



# IECEE OPERATIONAL DOCUMENT

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

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**Committee of Testing Laboratories (CTL)**

**Template (Provisional) Equipment List**



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IEC Central Office  
3, rue de Varembe  
CH-1211 Geneva 20  
Switzerland

Tel.: +41 22 919 02 11  
Fax: +41 22 919 03 00  
[info@iec.ch](mailto:info@iec.ch)  
[www.iec.ch](http://www.iec.ch)

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Equipment and Components (IECEE System)**

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# TESTING AND MEASURING EQUIPMENT/ALLOWED SUBCONTRACTING

## IEC 60601-1:2005 + Am.1:2012

### 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 Supply: 1 phase and 3 phase variacs	R
5.3	Ambient temperature, humidity, atmospheric pressure	Suitable devices for recording ambient temperature, humidity, atmospheric pressure	<a href="#">GDJS-015B</a>
5.7	Humidity preconditioning treatment	Environmental conditions: Climate chamber controlling temperature and humidity	
5.9.2	Accessible parts	Force gauge (30 N), standard test finger (figure 6), straight unjointed test finger, test hook (figure 7)	<a href="#">SMT-02T30</a> <a href="#">SMT-S15</a>
7.1.2	Legibility of markings	Illuminance meter	<a href="#">LMS-6000</a>
7.1.3	Durability of markings	Distilled water, ethanol (96% pure), isopropyl alcohol , 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)	<a href="#">WB2675A</a> <a href="#">SMT-1213</a> <a href="#">OSP1102</a>

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	<a href="#">OSP1102</a>
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)	<a href="#">LSP-500VARC</a>
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)	<a href="#">WB2675A</a>
8.8.3	Dielectric strength	High voltage tester, isolating transformer for HV-tests (fig. 28), stop watch / timer	<a href="#">HIPOT10-100KV</a>
8.8.4.1 a)	Ball pressure test	Test equipment according to IEC 60695-10-2	<a href="#">ZBP-T</a>
8.8.4.2	Resistance to environmental stress	Apparatus for ageing rubber in oxygen	<a href="#">HLST-500D</a>
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)	<a href="#">CK-1</a> <a href="#">SMT-02T30</a>
8.9.1.7	Material groups classification	Test equipment according to IEC 60112	S
8.9.3.4	Thermal cycling	Heating cabinet	<a href="#">GDJS-015B</a>
8.11.3.5	Cord anchorage	Force gauge (at least 100 N), torque gauge (at least 0.35 Nm)	<a href="#">SMT-368T4</a>
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 (10 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 <sup>2</sup> test surface, stop watch / timer, human body test mass (Figure 33)	R
10.1	X-radiation	Radiation meter	S
10.3	Microwave radiation	Radiation meter	S
10.4	Lasers	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	<a href="#">HVR-LS</a>
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

Clause	Measurement/testing	Testing / measuring equipment / material needed	Subcontracting
11.6.6	Cleaning and disinfection	Dielectric strength and leakage current tests as appropriate	<a href="#">WB2675A</a>
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 <sup>3</sup> ), 40 mm step, hardwood doorframe (40 mm <sup>2</sup> ), <i>circulating air oven</i>	<a href="#">SMT-B50H</a>
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
15.4.3.4	Primary Lithium batteries	Performance of the tests identified in IEC 60086-4	S
15.4.3.4	Secondary Lithium batteries	Performance of the tests identified in IEC 62133	S
15.4.6	Actuating parts of controls	Force gauge (at least 100 N), torque gauge (at least 6 Nm), stop watch / timer	R
15.4.7	Cord-connected hand-held and foot-operated control devices	Force gauge (minimum 1 350 N), 30 mm diameter test tool, stop watch / timer	R
15.4.7.3	Entry of liquids	Classification tests of IEC 60529	W
15.5.1.1	Transformers	Winding tester for transformers, temperature indicator/recorder suitable for this function and thermocouples variac, loads	R
15.5.2	Dielectric strength	5x voltage / 5x frequency dielectric strength test fixture, stop watch / timer	R
16.6	Leakage currents	As in sub-clause 8.7	R
A 10.4	Light emitting diodes (LEDs)	As specified in IEC 62471	S

Clause	Measurement/testing	Testing / measuring equipment / material needed	Subcontracting
G	Protection against hazards of ignition of flammable anaesthetic mixtures	4 mm & 12 mm diameter test rods, timer / stop watch, gasket test B-b of IEC 60068-2-2, force gauge (minimum 100 N), gas pressure meter (0 to 400 Pa range), voltmeter, ammeter, ohmmeter, meter for capacitance and inductance, ether/oxygen mixture (ether volume percentage 12,2 % $\pm$ 0,4 %), test apparatus for flammable mixtures (Figure G.7),	S
G.4.3	Prevention of electrostatic charges	antistatic material testing according to ISO 2882	S
L	Insulated winding wires for use without interleaved insulation	Sample is preparation according to IEC 60851-5:1996 & dielectric according to 60601-1; flexibility and adherence test 8 of IEC 60851-3:1996; mandrels of diameters according to Table L.1; heat shock test 9 of IEC 60851-6:1996; 2 mm diameter shot of stainless steel, nickel or nickel plated iron.	S



INTERNATIONAL  
ELECTROTECHNICAL  
COMMISSION

3, rue de Varembe  
PO Box 131  
CH-1211 Geneva 20  
Switzerland

Tel: + 41 22 919 02 11  
[info@iec.ch](mailto:info@iec.ch)  
[www.iec.ch](http://www.iec.ch)

IEC SYSTEM OF CONFORMITY ASSESSMENT  
SCHEMES FOR ELECTROTECHNICAL  
EQUIPMENT AND COMPONENTS (IECEE)

IECEE Secretariat c/o IEC  
3, rue de Varembe  
PO Box 131  
CH-1211 Geneva 20  
Switzerland

Tel: + 41 22 919 02 11  
[secretariat@iecee.org](mailto:secretariat@iecee.org)  
[www.iecee.org](http://www.iecee.org)