उत्पाद मैन्युअल

आई एस 13450 (भाग 2 / अनुभाग 44) 2016 / आईईसी 60601-2-44 : 2009 के अनुसार चिकित्सीय विद्युत् उपस्कर भाग 2 बुनियादी सुरक्षा और आवश्यक कार्य निष्पादन के लिए विशेष आवश्यकताएं अनुभाग 44 कंप्यूटिड टोमोग्राफी के लिए एक्स - रे उपकरण (पहला पुनरीक्षण) के लिए

दस्तावेज़ संख्या – पीएम/आईएस 13450(भाग 2 / अनुभाग 44) /1/अक्टूबर 2022

भारतीय मानक ब्यूरो की स्कीम-I (अनुरूपता मूलयांकन) विनियम, 2018 के तहत यह उत्पाद मैन्युअल प्रमाणीकरण के प्रचालन में रीति और पारिशिता 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

MEDICAL ELECTRICAL EQUIPMENT PART 2 PARTICULAR REQUIREMENTS FOR THE BASIC SAFETY AND ESSENTIAL PERFORMANCE SECTION 44 X-RAY EQUIPMENT FOR COMPUTED TOMOGRAPHY (FIRST REVISION)

ACCORDING TO IS 13450 (Part 2 / Sec 44): 2016 / IEC 60601-2-44 : 2009

Document No - PM/IS 13450 (Part 2/ Sec 44)/1/October 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
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New Delhi – 110002

PRODUCT MANUAL FOR

MEDICAL ELECTRICAL EQUIPMENT -PARTICULAR REQUIREMENTSFOR THE BASIC SAFETY AND ESSENTIAL PERFORMANCE- X-RAY EQUIPMENT FOR COMPUTED TOMOGRAPHY

ACCORDING TO IS 13450 (PART 2/SECTION 44) : 2016

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 ofobtaining BIS certification license/certificate.

1.	**Product**	:	IS 13450 (Part 2/ Sec 44): 2016
	Title	:	Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 44 - X-RAY EQUIPMENT FOR COMPUTED TOMOGRAPHY
	No. of Amendment	:	1
2.	**Sampling Guidelines:**		
a)	**Raw material**	:	Nil
b)	**Grouping guidelines**	:	Nil
c)	**Sample Size**	:	1 Nos
d)	**Surveillance Plan**		The licence is to be operated on Factory Testing basis. During surveillance inspection, complete factory testing is to be done. Time allocated for surveillance is two days. Second surveillance inspection may be planned based on risk based surveillance approach.
3.	**List of Test Equipment**	:	Please refer ANNEX –A
4.	**Scheme of Inspection and Testing**	:	Please refer ANNEX –B
5.	**Possible tests during surveillance**	:	All tests.
6.	**Scope of the licence**	:	As per below:

"Licence is granted to use Standard Mark as per IS 13450 (Part 2/Sec 44):2016 with the following scope:	
Name of the product:	Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 44 - X-RAY EQUIPMENT FOR COMPUTED TOMOGRAPHY
Model:	
Type:	Terrence, Computed Tomography (CT)) Scanner System along with patient table, Fixed/ portable type, __ slice, ____ kV, ___A, __ kW.
Protection against electric shock:	Class I/Internally Powered ME Equipment
Mode of Operation	Continuous/ Non-continuous Operation

ANNEX A

List of Test Equipment & Document

Major test equipment required to test as per the Indian Standard

Sl. No.	Tests used in with Clause Reference	Test Equipment
1.	General requirements, 201.4,4.11 201.4.5	Risk management File, Clamp meter
2.	ME Equipment Identification, marking and documents,201.7	Angle Protractor, Steel tape, Illumination source (100lx to 1500 lx), Isopropyl alcohol
3.	Protection against electrical hazards from ME Equipment, 201.8	Functional test, Risk Management File
4.	Limitation of voltage, current or energy,8.4	Electrical Safety Analyzer
5.	Limitation of high voltage to the nominal X-ray tube voltage, 8.4.101	Electrical Safety Analyzer
6.	Detachable high-voltage cable connections, 8.4.102	Screwdriver sets
7.	Unacceptably high voltage in the main part, 8.4.103	Risk management file
8.	Leakage currents and patient auxiliary currents, 8.7	Electrical Safety Analyzer
9.	Allowable values, 8.7.3	Electrical Safety Analyzer
10.	Creepage Distance & Air Clearance for CT scanners, 8.9, 8.9.1.101	Measuring tape, Feeler gauge, micrometer
11.	Protection against Mechanical Hazards of ME Equipment and ME Systems, 201.9	Risk management File
12.	Trapping Zone (Gaps, safe distances, Guards, other risk control measures, continuous activation) 9.2.2.2 to 9.2.2.6	Risk management File
13.	Other mechanical hazards associated with moving parts, 9.2.3.1, 9.2.3.2	Visual Inspection
14.	Emergency stopping devices, 9.2.4	Visual Inspection, Risk Management File
15.	Mechanical hazards associated with surfaces, corners and edges, 9.3	Visual Inspection, Risk Management File
16.	Instability Hazards, 9.4, 9.4.2 to 9.4.4	Visual Inspection, Risk Management File
17.	Expelled Parts Hazards, 9.5	Visual Inspection, Risk Management File
18.	Protective means, 9.5.1	Visual Inspection, Risk Management File
19.	Acoustic energy (including infra- and ultrasound),9.6	Sound level meter, Visual Inspection, Risk Management File
20.	Mechanical hazards associated with support system, 9.8.1, 9.8.2, 9.8.3.2	Visual Inspection
21.	Protection against unwanted and excessive radiation hazards, 201.10	Risk Management File

22.	ME equipment not intended to produce diagnostic or therapeutic X-radiation, 10.1.1	Risk Management File
23.	ME equipment intended to produce diagnostic or therapeutic X-radiation,10.2	Risk Management File
24.	Alpha, Beta, Gamma, Neutron and other particle radiation, 10.2	Risk Management File
25.	Lasers, 10.4	Risk Management File
26.	Other visible electromagnetic radiation, 10.5	Risk Management file
27.	Protection against excessive temperatures and other hazards, 201.11, Excessive temperatures in ME Equipment, 11.1	Data logger
28.	Fire prevention, 11.2	Risk Management file, Visual Inspection, Spark Ignition test apparatus as per Cl. 11.2.2.1
29.	Constructional requirements for fire enclosures, 11.3	Visual Inspection, Risk management File
30.	ME equipment and ME systems intended for use with flammable anesthetics, 11.4	Risk management File and accompanying documents
31.	Overflow in ME equipment, 11.6.2	Risk management File, Visual inspection, HV Tester
32.	Spillage on ME equipment and ME systems, 11.6.3	Risk management File, Visual inspection, HV Tester
33.	Leakage, 11.6.4	Risk management File
34.	Ingress of water and particulate matter, 11.6.5	Risk management File and accompanying documents
35.	Cleaning and disinfection, 11.6.6	Risk management File and accompanying documents
36.	Compatibility with substances used with ME equipment, 11.6.8	Risk management File
37.	Interruption of power supply/supply mains, 11.8	Multi meter, Risk management
38.	Accuracy of controls and instruments and protection against hazardous outputs,201.12, Accuracy of controls & Instruments, 12.1	Risk management File and accompanying documents
39.	Usability, 12.2	Risk management File and accompanying documents
40.	Alarm Systems, 12.3	Risk management File and accompanying documents
41.	Protection against hazardous output, 12.4	Risk management
42.	Hazardous Situations and Fault Conditions, 201.13	Risk management File and accompanying documents
43.	Specific hazardous situation,13.1	Risk management File, Design Document
44.	Single Fault conditions, 13.2	Electrical Safety Analyzer
45.	Electrical single fault condition, 13.2.2	Electrical Safety Analyzer

46.	Overheating of transformers, 15.5.1	Test setup as per Cl. 15.1 of IS 13450 (Part 1), HV tester, thermometer/ thermocouple
47.	Failure of Thermostats, 13.2.13, 15.4.2	Risk management File and accompanying documents
48.	Failure of temperature limiting devices, 13.2.13, 15.4.2	Risk management File and accompanying documents
49.	Leakage of liquid, 13.2.6	Risk management File
50.	Impairment of cooling that could result in a hazardous situation, 13.2.7	Risk management File and accompanying documents
51.	Locking of moving parts, 13.2.8	Risk management File and accompanying documents
52.	Interruption and short circuiting of motor capacitors, 13.2.9	Electrical Safety Analyzer
53.	Additional test criteria for motor operated ME Equipment, 13.2.10	Risk management File and accompanying documents
54.	Failure of parts that might result in a Mechanical hazard, 15.3	Visible Inspection
55.	ME equipment's with motors, 13.2.13.2	Risk management File and accompanying documents
56.	Programmable Electrical Medical Systems (PEMS), 14	Risk management File and accompanying documents
57.	ME equipment's with motors, Construction of ME Equipment,15	Visible Inspection, Test setup as per Cl. 15.3 of IS 13450 (Part 1)
58.	Arrangements of controls and indicators, 15.1	Visible Inspection
59.	Serviceability, 15.2	Visible Inspection
60.	Mechanical Strength, 15.3	Visible Inspection, Test setup as per Cl. 15.3 of IS 13450 (Part 1)
61.	Components and general assembly, 15.4	Visible Inspection
62.	Transformers in ME Equipment, 15.5	Visible Inspection
63.	ME Systems, 16	Risk management File and accompanying documents
64.	Electromagnetic compatibility, 17	Risk management File
65.	Electromagnetic Compatibility – Requirements & Tests,202	Risk management File
66.	Immunity testing of Essential performance, 202.101	Risk management File
67.	General requirements for Radiation protection in Diagnostic X-RAY Equipment, 203	Risk management File and accompanying documents
68.	Radiation Quality, 203.7	Risk management File and accompanying documents
69.	Limitation of the Extant of the X-RAY beam & Relationship between x-ray field and image reception area, 203.8	Risk management File, accompanying documents, measuring tape
70.	Focal spot to Skin Distance, 203.9	Measuring tape
71.	Protection against residual radiation, 203.11	Risk management File and accompanying documents

72.	Protection against leakage radiation, 203.12	Visual Inspection, Risk management File and accompanying documents
73.	Protection against Stray Radiation, 203.13	Visual Inspection, Risk management File and accompanying documents
74.	Emergency termination of X-Radiation, 203.101	Visual Inspection, Risk management File and accompanying documents
75.	Visual Indication, 203.102	Risk management File and accompanying documents
76.	Indication of operational ready state, 203.103	Visual Inspection
77.	Connection of External interlocks, 203.104	Visual Inspection
78.	Charging mode Interlock, 203.105	Visual Inspection, Risk management File and accompanying documents
79.	Control of Radiation Output, 203.106	Risk management File and accompanying documents
80.	Safety measures against excessive X-Radiation, 203.107	Risk management File and accompanying documents
81.	Dosimetry PHANTOM 203.108	Ray Safe Instrument
82.	Dose Statements 203.109	Ray Safe Instrument
83.	Dose Profile Statement 203.110	Ray Safe Instrument
84.	Sensitivity Profile statement 203.111	Risk management File and accompanying documents
85.	Display & Recording of CTDIvol & DLP 203.112	Ray Safe Instrument
86.	Geometric Efficiency in the Z-Direction 203.113	Visual Inspection
87.	Post Exposure display of changed CT conditions of operations,203.114	Visual Inspection, Risk management File and accompanying documents
88.	Indication and position of the TOMOGRAPHY Section 203.115	Measuring Tape, Scale

Note: Firm has to maintain a Risk Management File for each model in the scope of licence. The Risk Management File is to be submitted to BIS and will be verified at the time of surveillance.

ANNEX B

Scheme of Inspection and Testing

1. LABORATORY - A laboratory shall be maintained which shall be suitably equipped and staffed, where different tests given in the specification shall becarried 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 requirement of IS 13450(Part 2/Sec 44):2016

4. CONTROL UNIT – Each CT Scan machines shall constitute a control unit.

5. LEVELS OF CONTROL - The tests as indicated in column 1 of Table 1 and the levels ofcontrol 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 paragraph2

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 Method			No. of Sample	Frequency	Remarks
		Clause	Reference				
201.4 General requirements							
4	Risk management process for ME equipment or ME systems	201.4, 201.4.5	IS 13450 (Part 2/Sec 44)	R	Each machine		
5.9	Determination of Applied parts and accessible Parts	5.9.1 to 5.9.2.3	IS 13450 (Part 1)	R	Each machine		
201.7 ME Equipment identification, marking and documents							
7	ME Equipment Identification, marking and documents	201.7	IS 13450 (Part 2/Sec 44)	R	Each machine		
201.8 Protection against electrical hazards from ME Equipment							
8.1	Protection against electrical hazards	8.1	IS 13450 (Part 1)	R	Each machine		
8.4	Limitation of voltage, current or energy	8.4	IS 13450 (Part 1)	R	Each machine		
8.4.101	Limitation of high voltage to the nominal X-ray tube voltage.	201.8.4.101	IS 13450 (Part 2/Sec 44)	R	Each machine		
8.4.102	Detachable high-voltage cable connections	201.8.4.102	IS 13450 (Part 2/Sec 44)	R	Each machine		

8.4.103	Unacceptably high voltage in the main part	201.8.4.103	IS 13450 (Part 2/Sec 44)	R	Each machine		
8.5	Separation of parts	8.5.1 to 8.5.5.2	IS 13450 (Part 1)	R	Each machine		
8.7	Leakage currents and patient auxiliary currents	8.7	IS 13450 (Part 1)	R	Each machine		
8.7.3	Allowable values	8.7.3	IS 13450 (Part 1)	R	Each machine		
8.8	Insulation	8.8.1 to 8.8.4.1 201.8.8.	IS 13450 (Part 1) IS 13450 (Part 2/Sec 44)	R	Each machine		
8.9, 8.9.1.101	Creepage Distance & Air Clearance for CT scanners	201.8.9, 201.8.9.1.101	IS 13450 (Part 2/Sec 44)	R	Each machine		
8.11	MAINS PARTS, components and layout	8.11.1 to 8.11.6	IS 13450 (Part 1)	R	Each machine		
201.9 Protection against Mechanical Hazards of ME Equipment and ME Systems							
9.2.2	Trapping Zone (Gaps, safe distances, Guards, other risk control measures, continuous activation)	9.2.2.2 to 9.2.2.6	IS 13450 (Part 1)	R	One of each model	05 Years	Refer note 1
9.2.3	Other mechanical hazards associated with moving parts	9.2.3.1, 9.2.3.2					
9.2.4	Emergency stopping devices	9.2.4					
9.3	Mechanical hazards associated with surfaces, corners and edges	9.3					
9.4	Instability Hazards	9.4.2 to 9.4.4					
9.5 Expelled Parts Hazards							
9.5.1	Protective means	9.5.1	IS 13450 (Part 1)	R	One of each model	05 Years	Refer note 1

9.6 Acoustic energy (including infra- and ultrasound)							
9.6.2.1	Audible acoustic energy	9.6.2.1	IS 13450 (Part 1)	R	One of each model	05 Years	Refer note 1
9.7	Pressure vessels and parts subject to pneumatic and hydraulic	9.7.1 to 9.7.7	IS 13450 (Part 1)	R	One of each model	05 Years	Refer note 1
9.8	Mechanical hazards associated with support system	9.8.1, 9.8.2, 9.8.3.2	IS 13450 (Part 1)	R	One of each model	05 Years	Refer note 1
201.10 Protection against unwanted and excessive radiation hazards							
10.1.1	ME equipment not intended to produce diagnostic or therapeutic X-radiation	10.1.1	IS 13450 (Part 1)	R	One of each model	01 year	Refer note 1
10.1.2	ME equipment intended to produce diagnostic or therapeutic X-radiation	10.1.2	IS 13450 (Part 1)	R	One of each model	01 year	Refer note 1
10.2	Alpha, Beta, Gamma, Neutron and other particle radiation	10.2	IS 13450 (Part 1)	R	One of each model	01 year	Refer note 1
10.4	Lasers	10.4	IS 13450 (Part 1)	R	One of each model	01 year	Refer note 1
10.5	Other visible electromagnetic radiation	10.5	IS 13450 (Part 1)	R	One of each model	01 year	Refer note 1

201.11 Protection against excessive temperatures and other hazards							
11.1	Excessive temperatures in ME Equipment	11.1	IS 13450 (Part 1)	R	One of each model	05 years	Refer note 1
11.2	Fire prevention	11.2.1, 11.2.2, 11.2.3	IS 13450 (Part 1)	R	One of each model	05 years	Refer note 1
11.3	Constructional requirements for fire enclosures	-	IS/ IEC 60695-11-10	R	One of each model	05 years	Refer note 1
11.4	ME equipment and ME systems intended for use with flammable anesthetics	Annex G	IS 13450 (Part 1)	R	One of each model	05 years	Refer note 1
11.6.2	Overflow in ME equipment	11.6.2	IS 13450 (Part 1)	R	One of each model	05 years	Refer note 1
11.6.3	Spillage on ME equipment and ME systems	11.6.3	IS 13450 (Part 1)	R	One of each model	05 years	Refer note 1
11.6.4	Leakage	11.6.4	IS 13450 (Part 1)	R	One of each model	05 years	Refer note 1
11.6.5	Ingress of water and particulate matter	-	IS/IEC 60529	R	One of each model	05 years	Refer note 1
11.6.6	Cleaning and disinfection	11.6.6	IS 13450 (Part 1)	R	One of each model	05 years	Refer note 1
11.6.8	Compatibility with substances used with ME equipment	11.6.8	IS 13450 (Part 1)	R	One of each model	05 years	Refer note 1

11.8	Interruption of power supply/supply mains	11.8	IS 13450 (Part 1)	R	One of each model	05 years	Refer note 1
201.12 Accuracy of controls and instruments and protection against hazardous outputs							
12.1	Accuracy of controls & Instruments	201.12.1.101, 201.12.1.102, 201.12.1.103	13450 (Part 2/ Sec 44)	R	One of each model	05 years	Refer note 1
12.2	Usability	-	IS 13450 (Part 1/ Sec 6)	R	One of each model	05 years	Refer note 1
12.3	Alarm Systems	-	IS 13450 (Part 1/ Sec 8)	R	One of each model	05 years	Refer note 1
12.4	Protection against hazardous output	12.4	IS 13450 (Part 1)	R	One of each model	05 years	Refer note 1
201.13 Hazardous Situations and Fault Conditions							
13.1	Specific hazardous situation	13.1 to 13.1.4	13450 (Part 1)	R	One of each model	05 years	Refer note 1
13.2 Single Fault conditions							
13.2.2	Electrical single fault condition	13.2.2	13450 (Part 1)	R	One of each model	05 years	Refer note 1
13.2.3	Overheating of transformers	15.5.1	13450 (Part 1)	R	One of each model	05 years	Refer note 1
13.2.4	Failure of Thermostats	13.2.13, 15.4.2	13450 (Part 1)	R	One of each model	05 years	Refer note 1

13.2.5	Failure of temperature limiting devices	13.2.13, 15.4.2	13450 (Part 1)	R	One of each model	05 years	Refer note 1
13.2.6	Leakage of liquid	13.2.6	13450 (Part 1)	R	One of each model	05 years	Refer note 1
13.2.7	Impairment of cooling that could result in a hazardous situation	13.2.7	13450 (Part 1)	R	One of each model	05 years	Refer note 1
13.2.8	Locking of moving parts	13.2.8	13450 (Part 1)	R	One of each model	05 years	Refer note 1
13.2.9	Interruption and short circuiting of motor capacitors	13.2.9	13450 (Part 1)	R	One of each model	05 years	Refer note 1
13.2.10	Additional test criteria for motor operated ME Equipment	13.2.10	13450 (Part 1)	R	One of each model	05 years	Refer note 1
13.2.12	Failure of parts that might result in a Mechanical hazard	9, 15.3	13450 (Part 1)	R	One of each model	05 years	Refer note 1
13.2.13.3	ME equipment with motors	13.2.13.3	13450 (Part 1)	R	One of each model	05 years	Refer note 1
14	**Programmable Electrical Medical Systems (PEMS)**	14	13450 (Part 1) IS/ ISO 62304:2006	R	One of each model	05 years	Refer note 1
15	**Construction of ME Equipment**						
15.1	Arrangements of controls and indicators	-	IS 13450 (Part 1/ Sec 6)	R	One of each model	05 years	Refer note 1

15.2	Serviceability	15.2	13450 (Part 1)	R	One of each model	05 years	Refer note 1
15.3	Mechanical Strength	15.3	13450 (Part 1)	R	One of each model	05 years	Refer note 1
15.4	Components and general assembly	15.4	13450 (Part 1)	R	One of each model	05 years	Refer note 1
15.5	Transformers in ME Equipment	15.5	13450 (Part 1)	R	One of each model	05 years	Refer note 1
16	ME Systems	16	13450 (Part 1)	R	One of each model	05 years	Refer note 1
17	Electromagnetic compatibility	17 1.3	IS 13450 (Part 1), IS 13450 (Part 1/ Sec 2)	R	One of each model	05 years	Refer note 1
202 Electromagnetic Compatibility – Requirements & Tests							
202.101	Immunity testing of Essential performance	101	IS 13450 (Part 2/Sec 44)	R	One of each model	05 years	Refer note 1
203	**General requirements for Radiation protection in Diagnostic X-RAY Equipment**						
203.6	Radiation Management	203.6	IS 13450 (Part 2/Sec 44)	R	One of each model	05 years	Refer note 1
203.7	Radiation Quality	203.7	IS 13450 (Part 2/Sec 44)	R	One of each model	05 years	Refer note 1

203.8	Limitation of the Extant of the X-RAY beam & Relationship between x-ray field and image reception area	203.8	IS 13450 (Part 2/Sec 44)	R	One of each model	05 years	Refer note 1
203.9	Focal spot to Skin Distance	203.9	IS 13450 (Part 2/Sec 44)	R	One of each model	05 years	Refer note 1
203.11	Protection against residual radiation	203.11	IS 13450 (Part 2/Sec 44)	R	One of each model	05 years	Refer note 1
203.12	Protection against leakage radiation	203.12	IS 13450 (Part 2/Sec 44)	R	One of each model	05 years	Refer note 1
203.13	Protection against Stray Radiation	203.13	IS 13450 (Part 2/Sec 44)	R	One of each model	05 years	Refer note 1
203.101	Emergency termination of X-Radiation	203.101	IS 13450 (Part 2/Sec 44)	R	One of each model	05 years	Refer note 1
203.102	Visual Indication	203.102	IS 13450 (Part 2/Sec 44)	R	One of each model	05 years	Refer note 1
203.103	Indication of operational ready state	203.103	IS 13450 (Part 2/Sec 44)	R	One of each model	05 years	Refer note 1
203.104	Connection of External interlocks	203.104	IS 13450 (Part 2/Sec 44)	R	One of each model	05 years	Refer note 1
203.105	Charging mode Interlock	203.105	IS 13450 (Part 2/Sec 44)	R	One of each model	05 years	Refer note 1

203.106	Control of Radiation Output	203.106	IS 13450 (Part 2/Sec 44)	R	One of each model	05 years	Refer note 1
203.107	Safety measures against excessive X-Radiation	203.107	IS 13450 (Part 2/Sec 44)	R	One of each model	05 years	Refer note 1
203.108	Dosimetry PHANTOM	203.108	IS 13450 (Part 2/Sec 44)	R	One of each model	05 years	Refer note 1
203.109	Dose Statements	203.109	IS 13450 (Part 2/Sec 44)	R	One of each model	05 years	Refer note 1
203.110	Dose Profile Statement	203.110	IS 13450 (Part 2/Sec 44)	R	One of each model	05 years	Refer note 1
203.111	Sensitivity Profile statement	203.111	IS 13450 (Part 2/Sec 44)	R	One of each model	05 years	Refer note 1
203.112	Display & Recording of CTDIvol & DLP	203.112	IS 13450 (Part 2/Sec 44)	R	One of each model	05 years	Refer note 1
203.113	Geometric Efficiency in the Z-Direction	203.113	IS 13450 (Part 2/Sec 44)	R	One of each model	05 years	Refer note 1

Note-1: The test shall be done whenever there is a change in design of the product.

Note-2: The control unit and levels of control as decided by the Bureau are obligatory, to which the licensee shall comply with.

Note-3: The Licencee shall maintain a RISK MANAGEMENT FILE as per the requirements of IS 13450 (Part 1) : 2018/ IEC 60601-1 : 2012 and IS 13450 (Part 2/ Sec 44) : 2016/ IEC 60601-2-44 : 2009.