

User's Guide

Measuring leakage current of medical-use electrical devices



LEAK CURRENT HiTESTER for medical-use electrical devices **ST5540**

HIOKI

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- What is leak current testing?
- Product features
- Frequently asked questions

- **What is leak current testing?**
- Product features
- Frequently asked questions

What is leak current testing

Purpose

To check insulation performance

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

Criterion

Leak current value that would

flow to the human body (through a person)

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

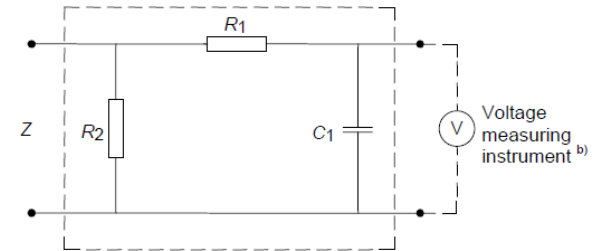
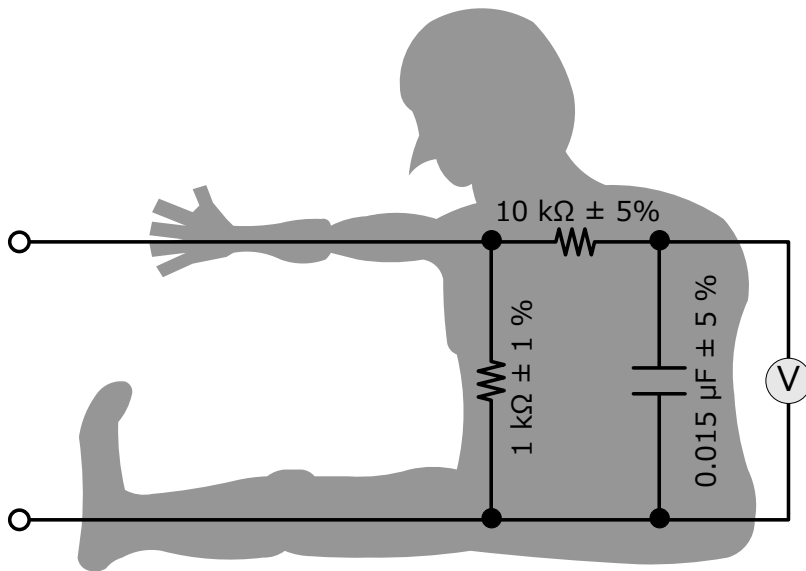
This type of leak current is distinct from current values that are used to determine the results of equipment leak current and withstand voltage tests.

Consequently, it differs from current as used in clamp tester and withstand voltage testing.



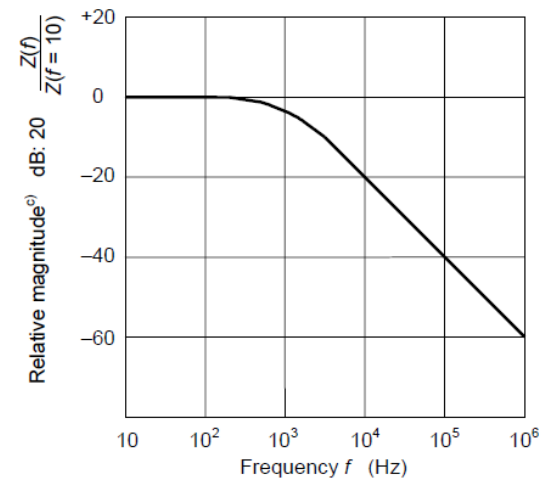
Person = Simulated human resistance

= 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

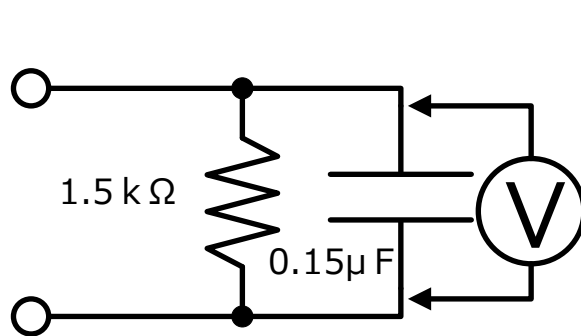


IEC 1408/12

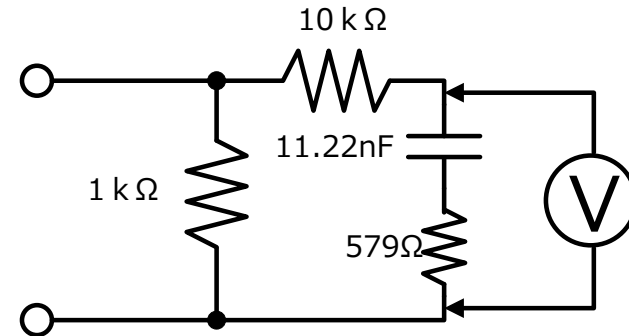
Source : IEC60601-1

Person = Simulated human resistance

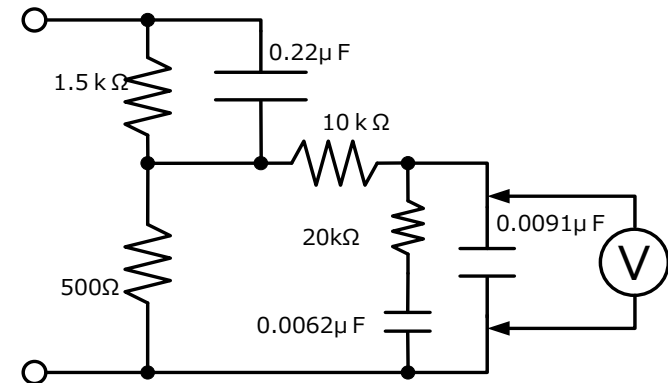
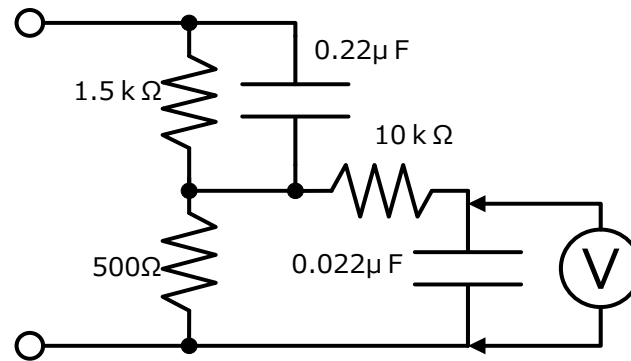
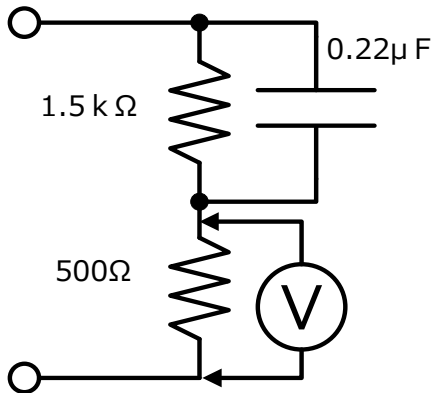
= Measurement network: Example



UL standard



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

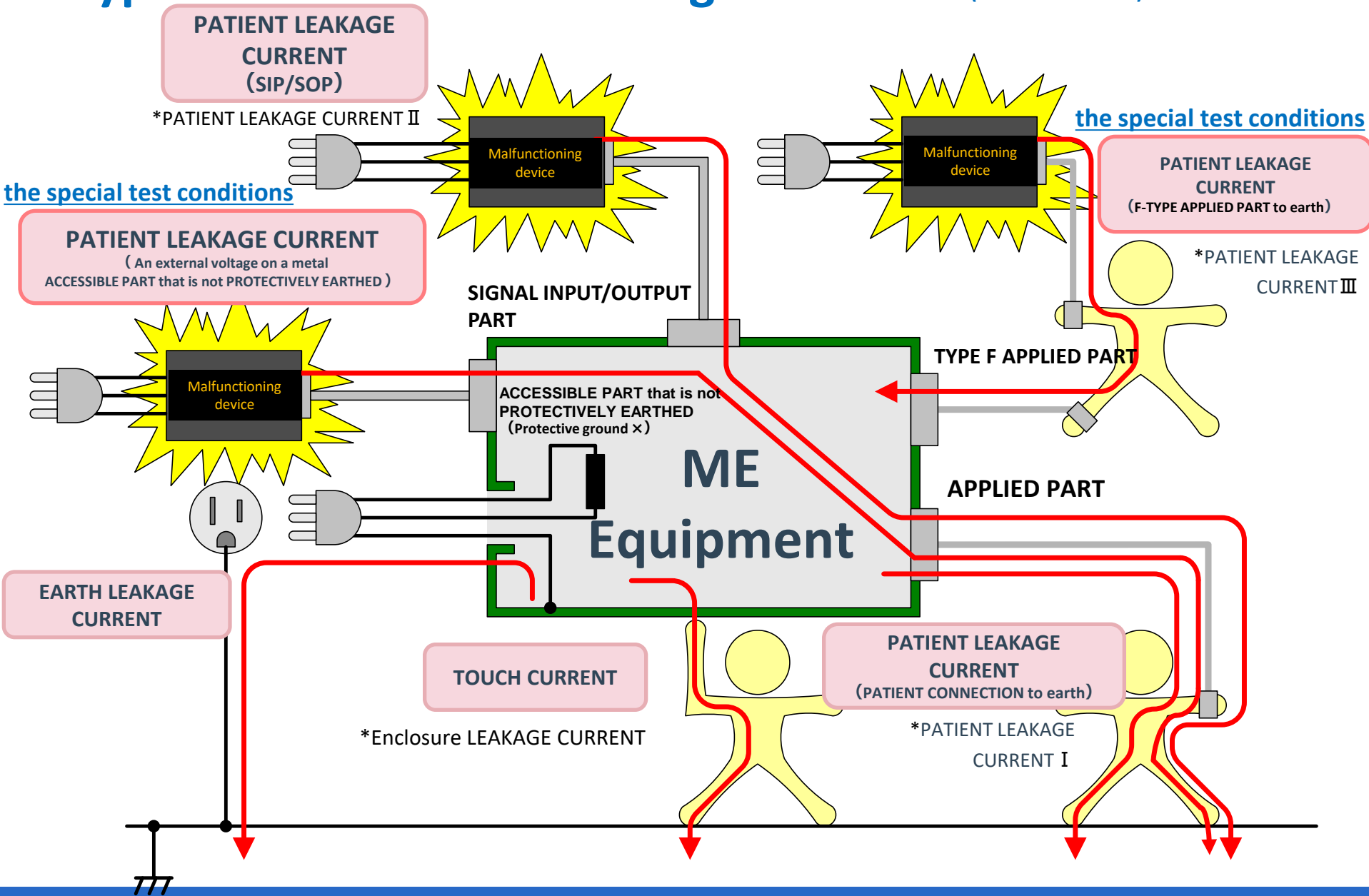


IEC 60990 (IEC 60065-1, IEC 60950-1, IEC 61010-1 etc)

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

Types of leak current testing

*Former name (JIST 0601-1:1999)

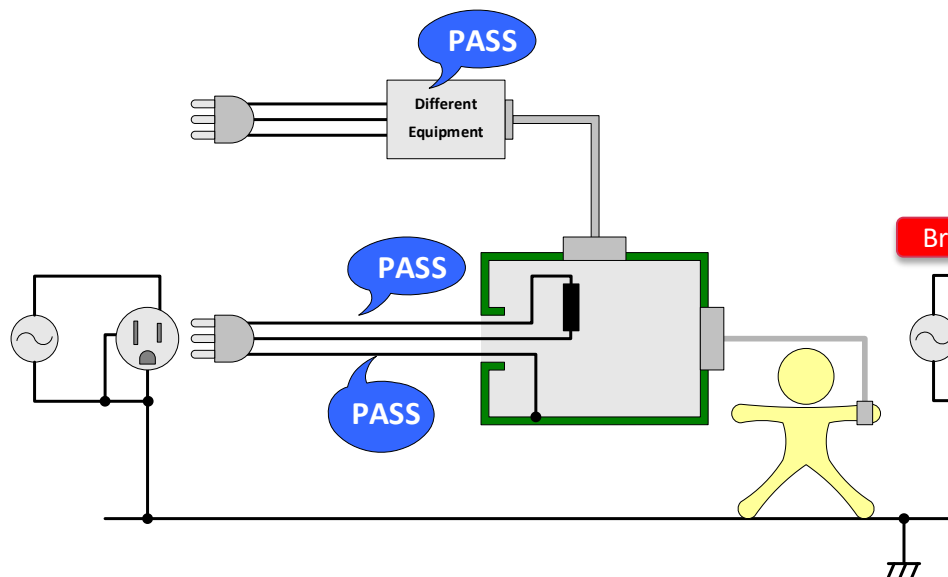


Test conditions for leak current testing

Leak current tests are defined so as to allow confirmation of how much leak current would flow under a variety of circumstances. Consequently, the tests must be carried out under a number of test conditions.

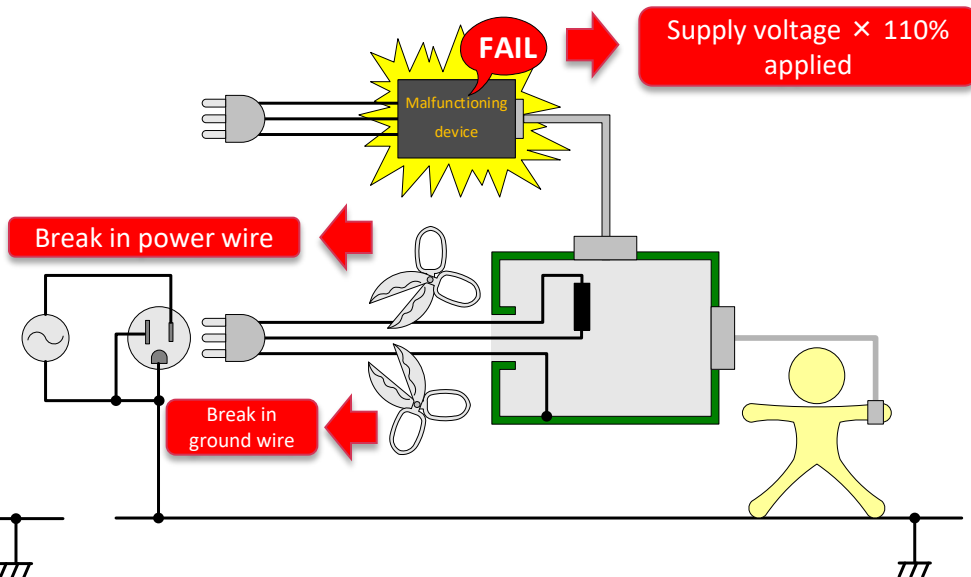
Normal conditions:

Indicates a completely normal set of conditions in which no malfunction has occurred.



Single fault condition:

A state in which a single malfunction has occurred
Power wire malfunction,
connection of a malfunctioning device,
break in a connecting wire, etc.



- What is leak current testing?
- **Product features**
- Frequently asked questions

1. The product can perform testing in compliance with IEC 60601-1 Ed. 3.0:2005, IEC 60601-1 Amd.1 Ed. 3.0:2014, and JIS T 0601-1:2017.

*IEC 60601-1, JIS T 0601-1 : Standards for medical devices

2. It provides an uninterrupted-power polarity switching function.

3. It supports current ratings of up to 20 A.

4. It can measure Protective conductor current.



5. It provides an extensive range of check functionality.

Differences between the ST5540 and the ST5541

■ 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 lines)	<ul style="list-style-type: none"> • Public agencies • Electric vehicle manufacturers • Manufacturers of general electrical devices • Household appliance industry • Information device industry 	<ul style="list-style-type: none"> • Electrical vehicle standards UL 2231-1 and UL 2231-2 • Electrical Appliances and Materials Safety Act • IEC, JIS, and UL standards
	● 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.

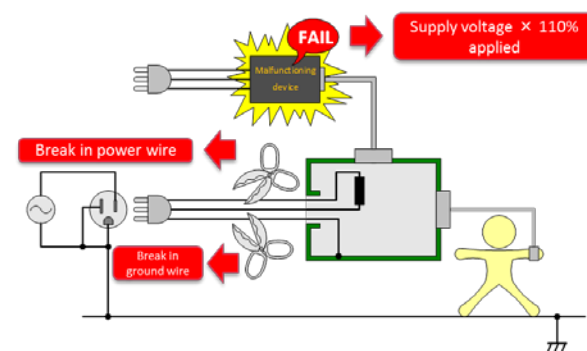
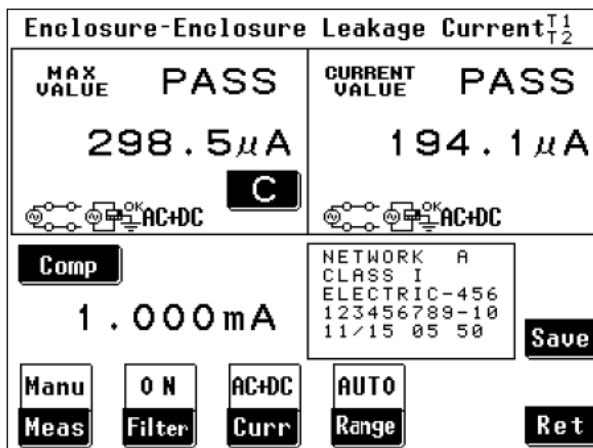
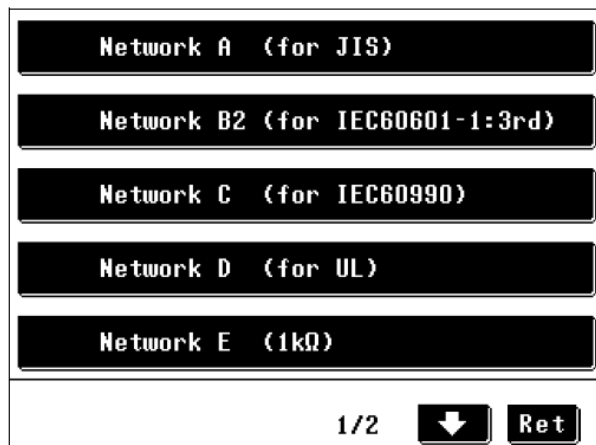
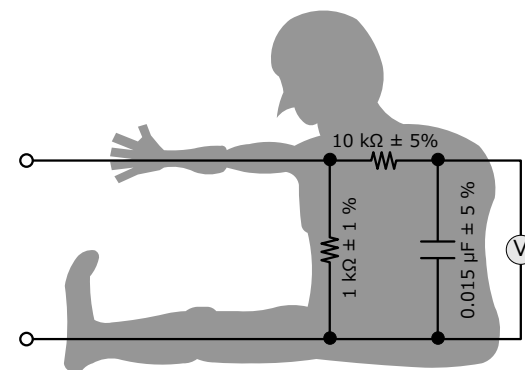
The ST5540 provides networks for medical-use electrical devices, while the ST5541 does not. Otherwise, all specifications are identical.

The product can perform testing in compliance with

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

and JIS T 0601-1:2017. IEC 60601-1 Ed.3.0:2005, IEC 60601-1 Amd.1 Ed.3.0:2014, JIS T 0601-1:2017.

- The product can perform testing in accordance with applicable IEC standards. It provides a simulated human circuit for each standard.
- Test conditions are easily implemented through automatic control of the ST5540's internal relays.
- **Since the allowable values defined by each standard are set by default,** the product can perform tests that conform to the standards out of the box.



Source : IEC 60601-1, JIS T 0601-1

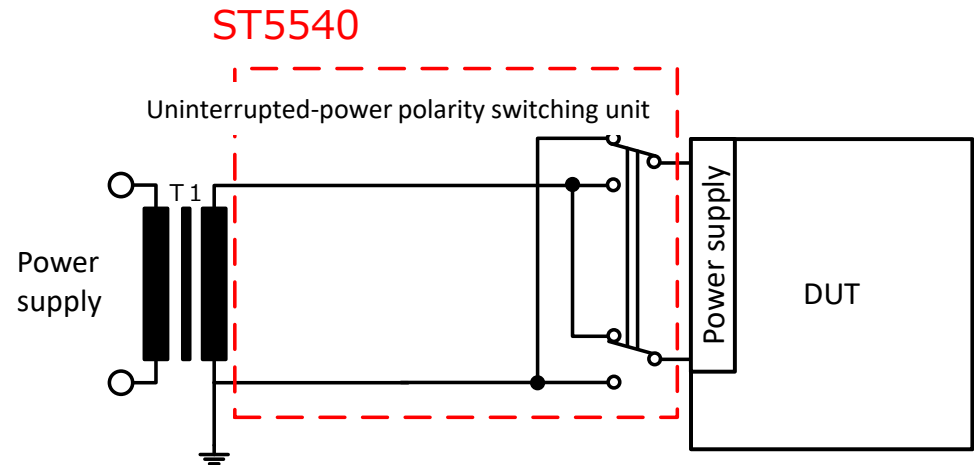
Uninterrupted-power polarity switching function

<Conventional method>

The ST5540 can perform normal switching.

Issues:

The DUT will lose power when the polarity is switched.

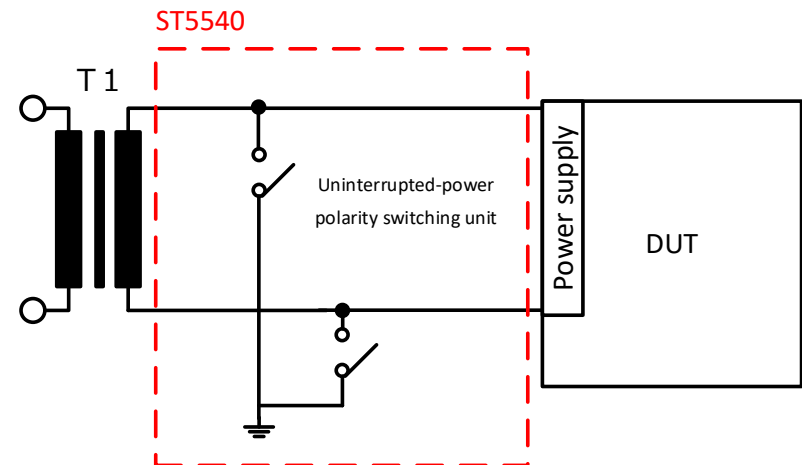


<Uninterrupted-power polarity switching>

HIOKI patent

The DUT doesn't lose power since polarity is switched with the power supply's L (live) and N (neutral) connected so that power continues to be supplied to the DUT.

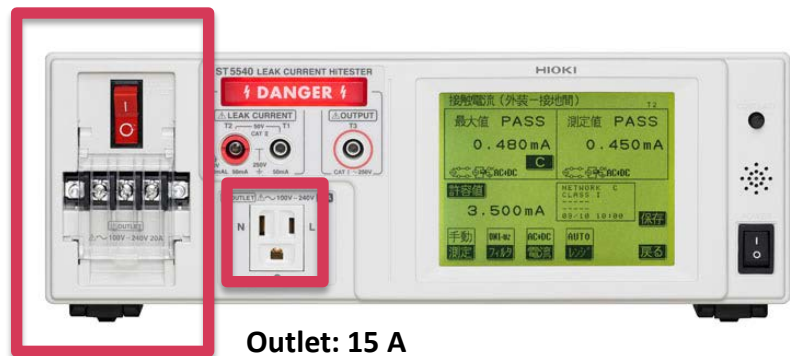
*Requires use of an isolation transformer.



Support for a rated capacity of up to 20 A

- Medical devices that incorporate a computer or sophisticated measurement system are becoming increasingly common. Consequently, these devices have increasingly high rated capacities. By increasing the rated capacity from 15 A for the previous product (the 3156) to 20 A, Hioki has made it possible to perform leak current testing for a broader range of medical devices.

Terminal block: 20 A



Outlet: 15 A



Source: Siemens Japan website
<https://www.healthcare.siemens.co.jp>

Protective conductor current measurement

- What is protective conductor current?

Protective conductor current is current that flows through a device's protective conductor.

Protective (ground) conductor:

Internal conductors or conductive components that connect parts in devices required to be grounded for safety with main protective ground terminals

(as defined by the Weblio Dictionary of Product Safety and EMC Terms).

In short, protective conductor current is **current that flows to the DUT's (device's) ground.**

In terms of meaning, the concept is closely related to ground leak current.

- Measurement method defined by IEC 60990:1999EC 60990:1999

8 Measurement of protective conductor current

8.3 Measuring method

The installation PROTECTIVE CONDUCTOR CURRENT shall be measured after installation by inserting an ammeter of negligible impedance (e.g. 0.5Ω) in series with the protective conductor.

Measurement of PROTECTIVE CONDUCTOR CURRENT is made with the EQUIPMENT and power distribution system running in all normal operating modes.

The ST5540 measures protective conductor current by **inserting 35 Ω in series** with the protective conductor. This value is used because it is small enough to be ignored (allowing the design safety guarantee to be maintained)

Source : IEC 60990:1999

Extensive check functionality

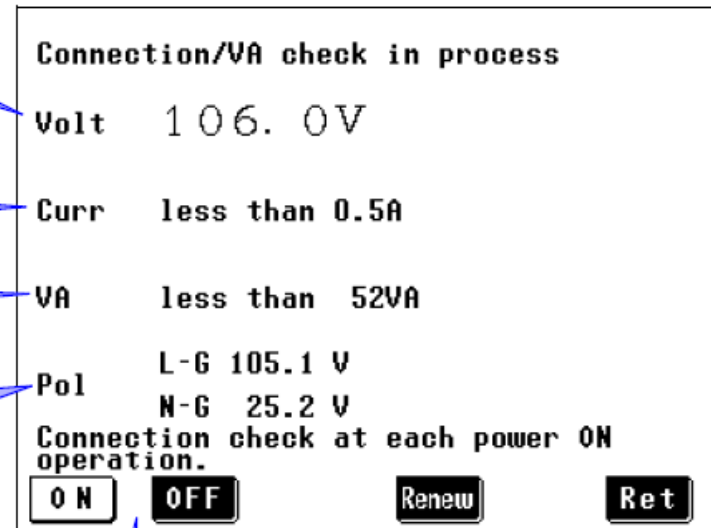
○ Wiring connection and VA check

Indicates the voltage of power supplied to [LINE IN].

Indicates the current consumption of the equipment under test.

Indicates the power consumption.

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.



Press **ON** or **OFF** to select whether the check is to be conducted each time power is turned.

Check again.

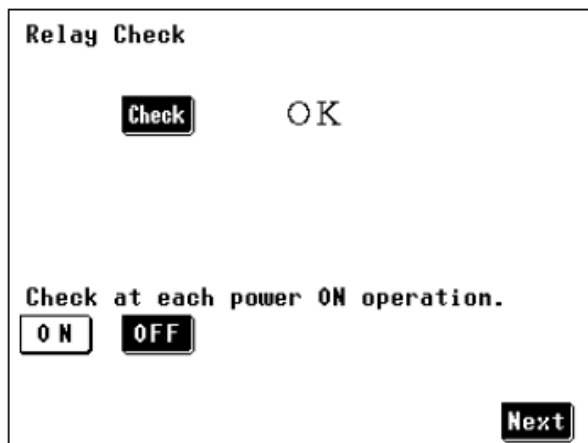
If the result of a check is determined to be abnormal, a FAIL result is shown for that item. You can display the reason for the abnormal reading by pressing the “CHECK” button.

Example: Wiring connection FAIL: Floating power supply

Power supply FAIL: Voltage of less than 80 V, etc.

Extensive check functionality

○ Relay check



LINE IN

The ST5540 uses numerous internal relays for functions such as switching between simulated human circuits (measurement networks) and switching test conditions (normal/single malfunction). In the relay check, the instrument automatically checks whether the relays related to measurement (primarily those that affect PASS/FAIL judgments) are operating properly.

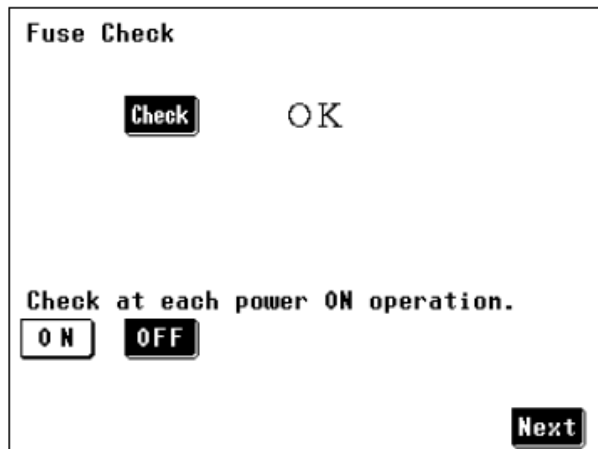
These checks must be performed with power supplied to the LINE IN terminals and with the circuit breaker in the “ON” position.

*Do not perform these checks with the DUT connected.

*The ST5540’s built-in fuse is checked when the relay check is carried out.

Extensive check functionality

○ Fuse check



In addition to the protective impedance defined by medical device standards and overinput protection for the simulated human circuit (measurement network), the product has an internal fuse. The fuse check automatically checks whether the protective fuse is malfunctioning.

This check must be performed with power supplied to the LINE IN terminals and with the circuit breaker in the "ON" position.

***Do not perform these checks with the DUT connected.**

***The fuse connected to the T2 terminal must be checked separately (see the description in the user's manual of the inspection that should be carried out before using the instrument).**

- What is leak current testing?
- Product features
- **Frequently asked questions**

Some answers to the questions included in this section incorporate measurement methods from applicable standards. **Please note that Hioki offers these as reference answers due to issues such as the specific interpretation of the standards in question.** Customers who wish to obtain an official answer to any of these questions are responsible for contacting the appropriate standard association or other body and determining which measurement methods to use accordingly.

Question:

What is the difference between IEC 60601-1 Ed.2.0:1998 (JIS T 0601-1:1999) and IEC 60601-1 Ed.3.0:2005 (JIS T 0601-1:2017)?

Answer:

The principal differences are listed below.

- Principal changes (from Ed. 2.0 to Ed. 3.0)
 - Allowable values for ground leak current have been relaxed.
 - Enclosure leak current has been changed to touch current (to harmonize with IEC 60950-1).
 - The names for patient leak current I and II have been changed, and the patient leak current II allowable values have been changed.
 - Patient leak current III has been changed to patient leak current under special test conditions.
 - Total patient leakage current has been added.
 - The measurement frequencies used by measurement devices have been clarified as 0.1 Hz to 1 MHz AC (noted in 8.7.4.4).
 - Switches have been added for dropping the protective ground terminal and enclosure to ground (S10, S12, S13).

- The names for patient leak current I and II have been changed, and **the patient leak current II allowable values have been changed.**

Answer: (continued)

The specific allowable values are shown below:

Current		Type B applied part		Type BF applied part		Type CF applied part	
		Normal conditions	Single fault condition	Normal conditions	Single fault condition	Normal conditions	Single fault condition
PATIENT LEAKAGE CURRENT (SIP/SOP)	DC	10 μ A	50 μ A	10 μ A	50 μ A	10 μ A	50 μ A
	AC	100 μ A	500 μ A	100 μ A	500 μ A	10 μ A	50 μ A
TOTAL PATIENT LEAKAGE CURRENT (SIP/SOP)	DC	50 μ A	100 μ A	50 μ A	100 μ A	50 μ A	100 μ A
	AC	500 μ A	1000 μ A	500 μ A	1000 μ A	50 μ A	100 μ A

Red: Change or addition

The name for patient leak current II has been changed to patient leak current (when external voltage is applied to SIP/SOP), **and test conditions (normal operation, single malfunction, and measurement current type [AC, DC]) have been added.**

Since test conditions have been added, allowable values have been generally revised.

These are the leak current tests that have undergone the most significant changes.

* SIP : Signal Input SOP : Signal Output

Question:

Is it necessary to perform measurement starting with a frequency of 0.1 Hz?

Answer:

Yes, since the measurement frequency for AC current has been clarified in IEC 60601-1:2005 as starting from 0.1 Hz. (By way of a reply to this question, Hioki is only able to note the language used in the standard.)

However, it may be possible to omit this step since the standard also contains the following language.

***The answer to this question depends on how you interpret the standard. The customer is responsible for making a final determination.**

8.7.4.4 Measurement Device (MD) c)

These requirements can be limited to a frequency range with an upper limit lower than 1 MHz if it can be proven (for example, by the use of an oscilloscope) that frequencies Above such an upper limit do not occur in the measured current.

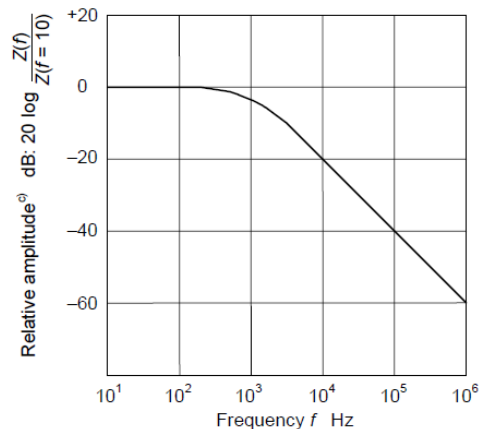
Although the above language is intended to relax the measuring instrument's specifications in the high-frequency band, it can also be interpreted as having a similar implication for the low-frequency band, meaning that measurement from 0.1 Hz to f Hz would be unnecessary if it can be proven that leak current does not occur at or below the frequency of f Hz, for example by using an oscilloscope.

Question:

Until now, we've used a simulated human circuit that we built in-house (or an ammeter) to make measurements, but we've observed differences in measured values when we use the ST5540. Why do such discrepancies occur?

Answer:

They are likely caused **by differences in the frequency characteristics of the simulated human circuit (in this case, your in-house circuit, the ammeter, and the ST5540).** Some standards define frequency characteristics beyond tolerances for resistors and capacitors used in simulated human circuits. For example, IEC 60601-1 and IEC 60990 offer the definitions shown in the following graph and table. Consequently, measured values from your in-house circuit and ammeter, whose frequency characteristics are not defined, differ from measured values obtained using the ST5540. Since the ST5540 has been designed with reference to these standards, its measured values agree with the standards.



Frequency Hz	Input impedance U/I	Transfer impedance U1/I
20	1 998	500
50	1 990	500
60	1 986	500
100	1 961	500
200	1 857	500
500	1 434	500
1 000	979	500
2 000	675	500
5 000	533	500
10 000	509	500
20 000	502	500
50 000	500	500
100 000	500	500
200 000	500	500
500 000	500	500
1 000 000	500	500

Source : IEC 60601-1 (graph on left), IEC 60990:1999 (table on right)

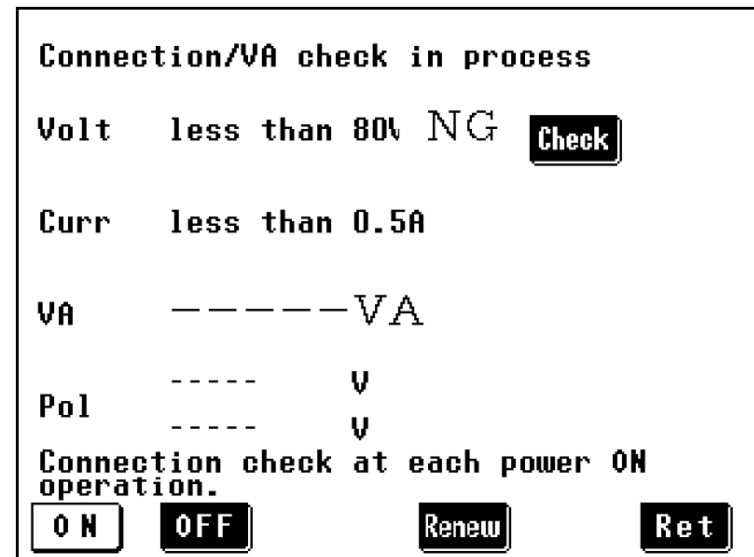
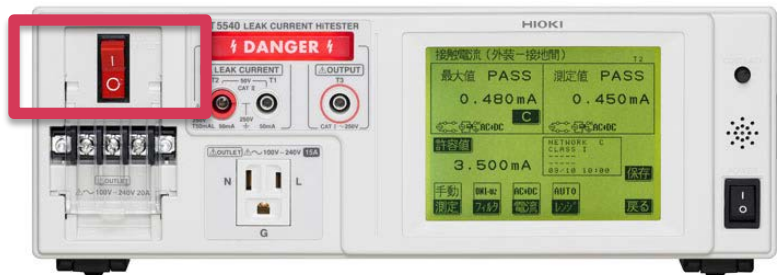
Question:

I'm supplying power to the ST5540's LINE IN terminals, but the instrument shows "Less than 80 V" as the wiring and VA check voltage.

Answer:

Turn the circuit breaker on the front of the instrument on. If the instrument shows "Less than 80 V" when the circuit breaker is in the "ON" position, the instrument may have experienced an internal circuit malfunction. Please have it serviced.

Circuit breaker



Question:

Is it possible to measure a 3-phase (4-phase) power supply device?
Please describe the specific method for doing so.

Answer:

Yes. Specifically, you would use the ST5540 as an ammeter with a simulated human circuit (network). (You would measure touch current [leak current between the enclosure and enclosure] or touch current [leak current between the enclosure and ground].) However, since you can't supply 3- or 4-phase power to the ST5540's LINE IN terminals, you won't be able to switch automatically among test conditions (power supply polarity switching and single-malfunction states).

There are two measurement methods, which are described in the instrument's User's Guide on page Q3-18 (starting on page 37).

Please refer to the next page for a more detailed look at the measurement methods.

Frequently asked question (5) 2 of 2

Answer:

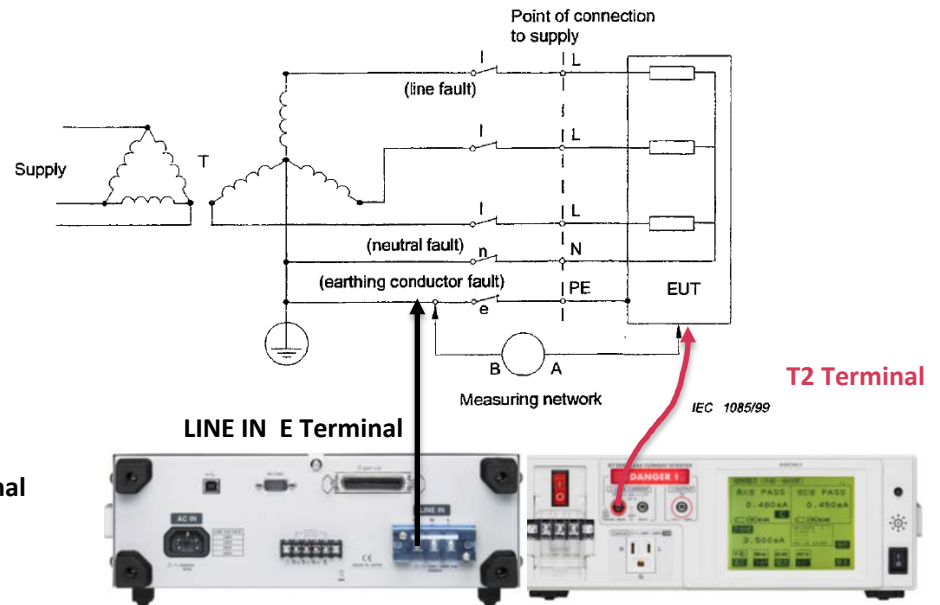
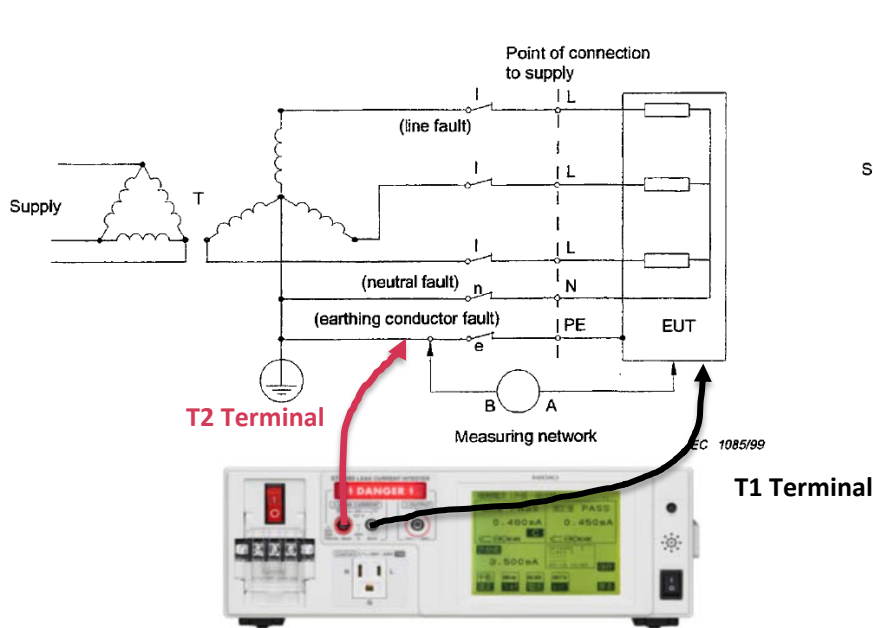
This description draws on information provided by IEC 60990.

The measurement circuit net in the figures below is where **the ST5540 would be inserted**. In the figures, “A” indicates the EUT enclosure, while “B” indicates the EUT ground, **illustrating measurement of touch current [leak current between the enclosure and ground]**. Each SW (“e,” etc.) indicates a test condition (malfunction condition). Consequently, these figures alone can be read as instructing you **to measure the touch current [leak current between the enclosure and ground] under the following conditions: ground wire malfunction, neutral wire malfunction, and wire (power supply) malfunction.**

There are two ways to implement this measurement (either may be used).

Left figure: Measuring the leak current between the enclosure and ground by measuring the touch current [leak current between the enclosure and enclosure] (by connecting either T1 or T2)

Right figure: Measuring the touch current [leak current between the enclosure and ground] (requiring the ground of the power supply used to power the EUT to be connected to the ST5540’s LINE IN E terminal)



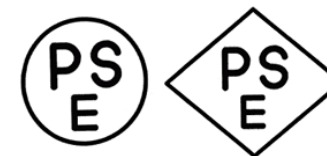
(Method for measuring the touch current [leak current between enclosure and enclosure])

(Method for measuring the touch current [leak current between enclosure and ground])

Source : IEC 60990:1999 Figure 11 for star-type TN or TT circuit 3-phase devices

Question:

I want to test leak current in accordance with the Act on Product Safety of Electrical Appliances and Materials. Please describe the necessary measurement method.



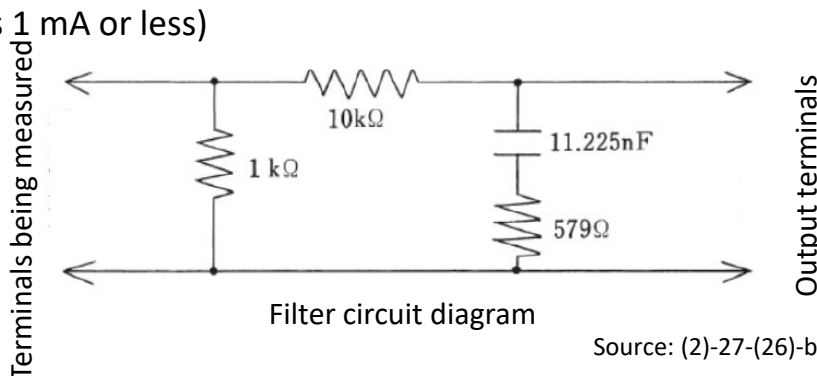
Answer:

You can do so by selecting Network A on the ST5540's network selection screen. The specific method can be found in "Interpretation of the Ordinance Concerning Technical Requirements for Electrical Appliances and Materials."

PSE (2)-27-(26)-b-(b)

In the event that it is significantly difficult to measure the current at each frequency, a judgment can be made using the following filter circuit based on a consideration of its frequency characteristics.

(Example judgment standard: 1 V or less; Converting to current based on the reference resistance of 1 kΩ supports interpreting the current as 1 mA or less)



Source: (2)-27-(26)-b-(b) in "Interpretation of the Ordinance Concerning Technical Requirements for Electrical Appliances and Materials"

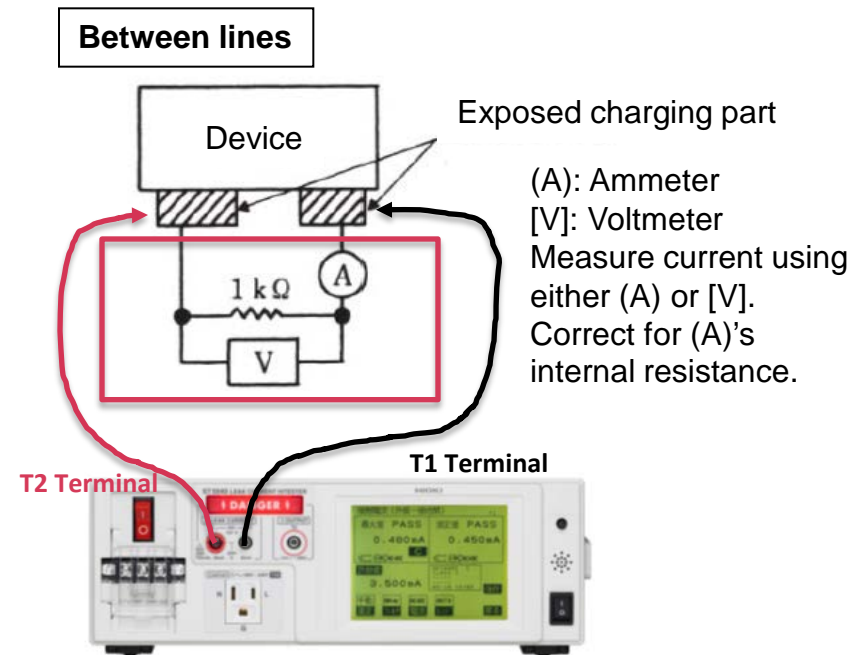
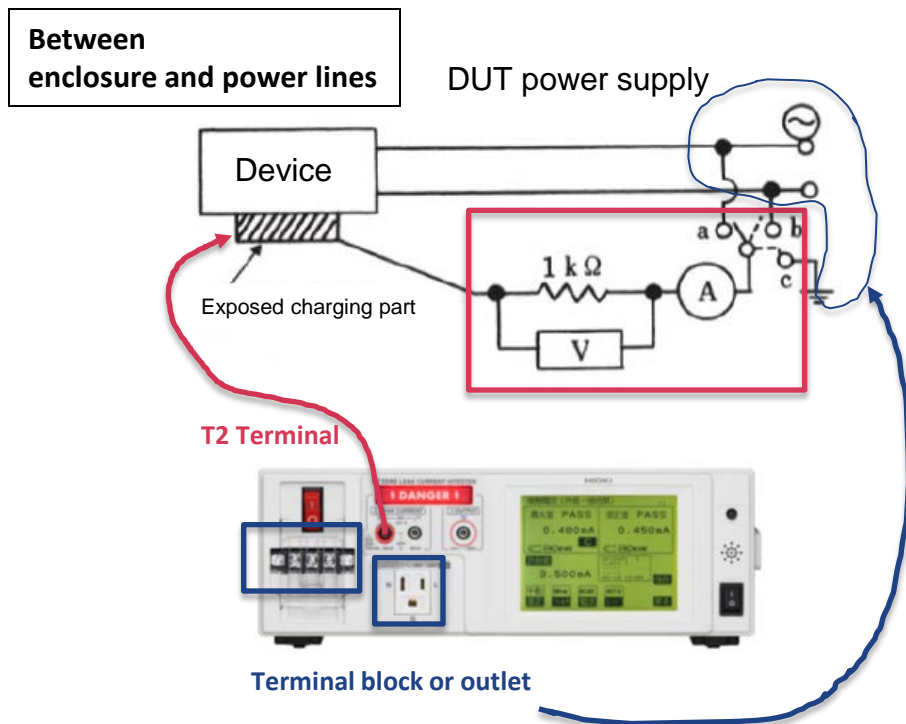
Answer:

This page offers a specific measurement method based on the “Interpretation of the Ordinance Concerning Technical Requirements for Electrical Appliances and Materials.”

That document provides two leak current measurement methods:

1. Touch current [leak current between enclosure and ground] and [leak current between enclosure and lines] (vs. ground)
2. Touch current [leak current between enclosure and enclosure] (between lines)

The red rectangle in the following figures indicates the ST5540. Both methods assume that power is being supplied to the ST5540’s LINE IN terminals.



Source: (2)-27-(26)-b-(b) in “Interpretation of the Ordinance Concerning Technical Requirements for Electrical Appliances and Materials”

Question:

Our instrument is displaying (measuring) leak current values even though nothing is connected. (Measured values are on the order of several microamperes). What could explain this phenomenon?

Answer:

There are two possible causes.

1. Effects of conductive noise reaching the measurement circuit
(For example, if the cable from the T2 terminal has been extended, the noise could be caused by the routing of that cable.)
2. Effects of noise from the power being supplied to the ST5540's LINE IN terminals

To address (1)

Since the ST5540 is measuring a minuscule current, if you have extended the cable, it is possible that the cable is picking up noise being radiated from the surrounding area (the measurement environment). Move the wire as far as possible from the noise source.

To address (2)

The ST5540 is measuring the leak current using the power being supplied from the LINE IN terminals and the ground. If the power being supplied from the LINE IN terminals includes noise, that noise will extend to the measurement circuit during leak current measurement. As a result, it will show up in measured values. You will need to reduce the power supply noise.

(Use a clean power supply, for example a stabilized power supply*.)

***Caution is necessary when using a stabilized power supply. Please see frequently asked question No. 8.**

Question:

I'm using a stabilized power supply, and the wiring and VA check yields a FAIL result. Please tell me how I can address this issue.

Answer:

Check the type of output being generated by the stabilized power supply you're using. The ST5540 can only make accurate measurements with a one-line ground power supply (a power supply whose neutral and ground lines are at the same potential). (Standards use figures to indicate that the N and ground lines are at the same potential; see the figure below.)

For example, Kikusui's PCR series uses a center-point ground, so N is not at the ground potential.

Example: With Kikusui's PCR series, ground is in the center when outputting 100 V

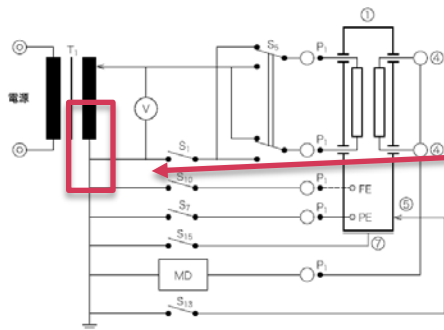
Between L (live) and ground: About 50 V

Between N and ground: About 50 V

A solution to this issue is described below.

Please check with the manufacturer of the stabilized power supply you're using before trying this solution.

Solution: Short N and ground on the output side (secondary side) of the stabilized power supply.
Force a short-circuit using a conductive piece of metal, jig, etc.



N and ground are connected on the secondary side of the isolation transformer T1.
This can be interpreted as presuming one-line ground wiring.

Source: Figure 15, IEC 60601-1

Review test (3 questions)

Question 1:

The ST5540 measures leak current passing through _____.

Question 2:

List two features of the ST5540.

Question 3:

List one change involving measurement (measuring instruments) from the old standard to IEC 60601-1:2005.

Review test (3 questions) Answer

Question 1:

The ST5540 measures leak current passing through _____.

The human body, a person

Question 2:

List two features of the ST5540.

- 1. Testing complies with IEC 60601-1 Ed.3.0:2005, IEC 60601-1 Amd.1 Ed.3.0:2014, and JIS T 0601-1:2017.**
- 2. The instrument features an uninterrupted-power polarity switching function.**
- 3. It supports current ratings of up to 20 A.**
- 4. It can measure protective conductor current.**
- 5. It provides an extensive range of check functionality.**

Question 3:

List one change involving measurement (measuring instruments) from the old standard to IEC 60601-1:2005.

The measurement frequency for measurement devices has been clarified as 0.1 Hz to 1 MHz AC.



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