Safety Standards Measurement Instruments

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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

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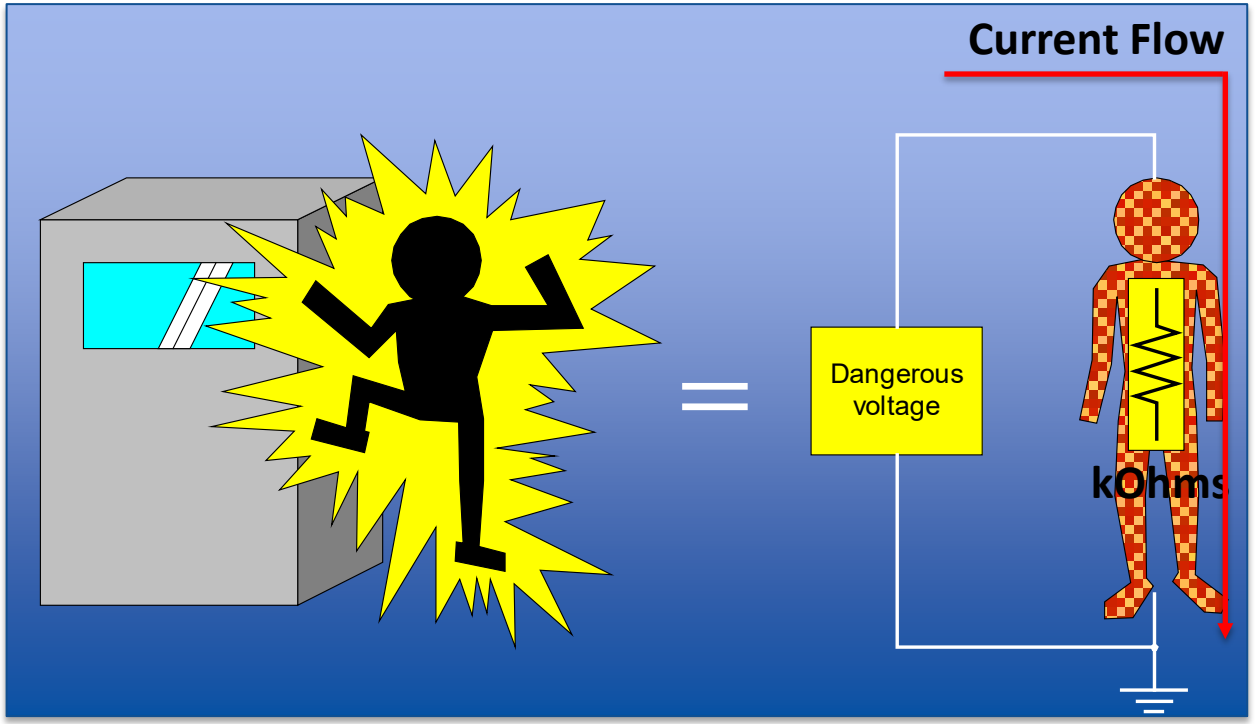
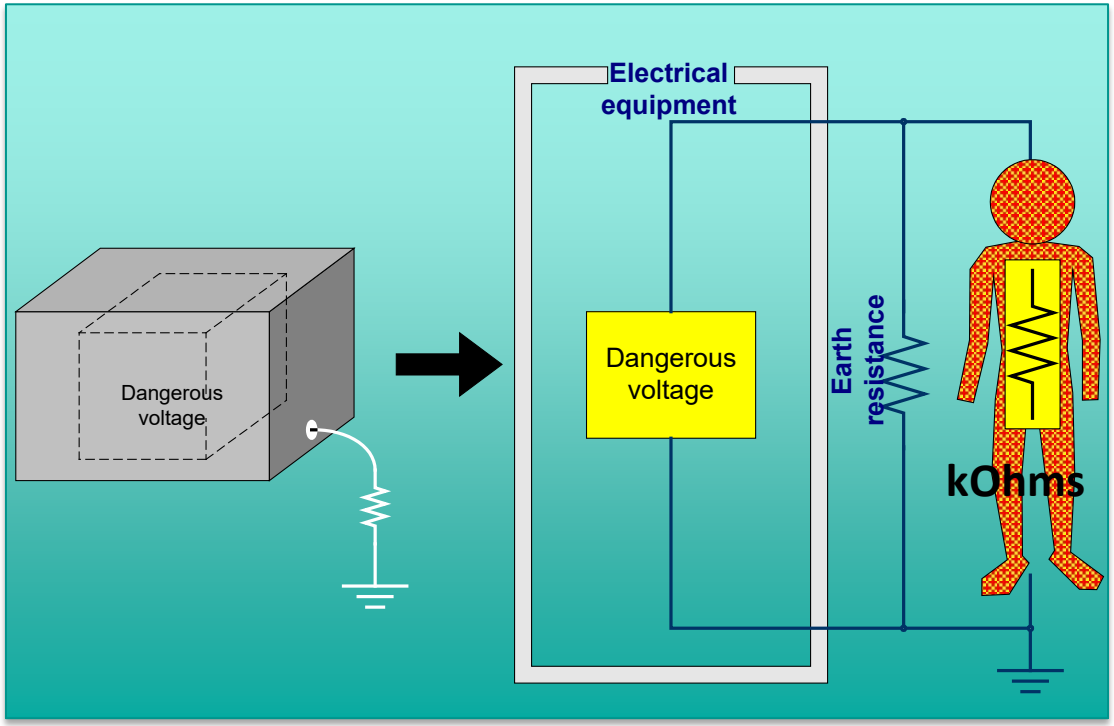
Cause of Electrical Shock

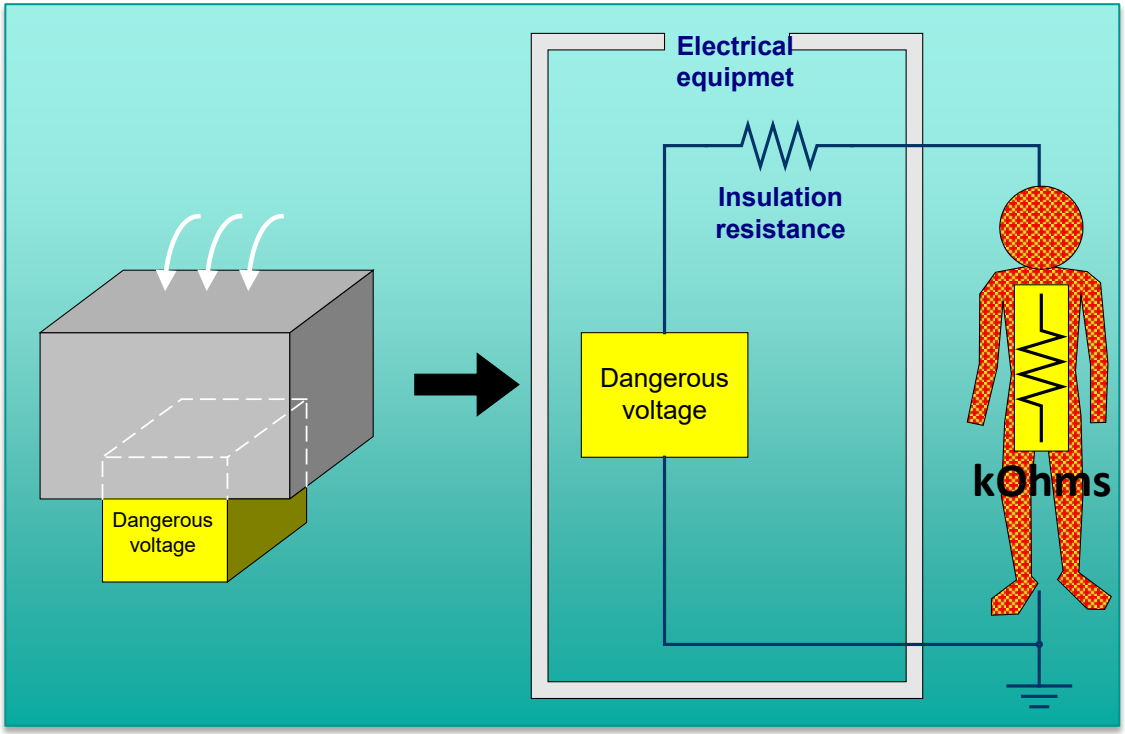


Countermeasure 1 : “Discharge” = Grounding



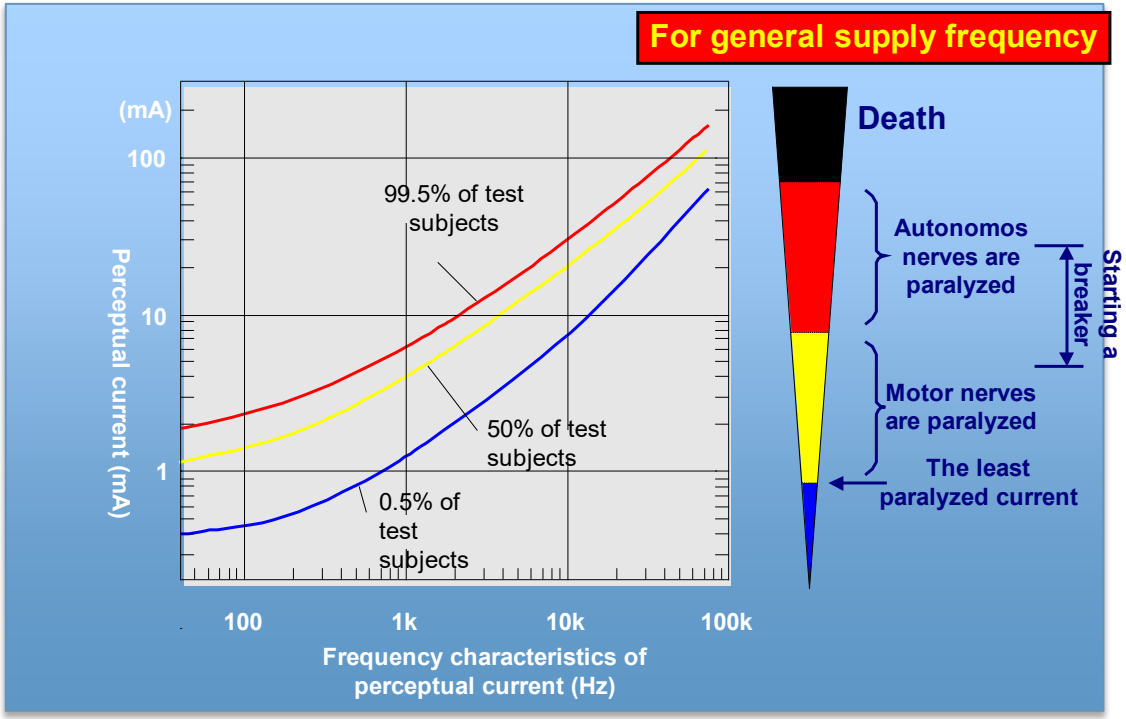
HIOKI

Countermeasure 2 : “Enclosure” = Isolation



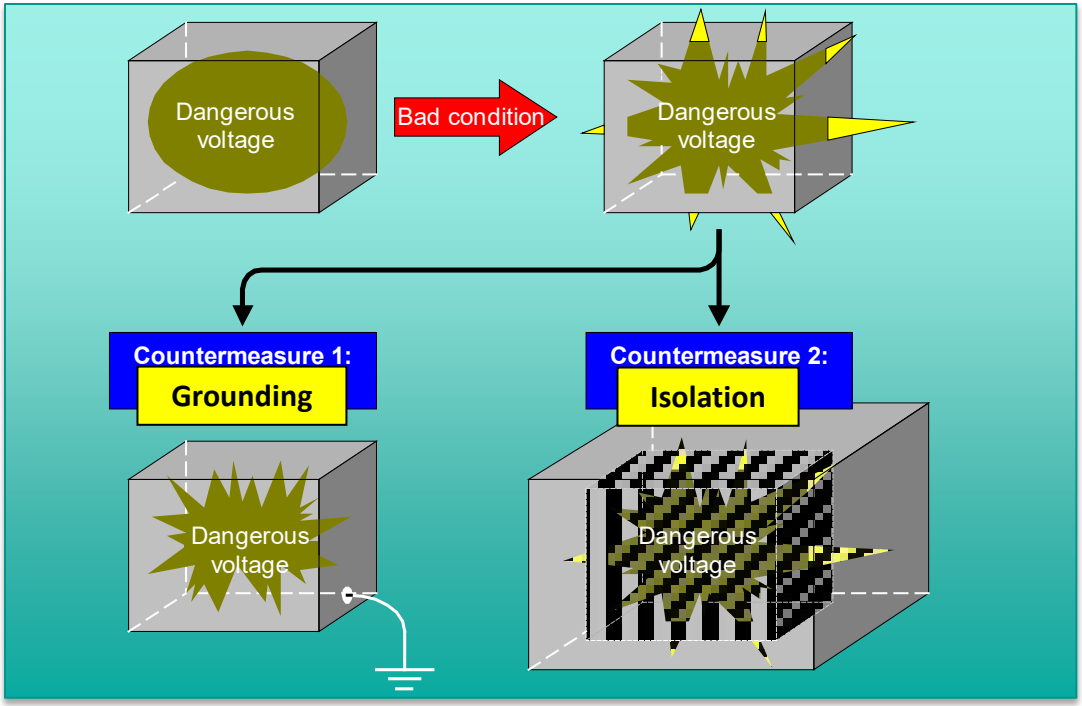
HIOKI

Electrocution



HIOKI

Double and triple protection standard



HIOKI

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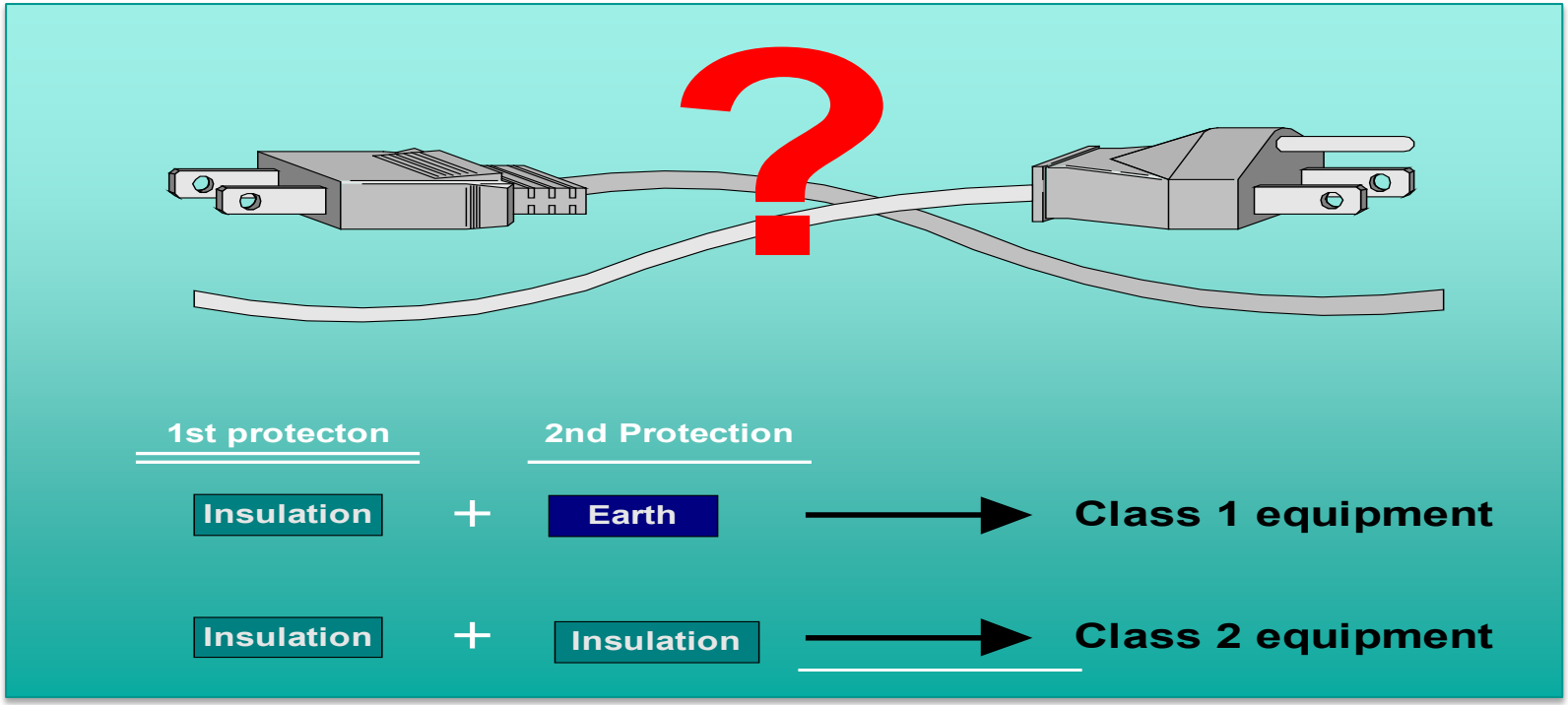
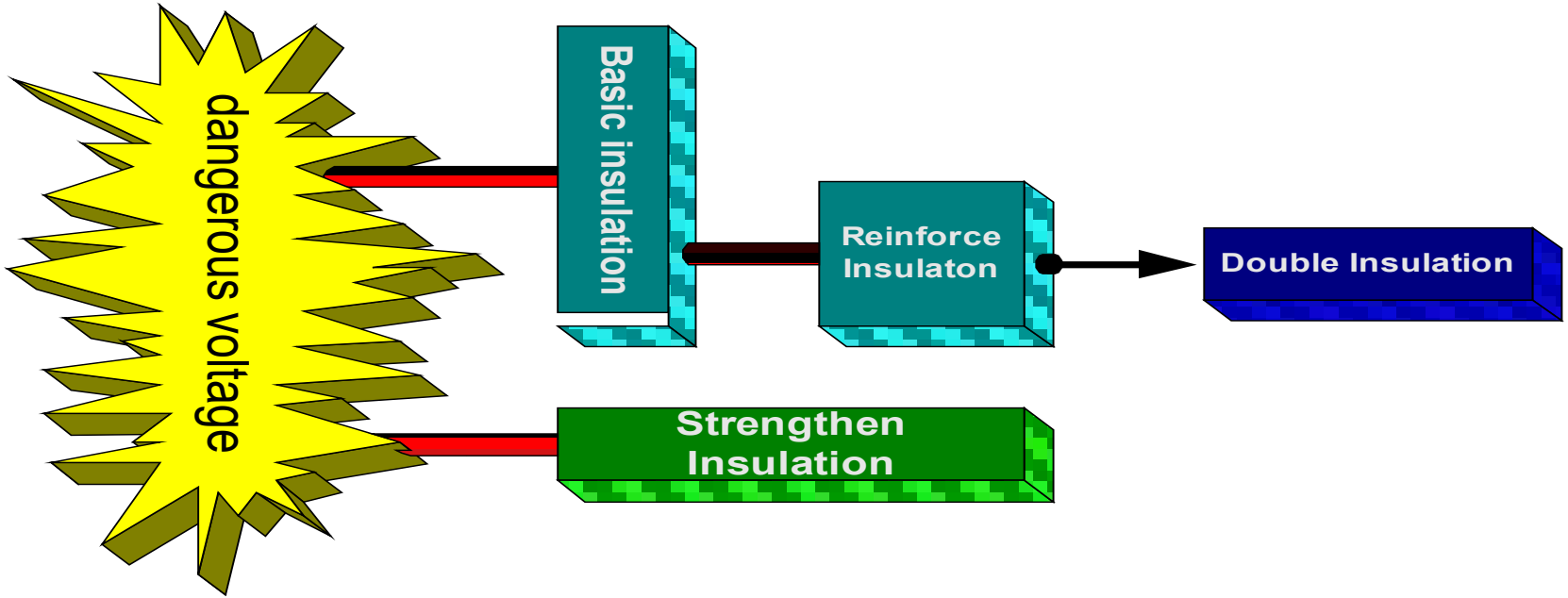
- Summary

HIOKI

Classification of electrical equipment

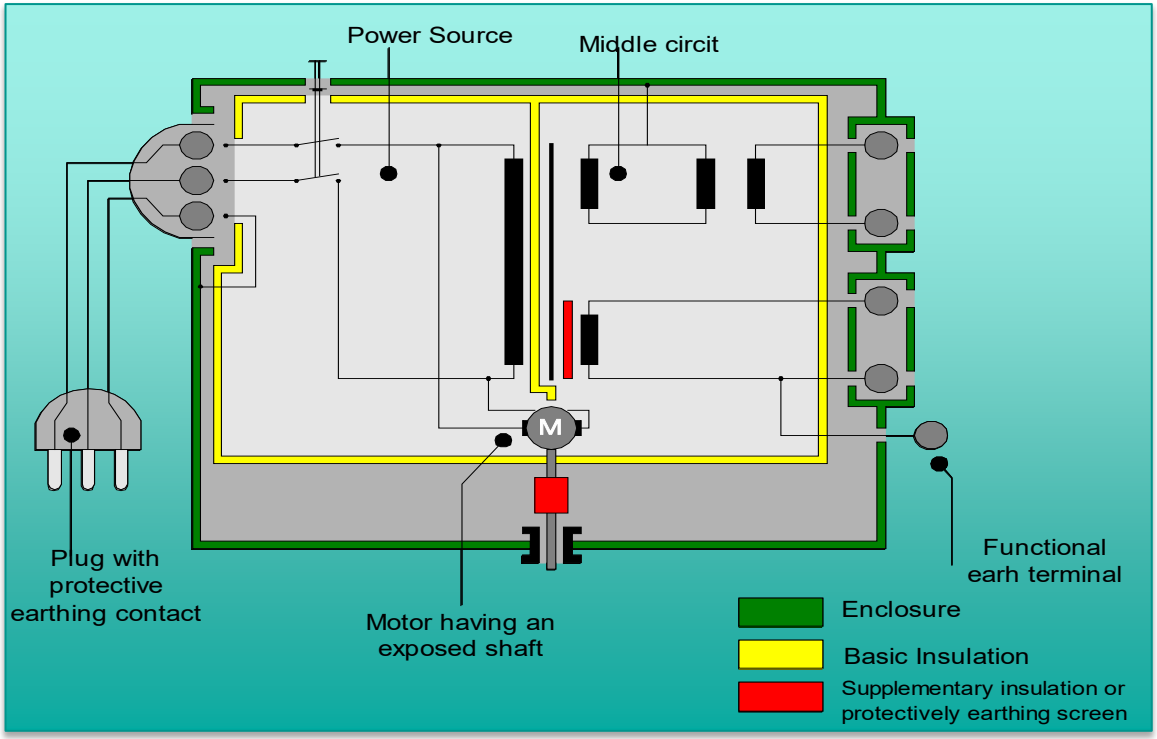


Insulation system



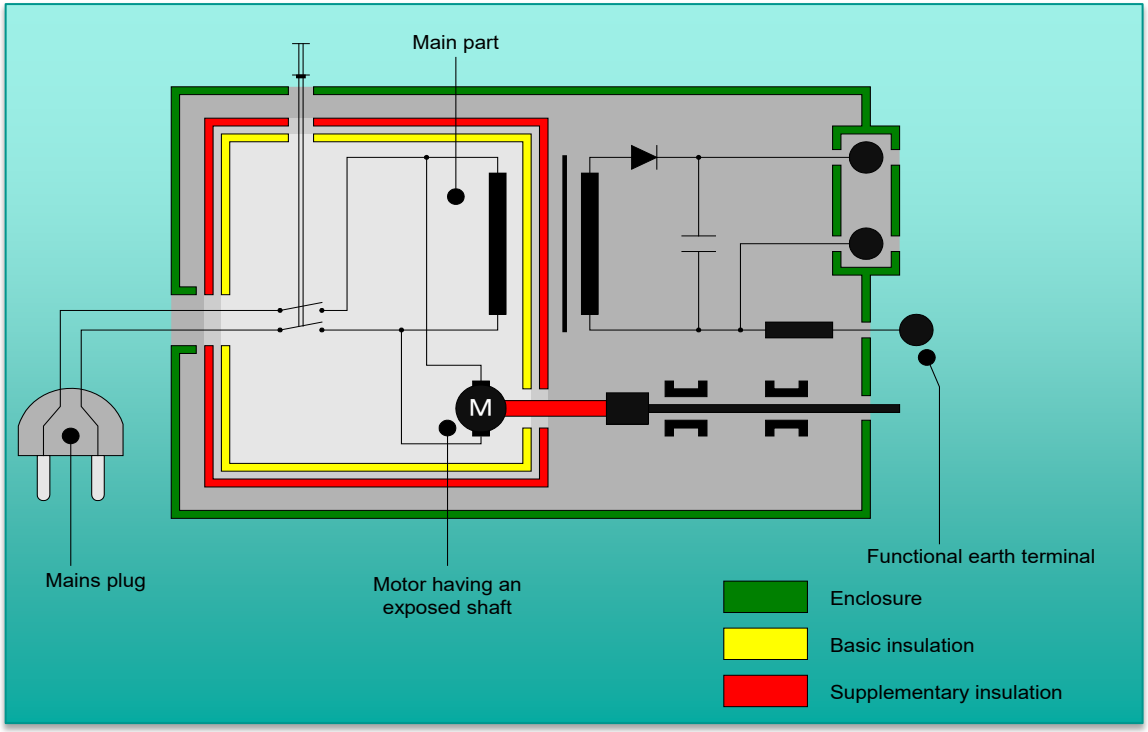
HIOKI

Class I equipment



HIOKI

Class II equipment



HIOKI

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

HIOKI

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

HIOKI

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Medical standard

IEC 60990:1999
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Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements

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Audio, video and similar electronic apparatus – Safety requirements

HIOKI

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

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

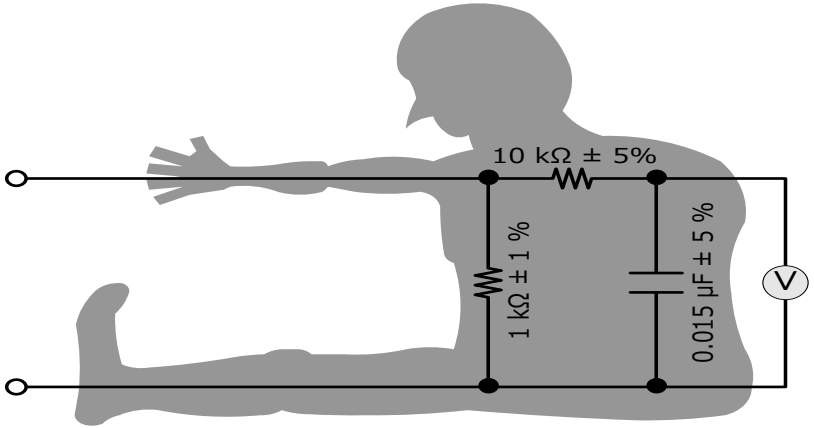
Leakage current values that would

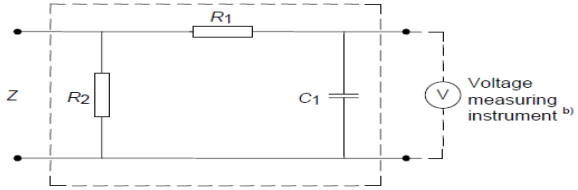
flow to the human body (through a person)

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

HIOKI

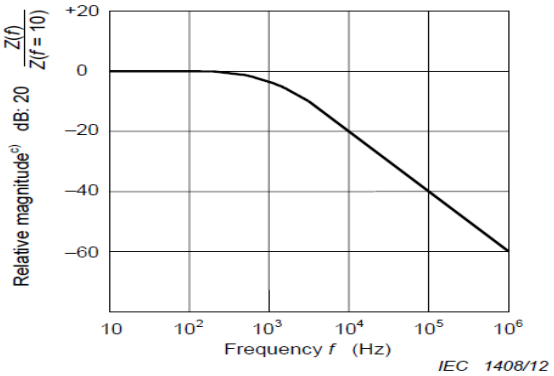
Person = Simulated human resistance
= Measurement network: Example





R_1 10 kΩ ± 5 %[a)]
R_2 1 kΩ ± 1 %[a)]
C_1 0,015 µF ± 5 %

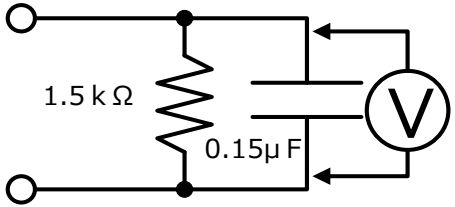
IEC 1407/12



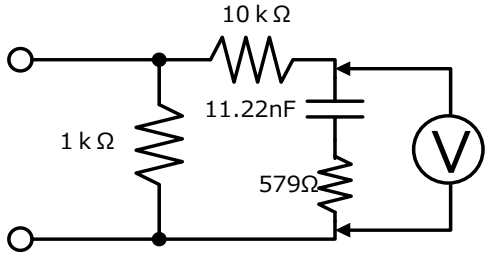
IEC 1408/12

Source：IEC60601-1

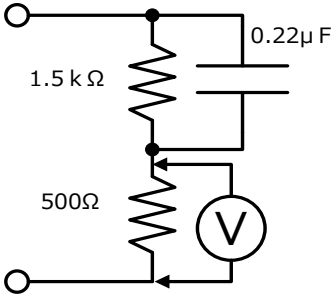
Person = Simulated human resistance
= Measurement network: Example

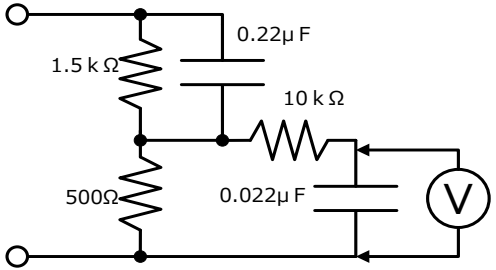


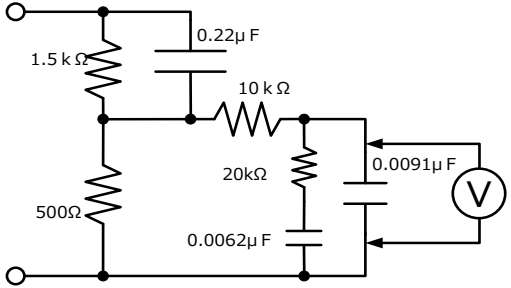
UL standard



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



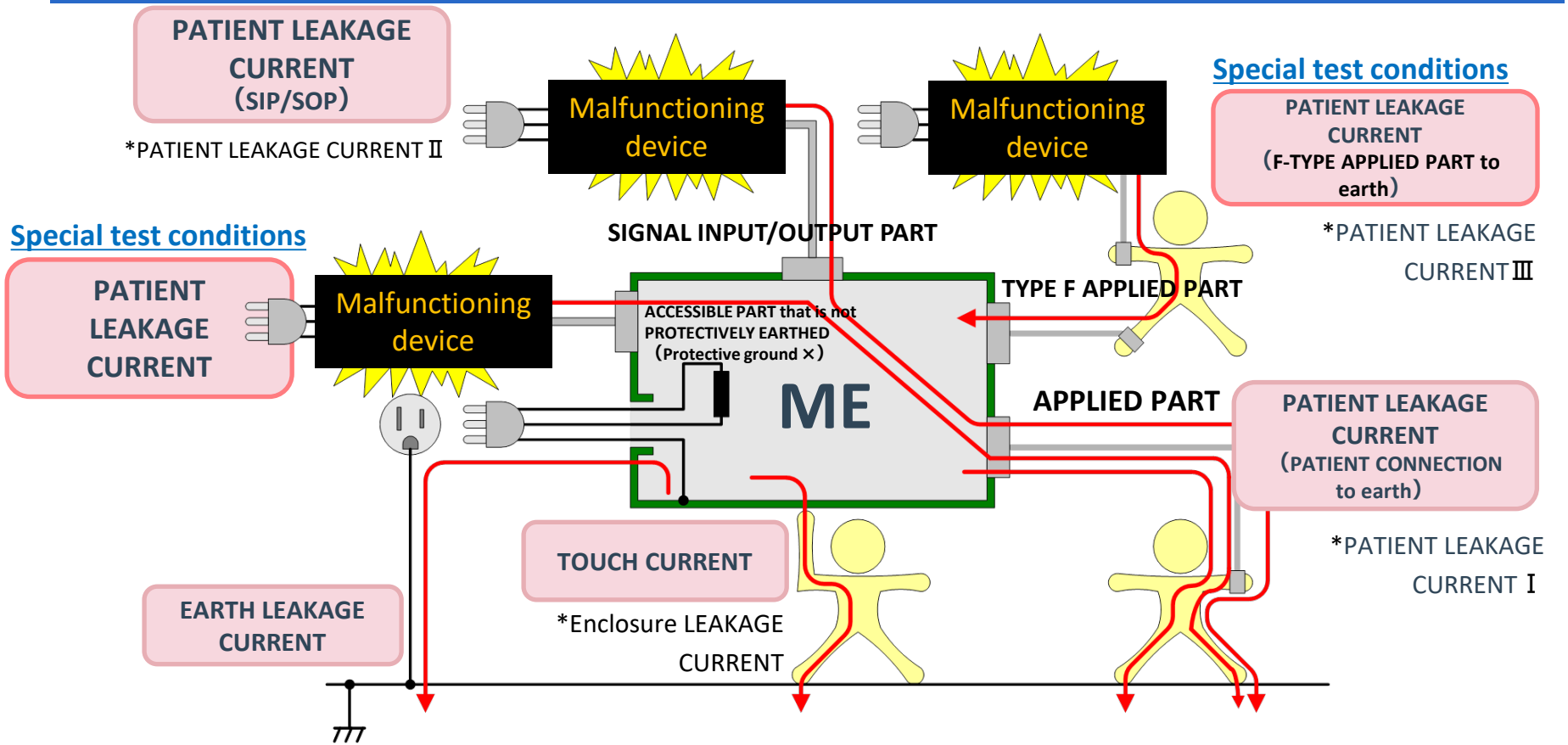




IEC 60990（IEC 60065-1,IEC 60950-1,IEC 61010-1 etc）

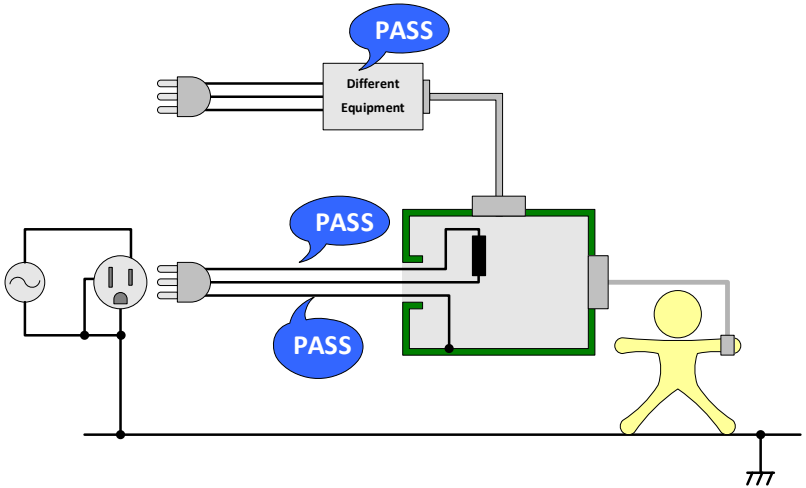
IEC 60990：Methods of measurement of touch current and protective conductor current

Types of leakage current

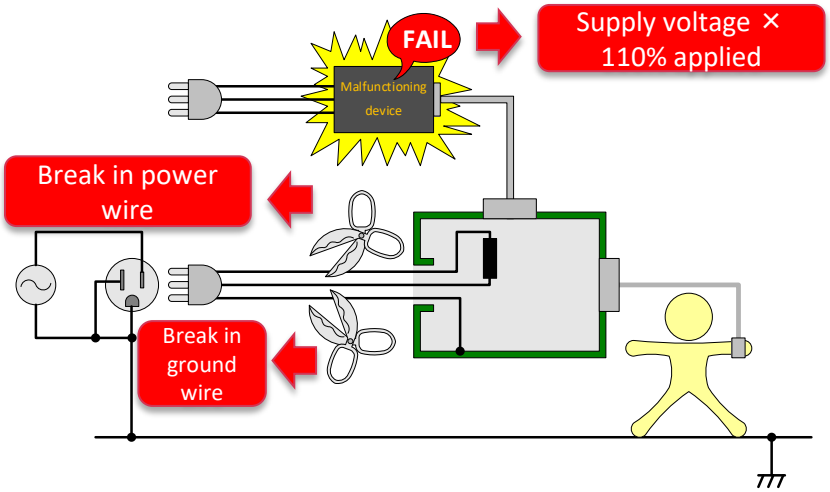


Test conditions for leakage current testing

Perform leakage current testing at normal and single fault conditions



Normal condition



Single fault condition

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ST5540 – features

- Perform testing in compliance with

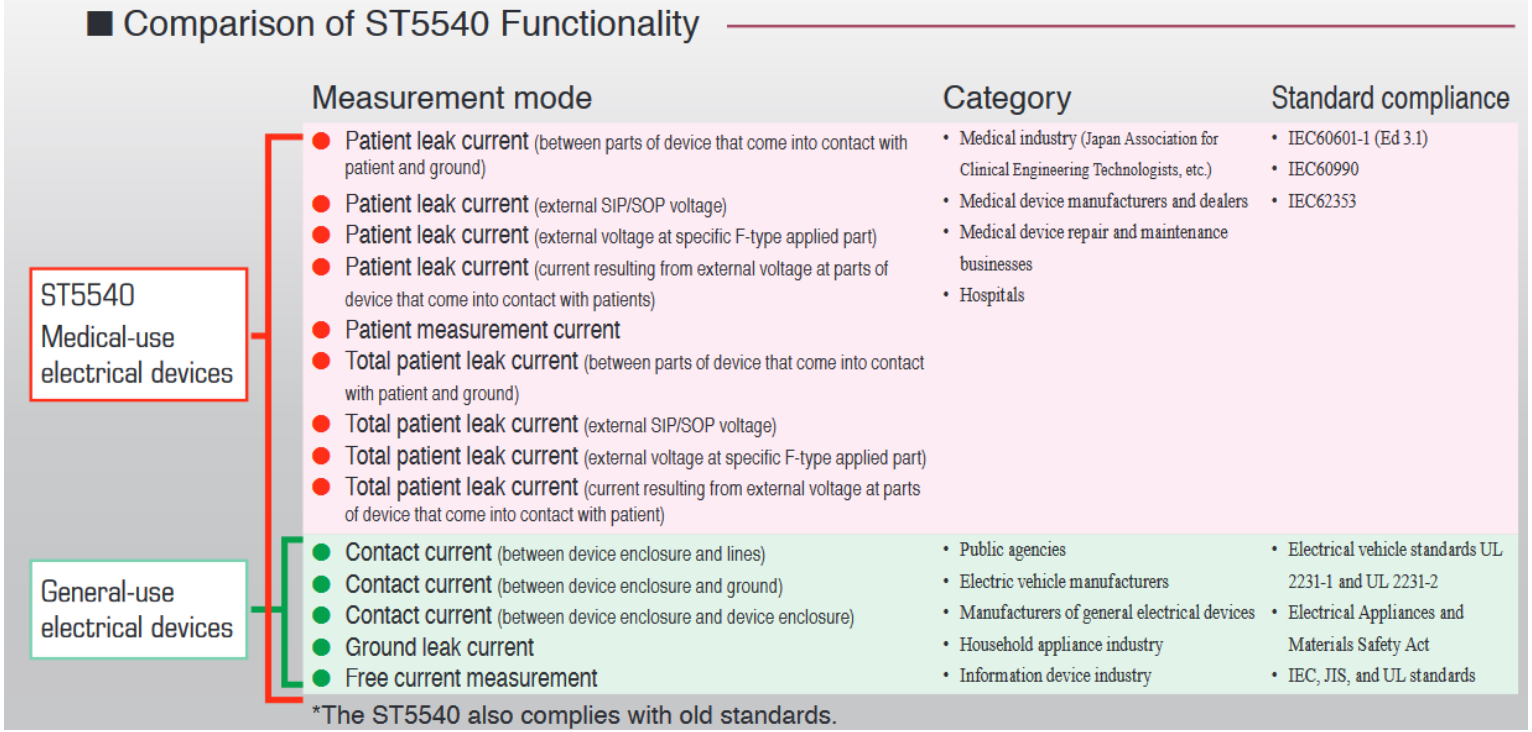
  IEC 60601-1 Ed. 3.0:2005, IEC 60601-1 Amd.1 Ed. 3.0:2014

  *IEC 60601-1：Standards for medical devices

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

HIOKI

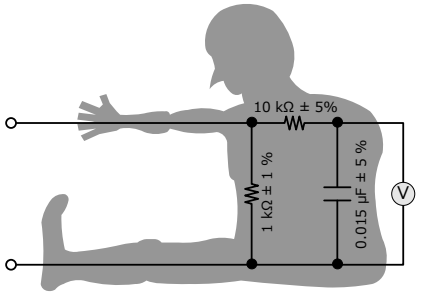
Standard compliance

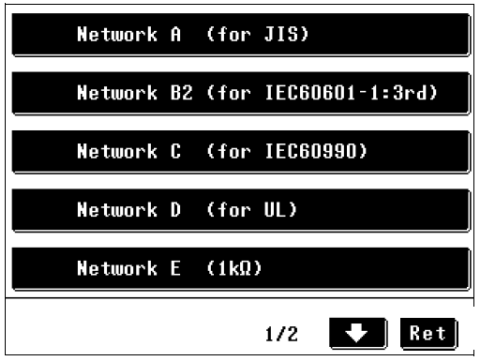


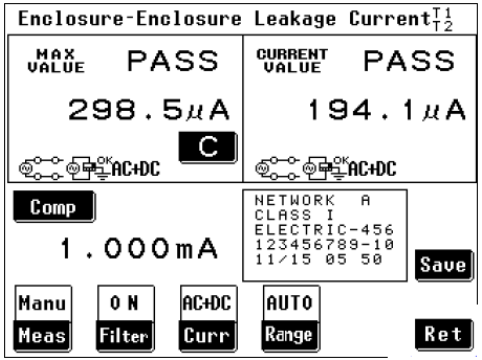
HIOKI

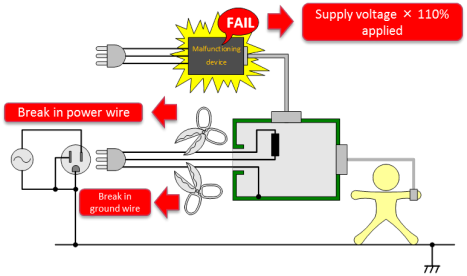
Easy to set up test sequences

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









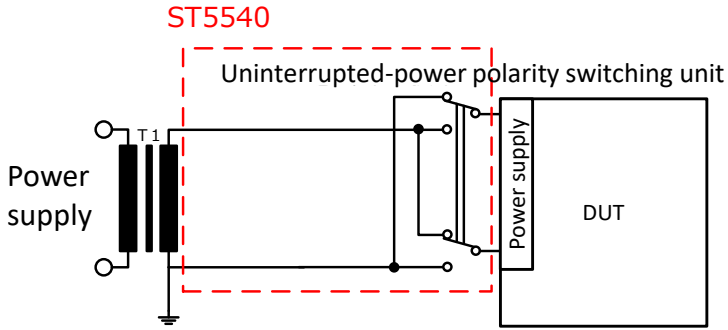
HIOKI

Uninterrupted-power polarity switching

Conventional method

Issues：

The DUT will lose power when the polarity is switched.

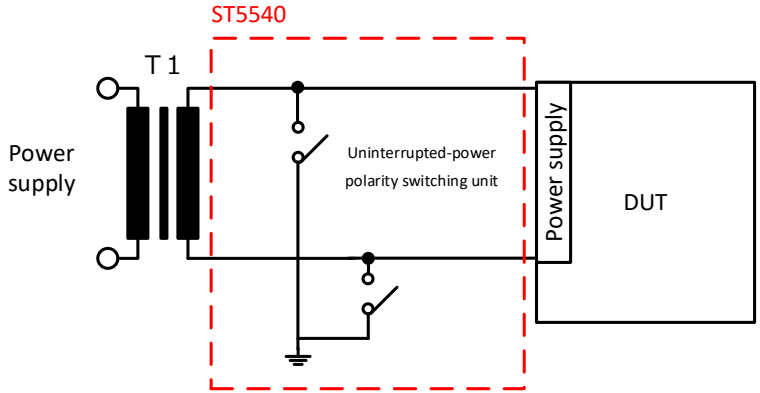


Uninterrupted-power polarity switching

Ground connection only switched

→ **No power interruption to DUT (Patented)**

***Requires use of an isolation transformer.**



HIOKI

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/

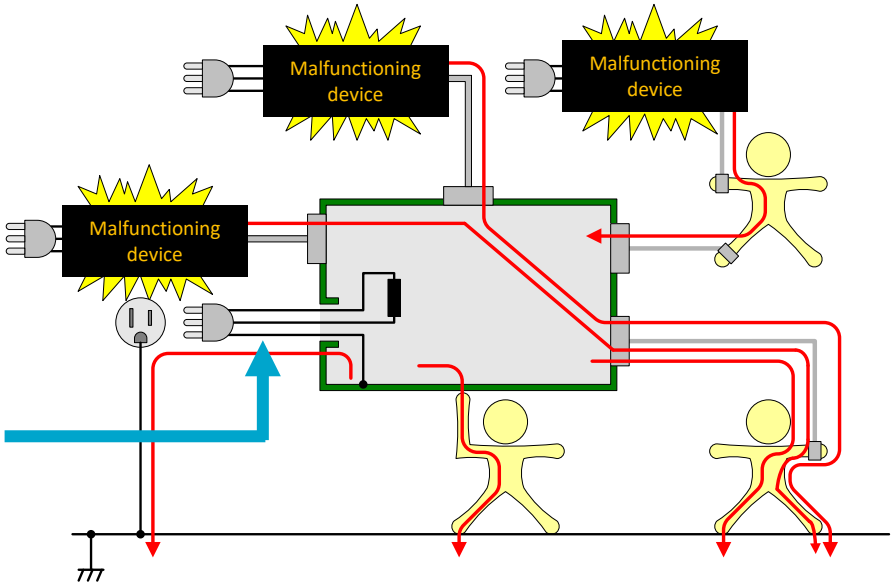
HIOKI

Protective conductor current measurement

<u>Protective conductor current</u> measurement in compliance with IEC 60990:1999

→ Require negligible resistance insertion for an ammeter

→ 35 Ω at the ST5540

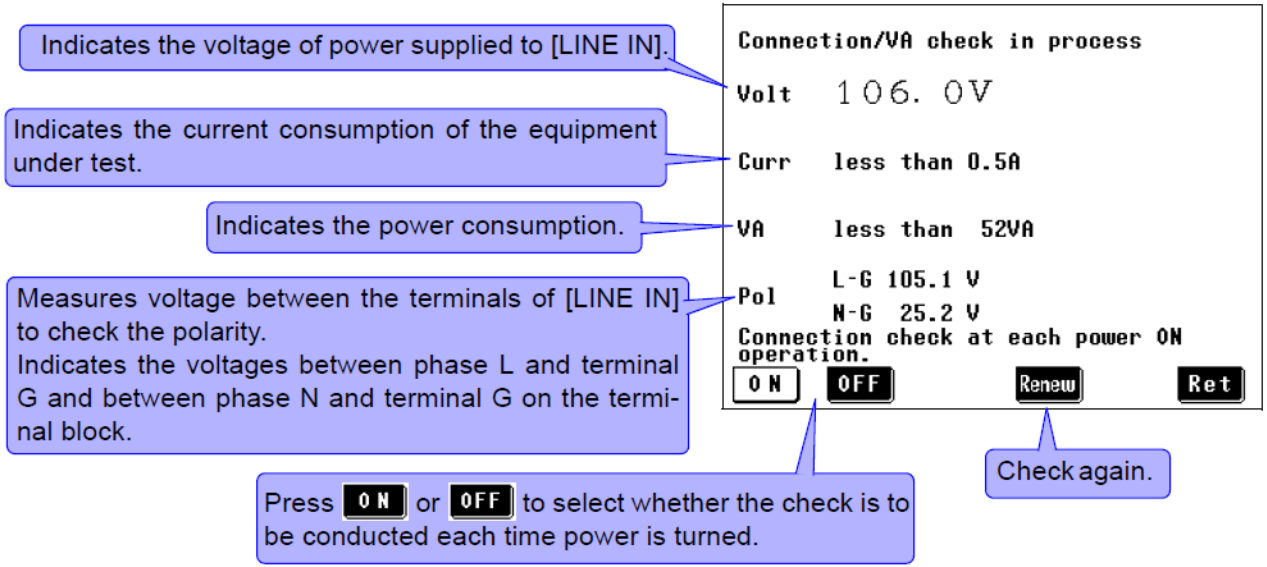


Protective conductor current (Normal condition)

HIOKI

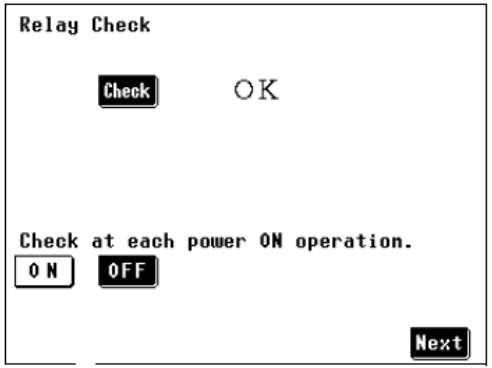
Operation check function 1

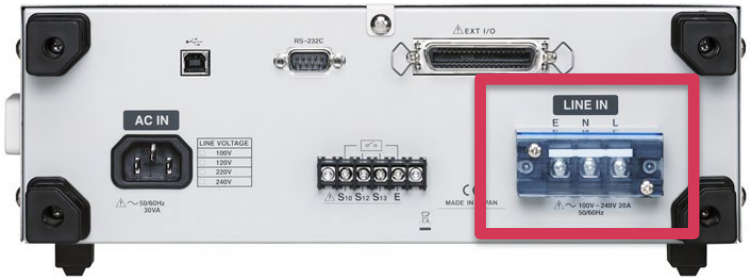
Wiring and VA check for the power supply of DUT



Operation check function 2

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





LINE IN

Power supply connected to the LINE IN

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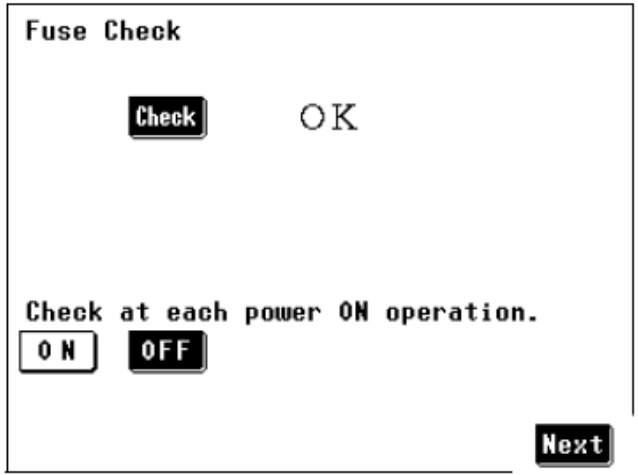
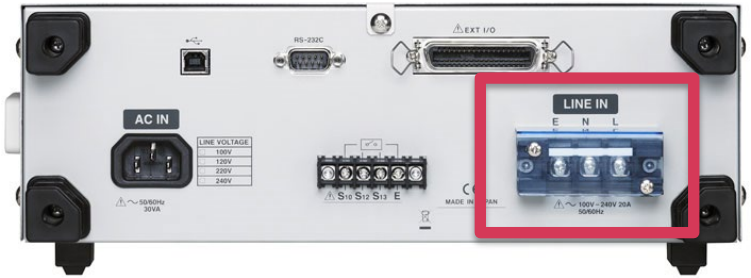
Operation check function 3

<u>Fuse check function</u> – Check internal fuses





LINE IN

Power supply connected to the LINE IN

HIOKI

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

HIOKI

Safety compliance testing

- Leakage Current Measurement

ST5540

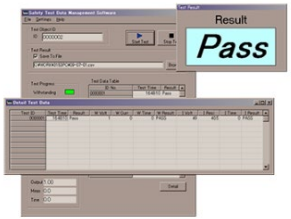
- **Insulation Test**
- **Withstanding Voltage (Hi-pot) Test**

3153
or
3174

- Protective Grounding (Ground Bond) Test

3157-01

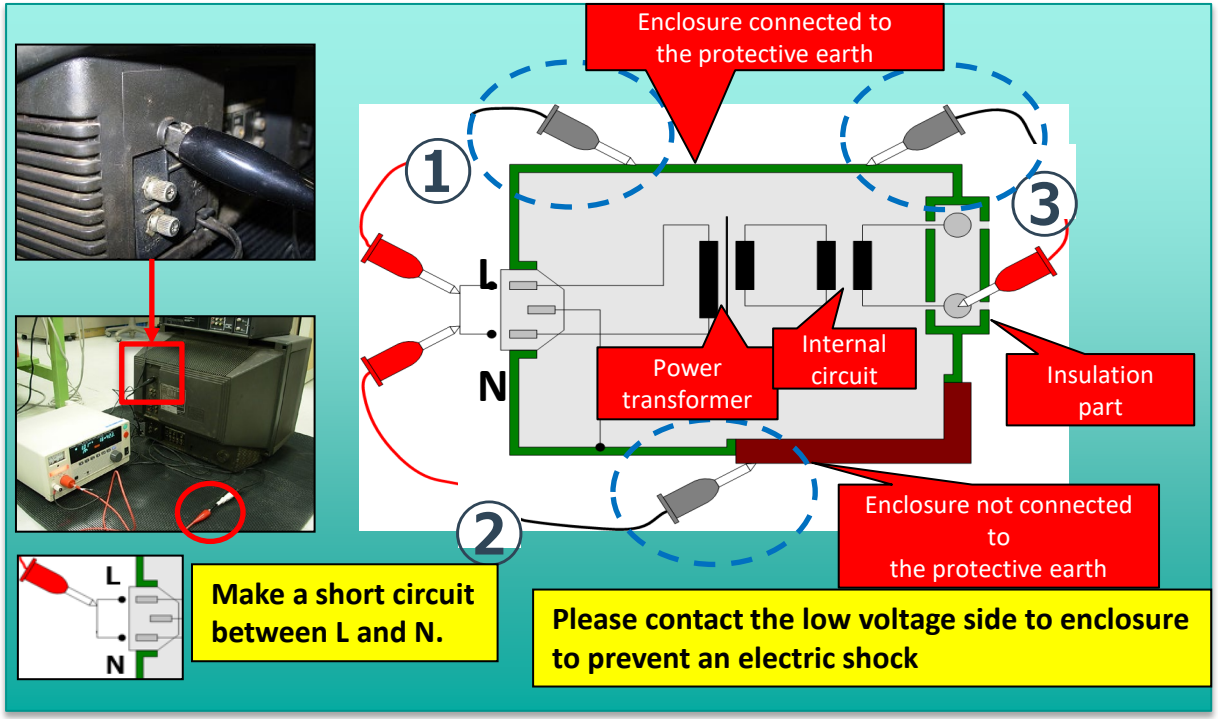
- Safety Test Data Management



9267

HIOKI

Hi-pot/Insulation resistance Testing



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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 MΩ

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 MΩ

HIOKI

Safety compliance testing

- Leakage Current Measurement

ST5540

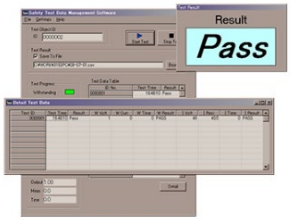
- Insulation Test
- Withstanding Voltage (Hi-pot) Test

3153
or
3174

- **Protective Grounding (Ground Bond) Test**

3157-01

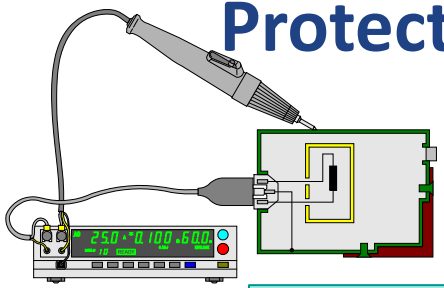
- Safety Test Data Management

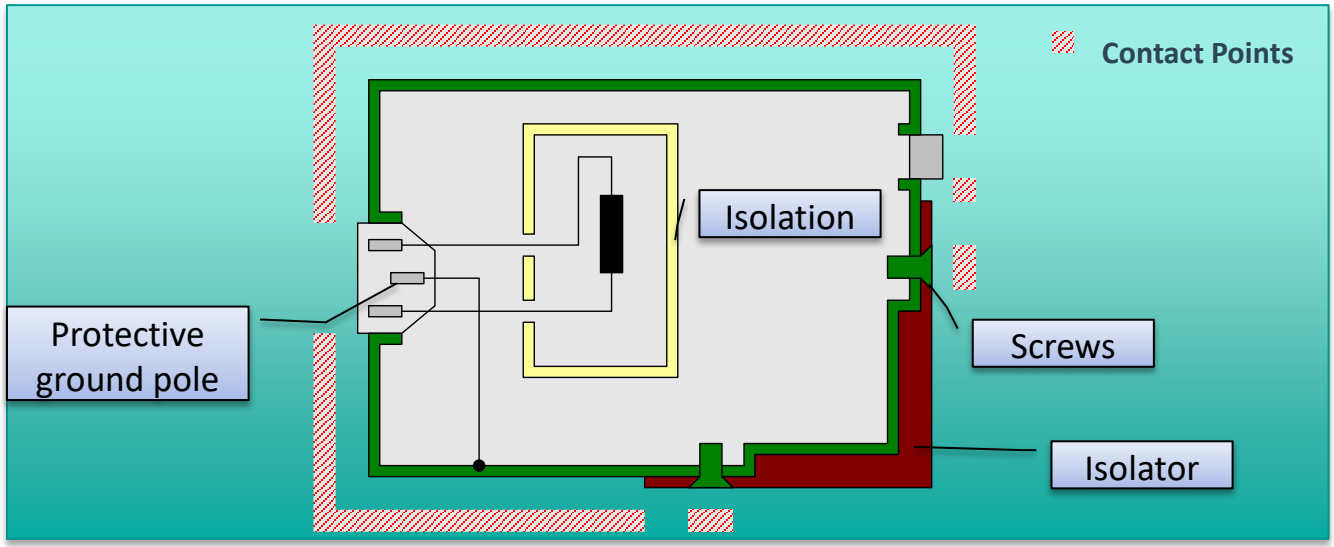


9267

HIOKI

Protective Grounding (Ground Bond) Test

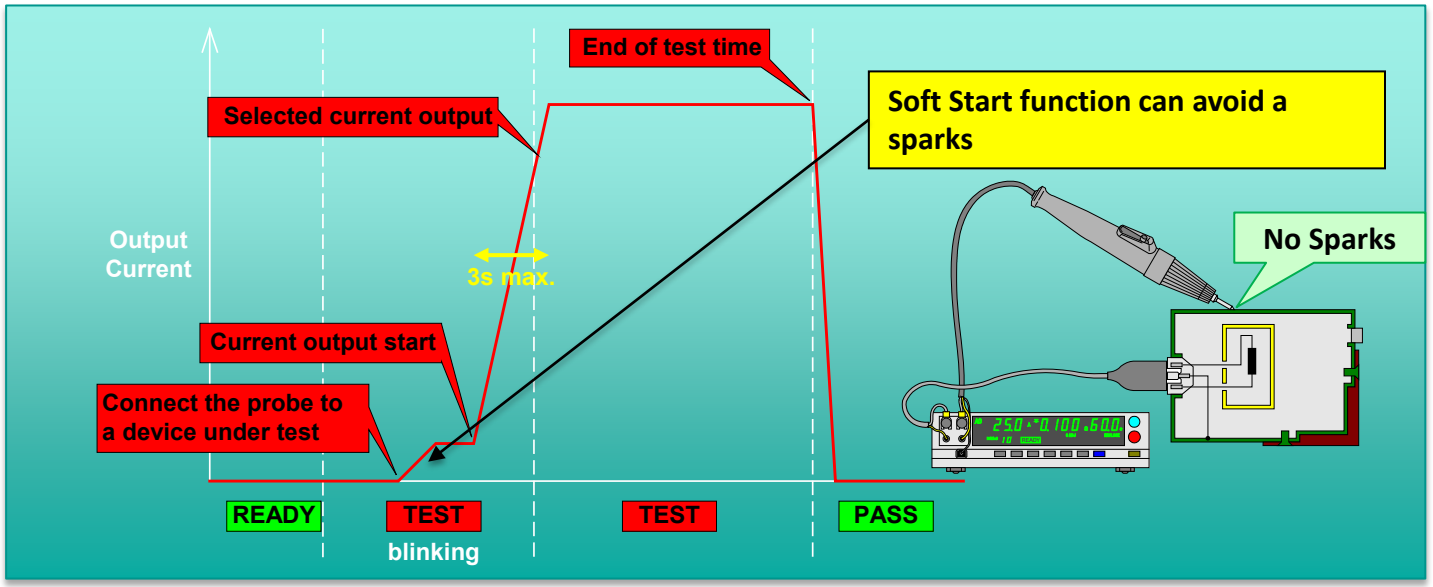




HIOKI

3157

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



Safety compliance testing

- Leakage Current Measurement

ST5540

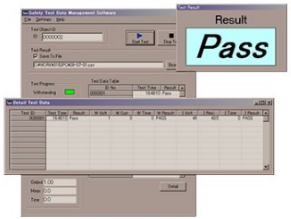
- Insulation Test
- Withstanding Voltage (Hi-pot) Test

3153
or
3174

- Protective Grounding (Ground Bond) Test

3157-01

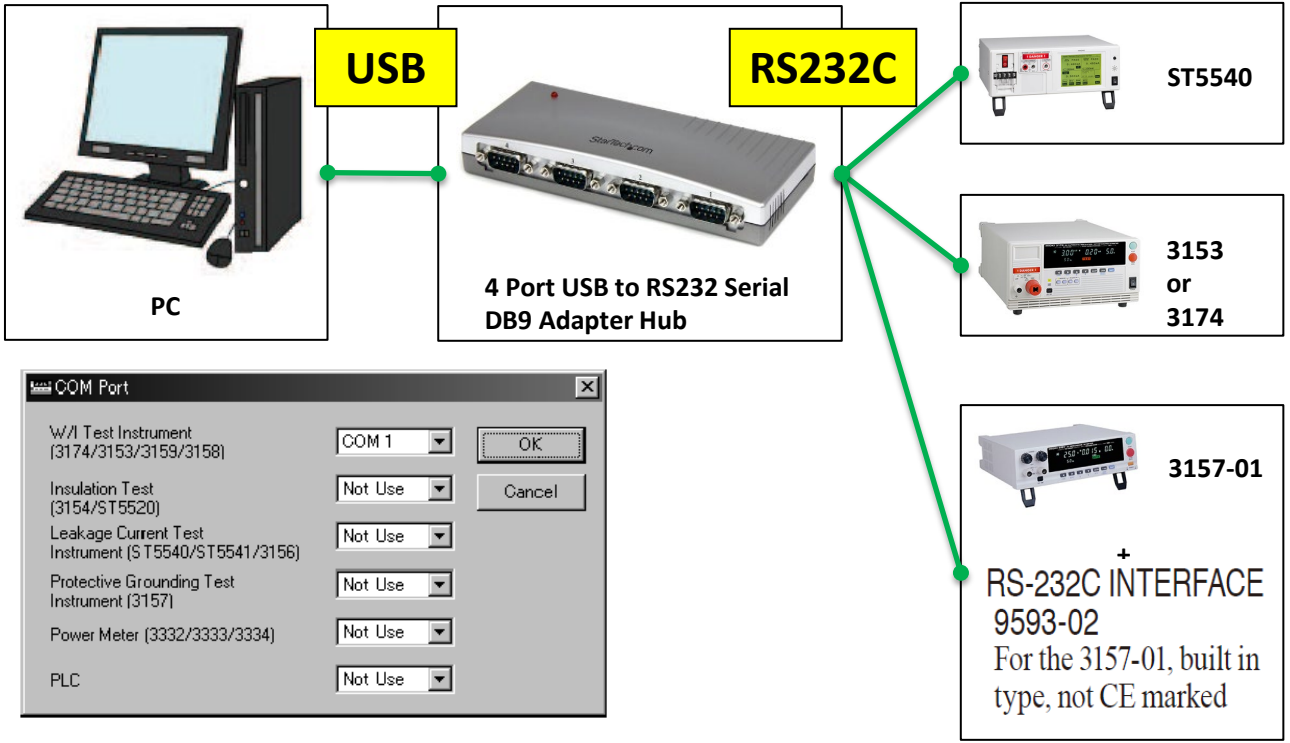
- **Safety Test Data Management**



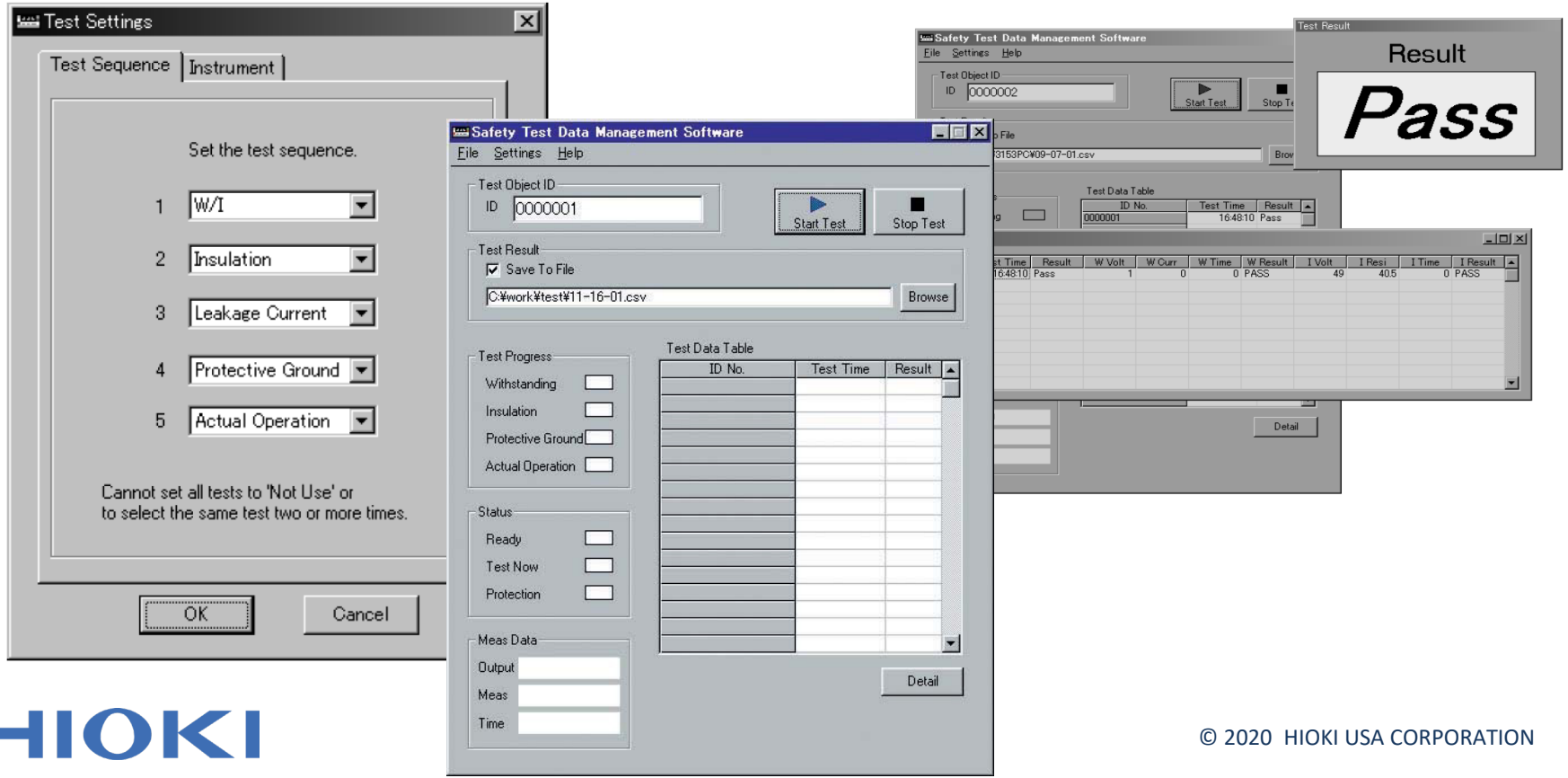
9267

HIOKI

Interface



Safety Test Data Management App 9267



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

HIOKI USA Corporation
6600 Chase Oaks Blvd. Suite 150
Plano, TX 75023, USA
Phone: 469-983-1700

https://www.hiokiusa.com

HIOKI

For more product information

ACA TMetrix
3585 Laird Road, Units 15-16,
Mississauga, ON L5L 5Z8
TEL:1-800-665-7301

Email: info@tmetrix.com

Website: ***https://tmetrix.com/***

ST5540

Hi-POT Tester
3153

AC GROUNDING HiTESTER
3157

Questions?

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