TECHNICAL REPORT

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Ophthalmic instruments — Tonometers

Instruments ophtalmiques — Tonomètres

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Contents

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The main task of technical committees is to prepare International Standards, but in exceptional circumstances a technical committee may propose the publication of a Technical Report of one of the following types:

— type 1, when the required support cannot be obtained for the publication of an International Standard, despite repeated efforts;

— type 2, when the subject is still under technical development or where for any other reason there is the future but not immediate possibility of an agreement on an International Standard;

— type 3, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example).

Technical Reports of types 1 and 2 are subject to review within three years of publication, to decide whether they can be transformed into International Standards. Technical Reports of type 3 do not necessarily have to be reviewed until the data they provide are considered to be no longer valid or useful.

ISO/TR 8612, which is a Technical Report of type 1, was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This document is being issued as a type 1 Technical Report providing a classification of tonometers and a description of the different principles of tonometry, as well as a compilation of specific construction requirements and test methods for these different types of tonometers.

At the time of publication of ISO/TR 8612, work on an International Standard on fundamental requirements and test methods for tonometers has already been started and it is intended to withdraw this Technical Report when the International Standard is published.

Introduction

The tonometer is one of the most important measuring instruments for the detection and diagnosis of glaucoma. The term “glaucoma” indicates diseases of the eye which may show an increase of the intraocular pressure (IOP) as one of the common symptoms and which may lead to lesions of the optic nerves and thus to scotomata and even blindness. The development of a glaucoma can follow an increase in IOP before pathological changes occur in the fundus of the eye. Results obtained by the use of tonometers give an indirect measurement of IOP and these results represent a close approach to the actual IOP.

Requirements relating to tonometers without subclause 4.5 (see [1], [2], [10], [11] and [13]) and the instructions for their verification without annex E were accepted at the meeting of the Committee on Standardization of Tonometers (ICST) of the International Council of Ophthalmology held in Paris in 1974.

The assessment of the IOP is made more difficult because each of these indirect methods, owing to the contact with the eye as a physical system, effects a change of volume and thus a pressure change as a result of the force exerted on the eye during the measurement procedure. Hence, the user does not measure the IOP in an unstressed eye but rather an increased pressure raised more or less by the measuring procedure.

The different principles of tonometry are described in annex A. Procedures for verifying requirements laid down for tonometers are described in annexes C to E.

It is recognized that each tonometer type may employ different parameters and/or correlations in order to assess IOP indirectly. Furthermore, within a given type, variations in specific design are anticipated. It follows that each type and/or design of a tonometer which fulfil the clinical criteria (annex B) may require a test method unique to the design of the instrument and set of physical criteria; by necessity, test method and requirements are clearly specific to the design of the instrument. This Technical Report is not, however, intended to preclude other types or designs not covered therein.

Ophthalmic instruments — Tonometers

1 Scope

This Technical Report specifies requirements and test methods for instruments designed to determine intraocular pressure (IOP). It lays down criteria for the clinical evaluation of different tonometer types (annex B), test methods for tonometers (annexes C to E) and physical criteria (clause 4) which, when satisfied by the instrument under test, verify that its measurement calibration meets the clinically relevant criteria.

This Technical Report is applicable to impression tonometers of the mechanical and mechanical-electrical type, to applanation tonometers of the mechanical-optical and mechanical-electrical type as well as air-impulse tonometers.

2 Classification of tonometers

2.1 Mechanical and mechanical-electrical impression tonometers

Instruments which measure the deformation of the cornea resulting from the application of the tonometer itself or the tonometer measuring head, i.e. the sinking-in of the plunger. The deformation is indicated by a digital or analog display or by a recording device.

2.2 Mechanical-optical applanation tonometers

Instruments which measure either the force necessary to flatten the cornea with a pressure body to a diameter between 2,5 mm and 4,0 mm depending on the type of instrument, or the diameter of the applanation circle at a known measuring force, indicated in scale divisions by a digital display or by a recording device.

2.3 Electromechanical applanation tonometers

Instruments which, by means of a measuring head, measure the force necessary to flatten the cornea to the diameter specified by the tonometer type. The force or the pressure is indicated in scale divisions by a digital display or by a recording device.

2.4 Air-impulse tonometers

Instruments employing a brief air impulse of increasing force which either measure the time or measure the instrument plenum chamber pressure necessary to deform the cornea to a consistent configuration. The time or the pressure is indicated by a digital display or by a recording device.

Air-impulse tonometers do not mechanically touch the cornea during the measuring procedure.

3 General design

3.1 The mechanical parts of the tonometers shall be composed of material with sufficient mechanical resistance and invariability.

3.2 The electrical parts of the tonometers shall be composed of material with sufficient mechanical resistance and electrical invariability.

3.3 The surfaces of the tonometer that are intended to come into contact with the cornea shall be composed of rust-free and acid-resistant steel or of material which is inert to biological tissue.

4 Specific construction requirements and limits of error

4.1 Mechanical impression tonometers

4.1.1 Effective load

The effective load of the lever-pointer-plunger system when the tonometer is in a vertical position shall be:

— (5,5 ± 0,15) g when indicating scale division “5”;

— (5,5 ± 0,20) g when indicating scale division “10”.

4.1.2 Mass and additional loads

The mass of the tonometer, without handle, shall be (16,5 ± 0,5) g.

The additional loads shall be

— with inscription 7,5: (2,0 ± 0,02) g;

— with inscription 10,0: (4,5 ± 0,02) g;

— with inscription 15,0: (9,5 ± 0,02) g.

4.1.3 Friction between plunger and plunger sleeve

When the tonometer is moved slowly and uniformly from the horizontal position into the vertical position with the plunger on the upper stop, the plunger shall begin to slide into the footplate hole before the angle of the tonometer axis to the horizontal exceeds 25°. During this manoeuvre the lever shall not touch the plunger.

NOTE — A drawing of footplate and plunger is given in figure C.5.

The tonometer shall be able to slide easily in its handle (see C.2.5).

4.1.4 Dimensions of footplate and plunger

The dimensions of the footplate shall be as given in table 1.

Table 1 — Dimensions of footplate

Dimensions in millimetres

Feature		Dimension
Diameter		10,1 ± 0,2
Radius of curvature of the spherical front surface		15,0 ± 0,25
Outside diameter of the spherical front surface, d_{min}		9,0 min.
Either	Diameter of the recess or counterbore on the front surface up to a minimum height h of 1,5 mm, d_2	3,3 max.
	Radius of the inside edge curvature, r	0,2 max.
Or	Diameter of the circle at the transition between footplate curvature and edge curvature of the recess of counterbore (central area), d_g	3,7 max.

The dimensions of the plunger shall be as given in table 2.

Table 2 — Dimensions of plunger

Dimensions in millimetres

Feature	Dimension
Diameter at the front surface up to a minimum height of 1,5 mm	3,0 ± 0,03
Radius of curvature of the spherical front surface	15,0 ± 0,75
Radius of the edge curvature	0,25 ± 0,015
Extension of the plunger below the spherical footplate, h_{max}	3,0 max.

4.1.5 Surface condition

The front surfaces of the footplate and of the plunger shall be smooth when felt with a finger and, when examined by unmagnified corrected vision under direct illumination, shall be free from surface imperfections that would damage the eye. The outside surface of the front surface of the footplate and the inside edge at the recess of counterbore shall be rounded.

4.1.6 Scale

The scale may be arranged parallel or inclined to the axis of the plunger. The scale shall be divided into at least 15 equal scale divisions (−1 to 15 or 0 to 15 respectively); the distance between two adjacent lines shall be equal to a plunger displacement of 0,05 mm, so that the displacement of the plunger shall correspond to the values given in table 3 depending on the number of scale divisions. The scale shall show integers only.

Table 3 — Plunger displacement

Values in millimetres

Scale division from	Scale division to	Plunger displacement values
−1	5	0,30 ± 0,01
−1	10	0,55 ± 0,02
−1	15	0,80 ± 0,03
−1	18	0,95 ± 0,05
0	5	0,25 ± 0,01
0	10	0,50 ± 0,02
0	15	0,75 ± 0,03
0	18	0,90 ± 0,05

The division of the scale shall consist of lines. The lines shall be straight, of equal width and directed towards the axis of the pointer. No line shall be wider than 1/4 of the distance between two lines nor more than 0,25 mm.

4.1.7 Pointer

In the area of the scale, the pointer shall not be wider than the smallest width of a line in the area of the scale. If the pointer moves over the scale, it shall overlap the shortest lines by at least one-third; the tip shall not extend beyond the scale lines. The distance between pointer and the plane of the scale shall not be greater than 1,0 mm in the area of the scale.

4.1.8 Plunger

At some point between scale indications 5 and 10, the plunger axis and the lower surface of the lever shall form a right angle at the point of contact.

4.1.9 Scale indication

When the instrument is tested on a test block with a radius of curvature of 14,75 mm, the pointer shall indicate −1,0 ± 0,2 on the scale; when tested on a test block with a radius of curvature of 16 mm, it shall indicate 0 ± 0,2 on the scale.

With the tonometer in position on the test block, the scale reading shall not vary by more than 0,4 scale divisions when the plunger is turned or moved laterally or when the lever is moved laterally.

4.1.10 Verticality of tonometer

When the tonometer is picked up without restraint at the holding point of the handle, the axis shall naturally assume a vertical position.

4.1.11 Recording device

If a recording device is used, the limits of error for the record shall be the same as for the scale readings.

4.2 Mechanical-electrical impression tonometers

4.2.1 Effective load

The effective load of the plunger measured with the instrument ready for use shall be (5,5 ± 0,1) g within the measuring range and with the measuring head in a vertical position.

4.2.2 Mass and additional loads

The mass of the tonometer measuring head, without handle, shall be (16,5 ± 0,5) g.

The additional loads shall be:

— with inscription 7,5: (2,0 ± 0,02) g;

— with inscription 10,0: (4,5 ± 0,02) g;

— with inscription 15,0: (9,5 ± 0,02) g.

4.2.3 Friction between plunger and plunger sleeve

After the tonometer measuring head is moved slowly and uniformly from the horizontal position into the vertical position after the plunger is moved 4 mm, the plunger shall begin to slide into the footplate hole before the angle of the tonometer axis to the horizontal exceeds 25°.

The tonometer shall be able to slide easily in its handle.

4.2.4 Dimensions of footplate and plunger

The dimensions of the footplate shall be as given in table 1. The dimensions of the plunger shall be as given in table 2.

4.2.5 Surface condition

The front surfaces of the footplate and of the plunger shall be smooth when felt with a finger and, when examined by unmagnified corrected vision under direct illumination, shall be free from surface imperfections that would damage the eye. The outside edge of the front surface of the footplate and the inside edge at the recess or counterbore shall be rounded.

4.2.6 Scale

The scale shall be divided into at least 15 equal scale divisions (–1 to 15 or 0 to 15, respectively); the distance between two adjacent lines shall be equal to a plunger displacement of 0,05 mm, so that the displacement of the plunger shall correspond to the values given in table 3, depending on the number of scale divisions. The scale shall show integers only.

If there is a digital read-out in a digital display, the last digit shall be changed by one unit for a displacement of the plunger of not more than 0,005 mm.

The interval between the dividing lines shall be not less than 4 mm and may be subdivided. The division of the scale shall consist of lines. The lines shall be straight, of equal width and directed towards the axis of the pointer. No line shall be wider than ¼ of the distance between two lines, nor more than 0,25 mm. The scale shall show integers only.

4.2.7 Pointer

In the area of the scale, the pointer shall be no wider than the smallest width of a line in the area of the scale. If the pointer moves over the scale, it shall overlap the shortest lines by at least one-third; the tip shall not extend beyond the scale lines.

4.2.8 Testing on test block

When the tonometer measuring head is placed on a test block having a curvature radius of 14,75 mm or 16,00 mm, the scale reading shall be –1,0 or 0,0 respectively, with a tolerance of ± 0,2 of a scale interval or ± 0,2 as indicated by the final digits.

When the tonometer measuring head is placed on the attached test block marked “15”, the scale reading shall not exceed 15 with a tolerance of ± 0,2 of a scale interval or ± 0,2 as indicated by the final digits.

With the tonometer measuring head in position on the test block, the scale reading shall not vary by more than 0,2 scale divisions or ± 0,2 as indicated by the final digits (i.e. 0,01 mm displacement of the plunger) when the plunger is turned or moved laterally.

4.2.9 Effect of variations in temperature or voltage on scale readings

4.2.9.1 At temperatures between 15 °C and 30 °C at constant operating voltage, the scale reading within the measuring range shall not vary by more than ± 0,2 of a scale interval or ± 0,2 as indicated by the final digits (0,01 mm displacement of the plunger).

4.2.9.2 During a fluctuation in operating voltage of ± 10 % at 20 °C, the scale reading shall not vary by more than ± 0,2 of a scale interval or ± 0,2 as indicated by the final digits (0,01 mm displacement of the plunger).

4.2.10 Recording device

If a recording device is used, the limits of error for the record shall be the same as for the scale readings.

If the tonometer is provided with a digital display, with each digit indicated by seven linear segments, it shall be possible to check the correct functioning of every segment.

4.3 Mechanical-optical applanation tonometers

4.3.1 Diameter of applanation circle

Mechanical-optical applanation tonometers which measure the force needed to obtain a given area of applanation shall have a constant value between 2,5 mm and 4,0 mm for the diameter of the applanation circle.

The tolerance for the diameter of the applanation circle shall be ± 0,02 mm.

4.3.2 Surface of pressure body

The front surface of the pressure body shall be smooth when felt with a finger and, when examined by unmagnified corrected vision under direct illumination, shall be free from surface imperfections that would damage the eye and shall have a diameter of at least 6,0 mm.

4.3.3 Measuring force

The measuring force shall be continuously adjustable within the minimum range from 0 to 49,0 mN[1]), without the range being altered and without the use of additional weights. The measured value of the force shall be clearly legible on a linearly divided scale.

The change in force required to move the pressure body in the opposite direction (reverse span) at the point of transition shall not exceed ± 0,29 mN.

4.3.4 Scale

Lines shall be used as graduations on the measuring scale. The lines shall be straight, of equal width and shall be engraved or otherwise permanently marked. No line shall be wider than 1/4 of the distance between two lines.

1) 1 mN = 10^{-3} N; 1 N is that force which, when applied to a body having a mass of 1 kg, gives it an acceleration of 1 $m \cdot s^{-2}$.

One scale unit shall represent either 0,98 mN or 1,96 mN. The main scale graduations shall be numbered. The width of the reference mark shall not be greater than the smallest width of the graduation lines on the measuring scale.

4.3.5 Tolerance for measurement of force

When the pressure body is adjusted to the verification position, the tolerance for the measured value of the force within the measuring range shall be ± 1,5 % of the nominal value, but not less than ± 0,49 mN, over a temperature range from 15 °C to 30 °C.

4.3.6 Recording device

If a recording device is used, the limits of error shall be the same as those specified in 4.3.5.

4.3.7 Tonometer used as limit gauge

If the tonometer is to be used as a limit gauge only, the diameter of the applanation circle and the measuring force shall be constant. Tolerances specified in 4.3.1 and 4.3.5 shall be applied.

4.4 Mechanical-electrical applanation tonometers

4.4.1 Diameter of applanation circle

4.4.1.1 For tonometers which measure the force required in applanation, the diameter of the applanation circle shall have a constant value not less than 2,5 mm.

The tolerance for the diameter of the applanation circle shall be ± 0,02 mm.

4.4.1.2 For tonometers which measure the diameter of the applanation circle, the force shall be constant. The diameter of the applanation surface shall be measured and the tolerance specified in 4.4.1.1 shall be applied.

In determining the pressure (force/area), the diameter of the applanation surface area can be equal to the diameter of the front surface of the measuring head.

4.4.2 Surface of pressure body

The front surface of the pressure body shall be smooth when felt with a finger and, when examined by unmagnified corrected vision under direct illumination, shall be free from surface imperfections that would damage the eye and shall have a diameter of at least 6,0 mm.

4.4.3 Measuring force

The measuring force shall be continuously adjustable within the minimum range from 0 to 49,0 mN, without the range being altered and without the use of additional weights. The measured value of the force shall be indicated on a linear scale or typed in scale divisions using a recorder, or indicated digitally.

The determination of the force applied to the front surface of the pressure body within the circle of applanation shall also be permitted to be made from a concentric circular plane the diameter of which is equal to or smaller than the radius of the circle of applanation using a mechanical-electrical measuring device.

The change of force required to move the pressure body in the opposite direction (reverse span) at the point of transition shall not exceed ± 0,29 mN.

4.4.4 Scale

If the force applied to flatten the cornea is recorded on a scale, lines shall be used as graduations on the measuring scale. The lines shall be straight, of equal width and shall be engraved or otherwise permanently marked. No line shall be wider than ¼ of the distance between two lines, nor more than 0,25 mm in width.

One scale unit shall represent either 0,98 mN or 1,96 mN. The main scale graduations shall be numbered. The width of the reference mark shall not be greater than the smallest width of the graduation lines on the measuring scale.

4.4.5 Pointer

If the force applied to flatten the cornea is recorded on a scale, the pointer shall not be wider than the smallest width of a line in the area of the scale. If the pointer moves over the scale, it shall overlap the shortest lines by at least one-third; the tip shall not extend beyond the scale lines.

4.4.6 Tolerance for measurement of force

When the pressure body is adjusted to the verification position of its range of movement, the tolerance for the measured value of the force within the measuring range shall be ± 1,5 % of the nominal value, but not less than ± 0,49 mN, over a temperature range from 15 °C to 30 °C.

4.4.7 Recording device

If a recording device is used, the limits of error shall be the same as those specified in 4.4.6.

4.5 Air-impulse tonometers

4.5.1 Alignment

Each type of air-impulse tonometer shall include mechanical and optical or opto-electronic means for achieving alignment relative to the patient's cornea, in three dimensions. The alignment shall be observed by means of an optical or a camera/monitor system.

4.5.2 Indication of measurements

The display shall be digital.

In the case of segment digital display, it shall be possible to check the correct functioning of every segment of each digit.

The measuring range shall extend from "12" to at least "50".

4.5.3 Verification of display

For the verification using apparatus such as that described in annex E, the correlation between the digital display and the measured value of force in the optimum alignment of the system, the air impulse on a face 2,5 mm in diameter for the named types shall be as given in table 4.

Table 4 — Correlation between digital display and measured value of the force of air impulse
for Non-Contact Tonometer II (NCT II) and XPERT Non-Contact Tonometer (XPERT NCT)

Digital display reading	Force of air impulse mN	Digital display reading	Force of air impulse mN	Digital display reading	Force of air impulse mN	Digital display reading	Force of air impulse mN
—	—	21	9,0	31	16,0	41	23,0
12	1,5	22	9,7	32	16,7	42	23,7
13	2,3	23	10,4	33	17,4	43	24,4
14	3,7	24	11,1	34	18,1	44	25,1
15	4,6	25	11,8	35	18,8	45	25,8
16	5,4	26	12,5	36	19,5	46	26,5
17	6,1	27	13,2	37	20,2	47	27,2
18	6,9	28	13,9	38	20,9	48	27,9
19	7,7	29	14,6	39	21,6	49	28,6
20	8,3	30	15,3	40	22,3	50	29,3

Other tables of correlation between digital display and measured value of the force of air impulse apply to other air-impulse tonometers. In these cases the manufacturer is required to publish this table with a detailed description of the verification procedure and apparatus.

4.5.4 Effect of variation in temperature or voltage on display

For digital display in the temperature range from 15 °C to 30 °C at constant operating voltage, the maximum permissible errors are:

— between digital readings "12" and "30": ± 1 as indicated by the final digit;

— between digital display readings "31" and "50": ± 2 as indicated by the final digits.

During a fluctuation in the operating voltage of ± 10 % at 20 °C, the maximum permissible error shall be ± 1 as indicated by the final digits.

5 Marking

5.1 Each tonometer shall be marked with the following information:

a) name of manufacturer or trademark;

b) country of manufacture;

c) serial number.

5.2 On each applanation tonometer with constant diameter of the applanation circle and variable measuring force, the diameter of the applanation circle shall be indicated, unless its value is 3,06 mm.

5.3 Each instrument and its necessary accessories, except for the pressure body of the mechanical-optical applanation tonometers and the measuring head of the mechanical-electrical impression tonometers and mechanical-electrical applanation tonometers, shall be marked with an individual serial number. Each tonometer measuring head with its associated plunger shall be identically numbered. All other parts of tonometers shall not be marked.

5.4 Each removable objective/tube unit shall bear the same number as the air impulse tonometer to which it relates.

5.5 On each air-impulse tonometer, the measurement range shall be indicated as given in the following example: "Measurement range from 12 to 50 on digital display".

Annex A
(informative)

Principles of tonometry

A.1 General

The following principles will prove clinically useful in obtaining a measurement which is an acceptable correlation with the IOP.

a) Impression principle

A plunger deforms the cornea to obtain a state of quasi-equilibrium between external and internal pressure and then the size of the "indentation" is measured.

b) Applanation principles

A plane surface is pressed against the cornea so as to determine the force necessary to flatten a defined area (Goldmann principle) or to determine the size of a flattened area subjected to a defined force (Maklakoff principle).

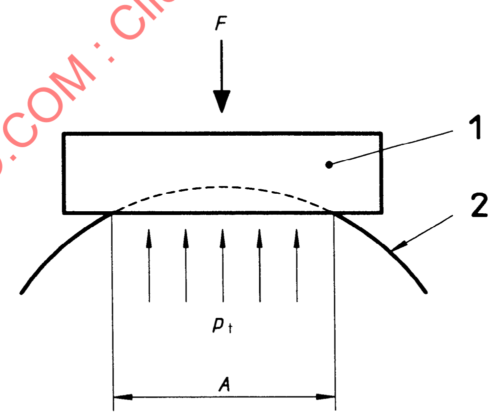
Both principles are based on the Imbert-Fick law, which states that if a plane surface is applied with force F to a thin spherical membrane within which a pressure p_t exists at equilibrium the following equation is valid:

$$p_t = \frac{F}{A} \qquad \dots (1)$$

where

A is the area of the applied surface;

p_t is the pressure increase due to the measuring procedure (see figure A.1).



1 Pressure body 2 Membrane

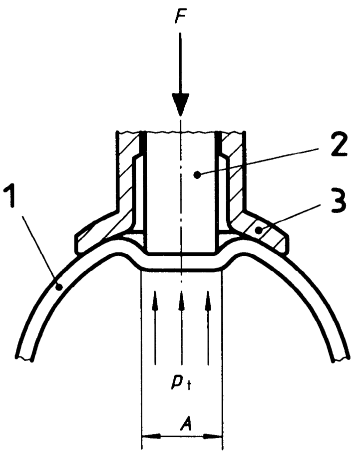
Figure A.1 — General principle of tonometry

A.2 Impression tonometry

Using an impression tonometer, Friedenwald investigated the relationship between the quotient F/p_t and the extent of the indentation (see figure A.2). The scale reading R of the tonometer was a measure of this relationship. The result of these measurements is given by:

$$p_t = \frac{F}{a + bR} \quad \text{. . . (2)}$$

where a and b are constants.



1 Cornea 2 Plunger 3 Footplate

Figure A.2 — Principle of impression tonometry

The pressure p_t determined in this way represents the pressure in the eye under the additional stress produced by the tonometer and the plunger pressure. However, knowledge of the pressure p_0 in the unstressed eye is more important. Both parameters, p_t and p_0, could only be interrelated after the concept of "rigidity" was introduced into the calculations [3]. Friedenwald demonstrated empirically that the resistance of the eye to change in the IOP can be described by a rigidity coefficient, K, according to the following equation:

$$K = \frac{\log p_t - \log p_0}{V_t} \quad \text{. . . (3)}$$

where V_t is the volume of indentation.

If this equation is solved for log p_0 and if p_t is replaced by equation (2), the following basic equation for impression tonometry is obtained:

$$\log p_0 = \log \frac{F}{a + bR} - KV_t \quad \text{. . .(4)}$$

In order to avoid the need to determine the rigidity whenever a measurement is made with the impression tonometer, conversion tables were produced for the pressure/scale-division relationship for practical use with the tonometer, using average values for a and b and using K = 0,021 5 mm^{-3} which was calculated statistically.

A.3 Applanation tonometry

A.3.1 Mechanical-optical applanation tonometry

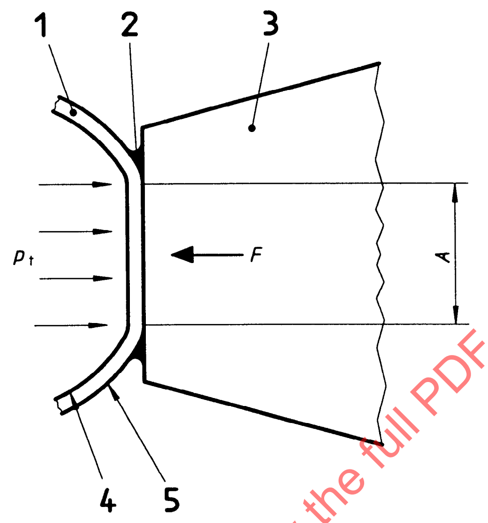
The theory of applanation tonometry (see figure A.3) is derived in a similar, but theoretically more exact, fashion from the Imbert-Fick law. In this case, owing to the physical properties of the cornea and its wetting liquid, two terms are added to equation (1) to give the following equation:

$$p_t = \frac{F}{A} - p_M + p_N \qquad \ldots (5)$$

where

p_M is a pressure caused by the characteristic rigidity of the eye;

p_N is the pressure due to surface tension of the liquid, the wetting properties of the cornea and the flattening surface of the pressure body.



Key

1 Cornea
2 Meniscus
3 Pressure body
4 Descemet-membrane
5 Bowman-membrane

Figure A.3 — Principle of applanation tonometry

The rigidity of the eye does not play as important a role in the applanation principle as it does in the impression principle, since the pressure on the eye is affected by the applied force alone. For a constant and sufficiently small applanation area, the following simple relationship, derived by Goldmann and Schmidt [5], is valid for p_0 and p_t.

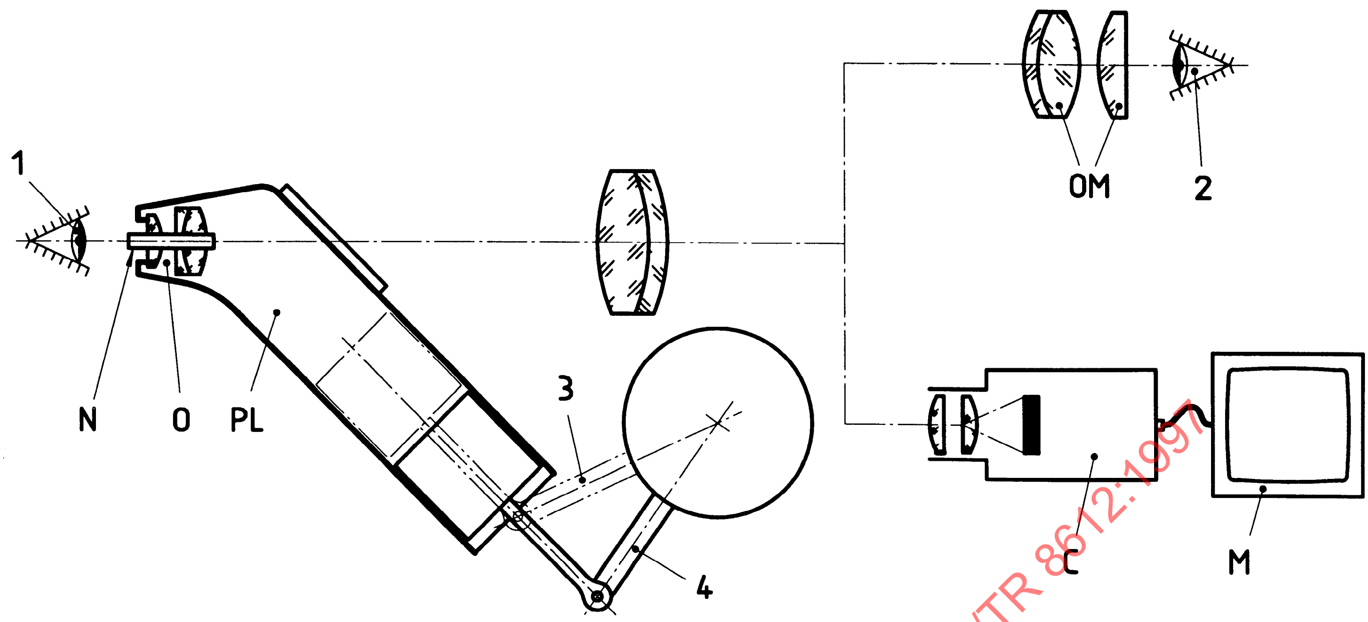
$$p_0 = 0{,}98\, p_t \qquad \ldots (6)$$

It was concluded that, as a good approximation, $p_0 \approx p_t$ is valid for an applanation circle diameter of 3,06 mm.

A.4 Air-impulse tonometry

Air-impulse tonometry differs from constant-face or constant-force applanation tonometry in that the cornea is flattened by a defined air impulse instead of by a mechanical surface. The time to flatten the cornea or the pressure in the pump system at the time of flattening is employed as means of assessing the IOP.

The following example illustrates the principle on which the method is based (see figure A.4). An air impulse, generated by a pump system (PL), passes through a nozzle (N) in the centre of the objective (O) and strikes the surface of the patient's cornea at a distance coinciding with the optimal alignment of the system. The axis of the nozzle coincides with the axis of the objective.



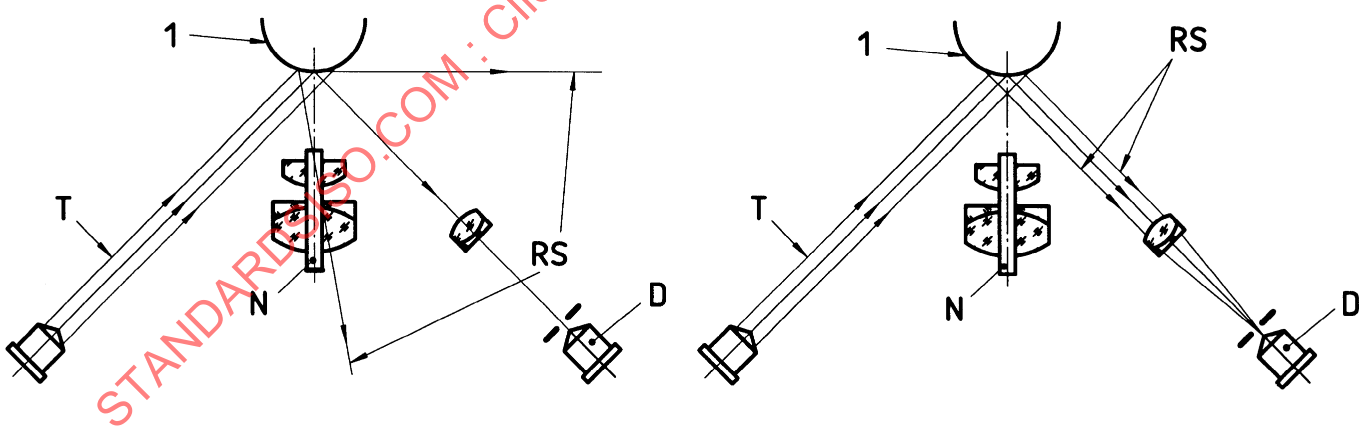
Key

O Objective
M Monitor
OM Optical monitoring system
N Nozzle
PL Pump system
C Camera
1 Patient's cornea
2 Observer
3 Energized
4 De-energized

Figure A.4 — Principle of air-impulse tonometry

The cornea is thus deformed and the deformation is increased until the marginal rays (RS) [see figures A.5a) and A.5b)] of a light beam (T), transversally incident on the cornea, are reflected parallel to the axial ray and the full light intensity falls on a radiation detector (D).

At this instant, which represents the point at which the cornea is flattened, the measurement is interrupted and the value of the pressure is digitally displayed on the observer's side in millimetres of mercury.



a) Reflection of the light beam before deformation of the cornea

b) Reflection of the light beam from the deformed cornea when marginal rays are parallel to axial ray

Key

D Radiation detector
RS Marginal rays
1 Patient's cornea
N Nozzle
T Light beam

Figure A.5 — Measuring system for air-impulse tonometry (perpendicular to the plane of figure A.4)

The result may be derived from the electronically timed interval from the beginning of the measuring process to the flattening of the cornea, or from the pressure in the pump system (PL) at the instant of flattening.

The tonometer is exactly aligned to the patient's eye with the aid of optically or optoelectronically generated indicators which are capable of permitting or automatically starting a measurement when the instrument-specific conditions are satisfied. The alignment is achieved with an optical (OM) or a camera/monitor (M) system.

In contrast to the tonometric measuring principles mentioned under A.2 and A.3, the mean value of at least three individual measurements on the same eye is taken as the measured value when air-impulse tonometers are used. The reason for this is that the individual measurement takes only a fraction of a second (e.g. 5 ms) and thus can be affected by the pulsation of the IOP.

Annex B
(informative)

Criteria for the clinical evaluation of different types of tonometers

B.1 General

Intraocular pressure (IOP) is clinically determined, indirectly, by tonometers which actually measure a value whose relationship to IOP is known. The evaluation of the clinical performance of each tonometer type is based upon comparative IOP determinations by a reference instrument which, by consensus, is a verified mechanical-optical applanation tonometer. Only if the test tonometer complies with the performance criteria cited below in B.2, shall physical and metrological specifications and test protocol(s) be formulated for the given tonometer type, and employed in its testing. When a tonometer is evaluated, it is of the utmost importance that results of these clinical comparison measurements are taken into account. A physical and metrological type-test for compliance with the construction regulations and error limits specified within clause 4 should be carried out only if the tonometer complies with the conditions of B.2.

B.2 Clinical evaluation criteria for tonometers

Based upon the applanation tonometry given by Goldmann and Schmidt [5], [6] as a reference system, guidelines for the parameters of the regression equation and for the permissible dispersion of the single values around the regression curve (see figure B.1) for clinical comparative measurements are specified [15], [16]:

B.2.1 For the equation of the regression line $y(x)$:

$$y(x) = a + bx$$

where

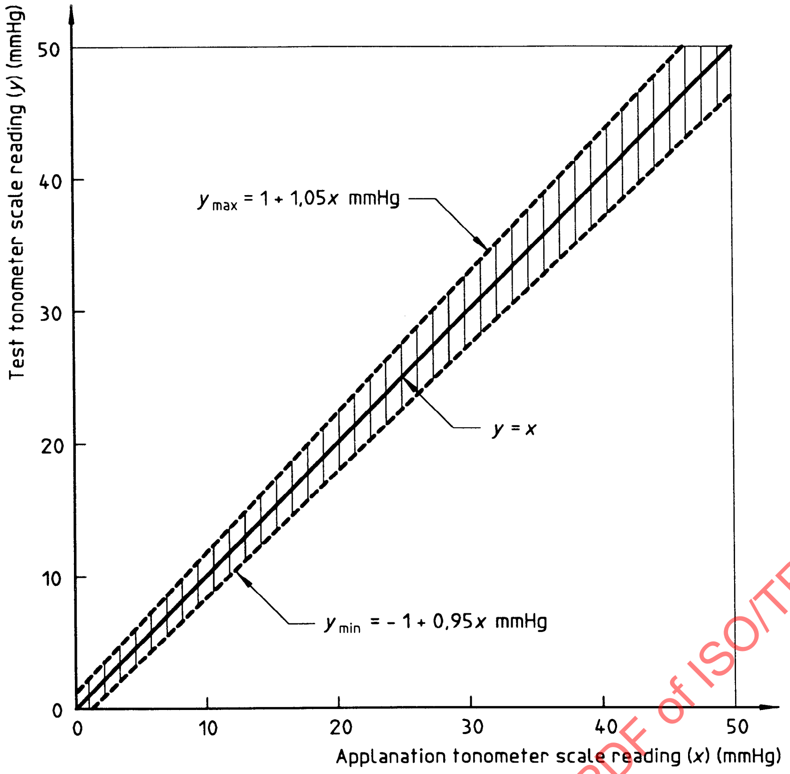
$$-1{,}0 \text{ mmHg} \leqslant a \leqslant +1{,}0 \text{ mmHg}$$
$$0{,}95 \leqslant b \leqslant 1{,}05$$

B.2.2 For the tolerance limits of the dispersion of the single values y_i ($i = 1 \ldots N$) of the regression curve

$$y_{max} = (a + 5) + bx + 0{,}001\, x^2$$
$$y_{min} = (a - 5) + bx - 0{,}001\, x^2$$

at least 95 % of all measured values having to lie within this tolerance zone (see figure B.2).

These conditions are only valid within the pressure range from 10 mmHg to no less than 50 mmHg, as determined by a verified applanation tonometer reference system.



$y = a + bx$

where

$-1{,}0 \text{ mmHg} \leqslant a \leqslant +1{,}0 \text{ mmHg}$;

$0{,}95 \leqslant b \leqslant 1{,}05$

Figure B.1 — Conditions concerning the regression curve [15]

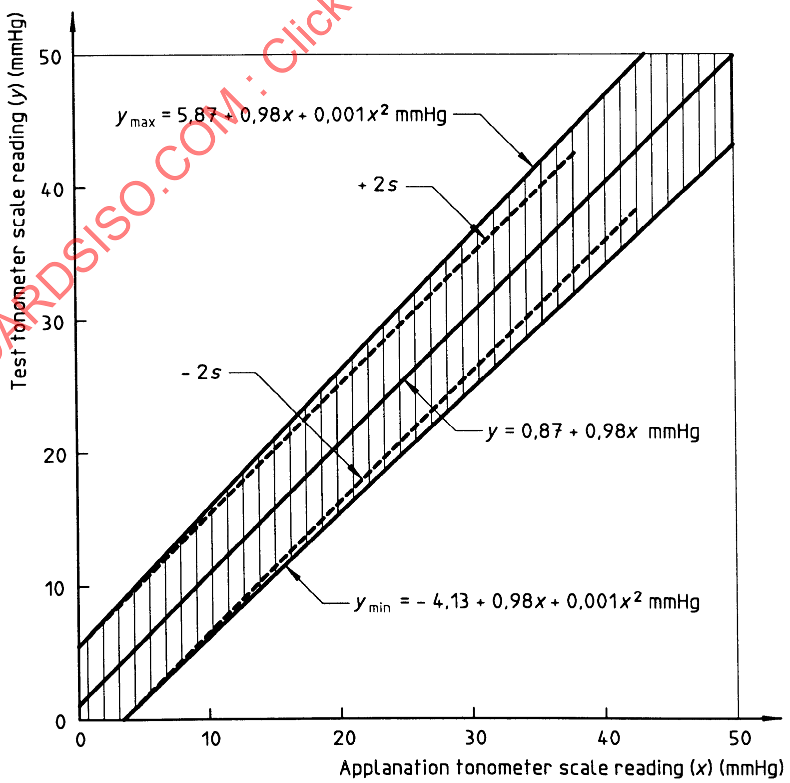


Figure B.2 — Example of a regression curve and the tolerance area for *y* values [15], [16]

B.3 Test plan for comparison measurements

The test plan for clinical comparative measurements on test persons, which complies with the International Standardization regulation, is based on an experimental protocol designed for two randomized observers (see table B.1):

$$\alpha_1(AT) \rightarrow \beta(XT) \rightarrow \alpha_2(AT)$$

Every measurement value β of the tonometer to be tested (XT) is compared with the mean value of the measured values α_1 and α_2 of the reference system (AT). As a result, time trends are taken into account.

Table B.1 — Randomized action plan for two observers

— Observer No. 1: 136 measurements, observer No. 2: 134 measurements

	1			2			3		
	Measurement			**Measurement**			**Measurement**		
	α_1	β	α_2	α_1	β	α_2	α_1	β	α_2
1	2 2 1 1 1	2 1 1 1 2	1 1 1 2 2	2 1 1 2 2	1 1 2 2 2	1 2 2 2 1	2 2 2 1 2	2 2 1 2 1	2 1 2 1 1
2	2 1 2 2 1	2 2 2 1 2	2 1 1 2 1	2 1 2 1 1	1 2 1 1 1	2 1 1 1 2	1 1 1 2 2	1 1 2 2 1	1 2 2 1 1
3	2 1 2 1 2	1 1 1 2 2	1 1 2 2 1	2 2 2 1 1	1 2 2 2 1	1 1 2 2 2	2 1 2 1 1	1 2 1 1 1	2 1 1 1 2
4	2 1 1 2 1	1 1 2 1 1	1 2 1 1 1	1 2 1 2 2	2 1 1 1 2	1 1 1 2 2	2 1 2 1 2	2 2 1 1 2	1 2 2 1 2
5	1 2 1 2 2	1 2 2 2 1	2 2 2 1 2	1 2 2 1 2	2 2 1 2 2	2 1 2 2 2	1 2 1 2 2	2 2 1 1 2	2 1 2 1 1
6	1 2 2 2 1	2 2 2 1 1	2 2 1 1 2	2 1 2 1 1	2 1 1 1 2	1 1 1 2 2	1 2 2 1 1	1 2 1 1 2	1 1 1 2 1

NOTE — The numbers in the first line and left row are given only for clarity.

B.3.1 Evaluation of the measurement results

The measurement results are analyzed as follows.

a) Determination of the pairs of values x_i, y_i:

$$x_i = \frac{\alpha_{1i} + \alpha_{2i}}{2} \text{ and } y_i = \beta_i \ (i = 1 \ldots N)$$

b) Entry of the pairs of values into the regression diagram:

$y_i(x_i)$ $(i = 1 \ldots N)$

c) Calculation of the regression equation and tolerance limits (B.2.2) for the individual values y_i and their entry into the regression diagram.

Due to the almost linear shape of the tolerance limits in the pressure range between 0 mmHg and about 35 mmHg, it is sufficient to calculate in this range the standard deviation s_i of the individual values y_i from the regression curve $y(x)$.

d) Comparison of the results with the standard values. According to B.2.2, 5 % of all measured values at most may lie outside the tolerance zone.

When the standard deviation is calculated, it should not exceed s = 2,5 mmHg.

B.3.2 Prerequisites for comparison measurements

When comparison measurements are carried out, the following prerequisites should be satisfied:

a) The patient shall not change his/her body posture throughout. It follows therefore, that a tonometer designed for use on supine patients should not be compared with a reference tonometer designed for measurements on sitting patients and vice versa. Further, the patient shall not stand up to change his place between the individual measurements.

b) Three measurements according to a predetermined scheme shall be carried out on each eye. The sequence in which the two observers carry out the measurements is fixed by a randomized procedure (see table B.1).

c) The lower limiting value for the number of pairs of values $N(x_i, y_i; i = 1 \ldots N)$ is N_{min} = 80. It is determined on the basis of a statistical method [15].

d) Both eyes of a patient can be included in the measuring process. They should be considered as being independent of each other.

Annex C
(informative)

Verification of mechanical and mechanical-electrical impression tonometers [8], [9] and [10]

C.1 Apparatus

C.1.1 Balance for determination of the mass of the tonometer without handle, effective mass of the plunger loaded by the lever-pointer system and determination of plunger displacement (transmission ratio), having a sensitivity of 0,01 g per scale division.

C.1.2 Analytical balance for examination of the additional weights reading 7,5, 10,0 and 15,0, having a sensitivity of 0,002 g per scale division.

C.1.3 Equipment for testing friction between plunger and plunger sleeve.

C.1.4 Equipment for testing curvature of the spherical front surfaces of footplate and plunger.

C.1.5 Equipment for testing transition circle (central area), including an optical limit gauge consisting of two lines whose distance from each other corresponds to the permitted dimensional tolerance limits for the transition circle specified in 4.1.4 or 4.2.4 (table 1).

C.1.6 Projector, with magnification × 50, and optical limit gauge consisting of two circle sectors, the radii of which correspond to the permitted dimensional tolerance limits for the radius of the plunger edge curvature specified in 4.1.4 or 4.2.4 (table 2).

C.1.7 Micrometer, with support, and with a measuring range at least from 0 to 15 mm, reading to 0,01 mm, for testing the diameter of the footplate and the diameter of the plunger at the front surface.

C.1.8 Limit gauges.

C.1.8.1 Limit gauge, disc-shaped, for testing the outside diameter of the spherical front surface of the footplate.

C.1.8.2 Limit gauge, consisting of a thin circular disc with a radius of 14,75 mm and a radial slot approximately 3,0 mm wide and having a depth corresponding to the permitted dimensional tolerance limit for the extension of the plunger below the footplate specified in 4.1.4 or 4.2.4 (table 2).

C.1.8.3 Limit gauge, consisting of a glass plate marked with a standard line the width of which is equal to the permitted maximum width of dividing lines on the scale specified in 4.1.7 and 4.2.7.

C.1.8.4 Slip gauge, manufactured to the permitted maximum limit for the pointer distance from the scale specified in 4.1.8.

C.1.9 Test spheres, having a radius of curvature of 14,75 mm or 16 mm ± 0,003 mm.

C.1.10 Cylindrical measuring gauge, having a diameter of 3,0 mm ± 0,002 mm, for testing the diameter of the bore or counterbore.

C.1.11 Cylindrical measuring gauge, the diameter of which is slightly smaller than the diameter of the tonometer bore with the plunger removed.

C.2 Verification procedures

C.2.1 Effective weight of the plunger loaded by the lever-pointer system (see figure C.1)

Place the desired test weight of 5,5 g on the balance pan (2) and place the tonometer to be tested in the receiving device (4) rigidly fastened to a slide (3). The tonometer centres itself; i.e. the measuring point, which on the right side is located vertically on the balance beam (1), shall align with the axis of the plunger. Then adjust the pointer to scale division line “5” or “10” by respectively lowering or lifting the slide in the guideway (6) with the aid of measuring screw (5), which in this case serves for moving the slide only.

The tonometer complies with the requirement as regards effective weight, specified in 4.1.1 or 4.2.1, if the reference point (8) found on the eyepiece scale of the measuring microscope (7) lies within the corresponding tolerance zone.

C.2.2 Displacement of the plunger (transmission ratio) (see figure C.1)

Insert the tonometer in the same position as described in C.2.1. Adjust scale division line “–1” on the measuring screw (5) to the reference mark, and load the balance pan (2) with a 16,5 g test weight, whereby the balance beam is tensionally connected to the fine-adjusting knurled-head screw (9). Adjust the reading of the tonometer to scale division line “–1” with the aid of the knurled-head screw. Adjustment of the tonometer pointer to the division lines to be tested is obtained by turning the measuring screw; each time, the location of the reference point of the measuring screw (5) with regard to the corresponding tolerance zones on the drum shall be observed.

The observed values shall comply with the requirements specified in 4.1.7 and/or 4.2.7.

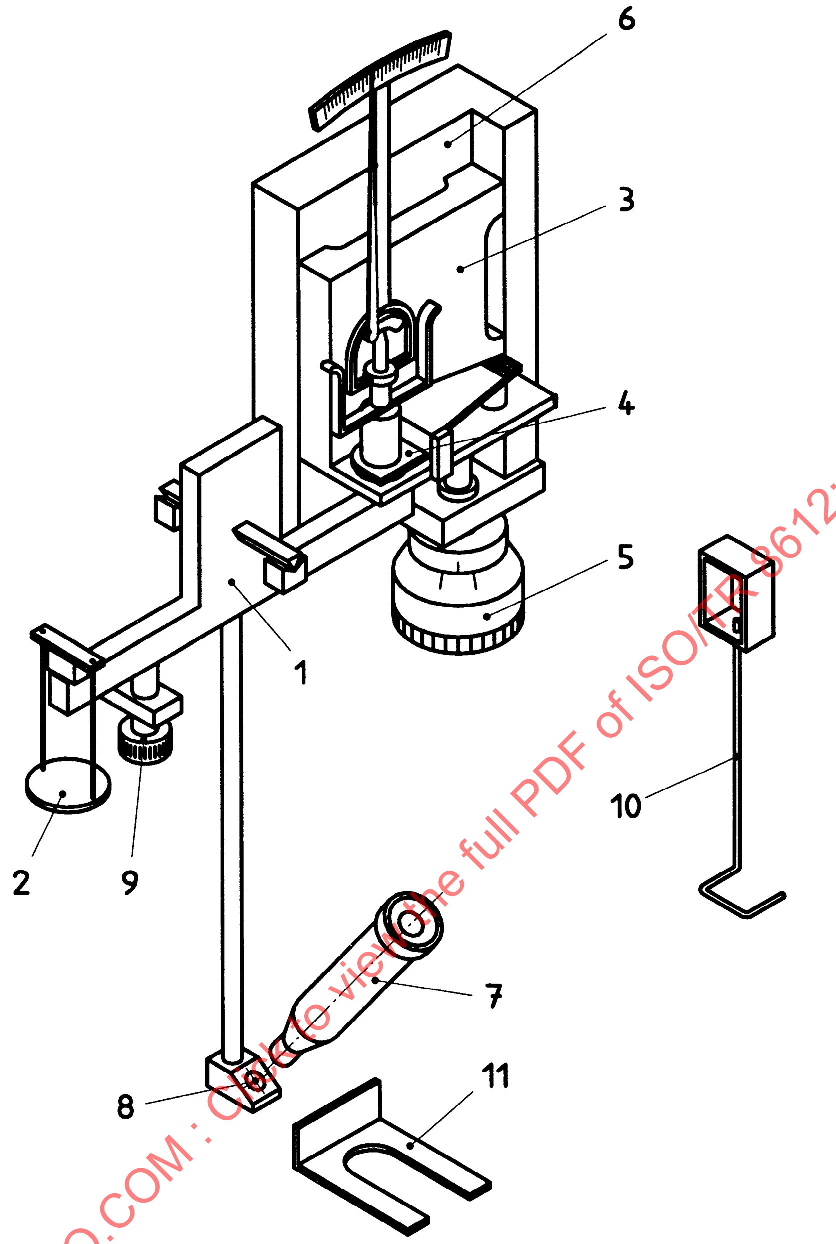
C.2.3 Mass of the tonometer (without handle) (see figure C.1)

Lift the slide (3) of the balance (B.1.1). Place a hook (10) on the measuring point of the beam of the balance, the mass of which is compensated by an additional test mass underneath the balance pan (2). Suspend the tonometer on the hook, whereby its handle is lifted as far as the middle of its free motion by the fork (11). Place the 16,5 g test mass on the balance pan (2).

The tonometer complies with the requirement regarding to its mass, specified in 4.1.2 or 4.2.2, if the reference point (8) lies within the corresponding tolerance zone on the eyepiece scale of the measuring microscope (7).

C.2.4 Additional weights

Additional weights shall be checked by comparison with standard weights on an analytical balance (C.1.2) or an electronic balance. The values shall comply with the requirements specified in 4.1.2 or 4.2.2.



Key

1 Balance beam
2 Balance pan
3 Slide
4 Receiving device
5 Measuring screw
6 Guideway
7 Microscope
8 Reference point
9 Knurled-head screw
10 Hook
11 Fork

Figure C.1 — Arrangement for verifying effective weight of the plunger loaded by lever-pointer system, displacement of the plunger and mass of tonometer (without handle)

C.2.5 Friction between plunger and plunger sleeve

Insert the tonometer into the measuring apparatus (C.1.3; see figure C.2) by its guide tube, and restrain its lever so that it does not touch the plunger during the movement. After removing the plunger as far as the upper limit stop, or 4 mm in the case of the mechanical-electrical impression tonometer, bring the tonometer from the horizontal position into the vertical position.

Repeat the test, but begin the movement from the opposite horizontal position.

The tonometer complies with the requirement specified in 4.1.3 or 4.2.3 if the plunger starts sliding before the angle specified in 4.1.3 or 4.2.3 is reached.

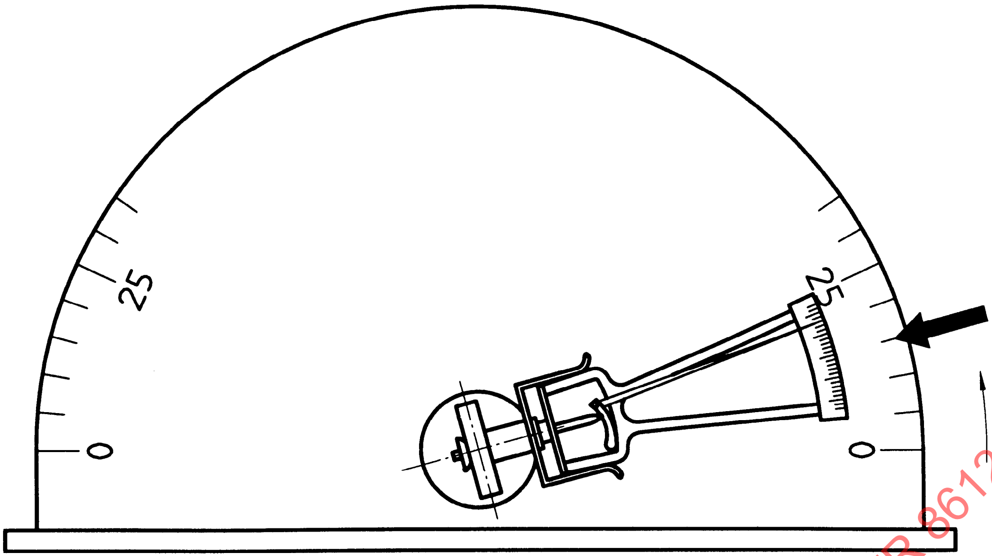


Figure C.2 — Measuring apparatus for testing friction between plunger and plunger sleeve

C.2.6 Radii of curvature of the front surfaces of footplate and plunger (see figure C.3)

Suspend the tonometer (9) on the receiver (5). Adjust the measuring disc support (2) so that the desired limit gauge (3) is down, and lift the slide (4) by turning the eccentric (6) until the gauge presses on the footplate under its own mass. The shape of the light slit (8) between gauge and footplate [see figure C.4 a)] is a sensitive indicator of whether or not the radius of curvature of the footplate is inside or outside the dimensional requirements specified in table 1.

NOTE — A stop incorporated in the apparatus allows the slide to move only if a measuring disc is down; thus possible damage to the measuring discs by improper handling of the appliance is avoided.

If the curvature radius of the plunger front surface is to be tested, hold the plunger in position of maximum extension under the footplate and repeat the procedure given above [see figure C.4 b)].

The tonometer complies with the dimensional requirements specified in 4.1.4 or 4.2.4 if the observed values indicated by the shape of the light slit are in accordance with the tolerance limits.

C.2.7 Diameter of the transition circle (central area) d_3 (see [2], [3] and [8])

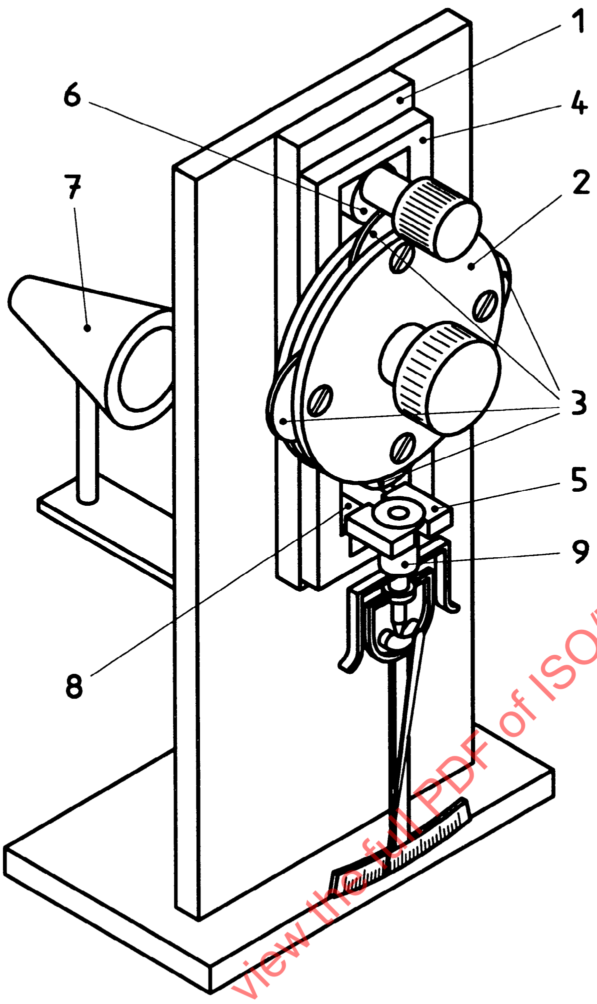
For verification of the value d_3 (see figure C.5), four test procedures, described in C.2.7.1 to C.2.7.4, are available.

C.2.7.1 Remove the plunger from the tonometer and coat the surface of the footplate with a thin film of Prussian blue. Place the footplate on the 14,75 mm radius test sphere (C.1.9) and rub this sphere against the footplate. When the footplate is removed, a bright circle can be seen. The internal part which is not tinted blue (see ISO 2495) corresponds to the "central area". Determine the diameter with the aid of an optical limit gauge (C.1.5).

C.2.7.2 By looking vertically down onto the footplate (see figure C.6) and by means of suitable illumination, determine the diameter of the transition circle with the aid of the optical limit gauge (C.1.5) placed in the micrometer eyepiece of a measuring microscope.

C.2.7.3 With the aid of special moulding plaster, make a cast of the bore or counterbore (see figure C.7). Determine the distance between the two transmission points, where the footplate curvature joins the edge curvature, by observing the silhouette and the optical limit gauge (C.1.5) in the micrometer eyepiece of the measuring microscope.

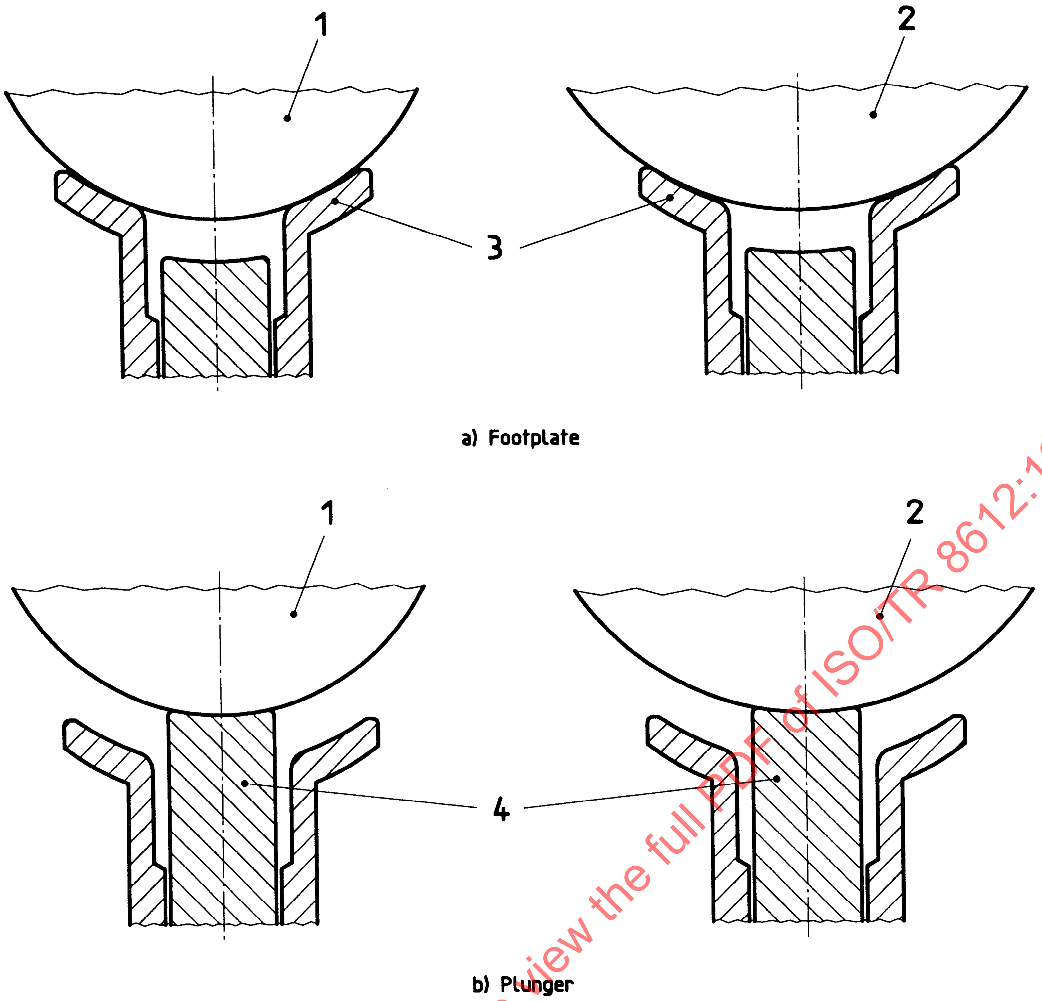
C.2.7.4 Project two lines ("dividing lines" in figure C.8) centrally onto the surface of the footplate. The distance between the lines is smaller than the diameter of the bore or counterbore. With the aid of a telescopic magnifier, examine the mirror image of the two lines and compare the diagonal distance of the marginal points, where the images of the dividing lines deviate from linearity, with the aid of the optical limit gauge (C.1.5).



Key

1 Base plate
2 Measuring disc support
3 Limit gauge
4 Slide
5 Receiver
6 Eccentric
7 Light source
8 Light slit
9 Tonometer

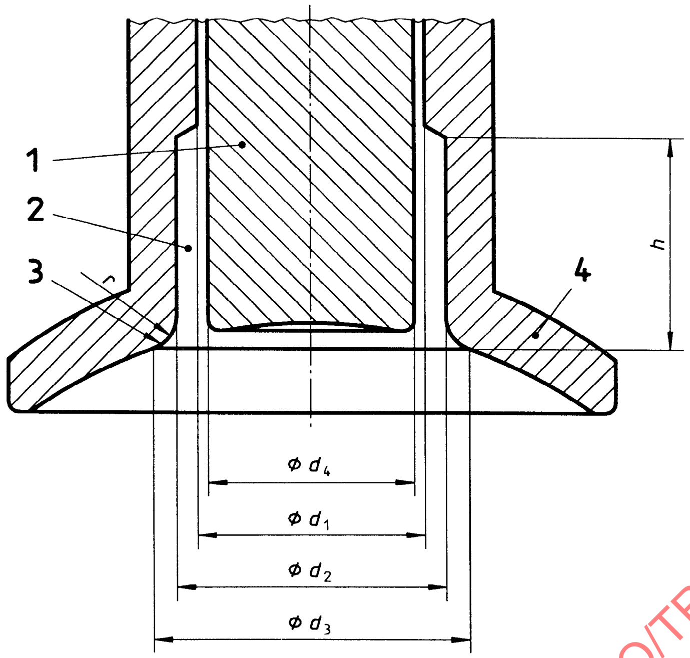
Figure C.3 — Arrangement for verifying radii of curvature of front surfaces of footplate and plunger



Key

1 Measuring disc at r_{min} (lower limit)
2 Measuring disc at r_{max} (upper limit)
3 Footplate
4 Plunger

Figure C.4 — Verification of radii of curvature of front surfaces of footplate and plunger

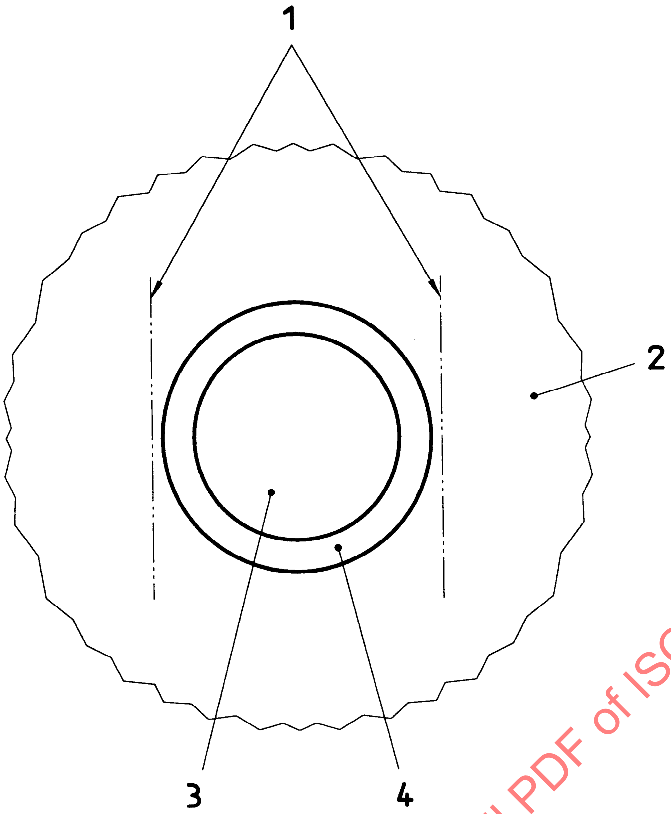


Key

1 Plunger
2 Air gap
3 Edge curvature
4 Footplate

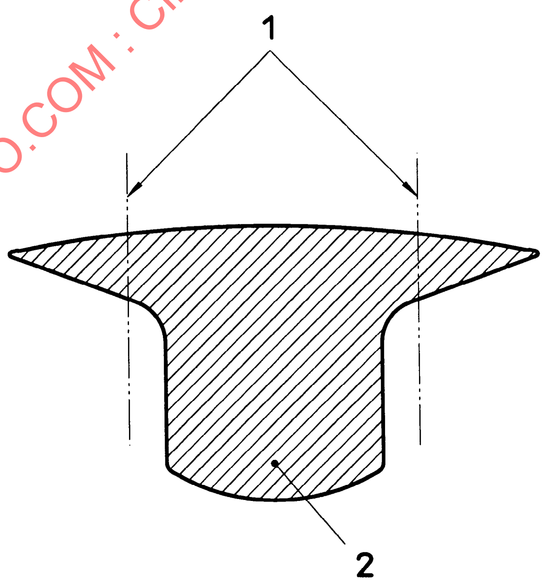
d_1: Diameter of the bore
d_2: Diameter of the bore hole
d_3: Diameter of the transition circle
d_4: Diameter of the plunger
h: Height of the bore hole
r: Radius of the inside edge curvature

Figure C.5 — Sectional drawing of footplate and plunger



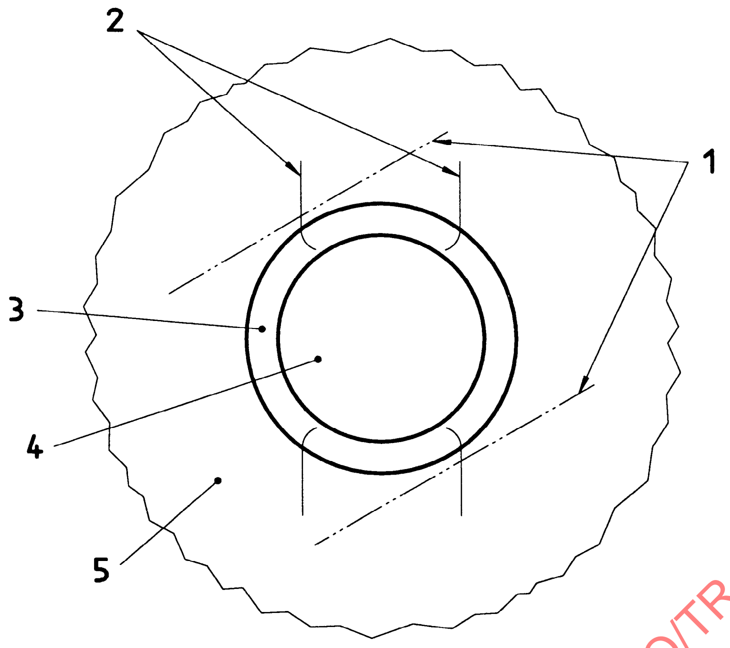
Key
1 Optical limit gauge for verifying value of d_3
2 Footplate
3 Bore hole
4 Inside edge curvature

Figure C.6 — Verification of diameter of transition circle using method described in C.2.7.2



Key
1 Optical limit gauge for verifying value of d_3
2 Silhouette of cast with special moulding plaster

Figure C.7 — Verification of diameter of transition circle using method described in C.2.7.3



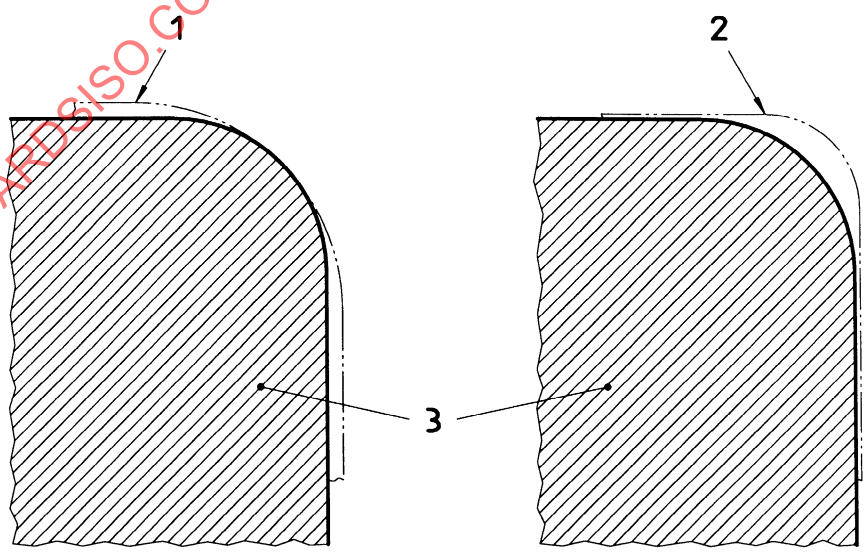
Key
1 Optical limit gauge for verifying value of d_3
2 Dividing lines
3 Inside edge curvature
4 Bore hole
5 Footplate

Figure C.8 — Verification of diameter of transition circle using method described in C.2.7.4

C.2.7.5 The tonometer complies with the dimensional requirements for the diameter of the transition circle, specified in 4.1.4 or 4.2.4, if the value of d_3 is within the permitted dimensional tolerance limits.

C.2.8 Curvature radius of edge curvature of plunger

With the aid of the projector (C.1.6), produce the silhouette of the plunger front surface side on a plane. Compare the silhouette with the optical limit gauge (C.1.6). Apply the circle sectors one after another to the silhouette of the edge curvature of the plunger so that a small slit of light is seen (see figure C.9).



Key
1 Optical limit gauge at r_{max} (upper limit)
2 Optical limit gauge at r_{min} (lower limit)
3 Silhouette of plunger

Figure C.9 — Verification of curvature radius of edge curvature of plunger

The tonometer complies with the dimensional requirements for the radius of the edge curvature of the plunger, specified in 4.1.4 or 4.2.4, only if the radius is equal to or greater than the lower limit or if it is equal to or smaller than the upper limit.

C.2.9 Diameter of plunger on the front surface side and outside diameter of footplate

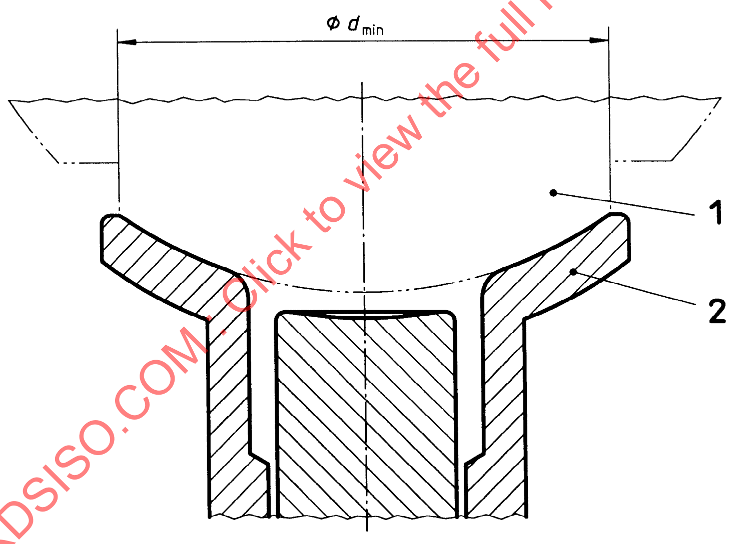
Determine the actual values for the diameter of the plunger on the front surface side and the outside diameter of the footplate with the aid of the micrometer (C.1.7) and compare with the corresponding dimensional requirements specified in 4.1.4 and 4.2.4.

The tonometer complies with the dimensional requirements specified in 4.1.4 or 4.2.4 if the actual values determined are within the permitted dimensional tolerance limits.

C.2.10 Outside diameter of spherical front surface of footplate

Compare the actual value for the outside diameter of the spherical front surface of the footplate with a circle sector of the limit gauge (C.1.8.1; see figure C.10), the width of which corresponds to the permitted minimum dimension, d_{min}. For this purpose, place the gauge perpendicularly on the front surface of the footplate in an axial plane.

The tonometer complies with the dimensional requirements specified in 4.1.4 or 4.2.4 if the outside diameter of the spherical front surface of the footplate is equal to or greater than d_{min}.



Key
1 Limit gauge set at d_{min} (minimum limit value)
2 Footplate

Figure C.10 — Verification of outside diameter of spherical front surface of footplate

C.2.11 Diameter of recess or counterbore on the front surface side

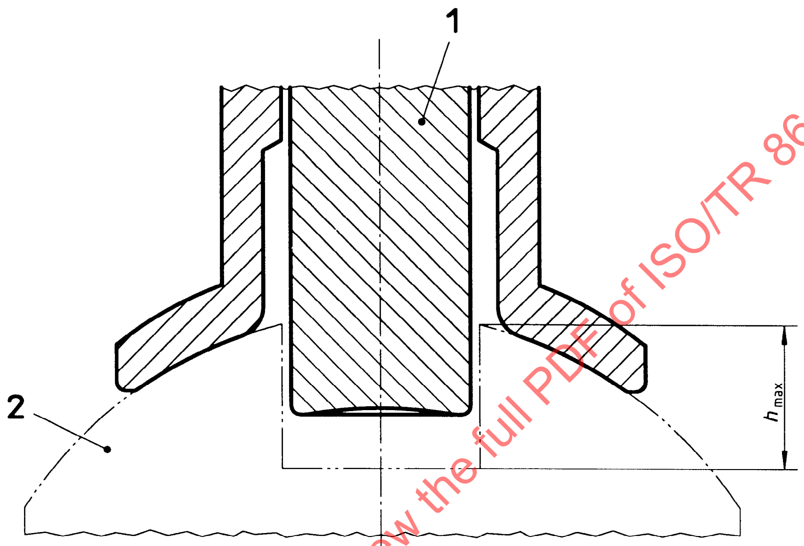
Remove the plunger from the tonometer. Test the recess or counterbore with the cylindrical measuring gauge (C.1.10), the diameter of which corresponds to the dimensional tolerance. Test the depth of the recess with the aid of a measuring gauge provided with a ring, the permitted depth value being limited by the ring and the closing surface.

The tonometer complies with the dimensional requirements specified in 4.1.4 or 4.2.4 if the measuring gauge enters without any play or does not enter the recess or counterbore, respectively, and if the depth of recess is within the dimensional tolerance limits.

C.2.12 Extension of plunger below footplate

For measuring the extension of the plunger below the footplate, place the limit gauge (C.1.8.2; see figure C.11) perpendicularly on the footplate from below in the plane of the axis, the tonometer being in an upright position.

The tonometer complies with the dimensional requirements specified in 4.1.4 or 4.2.4 if the plunger does not extend further than the maximum height limit value, h_{max}.



Key
1 Plunger
2 Limit gauge at h_{max} (maximum limit value)

Figure C.11 — Verification of extension of plunger below footplate

C.2.13 Width of the dividing lines on the scale

Check the maximum width of the lines using the limit gauge (C.1.8.3).

The tonometer complies with the requirements for the width of the dividing lines on the scale specified in 4.1.6 or 4.2.6 if the measured width is less than or equal to the width of the standard line.

C.2.14 Distance of the pointer from the scale

Test the distance of the pointer from the scale using the slip gauge (C.1.8.4).

The tonometer complies with the requirements for the distance of the pointer from the scale specified in 4.1.7 if the slip gauge can be inserted between the pointer and the scale.

C.2.15 Scale reading with the lower surface of the lever at right angles to the plunger axis at their point of contact

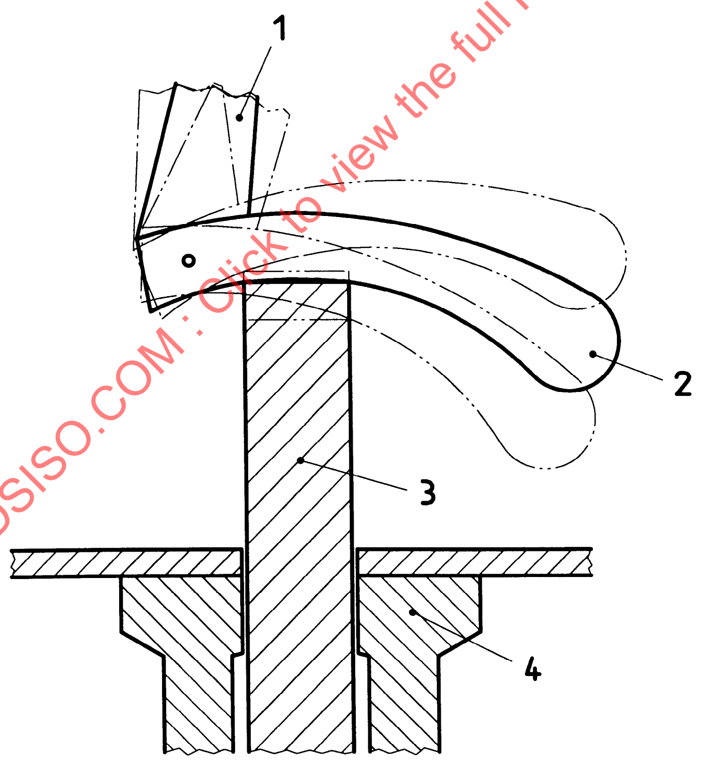
Remove the plunger from the tonometer. Insert the cylindrical measuring gauge (C.1.11) into the bore (see figure C.12) such that the lever touches both the top edges of its front surface simultaneously. Check whether the pointer moves within the permitted scale range. This test may be dispensed with in the case of tonometers whose lower plunger surface has a convex curvature towards the top (epicycloid lever) or is provided with a sphere or a knife-edge.

The tonometer complies with the requirements specified in 4.1.9 if the pointer moves within the permitted scale range at the setting specified above.

C.2.16 Scale readings on the test blocks

Assemble the tonometer under examination so that it is ready for use. Place it successively first on the test spheres (C.1.9) and then on the test block. Check to determine whether or not the indication is within the permitted tolerances.

The tonometer complies with the requirements specified in 4.1.9 or 4.2.8 if the scale readings are within the tolerance limits specified.



Key
1 Pointer
2 Lever
3 Cylindrical measuring gauge
4 Plunger sleeve

Figure C.12 — Arrangement for verifying scale readings with lower surface of lever at right angles to plunger axis at their point of contact

C.2.17 Variation of scale reading if plunger is moved or turned on the lever

Place the tonometer on the test block and move the plunger laterally backwards and forwards in the bore hole or counterbore. Then rock the lever on its bearing and finally turn the plunger round on its longitudinal axis.

The tonometer complies with the requirements specified in 4.1.9 if the scale readings do not vary by more than the permitted limits.

C.2.18 Effect of temperature on scale reading between 15 °C and 30 °C
(applicable to mechanical-electrical tonometer only)

This test should, in general, be carried out only once for each design.

With the operating voltage constant, heat the complete tonometer in a cabinet controllable within the temperature range 15 °C to 30 °C. Place the measuring head on a test sphere (C.1.9) and check the scale reading of the tonometer as the temperature is raised from 15 °C to 30 °C.

The tonometer complies with the requirements specified in 4.2.9.1 if the scale readings do not vary by more than the permitted limits.

C.2.19 Variation of reading on change of operating voltage
(applicable to mechanical-electrical tonometers)

This test should, in general, be carried out only once for each design.

With the tonometer at 20 °C ± 1 °C, place the measuring head on the test sphere (C.1.9). Vary the operating voltage by 10 % and check the scale reading of the tonometer.

The tonometer complies with the requirements specified in 4.2.9.2 if the scale readings do not vary by more than the permitted limits.

C.3 Test certificate

The results of the verification testing, carried out in accordance with this Technical Report, shall be given in a test certificate provided by the manufacturer in the countries where no legal verification is available. An example of a test certificate is illustrated on the following pages.

Test certificate for mechanical and mechanical-electrical impression tonometers
(verified in accordance with ISO/TR 8612)

Tonometer No.: ....

Sender: ....

Manufacturer: ....

Date: ....

Observer: ....

Controller: ....

Effective weight of plunger loaded by lever-pointer system:	**Requirement for nominal value:**	**Verification result:**
at scale reading “5”	(5,50 ± 0,15) g	....
at scale reading “10”	(5,50 ± 0,20) g	....
Mass of the tonometer without handle	(16,5 ± 0, 5) g	....
Additional weights:		
with inscription 7,5	(2,0 ± 0,02) g	....
with inscription 10,0	(4,5 ± 0,02) g	....
with inscription 15,0	(9,5 ± 0,02) g	....
Friction between plunger and plunger sleeve	25° max.	....
Friction between handle and handle sleeve	Does not affect movement	....
Footplate		
Diameter	(10,1 ± 0,2) mm	....
Radius of curvature of spherical front surface	(15,0 ± 0,25) mm	....
Outside diameter of spherical front surface	9,0 mm min.	....
Either		
Diameter of recess or counterbore (to a height of 1,5 mm min.) and	3,3 mm max.	....
radius of inside edge curvature	0,2 mm max.	....
or		
Diameter of transition circle (central area)	3,7 mm max.	....
Polish, surface condition, freedom from burrs	Clean, smooth, burr-free	....
Plunger		
Diameter at front surface (to a height of 1,5 mm min.)	(3,0 ± 0,03) mm	....
Radius of curvature of spherical front surface	(15,0 ± 0,7) mm	....
Radius of edge curvature	(0,25 ± 0,015) mm	....
Extension of plunger	3,0 mm max.	....
Polish, surface condition, freedom from burrs	Clean, smooth, burr-free	....

	Requirement for nominal value:	Verification result:
Displacement of plunger from scale reading:		
Either		
Scale division –1 to scale division 5	(0,30 ± 0,01) mm	....
Scale division –1 to scale division 10	(0,55 ± 0,02) mm	....
Scale division –1 to scale division 15	(0,80 ± 0,03) mm	....
Scale division –1 to scale division 18	(0,95 ± 0,05) mm	....
or		
Scale division 0 to scale division 5	(0,25 ± 0,01) mm	....
Scale division 0 to scale division 10	(0,50 ± 0,02) mm	....
Scale division 0 to scale division 15	(0,75 ± 0,03) mm	....
Scale division 0 to scale division 18	(0,90 ± 0,05) mm	....
Lines on the scale		
Straight, of equal width, directed in the axis of the pointer	—	....
Width of the lines	¼ line distance but 0,25 mm max.	....
Pointer		
Width	Width of lines, max.	....
Overlapping of the lines	1/3 min; not exceeded	....
Distance from the scale	1 mm max.	....
Angle between plunger and lever		
90° at scale reading between scale division "5" and "10"		....
Scale reading		
— tested on test sphere with radius 14,75 mm	–1 ± 0,2 scale division	....
	or	
	–1,0 ± 0,2 digital[1)]	....
— tested on test sphere with radius 16,00 mm	0,0 ± 0,2 scale division	....
	or	
	0,0 ± 0,2 digital[1)]	....
— tested on test blocks enclosed with radius 16,00 mm	0,0 ± 0,2 scale division	....
	or	
	0,0 ± 0,2 digital[1)]	....

1) As indicated by the final digits.

	Requirement for nominal value:	Verification result:
Variation of scale reading, if the tonometer is standing on the test sphere		
— with movement and turning of the plunger and movement of the lever	0,4 scale division	....
— with lateral movement and turning of the plunger	0,2 scale division	....
Electrical impression tonometer		
— with movement and turning of the plunger	0,2 scale division	....
	or	
	0,2 digital[1)]	....
— tested on test block marked 15,0	15,0 ± 0,2 scale division	....
	or	
	15,0 ± 0,2 digital[1)]	....
— with temperature varying between 15 °C and 30 °C (at constant operating voltage)	0,2 scale division	....
	or	
	0,2 digital[1)]	....
— with operating voltage fluctuating ± 10 % (at constant temperature)	0,2 scale division	....
	or	
	0,2 digital[1)]	....

Remarks: ....

....

....

Result: Verified .... Not verified.. Signature: ....

1) As indicated by the final digits.

Annex D
(informative)

Verification of mechanical-optical applanation tonometers having a constant diameter applanation circle [2], [8], [14], [17]

D.1 Apparatus

D.1.1 Optical limit gauge, for testing the diameter of the applanation circle, consisting of two pairs of lines; the distances between the lines of each pair correspond to the upper and lower permitted tolerance limits specified in 4.3.1. A dotted line traverses their midpoints (see figure D.1).

D.1.2 Balance, for testing the measuring force, the reverse span at the transitional movement of the pressure body into the opposite direction, and for checking the position of the measuring arm with reference to its free space of movement at equilibrium of forces. The sensitivity of the balance shall be 0,01 g per scale division.

D.2 Verification procedures

D.2.1 Diameter of the applanation circle

Substitute the optical limit gauge (D.1.1) for the examined eye. Place the dividing line due to the prisms so as to coincide with a dotted line. For a pressure body without doubling prisms, determine the applanation circle diameter by means of a lined square that is verified directly by comparison with the optical gauge.

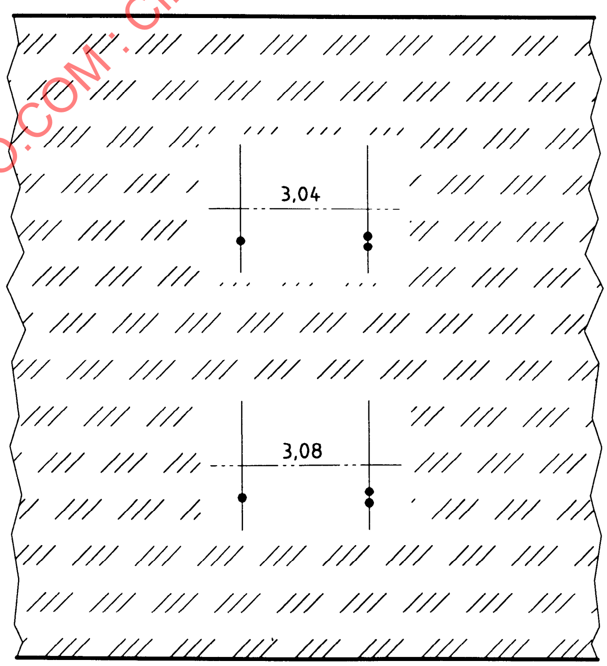


Figure D.1 — Optical limit gauge for verifying the diameter of the applanation circle
(in this case set for a value of 3,06 mm)

The tonometer complies with the tolerance requirements specified in 4.3.1 if the transposed line halves coincide or the transposed half-line for the lower tolerance limit is outside the upper scale interval or inside the upper scale interval for the upper tolerance limit (see figure D.2).

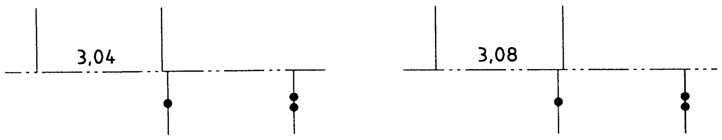


Figure D.2 — Verification of tolerance limits for the diameter of the applanation circle
(in this case having a value of 3,06 mm)

D.2.2 Measuring force, reverse span and central position of the tonometer arm

In order to test the measuring force, place the applanation tonometer on the balance (1) (D.1.2) with the aid of a suitable holding device (see figure D.3). To ensure that the contact between the applanation tonometer pressure body and the small contact wheel (6) of the balance is caused by the tonometer spring, place a mass of 0,5 g on the balance pan (2) and adjust the measuring force of the tonometer correspondingly. Then adjust the symmetric regulation of the tonometer arm amplitude using the three-coordinate fine adjustment. Check the adjustment by observing the position of the pointer (3) with reference to the zero index mark (4), deflecting the arm as far as both limits.

The adjustment of the contact point between the front surface of the pressure body and the small pivoted contact wheel follows the same principle, so that contact is located in the centre of the applanation surface. The contact point can be made visible by using a very small drop of thin oil, as shown in figure D.4.

Successively place weights in steps of 1 g on the balance from 1 g up to the maximum load. Increase the measuring force of the tonometer as the weights are added to the balance until the pointer again coincides with the zero index mark.

Then carry out the test starting with the maximum mass and with the tonometer measuring force being decreased.

Adjusting and checking of the applanation tonometer shall be carried out using a low-vibration device.

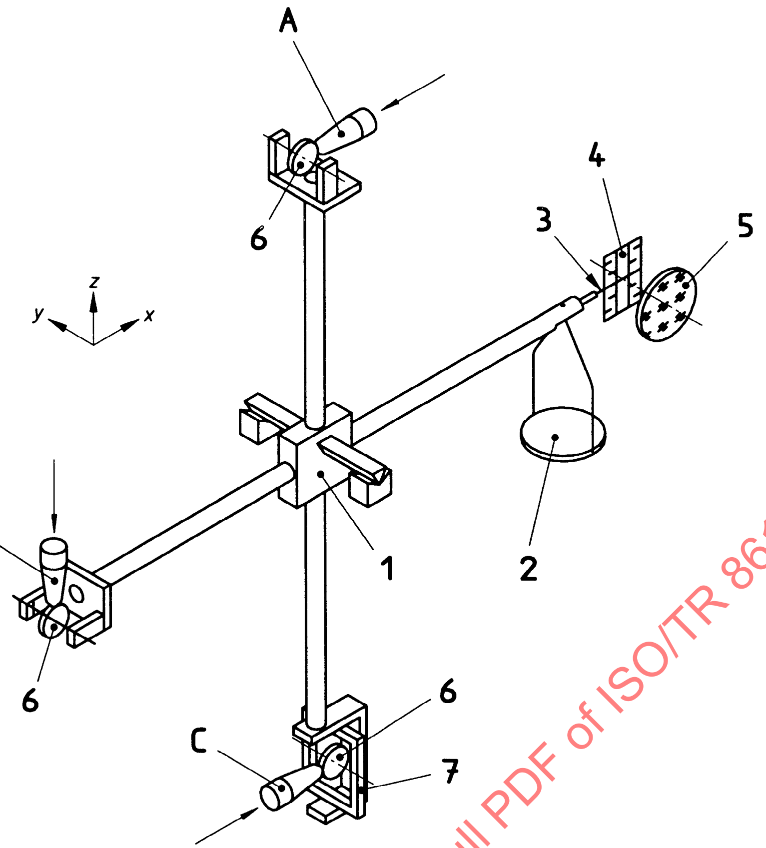
The reverse span at the transition of the movement of the pressure body into the opposite direction is necessary due to the difference in the correlated measuring values of the increasing, as compared with the decreasing, measuring forces.

The tonometer complies with the requirements specified in 4.3.3 and 4.3.5 if the deviations of the various values of the measuring force, as read on the tonometer scale, from the theoretical values do not exceed the permitted tolerance values and if the change of force required to move the pressure body in the reverse direction (reverse span) does not exceed the value specified in 4.3.3.

D.2.3 Width of the lines on the measuring drum

Check the width of the lines using the limit gauge (D.1.3).

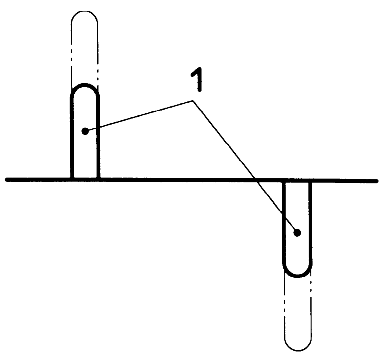
The tonometer complies with the requirements specified in 4.3.4 if the measured width is less than or equal to the width of the standard line.



Key

1 Balance
2 Balance pan
3 Pointer
4 Zero index
5 Magnifying lens
6 Contact wheel
7 Gimbal suspension
A to C Pressure bodies at different testing directions

Figure D.3 — Arrangement for verifying the measuring force



Key

1 Oil droplet

Figure D.4 — Oil droplet used to make contact point visible