



# **IECEE OPERATIONAL DOCUMENT**

**IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE System)**

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**Committee of Testing Laboratories (CTL)**

**Template (Provisional) Equipment List**





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Equipment and Components (IECEE System)**

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**Template (Provisional) Equipment List**

INTERNATIONAL  
ELECTROTECHNICAL  
COMMISSION

PRICE CODE

**ZZ**

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## TESTING AND MEASURING EQUIPMENT/ALLOWED SUBCONTRACTING IEC 60601-2-45:2011

### Part 2-45: Particular requirements for basic safety and essential performance of mammographic X-ray equipment and mammomagraphic stereotactic devices

“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
203.6.7.102 203.8.5.4.102.5.	Motion of anti-scatter grid	- Adequate Sand-filled bags or soft rubber blocks - Aluminium plate of 2mm thickness - Densitometer (Range 0 to 3,5)	W
201.8.8.3	Dielectric strength	- Required using of memory scope with measurement functions - High voltage dividers or kV meter	W
201.9.2.3.1	Unintended movement	- Force gauge	R
203.6.7.103.2	ARTEFACTS from grid lines	- PHANTOM of 20 mm PMMA - aluminium plate of 2 mm thickness with sufficient dimensions - densitometer	W
203.6.7.104.2	Maximum LOADING TIME	- 40 mm thick rectangular Polymethylmethacrylate (PMMA) PHANTOM with sides equal to or exceeding 150 mm.	W
203.8.5.4.102.6	Compression force	- Compression scale - soft rubber block 20 mm to 50 mm thick, and 100 mm to 120 mm long and wide	W
201.9.2.101.3	Biopsy needle positioning accuracy	- Test device for mammographic stereotactic devices	S
	Stability in normal use	- Dynamometer	
	Radiation output	- Adequate ion chamber associated to Electrometer-source/ or adequate Radiation dosimeter.	
203.10.1 203.7.6	Test for Half-value layer	- Adequate ion chamber associated to Electrometer-source/ or adequate Radiation dosimeter. - Aluminium filters (Purity $\geq 99,99\%$ )	W

Clause	Measurement/testing	Testing / measuring equipment / material needed	Subcontracting
203.11.101	Primary protective shielding	- Adequate ion chamber associated to Electrometer-source/ or adequate Radiation dosimeter. - Fit shielding of ion chamber	W
203.13.101	Protective barrier	- Adequate X-ray generator (35kV; percentage ripple $\leq 4\%$ ; Total filtration of 0,03mmMo)	W
	Reproducibility of radiation output without AEC activated	- Adequate ion chamber associated to Electrometer-source/ or adequate Radiation dosimeter. ( High sensibility)	
	Linearity and constancy	- Same equipment than above	
203.6.4.3.102.2	Accuracy and reproducibility of X-ray tube voltage	- Required using of memory scope with measurement functions - High voltage dividers or kV meter	W
203.6.4.3.102.3	Accuracy of X-ray tube current	- Required using of memory scope with measurement functions - Set of precision resistors - Differential amplifier	W
203.6.5.2	AEC requirements	- Appropriate phantom	W
	Accuracy of Irradiation time	- Required using of memory scope with measurement functions - High voltage dividers or kV meter	
	Accuracy of Current time product	- Required using of memory scope with measurement functions - High voltage dividers or kV meter - Set of precision resistors - Differential amplifier	

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