



IEC 60601-2-45 Edition (2001)
TESTING AND MEASURING EQUIPMENT/ALLOWED SUBCONTRACTING

R=Required by Lab

S=May be subcontracted

Clause	Measurement/testing	Testing / measuring equipment / material needed	Subcontracting
19	Continuous leakage currents and patient auxiliary currents	- Required using of memory scope with measurement functions - MD device	R
20	Dielectric strength	- High voltage divider	S
21.101.1	Motion of anti-scatter grid	- Adequate Sand-filled bags or soft rubber blocks - Aluminium plate of 2mm thickness - Densitometer (Range 0 to 3,5)	R
21.101.2	Strength of compression plate	- Adequate Sand-filled bags or soft rubber blocks	R
22.102.5	Compression force	- Compression scale - soft rubber block	S
22.103.3	Biopsy needle positioning accuracy	- Test device for mammographic stereotactic devices	S
24	Stability in normal use	- Dynamometer	R
29.1.105	Radiation output	- Adequate ion chamber associated to Electrometer-source/ or adequate Radiation dosimeter.	R
29.201.9	Test for Half-value layer	- Adequate ion chamber associated to Electrometer-source/ or adequate Radiation dosimeter. - Aluminium filters (Purity ³ 99,99%)	R
29.207.1	Primary protective shielding	- Adequate ion chamber associated to Electrometer-source/ or adequate Radiation dosimeter. - Fit shielding of ion chamber	R S
29.208.101	Protective barrier	- Adequate X-ray generator (35kV; percentage ripple \leq4%; Total filtration of 0,03mmMo)	S
50.102.1	Reproducibility of radiation output without AEC activated	- Adequate ion chamber associated to Electrometer-source/ or adequate Radiation dosimeter. (High sensibility)	R
50.102.2	Linearity and constancy	- Same equipment than above	R



Clause	Measurement/testing	Testing / measuring equipment / material needed	Subcontracting
50.103.1	Accuracy and reproducibility of X-ray tube voltage	<ul style="list-style-type: none"> - Required using of memory scope with measurement functions - High voltage dividers or kV meter 	R
50.103.2	Accuracy of X-ray tube current	<ul style="list-style-type: none"> - Required using of memory scope with measurement functions - Set of precision resistors - Differential amplifier 	R
50.103.3	Accuracy of Irradiation time	<ul style="list-style-type: none"> - Required using of memory scope with measurement functions - High voltage dividers or kV meter 	R
50.103.4	Accuracy of Current time product	<ul style="list-style-type: none"> - Required using of memory scope with measurement functions - High voltage dividers or kV meter - Set of precision resistors - Differential amplifier 	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 Guide 25 regarding validation are applicable, as the tests of this standard are not standardised tests.