Kenya National Workshop Agreement **CD/SERV/2014**

ICS

Sphygmomanometers, mercurial — Specification

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TECHNICAL COMMITTEE REPRESENTATION

The following organizations were represented on the Technical Committee:

Nursing Council of Kenya
Ministry of Health
Government Chemist' Department
Coast Provincial Hospital
County of Nairobi, City Council of Nairobi
Association for the Physically Disabled of Kenya (APDK)
Christian Health Association of Kenya (CHAK)
Kenyatta National Hospital
Kenya Bureau of Standards — Secretariat

REVISION OF KENYA STANDARDS

In order to keep abreast of progress in industry, Kenya Standards shall be regularly reviewed. Suggestions for improvements to published standards, addressed to the Managing Director, Kenya Bureau of Standards, are welcome.

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Foreword

This Kenya National Workshop Agreement (KNWA) Standard was prepared by a Joint Technical Committee comprising of the Nursing Council of Kenya (NCK) and the Kenya Bureau of Standards staff.

The Nursing Council of Kenya undertook to develop standards for non-pharmaceutical commodities to facilitate efficient exchange of commercial and technical information during the purchasing and procurement. This standard ensures that suppliers deliver goods which comply with the set specifications and performance.

Recent surveillance have indicated that these products are still useful due to a number of reasons including their being accurate relative to the digital ones, versatility as the parts can be replaceable and cheapness of technology.

The term “normative” has been used in this standard to define the application of the annex A to which it applies. A “normative” annex is an integral part of this standard.

During the development of this standard, reference was made to the following documents:

IS: 3390-1965 Sphygmomanometers, mercurial

This assistance is hereby highly acknowledged.

Sphygmomanometers, mercurial — Specification

1 Scope

This National Workshop Agreement lays down the requirements for mercurial sphygmomanometers used for measuring arterial blood pressure of human beings.

2 Nomenclature

2.1 For the purpose of this standard, the nomenclature for various parts, as indicated in Figure 1, shall apply.

3 Types, fasting and scale range

3.1 The sphygmomanometers shall be of the types, fastening and scale ranges as specified in 3.1.1 to 3.1.3.

3.1.1 Types

a) Type 1 — Portable,

b) Type 2 — Mountable/fixed, and

c) Type 3 — Inclined.

3.1.2 Fastening

The fastening arrangement of the cuff shall be such that the cuff should be capable of being held in position. The arrangement may be of bandage type, hook and rib type or any other convenient type. The fastening arrangement shall also satisfy the requirements given in 3.1.2.1

3.1.2.1 The cuff shall be tied round a rigid cylinder of appropriate size and then pressurized to 50 mm (6.66 kN/m^2) of mercury in stages and kept at each stage for 3 minutes, there shall be no sign of slip or failure of cuff, stitching or the fastening arrangement.

3.1.3 Scale range

Lower range; 0 mm of mercury

Upper range: 260 (34.66 kN/m^2) to 300 (40.0 kN/m) mm of mercury

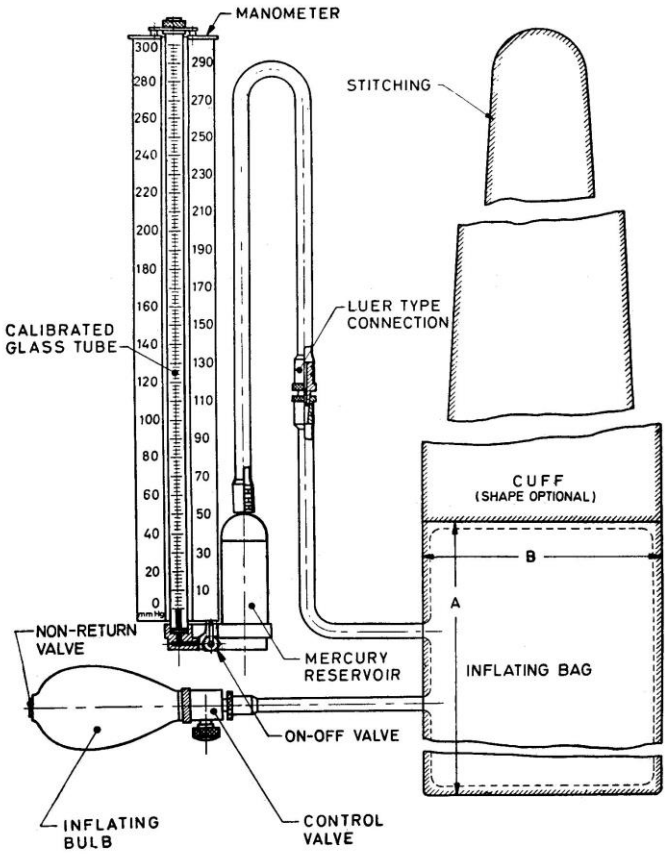

Figure 1 — General Assembly of Sphygmomanometer, Mercurial Type

Table 1 — Dimensions of inflating bag cuff pocket

Dimensions			
Sl.no.	**Sizes**	**A**	**B**
i)	Thigh, large	550	190
ii)	Thigh, small	400	190
iii)	Adult arm	240	140
iv)	Child arm	200	115
v)	Infant arm	135	75
vi)	New-born baby arm	95	40

NOTE. Larger sizes of the inflating bags may be acquired as agreed upon between the manufacturer and the buyer.

4 Material

4.1 Metal parts

The metal parts shall be fabricated from brass, aluminium alloy, steel or any other suitable metal intended. The metal parts shall be given a suitable corrosion resistant finish. If plating is done, it shall satisfy the corrosion resistance test specified in 7.5

4.2 Rubber parts

The rubber parts shall be made of natural or synthetic rubber. The inflating bulb, with its inlet valve in position, shall be capable ageing in an air-oven for 168 h at 70 ^{0}C ± 1 ^{0}C without showing appreciable stiffening, cracking or other change in condition. Rubber tubing shall have a minimum tensile strength and elongation at break before ageing as 105 kgf/cm^2 and 400 respectively. A reduction of 20 percent shall be permitted on tensile strength and 20 percent on elongation. The tensile strength and elongation shall be tested in accordance with KS ISO: 37-2011.

4.3 Glass Parts

The glass parts shall be made of clear glass. Glass shall show no evidence of corrosion, scumming, chipping or cracking, when subjected to the boil test as specified in 7.4.

4.4 Plastics

The plastics used shall be suitable for the purpose intended and shall not flake, peel or otherwise disintegrate in normal use. The plastics tube shall remain clear like glass after subjecting to boil test as specified in 7.4

4.5 Fabric

the fabric shall be of suitable cloth having minimum breaking load specified against in accordance with Annex A.

4.6 Sewing thread

the sewing thread used shall be such that it satisfies the requirements given in 3.1.2.1.

4.7 Mercury

The mercury used shall be clean, double distilled and of 99.9 percent purity.

4.8 Component part

4.8.1 Sphygmomanometers shall consist of an inflation system, a pressure measuring device (manometer), a housing for the manometer and its inflation system. These individual devices or replacement parts or complete sphygmomanometers- may be ordered by the purchaser.

4.8.2 Inflation system shall consist of a cuff, inflating bag, inflating bulb and a control valve.

4.8.2.1. **Cuff**

The cuff shall be of the material specified in 4.5. Cuff shall be of two layers of material. A pocket shall be provided for the inflating bag made according to dimensions A and B (see fig 1). It shall have an opening of about 50 mm on the side for entry of inflating bag and to accommodate its tubes. The cuff shall be long

enough to give proper fastening to the required size of thigh or arm. The deviation on dimensions shall be as given in 4.8.3.2.

4.8.3 Inflating bag

The inflating rubber bag shall be capable of withstanding an internal pressure of 450 mm of mercury without leaking, when tested as specified in 7.3.

4.8.3.1 The bag shall be of the following sizes:

	Length mm	Breath mm
Large thigh	500	175
Small thigh	380	175
Adult arm	225	125
Child arm	180	100
Infact arm	120	60
New-born baby arm	80	25

4.8.3.2 Deviation as given below shall be applied on the dimensions given in 4.8.3.1. and Fig. 1:

		mm
Below 100 mm	Bag	+0 -3
	Cuff pocket	- 0 +3
Above 100 mm and Below 200 mm	Bag	+0 -5
	Cuff pocket	-0 +5
Above 200 mm	Bag	+0 +10
	Cuff pocket	-0 +10

4.8.4 Tubing

Two lengths of rubber tubes, approximately 460 mm long each shall be attached to one long side of the bag and shall provide air entry from one end and exit from the other. These tubes shall be fitted with female Luer fittings conforming to ISO 594-2 to make leak-proof connections with the male Luer fitting attached to the extension tubes. The internal diameter of the tubes shall be 3 ± 0.5 mm and external diameter shall not be less than 8.0 mm for fitting to inflating bags of child and adult sizes, and not less than 6.0 mm for infant sizes.

4.8.5 Inflating bulb

The inflating bulb shall be made of natural rubber or plastics and shall be ovoid in shape. One end shall be securely fitted with an air inlet non –return valve. The other end shall be fitted over the proximal end of the control valve.

4.8.6 Control value

Control valve shall have a knurled thumb control device which shall be attached such that it does not become completely unscrewed when the cuff is tied round a rigid cylinder of appropriate diameter, control valve shall be effective in holding a pressure of 300 mm, 150 mm and 50 mm of mercury with a leakage rate not exceeding 10 mm of mercury per minute. The valve shall be tested at these points and at any intermediate points between 50 mm and 300 mm of mercury as may be deemed necessary to meet compliance (see also 7.2)

4.8.6.1 Control valve shall be capable of giving complete control by hand to give a reduction in pressure at the rate of 1 mmHg/s to free release.

4.8.6.2 One end of control valve shall be attached to the inflating bulb and the other end to one of the tubes of the inflating bag.

4.9 Pressure measuring device

4.9.1 The manometers shall consist of a graduated glass tube, a reservoir, a connection from reservoir to manometer tube, a rubber tube extension with a male Luer fitting and sufficient mercury for proper operation of the instruments. The manometer tube shall be of adequate length for the purpose intended and shall have an inside diameter of 4 mm ± 0.2 mm and wall thickness of not less than 2.0 mm. The manometer tube shall be calibrated and so designed in conjunction with the design of the remaining instrument as to be interchangeable, without calibration on the instruments of the same scale range of the same manufacturer. The scale markings and graduations shall be engraved and filled with pigment, etched and filled with pigment or accomplished by silk screening and fusing in or fusing on a pigment. The pigment shall be red, brown or black in colour and shall be permanent, meeting the requirements of boil test as given in 7.4. Any loss of pigment shall be a cause of rejection. The graduation shall extend from zero to full scale in 2-mm divisions with proportionately longer markings at each 10-mm division on the tube. The longer divisions shall be about 30 % to 40 % longer than the shorter ones. The numerals on a scale plate may also be affixed in the back of the glass or plastics tube, if required by the purchaser. The colour, in which the numerals are marked, shall be in clear contrast to the background in order to be easily read. The pressure unit, that is, 'mmHg' shall be marked on the scale plate (see 71.and 74)

4.9.2 Tube mounting and fittings

Tube shall be recess-mounted to prevent breakage and shall provide a leak-proof channel for the mercury and shall be easily removable for cleaning and replacement. The upper end of the tube shall be fitted with a removable device containing a filter which shall prevent loss of mercury while still allowing the tube at all times to be open to atmospheric pressure and which shall also serve to prevent rapid oscillation and fluctuations of the mercury column, that is, damped column. This device shall be easily removable and replaceable to allow the addition of mercury, when necessary.

4.9.3 Reservoir and connecting tube

The reservoir, trap and connection to the manometer shall be made from suitable material, such as cast iron, steel or high impact resistant plastics, which shall have no deleterious effect on mercury. The reservoir shall be of uniform cross-section, its diameter shall be at least four times that of the manometer tube and its design shall be such as to allow interchangeability of the manometer tubes within instruments of the same scale range of the same manufacture. The reservoir shall be fitted with the safety trap at the top to prevent passage of mercury to the extension tube which will be fitted to the top of the reservoir making a leak-proof connection. The connection from reservoir to the manometer tube shall be air-tight, and mercury-tight, an "On' and "Off" tap shall be provided in the connection from the reservoir to the manometer tube.

4.9.4 Extension tube

A rubber extension tube shall be fitted to the reservoir with a length not less than 300 mm and its end opposite to the reservoir shall be fifed with a male Luer fitting fitted to one of the tubes of the inflating bag.

4.10 Housing

For Type 1, the case shall be of robust design and suitable material. It shall give ample room to house the inflation system without damage. It shall be fitted with a device for setting and holding the lid at right angles. This device shall also prevent the accidental dropping of the lid when the instrument is in use. All parts shall be replaceable in case of breakage. The housing of the Type 2 shall be of wood or metal, and shall be of robust design.

4.11 Accessories

Besides an adult size cuff and inflating bag, the sphygmomanometers may be provided with one set of cuff and inflating bag of sizes specifically required by the purchaser. A cleaning brush to clean the manometer tube and a set of spare washers may be provided with each sphygmomanometer.

4.12 Accuracy

The assembled instrument shall be tested with the mercury column vertical for Type 1 and Type 2 and at the designed inclination for Type 3, and descending at an average rate of 2 mmHg approximately in 5 seconds, but the pressure shall be held constant while readings are being taken.

4.13 Leakage

The air leakage of the completely assembled sphygmomanometer, when tested in accordance with 7.2, shall not exceed 10 mmHg per minute.

5 Workmanship and finish.

5.1 Workmanship shall be of high grade**.**

5.2 Sphygmomanometer shall be free from defects which detract from the appearance and may impair their serviceability

6 Marking

6.1 Each sphygmomanometer shall be legibly and permanently marked with the name of trademark of the manufacturer and the manufacture's serial number.

6.1.1 The sphygmomanometer may also be marked with the Standard Mark.

NOTE The use of the Standard Mark is governed by the provisions of the Kenyan Bureau of Standards Act, Cap 496 and the Rules and Regulations made there-under. The Standard Mark on products covered by Kenyan Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well-defined system of inspection testing and quality control which is devised and supervised by KEBS and operated by the producer. Standard marked products are also continuously checked by KEBS for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the Standard Mark may be granted to manufacturers or producers, may be obtained from the Kenyan Bureau of Standards.

7 Test procedures

7.1 Calibration

All calibrations shall be accomplished with a properly standardized and certified mercurial manometer. One

calibration shall be made without tapping and with decreasing pressure only. Reading shall be taken at the highest point of the scale and at all other points which are multiples of 20 mm. The readings shall be taken with the pressure falling at a rate of 2 mm/^{s} approximately (see 4.9.1)

7.2 Leak test

When the cuff of each completely assembled sphygmomanometer is tied round a rigid bar of appropriate diameter and each valve (when valves are purchased separately) shall be subjected to an internal air pressure of 50, 150 and 300 mmHg. The instrument or the valve shall then be cut off from the air supply. The leakage as given in 4.8.6 and 4.13 shall be permitted.

7.3 Leakage test (inflating bag)

The bag shall be subjected to a pressure of 450 mmHg (gauge) for one minute. The bag shall be prevented from ballooning by the use of sufficient strength to withstand the pressure. There shall be no leakage (see 4.8.2).

7.4 Boil test

The graduated tube shall be completely immersed in distilled water in a closed vessel having a steam vent and boiled continuously for six hours, boiling distilled water added when necessary to compensate for evaporation. The tube shall be suspended in water so that it does not come in contact with the containing vessel. The glass shall not show any evidence of corrosion, chipping or cracking and the graduation shall not have appreciably deteriorated in intensity. (see 4.9.1)

7.5 Corrosion resistance test

the plated components shall be immersed in a 10 percent solution of citric acid at room temperature for 5 hours. They shall then be boiled in distilled water for 30 minutes and cooled while immersed in the same for 48 hours. The test shall be conducted in a glass container. The components shall throw no sign of corrosion.

8 Packaging

The sphygmomanometer shall be wrapped in a soft tissue paper and packed in a cardboard box or other equivalent box.

9 Instruction manual

Each sphygmomanometer shall be provided with a manual giving necessary instructions and precautions to be taken for its proper use. The instruction manual shall include technical specification of the sphygmomanometer, list of accessories and spare components to be supplied with the equipment.

Annex A
(normative)

Fabric specification for inflation bag and cuff pocket

Approximate count of yarn cotton (text)		Ends/cm	Picks/cm	Mass/m^2	Breaking load on 5.0X20 cm strips, min	
Warp	Weft				Warpway	Weftway
24s(25 text)	24s (25 text)	38	28	170	510(52)N	375(38)N