulation resistance test

- The risk of unacceptably high electrical fault currents can be minimised through design criteria through effective levels of **electrical insulation/isolation**
- Insulation can be achieved through physical spacing, and **creepage and clearance of components**
- High voltage (up to 4000V AC) is applied across different parts of the electronic design in order to stress the **dielectrics**

SafeTest 60+ Key Features

- Straight out of the box simplicity
- Test to international standards - including leakage testing to IEC 60601, 62353, 61010 and NFPA-99.
- Our enhanced entry-level electrical safety analyser for medical devices
- Point to point insulation testing 100K – 100M Ω
- Dynamic pass/fail thresholds during measurement
- Compact, robust and portable design
- Manual control of fault conditions and tests
- Accurate high current, low energy earth bond testing
- Patient leakage testing
- Point-to-point insulation testing
- Automatic warning of secondary earth/ground paths
- 12 Month warranty



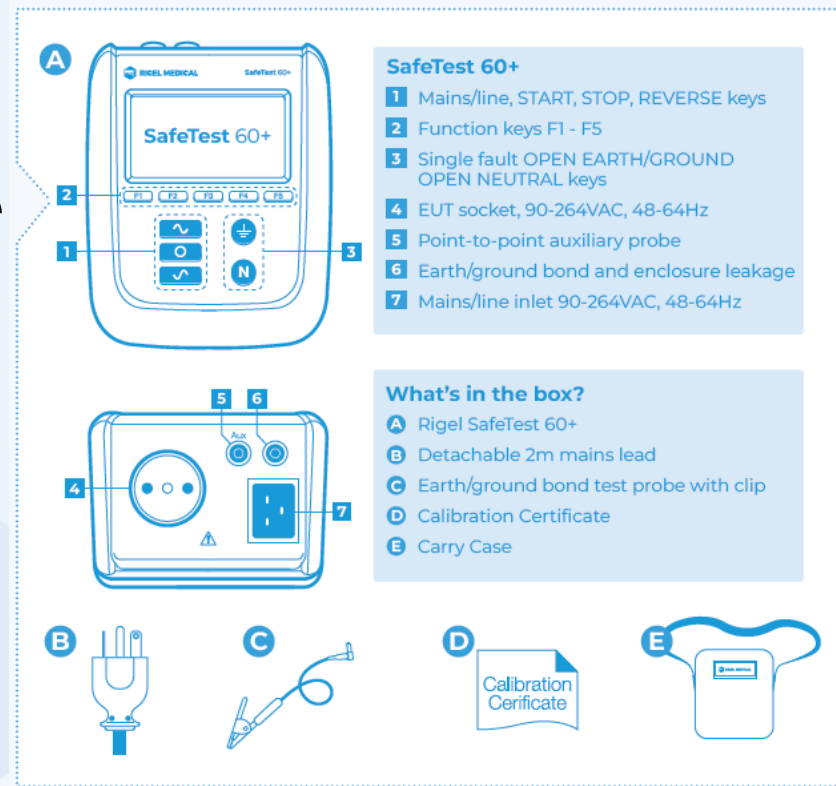
What's in the box?

In the box!

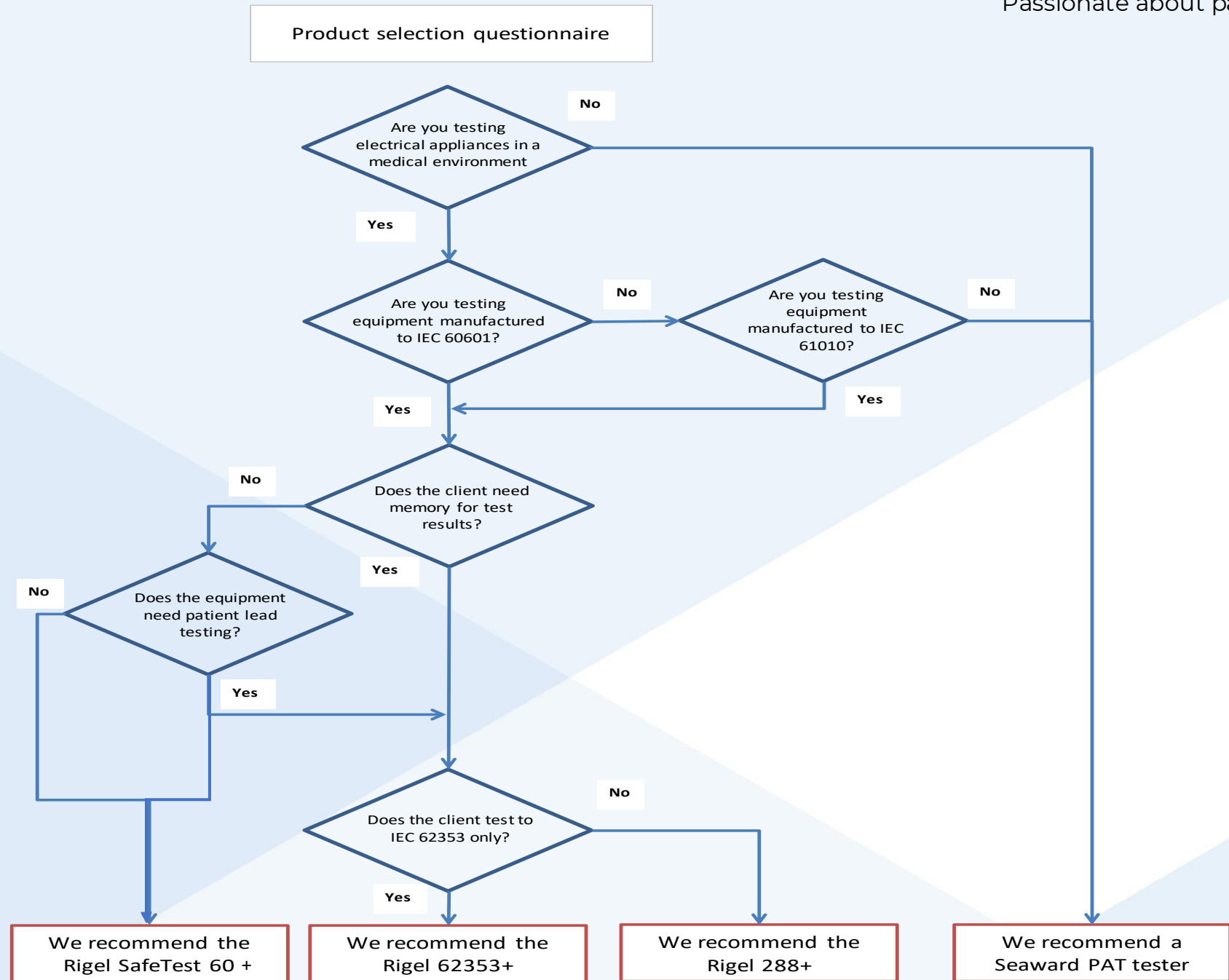
- Rigel SafeTest 60+
- Detachable 2m mains lead
- Earth/ground bond test probe with clip
- Calibration Certificate
- Carry Case

Optional Accessories:

- Earth bond cable
- Replacement carry case
- Patient lead adapter box
- Applied parts adapters

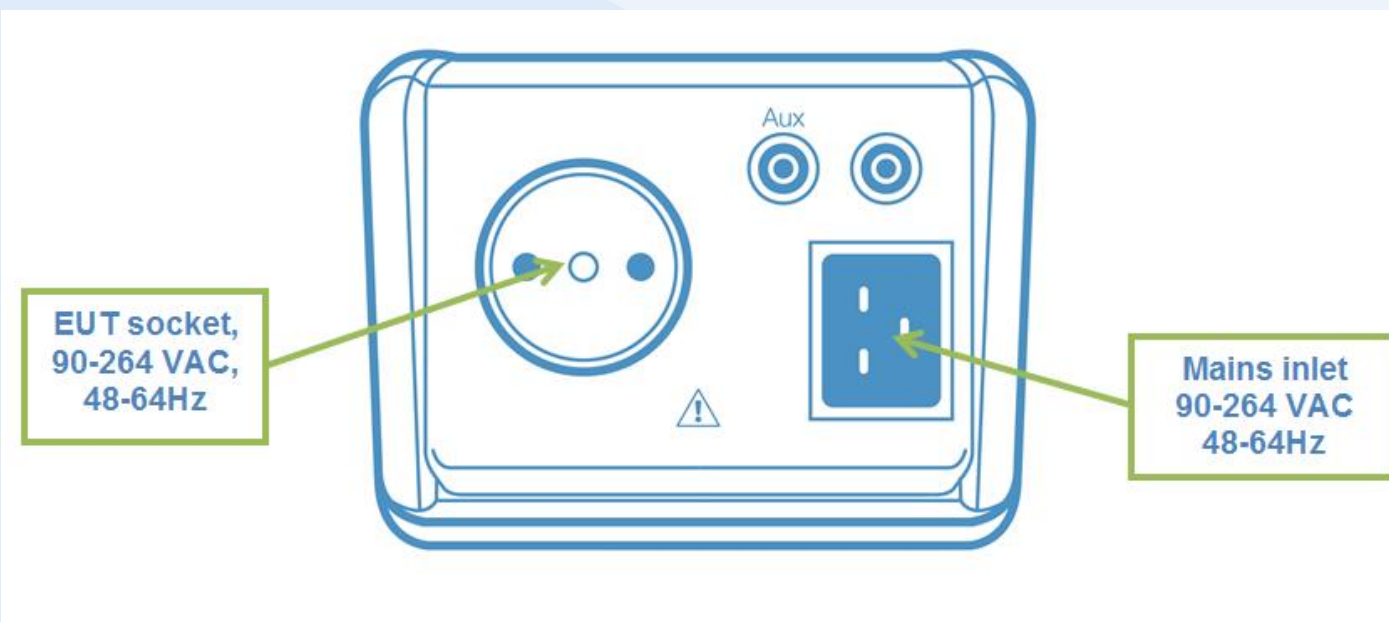


Choosing the right Electrical Safety Analyser



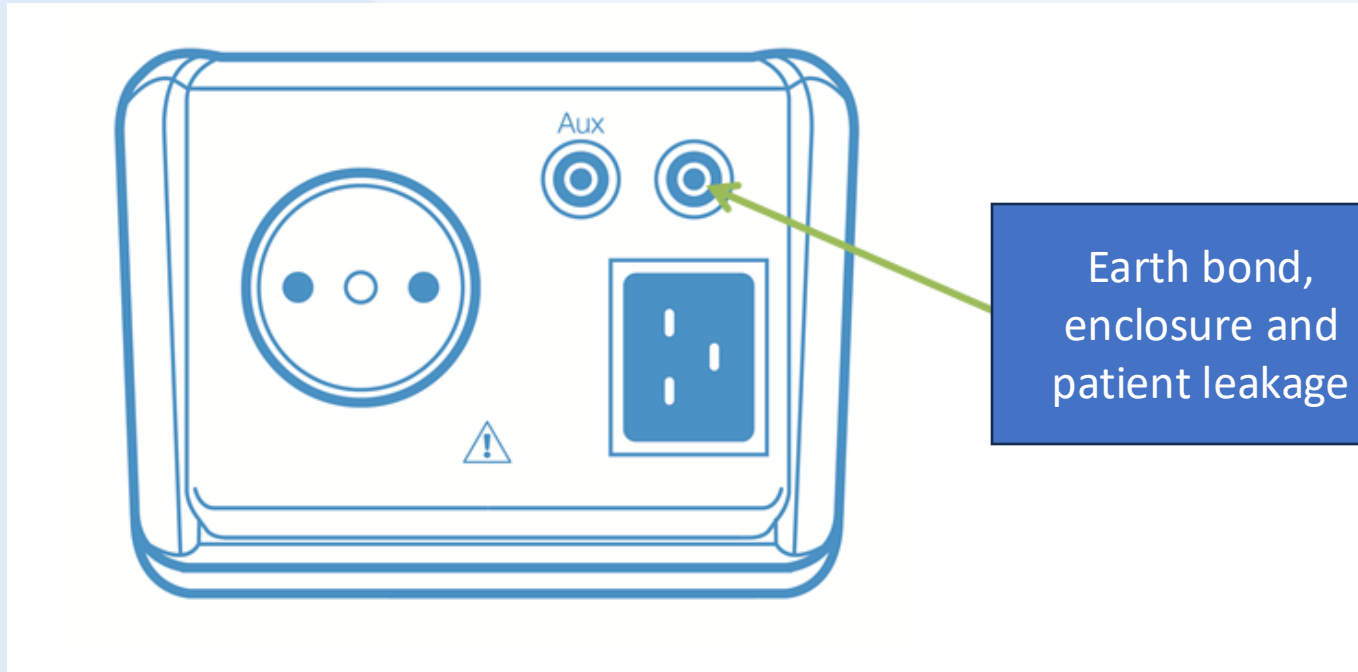
Operation

- The SafeTest 60+ works on any voltage between 90-264VAC 48-64Hz
- Output on the EUT socket equals incoming mains (ie 230V in = 230V out)



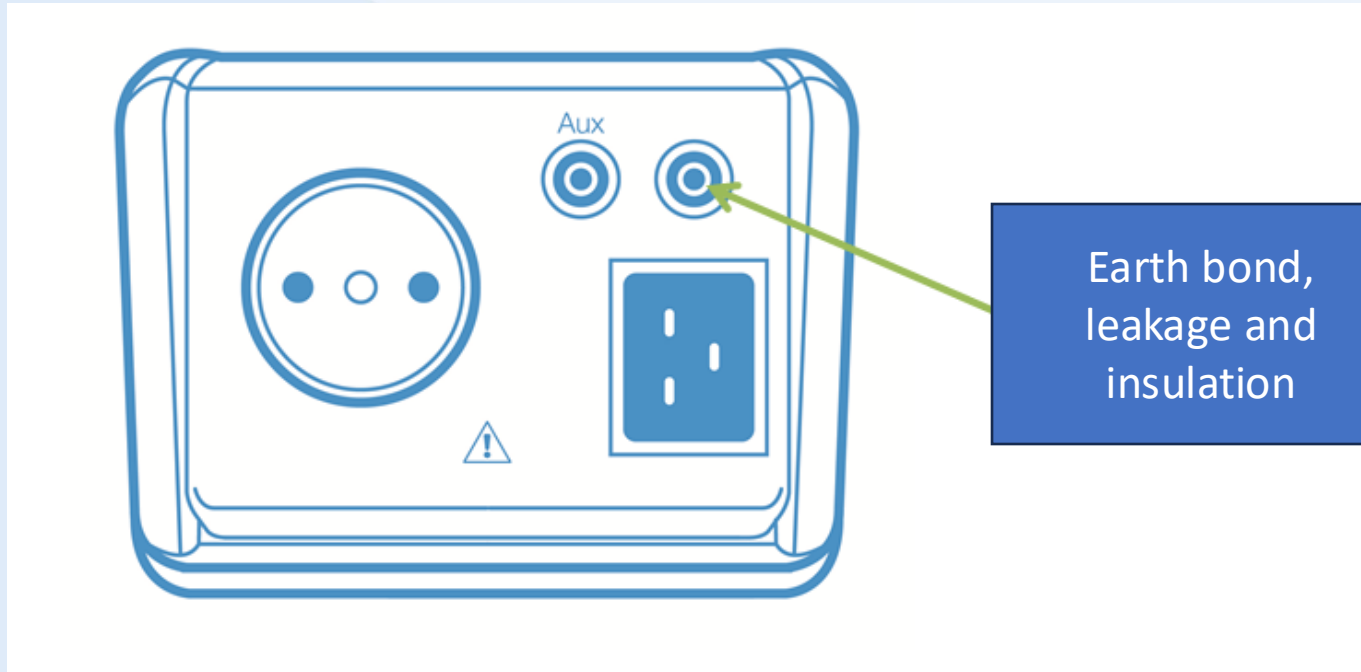
Operation

- Earth bond, enclosure leakage, and patient leakage are connected to the black 4 mm socket on the back panel



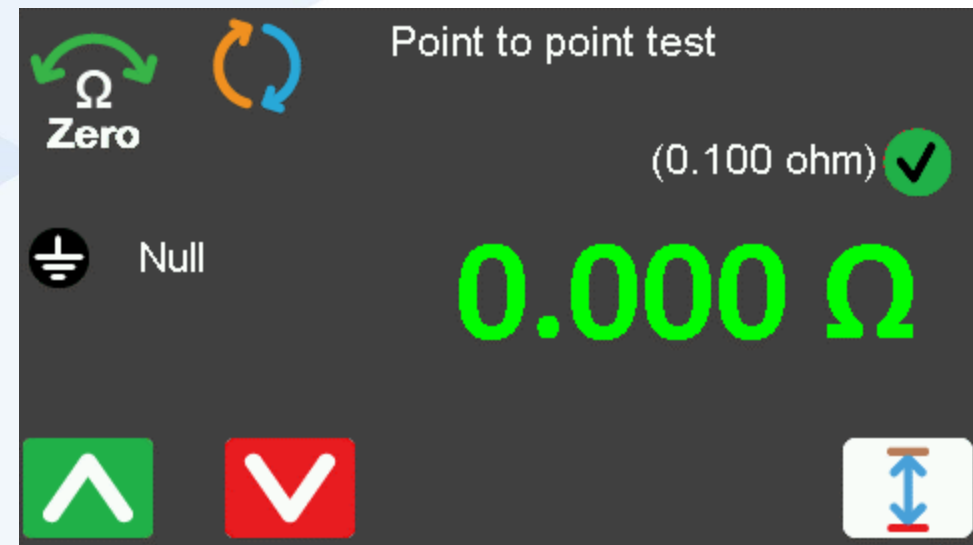
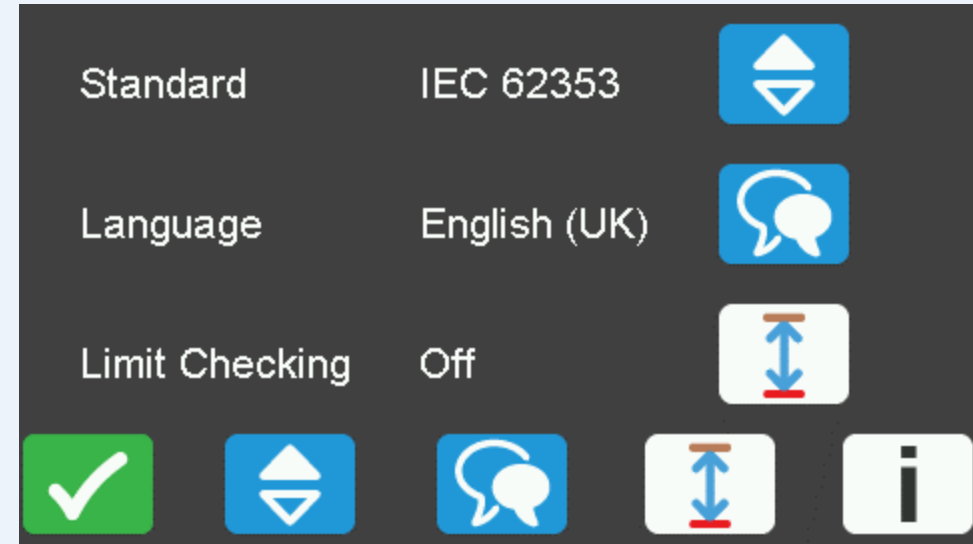
Operation

- **Point to point** leakage, earth bond and insulation probes are connected to the green 4 mm socket on the back panel



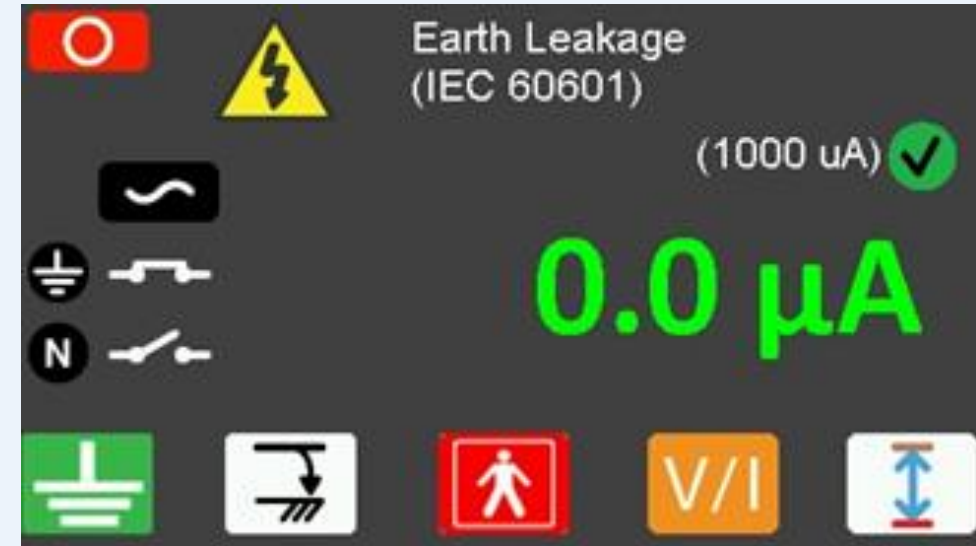
UI changes from the ST50

- **Settings** limits checking
 - Standards will default Class 1
 - Change to Limits save during power cycle
 - Limits will
- Language – Portuguese
- During the test limits can be changed by holding down F5 and adjusting F1 (increase) and F2 (decrease)
- Readings have conditional formatting **PASS/FAIL**



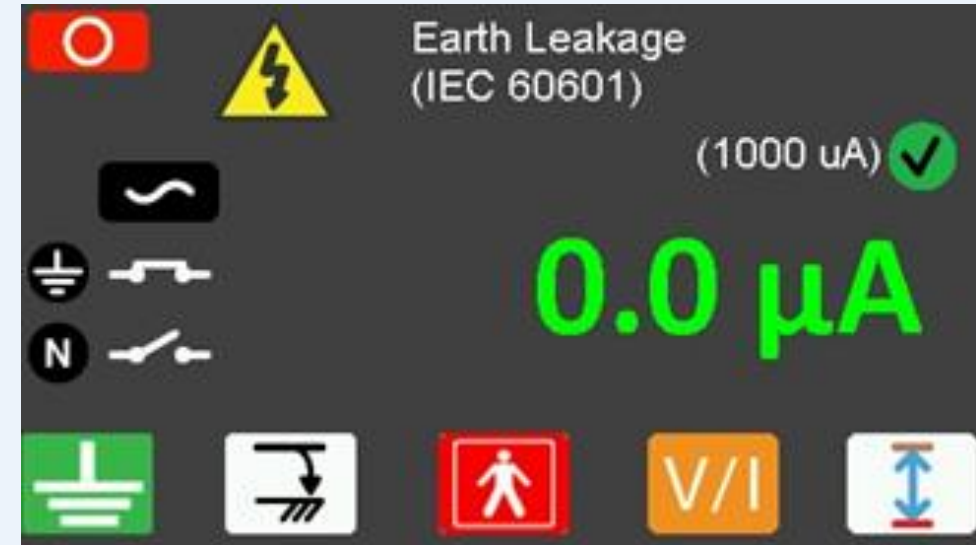
UI changes from the ST50

- Leakage
- The leakage menu now has all the leakage tests on one page derived from the selected standard
 - F1 now is [Earth Leakage](#)
- Patient leakage
 - The product can now measure Patient Leakage. All APs are shorted
 - The caveat is the user doing CF will have to do additional manipulation with APs the SafeTest 60+ does not cover



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