



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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Equipment and Components (IECEE System)**

Committee of Testing Laboratories (CTL)

Template (Provisional) Equipment List

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

PRICE CODE

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TESTING AND MEASURING EQUIPMENT/ALLOWED SUBCONTRACTING IEC 60601-2-2: 2009

Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

“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
201.8.4.101	Neutral electrode monitoring circuit	Test setup as per Figure 201.103, sound level meter	R
201.8.4.102	Neuromuscular stimulation	Capacitance meter, dc resistance meter	R
201.8.5.1.2	MOPP	Caliper, high voltage tester	R
201.8.5.2.3	Patient leads	Caliper, high voltage tester	R
201.8.7.3.101	Thermal effect of HF leakage current	RF ammeter, 200Ω load and measuring resistors, tape measure, setup according to figures 201.104 – 201.107	R
201.8.8.3.101	Active accessory insulation	0,9% saline solution, caliper, timer	R
201.8.8.3.102	Active accessory HF leakage	0,9% saline solution, caliper, HF voltage source with approx. sinusoidal waveform and f_{test} of 300 to 1000kHz, RF ammeter, HF capacitance meter, tape measure	R
201.8.8.3.103	Active accessory HF dielectric strength	0,9% saline solution, HF voltage source (approx. sinusoidal, frequency 400kHz±100kHz, waveform and crest factor as defined in this clause) , caliper, porous cloth, metal foil, timer	R
201.8.8.3.104	Active accessory mains frequency dielectric strength	AC or DC high voltage tester, ohmmeter, porous cloth, 0.9% saline, caliper, timer	R
201.8.10.4.2	Connection cords	Cord anchorage test apparatus as per Figure 201.108, aperture, weights, tape measure, dc source, ammeter	R
201.8.10.4.101.4	Footswitch	Force gauge (force ≥ 10N) applied over an area of 625 mm ²	R
201.11.6.3	Spillage	Measuring cup (1liter), timer, high voltage tester	R
201.11.6.5	Ingress of water or particulate matter	0,9% saline solution, caliper, timer, impedance analyser or other suitable devices for measuring ac impedance with ≥1kHz and <12V	R

Clause	Measurement/testing	Testing / measuring equipment / material needed	Subcontracting
201.11.8	Interruption of the power supply	Electrosurgical analyser or other suitable devices to measure output power	R
201.12.1.101	Accuracy of output control setting	Electrosurgical analyser or other suitable devices to measure output power, oscilloscope, various load resistances including 10Ω, 100Ω, 200Ω, 500Ω, 1000Ω, 2000Ω, setup as per Figures 201.109 and 201.110	R
201.12.1.102	Monotonicity of output control setting	Electrosurgical analyser or other suitable devices to measure output power, oscilloscope, various resistances including 10Ω, 100Ω, 200Ω, 500Ω, 1000Ω, 2000Ω, setup as per Figures 201.109 and 201.110	R
201.12.1.103	Accuracy of maximum output voltage	Oscilloscope	R
201.12.4.2	Indication of parameters relevant to safety	Electrosurgical analyser or other suitable devices to measure output power	R
201.12.4.2.101	Output indicator	Frequency analyser, sound level meter, tape measure	R
201.12.4.3.101	Output reduction means	Electrosurgical analyser or other suitable devices to measure output power	R
201.12.4.4.101	Maximum allowed output power in single fault condition	Electrosurgical analyser or other suitable devices to measure output power	R
201.12.4.4.102	Output power during simultaneous activation	Electrosurgical analyser, RF ammeter or other suitable devices to measure output power and HF current, test setup as per Figure 201.111	R
201.13.2.13.101	Protection against the effects of short-circuiting of the electrodes	Timer	R
201.15.4.1.102	Retention of detachable active electrodes	Pull tester, timer	R
201.15.101.2	NE cord attachment	DC or mains frequency source with a no-load voltage $\leq 6V$ capable of delivering a current of min. 1A but not more than 5A, ammeter	R
201.15.101.3	NE cord connector, no conductive parts on patient	Test finger as per Figure 6 of general standard	R
201.15.101.4	NE cord insulation	Tests as per 201.8.8.3.102a), 201.8.8.3.103, 201.8.8.3.104	R
201.15.101.5	NE thermal performance	HF voltage source, RF Ammeter, temperature scanning apparatus with an accuracy of better than 0.5°C and a spatial resolution as defined in this clause, caliper, environmental chamber (23±2°C), human subjects or surrogate medium or test device as defined in this clause, timer	W
201.15.101.6	NE contact impedance	HF voltage source, 20cm x 30 cm flat metallic plate, true r.m.s. voltmeter with an input impedance > 2kΩ, accuracy better than 5% over the 200kHz- 5000 kHz range, suitable true r.m.s. a.c. ammeter, HF LCR meter	R
201.15.101.7	NE adhesion	Timer, pull tester, caliper, 0.9% saline solution	R

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**IEC SYSTEM OF CONFORMITY ASSESSMENT
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