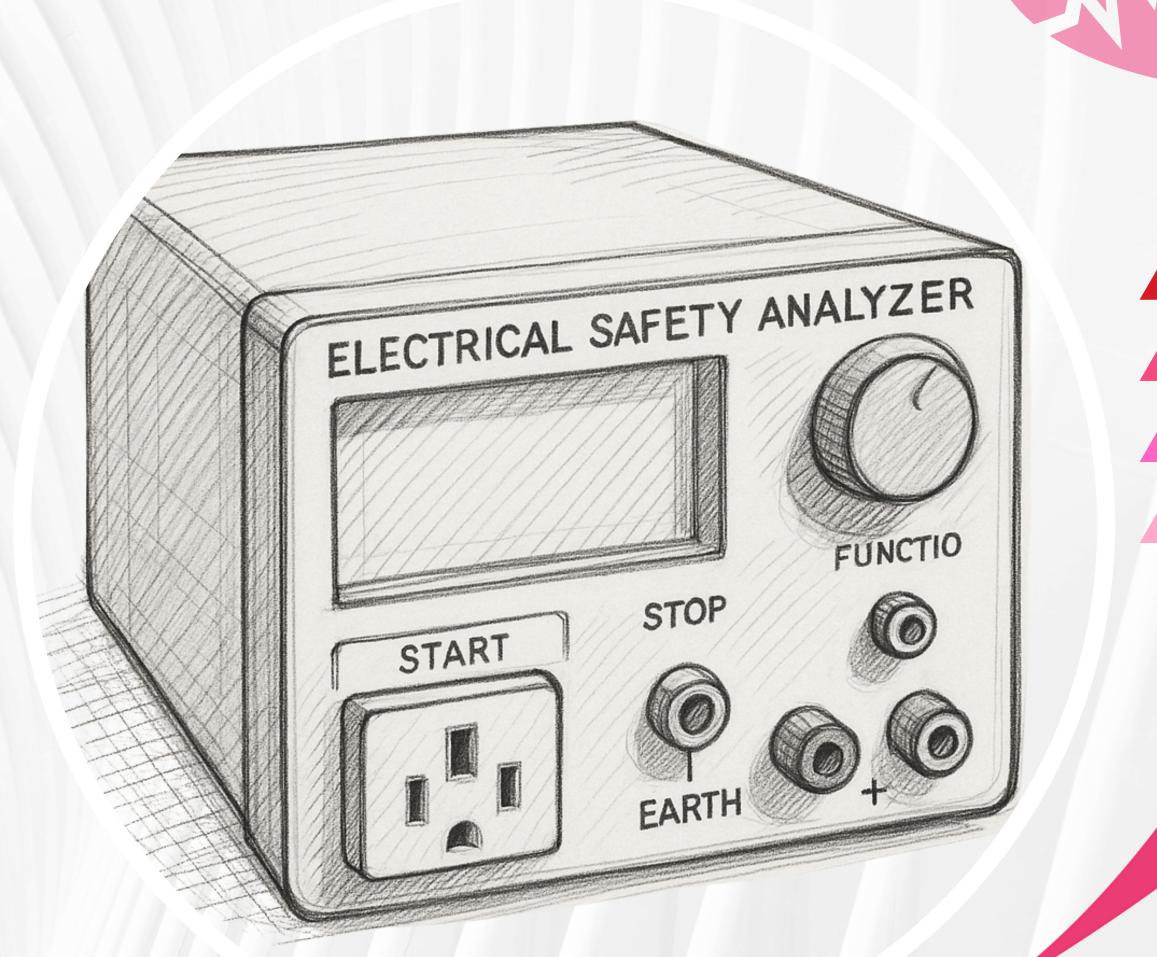


OF MEDICAL DEVICES: PRINCIPLES AND PRACTICAL APPLICATION USING RIGEL 288+ ANALYZER

A PRACTICAL GUIDE FOR HEALTHCARE ENVIRONMENTS



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ELECTRICAL SAFETY TESTING FOR MEDICAL EQUIPMENT

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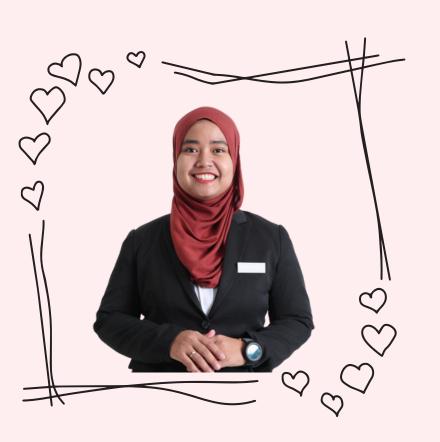
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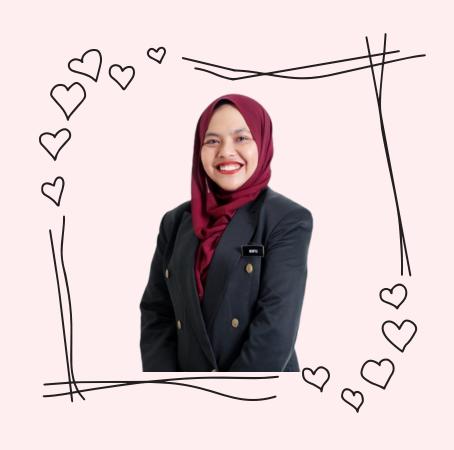


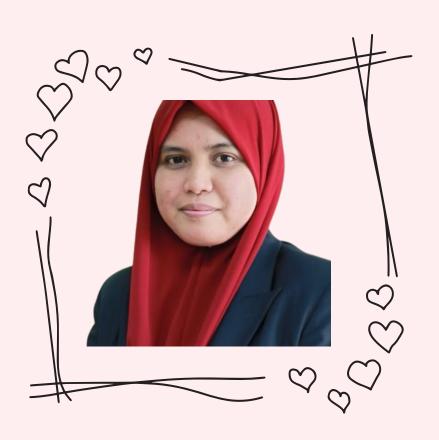




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A Practical Guide for Healthcare Environments



Electrical safety has always been a critical aspect in the field of electrical and electronic engineering. With the increasing use of electrical and medical devices in industries, laboratories, and healthcare settings, the need for precise and reliable safety testing has become more important than ever. To ensure that electrical equipment is safe for both users and patients, engineers and technicians rely on an instrument known as the Electrical Safety Analyzer (ESA).

This eBook is designed to provide readers with a comprehensive understanding of Electrical Safety Analyzers, their principles, applications, and practical importance in real-world scenarios. It introduces fundamental concepts of electrical safety, explains international standards and guidelines, and explores the methodologies used in safety testing. Through this, readers will gain insight into how ESAs are utilized to evaluate parameters such as earth continuity, insulation resistance, leakage current, and functional testing.

The content of this eBook is prepared to suit diploma students, technical trainees, and industry practitioners who wish to strengthen their knowledge of electrical safety testing. It also aims to bridge the gap between theoretical understanding and practical implementation, providing a structured pathway for learners to appreciate the relevance of safety compliance in electrical and medical technology. It is hoped that this eBook will serve as a valuable reso

urce, not only as a reference in classrooms and laboratories, but also as a guide for professionals who are committed to ensuring safety and compliance in their daily work. By mastering the use of Electrical Safety Analyzers, readers will be better equipped to contribute towards safer working environments and higher standards of electrical safety practices.



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CHAPTER 1:

& SAFETY ISSUES PURPOSE OF MEDICAL DEVICE REGULATION

INTRODUCTION

PUBLIC HEALTH & SAFETY ISSUES

Electrical medical devices play a vital role in diagnosis, treatment, and patient monitoring. However, because they are directly connected to patients or used in close proximity, these devices pose potential risks if not designed, manufactured, or maintained according to strict safety standards.

Some of the major public health and safety issues include:

- Electric shock hazards due to leakage current or poor insulation.
- Fire hazards caused by faulty wiring, overheating, or short circuits.
- Electromagnetic interference (EMI) that may disrupt device performance.
- Incorrect or unreliable readings, which may lead to misdiagnosis or inappropriate treatment.
- Patient vulnerability, especially in intensive care, surgical, and neonatal units where even small electrical currents can be life-threatening.

These risks highlight the importance of consistent safety testing, regulation, and monitoring throughout the lifecycle of medical equipment.



PUBLIC HEALTH & SAFETY ISSUE



Unavailability of pre-market control to assess safety, effectiveness and quality of medical device

Inadequate information for the public and health profesionals to make informed choices on medical devices

Lack of control over the usage of various medical devices and the usage of medical devices that have not been properly maintained and calibrated

The absence of post-market reporting system to identify and monitor medical devices with problems in the market

In the UK, legal obligations with regard to electrical safety are imposed on employers by "The Electricity at Work Regulations 1989"



Ensure public health & safety

Facilitate medical devices trade & industry

To allow patients for earlier access to new technology for early detection, diagnosis & treatment



Regulatory

FRAMEWORK & STANDARDS



International Electrotechnical Commission (IEC)

Non profit, non-governmental international standards organization that prepares and publishes International Standards for all electrical, electronic and related technologiies collectively known as "electrotechnology"

Design Time Safety & Performance

IEC 60601

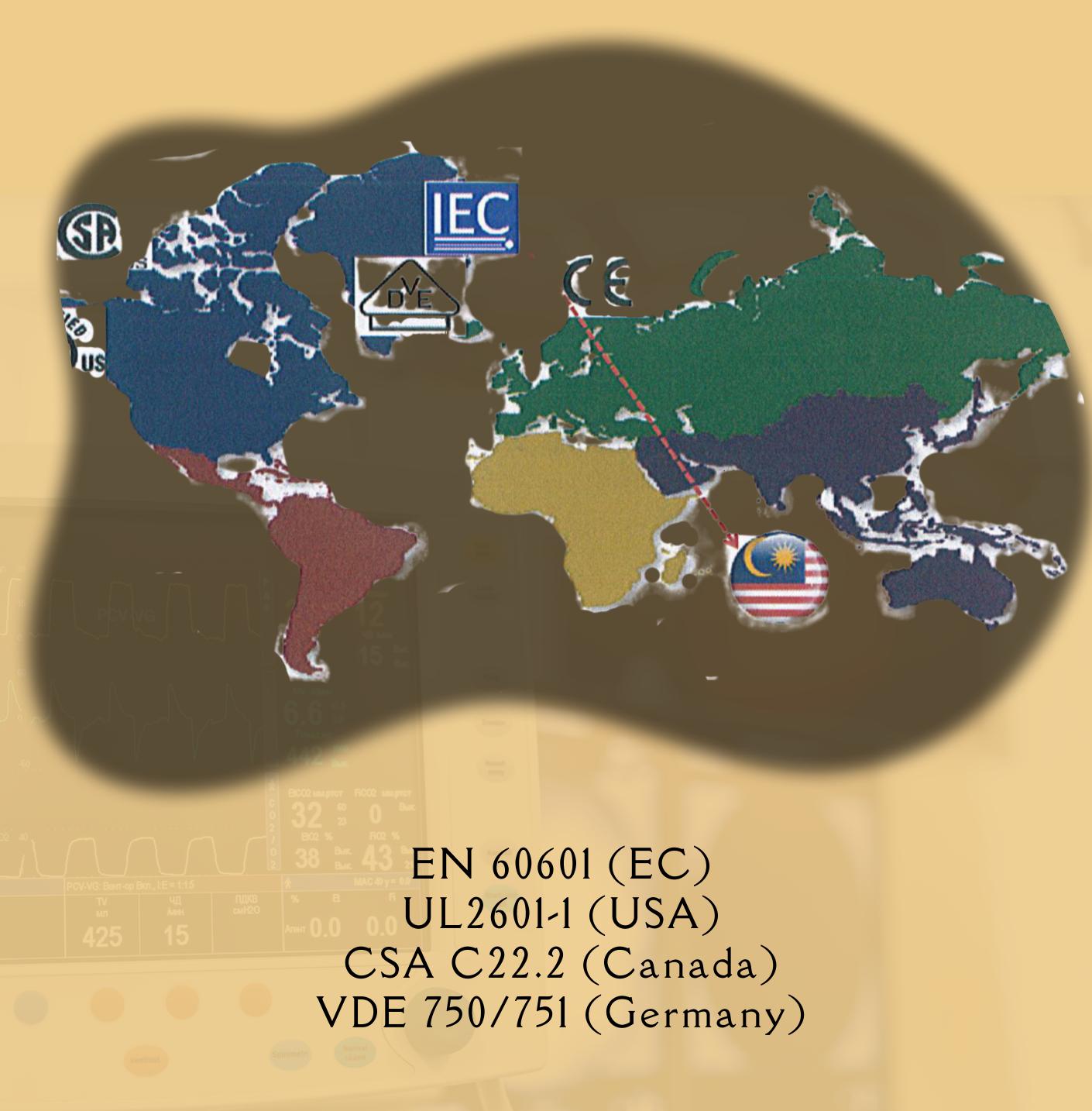


IEC 62353

Post-market testing & maintenance



Electrical Safety Standard for ME Equipment



Safety Stages through Product Life Cycle

2. Type Test
Hardware & Software of the product verified against design standards.
Product can be marketed after CE mark is obtained.

1. Design (R & D)
Subject to initial & clinical trials.
Electronic & Mechanical design
of the product must be in line
with IEC 60601

3. End of Line Test (Production)
The product being assembled,
tested & inspected.
Release into market place.

4. Acceptance (T &C)
Verify the device delivered in acceptable condition, without fault & available with accessories.
Electrical Safety & Performance test as part of reference for future maintenance.



5. Operator Training (User Training)
How to operate the device with the correct way. Reference: User Manual.
Safety Alert.

7. Maintenance (Repair)
Referred as Re-Active Maintenance.
Device create a fault OR require an upgrade, then it will susceptible to further inspections & testing.

6. Maintenance (Preventive)
Planned Preventive Maintenance
(PPM) referred as Pro-Active
Maintenance.
Scheduled inspections & tests to
verify the safety & operation are
within acceptable levels & criteria.

8. Decommissioning
Device (depends on its function & material content) required to follow a set process.
Hazardous product will need to follow a recycling process. Device can be made available to other organisations (2nd lifecycle can start at the Acceptance Stage).

IEC 62353:2014 Recommendation on New Product of ME Equipment



Once a design
is approved for manufacturing
& marketing, a subset of tests
will suffice to ensure the
product has been built &
assembled according to the
product quality & safety
requirement.

Subset of tests
(routine tests) are not clearly defined in IEC 60601 & can vary between manufacturers & product designs.

IEC 62353:2014 make recommendation that IEC 62353 can be used during final testing (final production line stage) & before new ME equipment goes into service.

Electrical Safety Standard for ME Equipment



IEC 60601 (referred as IEC 601)

Medical Electrical Equipment – General Requirements for Safety (1977)

01

IEC 62353

Medical Electrical Equipment – Recurrent Test and Test After Repair of Medical Electrical Equipment (2007)

02

IEC 61010

Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements (1990)

03







IEC 60601

01

All manufacturers of ME Equipment are required to use IEC 60601 Safety Standard to ensure product design intrinsically safe.

02

As a type testing standard

03

IEC 60601 is constructed from 2 parts:i. IEC 60601-1 (Collateral Standards)
ii. IEC 60601-2 & ISO/IEC 80601-2
(Particular Standards)

04

i. IEC 60601-1-X (Collateral Standards)
Primary Standard

Requirement for certain aspects safety & performance to the ME Equipment

05

ii. IEC 60601-2-X & ISO/IEC 80601-2-X

(Particular Standards)
Specific to various types of ME Equipment
Provides additional information to the
Collateral Standards.



IEC 60601-2-25 (Electrocardiograph-ECG)

This is a preview - click here to buy the full publication



IEC 60601-2-25

Edition 2.0 2011-10

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment -

Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs

Appareils électromédicaux -

Partie 2-25: Exigences particulières pour la sécurité de base et les performances essentielles des électrocardiographes

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

RICE CODE X

ICS 11.040.55; 11.040.99

ISBN 978-2-88912-719-1

IEC 60601-2-25 (Electrocardiograph-ECG)



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60601-2-25 © IEC:2011

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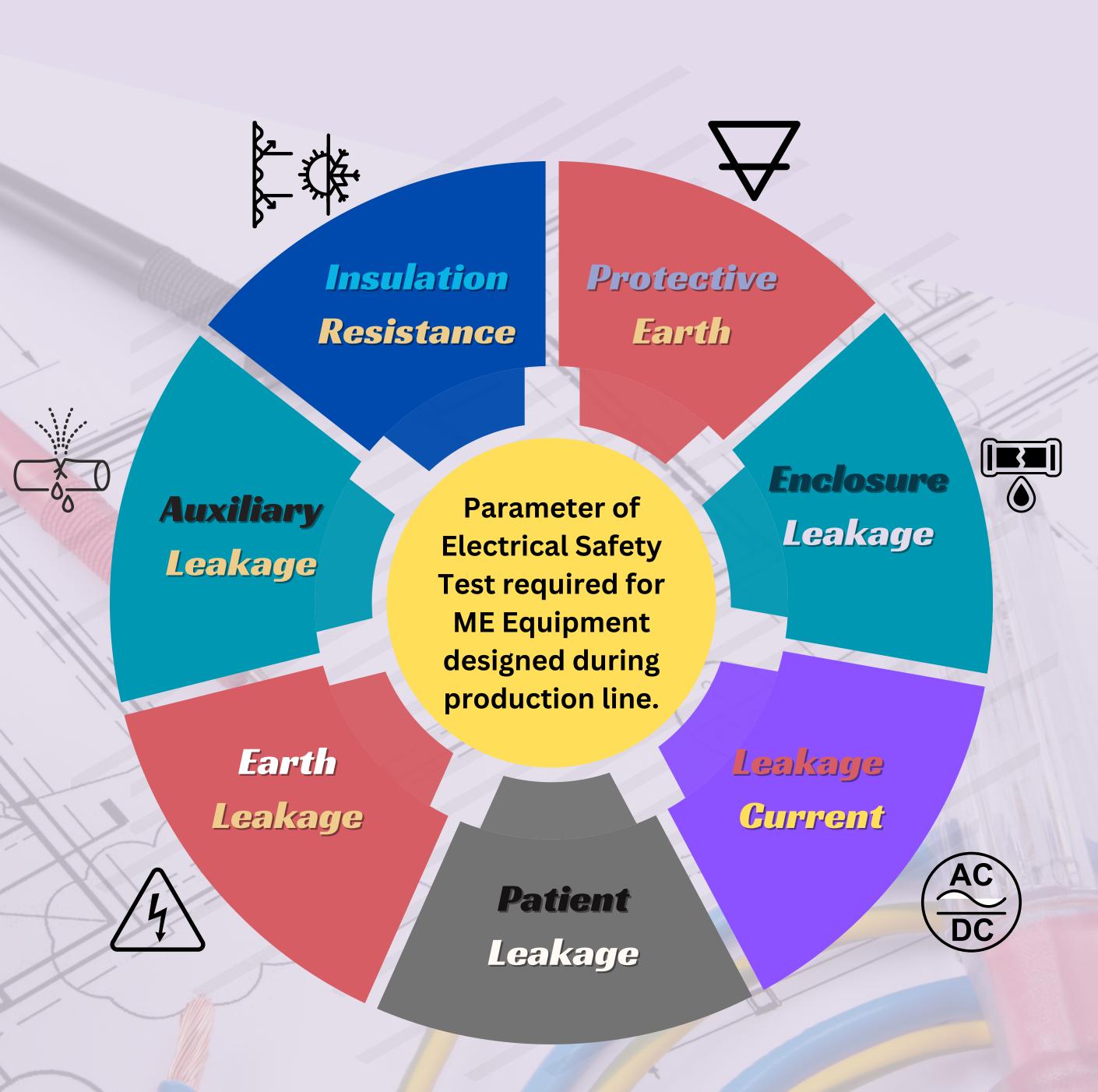
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IEC 60601 Parameter Test



Test Names Based on Selected Standard

| IEC60601 | |
|---|--|
| Protective Earth Resistance | |
| Earth Leakage Current | |
| Touch or Enclosure Leakage Current | |
| Patient Leakage Current | |
| Patient Auxiliary Leakage Current | |
| Mains on Applied Part (MAP) Leakage Current | |

| AAMI/NFPA 99 | | | |
|--------------------------------|--|--|--|
| Ground Wire Resistance | | | |
| Ground Wire Leakage Current | | | |
| Chassis Leakage Current | | | |
| Lead to Ground Leakage Current | | | |
| Lead to Lead Leakage Current | | | |
| Isolation Leakage Current | | | |

The Importance of Leakage Current in IEC 60601

Has both electrical & mechanical requirements to reduce electrical hazards in both under Normal Condition (NC) & Single Faults Condition (SFC).

Normal Condition (NC)
Equipment energized in both standby & full operation.

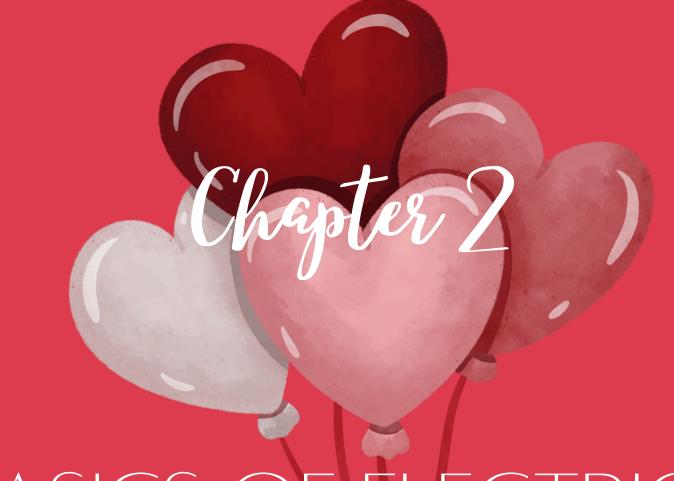
Single Fault Condition (SFC)
Electrical safety protection for the equipment is defective OR an abnormal condition is present.

Example:

- 1. Interruption of Ground conductor on Class I equipment.
- 2. Neutral Supply conductor to the equipment is OPEN.

Unlike other standards, electrical safety is not considered to be dependent on Voltage, but on Leakage Current (current that is not functional).

This is because even in a very low voltage, when the leakage currents go through body, it may cause fatal.



BASICS OF ELECTRICAL SAFETY

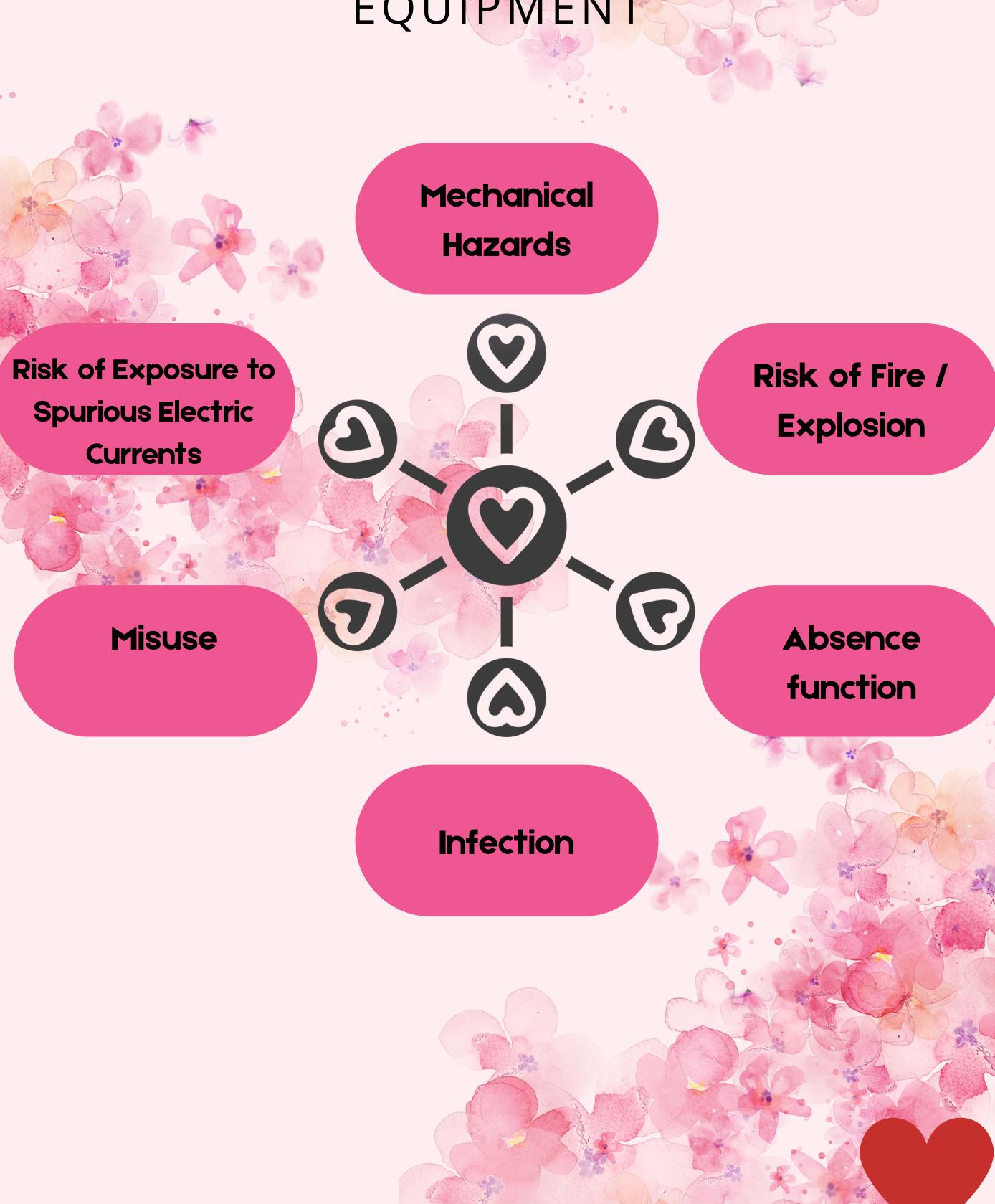


Types of Hazards

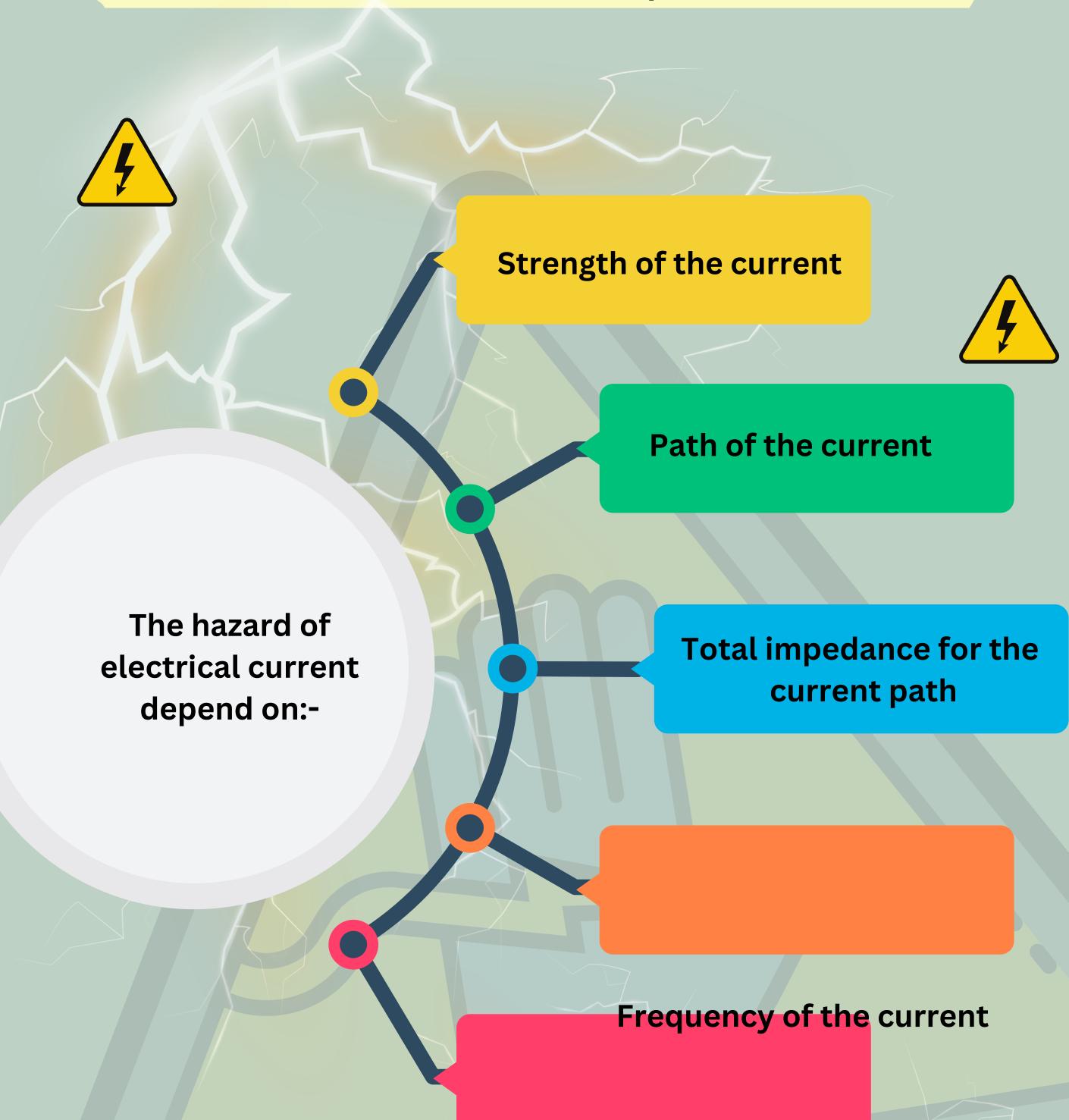
Key Terminologies (Leakgae Current, Protective Earth & Insulation Resistance)



OF MEDICAL ELECTRICAL
EQUIPMENT







Duration of the current being applied



Cont; nue

Electrical
current can be
extremely
dangerous to the
human body



Energy (power & time factor) releases by electrical current passing through human tissue can generate burns & excite or stimulate muscles of the respiratory system (intercostal).

Cont;nue

The most critical muscles are those in the human HEART (driven or excited by very tiny amounts of electrical currents.

When the heart is exposed to external electrical currents (electrical shock), the heart can lose its Normal Sinus Rhythm (NSR) & move into Ventricular Fibrillation.

This will stop the circulation of oxyhaemoglobin (oxygenated blood cells) to the brain & organs. When left untreated, it will result in death within 15 minutes.

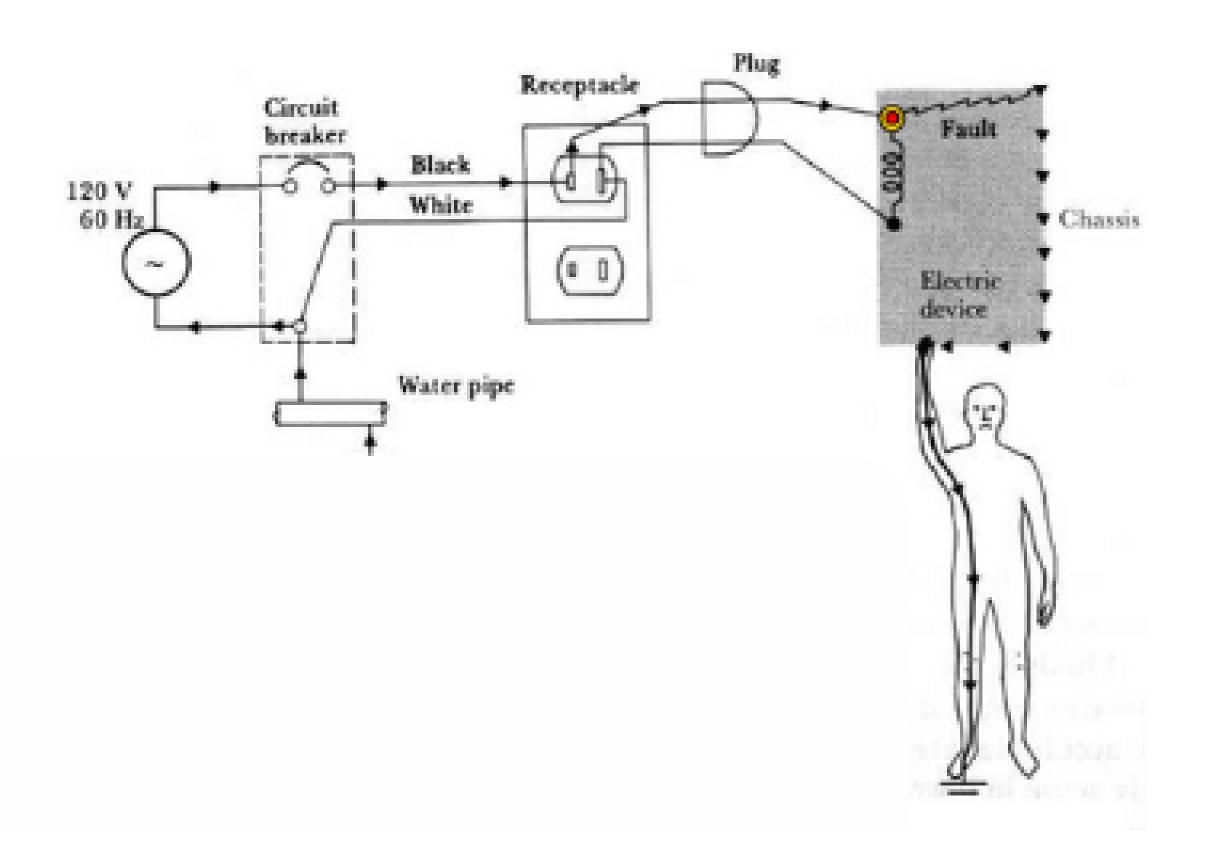
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The most common treatment of Ventricular Fibrillation is by using Defibrillator.



It deliver a very high current pulse (up to 100 A across the heart).

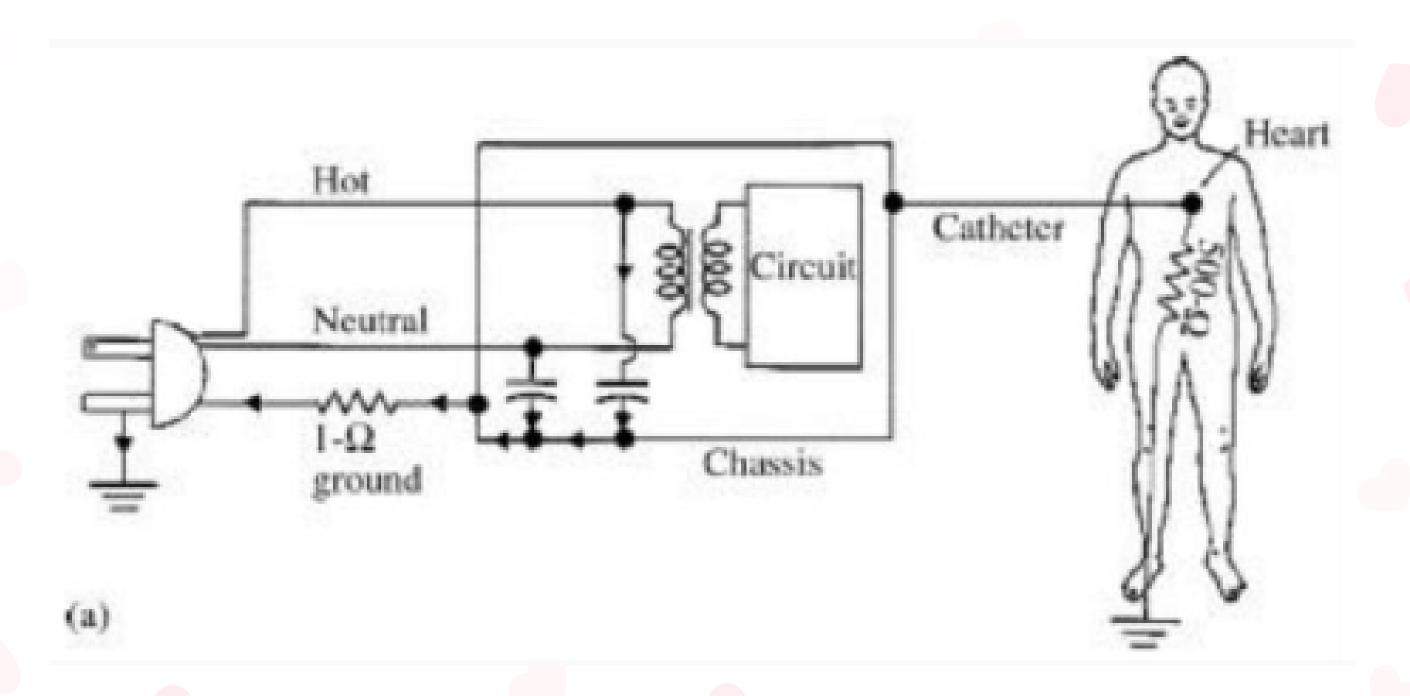
Ironically, the energy in that high current pulse is sufficient to temporarily clamp the heart muscles (stop the heart completely) before releasing it again & allowing the heart to resume in its NSR.



MACROSHOCK

HAZARDS

- Direct faults between the live conductor and the ground is not common, and technically speaking, ground connection is not necessray during normal operation
- In fact, a ground fault will not be detected during normal operation of the device, only when someone touches it, the hazard becomes known
- therefore, ground wire in devices and receptacles must be periodically tested

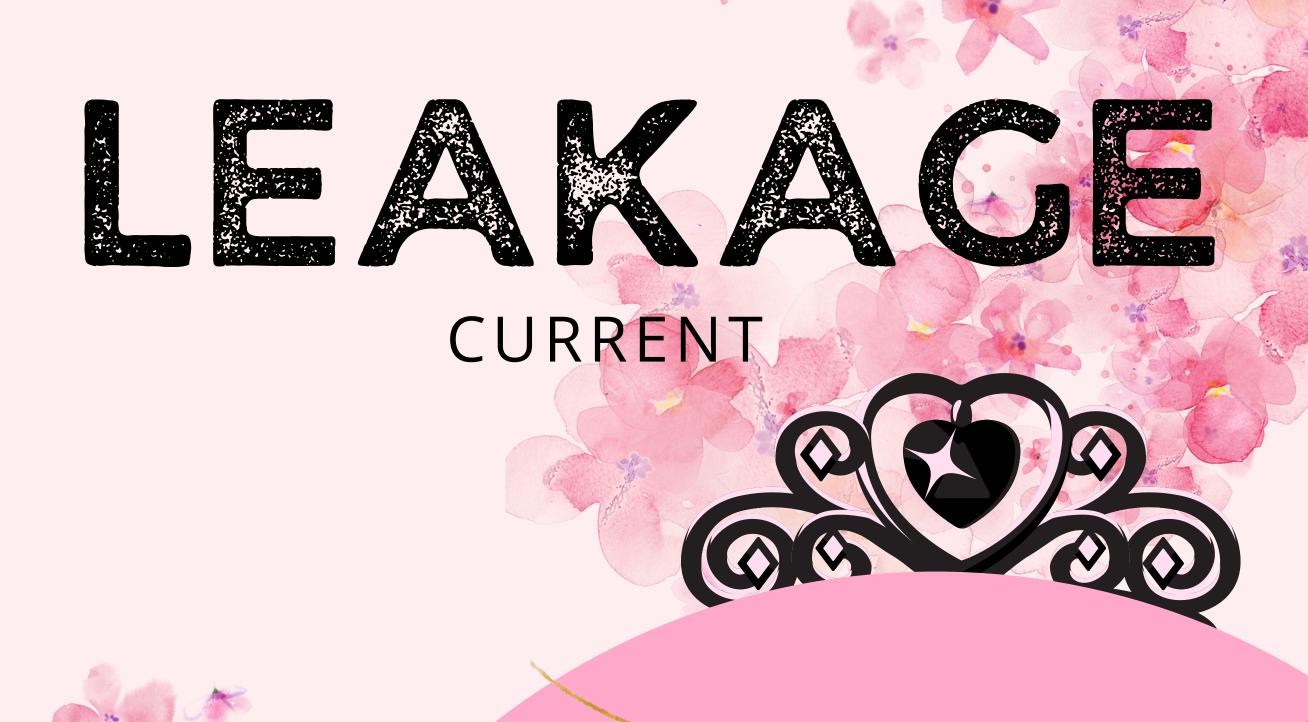


MICROSHOCK

HAZARDS

- Small currents inevitably flow between adjacent insulated conductors at different potentials leakage currents which flow through stray capacities, insulation, dust and moisture
- Leakage current flowing to the chassis flows safely to the ground, if alow resistance ground wire is available.







If a conductor is raised to a potential above earth, some current flow to earth. Amount depends on volatge on conductor, capacitance between conductor and earth and resistance between conductor and earth



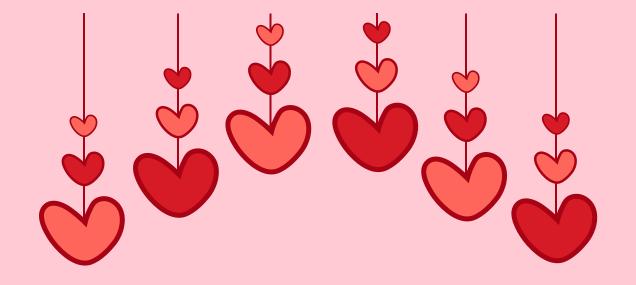
Inherent flow of non functional current from live electric parts



Magnitude of leakage current is determined by the value of the capacitance present



Originates due to capacitive coupling from the power transformer primary to other parts of the transformer/instrument



TYPES OF LEAKAGE CURRENT



ENCLOSURE LEAKAGE CURRENT: CURRENT FLOWS IN NORMAL CONDITION FROM THE ENCLOSURE (OR PART OF ENCLOSURE) THROUGH A PERSON IN CONTACT WITH AN ACCESSIBLE PART OF ENCLOSURE TO EARTH (OR ANOTHER PART OF THE ENCLOSURE)



EARTH LEAKAGE CURRENT: CURRENT FLOWS IN NORMAL CONDITION TO EARTH FROM MAIN PARTS OF APPARATUS VIA EARTH CONDUCTOR



PATIENT LEAKAGE CURRENT: CURRENT FLOWS THROUGH PATIENT FROM OR TO APPLIED PARTS OF THE PATIENT CIRCUITS







REGULATORY STANDARDS OVERVIEW



Types of Standards

Medical Active Device - Classification

& Insulation Resistance)

TYPES OF STANDARDS IEC 60601

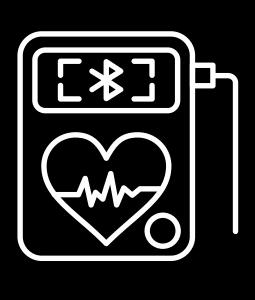


| Basic safety standards – Horizontal Standard | Indicates the general safety requirement to a wide range of product and or process | IEC 60601-1, General safety requirements of medical electrical equipment ISO 13485:2006 basic international standard for quality management system in medical devices industry |
|---|--|---|
| Group Safety standards- Semi horizontal standard | Indicates requirements applicable to similar products and or process | IEC 60601-1-2, general requirement of safety of medical electrical equipment electromagnetic compatibility |
| Product safety-Vertical standard | Are used for specific products and or process | IEC60601-2-12, particular requirements for safety of lung ventilators |





Classification





Protection against electrical shock (Class I, Class II , Class III)



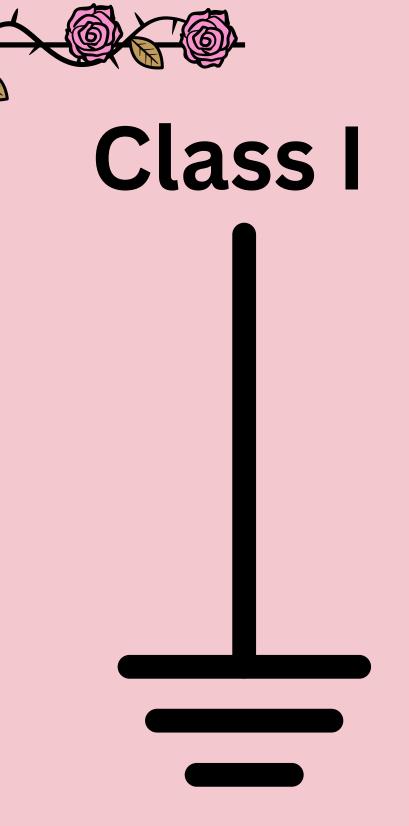
Degree of protection against electric shock (B,BF and CF)



Risk level associated with usage









Protection is the insulation between live parts and exposed conductive parts



Supllementary protection



Have fuses at the equipment end of the mains supply lead in both live and neutral conductors



3 prong power cord



Protection is double insulation or reinforced insulation preventing contact with live part

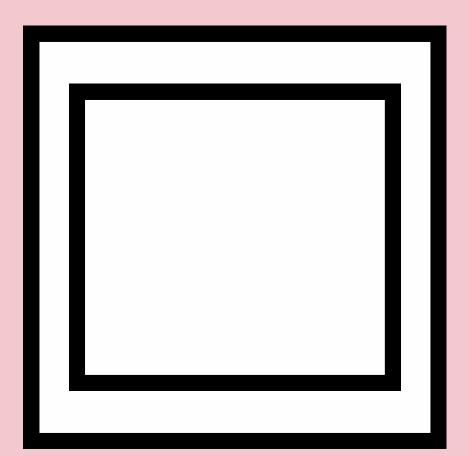


Have fuses at yhe equipment end of the mains supply lead



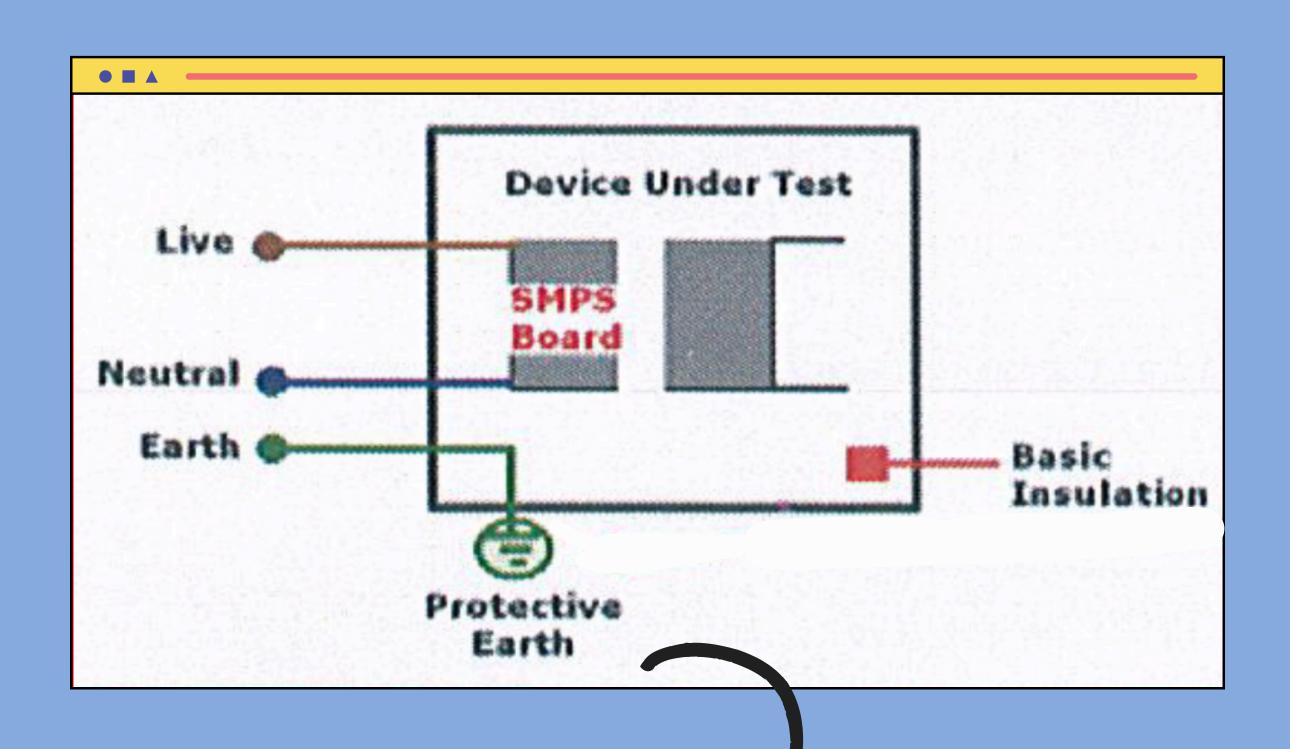
2 prong power cord

Class II





Class I Diagram



Switch Mode Power Supply





Protective Earth



Class I



Plastic casing does not necessarily indicate that the equipment is not Class I.



Protection is either **Double Insulation** OR **Reinforced Insulation**



Double Insulation

Basic Protection is afforded by the first layer of insulation.

Supplementary Protection is provided by a second layer of insulation

(preventing contact with live parts)



Reinforced Insulation

Single layer of insulation (twice as thick) but it has same protection against electrical shock as double insulation.



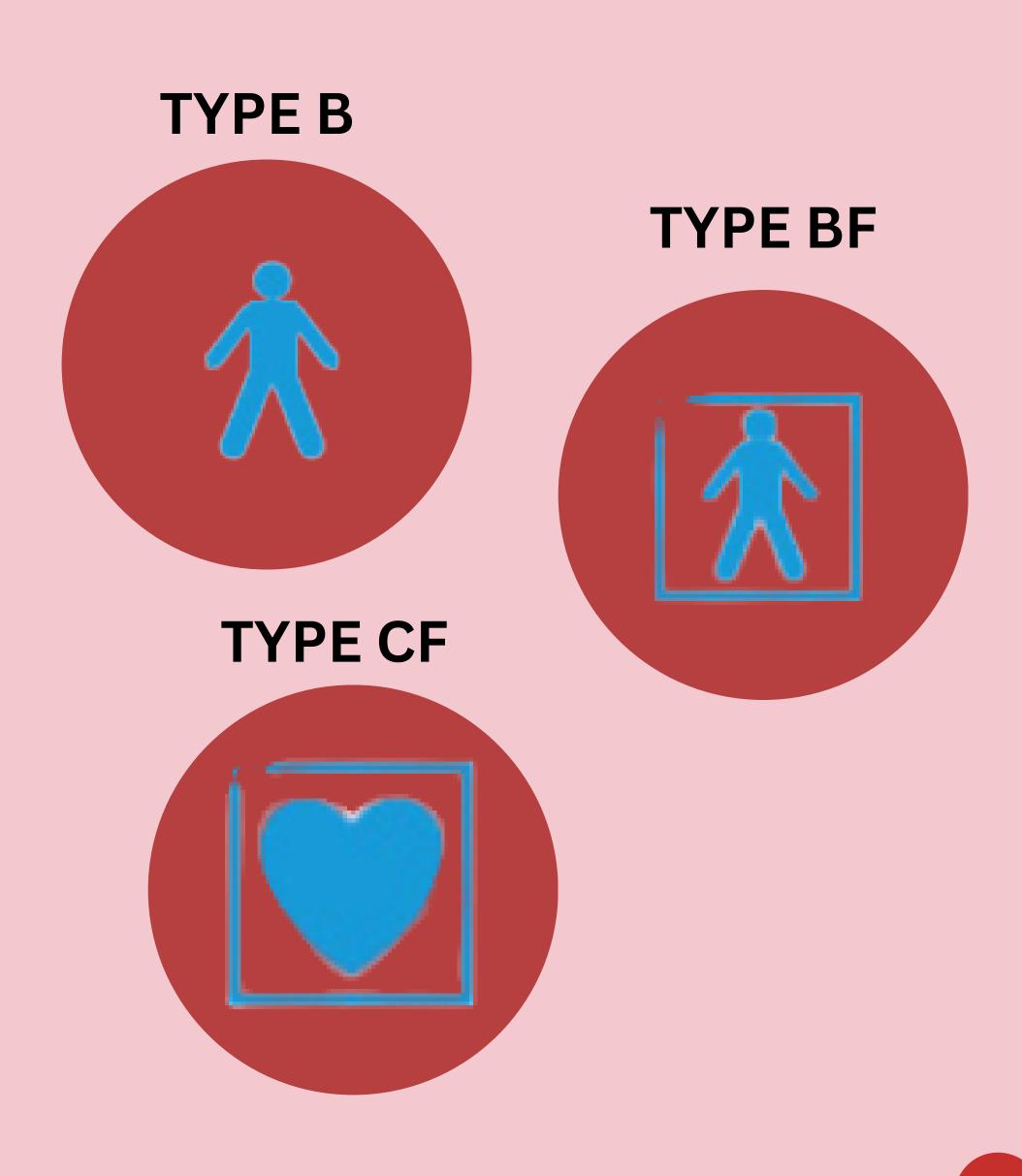
Protection relies on the fact that no voltage higher than safety extra low voltage (SELV) are present.

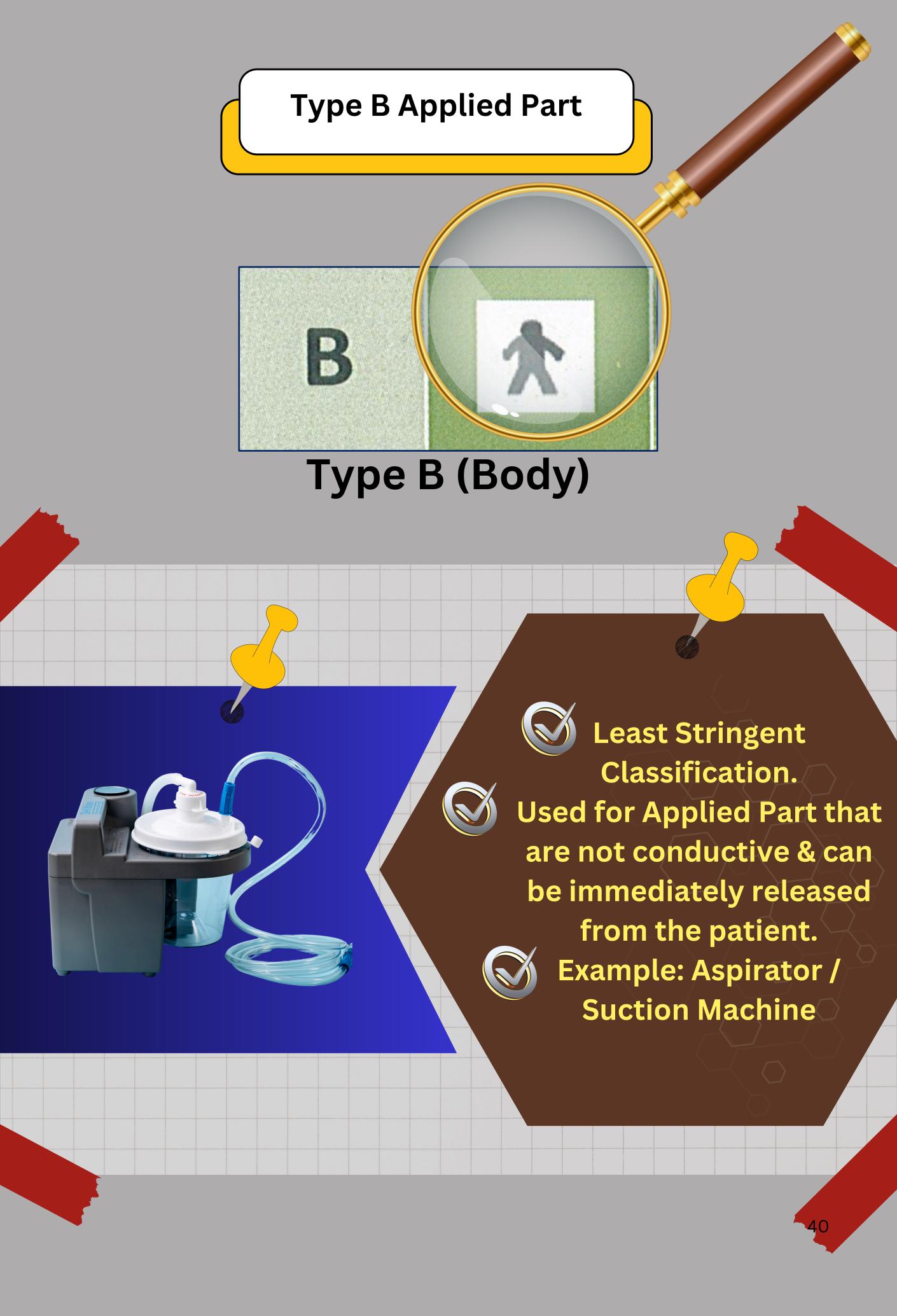
SELV is defined im turn in the relevant standard as a voltage not exceeding 25V ac or 60V dc.

Battery operated or SELV transformer

Not recognized for electrical safety requirement anymore

Limitations of voltage is not deemed sufficient to ensure safety of patient.











Type BF (Body Floating)

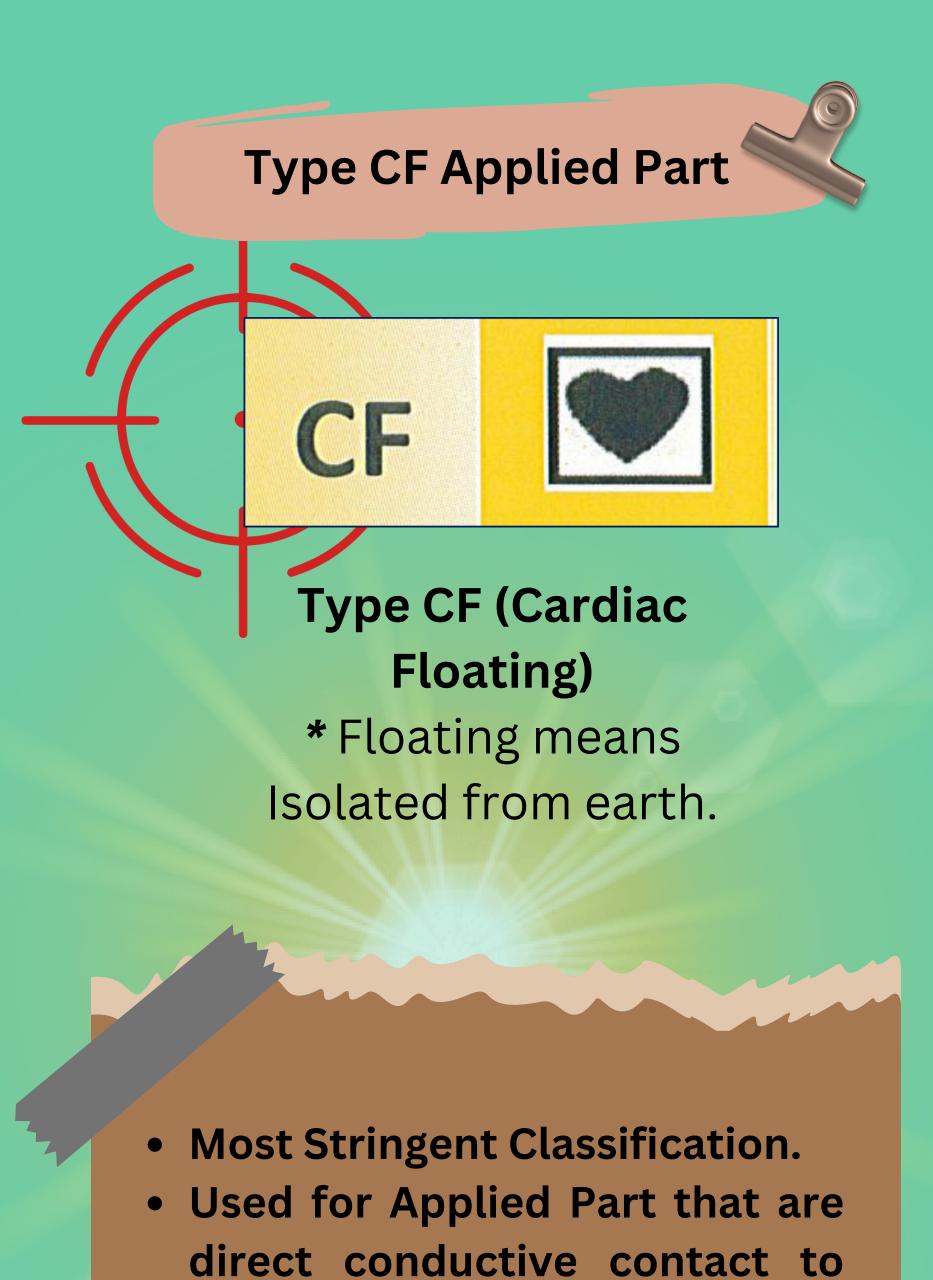
* Floating means Isolated from earth.

- Less Stringent Classification.
- Used for Applied Part that are conductive & having medium or long term contact with the patient.
- Example: Infusion Pump



The first IV infusion device was invented by Christopher Wren (who was a renowned English architect) in 1658.

Funfact!



the heart or other applications

• Example: Electrocardiograph

42

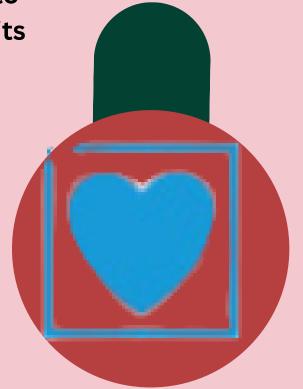
as considered necessary.

(ECG)

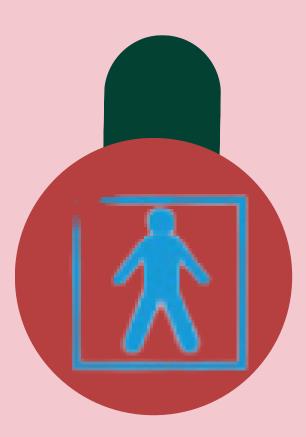
| Feature | Type B (Body) | Type BF (Body Floating) | Type CF (Cardiac Floating) | |
|---|--|---|---|--|
| Definition | Applied parts with the least stringent leakage current requirements. Suitable for non-invasive contact with the patient. | Applied parts with more stringent leakage current requirements. Patient connection is isolated ("floating") from earth. | Applied parts for direct cardiac connection or use on the heart. Most stringent leakage current limits. | |
| Typical Use | External devices not connected directly to the heart or critical organs. | External or invasive devices but not directly connected to the heart. | Devices that connect directly to the heart or measure from cardiac signals. | |
| Examples | Hospital beds, examination lights, ultrasound probes (non- invasive), MRI coils. | ECG electrodes, infusion pumps, incubators, operating tables, patient monitors. | Internal ECG catheters, pacemakers, defibrillator leads, heart catheters. | |
| Isolation from Earth | Basic insulation; may be earthed. | Floating from earth; double/reinforced insulation between patient and ground. | Fully floating; highest isolation between patient and ground. | |
| Leakage Current Limits (Normal Condition) | ≤100 µA | ≤100 µA | ≤10 µA | |
| Leakage Current Limits (Single Fault Condition) | ≤500 µA | ≤500 µA | ≤50 µA | |
| Symbol on Device | Capital "B" in a box. | Capital "BF" in a box. | Capital "CF" in a box. | |
| Typical Safety Testing | Earth leakage, insulation, visual inspection. | Patient leakage current test with floating reference, insulation tests. | Patient leakage current test under stringent conditions, isolation verification, dielectric strength test. | |



Instruction: Draw a line to connect each symbol to its correct statement.









IEC 60601 defines leakage current of three different sources:

1. Earth Leakage Current (Protective Conductor Current)

- Earth leakage current is the current that flows from the mains supply through the equipment's protective earth conductor back to ground. This test checks that the grounding system is functioning correctly and that the equipment does not pass excessive current through the protective earth.
- Purpose: Protects against shock hazards due to a fault in the insulation or a short to the metal enclosure.
- How it's measured: The device is powered normally, and current in the earth conductor is measured relative to ground.
- Typical limit: About ≤500 microamps under normal conditions,
 ≤1000 microamps under single-fault conditions (depending on equipment category).

- Enclosure leakage current is the current that could flow from exposed conductive parts of the enclosure or chassis to earth through a person touching it. This simulates an operator or healthcare worker touching the outer surface of the equipment.
- **Purpose:** Ensures that any conductive part accessible to the user or operator is safe to touch.
- How it's measured: A test circuit simulating human body impedance is connected between the exposed metal surfaces and earth ground to measure current flow.
- Typical limit: Around ≤100 microamps for Type B or BF applied parts and ≤10 microamps for Type CF applied parts under normal conditions, with higher but still limited current under single-fault conditions.

2. Enclosure Leakage Current (Touch Current)

3. Applied Part / Patient Leakage Current

- Applied part (or patient) leakage current is the current that can flow from the applied part through the patient to earth or between two applied parts. Because patients are more vulnerable, these limits are the most stringent.
- Purpose: Protects patients who may have direct electrical connection to the device (electrodes, catheters, probes).
- How it's measured: Current is measured between the applied parts and earth ground or between multiple applied parts, using a human body model circuit.
- Typical limit:
 - **Type B:** ≤100 microamps under normal conditions, ≤500 microamps under single fault.
 - Type BF: same as Type B.
 - Type CF: ≤10 microamps under normal conditions, ≤50 microamps under single fault.



25 A Test Current in IEC 60601



- High level of test current (25 A) will cause the temperature to rise throughout the protective grounding conductor path.
- In the event of a damaged protective grounding conductor (most strands are broken), a high current (25 A) test may also detect the damage by "fusing" the cable.
- Fusing occurs due to the heating effect of the test current (Current flow, generate heat & wire melts apart, resulting in an open circuit).

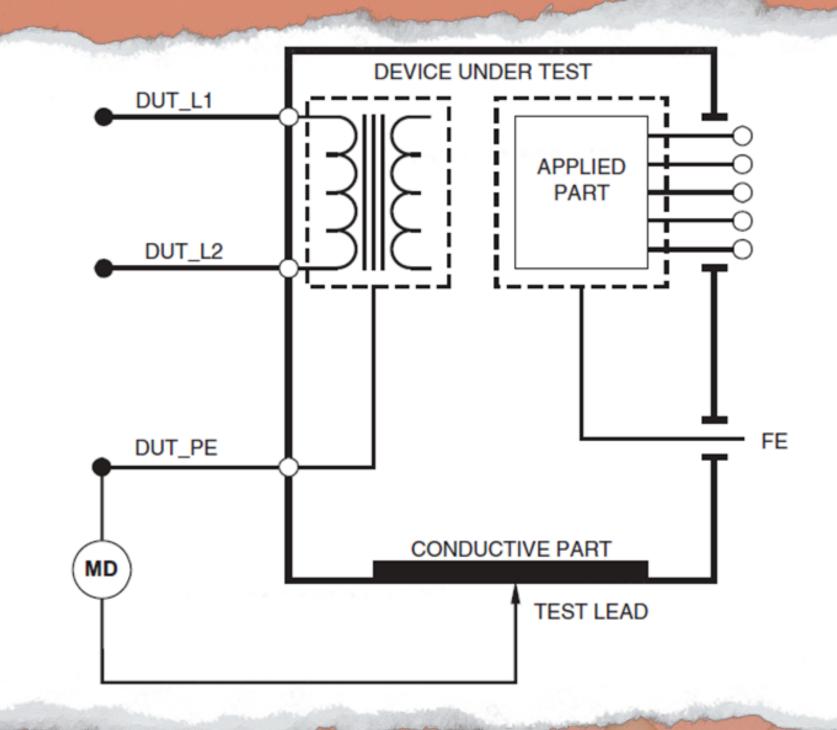
 The higher the current OR the longer the test duration, the higher the probability of fusing the damaged cable.



Leakage Current Limits of IEC 60601

| | Type B Applied Parts | | Type BF Applied Parts | | Type CF Applied Parts | |
|---------------------------------------|-------------------------|--------|--------------------------|--------|--------------------------|--------|
| Leakage Current Type | NC | SFC | NC | SFC | NC | SFC |
| Earth Leakage (General) | 0.5mA | 1mA | 0.5mA | 1mA | 0.5mA | 1mA |
| Enclosure Leakage | 0.1mA | 0.5mA | 0.1mA | 0.5mA | 0.1mA | 0.5mA |
| Patient Leakage (DC) | 0.01mA | 0.05mA | 0.01mA | 0.05mA | 0.01mA | 0.05mA |
| Patient Leakage (AC) | 0.1mA | 0.5mA | 0.1mA | 0.5mA | 0.01mA | 0.05mA |
| Patient Leakage (F- Type) | NA | NA | NA | 5mA | NA | 0.05mA |
| Patient Leakage (Mains on SIP/SOP) | NA | 5mA | NA | NA | NA | NA |
| Patient Auxiliary Current (DC) | 0.01mA | 0.05mA | 0.01mA | 0.05mA | 0.01mA | 0.05mA |
| Patient Auxiliary Current (AC) | 0.1mA | 0.5mA | 0.1mA | 0.5mA | 0.01mA | 0.05mA |

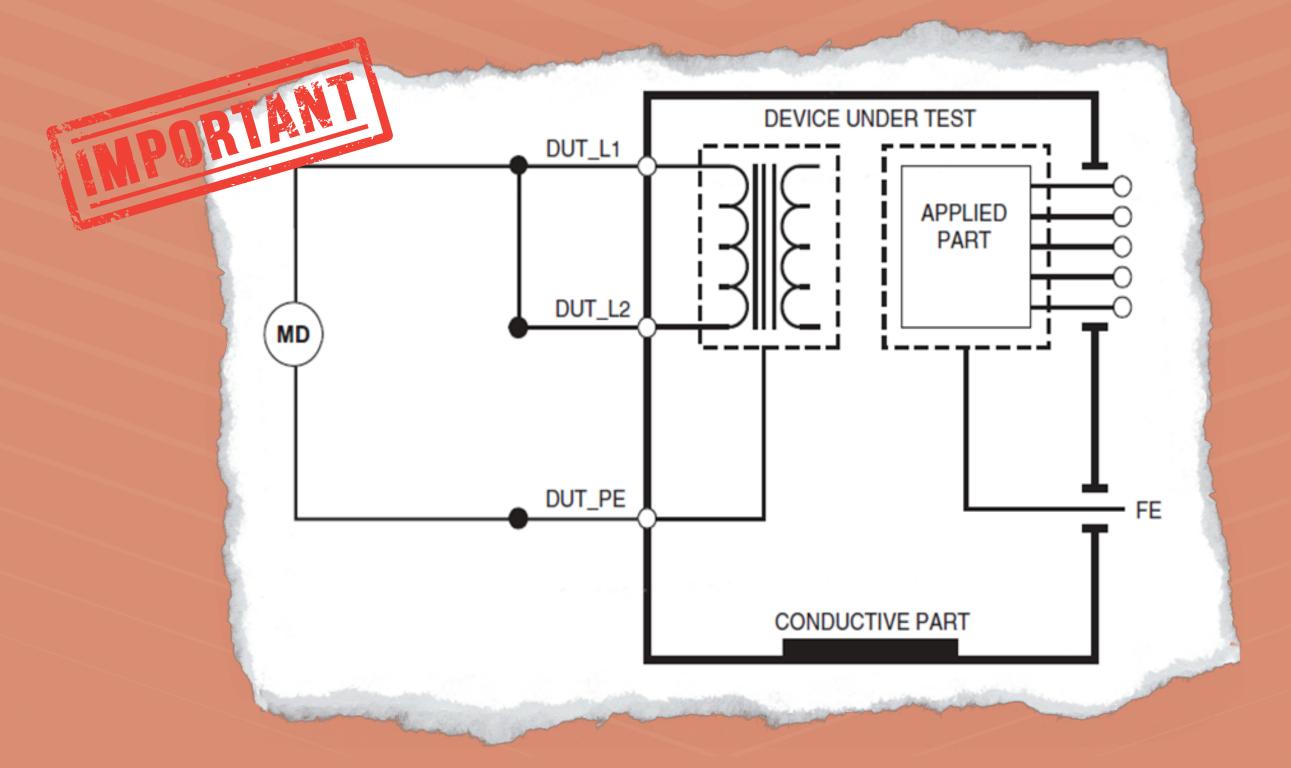
Protective Earth Resistance (PE)



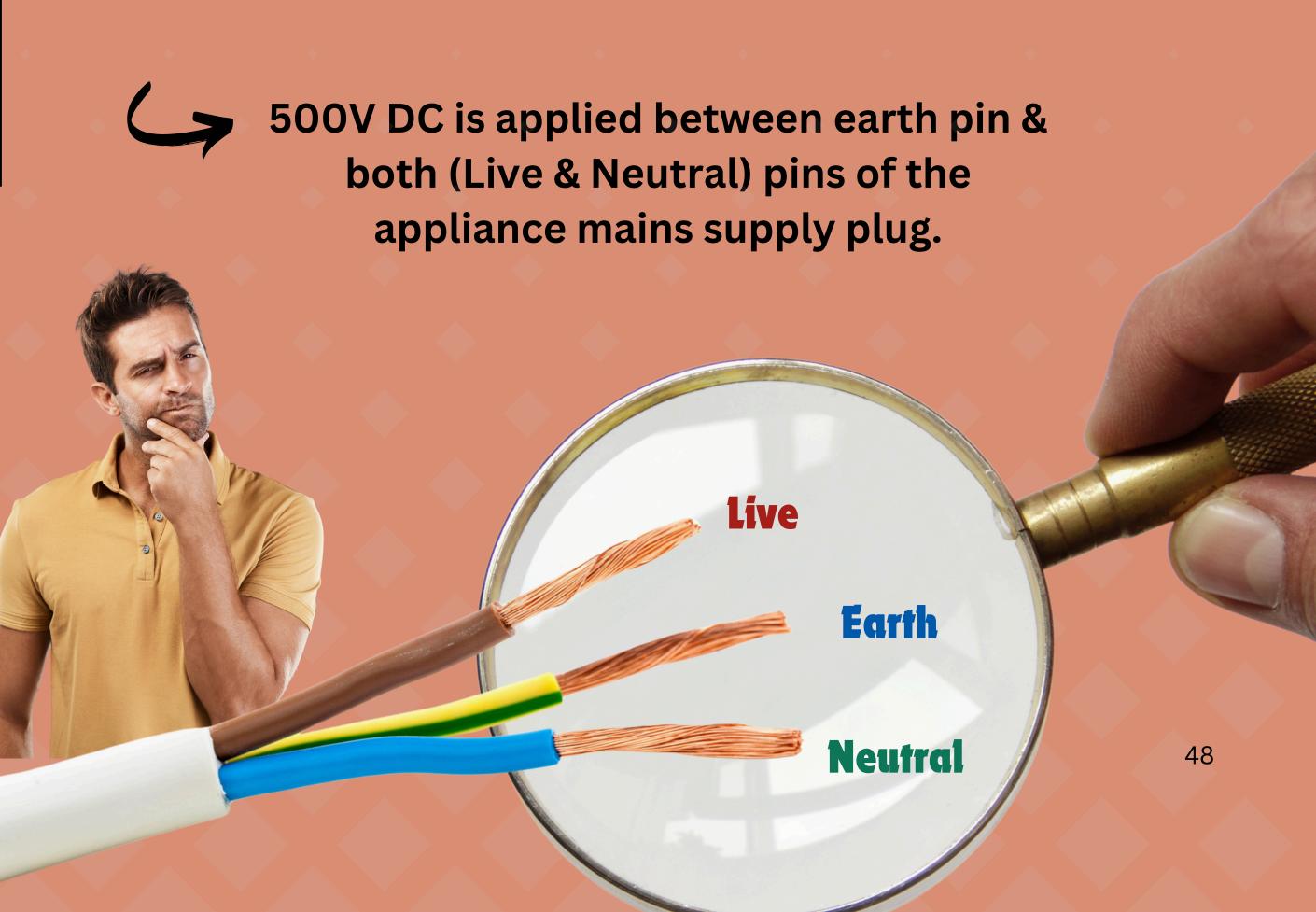
Protective Earth Resistance Test Schematic

Measure the impedance between the Analyzer's (MD) test receptacle's PE terminal & the exposed conductive parts of the Device Under Test (DUT) that are connected to the DUT's Protective Earth.

Insulation Resistance (Mains to PE)

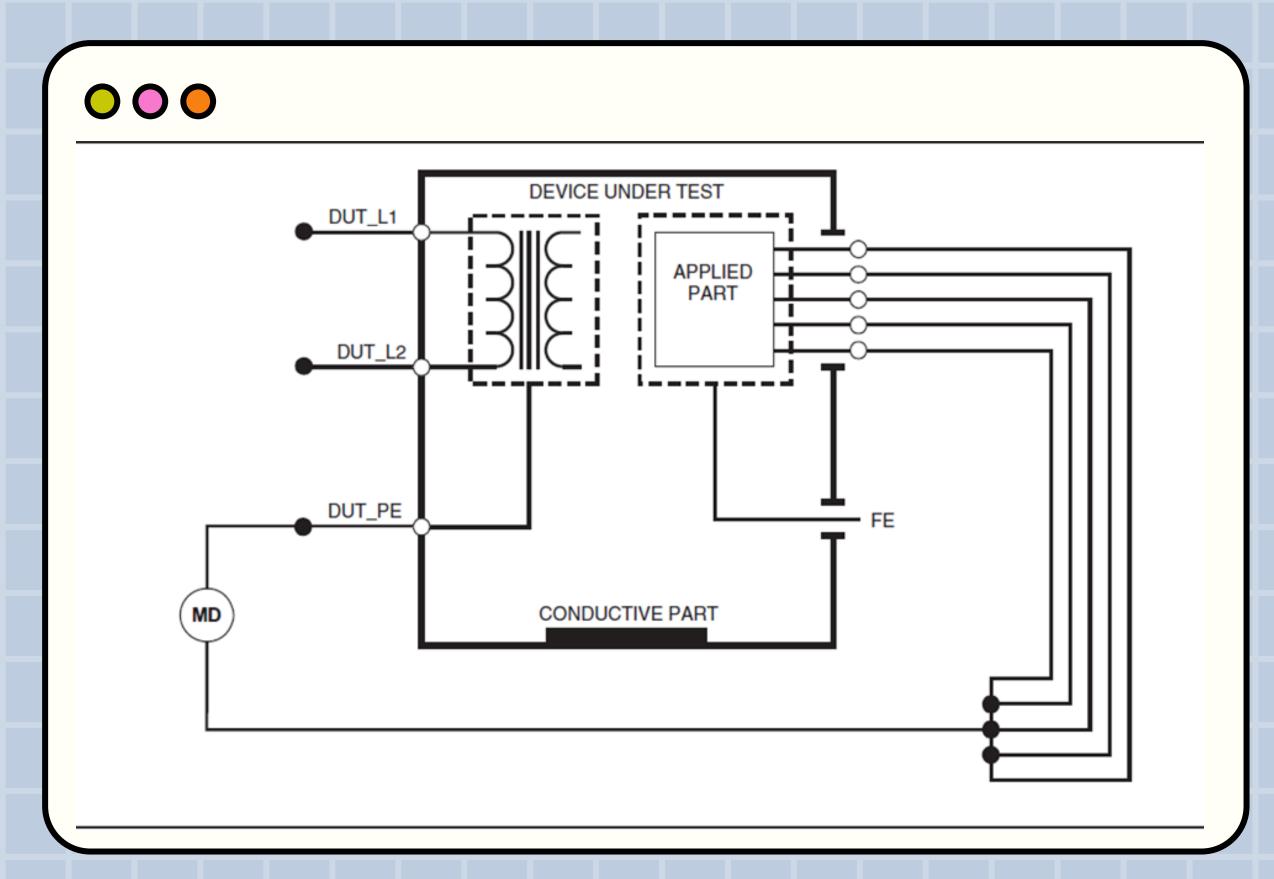


Insulation Resistance (Mains to PE) Test Schematic



Insulation Resistance (Applied Parts to PE)





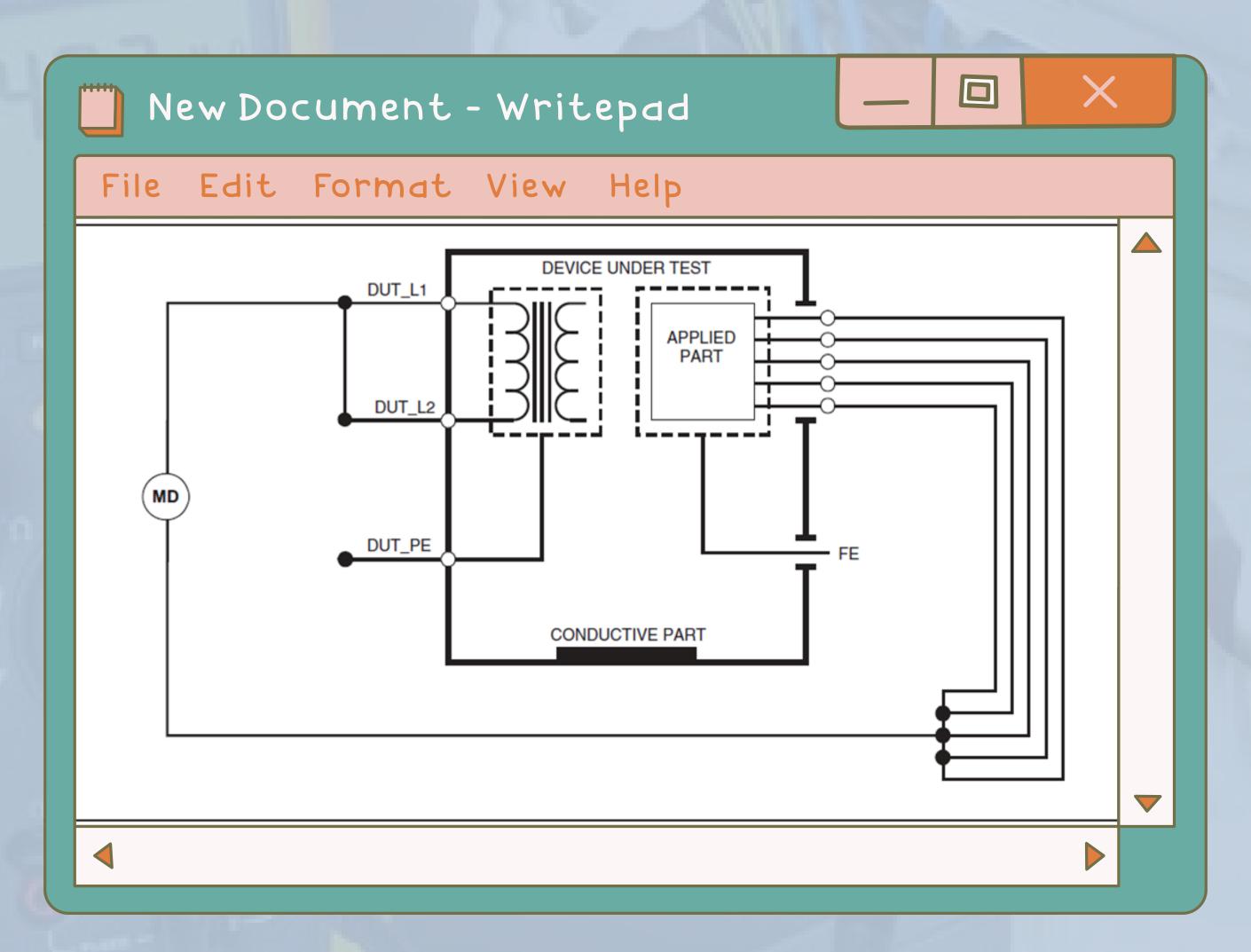
Insulation Resistance (Applied Parts to PE) Test Schematic



500 V DC is applied between earth pin & all applied parts combined.



Insulation Resistance (Mains to Applied Parts)



Insulation Resistance (Mains to Applied Parts)

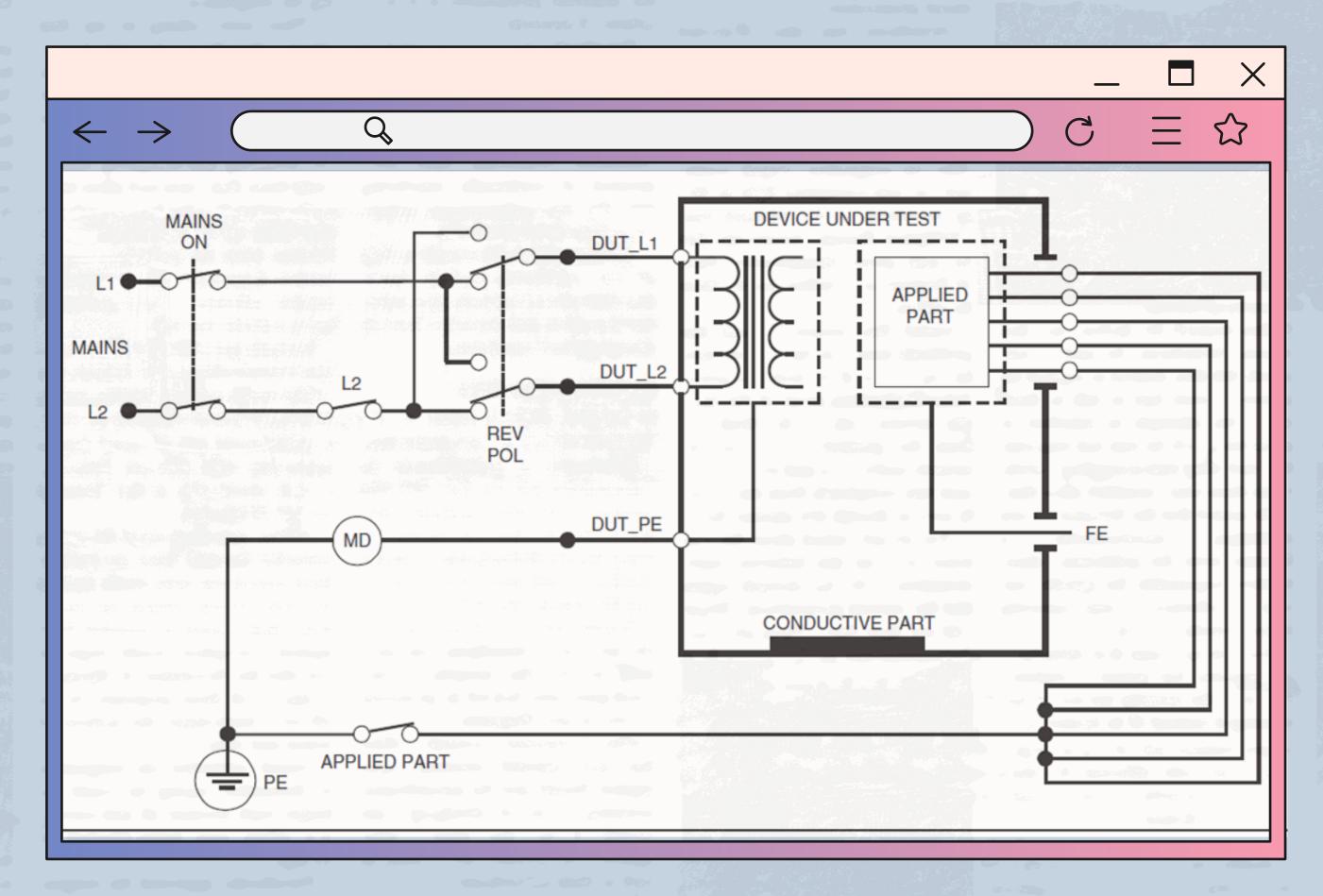
Test Schematic

500 V DC is applied between all the applied parts combined & both (Live & Neutral) of the appliance mains supply plug.



Earth Leakage Current in IEC 60601





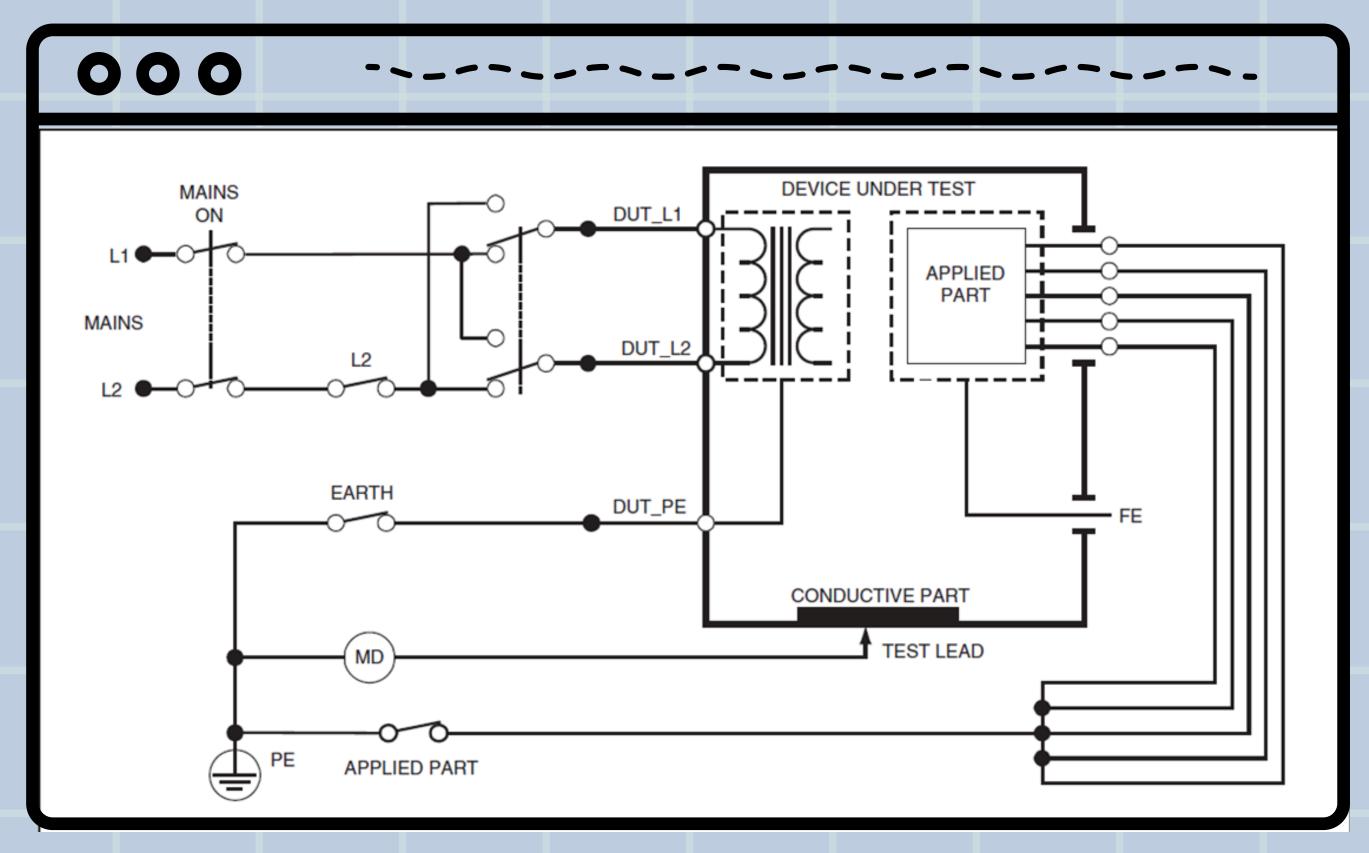
Earth Leakage Current Test Schematic

Measure the current flowing in the DUT's protective earth circuit.



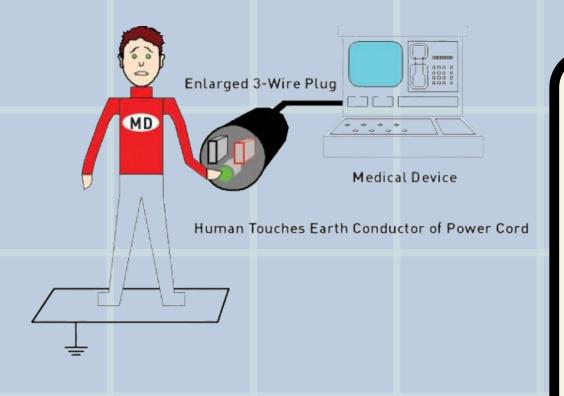


Enclosure Leakage / Touch Current in IEC 60601



Enclosure Leakage / Touch Current Test Schematic

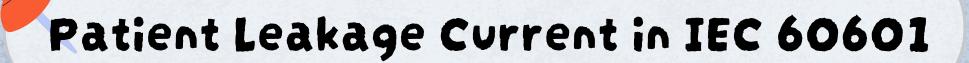
Measure the current flowing between the DUT's enclosure & protective earth.

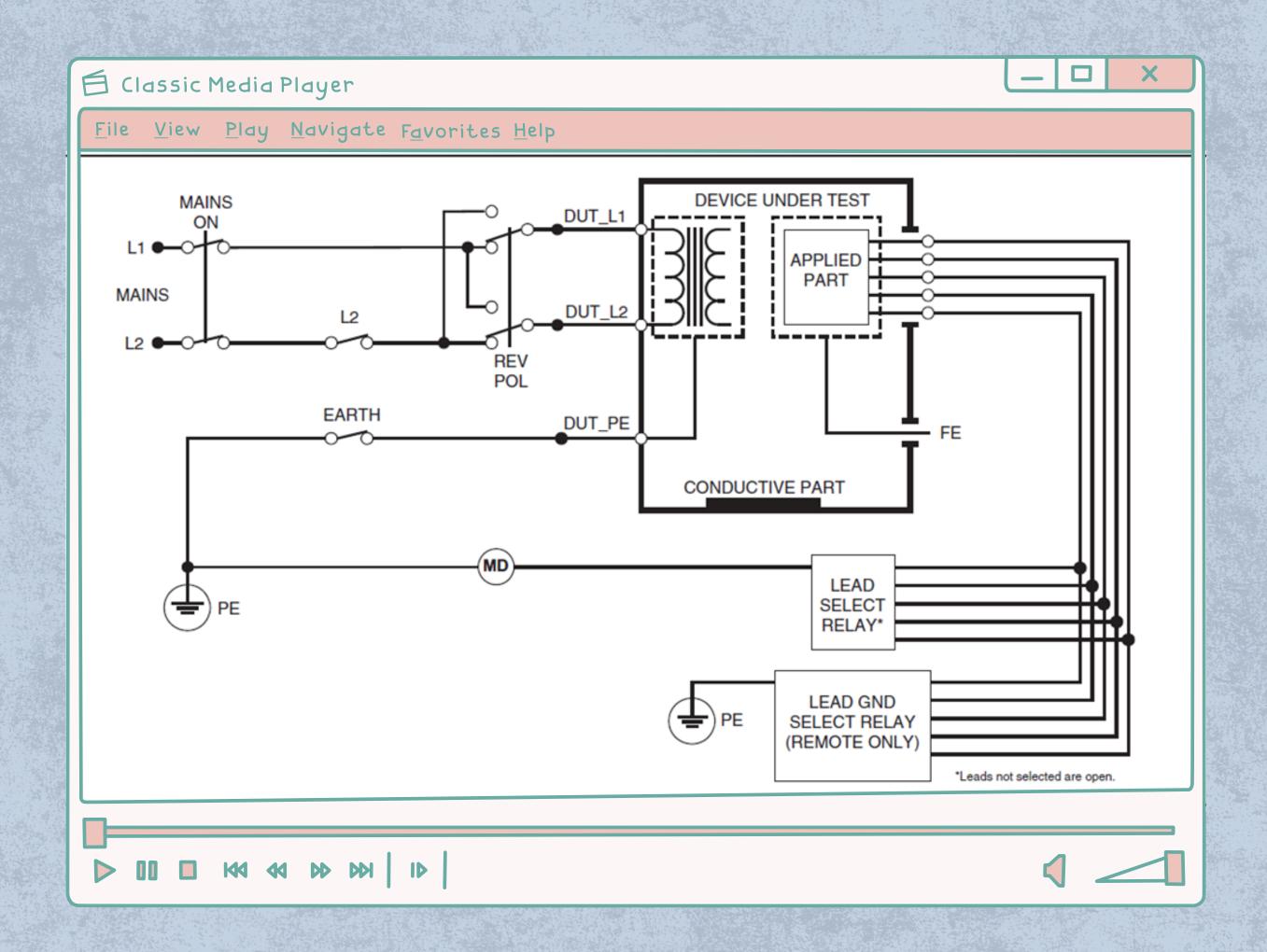


Outlet Condition:-

- Normal Polarity
- Normal Polarity, Open Earth
- Normal Polarity, Open Neutral
- Reversed Polarity
- Reversed Polarity, Open Earth
- Reversed Polarity, Open Neutral

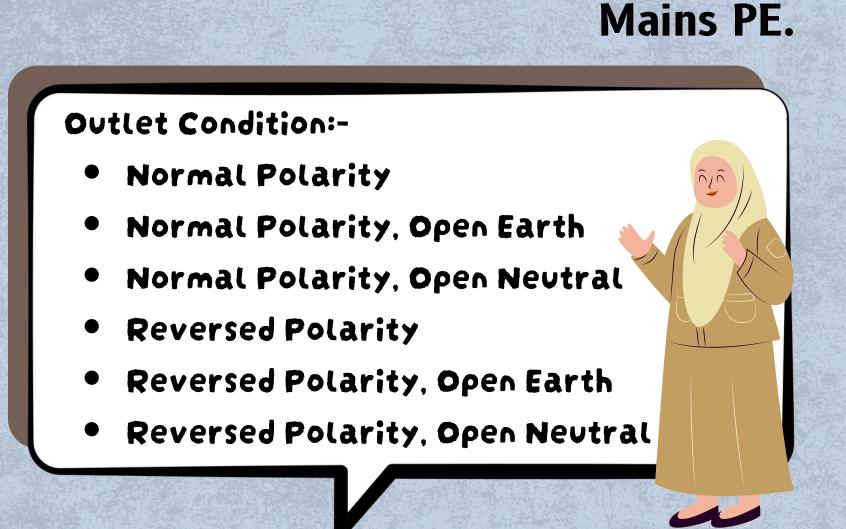
52

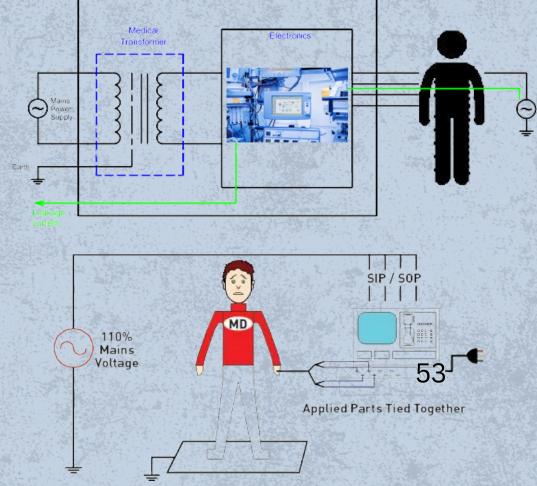




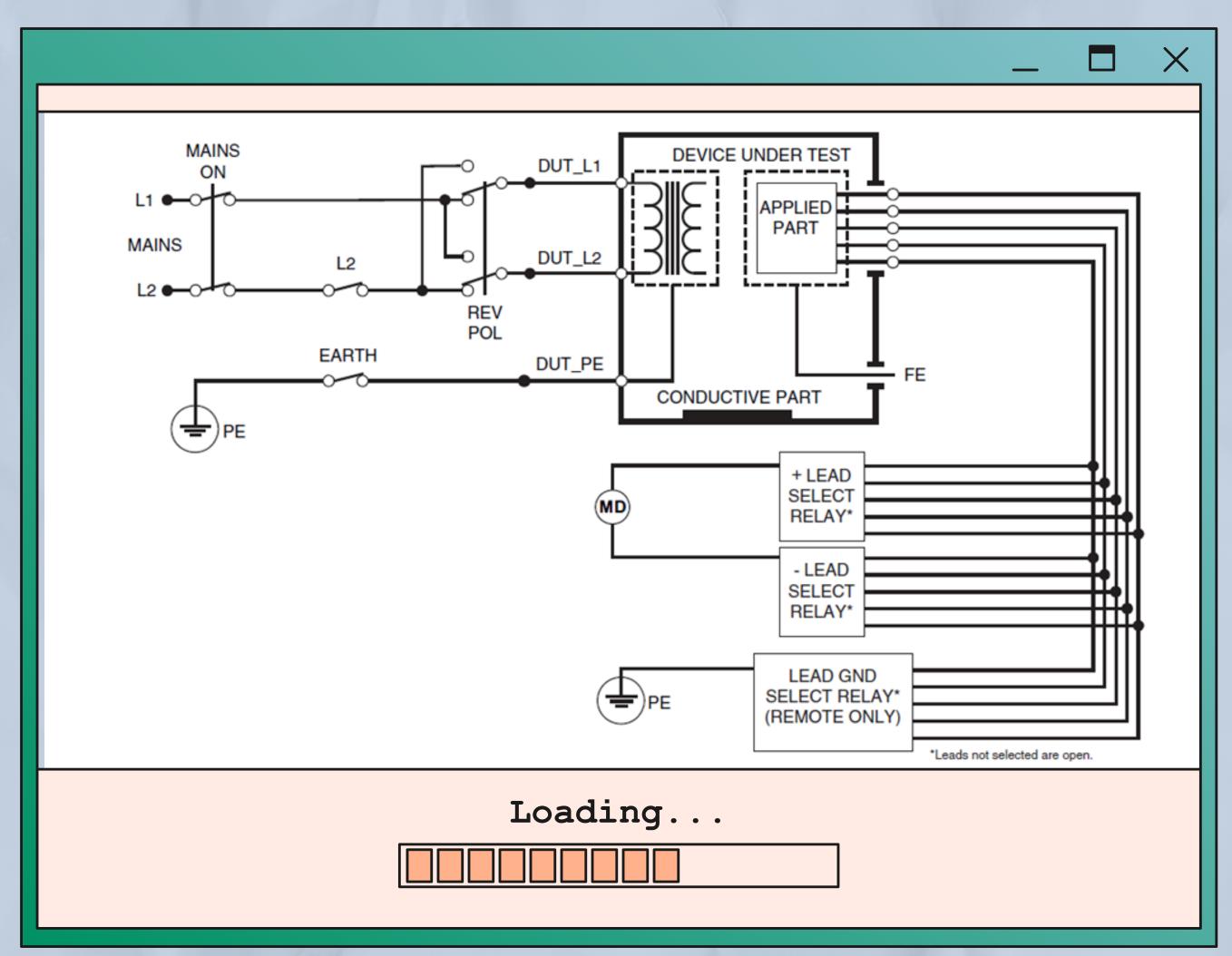
Patient Leakage Current Test Schematic

Measure the current flowing between a selected applied part, selected group of applied parts, or ALL applied parts & the





Patient Auxiliary Current in IEC 60601 X

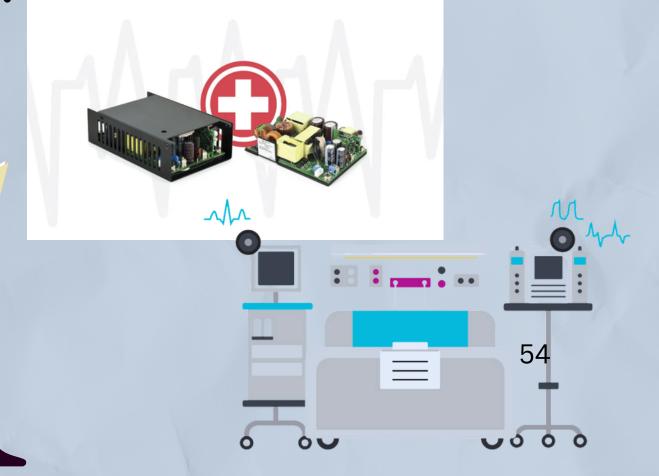


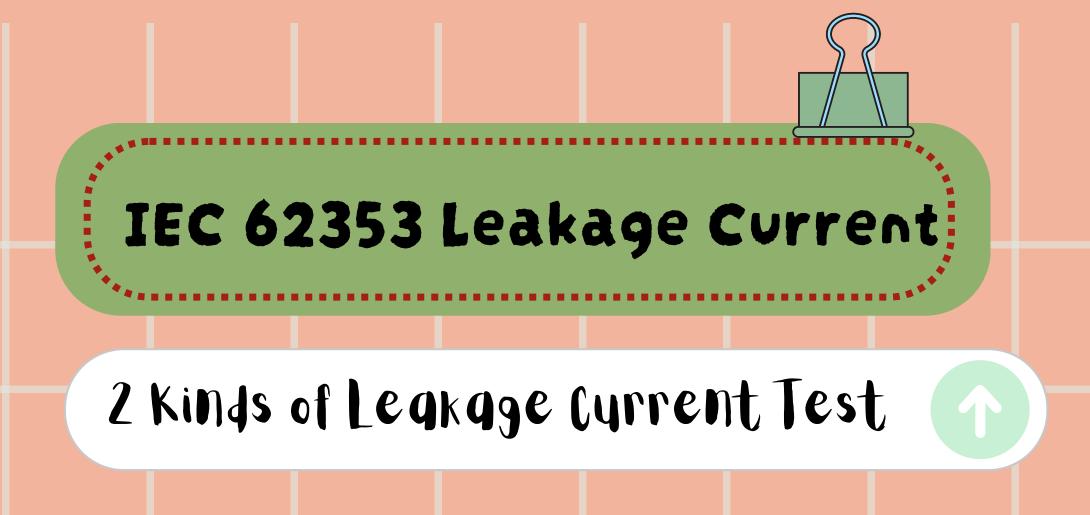
Patient Auxiliary Leakage Current Test Schematic

Measure the leakage current through each applied part or lead & selected combination of lead connections (all other or between two].



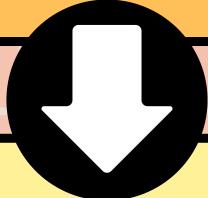
- **Normal Polarity**
- Normal Polarity, Open Earth
- **Normal Polarity, Open Neutral**
- Reversed Polarity
- Reversed Polarity, Open Earth
- Reversed Polarity, Open Neutral





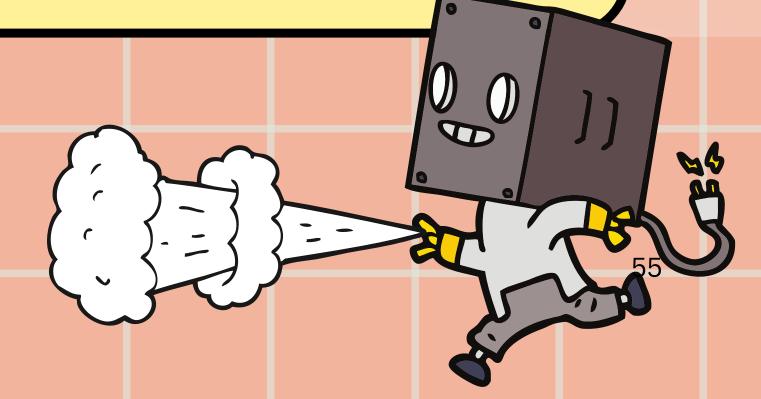
1. Equipment leakage current

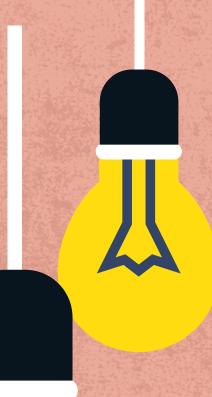
Total leakage deriving from the power supply to earth via the applied parts and enclosure.



2. Applied part leakage current

Leakage current flowing from an applied part to the enclosure or earth as a result of an external voltage on the applied part.





IEC 62353 Leakage Method

3 method of Leakage Current Test

Direct Leakage

Measurement of leakage current via a measuring device, placed directly in the path of the leakage current.

Differential Leakage

Measuring the imbalance between current in the Live conductor & the Neutral conductor as a result of leakage current.



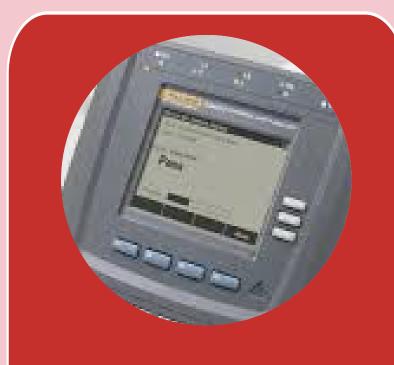
Alternative Method

Measurement of leakage when mains voltage is both on the Live & Neutral wire.

IEC 62353



The introduction of IEC 62353, to streamline and harmonies all standards that specify measure to ensure the safety of electromedical devices used in the diagnosis and treatment of patients



Although complementary with IEC 60601, the new standard is less complex and incorporate test beyond those type testing.



Significantly, 62353 recognizes that the laboratory conditions described in IEC 60601 may not always be relevant to working locations and that some type test specifications could be potentially damage equipment when it used in service.

Differences

Minimum test current of 200 mA for earth bond testing, compared with 25A required im IEC 60601-1

IEC 62353 provides details of methods for testing the insulation of medical device between mains parts and earth, between applied parts and earth and between applied parts and main parts.





- 1st Edition (2007), IEC 62353 widely published in most IEC member states.
- In year 2012,
- 1. Previous edition of VDE/ODE 75101 has been replaced with IEC 62353 in Germany & Austria.
- 2. Malaysia has adopted IEC 62353 (MS 62353) in Medical Device Act as minimum test requirement for ME equipment.



IEC 62353: 2014 Significant Changes

No pre-conditioning of equipment under test.

No elevated mains.

No destructive testing.

- Testing under single fault condition (SFC) only.
- Summarizing leakage into input (equipment leakage) and output (applied part leakage) safety.
- Testing at applied part level rather than at patient connection.

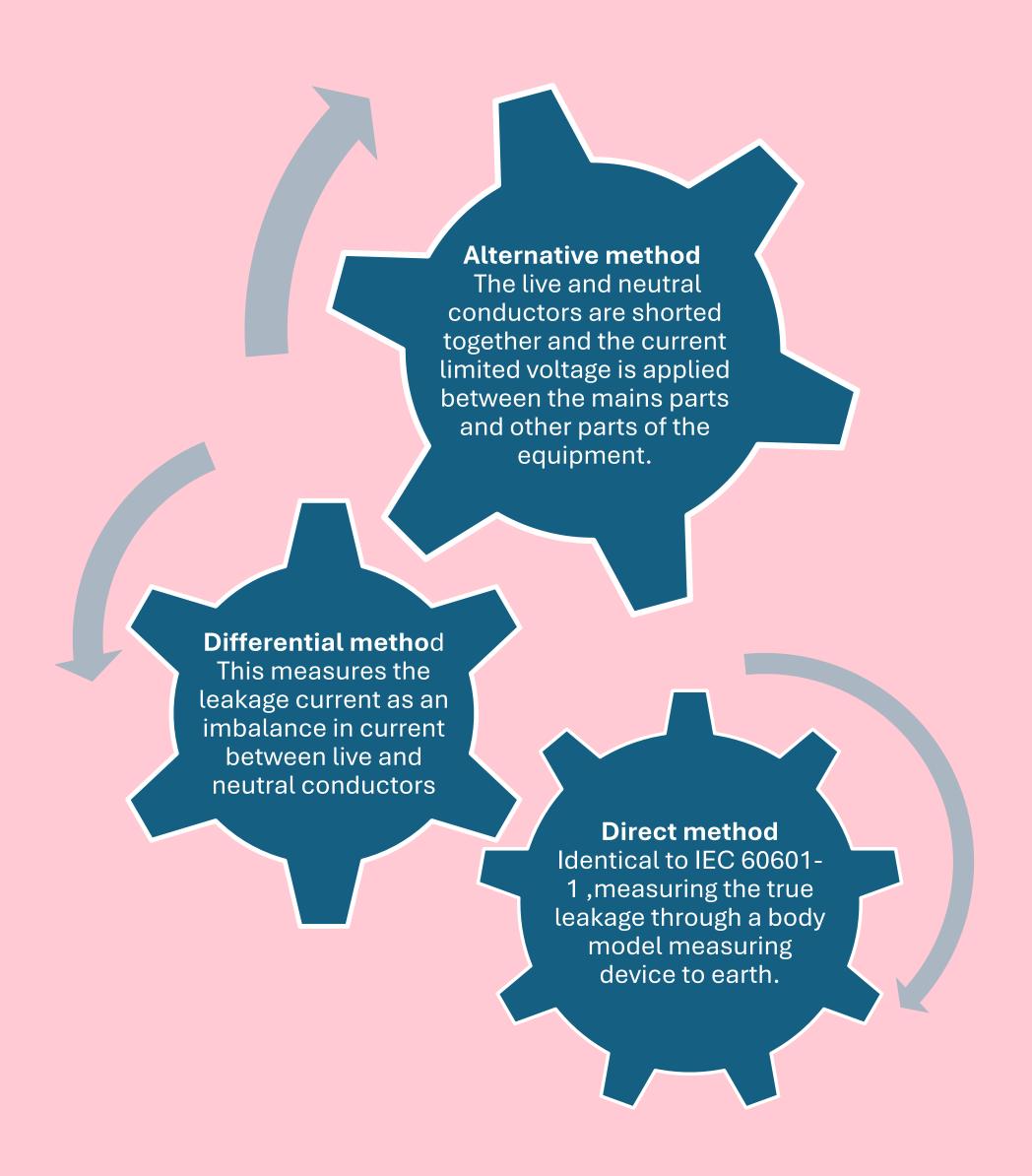
Different methods for conducting leakage tests subject to practicality.

200 mA Test Current Benefit in IEC 62353

- Increased safety of the operator.
- Reduced risk of damage to the in-service ME equipment.
- Smaller test instruments to include valid groundbond measurements.
- Increased flexibility of the test engineer due to lightweight test equipment.
- Cost reduction due to reduced down time of medical equipment.
- More economical availability of test equipment.

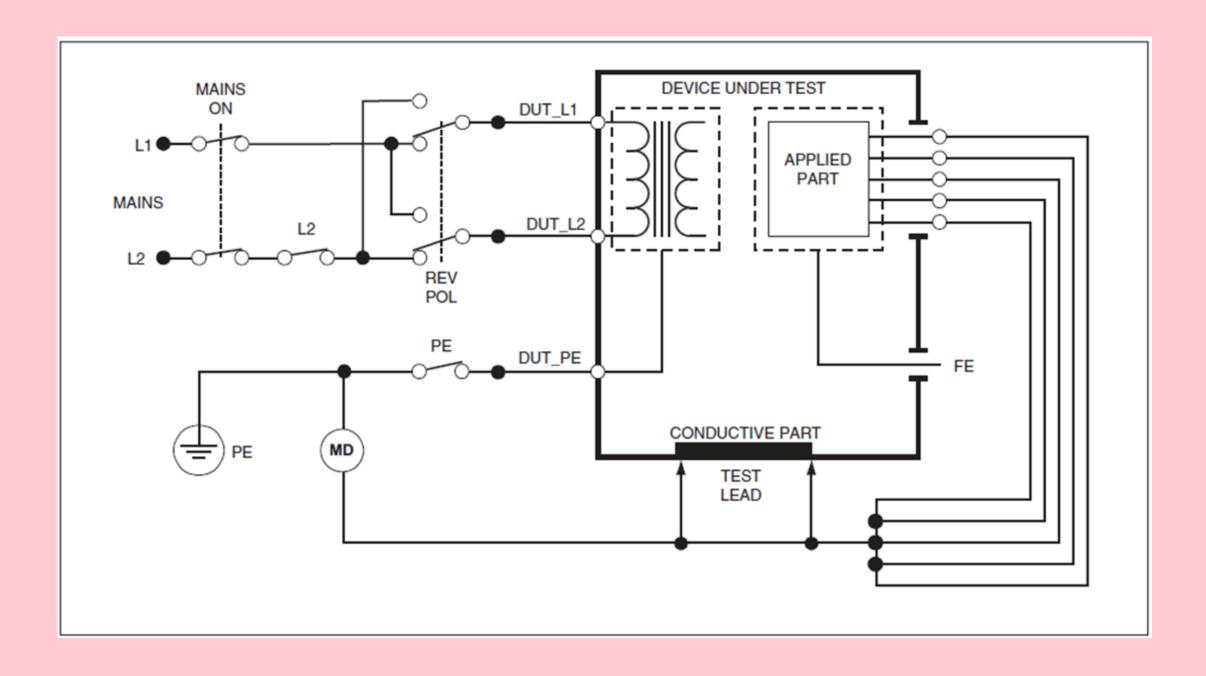


IEC 62353 specifies three methods to determine these types of leakage current:



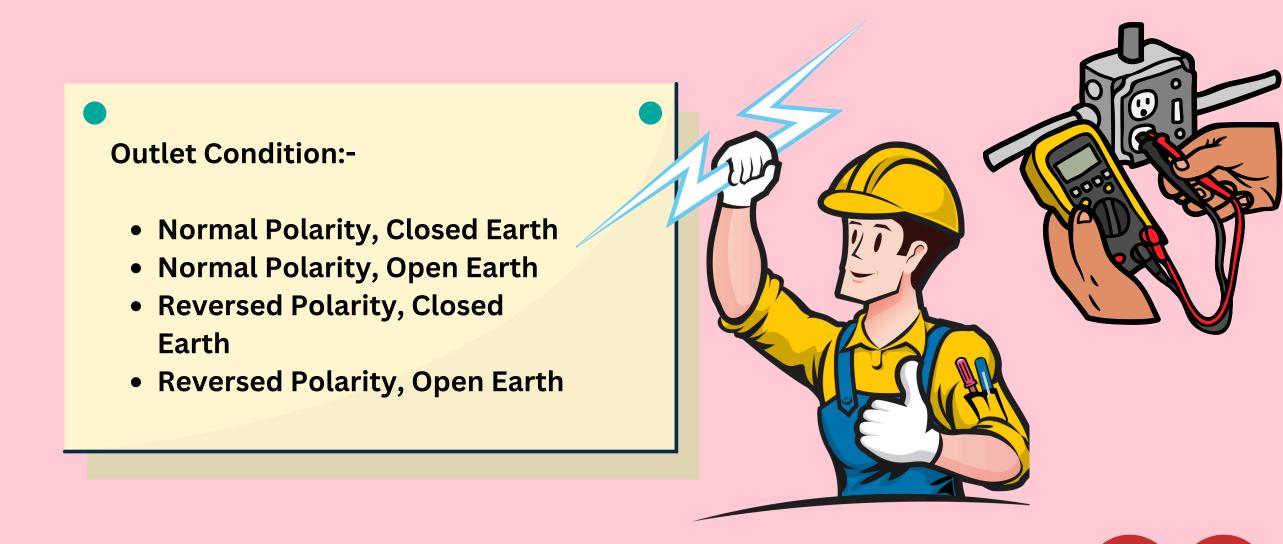






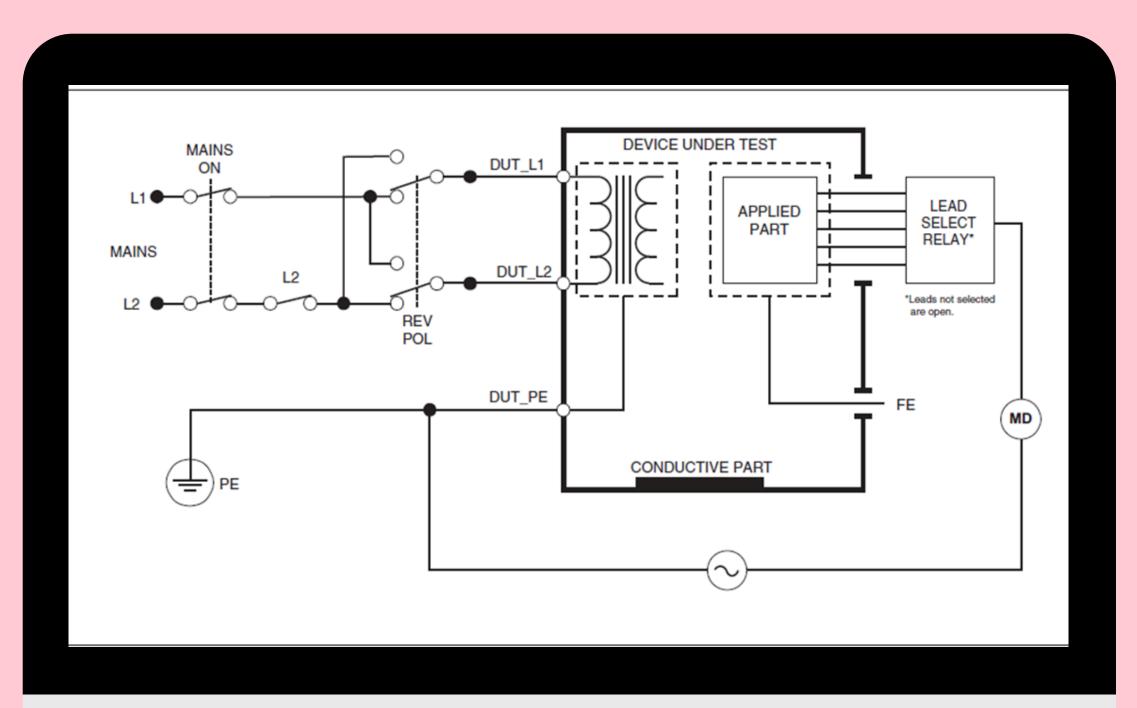
Direct Equipment Leakage Current Test Schematic BF & CF Applied Part ONLY

Measure the leakage current between all applied parts & the exposed conductive surface on the housing, to mains earth.



Direct Applied Parts Leakage Current in IEC 62353

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Direct Applied Parts Leakage Current Test Schematic BF & CF Applied Part ONLY

Measures the leakage current between all applied parts of a single function & the exposed conductive surface on the housing, to mains earth.

Outlet Condition:-

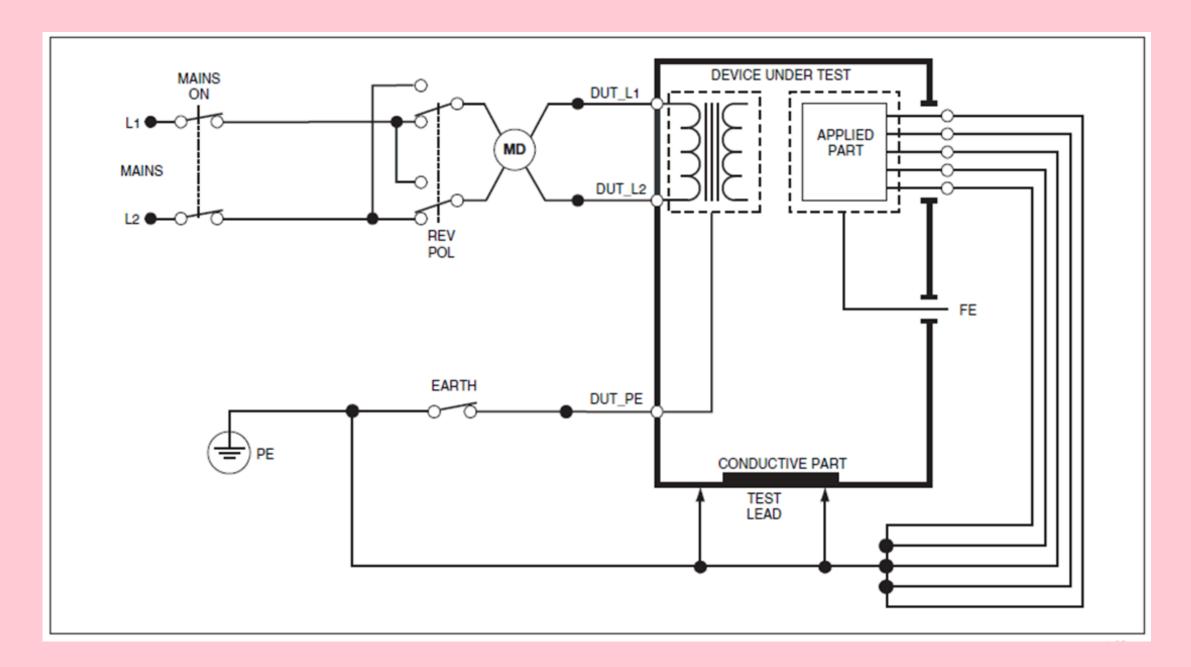
- Normal Polarity
- Reversed Polarity





Differential Leakage Current in IEC 62353





Differential Leakage Current Test Schematic

Measures the magnitudes of the differential current flowing in the Equipment Outlet Live & Neutral, with power applied to the equipment outlet. All applied parts should be connected during this test.



Outlet Condition:-

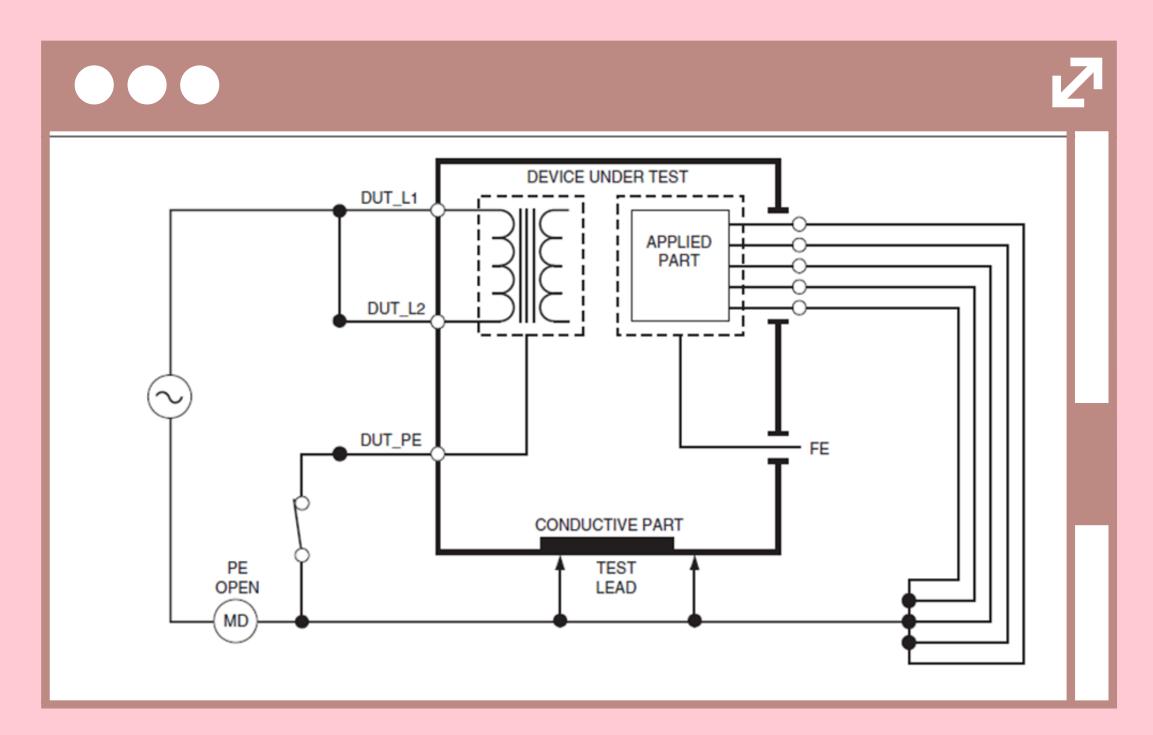
- Normal Polarity, Closed Earth
- Normal Polarity, Open Earth
- Reversed Polarity, Closed Earth
- Reversed Polarity, Open Earth



Q

Alternative Equipment Leakage Current in IEC 62353





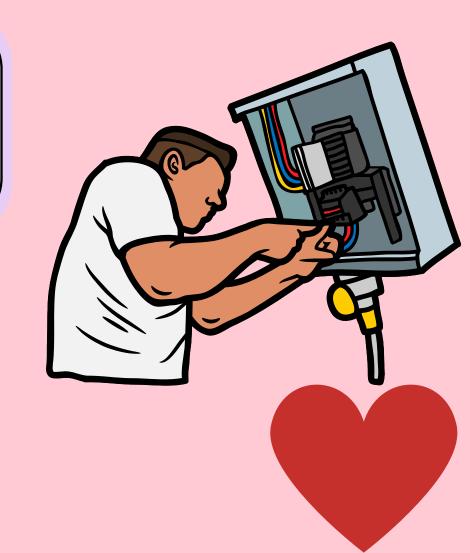
Alternative Equipment Leakage Current Test Schematic BF & CF Applied Part ONLY

Voltage source is applied between short-circuited equipment outlet mains Live, Neutral, and equipment outlet Earth, the exposed conductive surface on the housing and all applied parts short-circuited together.



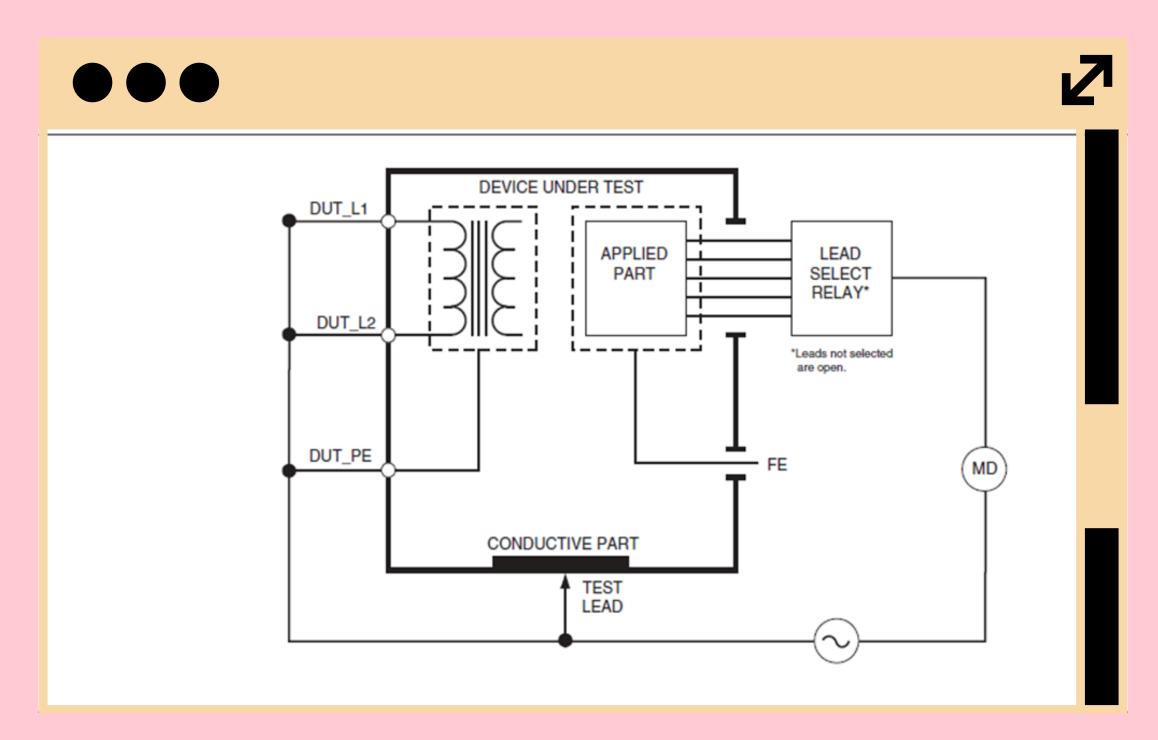
Outlet Condition:-

- Closed Earth
- Open Earth



Alternative Applied Parts Leakage Current in IEC 62353





Alternative Applied Parts Leakage Current Test Schematic BF & CF Applied Part ONLY



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Test voltage is applied between short-circuited applied parts of a single function & the short-circuited equipment outlet mains Live, Neutral, equipment outlet Earth & exposed conductive surface on the housing.



Leakage Current Limits of IEC 62353

| Current in μA (RMS) | APPLIED PART | | | |
|---|-----------------|-----------------|-----------------|--|
| Current in pA (Hivio) | Type B | Type BF | Type CF | |
| Equipment leakage – alternative method | | | | |
| Class I equipment Class II equipment | 1000μA 500μA | 1000μA 500μA | 1000μΑ 500μΑ | |
| For mobile x-ray generators | 5000 μΑ | | | |
| Equipment leakage - direct or differential method | | | | |
| Class I equipment Class II equipment (touch current) | 500μΑ 100μΑ | 500μΑ 100μΑ | 500μΑ 100μΑ | |
| For mobile x-ray generators | 2000 μΑ | | | |
| Applied part leakage current - alternative method (AC) | | | | |
| Class I & II | N/A | 5000μΑ | 50μΑ | |
| For defibrillation paddles class CF | N/A | N/A | 100μΑ | |
| Applied part leakage current - direct method (AC) | | | | |
| Class I & II | N/A | 5000µA | 50μΑ | |
| For defibrillation paddles class CF | N/A | N/A | 100μΑ | |

NOTE 1 This IEC 62353 standard does not provide measuring methods and allowable values for equipment producing DC leakage currents. In such a case the manufacturer should give information in accompanying documents.

NOTE 2 Particular standards may allow different values of leakage current.

IEC 60601 & IEC 62353 Test Comparison

IEC 60601

- 1. Earthbond (Protective Earth Resistance)
- 2. High Potential / Insulation Resistance (HIPOT)
- 3. Leakage Current
 - Earth
 - Enclosure / Touch
 - Patient (AC/DC)
 - Patient Auxiliary (AC/DC)
 - Patient Type F
 - Signal Input / Output Part (SIP/SOP SFC)

IEC 62353

- 1. Earthbond (Protective Earth Resistance) (Test current: 200 mA)
- 2. Insulation Resistance
- 3. Leakage Current (Equipment & Applied Part)
 - Direct Method
 - Differential Method
 - Alternative Method



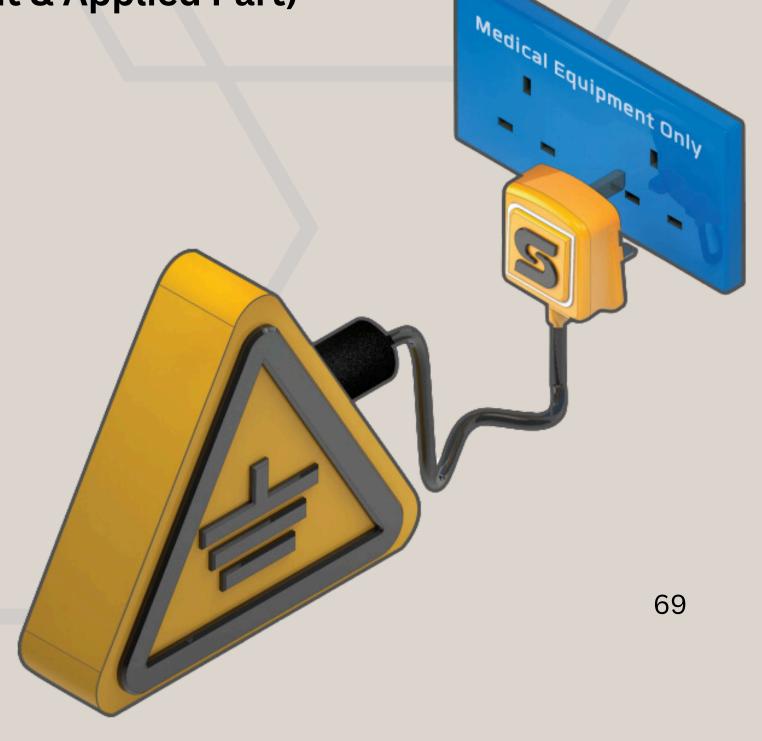
IEC 60601 & IEC 62353 Test Comparison

IEC 60601

- 1. Earthbond (Protective Earth Resistance)
- 2. High Potential / Insulation Resistance (HIPOT)
- 3. Leakage Current
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- Signal Input / Output Part (SIP/SOP SFC)

IEC 62353

- 1. Earthbond (Protective Earth Resistance) (Test current: 200 mA)
- 2. Insulation Resistance
- 3. Leakage Current (Equipment & Applied Part)
- Direct Method
- Differential Method
- Alternative Method



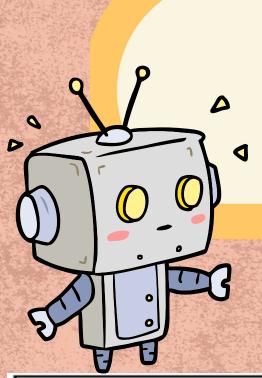
IEC 60601 & IEC 62353 Leakage Current Similarities

IEC 60601

- Earth leakage
- Earth leakage SFC neutral
- Enclosure leakage SFC earth
- Patient leakage
- Mains on applied parts
- Measured values
- Only direct method

IEC 62353

- Equipment leakage DIR/DIF
- Equipment leakage ALT
- Equipment leakage (enclosure probe disconnected)
- Applied part leakage
- Some are calculated
- Direct/differential and alternative



Schematic abbreviations

| Abbreviation | Meaning | |
|--------------|--|--|
| MD | Measuring Device | |
| FE | Functional Earth | |
| PE | Protective Earth | |
| Mains | Mains Voltage Supply | |
| L1 | Hot Conductor | |
| L2 | Neutral Conductor | |
| DUT | Device Under Test | |
| DUT_L1 | Device Under Test hot conductor | |
| DUT_L2 | Device Under Test neutral conductor | |
| DUT_PE | Device Under Test protective earth line | |
| REV POL | Reversed mains supply polarity | |
| LEAD GND | Lead to ground, used in Patient leakage test | |
| MAP | Mains on Applied Part | |
| MAP REV | Reverse mains on applied part source voltage | |
| PE Open | Open protective earth | |
| \odot | Test Voltage | |



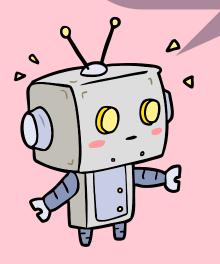


IEC 61010

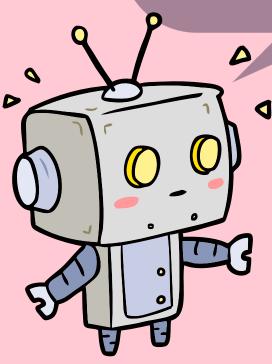


IEC 61010-1:2010 specifies general safety requirements for the following types of electrical equipment and their accessories, wherever they are intended to be used.

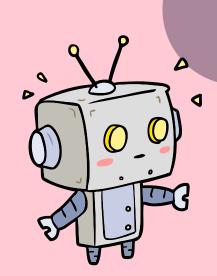
Electrical test and measurement equipment



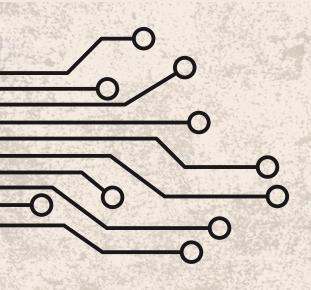
Electrical industrial process-control equipment



Electrical laboratory equipment Example: IEC 61010-2-101:2018 | IEC Webstore (in vitro diagnostic (IVD) medical equipment)











Bender Unimet 1100ST



Datrend ES601 Plus

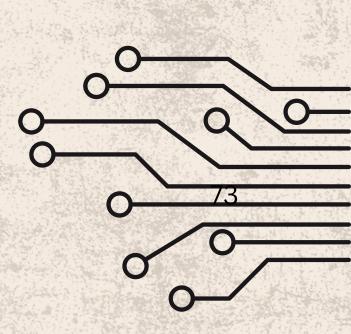






Datrend ES601 Plus

Gossen Metrawatt
Seculife ST







- 1. Metron QA-90
- 2. Bender Unimet 1100ST
- 3. Datrend ES601 Plus
- 4. Rigel 277 Plus
- 5. Fluke Biomedical 601 Pro SeriesXL
- 6. Gossen Metrawatt Seculife ST



Electrical Safety Analyzer







1. Metron QA-ST

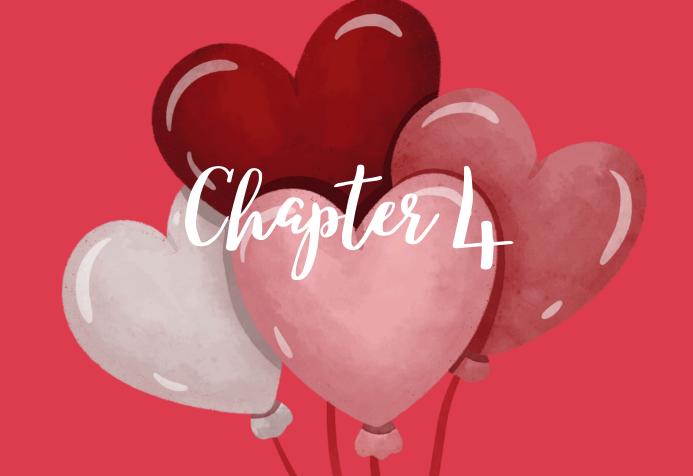
2. Fluke Biomedical ESA620

3. Netech DALE601

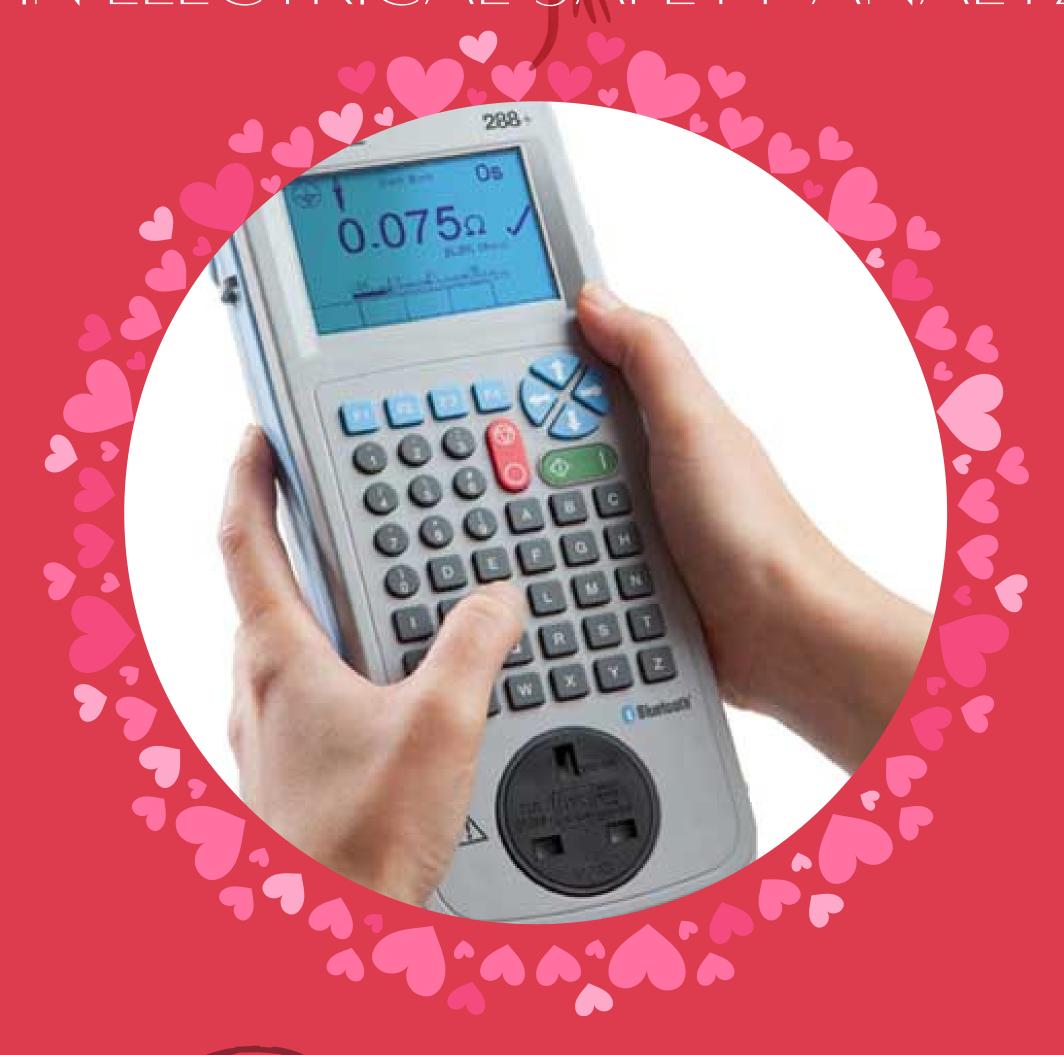
4. Rigel 266

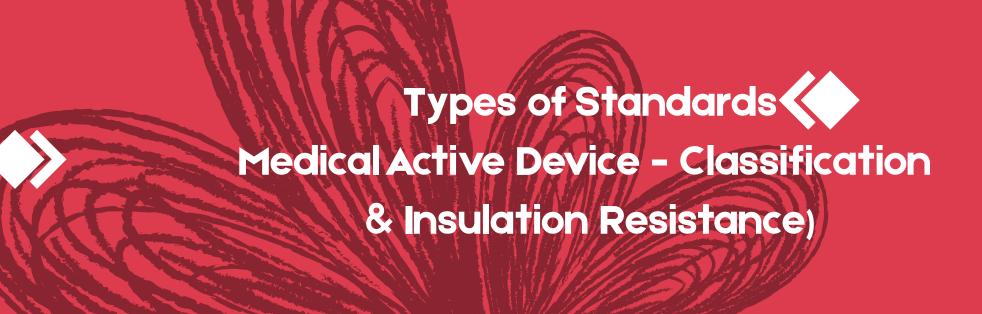
5.BC Biomedical SA-2000

75



AUGMENTED REALITY APPROACH IN ELECTRICAL SAFETY ANALYZER









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