	Technical Specification of Verification and Inspection for Non Invasive Mechanical Sphygmomanometers	S/N	CNMV 16-1
		Rev	2

1. This Technical Specification is developed pursuant to Paragraph 2, Articles 14 and 16 of the Weights and Measures Act.

2. The date of promulgation, document number, date of enforcement and content of amendment are listed as follows:

Rev.	Date of Promulgation	Document No. (Ching-Piao-Szu-Tsu)	Date of Enforcement	Content of Amendment
1	2003-06-10	No. 09240005420	2003-07-01	
2	2006-10-14	No.09540004330	2008-01-01	Rename of the title, S/N; and specifications for aneroid manometers added; and second edition revised

3. This technical specification is formulated with reference to the following international specifications:
   OIML R16-1 Non Invasive Mechanical Sphygmomanometers (2002)

Date of Promulgation	Bureau of Standards, Metrology and Inspection	Date of Enforcement
2006-10-14	**Ministry of Economic Affairs**	**2008-01-01**

1. Scope: this specification applies to non invasive mechanical sphygmomanometers used at the upper arm (hereinafter referred to as the sphygmomanometers). Sphygmomanometers which uses either a mercury or an aneroid manometers.

2. Construction:

2.1 Sphygmomanometers measure in kilopascals (kPa) or in millimeters of mercury (mmHg).

2.2 A sphygmomanometer shall be clearly marked with the following items:

(1) Model and serial number.

(2) Manufacturer's name or trademark.

(3) Measuring rRange and measuring unit of measurement.

2.3 Sphygmomanometer indication: the minimum scale interval shall be not more than 0.3kPa (2mmHg),The maximum capacity of sphygmomanometers shall be more than 34kPa（250 mmHg）.

2.4 Each fifth scale mark shall be indicated by greater length and each tenth scale mark shall be numbered. The scale shall be designed and arranged so that the measuring values can be read clearly and are easily recognized.

2.5 A portable device for mercury manometers shall be provided with an adjusting or locking mechanism to secure it in the specified position of use. The device shall be placed in the tube to prevent mercury from being spilled during use and transport.

2.6 The graduation line of mercury manometers shall be accurate, uniform and perpendicular to the centerline of mercury tube.

2.7 The mercury tube of mercury manometers shall be transparent and straight. The thickness of tube shall be uniform and there is no flaws such as scratches and bubbles to interfere with the moving of mercury column. There shall be no sluggish phenomenon and remains on the wall of tube.

2.8 Mercury used in the mercury manometers shall be pure and clean.

2.9 Mercury manometers shall integrate firmly and mercury shall not leak out.

2.10 Zero setting for aneroid manometers：

（1）The movement of the elastic sensing element including the pointer shall not be obstructed within 0.8 kPa (6 mmHg) below zero.

（2）Neither the dial nor the pointer shall be adjustable by the user.

3. Verification, inspection and maximum permissible errors:

3.1 Verification and inspection equipment: certificates of traceability shall be provided.

(1) Standard pressure gauge: with a capacity not less than 40kPa (300mmHg) and minimum scale interval less than 0.1kPa (0.8mmHg).

(2) Timing device: the minimum scale interval is not more than 1 second.

3.2 If a tolerance zone is shown at zero for mercury manometers, it shall not exceed the maximum permissible error of verification.

3.3 Pressurize the sphygmomanometer to the maximum measuring range and hold for 1 minute.The pressure reduction value shall not exceed the maximum permissible error of verification.

3.4 To verify sphygmomanometer shall pressurize test sphygmomanometer to maximum capacity and release pressure gradually. Within the range from 24 kPa (180 mmHg) to 11 kPa (80 mmHg), two places are selected under the condition of pressure steps not more than 7 kPa (50 mmHg), to compare with standard sphygmomanometer. Two more places, whose pressure is either higher than 24 kPa (180 mmHg) or lower than 11 kPa (80 mmHg), are selected to compare with standard sphygmomanometer. the indication errors shall not exceed the maximum permissible error of verification.

3.5 If a tolerance zone is shown at zero for aneroid manometers, it shall not exceed the maximum permissible error of verification.

3.6 The maximum permissible error of verification of the mercury manometers is ±0.3kPa (±2mmHg).

The maximum permissible error of verification of the aneroid manometers is ±0.4kPa (±3mmHg).

3.7 The inspection maximum permissible errors of mercury manometers are the same as the verification maximum permissible errors.

The maximum permissible error of inspection of the aneroid manometers is ±0.5kPa (±4mmHg).

4. Verification compliance mark of a sphygmomanometer:

4.1 The place of verification compliance mark of sphygmomanometer shall be obvious and on the body of a sphygmomanometer.