



## **IEC 60601-1 3rd Edition + AM1 Guidelines for MOOP and MOPP**

Prepared by: Ross Sacolles 12/17/2013

Class I: Working Voltage $\leq$ 250 Vrms $\leq$ 354 Vpk	Means of Operator Protection (MOOP) Operator Accessible Part $<240$ VA or Non-Accessible Part	Means of Patient Protection (MOPP) Applied Part - Type B	Means of Patient Protection (MOPP) Applied Parts - Type BF, CF
<b>Primary to Ground</b>	<b>1 MOOP</b>	<b>1 MOPP</b>	<b>1 MOPP</b>
	1 - Y2 Capacitors or 1 - Y1 Clause 8.5.1.3	1 - Y2 or Y1 Capacitor Clause 8.5.1.2	1 - Y2 or Y1 Capacitor Clause 8.5.1.2
	2.5/2.0 mm Creepage/ Clearance Pollution Degree 2, Material Group IIIa or IIIb (Clearance required increases if measured Vpk exceed 420 Vpk)	4/2.5 mm Creepage/Clearance	4/2.5 mm Creepage/Clearance
	1 layer insulation - Basic	1 layer insulation - Basic	1 layer insulation - Basic
	Dielectric = 1500 Vac Note: Test voltage increases if measured Vpk exceed 354 Vpk – See Table 7	Dielectric = 1500 Vac Note: Test voltage increases if measured Vpk exceed 354 Vpk – See Table 6	Dielectric = 1500 Vac Note: Test voltage increases if measured Vpk exceed 354 Vpk – See Table 6
<b>Primary to Plastic Enclosure</b>	<b>2 MOOP</b>	<b>2 MOPP</b>	<b>2 MOPP</b>
	Any thickness needed to comply with enclosure tests.	Any thickness needed to comply with enclosure tests.	Any thickness needed to comply with enclosure tests.
	Dielectric = 3000 Vac (copper foil wrapped around enclosure)	Dielectric = 4000 Vac (copper foil wrapped around enclosure)	Dielectric = 4000 Vac (copper foil wrapped around enclosure)
<b>Primary to Secondary</b>	<b>2 MOOP</b>	<b>2 MOPP</b>	<b>2 MOPP</b>
	2 - Y2 or Y1 Capacitors or 1 - Y1	2 - Y1 Capacitors (No Y2s allowed)	2 - Y1 Capacitors (No Y2s allowed)
	5/4 mm Creepage/Clearance Pollution Degree 2, Material Group IIIa or IIIb (Clearance required increases if measured Vpk exceed 420 Vpk)	8/5 mm Creepage/Clearance (Clause 8.9.4 - Enamel coatings on magnet wires are ignored)	8/5 mm Creepage/Clearance (Clause 8.9.4 - Enamel coatings on magnet wires are ignored)
	Dielectric = 3000 Vac	Dielectric = 4000 Vac  Note: Test voltage increases if measured Vpk exceed 354 Vpk – See Table 6	Dielectric = 4000 Vac  Note: Test voltage increases if measured Vpk exceed 354 Vpk – See Table 6
	1 layer, 0.4 mm thick or 2 layers, with 1 layer passing 3000 Vac dielectric test or 3 layers, with 2 layers passing 3000 Vac dielectric test.	1 layer, 0.4 mm thick or 2 layers, with 1 layer passing 4000 Vac dielectric test or 3 layers, with 2 layers passing 4000 Vac dielectric test.	1 layer, 0.4 mm thick or 2 layers, with 1 layer passing 4000 Vac dielectric test or 3 layers, with 2 layers passing 4000 Vac dielectric test.
<b>Secondary to Ground</b>	<b>Output may be floating (Functional), isolated by MOP (1 MOOP), connected to earth, or protectively earthed.</b>	<b>Output may be floating (Functional), isolated by MOP (1 MOOP), connected to earth, or protectively earthed.</b>	<b>1 MOPP</b>
	Non-approved capacitor okay if used for Functional or 1-Y2 capacitor for 1 MOOP.	Non-approved capacitor okay if used for Functional or 1-Y2 capacitor for 1 MOOP.	1 - Y2 or Y1 Capacitor

Class I: Working Voltage $\leq$ 250 Vrms $\leq$ 354 Vpk	Means of Operator Protection (MOOP) Operator Accessible Part $<240$ VA or Non-Accessible Part	Means of Patient Protection (MOPP) Applied Part - Type B	Means of Patient Protection (MOPP) Applied Parts - Type BF, CF
	Functional Insulation – if output is floating or 1 MOOP for isolated output.	Functional Insulation – if output is floating or 1 MOOP for isolated output.	Working Voltage: Equal to maximum rated mains voltage (240 V)  4/2.5 mm Creepage/Clearance
	Touch Current: (Applies to Operator Accessible Part only)  100 $\mu$ A NC 500 $\mu$ A SFC	Measure Patient Leakage:  Limits per Table 3 & 4	Measure Patient Leakage:  Limits per Table 3 & 4
	Dielectric = No Test	Dielectric = No Test	Dielectric = 1500 Vac

**NOTES:**

1. Interpolation is permitted for creepage requirements per Clause 8.9.1.6 for MOOP and MOPP. Also, refer to Table 14 (MOOP only) for additional clearances for insulation in mains part with peak working voltages exceeding the peak value of the nominal mains voltage.
2. Refer to Table 8 in the IEC standard document for multiplication factors for air clearances for altitudes up to 5000 m for altitudes  $>2000$  m (MOOP), and  $>3000$  m (MOPP).

**NOTE: If 10,000 ft (3048 m) is declared in the Product Specs the multiplication factor for 3000 to 4000 m should be used.**

Class II with FE: Working Voltage $\leq$ 250 Vrms $\leq$ 354 Vpk	Means of Operator Protection (MOOP) Operator Accessible Part $<$ 240 VA or Non-Accessible Part	Means of Patient Protection (MOPP) Applied Part - Type B	Means of Patient Protection (MOPP) Applied Parts - Type BF, CF
<b>Primary to Functional Earth:</b>	<b>2 MOOP</b>	<b>2 MOPP</b>	<b>2 MOPP</b>
	2 - Y2 Capacitors or 1 - Y1	2 - Y1 Capacitor (No Y2s allowed)	2 - Y1 Capacitor (No Y2s allowed)
	5/4 mm Creepage/Clearance Pollution Degree 2, Material Group IIIa or IIIb (Clearance required increases if measured Vpk exceed 420 Vpk)	8/5 mm Creepage/Clearance	8/5 mm Creepage/Clearance
	Dielectric = 3000 Vac	Dielectric = 4000 Vac  Note: Test voltage increases if measured Vpk exceed 354 Vpk – See Table 6	Dielectric = 4000 Vac  Note: Test voltage increases if measured Vpk exceed 354 Vpk – See Table 6
	1 layer, 0.4 mm thick or 2 layers, with 1 layer passing 3000 Vac dielectric test or 3 layers, with 2 layers passing 3000 Vac dielectric test.	1 layer, 0.4 mm thick or 2 layers, with 1 layer passing 4000 Vac dielectric test or 3 layers, with 2 layers passing 4000 Vac dielectric test.	1 layer, 0.4 mm thick or 2 layers, with 1 layer passing 4000 Vac dielectric test or 3 layers, with 2 layers passing 4000 Vac dielectric test.
<b>Primary to Plastic Enclosure:</b>	<b>2 MOOP</b>	<b>2 MOPP</b>	<b>2 MOPP</b>
	Any thickness needed to comply with enclosure tests.	Any thickness needed to comply with enclosure tests.	Any thickness needed to comply with enclosure tests.
	Dielectric = 3000 Vac (copper foil wrapped around enclosure)	Dielectric = 4000 Vac (copper foil wrapped around enclosure)	Dielectric = 4000 Vac (copper foil wrapped around enclosure)
<b>Primary to Secondary:</b>	<b>2 MOOP</b>	<b>2 MOPP</b>	<b>2 MOPP</b>
	2 - Y2 or Y1 Capacitors or 1 - Y1	2 - Y1 Capacitors (No Y2s allowed)	2 - Y1 Capacitors (No Y2s allowed)
	5/4 mm Creepage/Clearance Pollution Degree 2, Material Group IIIa or IIIb (Clearance required increases if measured Vpk exceed 420 Vpk)	8/5 mm Creepage/Clearance (Clause 8.9.4 - Enamel coatings on magnet wires are ignored)	8/5 mm Creepage/Clearance (Clause 8.9.4 - Enamel coatings on magnet wires are ignored)
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	1 layer, 0.4 mm thick or 2 layers, with 1 layer passing 3000 Vac dielectric test or 3 layers, with 2 layers passing 3000 Vac dielectric test.	1 layer, 0.4 mm thick or 2 layers, with 1 layer passing 4000 Vac dielectric test or 3 layers, with 2 layers passing 4000 Vac dielectric test.	1 layer, 0.4 mm thick or 2 layers, with 1 layer passing 4000 Vac dielectric test or 3 layers, with 2 layers passing 4000 Vac dielectric test.
<b>Secondary to Functional Earth:</b>	<b>Output may be floating (Functional), isolated by MOP (1 MOOP), connected to earth, or protectively earthed.</b>	<b>Output may be floating (Functional), isolated by MOP (1 MOOP), connected to earth, or protectively earthed.</b>	<b>1 MOPP</b>

Class II with FE: Working Voltage $\leq$ 250 Vrms $\leq$ 354 Vpk	Means of Operator Protection (MOOP) Operator Accessible Part $<$ 240 VA or Non-Accessible Part	Means of Patient Protection (MOPP) Applied Part - Type B	Means of Patient Protection (MOPP) Applied Parts - Type BF, CF
	Non-approved capacitor okay if used for Functional or 1-Y2 capacitor for 1 MOOP.	Non-approved capacitor okay if used for Functional or 1-Y2 capacitor for 1 MOOP.	1 – Y2 or Y1 Capacitor
	Functional Insulation – if output is floating or 1 MOOP for isolated output.	Functional Insulation – if output is floating or 1 MOOP for isolated output.	Working Voltage: Equal to maximum rated mains voltage (240 V)  4/2.5 mm Creepage/Clearance
	Touch Current: (Applies to Operator Accessible Part only)  100 $\mu$ A NC 500 $\mu$ A SFC	Measure Patient Leakage:  Limits per Table 3 & 4	Measure Patient Leakage:  Limits per Table 3 & 4
	Dielectric = No Test	Dielectric = No Test	Dielectric = 1500 Vac

**NOTES:**

1. Interpolation is permitted for creepage requirements per Clause 8.9.1.6 for MOOP and MOPP. Also, refer to Table 14 in the IEC standard document (MOOP only) for additional clearances for insulation in mains part with peak working voltages exceeding the peak value of the nominal mains voltage.
2. Refer to Table 8 in the IEC standard document for multiplication factors for air clearances for altitudes up to 5000 m for altitudes  $>$ 2000 m (MOOP), and  $>$ 3000 m (MOPP).  
**NOTE: If 10,000 ft (3048 m) is declared in the Product Specs the multiplication factor for 3000 to 4000 m should be used.**

Class II: Working Voltage $\leq$ 250 Vrms $\leq$ 354 Vpk	Means of Operator Protection (MOOP) Operator Accessible Part $<$ 240 VA or Non-Accessible Part	Means of Patient Protection (MOPP) Applied Part - Type B	Means of Patient Protection (MOPP) Applied Parts - Type BF, CF
<b>Primary to Plastic Enclosure</b>	<b>2 MOOP</b>	<b>2 MOPP</b>	<b>2 MOPP</b>
	Any thickness needed to comply with enclosure tests.	Any thickness needed to comply with enclosure tests.	Any thickness needed to comply with enclosure tests.
	Dielectric = 3000 Vac (copper foil wrapped around enclosure)	Dielectric = 4000 Vac (copper foil wrapped around enclosure)	Dielectric = 4000 Vac (copper foil wrapped around enclosure)
<b>Primary to Secondary</b>	<b>2 MOOP</b>	<b>2 MOPP</b>	<b>2 MOPP</b>
	2 - Y2 or Y1 Capacitors or 1 - Y1	2 - Y1 Capacitors (No Y2s allowed)	2 - Y1 Capacitors (No Y2s allowed)
	5/4 mm Creepage/Clearance Pollution Degree 2, Material Group IIIa or IIIb (Clearance required increases if measured Vpk exceed 420 Vpk)	8/5 mm Creepage/Clearance (Clause 8.9.4 - Enamel coatings on magnet wires are ignored)	8/5 mm Creepage/Clearance (Clause 8.9.4 - Enamel coatings on magnet wires are ignored)
	Dielectric = 3000 Vac	Dielectric = 4000 Vac  Note: Test voltage increases if measured Vpk exceed 354 Vpk – See Table 6	Dielectric = 4000 Vac  Note: Test voltage increases if measured Vpk exceed 354 Vpk – See Table 6
	1 layer, 0.4 mm thick or 2 layers, with 1 layer passing 3000 Vac dielectric test or 3 layers, with 2 layers passing 3000 Vac dielectric test.	1 layer, 0.4 mm thick or 2 layers, with 1 layer passing 4000 Vac dielectric test or 3 layers, with 2 layers passing 4000 Vac dielectric test.	1 layer, 0.4 mm thick or 2 layers, with 1 layer passing 4000 Vac dielectric test or 3 layers, with 2 layers passing 4000 Vac dielectric test.
	Touch Current: (Applies to Operator Accessible Part only)  100 $\mu$ A NC 500 $\mu$ A SFC	Measure Patient Leakage:  Limits per Table 3 & 4	Measure Patient Leakage:  Limits per Table 3 & 4

## Questions to Ask End-Product Customer to Determine Requirements and Proper Approval for Power Supply:

### **MOOP requirements:**

1. Is isolation required from Output to Ground?
2. Functional or connected to Ground?
3. Is output operator accessible?
4. If operator accessible, output voltage must be  $\leq 60$  Vdc or  $\leq 42.4$  Vpk and  $< 240$ VA. In addition, leakage current limit from output to neutral/ground must be 100  $\mu$ A NC and 500  $\mu$ A SFC.

### **MOPP requirements:**

1. Is isolation required from Output to Ground?
2. Functional or connected to Ground (Type B), or Floating (Type BF or CF)?
3. Type B may be provided with Functional insulation from output to ground or connected to ground. In addition, requirements for Operator Accessible output (item 4 above) applies if the output is accessible. If the output is not accessible in the end product, compliance with (item 4 above) is not required.
4. Type BF: Power Supply
  - Y1 or Y2 cap must be used from output to ground.
  - 4.0/2.5 mm min creepage/clearance from output to ground.
  - 1500 Vac dielectric strength test required from output to ground.
  - 100  $\mu$ A NC/500  $\mu$ A SFC leakage current limit from output to neutral/ground.
5. Type CF: Power Supply
  - Y1 or Y2 cap must be used from output to ground.
  - 4.0/2.5 mm min creepage/clearance from output to ground.
  - 1500 Vac dielectric strength test required from output to ground.
  - 10  $\mu$ A NC/50  $\mu$ A SFC leakage current limit from output to neutral/ground.
6. Type BF and CF: End Product
  - Patient leakage, 1500 Vac dielectric test, Floating output isolation and Y1 or Y2 type Secondary to Ground capacitors are not required if the output is not accessible in the end product and the Type BF and/or Type CF Applied Parts are isolated from the output and ground with 1-MOPP based on the AC Mains voltage or 2-MOPP based on the Secondary voltage.

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