MINISTRY OF INDUSTRY, COMMERCE AND TOURISM
NATIONAL INSTITUTE OF METROLOGY, STANDARDIZATION AND INDUSTRIAL QUALITY.

Resolution INMETRO number 24, February 22, 1996

The president of the National Institute of Metrology, Standardization and Industrial Quality - INMETRO, in full use of his legal capacity and provisions of paragraph “g”, sub-item 4.1 of the Resolution CONMETRO number 11, October 12, 1988,

Considering the need of maintaining the health of citizens with accurate measurements,

Considering the necessary regulation of measuring gauges used in the health business, resolves:

Art 1 - To approve the Technical Metrological Regulations establishing the conditions that must be complied with by the mechanical, aneroid-type sphygmomanometers

Art 2 - To subject those who do not abide by these Regulations to penalties as stated in article number 9 of Law 5966, December 11, 1973.

Art 3 - That aneroid-type, mechanical sphygmomanometers currently in place will continue to be used as long as they comply with the maximum allowable error as stated in item 8 of the Technical Metrological Regulations hereto annexed.

Art 4 - That the manufacturers and importers of the aneroid-type, mechanical sphygmomanometers must present their respective models according to the Technical Metrological Regulations annexed hereto, for consideration by INMETRO, within a maximum six-month time limit from the date of publication of the present Resolution.

Art 5 - All aneroid-type, mechanical sphygmomanometers, either manufactured or imported after July 1, 1996, must comply with the this authorized Technical Metrological Regulation.

Art 6 - This Resolution shall go into effect on the date of its publication and all other provisions are hereby revoked.

Julio Cesar Carmo Bueno
President of INMETRO

INMETRO TECHNICAL METROLOGICAL REGULATION NUMBER 24 OF FEBRUARY 22, 1996

1 OBJECTIVE AND FIELD OF APPLICATION

1.1 This Technical Metrological Regulation establishes the conditions that must be satisfied by sphygmomanometers used measure blood pressure in human beings.

1.2 The present Regulation is to be applied to aneroid-type, mechanical sphygmomanometers.

2 DEFINITIONS

2.1 Aneroid-type, mechanical sphygmomanometer: Instrument that utilizes an aneroid manometer for non-invasive blood pressure measurement by means of an inflatable armband.

2.2 Nominal range: Set of values for the measured pressure that can be supplied by the sphygmomanometer taking into account its range.

2.3 Measuring range: Set of pressure values that falls within the accepted sphygmomanometer margin of error, and is maintained within the specified limits.

2.4 Scope of use: Set of maximum and minimum pressure values.

2.5 Minimum limit: Numerical value that indicates the lowest pressure recorded by the instrument.

2.6 Maximum limit: Numerical value that indicates the highest pressure recorded by the instrument.

3 MEASUREMENT UNITS

3.1 The International Unit System (US) uses the Pascal (Pa) as the unit of pressure. It allows the use of mmHg and kPa units.

1 mmHg = 0.133 kPa
1 kPa = 7.518 mmHg

4 COMPONENTS

4.1 Aneroid Manometer: Instrument with an elastic sensor that changes form under pressure. A built-in indicator allows the reading to be read directly on the quantitative circular analog display.

4.2 Armband: A flexible and adjustable device that when inflated is used to stop the flow of blood in the artery, determining the pressure that begins the blood pressure measuring process.

4.2.1 Small Hose: Inflatable armband component.

4.3 Air exhaust control valve: Controls the exit of air in the armband and can be either manual or automatic.

4.4 Pump: Also known as an air pump, is flexible and anatomical in form used to inflate the small hose.

4.5 Unidirectional valve for air pump: Its purpose is to stop the reverse flow of air introduced into the small hose.

5 CONSTRUCTION CHARACTERISTICS

5.1 The pressure-sensitive element must be enclosed in an airtight container.

5.2 Armband

5.2.1 The small hose on the armband must have a minimum width of 35% and minimum length of 80 % of the circumference of the arm depending on the use it will be given (neonatal, medium and large).

5.2.2 The armband must have a device that will prevent it being used with dimensions other than the ones specified in section 5.2.1, or else it must contain instructions for placement and for closure around the arm.

5.2.3 The armband must be manufactured of flexible material and cannot be elastic.

5.3 An envelope must protect the internal components of the manometer so that it will not be affected by dust. This envelope must not make it difficult to read the display.

5.4 The indicator must cover a minimum of 1/3 and a maximum of 2/3 of the length of the smallest graduation marks. The width at the extremity of the indicator that is used for the reading must not be wider than the marks.

5.5 The maximum distance of the indicator in relation to the mark must not exceed 2 mm.

5.6 The sensor element must be manufactured of an appropriate material so that the manometer, after being subjected to 10,000 (ten thousand) cycles of pressure ranging from 20 mmHg to 220 mmHg or 3.0 kPA to 30 kPa at a maximum of 60 (sixty) cycles per minute, must not give errors that exceed those allowed.

5.7 No device can be used to restrict the movement of the indicator within a 15- degree angle below true zero (vacuum), nor any device that may limit the movement of the elastic sensor device to produce an artificial zero indicator.

5.8 The beginning and the end of the scale must not coincide.

5.9 The display and indicator must be protected so that the user cannot access them.

5.10 The pressure variation due to escaping air must not be above 4.0 mmHg/min or 0.5 kPa/min, when the sphygmomanometer is subjected to maximum pressure for five minutes.

5.11 The air exhaust control valve must allow adjustment of the pressure rate reduction for a value within 2.0 mmHg/s and 3.0 mmHg/s or 0.3 kPa/s and 0.4 kPa/s.

5.12 The sphygmomanometer must allow the quick expelling of air, varying the pressure from 260 mmHg to 15 mmHg or 35 kPa to 2.0 kPa over a maximum of 10 seconds.

5.13 The sphygmomanometer must not be deregulated or damaged if it should fall on a wood surface from a height of 5 centimeter.

6 SCALE

6.1 The readings on the scale must indicate the direct pressure values without having to use a multiplication or conversion factor.

6.2 The scale must be printed using a single color that contrasts with the display background.

6.3 Each fifth mark must be longer than the previous four.

6.4 The graduation marks must be clear, well delineated, and with uniform distance and width. The tracing errors must not be easily perceived and the width of the marks should not exceed 1/5 of the smaller distance between two consecutive marks on the scale.

6.5 The value of the smallest division of the sphygmomanometers must be 2 mmHg or 0.2 kPa.

6.6 The scale range must be equal to the nominal scale of the following values:

a) from 0 mmHg to a minimum of 260 mmHg:

b) from 0 kPa to a minimum of 35 kPa.

6.7 The scale must begin at the 0 mmHg or 0 kPa mark. A well-defined mark within a tolerance area around the zero point in the scale is allowed, as long as it does not exceed 3.0 mmHg or 0.4 kPa. The gradation marks within this area are optional.

6.8 The minimum distance between two consecutive marks on the scale must be 0.7 mm.

6.9 Each tenth mark on the sphygmomanometer must be labeled with Arabic numerals.

7 LEGEND

7.1 The instrument must display at least the following:

a) Pressure units

b) Name of manufacturer or trademark

c) Serial number

d) Model approval seal

7.2 The armband must indicate the appropriate arm circumference in accordance with sub-item 5.2.1 of this Regulation. The center of the small hose must be marked to indicate the correct positioning of the armband on the artery.

7.3 Supplemental inscriptions can be authorized when individual approval of the instrument models is obtained.

8 MAXIMUM ALLOWED ERROR MARGIN

8.1 The maximum allowed error margin for sphygmomanometers under environmental conditions of 15^{o}C to 25^{o}C and 20% to 90 % relative air humidity for each value of pressure during increase or decrease should not exceed +/- 3.0 mmHg or 0.4 kPa.

8.2 The difference between the extreme values measured under environmental conditions of 10^{o}C to 40^{o}C and relative air humidity of 90%, must be smaller than or equal to 3.0 mmHg or 0.4 kPa.

8.3 The difference between decreasing or increasing pressure at the same point read on the reference manometer, must be within 0 mmHg and +4 mmHg or 0 kPa and 0.5 kPa, where the reading at decreasing pressure will be taken after the manometer tested has been subjected to a maximum load for 5 minutes.

8.4 The errors mentioned in sub-item 8.1 must be observed at intervals of a maximum of 50 mmHg, or the corresponding value in kPa along the entire scale.

8.5 After being subjected to a temperature ranging from -20 ^{o} C for 24 hours to a temperature of 70 ^{o} C for 24 hrs and relative air humidity of 90%, the sphygmomanometer must be pass inspection as stated in sub-item 8.1.

9 METROLOGICAL CONTROL

9.1 Technical evaluation of the model

9.1.1 Each manufacturer or importer of sphygmomanometers must submit each manufactured or imported model for approval by INMETRO.

9.1.2 No modification can be made in a sphygmomanometer that has already been approved, without INMETRO's prior authorization.

9.1.3 The sphygmomanometer manufacturer or the latter's legal representative, as well as the importer must obtain INMETRO's approval of their models by filing an application accompanied by a detailed description of its construction, an explanation of the materials used and drawings of the instruments.

9.1.4 The manufacturer or the latter's legal representative as well as the importer must send INMETRO 5 (five) prototypes of each model which will be submitted for approval testing.

9.1.5 Of the instruments sent for technical model evaluation, 3 (three) will be returned to the applicant and the rest will remain at INMETRO, to be subsequently monitored in conformity with the approved model.

9.1.6 The approval of the model consists of an examination of prototypes submitted according to the provisions of this Regulation that includes the following:

a) A study of documentation: consists of an analysis of the description furnished by the manufacturer or importer when applying for approval of the model;
b) A sight inspection and airproofing test: consists of performing a sight inspection of the materials, checking whether the device can easily be read, monitoring the scale, indicator, smallest division, area of measurement, zero point mark, scale numerals, display of necessary legends and armband and the possibility of lacquer sealing;
c) A dimensional test: consists of verifying armband dimensions, distance of the indicator in relationship to the display, length of marks and distance between gradation marks;
d) A hysteresis test: consists in the application of a maximum load for a period of five minutes, according to sub-item 8.3;
e) Influence of temperature and humidity: consists of verifying the performance of the instrument when it is subjected to temperatures of + 10°C, +20°C and + 40°C with a constant relative air humidity of 90%, according to 8.1;
f) vibration and strength: consists of allowing the sphygmomanometer to fall freely from a height of five centimeter, according to sub-item 8.1;
g) maximum error margin determination: consists of applying an increasing and decreasing load in order to check the error margin for the values indicated by the sphygmomanometer, when compared to a standard;
h) fatigue test: consists of applying 10,000 cycles of pressure ranging from 20 mmHg to 220 mmHg or 3.0 to 30.0 kPa, at a maximum of 60 (sixty) cycles per minute, according to the tests described in sub-item 9.1.6, lines “d” and “g” after one hour has elapsed from the application of 10,000 cycles of pressure;
i) air escape test: consists of applying maximum pressure for five minutes, in order to check whether the drop in pressure is higher than 4.0 mmHg/min or 0.5 kPa/min;
j) test of the air exhaust control valve: consists of verifying whether it is possible to adjust the control valve to produce a reduction in pressure within the limits of 2.0 mmHg/s and 3.0 mmHg/s or 0.3 kPa/s and 0.4 kPa/s;
k) test of quick air exhaust: consists of applying pressure of 260 mmHg or 35 kPa and opening the quick air exhaust control valve and verifying the time passed until the pressure reaches 20 mmHg or 2.7 kPa;
l) verification test of construction characteristics: consists of checking for the existence of devices that might restrict the indicator’s movement according to sub-item 5.7, as well as ascertaining that the instrument is tamper proof, according to sub-item 5.9 and assessing the sphygmomanometer’s performance after the test described in item 8.5.

9.2 Initial Evaluation

9.2.1 This must be done on all manufactured sphygmomanometers, at the factory or other sites, at the discretion of INMETRO, before being certified for use and includes the following tests:

a) sight inspection
b) zero point indicator check
c) airproof check
d) determination of maximum indicator error margin;
e) air escape check; and
f) hysteresis test.

9.2.2 The manufacturer or importer must be available to perform the Initial Evaluation whenever required by INMETRO and its metrological entities.

9.2.3 The evaluation must be performed according to the provisions of paragraphs 8.1, 8.3 and 8.4.

9.3 Periodic evaluation

9.3.1 This must be performed once a year, preferably at the National Network of Legal Metrology - RNML site or at a location designated by INMETRO, and will include the following tests:

a) sight inspection;

b) zero point indicator check;
c) airproof check;
d) determination of maximum indicator error margin;
e) air escape check; and
f) hysteresis test.

9.3.2 The readings must be taken at increasing and decreasing pressures, in keeping with sub-item 8.4, with the last point corresponding to the upper limit of the scale.

9.3.3 The verification must be performed according to the provisions established in 8.1

9.4 Occasional evaluation

9.4.1 Occasional evaluations must be performed at the request of the instrument user, after repair and/or maintenance, or when INMETRO deems necessary.

9.4.2 This evaluation must be performed at the National Network of Legal Metrology - RNML site or at a location designated by INMETRO, and will include the following tests:

a) sight inspection;
b) zero point indicator check;
c) air proof verification;
d) determination of maximum indicator error margin;
e) air escape check and
f) hysteresis test.

9.4.3 The evaluation must be performed according to 8.1, 8.3 and 8.4.

9.5 Seal marks

9.5.1 Seal marks must be posted at a location deemed convenient for this purpose.

9.5.2 The sphygmomanometer seal must comply with seal diagram included in the Model Authorization Resolution.

9.5.3 The check mark must be placed so that it will not interfere with the visibility of the display and must indicate the ID and year in which it was checked by the executing organization.

10 GENERAL PROVISIONS

10.1 The manufacturers and importers of sphygmomanometers under the present Regulation must apply to INMETRO for authorization of their instrument models.

10.2 The manufactured and/or imported sphygmomanometers must comply with all the requirements as stated in the present Regulation.

10.3 For purposes of the present Regulation, the importer and the manufacturer are considered to be one and the same party.

10.4 The sphygmomanometers that do not comply with this Regulation can only be used after being repaired and then subsequently authorized after the pertinent evaluation.

10.5 If necessary, the supplemental safety characteristics can be studied while the model is being evaluated for approval.

10.6 A description manual in Portuguese, containing the following information, must accompany all instruments marketed in the country:

a) name or trademark and address of manufacturer;
b) correct method for using and reading of instrument;
c) technical specification, including armband dimensions;
d) test schedule;
e) instructions for cleaning and sterilization;
f) reference to the present Technical Metrological Regulation citing the number and date of the INMETRO Resolution that approved it.