



# Guide to Electrical Safety Testing

# Why Test?

**There are four main reasons why you should safety test your products prior to shipment**

<b>1. Safety</b>	Ensure that the product is not going to pose a hazard to the end user.
<b>2. Quality</b>	Detect workmanship defects and prevent faulty components from being installed.
<b>3. Cost Control</b>	Identify production problems before a product is shipped, preventing costly recalls.
<b>4. Liability</b>	Prevent product liability suits because the responsibility of performing electrical safety tests ultimately rests on the manufacturer

NRTLs (Nationally Recognized Testing Laboratories) set standards outlining tests that must be performed on a product before it's considered safe for the consumer market. NRTLs implement and enforce electrical safety testing to protect consumers from a potentially fatal electric shock.



**NRTL Examples:** Underwriters Laboratories (UL - United States), TUV Rheinland (Germany), Canadian Standards Association (CSA - Canada), ETL (Intertek - United States) and CCC (China Compulsory Certification - China)

**NRTL standards dictate that electrical products incorporate two lines of defense to protect the user from electrical shock**

Insulation	Safety Grounds
<ul style="list-style-type: none"> <li>• Separates power lines from low voltage circuits.</li> <li>• Separates power lines from isolated power supplies.</li> <li>• Isolates input power from the chassis or case of an electrical device.</li> </ul>	<ul style="list-style-type: none"> <li>• Allow dangerous fault currents to return to system ground.</li> <li>• Enables circuit breakers to open.</li> <li>• Safeguards against fire.</li> <li>• Protects against damage to electrical equipment.</li> </ul>

**Electrical products can be classified according to insulation type**

**Class I Products**



- Terminate in 3 prong line cord (line, neutral and ground).
- Ground prong connects to product chassis.
- Safety through basic insulation and proper grounding.

**Class II Products**



- Double insulated products.
- Terminate in 2 prong line cord (line and neutral).
- Safety through dual layer of insulation.

## NRTL standards generally specify two separate testing categories

<b>Type Test</b>	<ul style="list-style-type: none"> <li>• Performed as a laboratory or prototype test</li> <li>• Done on sample basis</li> <li>• Used to detect defects in product design</li> <li>• More rigorous testing</li> </ul>
<b>Production Line Test</b>	<ul style="list-style-type: none"> <li>• Performed on 100% of products on the production line.</li> <li>• Used to detect manufacturing or workmanship defects</li> </ul>

**As a manufacturer or test operator, it's up to you to ensure you have the proper knowledge and training to use high voltage equipment.**

Before working with an electrical safety test station, you need to make sure you are a qualified operator according to OSHA guidelines<sup>1</sup>.

### Occupational Safety and Health Administration

An agency of the United States Department of Labor charged with ensuring safe working conditions as well as enforcing standards and providing workplace training and education.



OSHA 1910.332 Subpart S • [osha.gov](https://www.osha.gov)




## Effects of the electrical current on the human body

Current	Reaction**
0.5 to 1 milliamp	Perception
5 milliamps	Slight shock felt, startled reaction
6 to 30 milliamps	Painful shock and inability to let go
30 to 150 milliamps	Extremely painful, respiratory arrest, ventricular fibrillation, death possible
10 amps	Cardiac arrest, severe burns

\*\*These effects are for voltages less than 600 volts. Many electrical safety instruments can output voltages in excess of 5000 volts which can cause more severe reactions at lower current levels.

<sup>1</sup>OSHA 29 CFR part 1910.332 Subpart S defines the training requirements for anyone exposed to voltages in excess of 50 volts.



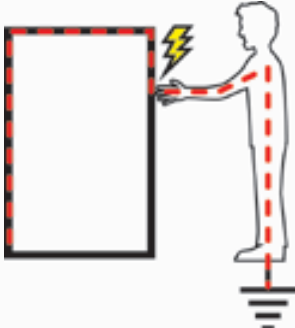
# A Qualified Operator Must Know

Knowledge	Example
<p>1. Determine whether an exposed conductor is energized or not.</p>	<p>Hipot instrument with the output voltage ON. HIGH VOLTAGE warning symbol illuminate RED when the instrument is outputting. This indicates that the instrument is in a dangerous state.</p> 
<p>2. Determine the nominal voltage of an electrical circuit by reading drawings, signs and labels. Know how to use the equipment. Every instrument should come with a user's manual. <i>Review this manual prior to using the equipment.</i></p>	<p>Product power cord with label displaying the nominal voltage and current of the device.</p> 
<p>3. Understand approach distances and corresponding voltages to which you may be exposed.<sup>2</sup></p>	<p>Associated Research instruments can output up to 5000 VAC. Always review product specifications before using the equipment.</p>
<p>4. You should be trained to identify and understand the relationship between electrical hazards and possible injury.</p>	<p>Refer to the table "Effects of Current on the Human Body" on the preceding page.</p>
<p>5. Know the safety features of the equipment and utilize them.</p>	<p>Most Associated Research instruments have an automatic discharge circuit that will discharge the DUT in less than 200 msec after the test completes. This ensures the DUT is safe for you to touch once the test has completed. <i>Smart GFI &amp; Interlock</i></p>
<p>6. Determine if Personal Protective Equipment (PPE) is necessary, what type of PPE<sup>3</sup> is necessary and how the PPE is rated. OSHA now requires in addition to being a Qualified Person, that you must wear PPE for protection from shock if you cross the Restricted Boundary.</p> <p><i>Note: The restricted boundary for live parts operating between 751 V and 15 kV is 2 feet x 2 inches.</i></p>	<p>This image contains high voltage gloves, safety glasses, a hard hat and high voltage boots. These are common examples of the PPE you should wear as an operator when using high voltage equipment.</p> 

<sup>2</sup> NFPA 70E Table 130.2(C) outlines approach boundaries to live parts for shock protection.

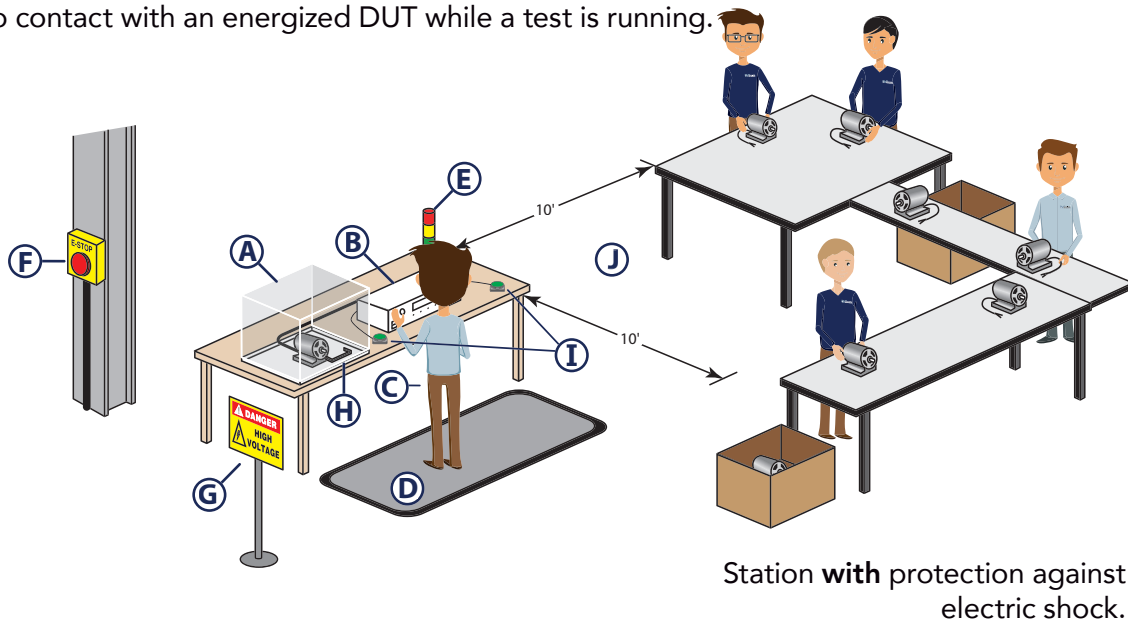
<sup>3</sup> NFPA 70E Section 130.7(C)(10) shall be used to determine the required PPE for the task.

# A Qualified Operator Must Know

Knowledge	Example
<p>7. Know the methods of release for victims who are being shocked.</p>	<p>Methods include using a non-conductive material (i.e. a fiberglass pole) to release someone from a live circuit. Using an E-Stop can also shut off power to the entire station and release the victim.</p>  <p><b>DO NOT</b> touch a person who is being shocked or you could also become part of the circuit!</p> 
<p>8. Understand that the instrument is a variable voltage power source that will output current to any available ground path. Contacting the DUT during the test can result in a dangerous shock hazard.</p>	<p>This image shows someone contacting a live circuit. The current flows directly through their body to ground causing severe, possibly fatal injuries.</p> 
<p>9. You must know the importance of discharging the DUT.</p>	<p>While all Associated Research instruments do have an automatic discharging circuit, lifting the high voltage or return lead from the DUT before the test is complete can leave the DUT charged. If the Hipot does not have a complete circuit, it cannot discharge the DUT at the end of the test.</p>
<p>10. Understand that each step in the work plan must be executed as planned.</p>	<p><b>DO NOT TAKE SHORT CUTS!</b></p> <p>Refer to <b>Test Station Safety Procedure Checklist (page 15)</b> to review your Hipot setup before you test.</p>

# Setting up a Safe Workstation

One of the best ways to prevent injury is to ensure that the test station is set up safely and securely. Test stations can be setup with or without direct protection depending on your requirements. Direct protection means that the operator cannot physically come into contact with an energized DUT while a test is running.



**A**

## DUT Safety Enclosure

This is wired to the Hipot instrument's Remote Safety Interlock. This protects you from touching the DUT while a test is in progress. If the enclosure door is opened, the instrument's high voltage is immediately disabled.

**E**

## Signal Tower Light

Gives an indication as to the status of the testing area. A green light indicates the test instrument is not outputting high voltage and the test area is safe. A red light indicates that the Hipot instrument is active and to stay clear of the test area.

**H**

## Non-Conductive Work Bench

Only use a work bench made of non-conductive material such as plastic or wood. This ensures no stray leakage current could flow through you during a test.

**B**

## Electrical Safety Instrument

Instrument used to test the DUT.

**F**

## Emergency Stop Button

Located on the perimeter of the test area. In the event of an emergency, someone outside the test area can hit the E-Stop button to immediately cut off power to the entire test station.

**I**

## Dual Remote Palm Switches

Two hand operation switches force the operator to place a hand on each switch and hold them throughout the test. The palm switches should be placed at least 21.6" (550mm) apart to prevent the operator from one hand activation of both switches.

**C**

## Test Operator

**G**

## Warning Signs

Mark the testing area with clearly posted signs that read: DANGER - HIGH VOLTAGE TEST AREA. AUTHORIZED PERSONNEL ONLY.

**J**

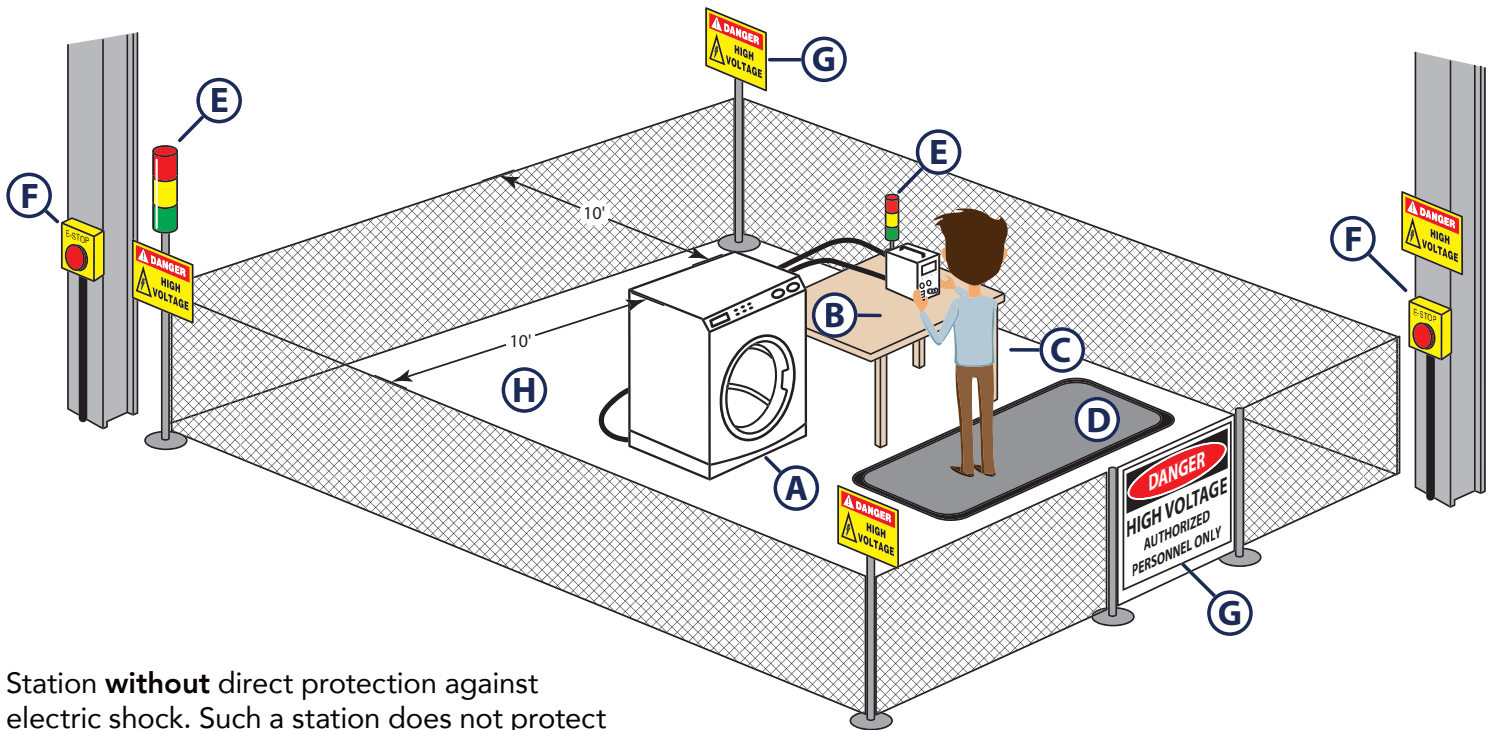
## NEC (National Electric Code) & NFPA (National Fire Protection Agency)

Stipulate that any unqualified workers shall not come within 10' of an EXPOSED energized circuit.

**D**

## High Voltage Insulation Mat

This isolates you from ground which provides an additional means of protection when operating high voltage equipment.



Station **without** direct protection against electric shock. Such a station does not protect the user from touching the DUT during a test.

Reference	Description
A	DUT – This large DUT prevents you from using a product safety enclosure. Instead, other precautions must be taken to ensure a safe testing station.
B	The Hipot Instrument – instrument used to test the DUT.
C	Test Operator.
D	High Voltage Insulation Mat – This isolates you from ground which provides an additional means of protection when operating high voltage equipment.
E	Signal Tower Light – gives an indication as to the status of the testing area. A green light indicates the Hipot instrument is not outputting high voltage and the test area is safe. A red light indicates that the Hipot instrument is active and to stay clear of the test area.
F	Emergency Stop Button – An E-stop button is located on the perimeter of the test area. In the event of an emergency, someone outside the test area can hit the E-Stop button to immediately cut off power to the entire test station.
G	Warning Signs <sup>4</sup> – Mark the testing area with clearly posted signs that read: DANGER-HIGH VOLTAGE TEST IN PROGRESS. UNAUTHORIZED PERSONNEL KEEP AWAY.
H	Sectioned Off Test Area – Since the size of the DUT restricts the use of an enclosure, this test area is sectioned off by a mesh fence to keep unauthorized personnel away from the testing station. NEC (National Electric Code) and NFPA (National Fire Protection Agency) <sup>5</sup> stipulate that any unqualified workers shall not come within 10 feet of an <u>EXPOSED</u> energized circuit.

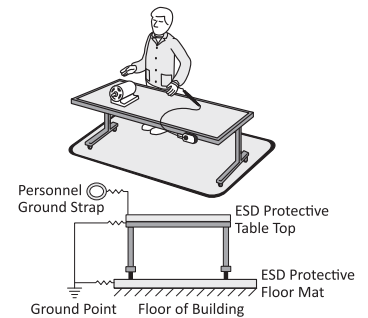
<sup>4</sup> High Voltage signs compliant to ANSI Z535-2011

<sup>5</sup> See NFPA 70E Table 130.2(C)

## Important Information Regarding ESD Stations

### WARNING

Do NOT setup electrical safety testing stations and ESD (electrostatic discharge) stations in the same area. ESD protocols are designed to protect a component or device from static discharge (not the operator from high voltage hazards). Do NOT use anti-static robes, benches, or floor mats during electrical safety testing. All of these items are used to intentionally ground the test operator which can cause injury or death to a high voltage test operator. Such stations are not designed for voltages above 250 VAC.



## Additional Methods for Test Safety

In some cases, you may not be able to use a roped off test area or DUT enclosure. When necessary, there are other methods that you can use to protect your operators:

### Dual Remote Palm Switches

Two hand operation switches force the operator to place a hand on each switch and hold them throughout the test. The palm switches should be placed at least 21.6 in (550 mm) apart to prevent the operator from one hand activation of both switches. Some switches have guards over the top to prevent one hand actuation and do not require a minimum distance of separation.



#### WHY IS THIS SAFE?

This does NOT allow the operator to touch the DUT as their hands must remain on the test switches during the test.



### Safety Probes

Use extended probes to contact the DUT during a test. A push button on the probe extends a conductive tip for contact to the DUT.

#### WHY IS THIS SAFE?

This forces the operator to hold extended probes so that they cannot touch the DUT or instrument while a test is running.



## Signal Tower Lights

These status lights illuminate RED when a test is running and GREEN when the test passes or the Hipot instrument is idle.

### WHY IS THIS SAFE?

Mounted lights warn operators in the nearby area to the status of the Hipot test and if the instrument is outputting high voltage.

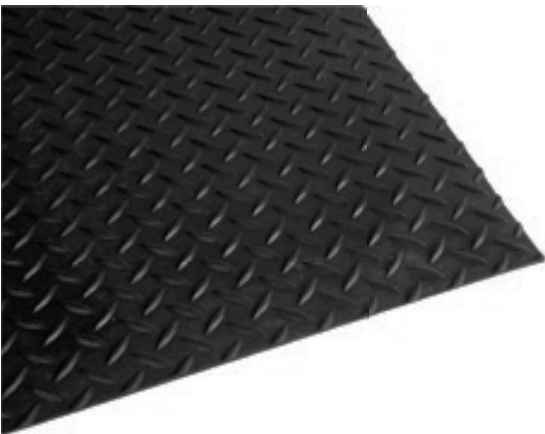


## Insulation Mats

High voltage insulation mats on the floor of the test area. The operator stands on the mat while testing.

### WHY IS THIS SAFE?

The mat isolates the operator from ground while testing which greatly mitigates the shock hazard.



## ALWAYS REMEMBER

- Keep the unqualified and unauthorized personnel away from the testing area. If this is not possible, the unqualified person must be supervised by a qualified operator while they are in the test area.
- Arrange the testing area out of the way of routine activity. Designate the area clearly.
- Never touch the DUT or the connections between the DUT and the instrument during a test.
- In the case of an emergency, or if problems arise, turn off the high voltage first.
- Properly discharge any DC-tested product before touching or handling connections.

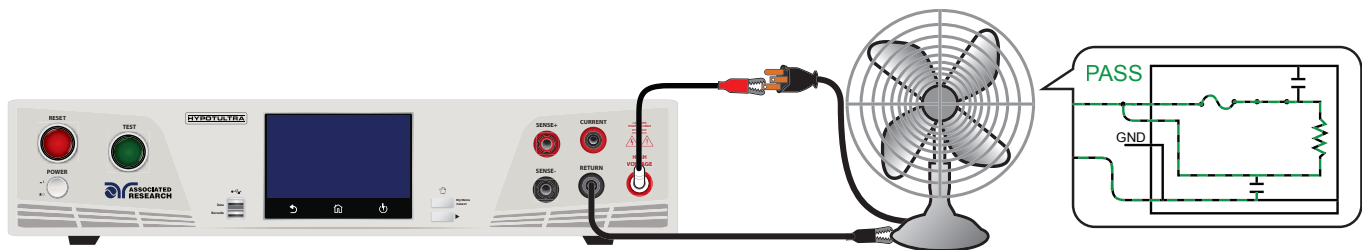
## The Hipot Test (Dielectric Voltage Withstand)

The Hipot<sup>6</sup> test is the most common type of safety test. This test is designed to stress a product's insulation beyond what it would encounter during normal use. The reasoning behind this test is that if the insulation can withstand high voltage for short period of time, it will be safe to use at nominal voltage throughout its useful life.

One of the main advantages of the Hipot test is its versatility. In addition to measuring leakage currents and detecting breakdowns, you can also use it to detect:

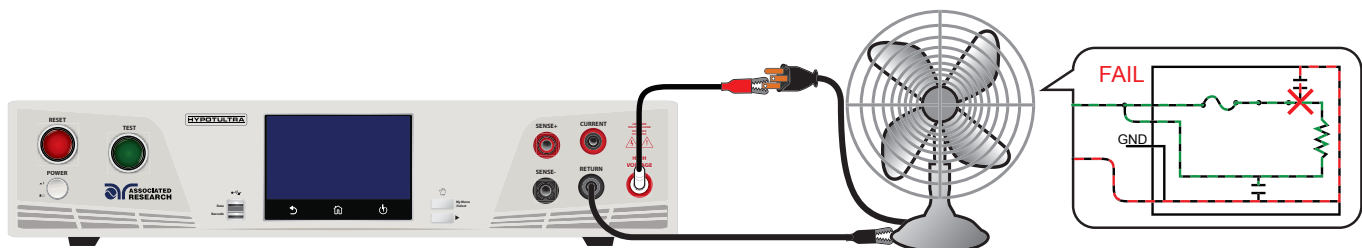
- **Material and workmanship defects.**
- **Weak points in the insulation.**
- **Small gap spacing between conductors. Air is just an insulator and Hipot voltage will “jump” through the air across gaps that are too small.**
- **Condensation, dirt and contaminants in the insulation.**

When running a Hipot test, high voltage is applied to the mains conductors (LINE and NEUTRAL). The Hipot return point is connected to the bare metal chassis of the fan. You're essentially creating a capacitor, where the product insulation is the dielectric material. The Hipot tester measures the resulting leakage current flowing through the insulation (represented as capacitors between mains and ground).



## Leakage Current and Dielectric Breakdown

Any electrical device will produce small levels of leakage current due to the voltages and internal capacitance present within the product. Under normal circumstances this leakage current isn't large enough to be perceived by the human body. Yet due to design flaws or manufacturing defects the insulation in a product can break down, resulting in excessive leakage current flow. This is exactly what a Hipot test is designed to check.



Dielectric breakdown is defined as the failure of insulation to prevent the flow of current. The best indication of dielectric breakdown is a leakage current measurement significantly higher than the nominal current measurement. The maximum leakage current is dependent upon the test voltage; therefore, the leakage current will vary depending upon the product being tested.

“Hipot” comes from the combination of “High Potential”

## AC vs. DC Hipot Tests

AC and DC Hipot tests have advantages and disadvantages that become evident depending on the characteristics of the DUT. The table below lists the advantages and disadvantages of each type of test.

AC Hipot	DC Hipot
<b>Advantages</b> <ul style="list-style-type: none"> <li>• Slow ramping of the test voltage isn't necessary due to the changing polarity of the applied waveform.</li> <li>• It is unnecessary to discharge the DUT after AC testing.</li> <li>• AC testing stresses the insulation alternately in both polarities. This makes it a more stringent Hipot test.</li> </ul>	<b>Advantages</b> <ul style="list-style-type: none"> <li>• The test can be performed at a much lower current level, saving power and with less risk to the test operator.</li> <li>• Leakage current measurement is a more accurate representation of the real current. This is due to the insulation capacitance charging after the ramp up cycle.</li> <li>• DC testing is the only option for some circuit components such as diodes and larger capacitance values.</li> </ul>
<b>Disadvantages</b> <ul style="list-style-type: none"> <li>• Measures only the total leakage current (from capacitive and resistive elements).</li> <li>• Requires a large Hipot transformer due to measuring the total leakage current.</li> </ul>	<b>Disadvantages</b> <ul style="list-style-type: none"> <li>• Must ramp up the test voltage so inrush leakage does not exceed Hipot instrument's capability.</li> <li>• Must discharge the DUT at the end of the test.</li> <li>• Only stresses insulation in one polarity. Not as stressful of a Hipot test.</li> <li>• Not always accepted by safety agencies.</li> </ul>

### A Note on Procedural Differences

Since a Hipot test is stressing the insulation of a DUT with high voltage, the applied test voltage must be the same value whether it is AC or DC.

$$\text{(Hipot Test Voltage)} = \text{(Nominal Input Voltage)} * 2 + 1000 \text{ V}$$

For a DC test use the following formula to assure that the DC voltage is the same value as the peak of the AC waveform:

$$\text{DC Hipot Test Voltage} = \text{(AC Hipot Test Voltage)} * 1.414$$

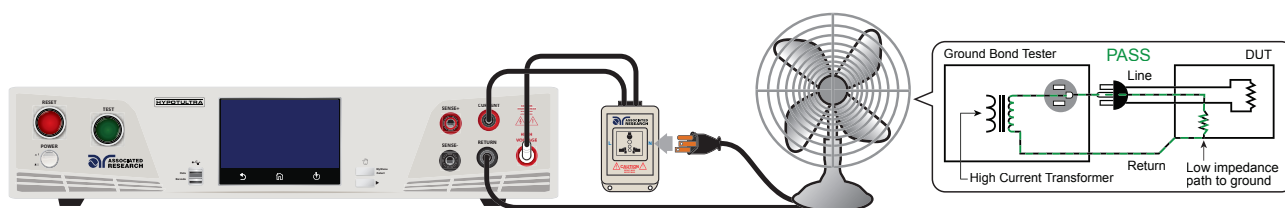
**Not sure about Hipot test voltage?** Always refer to the appropriate agency standard they may specify a different multiplier for the AC to DC hipot test voltage conversion.

## Ground Continuity Test

The Ground Continuity test often are required to be performed along with or prior to the Hipot test. Its purpose is to ensure that the DUT's safety ground connections have been made properly. This test checks for a connection between the third prong on a line cord (Class I product) and the product chassis or case.

## Ground Bond Test

The Ground Bond test determines whether the safety ground connection of a DUT can adequately handle the fault current resulting from insulation failure. By simulating a failure condition and circulating excessive current through the DUT's ground connection, the Ground Bond test helps to verify the integrity of the connection to earth ground. This means that potentially lethal fault current will flow to ground and not to a person that comes into contact with the DUT's metal enclosure.



During a Ground Bond test, high current flows from the ground pin of the DUT to the RETURN on the chassis. The Ground Bond instrument then displays the resulting ground circuit resistance.

## Ground Bond/Ground Continuity Test Considerations

### Current and Voltage Drop

Testing a ground circuit with a ground bond or continuity test involves running current through the circuit and measuring the resulting voltage drop. Since all products have different current ratings, the current and voltage drop for the test will also vary. A general range for each value is specified across NRTL standards.

### General Ground Bond/Ground Continuity test parameter values

Test Parameter	Value
Current	1.5 - 2.5 X instrument current rating*
Voltage Drop	4 V - 12 V

\*May also indicate extra condition of current = 25 - 40 A. It depends upon which value is higher (the calculated value or 25 - 40 A value).

This is illustrated in standards such as UL 60335-1 for household appliances. It stipulates a type test for ground bond:

**Test Current = 1.5 X Rated Current for appliance OR 25 A passed between ground pin and product case, whichever value is higher. The voltage drop across the circuit is not to exceed 12 V.**

For example, if my product has a rated current of 10 A, you would test the product at 25 A as  $1.5 \times 10 \text{ A} = 15 \text{ A}$ .

**Not sure about the Ground Bond current or Voltage Drop values?** When in doubt, you should always refer back to the appropriate NRTL standard.

## Test Time

The testing time for a ground bond and ground continuity test is left to the discretion of the manufacturer. Some standards do indicate a ground bond test time of 120 sec but most stipulate to run the test for the amount of time necessary to get a stable reading. If you're running a higher current test (10 A or greater), it is recommended to run the test for at least 5-10 sec. If you're running a low amperage ground continuity test, 1 sec is enough time to obtain a reading.

## Resistance Limits

The idea behind a ground bond/ground continuity test is to measure the resistance to ground to ensure the value is low enough so fault current will flow. The majority of NRTL standards give a range of maximum resistance values depending upon the nature of the product's ground wire or power cord.

### Ground Bond/Ground Continuity test resistance limits

Cord Type	Resistance Limit
Detachable power cord	0.1 $\Omega$
Permanently connected power cord	0.2 $\Omega$

**Check your NRTL standards!** It's important to remember that these values can vary from standard to standard. As a manufacturer, it's up to you to check your standard to ensure proper testing parameters.

## Ground Bond vs. Continuity

### Ground Continuity

- Verifies the **existence** of a ground connection.
- Readings generally given in  $\Omega$ s.
- The test is quick to set up and easy to perform.
- Usually used as an extra feature during the Hipot test.

### Ground Bond

- Verifies the **integrity** of a ground connection.
- Readings generally given in  $m\Omega$
- Provides more valuable safety information about DUT
- Can be combined with a Hipot test for a more complete safety testing system.

The Ground Continuity test does have limitations when it comes to testing the integrity of the ground conductor. Take the example of a line cord that has a 64 strand braided ground conductor wire. What if all of the strands were broken except for one?



A Ground Continuity test could pass a product that has only 1 strand of wire connecting its chassis to ground.



If a fault were to occur, this connection wouldn't be capable of handling the input current to the product and could create an open ground condition. A ground bond test would fail this test because the single wire would not be able to handle the high current and would burn up.

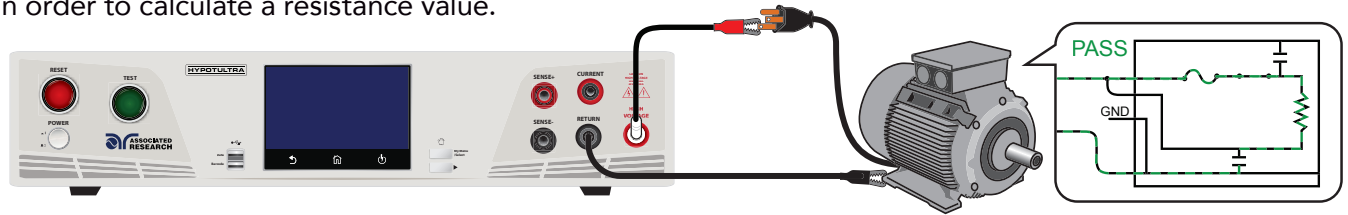


For this reason, many electrical product manufacturers have been turning to the Ground Bond test as a more thorough alternative to the Ground Continuity test.

**Not sure whether you need Ground Continuity or Ground Bond?** We're here to help! Call our technical support line +1-800-858-8378

## The Insulation Resistance Test

The Insulation Resistance (IR) test is used to provide a quantifiable value for the resistance of a product's insulation. The instrument applies a DC voltage across the insulation of a product and measures the corresponding leakage current in order to calculate a resistance value.



Although most IR instruments have a variable output voltage, the test is usually specified at 500 or 1000 volts.

The IR test is sometimes required by safety agencies to be performed subsequent to the Hipot test in order to make sure that the DUT's insulation was not damaged as a result of the high voltage applied to it.

## Insulation Resistance Test Considerations

### There are a few things to keep in mind when running an IR test:

- Since most products are capacitive in nature it is important to allow the test to run for an adequate period of time before recording any measurements. Test times can vary but a 1-10 min test should supply a stable reading.
- It is always a good idea to ramp up the voltage over a period of time. This ensures the DUT is not subjected to a voltage surge that could damage it. This will also help avoid false failures due to inrush current (as with the DC Hipot test).
- The most important parameter for the IR test is the resistance low limit. If the resistance is too low, more current will flow and the test will fail. Remember, the higher the resistance, the better the insulation. If no IR value is specified by an agency specification, the insulation resistance for an IR test at 1000 V or less should be at least 1 M $\Omega$ .

## Leakage Current Test

The Leakage Current test, like the hipot test, measures current flowing through or on the surface of a device's insulation. However, the Leakage Current test differs in that this measurement is performed while the product is running at rated voltage (or a high line condition of 110% rated voltage).

During a Leakage Current test, the leakage current is measured through what is known as a measuring device or "MD". The 60601-1 MD is shown in Figure 1. The MD is designed to simulate the impedance of the human body and is composed of 1k $\Omega$  and 10k $\Omega$  resistors shunted by a 0.015 $\mu$ F capacitor. The capacitor gives the MD a frequency weighted response, more closely resembling human body impedance than a current sensing resistor.

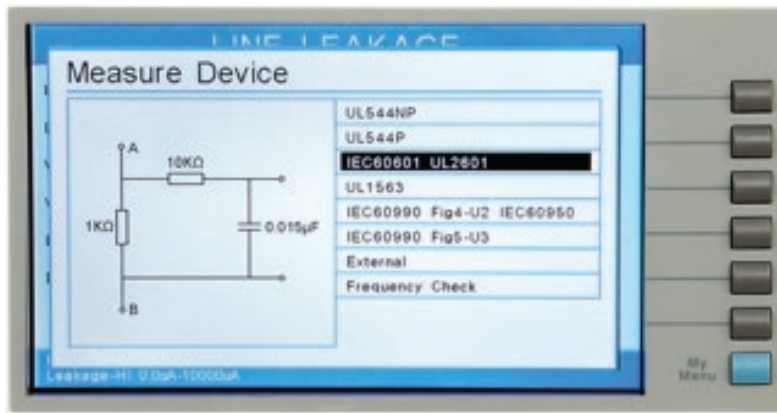


Figure 1: 60601-1 Measuring Device Diagram from OMNIA II

Another aspect of the Leakage Current test that sets it apart from other electrical safety tests is the fact that it incorporates fault conditions. These fault conditions are designed to simulate "worst case" scenarios that could happen during instrument operation. The three most common fault conditions are the opening of the neutral circuit, the reversal of line polarity and the opening of the ground circuit. A leakage current network is shown in Figure 2.

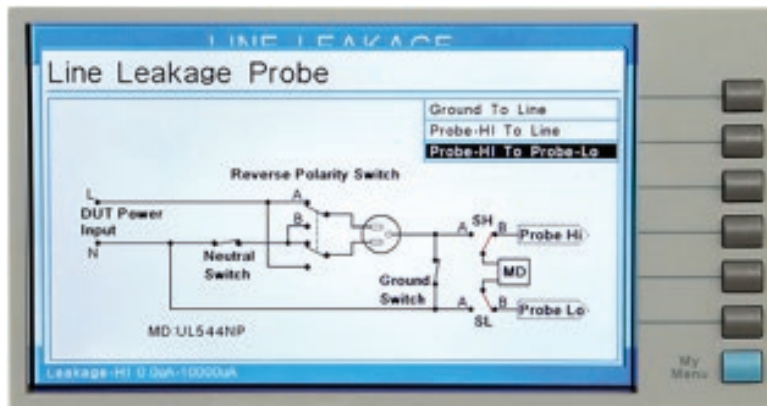


Figure 2: Leakage Current Configuration Diagram from OMNIA II



## ELECTRICAL SAFETY TESTS - THE LEAKAGE CURRENT TEST

The neutral switch represents simulation of the neutral fault condition, the reverse polarity switch represents the simulation of a polarity reversal and the ground switch represents the simulation of an open ground condition. The idea behind running tests under these various configurations is to measure exactly how much leakage current a patient or operator could be exposed to while the product is running and subjected to a series of fault scenarios. If the leakage current value is sufficiently low enough under all such fault conditions, the product should be able to operate normally throughout its lifecycle without posing a shock hazard.

For the IEC/UL 60601-1 3rd edition standard, the leakage current test must be run at 110% line voltage; using the 60601-1 MD (Figure 2) and running a product under the above mentioned fault conditions. Acceptable leakage current values range from 10uA all the way to 10mA (for more detailed information regarding exact leakage limits and testing scenarios, please refer to IEC 60601-1 3rd edition subclause 8.7). There are five main types of leakage tests that fall under the medical device standard. These tests and descriptions are shown in Table 1:

Table 1: Leakage Current Test Types

Leakage Test Type	Measured Leakage	Acceptable Leakage Values ( $\mu$ A) <sup>7</sup>
Earth Leakage	Total leakage current on system. Measured between mains conductors (line and neutral) and PE.	5000-10,000 $\mu$ A
Enclosure Leakage (Touch Current)	Leakage on accessible points of the device. Measured between enclosure points and mains reference.	50-1000uA
Patient Leakage General	Leakage on leads that have a patient connection. Measured between patient lead(s) and mains reference.	10-500uA
Patient Leakage Auxiliary	Leakage on patient leads of a different function. Measured between various patient leads.	10-500uA
Mains on Applied Part Leakage	Leakage on an applied part with mains voltage applied to the measuring device.	10-500uA

<sup>7</sup>Table 3 in IEC/UL 60601-1 3rd edition outlines acceptable leakage values per each type of leakage test.

# ELECTRICAL SAFETY TESTS - THE LEAKAGE CURRENT TEST

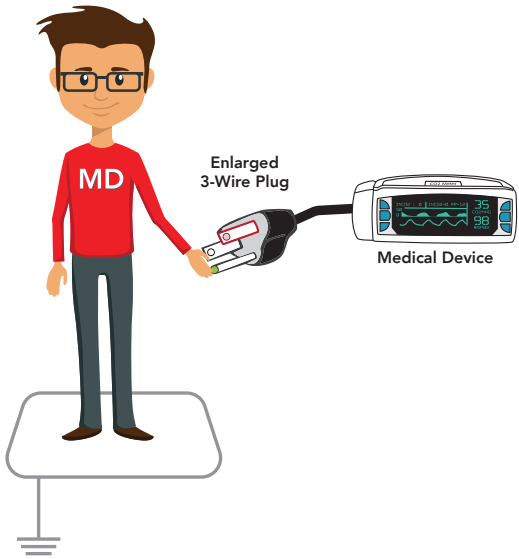


Figure 3 Earth Leakage Test

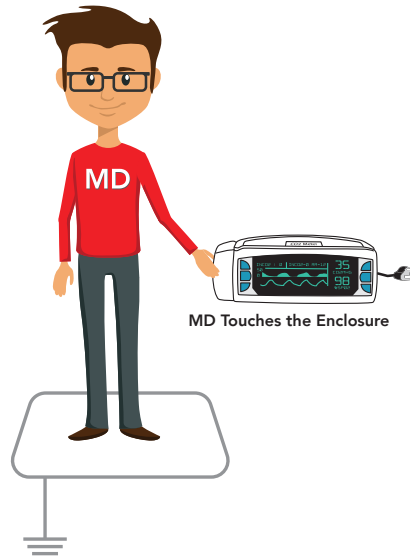
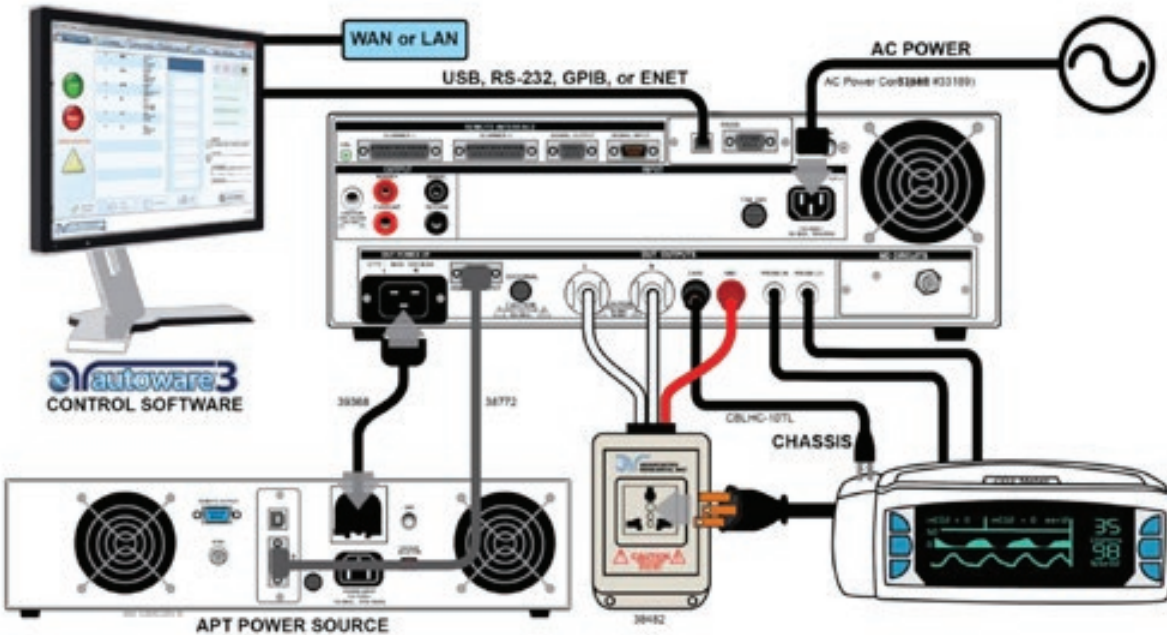
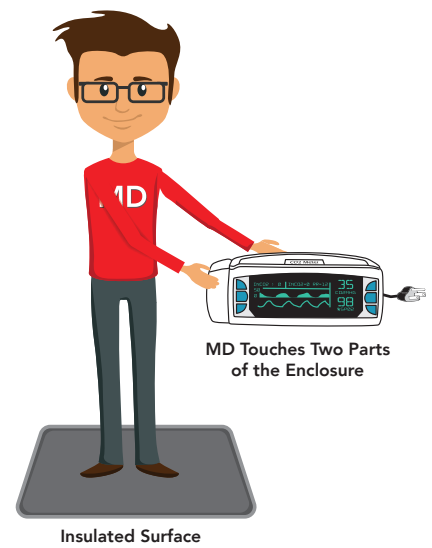


Figure 4 Enclosure Leakage Test



Just as with the hipot test, there are multiple insulation barriers that need to be considered for the leakage current testing sequence. Multiple testing points, along with various fault conditions for each type of leakage test have the potential to result in dozens, if not hundreds of leakage tests. This can pose an even more significant challenge to operators than the hipot test because they need to ensure the medical device is properly connected to the leakage current tester for each individual case. The operator must also ensure the proper limits and fault conditions are set for each leakage current test.

# Test Station Safety Procedure Checklist

## Prior to testing

- ✓ Verify the high voltage output is OFF before making any connections
- ✓ Visually inspect test lead for signs of excessive wear. If a test lead appears worn or damaged, do not use it. Find a replacement lead.
- ✓ Connect the low return side to the instrument first in order to prevent the DUT from becoming energized.
- ✓ If using alligator style clip leads, securely connect the clip lead to the exposed metal parts being tested.
- ✓ If using a instrument with a panel mounted receptacle, first connect the return clip lead and then plug the product's cord set into the instrument.
- ✓ When using a test fixture, be certain that it is properly closed and that all guards are in place.
- ✓ Double check the connections before beginning a test
- ✓ Double check all instrument settings before the test

## While Testing

- ✓ Handle both return and high voltage clips by their insulating material; never by the conductive metal.
- ✓ Keep the leads on the bench as close to the DUT as possible and avoid crossing test leads.
- ✓ Neatly coil any excess lead halfway between the instrument and the DUT
- ✓ Never touch any of the cables, connections or DUT's during a test.
- ✓ Have a "hot stick" on hand when doing DC testing (a hot stick is a non-conducting rod about two feet long with a metal probe connected to ground at one end). If a connection comes loose during the test, use the "hot stick" to discharge any surface that contacted the instrument's hot lead - simply turning off the power is not sufficient.
- ✓ After the test, turn off the high voltage.
- ✓ Discharge DC-tested products for the proper length of time.

## General Items

- ✓ Develop a standard test procedure and always follow it; don't take any shortcuts.
- ✓ Turn off the test instrument if it is not in use.

# COMMON SAFETY STANDARD REFERENCE CHART

Standard / Harmonized Standard	Testing Type	Dielectric Withstand			Ground Bond/Continuity			
		Test Voltage	Max I.	Test Time	Test Current	V Limit	Max. R	Test Time
IEC/UL 60601-1 3rd Edition Medical Electrical Equipment	Performance	500 – 4000 VAC or 707 – 5656 VDC	No Breakdown	60 s	10-25 A	≤ 6 V	≤ 0.1 Ω	5 s
	Production*	1000 – 3000 VAC		1 or 60 s	10-25 A	≤ 6 V	≤ 0.1 Ω	5 s
IEC 61730-2 UL 1703 Photovoltaic Modules & Panels	Performance	1000 VAC + 2 x rated V or 2000 VAC + 4 x rated V	50 uA	60 s	2.5 x Max Over Current Protection	≤ 12 V	≤ 0.1 Ω	120 s
	Production	1000 VAC + 2 x rated V or (1000 VDC + 2 x rated V) X 120%	50 uA	1 or 60 s	Continuity			
IEC 60335-1 Household Electrical Appliances	Performance	500 – 2400 VAC x rated V + 2400 VAC	No Breakdown	60 s	≥ 10 A	≤ 12 V	0.1 – 0.2 Ω	≤ 120 s
	Production	400 – 2500 VAC	5-30 mA	1 s	≥ 10 A	≤ 12 V	0.1 – 0.2 Ω	No time specified
UL 60335-1 Household Electrical Appliances	Performance	500V – 2400 VAC x rated V + 2400 VAC	No Breakdown	60 s	40 A	≤ 6.5 V	≤ 0.5 Ω	120 s
	Production	400 – 2500 VAC	5-30 mA	1 s	40 A	≤ 12 V	0.1 – 0.2 Ω	No time specified
IEC 60598-1 Luminaires	Performance	500 – 4 x rated V + 2000 VAC	No Breakdown	60 s	≥ 10 A	≤ 12 V	≤ 0.5 Ω	60 s
	Production	Not Specified - Responsibility of Manufacturer						
UL 1598 Luminaires	Performance	1000 VAC - 1000 VAC x 2 x rated V	No Breakdown	60 s	30 A	≤ 4 V	≤ 0.1 Ω	120 s
	Production	1200 VAC		1 s	Continuity		≤ 0.1 Ω	Continuity
IEC/UL 61010-1 & CSA 22.2 No. 61010-1 Laboratory Control Test & Measurement Equipment	Performance	840 - 11940 VAC or 1200 - 7500 VDC	No Breakdown	5 - 60 s	25 or 30 A	≤ 10 V or ≤ 12 V	≤ 0.1 Ω or < 4 V 0.133 Ω	60 or 120 s
	Production			5 s max ramp up 2 s dwell	Continuity			
EN 60204-1 Electrical Equipment of Machines	Performance	2 x rated V or 1000 VAC	No Breakdown	1 s	0.2 - 10 A	≤ 24 V	Refer to Section 18.2.2	No time specified
	Production	Not Specified - Responsibility of Manufacturer						
UL 2202 Electric Vehicle Charging System Equipment	Performance	500 VAC or 1000 VAC + 2 x rated V	No Breakdown	60 s	≤ 60 A	≤ 12 V	Continuity	120 – 240 s
	Production	1000 – 1700 VAC + 3.4 x rated V		60 or 1 s	Continuity			
IEC 61851-1 Electric Vehicle Conductive Charging System	Performance	1200 VAC + rated V or DC Equivalent	No Breakdown	60 s	Continuity			
	Production	Not Specified - Responsibility of Manufacturer						
UL 45A Portable Electrical Appliances	Performance	1000 VAC + 2 x rated V or DC equivalent	No Breakdown	60 s	Continuity			
	Production	1000 - 3000 VAC		1 s	Continuity			
EN 60950-1 EN 50116 Information Technology Equipment	Performance	1000 – 3000 VAC or 1414 – 4242 VDC	No Breakdown	120 s	30 A	≤ 12 V	≤ 0.1 Ω	60 s
	Production			1 - 4 s	25 A	≤ 12 V	≤ 0.1 Ω	1-4 s
UL 60950-1 CSA 22.2 No. 60950-1 Information Technology Equipment	Performance	1000 – 3000 VAC or 1414 – 4242 VDC	No Breakdown	60 s	≤ 40 A	≤ 12 V	≤ 0.1 Ω	60 s
	Production			1 – 6 s	Continuity			

\*As a result of performing risk analysis, many medical device manufacturers are performing leakage tests as part of 100% production line testing.

Earth Leakage		Insulation Resistance			Suggested Model	Testing Type	Standard / Harmonized Standard
Test Voltage	Max I.	Test Time	V Limit	Min.. R	ARI Instrument		
110% x rated V	5-10 mA	N/A			8206, 8207, 8256, 8257 or MedTEST	Performance	IEC/UL 60601-1 3rd Edition Medical Electrical Equipment
110% x rated V	5-10 mA	N/A			8204 or 8254	Production*	
Max rated V	10 uA – 1 mA	10 uA – 1 mA	500 VDC or Max rated V	40-400 MΩ	3145, 8206, 8207, 8256, 8257 or MedTEST	Performance	IEC 61730-2 UL 1703 Photovoltaic Modules & Panels
N/A		N/A			3145, 3770 or 7850	Production	
1.06 x rated V	0.25 – 5.0 uA	N/A			8256 or 8257	Performance	IEC 60335-1 Household Electrical Appliances
N/A		N/A			8204	Production	
1.06 x rated V	0.25 – 5.0 uA	N/A			8256 or 8257	Performance	UL 60335-1 Household Electrical Appliances
N/A		N/A			8204	Production	
Rated V	0.5 – 10 mA	60 s	500 VDC	1-4 MΩ	8206, 8207, 8256 or 8257	Performance	IEC 60598-1 Luminaires
					Hypot® III or 7850	Production	
N/A		No time specified	500 VDC	≥ 2 MΩ	8204 or 8254	Performance	UL 1598 Luminaires
N/A		N/A			Hypot® III or 7850	Production	
< 300 V	0.5 mA	N/A			8256, 8257 or MedTEST	Performance	IEC/UL 61010-1 & CSA 22.2 No. 61010-1 Laboratory Control Test & Measurement Equipment
N/A		N/A			3765 or 7850	Production	
N/A		No time specified	500 V	≥ 1 MΩ	8204 or 8254	Performance	EN 60204-1 Electrical Equipment of Machines
					Hypot® III or 7850	Production	
Rated V	0.5 - 0.75 mA or 5 mA	N/A			8206, 8207, 8256, 8257 or MedTEST	Performance	UL 2202 Electric Vehicle Charging System Equipment
N/A		N/A			Hypot® III or 7850	Production	
Touch Current Only		60 s	500 V	≥ 1 MΩ or ≥ 7 MΩ	8206, 8207, 8256, 8257 or MedTEST	Performance	IEC 61851-1 Electric Vehicle Conductive Charging System
					Hypot® III or 7850	Production	
< 300 V	0.5 – 3.5 mA	60 s	500 V	≥ 50 KΩ	8206, 8207, 8256, 8257 or MedTEST	Performance	UL 45A Portable Electrical Appliances
N/A		N/A			Hypot® III or 7850	Production	
< 300 V	0.25 – 3.5 mA	60 s	500 V	≥ 2 MΩ	8206, 8207, 8256, 8257 or MedTEST	Performance	EN 60950-1 EN 50116 Information Technology Equipment
N/A		N/A			8204 or 8254	Production	
< 300 V	0.25 – 3.5 mA	60 s	500 V	≥ 2 MΩ	8206, 8207, 8256, 8257 or MedTEST	Performance	UL 60950-1 CSA 22.2 No. 60950-1 Information Technology Equipment
N/A		N/A			Hypot® III or 7850	Production	



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