उत्पाद मैन्युअल

आई एस 13450 (भाग 2/अनुभाग 25):2018 / आई इ सी 60601-2-25:2011 के अनुसार चिकित्सीय विद्युत उपस्कर भाग 2 बुनयादी सुरक्षा और आवश्यक कार्य निष्पादन के लिए विशेष आवश्यकताएं अनुभाग 25 इलेक्ट्रोकार्डिओग्राफ्स के लिए

दस्तावेज़ संख्या – पी एम/ आई एस 13450(भाग 2/अनुभाग 25) /2/ दिसम्बर 2021

भारतीय मानक ब्यूरो की स्कीम-I (अनुरूपता मूलयाांकन) 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

Medical Electrical Equipment - Particular Requirements for the Basic Safety and Essential Performance - Electrocardiographs ACCORDING to IS 13450 (Part 2/ Sec 25): 2018/ IEC 60601-2-25: 2011

Document No.- PM/IS 13450(Part 2/Sec 25)/2/Dec 2021

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 -PARTICULAR REQUIREMENTS FOR THE BASIC SAFETY AND ESSENTIAL PERFORMANCE- ELECTROCARDIOGRAPHS ACCORDING TO IS 13450 (PART 2/SECTION 25):2018

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.

1.	**Product**	:	IS 13450 (Part 2/ Sec 25): 2018
	Title	:	Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 25 Electrocardiographs
	No. of Amendments	:	Nil
2.	**Sampling Guidelines:**		
a)	**Raw material**	:	Nil
b)	**Grouping guidelines**	:	Nil
c)	**Sample Size**	:	2 Nos. with accessories
d)	**Sampling for Surveillance**		Two Factory Samples [with sample size as mentioned at 2(c) above] to be drawn (No Market Sample) during an operative period of one year for all tests except EMC test. Licensee shall get the sample tested for EMC as per SIT and submit the test report to BIS for record
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:**	:	Please refer ANNEX –C
6.	**Scope of the Licence:**	:	Please refer ANNEX - D

BUREAU OF INDIAN STANDARDS
Manak Bhawan, 9, Bahadur Shah Zafar
Marg, New Delhi – 110002

ANNEX A

List of Test Equipment

Major test equipment required to test as per the Indian Standard

Sl. No.	Tests used in with Clause Reference	Test Equipment
1.	Humidity preconditioning treatment, 5.7	Conditioning chamber with temperature and humidity chamber
2.	Legibility of markings, 7.1.2	Angle Protractor, Steel tape
3.	Durability of markings, 7.1.3	Distilled water, ethanol 96%, Isopropyl alcohol, Stop watch
4.	Earth Leakage Current, 8.7.4.5, Touch Current, 8.7.4.6, Patient Leakage Current, 8.7.4.7	Figure 13 to Figure 18, Leakage Current Tester, metal foil, Test Pin as per Figure 8 or a particular tool as specified by manufacturer.
5.	Defibrillation Protection, 201.8.5.5.1	Defibrillator, Function generator
6.	Energy reduction test, 201.8.5.5.2	Defibrillator, HV source, set up as per Fig 201.104
7.	Impedance and current carrying capability, 8.6.4	AC/DC voltage source, multimeter
8.	Dielectric Strength, 8.8.3	High Voltage Tester
9.	Thermal Cycling Test, 8.9.3.4	Oven
10.	Requirements for amplitude and interval measurements, 201.12.1.101.2 and 201.12.1.101.3, Frequency response (201.12.4.107.1), Printing, electronic storage and transmission (201.12.4.108)	Simulator, Function Generator
11.	Indication of inoperable ECG (201.12.4.101), Leads (201.12.4.102), Noise level (201.12.4.106.1)	Function Generator, DC source, Timer/Stop watch, set up as per Fig 201.106
12.	Input impedenace , (201.12.4.103), Overload tolerance (201.12.4.105.2), Channel crosstalk (201.12.4.106.2)	Function Generator, setup as per Fig 201.106
13.	Common Mode Rejection, 201.12.4.105.1, Overload tolerance, 201.12.4.105.2	Function Generator, DC source, set up as per Fig 201.105
14.	Linearity and dynamic range, 201.12.4.107.2	Set up as per Fig 201.109
15.	Use with cardiac pacemakers, 201.12.4.109	Function generator, Pacemaker pulse generator, set up as per Fig 201.111

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 requirement of IS 13450(Part 2/Sec 25):2018

4. CONTROL UNIT –All ECG machines of same type manufactured in a day or 08 hours whichever is less 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.

7. 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							
4.2	Risk management process for ME equipment or ME systems	4.2	IS 13450 (Part 1)	-	Refer note 1		
201.5 General requirements for testing of ME Equipment							
5.9	Applied parts and accessible parts	5.9.1, 5.9.2	IS 13450 (Part 1)	S	One	05 years	Refer note 1
201.7 ME Equipment identification, marking and documents							
7	ME Equipment Identification, marking and documents	7.1.2, 7.1.3	IS 13450 (Part 1)	R	One	Every control unit	-
201.8 Protection against electrical hazards from ME Equipment							
8.1 13.2.2	Fundamental rule of protection against electric shock.	8.1	IS 13450 (Part 1)	R	One	Every control unit	-
8.4 Limitation of voltage, current or energy							
8.4.2 (a)	The currents from, to or between Patient connections.	8.4.2, 8.7.4	IS 13450 (Part 1)	R	One	Every control unit	-
8.4.2 (b)	The Leakage Currents from, to or between Accessible parts.						
8.4.2 (c)	Other accessible parts	8.4.2	IS 13450 (Part 1)	S	One	05 years	Refer note 1
8.4.2 (d)	Internal parts that are accessible	8.4.2					
8.4.3	ME equipment intended to be connected to a power source by a plug	8.4.3					
8.4.4	Internal capacitive circuits	8.4.4					

8.5 Separation of Parts							
8.5.1 Means of Protection (MOP)							
8.5.1.1	General						
	Fixing of components	8.10.1	IS 13450 (Part 1)	S	One	05 Years	Refer note 1
	Fixing of wiring	8.10.2					
	Connections between different parts of ME Equipment	8.10.3 or 5.9.2.1					
	Limitation of operating voltages	8.10.4.1					
	Connection Cords	8.11.3					
	Mechanical protection of wiring	8.10.5					
	Guiding rollers for insulated conductors	8.10.6					
	Insulation of internal winding	8.10.7, 11.1					
8.5.1.2 Means of Patient Protection (MOPP)							
8.5.1.2	Distance through solid insulation or use of thin sheet material	8.8.2, 8.8.3 or Annex L	IS 13450 (Part 1)	S	One	05 years	Refer note 1
	Dielectric Strength	8.8.3	IS 13450 (Part 1)	R	One	Every control unit	-
	Protective Earth Terminal	8.6.2 and 8.11.4.3					
	Protective earthing of moving parts	8.6.3					
	Impedance and current-carrying capability	8.6.4					
	Surface coatings	8.6.5					
	Plugs and sockets	8.6.6					
	Potential equalization conductor	8.6.7					
	Functional Earth Terminal	8.6.8					
	Class II ME Equipment	8.6.9, 8.8	IS 13450 (Part 1)	S	One	05 years	Refer note 1
8.5.1.3, Means of Operator Protection (MOOP)							
8.5.1.3	Solid insulation	8.5.1.3, 8.8.3	IS 13450 (Part 1)	R	One	Every control unit	-
	Creepage Distances and Air Clearances	8.5.1.3, 8.9.1, Table 13 to 16	IS 13450 (Part 1)	S	One	05 years	Refer note 1
	Protective earth connections	8.5.1.3, 8.6	IS 13450 (Part 1)	R	One	Every control unit	-

8.5.2	Separation of Patient Connections	8.5.2, 201.8.5.2.3	IS 13450 (Part 1) IS 13450 (Part 2/Sec 25)	R	One	Every control unit	-
8.5.5.1	Defibrillation Protection	8.5.5.1, 201.8.5.5.1	IS 13450 (Part 1) IS 13450 (Part 2/Sec 25)	R	One	Every control unit	-
8.5.5.2	Energy Reduction Test	8.5.5.2, 201.8.5.5.2					
8.8.4.1	Resistance to heat, General Overload test conditions	8.8.4.1	IS 13450 (Part 1)	S	One	Every month	-
8.8.4.2	Resistance to environmental stress	8.8.4.2					
8.9.3	Spaces filled with insulating compounds	8.9.3					
8.11.1	Isolation from Supply mains	8.11.1	IS 13450 (Part 1)	S	One	05 years	Actuator of supply mains switch shall comply with IEC 60447. No further testing is required if accompanied with Test certificate from supplier with each consignment.
8.11.2	Multiple Socket Outlets	8.11.2, 16.9.2.1	IS 13450 (Part 1)	S	One	05 years	Refer note 1
8.11.3	Power Supply Cords	8.11.3.2 to 8.11.3.3	IS 13450 (Part 1)	S	One	Every consignment received.	No further testing is required if accompanied with test certificate from the supplier.

8.11.3.4	Appliance Couplers	8.11.3.5, 8.11.3.6	IS 13450 (Part 1) Or IS/IEC 60320-1	S	One	Every consignment received	No further testing is required if accompanied with test certificate from the supplier
8.11.3.5	Cord anchorage	8.11.3.5	IS 13450 (Part 1)	S	One	05 years	Refer note 1
8.11.3.6	Cord guards	8.11.3.6 or 25.14	IS 13450 (Part 1) or IEC 60335-1	S	One	05 years	Refer note 1
8.11.4	Mains terminal devices	8.11.4	IS 13450 (Part 1)	S	One	05 years	Refer note 1
8.11.5	Mains fuses and over current releases	8.11.5					
8.11.6	Internal wiring of the Mains Part	8.11.6					
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 9.2.2.5	IS 13450 (Part 1)	S	One	05 years	Refer note 1
9.2.3	Other mechanical hazards associated with moving parts	9.2.3					
9.2.4	Emergency stopping devices	9.2.4					
9.2.5	Release of patient	9.2.5	IS 13450 (Part 1)	S	One	05 years	Refer note 1
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)	S	One	05 years	Refer note 1
9.5.2	Cathode Ray Tubes	9.5.2, 18	IS 13450 (Part 1), IEC 60065:2001 or IEC 61965				
9.6 Acoustic energy (including infra- and ultrasound)							
9.6.2.1	Audible acoustic energy	9.6.2.1	IS 13450 (Part 1)	S	One	05 years	Refer note 1

			Or ISO 3746, ISO 9614-1, IS 15575 (Part 1)				
9.6.2.2	Infrasound and ultrasound energy	9.6.2.2	IS 13450 (Part 1)	S	One	05 years	Refer note 1
9.6.3	Hand transmitted vibration		IS/ISO 5349-1	S	One	05 years	Refer note 1
9.7	Pressure vessels and parts subjected to pneumatic and hydraulic pressure	9.7	IS 13450 (Part 1)	S	One	05 years	No further testing is required, if accompanied with test certificate.
9.8	Mechanical hazards associated with support system	9.8	IS 13450 (Part 1)	S	One	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)	S	One	01 year	Refer note 1
10.1.2	ME equipment intended to produce diagnostic or therapeutic X-radiation	10.1.2					
10.2	Alpha, Beta, Gamma, Neutron and other particle radiation	10.2					
10.3	Microwave radiation	10.3	IS 13450 (Part 1)	S	One	01 year	Refer note 1
10.4	Lasers	-	IEC 60825-1	S	One	01 year	Refer note 1
10.5	Other visible electromagnetic radiation	10.5	IS 13450 (Part 1)	S	One	01 year	Refer note 1
10.6	Infrared radiation	10.6					
10.7	Ultraviolet radiation	10.7					
201.11 Protection against excessive temperatures and other hazards							
11.1	Excessive temperatures in ME Equipment	11.1	IS 13450 (Part 1)	S	One	05 years	Refer note 1
11.2	Fire prevention	11.2.1, 11.2.2, 15.3					
11.3	Constructional requirements for fire enclosures	-	IEC 60695-11-10	S	One	05 years	Refer note 1

11.4	ME equipment and ME systems intended for use with flammable anaesthetics	Annex G	IS 13450 (Part 1)	S	One	05 years	Refer note 1
11.5	ME equipment and ME systems intended for use in conjunction with flammable agents	11.5	IS 13450 (Part 1)	S	One	05 years	Refer note 1
11.6.2	Overflow in ME equipment	11.6.2					
11.6.3	Spillage on ME equipment and ME systems	11.6.3					
11.6.4	Leakage	13.2.6					
11.6.5	Ingress of water and particulate matter	-	IS/IEC 60529	S	One	05 years	Refer note 1
11.6.6	Cleaning and disinfection	11.6.6	IS 13450 (Part 1)	S	One	05 years	Refer note 1
11.6.7	Sterilization	11.6.7	IS 13450 (Part 1)	S	One	05 years	To be assessed and documented according to ISO 11135-1, ISO 11137-1 or ISO 17665-1.
11.6.8	Compatibility with substances used with ME equipment	11.6.8	IS 13450 (Part 1)	S	One	05 years	Refer note 1
11.7	Biocompatibility	11.7	IS 13450 (Part 1)	S	One	05 years	Assessed and documented according to guidance and principles of ISO 10993 series of standards. No further testing is required if received with test certificate from the supplier.

11.8	Interruption of power supply/supply mains	11.8	IS 13450 (Part 1)	S	One	05 years	Refer note 1
201.12 Accuracy of controls and instruments and protection against hazardous outputs							
12.1	Requirements for amplitude measurements	201.12.1.101.2	13450 (Part 2/ Sec 25)	R	One	Every control unit	-
	Requirements for absolute interval and wave duration measurements	201.12.1.101.3.1					
	Requirements for interval measurements on biological ECGs	201.12.101.3.2					
12.2	Usability	-	IEC 60601-1-6	S	One	05 years	Refer note 1
12.3	Alarm Systems	-	IEC 60601-1-8	S	One	05 years	Refer note 1
12.4	Protection against hazardous output	12.4	IS 13450 (Part 1)	S	One	05 years	Refer note 1
201.12.4.101	Indication of inoperable ECG	201.12.4.101	13450 (Part 2/ Sec 25)	R	One	Every control unit	-
201.12.4.102	Leads	201.12.4.102					
201.12.4.103	Input Impedence	201.12.4.103					
201.12.4.104	Required Gains	201.12.4.104	13450 (Part 2/ Sec 25)	R	One	Every control unit	-
201.12.4.105	Reduction of the effects of unwanted external voltages	201.12.4.105					
201.12.4.106	Baseline	201.12.4.106					
201.12.4.107 Distortion							
201.12.4.107.1	Frequency Response	201.12.4.107.1.1 or 201.12.4.107.1.2	13450 (Part 2/ Sec 25)	R	One	Every control unit	-
201.12.4.107.2	Linearity and dynamic range	201.12.4.107.2					
201.12.4.107.3	Sampling and amplitude quantisation during data acquisition	201.12.4.107.3	13450 (Part 2/ Sec 25)	R	One	Every control unit	-
201.12.4.108	Printing, electronic storage and transmission	201.12.4.108					
201.12.4.109	Use with cardiac pacemakers	201.12.4.109					
201.13 Hazardous Situations and Fault Conditions							
13.1	Specific hazardous situation	13.1.2,11.1.3	13450 (Part 1)	S	One	05 years	Refer note 1
13.2 Single Fault conditions							
13.2.3	Overheating of transformers	15.5.1	13450 (Part 1)	S	One	05 years	Refer note 1
13.2.4	Failure of Thermostats	13.2.13, 15.4.2					
13.2.5	Failure of temperature limiting devices	13.2.13, 15.4.2					
13.2.6	Leakage of liquid	13.2.6					

13.2.7	Impairment of cooling that could result in a hazardous situation	13.2.7					
13.2.8	Locking of moving parts	13.28					
13.2.9	Interruption and short circuiting of motor capacitors	13.2.9					
13.2.10	Additional test criteria for motor operated ME Equipment	13.2.10					
13.2.11	Failures of components in ME equipment used in conjunction with oxygen rich Environments	13.2.11					
13.2.12	Failure of parts that might result in a Mechanical hazard	9, 15.3					
14	Programmable Electrical Medical Systems (PEMS)	14, 1.4	13450 (Part 1) IEC 62304:2006	S	One	05 years	Refer note 1
15.1	Arrangements of controls and indicators	-	IEC 60601-1-6	S	One	05 years	Refer note 1
15.2	Serviceability	15.2	13450 (Part 1)	S	One	05 years	Refer note 1
15.3	Mechanical Strength	15.3					
15.4	Components and general assembly	15.4					
15.5	Transformers in ME Equipment	15.5					
16	ME Systems	16					
17	Electromagnetic compatibility	17, 202	IS 13450 (Part 1), 13450 (Part 2/ Sec 25), IEC 60601-1-2:2007	S	One	05 years	Refer note 1

Note-1: The test shall be done whenever there is a change in design or change in the material/ components.
Note-2: Sub-contracting is permitted to a laboratory recognized by the Bureau or Government laboratories empanelled by the Bureau.
Note-3: Levels of control given in column 3 are only recommendatory in nature. The manufacturer may define the control unit/batch/lot and submit his own levels of control in column 3 with proper justification for approval by BO Head.

ANNEX C

Possible tests in a day

1. Defibrillation Protection, Cl 201.8.5.5.1
2. Energy reduction test, Cl 201.8.5.5.2
3. Requirements for amplitude measurements, Cl 201.12.1.101.2
4. Requirements for interval measurements, Cl 201.12.1.101.3
5. Indication of inoperable ECG, Cl 201.12.4.101
6. Leads, Cl 201.12.4.102
7. Input impedance, Cl 201.12.4.103
8. Required Gains, Cl 201.12.4.104
9. Reduction of the effects of unwanted external voltage, Cl 201.12.4.105
10. Baseline, Cl 201.12.4.106
11. Distortion, Cl 201.12.4.107

ANNEX D

Scope of Licence

"Licence is granted to use Standard Mark as per IS 13450 (Part 2/Sec 25):2018 with the following scope:	
Name of the product:	Medical Electrical Equipment: Electrocardiographs- Requirements for Basic safety and essential performance
Model:	
Type:	12/6/3/2 Lead Wires, ……V AC/DC Supply, ...Hz, Continuous Operation, Pollution Degree
Protection against electric shock:	Class I/Class II
Protection against harmful ingress of water or particulate matter:	IP..
Suitability for use in oxygen rich environment:	Suitable/ Not suitable