



## PRODUCT MANUAL FOR SPHYGMOMANOMETER, MERCURIAL ACCORDING TO IS 3390:1988

*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.	<b>Product</b>	:	IS 3390:1988
	<b>Title</b>	:	SPHYGMOMANOMETER - MERCURIAL
	<b>No. of Amendments</b>	:	One
2.	<b>Sampling Guidelines:</b>		
a)	<b>Raw material</b>	:	As per clause 4 of IS 3390
b)	<b>Grouping guidelines</b>	:	Each type shall be tested for GoL/ CSoL
c)	<b>Sample Size</b>	:	One Sphygmomanometer
3.	<b>List of Test Equipment</b>	:	Please refer ANNEX –A
4.	<b>Scheme of Inspection and Testing</b>	:	Please refer ANNEX –B
5.	<b>Possible tests in a day :</b>		
	1. Calibration 2. Leak test 3. Leakage test of inflating bag		
6.	<b>Scope of the Licence :</b>		
	“Licence is granted to use Standard Mark as per IS 3390:1988 with the following scope:		
	Name of the product	Sphygmomanometer - Mercurial type	
	Type	Type 1/ Type 2/ Type 3	

**ANNEX A****List of Test Equipment***Major test equipment required to test as per the Indian Standard*

<b>Sr. No.</b>	<b>Tests Used with clause reference</b>	<b>Test Equipment</b>
1.	Dimensions	Steel Scale, Vernier calliper, Gauges
2.	Set up for testing (Clause 7.1, 7.2, 7.3, 4.12, 4.13, 3.1.2.1, 4.8.3, 4.8.6)	U tube mercury manometer, Air compressor
3.	Boil Test (Clause 7.4)	Burner Stove, Distilled water, Closed vessel with steam vent
4.	Corrosion resistance test (Clause 7.5)	Hot plate/ Gas stove, Distilled water, Citric acid, Stop watch, Glass apparatus

*The above list is indicative only and may not be treated as exhaustive.*

**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 requirements of IS 3390.

**4. CONTROL UNIT** – All instruments of the same Type, Fastening Arrangement and Scale Range produced in one day shall constitute a control unit.

**5. LEVELS OF CONTROL** - The tests as indicated in column 1 of Table 1 and the levels of control in column 3 of Table 1, shall be carried out on the whole production of the factory which is covered by this plan and appropriate records maintained in accordance with paragraph 2 above.

**5.1** All the production which conforms to the Indian Standards and covered by the licence should be marked with Standard Mark.

**6. 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 Methods Clause	Reference		No. of Sample	Frequency	Remarks
3.1.2.1	Cuff/ Stitching/ Fastening arrangement	3.1.2.1	IS 3390	R	Each piece		---
4	Materials	4.1 to 4.7, 7.5	IS 3390	S	One	Each consignment	No further testing is required, if accompanied with test certificate or ISI marked.
4.8.2.1	Cuff	4.8.2.1	IS 3390	R	Ten percent of total number of pieces from each consignment		Excluding clause 4.5
4.8.3	Inflating bag - Dimensions	4.8.3.1, 4.8.3.2	IS 3390	R	Ten percent of total number of pieces from each consignment		---
	Inflating bag – Leakage test	7.3	IS 3390	R	Each piece		---
4.8.4	Tubing	4.8.4	IS 3390	R	Ten percent of total number of pieces from each consignment		----
4.8.5	Inflating bulb	4.8.5	IS 3390	--	Each piece		Excluding material requirements
4.8.6	Control valve	4.8.6	IS 3390	R	Each piece		Excluding material requirements

4.9.1	Manometer tube-Dimension	4.9.1	IS 3390	R	Each glass tubing	Interchangeability shall also be checked
	Manometer tube-Calibration	7.1			One from each consignment of tubing of same dimension	
	Manometer tube-Boil Test	7.4			One from each consignment of tubing received	
4.9.2	Tube mounting and fitting	4.9.2	IS 3390	R	Each piece	---
4.9.3	Reservoir and connecting tube	4.9.3	IS 3390	R	Each piece	---
4.9.4	Extension tube	4.9.4	IS 3390	R	Each piece	---
4.10	Housing	4.10	IS 3390	R	Each piece	---
4.11	Accessories	4.11	IS 3390	R	Each piece	---
4.12	Accuracy	4.12	IS 3390	R	Each piece	---
4.13	Leakage test	4.13, 7.2	IS 3390	R	Each piece	---
5.	Workmanship and finish	5.1, 5.2	IS 3390	-	Each piece	---

Note-1: Sub-contracting is permitted to a laboratory recognized by the Bureau or Government laboratories empanelled by the Bureau.

Note-2: Levels of control given in column 3 are only recommendatory in nature. The manufacturer may define the control unit/batch/lot and submit his own levels of control in column 3 with proper justification for approval by BO Head.