at least at 7 kPa (50 mmHg) and 27 kPa (200 mmHg) and paragraph 6(4)(iv);

(e) internal nominal diameter and tolerance of the tube containing mercury; and

(f) detailed instructions for the safe handeling of mercury.

ANNEXURE A

TEST PROCEDURES (Mandatory)

1. Method of test for the maximum permissible errors of the cuff pressure indication

(1) Apparatus

(i) rigid metal vessel with a capacity of 500 ml ± 5 %;

(ii) calibrated reference manometer with an uncertainty less than 0.1 kPa (0.8 mmHg);

(iii) pressure generator, e.g. ball pump (hand pump) with a deflation valve;

(iv) T-piece connectors and hoses.

(2) Procedure

Replace the cuff with the vessel. Connect the calibrated reference manometer by means of a T-piece connector and hoses to the pneumatic system (see Figure 2). After disabling the electro-mechanical pump (if fitted), connect the pressure generator into the pressure system by means of another T-piece connector. Carry out the test in pressure steps of not more than 7 kPa (50 mmHg) between 0 kPa (0 mmHg) and the maximum pressure of the scale range.

(3) Expression of results

Express the results as the differences between the indicated pressure of the manometer of the device to be tested and the corresponding readings of the reference manometer.

2. Method of test for the influence of temperature on cuff pressure Indication

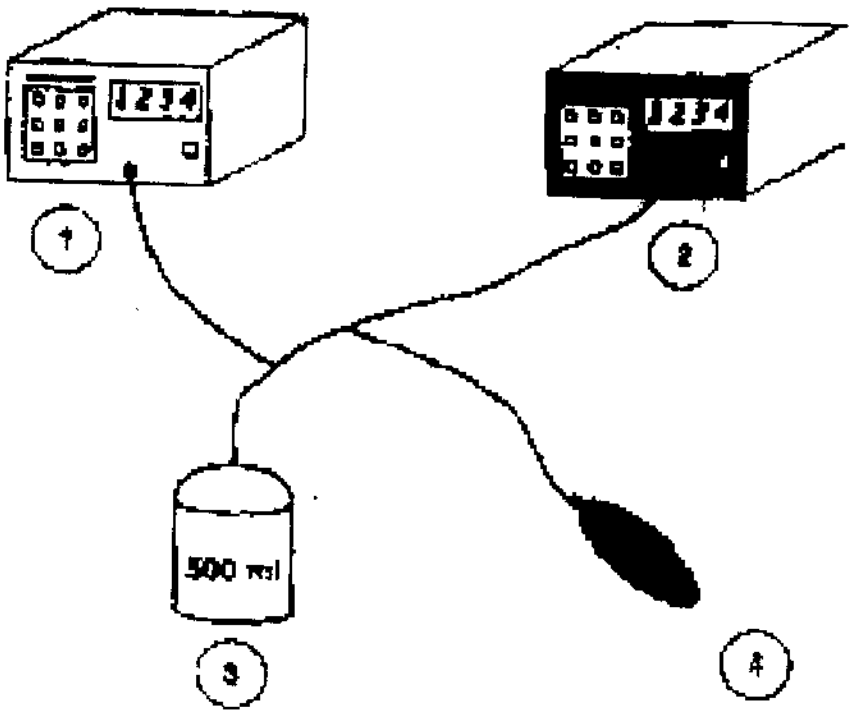
(1) Apparatus

(i) apparatus as specified in paragraph 1(1) of this Annexure plus

(ii) a climatic chamber.

(2) *Procedure*

Replace the cuff with the vessel. Connect the calibrated reference manometer by means of a T-piece connector to the pneumatic system (see Figure 3). After disabling the electromechanical pump (if fitted) connect the additional pressure generator into the pneumatic system by means of another T-piece connector.



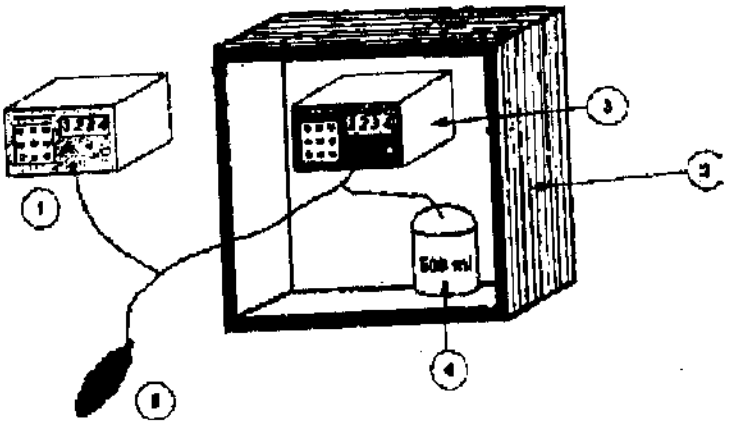
1 - Reference manometer

2 - Manometer of the device to be tested

3 - Metal vessel

4 - Pressure generator

Figure 2. Measurement system for determining the limits of error of the cuff pressure indication



1 - Reference manometer
2 - Climatic chamber
3 - Manometer of the device to be tested
4 - Metal vessel
5 - Pressure generator

Figure 3. Measurement system for determining the influence of temperature

For each of the following combinations of temperature and humidity, condition the device for at least 3 h in the climatic chamber to allow the device to reach steady conditions:—

- 10°C ambient temperature, 85% relative humidity (non-condensing);
- 20°C ambient temperature, 85% relative humidity (non-condensing);
- 40°C ambient temperature, 85% relative humidity (non-condensing).

Carry out the test of the cuff pressure indication as described in paragraph 1(2) of this Annexure for each of the combinations of temperature and humidity mentioned above.

(3) *Expression of results*

Express the results as the differences between the indicated pressure of the manometer of the device to be tested and the corresponding readings of the reference manometer at the relevant temperature value.

3. Method of test for the maximum permissible error after storage

(1) *Apparatus*

- apparatus as specified in paragraph 1(1) of this Annexure.

(2) *Procedure*

Replace the cuff with the vessel. Connect the calibrated reference manometer by means of a T-piece connector to the pneumatic system (see Figure 3). After disabling the electro-mechanical pump (if fitted), connect the additional pressure generator into the pneumatic system by means of another T-piece connector.

Store the instrument under test for 24 h at a temperature of –20°C and subsequently for 24 hours at a temperature of 70°C and a relative humidity of 85% (non-condensing).

Note : This is one test and not two separate tests.

Carry out the test in pressure steps of not more than 7 kPa (50 mmHg) between 0 kPa (0 mmHg) and the maximum pressure of the scale range.

(3) Expression of results

Express the results as the differences between the indicated pressure of the manometer of the device to be tested and the corresponding readings of the reference manometer.

4. Method of test for air leakage of the pneumatic system

(1) Apparatus

- rigid metal cylinder of an appropriate size;
- pressure generator, e.g. ball pump (hand pump) with a deflation valve;
- time measuring device.

(2) Procedure

Wrap the cuff around the cylinder.

Note : Electro-mechanical pumps which are part of the device may be used for the test.

Carry out the test over the whole measuring range at least five equally spaced pressure steps

(e.g.) 7 kPa (50 mmHg), 13 kPa (100 mmHg), 20 kPa (150 mmHg), 27 kPa (200 mmHg) and 34 kPa (250 mmHg). Test the air leakage over a period of 5 min and determine the measured value from this.

(3) Expression of results

Express the air leakage as the rate of the pressure loss per minute.

5. Method of test for pressure reduction rate for deflation valves

(1) Apparatus

- T-piece connector;
- calibrated reference manometer with signal output and an uncertainty less than 0.1 kPa (0.8 mmHg);
- artificial limbs [see Notes under paragraph 5(2) of this Annexure].
- recording unit.

(2) Procedure

Measure the pressure reduction rate either on human limbs or artificial limbs.

Note 1 : The intention is to use artificial limbs, but as these are still under consideration, measurements performed with human volunteers are acceptable.

Note 2 : It is intended that the properties of the artificial limbs reflect some elastic properties of human limbs.

Because cuff deflation rate may be influenced by the way that a cuff is applied, the cuff should be applied and removed for each of at least ten repeated measurements, on at least two different limb sizes. These two limb sizes should be equal to the upper and lower limits of limb circumferences for which a particular size of cuff is recommended to be used. A resetting of the deflation valve is permitted during the test.

Connect the calibrated reference manometer to the cuff by means of a T-piece connector. Connect the output of the calibrated reference manometer to the recording unit.

Plot the pressure reduction in the form of a pressure curve as a function of time.

(3) Expression of results

Determine the rate of pressure reduction by graphical evaluation (by drawing tangents) at the pressure values of 8.0 kPa (60 mmHg), 16.0 kPa (120 mmHg) and 24.0 kPa (180 mmHg). The pressure reduction rate is the mean value calculated separately for these three pressure values and for the various limb circumferences.

6. Method of test for the rapid exhaust valve

(1) Apparatus

- rigid metal vessel, with a capacity of 500 ml ± 5 %;
- calibrated reference manometer, with an uncertainty less than 0.1 kPa (0.8 mmHg);
- T-piece connector;
- time measuring device.

(2) Procedure

Carry out the test with the vessel in place of the cuff. Connect the calibrated reference manometer by means of a T-piece to the pneumatic system. Inflate to the maximum pressure and open the rapid exhaust valve.

(3) Expression of results

Measure the time between the pressure values specified in paragraph 6(2)(iii).

7. Method of test for the thickness of the scale marks and the scale spacing

(1) Apparatus

- scaled magnifying lens or similar device.

(2) Procedure

Determine the thickness of the scale marks and the scale spacing using the scaled magnifying lens.

8. Method of test for the internal diameter of the mercury tube

(1) Apparatus

- limit plug gauges or similar devices, with a tolerance less than 0.05 mm.

(2) Procedure

Test the nominal internal diameter of the tube at each end by using the limit plug gauge.

9. Method of test for security against mercury losses

(1) Apparatus

- collecting vessel of an adequate size;
- calibrated reference manometer, with an uncertainty less than 0.1 kPa (0.8 mmHg);
- T -piece connector;
- pressure generator, e.g. ball pump (hand pump) with a deflation valve.

(2) Procedure

Place the sphygmomanometer to be tested in the collecting vessel. Connect the pressure generator and a T-piece connector attached to a calibrated reference manometer directly to the hose leading to

the mercury reservoir. Use the pressure generator to raise the pressure in the manometer to 13.3 kPa (100 mmHg) greater than the maximum indicated scale reading on the test manometer. Maintain this pressure for 5s and then release the pressure in the system.

Check that no mercury has spilled.

10. Method of test for the influence of the mercury stopping device

(1) Apparatus

- time measuring device, e.g. a stopwatch or an electronic timing device;
- pressure generator, e.g. ball pump (hand pump) with a deflation valve.

(2) Procedure

Connect the pressure generator directly to the hose leading to the mercury reservoir, i.e. without connecting a cuff. When a gauge pressure of more than 27 kPa (200 mmHg) has been reached, occlude the tube and remove the pressure generator.

After removing the occlusion from the tube, measure the time taken for the mercury column to fall from the 27 kPa (200 mmHg) mark to the 5 kPa (40 mmHg) mark.

Check that the exhaust time does not exceed 1.5 s.

11. Method of test for the hysterisis error of the aneroid manometer

(1) Apparatus

(i) rigid metal vessel, with a capacity of 500 ml ± 5%;

(ii) calibrated reference manometer, with an uncertainty less than 0.1 kPa (0.8 mmHg);

(iii) pressure generator, e.g. ball pump (hand pump) with a deflation valve;

(iv) T-piece connectors.

(2) *Procedure*

Replace the cuff with the vessel. Connect the calibrated reference manometer by means of a T-piece connector to the pneumatic system. After disabling the electro-mechanical pump (if fitted) connect the additional pressure generator into the pneumatic system by means of another T-piece connector.

Test the device with increasing pressure steps of not more than 7 kPa (50 mmHg) to the scale maximum, at which point hold the pressure for 5 minutes and then decrease it by the same steps. Disconnect the calibrated reference manometer during the 5 minutes at maximum pressure.

(3) Expression of results

Express the results as the difference between the indicated values on the manometer at the same test pressure steps when increasing the pressure and when decreasing the pressure.

12. Method of test for the construction

(1) Apparatus

- alternating pressure generator, which generates a sinusoidal pressure variation between 3 kPa and 30 kPa (20 mmHg and 220 mmHg) at a maximum rate of 60 cycles per minute.

(2) Procedure

Carry out the procedure specified in paragraph 1 of this Annexure.

Connect the aneroid manometer directly to the alternating pressure generator and perform 10,000 alternating pressure cycles.

One hour after the stress test carry out the procedure as specified in paragraph 1 of this Annexure at the same test pressure levels as before the stress test.

(3) Expression of results

Express the results as the differences between the indicated values on the manometer at the same test pressure steps before and after the stress test.

PART VII-B

NON-INVASIVE AUTOMATED SPHYGMOMANOMETERS

1. Scope

This specification gives general performance, efficiency and mechanical and electrical safety requirements, including test methods for type approval, for non-invasive electronic or automated sphygmomanometers and their accessories which, by means of an inflatable cuff; are used for the non-invasive measurement of arterial blood pressure.

This specification only applies to devices measuring at the upper arm, the wrist or the thigh.

Note : Luer locks shall not be used with these devices [see paragraphs 6(11)(iii) and 7(5)].

2. Terminology

(1) Bladder :

It is the inflatable component of the cuff.

(2) Pressure in a blood vessel :

It refers to pressure in the arterial system of the body.

(3) Cuff :

It is that component of the sphygmomanometer,

comprising a bladder and a sleeve, which is wrapped around the limb of the patient.

(4) Diastolic blood pressure (value) :

The minimum value of the arterial blood pressure as a result of relaxation of the systemic ventricle.

Note : Because of hydrostatic effects, this value should be measured with the cuff at the heart level.

(5) Mean arterial blood pressure (value) :

It is the value of the integral of one cycle of the blood pressure curve divided by the time of one heart beat period.

Note : Because of hydrostatic effects, this value should be measured with the cuff at the heart level.

(6) Non-invasive blood pressure measurement :

Indirect measurement of the arterial blood pressure without arterial puncture is called non-invasive blood pressure measurement.

(7) Pneumatic system :

A system that includes all pressurized and pressure-controlling parts such as cuff, tubing, connectors, valves, transducer and pump is called pneumatic system.

(8) Sleeve :

It is essentially inelastic part of the cuff that encloses the bladder.

(9) Sphygmomanometer :

It is an instrument used for the non-invasive measurement of the arterial blood pressure.

(10) Systolic blood pressure (value) :

The maximum value of the arterial blood pressure as a result of the contraction of the systemic ventricle is called systolic blood pressure.

Note : Because of hydrostatic effects, this value should be measured with the cuff at the heart level.

(11) Electro-mechanical blood pressure measuring system :

It is that system that consists of:

(i) at least one cuff, which is connected to the pneumatic system;

(ii) at least one electro-mechanical transducer to measure cuff pressure;

(iii) at least one measured value display; and

(iv) if needed, signal inputs and outputs.

(12) Electro-mechanical pressure transducer :

It is that component that transforms pressure signals into electrical signals.

(13) Oscillometric method :

It is that method, wherein a cuff is placed on the limb and the pressure in the cuff is increased until the blood flow in the artery is interrupted and then the pressure in the cuff is slowly reduced.

Note : During the inflation and deflation of the cuff small pressure changes (oscillations) occur in the cuff as a result of the arterial blood pressure pulses. These oscillations, which first increase and then decrease, are detected and stored together with the corresponding cuff pressure values in the measurement system. With these stored values the systolic, diastolic and mean arterial blood pressure values can be mathematically derived using an appropriate algorithm. It is possible to carry out the measurement during the inflation phase.

(14) Zero setting :

The procedure that corrects a deviation of the pressure reading to 0 kPa (0 mmHg) at atmospheric pressure [gauge pressure: 0 kPa (0 mmHg)] is called zero setting.

(15) Patient simulator :

Device for simulating the oscillometric cuff pulses and/or auscultatory sounds during inflation and deflation.

Note : This device is not used for testing accuracy but is required in assessing stability of performance.

(16) Auscultatory method :

It is that technique whereby sounds (known as Korotkoff sounds) are heard over an occluded artery as the occluding pressure is slowly released, the appearance of sounds coinciding with the systolic blood pressure and the disappearance of sounds with the diastolic blood pressure. In children under the age of 13, "k4" (i.e. 4th phase Korotkoff sound) may be appropriate.

(17) Self-linearizing deflation valve :

The valve used for controlled linearizing exhaust of the pneumatic system during measurement.

3. Description of the category of instrument

The basic components of a sphygmomanometer are a cuff and bladder that can be wrapped around a patient's limb, a system for applying and releasing pressure to the bladder, and a means of measuring and displaying the instantaneous pressure in the bladder.

4. Units of measurement

The blood pressure shall be indicated either in kilo-pascals (kPa) or in millimetres of mercury (mmHg).

5. Metrological requirements

(1) Maximum permissible errors of the cuff pressure indication

For any set of conditions within the ambient temperature range of 15°C to 25°C and the relative humidity range of 20% to 85%, both for increasing and for decreasing pressure, the maximum permissible error for the measurement of the cuff pressure at any point of the scale range shall be ± 0.4 kPa (± 3 mmHg) in case of verifying the first time and ± 0.5 kPa (± 4 mmHg) for sphygmomanometers in use.

Testing shall be carried out in accordance with para 2 of Annexure A.

*(2) Maximum permissible errors of the overall system as measured by clinical tests**

The following maximum permissible errors shall apply for the overall system:—

- maximum mean error of measurement : ± 0.7 kPa ± 5 mmHg);
- maximum experimental standard deviation : 1.1 kPa (8 mmHg).

(3) Environmental performance

(i) *Storage* :

Blood pressure measuring systems shall maintain the requirements specified after storage for 24 h at a temperature of -5°C and for 24 hours at a temperature of 50°C and a relative humidity of 85% (non-condensing).

Testing shall be carried out at environmental conditions in accordance with paragraph 2 of Annexure A after the test sample has been placed for 24 h at a temperature of -5°C and immediately afterwards for 24 hours at a temperature of 50°C in a climatic chamber.

Note : Integrated multi-parameter monitors may contain components which may be damaged during storage. The general temperature range as stated in para 3 of Annexure A has therefore been reduced.

(ii) *Temperature, relative humidity* :

For the ambient temperature range of 10°C to 40°C and a relative humidity of 85% (non-condensing), the difference of the cuff pressure indication of the sphygmomanometer shall not exceed ± 0.4 kPa (± 3 mmHg).

Testing shall be carried out in accordance with paragraphs 2 and 11 of Annexure A.

The signal processing for the determination of the blood pressure values shall not be influenced within the range of temperature and relative humidity. For any set of conditions all the deviations between the reference pressure and the indicating cuff pressure of the instrument must be less than or equal to the maximum permissible error.

6. Technical requirements

(1) *General* :

Equipment, or parts thereof, using materials or having forms of construction different from those detailed in this Recommendation shall be accepted if it can be demonstrated that an equivalent degree of safety and performance is obtained.

(2) *Technical requirements for the cuff and bladder* :

The cuff shall contain a bladder. For reusable cuffs the manufacturer shall indicate the method for cleaning in the accompanying documents.

Note : The optimum bladder size is one with dimensions such that its width is 40% of the limb circumference at the midpoint of the cuff application and its length is at least 80%, preferably 100% of the limb circumference at the midpoint of cuff application. Use of the wrong size can affect the accuracy of the measurement.

(3) *Technical requirements for the display* :

The display shall be designed and arranged so that the information including measuring values can be read and easily recognized.

Testing shall be carried out by visual inspection.

If abbreviations are used on the display they shall be as follows:—

- "S" or "SYS" : systolic blood pressure (value);
- "D" or "DIA" : diastolic blood pressure (value);
- "M" or "MAP" : mean arterial blood pressure (value).

Single letter abbreviations shall be positioned in such a way to avoid confusion with SI units.

(4) Effect of voltage variations of the power source

(i) Internal electrical power source

(a) Changes of the voltage within the working range determined according to para 4(1) of Annexure A shall not influence the cuff pressure reading and the result of the blood pressure measurement.

(b) Outside this working range no cuff pressure reading and no result of the blood pressure measurement shall be displayed.

Testing shall be carried out in accordance with paragraphs 4(1) and 5(1) of Annexure A.

(ii) External electrical power source

(a) Changes of the voltage within the working range specified by the manufacturer shall not influence the cuff pressure reading and the result of the blood pressure measurement.

(b) Incorrect values resulting from voltage variations outside the limits given in paragraph 6(4)(ii)(a) shall not be displayed.

Testing shall be carried out according to para 4(4) (alternating current) and para 4(5) (direct current) of Annexure A.

Note: In the case of any malfunction of the equipment, deflation to below 2 kPa (15 mmHg) must be guaranteed within 180s in the case of adult patients and to below 0.7 kPa (5 mmHg) within 90s in the case of neonatal/infant patients.

(5) Pneumatic system

(i) *Air leakage:*

Air leakage shall not exceed a pressure drop of 0.8 kPa/min (6 mmHg/min).

Testing shall be carried out in accordance with paragraph 6 of Annexure A.

(ii) *Pressure reducing system for devices using the auscultatory method:*

The pressure reducing system for manually operated and automated deflation valves shall be capable of maintaining a deflation rate of 0.3 kPa/s to 0.4 kPa/s (2 mmHg/s to 3 mmHg/s) within the target range of systolic and diastolic blood pressure. For devices which control the pressure reduction as a function of the pulse rate, a deflation rate of 0.3 kPa/pulse to 0.4 kPa/pulse (2 mmHg/pulse to 3 mmHg/pulse) shall be maintained.

Note: Manually operated deflation valves should be easily adjustable to these values. Testing shall be carried out in accordance with paragraph 7 of Annexure 7.

(iii) *Rapid exhaust:*

During the rapid exhaust of the pneumatic system, with the valve fully opened, the time for the pressure reduction from 35 kPa to 2 kPa (260 mmHg to 15 mmHg) shall not exceed 10 seconds.

For blood pressure measuring systems having the capability to measure in a neonatal/in-fant mode, the time for the pressure reduction from 20 kPa to 0.7 kPa (150 mmHg to 5 mmHg) during the rapid exhaust of the pneumatic system with the valve fully opened shall not exceed 5s.

Testing shall be carried out in accordance with paragraph 8 of Annexure A.

(iv) *Zero setting:*

Blood pressure measuring systems shall be capable of automatic zero setting. The zero setting shall be carried out at appropriate intervals, at least starting after switching on the device. At the moment of the zero setting a gauge pressure of 0 kPa (0 mmHg) shall exist and be displayed thereafter. Devices performing zero setting only immediately after switching on, shall switch off automatically when the drift of the pressure transducer and the analog signal processing exceeds 0.1 kPa (1 mmHg).

Testing shall be carried out in accordance with para 9 and paragraph 10 of Annexure A.

(6) Electromagnetic compatibility

Either:

- electrical and/or electro-magnetic interferences shall not lead to degradations in the cuff pressure indication or in the result of the blood pressure measurement; or

- if electrical and/or electro-magnetic interferences lead to an abnormality, the abnormality shall be clearly indicated and it shall be possible to restore normal operation within 30 s after cessation of the electro-magnetic disturbance.

(7) Stability of the cuff pressure indication

The change in the cuff pressure indication shall not be more than 0.4 kPa (3 mmHg) throughout the pressure range after 10,000 simulated measurement cycles.

Testing shall be carried out in accordance with paragraph 12 of Annexure A.

(8) Pressure indicating device

(i) *Nominal range and measuring range:*

The nominal range for the cuff pressure measurement shall be specified by the manufacturer. The measuring and indication ranges of the cuff pressure shall be equal to the nominal range. Values of blood

pressure measurement results outside the nominal range of cuff pressure shall be clearly indicated as out of range.

Testing shall be carried out by visual inspection.

(ii) *Digital indication* :

The digital scale interval shall be 0.1 kPa (1 mmHg). If the measured value of a parameter is to be indicated on more than one display, all the displays shall indicate the same numerical value. Measured numerical values on the display(s), and the symbols defining the units of measurement shall be arranged in such a way so as to avoid misinterpretation. Numbers and characters should be clearly legible.

Testing shall be carried out by visual inspection.

(9) Signal input and output ports

The construction of the signal input and output ports (excluding internal interfaces, e.g. microphone signal input) relevant to the non-invasive blood pressure measurement shall ensure that incorrectly fitted or defective accessories shall not result in erroneous indication of cuff pressure or erroneous indication of blood pressure.

Testing shall be carried out in accordance with paragraph 13 of Annexure A.

(10) Alarms

If alarms are used they shall be of at least medium priority.

(11) Safety

(i) *Cuff pressure:*

It shall be possible to abort any blood pressure measurement at any time by single key operation and this shall lead to a rapid exhaust.

Testing shall be carried out in accordance with paragraph 14 of Annexure A.

(ii) *Unauthorized access* :

All controls which affect accuracy shall be sealed against unauthorized access.

Testing shall be carried out by visual inspection.

(iii) *Tubing connectors:*

Users of equipment intended for use in environments employing intravascular fluid systems shall take all necessary precautions to avoid connecting the output of the blood pressure measuring device to such systems as air might inadvertently be pumped into a blood vessel if, for example, Luer locks were used.

(iv) *Electrical safety:*

Electronic or automated sphygmomanometers shall comply with the relevant national safety regulations.

(v) *Resistance to vibration and shock:*

After testing, the device shall comply with the requirements of paragraph 5(1).

7. Metrological controls

(1) Model approval

At least three samples of a new type of sphygmomanometer shall be tested.

The tests to verify conformity to metrological and technical requirements shall be carried out according to Annexure A.

(2) Verification

(I) *Initial verification*

At initial verification the requirements of paragraphs 5(1) and 6(5)(i) shall be fulfilled.

Testing shall be carried out according to paragraphs 2 and 6 of Annexure A.

(ii) *Subsequent verification*

Each instrument of an approved type of sphygmomanometer shall be verified every 2 years or after repair. Requirement of paragraphs 5(1) and 6(5)(i) shall be fulfilled and tests must be carried out according to paragraphs 2 and 6 of Annexure A.

(3) Sealing

(I) Control marks will be put on lead seals for which corresponding punched screws shall be attached whenever necessary. These seals shall prevent, without destruction of the control marks:

(a) in the case of patient-monitors in which the sphygmomanometer is one part of a system: the manipulation of the metrologically relevant parts for measuring blood pressure;

(b) in the case of all other manometers: the opening of the casing.

(ii) If the construction of the instrument guarantees security against any interference, the metrological control marks or the security marks may be attached in the form of labels.

(iii) All seals shall be accessible without using a tool.

(4) Marking of the device

The device shall be marked with the following information:—

(i) name and/or trademark of manufacturer;

(ii) serial number and year of fabrication;

(iii) measuring range and measuring unit;

(iv) model approval number;

(v) centre of the bladder, indicating the correct position for the cuff over the artery; and

(vi) marking on the cuff indicating the limb circumference for which it is appropriate.

(5) Manufacturer's information

(i) The manufacturer's instruction manual shall contain the following information:

(a) explanation of the operating procedures which are important for correct application (such as the selection of the appropriate cuff size, positioning of the cuff and adjustment of the pressure reduction rate);

(b) a warning to users of equipment intended for use in environments employing intravascular fluid systems not to connect the output of the blood pressure measuring device to such systems as air might inadvertently be pumped into a blood vessel if, for example, Luer locks were used;

(c) methods for cleaning reusable cuffs;

(d) nature and frequency of the maintenance to ensure that the device operates properly and safely at all times; it is recommended that the performance should be checked at least every 2 years and after maintenance and repair, by re-verifying at least the requirements in paragraphs 5(1) and 6(5)(i) (testing at least at 7 kPa (50 mmHg) and 27 kPa (200 mmHg));

(e) a reference method for clinical tests carried out according to Annexure C or an equivalent method;

(f) a list of all components belonging to the pressure measuring systems, including

(g) a description of the operating principles of the blood pressure measuring device;

(h) remarks on the environment or operational factors which affect the performance (e.g. electro- magnetic fields, arrhythmia);

(i) specification of the single input/ output ports(s);

(j) specification of the rated voltage, if applicable;

(k) specification of the intended power source, if applicable;

(l) nominal range for the result of the blood pressure measurement;

(m) warm up time , if applicable;

(n) description of the meaning of the "out of range signal" and

(o) description of the alarms, if applicable.

ANNEXURE A

TEST PROCEDURES

(Mandatory)

1. *General*

For digital indications an uncertainty of 0.1 kPa (1 mmHg) shall allowed in any displayed value, because the display system cannot indicate a change of less than one unit.

2. Method of test for the maximum permissible errors of the cuff pressure indication

Requirements in paragraph 5(1) shall apply.

(1) Apparatus

(a) rigid metal vessel with a capacity of 500 ml ± 5%;

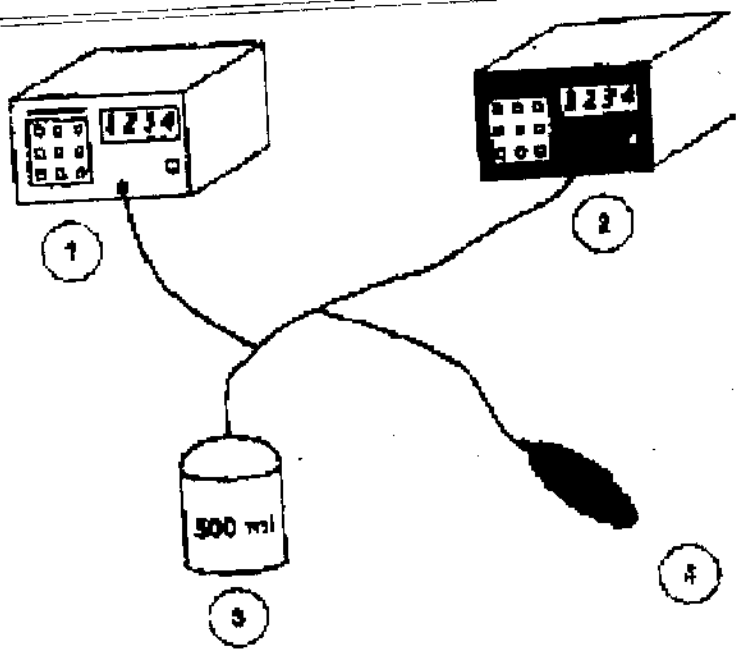
(b) calibrated reference manometer with an uncertainty less than 0.1 kPa (0.8 mmHg);

(c) pressure generator, e.g. ball pump (hand pump) with a deflation valve;

(d) T-piece connectors and hoses.

(2) *Procedure:*

Replace the cuff with the vessel. Connect the calibrated reference manometer by means of a T-piece connector and hoses to the pneumatic circuit (see Figure 1). After disabling the electro-mechanical



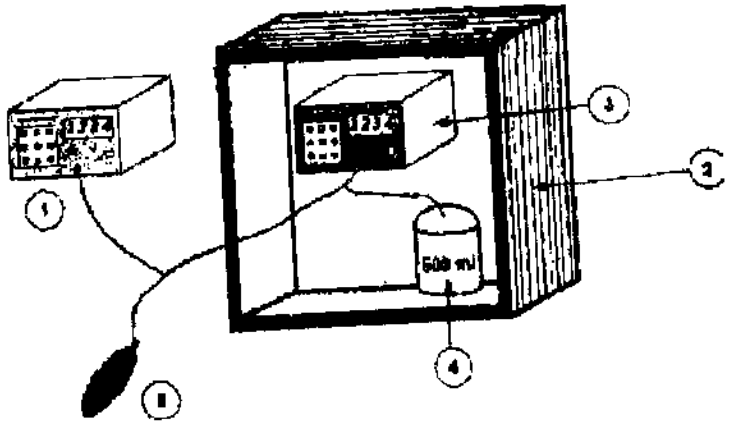
1 - Reference manometer
2 - Device to be tested
3 - Metal vessel
4 - Pressure generator

Figure 1: *Measurement system for determining the limits of error of the cuff pressure indication*

pump (if fitted), connect the additional pressure generator into the pressure system by means of another T-piece connector. Carry out the test in pressure steps of not more than 7 kPa (50 mmHg) between 0 kPa (0 mmHg) and the maximum pressure of the scale range.

(3) *Expression of results:*

Express the results as the differences between the indicated pressure of the manometer of the device to be tested and the corresponding readings of the reference manometer.



1 - Reference manometer
2 - Climatic chamber
3 - Device to be tested
4 - Metal vessel
5 - Pressure generator

Figure 2: *Measurement system for determining the influence of temperature*

3. Method of test for the influence of temperature on cuff pressure indication

(1) *Apparatus*

- apparatus as specified in paragraph 2(1) of Annexure A;
- climatic chamber.

(2) Procedure:

Replace the cuff with the vessel. Connect the calibrated reference manometer by means of a T-piece connector to the pneumatic system (see Figure 2). After disabling the electro-mechanical pump (if fitted), connect the additional pressure generator into the pneumatic system by means of another T-piece connector.

For each of the following combinations of temperature and humidity, condition the device for at least 3 h in the climatic chamber to allow the device to reach steady conditions:

(i) 10°C ambient temperature, 85% relative humidity (non-condensing);

(ii) 20°C ambient temperature, 85% relative humidity (non-condensing);

(iii) 40°C ambient temperature, 85% relative humidity (non-condensing).

Carry out the test of the cuff pressure indication as described in paragraph 2(2) of Annexure A for each of the combinations of temperature and humidity mentioned above.

(3) *Expression of results:*

Express the results as the differences between the indicated pressure of the manometer of the device to be tested and the corresponding indications of the reference manometer at the relevant temperature value.

4. Test methods for the effect of voltage variations of the power source on the cuff pressure indication

(1) Internal electrical power source

(i) *Apparatus*

- adjustable direct current voltage supply;
- voltmeter with an uncertainty of less than 0.5% of the measured value;
- calibrated reference manometer with an uncertainty of less than 0.1 kPa (0.8 mmHg).

(ii) *Procedure :*

Replace the internal electrical power source of the blood pressure measuring system with a DC voltage supply having an impedance which is equivalent to the impedance of the internal electrical power source specified by the manufacturer. Measure the variation in applied DC voltage supply with a voltmeter. Test the blood pressure measuring system by altering the DC voltage supply in steps of 0.1 V and determine the lowest voltage limit at which the cuff pressure reading is still displayed.

Carry out the test with the maximum permissible impedance of the internal electrical power source.

Carry out the test according to the procedure specified in paragraph 2 of Annexure A at the lowest voltage limit increased by 0.1 V and also at the nominal voltage.

(iii) *Expression of results:*

Express the results as the difference between the cuff pressure indication of the blood pressure measuring system to be tested and that of the reference manometer at the lowest voltage limit increased by 0.1 V and at nominal voltage.

(2) External electrical power source-alternating current

(i) *Apparatus*

(a) adjustable alternating current voltage supply;

(b) voltmeter with an uncertainty of less than 0.5 % of the measured value;

(c) calibrated reference manometer with an uncertainty of less than 0.1 kPa (0.8 mmHg).

(ii) *Procedure :*

Connect the blood pressure measuring system to the adjustable alternating current voltage supply. Measure the variation in AC voltage supply with the voltmeter.

Carry out the test according to the procedure specified in paragraph 2 of this Annexure.

- the maximum rated voltage, declared by the manufacturer, increased by 10%;
- the mean value of the maximum and minimum rated voltage, declared by the manufacturer;
- the minimum rated voltage, declared by the manufacturer, decreased by 10%.

(iii) *Expression of results:*

Express the results as the difference between the cuff pressure indication of the blood pressure measuring system to be tested and that of the reference manometer.

(3) External electrical power source-direct current

(i) *Apparatus:*

Use the apparatus listed in paragraph 4(1)(i) of this Annexure.

(ii) *Procedure:*

Connect the blood pressure measuring system to the DC voltage supply. Control the DC voltage supply by reference to a voltmeter.

Carry out the test according to the procedure specified in paragraph 2 of Annexure A at—

(a) the maximum rated voltage, declared by the manufacturer, increased by 10%;

(b) the mean value of the maximum and minimum rated voltage, declared by the manufacturer;

(c) the minimum rated voltage, declared by the manufacturer, decreased by 10%.

(iii) *Expression of results* :

Express the results as the difference between the cuff pressure indication of the blood pressure measuring system to be tested and that of the reference manometer.

(4) Voltage variations of the external electrical power source - alternating current

(i) *Apparatus:*

Use the apparatus listed in paragraph 4(2)(i) of this Annexure.

(ii) *Procedure:*

Connect the blood pressure measuring system to the AC voltage supply. Measure the variation in the AC voltage supply with the voltmeter. Test the blood pressure measuring system by altering the DC voltage supply in steps of 5V and determine the lowest voltage limit at which the cuff pressure reading is displayed.

Carry out the test according to the procedure specified in paragraph 2 of this Annexure at the lowest voltage limit increased by 5V and also at the rated voltage.

(iii) *Expression of results:*

Express the results as the difference between the cuff pressure indication of the blood pressure measuring system to be tested and that of the reference manometer at rated voltage and the lowest voltage limit increased by 5V.

(5) Voltage variations of the external electrical power source - direct current

(i) *Apparatus:*

Use the apparatus listed in paragraph 4(1)(i) of this Annexure.

(ii) *Procedure:*

Connect the blood pressure measuring system to the DC voltage supply. Measure the variation in the DC voltage supply with the voltmeter.

Test the blood pressure measuring system by altering the DC voltage supply in steps of 0.1 V and determine the lowest voltage limit at which the cuff pressure reading is displayed.

Carry out the test according to the procedure specified in paragraph 2 of Annexure A at the lowest voltage limit increased by 0.1 V and also at the rated voltage.

(iii) *Expression of results:*

Express the results as the difference between the cuff pressure indication of the blood pressure measuring system to be

tested and that of the reference manometer at rated voltage and at the lowest voltage limit increased by 0.1 V.

5. Test methods for the effect of voltage variations of the power source on the result of the blood pressure measurement

(1) Internal electrical power source

(i) *Apparatus*

- adjustable direct current voltage supply;
- voltmeter with an uncertainty less than 0.5% of the measured value;
- patient simulator [see paragraph 2(15)] for the auscultatory and/or oscillometric method, having additional deviations originating from the simulator of not more than 0.27 kPa (2 mmHg) for the mean value of the measurements and generating signals for blood pressure values of approximately

  — systolic: 16 kPa (120 mmHg);

  — diastolic: 11 kPa (80 mmHg);

  — pulse rate: 70 min-1-80min-1.

(ii) *Procedure:*

Replace the internal electrical power source of the blood pressure measuring system by a DC voltage supply having an impedance which is equivalent to the impedance of the internal electrical power source specified by the manufacturer. Devices intended to be used with consumer batteries shall be tested with an impedance of less than 1½.

Control the DC voltage supply by reference to the voltmeter.

Connect the blood pressure measuring system to the patient simulator. Carry out the test at the maximum permissible impedance of the internal electrical power source.

Carry out 20 simulated blood pressure measurements at the lowest voltage limit as determined in paragraph 4(1)(ii) of Annexure A increased by 0.1 V and at nominal voltage.

(iii) *Expression of results:*

Determine the mean value (systolic and diastolic values separately) of the 20 consecutive readings taken at each voltage level.

(2) External electrical power source - alternating current

(i) *Apparatus:*

- adjustable alternating current voltage supply;
- voltmeter with an uncertainty less than 0.5% of the measured value;
- patient simulator as described in paragraph 5(1)(i) of Annexure A.

(ii) *Procedure:*

Connect the blood pressure measuring system to the AC voltage supply.

Control the AC voltage supply by reference to the voltmeter. Connect the blood pressure measuring to the simulator.

Carry out 20 simulated blood pressure measurements each at:

- the maximum rated voltage, declared by the manufacturer, increased by 10%;
- the mean value of the maximum and minimum rated voltage, declared by the, manufacturer;
- the minimum rated voltage, declared by the manufacturer, decreased by 10%.

(iii) *Expression of results* :

Determine the mean value (systolic and diastolic values separately) of the 20 consecutive readings taken at each voltage level.

(3) External electrical power source - direct current

(i) *Apparatus*

(a) adjustable direct current voltage supply;

(b) voltmeter with an uncertainty less than 0.5 % of the measured value;

(c) patient simulator as described in paragraph 5(1)(i) of Annexure A.

(ii) *Procedure:*

Connect the blood pressure measuring system to the DC voltage supply.

Control the DC voltage supply by reference to the voltmeter. Connect the blood pressure measuring system to the simulator.

Carry out 20 simulated blood pressure measurements each at:

(a) the maximum rated voltage, declared by the manufacturer, increased by 10%;

(b) the mean value of the maximum and minimum rated voltage, declared by the manufacturer;

(c) the minimum rated voltage declared by the manufacturer, decreased by 10%.

(iii) *Expression of results:*

Determine the mean value (systolic and diastolic values separately) of the 20 consecutive readings taken at each voltage level.

6. Method of test for air leakage of the pneumatic system

(1) *Apparatus:*

6(1)(i) rigid metal cylinder of an appropriate size;

6(1)(ii) pressure generator, e.g. ball pump (hand pump) with deflation valve;

6(1)(iii) stopwatch.

(2) *Procedure*

If because of technical reasons, the test as described in this sub-clause cannot be performed, use an alternative test procedure specified by the manufacturer.

Carry out the test at constant temperature in the range 15°C to 25°C.

Before beginning the test, allow the blood pressure measuring system to reach working temperature.

Wrap the cuff around the cylinder (see 6.2) such that, for devices measuring at the upper arm and the thigh, the circumference of the applied cuff does not exceed that of the cylinder by more than 7%.

Note 1 : Electro-mechanical pumps which are a part of the system may be used for the test. Valves which are permanently opened may be disconnected for the test.

Note 2 : For this test no calibrated reference manometer is required because the cuff pressure display of the unit under test can be used when the error of the cuff pressure indication is taken into account. The advantage of this test is that the unit under test is in its original configuration. Additional connections can increase the leakage.

Carry out the test over the whole measuring range at least five equally spaced pressure steps [e.g. 7 kPa(50 mmHg), 13 kPa (100 mmHg), 20 kPa (150 mmHg), 27 kPa (200 mmHg) and 34 kPa (250 mmHg)]. Because the thermodynamic equilibrium is influenced by decreasing or increasing the pressure when changing to the next pressure step, wait at least 60 s before reading the values. Test the air leakage over a period of 5 minutes and determine the measured value from this.

(3) Expression of results:

Express the air leakage as the rate of pressure loss per minute.

7. Method of test for the pressure reduction rate

(1) Apparatus

(i) T-piece connectors;

(ii) calibrated reference manometer with signal output port and an uncertainty less than 0.1 kPa (0.8 mmHg);

(iii) artificial or human limbs;

(iv) recording unit.

(2) Procedure

Measure the pressure reduction rate either on human subjects or artificial limbs.

Note 1 : The intention is to use artificial limbs, but as these are still under consideration, measurements performed with human volunteers are acceptable.

Note 2 : Two limb sizes should be used, being equal to the upper and lower limits of limb

circumferences with which a particular size of cuff is recommended for use.

Note 3 : It is intended that the characteristics of the artificial limbs reflect some elastic characteristics of human limbs.

Because the cuff deflation rate may be influenced by the way that a cuff is applied, apply and remove the cuff for each of at least ten repeated measurements on at least two different limb sizes. The deflation may be reset.

Connect the calibrated reference manometer to the cuff by means of a T-piece. Connect the output part of the calibrated reference manometer to the recording unit.

(3) Expression of results

Determine the rate of pressure reduction (e.g. by graphical evaluation and drawing tangents) at the pressure values 8 kPa (60 mmHg), 16 kPa (120 mmHg) and 24 kPa (180 mmHg). Calculate the pressure reduction rate as the mean value calculated separately for the pressure values 8 kPa (60 mmHg), 16 kPa (120 mmHg) and 24 kPa (180 mmHg) and for the various limb circumferences.

If the pressure reduction rates are dependent on the pulse, record the pulse rate. In this case, express the result as pressure reduction rate per pulse.

8. Method of test for the rapid exhaust valve

(1) *Apparatus*

- two rigid vessels with capacities of 100 ml ± 5% and 500 ml ± 5%, respectively;
- calibrated reference manometer with an uncertainty less than 0.1 kPa (0.8 mmHg);
- T-piece connector;
- stopwatch.

(2) *Procedure*

Carry out the test with the 500 ml vessel in place of the cuff. For blood pressure measuring systems having the capability of measuring in a neonatal/infant mode and for devices measuring at the wrist, carry out the test with the 100 ml vessel in place of the cuff.

Connect the calibrated reference manometer by means of a T-piece to the pneumatic system.

Inflate at least to the maximum pressure given in paragraph 6(5)(iii), wait 60 seconds and activate the rapid exhaust valve.

Measure the time between the pressure values specified in paragraph 6(5)(iii) using the stopwatch.

(3) Expression of results

Express the results as the measured exhaust times.

9. Test method for the zero setting

(1) Apparatus

(i) rigid vessel with a capacity of 500 ml ± 5%;

(ii) calibrated reference manometer with an uncertainty less than 0.1 kPa (0.8 mmHg);

(iii) electro-mechanical pressure/suction pump;

(iv) pressure generator, e.g. ball pump (hand pump) with deflation valve;

(v) T-piece connectors;

(vi) hoses.

(2) Procedure and evaluation

If, because of technical reasons, the test as described in this sub-clause cannot be performed, use an alternative test procedure specified by the manufacturer.

To test the function of the zero setting, apply a pressure of + 0.8 kPa (+ 6 mmHg) and subsequently - 0.8 kPa (- 6 mmHg) to the pneumatic system and initiate a zero setting of the device. Ensure that all displayed pressure values have a systematic error of - 0.8 kPa (- 6 mmHg) and + 0.8 kPa (+ 6 mmHg), respectively.

Before beginning the test, allow the blood pressure measuring system to reach working temperature .

Set up the blood pressure measuring system to be tested as follows:—

- replace the cuff with the 500 ml vessel;
- insert the calibrated reference manometer into the pneumatic system by means of a T-piece connector;
- insert the pressure/suction pump into the pneumatic system by means of a T-piece connector;
- insert the pressure generator into the pneumatic system by means of a T-piece connector.

Note: If convenient, one adjustable pump may be used in place of the pressure/suction pump and pressure generator to generate the pressures.

Proceed in the following way:—

(a) Initiate a zero setting as described by the manufacturer. Set the blood pressure measuring system to the service mode, if available. Raise the pressure to 13 kPa (100 mmHg) immediately afterwards and record the displayed value.

(b) Generate a constant gauge pressure of + 0.8 kPa (+ 6 mmHg) in the pneumatic system by using the pressure/suction pump at the moment of zero setting. During this period close the deflation valve of the device under test or close the hose to it, e.g. by pinching the hose tightly. Set the blood pressure measuring system to the service mode, if available. Raise the pressure to 13 kPa (100 mmHg) immediately afterwards. The zero setting is operating correctly if the displayed value decreases by 0.8 kPa (6 mmHg) compared to the value taken in (a).

(c) Repeat (b) with a constant gauge pressure of - 0.8 kPa (- 6 mmHg) in the pneumatic system. Set the blood pressure measuring system to the service mode, if available. Raise the pressure to 13 kPa (100 mmHg) immediately afterwards. The zero setting is operating correctly if the displayed value increases by 0.8 kPa (6 mmHg) compared to the value taken in (a).

10. Test method for the drift of the cuff pressure indication

(1) *General*

This test applies for devices performing zero setting only immediately after switching on.

(2) Apparatus

- rigid vessel with a capacity of 500 ml ± 5%;
- calibrated reference manometer with an uncertainty less than 0.1 kPa (0.8 mmHg);
- stopwatch;
- T-piece connectors;
- patient simulator as described in paragraph 5(1)(i) of this Annexure.

(3) *Procedure and evaluation*

Replace the cuff with the 500 ml vessel. Insert the calibrated reference manometer and the patient simulator into the pneumatic circuit by means of T-piece connectors.

Before beginning the test, allow the blood pressure measuring system to reach operating temperature as described in the instructions for use.

Test the stability of the cuff pressure indication after the zero setting at a pressure value of 7 kPa (50 mmHg) according to the procedure specified in paragraph 2 of this Annexure.

Under the same environmental conditions determine the time (t_1) until the change of the cuff pressure indication exceeds 0.1 kPa (1 mmHg). Switch off the device and switch on afterwards. Perform one blood pressure measurement and wait until the device has switched off automatically. Determine the time (t_2) between switching on and automatically switching off. The time (t_2) shall be less than or equal to the time (t_1).

11. Test method for the stability of the blood pressure determination (influence of temperature and humidity)

(1) *Apparatus*

(i) patient simulator as described in paragraph 5(1)(i) of this Annexure.

(ii) climatic chamber, capable of adjustment to an accuracy of 1°C for the temperature and 5% for the relative humidity.

(2) *Procedure*

Carry out the testing of the signal processing by means of the patient simulator. For each of the

following combinations of temperature and humidity, place the blood pressure measuring system for at least 3 h in the climatic chamber to allow the system to reach steady conditions:

(i) 10°C ambient temperature, 85% relative humidity (non-condensing);

(ii) 20°C ambient temperature, 85% relative humidity (non-condensing);

(iii) 40°C ambient temperature, 85% relative humidity (non-condensing).

For each combination of temperature and humidity, take 20 consecutive readings of the blood pressure measuring system under test.

Place the blood pressure measuring system in the climatic chamber for at least 3 hours. At each combination of temperature and humidity switch on the blood pressure measuring system before starting the test. Wait until the warm up time (described in the instructions for use) has elapsed, carry out the measurement (20 consecutive readings) and switch off the blood pressure measuring system afterwards.

(3) *Expression of results*

Determine the mean value (systolic and diastolic values separately) of the 20 consecutive readings taken at each combination of temperature and humidity.

Note: Because the testing of the influence of temperature and humidity for the signal processing cannot be separated from the temperature/humidity effect on the pressure transducer and the deviations originating from the simulator, both contributions should be taken into account for the evaluation of the test.

12. Test methods for the stability of cuff pressure indication following prolonged usage

(1) *Procedure*

Carry out the test according to the procedure specified in paragraph 2 of this Annexure prior to prolonged usage.

Perform 10,000 simulated measurement cycles with the complete blood pressure measure-ment system at which at least the following cuff pressure values shall be reached:

- adult mode: 20 kPa (150 mmHg);
- neonatal/infant mode: 10 kPa (75 mmHg).

Note 1: For devices which measure with the auscultatory and oscillometric method this test should be carried out for both modes.

Note 2 : For devices which measure in both modes (adult and neonatal/infant) the test should be carried out in both modes.

(2) *Expression of results*

Express the result as the difference between the cuff pressure indication before and after 10,000 simulated blood pressure measurement cycles at the same test pressure and under the same environmental conditions.

13. Test methods for the effect of external voltages and abnormal connections to the signal input/output ports

(1) *Apparatus*

- rigid vessel with a capacity of 500 ml ± 5%;
- calibrated reference manometer with an uncertainty less than 0.1 kPa (0.8 mmHg);
- T-piece connectors;
- pressure generator, e.g. ball pump (hand pump) with deflation valve.

(2) *Procedure*

Replace the cuff with the 500 ml vessel, insert the calibrated reference manometer into the pneumatic system by means of a T-piece and proceed as follows:—

(i) Raise the pressure to 13 kPa (100 mmHg) and record the displayed value.

(ii) Repeat (i) whilst short circuiting all contacts of the signal input/output ports belonging to the non-invasive blood pressure measuring system.

(iii) Repeat (i) whilst applying the maximum voltage specified by the manufacturer to each contact belonging to the non-invasive blood pressure measuring system.

(3) Evaluation

Compare the indicated value under (i) with the indicated values under (ii) and (iii).

14. Test method for the cuff pressure deflation following an aborted measurement

(1) *Apparatus*

(I) calibrated reference manometer with an uncertainty less than 0.1 kPa (0.8 mmHg);

(II) T-piece connectors.

(2) *Procedure and evaluation*

Insert the calibrated reference manometer into the pneumatic system by means of a T-piece.

Start a blood pressure measurement. Abort the measurement during inflation. Start an-other measurement and abort it during the pressure reduction. If interval measurements are possible repeat the test in this mode.

Check by visual inspection whether the rapid exhaust is activated.

PART VIII
TAXIMETERS

1. Terminology

(a) *'Taximeter'*—A measuring instrument which totalizes continuously and indicates at any moment of the journey the charges payable by the passenger of a public vehicle as function of the distance travelled and, below a certain speed, of the length of time occupied, independent of supplementary charges, according to the authorised tariffs.

(b) *Basic distance tariff*—The tariff for distance corresponding to all the intervals except the initial interval.

(c) *Basic time tariff*—The tariff for time corresponding to all the intervals except the initial interval.

(d) *Cleared*—A taximeter is cleared when no indication of fare is shown and when all parts are in the positions in which they are designed to be, when the vehicle on which the taximeter is installed is not engaged by a passenger.

(e) *Reading face*—The side of a taximeter upon which the indications of interest to the passenger are indicated.

(f) *Fare*—That portion of the charge for the hire of a vehicle that is automatically calculated by a taximeter through the operation of the distance or time mechanism.

(g) *Flag*—A device by which the operating conditions of a taximeter is controlled.

(h) *Initial distance or time interval*—The interval corresponding to the initial money drop.

(i) *Money drop*—An increment of fare indication.

(j) *Initial money drop*—The initial charges appearing on the reading face of the taximeter at the time when it is hired by passenger.

(k) *Distance of time intervals*—The intervals corresponding to money drops following the initial money drop.

(l) *Constant 'k' of the taximeter*—The constant 'k' of a taximeter is a characteristic quantity showing the type and number of signals which the instrument must receive in order to indicate correctly a covered distance of 1 km.

This constant 'k' is expressed—

(i) in 'revolutions per indicated kilometre' (rev/km) if the information relating to the distance covered by the vehicle is introduced into the taximeter in the form of a number of revolutions of its main shaft (drive shaft at entry point to the instrument).

(ii) in 'impulse per indicated kilometre' (imp/km) if this information is introduced in the form of electrical signals.

According to the construction of the instrument the constant 'k' may be fixed or may be adjustable by fixed amounts.

(m) *Characteristic coefficient 'w' of the vehicle*—The characteristic coefficient 'w' of a vehicle is a quantity indicating the type and number of signals intended to drive the taximeter which appear at the component provided for this purpose, for a distance travelled of 1 km.

This coefficient 'w' is expressed—

(i) in 'revolutions per kilometre travelled' (rev/km.); or

(ii) in 'impulse per kilometre travelled' (imp/km),

depending on whether the information relating to the distance travelled by the vehicle appears in the form of a number of revolutions of the component driving the taximeter or in the form of electrical signals.

This coefficient varies as a function of several factors, principally the wear and pressure of the tyres, the load carried by the vehicle, the conditions under which the vehicle makes a journey. It shall be measured under the standard test conditions for the vehicle.

(n) *Adapting device*—A special device which allows the values of 'k' and 'w' to be adjusted in such a way that maximum permissible error laid down in paragraph 5(c) shall not be exceeded.

2. General

(a) The following units of measurements shall be used for taximeters:—

(I) the metre or kilometre, for distance

(II) the second, minute or hour for time.

(b) The fare for the journey shall be expressed in the legal monetary units.

3. Technical characteristics

(A) *General constructional features*

(a) The taximeter shall be robust and well-constructed. The functional parts of the taximeter shall be made of materials which guarantee adequate strength and stability.

(b) The casing of the taximeter and that of the adapting device as well as the covers of the transmission devices shall be so made that the essential parts of the mechanism are out of reach from outside and are protected against dust and humidity.

Access to devices for adjustment shall be made impossible without damage to the sealing arrangements.

(c) In the case of electronic taximeters, the electronic devices which calculate the charge payable shall operate without failure, and at any time it shall be possible to check their correct operation.

This may be achieved by means of a special control programme which is automatic or manually activated.

Any fault identified by this control programme shall be clearly indicated.

(B) *Measuring device—Calculating device*

(a) Except when the taximeter is being cleared, indications of fare shall be clearly visible at all times.

(b) The taximeter shall be so designed that it calculates and indicates the fare for the journey solely on the basis of:

(i) the distance travelled when the vehicle moves at a speed higher than the changeover speed; or

(ii) the period of time when the vehicle moves at a speed less than the changeover speed.

The changeover speed is attained by dividing the time tariff by the distance tariff and may vary according to the variation in these tariffs.

(c) The distance drive shall be made through the medium of the wheels, and the reverse motion shall not cause a reduction in the fare or distance shown.

(d) The time drive shall be obtained by a mechanical or electronic movement of the clock work, which can be activated only by operating the mechanism of the taximeter.

(e) If the working of the clockwork mechanism is operated by manual winding, it shall work for at least 8 hours without rewinding or for at least two hours if rewinding is necessary at each manual operation before it is set in operation.

The electronic clockwork, shall be capable of functioning at any time.

(f) During the distance drive, the first increment of fare indication (money drop) shall occur after travelling the initial distance. The subsequent money drops shall correspond to equal distance between each of them.

(g) During the time drive, the first increment of fare indication (money drop) shall occur after the initial time interval. The subsequent money drops shall correspond to equal time intervals between each of them.

(h) Without change of drive, the ratio between the initial distance and the subsequent distances shall be the same as the ratio between the initial time and subsequent time intervals.

(i) An adapting device, situated inside or outside the instrument case, shall allow the adaptation of the taximeter constant to the characteristic coefficient of the vehicle on which it is mounted, with an accuracy such that the maximum permissible errors laid down in paragraph 5(c) shall not be exceeded.

(j) The taximeter shall be so designed as to facilitate necessary adjustment of the calculating device for making it conform to the changes in the tariff.

(k) If the number of tariffs provided on the instrument is greater than the number of tariffs in force, the taximeter shall, in the superfluous positions, calculate and indicate a fare based on one of the authorised tariffs.

(C) *Control mechanism*

(a) The mechanism of the taximeter shall be capable of being set in motion after having been engaged by a single control mechanism.

For the electronic taximeter this mechanism may consist of various push buttons and switches for special operations.

The mechanism of the taximeter shall be capable of being set in motion in one of the positions indicated in clauses (b), (c) and (d).

(b) FREE position (for hire)

In this position—

(i) there shall be no indication of the fare to be paid or, this indication shall be equal to zero or to a value of the initial money drop but in the latter case, the indication shall be covered by a shutter;

(ii) the distance drive and the time drive shall not operate the device which indicates the fare to be paid;

(iii) the totalizer indicating the total distance travelled shall remain turned off;

(iv) the window through which possible extras are seen shall be blank or indicate "Zero".

(c) "WORKING" position (hired)—In this position, the time and distance drives and the extras indicator, if any, shall be engaged.

(d) "TO PAY" position—In this position, which shows the final total fare due from the passenger for the journey excluding any extras, the time drive shall be disconnected and the distance drive shall remain connected to the authorised tariff.

In case of electronic taximeters it is permitted, by operating a special button in the TO PAY position, to add any possible extras to the fare, and to indicate on the indicator, the total fare payable by the passenger. When this button is released the two amounts shall be indicated separately.

(e) The control mechanism, shall be so designed that starting from FREE position, the taximeter can be set successively in WORKING position and TO PAY position.

(f) The operation of the control mechanism is subject to the following restrictions:—

(i) Starting from the WORKING position, it shall not be possible to put the taximeter back in the "FREE" position without going through the "TO PAY" position.

(ii) Starting from the TO PAY position, it shall not be possible to put the taximeter in the WORKING position without going through the FREE position.

(D) *Indicating device*

(a) The "reading face" of the taximeter shall be so designed that the indications of interest to the passenger can be easily read by him.

(b) The fare to be paid, excluding possible extras, shall be ascertained from the fare indicator by simple reading of an indication in aligned figures having a minimum height of 10 mm.

When electronic indicating elements are used it shall be possible to check the operation of the indication.

(c) As soon as the instrument is put into operation from the FREE position by operating the control mechanism, the shutter, if any, covering the indication of fare to be paid, shall retract and a fixed amount corresponding to the initial money drop shall appear.

The fare indicator shall thereafter advance by successive steps of a constant monetary value, as soon as the amount of the initial money drop has been used up.

(d) The taximeter shall be provided with a device indicating at any moment on the reading face the engaged working position.

(e) The taximeter shall have a means for illuminating the readings appearing on the reading face and it shall be possible to replace the light bulbs without opening the sealed parts of the meter.

In the case of self-luminous indications no additional illumination is required if readability of the indications of interest to the passenger is ensured.

(E) *Optional additional devices*

The taximeter may in addition be provided with supplementary devices, such as—

(a) an indicator of extras independent of the fare indicator mentioned in clause 3(D)(b) and automatically returning to zero in the FREE position. In the TO PAY position it is permitted to add the extras to the fare by operating a push button;

(b) totalizers which give, in aligned figures having a minimum height of 4 mm, indications of—

(i) the total distance travelled by the vehicle;

(ii) the total distance travelled on hire;

(iii) the total number of "engagement";

(iv) the total number of money drop.

The totalizers may be also non-erasable electronic memories which can be recalled and indicated in the FREE position of the taximeter. The data in the memory shall be protected for at least 72 hours after a power supply failure;

(c) a device detecting the presence of a passenger (pressure sensor).