# Physikalisch-Technische Bundesanstalt

Medical metrology

# Guidelines for metrological verifications of medical devices with a measuring function (Edition 3.0)

## Part 1

Medical devices for the determination of auditory ability (tone and speech audiometers)

Medical devices for the determination of body temperatures
(with the exception of clinical mercury-in-glass, maximum- reading thermometers)

Measuring instruments for non-invasive blood pressure measurement

Medical devices for the determination of intraocular pressure (ocular tonometers)

Foot crank ergometers used to induce defined physical and reproducible physical stress in patients

Stephan Mieke and Thomas Schade (eds.)

## Preamble

These guidelines are the translation of the German „Leitfaden zu messtechnischen Kontrollen von Medizinprodukten mit Messfunktion (LMKM)“. The document describes the correct metrological verification of several medical devices with a measuring function. The present translation has no other purpose than to inform about the requirements in Germany and may serve as a technical resource for interested parties in the field. While in Germany, the original document has a certain legal relevance, the translation has no legal status, neither inside nor outside Germany.

## Explanatory notes

With the Ordinance on the installation, operation and use of medical devices (Medical Devices Operator Ordinance; MPBetreibV) entering into force on 7 July 1998, the group of persons authorised to verify medical devices (medical devices with a measuring function) was extended compared to the provisions of the Verification Ordinance applying until then. To maintain uniform requirements and quality standards regarding the practical implementation of the metrological verifications, PTB's Advisory Board for Medical Metrology, which includes representatives from industry, the scientific community, users and public authorities, decided that PTB's specialised laboratories would, in cooperation with the verification authorities, elaborate a guide for metrological verifications.
The product of this cooperation project, which was coordinated by Dr. S. Mieke (PTB) and T. Schade (from the Bavarian Office for Weights and Measures), entitled

**Guidelines for metrological verifications of medical devices with a measuring function,**

has been amended, **and its 3rd edition is now available.**

For practical reasons, these guidelines have been divided into two parts. Part 2 describes the metrological verification of therapy dosimeters and dosimeters for radiodiagnostics; part 1 addresses all the other measuring instruments listed in Annex 2 of the Medical Devices Operator Ordinance (MPBetreibV).

Following the decision of the General Assembly on Verification on the 23rd of November 1998, this guidelines were published and can be accessed and downloaded at:

http://www.ptb.de/cms/presseaktuelles/wissenschaftlich-technische-publikationen/publikationen-zum-medizinproduktegesetz.html.
The second ordinance revising the provisions applying to medical devices dated 27 September 2016, in section 14, paragraph 1, clause 3 of the Medical Devices Operator Ordinance (MPBetreibV) regulates that the currently valid version of the guidelines is to be made available and maintained on the website of the Physikalisch-Technische Bundesanstalt (PTB).

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**Guidelines for metrological verifications**
**of medical devices with a measuring function**

(Requirements for institutions, persons, measuring and testing facilities
as well as for the contents and scope of the verification procedures for medical devices
according to Annex 2 of the Medical Devices Operator Ordinance)

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## Foreword

The Council Directive 93/42/EEC concerning medical devices was transposed at the national level with the adoption of the Medical Devices Act on the 2nd of August 1994. Thus, German legislation does not prevent placing medical devices on the market and putting them into operation if they bear the CE marking confirming that these products have been subjected to a conformity assessment procedure in accordance with the above-mentioned Directive.

By affixing the CE marking, the manufacturer declares that such labelled products comply with all relevant provisions of the Directive concerning medical devices.

The general terms of the Directive concerning medical devices stipulate the manufacturer's duty of indicating on a case-by-case basis the type and frequency of maintenance measures and calibrations to ensure that the devices operate properly and safely at all times. The information provided is the manufacturer's responsibility and usually applies to medical devices of the same type.

In the case of medical devices for which measurement reliability is of particular significance, the relevant EU member state is obliged to ensure that these products will also meet the applicable requirements over their entire utilisation period after they have been put into operation. This is the reason why, in Germany, the legislator prescribes metrological verifications at regular intervals for certain medical devices with a measuring function as per the Medical Devices Operator Ordinance dated 29 June 1998, promulgated on 21 August 2002 (Federal Law Gazette I, p. 3396), last revised by the second ordinance amending the provisions relating to the legal aspects of medical devices dated 27 September 2016 (Federal Law Gazette I, p. 2203). The compliance with maximum permissible errors is checked by competent persons by means of suitable and traceable test equipment. The metrological verifications are carried out in the form of tests for each individual medical device and shall be independent of external interference (e.g. from manufacturers or operators). Persons in charge of the verifications shall notify the competent authorities before starting their activities; at the authorities' request, they shall provide the proof that the requirements have been met. This also includes the availability of the documents required for the proper execution of the metrological verification.

To ensure the uniform implementation of the regulations on metrological verifications of medical devices with a measuring function according to the provisions of the Medical Devices Operator Ordinance throughout Germany, the use of the following guidelines is recommended to the competent authorities and all other persons carrying out such verifications.

Pursuant to section 14, paragraph 1, clause 1 of the Medical Devices Operator Ordinance, the metrological verifications shall be deemed to have been performed correctly if the guidelines have been taken into account. In its 3rd version, that is currently available, the guidelines were elaborated by the editors after consultations with the relevant parties.

Pursuant to section 14, paragraph 2 of the Medical Devices Operator Ordinance, the verifications are conducted to determine if the medical device complies with the maximum permissible errors (MPEs). Furthermore, the guidelines also list suitable requirements and measures to ensure compliance with these MPEs. These may require additional tests and place additional specifications on the properties and the availability of necessary documents such as instructions for use.

These guidelines do not affect the current regulations in the fields of safety technology and radiation protection. Property rights of any kind are not covered by the guidelines.

## A General legal requirements placed on medical devices

### Requirements to be met by persons

Section 14 of the Medical Devices Operator Ordinance (MPBetreibV) [1] contains the following requirements to be met by persons conducting the verifications:

*Section 14, paragraph 5: The operator may entrust only the following persons with metrological verifications:*

*1. authorities responsible for metrology, or*

*2. persons, companies or institutions that fulfil (themselves or through their employees) the prerequisites mentioned in section 5 with regard to the metrological verifications of the individual medical devices.*

*Section 5 (Specific requirements): If the present ordinance demands specific requirements for a given task, this task may only be performed by persons who:*

*1. have up-to-date skills with regard to the task required based on appropriate training and relevant professional activities;*

*2. in terms of technical expertise, are independent from external interference from directly involved or third parties;*

*3. have the means, in particular capacities, instruments and other work equipment such as appropriate measurement and test equipment, that are necessary in order to properly and traceably carry out the respective task.*

The proof that a person can guarantee the proper execution of the metrological verification according to section 5, No. 1 of the Medical Devices Operator Ordinance (MPBetreibV) can, for example, be provided by:
- practical experience of a minimum of one year in the field of metrological verification of such medical devices on which the metrological verifications are to be performed,
- completed professional training in the relevant field,
- training conducted by the manufacturer on the medical devices to which metrological verifications are to be performed.

*Section 14, paragraph 6: Persons intending to conduct metrological verifications in the future, must notify the competent authority prior to conducting the first metrological verification and, upon request of the competent authority, deliver the proof that they meet the requirements according to section 5.*

### Requirements placed on measurement and test equipment

Section 14 of the Medical Devices Operator Ordinance (MPBetreibV) contains the following requirements with regard to the metrological standards that are used for metrological verifications:

*Section 14, paragraph 3: Unless otherwise stated in Annex 2, only metrological standards are to be used for metrological verifications that are traceable to a national or international standard and that comply with sufficiently small maximum permissible errors and measurement uncertainties. The maximum permissible errors and measurement uncertainties shall be regarded as sufficiently small if they comply with the requirements in paragraph 1, clause 2 of said guidelines or if they do not exceed one third of the maximum permissible errors and measurement uncertainties of the medical device to be verified.*

The metrological standards used for verifications must be metrologically traced on an annual basis. The metrological standards referenced here are working standards as defined in legal metrology, i.e. those standards that are directly employed for metrological verification. The general reverification deadline of one year corresponds to that in legal metrology. Exceptions

to this rule are listed in Annex 1 of these guidelines. The traceability can be proven by a calibration certificate that is issued by a DAkkS-certified calibration laboratory that is accredited for the relevant measurand, by a verification authority or by PTB. Calibrations that are recognized by PTB or DAkkS due to bilateral or multi-lateral agreements (e.g. within the scope of the European Cooperation for Accreditation (EA)) are equivalent to this calibration.

The traceability of metrological standards can also be established by a calibration that does not fulfil the aforementioned requirements. In this case, however, the metrological standard must be traceable as described above and the traceability must be clearly defined in the quality management handbook of the party performing the traceability check. The regulations must comply with those in the DAkkS Instruction Sheet 71 SD 0 005 (http://www.dakks.de/doc_allgemein) for the metrological traceability as amended.

Measuring and testing devices complying with the requirements listed in Part B of these guidelines, are considered as suitable in principle when they are metrologically traced as described. This does not exclude the possibility that also other measuring devices may be suitable, e.g. measuring and testing devices recommended by the manufacturers of the medical products to be tested. The suitability of the measurement and test equipment, however, must be verified according to section 5 of MPBetreibV in conjunction with section 14, paragraph 6 of MPBetreibV upon request by the competent authority.

**Maximum permissible errors to be complied with**

Section 14 of the Medical Devices Operator Ordinance (MPBetreibV) contains the following specifications with regard to the maximum permissible errors to be complied with:
*Section 14, paragraph 2: The metrological verifications are a means to determine if the medical product complies with the maximum permissible deviations (error limits) indicated in the guidelines according to paragraph 1, clause 2.*

According to Annex I, No. 10.1, clause 2 of the European Council Directive 93/42/EEC concerning medical devices, "the accuracy limits selected by the manufacturer" must be specified for medical products that are placed on the market in the Federal Republic of Germany according to the regulations of the Medical Devices Act (MPG) [2] or according to a comparable law that implements Directive 93/42/EEC in a member country of the EU. If these limits deviate from the specifications in these guidelines, and if a metrological verification is conducted on this basis, the presumption of conformity does not apply pursuant to section 14, paragraph 1, clause 2 of MPBetreibV, and the party that carried out the metrological verification must, if applicable, justify the reasons for this deviation to the competent authorities.

If the manufacturer has, in addition, also provided specifications or requirements (test procedures) for the performance of metrological verifications, it must be borne in mind that the requirements for the performance of metrological verifications are contained in section 14, paragraph 1 of the Medical Devices Operator Ordinance (MPBetreibV). According to these requirements, the metrological verifications must be conducted based on the recognised state-of-the-art.

**The outcome of the metrological verification**

Section 14 of the Medical Devices Operator Ordinance (MPBetreibV) places the following requirements on the documentation of the results of the metrological examination:

*Section 14, paragraph 7 No. 1: Those conducting the metrological verifications must 1. draw up a protocol on the metrological verification containing the date of the execution*

*and the results of the metrological verification including the measurement values determined, the measurement procedure and other evaluation results. [ … ]*

*Pursuant to clause 1, the protocol must be kept by the operator at least until the next metrological verification.*

**The marking of the metrological verification**

Section 14 of MPBetreibV contains the following specifications with regard to the marking after the metrological verification has been successfully completed:

*Section 14, paragraph 7, No. 2: Those conducting the metrological verifications must [ … ] attach a marking to the medical device after the metrological verification has been successfully completed; this marking must state in a clearly identifiable and traceable way the year of the next metrological verification and the authority or person that has conducted the metrological verification.*

The marking may also include the month if this is supported by the organization conducting the metrological examination. This type of marking must, however, not lead to ambiguities regarding the identification of the year. In addition to the month, the marking must clearly state the year of the next metrological verification. The deadline for the next verification is, in this case, determined by the month specified on the marking. The identity of the person (a natural or a legal person) who conducted the metrological verification shall likewise be shown in a clear way.

Markings of previously conducted metrological verifications shall be removed.

As a general rule, the marking should be indelibly affixed to the medical device. The removal of the marking should only be possible by using mechanical tools and by destroying the marking.

Section 14 of MPBetreibV does not regulate the protection of a metrologically verified medical device against tampering that might have negative effects on the metrological properties.

It is acceptable to attach security seals or similar seals to the devices – especially in the case of devices that were presented without any protection or similar security seals – if such seals will prevent misadjustments or modifications of metrologically important properties. If security seals are provided by the manufacturer, such seals must be affixed or renewed.

Legal ramifications will not ensue when security seals are missing or have been destroyed.

**Devices requiring metrological verification**

Section 14 of MPBetreibV contains the following statements:
*Section 14, paragraph 1, clause 1: For the medical devices specified in Annex 2, the operator shall conduct directly or by way of delegation metrological verifications in accordance with the generally accepted state-of-the-art pursuant to paragraph 4 of the aforementioned Annex 2.*
With the changes introduced in 2007, the Medical Devices Act (MPG) has extended the field of application of the metrological verification regulations:

*Section 2, paragraph 2: This Act shall also apply to the use, operation and maintenance of devices that have not been placed on the market as medical devices but are used with the intended purpose of a medical device within the sense of Annexes 1 and 2 of the Medical Devices Operator Ordinance. These are deemed to be medical devices within the sense of this Act.*

This affects, for example, the foot crank ergometers that were placed on the market as non-medical devices ("training devices") but are employed in the field of medical science for diagnosing and for therapy purposes.

**References**


[1] Medical Devices Operator Ordinance (*Medizinprodukte-Betreiberverordnung*) as promulgated on 21 August 2002 (Federal Law Gazette I, p. 3396), last revised by article 1 of the Ordinance of 27 September 2016 (Federal Law Gazette I p. 2203)

[2] Medical Devices Act (*Medizinproduktegesetz, MPG*) in the version as promulgated on 7 August 2002 (Federal Law Gazette I p. 3146), last revised by article 2 of the law of 18 July 2016 (Federal Law Gazette I p. 1666)

# B Additional requirements placed on special devices

## 1 Medical devices for the determination of hearing ability (tone and speech audiometers)

### 1.1 Requirements placed on facilities

Ambient temperature: 18 °C to 30 °C

Quiet measurement chamber for subjective testing of the audiometer at the test location.

### 1.2 Requirements placed on measurement and test equipment

The most important pieces of testing equipment to be provided for a metrological verification are listed below. This list is not exhaustive:

- Sound calibrator of at least Class 1 according to IEC 60942 [1] (according to IEC 942 [2] for existing devices) with a calibration certificate or test certificate of a national metrology institute (NMI), a verification authority or of the DAkkS;
- Acoustic coupler according to IEC 60318-3 [3] with 1-inch microphone, both with a calibration certificate or a test report issued by PTB or by the DKD (due to the metrological preconditions);
  and/or
- Ear simulator according to IEC 60318-1 [4] with 1/2-inch microphone, both with a calibration certificate issued by PTB or by the DKD (due to the metrological preconditions);
- Mechanical coupler (artificial mastoid) according to DIN EN 60318-6 [5] with a calibration certificate or issued by PTB or by the DKD (measurement of the mechanical impedance and the force sensitivity level with a measurement uncertainty of 0,4 dB; specification of the force sensitivity level at all audiometric frequencies between 125 Hz and 8000 Hz according to IEC 60645-1 [6] with a resolution of 0,1 dB);
- Sound level meter with a frequency weighting "Z" and free-field microphone, tested in frequency response, scale division, range switching and pulse according to the specifications of Class 1 according to IEC 61672-1 [7] (with "Lin" frequency weighting for existing devices according to IEC 60651 [8]) with a calibration or test certificate;
- For pure tone audiometers: the sound level meter additionally calibrated in voltage units for bone-conduction measurements;
- Heat-cooling box with a temperature constancy of (23 ± 1) °C, including surface sensor (contact thermometer);
- Suitable reference recordings of the speech material (only for the relevant devices);
- Frequency meters;
- Harmonic distortion meter; minimum resolution 0.1 %;
- Measuring equipment for application force;
- Third-octave filters.

The standards used for the metrological verification according to Annex 1 Table 1, must be calibrated with a calibration certificate in the German or in the English language issued by a national metrology institute or a verification authority or by the DKD, if applicable. This calibration certificate shall have a validity period of at least 3 years from the date of its issue. For the reverification intervals for the above-listed devices and equipment, please refer to Annex 1.

## 1.3 Content and scope of the metrological verification

### 1.3.1 Metrological verification of pure-tone audiometers

The following tests must be performed on pure-tone audiometers:

a) All controls must be checked for free movement; it must be checked whether they are bent out of shape or overtorqued.
b) Plugs, AC power cords and accessory cables must be inspected for signs of ageing and damage (only visual inspection).
c) The sealing cushions of the headphones must be checked for cracks, fractures and other signs of ageing and be replaced, if necessary.
d) At low hearing levels, the signals must be monitored for background noises and for unwanted sound radiation (crosstalk when monitoring a signal on the other channel or a change in sound quality when turning on the masking noise). It must be checked that the level controls to be adjusted are not generating mechanical or electrical background noises while the test tone is presented. It must be ensured that the sound switch operates at a low sound level and that no sound emitted by the audiometer can be heard at the test person's place.
e) The test signals are to be monitored at higher levels (e.g. at a hearing level of 60 dB via air conduction and at a hearing level of 40 dB via bone conduction) in all relevant settings (for all headphones) and at all frequencies; care must be taken to ensure the proper functioning, a sufficiently low distortion and the absence of sound switch noises.
f) It must be checked whether the test person response system is working properly.
g) In the case of automatically recording audiometers with mechanical function, the recording stylus and the mechanical function of limit switches and frequency changeover switches must be inspected. It must be ensured that no interfering noise emitted by the device can be heard at the test person's place.

The following additional tests must be carried out in accordance with IEC 60645-1 [6] and the procedure must be confirmed in a protocol. The applicable sections of this standard are indicated in brackets. At least the measurement values at the frequency of 1000 Hz must be recorded.

h) The application forces of the headbands for the headphones (e.g. section 9.1.1, letter h) and for the bone-conduction vibrator (section 9.2.2) have to be tested. It is necessary to ensure that the rotational joints can be freely moved without being too loose.
i) Frequency accuracy (section 6.1.2);
j) Total harmonic distortion (section 6.1.3);
k) Accuracy of sound pressure and force level for one audio level setting each (section 7.3, paragraph 1);
l) Accuracy of the masking noise levels for any setting of the hearing level (section 7.5.3, clause 1).

For pure-tone audiometers without type approval that were already in use or were kept ready for use before 1 January 1992, section 7.5.3 "Accuracy of the masking noise levels" from IEC 60645-1 [6] can be omitted when the metrological verifications are conducted; however, section 9 "Transducer" of this standard shall additionally apply.

The metrological verification services must inform the users that a device shall be inspected subjectively once per week (according to letters a) to g), supplemented by a full audiogram on an otologically normal person). When the audiometer is infrequently used, the interval between two device inspections may be longer. The metrological verification services must

provide suitable checklists for these inspections. If deficiencies are observed during such subjective device controls, a repair service must be notified without delay.

### 1.3.2 Maximum permissible errors for pure-tone audiometers in the case of missing manufacturer's specifications

The maximum permissible errors specified in the standard IEC 60645-1 [6] and/or -4 [9] shall apply to pure-tone audiometers.

The maximum permissible errors specified in DIN 45620 "Audiometer terminology, requirements, testing" (1985 edition ) [10] shall apply to pure-tone audiometers built in accordance with this standard.

For pure-tone audiometers that were already in use or were kept ready for use before 1 January 1992, the maximum permissible errors shall be 1.25 times larger than those according to DIN 45620 [10].

### 1.3.3 Metrological verifications on speech audiometers

The following tests have to be carried out on speech audiometers:

a) All controls must be checked for free movement; it must be checked whether they are bent out of shape or overtorqued.
b) Plugs, AC power cords and accessory cables must be examined for signs of ageing and damage.
c) The sealing cushions of the headphones must be examined for cracks, fractures and signs of ageing and be replaced, if necessary.
d) It must be checked whether the level indicator is set to the reference value.
e) The signals (speech signals and masking noises) must be monitored for all acoustic transducers at low audio levels for background noises (e.g. inherent noises of the playback device for the sound carrier or humming noises) and for unwanted sound radiation (crosstalk, if a signal is monitored on the other channel, or changes in a sound quality when the masking noise is turned on). It must be checked whether the level controls are attenuating the voice signals and the masking noise over the entire dynamic range.
f) The speech signals are to be monitored at higher levels (e.g. at a speech sound level of 50 dB via air conduction and a speech sound level of 30 dB via bone conduction) in all settings that come into question (for both earphones and using the loudspeaker), ensuring their proper functioning and a sufficiently low distortion.
   In the case of speech audiometers using a vinyl disc, magnetic tape or a magnetic tape cassette as the recording medium, the wear and tear of the recording medium must be checked by comparison with a sound carrier in mint condition.
g) It must be checked whether the test signals and the answers of the test persons can be heard correctly at the audiometrist's place.

The following additional tests must be carried out in accordance with IEC 60645-2 [11]. The applicable sections of this standard, if any, are indicated in brackets. At least the measurement values according to i) and j) have to be recorded.

h) The application forces of the headbands for the headphones and for the bone-conduction vibrator. It must be ensured that the rotational joints are free to move without being particularly loose.
i) Over-all frequency response of the speech audiometer (section 10.1 of IEC 60645-2 [11]; if the audiometer was built in accordance with DIN 45624 [12]: section 5.1.1), except for the devices mentioned under clause 1.3.7.

*Note:* The reference curves for the German language speech test according to DIN 45626-1 [13] and for other German language speech tests apply only to free-field equalized audiometers. Speech audiometers without free-field equalization filters (including those according to IEC 60645-2 [11]) are therefore not unsuitable and may not be further used[2].

j) Output sound pressure level (section 9)
*Note:* When measuring the speech sound level during playback via loudspeakers, it must be ensured that the distance and the radiation angle of the loudspeaker relative to the test person's place correspond to the specifications in the instructions for use.

k) Level of masking noise (section 13.2)

The metrological verification services must inform the users of the devices that a subjective inspection of the devices must be carried out once per week (in accordance with letters a) to g)). If the audiometer is infrequently used, the interval between two device inspections may be longer. Suitable checklists must be provided for these inspections by the metrological verification services. If deficiencies are found during such subjective device inspections, a repair service must be notified without delay.

### 1.3.4 Maximum permissible errors for speech audiometers in the case of missing manufacturer's specifications

The maximum permissible errors specified in the standard IEC 60645-2 [11] shall apply to speech audiometers.

For speech audiometers that were still built according to DIN 45624 [12], the maximum permissible errors specified therein shall apply.

For such speech audiometers that were already in use or were kept ready for use before 1 January 1992, the maximum permissible errors are 1,25 times the maximum permissible errors according to DIN 45624.

### 1.3.5 Safety measures for pure-tone and speech audiometers

Damaged protective seals required by the manufacturer or by the PTB type approval, must be replaced. It is acceptable to attach security seals or similar seals to the devices – especially in the case of devices that were presented without any protection or similar security seals – if such seals will prevent misadjustments or modifications of metrologically important properties.

### 1.3.6 Audiometers placed on the market before 14 June 1998 which were not used for medical purposes but were type-examined and accepted by PTB

Audiometers placed on the market before 14 June 1998 which were not used for medical purposes (e.g. by hearing device acousticians) but were type-examined and accepted by PTB, must be metrologically verified in the same way as conformity-assessed audiometers in accordance with section 14, paragraph 3 of the Medical Devices Operator Ordinance (MPBetreibV).

[2] The free-field equalizer can also be realized by pre-distorted speech material, that is documented for a certain type of headphones in the instructions for use for the audiometer. In these cases, no separate free-field equalization filter is required in the audiometer.

### 1.3.7 Audiometers placed on the market before 14 June 1998 which were not used for medical purposes and were not type-examined and accepted by PTB and do not bear a CE marking

Audiometers which were placed on the market before 14 June 1998 and were not used for medical purposes (e.g. by hearing device acousticians), were not subject to type-examination and acceptance by PTB. For these devices, which also do not bear a CE mark, retrofitting a free-field equalization filter cannot be requested. They must be metrologically verified in accordance with the state of the art at that time, i.e., according to the requirements according to DIN 45620 [10] and/or DIN 45624 [12].

## 1.4 References


| | |
|---|---|
| [1] IEC 60942 | Electroacoustics – Sound calibrators; German version DIN EN 60942 (2004-05) |
| [2] IEC 942 | Sound calibrators; German version DIN IEC 942 (1990-03) |
| [3] IEC 60318-3 | Electroacoustics – Simulators of human head and ear – Part 3: Acoustic coupler for the calibration of supra-aural earphones used in audiometry; German version DIN EN 60318-3 (2015-09) |
| [4] IEC 60318-1 | Electroacoustics – Simulators of human head and ear – Part 1: Ear simulator for the measurement of supra-aural and circumaural earphones; German version DIN EN 60318-1 (2010-07) |
| [5] IEC 60318-6 | Acoustics – Simulators of the human head and ear – Part 6: Mechanical coupler for measurements on bone-conduction vibrators (IEC 60318-6:2007); German version EN 60318-6:2008 (2009-02) |
| [6] IEC 60645-1 | Electroacoustics – Audiometric equipment – Part 1: Equipment for pure-tone audiometry; German version DIN EN 60645-1 (2015-11) |
| [7] IEC 61672-1 | Electroacoustics – Sound level meters – Part 1: Specifications; German version DIN EN 61672-1 (2014-07) |
| [8] IEC 60651 | Sound level meters superseded by: IEC 61672-1, IEC 61672-2; German version DIN EN 60651 (1994-05) superseded by DIN EN 61672-1 (2003-10), DIN EN 61672-2 (2004-08) |
| [9] IEC 60645-4 | Audiometers – Part 4: Equipment for extended high-frequency audiometry superseded by [1]; German version DIN EN 60645-4 (1995-06) |
| [10] DIN 45620 | Audiometer; Begriffe, Anforderungen, Prüfung (withdrawn) (1985-03) replaced by [6] |
| [11] IEC 60645-2 | Audiometers – Part 2: Equipment for speech audiometry; German version DIN EN 60645-2 (1997-04) |
| [12] DIN 45624 | Audiometer; Begriffe, Anforderungen, Prüfung (withdrawn) (1978-04) |
| [13] DIN 45626-1 | Tonträger mit Sprache für Gehörprüfung - Teil 1: Tonträger mit Wörtern nach DIN 45621-1 (Recording 1969) (1995-8) |

## 2 Medical devices for the determination of body temperatures (with the exception of clinical mercury-in-glass, maximum- reading thermometers)

*Note:* The Medical Devices Operator Ordinance (MPBetreibV) still uses the term "mercury-in-glass thermometer". Due to technical progress, this exception also includes glass thermometers with metallic filling.

### 2.1 Medical electrothermometers and medical electrothermometers with replaceable temperature sensors

#### 2.1.1 Requirements placed on facilities

The metrological verification must be carried out under the following reference conditions:

ambient temperature: (23 ± 5) °c
relative air humidity: (50 ± 20) %
supply voltage: within the specified range of the device.

#### 2.1.2 Requirements placed on measuring and testing facilities

The following requirements are to be understood in such a way that they must be met by the metrology and testing facilities required for the proper performance of the metrological verification.

- Reference thermometers with a measurement uncertainty not larger than 0,02 °C (coverage factor k = 2) for the determination of the temperature of the reference water bath. The reference thermometer must be traceable to a national standard.
- Reference water bath, well controlled and circulated, with a minimum volume of 5 litres, in order to generate reference temperatures over the measurement range. It is necessary to ensure that there is a temperature stability better than ± 0,02 °C over the specified temperature measurement range of the thermometer. A local temperature deviation not greater than ± 0,01 °C within the working area at a specified temperature must be maintained. This local temperature deviation must be ensured under all conditions and variances of the loading with thermometer test objects.
- Simulator for temperature probes (e.g. calibrated decade resistance) with an extended measurement uncertainty not greater than the equivalent of 0,03 °C (calculated for a coverage factor $k$ = 2) within the temperature measurement range. The simulator shall be traced back to national standards.
- Testing device for temperature probes (e.g. a calibrated digital multimeter or ohmmeter that does not put a higher load on the sensor than the maximum permissible auxiliary power) with an equivalent maximum measurement uncertainty not greater than 0,03 °C (calculated for a coverage factor of $k$ = 2) within the temperature measurement range. The testing device must be traceable to national standards.

#### 2.1.3 Content and scope of the metrological examinations

##### 2.1.3.1 Condition check

The person conducting the metrological verification must be provided with the instructions for use.

The device must be CE marked showing the identification number of the conformity assessment body (i.e. notified body) or the approval mark of the Physikalisch-Technische Bundesanstalt. Devices that have already been metrologically verified in the past are labelled with the mark of the body that has conducted the last conformity assessment procedure.

Measuring devices that have not been placed on the market as medical devices but are used as medical devices as defined in Annex 2 of the Medical Devices Operator Ordinance (MPBetreibV) must also be subjected to a metrological verification. They are classified as medical devices within the sense of the Medical Devices Act.

All components of the device must correspond to the description in the instructions for use. Scales, labels and designations must comply with the standard ISO 80601-2-56 [1] or with the manufacturer's specifications (e.g. in the instructions for use). The device must be free of obvious defects.

#### 2.1.3.2 Maximum permissible errors (MPEs)

##### 2.1.3.2.1 Compact thermometers (temperature sensor and display unit in one casing)

The temperature sensor of the thermometer must be immersed in a reference water bath at a constant temperature until a temperature equilibrium has been reached. The temperature indicated by the test object must be compared with the temperature indicated by the reference thermometer. Next, the bath temperature is changed, and the measurement is repeated after the temperature equilibrium has been restored. The difference between the measured temperatures and the reference temperatures must fulfil the specifications for the maximum permissible errors according to ISO 80601-2-56 [1] or according to the manufacturer's specifications.

For the metrological verifications, at least 3 temperature points, evenly spaced over the measuring range, have to be selected.

##### 2.1.3.2.2 Indicating device

The measurement deviation of an indicator must be determined by using a device that simulates the corresponding physical properties of the temperature sensor (temperature sensor simulator).

*Note:* A calibrated decade resistance can be used, for instance, to simulate a resistance temperature sensor. To convert the resistance values into temperature values, the respective table of the manufacturer or a better suited realization of the characteristic curve (e.g. CCT Guide on Secondary Thermometry "Thermistor Thermometry") must be used. Accordingly, adjustable voltage sources can be used to simulate thermocouples.

The difference between the temperatures returned by the indicating device and the accordingly simulated temperature values must fulfil the specifications referring to the maximum permissible errors according to ISO 80601-2-56 [1] or according to the manufacturer's specifications.

The required number of measurements at different temperatures is the same as described in 2.1.3.2.1.

##### 2.1.3.2.3 Replaceable temperature sensors

A replaceable temperature sensor must be immersed in a reference water bath. The output signal of the temperature sensor is measured with a suitable measuring instrument (testing device for temperature sensors) and converted into temperature values. The compliance with

the maximum auxiliary power must be ensured. To convert the resistance values into temperature values, the conversion table of the manufacturer or a better suited realization of the characteristic curve (e.g. CCT Guide on Secondary Thermometry "Thermistor Thermometry") must be used. Each determined value of the temperature sensor must be compared with the temperature value of the reference thermometer. The difference between the two temperature values must fulfil the specifications referring to the maximum permissible errors according to ISO 80601-2-56 [1] or according to the manufacturer's specifications.

The required number of measurements at different temperatures is the same as described in 2.1.3.2.1.

#### 2.1.3.3 Insulation resistance (only replaceable temperature sensors)

The temperature sensor is immersed in a physiological saline solution (9,5 g NaCl per litre of demineralized water) at ambient temperature in a body cavity over a length corresponding to the intended immersion depth, at least however, to a depth of 50 mm.

After a waiting time of at least one minute, the resistance between short-circuited electrical contacts of the temperature sensor and an electrode in the physiological saline solution must be measured. The measuring instrument used for this process should apply a voltage of 10 V ± 1 V between the contacts of the temperature sensor and the electrode. The measured insulation resistance must be higher than a parallel resistance that would change the output signal of the temperature sensor corresponding to a temperature of 0,02 °C. To calculate the minimum insulation resistance, the highest resistance value of the temperature sensor in the specified measurement range must be used.

### 2.1.4 References


[1] ISO 80601-2-56: Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement (ISO 80601-2-56:2009);
German version EN ISO 80601-2-56: 2013-02

## 2.2 Infrared radiation thermometers

### 2.2.1 Requirements placed on facilities

The metrological verifications must be conducted under the following reference conditions:

Ambient temperature: 23 °C ± 5 °C, but not lower than the permissible ambient temperature for the device in operation.

relative air humidity: 50 % ± 20 %

Supply voltage within the specified range of the device.

### 2.2.2 Requirements placed on measurement and test equipment

The following requirements are to be understood in such a way that they must be met by the metrology and testing facilities required for the proper performance of the metrological verification.

- Reference thermometers with a measurement uncertainty not greater than 0.03 °C (coverage $k = 2$) for determining the temperature of the water bath. The reference thermometer must be traceable to national standards.
- Controlled reference water bath with circulation and a minimum volume of 5 litres. A temperature stability better than ± 0.02 °C and a local temperature deviation not greater than ± 0.01 °C at a specified temperature within the working area must be maintained.
- A reference cavity radiator (black-body radiator), immersed in the reference water bath with a measurement uncertainty of its radiance temperature that is not greater than 0.07 °C (coverage factor $k = 2$) within the temperature measurement range. If a reference cavity radiator is used as recommended in ISO 80601-2-56 [1], the traceability to the national standards can be established by the calibration of the reference thermometer described above.

### 2.2.3 Content and scope of the metrological verifications

#### 2.2.3.1 Condition check

The person conducting the metrological verification must be provided with the instructions for use.

The device must be CE marked showing the identification number of the conformity assessment body (i.e. notified body) or the approval mark of the Physikalisch-Technische Bundesanstalt. Devices that have already been metrologically verified in the past are labelled with the mark of the body that has conducted the last conformity assessment procedure.

All components of the device, including the protection foil as may be prescribed, must correspond to the description in the instructions for use. Scales, labels and designations must comply with the standard ISO 80601-2-56 [1] or with the manufacturer's specifications (e.g. in the instructions for use). The device must be free of obvious defects.

Measuring devices that have not been placed on the market as medical devices but are used as medical device as defined in Annex 2 of the Medical Devices Operator Ordinance (MPBetreibV) must also be subjected to a verification. They are classified as medical devices within the sense of the Medical Devices Act.

#### 2.2.3.2 Maximum permissible errors (MPEs)

The measuring head of the thermometer must be inserted in a reference cavity radiator. The temperature indicated by the test object in the calibration mode must be compared with the radiation temperature of the reference cavity radiator. The difference between the indicated temperatures and the reference temperatures must fulfil the specifications for maximum permissible errors according to ISO 80601-2-56 [1] or according to the manufacturer's specifications.

If the infrared ear thermometer has been calibrated in a mode other than the calibration mode, the measured value obtained must be converted in accordance with the correction procedures specified by the manufacturer before the difference to the radiation temperature of the reference cavity radiator is determined.

Differences in the emissivity between the cavity radiator used for calibration and the cavity radiator used for the metrological verification must be taken into account!

The inspection shall be conducted at three cavity radiator temperatures distributed approximately evenly over the temperature indication range.

### 2.3 References

[1] ISO 80601-2-56: Medical electrical equipment – Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement (2013-02)

# 3 Measuring instruments for the non-invasive measurement of blood pressure

## 3.1 Requirements placed on facilities

Ambient temperature: 10 °C to 40 °C

Relative air humidity: 15 % to 85 %

## 3.2 Requirements placed on measurement and test equipment

| | |
|---|---|
| Pressure measurement: | Calibrated reference overpressure gauge or dead weight tester with weights with a maximum measurement error of 0,8 mmHg or 0,1 kPa<br>Note 1: For reference overpressure gauges with scale units, a scale interval of 1 mmHg is sufficient. |
| Time measurement: | Maximum measurement error: 1 % of the waiting time or 0,1 s, whichever value is higher. |
| Pressure generator: | e.g. inflation bulb (hand pump) with deflation valve |
| Replacement volume: | Rigid metal vessels with a capacity of 500 ml or 100 ml.<br>Note 3: For a rapid heat exchange of the heated or cooled air by compression or decompression, the vessel must be made of metal. |
| Collecting tank for mercury: | A collecting tank sufficiently sized to contain spilling mercury. If a mercury manometer is constantly used as a reference overpressure gauge or if mercury manometers are frequently verified, the installation of an additional suction device is required within the work place directly above the test location. |

Recommended testing facility:

| | | |
|---|---|---|
| Patient simulator: | Additional measurement errors caused by the simulator must not deviate by more than 2 mmHg (0,27 kPa) from the mean value. The patient simulator should generate signals with approximately the following blood pressure values: | |
| | systolic: 120 mmHg | (16,0 kPa) |
| | diastolic: 80 mmHg | (10,7 kPa) |
| | pulse rate: 70 to 80 $min^{-1}$ | |

## 3.3 Content and scope of the metrological verification

### 3.3.1 Condition check

The person conducting the metrological verification must be provided with the instructions for use.

The device must be CE marked showing the identification number of the conformity assessment body (i. e. notified body) or the approval mark for verification of the Physikalisch-Technische Bundesanstalt. Devices that have already been verified in the past are labelled with the mark of the body that conducted the last metrological verification.

All components of the device, including the cuff, must comply with the description in the instructions for use or the approval document. Scales, labels and descriptions must comply

with the minimum requirements according to the standards ISO 81060-1 [1], IEC 80601-2-30 [2] or with the manufacturer's specifications (e.g. instructions for use).

Measuring devices that have not been placed on the market as medical devices but are used as a medical device as defined in Annex 2 of the Medical Devices Operator Ordinance (MPBetreibV) must also be subjected to a verification. They are classified as medical devices within the scope of the Medical Devices Act.

The device, including the cuff, must be free of obvious defects.

### 3.3.2 Functional performance test

The metrological verification of automated non-invasive sphygmomanometers is performed on a test subject or, unless not exempt by the manufacturer, on a patient simulator. It must be examined whether the measurement process complies with the specifications in the instructions for use or in the approval certificate. Automated non-invasive sphygmomanometers must indicate plausible results when used as intended (i.e. results within the expected range).

### 3.3.3 Air leakage testing (only for non-automated non-invasive sphygmomanometers)

The complete, non-automated non-invasive sphygmomanometer must fulfil the minimum requirements according to clause 7.2.1 of ISO 81060-1 [1] (air leakages) or comply with the manufacturer's specifications in the instructions for use or in the PTB Approval Certificate.

The leakage must be checked at pressures of 50 mmHg and 200 mmHg according to clause 7.2.1 of ISO 81060-1 [1].

### 3.3.4 Stopping devices for the tube and the reservoir containing mercury (only in the case of mercury manometers)

The stopping devices that prevent the mercury from spilling must comply with and be tested according to clause 8.4 of ISO 81060-1 [1] (Prevention of mercury spillage in normal use). In addition, the correct functioning of the stopping device for the tube must be examined according to the procedure described in clause 7.4 of ISO 81060-1 [1] (Dynamic response in normal use).

### 3.3.5 Maximum permissible errors of the cuff pressure

The maximum permissible errors (MPEs) of the cuff pressure must be checked for compliance with the manufacturer's specifications in the instructions for use, or:

- In the case of non-automated non-invasive sphygmomanometers which must fulfil the requirements for the temperature range between 10 °C and 40 °C and for the relative air humidity range between 15 % and 85 % (non-condensing), the maximum permissible error limit of the cuff pressure at any point of the nominal measurement range shall not exceed ± 3 mmHg (± 0,4 kPa) or ± 2 % of the indicated value, whichever is greater according to clause 7.1.1 of ISO 81060-1 [1] (Limits of the error of the cuff pressure indication ),
- In the case of automated non-invasive sphygmomanometers which must fulfil the requirements for the temperature range between 10 °C and 40 °C and the relative air humidity range between 15 % and 85 % (non-condensing), the maximum permissible error limit of the cuff pressure at any point of the nominal measurement range must not exceed ± 3 mmHg (± 0,4 kPa) or ± 2 % of the indicated value, whichever value is

greater according to clause 201.12.1.102 of IEC 80601-2-30 [2] (Limits of the error of the manometer from environmental conditions).

The metrological verification should start at the highest pressure value, be continued in pressure ranges of 50 mmHg at a maximum, and reach 0 mmHg.

### 3.4 References


[1] ISO 81060-1: Non-invasive sphygmomanometers – Part 1: Requirements and test methods for non-automated measurement types (2012-08)

[2] IEC 80601-2-30: Medical electrical equipment – Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers (2016-02)

*Note:*
ISO 80601-2-30:2011-05 is valid only until 14 April 2018.

## 4 Medical devices to determine intraocular pressure (eye tonometers)

### 4.1 Requirements placed on facilities

Air conditioning of the test rooms is not necessary for the metrological verification; the following ambient conditions must be complied with:

Ambient temperature: 15 °C to 35 °C

Relative air humidity: 10 % to 85 %

Air pressure: 800 hPa to 1060 hPa (only for air pulse tonometers)

The test rooms must provide vibration-free working conditions (e.g. no vibrations from traffic, etc.).

### 4.2 Requirements placed on measurement and test equipment

#### 4.2.1 Measurement and test equipment for the metrological verification of impression tonometers

Weight balance to determine the effective masses of the lever-pointer-plunger system and of the mass of the tonometer without a holder (minimum requirements).

Measurement range: 5 g up to at least 18 g

Measurement uncertainty: ≤ 0,050 g

Weight balance to determine the mass of the additional weights (minimum requirements):

Measurement range: 1,5 g up to at least 10 g

Measurement uncertainty: ≤ 0,005 g

Length measuring instrument to determine the plunger displacement (minimum requirements):

Measurement range: from 0 mm up to at least 5 mm

Measurement uncertainty: 0,003 mm

Test blocks:

1st sphere: Radius of curvature: 16,00 mm

Measurement uncertainty: ≤ 0,05 mm

2nd sphere: Radius of curvature: 14,75 mm

Measurement uncertainty: ≤ 0,05 mm

Goniometer to determine the friction:

Measurement uncertainty: 2°

#### 4.2.2 Measurement and test equipment for the metrological verification of applanation tonometers

Determination of the diameter of the applanation circle of the tonometer prism:

Glass reticle:

Measurement uncertainty: ≤ 0,002 mm

Microscope:

At least 10-fold magnification

Test equipment for force measurement (minimum requirements):

Measurement range: 9 mN up to a minimum of 80 mN

Measurement uncertainty in the measurement range of 9 mN to 50 mN: ≤ 0,17 mN

Measurement uncertainty in the measurement range above 50 mN: ≤ 0,20 mN

### 4.2.3 Measurement and test equipment for the metrological verification of non-contact tonometers

PTB test equipment:
Measurement range (minimum requirements): 10 mmHg up to a minimum of 50 mmHg

Measurement uncertainty in the measurement range of 10 mmHg to 15 mmHg: ≤ 0,4 mmHg

Measurement uncertainty in the measurement range of 15 mmHg to 30 mmHg: ≤ 0,5 mmHg

Measurement uncertainty in the measurement range of 30 mmHg to 50 mmHg: ≤ 0,8 mmHg

*Note*: To ensure the internal quality assurance of the long-term stability of the PTB test equipment, it is strongly recommended to test it from time to time, e.g. every 6 weeks, always using the same (reference) non-contact tonometer.

## 4.3 Content and scope of the metrological verification

### 4.3.1 Condition check

The person conducting the metrological verification must be provided with the instructions for use. Impression and applanation tonometers with PTB type approval (before 1998) were often placed on the market without instructions for use. The device must either be CE marked showing the identification number of the conformity assessment body (i. e. notified body) or the approval mark of Physikalisch-Technische Bundesanstalt. All components of the device must comply with the description in the instructions for use. Scales, labels and descriptions must comply either with the manufacturer's specifications or with the specifications for type-approved devices as specified in Annex 15-8 [1] to the Verification Ordinance (Eichordnung; EO) as applicable pursuant to the previous law until 1998.

The device must be clean and free of obvious defects.

Measurement devices that were not placed on the market as medical devices but have a medical intended purpose as defined in Annex 2 of the Medical Devices Operator Ordinance (MPBetreibV), must also be subjected to metrological verification. They are classified as medical devices within the scope of the Medical Devices Act.

### 4.3.2 Metrological verifications

The compliance with the manufacturer's specifications – in the case of older devices – with the specifications in the PTB Approval Certificate must be checked.

#### Visual inspection of tonometers

All types of tonometers must be checked to ensure that they bear the prescribed markings, in particular the CE markings with the number of the conformity assessment body (i. e. notified body).

#### 4.3.2.1 Metrological verifications on impression tonometers

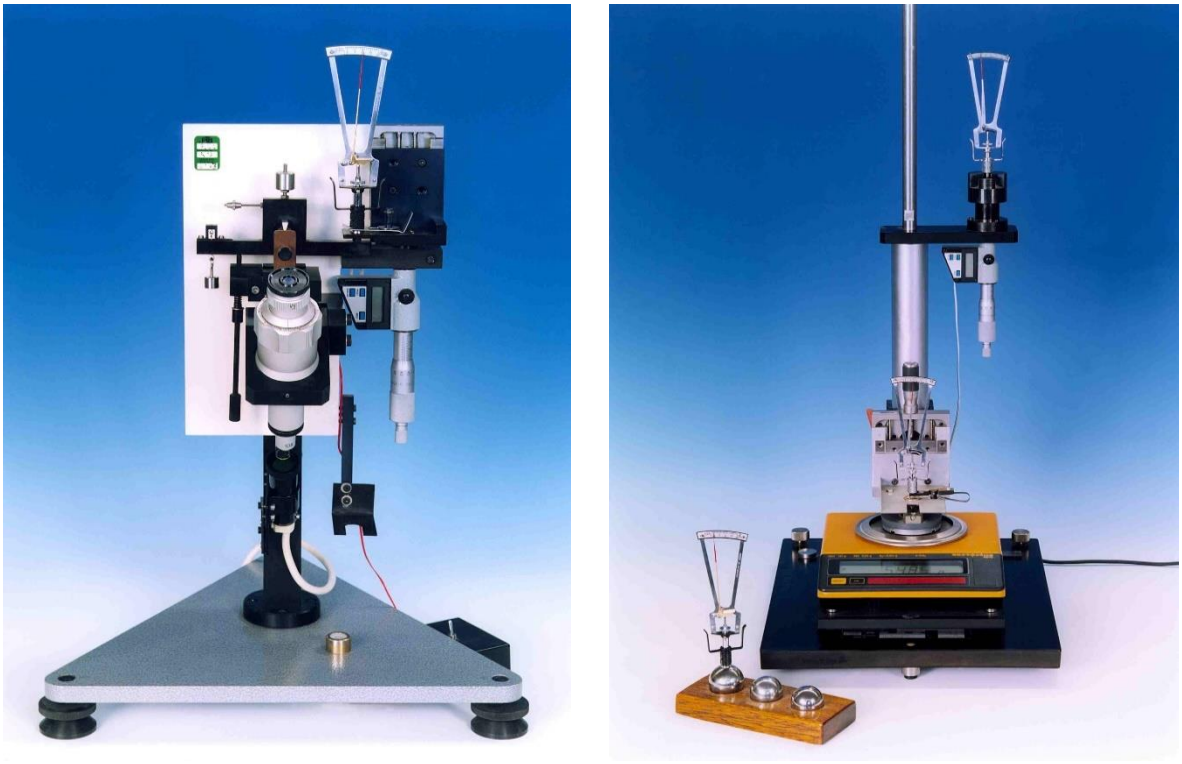

Figure 4.1: Measuring instruments for the verification of impression tonometers.
Left: Mechanical beam balance to determine the mass of the tonometers as well as a micrometre screw for measuring the plunger displacement of the tonometer.
Right: Electronic balance to determine the tonometer masses as well as a micrometre screw for measuring the plunger displacement of the tonometer.
Right, frontal: Test blocks for the verification of the zero indication.

**Visual inspection of the impression tonometer**

In addition to the visual inspection described above, impression tonometers must be checked for friction between the plunger and the plunger sleeve of the tonometer, the integrity of the surfaces and the edges of the footplate and the plunger and, in the case of purely mechanical impression tonometers, the mechanical condition of the pointer (not bent out of shape, distance to the scale approx. 1 mm). As the individual components of impression tonometers are usually not interchangeable, at least the plunge, the nut (if any) and the lever-pointer-plunger system must be clearly marked as parts of one system, e.g. by identical numbers.

**Weighing procedures for impression tonometers**

The total mass of the tonometer without the holder must be determined. Unless otherwise specified, it shall be (including the indication of the limit value of maximum permissible measurement error):

16,5 g ± 0,5 g

The effective mass of the lever-needle-scale system must be determined at the scale divisions 5 and 10. Unless otherwise specified, it shall be (including the indication of the limit value of the maximum permissible measurement deviation):

at scale division 5: 5,50 g ± 0,15 g

at scale division 10: 5,50 g ± 0,20 g

The mass of the additional weights must be examined; the 2 or 3 masses commonly used are listed in **Fehler! Verweisquelle konnte nicht gefunden werden.**:

Table 4.1: Masses of the additional weights

| **Marking** | **Mass in g** | **Maximum permissible measurement error in g** |
|---|---|---|
| 7,5 | 2,00 | ± 0,02 |
| 10 | 4,50 | ± 0,02 |
| 15 | 9,50 | ± 0,02 |

**Zero indication and displacement of the plunger**

The zero indication must be examined by means of two test blocks, see Table 4.2.

Table 4.2: Zero indicator measured on test blocks

| **Radius of the test block in mm** | **Indication of the tonometer in scale values** | **Maximum permissible measurement error in scale values** |
|---|---|---|
| 14,75 | -1,0 | ± 0,2 |
| 16,00 | 0,0 | ± 0,2 |

The plunger displacement must be verified for the values indicated in Table 4.3.

Table 4.3: Plunger displacement and indication of the impression tonometer

| **Scale values** | **Plunger displacement in mm** | **Maximum permissible measurement error maximal in mm** |
|---|---|---|
| -1 to 5 | 0,30 | ± 0,01 |
| -1 to 10 | 0,55 | ± 0,02 |
| -1 to 15 | 0,80 | ± 0,03 |
| -1 to 18 | 0,95 | ± 0,05 |

**Determination of the friction between the plunger and the plunger sleeve**

When the tonometer moves smoothly and continuously from the horizontal to the vertical position with the plunger in the upper position (see Fig. 4.2, left-hand side), the plunger must begin to slide downwards into the hole of the footplate at 25° at the latest. During this test, the lever-pointer system must not touch the plunger, see Fig. 4.2, right-hand side.

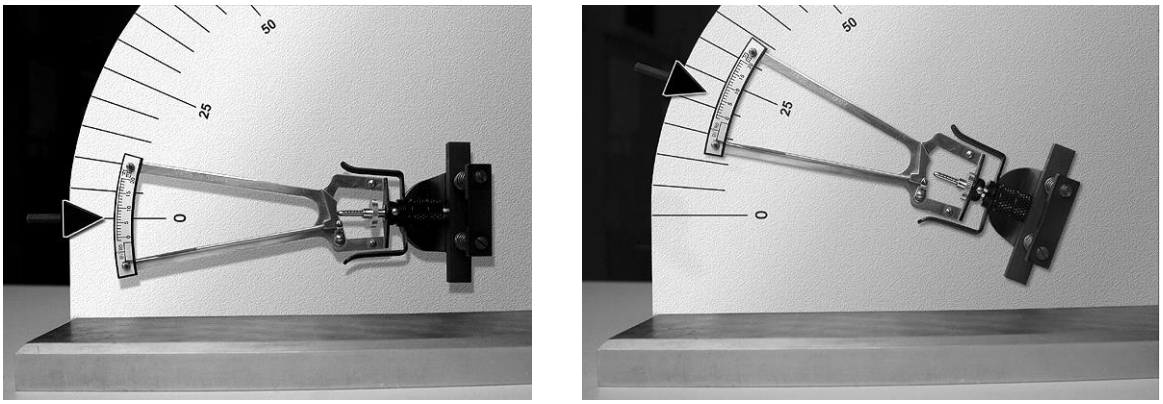


Figure 4.2, left: Tonometer in the horizontal position with the plunger in the upper position, indication below the scale value 0.

Figure 4.2, right: The plunger slides down into the hole of the footplate at an angle of less than 25°. Please note that the lever-pointer system does not touch the plunger and is still in its initial position.

### 4.3.2.2 Metrological verifications of mechanical-optical applanation tonometers

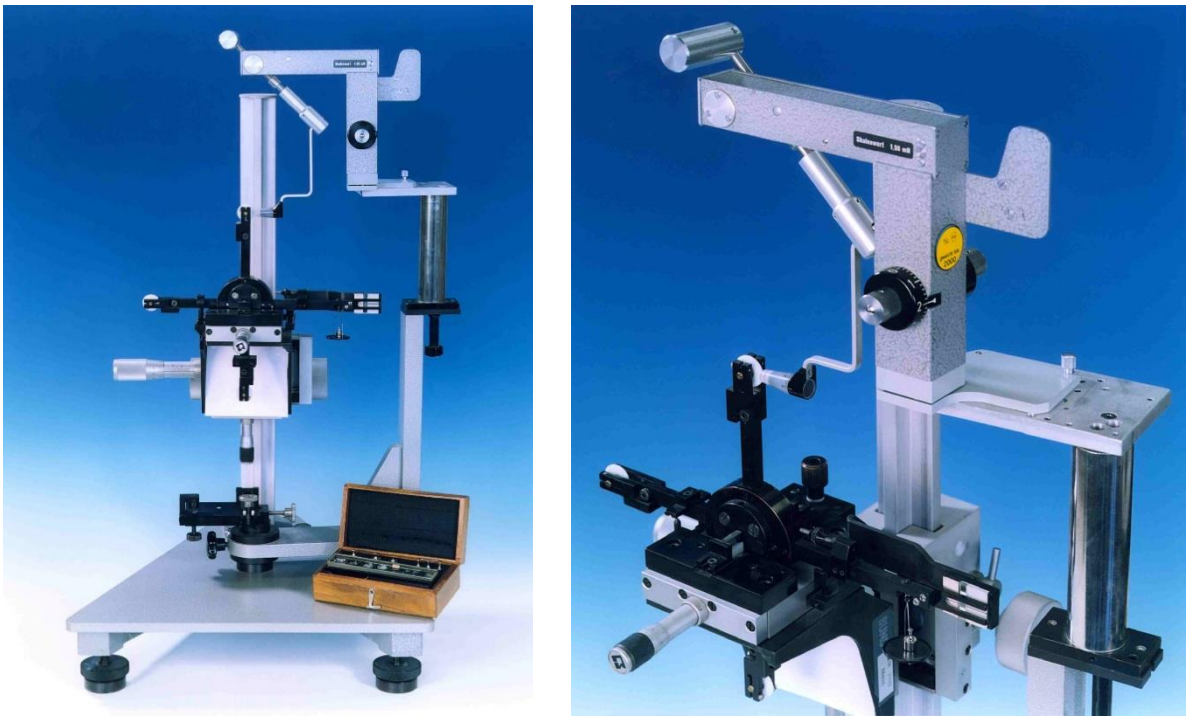

Figure 4.3: Cross beam balance for the verification of applanation tonometers;
left: Overall view with tonometer; right: Detailed view with tonometer

**Verification of the diameter of the applanation circle of the tonometer prism**

The diameter of the applanation circle must be tested for all tonometer prisms used by means of a suitable reticle. The manufacturer of the applanation tonometer must specify the suitable type of tonometer prism and the nominal value of the diameter of the applanation circle.

In general, the diameter of the applanation circle of the tonometer prism has the following dimensions (with the specification of the limit value of the maximum permissible measurement error):

3,06 mm ± 0,2 mm.

**Verification of the tonometer prism**

The entire contact surface of the tonometer prism must be even, smoothly polished and free of scratches. The peripheries of this surface must be free of protrusions and fragment fractures.

**Verification of the measuring force of the tonometer**

In the following, the verification of the measuring force by means of a cross beam balance is described as this device is the most frequently used test equipment. Other force measuring devices can be used if they are suitable and metrologically traceable, e.g. the optical-interference test equipment manufactured by SIOS Meßtechnik company, Ilmenau.

The tonometer must be aligned in such a way that the contact wheel of the cross-beam balance lies centrally against the tonometer prism. To ensure that measurements are taken in the centre of the horizontal travel range of the tonometer prism and that measurement errors are avoided when the margins are reached, the procedure described below shall be followed:

- The weighing pan must be loaded with a weight of 1 g;
- The tonometer must be set to scale value 2 (corresponding to a force of 19,61 mN);
- The displacement of the pointer on the beam balance must be observed;
- The tonometer must be set to scale value 0 (corresponding to a force of 0 mN);
- The displacement of the pointer on the balance must be observed;
- The horizontal alignment of the tonometer is accurate when the displacements in the upward and downward directions are symmetrical, otherwise the described adjustment procedure must be repeated.

  *Note:* The permissible movement of the prism is limited by a front and rear stopper. For safety reasons, all known applanation tonometers are additionally equipped with an overload protection.

After the adjustment has been completed, the verification is performed in the upwards and downwards direction in increments of 1 scale division (corresponding to a force of 9,81 mN) within the measurement range specified by the manufacturer (see Table 4.4).

*Note:* If a prism with an applanation circle diameter of 3,06 mm ± 0,02 mm is used, 10 mmHg correspond to the tonometer scale division of 1 or to a force of 9,81 mN.

The hysteresis error of the force must be determined at all measuring points when the prism movement returns from the tonometer and moves in the opposite direction (downward movement). The manufacturer's specifications must be used for the verification. Unless

otherwise specified by the manufacturer, the value 0,49 mN shall apply for the reversal hysteresis.

Tonometers with the ability to perform measurements in any desired position, must be tested in the vertical and horizontal direction. The preparations for the verification as well as the verification procedure in the horizontal direction must be carried out analogously to the verification in the vertical direction.

Table 4.4: Verification steps for the measurement force of the tonometer. The manufacturer's specifications for the measurement range must be taken into account.

| **Reference force in mN** | **Maximum permissible measurement error in mN** | **Permissible setting range* at the tonometer in scale values** |
|---|---|---|
| 9,81 | ± 0,49 | 0,95 – 1,05 |
| 19,61 | ± 0,49 | 1,95 – 2,05 |
| 29,42 | ± 0,49 | 2,95 – 3,05 |
| 39,23 | ± 0,59 | 3,94 – 4,06 |
| 49,03 | ± 0,74 | 4,92 – 5,08 |
| 58,84 | ± 0,88 | 5,91 – 6,09 |
| 68,65 | ± 1,03 | 6,90 – 7,10 |
| 78,45 | ± 1,18 | 7,88 – 8,12 |

*) The scale values specified in this table apply only to prisms with an applanation circle diameter of 3,06 mm (reference value).

#### 4.3.2.3 Metrological verification of non-contact tonometers

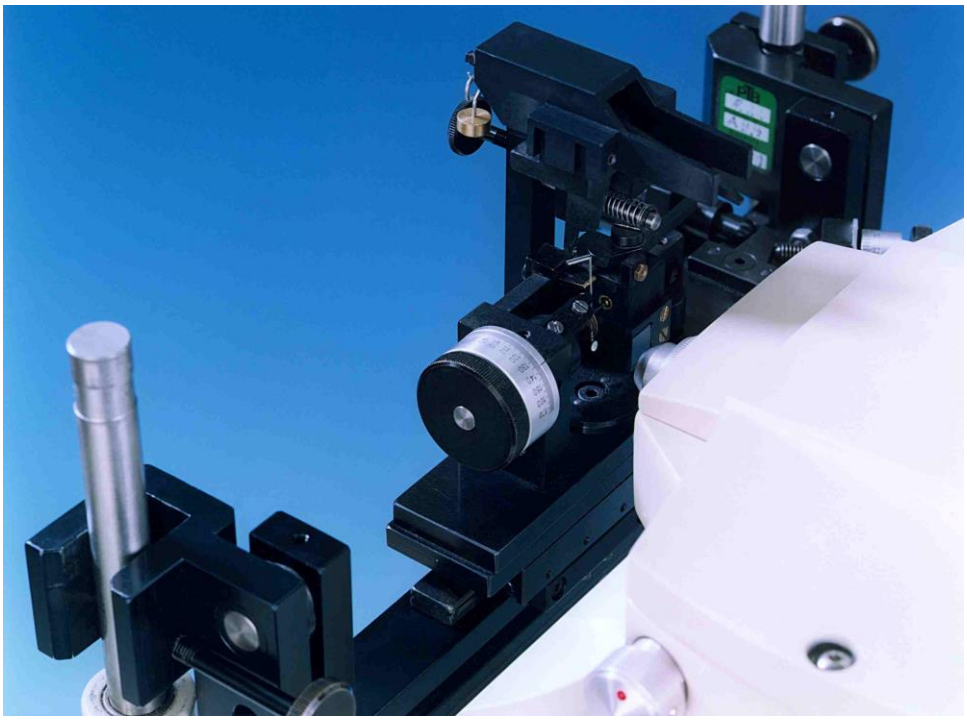

Figure 4.4: PTB test equipment for the metrological verification of non-contact tonometers

The metrological verification of non-contact tonometers can only be performed by means of a test equipment that allows the simulation of the measurements of the intraocular. Apart from a few exceptions, all non-contact tonometers placed on the market with PTB type approval under the old law (approx. until 1998), can be metrologically verified with the PTB test equipment (see Figure 4.4). Air pulse tonometers placed on the market at a later point of time can often also be verified with this equipment. In addition to the verification by means of the PTB test equipment, tests can also be performed using rubber spherical caps if their suitability has been proven – usually by a PTB or a CMI[3] test certificate.

The manufacturer must determine the reference values for the metrological verification by using a non-contact tonometer of a special construction type that has been clinically tested according to ISO 8612 [2] and a compatible test equipment. Thus, the manufacturer of the tonometer to be verified knows the reference values that this tonometer type must display during the simulated measurement. The reference values are only valid for certain non-contact tonometer – test equipment combinations; as a rule, they are not transferable to other types of tonometers. If the reference values are not evident from the accompanying instructions for use or from other supplementary documents, they must be obtained from the manufacturer.

**Verification procedure**

At least 10 repeat measurements shall be performed for at least 3 simulated intraocular pressures (reference values) of the test equipment. From these values, the arithmetic mean value for each simulated intraocular pressure shall be calculated. Unless specified otherwise by the manufacturer or in the PTB Approval Certificate, the maximum permissible measurement error $\Delta x$ of the arithmetic mean is as follows:

1. for the reference value in the low range: $\Delta x_{low} \leq 1{,}0\ mmHg\ (0{,}13\ kPa)$
2. for the reference value in the intermediate range: $\Delta x_{intermediate} \leq 1{,}5\ mmHg\ (0{,}20\ kPa)$
3. for the reference value in the high range: $\Delta x_{high} \leq 2{,}0\ mmHg\ (0{,}27\ kPa)$

## 4.4 References


[1] Annex 15-8: To the Verification Ordinance (Eichordnung; EO) of 12 August 1988 (Federal Law Gazette, p. 1657) in the version of the 2nd Ordinance for the Amendment of the Verification Ordinance of 21 April 1994 (Federal Law Gazette, p. 1293)

[2] ISO 8612: Ophthalmic Instruments – Tonometers (2009)


[3] CMI: Czech Metrology Institute

## 5 Foot crank ergometers used to induce a defined reproducible physical stress in patients

Foot crank ergometers used to induce a defined reproducible physical stress in patients (Annex 2 of the Medical Devices Operator Ordinance (MPBetreibV) are subject to metrological verification when the manufacturer has placed them on the market as a medical product with the above-mentioned intended purpose.

A metrological verification is necessary if a foot crank ergometer has been placed on the market as a medical device for inducing a defined reproducible physical stress in patients and if this ergometer is operated by the user with this intended purpose specified by the manufacturer or if it is used within the sense of section 2 of the Medical Devices Operator Ordinance (MPBetreibV).

Measuring devices that have not been placed on the market as medical devices but are used for the purpose of a medical device as defined in Annex 2 of the Medical Devices Operator Ordinance (MPBetreibV), must also be subjected to a metrological verification. They are classified as medical devices within the sense of the Medical Devices Act (MPG).

Pursuant to section 3, paragraph 1 of the Medical Devices Act (MPG), medical devices are used for diagnostic or therapeutic purposes. The use of ergometers at a power exceeding 400 W, does not usually fulfil this requirement. This power range is, therefore, not the subject of the verification procedure of these guidelines, unless diagnostic or therapeutic reasons require it.

### 5.1 Requirements placed on facilities

Ambient temperature: 15 °C to 25 °C

Relative air humidity: 20 % to 85 %

### 5.2 Requirements placed on measurement and test equipment

Test equipment with the following properties shall be used for the metrological verification:

Power measurement: Ergometer test equipment to determine the power consumed at the crank shaft of the ergometer from the braking torque and revolution speed. The power consumed by the ergometer must be determined from the product of the braking torque at the crank and its angular velocity. The maximum measurement error must not exceed 2 % or 1,8 W, whichever value is higher, when the maximum measurement error of the crank ergometer is not specified better than 5 % or 3 W.
Digital step of the indication: $\leq$ 0,1 W.
If the manufacturer of the crank ergometer to be tested specifies maximum permissible errors smaller than 5 % or 3 W, respectively, the maximum permissible measurement error of the ergometer test

equipment must not exceed 1/3 of this MPE[4]. In practice, crank ergometers with specifications below 3 % of the power or 3 W are currently not metrologically traceable.
The indication of the measurement value must correspond to the mean value of the consumed power over at least 3 complete revolutions of the crank shaft. The averaging must take account of the time dependence of the measurands of the braking torque and the revolution speed.

Measurement of the revolution speed:

Maximum error of the measurement of the speed indicator of the drum on the driving side of the ergometer: 0,5 %. The maximum permissible measurement error of the test equipment must not exceed 1/3 of this maximum permissible error.

Digital step of the indication: $\leq$ 0,1 $min^{-1}$

For the measurement range of the crank ergometer, please refer to the data sheet or the instructions for use of the crank ergometer.

The measurement range of the ergometer test equipment must correspond to the specified measurement range of the ergometers, at least, however, to the characteristic curve field of the working range of the braking torque control for crank ergometers according to DIN VDE 0750-238 [1] (25 W to 400 W), unless the equipment is only used for the verification of ergometers with a smaller working range due to their design.

Adapters for certain ergometers provided by the manufacturer must be used.

The test equipment for ergometers must be traceable to a national standard. A corresponding certificate must always be available as proof of a valid verification.

## 5.3 Content and scope of the metrological verification

### 5.3.1 Condition check

The person conducting the metrological verification must be provided with the instructions for use.

The device must be CE marked showing the identification number of the conformity assessment body (i.e. notified body) or the approval mark for the issuing of a declaration of conformity by the Physikalisch-Technische Bundesanstalt. The declaration of conformity must be available.

All parts of the device must comply with the description in the instructions for use. Scales, indicators, markings and designations must comply with the manufacturer's specifications (e.g. in the instructions for use), with the specifications according to DIN VDE 0750-238 [1], with the requirements according to OIML R 128 [2] or, in the case of instruments approved by PTB, with the respective approval.

[4] The maximum permissible measurement error of 2 % or 1,8 W for ergometer test equipment for the metrological verification of crank ergometers that have maximum permissible errors of 5 % or 3 W results from the availability of the respective test equipment at the time when the metrological verification was introduced. As this equipment is still in use today, the value has not been lowered.

The device, including its accessories, must be free of obvious defects.

### 5.3.2 Functional performance test

A test run must be carried out – while taking into account the instructions for use – in order to determine if the ergometer absorbs power output. (This test run makes sense because no further testing is required in the case of a failure.)

### 5.3.3 Maximum permissible errors (MPEs)

The maximum permissible errors must be checked over the entire measurement range specified by the manufacturer, provided the measurement range lies within the scope of application according to section 3, paragraph 1 of the MPG (see above), with test equipment for ergometers as described in clause 5.2. For the tests described below, the maximum permissible errors specified in the instructions for use of the foot crank ergometer must be observed. In the absence of such specifications, the specifications of standard DIN VDE 0750-238 [1] or of OIML R128 [2] shall apply.

*Note: For the metrological verification, the ergometer test equipment must be applied to the power indication at least in the same way as it is applied for the averaging of the value (see clause 5.2, power measurement). Consequently, at least the same number of complete revolutions of the crank shaft is necessary.*

#### 5.3.3.1 Verification of the revolution speed indication

The maximum deviation of the revolution speed indication of the ergometer must be determined in the revolution speed range from 40 $min^{-1}$ to 100 $min^{-1}$ in steps of a maximum of (20 ± 2) $min^{-1}$ by comparison with the revolution speed measured by the test equipment. Measurement errors due to freewheeling must be avoided by setting a base load of approx. 100 W.

#### 5.3.3.2 Verification of the power consumption

When determining the maximum permissible error of the power consumed by the ergometer, the time constant and the stabilization behaviour of the ergometer must be taken into account for the regulation of the power consumed. According to DIN VDE 0750-238 [1], the time constant must not exceed 4 s, i.e. the measurement should be made at the earliest after 20 s, because this will ensure that the controller is in a steady-state condition.

The ergometer is pre-loaded with 200 W at a revolution speed of 60 $min^{-1}$ for approximately 5 to 10 min, so that the normal mechanical properties are restored – especially after longer periods of rest . Runtimes significantly longer than 10 min. must be avoided because they lead to heating that does not occur during the normal use of the ergometer.

- The measurement errors are then determined by means of the ergometer test equipment at the set values of 25 W, 50 W, 100 W, 150 W, 250 W and, at or near the upper limit of the measurement range, at the revolution speed of 60 $min^{-1}$, respectively.
  Furthermore, the measurement error within the working range specified in the instructions for use must be determined at least on three spots selected by the inspector, specifically in the speed ranges and power ranges that are most frequently used by the operator.
- In addition, in the case of ergometers with a speed-independent working range, the test with ergometer test equipment must be checked for compliance with the

maximum permissible errors of the power when the speed is changed. At the set power values of 25 W and 150 W, the revolution speed is therefore varied in steps of 10 $min^{-1}$ within the speed-independent working range specified in the instructions for use.

### 5.4 References


[1] DIN VDE 0750-238: Medical electrical equipment - Part 238: Particular requirements for the safety of crank ergometers (2002-10)

[2] OIML R 128 Ergometers for foot crank work (2000)


## Annex 1: Particular specifications for the reverification intervals of metrological standards

The metrological standards used for metrological verifications (MV) must be traced to a national standard on an annual basis, irrespective of the method of tracing. Exceptions to this rule are listed in Table 1. The reverification extends to all measurement and test equipment, for example also to balances, test spheres, etc.

Table1: Metrological standards with reverification intervals of more than 1 year. The column "Reverification can be carried out by" relates to the German situation.

| Standard for MV of | Type of standard | Recalibration intervals (years) | Recalibration can be carried out by | | |
|---|---|---|---|---|---|
| | | | PTB | EB* | D-K** |
| Audiometers | Sound calibrators, | 3 | x | x | x |
| | ear simulators and acoustic couplers including | | | | |
| | pressure microphones; | 3 | x | | x |
| | Mechanical couplers; | 3 | x | | |
| | Frequency meters; | 3 | x | x | x |
| | Harmonic distortion meters; | 3 | | x | x |
| | Measuring equipment for pressing forces; | 6 | x | x | |
| | Sound level meters with | | | | x |
| | free-field microphones; | 3 | x | x | |
| | Third octave filters. | 3 | x | x | |
| Medical thermometers | Mercury-in-glass thermometers | 3 | | x | x |
| Medical thermometers | Resistance decades | 2 | | x | x |
| Non-invasive sphygmomanometers | Liquid column manometers; | 5 | | x | x |
| | Piston manometers | 5 | x | x | x |

| | | | | | |
|---|---|---|---|---|---|
| Ocular tonometers | Test equipment for indentation, applanation and non-contact tonometers | 3 | x*** | x | |
| Dosimeters | Dosimeters | 3 | x | x | x |
| Foot crank ergometers | Test equipment for ergometers | 2 | x | | x |

*) EB: *Eichbehörde* [verification authority] (since not every verification authority is able to perform all calibrations, the details can be obtained from the local verification authority at www.eichamt.de).

**) D-K: Calibration laboratories accredited by the German accreditation body DAkkS (a list of calibration capabilities is available on the internet at: http://www.dakks.de/content/akkreditierte-stellen-dakks)

***) Recalibration is performed by the Czech Metrology Institute (CMI) in Most,
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