

Safety Standards Guide

Electrical Safety Compliance



- IEC/UL 60601-1 3rd Edition
- UL 1598/CSA C22.2 No. 250.0-08 3rd Edition
- BS EN 60204-1:2006 + A1:2009
- IEC/UL 60335-1 5th Edition
- IEC 60598-1 7th Edition
- IEC/UL 60950-1 2nd Edition
- IEC/UL 61010-1 3rd Edition

How To Use This Guide

FIND the safety standard that applies to your product. Each page of this document details the electrical safety tests for various safety standards.

REVIEW the electrical safety testing requirements for the standard and determine which tests you need to perform.

MATCH these requirements with the Associated Research instrument that will fit your testing needs. If you need to perform multiple tests, look for a complete solution in the OMNIA® II Series or HypotULTRA® 7804/54 instruments.

This document is meant for reference purposes only. It is not a replacement for the necessary safety standards.

NOTE: This is an interactive PDF, please use our [quick links](#) to be brought to that Series web page to learn more about the instrument.

**BS EN 60204-1:2006
+ A1:2009**
Safety of Machinery



18.2.2 Test 1 Verification of the Continuity of the Protective Bonding Circuit (Ground Bond Test)

REQUIREMENT	PASS CRITERIA
0.2 A ≤ Test Current ≤ 10 A	No load voltage ≤ 24 V AC or DC
★ SOLUTION: HYAMP® III 3130 and 3145	

18.3 Insulation Resistance Tests (IR Test)

REQUIREMENT	PASS CRITERIA
Test voltage = 500 V DC IR value measured between power circuit conductors and grounding circuit	Minimum insulation resistance ≥ 1 MΩ Exception - a value of 50 kΩ or more is allowed for certain parts of electrical equipment. See 18.3 for details.
★ SOLUTION: HypotULTRA® 7850 or Hypot III® 3770	

18.4 Voltage Tests (Hipot Test)

REQUIREMENT	PASS CRITERIA
Test voltage = 1000 V or 2 * Rated Supply Voltage of DUT (whichever is greater) Test time = 1 sec Tested at rated frequency	No disruptive discharge or breakdown on DUT insulation
★ SOLUTION: HypotULTRA® 7850 or Hypot III® 3765	

Production line testing is not defined in this standard. Production line testing requirements are the responsibility of the manufacturer.

**IEC/UL 60335-1
5th Edition**



13.2 Leakage Current at Operating Temperature (Leakage Current Test)

REQUIREMENT	PASS CRITERIA
Heating appliances tested at 1.15 time rated input power Motor operated appliances tested at 1.06 times rated input V Tested with open ground, reverse polarity and open neutral Tested with IEC 60990 Fig. 4	Maximum touch leakage current ~ 0.35 mA peak - 3.5 mA depending upon appliance type NOTE: Associated Research equipment cannot perform leakage testing on balanced or 3 phase systems.
★ SOLUTION: LINECHEK® II 620L	

**IEC/UL 60335-1
5th Edition Continued**

13.3 Electric Strength Test at Operating Temperature (Hipot Test)

REQUIREMENT	PASS CRITERIA
500 VA Hipot Instrument Required Test voltage - Refer to Table 4 Test time = 60 sec Frequency = 50 Hz or 60 Hz	No breakdown on product insulation
★ SOLUTION: HypotULTRA® 7800 or Hypot III® 3780	

16.2 Leakage Current (Leakage Current Test)

REQUIREMENT	PASS CRITERIA
Tested at 1.06 time rated input voltage Tested with open ground, reverse polarity and open neutral Tested with IEC 60990 Fig. 4	Maximum touch leakage current ~ 0.25-3.5 mA depending upon appliance type NOTE: Associated Research equipment cannot perform leakage testing on balanced or 3 phase systems.
★ SOLUTION: LINECHEK® II 620L	

16.3 Electric Strength Test (Hipot Test)

REQUIREMENT	PASS CRITERIA
500 VA Equipment Required Test voltage - Refer to Table 7 Test voltage for Class 0 and Class I appliances = 1250 V AC Test voltage for Class II appliances = 1750 V AC Test time = 5 sec ramp up, 60 sec dwell	No breakdown on product insulation
★ SOLUTION: HypotULTRA® 7800 or Hypot III® 3780	

27.5 Provision for Earthing Test (AC Ground Bond Test)

REQUIREMENT	PASS CRITERIA
Current = 25 A OR 1.5 * highest rated current (whichever is greater) passed through protective earthing circuit. No load voltage ≤ 12 V AC or DC	Impedance protective earthing circuit on the DUT ≤ 100 mΩ
★ SOLUTION: HypotULTRA® 7804 or HYAMP® III 3130/3140	

Annex A (Routine Tests)

ROUTINE GROUND BOND	ROUTINE HIPOT
Test Current = 10 A No load voltage ≤ 12 V AC or DC Impedance of earthing conductor for cord connected equipment ≤ 200 mΩ Impedance for all other appliances ≤ 100 mΩ	Test voltage - Refer to Table A.1 Leakage current limit ≤ 5 mA Leakage current limit for high leakage appliances ≤ 30mA
★ SOLUTION: HypotULTRA® 7804 or HYAMP® III 3130/3140 AND Hypot® III 3705	

IEC 60598-1 7th Edition

YOUR COMPLETE SOLUTION



OMNIA® II 8256/8257
6-in-1 Instrument

7.2.3 Provisions for Earthing (Ground Bond Test)

REQUIREMENT	PASS CRITERIA
Test current ≥ 10 A passed between earthing contact point and accessible conductive parts No load voltage ≤ 12 V AC or DC Test time ≥ 60 sec	Impedance protective earthing circuit on the DUT $\leq 500\text{m}\Omega$

★ SOLUTION: [HypotULTRA® 7804](#) or [HYAMP® III 3130/3145](#)

10.2.1 Insulation Resistance (IR Test)

REQUIREMENT	PASS CRITERIA
Test voltage = 500 V DC or 100 V DC for SELV parts Test time = 60 sec	Minimum insulation resistance - Refer to Table 10.1

★ SOLUTION: [HypotULTRA® 7850](#) or [Hypot® III 3770](#)

10.2.2 Electric Strength Test (Hipot Test)

REQUIREMENT	PASS CRITERIA
Test voltage - Refer to Table 10.2 500 VA equipment required Test time = 60 sec	No breakdown on product insulation If DUT enclosure is non-conductive, use metal foil as conductive medium for return point

★ SOLUTION: [HypotULTRA® 7800](#) or [Hypot® III 3780](#)

10.3 Touch Current and Protective Conductor Current (Leakage Current Test)

REQUIREMENT	PASS CRITERIA
Tested at rated voltage Tested with open ground, open neutral and reverse polarity Tested for single phase equipment connected line-to-neutral Tested with measuring device G.2 (IEC 60990-1 Fig. 4 U2 & U1) and G.3 (IEC 60990-1 Fig. 5 U3)	No breakdown on product insulation If DUT enclosure is non-conductive, use metal foil as conductive medium - Maximum touch leakage and earth leakage current - Refer to Table 10.3 NOTE: Associated Research Instruments do not contain leakage network G.4. Other networks must be manually built into our External MD. LINECHEK II 620L does not contain leakage network IEC 60990-1 Fig. 4 U1

★ SOLUTION: [LINECHEK® II 620L](#)

IEC/UL 60950-1 2nd Edition

YOUR COMPLETE SOLUTION



OMNIA® II 8206/8207
6-in-1 Instrument

2.6.3.4 Resistance of Earthing Conductors (Ground Bond Test)

REQUIREMENT	PASS CRITERIA
Current = 2 * protective current rating of bonding conductor Test time = 120 sec	Impedance protective earthing circuit on the DUT $\leq 100\text{m}\Omega$ Voltage drop across protective bonding circuit ≤ 2.5 V

★ SOLUTION: [HypotULTRA® 7804](#) or [HYAMP® III 3130/3140](#)

5.1 Touch Current and Protective Conductor Current (Leakage Current Test)

REQUIREMENT	PASS CRITERIA
Tested at rated voltage Tested with open ground, open neutral and reverse polarity Tested for single phase equipment connected line-to-neutral Tested with measuring device D.1 (IEC 60990-1 Fig. 4 U2)	Maximum touch leakage current $\sim 0.25 - 3.5$ mA R.M.S Maximum earth leakage current $\leq 5\%$ input current Refer to Table 5A for details NOTE: Associated Research equipment cannot perform leakage testing on balanced or 3 phase systems.

★ SOLUTION: [LINECHEK® II 620L](#)

5.2 Dielectric Withstand Test (Hipot Test)

REQUIREMENT	PASS CRITERIA
Test voltage - See tables 5B and 5C Test time = 60 sec Tested at 50 Hz, 60 Hz or DC equivalent (1.414 * AC Voltage Test)	No dielectric breakdown If DUT enclosure is non-conductive, use metal foil as conductive medium for return point.

★ SOLUTION: [HypotULTRA® 7820/7850](#) or [Hypot® III 3705/3765](#)

Annex U.3.1 Routine Hipot Testing

REQUIREMENT	PASS CRITERIA
Test voltage = 1500 V AC for Basic or Supplementary Insulation Test voltage = 3000 V AC for Reinforced Insulation	No dielectric breakdown shall occur Test voltage = 1500 V AC for Basic or Supplementary Insulation Test voltage = 3000 V AC for Reinforced Insulation

★ SOLUTION: [HypotULTRA® 7820/7850](#) or [Hypot® III 3705/3765](#)

IEC 61010-1 3rd Edition

YOUR COMPLETE SOLUTION



OMNIA® II 8256/8257
6-in-1 Instrument

5.6.3 Limit Values for Accessible Parts (Leakage Current Test)

REQUIREMENT	PASS CRITERIA
Tested in Normal Conditions (NC) and Single Fault Conditions (SFC) NOTE: AR Instruments contain leakage network A.1. Other networks must be manually built into our External MD.	Leakage Current (NC) ≤ 0.5 mA R.M.S. OR ≤ 0.7 mA Peak OR ≤ 2 mA DC Leakage Current (SFC) ≤ 3.5 mA R.M.S. OR 5 mA Peak OR 15 mA DC
★ SOLUTION: LINECHEK® II 620L	

6.5.2.4 Impedance of Protective Bonding of Plug Connected Equipment (Ground Bond Test)

REQUIREMENT	PASS CRITERIA
Current = 25 A AC or DC or 2 * highest rated current (whichever is greater) passed through protective earthing circuit Test time = 60 sec Frequency = Rated or DC	Impedance between ground pin and protectively earthed point(s) on the DUT ≤ 100 m Ω For DUTs with non-detachable supply cord, impedance of the DUT ≤ 200 m Ω
★ SOLUTION: HypotULTRA® 7804 or HYAMP® III 3130/3140	

6.5.2.5 Impedance of Protective Bonding of Permanently Connected Equipment (Ground Bond Test)

REQUIREMENT	PASS CRITERIA
Current of 2 * specified over current protection value passed through protective conductor and chassis points Test time = 60 sec	Voltage drop across circuit ≤ 10 V AC R.M.S. or DC
★ SOLUTION: HypotULTRA® 7804 or HYAMP® III 3130/3140/3145	

6.8.3.1 The AC Voltage Test (AC Hipot Test)

REQUIREMENT	PASS CRITERIA
Test voltage - Refer to Table 5 500 VA Equipment Required Test time = 5 sec ramp up, 60 sec dwell	No flashover or breakdown on product insulation
★ SOLUTION: HypotULTRA® 7800 or Hypot® III 3780	

IEC 61010-1 3rd Edition Continued

6.8.3.2 The DC Voltage Test (DC Hipot Test)

REQUIREMENT	PASS CRITERIA
Test voltage - Refer to Table 5 Test time = 5 sec ramp up, 60 sec dwell	No flashover or breakdown on product insulation
★ SOLUTION: HypotULTRA® 7850 or Hypot® III 3765	

Annex F - Routine Tests

THE CONTINUITY TEST	THE HIPOT TEST
A continuity test to be run on the protective earth circuit No current value specified. Simple continuity test to show existence of protective earth circuit	Test voltage - Refer to Table F.1 No flashover or breakdown on product insulation
★ SOLUTION: Hypot® III 3705	

YOUR COMPLETE SOLUTION



OMNIA® II 8206/8207
6-in-1 Instrument

IEC 60601-1 3rd Edition

8.6.4 Impedance and Current Carrying Capability (AC Ground Bond Test)

REQUIREMENT	PASS CRITERIA
Current = 25 A OR 1.5 * highest rated current (whichever is greater $\pm 10\%$) passed through protective earthing circuit. Frequency = 50 or 60 Hz, no load voltage ≤ 6 V	Impedance protective earthing circuit on the DUT ≤ 100 m Ω For DUTs with non-detachable supply cord, impedance for DUT ≤ 200 m Ω
★ SOLUTION: HypotULTRA® 7804 or OMNIA® II 8206/8207 or HYAMP® III 3130/3140	

8.7 Leakage Current and Patient Auxiliary Current* (Leakage Current Test)

REQUIREMENT	PASS CRITERIA
Tested in Normal Conditions (NC) & Single Fault Conditions (SFC) Tested with supply at 110% highest rated mains voltage Tested at highest rated supply frequency	Earth Leakage Current ≤ 5 mA (NC) or 10 mA (SFC) Touch Current ≤ 100 μ A (NC) or 500 μ A (SFC) Patient Leakage Current - Refer to Tables 3 and 4
★ SOLUTION: OMNIA® II 8206/8207 or LINECHEK® II 620L	

*Section 8.7 consists of a number of various leakage tests. Further details are given in the below diagram

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8.7.4 Leakage Current Measurements

Earth Leakage Current: Figure 13, Section 8.7.4.5	<ul style="list-style-type: none"> — Patient Lead to Earth: Fig. 15, Section 8.7.4.7a — Mains on Applied Part (for F-Type Patient Leads): Fig. 16, Section 8.7.4.7b — Mains on Signal I/O Ports: Fig. 17, Section 8.7.4.7c — Mains on Non-Protectively Earthed Chassis Point: Fig. 18, Section 8.7.4.7d
Touch Current (Enclosure Leakage): Figure 14, Section 8.7.4.6	
Patient Leakage General: Section 8.7.4.7	
Patient Auxiliary (Patient Lead to Lead): Fig. 19, Section 8.7.4.8	

★ **SOLUTION:** OMNIA® II 8206/8207 or LINECHECK® II 620L AND OPTIONAL APT POWER SOURCE

8.8.3 Dielectric Strength (Hipot Test)

REQUIREMENT	PASS CRITERIA
Test voltage - Refer to tables 6 and 7 Test time = 10 sec ramp up, 60 sec dwell & 10 sec ramp down Tested at 50Hz, 60Hz or DC equivalent (1.414 * AC test voltage)	No dielectric breakdown If DUT enclosure is non-conductive, use metal foil as conductive medium for return point.

★ **SOLUTION:** HypotULTRA® 7820/7850 or OMNIA® II 8206/8207 or Hypot® III 3705/3765/3770

Annex L - Section L. 4 (Routine Tests)

REQUIREMENT	PASS CRITERIA
Test voltage - Refer to tables 6 and 7 of section 8.8.3 Minimum test voltage values=1500 V r.m.s or 2100 V peak for basic or supplementary insulation 3000 V r. m. s or 4200 V peak for reinforced insulation	No dielectric breakdown

★ **SOLUTION:** HypotULTRA® 7820/7850 or OMNIA® II 8206/8207 or Hypot® III 3705/3765/3770

Production line testing is defined in Annex L for dielectric withstand testing. Other production line testing requirements are the responsibility of the manufacturer. As a result of performing risk analysis, many medical device manufacturers are performing leakage current tests as part of 100% production line testing.

UL 1598/CSA C22.2 No. 250.0-08 3rd Edition

YOUR COMPLETE SOLUTION



OMNIA® II 8204
4-in-1 Instrument



HypotULTRA® 7804
4-in-1 Instrument

17.1 Dielectric Voltage Withstand Test (Hipot Test)

REQUIREMENT	PASS CRITERIA
Test voltage = 1000 V AC for incandescent luminaries Test voltage = 1000 + 2 * Rated Voltage for all other luminaries Test time = 60 sec	No breakdown on product insulation If DUT enclosure is non-conductive, use metal foil as conductive medium for return point.

★ **SOLUTION:** HypotULTRA® 7820 or Hypot® III 3705

17.2 Bonding Circuit Impedance (Ground Bond Test)

REQUIREMENT	PASS CRITERIA
Test current = 30 A passed between earthing contact point and accessible conductive parts No load voltage ≤ 12 V AC or DC Test time = 60 - 120 sec (Refer to clause 17.2.4)	Impedance protective earthing circuit on the DUT ≤ 100 mΩ

★ **SOLUTION:** HypotULTRA® 7804 or HYAMP® III 3130/3145

17.5 Insulation Resistance Test (IR Test - Mexico Only)

REQUIREMENT	PASS CRITERIA
Test voltage = 500 V DC IR value measured between live parts of opposite polarity and live parts of DUT enclosure	Minimum insulation resistance ≥ 2 MΩ

★ **SOLUTION:** HypotULTRA® 7804/7850 or Hypot® III 3705

18 Factory Production Tests

18.1 DIELECTRIC VOLTAGE-WITHSTAND	18.2 GROUNDING CONTINUITY
Test voltage = 1200 V AC between primary circuit and accessible dead metal chassis Test time = 1 sec No insulation breakdown	Test current = 30 A passed between earthing contact point and accessible conductive parts No load voltage ≤ 12 V AC or DC Impedance of ground circuit ≤ 100 mΩ

★ **SOLUTION:** HypotULTRA® 7804 or Hypot® III 3705 or HYAMP® III 3130