उत्पाद मैनुअल
चिकित्सीय विध्युत उपस्कर
भाग २ बुनियादी सुरक्षा एवं आवश्यक निष्पादन के लिए विशिष्ट अपेक्षाएँ
अनुभाग 65डेंटल इंट्रारे उपकरण-ओरल एक्स-
आईएस 13450 (भाग 2/धारा 65): 2024 के अनुसार

PRODUCT MANUAL
MEDICAL ELECTRICAL EQUIPMENT
PART 2 PARTICULAR REQUIREMENTS FOR THE BASIC SAFETY AND ESSENTIAL PERFORMANCE
SECTION 65 DENTAL INTRA-ORAL X-RAY EQUIPMENT
according to IS 13450 (Part 2/Sec 65): 2024

यह उत्पाद नियमावली सभी क्षेत्रीय/शाखा कार्यालयों और लाइसेंसधारियों द्वारा विभिन्न उत्पादों के लिए भारतीय मानक ब्यूरो (अनुरूपता मूल्यांकन) विनियम, 2018 की योजना-I के अंतर्गत प्रमाणन के संचालन में एकरूपता और पारदर्शिता सुनिश्चित करने के लिए संदर्भ सामग्री के रूप में उपयोग की जाएगी। बीआईएस प्रमाणन प्राप्त करने के इच्छुक भावी आवेदक भी इस दस्तावेज़ का उपयोग कर सकते हैं।

This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure uniformity 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.

1.	**मानक संख्या / IS No.**	:	IS 13450 (Part 2/Sec 65): 2024
	शीर्षक / Title	:	MEDICAL ELECTRICAL EQUIPMENT PART 2 PARTICULAR REQUIREMENTS FOR THE BASIC SAFETY AND ESSENTIAL PERFORMANCE SECTION 65 DENTAL INTRA-ORAL X-RAY EQUIPMENT
	संशोधनों की संख्या **No. of amendments**	:	0
2.	**नमूनाकरण दिशानिर्देश / Sampling Guidelines**		
a)	**कच्चा माल** **Raw material**	:	Components – As per Cl 4.8 of IS 13450 Part 1: 2024. *Note: This section indicates the requirements for raw material (if specified in the IS) for which compliance is to be established during Grant of Licence/Change in Scope of Licence/Factory Surveillance.*
b)	**समूहीकरण दिशानिर्देश** **Grouping Guidelines**	:	Please refer **ANNEX – A**
c)	**नमूने का परिमाण** **Sample Quantity**	:	1 Equipment (with all the accessories)
d)	**परीक्षण अनुरोध में घोषित किए जाने वाले पैरामीटर / Parameters to be Declared in Test Request**		As per scope of licence *Note: Apart from the above, any other requirements/ parameters may also be declared as per the standard, as applicable.*

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3.	**परीक्षण उपकरण की सूची** **List of Test Equipment**	:	Please refer **ANNEX – B**
4.	**निरीक्षण एवं परीक्षण योजना** **Scheme of Inspection and Testing**	:	Please refer **ANNEX – C**
5.	**एक दिन में संभावित परीक्षण** **Possible tests in a day**	:	Tests as given in Table 1 of ANNEX C with frequency 'Each Medical equipment' *Note: This section is for the guidance of BIS Certification Officers/ Technical Auditors of BIS Authorized Outside Surveillance Agencies(OSAs) during factory inspection to provide ready reference regarding the tests which can be witnessed during the inspection in the factory by the officer/ auditor.*
6.	**निगरानी के लिए दिशानिर्देश** **Guidelines for Surveillance**	:	Factory surveillance may be conducted over a two-day period, during which all applicable testing—including Clause 203 (Radiation protection in diagnostic X-ray equipment)—may be carried out on-site. Additionally, one surveillance sample may be drawn for independent testing once every three years.
7.	**लाइसेंस का दायरा / Scope of the Licence:**		

"Licence is granted to use Standard Mark as per **IS 13450 (Part 2/Sec 65): 2024** with the following scope:

Name of the product	Basic Safety and Essential Performance of Dental Intra-Oral X-Ray Equipment
Type	Stationary (or) Fixed / Mobile / Portable / Hand-held
Model (s)	
Rating	Rated Voltage …. V (or) Rated Voltage Ranges(s) ……V, Frequency…. Hz, Single phase / Three Phase, Rated Current …. A (or) Input power ……. W / VA
Loading Factors	Max kVp, Max mA, Max Power Output
Power supply	Internal Electrical Power Source/ Supply Mains or Both
Protection against electric shock	Class – I / Class – II/ Internally Powered
Mode of Operation	Continuous / Non-Continuous
Protection against harmful ingress of water or particulate matter	
Suitability for use in oxygen rich environment	Suitable/ Not suitable

ANNEX -A
Grouping Guidelines

1. Manufacturer shall submit declaration as per scope of licence & as given below for each model of Dental Intra-Oral X-Ray Equipment they intend to cover in the scope of licence. Further, the manufacturer shall also declare the essential accessories (if any) supplied along with the model.

2. For Grant of Licence/ Change in Scope of Licence, each Model of X-ray Equipment is to be tested.

3. During the operation of the Licence, BO shall ensure that all the model(s) covered in the Scope of the Licence are tested in rotation to the extent possible.

4. A change in the X-ray monoblock assembly/X-ray tube, high-voltage generator, loading factors, total filtration, beam limiting device, radiation shielding, internal power source or software that can affect the radiation output or the Scope of the Licence shall be treated as a different model.

Declarations (To be declared by the manufacturer)	
Type of X-ray generator / monoblock assembly	X-ray monoblock assembly model …… ; High-voltage generator: Constant potential / One-peak / Other (declare)
Loading factors	Nominal X-ray tube voltage …..kV (fixed / selectable: ……) X-ray tube current …..mA (fixed / selectable: ……) Irradiation time range ..s; Current time product range ….. mA Nominal electric power …..W; Nominal anode input power …..W
Target angle, focal spot and reference axis	Target angle ….° with respect to the reference axis ……; Nominal focal spot value (IS 18443 / IEC 60336) ….. mm
Filtration	Inherent ….mm Al; Added ….mm Al; Total filtration ….mm Al equivalent
Beam limiting device (cone)	Exit field size(s): circle of ….. mm diameter / rectangular ….. x ….. mm; Minimum focal spot to skin distance ….. cm; Detachable: Yes /No
Operation	Hand-held during loading / Not intended to be hand-held during loading
Stray radiation protection (hand-held equipment)	Non-removable shield of ….. mm lead equivalence at 70 kV; Means for support / second irradiation switch for operation from ≥ 2 m: Yes/ No
Means to prevent unauthorized initiation of irradiation (hand-held equipment)	Physical key / Password / Other (to be declared)
Indications	Loading state: yellow indicator / audible signal; Ready state: green indicator / other (declare)
Image receptor compatibility	Film / Phosphor plate / Electronic X-ray image receptor (supplied: Yes / No)
Reproducibility and accuracy declarations	Accuracy of kV (± %), mA (± %), time (± % or ± ms); Coefficient of variation of air kerma ≤ 0,05; Leakage radiation at reference loading conditions ….. mGy/h
Expected service life	….. years
Any other declarations (to be declared by the manufacturer)	
Accessories (provided with the Medical Equipment)	

ANNEX- B

List of Test Equipments

(Indicative List, For Guidance Only)

Sl. No.	Tests used in with Clause Reference	Test Equipment
1.	General requirement for Risk Management, Cl 201.4, PEMS documentation, 14	(i) Inspection of the manufacturer's policy for determining criteria for RISK acceptability; (ii) Inspection of the RISK MANAGEMENT plan for the particular ME EQUIPMENT or ME SYSTEM under consideration; and (iii) Confirming the MANUFACTURER has prepared a RISK MANAGEMENT FILE containing the RISK MANAGEMENT RECORDS and other documentation required by the standard for the particular ME EQUIPMENT or ME SYSTEM under consideration.
2.	Essential Performance, Cl. 201.4.3 Cl. 4.3 of IS 13450 Part 1	Inspection of Risk Management File
3.	Expected Service Life, Cl. 201.4 (Cl. 4.4 of IS 13450 Part 1)	Inspection of Risk Management File
4.	Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS, Cl. 201.4 (Cl. 4.5 of IS 13450 Part 1)	Inspection of Risk Management File
5.	ME Equipment or ME System Parts that contact the patient, Cl. 201.4.6	Inspection of Risk Management File
6.	Single Fault Condition for ME Equipment, Cl. 201.4.7	Inspection of Risk Management File
7.	Components of ME Equipment, Cl. 4.8 of IS 13450 Part 1	Compliance is checked by inspection and, where necessary, by test.
8.	Use of Component with High -Integrity Characteristics in ME Equipment, Cl. 201.4 (Cl. 4.9 of IS 13450 Part 1)	Inspection of Risk Management File
9.	Power Supply, Cl. 201.4 (Cl. 4.10 of IS 13450 Part 1)	Inspection of Accompanying document
10.	Power Input, Cl. 201. 4 (Cl. 4.11 of IS 13450 Part 1)	Power Input Test Apparatus/Power Analyzer/ Multimeter
11.	Ambient Temperature, Cl. 201. 5 Cl. 5.3 of IS 13450 Part 1	Temperature & Air Velocity Meter
12.	Applied Parts, Cl. 201.5 (Cl. 5.9.1 of IS 13450 Part 1)	Inspection of Accompanying document
13.	Accessible Parts, Cl. 201. 5 (Cl. 5.9.2 of IS 13450 Part 1)	Test Finger as per Figure 6 of IS 13450 Part 1, Test Hook as per Figure 7 of IS 13450 Part 1, Actuating Mechanisms
14.	Humidity preconditioning treatment, Cl. 201.5 Cl. 5.7 of IS 13450 Part 1	Conditioning chamber with temperature and humidity chamber
15.	Durability of markings, Cl. 201.7 (Cl. 7.1.3 of IS 13450 Part 1)	Distilled water, ethanol 96%, Isopropyl alcohol, Stop watch
16.	Protective Earth Terminal, Cl. 201.8 Cl. 8.6.2 of IS 13450 Part 1	Visual Inspection
17	Protective earthing of moving parts, Cl. 201.8 Cl. 8.6.3 of IS 13450 Part 1	Visual Inspection & Inspection of Risk Management File
18.	Impedance and current carrying capability, Cl. 201.8 (Cl. 8.6.4 of IS 13450 Part 1)	AC/DC voltage source, Multimeter/ Earth Resistance Tester
19.	Earth Leakage Current, Cl.201.8 (Cl.8.7.4.5 of IS 13450 Part 1), Touch Current, Cl. 201.8 (Cl.8.7.4.6 of IS 13450 Part 1), Patient Leakage Current, Cl. 201.8 Cl. 8.7.4.7 of IS 13450 Part 1	Figure 13 to Figure 18 of IS 13450 Part 1, Leakage Current Tester, metal foil
20.	Dielectric Strength, Cl. 201.8 (Cl. 8.8.3 of IS 13450 Part 1)	High Voltage Tester
21.	Mechanical strength and resistance to heat of Insulation other than wire insulation, Cl. 201.8 Cl. 8.8.4.1 of IS 13450 Part 1	Ball Test Apparatus as per Figure 21 of IS 13450 Part 1
22	Resistance to environmental stress of insulation other than wire, Cl. 201.8 (Cl. 8.8.4.2 of IS 13450 Part 1)	Inspection, by measurement and for natural latex rubber, Oxygen Cylinder

23.	Creepage Distances and Air Clearances Cl. 201.8 (Cl. 8.9 of IS 13450 Part 1)	Vernier Caliper, Filler Gauge
24	HAZARDS associated with surfaces, corners and edges, Cl 201.9.3	Inspection of Risk Management File
25	Protection against unwanted and excessive radiation HAZARDS, Cl. 201.10	Inspection of Risk Management File
26	Protection against excessive temperatures and other hazards, Cl. 201.11	Temp. Data logger
27	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME Equipment, Cl. 201.11.6	Inspection of Risk Management File
28	Accuracy of controls and instruments and protection against hazardous outputs, Cl. 201.12	Inspection of Risk Management File
29	Hazardous Situations and fault conditions, Cl. 201.13	Inspection of Risk Management File
30	Mechanical strength, 15.3 (push, impact and drop tests as applicable per Table 28; drop test for HAND-HELD equipment 15.3.4.1)	Push test apparatus / force gauge, impact test steel ball and release arrangement, 50 mm ± 5 mm thick hardwood board on rigid base, drop fixture, measuring tape
31	Batteries, 15.4.3 (housing, polarity, overcharging, lithium battery compliance, excessive current protection)	Battery test report (IS 16046 (Part 2) / IEC 62133-2), programmable DC source / battery charger-discharger, DC power supply with current limiting, document inspection
32	ME Systems, Cl. 201.16	Visual inspection, inspection of appropriate documents or certificates and Risk Management File.
33	Electromagnetic compatibility, Cl. 201.17, Cl.202	Inspection of the equipment and/or the Risk Management File, and Test as Specified in IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020.
34.	Accuracy of X-RAY TUBE VOLTAGE, 203.6.4.3.102.2	Non-invasive kV meter / X-ray multimeter (calibrated)
35	Accuracy of X-RAY TUBE CURRENT / CURRENT TIME PRODUCT, 203.6.4.3.102.3	Non-invasive mA / mAs meter or X-ray multimeter, digital storage oscilloscope
36	Accuracy of IRRADIATION TIME, 203.6.4.3.102.4 and 203.4.101.1	Radiation time meter / X-ray multimeter, digital storage oscilloscope with radiation detector
37	Linearity of AIR KERMA, 203.6.3.1.101; Coefficient of variation of AIR KERMA, 203.6.3.2.101; reproducibility for internally powered equipment, 203.6.3.2.103	Calibrated dosimeter (ionization chamber / solid-state detector) with electrometer, X-ray multimeter, stop watch, programmable DC source / battery charger-discharger (for charge states)
38	LEAKAGE RADIATION in the LOADING STATE, 203.12.4	Calibrated dosimeter / survey meter with ionization chamber, lead blocking cap for radiation aperture, measuring jig / tape
39	HALF-VALUE LAYER and TOTAL FILTRATION, 203.7.1	Calibrated dosimeter, high-purity aluminium filters of known thickness, filter holder / stand
40	Limitation of X-RAY TUBE VOLTAGE, 203.7.101	Inspection; X-ray multimeter / kV meter
41	EXIT FIELD SIZE, X-RAY FIELD and alignment, 203.8.5.4	Radiographic film / phosphor plate / electronic image receptor or X-ray field test tool, vernier caliper, steel rule
42	FOCAL SPOT TO SKIN DISTANCE, 203.9	Steel tape / measuring scale
43	STRAY RADIATION profile and protective shield (0,25 mm lead equivalence at 70 kV), 203.13.4, 203.13.101	Calibrated dosimeter, lead / aluminium attenuators, scatter phantom, measuring stand
44	Indication of LOADING STATE and READY STATE; means against unauthorized initiation; release of control between irradiations, 203.6.2.1, 203.6.4.2, 203.6.4.101	Visual inspection, stop watch, functional test set-up

Note 1*: The above list is indicative only and may not be treated as exhaustive.*
Note 2*: The licensee shall maintain a Technical file and Risk Management File as per the provisions of IS 13450 (Part 2/ Sec 65): 2024 for each model in the scope of licence.*
Note 3*: The Technical File and Risk Management File shall be maintained by the licensee till the End of Life for each model.*

ANNEX C
Scheme of Inspection and Testing

1. QUALITY ASSURANCE PLAN

1.1 It is expected that during operation of BIS licence manufacturers will implement a Quality Assurance Plan (QAP) i.e. a plan of regular testing and in-process controls, designed to ensure that the product bearing the Standard Mark conforms to all requirements of the Indian Standard.

1.2 The manufacturers shall define a Quality Assurance Plan (QAP) defining the control unit (i.e. lot/batch etc.), the levels of control (i.e. the frequency and number of samples for conducting the different tests as per the Indian Standard) and declare the arrangement for testing i.e. whether in-house or sub-contracting/ sharing for each applicable test and submit the same to BIS Branch Office for information. The manufacturer shall comply with the QAP and maintain test records in accordance with para 2.1.

1.3 Recommended Levels of Control/ Control Unit:

1.3.1 For the guidance of manufacturers in preparing the Quality Assurance Plan, recommended levels of control are given in Table 1. Manufacturer has the discretion of declaring their own levels of control or accept the levels of control given in this document.

1.3.2 The manufacturer shall ensure inspection and testing as per the Quality Assurance Plan submitted by them on the whole production of the factory which is covered by this plan.

1.4 However, all manufacturers shall ensure compliance of their products to all the requirements of the Indian Standard.

2. ENSURING COMPLIANCE THROUGH TESTING

The manufacturers shall ensure compliance of their products to all the requirements of the Indian Standard for which they may have in-house test facilities. However, there is no obligation to maintain in-house laboratory. Licensee may use alternative arrangements for tests of the production as per the declared QAP. Various alternatives are available for operation of BIS certification as given below and the relevant guidelines for availing such relaxations by the manufacturers, as amended from time to time, are to be referred:

i) Shared testing resources like common facility,
ii) Cluster based testing facility,
iii) Sub-contracting to outside laboratories which may either be:
  a) BIS recognised/ empanelled laboratories, or
  b) Any accredited laboratory as per ISO/IEC 17025

2.1 Test Records- The manufacturers shall maintain test records for the tests carried out (either in-house or at a sub-contracted or at shared test facility) to establish conformity of the product to the Standard for operation of licence. For the tests being subcontracted or conducted at a shared test facility, test results issued by the laboratories or test facilities, shall be made available for inspection by BIS.

2.1.1 **Technical File**- Licensee shall maintain a Technical File for each model being manufactured by them. The Technical file shall be submitted to BIS at the time of Grant of Licence/ Inclusion/ Surveillance.

2.1.1.1 The Technical File shall be maintained till the End of Life of the model.

2.1.1.2 Licensee shall declare the frequency for periodic review in Technical file to BIS and record of review to be maintained. In case of any change in the Technical file due to any periodic review/ change in the product, the licensee shall inform the same to BIS at the earliest and provide the copy of the latest version of Technical File to BIS within 30 days of issue of the revised/ modified Technical File.

2.1.1.3 For changes in the product which shall affect the Scope of the Licence, the modified product shall be treated as a different model and separate Technical File shall be maintained for the same.

2.1.1.4 The technical file shall consist of the following documents:

2.1.1.4.1 A general description of the product;

2.1.1.4.2 Product Manual and/ or Instructions for use; (including the statements and information required in accompanying documents by Table 201 C.102 of IS 13450 (Part 2/Sec 65));

2.1.1.4.3 Instructions for repair/ service for the product/ components, if required;

2.1.1.4.4 Frequency of periodic repair/ service for the product/ components, if required;

2.1.1.4.5 Conceptual product design and manufacturing drawings and, where appropriate, list of components, electrical circuit design, etc. with descriptions and explanations needed for the understanding of these drawings;

2.1.1.4.6 Technical description of the X-ray source assembly (reference axis, target angle(s), focal spot position, nominal focal spot value(s), exit field size(s)) and loading factors (Cl 201.7.9.2.1.101 and 201.7.9.3.101);

2.1.1.4.7 A list of the all Indian/ International standards applied in full or in part during the conformity assessment process with copy of test certificate/ test report;

2.1.1.4.8 Test reports/ Test Certificates and Risk Assessment File for the product and/ or components as per relevant Clauses of the Indian Standard;

2.1.1.4.9 Copies of Conformity Assessment documentation for critical product components;

2.1.1.4.10 Copy of BIS licences for the product/ components, wherever applicable;

2.1.1.4.11 A copy of the Declaration of Conformity for other International Standards;

2.1.1.4.12 Other documents, if found necessary by the manufacturer and/ or by BIS may also be a part of the Technical File

2.1.2 **Risk Management File**- The licensee shall maintain a Risk Management File for each model in the scope of licence as per the requirement of IS 13450 (Part 2/ Sec 65): 2024. The Risk Management File shall be submitted to BIS at the time of Grant of Licence/Inclusion/Surveillance.

2.1.2.1 The Risk Management File shall be maintained till the End of Life of the model.

2.1.2.2 Licensee shall declare the frequency for periodic review of Risk Management File and record of review in the file to be maintained. In case of any change in the Risk Management File due to any periodic review/ change in the product, the licensee shall inform the same to BIS at the earliest and provide the copy of the latest version of Risk Management File to BIS within 30 days of issue of the revised/ modified Technical File.

3. PACKING AND MARKING

The Standard Mark as given in the Schedule of the licence shall be incorporated legibly and indelibly on each equipment provided always that the product so marked conforms to each requirement of the specification.

3.1 Packing and Marking shall be done as per Cl. 201.7 & Cl.203.5 of IS 13450 (Part 2 / Sec 65): 2024.

3.2 **Additional Marking requirements**: The equipment shall also be marked with the following additional requirement on the product and its packaging:

a) "For BIS certification details please visit www.bis.gov.in"

4. REJECTION

The production which conforms to the Indian Standard and covered under the scope of this licence shall be marked with the Standard Mark. 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

(Recommended Levels of Control by BIS- for Guidance Only)

-1				-2		
Test Details				**Levels of Control**		
Cl.	**Requirement**	**Test Method**		**No. of Sample**	**Frequency**	**Remarks**
		Clause	**Reference**			
201.4	**General requirements**					
4.1	Conditions for application to ME EQUIPMENT or ME SYSTEMS	4.1	IS 13450 (Part 1)	One	Each Medical Equipment	
4.2	Risk management process for ME equipment or ME systems	4.2	IS 13450 (Part 1)	One		
201.4.3	Essential Performance	4.3	IS 13450 (Part 1)	One		
201.4.3.101	Additional requirements for essential performance	201.4.3.101 Table 201.101	IS 13450 (Part 2/ Sec 65)	One		
4.4	EXPECTED SERVICE LIFE	4.4	IS 13450 (Part 1)	One		Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
4.5	Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS	4.5		One		
4.6	ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT	4.6		One		
4.7	SINGLE FAULT CONDITION for ME EQUIPMENT	4.7		One		
4.8	Components of ME EQUIPMENT	4.8		One	Each Consignment	No further testing if accompanied with Test Certificate or ISI Mark or covered in Risk Management file
4.9	Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT	4.9		One		

201.4.10	**Power supply**					
4.10.1	Source of power for ME EQUIPMENT	4.10.1	IS 13450 (Part 1)	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
4.10.2	SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS	4.10.2 201.4.10.2	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 65)	One		
4.11	Power input	4.11	IS 13450 (Part 1)	One		
201.7	**ME Equipment identification, marking and documents**					
7.1	ME Equipment Identification, marking and documents	7.1	IS 13450 (Part 1)	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
201.7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts	7.2 201.7.2	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 65)	One		
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts	7.3	IS 13450 (Part 1)	One		
7.4	Marking of controls and instruments	7.4		One		
7.5	Safety signs	7.5		One		
7.6	Symbols	7.6		One		
7.7	Colours of the insulation of conductors	7.7		One		
201.7.8	Indicator lights and controls	7.8, 201.7.8.1	IS 13450 (Part 1)	One		
201.7.9	ACCOMPANYING DOCUMENTS	7.9 201.7.9	IS 13450 (Part 2/ Sec 65)	One		
201.8	**Protection against electrical hazards from ME Equipment**					
8.1	Fundamental rule of protection against electric shock	8.1	IS 13450 (Part 1)	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
8.2	Requirements related to power sources	8.2	IS 13450 (Part 1)	One		
8.3	Classification of APPLIED PARTS	8.3	IS 13450 (Part 1)	One		
8.4	**Limitations of voltage, current or energy**					
8.4.2 (a)	The currents from, to or between Patient connections	8.7.4	IS 13450 (Part 1)	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
8.4.2 (b)	The Leakage Currents from, to or between Accessible parts	8.7.4	IS 13450 (Part 1)	One		
8.4.2 (c)	Other accessible parts	8.4.2	IS 13450 (Part 1)	One	Once in 03 year	Refer Note 1
8.4.2 (d)	Internal parts that are accessible	8.4.2	IS 13450 (Part 1)	One		
8.4.3	ME equipment intended to be connected to a power source by a plug	8.4.3	IS 13450 (Part 1)	One		
8.4.4	Internal capacitive circuits	8.4.4		One		
8.5	**Separation of Parts**					
8.5.1.2	Means of Patient Protection (MOPP)	8.5.1.2	IS 13450 (Part 1)	One	Once in 03 years	Refer Note 1
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)	8.5.1.2	IS 13450 (Part 1)	One		

201.8.5.1.101	Additional limitation of voltage, current or energy	201.8.5.1.101	IS 13450 (Part 2/ Sec 65)			
8.5.2	Separation of PATIENT CONNECTIONS	8.5.2	IS 13450 (Part 1)	One		
8.5.3	MAXIMUM MAINS VOLTAGE	8.5.3	IS 13450 (Part 1)	One		
8.5.4	WORKING VOLTAGE	8.5.4	IS 13450 (Part 1)	One		
8.5.5	DEFIBRILLATION - PROOF APPLIED PARTS	8.5.5	IS 13450 (Part 1)	One		
8.5.5.1	Defibrillation Protection	8.5.5.1	IS 13450 (Part 1)	One		
8.5.5.2	Energy Reduction Test	8.5.5.2	IS 13450 (Part 1)	One		
8.6	**Protective earthing, functional earthing and potential equalization of ME EQUIPMENT**					
8.6.1	Applicability of requirements	8.6.1	IS 13450 (Part 1)	One	Once in 03 years	Refer Note 1
8.6.2	PROTECTIVE EARTH TERMINAL	8.6.2	IS 13450 (Part 1)	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
8.6.3	Protective earthing of moving parts	8.6.3	IS 13450 (Part 1)	One		
8.6.4	Impedance and current-carrying capability	8.6.4	IS 13450 (Part 1)	One	Once in 03 years	Refer Note 1
8.6.5	Surface Coatings	8.6.5	IS 13450 (Part 1)	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
8.6.6	Plugs and sockets	8.6.6		One		
8.6.7	POTENTIAL EQUALIZATION CONDUCTOR	8.6.7		One		
8.6.8	FUNCTIONAL EARTH TERMINAL	8.6.8		One		
8.6.9	CLASS II ME EQUIPMENT	8.6.9		One		
8.7	**LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS**					
8.7.1	General Requirements	8.7.1	IS 13450 (Part 1)	One	Once in 03 years	Refer Note 1
8.7.2	SINGLE FAULT CONDITIONS	8.7.2				
8.7.3	Allowable values	8.7.3 201.8.7.3	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 65)			
8.7.4	Measurements	8.7.4	IS 13450 (Part 1)	One		
8.8	**Insulation**					
8.8.2	Distance through solid insulation or use of thin sheet material	8.8.2	IS 13450 (Part 1)	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
201.8.8.3	Dielectric strength	8.8.2 201.8.8.3	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 65)	One		
8.8.4	**Insulation other than wire insulation**					
8.8.4.1	Mechanical strength and resistance to heat	8.8.4.1	IS 13450 (Part 1)	One	Once in 03 years	Refer Note 1
8.8.4.2	Resistance to environmental stress	8.8.4.2	IS 13450 (Part 1)	One		

8.9	**CREEPAGE DISTANCES and AIR CLEARANCES**					
8.9.1	Values	8.9.1	IS 13450 (Part 1)	One	Once in 03 years	Refer Note 1
8.9.2	Applications	8.9.2		One		
8.9.3	Spaces filled by insulating compound	8.9.3		One		
8.9.4	Measurement of CREEPAGE DISTANCES AND AIR CLEARANCES	8.9.4		One		
8.1	**Components and wiring**					
8.10.1	Fixing of components	8.10.1	IS 13450 (Part 1)	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
8.10.2	Fixing of wiring	8.10.2		One		
8.10.3	Connections between different parts of ME EQUIPMENT	8.10.3		One		
8.10.4	Cord-connected HAND-HELD parts and cord- connected foot-operated control devices	8.10.4		One		
8.10.5	Mechanical protection of wiring	8.10.5		One		
8.10.6	Guiding rollers for insulated conductors	8.10.6		One		
8.10.7	Insulation of internal wiring	8.10.7		One		
8.11	**MAINS PARTS, components and layout**					
8.11.1	Isolation from Supply mains	8.11.1	IS 13450 (Part 1)	One	Once in 03 years	Refer Note 1,3
8.11.2	Multiple Socket Outlets	8.11.2		One		Refer note 1
8.11.3	**Power Supply Cords**					
8.11.3.1	Application	8.11.3.1	IS 13450 (Part 1)	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
8.11.3.2	Types	8.11.3.2		One		
8.11.3.3	Cross-sectional area of POWER SUPPLY CORD conductors	8.11.3.3		One		
8.11.3.4	Appliance Couplers Cord anchorage Cord guards	8.11.3.4 8.11.3.5 8.11.3.6	IS 13450 (Part 1) or IS/IEC 60320-1	One		
8.11.4	Mains terminal devices	8.11.4	IS 13450 (Part 1)	One		
8.11.5	Mains fuses and over current releases	8.11.5	IS 13450 (Part 1)	One		
8.11.6	Internal wiring of the Mains Part	8.11.6	IS 13450 (Part 1)	One		
201.9	**Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS**					
9.1	MECHANICAL HAZARDS of ME EQUIPMENT	9.1	IS 13450 (Part 1)	One	Each Medical Equipment	Refer note 1
9.2	MECHANICAL HAZARDS associated with moving parts	9.2	IS 13450 (Part 1)	One		
9.3	MECHANICAL HAZARD associated with surfaces, corners and edges	9.3	IS 13450 (Part 1)	One		
9.4	Instability HAZARDS	9.4	IS 13450 (Part 1)	One	Once in 03 years	
9.5	Expelled parts HAZARD	9.5	IS 13450 (Part 1)	One		
9.6	Audible acoustic energy	9.6	IS 13450 (Part 1)	One		
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure	9.7	IS 13450 (Part 1)	One		

9.8	MECHANICAL HAZARDS associated with support systems	9.8 201.9.8.4	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 65)	One		
201.1	**Protection against unwanted and excessive radiation HAZARDS**					
10.1	X-Radiation	10.1	IS 13450 (Part 1)	One	Once in 03 years	Refer note 1
10.2	Alpha, beta, gamma, neutron and other particle radiation	10.2	IS 13450 (Part 1)	One		
10.4	Lasers	10.4	IS 13450 (Part 1)	One		
10.5	Other visible electromagnetic radiation	10.5	IS 13450 (Part 1)	One		
10.6	Infrared radiation	10.6	IS 13450 (Part 1)	One		
10.7	Ultraviolet radiation	10.7	IS 13450 (Part 1)	One		
201.11	**Protection against excessive temperatures and other HAZARDS**					
11.1	Excessive temperatures in ME EQUIPMENT	11.1	IS 13450 (Part 1)	One	Once in 03 years	Refer note 1
11.2	Fire Prevention	11.2	IS 13450 (Part 1)	One		
11.3	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT	11.3	IS 13450 (Part 1)	One		
11.4	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable anaesthetics	11.4	IS 13450 (Part 1)	One		
11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents	11.5	IS 13450 (Part 1)	One		
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT	11.6	IS 13450 (Part 1)	One		
11.7	Biocompatibility of ME EQUIPMENT and ME SYSTEMS	11.7	IS 13450 (Part 1)	One		
11.8	Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT	11.8	IS 13450 (Part 1)	One		
201.11.101	Protection against excessive temperatures of BEAM LIMITING DEVICES	201.11.101	IS 13450 (Part 2/ Sec 65)	One		
201.12	**Accuracy of controls and instruments and protection against hazardous outputs**					
12.1	Accuracy of controls and instruments	12.1	IS 13450 (Part 1)	One	Each Medical Equipment	
12.2	USABILITY of ME EQUIPMENT	12.2	IS 13450 (Part 1)	One		
12.3	ALARM SYSTEMS	12.3	IS 13450 (Part 1)	One		
12.4	Protection against hazardous output conditions	12.4	IS 13450 (Part 1)	One	Once in 03 years	Refer note 1

201.13	**HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT**					
13	HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	13	IS 13450 (Part 1)	One	Once in 03 years	Refer note 1
201.14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**					
14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	14	IS 13450 (Part 1)	One	Once in 03 years	Refer note 1
201.15	**Construction of ME EQUIPMENT**					
15.1	Arrangements of controls and indicators of ME EQUIPMENT	15.1	IS 13450 (Part 1)	One	Once in 03 years	Refer note 1
15.2	Serviceability	15.2				
15.3	Mechanical strength	15.3				
15.4	ME EQUIPMENT components and general assembly	15.4				
15.5	MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5	15.5				
201.16	**ME SYSTEMS**					
16.1	General requirements for the ME SYSTEMS	16.1	IS 13450 (Part 1)	One	Once in 03 years	Refer note 1
16.2	ACCOMPANYING DOCUMENTS of an ME SYSTEM	16.2				
16.3	Power Supply	16.3				
16.4	Enclosures	16.4				
16.5	Separation Devices	16.5				
16.6	Leakage Current	16.6				
16.7	Protection against MECHANICAL HAZARDS	16.7				
16.8	Interruption of the power supply to parts of an ME SYSTEM	16.8				
16.9	ME SYSTEM connections and wiring	16.9				
201.17	**Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS**					
17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	17	IS 13450 (Part 1)	One	Once in 03 years	Refer note 1
202	**Electromagnetic disturbances – Requirements and tests**					
202	Electromagnetic disturbances – Requirements and tests	202	IS 13450 (Part 2/Sec 65) IS 13450 (Part 1/ Sec 2)	One	Once in 03 years	Refer note 1
203	**RADIATION PROTECTION in diagnostic X-RAY EQUIPMENT**					
203	RADIATION PROTECTION in diagnostic X-RAY EQUIPMENT	203	IS 13450 (Part 2/Sec 65) IS 13450 (Part 1/ Sec 3)	One	Each Medical Equipment	
203.4.101	Irradiation Time	203.4.101	IS 13450 (Part	One		

203.5	ME EQUIPMENT identification, marking and documents	203.5	2/Sec 65) IS 13450 (Part 1/ Sec 3)			
203.6	Radiation Management	203.6		One		
203.7	Radiation quality	203.7		One		
203.8	Beam limitation	203.8		One		
203.9	Focal spot to skin distance	203.9		One		
203.11	Residual radiation	203.11				
203.12	Leakage radiation	203.12		One		
203.13	Stray radiation	203.13		One		

Note-1: *The tests may be carried out at the given frequency for each model produced during the period. In addition, the test(s) shall be done whenever there is a change in design of the product, components or parts.*