



IEC 60601-2-46 - Edition 1998
TESTING AND MEASURING EQUIPMENT/ALLOWED SUBCONTRACTING

R=Required by Lab

S=May be subcontracted

W = May be witnessed, equipment not necessary in CBTL

Clause	Measurement/testing	Testing / measuring equipment / material needed	Subcontracting
21	Mechanical strength	Means to apply 2.20 X the rated working load (static weight) calibrated weights or calibrated scales to make up suitable test loads.	R
		Calibrated Vernier gauge	R
24	Stability in normal use	Calibrated scales to measure test load weights according to Figure 102, measurement capability > 55kg +/-2%	R
24.3.101	Mobile operating tables	10° Test slope and calibrations means (Incline and clinometer)	R
36.101	Electromagnetic Compatibility	HF Surgical generator with a rated out put of 400W and quasi-squarewave output between 400KHz and 1MHz	W
56c)	Inadvertent operation (foot pedal)	Calibrated force gauge calibrated at 10N	R

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/IEC 17025 regarding validation are applicable, as the tests of this standard are not standardised tests.