उत्पाद मैन्युअल

आई एस/ आईईसी 80601-2-58 : 2016 के अनुसार

चिकित्सीय विद्युत् उपस्कर भाग 2 बुनियादी सुरक्षा और आवश्यक कार्य निष्पादन के लिए विशेष आवश्यकताएं अनुभाग 58 नेत्र शल्य चिकित्सा के लिए लेंस हटाने वाले उपकरण और विट्रोक्टोमी उपकरण के लिए

दस्तावेज़ संख्या – पीएम/आईएस/ आईईसी 80601-2-58/1/ जनवरी 2023

भारतीय मानक ब्यूरो की स्कीम-I (अनुरूपता मूलयाांकन) 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 the Basic Safety and Essential Performance Section 58 Lens removal devices and vitrectomy devices for ophthalmic surgery

ACCORDING TO IS / IEC 80601-2-58 : 2016

Document No - PM/IS/IEC 80601-2-58/1/January 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 REQUIREMENTS FOR THE BASIC SAFETY AND ESSENTIAL PERFORMANCE - LENS REMOVAL DEVICES AND VITRECTOMY DEVICES FOR OPHTHALMIC SURGERY ACCORDING TO

IS/IEC 80601 -2- 58 : 2016

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/IEC 80601 -2- 58 : 2016
	Title	:	Medical electrical equipment Part 2 Particular requirements for the basic safety and essential performance Section 58 Lens removal devices and vitrectomy devices for ophthalmic surgery
	No. of Amendments	:	Nil
2.	**Sampling Guidelines:**		
a)	**Raw material**	:	Nil
b)	**Grouping guidelines**	:	NIL. Each Model shall be tested for all parameters for considering GoL/ Inclusion of additional variety
c)	**Sample Size**	:	One no. with accessories
d)	**Sampling for surveillance**		Feedback from Organized buyers to taken instead of MS. Two factory surveillance to be carried out in each year. However, only one sample to be drawn for general requirements in a year. Further, testing on one Factory Sample for EMC requirements to be carried out once in three years. Second surveillance inspection may be planned based on risk based surveillance approach.
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 License**	:	As per below table

Scope of Licence

"Licence is granted to use Standard Mark as per IS/IEC 80601 - 2 - 58 : 2016 with the following scope:"	
Name of the product:	MEDICAL ELECTRICAL EQUIPMENT - Lens Removal Devices and Vitrectomy Devices for Ophthalmic Surgery
Model No.:	
Type:	……V AC/DC Supply, ...Hz, …..VA(max), Mode of operation:…., Pollution Degree….
Functions:	Diathermy, Laser, Illumination
Mechanism:	PHACOFRAGMENTATION ,LIQUEFACTION or LASER FRAGMENTATION
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
Accessories:	
Other relevant aspects may also be mentioned in the scope.	

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.	General Requirements, 201.4	Risk Management File
2.	Humidity preconditioning treatment, 5.7, 201.5	Conditioning chamber with temperature and humidity chamber
3.	Legibility of markings, 7.1.2, 201.7	Angle Protractor, Steel tape
4.	Durability of markings, 7.1.3	Distilled water, ethanol 96%, Isopropyl alcohol, Stop watch
5.	Protection against electrical hazards from ME Equipment, 201.8	Functional test, Risk Management File
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, Test Pin as per Figure 8 or a particular tool as specified by manufacturer.
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.	Protection against Mechanical Hazards of ME Equipment and ME Systems, 201.9	Risk Management File, Visual Inspection
11.	Protection against unwanted and excessive radiation hazards, 201.10	Risk Management File
12.	Protection against excessive temperatures and other hazards, 201.11	Risk Management File
13.	Accuracy of static irrigation pressure, 201.12.1.101.1	Digital Thermohygrometer, Air Conditioner, Pressure meter, Stop watch, Steel Rule
14.	Accuracy of aspiration pressure, 201.12.1.101.2	Digital Thermohygrometer, Air Conditioner, Pressure meter, Stop watch, Steel Rule, Measuring cylinder jar
15.	Accuracy of diathermy power, 201.12.1.101.3	Universal Power Analyzer, Digital multimeter
16.	Accuracy of diathermy frequency, 201.12.1.101.4	Oscilloscope with high frequency 100X and high impedance 10 MΩ probe
17.	Accuracy of illumination output, 201.12.1.101.5	Integrating sphere photo meter stop watch
18.	Accuracy of ultrasonic velocity of TIP, 201.12.1.101.7	Microscope, Vernier Caliper, Steel Rule

19.	Accuracy of velocity of fluid entering eye for liquefaction, 201.12.1.101.8	Pressure Transducer, Scale, Stop Watch
20.	Accuracy of vitrectomy probe cut rate, 201.12.1.101.8	Stroboscope, Microscope, Monitor
21.	Hazardous output for illumination, 201.12.4.101.5	Solar Meter for short wavelength, Power/ Energy meter long wavelength
22.	Hazardous Situations and Fault Conditions, 201.13	Risk Management File, Accompanying documents
23.	Programmable Electrical Medical Systems (PEMS), 201.14	Risk Management File, Accompanying documents
24.	Construction of ME Equipment, 201.15	Visible Inspection, Test setup as per Cl. 15.3 of IS 13450 (Part 1)
25.	ME Systems, 201.16	Risk Management File, Accompanying documents
26.	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS, 201.17	Risk Management File
	Electromagnetic disturbances – Requirements and tests, 202	Risk Management File

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/IEC 80601-2-58 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 (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/IEC 80601 -2-58 : 2016.

4. **CONTROL UNIT –** All devices of same Model (same Type, Functions, Mechanism, Protection against electric shock, Protection against harmful ingress of water or particulate matter, Suitability for use in oxygen rich environment) manufactured in a week shall constitute a control unit.

5. **LEVELS OF CONTROL -** The tests as indicated in column 1 of Table 1A and the levels of control in column 3 of Table 1A, 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.
- 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/IEC 80601-2-58. 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							
4.2	Risk management process for ME equipment or ME systems	4.2	IS 13450 (Part 1)	-	Each Unit		
201.4.101	Additional functions (DIATHERMY function, LASER function, illumination function)	201.4.101	IS/IEC 80601-2-58	--	Each Unit		
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 of each model	05 years	Refer note 1
201.7 ME Equipment identification, marking and documents							
7	ME Equipment Identification, marking and documents	7.1.2, 7.1.3 201.7	IS 13450 (Part 1), IS/IEC 80601-2-58	R	Each 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	Each 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	Each 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 of each	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			model		
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 of each model	05 Years	Refer note 1
	Fixing of wiring	8.10.2					
	Connections between different parts of ME Equipment	8.10.3, 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, Annex L	IS 13450 (Part 1)	S	One of each model	05 years	Refer note 1
	Dielectric Strength	8.8.3	IS 13450 (Part 1)	R	One of each model	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 of each model	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 of each model	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 of each model	05 years	Refer note 1
	Protective earth connections	8.5.1.3, 8.6	IS 13450 (Part 1)	R	One of each model	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 of each model	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 of each model	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 of each model	Every control unit	-
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 of each model	Every consignment received.	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 of each model	05 years	Refer note 1
8.11.3	Power Supply Cords	8.11.3.2 , 8.11.3.3	IS 13450 (Part 1)	S	One of each model	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), IS/IEC 60320-1	S	One of each model	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 of each model	05 years	Refer note 1
8.11.3.6	Cord guards	8.11.3.6, 25.14	IS 13450 (Part 1) or IEC 60335-1	S	One of each model	05 years	Refer note 1
8.11.4	Mains terminal devices	8.11.4	IS 13450 (Part 1)	S	One of each model	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 of each model	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					
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 of each model	05 years	Refer note 1
9.5.2	Cathode Ray Tubes	9.5.2, 18	IS 13450 (Part 1), IS 616 or IS/ 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) Or ISO 3746, ISO 9614-1, IS 15575 (Part 1)	S	One of each model	05 years	Refer note 1
9.6.2.2	Infrasound and ultrasound energy	9.6.2.2	IS 13450 (Part 1)	S	One of each model	05 years	Refer note 1
9.6.3	Hand transmitted vibration		IS/ISO 5349-1	S	One of each model	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 of each model	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 of each model	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 of each model	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 of each model	01 year	Refer note 1
10.4	Lasers	-	IEC 60825-1	S	One of each model	01 year	Refer note 1
10.5	Other visible electromagnetic radiation	10.5	IS 13450 (Part 1)	S	One of each model	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	11.1 201.11.1.2	IS 13450 (Part 1) IS/IEC 80601-2-58	S	One of each model	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 of each model	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 of each model	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 of each model	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 of each model	05 years	Refer note 1
11.6.6	Cleaning and disinfection	11.6.6	IS 13450 (Part 1)	S	One of each model	05 years	Refer note 1
11.6.7	Sterilization	11.6.7 201.11.6.7	IS 13450 (Part 1) IS/IEC 80601-2-58	S	One of each model	01 years	
11.6.8	Compatibility with substances used with ME equipment	11.6.8	IS 13450 (Part 1)	S	One of each model	05 years	Refer note 1
11.7	Bio-compatibility	11.7	IS 13450 (Part 1)	S	One of each model	01 years	
11.8	Interruption of power supply/supply mains	11.8	IS 13450 (Part 1)	S	One of each model	05 years	Refer note 1

201.12 Accuracy of Controls and Instruments and Protection against Hazardous Outputs							
12.1	Accuracy of DIATHERMY power	201.12.1.101.3	IS/IEC 80601-2-58	S	One of each model	05 years	Refer note 1
	Accuracy of DIATHERMY frequency	201.12.1.101.4	IS/IEC 80601-2-58	R	One of each model	Every control unit	--
	Accuracy of illumination output	201.12.1.101.5					
	Accuracy of ultrasonic velocity of TIP	201.12.1.101.7					
	Accuracy of velocity of fluid entering eye for LIQUEFACTION	201.12.1.101.8					
	Accuracy of VITRECTOMY PROBE cut rate	201.12.1.101.9					
	Accuracy of static IRRIGATION pressure	201.12.1.101.1					
	Accuracy of ASPIRATION pressure	201.12.1.101.2					
12.2	Usability	-	IEC 60601-1-6	S	One of each model	05 years	Refer note 1
12.3	Alarm Systems	-	IEC 60601-1-8	S	One of each model	05 years	Refer note 1
12.4	Protection against hazardous output	12.4	IS 13450 (Part 1)	S	One of each model	05 years	Refer note 1
201.12.4.101.3	Hazardous output for DIATHERMY power	201.12.4.101.3	IS/IEC 80601-2-58	S	One of each model	05 years	Refer note 1
201.12.4.101.1	Hazardous output for static IRRIGATION pressure	201.12.4.101.1	IS/IEC 80601-2-58	R	One of each model	Every control unit	--
201.12.4.101.2	Hazardous output for ASPIRATION	201.12.4.101.2					
201.12.4.101.4	Hazardous output for DIATHERMY frequency	201.12.4.101.4					
201.12.4.101.5	Hazardous output for Illumination	201.12.4.101.5					
201.12.4.101.7	Hazardous output for ultrasonic velocity of TIP	201.12.4.101.7					
201.12.4.101.8	Hazardous output for velocity of fluid entering eye for LIQUEFACTION	201.12.4.101.8					

201.12.4.101.9	Hazardous output for VITRECTOMY PROBE cut rate	201.12.4.101.9					
201.13 Hazardous Situations and Fault Conditions							
13.1	Specific hazardous situation	13.1.2,11.1.3	13450 (Part 1)	S	One of each model	05 years	Refer note 1
13.2 Single Fault conditions							
13.2.3	Overheating of transformers	15.5.1	13450 (Part 1)	S	One of each model	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 of each model	05 years	Refer note 1
15.1	Arrangements of controls and indicators	-	IEC 60601-1-6	S	One of each model	05 years	Refer note 1
15.2	Serviceability	15.2	13450 (Part 1)	S	One of	05 years	Refer note 1
15.3	Mechanical Strength	15.3					

15.4	Components and general assembly	15.4			each model		
15.5	Transformers in ME Equipment	15.5					
16	ME Systems	16					
17	Electromagnetic compatibility	17, 202	IS 13450 (Part 1), IS/IEC 80601-2-58, IS13450(Part 1/Sec 2)	S	One of each model	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 as per frequency in the levels of control.
Note-2: Manufacturer shall carry out the type test (test indicated to be carried out once in a year/ once in five years) as per the Levels of Control indicated in the table above and submit the report to BIS for verification and records.
Note-3: Licencee shall maintain a Technical File and Risk Management File for each model as per the provisions defined in the Scheme of Inspection and Testing.
Note-4: Sub-contracting is permitted to a laboratory recognized by the Bureau or Government laboratories empanelled by the Bureau.
Note-5: Levels of control given in column obligatory in nature which are to be followed by the manufacturer.

ANNEX C

Possible tests in a day

1. Cl. 201.12.1.101.1(Accuracy of static IRRIGATION pressure)
2. Cl. 201.12.1.101.2 (Accuracy of ASPIRATION pressure)
3. Cl. 201.12.1.101.4 (Accuracy of DIATHERMY frequency)
4. Cl. 201.12.1.101.5 (Accuracy of illumination output)
5. Cl. 201.12.1.101.7 (Accuracy of ultrasonic velocity of TIP)
6. Cl. 201.12.1.101.8 (Accuracy of velocity of fluid entering eye for LIQUEFACTION)
7. Cl. 201.12.1.101.9 (Accuracy of VITRECTOMY PROBE cut rate)
8. Verification of Risk Management File
9. Verification of Technical File