3 Ways to Simplify Medical Device Testing:

Electrical Safety Testing per UL/IEC 60601-1 3rd Edition

Electrical Safety Testing Medical Devices: Uncertainty and Shifting Requirements

Strict requirements outlined in medical testing standards have always been a challenge for medical manufacturers and end users alike. The IEC/UL 60601-1 3rd edition standard requires a series of electrical safety tests to ensure that the medical product being tested is safe for use in the field and will not pose a shock hazard to the end user or patient. The required electrical safety tests include the protective bonding or ground bond test, dielectric withstand test and the line leakage test. While this series of tests isn't technically required for 100% production line testing of a product, not all end users find this excuse sufficient. This is yet another difficulty faced by manufacturers: not all end users require the same tests. Many hospitals will not purchase medical equipment if it has not been run through the entire series of electrical safety tests on the production line.

How can the manufacturer cover all testing requirements? More importantly, how can this be done in the most efficient and economical manner? Associated Research Inc. recommends that no matter what the end user requirements, it's sound practice to run as many of these tests as possible for 100% production line testing. This paper will discuss each type of test and the test parameter requirements per IEC/UL 60601-1 3rd edition. Additionally, it will outline three methods for simplifying a complex test setup using full medical device testing example.

Ground Bond Test

The first step in ensuring the electrical safety of a product is to test the product's ground circuit. The protective bonding or "ground bond" test is used to analyze the integrity of the safety ground of an electrical device. The safety ground needs to be able to handle any fault current that could be imposed upon it due to a product or insulation failure. A low impedance path to ground will allow circuit protection devices such as fuses or circuit breakers to open when fault current flows through them. In order for this system of protection to operate effectively, there must be continuity between conductive components and the product's ground terminal.

Associated Research, Inc.
13860 West Laurel Drive, Lake Forest, IL 60045
P: 1-847-367-4077 **F:** 1-847-367-4080
info@arisafety.com / www.arisafety.com

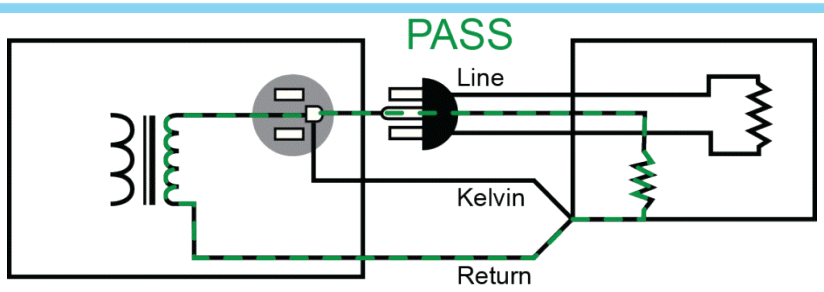


Figure 1: Circuit for a Ground Bond Test

Figure 1 shows a standard ground bond test circuit. The ground bond tester injects current onto the ground pin of a product and looks for a return path on the chassis or protective earth (PE). Simultaneously, the instrument must measure the voltage drop across the safety ground circuit to calculate the impedance of the circuit. The 60601-1 standard protective bonding specs are as follows for an instrument's grounding circuit:

Ground Bond Testing Specifications			
Highest Rated Current (Ar)	Test Current	Voltage Drop	Maximum Resistance*
Ar ≤ 16.667A	25A	6V	100mΩ
Ar > 16.667A	1.5*Ar	6V	100mΩ

*For permanently connected cord equipment, the limit is raised to 200mΩ

Dielectric Withstand Test

The dielectric withstand test, commonly referred to as the high potential or "hipot" test is an electrical safety test designed to stress the insulation of a device beyond what it would encounter during normal use. The logic behind running such a test is that if the insulation of a device can handle the force of high potential for a short duration, it will be able to operate at rated voltage without posing a shock hazard to the user. A hipot test circuit can generally be modeled as the device capacitance (C), insulation resistance (R_L) and small amounts of contact resistance (R_A). This model is shown in Figure 2.

Associated Research, Inc.
13860 West Laurel Drive, Lake Forest, IL 60045
P: 1-847-367-4077 **F:** 1-847-367-4080
info@arisafety.com / www.arisafety.com

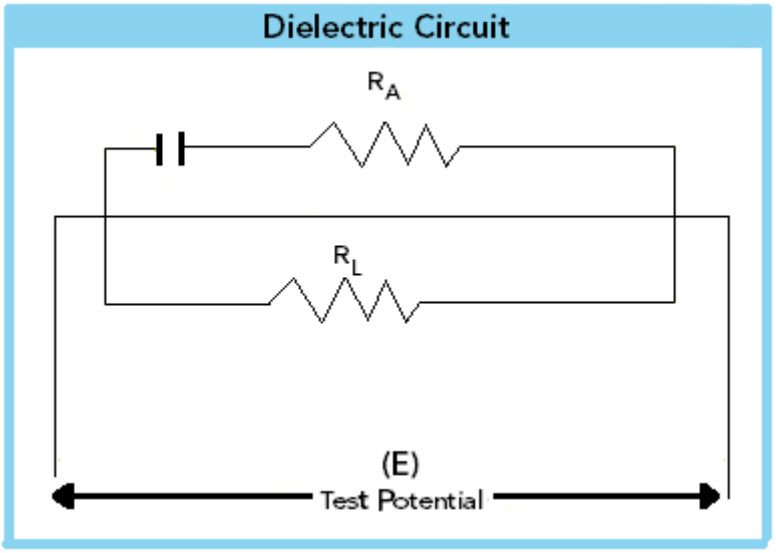


Figure 2: Dielectric Withstand Circuit Diagram

The purpose of the hipot test is to stress insulation. It's analogous to hitting a car windshield with a hammer to observe if the glass can handle the force of the blow. During a hipot test, high voltage is applied across an insulation barrier and the resulting leakage current is measured. For example, in testing a medical device that terminates in a three prong cord, high voltage would be applied to the mains current carrying conductors (line and neutral) and the return path would be the ground plane or protective earth conductor. Figure 3 illustrates a common hipot test setup.

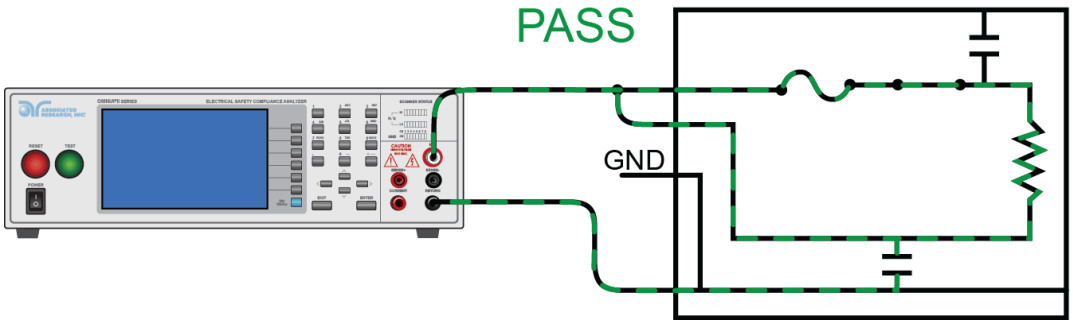


Figure 3: Hipot Testing Diagram

In this image, the device under test (DUT) is shown as a circuit diagram. The mains circuit consists of a fuse and resistance. The two capacitors represent the insulation barriers between the mains circuit ground plane. The green dashes indicate the flow of leakage current through the DUT when high voltage is applied.

Medical devices generally have several insulation barriers. This includes but is not limited to the insulation between the mains conductors and PE, patient leads and mains conductors and insulation between individual patient leads. Each insulation barrier needs to be tested, often times at different voltage levels. For more information on insulation barriers, Annex J of IEC 60601-1 outlines a survey of insulation paths. Additionally, tables 6 and 7 of the standard outline hipot test voltage values depending upon the peak operating voltage of the medical device and the insulation barrier. Table 1 below illustrates an example of various hipot test voltage values with regards to peak working voltage and the type of solid insulation barrier:

Peak Working Voltage (Vpeak)	Peak Working Voltage (Vd.c.)	Hipot Test Voltage (V rms)	
		Protection from Mains Circuits*	Protection from Secondary Circuits*
42.4V – 184.0V	60.0V-184.0V	1000-2000V	500 – 1751V
184.0-354.0V	184.0-354.0V	1500-3000V	1097-2390V
354.0-848.0V	354.0-848.0V	1494-3000V	1500-4000V

*Note: Test voltage levels will vary depending upon the means of operator protection and patient protection. For information, please refer to IEC 60601-1 3rd edition subclause 8.8.3.

Table 1 – Hipot Test Specifications

The main issue for manufacturers is the fact that they may be required to run multiple hipot tests on the same medical device between different points on the device. This adds complexity and can also create additional errors.

Line Leakage Test

The line leakage test, like the hipot test, measures current flowing through or on the surface of a device's insulation. However, the line leakage 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 line leakage test, the leakage current is measured through what is known as a measuring device or "MD". The 60601-1 MD is shown in figure 4. The MD is designed to simulate the impedance of the human body and is composed of 1kΩ and 10kΩ resistors shunted by a 0.015μF capacitor. The capacitor gives the MD a frequency weighted response, more closely resembling human body impedance than a current sensing resistor.

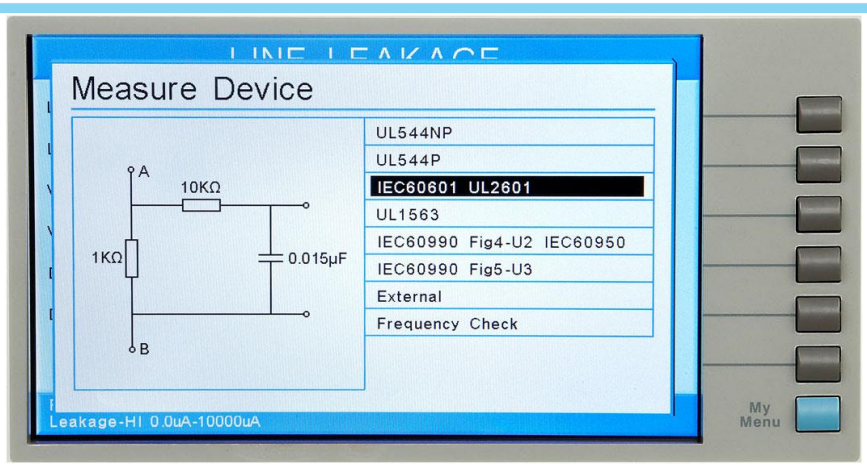


Figure 4: 60601-1 Measuring Device Diagram from OMNIA II

Another aspect of the line leakage 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 line leakage network is shown in Figure 5.

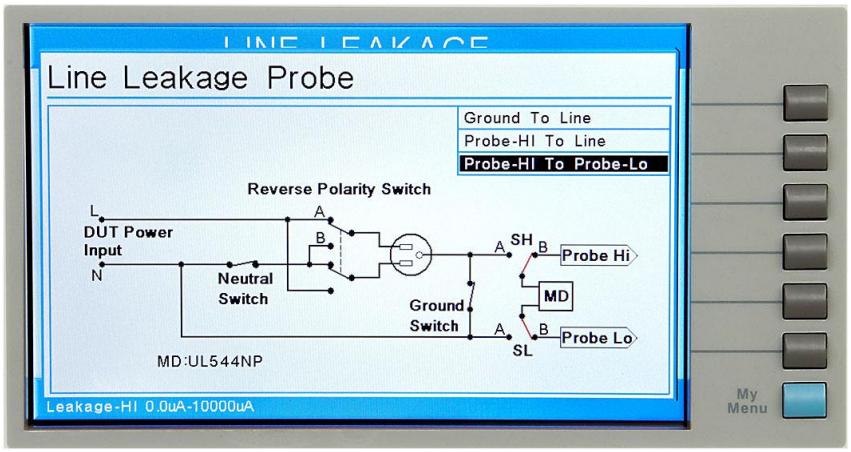


Figure 5: Line Leakage Configuration Diagram from OMNIA II

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.

Associated Research, Inc.
13860 West Laurel Drive, Lake Forest, IL 60045
P: 1-847-367-4077 **F:** 1-847-367-4080
info@arisafety.com / www.arisafety.com

For the IEC/UL 60601-1 3rd edition standard, the line leakage test must be run at 110% line voltage; using the 60601-1 MD (Figure 4) 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 2:

Leakage Test Type	Measured Leakage	Acceptable Leakage values (μA)*
Earth Leakage	Total leakage current on system. Measured between mains conductors (line and neutral) and PE.	5000-10,000μA
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

*Note: Table 3 in IEC/UL 60601-1 3rd edition outlines acceptable leakage values per each type of leakage test.

Table 2: Line Leakage Test Types

Just as with the hipot test, there are multiple insulation barriers that need to be considered for the line leakage 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 line leakage tester for each

individual case. The operator must also ensure the proper limits and fault conditions are set for each line leakage test.

3 Ways to Simplify a Medical Device Testing Solution

The question manufacturers need to be asking themselves is "How can I setup and run these tests as quickly and easily as possible?" The Associated Research Inc. medical device testing setup answers this question with a three point approach: all inclusive instrumentation, automation and ease of use.

All Inclusive Instrumentation

Associated Research Inc. has recently released the OMNIA II 8200 series of electrical safety compliance analyzers. Models 8206 and 8207 are 6-in-1 and 7-in-1 units respectively that can perform AC hipot, DC hipot, AC ground bond, DC continuity, insulation resistance, functional run and line leakage tests. The 8207 also has a built in 500VA, 0-277VAC adjustable power supply for functional run and line leakage testing. Not only does using an all in one unit simplify the setup process, it also helps operators avoid the tedious task of performing calibrations and validations on multiple pieces of equipment. Providing a built in source allows the user to run the DUT for a line leakage test without taking up extra rack space with an external supply.

Automation

The key to automating such a complex testing setup lies in the ability of the OMNIA II instrument to not only perform all of the necessary tests in one sequence, but also to link up to external multiplexers and off-the-shelf Autoware III software for setting up test sequences and recording all data. Associated Research offers high voltage scanning matrixes (model SC6540) designed to work with nearly any Associated Research instrument. Connection to the scanners mitigates operator error by automatically switching connection points for each individual test. While the entire sequence can be set manually through the front panel of the 8207, utilizing software to remotely set and save test sequences is a more efficient method of creating the testing sequence.

Ease of Use

The Autoware III program is an out of the box software for directly controlling Associated Research instruments. It provides a graphical user interface for setting up and navigating test settings. Much like modern operating systems, a drag and drop interface allows for customization of test routines. Autoware III can be used to set all test parameters, save the sequence for later use and record all test results. This program also has the capability to associate a product's model and serial number with a particular test sequence. When the model and/or serial number is entered by the operator, the proper test sequence automatically loads. Additionally, text, audio and video instruction prompts can be added to each step

of the test sequence. This allows detailed instructions to be added to each test. This negates user error in running an incorrect test sequence.

The following testing setup example will highlight these three key simplification techniques and demonstrate just how a complex testing sequence can be setup and executed. The below images and descriptions outline setting up individual tests to build a sequence with the software.

Simplifying the Testing Solution: A Medical Device Testing Example

The 8207, in tandem with SC6540 scanning matrixes and Autoware III software provides a fully automated testing solution for medical device testing.

For this example, the end user needs to run the test sequence outlined in Table 3 below. The diagram in Figure 6 represents the system utilized for testing this DUT. The DUT represents the medical device. The patient leads are labeled P1 and P2.

Test	Test Circuit	Test Parameters
Ground Bond	Ground pin to chassis enclosure	25A, 10sec, 6V drop, 0.1Ω resistance high limit
AC Hipot	Mains conductors to chassis enclosure	1500V, 5sec ramp up, 60sec dwell, 5 sec ramp down, 10.00mA leakage current high limit
AC Hipot	P1 to P2	4000V, 5sec ramp up, 60sec dwell, 5 sec ramp down, 10.00mA leakage current high limit
Earth Leakage	Mains conductors to ground	264VAC, 5mA leakage current high limit
Patient General Leakage	Patient leads (P1 and P2) to mains reference	264VAC, 500uA single fault, 100uA normal conditions
Patient Auxiliary Leakage	P1 to P2	264VAC, 500uA single fault, 100uA normal conditions
Mains on Applied Part	Mains to P1 and Mains to P2	264VAC DUT power and 264VAC on applied part, 50uA leakage current high limit

Table 3 – Safety Testing Sequence

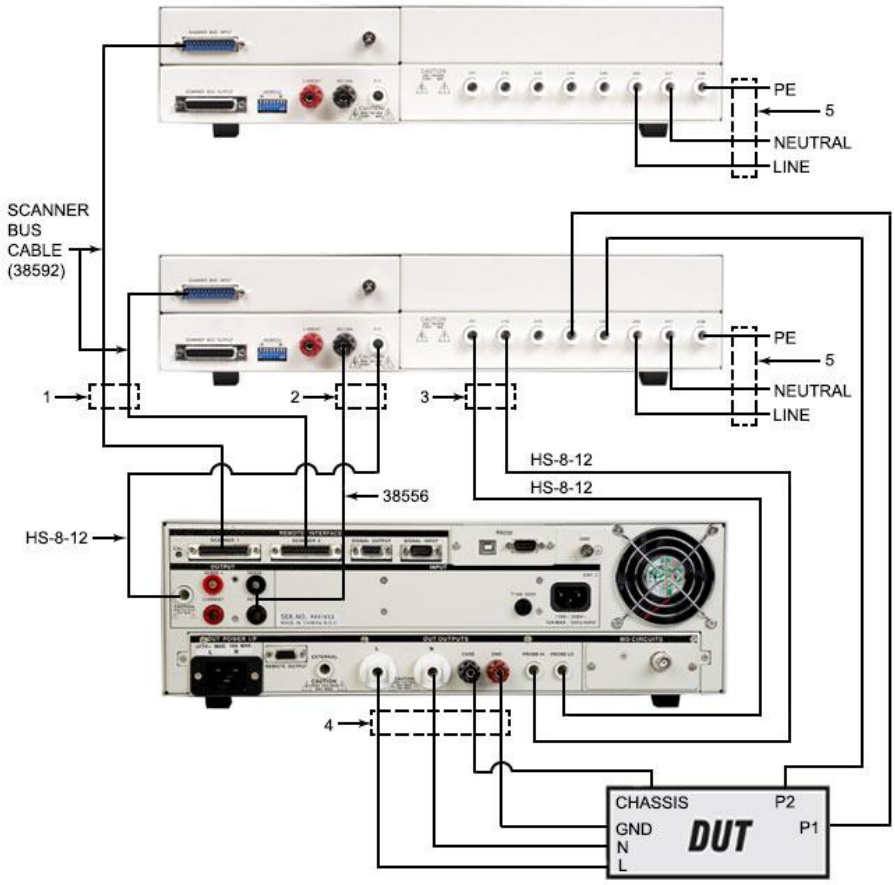


Figure 6: OMNIA II 8207 Connected to Medical Device (DUT)

The other instruments in the setup are as follows (from top to bottom):

- SC6540 HN 8 channel high voltage scanning matrix
- Another SC6540 HN 8 channel high voltage scanning matrix
- OMNIA II 8207 7-in-1 electrical safety tester

The interconnections in the setup are as follows:

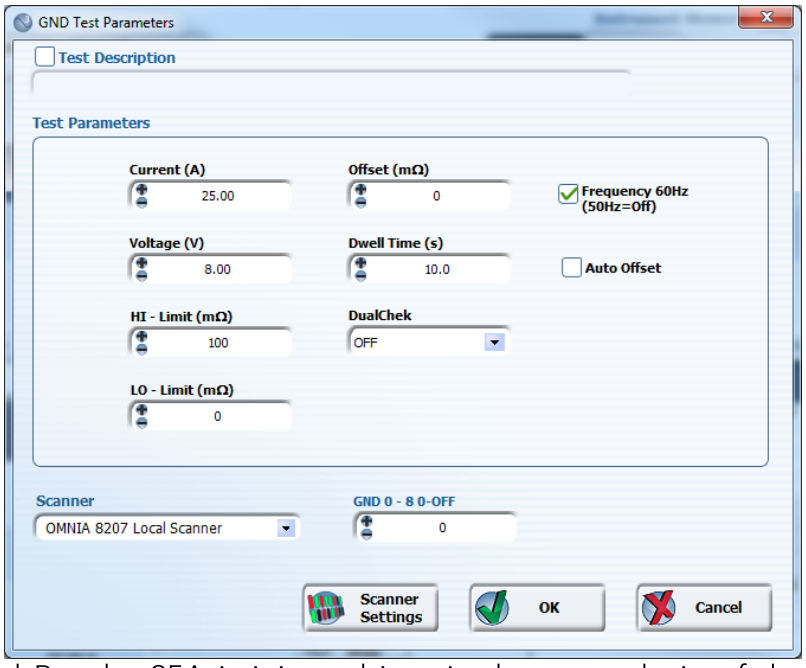
1. The 8207 controls each slave scanner via a scanner bus cable from the OMNIA's scanner bus outputs (there are two) to the each scanner's bus input. This allows the OMNIA II to talk to the scanners for setting scanner channels for each test.
2. The 8207 is connected to the middle scanner via the high voltage (cable HS-8-12) and return leads (cable 38556). This will allow for hipot testing the patient leads as they are connected to channels 5 and 6 of that scanner.

3. The 8207 is connected to the middle scanner via the Probe Hi and Probe Lo connections (two HS-8-12 cables). Probe Hi is connected to channel 2 and Probe Lo is connected to channel 1. This will allow for patient leakage and mains on applied part measurements.
4. The mains conductors of the DUT (line, neutral and ground) are connected directly to the rear output of the 8207 L, N and GND terminals. The CASE lead from the OMNIA II connects to the chassis of the DUT. This is the return point for ground bond and hipot testing. This will allow for mains hipot testing, ground bond testing as well as all mains reference measurements for the line leakage testing sequence.
5. Finally, each scanner is connected to an isolation transformer (note: see link on page 15 for more information regarding isolation transformers). These are the Line, Neutral and PE (protective earthing or grounding point) connections on channels 6, 7 and 8 of each scanner. This will allow for the mains on applied part testing. (Note: for more information regarding mains on applied part or mains on Signal I/O testing schematics, please refer to figures 14 and 16 in the IEC 60601-1 3rd edition standard).

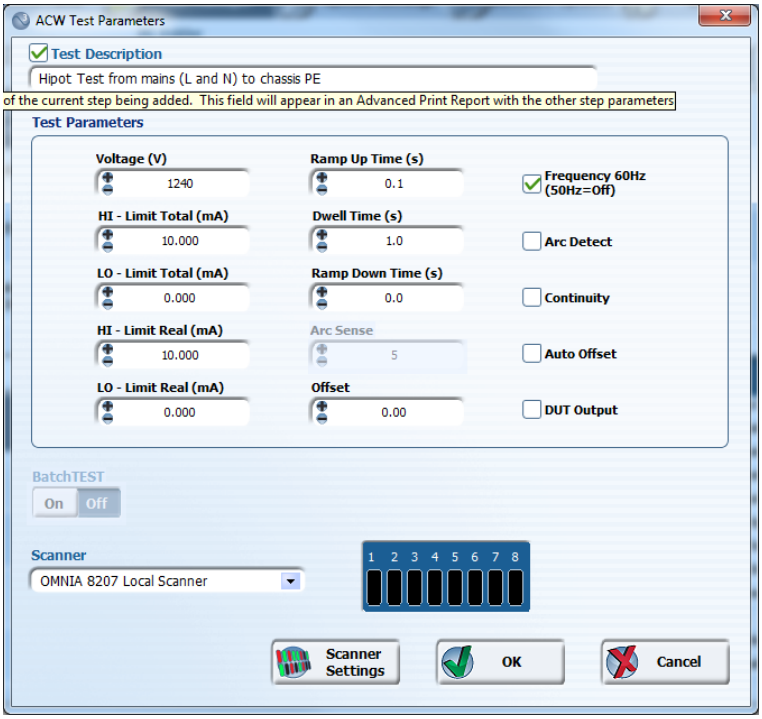
A few notes on the below sequence setup:

- Scanner channels can be set to one of the following states: HIGH (red), LOW (green) or OPEN (black).
- Scanner channels set HIGH are automatically connected to high voltage from the OMNIA II for any hipot test. During any other test, HV is not being generated by the OMNIA.
- Setting multiple channels both high and both low shorts those channels together.
- Scanner 1 (the middle scanner in the image) will represent channels 1-8. The top scanner will represent channels 9-16.
- There is only one line leakage test shown below for each leakage test type. In an actual test setup, each of these leakage setups would actually have 4-8 tests to cover all fault conditions. Thus, for this setup, if all fault scenarios are accounted for, there would be 40 line leakage tests.
- For the line leakage tests (LLT), there are additional parameters for setting a power source (bottom right hand side of LLT parameters screen). This is the built in 500VA supply for the 8207.

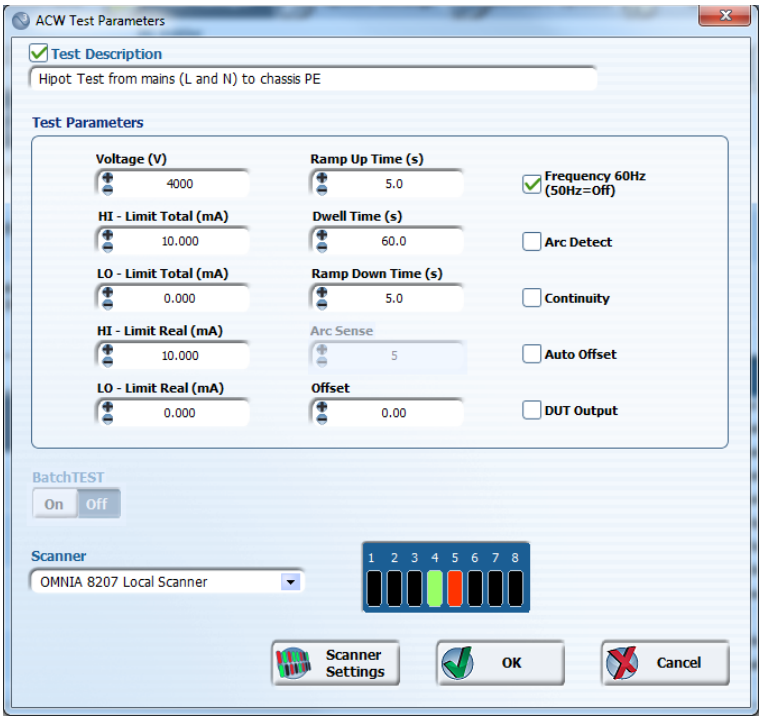
The Active Link™ feature for the line leakage tests allows the DUT to remain powered up in between all line leakage tests. Thus, the DUT only needs to boot up fully on the first line leakage test. For medical devices that are controlled by a microprocessor, this will reduce total testing time as the device will not shut down between every line leakage test.



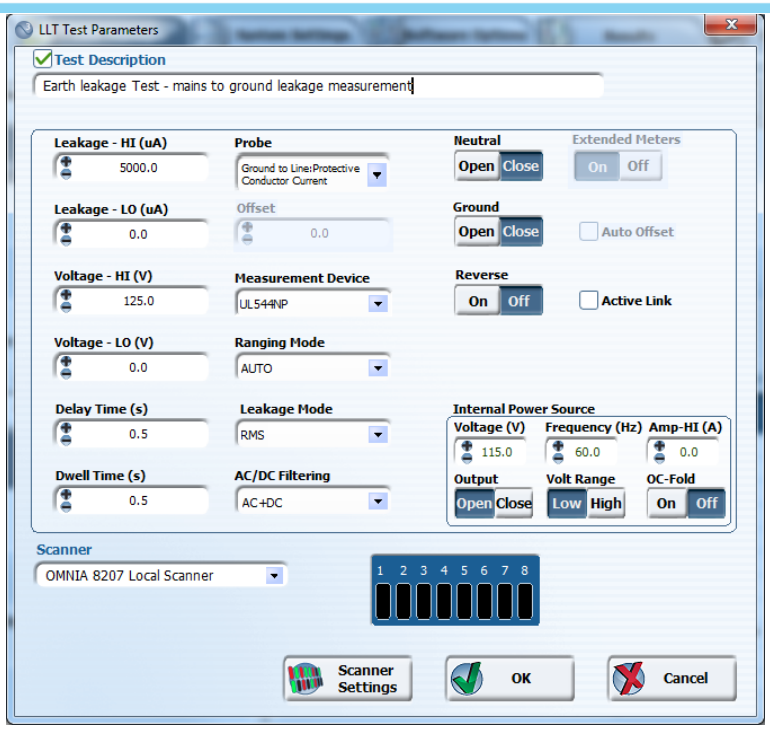
1. Ground Bond – 25A is injected into in the ground pin of the DUT via the GND terminal on rear panel of the OMNIA. The return path is the chassis point connected to CASE on the rear panel of the OMNIA. A resistance measurement is taken and displayed.



2. Mains AC hipot – The Line and Neutral connections on the rear panel of the OMNIA II are shorted together. High voltage is applied on these two shorted terminals. The return path is the chassis point connected to CASE on the rear panel of the OMNIA. A leakage current measurement is taken and displayed.

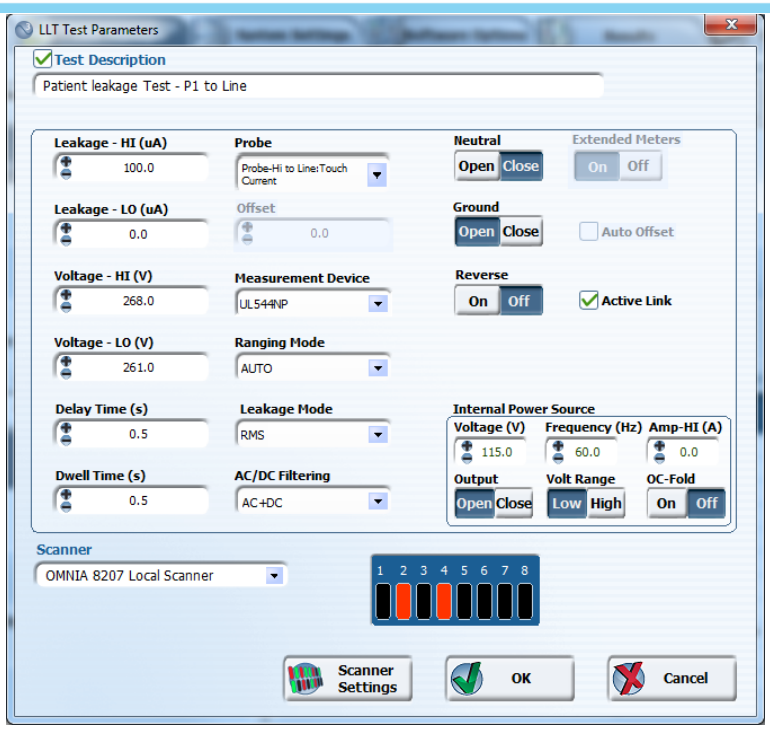


3. AC Patient Lead Hipot – Scanner channel 4 (P1) is set high which connects to high voltage and channel 5 (P2) is set low which connects to return. The leakage value between the leads is measured and displayed. NOTE: DUT HV is set OFF. This ensures no high voltage is output through the LINE and NEUTRAL connections on the rear panel of the OMNIA II so that the DUT is not overstressed.



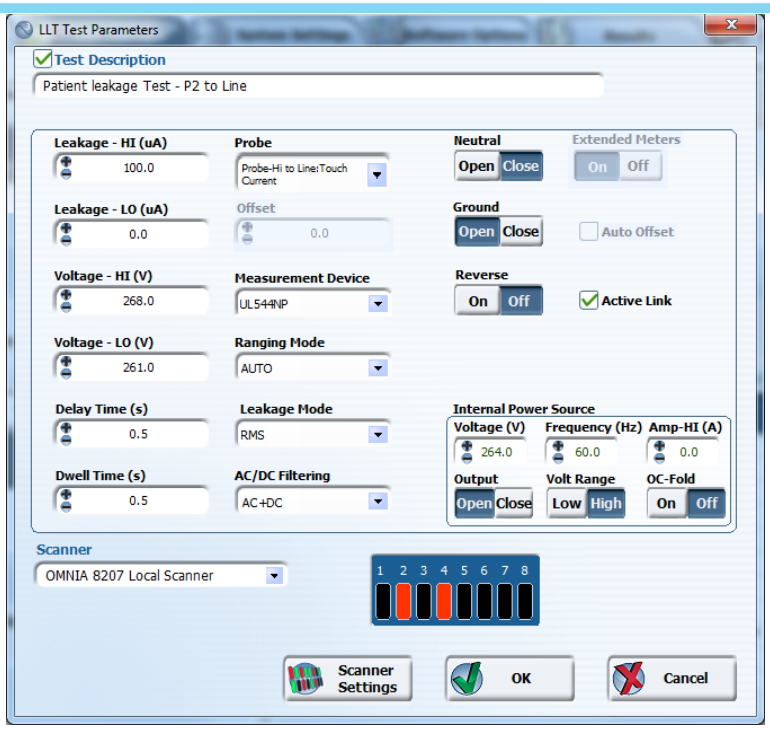
4. Earth Leakage – The internal power source powers up the DUT via the line and neutral connections on the rear panel of the OMNIA. The Probe configuration is set to G-L (ground to line) so the leakage current present while the product is running is measured internally on the OMNIA II via the GND and Line conductors, through the 60601-1 measuring device. This value is then displayed.

Associated Research, Inc.
13860 West Laurel Drive, Lake Forest, IL 60045
P: 1-847-367-4077 **F:** 1-847-367-4080
info@arisafety.com / www.arisafety.com

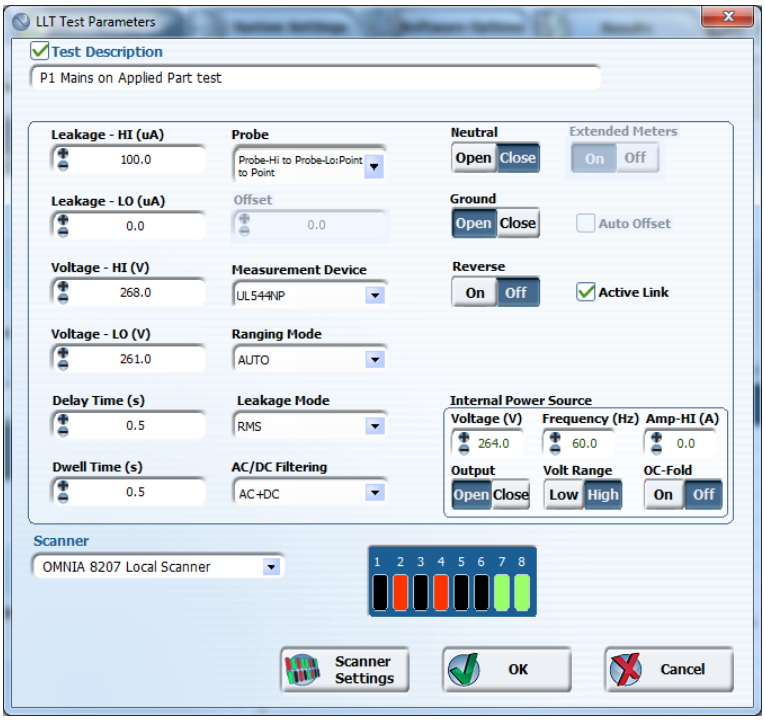


5. Patient Leakage for P1 - The internal power source powers up the DUT via the line and neutral connections on the rear panel of the OMNIA. The Probe configuration is set to Probe Hi to Line, thus placing the MD between the Probe Hi and line terminals. Scanner channels 2 and 4 are both set high. This shorts Probe Hi (channel 2) to P1 (channel 4) so that the leakage current traces a path from the patient lead, back through Probe hi, through the MD and back to the line reference.

Associated Research, Inc.
13860 West Laurel Drive, Lake Forest, IL 60045
P: 1-847-367-4077 **F:** 1-847-367-4080
info@arisafety.com / www.arisafety.com

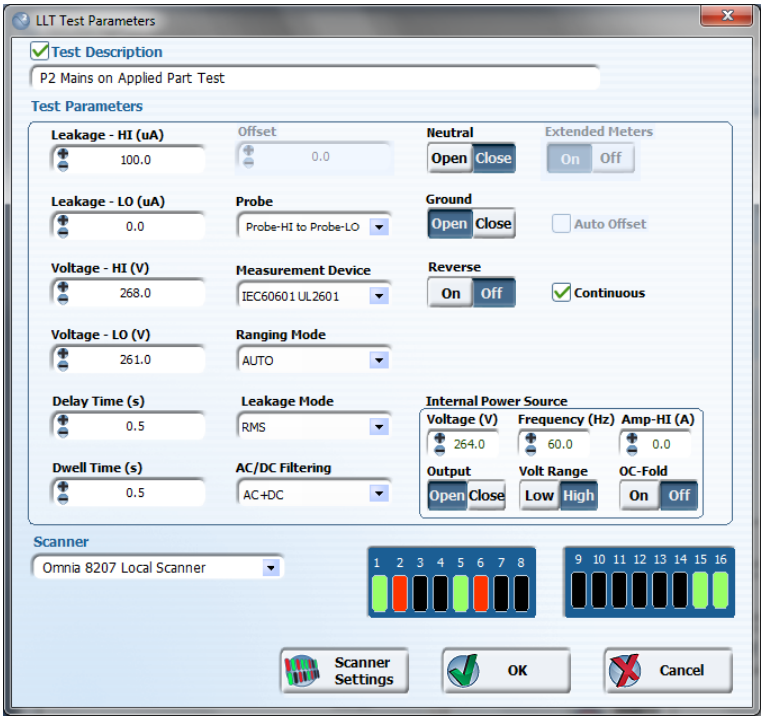


6. Patient Leakage for P2 – This test works in the same fashion as patient leakage to P1. The only difference for this test is the scanner channel setting. Probe Hi (channel 2) and P2 (channel 5) are both set high to take the measurement on P2.



Associated Research, Inc.
13860 West Laurel Drive, Lake Forest, IL 60045
P: 1-847-367-4077 **F:** 1-847-367-4080
info@arisafety.com / www.arisafety.com

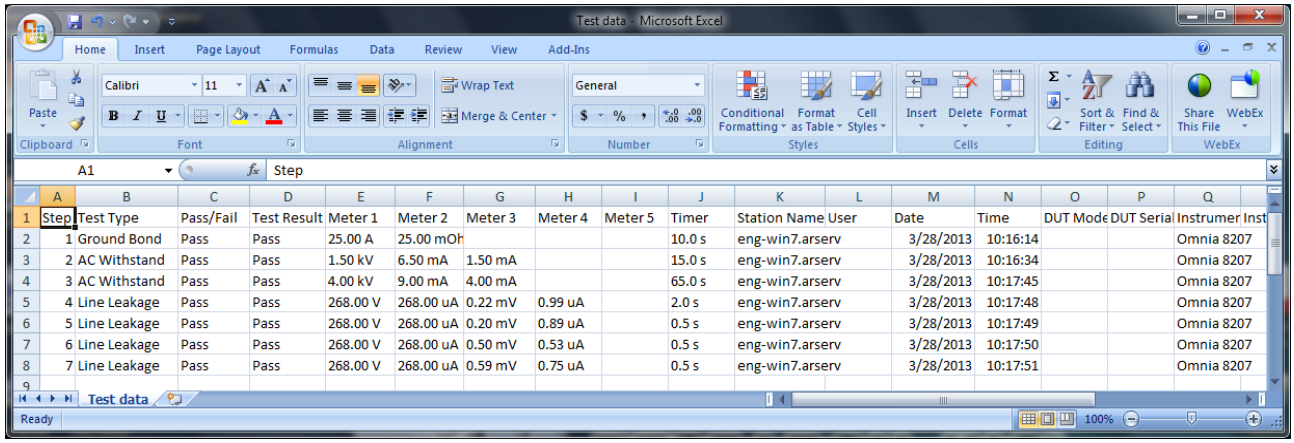
7. P1 Mains on Applied Part Test - The internal power source powers up the DUT via the line and neutral connections on the rear panel of the OMNIA. The Probe configuration is set to Probe Hi to Probe Lo, thus placing the MD between the Probe Hi and Probe Lo terminals. The scanners channels are set such that mains voltage from an isolation transformer is applied to Probe Hi on one side and the patient lead is connected to Probe Lo on the other side of the circuit. Scanner channels 2 and 6 are both set high. This shorts Probe Hi (channel 2) to Line voltage (channel 6). Scanner channels 1 and 4 are both set low. This shorts Probe Lo (channel 1) to P1 (channel 4). The leakage current traces a path from the patient lead, back through Probe hi, through the MD and back to the isolation transformer. Also note that the second scanner has channels set for this test. This is to provide the line or neutral from the isolation transformer to be tied (or opened) to a PE or ground connection per the 60601-1 standard. Thus, channel 15 (neutral) and channel 16 (PE) are both set low to short them together. A separate scanner is used so that this connection is not included as part of the Probe Hi or Probe Lo measurement.



8. P2 Mains on Applied Part Test – This test operates in the same fashion as P1 mains on applied part. The only difference is the scanner channel settings. Scanner channels 2 and 6 are both set high. This shorts Probe Hi (channel 2) to Line voltage (channel 6). Scanner channels 1 and 5 are both set low. This shorts Probe Lo (channel 1) to P2 (channel 5). The leakage current traces a path from the patient lead, back through Probe Hi, through the MD and

back to the isolation transformer. Again, channels 15 and 16 (neutral and PE) are both set low to short neutral to PE per figure 16 in the 60601-1 standard.

Once the test sequence has completed, all results are automatically sent to a tab delimited text file via the Autoware III software. An example test file is shown below. The results include all test measurements, test step notes and whether or not the test passed or failed:



Step	Test Type	Pass/Fail	Test Result	Meter 1	Meter 2	Meter 3	Meter 4	Meter 5	Timer	Station Name	User	Date	Time	DUT Mode	DUT Serial	Instrumer	Inst
1	Ground Bond	Pass	Pass	25.00 A	25.00 mOh				10.0 s	eng-win7.arserv		3/28/2013	10:16:14			Omnia 8207	
2	AC Withstand	Pass	Pass	1.50 kV	6.50 mA	1.50 mA			15.0 s	eng-win7.arserv		3/28/2013	10:16:34			Omnia 8207	
3	AC Withstand	Pass	Pass	4.00 kV	9.00 mA	4.00 mA			65.0 s	eng-win7.arserv		3/28/2013	10:17:45			Omnia 8207	
4	Line Leakage	Pass	Pass	268.00 V	268.00 uA	0.22 mV	0.99 uA		2.0 s	eng-win7.arserv		3/28/2013	10:17:48			Omnia 8207	
5	Line Leakage	Pass	Pass	268.00 V	268.00 uA	0.20 mV	0.89 uA		0.5 s	eng-win7.arserv		3/28/2013	10:17:49			Omnia 8207	
6	Line Leakage	Pass	Pass	268.00 V	268.00 uA	0.50 mV	0.53 uA		0.5 s	eng-win7.arserv		3/28/2013	10:17:50			Omnia 8207	
7	Line Leakage	Pass	Pass	268.00 V	268.00 uA	0.59 mV	0.75 uA		0.5 s	eng-win7.arserv		3/28/2013	10:17:51			Omnia 8207	

Conclusion

Navigating electrical testing requirements per the IEC/UL 60601-1 3rd edition standard can be a labyrinth of confusion. To complicate matters further, customer requirements for testing medical devices can vary. The best method for avoiding non-compliance is covering all testing bases. Running ground bond, dielectric withstand and line leakage testing on 100% of medical devices ensures compliance for electrical safety testing. While such a complex series of tests can prove daunting to setup and perform, there are efficient methods for running these testing sequences. Using the OMNIA II, SC6540 matrixes and Autoware III software, manufacturers have the ability to setup and perform all necessary electrical safety tests.

The Associated Research Inc. testing solution implements 3 methods for efficient testing. First, the OMNIA II provides all-in-one instrumentation. Automating the setup is made simple using Autoware III, which can directly control the OMNIA II and scanning multiplexers. The Autoware III program will also record all test results as is mandated for the FDA for electrical medical device testing. The results are output as a tab delimited text file which allows

them to be reviewed via multiple programs including Microsoft Excel and Microsoft Access. All instruments and software have been designed to operate as an intergrated system, greatly reducing not only the installation time and difficulty, but also testing time and operator error.

For more information regarding the Associated Research Inc. instruments and software, visit the website at www.arisafety.com/products.

For information on isolation transformers, visit the website for Associated Power Technologies at http://www.aptsources.com/.

Associated Research, Inc.
13860 West Laurel Drive, Lake Forest, IL 60045
P: 1-847-367-4077 **F:** 1-847-367-4080
info@arisafety.com / www.arisafety.com