PRODUCT MANUAL FOR

Medical Electrical Equipment - Part 2- Particular Requirements for Basic Safety and Essential Performance- Sec 61 Pulse Oximeter Equipment
IS/IEC 80601 (Part 2 / Sec 61): 2017

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 हैI

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 80601 (Part 2/ Sec 61): 2017
	शीर्षक **Title**	:	Medical Electrical Equipment - Part 2- Particular Requirements for Basic Safety and Essential Performance- Sec 61 Pulse Oximeter Equipment
	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**	:	All possible tests as specified IS 80601 (Part 2 / Sec 61): 2017

6. लाइसेंस का दायरा /Scope of the Licence:

"License is granted to use Standard Mark as per ***IS 80601 (Part 2/Sec 61):2017*** with the following scope:

Name of the product		Medical Electrical Equipment - Part 2- Particular Requirements for Basic Safety and Essential Performance- Sec 61 Pulse Oximeter Equipment
Model		
Displayed range	**SpO2**	
	Pulse Rate	
Alarm System		With Alarm System / without Alarm System
Type		Stationary (or) Fixed / Mobile / Portable / Hand-held
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
Protection against electric shock		Class – I / Class – II Type BF Applied Parts / Type CF Applied Parts
Additional Power Source		With / without internal power source
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
Type of Probe(s), Probe cable extender(s) and Monitor		(To be declared by the manufacturer)

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 'Pulse Oximeter Equipment' they intend to cover in the scope of licence.

2. For Grant of Licnce/ Change in Scope of Licence, each 'Model' of 'Pulse Oximeter Equipment' is to be tested.

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

Note: Firm shall declare the following parameters for each of the Model of Pulse Oximeter Equipment:

a) IP Classification (as per CL. 201.7.2.9.101)
b) Accessories to be supplied with the Pulse Oximeter 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.	Accessible Parts 5.9.2	Test Finger with accessibility test apparatus
3.	Humidity preconditioning treatment, 5.7	Conditioning chamber with temperature and humidity chamber
4.	Durability of markings, 7.1.3	Distilled water, ethanol 96%, Isopropyl alcohol, Stop watch
5.	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
6.	Impedance and current carrying capability, 8.6.4	AC/DC voltage source, Multimeter/Earth Resistance Tester
7.	Dielectric Strength, 8.8.3	High Voltage Tester
8.	Creepage Distances And Air Clearances 8.9	Vernier Caliper, Filler Gauge

Note 1: The licensee shall maintain a Technical file and Risk Management File as per the provisions of IS/IEC 80601 (Part 2/ Sec 61): 2017 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 in the scope of licence as per the requirement of IS / IEC 80601 (Part 2/ Sec 61): 2017. 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 Technical File.

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

3.1 Packing and Marking shall be done as per Cl. 201.7 of IS / IEC 80601 (Part 2/ Sec 61): 2017.

3.2 **Additional Marking requirements**: The material shall also be marked with the following additional requirement on each product and 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							
201.4.1	Conditions for application to ME EQUIPMENT or ME SYSTEMS	4.1	IS 13450 (Part 1)	R	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
201.4.2	Risk management process for ME equipment or ME systems	4.2	IS 13450 (Part 1)	R	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
201.4.3	**Essential Performance**						
201.4.3.101	Additional ESSENTIAL PERFORMANCE requirements	Table 201.101 201.4.3.101	IS 13450 (Part 1) IS/IEC 80601-2-61	R	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
201.4.4	EXPECTED SERVICE LIFE	201.4.4	IS 13450 (Part 1)	R	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
201.4.5	Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS	201.4.5	IS 13450 (Part 1) IS/IEC 80601-2-61	R			

201.4.6	ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT	201.4.6	IS 13450 (Part 1) IS/IEC 80601-2-61	R			
201.4.7	SINGLE FAULT CONDITION for ME EQUIPMENT	13.1 13.2	IS 13450 (Part 1) IS/IEC 80601-2-61	S			
201.4.8	Components of ME EQUIPMENT	201.4.8	IS 13450 (Part 1) IS/IEC 80601-2-61	R	One	Each Consignment	No further testing if accompanied with Test Certificate or ISI Mark or covered in Risk Management file
201.4.9	Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT	201.4.9	IS 13450 (Part 1) IS/IEC 80601-2-61				
4.10	**Power supply**						
4.10.1	Source of power for ME EQUIPMENT	4.10.1	IS 13450 (Part 1)	R	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
4.10.2	SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS	4.10.2	IS 13450 (Part 1)	R			
4.11	Power input	4.11	IS 13450 (Part 1)	R			
201.7	**ME Equipment identification, marking and documents**						
201.7	ME Equipment Identification, marking and documents	7	IS 13450 (Part 1)	R	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
201.7.2.3	Consult ACCOMPANYING DOCUMENTS	201.7.2.3	IS/IEC 80601-2-61	R			

201.7.2.9.101	IP classification	201.7.2.9.101	IS/IEC 80601-2-61	R			
201.7.2.13.101	Additional requirements for physiological effects	201.7.2.13.101	IS/IEC 80601-2-61	R			
201.7.2.17.101	Additional requirements for protective packaging	201.7.2.17.101	IS/IEC 80601-2-61	R			
201.7.2.101	Additional requirements for marking on the outside of ME EQUIPMENT parts	201.7.2.101	IS/IEC 80601-2-61	R			
201.7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts	7.3	IS 13450 (Part 1)	R			
201.7.4	Marking of controls and instruments	7.4 201.7.4.3	IS 13450 (Part 1) IS/IEC 80601-2-61	R			
201.7.4.3	Units of measurement	201.7.4.3		R			
201.7.5	Safety signs	7.5		R			
201.7.6	Symbols	7.6		R	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File

201.7.7	Colours of the insulation of conductors	7.7	IS 13450 (Part 1)	R			
201.7.8	Indicator lights and controls	7.8	IS 13450 (Part 1)	R			
201.7.9	ACCOMPANYING DOCUMENTS	7.9	IS 13450 (Part 1)	R			
201.7.9.2	Instructions for use	201.7.9.2	IS/IEC 80601-2-61	R	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
201.7.9.2.1.101	Additional general requirements	201.7.9.2.1.101	IS/IEC 80601-2-61	R			
201.7.9.2.2.101	Additional requirements for warnings and safety notices	201.7.9.2.2.101	IS/IEC 80601-2-61	R			
201.7.9.2.9.101	Additional requirements for operating instructions	201.7.9.2.9.101	IS/IEC 80601-2-61	R			
201.7.9.3.1.101	Additional general requirements	201.7.9.3.1.101	IS/IEC 80601-2-61	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	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
8.2	Requirements related to power sources	8.2	IS 13450 (Part 1)	R			

8.3	Classification of APPLIED PARTS	8.3	IS 13450 (Part 1)	R			
201.8.3.101	Additional requirements for classification of APPLIED PARTS	201.8.3.101	IS/IEC 80601-2-61	R	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
8.4	**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	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
8.4.2 (b)	The Leakage Currents from, to or between Accessible parts	8.7.4	IS 13450 (Part 1)	R	One		
8.4.2 (c)	Other accessible parts	8.4.2	IS 13450 (Part 1)	R	One		
8.4.2 (d)	Internal parts that are accessible	8.4.2	IS 13450 (Part 1)	R	One		
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		
8.4.4	Internal capacitive circuits	8.4.4	IS 13450 (Part 1)	S	One		
8.5	**Separation of Parts**						
8.5.1.2	Means of Patient Protection (MOPP)	8.5.1.2	IS 13450 (Part 1)	S	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)	8.5.1.2	IS 13450 (Part 1)	S	One		
8.5.2	Separation of PATIENT CONNECTIONS	8.5.2 201.8.5.2.3	IS 13450 (Part 1)	S	One		

8.5.3	MAXIMUM MAINS VOLTAGE	8.5.3	IS 13450 (Part 1)	S	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
8.5.4	WORKING VOLTAGE	8.5.4	IS 13450 (Part 1)	S	One		
8.5.5	DEFIBRILLATION - PROOF APPLIED PARTS	8.5.5	IS 13450 (Part 1)	S	One		
8.5.5.1	Defibrillation Protection	8.5.5.1	IS 13450 (Part 1)	S	One		
8.5.5.2	Energy Reduction Test	8.5.5.2	IS 13450 (Part 1)	S	One		
8.6	**Protective earthing, functional earthing and potential equalization of ME EQUIPMENT**						
8.6.1	Applicability of requirements	8.6.1	IS 13450 (Part 1)	R	One	Once in a month for each 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	IS 13450 (Part 1)	S	One	Once in a month for each model manufactured during that period
8.7.2	SINGLE FAULT CONDITIONS	8.7.2	IS 13450 (Part 1)	S	One	
8.7.3	Allowable values	8.7.3	IS 13450 (Part 1)	S	One	
8.7.4	Measurements	8.7.4	IS 13450 (Part 1)	S	One	
8.8	**Insulation**					
8.8.2	Distance through solid insulation or use of thin sheet material	8.8.2	IS 13450 (Part 1)	R	One	Once in a month for each model manufactured during that period
8.8.3	Dielectric strength	8.8.2	IS 13450 (Part 1)	R		
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 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	Values	8.9.1	IS 13450 (Part 1)	S	One	Once in a month for each model manufactured during that period
8.9.2	Applications	8.9.2	IS 13450 (Part 1)	S	One	

8.9.3	Spaces filled by insulating compound	8.9.3	IS 13450 (Part 1)	S	One	Once in a month for each model manufactured during that period	
8.9.4	Measurement of CREEPAGE DISTANCES AND AIR CLEARANCES	8.9.4	IS 13450 (Part 1)	S	One		
8.10	**Components and wiring**						
8.10.1	Fixing of components	8.10.1	IS 13450 (Part 1)	R	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
8.10.2	Fixing of wiring	8.10.2	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			
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	Each Medical	Testing and assessment of the product to be done as specified in the Technical File

8.11.2	Multiple Socket Outlets	8.11.2	IS 13450 (Part 1)	R		Equipment	and Risk Assessment File	
8.11.3	**Power Supply Cords**							
8.11.3.1	Application	8.11.3.1	IS 13450 (Part 1)	R	One		Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
8.11.3.2	Types	8.11.3.2	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 EQUIPMENT	9.1	IS 13450 (Part 1)	S	One	Once in a month for each model manufactured during that period		
9.2	MECHANICAL HAZARDS associated with moving parts	9.2	IS 13450 (Part 1)	S	One			
9.3	MECHANICAL HAZARD associated with surfaces, corners	9.3	IS 13450 (Part 1)	S	One			

	and edges					
9.4	Instability HAZARDS	9.4,	IS 13450 (Part 1)	S	One	Once in a month for each 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 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 model manufactured during that period	
201.11.1.2.2	APPLIED PARTS intended to supply heat to a PATIENT	201.11.1.2.2	IS/IEC 80601-2-61	S	One		
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	11.6 201.11.6.5.101	IS 13450 (Part 1) IS/IEC 80601-2-61	R	One		

11.7	Biocompatibility of ME EQUIPMENT and ME SYSTEMS	11.7	IS 13450 (Part 1)	R	One	Once in 03 years	Refer note 1
11.8	Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT	201.11.8 201.11.8.101.1 201.11.8.101.2 201.11.8.101.3	IS/IEC 80601-2-61	R	One	Every Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
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	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
201.12.1.101	SpO2 ACCURACY of PULSE OXIMETER EQUIPMENT	201.12.1.101 201.12.1.102 201.12.1.103 201.12.1.104	IS/IEC 80601-2-61	R			
12.2	USABILITY of ME EQUIPMENT	12.2	IS 13450 (Part 1)	R			
12.3	ALARM SYSTEMS	201.12.3	IS/IEC 80601-2-61	R			
12.4	Protection against hazardous output	12.4.1 to 12.4.4 201.12.4.101 201.12.4.102	IS 13450 (Part 1) IS/IEC 80601-2-61	S S	One	Once in a month for each model manufactured during that period	
201.13	**HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT**						
13	HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	13 201.13.101	IS 13450 (Part 1) IS/ IEC 80601-2-61	S	One	Once in a month for each model manufactured during that period	
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 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)	R	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
15.2	Serviceability	15.2	IS 13450 (Part 1)	R			
15.3	Mechanical strength	15.3	IS 13450 (Part 1)	S	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
	Additional requirements for rough handling	201.15.3.5.101	IS/ IEC 80601-2-61	S	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
15.4	Indicators	15.4	IS 13450 (Part 1)	R	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
201.15.101	Mode of operation	201.15.101	IS/ IEC 80601-2-61	R	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
201.16	**ME SYSTEMS**						
16	ME SYSTEMS	16	IS 13450 (Part 1)	S	One	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 model manufactured during the period

201.101	PULSE OXIMETER PROBES and PROBE CABLE EXTENDERS	201.101	IS/ IEC 80601-2-61	S	One	Once in 03 years	For each model manufactured during the period
201.102	Saturation pulse INFORMATION SIGNAL	201.102	IS/ IEC 80601-2-61	S	One	Once in 03 years	For each model manufactured during the period
201.103	FUNCTIONAL CONNECTION	201.103	IS/ IEC 80601-2-61	S	One	Once in 03 years	For each model manufactured during the period
202	**Electromagnetic disturbances – Requirements and tests**						
202	Electromagnetic disturbances – Requirements and tests	202 202.4.3.1 202.5.2.2.1 202.8.1.101 202.8.2	IS 13450-1-2 IS/IEC 80601-2-61	S	One	Once in 03 years	For each model manufactured during the period
206	Usability	206	IS 13450-1-6	R	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
208	General requirements, tests and guidance for ALARM SYSTEMS IN MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS	208 208.6.1.2.101 208.6.5.4.101 208.6.8.5.101	IS 13450-1-8 IS/IEC 80601-2-61	R			
211	Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	211	IS 13450-1-11	S	One	Once in every 3 years	For each model manufactured during the period
212	Requirements for medical electrical equipment and medical	212	IS 13450-1-12	S	One	Once in every 3 years	For each model manufactured during the period

	electrical systems used in the emergency medical services environment						