



IEC 60601-1-11 - Edition 1 TESTING AND MEASURING EQUIPMENT/ALLOWED SUBCONTRACTING

R=Required by Lab

S=May be subcontracted

W=Maybe Witnessed in MTL/CTF, equipment not necessary in CBTL

Clause	Measurement/testing	Testing / measuring equipment / material needed	Subcontracting
4.2.1, 4.2.2, 4.2.3	- Environmental conditions of transport and storage between uses - Environmental operating conditions - Environmental shock to TRANSIT-OPERABLE ME EQUIPMENT	Cycling Environmental chamber: Temperature range: – 25 °C to + 70 °C - 25 °C without relative humidity control; and + 70 °C at a relative humidity up to 93 %, non-condensing; With timer capability of least 6 hours.(monitoring and trending) Relative humidity (rh) range : less than or equal to 15 % rh ± 3 % to and greater than or equal to 93 % rh ± 3 % – An atmospheric pressure range of 700 hPa to 1 060 hPa.	R
5	General requirements for testing ME EQUIPMENT/ Accessible parts	Small finger probe 5.6 mm diameter (Figure 1) or as per IEC 61032 figure 13	W R
8.3.1	Ingress of water or particulate matter into ME EQUIPMENT / IP testing	IEC 60529:1989 – Tests apparatus according to IP22 and IP21	W
8.3.2	Ingress of water or particulate matter into ME SYSTEMS / IP Testing	IEC 60529 test equipment	W
10.1.2	Requirements for Mechanical strength for NON-TRANSIT-OPERABLE ME EQUIPMENT / Shock and Vibration	Shock test in accordance with IEC 60068-2-27:2008 – test type 1, 2 Broad-band random vibration test in accordance with IEC 60068-2-64:2008	S
10.1.3	Requirements for Mechanical strength for TRANSIT-OPERABLE ME EQUIPMENT / Shock and Vibration	Shock test in accordance with IEC 60068-2-27:2008 – test type 1, 2 Broad-band random vibration test in accordance with IEC 60068-2-64:2008 Free fall in accordance with IEC 60068-2-31:2008 - PROCEDURE 1	S
12.1	Additional requirements for electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS / Emissions classification	Class B according to CISPR 11:2009.	S
12.5	Additional requirements for ELECTROSTATIC DISCHARGE / ESD tests	ESD testing as per IEC 60601-1-2:2007 (clause 6.2.2.2) and stand test finger (Figure 6)as per IEC 60601-1:2005	S



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13.1	Additional requirement for generation of ALARM SIGNALS / Alarm signal	Sound measurement equipment according requirements of IEC 60601-1-8:2006 clauses 6.3.1 and 6.3.3.2.	S
13.2	Additional requirement for ALARM SIGNAL volume / Alarm volume		

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 Guide 17025 regarding validation are applicable, as the tests of this standard are not standardized tests.