



## IEC 60601-1 Edition 2(1988) TESTING AND MEASURING EQUIPMENT/ALLOWED SUBCONTRACTING/ALLOWED WITNESSING

R=Required by Lab

S=May be subcontracted

W = May be witnessed in MTL laboratory, equipment not necessary at CBTL

Clause	Measurement/testing	Testing / measuring equipment / material needed	Subcontracting
4	Humidity preconditioning	Humidity cabinet	R
6	Durability of markings	Cloth, distilled water, Isopropyl alcohol and methylated spirit & a suitable timer / stop watch	R
7	Power input	Suitable devices for the voltage, current / power and frequency	R
10	Environmental conditions	Climate chamber controlling temperature and humidity or room with the conditions required	R
	Supply	1 phase and 3 phase variacs	R
15	Limitations voltage / energy	Suitable oscilloscope, recorder / set-up or equivalent suitable device & RCL meter	R
16	Enclosures and protective covers	Pull / push tester, test hook, test finger, test pin	R
		test rods 4 mm / 10 mm (fig. 7-9)	R
17	Defibrillator proof testing	5 kV test circuit & oscilloscope interface circuit according to Figures 50 & 51, oscilloscope	W
18	Earth resistance	Earth resistance tester	R
19	Leakage currents	Variac, mV-meter, diverse circuits (fig. 14-27)	R
		Measuring device (fig. 15), alu-foil, isolation transformers (fig. 10-12)	R
20	Dielectric strength test	High voltage tester, isolating transformer for HV-tests (fig. 28)	R
21	Mechanical strength	Impact hammer, weights	R
		Hard wood plate	R
		Balance	R



Clause	Measurement/testing	Testing / measuring equipment / material needed	Subcontracting
24	Stability tests	Inclinometer or trigonometric calculation (slope up to 10 °)	R
25	Expelled parts	As described per IEC 60065	S
29	X radiation	Radiation meter	W
36	EMC requirements	EMC; measuring equipment as required in IEC 60601-1-2	S
37	Flammable gases	See clauses 39 and 40	S
39	Common requirements AP and APG equipment	Voltmeter; test rods 4 mm, 12 mm Resistance meter according to ISO 471/1853/2878	R
40	Requirements AP equipment	Voltmeter, Amperemeter, RCL meter, temperature meter	R
41	Requirements APG equipment	Same equipment as for clause 40 inclusive special gases	R
42	Heating tests	Voltmeter, ampere meter (AC / DC)	
		Temperature indicator / recorder suitable for this function and thermocouples, test corner	R
		4 wire resistance measuring unit	R
44	Spillage, liquids, sterilisation	Measuring cups	R
		Pipette	R
		Humidity chamber	R
		Different liquids for cleaning	W
		IP appliances	W
		Sterilisation to client specification	W
	Sterilisation with steam	W	
45	Pressure	Pressure gauges	R
51	Hazardous output	Voltmeter; amperemeter; oscilloscope	R
52	Abnormal operation and fault conditions	Apparatus for ball pressure test (fig. 48), oven, suitable timer / stop watch, same equipment as in clause 42	R
53	Environmental tests	Humidity chamber	R
56	Components	Counter; torque tester; weights	R
		IP appliances as per clause 44	W
57	Mains part	Pull tester; different sizes of cables;	R



Clause	Measurement/testing	Testing / measuring equipment / material needed	Subcontracting
		Winding tester for transformers	R
		Micrometer; sliding calliper	R
59	Construction and layout	Ball pressure test apparatus (fig. 48); oven	R
		Micrometer; callipers, force gauge, multimeter	R
		Apparatus for rubber ageing in oxygen	S
Appendix F	Flammable mixtures	See also clause 37 – 40, test apparatus	S

Note: The presence of equipment alone does not indicate a satisfactory situation. Assessors must evaluate the equipment design, calibration, uncertainty and documentation to ensure compliance with the directions of the standard. The requirements of ISO/IEC 17025 regarding validation are applicable, as the tests of this standard are not standardized tests.