ASSOCIATED RESEARCH
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# MedTEST Application Note

## IEC/UL 60601-1 3rd Edition

This Application note provides an example of how to test a medical device per IEC/UL 60601-1 3rd Edition using the Associated Research MedTEST System.

Table 1 lists all the instruments shown in the test setup used as an example in this document.

| Instrument Name/Model | Capabilities and Functions |
|---|---|
| OMNIA II model 8207 Electrical Safety Compliance Analyzer | Ground Bond/Continuity, AC/DC Withstand, Insulation Resistance, Leakage Current, Functional Run and built-in 500 VA AC Source |
| SC6540 Scanning Matrix Main 16 Channel HV | 16 high voltage channels for multi-point testing |
| SC6540 Scanning Matrix Secondary 8 Channel HV | 8 high voltage channel for additional test points |
| Associated Power Technologies model APT320XAC | Programmable AC output 2 kVA |
| Class 1 Medical Device with 2 Applied Parts labeled as DUT – Device Under Test | Can be any medical device with applied parts. Applied part is a part of Medical Electrical Equipment that in normal use necessarily comes into physical contact with the patient to perform its function. |

**Table 1**

## Impedance and Current Carrying Capability (Ground Bond Test)

IEC/UL 60601-1 Clause 8.6.4 Impedance and Current Carrying Capability

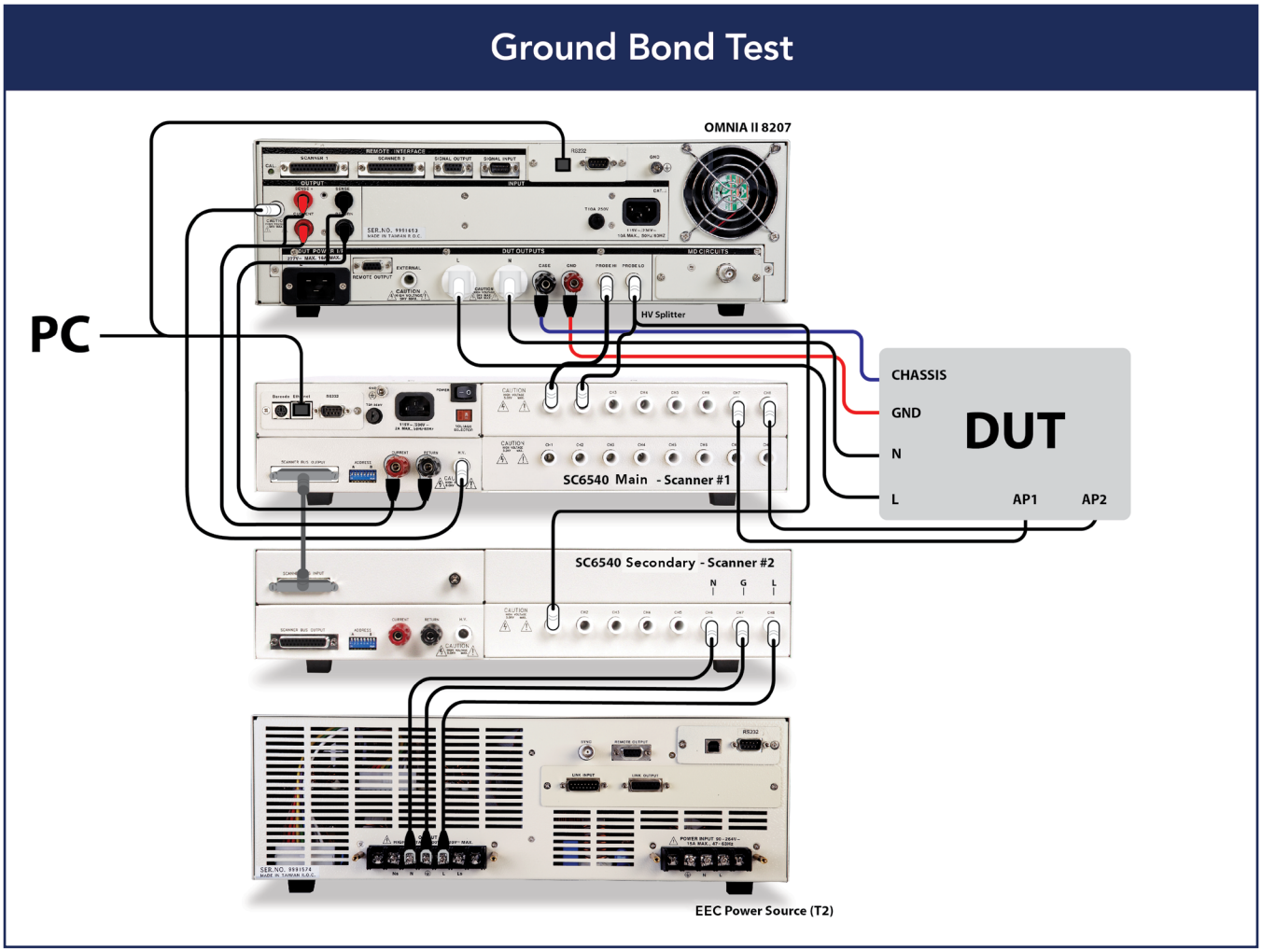


**Figure 1 - Ground Bond Test Connections**

Active connections are shown in red in Figure 1.

| Test Type | Points Under Test | Active Connections | Scanner Channels |
|---|---|---|---|
| Ground Bond | DUT GND – DUT Chassis | GND and CASE | None |

**Table 2**

**Dielectric Strength (The Hipot Test)**
IEC60601-1 Clause 8.8.3 Dielectric Strength

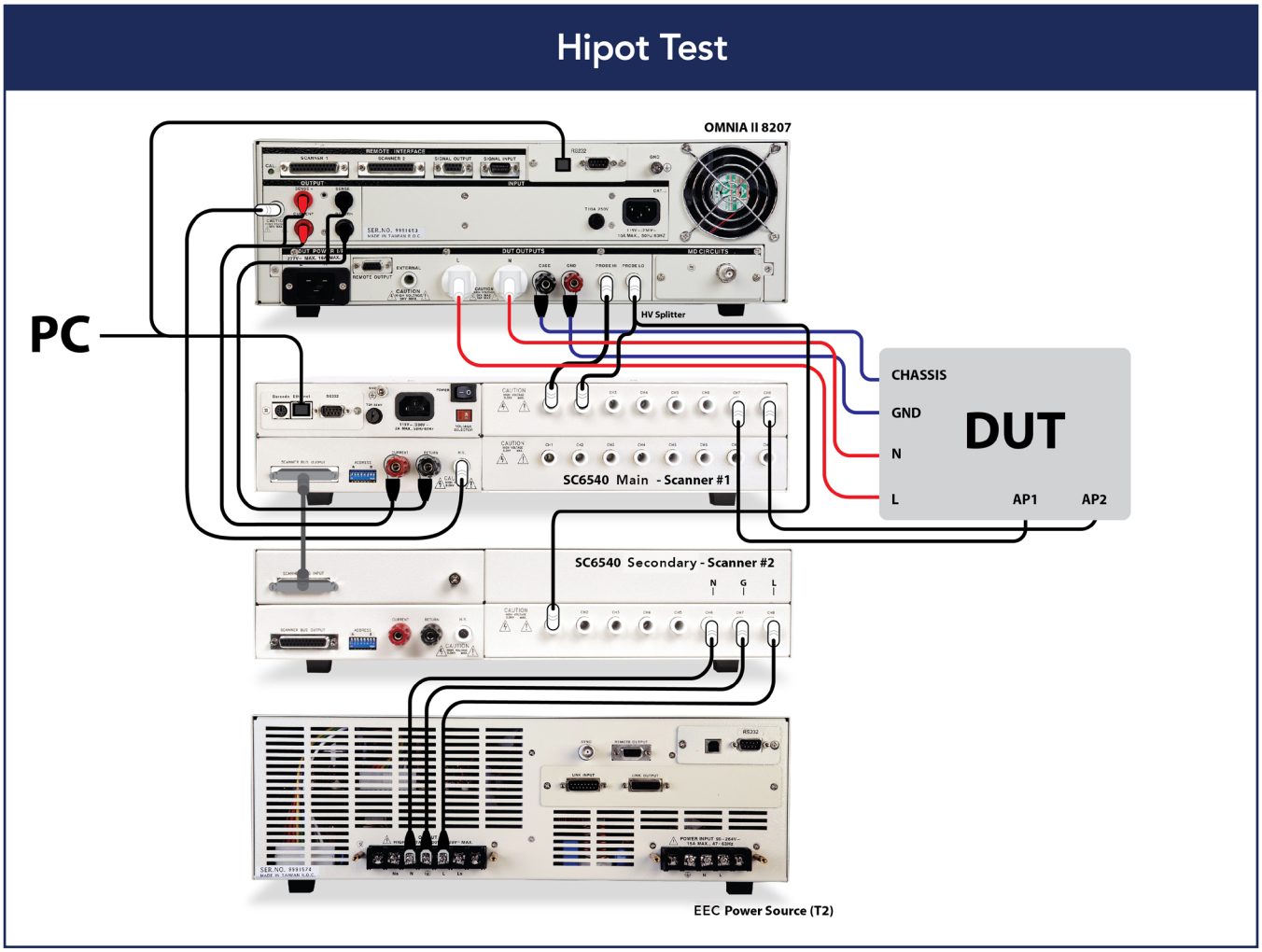


**Figure 2 - Hipot Test Connections**

Active connections are shown in red Figure 2.

| Test Type | Points Under Test | Active Connections | Scanner Channels |
|---|---|---|---|
| Hipot | DUT Mains to Chassis | L, N and Case | None |

**Table 3**

## Dielectric Strength (Applied Part Hipot Test)

IEC/UL 60601-1 Annex L - Section L. 4

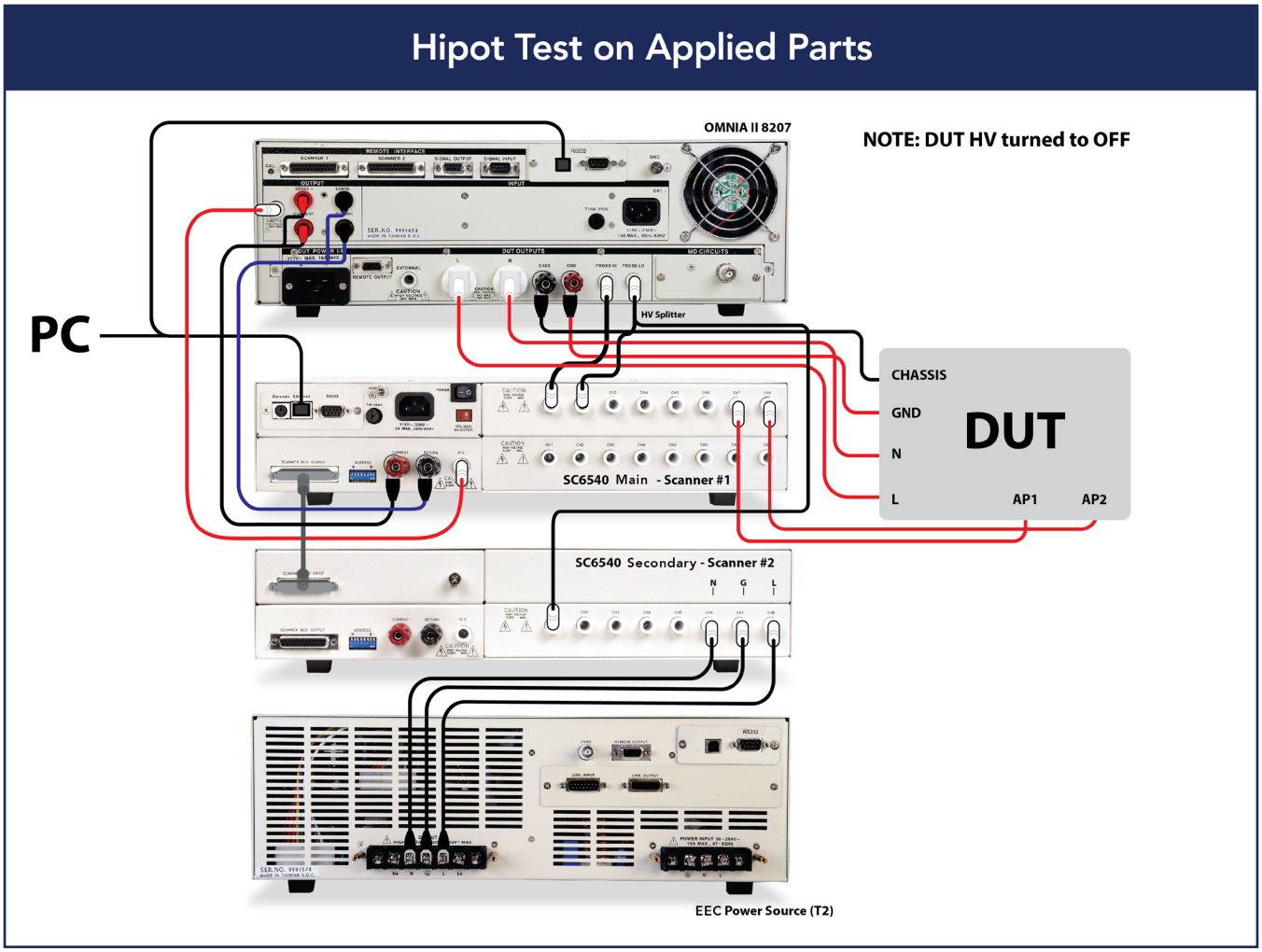


Figure 3

| Test Type | Points Under Test | Active Connections | Scanner Channels |
|---|---|---|---|
| Applied Part Hipot | DUT Mains to Applied Part (AP1 or AP2) | L, N and Return<br>*Disconnect GND lug of the 38578 box from Omnia and the Case connection | Scanner 1: CH15 or CH16 set to Lo |
| | Applied Part to DUT Mains | AP1 or AP2 and DUT L, N or GND<br>*Disconnect GND lug of the 38578 box from Omnia and the Case connection | --- |

Table 4

## Leakage Current and Patient Auxiliary Current

IEC/UL 60601-1 Clause 8.7 Leakage Current and Patient Auxiliary Current* (The Leakage Current Test)

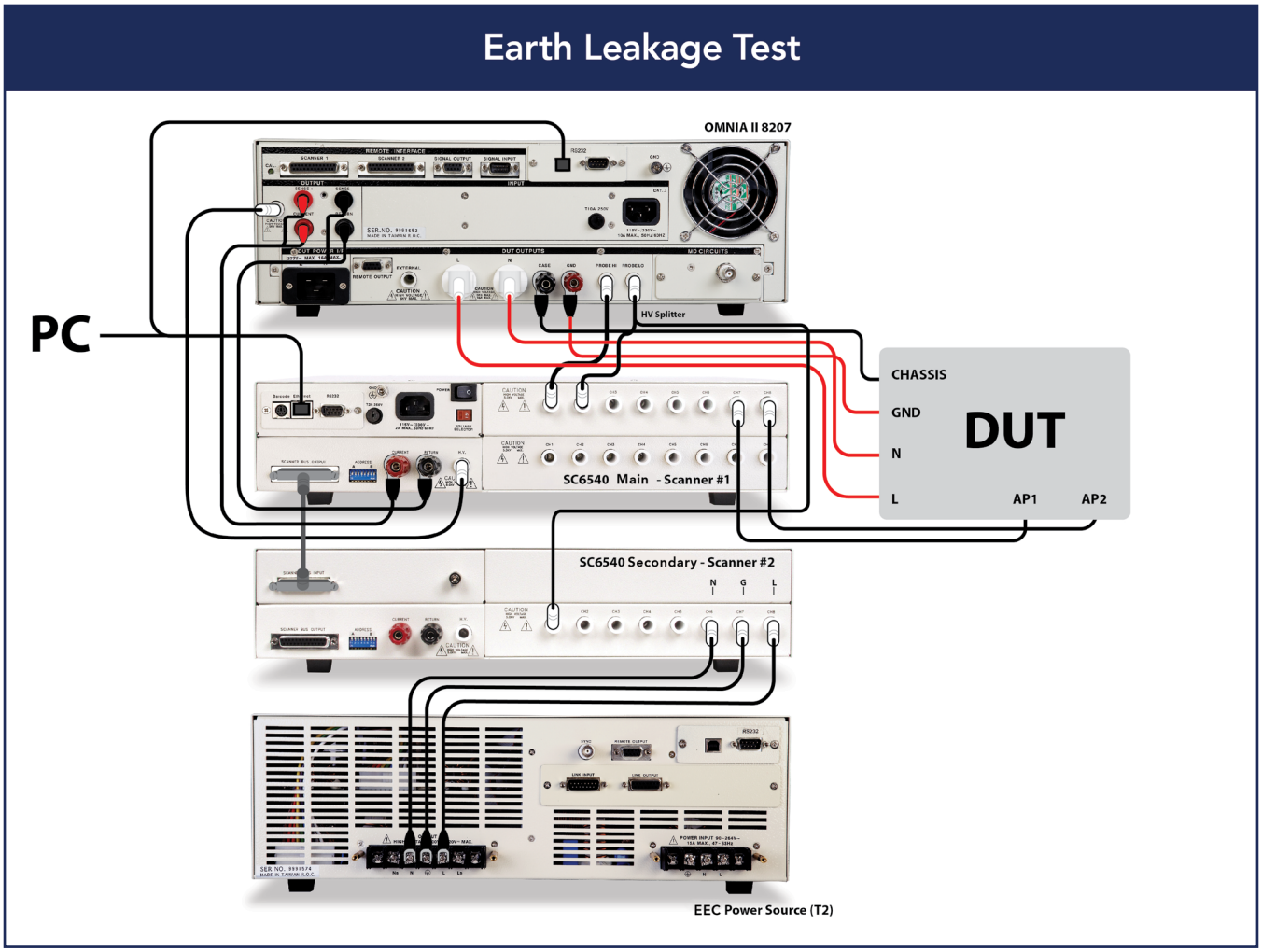


**Figure 4**

| Test Type | Points Under Test | Active Connections | Scanner Channels |
|---|---|---|---|
| LCT - Earth Leakage | N and GND | L, N and GND | None |

**Table 5**

## Enclosure Leakage Test

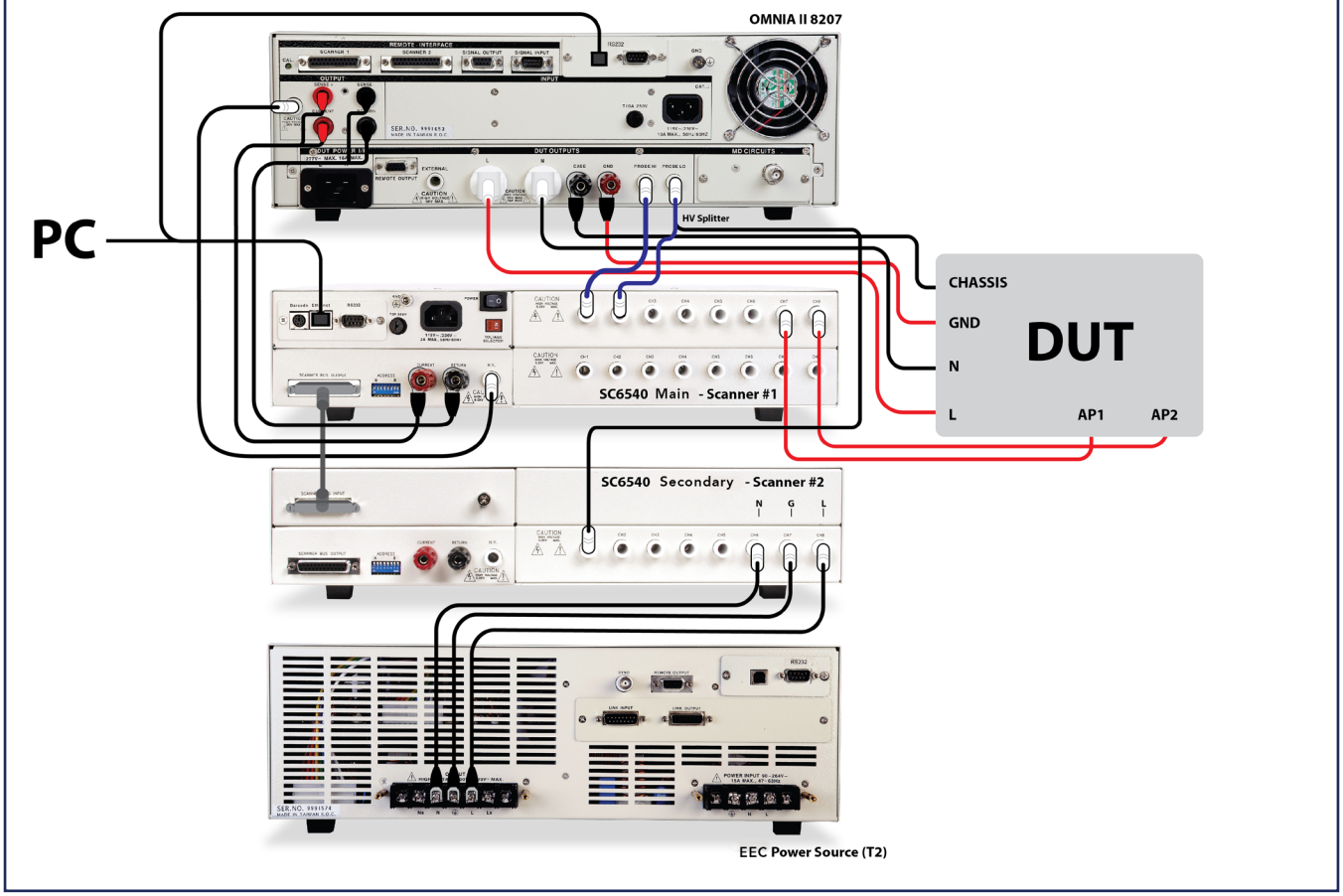


Figure 5

| Test Type | Points Under Test | Active Connections | Scanner Channels |
|---|---|---|---|
| LCT - Enclosure Leakage | Enclosure points (EP1 or EP2) | L, N and Probe Hi<br>*LCT - Enclosure Leakage | Scanner 1: CH 9 Hi and CH15/CH16 Hi depending on point under test. |

Table 6

## Applied Part Leakage

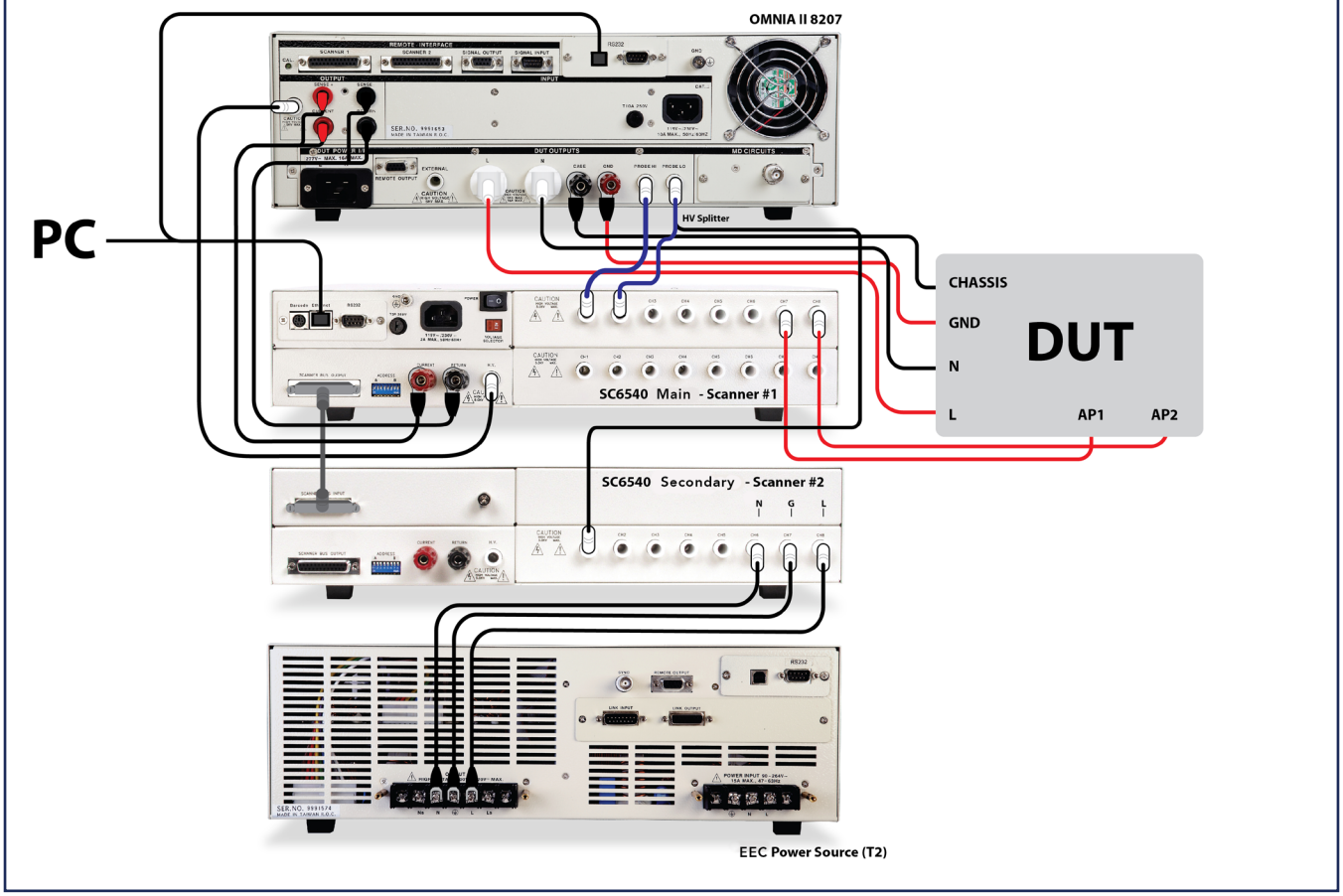


Figure 6

| Test Type | Points Under Test | Active Connections | Scanner Channels |
|---|---|---|---|
| LCT - Applied Part Leakage | Applied Parts AP1 and/or AP2<br>*There can be more than two applied parts | L, N and Probe Hi and Probe Lo<br>*Probe Configuration – Probe Hi to Line for single Applied part and Probe Hi to Probe Lo for testing between two Applied Parts | Scanner 1: Single applied part – CH9 Hi and CH15/16 Hi<br>Two Applied parts – (CH9 and CH15) Hi (CH10 and CH16) Lo |

Table 7

## Mains on Applied Part Leakage

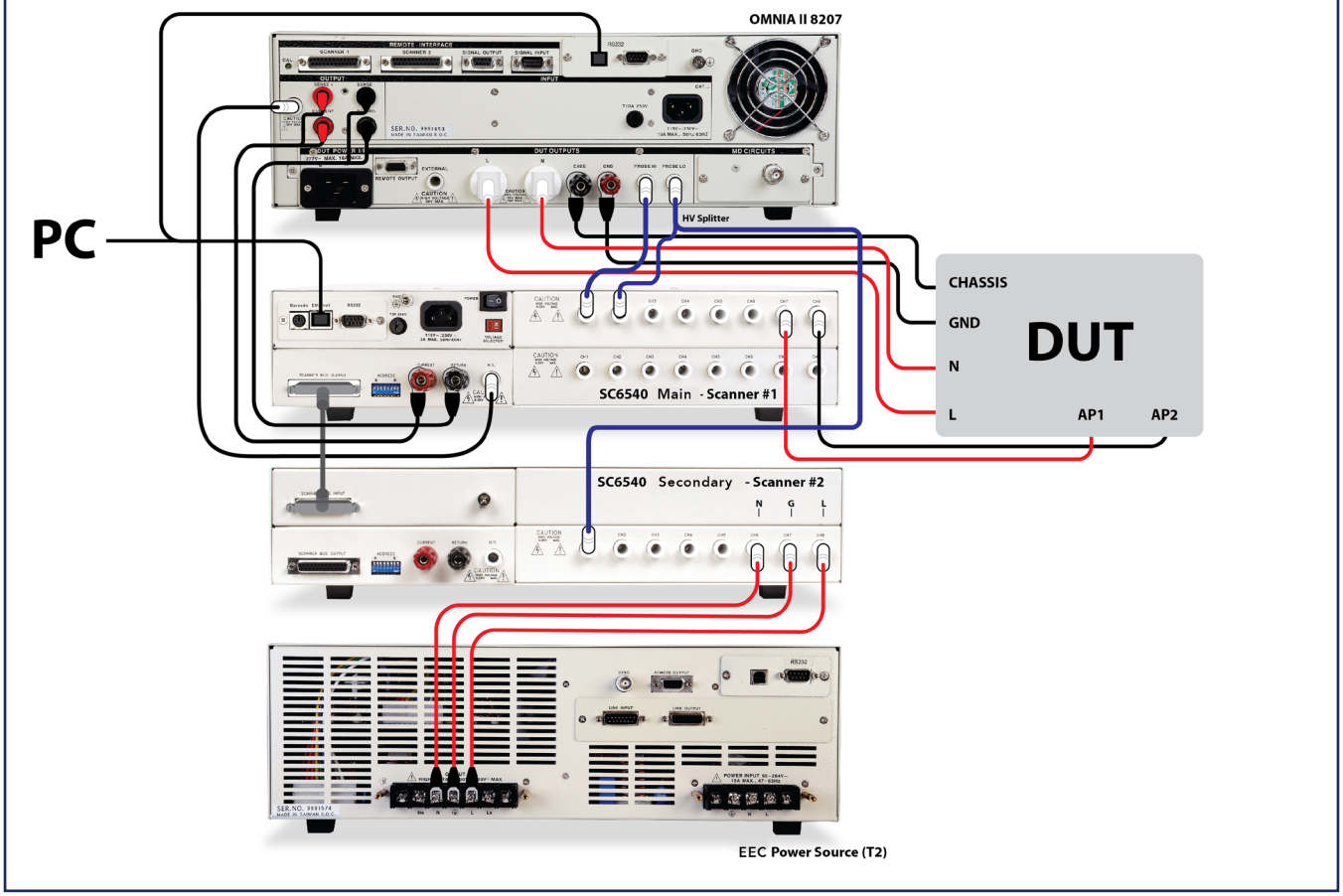


Figure 6

| Test Type | Points Under Test | Active Connections | Scanner Channels |
|---|---|---|---|
| LCT – Mains Applied Part Leakage | L, N, Probe Hi and Probe Lo | L, N and Probe Hi and Probe Lo<br>*Probe Configuration – Probe Hi to Probe Lo | Scanner 1: (CH7 and CH1) Hi<br><br>Scanner 2: (CH1 and CH8) HI, (CH6 and CH7) Lo |

Table 7