PRODUCT MANUAL FOR
OPHTHALMIC INSTRUMENTS — TONOMETERS
ACCORDING TO IS / ISO 8612: 2009

उत्पाद मैन्यूअल
नेत्र सम्बन्धी उपकरण - टोनोमीटर
आईएस / आईएसओ 8612: 2009 के अनुसार

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 8612: 2009
	शीर्षक **Title**	:	Ophthalmic Instruments — Tonometers
	संशोधनों की संख्या **No. of amendments**	:	Nil
2.	**नमूना दिशानिर्देश** **Sampling Guidelines**		
a)	**कच्चामाल** **Raw material**	:	None
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**	:	Please refer **ANNEX – C**

	Testing		
5.	**एक दिन में संभावित परीक्षण** **Possible tests in a day**	:	All tests as specified in IS / ISO 8612
6.	**लाइसेंस का दायरा /Scope of the Licence:**		

"License is granted to use Standard Mark as per ***IS / ISO 8612: 2009*** with the following scope:	
Name of the product	Ophthalmic Instruments — Tonometers
Model(s)	
Type of instrument	Active Ophthalmic instrument / Non-active Ophthalmic instrument
Rating (Only for Active Ophthalmic InstrumentP)	Rated Voltage …..V (or) Rated Voltage Ranges(s) ……V, ac Frequency …. Hz, Single phase / Three Phase, Rated Current …. A, Input power …….W (or) ….kVA
Display Type	Analog / Digital
IOP Range	….. to ….mN (mmHg)
Accuracy	….mN (mmHg)

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 'Ophthalmic Instruments — Tonometers' they intend to cover in the scope of licence.

2. For Grant of Licence/ Change in Scope of Licence, each 'Model' of 'Ophthalmic Instruments — Tonometers' 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 1: Firm shall declare the following parameters for each of the Model of Ophthalmic Instruments — Tonometers:

a) Degree of ingress protection as per Cl. 11.6 of IS 17724 (Part 1)
b) Pollution degree
c) Type of Mounting - Head Mounted / Plate Mounted
d) List of essential accessories

Note 2: The manufacturer shall also submit the accompanying documents as per Cl.6 of IS / ISO 8612: 2009.

ANNEX- B
List of Test Equipment & Documents
Major test equipment required to test as per the Indian Standard

Sl. No.	Tests used in with Clause Reference	Test Equipment
1.	Measuring force, reverse span and central position of the tonometer arm (Cl. 4.2.1, A.2.3.3)	- Force gauge - Master Rod
2	Surface of tonometer head (Cl. 4.2.1, A.1.3)	Digital vernier caliper
3	Design compliance test (Cl. 4.2.1)	Reference Tonometer
4	Flatness test (Cl. 4.2.1, A.2.3.6)	- Optical Apparatus containing low pressure sodium lamp capable of producing radiation of wavelength 589 nm - Glass optical flat 1/8 wave - 10X Magnifier
5	Diameter of the applanation circle (Cl. 4.2.1, A.2.3.2)	Optical limit gauge

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

Note 2: The licensee shall maintain a Risk Management File as per the provisions of IS/ISO 15004 (Part 1): 2020 for each model in the scope of license.

Note 3: The 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 Control 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 Control system 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 2.5.

1.3 **RECOMMENDED LEVELS OF CONTROL/CONTROL UNIT**:

1.3.1 As mentioned above, recommended levels of control are given in **Table 1 for guidance only**.

1.3.2 The tests as indicated in Table 1 and at the levels of control in column 3 of Table 1 or the Quality Assurance Plan as submitted by the manufacturer to BIS may be carried out on the whole production of the factory which is covered by this plan and records maintained in accordance with para 2.5.

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 where test equipment is required in house i.e "R" or whether it can be subcontracted as "S". Subcontracting is permitted to BIS recognized/empanelled laboratory or any other laboratory having valid accreditation as per IS/ISO/IEC 17025, test reports issued by the laboratories shall be available for inspection by BIS.

2.2 **For MSME manufacturers, the requirement of maintaining a laboratory/in-house testing facility is 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 (including foreign manufacturers) shall maintain an in-house laboratory,** which shall be suitably equipped (as given in column 2 of Table 1) and staffed, 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 test equipment.

2.3.1 Alternatively, in lieu of an in-house laboratory, these manufacturers can also utilize the provisions of Sharing

of testing facilities as per the Annexure-X (Relaxation in test facilities) of the guidelines for Grant of Licence available on BIS website www.bis.gov.in. (Under Conformity Assessment>Product Certification Process)

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 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 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.

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;

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/ISO 15004 (Part 1): 2020. 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 the model.

2.5.2.2 Licencee shall declare the frequency of periodic review of the 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.

3. PACKING AND MARKING - The Standard Mark as given in the Schedule of the licence shall be incorporated legibly and indelibly on each Ophthalmic Instruments — Tonometers provided always that the material so marked

conforms to each requirement of the specification.

3.1 Marking shall be done as per Cl. 8 of IS / ISO 8612: 2009.

3.2 **Additional Marking requirements**: The material shall also be marked with the following additional requirement on the packing of each tonometers:

a) "For BIS certification details please visit www.bis.gov.in"
b) The manufacturer shall also provide the operating principles of the certified tonometer as per Cl. 7 of IS / ISO 8612: 2009

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**				
	Materials	4.5.1 4.5.2	ISO 15004-1	S	One	Each Consignment	No further testing is required is accompanied with test certificate
	Requirements						
4.2	Design compliance testing	4.2.1, Table 1and Annex B 4.2.2, Table 1and Annex B	IS/ISO 8612	R	Each Tonometer		
4.3	Verification	4.3.1 4.2.1 4.3.2, Table 1	IS/ISO 8612	R	Each Tonometer		
4.4	Construction and function	4.4.1 4.4.2	IS/ISO 8612	R	Each Tonometer		
	Fundamental requirements						
	Design	4.2	ISO 15004-1	S	One	Once in every six months for each type of model manufactured during that period to ensure that the risks have been eliminated or reduced to level compatible with the generally acknowledged state of the art	
	Performance	4.3	ISO 15004-1	S	Each Tonometer		
	Combination of different devices	4.4	ISO 15004-1	S	One	Once in every six months for each type of model manufactured during that period	
	Protection against contaminants	4.6	ISO 15004-1	S	Each Tonometer		
	Scales and displays	4.7	ISO 15004-1	S	Each Tonometer		
	Thermal hazards	4.8	ISO 15004-1	S	One	Once in every six months for each type of model manufactured during that period	
	Mechanical hazards	4.9	ISO 15004-1	S			

	Particular requirements for active ophthalmic instruments					
6.1	**Electrical Safety**					
	RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS and ESSENTIAL PERFORMANCE	4.2	IS 13450 (Part 1)	R	Each Medical Equipment	
	ESSENTIAL PERFORMANCE	4.3	IS 13450 (Part 1)	R	Each Medical Equipment	
	Conditions for application to ME EQUIPMENT or ME SYSTEMS	4.1	IS 13450 (Part 1)	R	Each Medical Equipment	
	Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS	4.5	IS 13450 (Part 1)	R	Each Medical Equipment	
	ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT	4.6	IS 13450 (Part 1)	R	Each Medical Equipment	
	SINGLE FAULT CONDITION for ME EQUIPMENT	4.7	IS 13450 (Part 1)	R	Each Medical Equipment	
	Components of ME EQUIPMENT	4.8	IS 13450 (Part 1)	R	Each Medical Equipment	
	Use of	4.9	IS 13450 (Part 1)	R	Each	

	COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT				Medical Equipment	
	Power supply					
	Source of power for ME EQUIPMENT	4.10.1	IS 13450 (Part 1)	R	Each Medical Equipment	
	SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS	4.10.2	IS 13450 (Part 1)	R	Each Medical Equipment	
	General requirements for testing ME EQUIPMENT	5.1 to 5.7	IS 13450 (Part 1)	R	Each Medical Equipment	
	Determination of APPLIED PARTS and ACCESSIBLE PARTS	5.9	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	ME EQUIPMENT identification, marking and documents	7.2 to 7.8.2 Annex C	IS 13450 (Part 1)	S	Each Medical Equipment	
	Energy consumption (power input)	4.11	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Limitation of voltage, current or energy	8.4	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Separation of parts	8.5.1 to 8.5.4	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	CREEPAGE DISTANCES and AIR CLEARANCES	8.9	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	HAZARDS associated	9.2	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period

	with moving parts					Except 9.2.2.4.1
	HAZARD associated with surfaces, corners and edges	9.3	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Serviceability	15.2	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Accuracy of controls and instruments and protection against hazardous outputs	12.1 12.4	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Instability HAZARDS	9.4	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Noise, vibration and acoustic energy	9.6	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT	11.8	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Protective earthing, functional earthing and potential equalization of ME EQUIPMENT	8.6	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	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
	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS and dielectric strength at steady-state operating	8.4.2 8.7 8.8.3.	IS 13450 (Part 1)	R	Each Medical Equipment	

	temperature					
	Humidity preconditioning treatment	5.7	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS and dielectric strength after humidity preconditioning at ambient temperature in the laboratory	8.4.2 8.7 8.8.3	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	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
	HAZARDS associated with support systems	9.8	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	HAZARDOUS SITUATIONS and fault conditions	13	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5	15.5	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	ME EQUIPMENT components and general assembly	15.4 8.10	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	MAINS PARTS,	8.11	IS 13450 (Part 1)	S	One	Once in every six months for each type of model

	components and layout					manufactured during that period
	Insulation other than wire insulation	8.8.4	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Fire prevention and constructional requirements for fire ENCLOSURES of ME EQUIPMENT	11.2 11.3	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Overflow, spillage, leakage, ingress of water, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT	11.6	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	VERIFICATION of markings	7.1 7.2 to 7.8.2 Annex C		R	Each Medical Equipment	
6.2	Optical radiation hazard		ISO 15004 (Part 2)	S	One	Once in every six months for each type of model manufactured during that period
	EMC Requirements		IS 13450 (Part 1/ Sec 2)	S	One	Once in every three years for each type of model manufactured during that period