उत्पाद मैन्युअल
आई एस 7620 (भाग 2) : 1986 के अनुसार
नैदानिक चिकित्सा एक्स-रे उपकरणों के लिए विशिष्टि भाग 2 प्रदर्शन आवश्यकताएँ के लिए
दस्तावेज़ संख्या – पीएम/आईएस 7620 (भाग 2) /1/ मई 2022

भारतीय मानक ब्यूरो की स्कीम-I (अनुरूपता मूलयांकन) विनियम, 2018 के तहत यह उत्पाद मैन्युअल प्रमाणीकरण के प्रचालन में रीति और पारिर्शिता की सुसंगतता सुनिश्चित करने के लिए सभी क्षेत्रीय/शाखा कार्यालयों और लाइसेंसी द्वारा संदर्भ सामग्री के रूप में उपयोग किया जाएगा। बीआईएस प्रमाणीकरण लाइसेंस/ प्रमाणपत्र प्राप्त करने के इच्छुक भावी आवेदकों द्वारा भी इस दस्तावेज़ का उपयोग किया जा सकता है ।

PRODUCT MANUAL FOR
SPECIFICATION FOR DIAGNOSTIC MEDICAL X-RAY EQUIPMENT:
PART 2 PERFORMANCE REQUIREMENTS
ACCORDING TO IS 7620 (Part 2) : 1986
Document No - PM/IS 7620 (Part 2)/1/May 2022

This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure coherence of practice and transparency in operation of certification under Scheme-I of Bureau of Indian Standards (Conformity Assessment) Regulations, 2018 for various products. The document may also be used by prospective applicants desirous of obtaining BIS certification licence/certificate.

भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS
मानक भवन, ९, बहादुर शाह ज़फ़र मार्ग
Manak Bhawan, 9, Bahadur Shah Zafar Marg
नई दिल्ली- ११०००२
New Delhi – 110002

PRODUCT MANUAL FOR
MEDICAL ELECTRICAL EQUIPMENT- DIAGNOSTIC X-RAY MACHINE
PART 2- PERFORMANCE REQUIREMENTS
ACCORDING TO IS 7620 (Part 2): 1986

This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure coherence of practice and transparency in operation of certification under Scheme-I of Bureau of Indian Standards (Conformity Assessment) Regulations, 2018 for various products. The document may also be used by prospective applicants desirous of obtaining BIS certification license/certificate.

1.	**Product**	:	IS 7620 (Part 2): 1986
	Title	:	Medical Electrical Equipment- Diagnostic X-Ray Machine - Performance Requirements
	No. of Amendments	:	0
2.	**Sampling Guidelines:**		
a)	**Raw material**	:	As per cl. 3 of IS 7620 (Part 2)
b)	**Grouping guidelines**	:	Sample of each variety and type to be tested
c)	**Sample Size**	:	One piece
3.	**List of Test Equipment**	:	Please refer ANNEX – A.
4.	**Scheme of Inspection and Testing**	:	Please refer ANNEX – B.
5.	**Possible tests in a day**	:	As the licence is operated on Factory Testing basis, complete testing of a sample shall be done in factory. **(two mandays are required for complete testing of product as per IS 7620 (Part 2) : 1986 and three mandays are required for complete testing of product as per IS 7620 (Part 1) : 1986)**

6.	**Scope of the Licence :**
	Licence is granted to use Standard Mark as per IS 7620 (Part 2): 1986 with the following scope: "Stationary/Mobile Medical electrical equipment- Diagnostic X-ray machine _____ type, _____frequency generator, for rated line voltage___V, frequency _____ Hz,_____phase, current_____A, Rated Peak Output Voltage_____kVp, output power _____W, Class of Timer___" *Other relevant aspects may also be mentioned in the scope.*

NOTE 1 - IS 7620 (Part 1) : 1986 covers the General and Safety requirement of the product 'Diagnostic X-ray machine', whereas the IS 7620 (Part 2) : 1986 covers the performance requirement of the product. Further, the IS 7620 (Part 1) : 1986 is mandatory under the AERB's QCO dated October 1994.

NOTE 2 - Grant of licence as per IS 7620 (Part 2) : 1986 to be considered only when the applicant is already having an operative licence as per IS 7620 (Part 1) : 1986 or has applied for grant of licence as per IS 7620 (Part 1) : 1986 as well. In such a scenario, the compliance to both the Indian Standards IS 7620 (Part1): 1986 and IS 7620 (Part 2) : 1986 to be established for considering grant of licence.

NOTE 3 – Licence as per IS 7620 (Part 2) : 1986 to be granted only when compliance to the requirements of both IS 7620 (Part 1) : 1986 and IS 7620 (Part 2) : 1986 is established.

ANNEX A

List of Test Equipment

Major test equipment required to test as per the Indian Standard

Sr. No.	Test Equipment	Tests used in with Clause Reference
1	Vernier caliper/ Micrometer	Sheet metal thickness Cl. 3.1.4
2	Measuring Tape	Height of table top Cl. 3.8.1
		Table sag Cl. 3.8.5
		Dimension of screen frame Cl. 3.8.7
		Maximum and minimum travel Cl.3.8.9, 3.9.1, 3.9.2, 3.9.3
3	Force meter	Maximum drag force Cl. 3.8.8, Cl. 3.9.4
4	Temperature indicator with thermocouples	Temperature rise test – Cl. 3.4
5	Ray safe X2 QA kit	Filtration at table top Cl.3.8.4
		Test for Accuracy of Indications-*Peak Kilovolts* Cl. 6.2.1
		Test for Accuracy of Indications-*Milliamperes* Cl. 6.2.2
		Test for Stabilization With Internal temperature changes Cl. 6.3
		Milliampere Stabilization Test Cl. 6.5
6	Digital Timer/Digital Stopwatch	Timer Test for X-ray Control Cl. 6.6
7	Digital Oscilloscope	Timer Test for X-ray Control Cl. 6.6
8	Automatic Test Device	Recycling Time Test Cl. 6.4
9	Digital Multimeter	Voltage and current test Cl. 6.7
10	Digital Clamp Meter	Voltage and current test Cl. 6.7
11	Step Wedge	Installation Tests- *Step Wedge Tests* Cl. 6.9.1
12	Spinning Top	Installation Tests- *Step -Spinning Top Test* Cl. 6.9.2
13	Grid Pattern Test	Grid Pattern Test Cl. 6.10
14	Grid Clean up test Water Phantom	Grid Clean up Test Cl. 6.11
15	Potter-Bucky Motion test setup	Potter-Bucky Motion and Synchronism Test Cl. 6.12
16	Rody section Devices test setup	Rody section Devices test Cl. 6.13.1
17	Spring Balance	Test on X-ray Table Cl. 6.14, Cl. 3.8.8 Test on Tube Stand Cl. 6.15, Cl. 3.9.4
18	Measuring weights	Table sag Cl. 3.8.5

The above list is indicative only and may not be treated as exhaustive.

ANNEX B

Scheme of Inspection and Testing

1. LABORATORY - A laboratory shall be maintained which shall be suitably equipped (as per the requirement given in column 2 of Table 1) and staffed, where different tests given in the specification shall be carried out in accordance with the methods given in the specification.

1.1 The manufacturer shall prepare a calibration plan for the test equipment.

2. TEST RECORDS – The manufacturer shall maintain test records for the tests carried out to establish conformity.

3. LABELLING AND MARKING – As per the requirements of IS 7620 (Part 2): 1986.

4. CONTROL UNIT – All X-ray machines, tables, tubes stand of the same type, design and rating manufactured in a month shall constitute a control unit.

5. LEVELS OF CONTROL - The tests as indicated in column 1 of Table 1 and the levels of control in column 3 of Table 1, shall be carried out on the whole production of the factory which is covered by this plan and appropriate records maintained in accordance with paragraph 2 above.

6. REJECTIONS – Disposal of non-conforming product shall be done in such a way so as to ensure that there is no violation of provisions of BIS Act, 2016.

TABLE 1

(1)				(2)	(3)	
Test Details				**Test equipment requirement R: required (or) S: Sub- contracting permitted**	**Levels of Control**	
Cl.	**Requirement**	**Test Methods**			**No. of Sample**	**Frequency**
		Clause	**Ref**			
3	General requirements	3, 6.1	IS 7620 (Part 2)	R	Each machine*	
4	Marking	4		R	Each machine	
6.2	Accuracy of indications	6.2.1		R	One	Each control unit
		6.2.2		R		
6.3	Test for Stabilization	6.3		R	Each machine	
6.4	Recycling time test	6.4				
6.5	Milliampere Stabilization	6.5				
6.6	Timer set for X-Ray control	6.6.1 to 6.6.5				
6.7	Stator voltage and current test	6.7				
6.8	Interlock Tests	6.8				
6.9	Installation Tests	6.9.1 to 6.9.2				
6.10	Grid Pattern Test	6.10.1 to 6.10.5		S**	One	Once in six months of the same type, design and rating
6.11	Grid Clean up Test	6.11.0 to 6.11.5				
6.12	Potter-Bucky Motion and synchronism Test	6.12.0 to 6.12.10		R	One	Once in six months of the same type, design and rating
6.13	Rody section Devices	6.13.1 to 6.13.6				
6.14	Test on X-Ray Table	6.14			Each machine	
6.15	Test on Tube Stand	6.15				

The test records as mentioned in Scheme of Inspection and Testing of PM/ IS 7620 (Part 1)/ 2/July 2020 for IS 7620 (Part 1) also needs to be maintained in addition to that specified above.

* The components and parts of X-Ray equipment under mandatory certification shall be marked with BIS Standard Mark. Other components/ parts shall be either marked with BIS Standard Mark or a test certificate shall be obtained from the supplier of components or parts, as applicable.

**Manufacturer's TC may be accepted.

Note: Levels of control given in column 3 are obligatory in nature, to which the licensee shall comply with.