Attachment No. (1)

Digital Clinical Thermometers

1.1 Domain:

The Requirements in this Attachment apply to Digital Clinical Thermometers with maximum temperature determination. Designed to measure a person internal temperature, excluding Thermometers designed to measure skin temperature.

2.1 Definitions

The Definitions contained in International Organisation of Legal Metrology Recommendation No. OIML R115 shall be considered an integral part of Attachment No. (1) of this Resolution.

3.1 Degrees of control and scale:

1. Control-grade Thermometers, a scale of C° 0.001
2. Control-grade Thermometers, a scale of C° 0.01

4.1 Design Requirements:

1. Digital Clinical Thermometers shall be manufactured in accordance with the International Organisation for Legal Metrology Recommendation No. OIML R115, to the extent that it does not conflict with this Resolution.
2. The Measurement Range shall be at least from 35.5°C to 42.0°C, and when the Measurement Range is larger, the Measurement Range can be divided into partial periods, while the range from 35.5°C to 42.0°C shall be kept continuous.
3. The Temperature Measurement Units shall be expressed in C°.
4. The Manufacturer shall determine the response time for the measurement.
5. The Thermometer may be an interchangeable probe attached to indicator unit consistent with the response characteristics of the probe or a probe permanently attached to the indicator unit.
6. Weak value of the Electric Power Source shall not lead to giving incorrect measurement values.
7. Signs and explanatory data:
    a. Manufacturers shall provide the necessary space for metrological markings.
    b. Manufacturers shall install the following signs and explanatory information on the Thermometer or its separate parts:
        - Name and address of the Manufacturer or Supplier, and/or brand.

- Make, model, Batch number or serial number.
- Indicator of the direction or position used, where appropriate.

c. Single-use thermal sensors shall be sealed inside a package containing the full information and Measurement Range, in addition to providing appropriate space on the package to place metrological marks. It shall also be clear whether the package has been opened, in addition to providing a statement indicating that the User may not open the package except immediately before use.

8. Labelling.

The Manufacturer shall provide the User with Instructions Guide, including the following information:

1. Correct and safe use.
2. Measurement Range.
3. Directions and warnings for cleaning and sterilising the Scale.
4. Illustration of appropriate equipment and variable parts such as sensors and batteries including the value.
5. Nominal voltage difference if possible.
6. Minimum time to reach thermal equilibrium.
7. Describe the transition from the expected temperature measurement state to the actual temperature measurement state.
8. Self-Examining Device instructions.
9. Suitable weather conditions for using, storing and transporting the Scale.
10. Periodic maintenance.

The Manufacturer shall also provide the Medical Thermometer with certain specific information upon request regarding the possibility of substandard performance if used under the influence of the following conditions:

- Outside the climatic conditions in terms of temperature and humidity previously described.
- After accidental mechanical shock.

5.1. Maximum Permissible Error

The Maximum Permissible Error Values under the influence of reference conditions shall be in accordance with what is shown in Table (1-1)

Table (1-1). Maximum Permissible Error

	Maximum Permissible Error	
Accuracy Scale	**Within Range** From C° 35.5 to C° 42.0	**Out of Range** From C° 35.5 to C° 42.0
Class I	C° 0.15±	C° 0.30±
Class II	C° 0.2±	C° 0.4±

6.1 Reference conditions for measurement:

- Ambient temperature – (C° 5 ± C° 23).
- Relative humidity = (50 ± %20).
- Battery voltage difference within the range specified by the Manufacturer.

7.1 Type Approval Requirements:

1. Importers or Manufacturers of Digital Clinical Thermometers shall submit a Type Approval Certificate in accordance with this Resolution, issued by an internationally recognised body or approved by the Ministry.
2. If the Type Approval Certificate is unavailable, three samples shall be taken to conduct possible tests on them in accordance with this Resolution.

8.1 Requirements of the Conformity Assessment

1. Importers or Manufacturers of Digital Clinical Thermometers shall submit a Type Conformity Certificate in accordance with this Resolution, issued by internationally recognised body or approved by the Ministry.
2. The Ministry shall take samples for the purposes of accepting or rejecting the Batch according to Table (M1-3) shown in Attachment (1) to conduct possible tests on them.

9.1 Initial Verification Requirements:

1. For the purposes of Conformity with the Initial Verification Requirements, the following Examination shall be performed:
   a. Virtual Examination.
   b. Maximum Permissible Error Examination.
2. No party may use a Medical Thermometer that has not been verified by Entity approved by the Ministry.
3. The Supervised Entity shall bear all costs of the Initial Verification.

10.1 Periodic Verification Requirements:

1. Medical Thermometers shall be examined periodically on annual basis.
2. For the purposes of Periodic Verification, the Initial Verification Requirements stated in Clause 1.9 of this Attachment are applied.
3. No party may use a Medical Thermometer that has not been verified by Entity approved by the Ministry.
4. The Supervised Entity shall bear all costs of the Periodic Verification.

11.1 Periodic Verification Requirements:

1. The Ministry has the right to conduct Sudden Verification on all Licensed Entities in the Domain of manufacturing, importing, renting and using Medical Thermometers to indicate the extent of their compliance with this Resolution.
2. The Ministry shall bear all costs of the Sudden Verification if the results are consistent, while the Supervised Entity shall bear all costs if the Verification results are not in accordance with this Resolution.

12.1 Verification Procedures

The Ministry shall prepare Examination and Verification Procedures in accordance with the recommendations of the International Organisation of Legal Metrology or accepted international practices in this Domain.

13.1 References

Recommendation of the International Organisation of Legal Metrology No. OIML R115

Attachment No. (2)

Electrical Medical Clinical Thermometer

1.2 Domain:

The Requirements in this Attachment apply to all Electrical Medical Clinical Thermometers.

2.2 Definitions

The Definitions contained in International Standard ISO 80601-2-56:2017 shall be deemed an integral part of Attachment No. (2) of this Resolution.

3.2 Design Requirements:

1. Electrical Medical Clinical Thermometers shall be manufactured in accordance with International Standard ISO 80601-2-56:2017 to the extent that does not conflict with this Resolution.
2. The Measurement Range shall be at least from 34°C to 43.0°C, and when the Measurement Range is larger, the Measurement Range can be divided into partial periods.
3. The Temperature Measurement Units shall be expressed in C°, and the Fahrenheit unit may be used in addition to it.
4. Maximum Permissible Error:
   a. The Maximum Permissible Error Values for the range C°34 to C° 43 and under ambient conditions from 16 to 35°C and a relative (non-condensing) humidity of up to a minimum of 85% shall be C°0.3±.
   b. The Maximum Permissible Error Values out of the range C°34 to C° 43 and out the ambient conditions from 16 to 35°C and a relative (non-condensing) humidity of up to a minimum of 85% shall be C°0.4±.
5. The Thermometer shall maintain the Maximum Permissible Error limits when stored in conditions from 20 to 55°C and non-condensing relative humidity up to (85%) for a period of 28 days.
6. Electromagnetic Approval:

   The Thermometer shall meet the Requirements of EN 6061-2-1 for Electromagnetic Approval.
7. Mechanical Shock:

   The Thermometer shall meet the Requirements of ISO 80601-2-56:2017 for tolerance to mechanical shock.

8. Unit for displaying the measurement value:
    a. The height of the numbers appearing on the screen shall be 4 mm or it shall be equipped with a magnifying lens to give the numbers the desired size.
    b. The Meter shall give visual warning signals or not display a measurement value when one or more of the following falls outside the limits stated by the Manufacturer:
        - The value of the Electric Voltage Source.
        - Measurement Range.
        - The Ambient Temperature Range.
9. Fluctuation in the value of the Electric Power Source:

    The Thermometer shall meet the Requirements of ISO 80601-2-56:2017 for fluctuation of the value of the electrical power supply.
10. Thermometer working systems:

    The Thermometer shall meet the Requirements of International Standard ISO 80601-2-56:2017 materials, cleaning and sterilisation methods, use and safety.
11. The signs and explanatory and indicative data that shall be provided by the Manufacturer. The Thermometer shall meet the Requirements of International Standard ISO 80601-2-56:2017 regarding the signs and explanatory and indicative data that shall be provided by the Manufacturer.

4.2 Type Approval Requirements:

1. Importers or Manufacturers of Electrical Medical Clinical Thermometers shall submit a Type Approval Certificate in accordance with this Resolution, issued by an internationally recognised body or approved by the Ministry.
2. If the Type Approval Certificate is unavailable, three samples shall be taken to conduct all possible tests on them in accordance with this Resolution.

5.2 Requirements of the Conformity Assessment

1. Importers or Manufacturers of Electrical Medical Clinical Thermometers shall submit a Type Conformity Certificate in accordance with this Resolution, issued by internationally recognised body or approved by the Ministry.
2. The Ministry shall take samples for the purposes of accepting or rejecting the Batch according to Table (M1-3) shown in Attachment (1) to conduct possible tests on them.

6.2 Initial Verification Requirements:

1. For the purposes of Conformity with the Initial Verification Requirements, the following Examination shall be performed:
   a. Virtual Examination
   b. Maximum Permissible Error Examination
2. No party may use a Medical Thermometer that has not been verified by Entity approved by the Ministry.
3. The Supervised Entity shall bear all costs of the Initial Verification.

7.2 Periodic Verification Requirements:

1. Electric Thermometers shall be examined periodically on annual basis.
2. For the purposes of Periodic Verification, the Initial Verification Requirements stated in Clause 6-2 of this Attachment are applied.
3. No party may use a Medical Thermometer that has not been verified by Entity approved by the Ministry.
4. The Supervised Entity shall bear all costs of the Periodic Verification.

8.2 Sudden Verification Requirements:

1. The Ministry has the right to conduct Sudden Verification on all Licensed Entities in the Domain of manufacturing, importing, renting and using Medical Thermometers to indicate the extent of their compliance with this Resolution in coordination with the various Licensing Authorities of Health Facilities using the Concerned Devices.
2. The Ministry shall bear all costs of the Sudden Verification if the results are consistent, while the Supervised Entity shall bear all costs if the Verification results are not in accordance with this Resolution.

9.2 Verification Procedures

The Ministry shall prepare Examination and Verification Procedures in accordance with the recommendations of the International Organisation of Legal Metrology or accepted international practices in this Domain.

10.2 References:

International Standard: 2017:56.2.80601 ISO

Attachment No. (3)

Non-Invasive Mechanical Automated Sphygmomanometers

1.3 Domain:

– Mechanical and pneumatic Sphygmomanometers and their parts and accessories.

2.3 Definitions

The Definitions contained in International Organisation of Legal Metrology Recommendation No. OIML R 16-1:2002 shall be considered an integral part of Attachment No. (3) of this Resolution.

3.3 Technical Requirements

1. Mechanical Medical Sphygmomanometers, parts and accessories contained in this Attachment shall meet the Requirements contained in OIML Recommendation R 16-1, to the extent that they are not inconsistent with this Resolution.

2. Measurement Units:

The value of Arterial Blood Pressure shall be expressed in (kpa) or (mm Hg).

3. Maximum Permissible Error for Cuff Pressure Indication:

A. Under the influence of Ambient Weather Conditions:

The Maximum Permissible Error Value for any point of the Scale within the Ambient Air Temperature from 15° to 25°C and relative humidity within the range from 20% to 85% shall not exceed (± 3 mm Hg) in the case of Initial Verification and ± 4 mm Hg)) in case of Subsequent Verification.

B. Under Storage Conditions:

The Arterial Blood Pressure Monitor shall maintain the Maximum Permissible Error Value Requirements after storage for 24 hours at 20°C and at –70°C and 85% relative humidity (Non-condensing) for another 24 hours.

C. Under the influence of changing temperatures:

Under the influence of a range of air temperatures from 10 to 40°C and a relative humidity of 85% (Non-condensing), the difference in the value of the Cuff pressure of the pressure Measuring Device shall not exceed (±3 mm Hg)

4. Technical Requirements for the Cuff and Pressure Fascia:

– The Cuff shall contain Pressure Fascia. If it may be used for more than once, the Manufacturer shall indicate how to clean it.

5. Technical Requirements for the compressed air system:

A. The pressure drop due to air leakage shall not exceed mmHg/4 min.

B. The manual vacuum valve shall be able to easily adjust the pressure drop rate (2 mmHg/s - 3 mmHg/s).

C. The time for rapid pressure relief from (260 mmHg) to (15 mmHg) shall not exceed 10 seconds.

6. Technical Requirements for pressure indication means:

A. The minimum Nominal Range of the manometer shall be (0 mmHg/s - 260 mmHg)

B. The pressure gauge scale shall be designed to be easy, orderly, and clear to read.

C. Scale shall start at 0 mmHg.

D. The amount of scale shall be (2 mmHg), the fifth mark shall be shown in a larger font, and the pressure value shall be printed at the number 10 and its multiples.

E. The distance between the two steps shall not be less than 1.0m, and the thickness of the Scale line shall not exceed 20% of the distance between the two smallest steps.

7. Additional technical Requirements for pneumatic Sphygmomanometers:

A. The tolerance at the zero value shall not exceed 3 mm Hg (±) and the zero point shall be marked, but scale through the tolerance zone is optional.

B. There shall be no obstruction to the movement of the indicator or the sensitive part within the range (6 mm Hg) below zero.

C. The system shall not allow correction of pointer location or scale by the User

D. The pointer shall cover approximately 1/3 to 2/3 of the length of the shortest scale, the width of the pointer in the Scale area shall be greater than the width of the Scale mark, and the distance between the pointer and the dial shall not exceed 2 mm.

E. The Hysteresis value of the Device shall not exceed (4 mmHg) over the entire Measurement Range.

F. The materials from which the Device is manufactured and the method of its installation shall ensure stability suitable for the measurement. Aging shall also be done for the pressure and temperature sensitive element. The Device reading after 10000 measurement cycles shall not differ from (3 mmHg).

8. Safety Requirements shall meet the Requirements contained in the recommendation issued by the International Organisation of Legal Metrology OIML R 16-1.

9. Label Card.

The Label Card shall contain the following information:

– The name and/or trademark of the Manufacturer.

– Serial number and year of manufacture.

– Measurement Unit and scope.

– Type Approval number or mark.

– The centre of the Compressive Fascia, which shall indicate the correct location of the Fascia over the artery.

– A mark on the Fascia showing the appropriate circumference of the limb.

4.3 Type Approval Requirements:

1. Importers or Manufacturers of Sphygmomanometers shall submit a Type Approval Certificate in accordance with this Resolution, issued by an internationally recognised body or approved by the Ministry.

2. If the Type Approval Certificate is unavailable, three samples shall be taken to conduct all possible tests on them in accordance with this Resolution.

5.3 Requirements of the Conformity Assessment

1. Importers or Manufacturers of Sphygmomanometers shall submit a Type Conformity Certificate and for all the Devices issued by an internationally recognised body or approved by the Ministry.

2. The Ministry shall take samples for the purposes of accepting or rejecting the Batch according to Table (M1-3) shown in Attachment (1) to conduct possible tests on them.

6.3 Initial Verification Requirements:

1. For the purposes of Conformity with the Initial Verification Requirements, the following Examination shall be performed:

A. Virtual Examination.

B. Examining the Maximum Permissible Error under the influence of Ambient Weather Conditions.

C. Air Leakage Examination.

D. No party may use a Medical Pressure Device that has not been verified by Entity approved by the Ministry.

E. The Supervised Entity shall bear all costs of the Initial Verification.

7.3 Periodic Verification Requirements:

1. For the purposes of Conformity with Periodic Verification Requirements, the following Examinations shall be performed once a year on all Devices used in hospitals, clinics and laboratories:

A. Virtual Examination.

B. Examining the Maximum Permissible Error under the influence of Ambient Weather Conditions.

C. Air Leakage Examination.

D. No party may use a Medical Pressure Device that has not been verified by Entity approved by the Ministry.

E. The Supervised Entity shall bear all costs of the Periodic Verification.

8.3 Post-Maintenance Verification Requirements:

1. For the purposes of Conformity with the Post-Maintenance Verification Requirements, the following Examinations shall be performed:

A. Virtual Examination.

B. Examining the Maximum Permissible Error under the influence of Ambient Weather Conditions.

C. Air Leakage Examination.

E. No party may use a Medical Pressure Device that has not been verified by Entity approved by the Ministry.

E. The Supervised Entity shall bear all costs of Post-Maintenance Verification.

9.3 Periodic Verification Requirements:

1. The Ministry has the right to conduct Sudden Verification on all Licensed Entities in the Domain of manufacturing, importing, renting and using Sphygmomanometers to indicate the extent of their compliance with this Resolution.

2. The Ministry shall bear all costs of the Sudden Verification if the results are consistent with this Resolution, while the Supervised Entity shall bear all costs if the Verification results are not in accordance with this Resolution.

10.3 Metrological Requirements

All Medical Pressure Devices shall bear Verification marks approved by the Ministry.

11.3 Verification Procedures

The Ministry shall prepare Examination and Verification Procedures in accordance with the recommendations of the International Organisation of Legal Metrology or accepted international practices in this Domain.

12.3 References:

Recommendation of the International Organisation of Legal Metrology No. R OIML 16-1.

Attachment (4)

Non-Invasive Automated Medical Blood Pressure Measuring Device

Non-Invasive Automated Sphygmomanometers

1.4 Domain:

Non-Invasive Automated Sphygmomanometers and accessories that use an inflatable Cuff to measure Arterial Blood Pressure on the upper arm, wrist or thigh.

2.4 Definitions

The Definitions contained in International Organisation of Legal Metrology Recommendation No. OIML R 16-2 shall be considered an integral part of Attachment No. (4) of this Resolution.

3.4 Technical Requirements

1. Automated Medical Sphygmomanometers, parts and accessories contained in this Attachment shall meet the Requirements contained in OIML Recommendation R 16-2, to the extent that they are not inconsistent with this Resolution.

2. Measurement Units:

The value of Arterial Blood Pressure shall be expressed in (kpa) or (mm Hg).

3. Maximum Permissible Error for Cuff Pressure Indication:

The Maximum Permissible Error Value for any point of the Scale within the Ambient Air Temperature from 15° to 25°C and relative humidity within the range from 20% shall not exceed (± 3 mm Hg) in the case of Initial Verification and ± 4 mm Hg) in case of Subsequent Verification.

4. The Maximum Permissible Error in laboratory measurements.

– The Maximum Permissible Error Average shall not exceed (±5mm Hg).

– The Maximum Standard Deviation shall not exceed (± 8 mm Hg).

5. Maximum Permissible Error under storage conditions:

The Arterial Blood Pressure Meter shall maintain the Maximum Permissible Error Value Requirements after storage for 24 hours at 5°C and at –50°C and 85% relative humidity (Non-condensing) for another 24 hours.

6. Under the influence of changing temperatures:

The pressure difference of the Cuff within the range of air temperatures from 10°C to 40°C and a relative humidity of 85% (Non-condensing) shall not exceed 3 mm Hg (±).

7. Technical Requirements for the Cuff and Pressure Fascia:

The Cuff shall contain Pressure Fascia. If it may be used for more than once, the Manufacturer shall indicate how to clean it.

8. Technical Requirements for the Display Screen:

If symbols are used on the Display Screen, the following abbreviations shall indicate the following, taking care not to write them in a way that leads to confusion between them and symbols for Measurement Units.

– "S" or "SYS": systolic Blood Pressure (value).

– "D" or "DIA": diastolic Blood Pressure (value).

– "M" or "MAP": means arterial Blood Pressure (value).

9. The effect of changing the value of the energy source:

– Weakness of the value of the internal Electric Power Source in the Device, or fluctuation in the value of the External Electric Power Source entering the Device shall not lead to giving false measurement values.

– In the event of a malfunction in the Device, this shall cause the Cuff Pressure to drop below 15 mm Hg within 180 s for adult patients, and below 5 mm Hg within 90 s for newborn or minor patients.

10. Air system:

A. The pressure drop due to air leakage shall not exceed (6 mm Hg/min).

B. The manual vacuum valve shall be able to easily adjust the pressure drop rate (2 mmHg/s - 3 mmHg/s).

C. The time for rapid pressure relief when the valve is fully open, from 260 mmHg to 15 mmHg, shall not exceed 10 seconds. In the event that the Device is capable of measuring the Blood Pressure of newborns or minors, the time for rapid pressure relief, when The valve is fully open from 150 mmHg to 5 mmHg for 5 s.

11. Beeping:

Sphygmomanometers shall be able to beep automatically and at appropriate intervals, at least when the Device is turned on. In this case, the Device shall be provided with a mechanism to shut it down if the error exceeds (1 mm Hg).

12. Electromagnetic Compatibility:

Electromagnetic interference shall not lead to deviations exceeding the Maximum Permissible Error Value. If the interference leads to larger deviations, the Device shall be able to distinguish these deviations, shut down the Device, or disable the appearance of the pressure value on the screen. If the interference disappears, we shall be Able to restart the Device within 30 s.

13. Stability of Cuff Pressure Indication:

The change in the Cuff Pressure Indicator value after 10000 measuring cycles shall not exceed (3 mmHg)

14. Nominal Range and Measurement Range:

The Manufacturer shall specify the Nominal Range of measurement which shall be consistent for all parts of the Device. If measurements outside the Nominal Range of the Device appear, they shall be completely clear.

15. Scale and showing the measurement result:

– The Scale intervals for the Device shall be (1 mmHg).

– If the result appears on more than one screen, all results shall be numerically identical.

– The measurement result, measurement units and symbols shall be clearly arranged.

16. Signs and openings for entrances and exits:

Inlet and outlet openings and signals shall be arranged and designed in such a way as to prevent false connections or give rise to false results.

17. Stimulants:

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

18. Safety:

A. It shall be possible to stop any Blood Pressure Measurement and perform a rapid pressure relief at any time in an easy and clear manner.

B. All parts affecting the measurement result shall be protected.

C. Sphygmomanometers shall meet the Requirements contained in the International Organisation for Legal Metrology document OIML D11.

19. Label Card:

The Label Card shall contain the following information:

– The name and/or trademark of the Manufacturer.

– Serial number and year of manufacture.

– Measurement Unit and scope.

– Type Approval number or mark.

– The centre of the Compressive Fascia, which shall indicate the correct location of the Fascia over the artery.

– A mark on the Fascia showing the appropriate circumference of the limb.

20. Instructions Guide:

– An indication that this Device was manufactured in accordance with the recommendation of the International Organisation of Legal Metrology OIML R 16.2:2002

– An Instructions Guide that shows the correct method of use, the necessary warnings, care and maintenance methods, its accessories, operation conditions, a list of the Device accessories, the Electric voltage difference or type of batteries used, details of the warnings, and the required heating time for the Device.

– A statement indicating the necessity of Periodic Verification of the Device, every two years as a maximum, for values (50 mmHg) and (200 mmHg).

– Ways to clean the Cuff.

4.4 Type Approval Requirements:

1. Importers or Manufacturers of Sphygmomanometers shall submit a Type Approval Certificate in accordance with this Resolution, issued by an internationally recognised body or approved by the Ministry.

2. If the Type Approval Certificate is unavailable, three samples shall be taken to conduct possible tests on them in accordance with this Resolution.

5.4 Requirements of the Conformity Assessment:

1. Importers or Manufacturers of Sphygmomanometers shall submit a Type Conformity Certificate and for all the Devices issued by an internationally recognised body or approved by the Ministry.

2. The Ministry shall take samples for the purposes of accepting or rejecting the Batch according to Table (M1-3) shown in Attachment (1) to conduct possible tests on them.

6.4 Initial Verification Requirements:

1. For the purposes of Conformity with the Initial Verification Requirements, the following Examinations shall be performed:

A. Virtual Examination.

B. Examining the Maximum Permissible Error under the influence of Ambient Weather Conditions.

C. Air Leakage Examination.

2. No party may use a Medical Pressure Device that has not been verified by Entity approved by the Ministry.

3. The Supervised Entity shall bear all costs of the Initial Verification.

7.4 Periodic Verification Requirements:

1. For the purposes of Conformity with Periodic Verification Requirements, the following Examinations shall be performed once a year on all Devices used in hospitals, clinics and laboratories:

A. Virtual Examination.

B. Examining the Maximum Permissible Error under the influence of Ambient Weather Conditions.

C. Air Leakage Examination.

2. No party may use a Medical Pressure Device that has not been verified by Entity approved by the Ministry.

3. The Supervised Entity shall bear all costs of the Periodic Verification.

8.4 Post-Maintenance Verification Requirements:

1. For the purposes of Conformity with the Post-Maintenance Verification Requirements, the following Examinations shall be performed:

A. Virtual Examination.

B. Examining the Maximum Permissible Error under the influence of Ambient Weather Conditions.

C. Air Leakage Examination.

2. No party may use a Medical Pressure Device that has not been verified by Entity approved by the Ministry.

3. The Supervised Entity shall bear all costs of the Periodic Verification.

9.4 Sudden Verification Requirements:

1. The Ministry has the right to conduct Sudden Verification on all Licensed Entities in the Domain of manufacturing, importing, renting and using Sphygmomanometers to indicate the extent of their compliance with this Resolution.

2. The Ministry shall bear all costs of the Sudden Verification if the results are consistent, while the Supervised Entity shall bear all costs if the Verification results are not in accordance with this Resolution.

10.4 Metrological Requirements

All Medical Pressure Devices shall bear Verification marks approved by the Ministry.

11.4 Verification Procedures

The Ministry shall prepare Examination and Verification Procedures in accordance with the recommendations of the International Organisation of Legal Metrology or accepted international practices in this Domain.

12.4 References:

– Recommendation of the International Organisation of Legal Metrology No. OIML R 16-2.

Attachment (5)

Glass Automatic Pipettes

Glass Automatic Pipettes

1.5 Domain:

Glass Automatic Pipettes used as Volume Standards

2.5 Definitions

Capacity: The Volume of the Pipette in ml or at the Reference Temperature.

Delivery Time: The time from the beginning of the water flow until it ends when the drain hole is open.

3.5 Metrological Requirements

1. The Reference Temperature is 20°C unless otherwise stated on the Pipette in a non-removable manner.

2. The Delivery Time and the Maximum Permissible Error for the preferred nominal capacities shall be as shown in Table (5-1).

Table (1-5). The Delivery Time and Maximum Permissible Error.

MPE ± ml	**Delivery Time (s)**		**Nominal Capacity (ml)**
	Maximum	***Minimum***	
0.06	20	10	5

0.08	30	15	10
0.12	30	15	20
0.12	40	20	25
0.15	60	30	50
0.20	60	30	100
0.4	60	30	200
0.4	80	50	250
0.5	100	60	500
1	100	60	1,000
1	140	80	2,000
1.2	140	80	2,500
2.5	150	100	5,000
5	180	120	10,000

4.5 Device Information:

All Devices shall contain the following information:

1. The nominal capacity of the Automatic Pipette using legal Measurement Units.
2. Reference Temperature.
3. The Device ID No.
4. The specification according to which the Device was designed.
5. Uncertainty in the actual measurement and capacity, if it contradicts what is stated in Table (5-1).

5.5 In the event that the specification according to which the Device is manufactured has Requirements different from the Requirements stated in this Resolution, the Device shall meet all the Requirements stipulated in that specification, with the necessity that the specification according to which the Device is manufactured be fixed in a way that cannot be removed from the Device.

6.5 Requirements for Initial Verification and Periodic Verification:

Any unverified Automatic Pipette shall not be used and shall be verified by an accredited laboratory.

7.5 References:

OIML D 26

Attachment No. (6)

Graduated Pipettes

Graduated Pipettes

1.6 Domain:

Graduated Pipettes used as Volume Standards

2.6 Definitions :

– Capacity: The Volume corresponding to any Scale mark and equal to the Volume of water discharged from the Pipette after filling it to the Scale mark under standard conditions.

– Nominal Capacity: The upper value in the Scale shown on the Pipette.

– Delivery Time: The time it takes to empty the Pipette of water from the highest mark to the point at which the liquid stops.

– Waiting Time: The period between completing the liquid emptying and taking the final reading of the liquid Volume.

3.6 Metrological Requirements:

1. Reference Temperature: It shall be 20°C.

2. Nominal capacity: It is preferable that the Graduated Pipettes have one of the following nominal capacities:

1 cm3, 2 cm3, 5 cm3, 10 cm3

3. The Maximum Permissible Error: It shall not exceed the values shown in Table (6-1).

Table (6-1). Maximum Permissible Error

Maximum Permissible Error mL	Nominal capacity mL
0.006	1
0.01	2
0.03	5
0.05	10
0.1	25

4.6 Device Information:

All Devices shall contain the following information:

1. Nominal capacity.

2. Reference Temperature.

3. Class.

4. Waiting time to complete unloading (Delivery Time).

5. The Device ID No.

6. The specification according to which the Device was manufactured.

7. Uncertainty in the actual measurement and capacity, if it contradicts what is stated in Table (6-1).

8. Minimum scale value.

5.6 In the event that the specification according to which the Device is manufactured has Requirements different from the Requirements stated in this Resolution, the Device shall meet all the Requirements stipulated in that specification, with the necessity that the specification according to which the Device is manufactured be fixed in a way that cannot be removed from the Device.

6.6 Requirements for Initial Verification and Periodic Verification:

Any unverified Graduated Pipette shall not be used and shall be verified by an accredited laboratory.

7.6 References:

OIML R 40.

Attachment No. (7)

Graduated Flasks

Flasks

1.7 Domain:

Graduated Flasks used as Volume Standards.

2.7 Definitions

1. The capacity (Contain) in the reference Graduated Flask corresponding to any scale mark <<In>>. The Volume of Contain water is equal to the content in the Flask at the Reference Temperature, when filled to that mark.

2. The capacity (Deliver) in the reference Graduated Flask corresponding to any scale mark <<Ex>>. The Volume of Deliver water is equal to the content in the Flask at the Reference Temperature, when filled to that mark.

3. Nominal Capacity: The upper value in the Scale shown on the Pipette.

3.7 Metrological Requirements

1. The Reference Temperature is 20% C unless otherwise stated.

2. It is preferable that the Flasks have the following nominal capacities:

i. 1 × 10n cm3, 2 × 10n cm3, 5 × 100 cm3.

3. Maximum Permissible Error:

Maximum Permissible Error in Flasks of type <<In >>. For any scale mark, it shall not exceed the values shown in column (E1) of Table (1-7).

Maximum Permissible Error in Flasks of type <<In >>. Between any two scale marks, the values in column (E2) of the table shall not exceed (2-7).

Maximum Permissible Error in Flasks of type <<Ex >>. For any scale mark or between any two scale marks, 50% is greater than the class <<In>>.

Table (1-7) Maximum Permissible Error

MPE ± cm3		Nominal Capacity cm3
E2	E1	
0.02	0.05	10
0.03	0.08	20
0.05	0.12	50
0.06	0.20	100
0.09	0.30	200
0.15	0.50	500
0.22	0.80	1,000
0.33	1.20	2,000
0.75	2.50	5,000
1.50	5.00	10,000

4.7 Device Information:

All Devices shall contain the following information:

1. The nominal capacity using legal Measurement Units.

2. Reference Temperature.

3. The abbreviation Ex to indicate the deliver Volume, or the abbreviation In to indicate the contain Volume.

4. ID No.

5. Maximum Permissible Error.

6. The specification according to which the Device was designed.

7. Uncertainty in the actual measurement and capacity, if it contradicts what is stated in Table (7-1).

8. Minimum Scale Value.

5.7 In the event that the specification according to which the Device is manufactured has Requirements different from the Requirements stated in this Resolution, the Device shall meet all the Requirements stipulated in that specification, with the necessity that the specification according to which the Device is manufactured be fixed in a way that cannot be removed from the Device.

6.7 Requirements for Initial Verification and Periodic Verification:

Any unverified Graduated Flask shall not be used and shall be verified by an accredited laboratory.

7.7 Reference:

OIML R 43.

Attachment No. (8)

Pycnometers

Pycnometers

1.8 Domain

Pycnometers used in laboratories.

2.8 Definitions

– Nominal Capacity: The Volume of the Device in ml.

3-8 Metrological Requirements

1. The Reference Temperature is 20%^{C}unless otherwise stated.

2. Nominal capacity: It is preferable for Pycnometers to have the nominal capacities shown in Table (8-1) and according to their type.

3. The Maximum Permissible Error: It shall not exceed the values shown in Table (8-1).

Table (8-1) . Nominal capacities and Maximum Permissible Error for Pycnometers according to their type

MPE	Nominal Capacity (ml)	Designation	Type

±ml			
5	1, 2, 5, 10	Lipkin	1
5	5,10,25	Sprengel	2
10	1, 2, 5, 10, 25, 50, 100	Gay-Lussac	3
5	10, 25, 50, 100	Reischauer	4
15	25, 50	Hubbard	5
50	10, 25, 50, 100	Ground-in Thermometer	6

4.8 Device Information:

All Devices shall contain the following information:

1. The nominal capacity using legal Measurement Units.
2. Reference Temperature.
3. ID No.
4. Maximum Permissible Error.
5. The specification according to which the Device was designed.
6. Uncertainty in the actual measurement and capacity, if it contradicts what is stated in Table (8-1).

5.8 In the event that the specification according to which the Device is manufactured has Requirements different from the Requirements stated in this Resolution, the Device shall meet all the Requirements stipulated in that specification, with the necessity that the specification according to which the Device is manufactured be fixed in a way that cannot be removed from the Device.

6.8 Requirements for Initial Verification and Periodic Verification:

Any unverified Density Meter shall not be used and shall be verified by an accredited laboratory.

7.8 Reference:

ISO-3507.

Attachment No. (9)

Burettes

Burettes

1.9 Domain

Burettes used as Volume Standards.

2.9 Definitions

– Capacity is the Volume corresponding to any scale mark, and is equal to the Volume of water at the standard temperature when it is emptied from zero to the required scale mark.

– Nominal Capacity: The upper value in the Scale shown on the Burets.

– Delivery Time: The time from the beginning of the water flow until it ends when the drain hole is open.

3.9 Metrological Requirements:

1. The Reference Temperature is20 s unless otherwise stated.

2. It is preferable that the nominal capacities of the burets be as in Table (9-1) in this Attachment.

3. The Maximum Permissible Error and Delivery Time shall be within the upper and lower limits as in Table (9-1).

Table (9-1). Nominal capacities and deliver times of burets

Maximum Permissible Error (±ml)	**Delivery Time (s)**		**Nominal Capacity (ml)**
	Max.	**Min.**	
0.02	100	70	10
0.03	170	120	25
0.05	150	105	50
0.1	150	100	100

4.9 Device Information:

All Devices shall contain the following information:

1. The nominal capacity using legal Measurement Units.

2. Reference Temperature.

3. The Device ID No.

4. Delivery Time.

5. Uncertainty in the actual measurement and capacity, if it contradicts what is stated in Table (9-1).

6. Minimum Scale Value.

5.9 In the event that the specification according to which the Device is manufactured has Requirements different from the Requirements stated in this Resolution, the Device shall meet all

the Requirements stipulated in that specification, with the necessity that the specification according to which the Device is manufactured be fixed in a way that cannot be removed from the Device.

6.9 Requirements for Initial Verification and Periodic Verification:

Any unverified Graduated Burette shall not be used and shall be verified by an accredited laboratory.

7.9 Reference:

OIML R 41.

Attachment No. (10)

Graduated Cylinders

Graduated Cylinders

1.10 Domain:

Graduated Cylinders used as Volume Standards.

2.10 Definitions

– Capacity: The Volume of the Cylinder in ml or cm3 at the Reference Temperature.

– Nominal Capacity: The upper value in the Scale shown on the Cylinder.

3.10 Metrological Requirements

1. The Reference Temperature is 20%^{C}unless otherwise stated.

2. It is preferable that the inserted Cylinders have nominal capacities as shown in Table (110).

3. The Graduated Cylinders are classified according to their degree of accuracy into the following categories:

– Class 1a

– Class 1b

– Class 2

4. Maximum Permissible Error

The Maximum Permissible Error: It shall not exceed the values shown in Table (10-1).

Table (10-1). Maximum Permissible Error for Graduated Cylinders

MPE ± ml			Nominal
Class	Class	Class	Capacity
(2)	(1b)	(1a)	(ml)
0.2	0.1	0.05	5
0.3	0.2	0.10	10

0.5	0.5	0.25	25
1.0	1.0	0.50	50
1.0	1.0	0.50	100
2.0	2.0	1.00	250
0.5	0.5	0.25	500
10.0	10.0	5.00	1,000
20.0	20.0	10.00	2,000

4.10 Device Information:

All Devices shall contain the following information:

1. The nominal capacity using legal Measurement Units.

2. In 20 °C or in 20 °C.

3. ID No.

4. Maximum Permissible Error.

5. The specification according to which the Device was designed.

5.10 In the event that the specification according to which the Device is manufactured has Requirements different from the Requirements stated in this Resolution, the Device shall meet all the Requirements stipulated in that specification, with the necessity that the specification according to which the Device is manufactured be fixed in a way that cannot be removed from the Device.

6.10 Requirements for Initial Verification and Periodic Verification:

Any unverified Graduated Burette shall not be used and shall be verified by an accredited laboratory.

7.10 Reference:

ISO 4788.

Attachment No. (11)

Medical Syringes

Medical Syringes

1.11 Domain:

Medical Syringes, which are used only once.

2.11 Definitions

– Capacity is the Volume corresponding to any scale mark, and is equal to the Volume of water at a temperature of 20°C supplied by the Syringe when the approved mark moves over the entire scale or over a specific part of it.

– Nominal Capacity: The upper value in the Scale shown on the Syringes.

3.11 Technical Requirements for disposable Medical Syringes:

– Disposable Medical Syringes shall meet all Requirements contained in International Standard ISO 7886-1.

4.11 Device Information:

All Devices shall contain the following information:

1. The nominal capacity using legal Measurement Units.
2. Expiry date.
3. The name and trademark of the Manufacturer or the trade name of the Manufacturer or Supplier.
4. Batch and operational number or serial number.
5. Measure the needle used.
6. Country of Origin.

5.11 Type Approval Requirements:

1. Importers or Manufacturers of Medical Syringes shall submit a Type Approval Certificate in accordance with this Resolution, issued by an internationally recognised body or approved by the Ministry.
2. If the Type Approval Certificate is unavailable, three samples shall be taken to conduct possible tests on them in accordance with this Resolution.

6.11 Requirements of the Conformity Assessment Body

1. Importers or Manufacturers of Medical Syringe shall submit a Type Conformity Certificate in accordance with this Resolution, and for all Syringe issued by internationally recognised body or approved by the Ministry.
2. The Ministry shall take samples for the purposes of accepting or rejecting the Batch according to Table (M1-2) shown in Attachment (1) to conduct Initial Verification Examinations as specified in Clause No. 7.11 of Attachment No.(11).

7.11 Initial Verification Requirements:

1. For the purposes of Conformity with the Initial Verification Requirements, the following Examinations shall be performed:

* Virtual Examination

* Maximum Permissible Error Examination

2. No party may use Medical Syringes that do not have a certificate of Conformity or a certificate of Batch Verification from an entity approved by the Ministry.

3. The Supervised Entity shall bear all costs of the Initial Verification.

8.11 Periodic Verification Requirements:

1. The Ministry has the right to conduct Sudden Verification on all Licensed Entities in the Domain of manufacturing, importing, renting and using Medical Syringes to indicate the extent of their compliance with this Resolution.

2. The Ministry shall bear all costs of the Sudden Verification if the results are consistent, while the Supervised Entity shall bear all costs if the Verification results are not in accordance with this Resolution.

9.11 Verification Procedures:

The Ministry shall prepare the Examination and Verification Procedures in accordance with the Recommendations of the International Organisation of Legal Metrology or accepted international practices in this Domain.

10.11 References:

.ISO 7886-1.

Attachment No. (12)

Measurement Devices that are verified using reference materials.

1.12 Domain:

1. Glouco Meter, portable and used for initial diagnostic purposes by patients or Health Facilities.

2.12 Metrological Requirements

1. The Maximum Permissible Error: It shall not exceed the values shown in Table (12-1).

2. Suitable quantities of reference materials shall be permanently available to confirm that the reading of the Measuring Device is within the permitted limits that fulfil the purpose of using the Measuring Device.

3. The actual value and uncertainty value of the reference material shall be known and issued by a recognised body, and conform to international standard specifications accepted by the Competent Authorities.

4. Certified reference materials shall be used whenever possible. Otherwise, the reference material shall have a value determined by scientifically accepted and fully documented measurement procedures.

5. The reference material shall be homogeneous, highly stable, and stored in correct environmental conditions and methods in accordance with the Manufacturer instructions.

6. You shall ensure that the Device reading is correct before each use.

7. The uncertainty in the reading of the Device or in the reference material may not be greater than values acceptable for Medical purposes.

Table (12-1). Maximum Permissible Error

No.	The Device	Maximum Permissible Error
1.	Glouco Meter Concentration	The error in 95% of individual test results shall be within ±0.83 mmol/L (15mg/dL) at a sugar concentration of less than 4.2mmol/L (<75 mg/dL). It shall fall within ±20% at a sugar concentration greater than (≥75 mg/dL) 4.2 mmol/L. Reference: ISO 15197.

3.12 Requirements for Initial, Periodic, Sudden and Post-Maintenance Verification:

1. The Ministry has the right to take samples in accordance with Table (M1-2) to confirm their compliance with the Obligatory Requirements in the manner it deems appropriate.

2. It is not permitted to use or offer any Device for sale, use or rental unless it meets the conditions contained in these Requirements.

4.12 Verification procedures

The Ministry shall prepare the Examination and Verification Procedures in accordance with the Recommendations of the International Organisation of Legal Metrology or accepted practices in this Domain.

Attachment No. (13)

Equipment for measuring doses of ionising radiation

1.13 Domain:

All Medical Examination equipment that includes ionising radiation dosimeters used for non-diagnostic Medical purposes in Medical Facilities.

2.13 Obligatory Requirements

All ionising radiation dosimetry equipment shall meet the following Requirements:

1. Ionising radiation dosimetry equipment shall be compatible with the International Electrotechnical Commission (IEC) and the International Organisation for Standardisation (ISO).
2. Equipment for measuring ionising radiation doses shall be calibrated by an approved body before putting it into use.
3. It shall be calibrated periodically according to the Requirements of the Federal Authority for Nuclear Regulation, and after any maintenance operation that affects the measurement process.
4. The process of calibrating ionising radiation dosimetry equipment shall be carried out by accredited laboratories in accordance with the international standard ISO/IEC 17025.
5. Calibrating radiation equipment shall be carried out by accredited laboratories in accordance with the international standard ISO/IEC 17025.
6. If the Calibration laboratories are not accredited, the Entity that owns the Measuring Device shall be responsible for ensuring that the laboratory is competent to carry out Calibration Operations, in accordance with the Requirements of the Federal Authority for Nuclear Regulation.
7. The Measurement Units used in measurements shall be according to the International System of Measurement Units.

Attachment No. (14)

Measuring Devices that shall have a Calibration Certificate.

1.14 Domain:

– Non-Glass Automatic Pipettes.

– (Masses).

– Balances.

– Thermometers used to measure the temperature of ovens, coolers, water baths, baby incubators, etc. (Thermometers for ovens, coolers, water bathes, incubators, etc.).

– Autoclaves

2.14 Metrological Requirements

– The Devices mentioned in Clause (14.1) shall carry a Calibration Certificate in accordance with the Requirements contained in the specification for accreditation of testing and Calibration laboratories ISO/IEC 17025.

– Each entity shall determine the Maximum Permissible Error Value for each Device, and document this so that the sum of the deviation value in the Device reading and the measurement uncertainty does not exceed one third of the acceptable value for the Medical purposes for which it is used.

– You shall not use any Device whose Error Value exceeds the Maximum Permissible Error Value allowed for it.

– In general, the value of the Maximum Permissible Error, including the uncertainty value of any Devic, shall not exceed one third of the value of the permissible error for Medical purposes.

– The Measuring Devices contained in this Attachment shall be recalibrated in accordance with Table (14.1) or in accordance with international practices in this Domain.

Table (14.1). Time period for Recalibration

No.	The Scale	Maximum Recalibration
1	Non-Glass Automatic Pipettes.	One Year
2	Masses	Two years
3	Mass Scales	One Year
4	Thermometers used to measure the temperature of ovens, coolers, water baths, baby incubators, etc. (Thermometers for ovens, coolers, water bathes, incubators, etc.).	One Year
5	Sterilisers	One Year

– If internal Calibration is performed for the standards contained in this Attachment, the entity conducting the Calibration process shall prove its ability to meet the Requirements of ISO 17025.

– The following shall be attached to each Device:

– Calibration date.

– Subsequent Calibration date.

– Calibration Certificate number.

Attachment (1)

1. This Attachment shows the tables for sampling, as follows:

A. Table (M1-1) for taking the number of mini samples, which was prepared in accordance with International Standard (ISO 28591) by the double miniature method at a quality acceptance limit (AQL) equal to 1.00, according to the 5-s sampling level.

B. Table (M1-2) for taking an average number of samples, which was prepared in accordance with the International Standard (ISO 2859-1) according to the second sampling level II table for taking double mini verification samples at the quality acceptance limit (AQL) equal to 1.00.

C. Table (M1-3) for extended sampling, which was prepared in accordance with International Standard (ISO 2859-1) according to sampling level II double natural sampling table at the lower quality acceptance limit (with a ratio of 0.65).

2. Basis for rejection and acceptance:

2.1 If the number of defective samples taken in the first Stage is less than or equal to the number of defective samples for acceptance purposes, the Batch shall be accepted.

2.2 If the number of defective samples taken in the first Stage is less than or equal to the number of defective samples for rejection purposes, the Batch shall be rejected.

2.3 If the number of defective samples taken in the first Stage falls between the number of defective samples for acceptance purposes and the number of defective samples for rejection purposes, samples are taken for the second Stage of Examination, and the Batch is rejected or accepted according to the results of this Stage.

2.4 The entire Batch shall be rejected if the Maximum Permissible Error for one or more Measuring Devices exceeds twice the Maximum Permissible Error. However, with the approval of the Ministry, the owner, Manufacturer, or importer of Measuring Devices may be allowed to sort them completely to examine whether conforming Devices are accepted and non-conforming Devices rejected.

Table (M1-1). Table for taking a number of mini samples

Batch Size	Stage	Number of samples required for testing	Number of defective samples for purposes	
			Acceptance Batch	Rejection Batch
2-150	First	2	0	1
151-500	First	3	0	1
501-1200	First	5	0	1
1201-10000	First	8	0	2
	Second	8	1	2
10001-35000	First	13	0	2
	Second	13	1	2
35001-500000	First	20	0	2
	Second	20	1	2
Greater than 500000	First	32	0	3
	Second	32	3	4

Table (M1-2). Table for taking a number of wide samples

Batch Size	Stage	Number of samples required for testing	Number of defective samples for purposes	
			Acceptance Batch	Rejection Batch
50-2	First	2	0	1
51-90	First	3	0	1
91-150	First	5	0	1
151-280	First	8	0	2
	Second	8	1	2
281-500	First	13	0	2
	Second	13	1	2
1200-501	First	20	0	2
	Second	20	1	2
1201-3200	First	32	0	3
	Second	32	3	4
3201-10000	First	50	1	3
	Second	50	4	5
35000-10001	First	80	2	4
	Second	80	5	6
150000-35001	First	125	3	6
	Second	125	7	8
500000-150001	First	200	4	7
	Second	200	10	11
Greater than 500000	First	315	5	9
	Second	315	12	13

Table (M1-3). Table for taking a number of wide samples

Batch Size	Stage	Number of samples required for testing	Number of defective samples for purposes	
			Acceptance Batch	Rejection Batch
8-2	First	2	0	1
15-9	First	2	0	1
	Second	2	0	1
25-16	First	3	0	1
	Second	3	0	1
50-26	First	5	0	1
	Second	5	0	1
51-90	First	8	0	1
	Second	8	0	1
91-150	First	13	0	1
	Second	13	0	1
151-280	First	20	0	1
	Second	20	0	1
281-500	First	32	0	2
	Second	32	1	2
1200-501	First	50	0	2
	Second	50	1	2
1201-3200	First	80	0	3
	Second	80	3	4
3201-10000	First	125	1	3
	Second	125	4	5
35000-10001	First	200	2	5
	Second	200	6	7
150000-35001	First	315	3	6
	Second	315	9	10

150001-500000	First	500	5	9
	Second	500	12	13
Greater than 500000	First	800	7	11
	Second	800	18	19