उत्पाद मैन्युअल

आई एस 13450 (भाग 2 / अनुभाग 21) : 2023 / आईईसी 60601-2-21 : 2020 के अनुसार चिकित्सीय विद्युत् उपस्कर भाग 2 बुनियादी सुरक्षा और आवश्यक कार्य निष्पादन के लिए विशेष आवश्यकताएँ अनुभाग 21 शिशु रेडियंट वार्मर (पहला पुनरीक्षण) के लिए

दस्तावेज़ संख्या – पीएम/आईएस 13450(भाग 2 / अनुभाग 21) /1/नवंबर 2023

भारतीय मानक ब्यूरो की स्कीम-I (अनुरूपता मूलयांकन) विनियम, 2018 के तहत यह उत्पाद मैन्युअल प्रमाणीकरण के प्रचालन में रीति और पारिशिता की सुसंगतता सुनिश्चित करने के लिए सभी क्षेत्रीय/शाखा कार्यालयों और लाइसेंसी द्वारा संदर्भ सामग्री के रूप में उपयोग किया जाएगा। बीआईएस प्रमाणीकरण लाइसेंस/ प्रमाणपत्र प्राप्त करने के इच्छुक भावी आवेदकों द्वारा भी इस दस्तावेज़ का उपयोग किया जा सकता है ।

PRODUCT MANUAL FOR

MEDICAL ELECTRICAL EQUIPMENT PART 2 PARTICULAR REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE SECTION 21 INFANT RADIANT WARMERS (FIRST REVISION)

ACCORDING TO IS 13450 (Part 2 / Sec 21): 2023 / IEC 60601-2-21: 2020

Document No - PM/IS 13450 (Part 2/ Sec 21)/IEC 60601-2-21/1/November 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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1.	**Product**	:	IS 13450 (Part 2/ Sec 21) : 2023/IEC 60601-2-21 : 2020
	Title	:	Medical Electrical Equipment Part 2 Particular Requirements for Basic Safety and Essential Performance Section 21 Infant Radiant Warmers (First Revision)
	No. of Amendments	:	Nil
2.	**Sampling Guidelines:**		
a)	**Raw material**	:	Nil
b)	**Grouping guidelines**	:	Please refer **ANNEX – B**
c)	**Sample Size**	:	1 unit with accessories.
3.	**List of Test Equipment**	:	Please refer **ANNEX – C**
4.	**Scheme of Inspection and Testing**	:	Please refer **ANNEX – D**
5.	**Possible tests in a day**	:	Please refer **ANNEX – E**
6.	**Scope of the License**	:	As per **ANNEX – A**

ANNEX –A

Scope of Licence

"Licence is granted to use Standard Mark as per IS 13450 (Part 2/ Sec 21) : 2023/IEC 60601-2-21 : 2020 with the following scope:"	
Name of the product:	MEDICAL ELECTRICAL EQUIPMENT - Infant Radiant Warmers
Model:	
Type:	Rated Voltage:…V AC/DC Supply, 1/3 Phase, Rated Current:…….A, Rated Frequency: ……Hz, Weight of Equipment: … kg,
Functions:	With/ without Oxygen monitor/controller; With/ without integrated weighing scale; With/ without CO_2 concentrator; With/ without pre-warm mode, With/ without internal battery
Mode of operation:	Continuous Duty/Intermittent Duty
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
Types and number of probes:	

ANNEX -B

Grouping Guidelines

1. Manufacturer shall submit declaration for each of their model of Infant Radiant Warmers they intend to cover in the scope of licence, as per the format given in Annex – A of this Product Manual. Further, the manufacturer shall declare the essential accessories (if any) supplied along with each of the model.

2. For grant of licnce/ change in scope of licence, each ~~variety/~~ model of Infant Radiant Warmer to be tested.

3. During the operation of the Licence, BO shall ensure that all the ~~varieties~~ model covered in the Licence are tested in rotation to the extent possible.

ANNEX -C

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.	Power Input, 4.11	Power Input Test Apparatus/Power Analyzer
2.	Ambient Temperature 5.3	Temperature & Air Velocity Meter
3.	Accessible Parts 5.9.2	Test Finger with accessibility test apparatus
4.	Humidity preconditioning treatment, 5.7	Conditioning chamber with temperature and humidity chamber
5.	Durability of markings, 7.1.3	Distilled water, ethanol 96%, Isopropyl alcohol, Stop watch
6.	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
7.	Impedance and current carrying capability, 8.6.4	AC/DC voltage source, Multimeter/Earth Resistance Tester
8.	Dielectric Strength, 8.8.3	High Voltage Tester
9.	Creepage Distances And Air Clearances 8.9	Vernier Caliper
10.	Accuracy of SKIN TEMPERATURE SENSOR 201.12.1.101 Accuracy of BABY CONTROLLED RADIANT WARMER operation 201.12.1.103	Water Bath, Thermometer, USB Data Logger
11.	Accuracy Of Distribution Of Irradiation To The Mattress 201.12.1.102	Circular Aluminum Discs, USB Data Logger
12.	Spillage on ME EQUIPMENT and ME SYSTEMS 201.11.6.3	Isotonic Water

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 21) : 2023/ IEC 60601-2-21 : 2020 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-D

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** – 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 21) : 2023/ IEC 60601-2-21 : 2020.
   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 –** All devices of same variety/ model number manufactured in a day 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.

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; and
- 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 13450 (Part 2/ Sec 21) : 2023/ IEC 60601-2-21 : 2020. 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							
201.4	Risk management process for ME equipment or ME systems	4	IS 13450 (Part 1)	R	One	Once in 03 years	Refer Note 1
201.4.1	Conditions for application to ME Equipment or ME Systems	201.4.1	IS 13450 (Part 2/ Sec 21)	R	One	Once in 03 years	Refer Note 1
201.4.3.101	Essential Performance	201.4.3.101	IS 13450 (Part 2/ Sec 21)	R	One	Every Control Unit	Refer Note 2
201.5 General requirements for testing of ME Equipment							
201.5	General requirements for testing ME EQUIPMENT	5	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
201.5.3	Ambient temperature, humidity, atmospheric pressure	201.5.3	IS 13450 (Part 1), IS 13450 (Part 2/ Sec 21)	S	One	Once in 03 years	Refer Note 1
201.5.4	Other conditions	201.5.4	IS 13450 (Part 1), IS 13450 (Part 2/ Sec 21)	S	One	Once in 03 years	Refer Note 1
201.7 ME Equipment identification, marking and documents							
7	ME Equipment Identification, marking and documents	7	IS 13450 (Part 1)	R	One	Every Control Unit	Refer Note 2
201.7.2.101	Oxygen monitor	201.7.2.101	IS 13450 (Part 1), IS 13450 (Part 2/ Sec 21)	R	Refer Note 2		
201.7.2.102	Distance markings	201.7.2.102	IS 13450 (Part 1),	R			

			IS 13450 (Part 2/ Sec 21)		Refer Note 2		
201.7.4.2	Control devices	201.7.4.2	IS 13450 (Part 1), IS 13450 (Part 2/ Sec 21)	R	One	Every Control Unit	Refer Note 2
201.7.9.2.2	Warning and safety notices	201.7.9.2.2	IS 13450 (Part 1), IS 13450 (Part 2/ Sec 21)	R	One	Every Control Unit	Refer Note 2
201.7.9.2.9	Operating instructions	201.7.9.2.9	IS 13450 (Part 1), IS 13450 (Part 2/ Sec 21)	R	One	Every Control Unit	Refer Note 2
201.7.9.2.13	Maintenance	201.7.9.2.13	IS 13450 (Part 1), IS 13450 (Part 2/ Sec 21)	R	One	Every Control Unit	Refer Note 2
201.7.9.2.14	ACCESSORIES, supplementary equipment, used material	201.7.9.2.14	IS 13450 (Part 1), IS 13450 (Part 2/ Sec 21)	R	One	Every Control Unit	Refer Note 2
201.7.9.3.1	Technical description – General	7.9, 201.7.9.3.1	IS 13450 (Part 1), IS 13450 (Part 2/ Sec 21)	R	One	Every Control Unit	Refer Note 2
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	One	Every Control Unit	Refer Note 2
8.2	Requirements related to power sources	8.2	IS 13450 (Part 1)	R	Refer Note 2		
8.3	Classification of APPLIED PARTS	8.3	IS 13450 (Part 1)	R	Refer Note 2		
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)	R	One	Every	Refer Note 2

						Control Unit	
8.4.2 (b)	The Leakage Currents from, to or between Accessible parts.	8.7.4	IS 13450 (Part 1)	R	One	Every Control Unit	Refer Note 2
8.4.2 (c)	Other accessible parts	8.4.2	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.4.2 (d)	Internal parts that are accessible	8.4.2	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.4.3	ME equipment intended to be connected to a power source by a plug	8.4.3	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.4.4	Internal capacitive circuits	8.4.4	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.5	Separation of Parts						
8.5.1	MEANS OF PROTECTION (MOP)	8.5.1	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.5.1.2	Means of Patient Protection (MOPP)						
	Distance through solid insulation or use of thin sheet material	8.8.2, 8.8.3, Annex L	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
	Dielectric Strength	8.8.3	IS 13450 (Part 1)	R	One	Every Control Unit	Refer Note 2
	Protective Earth Terminal	8.6.2, 8.11.4.3	IS 13450 (Part 1)	R	One	Every Control Unit	Refer Note 2
	Protective earthing of moving parts	8.6.3	IS 13450 (Part 1)	R	Refer Note 2		
	Impedance and current-carrying capability	8.6.4	IS 13450 (Part 1)	R	One	Every Control	Refer Note 2

						Unit	
	Surface coatings	8.6.5	IS 13450 (Part 1)	R	Refer Note 2		
	Plugs and sockets	8.6.6	IS 13450 (Part 1)	R	Refer Note 2		
	Potential equalization conductor	8.6.7	IS 13450 (Part 1)	R	Refer Note 2		
	Functional Earth Terminal	8.6.8	IS 13450 (Part 1)	R	Refer Note 2		
	Class II ME Equipment	8.6.9, 8.8	IS 13450 (Part 1)	R	One	Every Control Unit	Refer Note 2
8.5.2	Separation of PATIENT CONNECTIONS	8.5.2	IS 13450 (Part 1)	R	One	Every Control Unit	Refer Note 2
8.5.3	MAXIMUM MAINS VOLTAGE	8.5.3	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.5.4	WORKING VOLTAGE	8.5.4	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.5.5	DEFIBRILLATION-PROOF APPLIED PARTS	8.5.5	IS 13450 (Part 1)	R	One	Every Control Unit	Refer Note 2
8.5.5.1	Defibrillation Protection	8.5.5.1	IS 13450 (Part 1)	R	One	Every Control Unit	Refer Note 2
8.5.5.2	Energy Reduction Test	8.5.5.2	IS 13450 (Part 1)	R	One	Every Control Unit	Refer Note 2
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)	S	One	Once in 03 years	Refer Note 1
8.6.2	PROTECTIVE EARTH TERMINAL	8.6.2	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.6.3	Protective earthing of moving parts	8.6.3	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.6.4	Impedance and current-carrying capability	8.6.4	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.6.5	Surface Coatings	8.6.5	IS 13450 (Part 1)	R	Refer Note 2		
8.6.6	Plugs and sockets	8.6.6	IS 13450 (Part 1)	R	Refer Note 2		
8.6.7	POTENTIAL EQUALIZATION CONDUCTOR	8.6.7	IS 13450 (Part 1)	R	Refer Note 2		
8.6.8	FUNCTIONAL EARTH TERMINAL	8.6.8	IS 13450 (Part 1)	R	Refer Note 2		
8.7	**LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS**						
8.7.1	General Requirements	8.7.1	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.7.2	SINGLE FAULT CONDITIONS	8.7.2	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.7.3	Allowable values	8.7.3	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.7.4	Measurements	8.7.4	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.8	**Insulation**						
8.8.1	General						

8.8.2	Distance through solid insulation or use of thin sheet material	8.8.2	IS 13450 (Part 1)	R	One	Every Control Unit	Refer Note 2
8.8.3	Dielectric strength	8.8.2	IS 13450 (Part 1)	R	One	Every Control Unit	Refer Note 2
8.8.4	Insulation other than wire insulation						
	Resistance to heat, General Overload test conditions	8.8.4.1	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
	Resistance to environmental stress	8.8.4.2	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.9	**CREEPAGE DISTANCES and AIR CLEARANCES**						
8.9.1	Values	8.9.1	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.9.2	Applications	8.9.2	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.9.3	Spaces filled by insulating compound	8.9.3	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.9.4	Measurement of CREEPAGE DISTANCES AND AIR CLEARANCES	8.9.4	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.10	**Components and wiring**						
8.10.1	Fixing of components	8.10.1	IS 13450 (Part 1)	R	Refer Note 2		
8.10.2	Fixing of wiring	8.10.2	IS 13450 (Part 1)	R	Refer Note 2		
8.10.3	Connections between different parts of ME EQUIPMENT	8.10.3	IS 13450 (Part 1)	R	One	Every Control Unit	Refer Note 2

8.10.4	Cord-connected HAND-HELD parts and cord-connected foot-operated control devices	8.10.4	IS 13450 (Part 1)	R	One	Every Control Unit	Refer Note 2
8.10.5	Mechanical protection of wiring	8.10.5	IS 13450 (Part 1)	R	One	Every Control Unit	Refer Note 2
8.10.6	Guiding rollers for insulated conductors	8.10.6	IS 13450 (Part 1)	R	One	Every Control Unit	Refer Note 2
8.10.7	Insulation of internal wiring	8.10.7	IS 13450 (Part 1)	R	One	Every Control Unit	Refer Note 2
8.11	**MAINS PARTS, components and layout**						
8.11.1	Isolation from Supply mains	8.11.1	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1,3
8.11.2	Multiple Socket Outlets	8.11.2, 16.9.2.1	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
8.11.3	Power Supply Cords						
8.11.3.1	Application	8.11.3.1	IS 13450 (Part 1)	S	One	Every consignmentreceived	Refer Note 4
8.11.3.2	Types	8.11.3.2	IS 13450 (Part 1)	S	One	Every consignmentreceived	Refer Note 4
8.11.3.3	Cross-sectional area of POWER SUPPLY CORD conductors	8.11.3.3	IS 13450 (Part 1)	S	One	Every consignmentreceived	Refer Note 4
8.11.3.4	Appliance Couplers	8.11.3.4 8.11.3.5, 8.11.3.6	IS 13450 (Part 1) or IS/IEC 60320-1	S	One	Every consignmentreceived	Refer Note 4

8.11.4	Mains terminal devices	8.11.4	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
8.11.5	Mains fuses and over current releases	8.11.5	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
8.11.6	Internal wiring of the Mains Part	8.11.6	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
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)	S	One	Once in 03 years	Refer note 1
9.2	MECHANICAL HAZARDS associated with moving parts	9.2	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
9.3	MECHANICAL HAZARD associated with surfaces, corners and edges	9.3	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
9.4	Instability HAZARDS	9.4, 201.9	IS 13450 (Part 1), IS 13450 (Part 2/ Sec 21)	S	One	Once in 03 years	Refer note 1
	Instability in transport position	9.4.2.1, 201.9.4.2.1	IS 13450 (Part 1), IS 13450 (Part 2/ Sec 21)	S	One	Once in 03 years	Refer note 1
9.5	Expelled parts HAZARD	9.5	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
9.6	Audible acoustic energy	9.6, 201.9.6.2.1	IS 13450 (Part 1), IS 13450 (Part 2/ Sec 21)	S	One	Once in 03 years	Refer note 1
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure	9.7	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
9.8	MECHANICAL HAZARDS associated with support systems	9.8,	IS 13450 (Part 1),	S	One	Once in 03 years	Refer note 1

		201.9.8	IS 13450 (Part 2/ Sec 21)				
	Supports and mounting brackets for ACCESSORIES	201.9.8.101	IS 13450 (Part 2/ Sec 21)	S	One	Once in 03 years	Refer note 1
	Strength if PATIENT or OPERATOR support or suspension systems	201.9.8.3.1, 201.9.8.3.101	IS 13450 (Part 2/ Sec 21)	S	One	Once in 03 years	Refer note 1
201.10 Protection against unwanted and excessive radiation HAZARDS							
10.1	X-Radiation	10.1	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
10.2	Alpha, beta, gamma, neutron and other particle radiation	10.2	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
10.3	Microwave radiation	10.3	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
10.4	Lasers	10.4	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
10.5	Other visible electromagnetic radiation	10.5	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
10.6	Infrared radiation	10.6, 201.10.6	IS 13450 (Part 1), IS 13450 (Part 2/ Sec 21)	S	One	Once in 03 years	Refer note 1
10.7	Ultraviolet radiation	10.7	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
11 Protection against excessive temperatures and other HAZARDS							
11.1	Excessive temperatures in ME EQUIPMENT	11.1, 201.11	IS 13450 (Part 1), IS 13450 (Part 2/ Sec 21)	S	One	Once in 03 years	Refer note 1

	APPLIED PARTS not intended to supply heat to a PATIENT	201.11.1.2.2	IS 13450 (Part 2/ Sec 21)	S	One	Once in 03 years	Refer note 1
	GUARDS	201.11.1.4	IS 13450 (Part 2/ Sec 21)	S	One	Once in 03 years	Refer note 1
11.2	Fire Prevention	11.2	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
11.3	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT	11.3	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
11.4	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics	11.4	IS 13450 (Part 1)	S	One	Once in 03 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	Once in 03 years	Refer note 1
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, 201.11.6	IS 13450 (Part 1), IS 13450 (Part 2/ Sec 21)	R	One	Every Control Unit	Refer note 2
	Spillage on ME EQUIPMENT and ME SYSTEMS	201.11.6.3	IS 13450 (Part 2/ Sec 21)	R	One	Every Control Unit	Refer note 2
11.7	Biocompatibility of ME EQUIPMENT and ME SYSTEMS	11.7	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
11.8	Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT	11.8, 201.11.8	IS 13450 (Part 1), IS 13450 (Part 2/ Sec 21)	S	One	Once in 03 years	Refer note 1
12 Accuracy of controls and instruments and protection against hazardous outputs							
12.1	Accuracy of controls and instruments	12.1, 201.12.1	IS 13450 (Part 1), IS 13450 (Part 2/ Sec	R	One	Every Control Unit	Refer note 2

			21)				
	Accuracy of SKIN TEMPERATURE SENSOR	201.12.1.101	IS 13450 (Part 2/ Sec 21)	R	One	Every Control Unit	Refer note 2
	Accuracy of distribution of irradiation to the MATTRESS	201.12.1.102	IS 13450 (Part 2/ Sec 21)	R	One	Every Control Unit	Refer note 2
	Accuracy of BABY CONTROLLED RADIANT WARMER operation	201.12.1.103	IS 13450 (Part 2/ Sec 21)	R	One	Every Control Unit	Refer note 2
	Oxygen control	201.12.1.104	IS 13450 (Part 2/ Sec 21)	R	One	Every Control Unit	Refer note 2
	Weighing scale	201.12.1.105	IS 13450 (Part 2/ Sec 21)	R	One	Every Control Unit	Refer note 2
12.2	USABILITY of ME EQUIPMENT	12.2, 201.12.2	IS 13450 (Part 1), IS 13450 (Part 2/ Sec 21)	R	One	Every Control Unit	Refer note 2
	USABILITY of control	201.12.2.101	IS 13450 (Part 2/ Sec 21)	R	Refer note 2		
	USABILITY of mode of operation	201.12.2.102	IS 13450 (Part 2/ Sec 21)	R	Refer note 2		
	Time and irradiance limits in the MANUAL MODE	201.12.2.103	IS 13450 (Part 2/ Sec 21)	R	One	Every Control Unit	Refer note 2
	Heat output level at PREWARM MODE	201.12.2.104	IS 13450 (Part 2/ Sec 21)	R	Refer note 2		
12.3	ALARM SYSTEMS	12.3,	IS 13450 (Part 1),	R	One	Every Control	Refer note 2

		201.12.3	IS 13450 (Part 2/ Sec 21)			Unit	
	Interruption of power supply	201.12.3.101	IS 13450 (Part 2/ Sec 21)	R	One	Every Control Unit	Refer note 2
	Open and short circuit of the SKIN TEMPERATURE SENSOR in BABY CONTROLLED RADIANT WARMER operation	201.12.3.102	IS 13450 (Part 2/ Sec 21)	R	One	Every Control Unit	Refer note 2
	AUDIO PAUSED of auditory ALARM SIGNALS during MANUAL MODE	201.12.3.103	IS 13450 (Part 2/ Sec 21)	R	One	Every Control Unit	Refer note 2
	AUDIO PAUSED	201.12.3.104	IS 13450 (Part 2/ Sec 21)	R	One	Every Control Unit	Refer note 2
	Alarm function test	201.12.3.105	IS 13450 (Part 2/ Sec 21)	R	One	Every Control Unit	Refer note 2
12.4	Protection against hazardous output	12.4, 201.12.4	IS 13450 (Part 1), IS 13450 (Part 2/ Sec 21)	S	One	Once in 03 years	Refer note 1
	CO_2 concentration	201.12.4.2.101	IS 13450 (Part 2/ Sec 21)	R	One	Every Control Unit	Refer note 2
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 03 years	Refer note 1
14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)							

14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	14	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
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 03 years	Refer note 1
15.2	Serviceability	15.2	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
15.3	Mechanical strength	15.3, 201.15.3	IS 13450 (Part 1), IS 13450 (Part 2/ Sec 21)	S	One	Once in 03 years	Refer note 1
	Rough handling test	201.15.3.5	IS 13450 (Part 2/ Sec 21)	S	One	Once in 03 years	Refer note 1
15.4	ME EQUIPMENT components and general assembly	15.4, 201.15.4	IS 13450 (Part 1), IS 13450 (Part 2/ Sec 21)	S	One	Once in 03 years	Refer note 1
	Temperature sensors	201.15.4.1.101	IS 13450 (Part 2/ Sec 21)	R	One	Each week	Refer note 1
	Application	201.15.4.2.1	IS 13450 (Part 2/ Sec 21)	R	One	Each week	Refer note 1
	Temperature settings	201.15.4.2.2	IS 13450 (Part 2/ Sec 21)	R	One	Each week	Refer note 1
	Range of CONTROL TEMPERATURE	201.15.4.2.2.101	IS 13450 (Part 2/ Sec 21)	R	One	Each week	Refer note 1
16 ME SYSTEMS							

16	ME SYSTEMS	16	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
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 05 years	Refer note 1
202 Electromagnetic disturbances – Requirements and tests							
202	**Electromagnetic disturbances – Requirements and tests**	202	IS 13450 (Part 1/ Sec 2)	S	One	Once in 05 years	Refer note 1
202.8.9	IMMUNITY TEST LEVELS	202.8.9	IS 13450 (Part 2/ Sec 21)	S	One	Once in 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 or once in 03 years.
Note-2: Firm to have adequate in-process controls to check compliance of this parameter as per the Indian Standard. However, appropriate records shall be maintained by the manufacturer for evidence of conformity.
Note-3: 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.
Note-4: No further testing is required if accompanied with BIS Standard Mark/ test certificate from the supplier.
Note-5: Sub-contracting is permitted to a laboratory recognized by the Bureau or Government laboratories empanelled by the Bureau.
Note-6: Levels of control given in column obligatory in nature which are to be followed by the manufacturer.
Note-7: Manufacturer to carry out complete testing including EMC requirements (Cl. 17, 202) once in five years for each model in scope of licence and submit the test report to BIS.

ANNEX E

Possible tests in a day

1. Power Input , 4.11
2. ME EQUIPMENT identification, marking and documents, 201.7
3. Impedance and current carrying capability, 8.6.4
4. Dielectric Strength, 8.8.3
5. Spillage on ME equipment and ME Systems, 201.11.6.3
6. Accuracy of SKIN TEMPERATURE SENSOR, 201.12.1.101
7. Accuracy of distribution of irradiation to the MATTRESS, 201.12.1.102
8. Interruption of power supply, 201.12.3.101
9. Open and short circuit of the Skin Temperature Sensor In Baby Controlled Radiant Warmer operation, 201.12.3.102
10. Audio Paused of auditory Alarm Signals during Manual Mode, 201.12.3.103
11. Audio Paused, 201.12.3.104
12. Alarm function test, 201.12.3.105
13. Range of Control Temperature, 201.15.4.2.2.101
14. Temperature sensors, 201.15.4.1.101
15. Application, 201.15.4.2.1
16. Temperature settings, 201.15.4.2.2