



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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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
www.iec.ch

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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: 2006

Part 2-2: Particular requirements for the safety of high frequency surgical equipment

“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
17h)	Defibrillator protection	Setup as per Figure 50 of General Standard, with the exception of the test voltage (2kV)	W
19.3.101	Thermal effects of HF leakage current	RF ammeter, tape measure, setup according to figures 103 ($C_1 \leq 0,005\mu\text{F}$, $C_2=C_3 \leq 0,025\mu\text{F}$, X_{C2} , $X_{C3} \leq 1\Omega$), and figures 104-107 with 200 Ω load and measuring resistors	R
20	Tests for HF surgical accessories	See 59.103 and 59.104.	R
20	Tests for endoscopically used accessories	As per instrument list of IEC 60601-2-18	See Note 1
39.3.101	Common requirements for category AP and APG equipment – Foot switches	Resistance meter	R
44.3	Spillage	Measuring cup (1liter), timer, dielectric strength tester	R
44.6	Ingress of liquids, foot switches and finger switches	0.9% saline solution, caliper, timer, impedance analyser or other suitable devices for measuring ac impedance with $\geq 1\text{kHz}$ and $< 12\text{V}$	R
50.1	Marking of controls and instruments	Electrosurgical analyser or other suitable devices to measure output power, oscilloscope, various resistances including 10 Ω , 100 Ω , 200 Ω , 500 Ω , 1000 Ω , 2000 Ω , setup as per Figures 108 and 109	R
50.2	Accuracy of controls and instruments	Electrosurgical analyser or other suitable devices to measure output power, oscilloscope, various resistances including 10 Ω , 100 Ω , 200 Ω , 500 Ω , 1000 Ω , 2000 Ω , setup as per Figures 108 and 109	R
51.2	Indication of parameters relevant to safety	Electrosurgical analyser or other suitable devices to measure output power	R
51.5	Incorrect output	Electrosurgical analyser or other suitable devices to measure output power	R
51.101	HF surgical equipment switched off and on again or when mains supply interrupted and re-established	Electrosurgical analyser or other suitable devices to measure output power	R

Clause	Measurement/testing	Testing / measuring equipment / material needed	Subcontracting
51.102	HF surgical equipment providing simultaneous activation of more than one patient circuit	Electrosurgical analyser, RF ammeter or other suitable devices to measure output power and HF current, test setup as per Figure 110	R
52.101	Short-circuit of electrodes	Timer	R
56.3	Connections	Caliper, high voltage tester	R
56.101.1	Switch sensors	Voltmeter, resistor $\geq 1k\Omega$, leakage current test equipment and setups as per Clause 19 of general standard	R
56.101.4	Footswitches	Force gauge (force $\geq 10N$), force applied over an area of 625 mm ²	R
56.102	Cord anchorage of active accessories	Cord anchorage test apparatus as per Figure 111, aperture, weights, tape measure, dc source, ammeter	R
56.103.2	Retention of detachable active electrodes	Pull tester, timer	R
59.101	Neutral electrode monitoring circuit	Test setup as per Figure 112, sound level meter	R
59.102	Output indicator	Frequency analyser, sound level meter, tape measure	R
59.103	Active accessory insulation	0.9% saline solution, caliper, timer	R
59.103.5	Insulation applied to cords for active accessories intended for monopolar application	0.9% saline solution or saline-soaked cloth, caliper, HF voltage source with approx. sinusoidal waveform and f_{test} of 300 to 1000kHz, RF ammeter	R
59.103.6	HF dielectric strength	0.9% saline solution, HF voltage source (approx. sinusoidal, frequency 400kHz \pm 100kHz, waveform and crest factor as defined in this clause), caliper, porous cloth, metal foil, timer	R
59.103.7	Mains frequency dielectric strength	AC or DC high voltage tester, ohmmeter, porous cloth, metal foil, 0.9% saline, caliper	R
59.104.2	Neutral electrode cable connection	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
59.104.3	Neutral electrode cord	Test finger as per Figure 7 of general standard	R
59.104.4	Insulation of NE cords	Tests as per 59.104.5, 59.103.6, 59.103.7	R
59.104.5	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 \pm 2°C), human subjects or surrogate medium or test device as defined in this clause, timer	W
59.104.6	Neutral electrode contact impedance	HF voltage source, 20cm x 30 cm flat metallic plate, true r.m.s. voltmeter with an input impedance $> 2k\Omega$, accuracy better than 5% over the 200kHz- 5000 kHz range, suitable true r.m.s. a.c. ammeter, HF LCR meter	R
59.104.7	NE adhesive peel strength	Timer, pull tester, caliper, 0.9% saline solution	R
59.105	Neuromuscular stimulation	Capacitance meter, dc resistance meter	R

Note 1: Refer to the mentioned instrument lists for the "R", "S", "W" or "SP".

**INTERNATIONAL
ELECTROTECHNICAL
COMMISSION**

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

Tel: + 41 22 919 02 11
info@iec.ch
www.iec.ch

**IEC SYSTEM OF CONFORMITY ASSESSMENT
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EQUIPMENT AND COMPONENTS (IECEE)**

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

Tel: + 41 22 919 02 11
secretariat@iecee.org
www.iecee.org