

Safety Standards Measurement Instruments

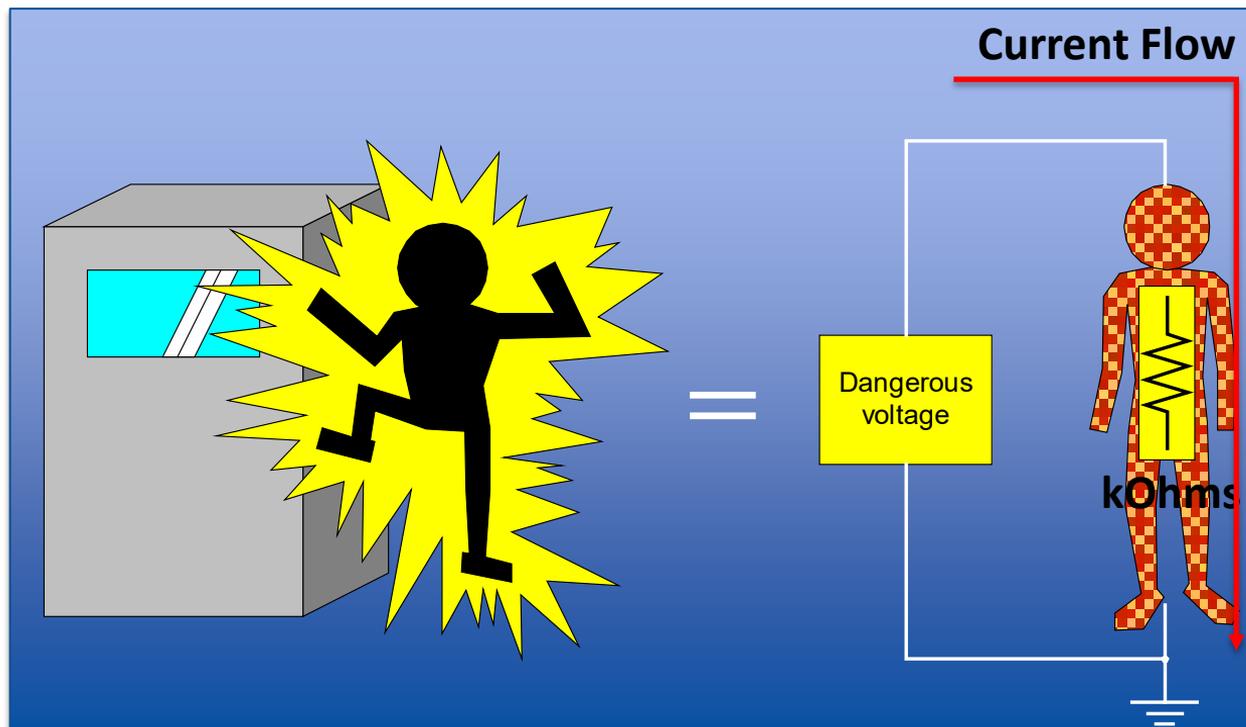


HIOKI

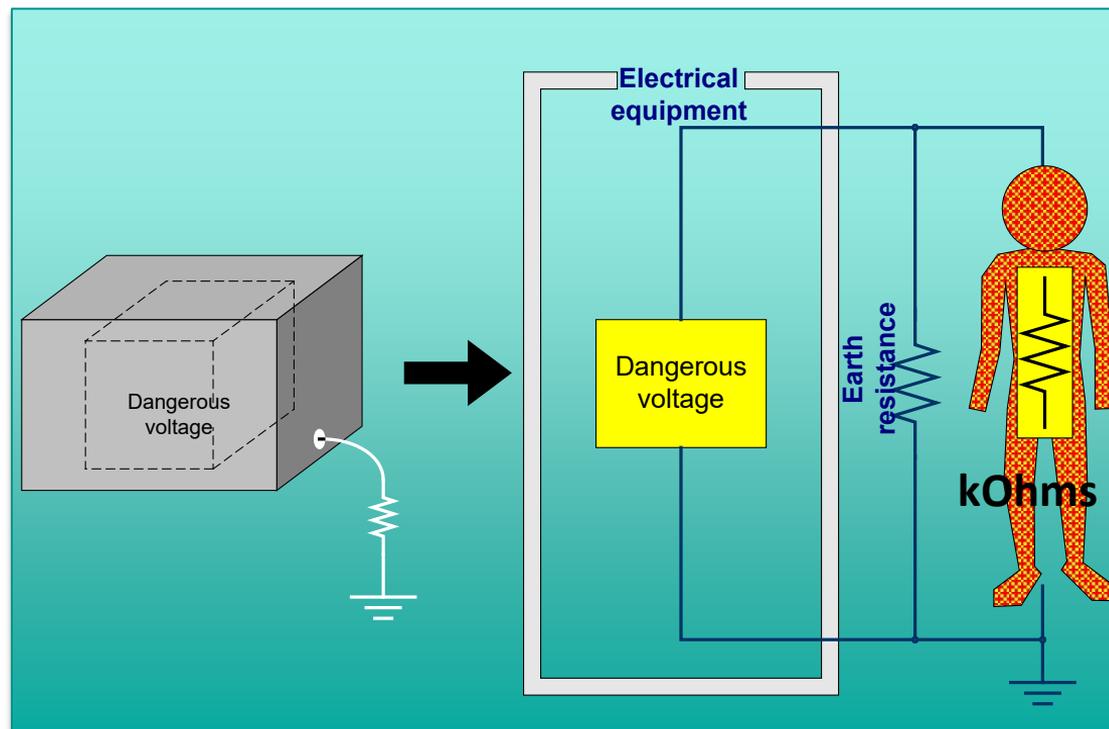
Agenda

- **Avoiding accidental electrical shock**
- **Classification of electrical equipment**
- **Safety standards for electrical equipment**
- **Leakage current test**
- **Other test equipment for safety compliance testing**
- **Summary**

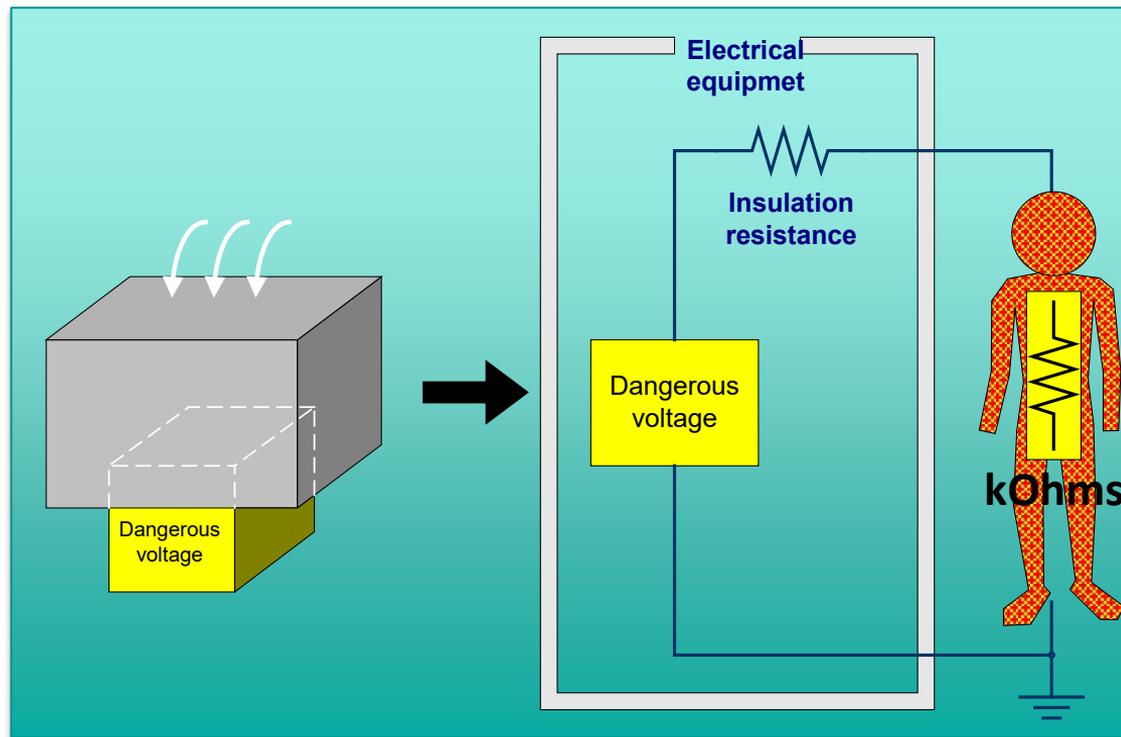
Cause of Electrical Shock



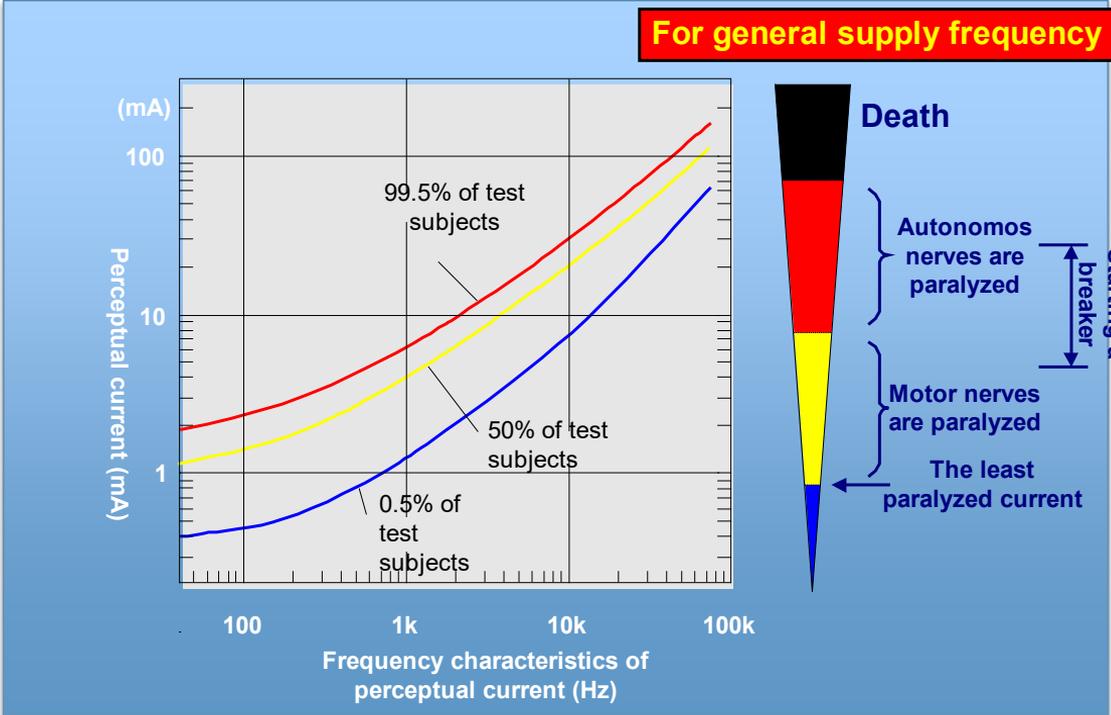
Countermeasure 1 : “Discharge” = Grounding



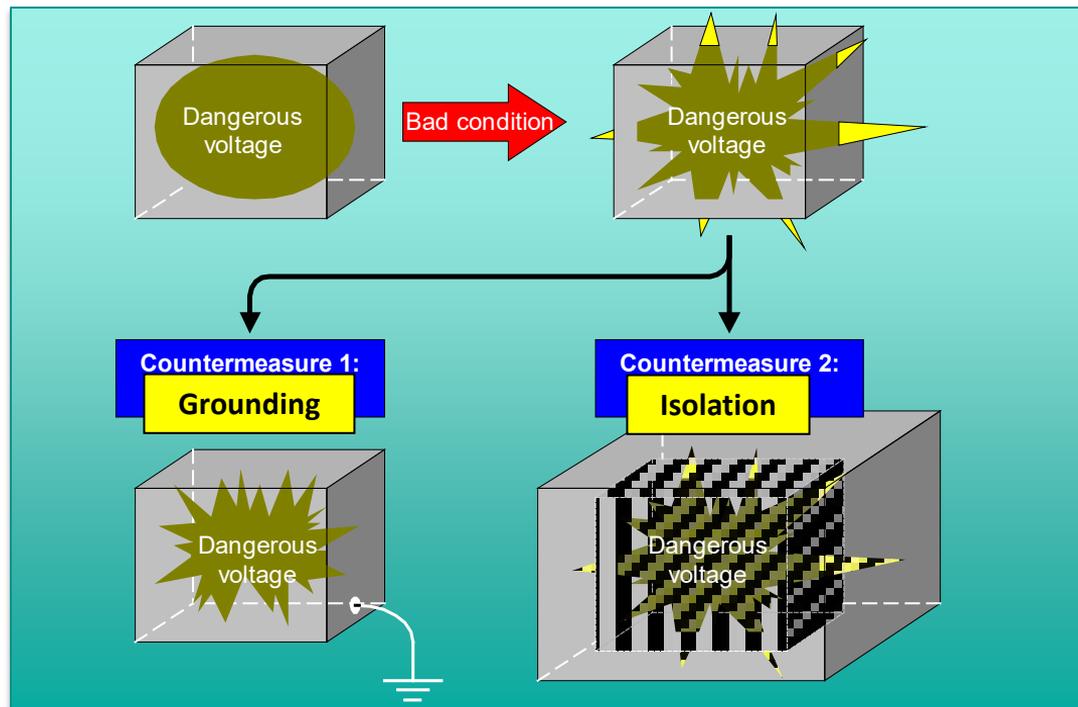
Countermeasure 2 : “Enclosure” = Isolation



Electrocution

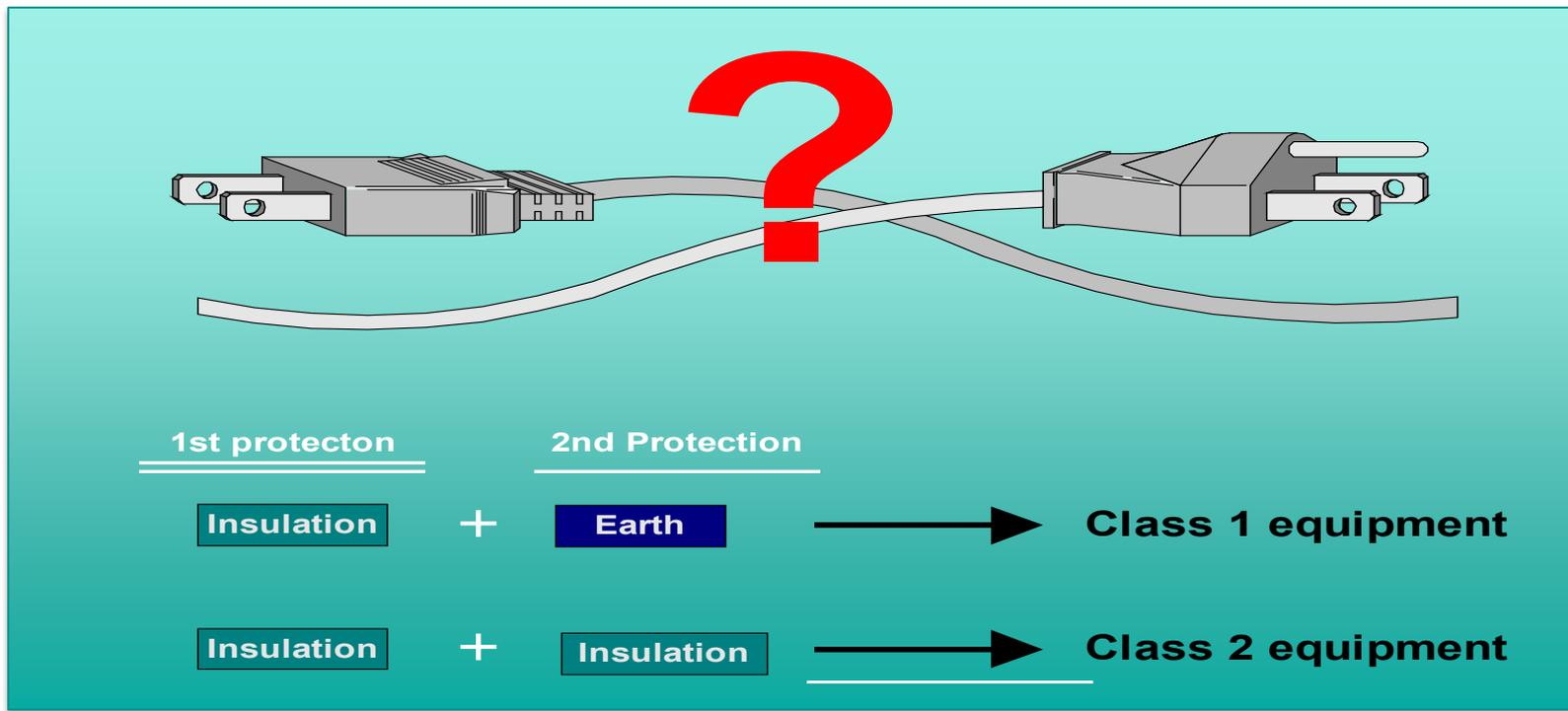


Double and triple protection standard

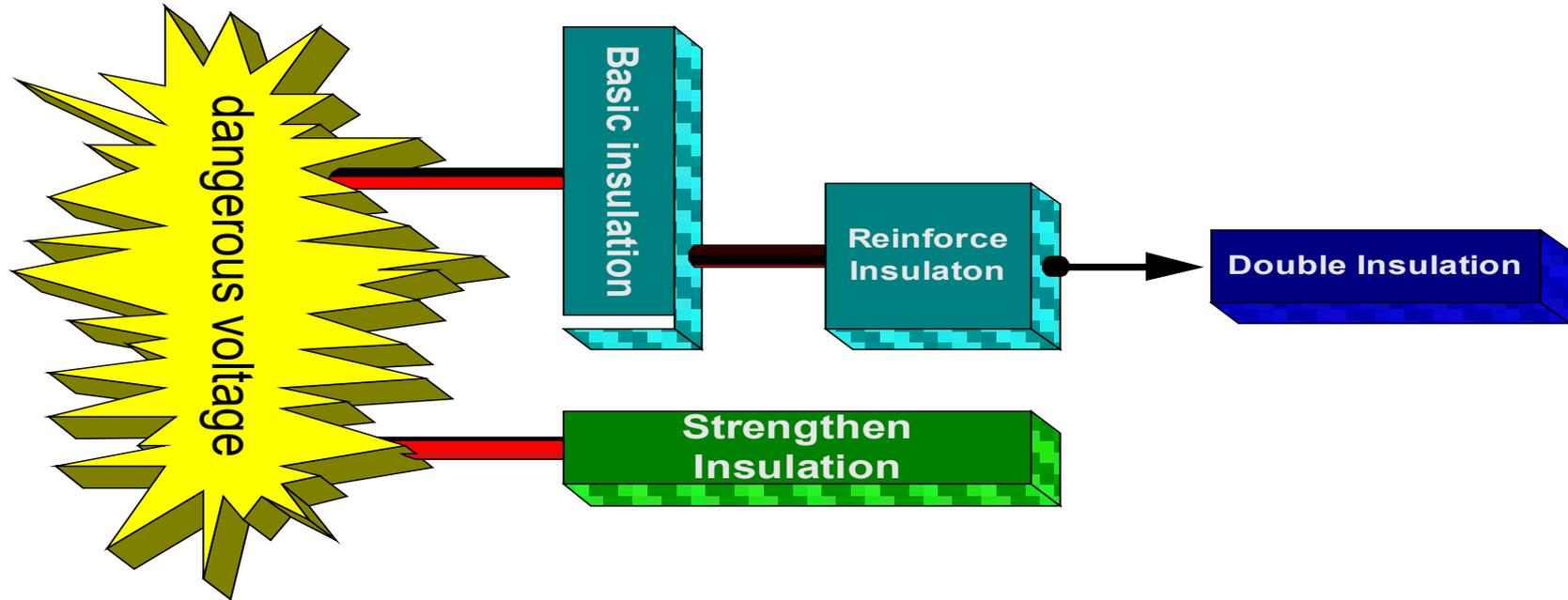


- Avoiding accidental electrical shock
- **Classification of electrical equipment**
- Safety standards for electrical equipment
- Leakage current test
- Other test equipment for safety compliance testing
- Summary

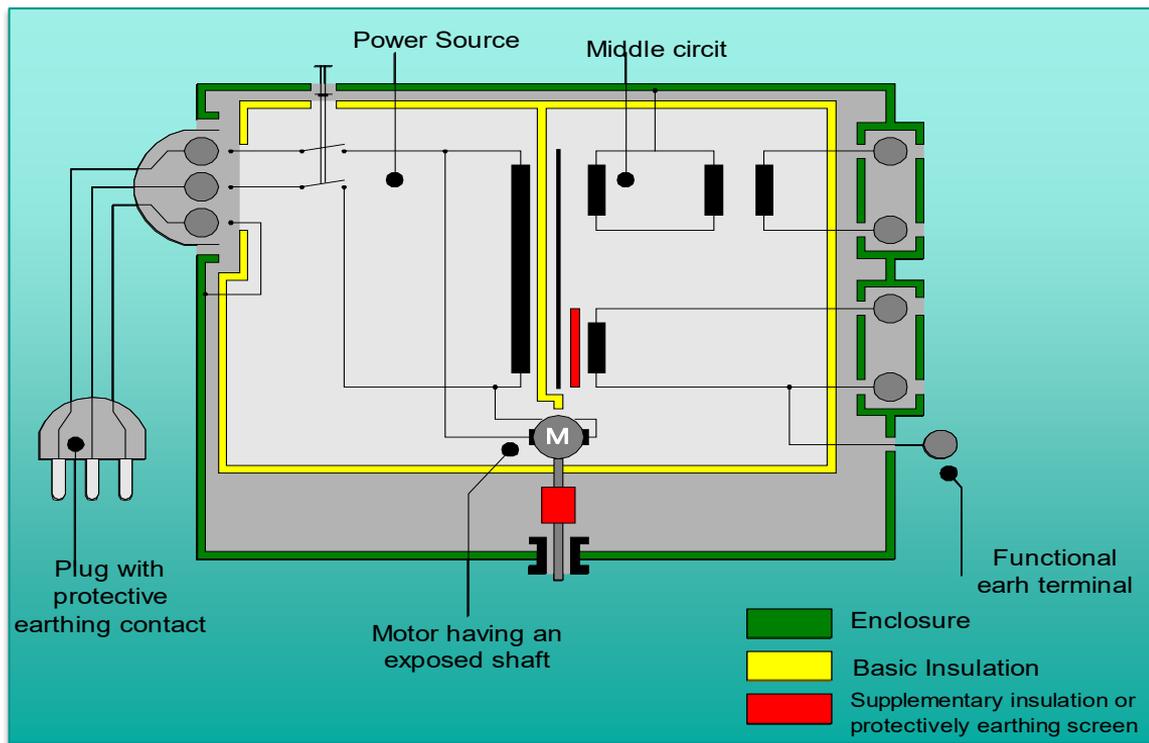
Classification of electrical equipment



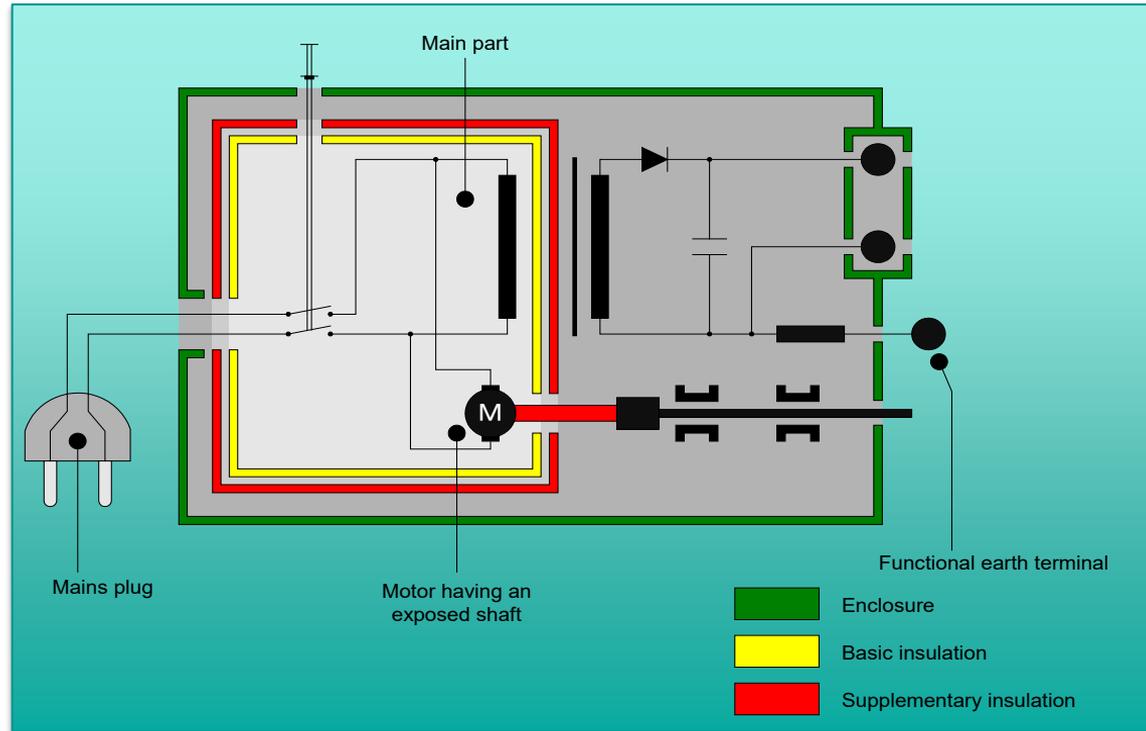
Insulation system



Class I equipment



Class II equipment



- Avoiding accidental electrical shock
- Classification of electrical equipment
- **Safety standards for electrical equipment**
- Leakage current test
- Other test equipment for safety compliance testing
- Summary

Safety Standards for Electrical Equipment

IEC 60601-1:2005+AMD1:2012, or IEC 60601-1 Edition 3.1

Medical electrical equipment-Part1:General requirements for basic safety and essential performance

IEC 60990:1999

Methods of measurement of touch current and protective conductor current

IEC 61010-1:2010

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

IEC 60065:2010

Audio, video and similar electronic apparatus – Safety requirements

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What is leakage current testing for electrical equipment's safety validation?

Purpose

To check insulation performance

Leak current testing is extremely important, particularly for medical-use electrical devices (medical devices)

Criterion

Leakage current values that would

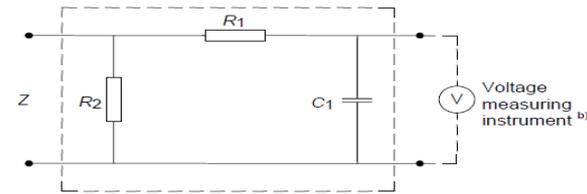
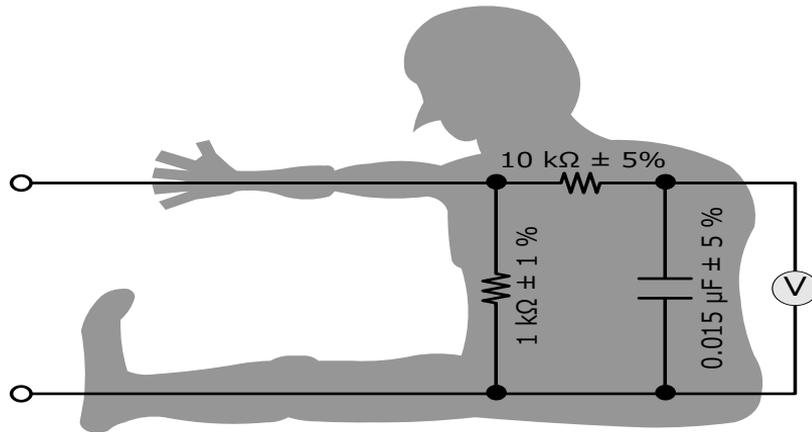
flow to the human body (through a person)

(Applicable standards define a person in terms of simulated human resistance.)



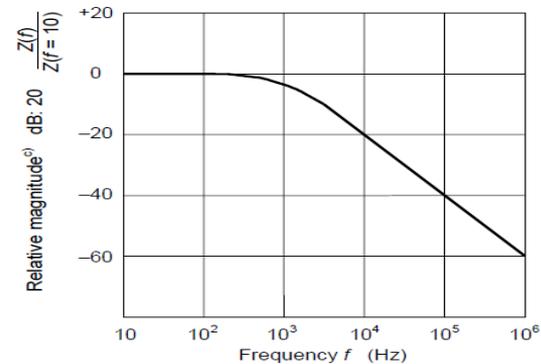
Person = Simulated human resistance

= Measurement network: Example



R_1 $10\text{ k}\Omega \pm 5\%$ ^{a)}
 R_2 $1\text{ k}\Omega \pm 1\%$ ^{a)}
 C_1 $0.015\text{ }\mu\text{F} \pm 5\%$

IEC 1407/12

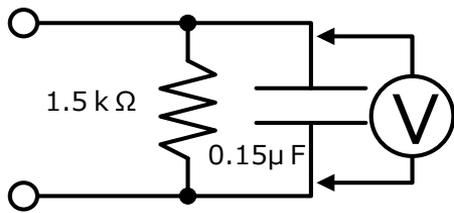


IEC 1408/12

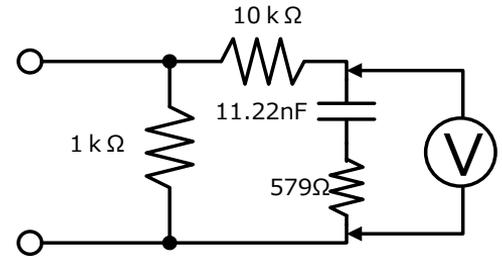
Source : IEC60601-1

Person = Simulated human resistance

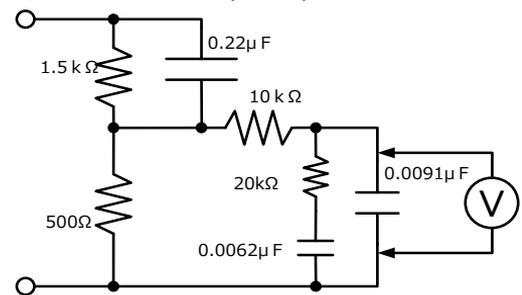
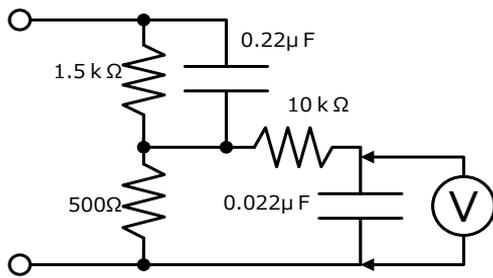
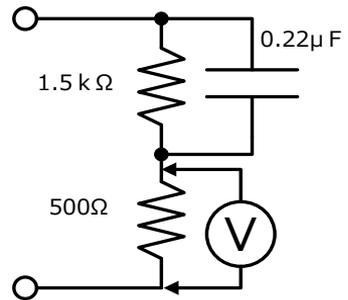
= Measurement network: Example



UL standard



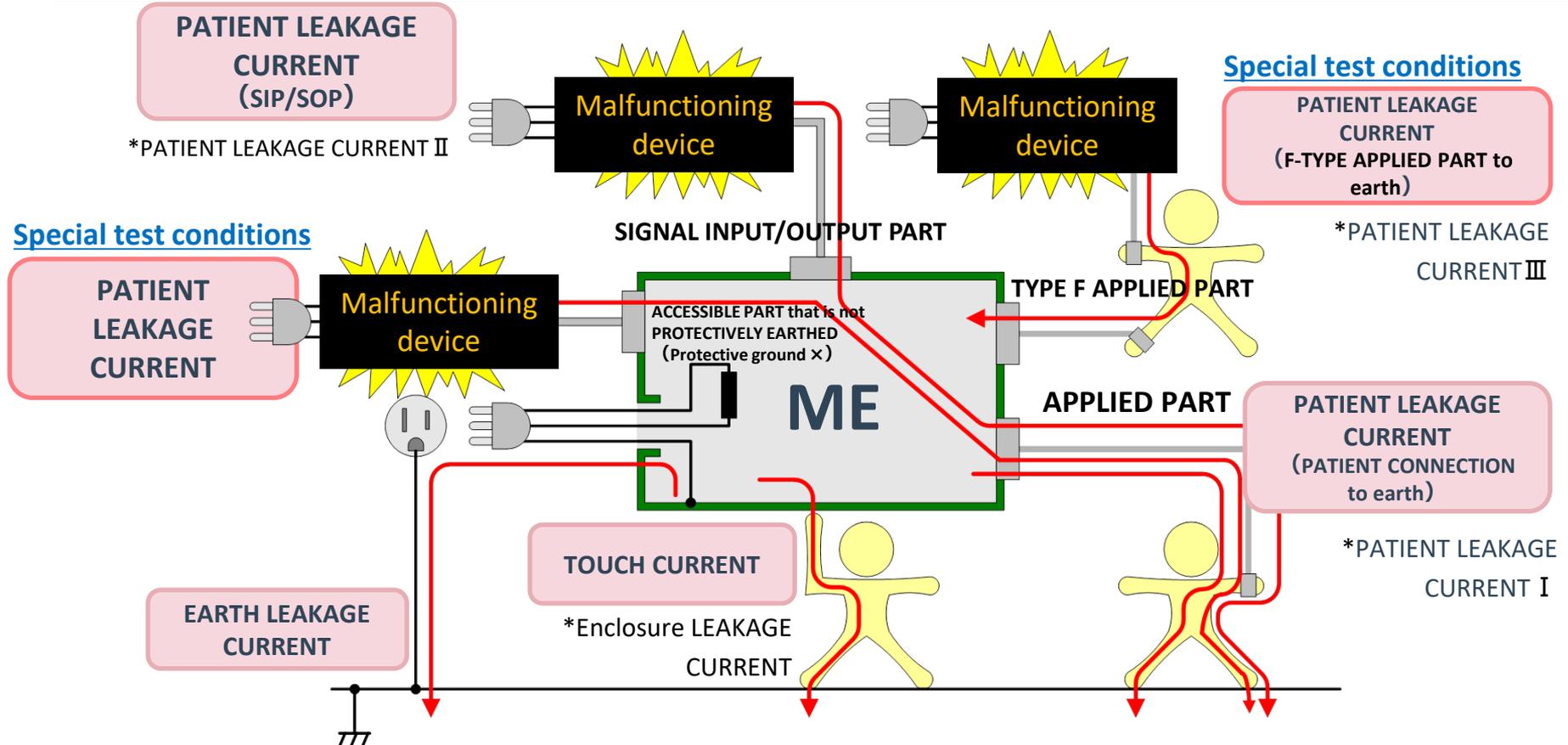
Act on Product Safety of Electrical Appliances and Materials (PSE)



IEC 60990 (IEC 60065-1, IEC 60950-1, IEC 61010-1 etc)

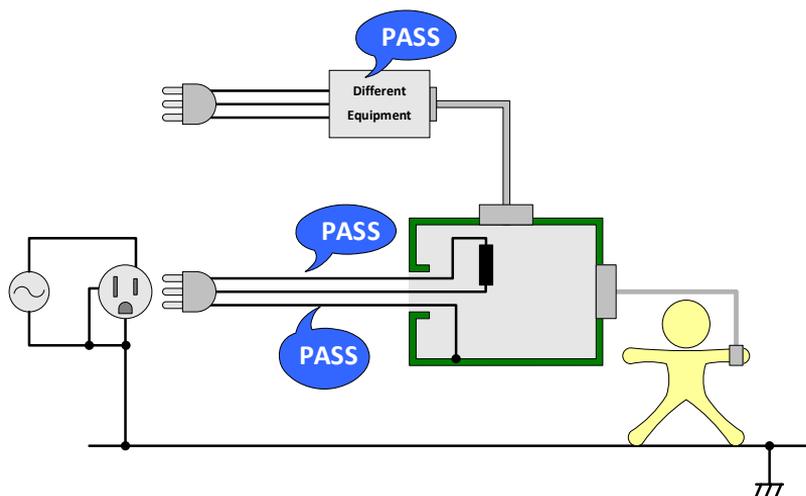
IEC 60990 : Methods of measurement of touch current and protective conductor current

Types of leakage current

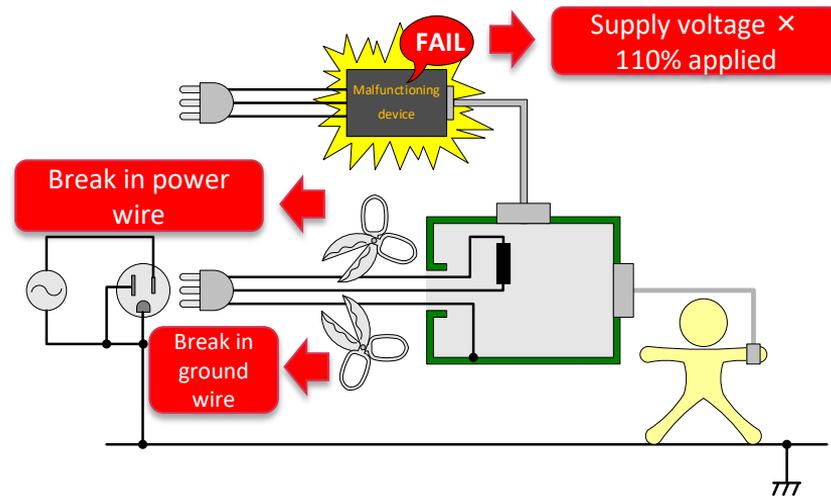


Test conditions for leakage current testing

Perform leakage current testing at normal and single fault conditions



Normal condition



Single fault condition

ST5540 – features

- Perform testing in compliance with

IEC 60601-1 Ed. 3.0:2005, IEC 60601-1 Amd.1 Ed. 3.0:2014

*IEC 60601-1 : Standards for medical devices

- Uninterrupted-power polarity switching function
- Current ratings: 20 A
- Measure protective conductor current.
- Operation check functionality.

Standard compliance

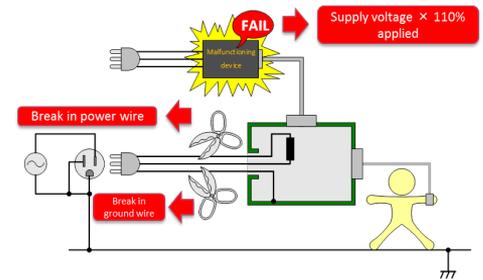
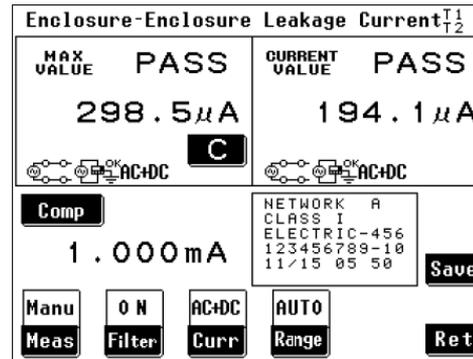
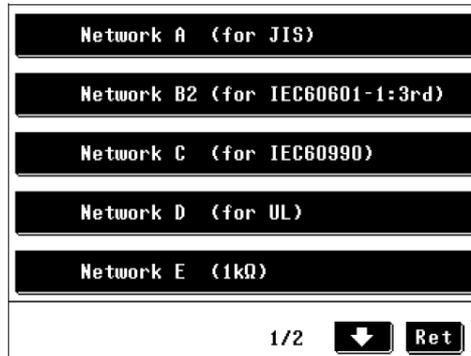
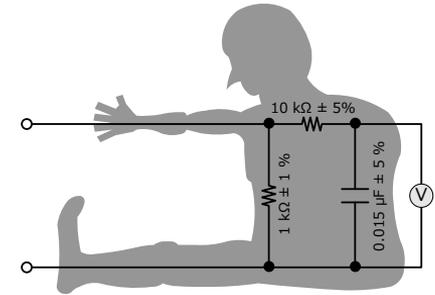
■ Comparison of ST5540 Functionality

	Measurement mode	Category	Standard compliance
ST5540 Medical-use electrical devices	● Patient leak current (between parts of device that come into contact with patient and ground)	<ul style="list-style-type: none"> • Medical industry (Japan Association for Clinical Engineering Technologists, etc.) • Medical device manufacturers and dealers • Medical device repair and maintenance businesses • Hospitals 	<ul style="list-style-type: none"> • IEC60601-1 (Ed 3.1) • IEC60990 • IEC62353
	● Patient leak current (external SIP/SOP voltage)		
	● Patient leak current (external voltage at specific F-type applied part)		
	● Patient leak current (current resulting from external voltage at parts of device that come into contact with patients)		
	● Patient measurement current		
	● Total patient leak current (between parts of device that come into contact with patient and ground)		
	● Total patient leak current (external SIP/SOP voltage)		
	● Total patient leak current (external voltage at specific F-type applied part)		
	● Total patient leak current (current resulting from external voltage at parts of device that come into contact with patient)		
	General-use electrical devices		
● Contact current (between device enclosure and ground)			
● Contact current (between device enclosure and device enclosure)			
● Ground leak current			
● Free current measurement			

*The ST5540 also complies with old standards.

Easy to set up test sequences

- Embedded human body resistance networks for safety standards
- Easy to set up test sequences



Uninterrupted-power polarity switching

Conventional method

Issues :

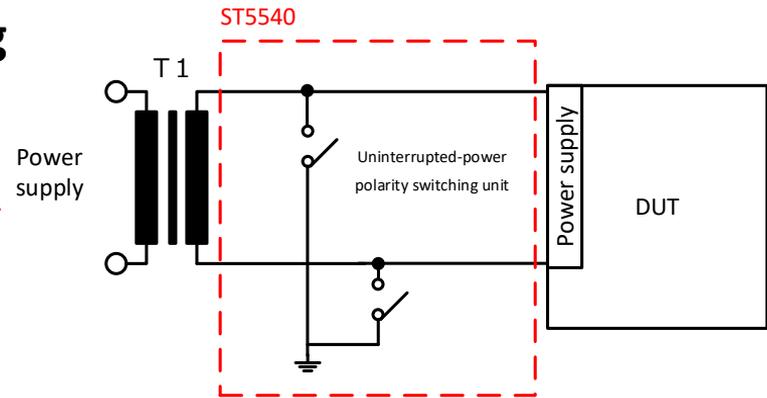
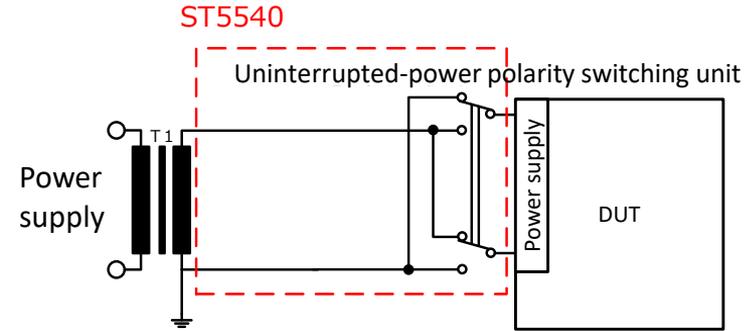
The DUT will lose power when the polarity is switched.

Uninterrupted-power polarity switching

Ground connection only switched

→ No power interruption to DUT (Patented)

*Requires use of an isolation transformer.



Current supply to DUT

Increase of current consumption in modern medical equipment

→ Require supply of higher current

Terminal block: 20 A



Source : Siemens Healthineer website

<https://www.siemens-healthineers.com/en-us/>

Protective conductor current measurement

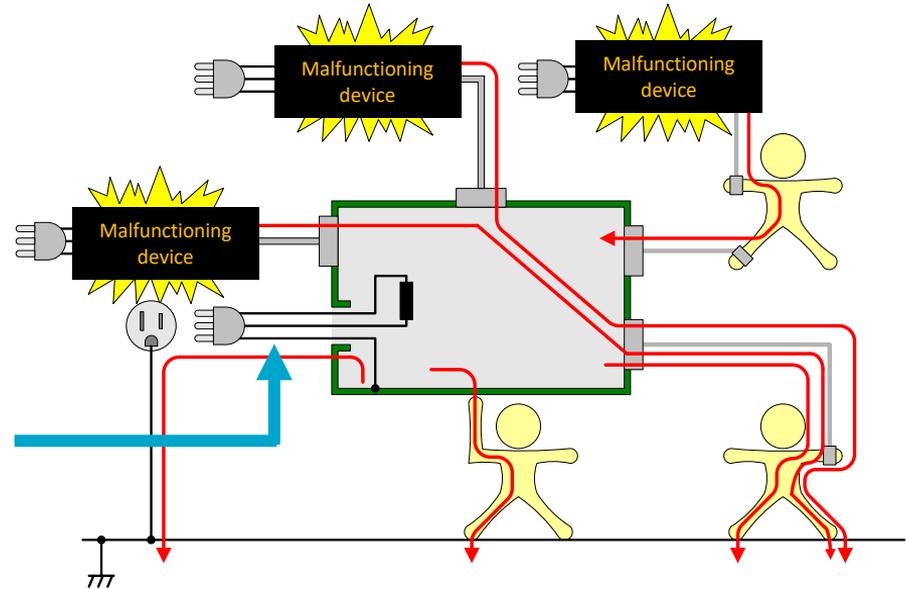
Protective conductor current
measurement in compliance with

IEC 60990:1999

→ Require negligible resistance
insertion for an ammeter

→ **35 Ω** at the ST5540

Protective conductor current
(Normal condition)



Operation check function 1

Wiring and VA check for the power supply of DUT

The diagram illustrates the 'Connection/VA check in process' screen on a device. The screen displays the following information:

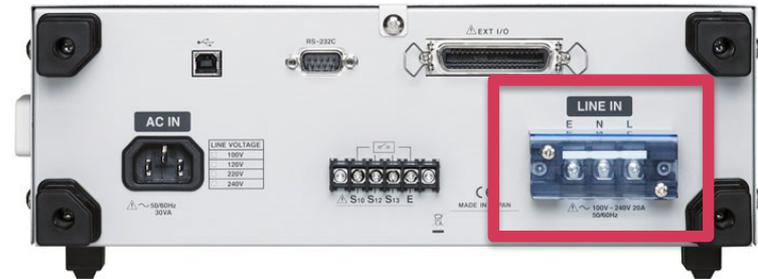
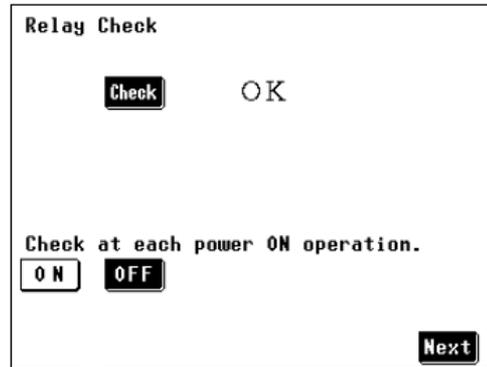
- Connection/VA check in process**
- Volt** 106.0V
- Curr** less than 0.5A
- VA** less than 52VA
- Po1** L-G 105.1 V
- Po1** N-G 25.2 V
- Connection check at each power ON operation.**
- Buttons: **ON**, **OFF**, **Renew**, **Ret**

Callouts provide the following explanations:

- Indicates the voltage of power supplied to [LINE IN].** (Points to the Volt reading)
- Indicates the current consumption of the equipment under test.** (Points to the Curr reading)
- Indicates the power consumption.** (Points to the VA reading)
- Measures voltage between the terminals of [LINE IN] to check the polarity. Indicates the voltages between phase L and terminal G and between phase N and terminal G on the terminal block.** (Points to the Po1 readings)
- Press **ON** or **OFF** to select whether the check is to be conducted each time power is turned.** (Points to the ON and OFF buttons)
- Check again.** (Points to the Renew button)

Operation check function 2

Relay check function – Check internal relays for human body resistance networks and normal/single fault condition)

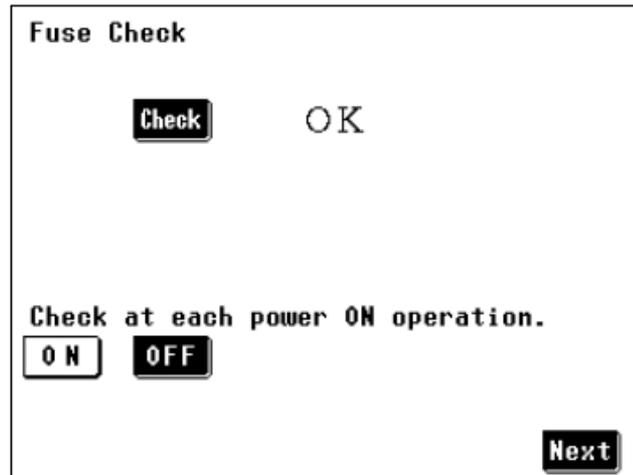


LINE IN

Power supply connected to the LINE IN

Operation check function 3

Fuse check function – Check internal fuses



LINE IN

Power supply connected to the LINE IN

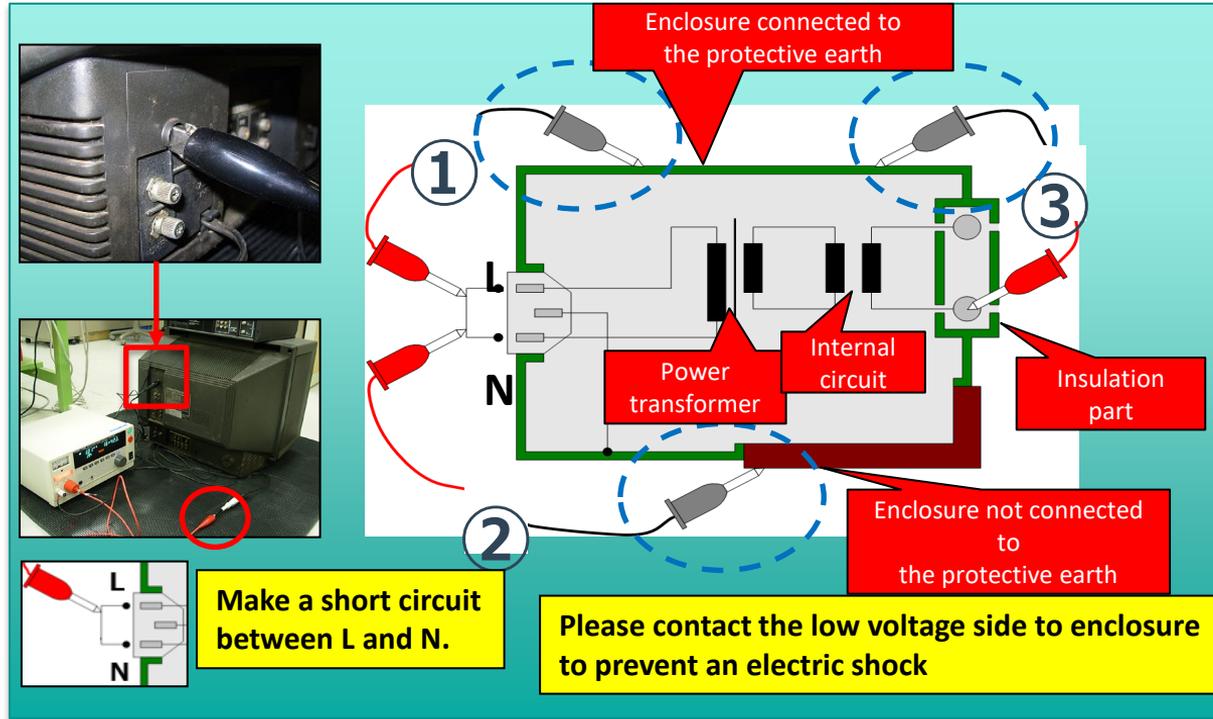
- Avoiding accidental electrical shock
- Classification of electrical equipment
- Safety standards for electrical equipment
- Leakage current test
- **Other test equipment for safety compliance testing**
- Summary

Safety compliance testing

- Leakage Current Measurement
- Insulation Test**
- Withstanding Voltage (Hi-pot) Test**
- Protective Grounding (Ground Bond) Test
- Safety Test Data Management



Hi-pot/Insulation resistance Testing



3153 vs. 3174

3153

Automatic Insulation
AC/DC Withstanding Tester
Stable Output

Voltage Withstand Testing

AC: 0.20 to 5.00 kV, 500 VA
DC: 0.20 to 5.00 kV, 50 VA
0.01 to 100.0 mA

Insulation Testing

DC: 50 to 1200 V
0.10 to 9999 M Ω



3174

Automatic Insulation
AC Withstanding Tester
Stable Output

Voltage Withstand Testing

AC: 0.2 V to 5.00 kV
0.01 mA to 20.0 mA

Insulation Testing

DC: 500/1000 V
0.5 to 2000 M Ω

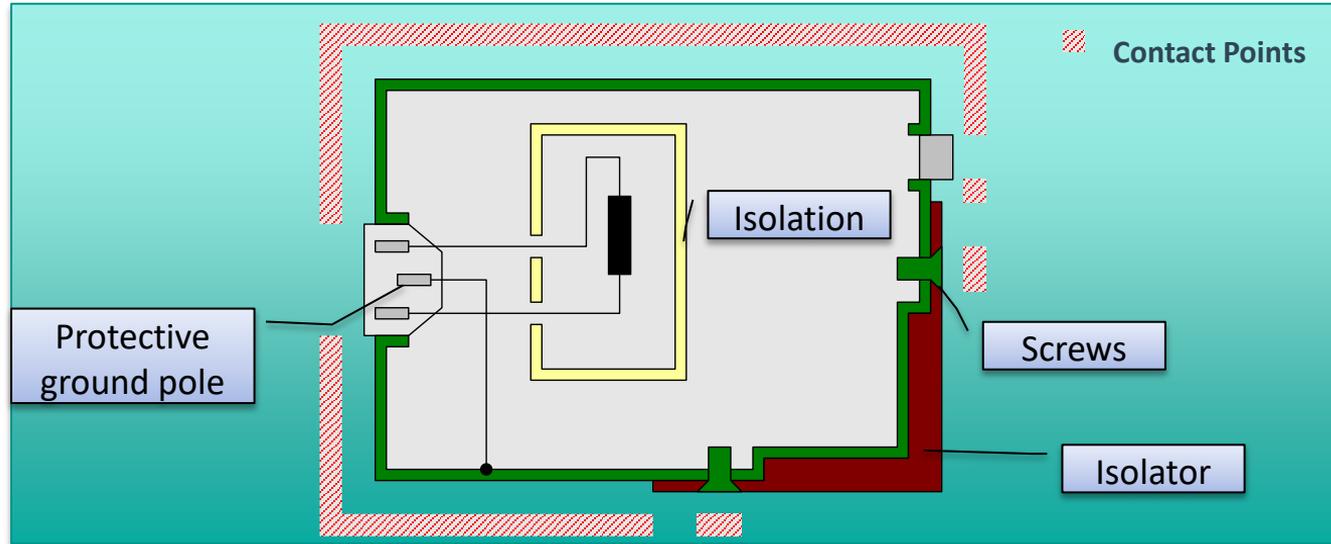
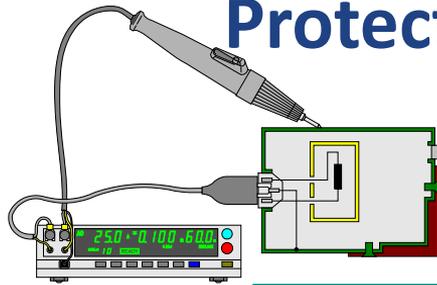


Safety compliance testing

- Leakage Current Measurement
- Insulation Test
- Withstanding Voltage (Hi-pot) Test
- Protective Grounding (Ground Bond) Test**
- Safety Test Data Management

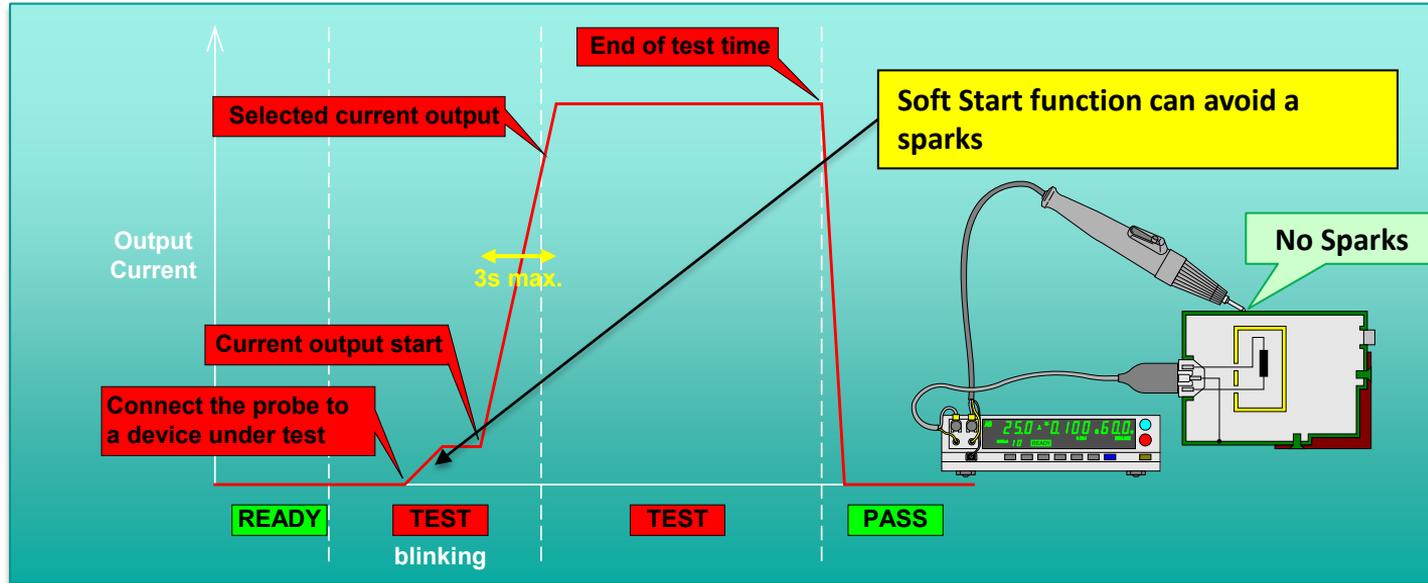


Protective Grounding (Ground Bond) Test



3157

- AC 3.0A ~ 31.0A Output
- No-load voltage Less than 6V
- Soft Start function

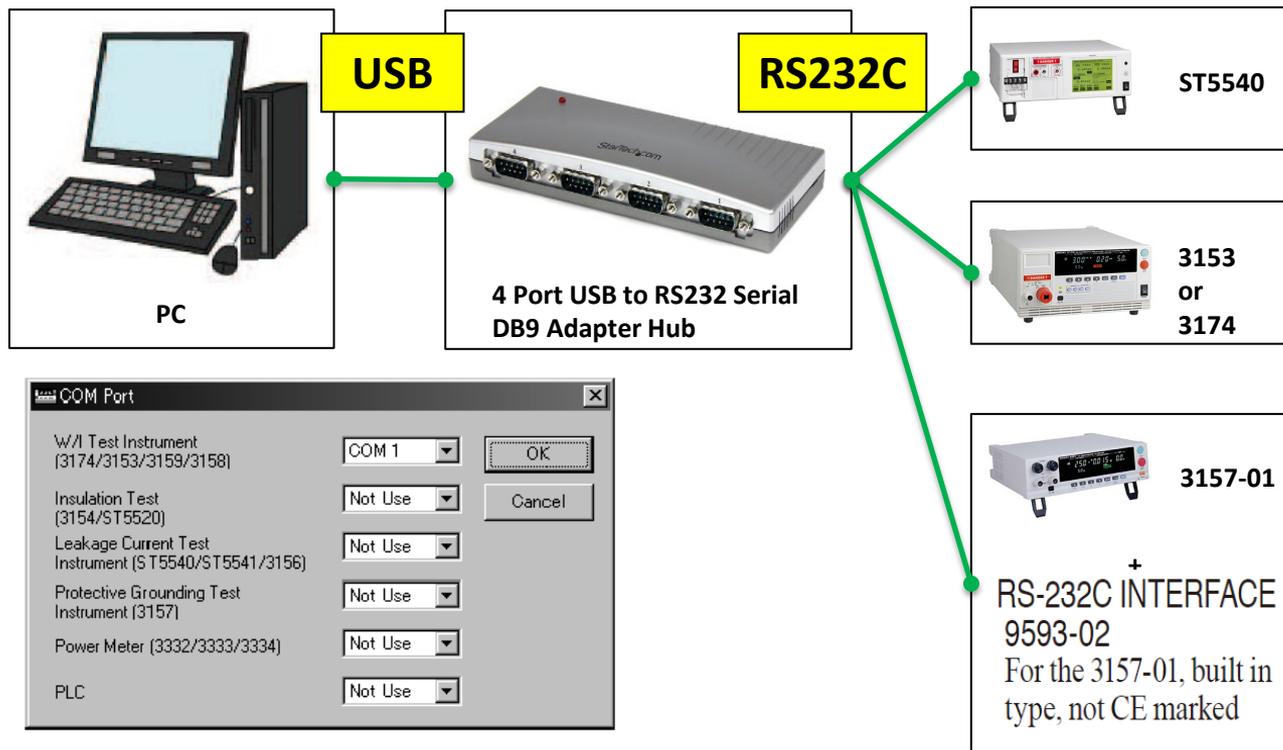


Safety compliance testing

- Leakage Current Measurement
- Insulation Test
- Withstanding Voltage (Hi-pot) Test
- Protective Grounding (Ground Bond) Test
- Safety Test Data Management**



Interface



Safety Test Data Management App 9267

The screenshot displays the Safety Test Data Management Software interface, which includes several windows and a main application window.

Test Settings Window: This window allows users to configure the test sequence. It features five dropdown menus for selecting test items:

- 1 W/I
- 2 Insulation
- 3 Leakage Current
- 4 Protective Ground
- 5 Actual Operation

A note at the bottom states: "Cannot set all tests to 'Not Use' or to select the same test two or more times." Buttons for "OK" and "Cancel" are located at the bottom.

Safety Test Data Management Software Window: This is the main application window. It includes a menu bar (File, Settings, Help) and a toolbar with "Start Test" and "Stop Test" buttons. The "Test Object ID" field is set to "0000001". The "Test Result" section has a checked "Save To File" option and a file path "C:\work\test\11-16-01.csv". Below this is a "Test Progress" section with checkboxes for "Withstanding", "Insulation", "Protective Ground", and "Actual Operation". The "Status" section has checkboxes for "Ready", "Test Now", and "Protection". The "Meas Data" section has input fields for "Output", "Meas", and "Time". A "Test Data Table" is displayed with columns for "ID No.", "Test Time", and "Result".

Test Data Table: The table shows the following data:

ID No.	Test Time	Result
0000001	16:48:10	Pass

Result Window: A separate window displays the test result: "Result Pass".

Background Window: A larger window in the background shows a detailed "Test Data Table" with columns for "Test Time", "Result", "W Volt", "W Curr", "W Time", "W Result", "I Volt", "I Resi", "I Time", and "I Result". The first row of data is:

Test Time	Result	W Volt	W Curr	W Time	W Result	I Volt	I Resi	I Time	I Result
16:48:10	Pass	1	0	0	PASS	49	405	0	PASS

Summary

Electrical equipment requires to be tested referring to safety standards below

- IEC 60601-1: **Medical standard**
- IEC 61010-1
- IEC 60990, etc.

Electrical safety is validated by;

- Leakage current test – ST5540
- Hi-pot and Insulation resistance test – 3153 or 3174
- Protective grounding test – 3157

Leakage current test by ST5540

- Complies with IEC 60601-1
- Equips human body networks for medical standards
- Uninterrupted power-polarity switching (Patented)
- 20 A current rating & OP. check functions

For more information

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Email: info@tmetrix.com

Website: <https://tmetrix.com/>



ST5540



**Hi-POT Tester
3153**



**AC GROUNDING HiTESTER
3157**

Questions?

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