IECEE OD-5003-1

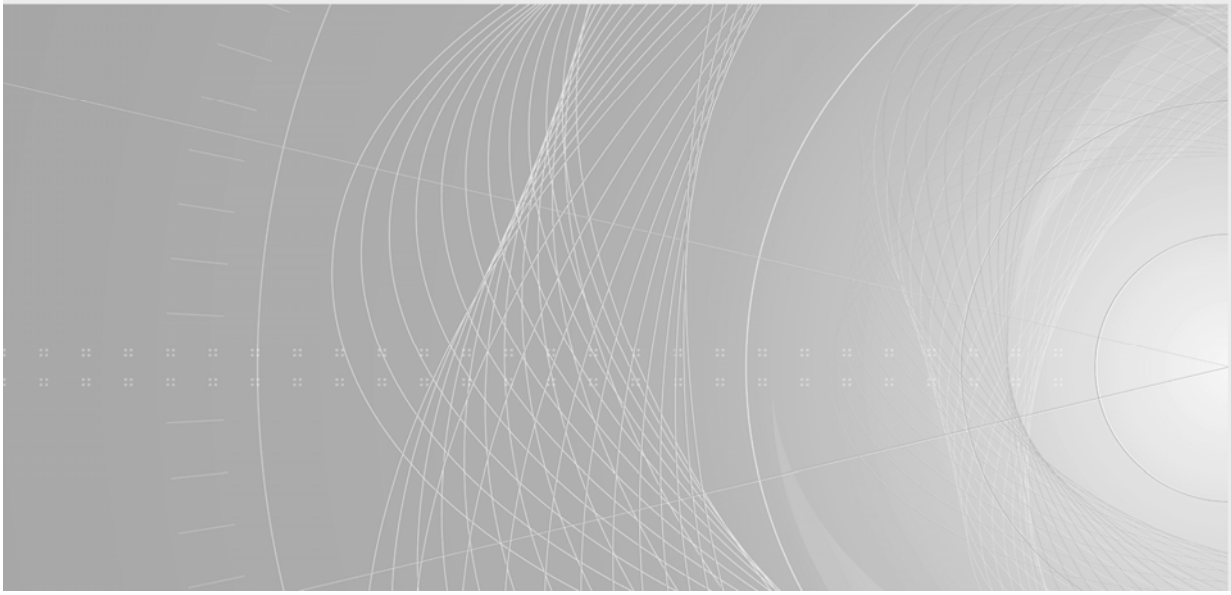
Edition 1.0 2015-06-03

IECEE
OPERATIONAL DOCUMENT

IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE System)

Committee of Testing Laboratories (CTL)

Template (Provisional) Equipment List



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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

PRICE CODE ZZ

TESTING AND MEASURING EQUIPMENT/ALLOWED SUBCONTRACTING
IEC 60601-1:2005
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

"R" Required
"S" May be subcontracted, see OD 2012
"SPTL" Specialized Facility, see IECEE 02-2
"W" Witness testing in the categories "MED" and "MEAS"
"3PPS" Three Phase Power Supply required

Clause	Measurement/testing	Testing / measuring equipment / material needed	Subcontracting
4.11	Power input	Suitable devices for the voltage, current/power and frequency	R
5.3	Ambient temperature, humidity, atmospheric pressure	Suitable devices for recording ambient temperature, humidity, atmospheric pressure	R
5.7	Humidity preconditioning treatment	Environmental conditions: Climate chamber controlling temperature and humidity	R
5.9.2	Accessible parts	Force gauge (30 N), standard test finger (figure 6), straight unjointed test finger, test hook (figure 7)	R
7.1.2	Legibility of markings	Illuminance meter	R
7.1.3	Durability of markings	Distilled water, methylated spirit, isopropyl alcohol *(purity not specified: do we need a CTL decision?)*, timer / stop watch	R
8.4.2	Accessible parts including applied parts	Oscilloscope, oscilloscope leads, suitable instruments for measuring voltage, current, capacitance, test pin (Figure 8), metal test rod (D = 4 mm, L = 100 mm), force gauge (10 N)	R

Clause	Measurement/testing	Testing / measuring equipment / material needed	Subcontracting
8.4.3, 8.4.4	Limitations voltage and energy	Suitable oscilloscope recorder /set-up & RCL meter	R
8.5.5.1	Defibrillation protection	5 kV test circuit & oscilloscope interface circuit according to Figures 9 & 10, oscilloscope	S
8.5.5.2	Energy reduction test	The test circuit according to Figure 11, oscilloscope, oscilloscope leads	S
8.6.4	Impedance and current-carrying capability	Current source (25 A minimum, 50 or 60 Hz, 6 V maximum)	R
8.7	Leakage currents and patient auxiliary currents	Measuring device according to Figure 12, mains isolation transformers, variacs, voltmeter, millivoltmeter, aluminium foil, diverse circuits (fig. 13-20)	R
8.8.3	Dielectric strength	High voltage tester, isolating transformer for HV-tests (fig. 28), stop watch / timer	R
8.8.4.1 a)	Ball pressure test	Test equipment according to IEC 60695-10-2	R
8.8.4.2	Resistance to environmental stress	Apparatus for ageing rubber in oxygen	S
8.9	Creepage distances and air clearances	Oscilloscope, oscilloscope leads, callipers, micrometer, spacing gauges, force gauge (2 N & 30 N), standard test finger (figure 6)	R
8.9.1.7	Material groups classification	Test equipment according to IEC 60112	S
8.9.3.4	Thermal cycling	Heating cabinet	R
8.11.3.5	Cord anchorage	Force gauge (at least 100 N), torque gauge (at least 0.35 Nm)	R
8.11.3.6	Cord guards	Weights, angle gauge, radius gauge	R

Clause	Measurement/testing	Testing / measuring equipment / material needed	Subcontracting
9.4	Instability hazards	5° & 10° inclined planes or inclinometer or trigonometric calculation, force gauge (at least 220 N), 20 cm by 20 cm test surface, weights, test threshold (20 mm high and 80 mm wide), 7 cm strap, stop watch / timer	R
9.5.2	Cathode ray tubes	The relevant tests of IEC 60065, Clause 18.	S
9.6.2.1	Audible acoustic energy	A-weighted sound pressure level according to ISO 3746, ISO 9614-1 or IEC 61672-1	S
9.6.3	Hand-transmitted vibration	Measurements are made in accordance with ISO 5349-1.	S
9.7.5	Pressure vessels	Hydraulic pressure test apparatus	S
9.8	Hazards associated with support systems	Weights or load cell, 0.1 m^2 test surface, stop watch / timer, human body test mass (Figure 33)	R
10.1	X-radiation	Radiation meter	S
10.4	Lasers and light emitting diodes (LEDs)	Test equipment according to IEC 60825-1	S
11.1	Excessive temperatures	Temperature indicator/recorder suitable for this function and thermocouples, 4 wire resistance unit, test corner, variac	R
11.2	Fire prevention	Spark ignition test apparatus (Figure 34), oxygen gas analyzer	S
11.3	Constructional requirements for fire enclosures	FV tests specified in IEC 60695-11-10	S
11.6.2	Overflow	15° inclined plane or inclinometer or trigonometric calculation, stop watch / timer, high voltage tester	R
11.6.3	Spillage	Flask or graduated cylinder, stop watch / timer	R
11.6.5	Ingress of water or particulate matter	Classification tests of IEC 60529	W
11.6.6	Cleaning and disinfection	Dielectric strength and leakage current tests as appropriate	R

Clause	Measurement/testing	Testing / measuring equipment / material needed	Subcontracting
11.6.7	Sterilization	Sterilisation to client specification	S
13	Hazardous situations and fault conditions	stop watch / timer, voltmeter, ammeter, temperature indicator / recorder suitable for this function and thermocouples, 4 wire resistance unit, cheesecloth	R
15.3	Mechanical strength	Force gauge (250 N minimum), circular plane surface 30 mm in diameter, 500 g steel ball, 50 mm thick hardwood board (hardwood > 600 kg/m^3), 40 mm step, hardwood doorframe (40 mm^2), *circulating air oven*	R
15.4.2	Temperature and overload control devices	Positive temperature coefficient devices (PTC's) with IEC 60730-1: 1999, clauses 15, 17, J.15 and J.17	S

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