उत्पाद मैन्युअल

आई एस 13450 (भाग 2 / अनुभाग 37) : 2019 / आईईसी 60601-2-37 : 2007 के अनुसार चिकित्सीय विद्युत् उपस्कर भाग 2 बुनियादी सुरक्षा और आवश्यक कार्य निष्पादन के लिए विशेष आवश्यकताएं अनुभाग 37 अल्ट्रासोनिक चिकित्सा नैदानिक और निगरानी उपकरण के लिए

दस्तावेज़ संख्या – पीएम/आईएस 13450(भाग 2 / अनुभाग 37) /1/ अगस्त 2023

भारतीय मानक ब्यूरो की स्कीम-I (अनुरूपता मूल्यांकन) विनियम, 2018 के तहत यह उत्पाद मैन्युअल प्रमाणीकरण के प्रचालन में रीति और पारिशीता 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 37 ULTRASONIC MEDICAL DIAGNOSTIC AND MONITORING EQUIPMENT ACCORDING TO IS 13450 (Part 2 / Sec 37): 2019 / IEC 60601-2-37 : 2007

Document No - PM/IS 13450 (Part 2/ Sec 37)/ IEC 60601-2-37/1/August 2023

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.

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PRODUCT MANUAL FOR

MEDICAL ELECTRICAL EQUIPMENT -PARTICULAR REQUIREMENTSFOR THE BASIC SAFETY AND ESSENTIAL PERFORMANCE- X-RAY EQUIPMENT FOR ULTRASONIC MEDICAL DIAGNOSTIC AND MONITORING EQUIPMENT

ACCORDING TO IS 13450 (PART 2/SECTION 37) : 2019/ IEC 60601-2-37 : 2007

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 37): 2019/ IEC 60601-2-37 : 2007
	Title	:	Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 37 - Ultrasonic medical diagnostic and monitoring equipment
	No. of Amendment	:	0
2.	**Sampling Guidelines:**		
a)	**Raw material**	:	Nil
b)	**Grouping guidelines**	:	Nil
c)	**Sample Size**	:	1 Unit
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**	:	As per below:

"Licence is granted to use Standard Mark as per IS 13450 (Part 2/ Sec 37) : 2019/ IEC 60601-2-37 : 2007 with the following scope:	
Name of the product:	Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 37 - Ultrasonic medical diagnostic and monitoring equipment
Model No.:	
Type:	Mobile/ Portable
Rating:	Rated line voltage _____V, Frequency _____ Hz, ____ phase, Current _____ A, Rated Peak Output Voltage _____V, Output power _____ W
Maximum No. of probe	Upto …. probes
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	Multimeter, Current Meter/ Electrical Safety Analyzer
5.	ACCESSIBLE PARTS and APPLIED PARTS, 8.4.2	Multimeter/ Electrical Safety Analyzer
6.	Leakage currents and patient auxiliary currents, 8.7	Multimeter, Isolation Transformer
7.	Allowable values, 8.7.3	Multimeter/ Electrical Safety Analyzer
8.	Insulation 8.8.1	Insulation resister meter
9.	Distance through solid insulation or use of thin sheet material 8.8.2	Insulation resister meter
10.	Dielectric Strength 8.8.3	HV Test
11.	Insulation other than wire insulation 8.8.4	Insulation resister meter, HV Test
12.	Protection against Mechanical Hazards of ME Equipment and ME Systems, 9	Risk management File
13.	HAZARDS associated with moving parts 9.2.1 to 9.2.5	Risk management File
14.	Other mechanical hazards associated with moving parts, 9.2.3.1, 9.2.3.2	Visual Inspection
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.	Acoustic energy (including infra- and ultrasound),9.6	Visual Inspection, Risk Management File

18.	Protection against excessive temperatures and other hazards, 201.11	Data logger
19.	Fire prevention, 11.2, 11.2.1	Risk Management file, Visual Inspection, Spark Ignition test apparatus as per Cl. 11.2.2.1
20.	Constructional requirements for fire enclosures, 11.3	Visual Inspection, Risk management File
21.	Cleaning and disinfection, 11.6.6	Risk management File and accompanying documents
22.	Compatibility with substances used with ME equipment, 11.6.1	Risk management File
23.	Interruption of power supply/supply mains, 11.8	Multi meter, Risk management
24.	Accuracy of controls and instruments and protection against hazardous outputs,201.12, Accuracy of controls & Instruments, 12.1	Risk management File and accompanying documents
25.	Protection against hazardous output, 12.4	Risk management
26.	Hazardous Situations and Fault Conditions, 13, 201.13	Risk management File and accompanying documents
27.	Specific hazardous situation,13.1	Risk management File, Design Document
28.	Single Fault conditions, 13.2	Electrical Safety Analyzer/Isolation Transformer
29.	Mechanical Strength, 15.3	Visible Inspection, setup as per Cl. 15.3 of IS 13450(Part 1)
30.	Components and general assembly, 15.4	Visual Inspection
31.	Temperature and overload control devices, 15.4.2	Risk management File and accompanying documents
32.	Transformers in ME Equipment, 15.5	Visual Inspection
33.	Overheating of transformers, 15.5.1	thermometer/ thermocouple

Note 1: The above list is indicative only and may not be treated as exhaustive.

Note 2: The licencee shall maintain a Technical File as specified in Annex –B for each model being in the scope of licence.

Note 3: The licencee shall maintain a Risk Management File as per the provisions of IS 13450 (Part 2/ Sec 37) : 2019/ IEC 60601-2-37 : 2007 for each model in the scope of licence.

Note 4: The Technical File and Risk Management File shall be maintained by the licencee till the End of Life for the model.

Note 5: The Technical File and the Risk Management File is to be submitted to BIS at the time of Grant of Licence/ Inclusion/ 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 – The Standard Mark as given in the Schedule of the licence shall be incorporated legibly and indelibly on each appliance and also on its packaging.

3.1 Marking and Labelling shall be as per the requirement of IS 13450(Part 2/Sec 37) : 2019/ IEC 60601-2-37 : 2007.

3.2 In addition, the licence no. CM/L-_____ and details of BIS website shall be marked at an appropriate place as follows: "For details of BIS certification please visit www.bis.gov.in".

4. CONTROL UNIT – Each Ultrasonic medical diagnostic and monitoring equipment 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 paragraph 2.

6. 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.

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

6.2 Licencee 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 licencee 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.

6.3 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.

6.4 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;
- Copy of BIS licences for the product/ components, wherever applicable;
- A copy of the Declaration of Conformity for other International Standards;
- Other documents, if found necessary by the manufacturer and/ or by BIS may also be a part of the Technical File.

7. RISK MANAGEMENT FILE - The licencee shall maintain a Risk Management File for each model in the scope of licence as per the requirement of IS 13450 (Part 2/ Sec 37) : 2019/IEC 60601-2-37 : 2007. The Risk Management File shall be submitted to BIS at the time of Grant of Licence/Inclusion/Surveillance.

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

7.2 Licencee shall declare the frequency for periodic review in Risk Management File to BIS 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 licencee 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.

8. 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 equipmentor ME systems	4 201.4	IS 13450 (Part 1) IS 13450 (Part 2/Sec 37)	R	Each machine		
4.1	Conditions for application to ME EQUIPMENT or ME SYSTEMS	201.4.1	IS 13450 (Part 2/Sec 37)	R	One of each model	One Year	Refer note 1
4.3	ESSENTIAL PERFORMANCE	201.4.3	IS 13450 (Part 2/Sec 37)	R	One of each model	One Year	Refer note 1
4.3.101	Additional ESSENTIAL PERFORMANCE requirements	201.4.3.101	IS 13450 (Part 2/Sec 37)	R	One of each model	One Year	Refer note 1
201.5 General requirements for testing ME EQUIPMENT							
201.7 ME EQUIPMENT identification, marking and documents							
7	ME EQUIPMENT identification, marking and documents	7	IS 13450 (Part 1)	R	Each machine		
7.2.9	IP Classification	7.2.9	IS 13450 (Part 1) IS 13450 (Part 2/Sec 37)	R	Each machine		
7.2.13	Physiological effects	201.7.2.13	IS 13450 (Part 2/Sec 37)	R	Each machine		

7.2.101	Acoustic output	201.7.2.101	IS 13450 (Part 2/Sec 37)	R	Each machine		
7.9.2.2	Warning and safety notices	201.7.9.2.2	IS 13450 (Part 2/Sec 37)	R	Each machine		
7.9.2.10	Messages	201.7.9.2.10	IS 13450 (Part 2/Sec 37)	R	Each machine		
7.9.2.12	Cleaning, disinfection and sterilization	201.7.9.2.12	IS 13450 (Part 2/Sec 37)	R	Each machine		
7.9.3	Technical Description	7.9.3 201.7.9.3.101	IS 13450 (Part 1) IS 13450 (Part 2/Sec 37)	R	Each machine		
201.8 Protection against electrical hazards from ME Equipment							
8	Protection against electrical hazards from ME Equipment	8 201.8	IS 13450 (Part 1) IS 13450 (Part 2/Sec 37)	R	Each machine		
8.7.4.7	Measurement of the PATIENT LEAKAGE CURRENT	201.8.7.4.7	IS 13450 (Part 2/Sec 37)	R	Each machine		
8.7.4.8	Measurement of the PATIENT AUXILIARY CURRENT	201.8.7.4.8	IS 13450 (Part 2/Sec 37)	R	Each machine		
8.8.3	Dielectric strength	201.8.8.3	IS 13450 (Part 2/Sec 37)	R	Each machine		
8.9.3.4	Thermal Cycling	201.8.9.3.4	IS 13450 (Part 2/Sec 37)	R	Each machine		
8.10.4	Cord-connected HAND-HELD parts and cord-connected foot-operated control devices	201.8.10.4	IS 13450 (Part 2/Sec 37)	R	Each machine		
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS							
9	Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	9	IS 13450 (Part 1)	R	One of each model	Once in 3 years	Refer Note 1

201.10 Protection against unwanted and excessive radiation HAZARDS							
10	Protection against unwanted and excessive radiation HAZARDS	10 201.10	IS 13450 (Part 1) IS 13450 (Part 2/Sec 37)	R	One of each model	Once in 3 years	Refer Note 1
10.101	Ultrasonic Energy	201.10.101	IS 13450 (Part 2/Sec 37)	R	One of each model	Once in 3 years	Refer Note 1
201.11 Protection against excessive temperatures and other HAZARDS							
11	Protection against excessive temperatures and other HAZARDS	11	IS 13450 (Part 1) IS 13450 (Part 2/Sec 37)	S	One of each model	Once in 3 years	Refer Note 1
11.1.2.2	APPLIED PARTS not intended to supply heat to the PATIENT	11.1.2.2	IS 13450 (Part 2/Sec 37)	S	One of each model	Once in 3 years	Refer Note 1
11.1.3	Measurements	11.1.3	IS 13450 (Part 2/Sec 37)	S	One of each model	Once in 3 years	Refer Note 1
11.1.3.1	Test conditions	201.11.1.3.1	IS 13450 (Part 2/Sec 37)	S	One of each model	Once in 3 years	Refer Note 1
11.1.3.2	Operating settings	201.11.1.3.2	IS 13450 (Part 2/Sec 37)	S	One of each model	Once in 3 years	Refer Note 1
11.1.3.3	Test Duration	201.11.1.3.3	IS 13450 (Part 2/Sec 37)	S	One of each model	Once in 3 years	Refer Note 1
11.1.3.4	Test measurement	201.11.1.3.4	IS 13450 (Part 2/Sec 37)	S	One of each model	Once in 3 years	Refer Note 1
11.1.3.5	Test criteria	201.11.1.3.5	IS 13450 (Part 2/Sec 37)	S	One of each model	Once in 3 years	Refer Note 1

11.6.5	Ingress of water	201.11.6.5	IS 13450 (Part 2/Sec 37)	S	One of each model	Once in 3 years	Refer Note 1
201.12 Accuracy of controls and instruments and protection against hazardous outputs							
12	Accuracy of controls and instruments and protection against hazardous outputs	12	IS 13450 (Part 1) IS 13450 (Part 2/Sec 37)	S	One of each model	Once in 3 years	Refer Note 1
12.1	Accuracy of controls and instruments	12.1 201.12.1	IS 13450 (Part 1) IS 13450 (Part 2/Sec 37)	S	One of each model	Once in 3 years	Refer Note 1
12.4.2	Indication of parameters relevant to safety	12.4.2 201. 12.4.2	IS 13450 (Part 1) IS 13450 (Part 2/Sec 37)	S	One of each model	Once in 3 years	Refer Note 1
12.4.3	Accidental selection of excessive output values	12.4.3 201.12.4.3	IS 13450 (Part 1) IS 13450 (Part 2/Sec 37)	S	One of each model	Once in 3 years	Refer Note 1
12.4.5.1	Limits	12.4.5.1 201.12.4.5.1	IS 13450 (Part 1) IS 13450 (Part 2/Sec 37)	S	One of each model	Once in 3 years	Refer Note 1
201.13 Hazardous situations and fault conditions							
13	Hazardous situations and fault conditions	13 201.13	IS 13450 (Part 1) IS 13450 (Part 2/Sec 37)	S	One of each model	Once in 3 years	Refer Note 1
13.1.2	Emissions, deformation of ENCLOSURE or exceeding maximum temperature	13.1.2 201.13.1.2	IS 13450 (Part 1) IS 13450 (Part 2/Sec 37)	S	One of each model	Once in 3 years	Refer Note 1
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)							
14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	14	IS 13450 (Part 1)	S	One of each model	Once in 3 years	Refer Note 1

201.15 Construction of ME EQUIPMENT							
15	**Construction of ME EQUIPMENT**	15	IS 13450 (Part 1)	S	One of each model	Once in 3 years	Refer Note 1
201.16 ME SYSTEMS							
16	**ME SYSTEMS**	16	IS 13450 (Part 1)	S	One of each model	Once in 3 years	Refer Note 1
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS							
17	**Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS**	17 201.17	IS 13450 (Part 1) IS 13450 (Part 2/Sec 37)	S	One of each model	Once in 5 years	Refer Note 1, 2
202.6 ELECTROMAGNETIC COMPATIBILITY							
202.6	ELECTROMAGNETIC COMPATIBILITY	6 202.6	IS 13450 (Part1/Sec 2) IS 13450 (Part 2/Sec 37)	S	One of each model	Once in 5 years	Refer Note 1, 2
202.6.1	Protection of radio services	6.1 202.6.1	IS 13450 (Part1/Sec 2) IS 13450 (Part 2/Sec 37)	S	One of each model	Once in 5 years	Refer Note 1, 2
202.6.2	IMMUNITY	6.2 202.6.2	IS 13450 (Part1/Sec 2) IS 13450 (Part 2/Sec 37)	S	One of each model	Once in 5 years	Refer Note 1, 2

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

Note-2: Licencee to undertake complete testing including EMC requirements once in 5 years and submit test report to BIS.

Note-3: The control unit and levels of control as decided by the Bureau are obligatory, to which the licensee shall comply with.

Note-4: The Licencee shall maintain a RISK MANAGEMENT FILE as per the requirements of IS 13450 (Part 1) : 2018/ IEC 60601-1 : 2012 and IS IS 13450 (Part 2/ Sec 37): 2019/ IEC 60601-2-37 : 2007.

Annex – C

Possible tests in a day

1. General Requirements (Cl. 201.4)
2. ME Equipment Identification, marking and documents (Cl. 201.7)
3. Protection Against Electrical Hazards From Me Equipment (Cl. 201.8)
4. Limitation of voltage, current or energy (Cl. 8.4)
5. Impedance and current carrying capability (Cl. 8.6.4)
6. Leakage currents and patient auxiliary currents (Cl. 8.7)
7. Insulation (Cl. 8.8.1)
8. Dielectric strength (Cl. 201.8.8.3)
9. Insulation other than wire (Cl. 8.8.4)
10. APPLIED PARTS not intended to supply heat to the PATIENT (Cl. 201.11)