चिकित्सा विद्युत उपकरण
भाग 2 बुनियादी सुरक्षा और आवश्यक प्रदर्शन निष्पादन के लिए विशेष आवश्यकताएँ
धारा 2 उच्च आवृत्ति शल्य चिकित्सा उपकरण और उच्च आवृत्ति शल्य चिकित्सा सहायक उपकरण
आई एस 13450 (भाग 2 / अनुभाग 2): 2024

PRODUCT MANUAL FOR
Medical Electrical Equipment Part 2 Particular Requirements for Basic Safety and Essential Performance Section 2 High frequency Surgical Equipment and High Frequency Surgical Accessories
IS 13450 (Part 2 / Sec 2): 2024

विभिन्न उत्पादों के लिए भारतीय मानक ब्यूरो) अनुरूपता मूल्यांकन (विनियम, 2018 की योजना -I के तहत प्रमाणन के संचालन में एकरूपता और पारदर्शिता के लिए इस उत्पाद मैनुअल का उपयोग सभी क्षेत्रीय / शाखा कार्यालयों और लाइसेंसधारियों द्वारा संदर्भ सामग्री के रूप में किया जाएगा। दस्तावेज़ का उपयोग बीआईएस प्रमाणन प्राप्त करने के इच्छुक संभावित आवेदकों द्वारा भी किया जा सकता है।

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 2): 2024
	शीर्षक **Title**	:	Medical Electrical Equipment Part 2 Particular Requirements for Basic Safety and Essential Performance Section 2 High frequency Surgical Equipment and High Frequency Surgical Accessories
	संशोधनों की संख्या **No. of amendments**	:	Nil
2.	**नमूना दिशानिर्देश** **Sampling Guidelines**		
a)	**कच्चामाल** **Raw material**	:	Components – As per Cl 4.8 of IS 13450 (Part 1):2018
b)	**समूहीकरण दिशानिर्देश** **Grouping Guidelines**	:	Please refer **ANNEX – A**
c)	**नमूने का परिमाण** **Sample Quantity**	:	1 machine (with all the accessories)
3.	**परीक्षण उपकरणों की सूची** **List of Test Equipment**	:	Please refer **ANNEX – B**

4.	**निरीक्षण और परीक्षण की स्कीम Scheme of Inspection and Testing**	:	Please refer **ANNEX – C**
5.	**एक दिन में संभावित परीक्षण Possible tests in a day**	:	Please refer **ANNEX – D**
6.	**लाइसेंस का दायरा /Scope of the Licence:**		

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

Name of the product	Medical Electrical Equipment Part 2 Particular Requirements for Basic Safety and Essential Performance Section 2 High frequency Surgical Equipment and High Frequency Surgical Accessories
Model	
Mode of Operation	Monopolar / Bipolar / Both (Monopolar & Bipolar) / Any other
Rating	Rated Voltage …..V (or) Rated Voltage Ranges(s) ……V, ac Frequency …. Hz, Single phase / Three Phase, Rated Current …. A, Input power …….W (or) ….kVA
Internal Power Source	With / without internal power source
Type	Stationary (or) Fixed / Mobile / Portable / Hand-held
Protection against electric shock	Class – I / Class – II Type B Applied Parts / Type BF Applied Parts / Type CF Applied Parts
Protection against harmful ingress of water or particulate matter	
Suitability for use in oxygen rich environment	Suitable/ Not suitable
Method of Sterilization	By ethylene oxide gas / By irradiation such as gamma ray / By moist heat such as by autoclave / By other methods validated and described by the manufacturer
Accessories to be supplied with the High frequency Surgical Equipment and High Frequency Surgical Accessories	

ANNEX -A

Grouping Guidelines

1. Manufacturer shall submit the declaration for each of the parameters as specified in scope of the licence (as per Sl. No. 6 above) of each model of 'High frequency Surgical Equipment and High Frequency Surgical Accessories' they intend to cover in the scope of licence.

2. For Grant of Licnce/ Change in Scope of Licence, each 'Model' of 'High frequency Surgical Equipment and High Frequency Surgical Accessories' is to be tested. However, change in aesthetic (i.e. colour, visual design, etc) may not be treated as different model.

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.

Note: Firm shall declare the following parameters for each of the Model of High frequency Surgical Equipment and High Frequency Surgical Accessories:

a) IP Classification (as per CL. 7.2.9 of IS 13450 (Part 1))
b) Active Accessory, Active Connector, Active Electrode, Active Electrode Insulation, Active Handle, Active Output terminal.
c) Any associated equipment to be used with HF Equipment.

ANNEX- B
LIST OF TEST EQUIPMENTS
(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sl. No.	Tests used in with Clause Reference	Test Equipment
1.	Power Input, 4.11	Power Input Test Apparatus/Power Analyzer / Multimeter
2.	Applied Part, 7.2.10	Visual Inspection
3.	Colors of indicator light, 7.8.1	Visual Inspection
4.	General, 7.9.3.1 Neutral Electrode Monitoring circuit, 8.4.101	Electrosurgical Analyzer
5.	Defibrillation- Proof Applied Parts, 201.8.5.5	Defibrillator, Function generator
6.	General Requirement, 201.8.7.1	Leakage Current Tester, metal foil, Test Pin or Electrosurgical Analyzer
7.	Thermal Effect of HF leakage Current, 8.7.3.101	Leakage Current Tester, metal foil, Test Pin or Electrosurgical Analyzer
8.	Dielectric Strength, 8.8.3	High Voltage Tester
9.	Impedance Sensing activation, 8.10.4.101.3	AC/DC voltage source, multimeter
10.	Interruption of the power supply/ Supply mains to ME Equipment	Electrosurgical Analyzer
11.	Accuracy of output control setting, 12.1.101	Electrosurgical Analyzer
12	Monotonicity of output control settings, 12.1.102	Electrosurgical Analyzer
13	Accuracy of Maximum Output Voltage, 12.1.103	Electrosurgical Analyzer
14	Usability of ME Equipment, 12.2	Visual Inspection
15.	Use of HIGH CURRENT MODE (12.4.101)	Function Generator, DC source, Timer/Stopwatch

Note 1: The licensee shall maintain a Technical file and Risk Management File as per the provisions of IS 13450 (Part 2 / Sec 2): 2024 for each model in the scope of license.

Note 2: 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 manufacturers (licensees/applicants) will implement a Quality Assurance Plan 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 defining the control unit (i.e. lot/batch etc.) and the levels of control (i.e. the frequency and number of samples for conducting the different tests as per the Indian Standard) and submit the same to BIS Branch Office for information. The manufacturer shall comply with the same and maintain test records in accordance with para 2.4.

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.

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. Alternatively, the manufacturer has the option of adherence to the quality plan as per levels of control recommended in column 3 of Table 1.

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

2. **ENSURING COMPLIANCE THROUGH TESTING**- It is expected that manufacturers (licensees/applicants) will establish a suitably equipped and staffed in house laboratory (In house testing facility) for testing at least those parameters of the Indian Standard which require routine testing for ensuring quality of the product. This includes in-process controls as may be defined and put in place by the manufacturer and testing parameters/requirements which can only be performed in the factory.

2.1 For the guidance of manufacturers, Table 1 giving the recommended levels of control is given below. Column 2 of Table 1 indicates routine tests where test equipment is required in house as "R" or other tests which can be subcontracted as "S". Subcontracting is permitted to BIS recognized/empanelled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025.

2.2 For MSME manufacturers, the requirement of maintaining a laboratory/in-house testing facility for routine tests (indicated as "R" in Column 2 of Table 1) is also optional.

2.2.1 MSME manufacturers may utilize common cluster based facilities as per guidelines for the utilization of cluster based test facilities by MSMEs or the provisions of Sharing of testing facilities or get testing done from BIS recognized/empaneled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025.

2.3 **Large Scale manufacturers shall maintain an in-house laboratory equipped at least with test facilities for routine tests (indicated as "R" in Column 2 of Table 1)**, where different tests given in the specification shall

be carried out in accordance with the method given in the specification. They shall also implement a calibration plan for the in-house test equipment.

2.3.1 Alternatively, in lieu of an in-house laboratory, large scale manufacturers can also utilize the provisions of Sharing of testing facilities as per the Guidelines for Grant of Licence available on BIS website www.bis.gov.in. (Under Conformity Assessment>Product Certification Process). Even for subcontracted tests, provisions for sharing of testing facilities can be utilized.

2.4 **TEST RECORDS**- The manufacturers maintaining an in-house laboratory or utilizing common cluster based facilities or shared test facilities shall maintain test records for the tests carried out to establish conformity. For the tests being subcontracted to BIS recognized/empanelled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025, test reports issued by the laboratories shall be available for inspection by BIS.

2.5.1 TECHNICAL FILE- Licencee 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.

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

2.5.1.2 Licencee shall declare the frequency of periodic review of Technical file to BIS and record of review shall be maintained. In case of any change in the Technical file due to any periodic review/ change in the product, the licencee shall inform the same to BIS and submit the copy of the latest version of Technical File to BIS within 30 days of issue of the revised/ modified Technical File.

2.5.1.3 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.

2.5.1.4 The technical file shall consist of the following documents:

- A general description of the product;
- Product Manual and/ or Instructions for use;
- Instructions for repair/ service for the product/ components, if required;
- Frequency of periodic repair/ service for the product/ components, if required;
- 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;
- 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;
- Test reports/ Test Certificates and risk assessment file for the product and/ or components as per relevant Clauses of the Indian Standard;
- Copies of conformity assessment documentation for critical product components and accessories;

2.5.2 RISK MANAGEMENT FILE- The licencee shall maintain a Risk Management File for each model of High frequency Surgical Equipment and High Frequency Surgical Accessories as per the requirement of IS 13450 (Part 2 / Sec 2): 2024. The Risk Management File shall be submitted to BIS at the time of Grant of Licence/Inclusion/Surveillance.

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

2.5.2.2 Licencee shall declare the frequency of periodic review of Risk Management File to BIS and record of review shall be maintained. In case of any change in the Risk Management File due to any periodic review/ change in the product, the licencee shall inform the same to BIS and submit the copy of the latest version of Risk Management File to BIS within 30 days of issue of the revised/ modified Risk Management File.

3. PACKING AND MARKING - The Standard Mark as given in the Schedule of the licence shall be incorporated legibly and indelibly on each High frequency Surgical Equipment and High Frequency Surgical Accessories provided always that the High frequency Surgical Equipment and High Frequency Surgical Accessories so marked conforms to each requirement of the specification.

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

3.2 **Additional Marking requirements**: The High frequency Surgical Equipment and High Frequency Surgical Accessories shall also be marked with the following additional requirement on each product and its packaging:

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

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

4. HYGIENIC CONDITIONS (if applicable) – NA.

5. REJECTION - 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**						
4.1	Conditions for application to ME EQUIPMENT or ME SYSTEMS	4.1	IS 13450 (Part 1)	R	Each Medical Equipment		Technical documentation - Compliance shall be checked by inspection of the RISK MANAGEMENT FILE.
201.4.1.101	Additional conditions for application						
4.2	Risk management process for ME equipment or ME systems	4.2.1 4.2.2 4.2.3 201.4.2.3.101	IS 13450 (Part 1) IS 13450-2-2	R			
4.3	Essential Performance	4.3	IS 13450 (Part 1)	R			
4.4	EXPECTED SERVICE LIFE	4.4	IS 13450 (Part 1)	R	Each Medical Equipment		Technical documentation - Compliance shall be checked by inspection of the RISK MANAGEMENT FILE.
4.5	Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS	4.5	IS 13450 (Part 1)	R			

4.6	ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT	4.6	IS 13450 (Part 1)	R			
4.7	SINGLE FAULT CONDITION for ME EQUIPMENT	13.1 13.2 201.4.7.101	IS 13450 (Part 1) IS 13450-2-2	S			
4.8	Components of ME EQUIPMENT	4.8	IS 13450 (Part 1)	R	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	IS 13450 (Part 1)				
4.10	**Power supply**						
4.10.1	Source of power for ME EQUIPMENT	4.10.1	IS 13450 (Part 1)	R	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	IS 13450 (Part 1)	R			
4.11	Power input	4.11 201.4.11	IS 13450 (Part 1) IS 13450-2-2	R			
201.7	**ME Equipment identification, marking and documents**						
7	ME Equipment Identification, marking and documents	7	IS 13450 (Part 1)	R	Each Medical Equipment		
201.7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts ACCESSORIES	201.7.2 201.7.2.8.2 201.7.2.10	IS 13450 (Part 1) IS 13450-2-2	R			

			201.7.2.10.101				
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts		7.3	IS 13450 (Part 1)	R		
7.4	Marking of controls and instruments		7.4 201.7.4.2	IS 13450 (Part 1)	R		
7.5	Safety signs		7.5		R		
7.6	Symbols		7.6		R	Each Medical Equipment	
7.7	Colours of the insulation of conductors		7.7	IS 13450 (Part 1)	R		
7.8	Indicator lights and controls		7.8 201.7.8.1 201.7.8.2	IS 13450 (Part 1) IS 13450-2-2	R		
7.9	ACCOMPANYING DOCUMENTS		7.9 201.7.9.2.15 201.7.9.3	IS 13450 (Part 1)	R		
201.7.9.2	Instructions for use	General	7.9.2.1	IS 13450 (Part 1)	R		
		Warning and safety notices	7.9.2.2 201.7.9.2.2.101	IS 13450 (Part 1) IS 13450-2-2	R		
		ME EQUIPMENT specified for connection	7.9.2.3	IS 13450 (Part 1)	R		

		to a separate power supply					
		Electrical power source	7.9.2.4	IS 13450 (Part 1)	R		
		ME EQUIPMENT description	7.9.2.5	IS 13450 (Part 1)	R		
		Installation	7.9.2.6	IS 13450 (Part 1)	R		
		Isolation from the SUPPLY MAINS	7.9.2.7	IS 13450 (Part 1)	R		
		Start-up PROCEDURE	7.9.2.8	IS 13450 (Part 1)	R		
		Operating instructions	7.9.2.9	IS 13450 (Part 1)	R		
		Messages	7.9.2.10	IS 13450 (Part 1)	R		
		Shutdown PROCEDURE	7.9.2.11	IS 13450 (Part 1)	R		
		Cleaning, disinfection and sterilization	7.9.2.12	IS 13450 (Part 1)	R		
		Maintenance	7.9.2.13	IS 13450 (Part 1)	R		
		ACCESSORIES, supplement	7.9.2.14 201.7.9.2.14	IS 13450 (Part 1) IS 13450-2-2	R		

		ary equipment, used material					
		Environmental protection	7.9.2.15	IS 13450 (Part 1)	R		
		Reference to the technical description	7.9.2.16	IS 13450 (Part 1)	R		
		ME EQUIPMENT emitting radiation	7.9.2.17	IS 13450 (Part 1)	R		
		ME EQUIPMENT and ACCESSORIES supplied sterile	7.9.2.18	IS 13450 (Part 1)	R		
		Unique version identifier	7.9.2.18	IS 13450 (Part 1)	R		
201.7.9.3	Technical description		201.7.9.3.1	IS 13450-2-2	R		
201.8	**Protection against electrical hazards from ME Equipment**						
8.1	Fundamental rule of protection against electric shock		8.1	IS 13450 (Part 1)	R	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)	R		
8.3	Classification of APPLIED PARTS	8.3	IS 13450 (Part 1)	R		
8.4	Limitations of voltage, current or energy	8.4	IS 13450 (Part 1)	R	One	Once in a month for each type of model manufactured during that period
201.8.4.101	NEUTRAL ELECTRODE monitoring circuit	201.8.4.101	IS 13450-2-2	R		
201.8.4.102	Neuromuscular stimulation	201.8.4.102	IS 13450-2-2	R		
8.5	**Separation of Parts**					
201.8.5.1.2	Means of Patient Protection (MOPP)	201.8.5.1.2	IS 13450-2-2	S	One	Once in a month for each type of model manufactured during that period
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)	8.5.1.2	IS 13450 (Part 1)	S		
8.5.2	Separation of PATIENT CONNECTIONS	8.5.2	IS 13450 (Part 1)	S		
201.8.5.2.3	PATIENT leads or PATIENT cables	201.8.5.2.3	IS 13450-2-2	S		
8.5.3	MAXIMUM MAINS VOLTAGE	8.5.3	IS 13450 (Part 1)	S	One	Once in a month for each type of model manufactured during that period
8.5.4	WORKING VOLTAGE	8.5.4	IS 13450 (Part 1)	S		
8.5.5.1	Defibrillation Protection	8.5.5.1	IS 13450 (Part 1)	S		
8.5.5.2	Energy Reduction Test	8.5.5.2	IS 13450 (Part 1)	S		
201.8.5.5	DEFIBRILLATION -	201.8.5.5	IS 13450-2-2	S		

	PROOF APPLIED PARTS					
8.6	**Protective earthing, functional earthing and potential equalization of ME EQUIPMENT**					
8.6.1	Applicability of requirements	8.6.1 201.8.6.1	IS 13450 (Part 1) IS 13450-2-2	R	One	Once in a month for each type of model manufactured during that period
8.6.2	PROTECTIVE EARTH TERMINAL	8.6.2	IS 13450 (Part 1)	R		
8.6.3	Protective earthing of moving parts	8.6.3	IS 13450 (Part 1)	R		
8.6.4	Impedance and current-carrying capability	8.6.4	IS 13450 (Part 1)	R		
8.6.5	Surface Coatings	8.6.5	IS 13450 (Part 1)	R		
8.6.6	Plugs and sockets	8.6.6	IS 13450 (Part 1)	R		
8.6.7	POTENTIAL EQUALIZATION CONDUCTOR	8.6.7	IS 13450 (Part 1)	R		
8.6.8	FUNCTIONAL EARTH TERMINAL	8.6.8	IS 13450 (Part 1)	R		
8.6.9	CLASS II ME EQUIPMENT	8.6.9	IS 13450 (Part 1)	R		
8.7	**LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS**					
8.7.1	General Requirements	8.7.1 201.8.7.1	IS 13450 (Part 1) IS 13450-2-2	S	One	Once in a month for each type of model manufactured during that period
8.7.2	SINGLE FAULT CONDITIONS	8.7.2	IS 13450 (Part 1)	S		
8.7.3	Allowable values	8.7.3 201.8.7.3 201.8.7.3.101	IS 13450 (Part 1) IS 13450-2-2	S		
8.7.4	Measurements	8.7.4	IS 13450 (Part 1)	S		

8.8	**Insulation**					
8.8.2 201.8.8.2	Distance through solid insulation or use of thin sheet material	8.8.2 201.8.8.2	IS 13450 (Part 1) IS 13450-2-2	R	One	Once in a month for each type of model manufactured during that period
8.8.3 201.8.8.3	Dielectric strength	8.8.2 201.8.8.3	IS 13450 (Part 1) IS 13450-2-2	R		
201.8.8.3.101	ACTIVE ACCESSORY insulation	201.8.8.3.101	IS 13450-2-2			
201.8.8.3.102	ACTIVE ACCESSORY HF leakage	201.8.8.3.102	IS 13450-2-2			
201.8.8.3.103	ACTIVE ACCESSORY HF dielectric strength	201.8.8.3.103	IS 13450-2-2			
201.8.8.3.104	ACTIVE ACCESSORY mains frequency dielectric strength	201.8.8.3.104	IS 13450-2-2			
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)	S	One	Once in a month for each type of model manufactured during that period
8.8.4.2	Resistance to environmental stress	8.8.4.2	IS 13450 (Part 1)	S	One	
8.9	**CREEPAGE DISTANCES and AIR CLEARANCES**					
8.9.1 201.8.9.1.5	Values ME EQUIPMENT RATED for high altitudes	8.9.1 201.8.9.1.5	IS 13450 (Part 1) IS 13450-2-2	S	One	Once in a month for each type of model manufactured during that period
8.9.2	Applications	8.9.2	IS 13450 (Part 1)	S		

8.9.3	Spaces filled by insulating compound	8.9.3	IS 13450 (Part 1)	S			
8.9.4	Measurement of CREEPAGE DISTANCES AND AIR CLEARANCES	8.9.4	IS 13450 (Part 1)	S			
8.10	**Components and wiring**						
8.10.1	Fixing of components	8.10.1	IS 13450 (Part 1)	R			
8.10.2	Fixing of wiring	8.10.2	IS 13450 (Part 1)	R			
8.10.3	Connections between different parts of ME EQUIPMENT	8.10.3	IS 13450 (Part 1)	R			
8.10.4	Cord-connected HAND-HELD parts and cord- connected foot-operated control devices	8.10.4	IS 13450 (Part 1)	R			Subclause 8.10.4.1 of the IS 13450-1 does not apply.
201.8.10.4.2	Connection cords	201.8.10.4.2	IS 13450-2-2	R			
201.8.10.4.101	SWITCH SENSORS						
	General	201.8.10.4.101.1	IS 13450-2-2	R			
	Non-continuous activation	201.8.10.4.101.2	IS 13450-2-2	R			
	Impedance sensing activation	201.8.10.4.101.3	IS 13450-2-2	R			
	Footswitches	201.8.10.4.101.4	IS 13450-2-2	R			
8.10.5	Mechanical protection of wiring	8.10.5	IS 13450 (Part 1)	R			
8.10.6	Guiding rollers for insulated conductors	8.10.6	IS 13450 (Part 1)	R			

8.10.7	Insulation of internal wiring	8.10.7	IS 13450 (Part 1)	R			
8.11	**MAINS PARTS, components and layout**						
8.11.1	Isolation from Supply mains	8.11.1	IS 13450 (Part 1)	R	One	Once in a month for each type of model manufactured during that period	
8.11.2	Multiple Socket Outlets	8.11.2	IS 13450 (Part 1)	R			
8.11.3	**Power Supply Cords**						
8.11.3.1	Application	8.11.3.1	IS 13450 (Part 1)	R	One	Once in a month for each type of model manufactured during that period	
8.11.3.2	Types	8.11.3.2	IS 13450 (Part 1)	R			
8.11.3.3	Cross-sectional area of POWER SUPPLY CORD conductors	8.11.3.3	IS 13450 (Part 1)	R			
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	R			
8.11.4	Mains terminal devices	8.11.4	IS 13450 (Part 1)	R			
8.11.5	Mains fuses and over current releases	8.11.5	IS 13450 (Part 1)	R			
8.11.6	Internal wiring of the Mains Part	8.11.6	IS 13450 (Part 1)	R			
201.9	**Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS**						
9.1	MECHANICAL HAZARDS of ME	9.1	IS 13450 (Part 1)	S	One	Once in a month for each type of model manufactured during that period	

	EQUIPMENT					
9.2	MECHANICAL HAZARDS associated with moving parts	9.2	IS 13450 (Part 1)	S	One	
9.3	MECHANICAL HAZARD associated with surfaces, corners and edges	9.3	IS 13450 (Part 1)	S	One	
9.4	Instability HAZARDS	9.4,	IS 13450 (Part 1)	S	One	Once in a month for each type of model manufactured during that period
9.5	Expelled parts HAZARD	9.5	IS 13450 (Part 1)	S	One	
9.6	Audible acoustic energy	9.6	IS 13450 (Part 1)	S	One	
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure	9.7	IS 13450 (Part 1)	S	One	
9.8	MECHANICAL HAZARDS associated with support systems	9.8	IS 13450 (Part 1)	S	One	
201.10	**Protection against unwanted and excessive radiation HAZARDS**					
10.1	X-Radiation	10.1	IS 13450 (Part 1)	S	One	Once in every three years for each type of model manufactured during that period
10.2	Alpha, beta, gamma, neutron and other particle radiation	10.2	IS 13450 (Part 1)	S	One	
10.3	Microwave radiation	10.3	IS 13450 (Part 1)	S	One	

10.4	Lasers	10.4	IS 13450 (Part 1)	S	One	
10.5	Other visible electromagnetic radiation	10.5	IS 13450 (Part 1)	S	One	
10.6	Infrared radiation	10.6	IS 13450 (Part 1)	S	One	
10.7	Ultraviolet radiation	10.7	IS 13450 (Part 1)	S	One	
201.11	**Protection against excessive temperatures and other HAZARDS**					
11.1	Excessive temperatures in ME EQUIPMENT	11.1	IS 13450 (Part 1)	S	One	Once in a moth for each type of model manufactured during that period
201.11.1.1	Maximum temperature during NORMAL USE	201.11.1.1	IS 13450-2-2	S		
201.11.1.2.1	APPLIED PARTS intended to supply heat to a PATIENT	201.11.1.2.1	IS 13450-2-2	S		
201.11.1.2.2	APPLIED PARTS not intended to supply heat to a PATIENTx	201.11.1.2.2	IS 13450-2-2	S		
11.2	Fire Prevention	11.2	IS 13450 (Part 1)	S	One	
11.3	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT	11.3	IS 13450 (Part 1)	S	One	
11.4	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics	11.4	IS 13450 (Part 1)	S	One	

11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents	11.5	IS 13450 (Part 1)	S	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)	R	One		
201.11.6.3	Spillage on ME EQUIPMENT and ME SYSTEMS	201.11.6.3	IS 13450-2-2	R	One		
201.11.6.5	Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS	201.11.6.5	IS 13450-2-2	R	One		
201.11.6.7	Sterilization of ME EQUIPMENT and ME SYSTEMS	201.11.6.7	IS 13450-2-2	R	One		
11.7	Biocompatibility of ME EQUIPMENT and ME SYSTEMS	11.7	IS 13450 (Part 1)	R	One	Once in 03 years	
11.8	Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT	11.8	IS 13450 (Part 1)	R	Every Medical Equipment		

201.11.8	Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT	201.11.8	IS 13450-2-2	R	Every Medical Equipment	
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)	R	Each Medical Equipment	
201.12.1.101	Accuracy of output control setting	201.12.1.101	IS 13450-2-2	R		
201.12.1.102	Monotonicity of output control setting	201.12.1.102	IS 13450-2-2	R		
201.12.1.103	Accuracy of MAXIMUM OUTPUT VOLTAGE	201.12.1.103	IS 13450-2-2	R		
12.2	USABILITY of ME EQUIPMENT	12.2 201.12.2	IS 13450 (Part 1) IS 13450-2-2	R		
12.3	ALARM SYSTEMS	12.3	IS 13450 (Part 1)	R		
12.4	Protection against hazardous output	12.4.1 to 12.4.4	IS 13450 (Part 1)	S	One	Once in a month for each type of model manufactured during that period
201.12.4.2	Indication relevant to safety	201.12.4.2	IS 13450-2-2	S		
201.12.4.101	Use of HIGH CURRENT MODE	201.12.4.101	IS 13450-2-2	S		
201.12.4.2.101	Output indicator	201.12.4.2.101	IS 13450-2-2	S		
201.12.4.3.101	Output reduction means	201.12.4.3.101	IS 13450-2-2	S		
201.12.4.4.101	Maximum allowed output power in SINGLE FAULT	201.12.4.4.101	IS 13450-2-2	S		

201.12.4.4.102	CONDITIONS Output power during simultaneous activation	201.12.4.4.102	IS 13450-2-2	S			
201.13	**HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT**						
13	HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	13	IS 13450 (Part 1)	S	One	Once in a month for each type of model manufactured during that period	
201.13.2.13.101	Protection against the effects of short-circuiting of the electrodes	201.13.2.13.101	IS 13450-2-2	S	One		
201.14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**						
14	Programmable Electrical Medical Systems (PEMS)	14	IS 13450 (Part 1)	S	One	Once in 03 years	For each type of model manufactured during the period
201.15	**Construction of ME EQUIPMENT**						
15.1	Arrangements of controls and indicators of ME EQUIPMENT	15.1	IS 13450 (Part 1)	S	One	Once in every six month for each type of model manufactured during that period	
15.2	Serviceability	15.2	IS 13450 (Part 1)	S			
15.3	Mechanical strength	15.3	IS 13450 (Part 1)	S	One	Once in every six month for each type of model manufactured during that period	
15.4	Indicators	15.4	IS 13450 (Part 1)	S	One	Once in every six month for each type of model manufactured during that period	
201.15.4.1.101	Compatibility with third party ACTIVE ELECTRODES	201.15.4.1.101	IS 13450-2-2	S	One	Once in every six month for each type of model manufactured during that period	
201.15.4.1.102	Retention of detachable ACTIVE	201.15.4.1.102	IS 13450-2-2	S	One	Once in every six month for each type of model manufactured during that period	

	ELECTRODES						
201.15.101	NEUTRAL ELECTRODES	201.15.101	IS 13450-2-2	S	One	One	Once in a month for each type of model manufactured during that period
201.15.101.1	General requirements for NEUTRAL ELECTRODES	201.15.101.1	IS 13450-2-2	S	One		
201.15.101.2	NE cord attachment	201.15.101.2	IS 13450-2-2	S	One		
201.15.101.3	NE cord connector	201.15.101.3	IS 13450-2-2	S	One		
201.15.101.4	NE cord insulation	201.15.101.4	IS 13450-2-2	S	One		
201.15.101.5	NE thermal performance	201.15.101.5	IS 13450-2-2	S	One One		
201.15.101.6	NE contact impedance	201.15.101.6	IS 13450-2-2	S			
201.15.101.7	NE adhesion	201.15.101.7	IS 13450-2-2	S	One		
201.15.101.8	NE shelf life	201.15.101.8	IS 13450-2-2	S	One		
201.15.101.9	Adult NEUTRAL ELECTRODES for conventional procedures	201.15.101.9	IS 13450-2-2	S	One One		
201.16	**ME SYSTEMS**						
16	ME SYSTEMS	16	IS 13450 (Part 1)	S	Each Medical Equipment		Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
201.17	**Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS**						
17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	17	IS 13450 (Part 1)	S	One	Once in 03 years	For each type of manufactured during the period
202	**Electromagnetic disturbances – Requirements and tests**						

202	Electromagnetic disturbances – Requirements and tests	202	IS 13450-1-2	S	One	Once in 03 years	For each type of model manufactured during the period
202.5.2.2.4	Requirements applicable to ME EQUIPMENT that includes RF transmitters	202.5.2.2.4	IS 13450-2-2	S			
202.5.2.2.6	Requirements applicable to ME EQUIPMENT that includes RF transmitters	202.5.2.2.6	IS 13450-2-2	S			
202.7	ELECTROMAGNETIC EMISSIONS requirements for ME EQUIPMENT and ME SYSTEMS	202.7	IS 13450-2-2	S			
202.8	Electromagnetic IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS	202.8	IS 13450-2-2	S			
208	General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	208	IS 13450-1-8	S	One	Once in 03 years	For each type of model manufactured during the period