ASSOCIATED RESEARCH
A DIVISION OF IKONIX USA

Automation Leads To Efficiency

The case for software and automating your medical device testing workstation

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 testing is safe for use and will not pose a shock hazard to the end user or patient. Employing our Autoware software with our MedTEST system allows manufacturers to efficiently test to IEC/UL 60601-1 in a production environment. In fact, we've seen manufacturers save 11 minutes off their test procedure by implementing our system. Here's how they did it.

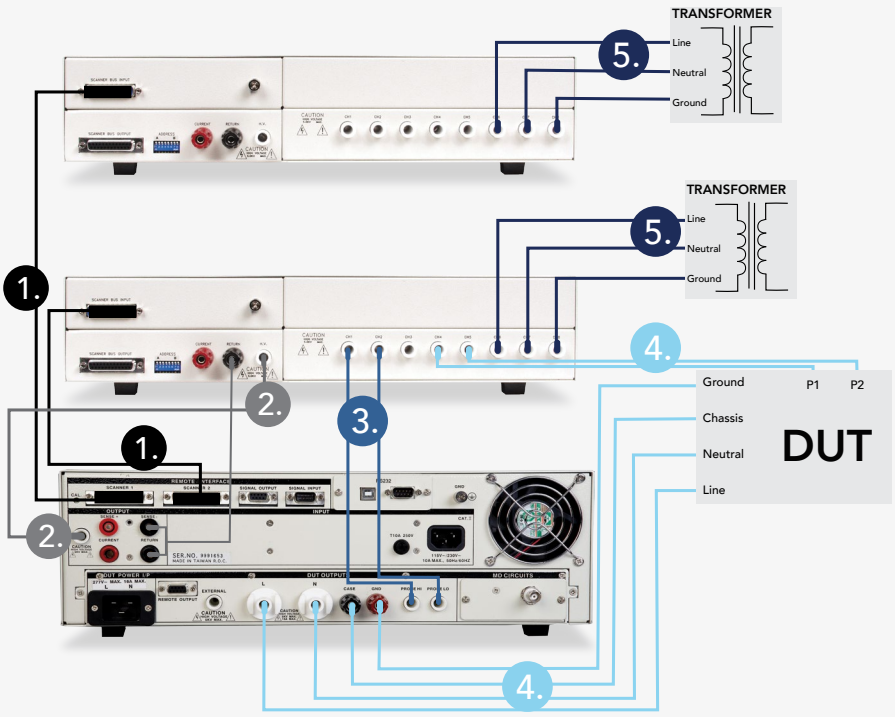
Implement a MedTEST system

OMNIA® II 8207 + Autoware® + SC6540

Common IEC/UL 60601-1 Test Sequence

Ground Bond → AC Hipot (Mains to chasis) → AC Hipot (Patient Lead Hipot) → Earth Leakage → Patient General Leakage → Patient Auxiliary Leakage → Mains On Applied Parts

How Our MedTEST Solution Works



1. OMNIA II controls each scanning matrix from the bus outputs. This allows the OMNIA II to talk to the scanners for setting the proper channels for each step.

2. Connect the first scanning matrix to the OMNIA II via the High Voltage and return leads. This allows for Hipot testing patient leads (connected to channels 5 & 6 in the diagram).

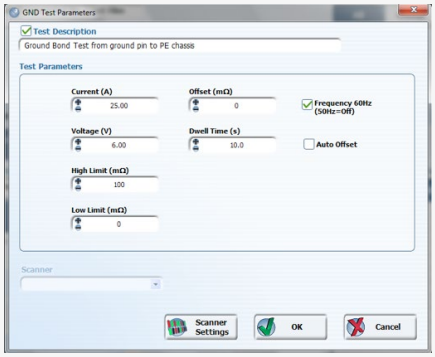
3. Connect the second scanning matrix to the OMNIA II via the Probe Hi and Probe Lo connections. This will allow for patient leakage and mains on applied part measurement (connected to channels 1 –Probe Hi and channels 2 –Probe Lo)

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.

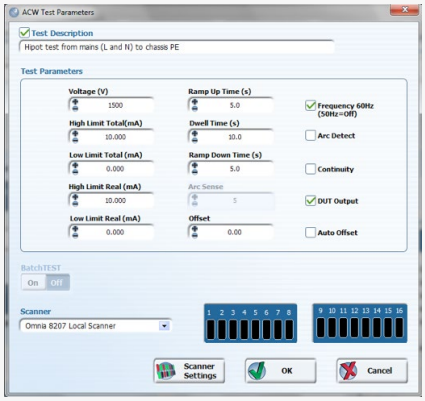
5. Each scanner is connected to an isolation transformer. These are the Line, Neutral and PE (protective earthing or grounding point) connections on channels 6, 7 and 8 of each scanning matix. This will allow for the mains on applied part testing.

Our Active Link® feature has proven to be a big time savings for medical device manufacturers. Active Link 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.

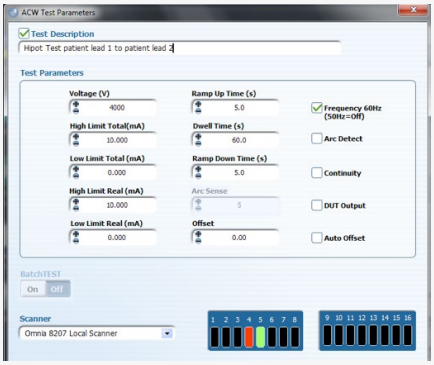
The Autoware III Sequence



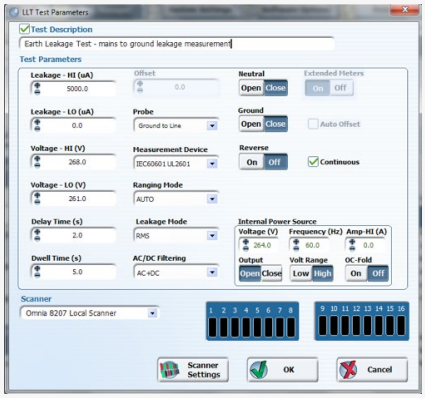
1. Ground Bond – 25A is injected into in the ground pin of the DUT via the GND terminal on rear panel of the OMNIA. The return path is the chassis point connected to CASE on the rear panel of the OMNIA. A resistance measurement is taken and displayed.



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.

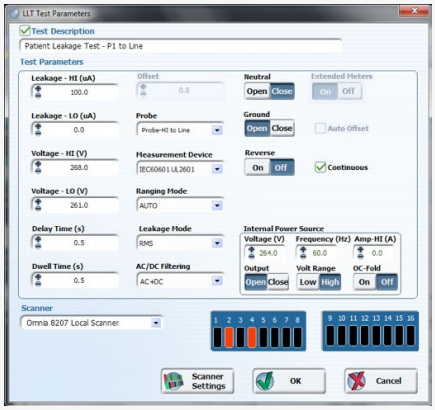


3. AC Patient Lead Hipot – Scanner channel 4 (P1) is set high which connects to high voltage and channel 5 (P2) is set low which connects to return. The leakage value between the leads is measured and displayed. NOTE: DUT HV is set OFF. This ensures no high voltage is output through the LINE and NEUTRAL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

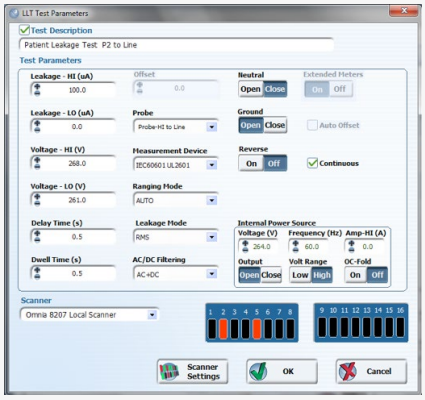


4. Earth Leakage – The internal power source powers up the DUT via the line and neutral connections on the rear panel of the OMNIA. The Probe configuration is set to G-L (ground to line) so the leakage current present while the product is running is measured internally on the OMNIA II via the GND and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

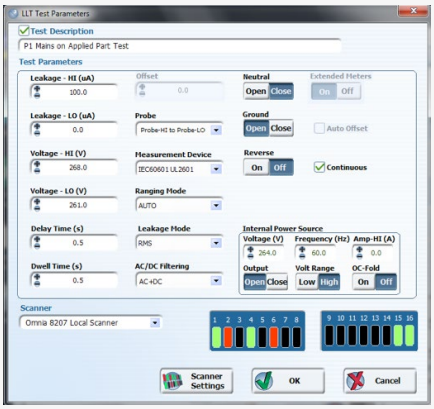
The Autoware III Sequence



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.

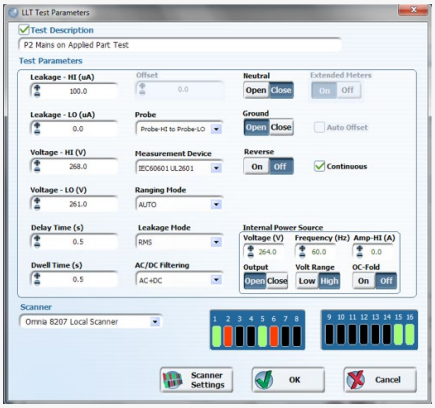


6. Patient Leakage for P2 – This test works in the same fashion as patient leakage to P1. The only difference for this test is the scanner channel setting. Probe Hi (channel 2) and P2 (channel 5) are both set high to take the measurement on P2.

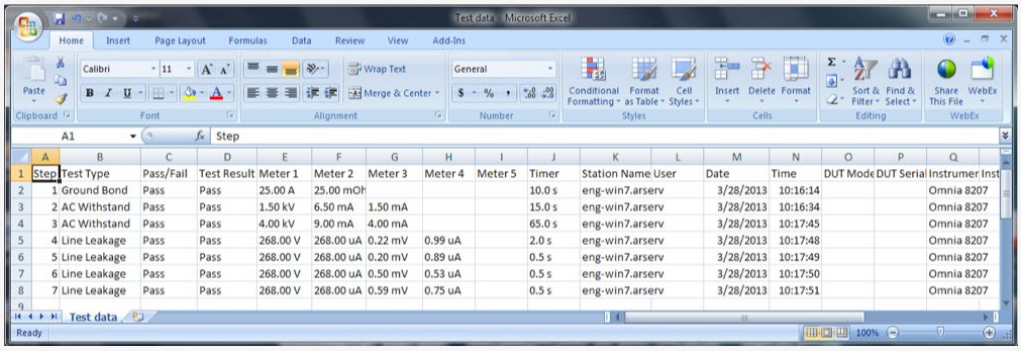


7. P1 Mains on Applied Part Test - The internal power source powers up the DUT via the line and neutral connections on the rear panel of the OMNIA. The Probe configuration is set to Probe Hi to Probe Lo, thus placing the MD between the Probe Hi and Probe Lo terminals. The scanners channels are set such 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.

The Autoware III Sequence



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.



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	

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 above. The results include all test measurements, test step notes and whether or not the test passed or failed:

Conclusion

Navigating electrical testing requirements per the IEC/UL 60601-1 3rd edition standard can be confusing. 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 Leakage Current 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.

Learn more about MedTEST and How it can Simplify your Complex Testing!