PRODUCT MANUAL FOR

Medical Electrical Equipment - Part 2- Particular Requirements for Basic Safety and Essential Performance- Sec 13 Anaesthetic Workstation
as per IS 13450 (Part 2 / Sec 13): 2024

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 13450 (Part 2 / Sec 13): 2024
	शीर्षक **Title**	:	Medical Electrical Equipment - Part 2- Particular Requirements for Basic Safety and Essential Performance- Sec 13 Anaesthetic Workstation
	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**	:	Please refer **ANNEX – D**
6.	**लाइसेंस का दायरा /Scope of the Licence:**		

"License is granted to use Standard Mark as per ***IS 13450 (Part 2 / Sec 13): 2024*** with the following scope:

Name of the product	Medical Electrical Equipment - Part 2- Particular Requirements for Basic Safety and Essential Performance- Sec 13 Anaesthetic Workstation
Model	
Delivered volume (V_{del})	
Type of anaesthetic vapour delivery system	Interchangeable / Non-interchangeable
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
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

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 'Anaesthetic Workstation' they intend to cover in the scope of licence.

2. For Grant of Licnce/ Change in Scope of Licence, each 'Model' of 'Anaesthetic Workstation' 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 (alongwith their respective component identification no.) for each of the Model of Anaesthetic Workstation':

a) IP Classification (as per CL. 7.2.9 of IS 13450 (Part 1))
b) Anaesthetic gas delivery systems as per Cl. 201.101
c) Anaesthetic breathing system as per Cl. 201.102
d) AGSS as per Cl. 201.103
e) Anaesthetic vapour delivery systems as per Cl. 201.104
f) Anaesthetic ventilator as per Cl. 201.105
g) Display of pressure-volume loops as per Cl. 201.106
h) Accessories to be supplied with the Anaesthetic Workstation

ANNEX- B
LIST OF TEST EQUIPMENTS
(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sl. No.	Tests used in with Clause Reference	Test Equipment
1.	Protection against electrical hazard, 201.8	Multimeter, Electrical safety analyzers.
2.	Alarm condition, 201.11.8.102	Sound level meter
3.	Exhaled volume monitoring, 208.11.8.102	Flow analyzer, Spirometer
4.	Anesthetic breathing system integrity alarm 201.14.4.105	Sound level meter
5.	Pressure Regulators 201.12.4.104	Pressure gauge
6.	Leakage 201.101.5, 201.101.5.1, 201.101.5.2	Pressure gauge
7.	Gas mixtures 201.101.7	Flow analyzers, Oxygen sensors
8.	Graduations of accuracy 201.101.6.1	Flow meter, Flow analyzers
9.	Oxygen flush, 201.101.8	Flowmeter, Flow analyzers
10.	Pressure limitation protection device 201.102.2	Flowmeter
11.	Ports & connectors 201.120.2	Vernier caliper, Micrometer
12.	Leakage 201.102.6	Pressure gauge
13.	Inspiratory & expiratory pressure flow characteristics 201.102.9.3	Flow analyzer, Flow meter.
14.	Inspiratory & expiratory valves 201.102.10	Flow meter, pressure gauge, flow analyzer.
15.	Pressure & flow rate characteristic 201.102.10.3	Flow meter, pressure gauge, flow analyzer
16.	Additional requirement for AGSS 201.103	Manometer, Flow analyzer
17.	Additional requirement for vapor delivery system, 201.104	Flow Analyzer, Manometer, Flowmeter.

Note 1: The licensee shall maintain a Technical file and Risk Management File as per the provisions of IS 13450 (Part 2 / Sec 13): 2024 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;
- Design documentation as per Cl. 201.4.4;
- 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 13450 (Part 2 / Sec 13): 2018. 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 Anaesthetic Workstation provided always that the material so marked conforms to each requirement of the specification.

3.1 Marking shall be done as per Cl. 201.7 of IS 13450 (Part 2 / Sec 13): 2018.

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**						
4.1	Conditions for application to ME EQUIPMENT or ME SYSTEMS	4.1	IS 13450 (Part 1)	R	Each Medical Equipment		Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
4.2	Risk management process for ME equipment or ME systems	4.2	IS 13450 (Part 1)	R			
201.4.3	**Essential Performance**						
	Additional ESSENTIAL PERFORMANCE requirements	4.3 Table 201.102	IS 13450 (Part 1) IS 13450-2-13	R	Each Medical Equipment		
Table 201.102	Oxygen flow under all conditions except the failure of the oxygen supply (pipeline or cylinder) to the *anaesthetic workstation* or generation of a *technical alarm condition*						
	oxygen supply failure alarm)	201.12.4.107.1	IS 13450-2-13	R			
	oxygen supply failure protection device	201.12.4.107.2	IS 13450-2-13	R			
	interruption of the	201.101.2	IS 13450-2-13	R			

	electrical power supply					
	oxygen flush	201.101.8	IS 13450-2-13	R		
Table 201.102	Delivery of a non-hypoxic gas mixture to the *patient* or generation of a *technical alarm condition*					
	alarm condition for power supply failure	201.11.8.102	IS 13450-2-13	R		
	internal electrical power source	201.11.8.103	IS 13450-2-13	R		
	protection against hazardous output	201.12.4	IS 13450-2-13	R		
	reverse flow and cross flow protection device	201.101.4.2.3	IS 13450-2-13	R		
	gas mixers	201.101.7	IS 13450-2-13	R		
	oxygen flush	201.101.8	IS 13450-2-13	R		
Table 201.102	Non-delivery of excessive concentrations of a volatile anaesthetic agent or generation of a *technical alarm condition*					
	delivered vapour concentration	201.104.2	IS 13450-2-13	R		
	anaesthetic agent monitoring equipment	201.12.4.103.3	IS 13450-2-13	R		
Table 201.102	*Airway pressure* monitoring and associated alarm					
	airway pressure monitoring equipment	201.12.4.109	IS 13450-2-13	R		
4.4	EXPECTED SERVICE LIFE	4.4 201.4.4	IS 13450 (Part 1) IS 13450-2-13	R		
4.5	Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS	4.5	IS 13450 (Part 1)	R		

4.6	ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT	4.6	IS 13450 (Part 1)	R			
4.7	SINGLE FAULT CONDITION for ME EQUIPMENT	13.1 13.2	IS 13450 (Part 1)	S			
4.8	Components of ME EQUIPMENT	4.8	IS 13450 (Part 1)	R	One	Each Consignment	No further testing if accompanied with Test Certificate or ISI Mark or covered in Risk Management file
4.9	Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT	4.9	IS 13450 (Part 1)				
4.10	**Power supply**						
4.10.1	Source of power for ME EQUIPMENT	4.10.1	IS 13450 (Part 1)	R	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	Each Medical Equipment		
	Requirements for pneumatic power input	201.4.10.101	IS 13450-2-13				
4.11	Power input	4.11	IS 13450 (Part 1)	R			
201.7	**ME Equipment identification, marking and documents**						
7.1	General	7.1	IS 13450 (Part 1)	R	Each Medical Equipment		
7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts	7.2 201.7.2.3 201.7.2.21	IS 13450 (Part 1) IS 13450-2-13	R			
201.7.2.101	Marking with year of manufacture or use-by	201.7.2.101	IS 13450-2-13	R			

	date					
201.7.2.102	Operator-accessible gas-specific inlet and outlet	201.7.2.102	IS 13450-2-13	R		
201.7.2.103	Operator-accessible gas power supply outlet	201.7.2.103	IS 13450-2-13	R		
201.7.2.104	Components, parts and accessories containing phthalates	201.7.2.104	IS 13450-2-13	R		
201.7.2.105	Cylinder and pipeline pressure indicators	201.7.2.105	IS 13450-2-13	R		
201.7.2.106	Magnetic resonance environment	201.7.2.106	IS 13450-2-13	R		
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts	7.3	IS 13450 (Part 1)	R		
7.4	Marking of controls and instruments	7.4 201.7.4.2	IS 13450 (Part 1) IS 13450-2-13	R		
4.3	Units of measurement	4.3 201.7.4.3	IS 13450 (Part 1) IS 13450-2-13	R		
7.5	Safety signs	7.5		R		
7.6	Symbols	7.6		R		
7.7	Colours of the insulation of conductors	7.7	IS 13450 (Part 1)	R		
7.8	Indicator lights and controls	7.8	IS 13450 (Part 1)	R		
7.9	ACCOMPANYING DOCUMENTS	7.9 201.7.9.1	IS 13450 (Part 1) IS 13450-2-13	R		
	General	201.7.9.2.1	IS 13450-2-13	R		
	Warnings and safety notices	201.7.9.2.2	IS 13450-2-13	R		

	Start-up procedure	201.7.9.2.8	IS 13450-2-13	R		
	Additional requirements for the instructions for use	201.7.9.2.101	IS 13450-2-13	R		
	General	201.7.9.3.1	IS 13450-2-13	R	Each Medical Equipment	
	Components	201.7.9.3.101	IS 13450-2-13	R		
	Anaesthetic workstations intended to be mounted to a wall or ceiling pendant	201.7.9.3.102	IS 13450-2-13	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	Each Medical Equipment	
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		
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	Each Medical Equipment	
8.4.2 (b)	The Leakage Currents from, to or between Accessible parts	8.7.4	IS 13450 (Part 1)	R		
8.4.2 (c)	Other accessible parts	8.4.2	IS 13450 (Part 1)	R		
8.4.2 (d)	Internal parts that are accessible	8.4.2	IS 13450 (Part 1)	R		
8.4.3	ME equipment intended to be connected to a	8.4.3	IS 13450 (Part 1)	R	Each Medical	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File

	power source by a plug				Equipment	
8.4.4	Internal capacitive circuits	8.4.4	IS 13450 (Part 1)	R		
8.5	**Separation of Parts**					
8.5.1.2	Means of Patient Protection (MOPP)	8.5.1.2	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)	8.5.1.2	IS 13450 (Part 1)	S		
8.5.2	Separation of PATIENT CONNECTIONS	8.5.2	IS 13450 (Part 1)	S		
8.5.3	MAXIMUM MAINS VOLTAGE	8.5.3	IS 13450 (Part 1)	S		
8.5.4	WORKING VOLTAGE	8.5.4	IS 13450 (Part 1)	S		
8.5.5.2	Energy Reduction Test	8.5.5.2	IS 13450 (Part 1)	S		
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	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
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)	R	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
8.7.2	SINGLE FAULT CONDITIONS	8.7.2	IS 13450 (Part 1)	R		
8.7.3	Allowable values	8.7.3	IS 13450 (Part 1)	R		
8.7.4	Measurements	8.7.4	IS 13450 (Part 1)	R		
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 every six months for each type of 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 every six months for each type of model manufactured during that period
8.8.4.2	Resistance to environmental stress	8.8.4.2	IS 13450 (Part 1)	S		
8.9	**CREEPAGE DISTANCES and AIR CLEARANCES**					
8.9.1	Values	8.9.1	IS 13450 (Part 1)	S	One	Once in every six months for each type of model

8.9.2	Applications	8.9.2	IS 13450 (Part 1)	S		manufactured during that period
8.9.3	Spaces filled by insulating compound	8.9.3	IS 13450 (Part 1)	S		
8.9.4	Measurement of CREEPAGE DISTANCES AND AIR CLEARANCES	8.9.4	IS 13450 (Part 1)	S		
8.10	**Components and wiring**					
8.10.1	Fixing of components	8.10.1	IS 13450 (Part 1)	R	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	Once in a month for each type of model manufactured during that period

8.11.2	Multiple Socket Outlets	8.11.2	IS 13450 (Part 1)	R		
8.11.3	**Power Supply Cords**					
8.11.3.1	Application	8.11.3.1	IS 13450 (Part 1)	R	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		
201.8.11.3.101	Additional requirements for power supply cords	201.8.11.3.101	IS 13450-2-13	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)	R	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
9.2	MECHANICAL HAZARDS associated with moving parts	9.2 201.9.2.1	IS 13450 (Part 1) IS 13450-2-13	R		

	Maintenance points	201.9.2.101	IS 13450-2-13	R		
	Lighting	201.9.2.102	IS 13450-2-13	R		
	Integrated seating	201.9.2.103	IS 13450-2-13	R		
	Arrangement of control positions	201.9.2.104	IS 13450-2-13	R		
9.3	MECHANICAL HAZARD associated with surfaces, corners and edges	9.3	IS 13450 (Part 1)	R		
9.4	Instability HAZARDS	9.4	IS 13450 (Part 1)	S		
9.5	Expelled parts HAZARD	9.5	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
9.6	Audible acoustic energy	9.6	IS 13450 (Part 1)	S		
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure	9.7	IS 13450 (Part 1)	S		
9.8	MECHANICAL HAZARDS associated with support systems	9.8	IS 13450 (Part 1)	S		
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 type of 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	10.5	IS 13450 (Part 1)	S	One	

	radiation					
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 every six months for each type of model manufactured during that period
11.2	Fire Prevention	11.2	IS 13450 (Part 1)	S		
11.3	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT	11.3	IS 13450 (Part 1)	S		
11.4	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics	11.4	IS 13450 (Part 1)	S		
11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents	11.5	IS 13450 (Part 1)	S		
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT	11.6 201.11.6.3 201.11.6.8	IS 13450 (Part 1) IS 13450-2-13	R	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File

11.7	Biocompatibility of ME EQUIPMENT and ME SYSTEMS	11.7	IS 13450 (Part 1)	S	One	Each consignment	No further testing if accompanied with Test Certificate
11.8	Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT	11.8	IS 13450 (Part 1)	R	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File	
	General requirements	201.11.8.101	IS 13450-2-13	R			
	Alarm condition for power supply failure	201.11.8.102	IS 13450-2-13	R			
	Internal electrical power source	201.11.8.103	IS 13450-2-13	R			
201.11.101	Internal electrical power source	201.11.101	IS 13450-2-13	R			
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	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File	
12.2	USABILITY of ME EQUIPMENT	12.2	IS 13450 (Part 1)	R			
12.3	ALARM SYSTEMS	12.3	IS 13450 (Part 1)	R			
12.4	Protection against hazardous output	12.4.1 to 12.4.4	IS 13450 (Part 1)	R			
	Accidental adjustment of operating controls	201.12.4.101	IS 13450-2-13	R			
	Additional requirements for anaesthetic workstations	201.12.4.102	IS 13450-2-13	R			
201.12.4.103	Respiratory gas monitoring equipment				Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File	
	Carbon dioxide monitoring equipment	201.12.4.103.1	IS 13450-2-13	R			
	Oxygen monitoring	201.12.4.103.2	IS 13450-2-13	R			

	equipment					
	Anaesthetic agent monitoring equipment	201.12.4.103.3	IS 13450-2-13	R		
201.12.4.104	Exhaled volume monitoring equipment					
	Accuracy	201.12.4.104.1	IS 13450-2-13	R		
	Alarm conditions	201.12.4.104.2	IS 13450-2-13	R		
201.12.4.105	Anaesthetic breathing system integrity alarm condition	201.12.4.105	IS 13450-2-13	R		
201.12.4.106	Anaesthetic breathing system continuing-positive-pressure alarm condition	201.12.4.106	IS 13450-2-13	R		
201.12.4.107	Anaesthetic gas delivery system oxygen supply and delivery					
	Oxygen supply failure alarm system	201.12.4.107.1	IS 13450-2-13	R		
	Oxygen supply failure protection device	201.12.4.107.2	IS 13450-2-13	R		
	Hypoxic mixture delivery selection protection device	201.12.4.107.3	IS 13450-2-13	R		
201.12.4.108	Protection device for the workplace environment	201.12.4.108	IS 13450-2-13	R		
201.12.4.109	Airway pressure monitoring equipment	201.12.4.109	IS 13450-2-13	R		
201.13	**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 every six months for each type of model manufactured during that period
201.13.101	Simultaneous failure	201.13.101	IS 13450-2-13	S		

201.14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**					
14	Programmable Electrical Medical Systems (PEMS)	14	IS 13450 (Part 1)	S	One	Once in three years for each type of model manufactured during that period
	Identification of known and foreseeable hazards	201.14.6.1	IS 13450-2-13	S		
201.14.101	Software life cycle processes	201.14.101	IS 13450-2-13	S	One	Once in three years for each type of model manufactured during that period or whenever there is a change in software
201.15	**Construction of ME EQUIPMENT**					
15.1	Arrangements of controls and indicators of ME EQUIPMENT	15.1	IS 13450 (Part 1)	R	One	Once in a month for each type of model manufactured during that period
15.2	Serviceability	15.2	IS 13450 (Part 1)	R		
15.3	Mechanical strength	15.3 201.15.3.5	IS 13450 (Part 1) IS 13450-2-13	R		
15.4	ME EQUIPMENT components and general assembly	15.4	IS 13450 (Part 1)	R		
201.15.101	Operator-detachable, flow-direction-sensitive parts and accessories	201.15.101	IS 13450-2-13	R	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	16 201.16.9.2.1	IS 13450 (Part 1) IS 13450-2-13	S	One	Once in every six months for each type of model manufactured during the period
201.16.101	Additional requirements for signal input/output part					
	General	201.16.101.1	IS 13450-2-13	S	One	Once in every six months for each type of model manufactured during the period
	Connection to other equipment for network/data coupling	201.16.101.2	IS 13450-2-13	S		
	Connection to distributed alarm	201.16.101.3	IS 13450-2-13	S		

	system/information system					
	Connection for remote control	201.16.101.4	IS 13450-2-13	S		
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 every three years for each type of model manufactured during the period
201.101	**Additional requirements for anaesthetic gas delivery systems**					
201.101.1	Identification and documents				Each Medical Equipment	
	Instructions for use	201.101.1.1	IS 13450-2-13	R		
	Technical description	201.101.1.2	IS 13450-2-13	R		
201.101.2	Interruption of the electrical power supply	201.101.2	IS 13450-2-13	R		
201.101.3	Protection against cross-contamination of volatile anaesthetic agents	201.101.3	IS 13450-2-13	R	Each Medical Equipment	
201.101.4	Medical gas supply					
201.101.4.1	Cylinder supplies					
201.101.4.1.1	Inlet connector	201.101.4.1.1	IS 13450-2-13	R	Each Medical Equipment	
201.101.4.1.2	Inlet filtration	201.101.4.1.2	IS 13450-2-13	R		
201.101.4.1.3	Pressure regulators	201.101.4.1.3	IS 13450-2-13	R	Each Medical Equipment	
201.101.4.1.4	Reserve oxygen supply	201.101.4.1.4	IS 13450-2-13	R		
201.101.4.2	Pipeline supplies					
201.101.4.2.1	Inlet connector	201.101.4.2.1	IS 13450-2-13	R	Each Medical Equipment	
201.101.4.2.2	Inlet filtration	201.101.4.2.2	IS 13450-2-13	R		
201.101.4.2.3	Reverse flow and cross-	201.101.4.2.3	IS 13450-2-13	R		

	flow protection device					
201.101.4.3	Pressure or content monitoring equipment	201.101.4.3	IS 13450-2-13	R		
201.101.5	Anaesthetic gas delivery system leakage					
201.101.5.1	Leakage prior to the flow rate adjustment control element	201.101.5.1	IS 13450-2-13	R	Each Medical Equipment	
201.101.5.2	Leakage after the flow rate adjustment control element	201.101.5.2	IS 13450-2-13	R		
201.101.6	Gas flow rate metering					
201.101.6.1	Graduations and accuracy	201.101.6.1	IS 13450-2-13	R		
201.101.6.2	Flow rate adjustment control	201.101.6.2	IS 13450-2-13	R		
201.101.6.3	Carbon dioxide flow rate adjustment control	201.101.6.3	IS 13450-2-13	R		
201.101.7	Gas mixers	201.101.7	IS 13450-2-13	R		
201.101.8	Oxygen flush	201.101.8	IS 13450-2-13	R		
201.101.9	*Fresh-gas outlet*	201.101.9	IS 13450-2-13	R		
201.101.10	Interface to *interchangeable anaesthetic vapour delivery systems*	201.101.10	IS 13450-2-13	R		
201.102	Additional requirements for an *anaesthetic breathing system*					
201.102.1	Identification, marking and documents				Each Medical Equipment	
201.102.1.1	Marking					
201.102.1.1.1	Non-metallic parts	201.102.1.1.1	IS 13450-2-13	R		
201.102.1.1.2	Bag/ventilator control	201.102.1.1.2	IS 13450-2-13	R		
201.102.1.1.3	Absorbent bypass	201.102.1.1.3	IS 13450-2-13	R	Each	

201.102.1.1.4	Inspiratory and expiratory ports of a circle absorber assembly	201.102.1.1.4	IS 13450-2-13	R	Medical Equipment	
201.102.1.2	Instructions for use	201.102.1.2	IS 13450-2-13	R		
201.102.2	Pressure limitation protection devices	201.102.2	IS 13450-2-13	R		
201.102.2.1	Maximum limited pressure protection device	201.102.2.1	IS 13450-2-13	R		
201.102.2.2	Adjustable pressure limit protection device	201.102.2.2	IS 13450-2-13	R		
201.102.3	Packaging of parts of anaesthetic breathing systems	201.102.3	IS 13450-2-13	R		
201.102.4	Electrical conductivity	201.102.4	IS 13450-2-13	R		
201.102.5	Ports and connectors					
201.102.5.1	Patient connection port	201.102.5.1	IS 13450-2-13	R	Each Medical Equipment	
201.102.5.2	Exhaust port connector	201.102.5.2	IS 13450-2-13	R		
201.102.5.3	Reservoir bag connector					
201.102.5.3.1	Arrangement and connector	201.102.5.3.1	IS 13450-2-13	R	Each Medical Equipment	
201.102.5.3.2	Marking	201.102.5.3.2	IS 13450-2-13	R		
201.102.5.3.3	Connectors of the reservoir bag connecting tube	201.102.5.3.3	IS 13450-2-13	R		
201.102.5.4	Anaesthetic ventilator port connector	201.102.5.4	IS 13450-2-13	R		
201.102.5.5	Anaesthetic breathing system port connector	201.102.5.5	IS 13450-2-13	R		
201.102.5.6	Inspiratory and expiratory port connectors of a *circle absorber assembly*					
201.102.5.7	Other port connectors	201.102.5.7	IS 13450-2-13	R	Each	

201.102.6	Leakage	201.102.6	IS 13450-2-13	R	Medical Equipment	
201.102.7	Inspiratory and expiratory pressure/flow rate characteristics	201.102.7	IS 13450-2-13	R		
201.102.8	Anaesthetic breathing system parts and accessories					
201.102.8.1	Y-piece	201.102.8.1	IS 13450-2-13	R	Each Medical Equipment	
201.102.8.2	Exhaust valve	201.102.8.2	IS 13450-2-13	R		
201.102.8.3	Breathing tubes	201.102.8.3	IS 13450-2-13	R		
201.102.9	Circle absorber assemblies	201.102.9	IS 13450-2-13	R		
201.102.9.1	Constructional requirements	201.102.9.1	IS 13450-2-13	R		
201.102.9.2	Absorbent bypass mechanism	201.102.9.2	IS 13450-2-13	R		
201.102.10	Resistance to flow rate	201.102.10	IS 13450-2-13	R		
201.102.10.1	Constructional requirements	201.102.10.1	IS 13450-2-13	R		
201.102.10.2	Opening pressure	201.102.10.2	IS 13450-2-13	R		
201.102.10.3	Pressure flow-rate characteristics	201.102.10.3	IS 13450-2-13	R		
201.102.10.4	Reverse flow rate and dislocation	201.102.10.4	IS 13450-2-13	R		
201.102.11	Fresh-gas inlet	201.102.11	IS 13450-2-13	R		
201.102.12	Ventilation modes	201.102.12	IS 13450-2-13	R		
201.103	Additional requirements for an *AGSS*					
201.103.1	Identification, marking and documents					
201.103.1.1	Marking	201.103.1.1	IS 13450-2-13	R		
201.103.1.2	Instructions for use	201.103.1.2	IS 13450-2-13	R	Each Medical Equipment	
201.103.2	Pressure relief	201.103.2	IS 13450-2-13	R		

	protection device					
201.103.3	General requirements					
201.103.3.1	Normal condition					
201.103.3.1.1	AGSS inlet pressure	201.103.3.1.1	IS 13450-2-13	R	Each Medical Equipment	
201.103.3.1.2	Induced flow rate for active AGSS	201.103.3.1.2	IS 13450-2-13	R		
201.103.3.1.3	Flow resistance for active AGSS	201.103.3.1.3	IS 13450-2-13	R		
201.103.3.1.4	Spillage to atmosphere	201.103.3.1.4	IS 13450-2-13	R		
201.103.3.1.5	Leakage	201.103.3.1.5	IS 13450-2-13	R		
201.103.3.2	Single fault condition					
201.103.3.2.1	Pressure	201.103.3.2.1	IS 13450-2-13	R	Each Medical Equipment	
201.103.3.2.2	Induced flow rate for active AGSS	201.103.3.2.2	IS 13450-2-13	R		
201.103.3.2.3	Subatmospheric pressure at the input of the receiving system for active AGSS	201.103.3.2.3	IS 13450-2-13	R		
201.103.4	Connectors					
201.103.4.1	Hose connectors	201.103.4.1	IS 13450-2-13	R	Each Medical Equipment	
201.103.4.2	Connections between parts of transfer systems and receiving systems	201.103.4.2	IS 13450-2-13	R		
201.103.4.3	Connections to diverting respiratory gas monitors	201.103.4.3	IS 13450-2-13	R		
201.103.5	Transfer system					
201.103.5.1	Inlet	201.103.5.1	IS 13450-2-13	R	Each Medical Equipment	
201.103.5.2	Outlet	201.103.5.2	IS 13450-2-13	R		

201.103.6	Receiving system					
201.103.6.1	Inlet connectors	201.103.6.1	IS 13450-2-13	R	Each Medical Equipment	
201.103.6.2	Outlet connectors	201.103.6.2	IS 13450-2-13	R		
201.103.6.3	Hoses	201.103.6.3	IS 13450-2-13	R		
201.103.6.4	Particle filter for active AGSS	201.103.6.4	IS 13450-2-13	R		
201.103.7	Transfer systems and receiving systems with integral power device for active AGSS	201.103.7	IS 13450-2-13	R		
201.103.8	Visual indicator for active AGSS	201.103.8	IS 13450-2-13	R		
201.104	Additional requirements for interchangeable and non-interchangeable anaesthetic vapour delivery systems					
201.104.1	Identification, marking and documents	201.104.1	IS 13450-2-13	R	Each Medical Equipment	
201.104.1.1	Marking	201.104.1.1	IS 13450-2-13	R		
201.104.1.2	Instructions for use	201.104.1.2	IS 13450-2-13	R		
201.104.2	Delivered vapour concentration					
201.104.2.1	Controls	201.104.2.1	IS 13450-2-13	R		
201.104.2.2	Accuracy	201.104.2.2	IS 13450-2-13	R		
201.104.3	Vapour concentration during and after oxygen flush	201.104.3	IS 13450-2-13	R		
201.104.4	Connectors	201.104.4	IS 13450-2-13	R		
201.104.5	Cross-contamination	201.104.5	IS 13450-2-13	R		
201.104.6	Anaesthetic vapour delivery system filling	201.104.6	IS 13450-2-13	R		
201.104.7	Packaging of anaesthetic vapour	201.104.7	IS 13450-2-13	R	Each Medical	

	delivery system parts and accessories				Equipment	
201.105	Additional requirements for an anaesthetic ventilator					
201.105.1	Instructions for use	201.105.1	IS 13450-2-13	R	Each Medical Equipment	
201.105.2	Pressure limitation protection device					
201.105.2.1	Maximum limited pressure protection device	201.105.2.1	IS 13450-2-13	R	Each Medical Equipment	
201.105.2.2	Adjustable pressure limit protection device	201.105.2.2	IS 13450-2-13	R		
201.105.3	Activation of automatic ventilation	201.105.3	IS 13450-2-13	R		
201.105.4	Anaesthetic breathing system port connector	201.105.4	IS 13450-2-13	R		
201.105.5	Interruption of the electrical or pneumatic power supply	201.105.5	IS 13450-2-13	R		
201.105.6	Exhaust port connector	201.105.6	IS 13450-2-13	R		
201.105.7	Timed ventilatory hold					
201.105.7.1	Expiratory hold	201.105.7.1	IS 13450-2-13	R	Each Medical Equipment	
201.105.7.2	Inspiratory hold	201.105.7.2	IS 13450-2-13	R		
201.105.8	Subatmospheric pressure	201.105.8	IS 13450-2-13	R		
201.106	Display of pressure-volume loops	201.106	IS 13450-2-13	R	Each Medical Equipment	
201.107	Clinical evaluation	201.107	IS 13450-2-13	R		
202	Electromagnetic disturbances — Requirements and tests	202	IS 13450-2-13	S	One	Once in every three years for each type of model manufactured during the period
206	Usability	206	IS 13450-2-13	S	One	Once in six months for each type of model manufactured

	Primary operating functions	206.6.2.2.2	IS 13450-2-13	S		during the period
208	General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	208	IS 13450-2-13	R	Each Medical Equipment	
	Technical description	208.5.2.2	IS 13450-2-13	R		
	Global indefinite alarm signal inactivation states	208.6.8.3	IS 13450-2-13	R		
	Termination of inactivation of alarm signals	208.6.8.4	IS 13450-2-13	R		
	Alarm system logging	208.6.12	IS 13450-2-13	R		
210	Process requirements for the development of physiologic closed-loop controllers	210	IS 13450-2-10	S	One	Once in every three years for each type of model manufactured during the period
212	Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment	212	IS 13450-2-12	S		

Annex D
Possible tests in a day

1. Alarm condition, Cl 201.11.8.102
2. Exhaled volume monitoring Cl 201.12.4.104
3. Anaesthetic breathing system integrity alarm, Cl 201.12.4.105,106,107
4. Pressure regulators Cl 201.101.4.1.3
5. Leakage, Cl 201.102.5
6. Oxygen flush, Cl 201.101.8
7. Pressure limitation protection device, Cl 201.102.2
8. Leakage, CL201.102.6
9. AGSS, Cl 201.103
10. Vaporizer, Cl 201.102