

# 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

#### YOUR COMPLETE SOLUTION



OMNIA® II 8204  
4-in-1 Instrument



HypotULTRA® 7804  
4-in-1 Instrument

#### 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: <a href="#">HYAMP® 3240</a>	

#### 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: <a href="#">HypotULTRA® 7850</a> or <a href="#">Hypot® 3870</a>	

#### 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: <a href="#">HypotULTRA® 7850</a> or <a href="#">Hypot® 3865</a>	

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

#### YOUR COMPLETE SOLUTION



OMNIA® II 8256/8257  
6-in-1 Instrument

#### 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: <a href="#">LINECHEK® II 620L</a>	

# 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
★ <b>SOLUTION:</b> <a href="#">HypotULTRA® 7800</a> or <a href="#">Hypot® 3880</a>	

### 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.
★ <b>SOLUTION:</b> <a href="#">LINECHEK® II 620L</a>	

### 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
★ <b>SOLUTION:</b> <a href="#">HypotULTRA® 7800</a> or <a href="#">Hypot® 3880</a>	

### 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
★ <b>SOLUTION:</b> <a href="#">HypotULTRA® 7804</a> or <a href="#">HYAMP® 3240</a>	

### 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
★ <b>SOLUTION:</b> <a href="#">HypotULTRA® 7804</a> or <a href="#">HYAMP® 3240</a> AND <a href="#">Hypot® 3805</a>	

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

★ **SOLUTION:** HypotULTRA® 7804 or HYAMP® 3240

### 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® 3870

### 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® 3880

### 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 ≤ 100 mΩ Voltage drop across protective bonding circuit ≤ 2.5 V

★ **SOLUTION:** [HypotULTRA® 7804](#) or [HYAMP® 3240](#)

### 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 ~ 0.25 - 3.5 m A R.M.S Maximum earth leakage current ≤ 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® 3805/3865](#)

### 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® 3805/3865](#)

# 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
<p>Tested in Normal Conditions (NC) and Single Fault Conditions (SFC)</p> <p>NOTE: AR Instruments contain leakage network A.1. Other networks must be manually built into our External MD.</p>	<p>Leakage Current (NC) <math>\leq 0.5</math> mA R.M.S. OR <math>\leq 0.7</math> mA Peak OR <math>\leq 2</math> mA DC</p> <p>Leakage Current (SFC) <math>\leq 3.5</math> mA R.M.S. OR 5 mA Peak OR 15 mA DC</p>

★ **SOLUTION:** [LINECHEK® II 620L](#)

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

REQUIREMENT	PASS CRITERIA
<p>Current = 25 A AC or DC or 2 * highest rated current (whichever is greater) passed through protective earthing circuit</p> <p>Test time = 60 sec</p> <p>Frequency = Rated or DC</p>	<p>Impedance between ground pin and protectively earthed point(s) on the DUT <math>\leq 100</math> m<math>\Omega</math></p> <p>For DUTs with non-detachable supply cord, impedance of the DUT <math>\leq 200</math> m<math>\Omega</math></p>

★ **SOLUTION:** [HypotULTRA® 7804](#) or [HYAMP® 3240](#)

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

REQUIREMENT	PASS CRITERIA
<p>Current of 2 * specified over current protection value passed through protective conductor and chassis points</p> <p>Test time = 60 sec</p>	<p>Voltage drop across circuit <math>\leq 10</math> V AC R.M.S. or DC</p>

★ **SOLUTION:** [HypotULTRA® 7804](#) or [HYAMP® 3240](#)

### 6.8.3.1 The AC Voltage Test (AC Hipot Test)

REQUIREMENT	PASS CRITERIA
<p>Test voltage - Refer to Table 5</p> <p>500 VA Equipment Required</p> <p>Test time = 5 sec ramp up, 60 sec dwell</p>	<p>No flashover or breakdown on product insulation</p>

★ **SOLUTION:** [HypotULTRA® 7800](#) or [Hypot® 3880](#)

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### 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
★ <b>SOLUTION:</b> <a href="#">HypotULTRA® 7850</a> or <a href="#">Hypot® 3865</a>	

### 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
★ <b>SOLUTION:</b> <a href="#">Hypot® 3805</a>	

# IEC 60601-1

## 3rd Edition

### YOUR COMPLETE SOLUTION



**OMNIA® II 8206/8207**  
6-in-1 Instrument

### 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 ±10%) passed through protective earthing circuit. Frequency = 50 or 60 Hz, no load voltage ≤ 6 V	Impedance protective earthing circuit on the DUT ≤ 100 mΩ For DUTs with non-detachable supply cord, impedance for DUT ≤ 200 mΩ
★ <b>SOLUTION:</b> <a href="#">HypotULTRA® 7804</a> or <a href="#">OMNIA® II 8206/8207</a> or <a href="#">HYAMP® 3240</a>	

### 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 µA (NC) or 500 µA (SFC) Patient Leakage Current - Refer to Tables 3 and 4
★ <b>SOLUTION:</b> <a href="#">OMNIA® II 8206/8207</a> or <a href="#">LINECHECK® II 620L</a>	

\*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

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

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

★ **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® 3805/3865/3870**

### 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® 3805/3865/3870**

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® 3805](#)

### 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® 3240](#)

### 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® 3805](#)

## 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® 3805](#) or [HYAMP® 3240](#)