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TNO Quality Guideline

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Portable in-vitro blood monitor systems for (self)-monitoring; General requirements and test methods

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Contents

1 Scope

This TNO Quality Guideline specifies general procedures for the determination of ergonomic, functional and technical performance criteria for quantitative *in vitro* blood monitoring systems for (self)-management.

The primary goal of the TNO Quality Guideline is to assure the ergonomic, functional and technical performance of non-implantable blood monitoring systems for (self)-measurement and to specify procedures by which compliance with the requirements can be verified, if applicable.

Those requirements, which are unique to (self)-measurement, are addressed in this guideline. Other general requirements for *in vitro* diagnostic medical devices are covered by appropriate general standards for *in vitro* diagnostic medical devices.

A number of particular TNO Quality Guidelines are developed or in developing, apply to blood monitors for (self)-management related to a specific area, for blood monitoring of glucose (BGM), coagulant (BCM), ketonen (BKM), etc.

The primary intended users of this Quality Guideline are manufacturers of such systems and those other organizations (e.g., certification bodies) having the responsibility for assessing the performance of these systems.

This TNO Quality Guideline does not apply to measurement procedures with results on an ordinal scale (e.g.: visual, semi-quantitative test methods). It can be used, however, as a general framework for evaluating performance of such a test system.

2 Normative references

The following standards and guidelines contain provisions, which through reference in this text constitute provisions of the TNO Quality Guideline. At the time of publication, the editions indicated were valid. All standards and guidelines are subject to revision, and parties to agreements based on this guideline are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below.

ISO/DIS 15197	Determination of performance criteria for In-Vitro blood glucose monitoring systems for management of human diabetes mellitus
ISO 3743	Acoustics-Determination of Sound Power Levels of Noise Sources-Engineering Methods for Special Reverberation Test Rooms
ISO 3744	Engineering methods for determination of sound pressure levels for sources in free-field conditions over a reflecting plane
ISO 3534-1	Vocabulary and Symbols - Part 1: Probability and General Statistical Terms
NRSCL 8A3	Terminology and Definitions for Use in NCCLS Documents
EN 376	Labeling of in vitro diagnostic reagents for self testing
EN 475	Medical devices – Electrically generated alarm signals
EN 592	In vitro diagnostic systems; Requirements for user manual for in vitro diagnostic systems for home use
IEC 529	Degrees of Protection Provided by Enclosures (IP Code)
IEC 878	Graphical Symbols for Electrical Equipment in Medical Practice
IEC 60601-1	Medical Electrical Equipment, Par 1: General Requirements for Safety
IEC 60601-1-2	Collateral standard: (2001-09) Electromagnetic compatibility
EN 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use, Part 1: General requirements
ISO/IEC Guide 37	Instructions for use of products of consumer interest
ANSI/AAMI HE48	Recommended Practice, Human Factor Engineering. Guidelines and Practices for the Design of Medical Devices (Association for the Advancement of Medical Instrumentation)

3 Definitions

For the purposes of this Quality Guideline, the following definitions apply:

3.1 **Accessories**: Parts and materials supplied with the meter (e.g. reagent systems, quality control material, documentation, communication cable, etceteras).

3.2 **Auditory**: Detectable by hearing.

3.3 **Blood monitoring system:** A measuring system which is intended by the manufacturer to be used *in vitro* on blood samples derived from the human body for the purpose of monitoring specific concentrations of matter into blood.

3.4 **Blood monitor or meter:** The instrument component of a blood monitoring system, commonly referred to as "meter".

3.5 **Calibration**: Adjusting the meter to the reagent system.

3.6 **Checking means**: A kind of quality control material for checking the proper function of the meter.

3.7 **Contact knob**: An operating control that shall be pressed in a distance of less than 2 mm to activate it.

3.8 **Erasure** is defined as:

- Removal of a measured value from the memory;
- The overwriting of a measured value from the memory by a successive measurement.

3.9 **Housing**: The external surface of the meter, including:

- All contactable parts, knobs, handles, etc.;
- All contactable covers, cover caps, etc.

3.10 **IVDD:** In-Vitro Diagnostic Directive.

3.11 **Label:** Any printed, written or graphic information affixed on a product of packaging.

3.12 **Labeling:** All printed, written, graphic or other information affixed to, or accompanying an *in vitro* diagnostic medical device including labels on any of its packaging, users manuals and package inserts.

3.13 **Legibility:** the attribute of alphanumeric characters that makes it possible for each one to be identifiable forms each other. This depends on such features as stroke width, form of characters, contrast, and illumination (discriminability).

3.14 **Lot**: a quantity produced in one manufacturing cycle.

3.15 **Measurement cell**: The interface between the reagent system and the measuring circuit of the meter.

3.16 **Measuring system**: The combination of the meter and the reagent system.

3.17 **Original packaging**: The packaging in which the meter including the accessories is supplied.

3.18 **Package insert:** Instructions for use and other information supplied with any reagent system and any quality control material as part of a specific monitoring system that is not attached to any part of the package.

3.19 **Pictogram**: A representation or information in pictorial graphics script, including software.

3.20 **Properly function**: In according to the manufacturer's specifications.

3.21 **Pushbutton**: An operating control that shall be pressed in a distance of more than 2 mm for activation.

3.22 **Quality control material:** A substance, material or article intended by its manufacturer to verify the performance characteristics of an in vitro diagnostic medical device.

3.23 **Quality control range:** The range of statistically justified acceptable values specified by the manufacturer, for results obtained using the quality control material.

3.24 **Readability:** a quality that makes possible the recognition of the information content of material when it is presented by (alphanumeric) characters in meaningful groupings, such as words, sentences, or continuous text.

3.25 **Reagent system:** The part of the *in vitro* diagnostic medical device that produces a signal via a chemical, or electrochemical reaction, which allows the analyte (e.g. glucose, coagulant, ketonen, etceteras) to be detected and its concentration measured in a sample.

3.26 **Relief**: An impression to be perceived by the user in a tactile fashion, with a minimal 2 mm height difference with respect to the surrounding surface, and wherein the minimum surface dimension is 2 mm.

3.27 **Supplementary tools:** All kind of tools; excluding coins.

3.28 **Tactile**: To be perceived by the sense of touch.

3.29 **User or lay user:** An individual who does not have a special medical and/or technical education.

3.30 **User manual:** Information supplied by the manufacturer concerning the proper use of an in vitro diagnostic medical device system, including the safe and correct operation, maintenance, and basic trouble of the instrument.

3.31 **Visual**: To be perceived by the eye.

4 Design

4.1 Ergonomic/human factor aspects

Blood monitoring systems are intended for (self-) measurement by users, which includes individuals with a broad range of physical and mental abilities. These systems are often transported by the individual users who shall conduct measurements in a variety of settings.

NOTE 1: **It is not expected that a single system have all features or settings as described, so the applicability of the requirements are depend on the presence of that.**

In consideration of the above, the design of the blood monitoring system shall take into consideration ergonomic and relevant human factors for the following:

- ease of operation;
- ease of maintenance;
- protection from "wear and tear" that might typically be encountered in the use environment;
- readability of the measured results;
- user verification of proper system function:
- Information with regard to visibility, legibility and readability of the presentation.

4.1.1 Ease of operation

4.1.1.1 General

The examination shall be performed as described in 8.1.1. The following requirements are applicable:

a) Checking means shall be available so that the user can check the proper function of the meter.

b) The meter shall be supplied with instructions for use and written in the official language(s) of the user.

4.1.1.2 Battery

The examination shall be performed as described in 8.1.2. The following requirements are applicable:

a) The battery, with which the meter functions, if interchangeable, shall be available from a retailer.

b) The battery, with which the meter functions, if interchangeable, shall be able to be removed and replaced without supplementary tools.

c) If improper placement of the battery is possible, this shall not have any harmful effect for the meter.

d) During the replacement of the battery, the measured values and other data stored in the meter shall be maintained for a period of 2 minutes after interruption of the supply voltage.

e) The removal/replacement of the battery shall be possible without touching the internal electronics. During handling, the housing of the meter shall fulfil the IP2X protecting regulations.

4.1.1.3 Operating controls

The examination shall be performed as described in 8.1.3. The following requirements are applicable:

Points a to g inclusive are not applicable for controls for which only one parameter is installed or for controls which are for initial use only (e.g. the installing of date, time, etc.). An exception is controls for calibrating the meter.

a) Operating controls shall be designed in such a way that they are distinguishable by tactile means (relief) and visually (color/label).

b) Operating controls to be used for a measurement shall be placed in such a way that they can be operated either left-handed or right-handed, with the display remaining directly readable in either case.

c) Contact knobs or pushbuttons with relief shall have a maximum size of at least 10 mm and a minimum size of at least 3 mm.

d) Pushbuttons without relief with a displacement of >2 mm shall have a minimum size of 19 mm.

e) Actuation of contact knobs with a displacement of ≤ 2 mm shall be accompanied by a visual signal.

f) The distance between the centre lines of contact knobs or pushbuttons shall be a minimum of 17 mm, alternatively the space between the operating controls shall be a minimum of 3 mm.

g) All operating controls shall be able to be actuated without auxiliary means.

4.1.1.4 Handling of reagent systems

The examination shall be performed as described in 8.1.4.
The following requirements are applicable:

a) On introduction, the reagent system that is to be inserted in the meter shall be placed in such a way that the reagent system can be supported on the meter.

b) It shall be possible to perform a measurement with one hand.

c) During the performance of the measurement procedure, the unintentional activation of operating controls immediately adjacent to controls needed for performing the measurement shall not cause interference.

d) During performance of the measurement procedure, an accidentally moving of the meter shall not cause malfunction of the measurement process and value.

e) An incorrect introduction/application of the reagent system shall not display any misleading value.

4.1.1.5 Operating forces

The examination shall be performed as described in 8.1.5.
The following requirements are applicable:

a) The operating force of the introduction/application of reagent systems, in particular strip shaped reagent systems, with relief into or onto the meter shall be ≤ 4 N. The operating force of strip shaped reagent systems, without relief shall be ≤ 2.8. N, assuming finger pressure at a 45° angle ± 5°.

b) The operating force of the introduction/application of other types of reagent systems into or onto the METER, with relief shall be ≤ 11 N and without relief shall be ≤ 8 N.

c) The sliding force (e.g. actuation of slide covers) with relief shall be ≤ 11 N. The sliding force without relief shall be ≤ 8 N, assuming a pressure load at an angle of 45° ± 5° with one finger.

d) The pressure force for displacement of not specified components shall not be greater than 23 Newton.

e) The torque on rotating components shall not be greater than 42 Nm * 10^{-3}.

4.1.1.6 Accuracy of timing

The examination shall be performed according to 8.1.6.

For meters with a "timer function", whereby the user possible can influence the measured results by decreasing or increasing the timing, the following requirement is applicable. Deviation from the prescribed times by 5 s. earlier or later shall have no more than a 15% effect on the measured value with respect to the value obtained in the case of the prescribed procedure.

4.1.1.7 Automatic shutoff of the meter

The examination shall be performed according to 8.1.7. The following requirements are applicable:

a) A meter without a memory for measured values shall display the measured values for a minimum of 5 min after measurement is complete before the meter shuts itself off.

b) A meter that has a memory for blood value(s) shall display the measured value for a minimum of 1 min after the measurement is complete before the meter shuts itself off.

c) It is permissible that a meter shut itself off after removing the reagent system when the meter has the capability to store and recall the last measurement.

4.1.1.8 Auditory signal

The examination shall be performed according to 8.1.8.

Meters who have auditory signals shall meet the requirements of EN 475. The following requirements are applicable:

a) For meters with a "timer function", the signal for completion of a timing sequence shall meet the requirements of EN 475 table 2: "Characteristics of

the medium priority auditory signal".

- Pulse frequency between 150 and 1000 Hz.
- Effective pulse duration between 250 and 500 ms.
- Amplitude between 45 and 85 dB (A).

b) Signals for cue, alert or warn the user, but others than a "timer function", shall meet the requirements of EN 475 table 4: "Characteristics of the low priority auditory signal".

- Pulse frequency between 150 and 1000 Hz.
- Effective pulse duration between 150 and 250 ms.
- Amplitude between 45 and 60 dB(A).

c) There shall be a clearly visible indication when the auditory signal for completion of a timing sequence has been switched off.

4.1.1.9 Memory and data storage

The examination shall be performed as described in 8.1.9.
The following requirements are applicable:

a) The meter shall store the last measured value automatically.

b) It shall be possible to recall the last stored value by the user.

c) When a meter can store more than 14 values, the values shall be stored and recalled by the user, with indication of date and time.

d) For meters having statistical calculation features, measurements with quality control material shall not be calculated.

e) When a meter can add events in combination with a value, a list of all possible general events shall be available, storable, recallable and editable.

f) When a meter can adding daily used insulin doses and other information, it shall be stored, recalled and edited by the user, with indication of date and time.

g) When data can be stored to a PC, the storing data contains at least date and time with every value, doses or other information in combination with a value or doses.

4.1.2 Ease of maintenance

The examination shall be performed according to 8.2.
The following requirements apply with respect to the maintenance and cleaning of the meter:

a) If the manufacturer of the meter prescribes a certain form of maintenance for the measurement cell to guarantee good operation, the design shall be such that the parts in question can be made accessible for cleaning without auxiliary means.
b) The cleaning and/or disinfecting means for these parts, prescribed by the manufacturer, shall be available from the retailer.
c) The housing of the meter shall be able to be cleaned with the prescribed products or with household agents.

4.1.3 Protection from "wear and tear"

Protection from "wear and tear" that might typically be encountered in the use environment.

4.1.3.1 Low battery voltage

The examination shall be performed according to 8.3.1. The following requirements are applicable:

a) The meter shall indicate when the battery power is nearly depleted.
b) After this it shall still be possible to perform a minimum of 10 measurements.

4.1.3.2 Durability of labeling

The examination shall be performed according to 8.3.2.
The following requirements are applicable:

a) Labeling on the housing of the meter and in parts made functionally accessible for the user of the meter shall be applied in such a way that they remain firmly attached and fully legible after performance of test 8.8.4.

b) Indications on operating controls, warnings and instructional labels or drawings intended to promote safe use of the meter shall be located at a noticeable and suitable place.
These labels shall be legible at a distance of 50 cm for the user with normal sight.

c) Labels intended for the use mentioned under item b. shall be legibly and indelibly.

4.1.4 Readability of the measured results

4.1.4.1 Information on the display

The examination shall be performed according to 8.4.1. The following requirements are applicable:

a) The meter shall exclusively give the indication "high" or "low" in the case of measurements outside of the specified range.

b) If the reagent system is not placed in/on the meter, or not in the prescribed way, the measurement procedure shall not be possible, or an error indication shall be issued after the measurement procedure has been completed.

c) In general the information needed on the display during the performance of a measurement (timer value, measuring value and error indications) shall have a minimum character height of 10 mm. These characters shall be legible by the user of the meter with normal vision at a distance of 50 cm and at an angle of $15 \pm 5°$.

d) The various types of information on the display shall be distinguishable by variations in location, color, size, shape or message.

e) A minimum dimension of 2.5 mm ± 0.5 mm is applicable for pictograms.

4.1.4.2 User verification of proper system function

The examination shall be performed according to 8.5. The following requirements are applicable:

a) When the meter is put into use, it shall at least be possible to establish whether the segments of the display for metering the value and the code of the reagent system are functioning properly.

b) When the meter is put into use and if the meter shall be adjusted to the quality control material or reagent system, it is necessary to display the code for the reagent system to which the meter is adjusted.

c) If item b. is not fulfilled, the meter shall be able to be performed with the aid of quality control material, without changing the code set for the reagent system.

d) The measured value obtained with the quality control material shall be reported on the quality control material and/or the packaging of the reagent system.

e) It shall be possible to test the meter for reliability in combination with the reagent system.

5 Labeling and documentation

NOTE 2: The applicability of the requirements is depending of the presence of the specified features or settings.

5.1 Blood monitor labels

The labels shall include the information as described in the IVDD.

5.2 User manual for the blood monitoring system

The user manual shall include the information as described in the IVDD.

5.2.1 Detailed information

The examination shall be performed according to 8.6.1.
The following special requirements are applicable as well:

o) Description of the functions of the operating controls.
p) Listing of the various types of information supplied by the meter.
q) Explanation of the method how to replace the battery.
r) The available time, during replacement of the battery, before the stored data is disturbed.
s) Method of cleaning the measurement cell and its immediate environment.
t) Maintenance method and maintenance period (if applicable) for the housing.
u) Proper procedure in the case of a defective or presumed defective meter.

5.2.2 Form of presentation

The user manual shall be presented in a clear and concise manner that is readily understood by lay users. The information shall be easy to read and well organized. The text and the terminology shall be not unnecessarily technical or scientific. Symbols and illustrations shall be used wherever possible.

5.3 Reagent system and control material labels

The labels shall include the information as described in the IVDD.

5.3.1 Information

The examination shall be performed according to 8.7.1.

- Available quality control material and auxiliaries.

6 Meter design and interference aspects

The general design and interference aspects are described in this paragraph.
Additional requirements are described in particular TNO Quality Guidelines.

6.1 Resistance to vibration and shock

The examination shall be performed according to 8.8.1. The following requirements are applicable:

a) After completion of the test, no damage shall be detectable with the naked eye that could have a harmful effect on the safe operation of the meter.

b) The meter shall function properly after completion of the test.

6.2 Resistance to dropping

The examination shall be performed according to 8.8.2. The following requirements are applicable:

a) The meter shall be able to withstand a free fall of 1 meter, with or without the protective casing.

b) After completion of the test, no damage shall be detectable with the naked eye that could have a harmful effect on the safe operation of the meter.

c) The meter shall function properly after completion of the test.

6.3 Strength of the housing

The examination shall be performed according to 8.8.3. The following requirements are applicable:

a) The strength of the housing of the meter shall be able to withstand a force of 45 N.

b) The strength of the housing, or any part of the housing, except the display (LCD unit), shall be able to withstand impact with energy of 0.5 J.

c) After completion of the test, no damage shall be visible to the naked eye that could adversely affect the safe operation of the meter.

d) The meter shall function properly after completion of the test.

6.4 Resistance to climatic effects

The examination shall be performed according to 8.8.4. The following requirements are applicable:

a) After completion of the test, no damage shall be visible to the naked eye that could adversely affect the safe operation of the meter.

b) Stickers or text shall not come off or become illegible.

c) The meter shall be able to function properly after completion of the test.

6.5 Electromagnetic compatibility (EMC)

6.5.1 Electrostatic discharge

The examination shall be performed according to 8.9.1. The following requirements are applicable:

a) The meter with connected communication cable (if applicable) shall be tested with electrostatic discharges up to a maximum of 15 kV. The meter shall not exhibit permanently visible defects after each level of the required electrostatic discharges.

b) The electrostatic discharges shall not have a harmful effect on the performance of the meter (e.g. stored data, settings or indications) and the safe operation of meter.

6.5.2 Radiated radio frequency (RF) fields

The examination shall be performed according to 8.9.2. The following requirements are applicable:

a) The meter with connected communication cable and PC (if applicable) shall not exhibit erroneous indications during the radio frequency sweep.

b) After the application of the radio frequency sweep, the stored data of the meter shall not be changed as result of the application of the test. The radiated fields shall not have a harmful effect on the safe operation of the meter.

6.6 Protection against electric shock and patient leakage current

The applicable European electrical safety standards are valid.

7 Technical performance evaluation

The imprecision and accuracy requirements of the in-vitro blood measuring system are described in particular TNO Quality Guidelines.

8 Test methods

The general test methods are described in this paragraph.

Additional test methods are described in particular TNO Quality Guidelines.

Unless otherwise stated in the measurement procedures described, the following applies:

- All measurements shall be carried out under standard ambient test conditions according to IEC 68-1, at a temperature of 15 - 35° C and a relative humidity of 25 - 75%.
- Linear measurements shall be determined to an inaccuracy of ± 0.5 mm.
- Control-forces shall be established to an inaccuracy of ± 1 N.
- Unless others specified, all measurements are taken with one meter.
- If the test fails the requirement the test shall be repeated with five new meters. All meters shall meet the requirements. If not, the test failed.

The design and assembly of the product to be tested in the original packaging shall be recorded. Attention is paid to the following:

a. Name of the manufacturer.
b. Name of the supplier.
c. Package description.
d. Photograph of the meter and accessories supplied.
e. Labeling of the meter and accessories:
    - Serial number and/or
    - (Proto) type number
    - Model name and/or number
    - Type.
f. A description of the monitoring system, the meter, its accessories and documentation.
g. Special features of the meter.

8.1 Ease of operation

8.1.1 General

The ease of operation in general shall be examined for compliance with the criteria laid down in 4.1.1.1. The findings shall be noted.

a) Perform measurements with the quality control materials, and compare the results with the specifications. Make note of results.
b) Check the language used on the labeling and documentation for the intended area(s).

8.1.2 Battery

The working of the battery shall be examined for compliance with the criteria laid down in 4.1.1.2. The findings shall be noted.

a) Check the reliability of the battery.
b) Check the way in which the battery is to be replaced.
c) Check the functioning of meter if the battery is positioned incorrectly.
d) Note the information stored in the memory of the meter, and then disconnect the battery. Reconnect the battery within 120 ± 5 s. and compare the data in the memory with the recorded data.
e) Open the battery compartment and check whether the compartment is enclosed in such a way that the internal electronics cannot be reached using a test finger of ≥ 12 mm diameter (degree of protection IP2X; reference IEC 529).

8.1.3 Operating controls

The working of the operation controls shall be examined for compliance with the criteria laid down in 4.1.1.3. The findings shall be noted.

a) The examination is performed by visual inspection.
b) Use quality control materials and reagent systems to perform a measurement while operating the meter with the right hand. Repeat the measurement with the left hand.

c) Determine the dimensions with sliding calipers.

d) Determine the dimensions with sliding calipers.

e) The examination is performed by visual inspection.

f) Determine the dimensions with sliding calipers.

g) The examination is performed by visual inspection.

8.1.4 Handing of reagent systems

The handling of the reagent system shall be examined for compliance with the criteria laid down in 4.1.1.4. The findings shall be noted.

a) The examination is performed by visual inspection. Measure the dimensions using sliding calipers.

b) Place the meter, ready for use on a untreated, undamaged aluminium plate. Using quality control materials and reagent systems, perform a measurement, operating the meter with one hand. Compare the output with the quality control range of the used quality control material.

c) Perform a measurement in duplicate using quality control materials and reagent systems. Then examination whether it is possible to disturb the measurement by pressing buttons located in the immediate vicinity of the controls necessary for performing the measurement.

d) Place the meter on the untreated, undamaged aluminium plates. Perform a measurement in duplicate with the aid of a quality control material from the supplier in question in combination with a reagent system (reference value).

e) The examination is performed by visual inspection.

Again, perform measurements and immediately after the beginning of the measurement cycle of the meter, move it by sliding it over a distance of 10 ± 1 cm or rotating it maximally, if the meter design permits or promotes this. Determine the average error in output that takes place in this way with regard to the value found in the case of item e. Calculate the coefficient of variation.

8.1.5 Operating forces

The operation forces shall be examined for compliance with the criteria laid down in 4.1.1.5. The findings shall be noted.

a) Use a bench for measuring tensile strength/pressure strength in order to measure the force. The speed is 100 mm/min. The reagent system is fitted in a clamp. Determine the maximum force in the direction of motion of the reagent system until it has been fitted completely into the meter. The maximum tensile force is established before the reagent system strikes a possible stop. Carry out this test 10 times and calculate the average force and SD.

b) See measurement as under a).

c) Use a bench for measuring tensile strength/pressure strength in order to measure the force. The speed is 100 mm/min. For de actuation of a *slide with relief*, a hook is placed behind the relief on the slide. For the actuation of a *slide without relief*, a hook is placed on the back of the slide. Determine the maximum force in the direction of movement of the slide until the slide comes loose and moves. The maximum tensile force before the slide encounters a possible (end) stop is measured. Carry out this test 10 times and calculate the average force and SD.

d) Use a bench for measuring tensile strength/pressure strength in order to measure the force. The speed is 100 mm/min.
Set up the meter and determine the maximum force for all the parts in question necessary to carry out the required action.
Carry out this test 10 times and calculate the average force and SD.

f) Use a torque-measuring device in order to measuring the torque. The outline speed is 100 mm/min. Set up the meter and determine the maximum torque for all the parts in question necessary to carry out the required action. Carry out this test 10 times and calculate the average force and SD.

8.1.6 Accuracy of timing

The accuracy of timing shall be examined for compliance with the criteria laid down in 4.1.1.6. The findings shall be noted.

- Perform a duplicate measurement (reference measurement) using quality control materials and reagent systems at the prescribed time points, preferably with a quality control range in the middle of the measurement range.
- Repeat this measurement as often as necessary, each time exceeding the time specified by the manufacturer during the measurement cycle by 5 ± 1 s.
- Repeat the test, but now taking a time 5 ± 1 s. shorter than that prescribed.
- Calculate the total average percentage deviation with respect to the value

obtained in a measurement performed using the prescribed time(s). From this calculate the coefficient of variation.

8.1.7 *Automatic shutoff of the meter*

The automatic shutoff of the meter shall be examined for compliance with the criteria laid down in 4.1.1.7. The findings shall be noted.

a / b) Perform a measurement using quality control materials and reagent systems. Using a chronograph or stopwatch, determine the time from the instant when the measured value is displayed until the time when the meter switches itself off. Calculate the average of five runs.

c) The examination takes place by visual inspection.

8.1.8 *Auditory signal*

The auditory signal shall be examined for compliance with the criteria laid down in 4.1.1.8. The findings shall be noted.

- A-weighted sound pressure level measured as described in ISO 3744. In an anechoic room (a room with a low background noise, without reflecting walls) determine the power per octave band of the auditory signal of the meter in dBA at a distance of 50 ± 2 cm.
- Note the highest value and the octave band at which this was measured.

If no anechoic room is available, a method as suggested in ISO 3743 can be followed. In this case, requirements are imposed on the source room with regard to the delay time and the volume.

8.1.9 *Memory and data storage*

The memory and data storage shall be examined for compliance with the criteria laid down in 4.1.1.9. The findings shall be noted.

- The examination of point a) to g) takes place by measuring and visual inspection.

- When data can be stored to a PC, install the required software and hardware as specified by the manufacture. Take, depend of the possibility of the software, one or more meters, filled with data, and store it to a PC. Control the presence of all data and meters in the software used.

8.2 Ease of maintenance

The ease of maintenance shall be examined for compliance with the criteria laid down in 4.1.2. The findings shall be noted.

a) Determine and note the way in which the measurement cell and its immediate environment are to be maintained.
b) Check the general availability of the prescribed products.
c) Note the prescribed means and determine whether or not these fulfil the requirements.

8.3 Protection from "wear and tear"

8.3.1 Low battery voltage

The low battery voltage shall be examined for compliance with the criteria laid down in 4.1.3.1. The findings shall be noted.

- With the aid of quality control materials and reagent systems perform a measurement in duplicate (reference values), preferably with a quality control range in the middle of the measurement range.

a) Using an external battery simulator, decrease the supply voltage to a level at which the meter indicates that the battery shall be replaced. Note this voltage level.
b) Using quality control materials and reagent systems and perform 10 measurements and determine the average percentage deviation with respect to the average reference value. Calculate the coefficient of variation.

8.3.2 Durability of labeling

The durability of labeling shall be examined for compliance with the criteria laid down in 4.1.3.2. The findings shall be noted.

a) After completion of test 8.8.4, determine the permanence of fastening of the labels. Check whether self-adhesive stickers have been used for labels intended to promote safe use of the meter.
b) Evaluate the position of the labels and the letter height used. Test the legibility at a distance of 50 ± 5 cm and an illumination of 215 ± 20 Lux.
c) The examination is performed by visual inspection.

8.4 Readability of the measured results

8.4.1 Information on the display

The information on the display shall be examined for compliance with the criteria laid down in 4.1.4.1. The findings shall be noted.

a) Using quality control material and reagent systems, check whether the meter fulfils the requirements imposed.
b) Using quality control materials and reagent systems, check whether the meter fulfils the requirements imposed. If a measured value is displayed despite the improper procedure, the deviation from the expected measured value shall be calculated.
c) Determine the character height using sliding callipers and check the legibility at a distance of 50 cm ± 5 cm and at an angle of 15 ± 5°.
d) Note the way in which the various types of information are distinguished from one another.
e) Determine the size of the pictograms with the help of a sliding calliper.

8.5 User verification of the proper system function

The user verification of proper system function shall be examined for compliance with the criteria laid down in 4.1.5. The findings shall be noted.

a) The examination is performed by visual inspection.

b) The examination is performed by visual inspection.

c) Perform the checking procedure, and depending on the results of the test under b, check whether the meter fulfils the requirements.

d) The examination is performed by visual inspection.

e) The examination is performed by visual inspection.

8.6 User manual for the blood monitor system

8.6.1 Detailed information

The detailed information shall be examined for compliance with the criteria laid down in 5.2.1. The findings shall be noted.

8.7 Reagent and control material labels

8.7.1 Information

The information shall be examined for compliance with the criteria laid down in 5.3.1. The findings shall be noted. The examination is performed by visual inspection.

8.8 Meter design and interference aspects

8.8.1 Vibration resistance and shock

The vibration and shock resistance shall be examined for compliance with the criteria laid down in 6.1. The findings shall be noted.

- Using quality control material, perform a measurement in the middle of the measurement range of the meter in duplicate. Likewise check the correct operation of the segments in the display.
- Fix the meter on the vibration and shock unit, including and/or excluding the protective casing or pouch, depending on whether or not the manufacturer of the meter states that this packaging shall be removed from the meter while

measuring the values. Make sure that the protective casing or pouch is closed in the normal way when fixing the meter on the vibration unit.

- Vibrate and shock the meter in accordance with 8.8.1.1 and 8.8.1.2.
- The examination is performed by visual inspection.
- Using the same quality control material, perform a measurement in duplicate and compare the average value with the average value previously obtained in the test. Calculate the coefficient of variation.
- Likewise check the correct operation of the segments in the display.

8.8.1.1 Vibration test

Subject the meter to vibration in according to IEC 68-2-64, test Fh: "Vibration, broad band random (digital control) and guidance".

Subject the meter to the conditions specified in IEC 721-3-7 Class 7M3 as follow:
Acceleration spectral density 3 m^2/s^3, frequency range 10 – 200 Hz.
Acceleration spectral density 1 m^2/s^3, frequency range 200 – 500 Hz.
Vibrate the meter in a vertical direction and in two other directions perpendicular to one other in a horizontal plane.
The vibration time shall be 1 hour in each direction.

NOTE: Meters with limited conditions for vibration shall be subjected to the test at the acceptable conditions, and these acceptable conditions shall be stated in the instructions for use.

8.8.1.2 Shock test

Subject the meter after each vibration test to the shock tests in accordance with IEC 68-2-27 "Test Ea and guidance: Shock".

Subject the meter to the conditions specified in IEC 721-3-7 Class 7M3 as follow:

- To a shock response spectrum Type I: 300 m/s^2 and
- To a shock response spectrum Type II: 1000 m/s^2.
- The number of shocks shall be 50 positive and 50 negative.

NOTE: For intensive transportation of equipment over heavy surfaces, the Type I shock test shall be over a number of 100 positive and 100 negative.

8.8.2 Resistance to dropping

The resistance to dropping shall be examined for compliance with the criteria laid down in 6.2. The findings shall be noted.

a. With the aid of quality control material, perform a duplicate measurement in the middle of the measurement range of the meter. Likewise check the correct operation of the segments in the display.

b. Place the meter in its protective casing or pouch.

c. The meter shall be tested according to the conditions as specified in IEC 721-3-7 Class 7M3:

Fall height 1.0 m for products with a mass less than 1 kg.

Fall height 0.5 m for products with a mass more than 1 kg but less than 10 kg.

Fall height 0.25 m for products with a mass more than 10 kg.

The meter undergo one fall from three different starting positions onto a smooth hard, rigid test surface of steel of 3 mm thickness backed by wood of between 10 mm and 19 mm thickness.

e. The examination is performed by visual inspection. Likewise check the correct operation of the segments in the display.

f. If the test is withstood well, the test shall be repeated without the protective casing or pouch.

g. Using the same quality control material, perform a measurement in duplicate and compare the average value with the average value previously obtained in the test.

8.8.3 Strength of the housing

The strength of the housing shall be examined for compliance with the criteria laid down in 6.3. The findings shall be noted.

a. Using quality control material, perform a measurement in duplicate in the middle of the measurement range of the meter. Also check the correct operation of the segments in the display.

b. Place a weight of 4.5 kg distributed over a surface area of 625 mm^2, at various points on the housing of the meter.

c. Test the impact resistance of the housing of the meter (excluding knobs, display, etc. in so far as these components do not contribute to the instrument's strength). (Appendix G of IEC 601-1).

d. The examination is performed by visual inspection.

e. Using quality control material, perform a measurement in duplicate. Likewise check the correct operation of the segments in the display.

8.8.4 Resistance to climatic effects

The resistance to climatic effects shall be examined for compliance with the criteria laid down in 6.4. The findings shall be noted.

- Supply a freshly checked, prescribed battery in the meter.
- Stabilize the climate in the cabinet at 25 ± 2°C and 60 ± 15% relative humidity.
- Using quality control material, perform a measurement in duplicate preferably in the middle of the measuring range outside the climatic cabinet, using two meters (reference values). If possible, store these values in the memory of the meter.
- Place one meter without and one with its protective casing or pouch in the centre of the climatic cabinet and allow this apparatus to acclimatize for 24 hr. Switch the meters "off"!

d. Increase the relative humidity in the climatic cabinet to 95-100% for a maximum of 1 hr.

e. Start the 24 hour cycle according to IEC 68-2-30, variant 1. Select the highest value (55 ± 2° C) as the top temperature, and allow the test to continue for 6 cycles.

- End the test by decreasing the RH in the climatic cabinet within a period of half an hour to 75 ± 2% at a temperature of 25 ± 2°C.
- Remove the meters from the climatic cabinet, and allow them to acclimatize for 2 hr at an ambient temperature of 10-40°C and an RH of 30-75%.

a. The examination is performed by visual inspection. In this process, also pay attention to the labels in so far as these contribute to the safe operation of the meter.

b. The examination is performed by visual inspection.

c. Using the same quality control material, perform a measurement in duplicate.

8.9 Electromagnetic compatibility (EMC)

The electromagnetic compatibility shall be examined for compliance with the criteria laid down in 6.5. The findings shall be noted.
If the meter can be stored data to a PC, the meter shall be with a communication cable supplied by the manufacturer and connected as specified by the manufacturer.

NOTE – The tests specified in 8.9.1 and 8.9.2 are based on the requirements given in the collateral standard IEC 60601-1-2 (2001-09), 2nd Edition. In this standard, EMC references are given to the IEC 61000-4-1 (IEC 61000-4-2, Edition 1.1 (1999) and IEC 61000-4-3, Edition 1.1 (1998) in particular). The span of the sweep in this guideline covers all the frequencies of mobile communication systems.

The requirements given in 6.5.1 and 6.5.2 are requirements substituting those specified in IEC 60601-1-2 as the latter standard covers requirements for electro-medical appliances in general only, and it does not address specific devices such as meters.

8.9.1 Electrostatic discharges

With the aid of quality control material perform a measurement in duplicate in the center of the measurement range of the meter. Likewise check the proper action of the segments in the display.

Switch the meter on and start the meter measurement cycle using quality control material. Present the discharges during this measurement cycle and the following time period in which the meter displays the measured value. If the measurement cycle is too brief to permit performance of this examination, the measurement cycle shall be restarted as often as necessary.

The meter is placed on a metal reference plane as specified in IEC 61000-4-2, Edition 1.1 (1999). This plane is provided with an insulating layer to prevent discharges to the plane. Contact discharges of ±2, ±4 and ±8 kV shall be applied to conductive accessible parts and coupling planes. Air discharges of ±8, ±10, ± 13 and ±15 kV shall be applied to non-conductive accessible parts. The number of discharges at each level

and polarity shall be 10 with a time interval of minimally 1 s between the individual discharges. Charge retention between individual test discharges is crucial (see 601-1-2). Air ionizers are best suited for this purpose.

Using the same quality control material, perform a measurement in duplicate after finishing the whole test.
Also check the correct operation of the segments in the display, the memory as well as the code number, and check both the auditory and visual signals for proper operation.

8.9.2 *Radiated fields (RF)*

The test shall be performed in accordance with IEC 61000-4-3, and TEM cells or GTEM cells may be used as described in Annex D. As stated in IEC 61000-4-3, the requirement for field uniformity shall be fulfilled in the area corresponding to the unit under test.

Using quality control material in duplicate, perform a measurement in the middle of the measurement range of the meter. Likewise check the correct operation of the segments in the display.

The test level shall be 10 V/m (amplitude of the unmodulated carrier) at 80 MHz – 2.5 GHz (see IEC 6061-1-2). The test signal shall be AM modulated with 1 kHz sinusoidal and to a modulation depth of 80 %. The test shall be carried out according to the existing standard and performed in each of the three axes of the meter (minimum).

Switch the meter on and start the meter measurement cycle using quality control material. Alter the test signals during this measurement cycle and the subsequent period in which the meter displays the measured value. If this time is too short to permit performance of this examination, the measurement cycle shall be restarted as often as necessary.

Using the same quality control material, perform a measurement in duplicate after finishing the whole test.

Also check the correct operation of segments in the display, the memory as well as the code number, and check both the auditory and visual signals for proper operation.