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Ophthalmic optics — Contact lenses — Tolerances and methods for measurement of multifocal contact lens addition power

Optique ophtalmique — Lentilles de contact — Tolérances et méthodes de mesure de la puissance additionnelle des lentilles de contact multifocales

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Contents

Page

Foreword ... **iv**

1 Scope ... **1**

2 Normative references ... **1**

3 Terms and definitions ... **1**

4 Tolerances ... **2**
- 4.1 Tolerance limits ... 2
- 4.2 Conditioning of contact lenses prior to testing ... 2
- 4.3 Tolerances for rigid and soft contact lenses ... 3

5 Methods of measurement for multifocal add power ... **3**
- 5.1 General ... 3
- 5.2 Wavefront sensor ... 3
  - 5.2.1 Wavefront instrument specification ... 3
  - 5.2.2 Wavefront calibration ... 3
  - 5.2.3 Wavefront method of measurement ... 4
  - 5.2.4 Power profile examples ... 4
  - 5.2.5 Bifocal contact lens ... 6
- 5.3 Focimeter ... 7
  - 5.3.1 Principle ... 7
  - 5.3.2 Focimeter specification ... 8
  - 5.3.3 Focimeter calibration ... 9
  - 5.3.4 Measurement of most plus and least plus power ... 9

6 Ring test results ... **10**
- 6.1 Ring test objectives ... 10
- 6.2 Ring test background ... 10
- 6.3 Ring test executive summary ... 11
  - 6.3.1 WFS calibration verification using (13) certified low-power glass lenses ... 11
  - 6.3.2 Focimeter calibration verification using (10) standard B+L calibration lenses ... 12
  - 6.3.3 WFS gauge repeatability and reproducibility (GR&R) using PV2 MF HA lenses ... 12
  - 6.3.4 Focimeter gauge repeatability and reproducibility (GR&R) using PV2 MF HA lenses ... 12
- 6.4 Calibration lens accuracy requirements ... 12
  - 6.4.1 Focimeters ... 13
  - 6.4.2 Wavefront sensor low-power lenses ... 13

7 Discussion ... **15**
- 7.1 Ring test conclusions ... 15
- 7.2 Ring test recommendations ... 15
- 7.3 Multifocal add-power measurement challenges ... 15
  - 7.3.1 Immersed wavefront sensor measurement challenges ... 15
  - 7.3.2 In-air wavefront sensor measurement challenges ... 18
- 7.4 Questions to answer before the TS moves to become a standard ... 18

Bibliography ... **20**

Foreword

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This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

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Ophthalmic optics — Contact lenses — Tolerances and methods for measurement of multifocal contact lens addition power

1 Scope

This document specifies proposals for the tolerances and methods for measuring the base and add power of refractive/symmetric multifocal contact lenses. This document is not intended to measure current production lenses (or similar) and does not include measurement of diffractive multifocal contact lenses nor the measurement of distance (or label) power.

This document is intended to obtain additional feedback from clinicians, manufacturers, and health authorities on the proposals for tolerances and test methods. This document is not intended to be used in any quality system or by any governing body to control the manufacturing or acceptance of contact lenses.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9342-1, *Optics and optical instruments — Test lenses for calibration of focimeters — Part 1: Reference lenses for focimeters used for measuring spectacle lenses*

ISO 18369-3:2017, *Ophthalmic optics — Contact lenses — Part 3: Measurement methods*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
power map
localized radial back vertex power (in-air) as a function of two- dimensional coordinates from the centre of the lens

3.2
power profile
one-dimensional localized optical power as a function of radial distance from the centre of the lens as derived from the power map, thereby creating the power-map equivalent of a power profile

3.3
average most plus power
area-weighted average power across an annular zone corresponding to the most plus region of a progressive optical zone

3.4
average least plus power
base power
area-weighted average power across an annular zone corresponding to the least plus region of a progressive optical zone

3.5
distance power
label power
power, determined clinically, to produce the best distance vision

Note 1 to entry: The distance power may not equal the measured base power. In this case, a regression will be required to determine the distance power from the base power. Clinicians should contact the manufacturer's Professional Services for the regression(s).

3.6
measure add power
difference between the average most plus and average least plus power of the contact lens

Note 1 to entry: The average most plus and least plus powers are measured over optical zones provided by the manufacturer.

3.7
label add power
the clinically determined add power of the multifocal contact lens

Note 1 to entry: The label add power may not equal the measured add power. A regression may be required to determine the label add power from the measured add power.

3.8
localized radial back vertex power

$$P(r)=\frac{1}{r}\frac{\partial W(r,\theta)}{\partial r}$$

where $W(r, \theta)$ is the measured wavefront

Note 1 to entry: The definition of associated terms, such as bifocal or progressive contact lens, can be found in ISO 18369-1.

4 Tolerances

4.1 Tolerance limits

When tested as specified in ISO 18369-3, the dimensional and optical properties for multifocal contact lenses addition power (or add power) shall be as specified within the appropriate tolerance lines given in Table 1 and Table 2.

The proposed add power tolerance is based on a variety of sources, including the results of the ring testing discussed in this specification, guidance found in the national standard ANSI Z80.20-2016, the combined statistical nature of how add power is computed as a difference and the 0,25 D tolerance on spherical power, and feedback from clinicians and manufacturers.

4.2 Conditioning of contact lenses prior to testing

Contact lenses shall be equilibrated in standard saline or packing solution, unless otherwise specified in the relevant test methods specified in ISO 18369-3.

4.3 Tolerances for rigid and soft contact lenses

Optical tolerances for rigid and soft contact lenses are given in Table 1 and Table 2.

Table 1 — Optical tolerances for rigid contact lenses

Dimension	Tolerance limit	Relevant method
Multifocal add power	±0,38 D	5.2 or 5.3

Table 2 — Optical tolerances for soft contact lenses

Dimension	Tolerance limit	Relevant method
Multifocal add power	±0,38 D	5.2 or 5.3

5 Methods of measurement for multifocal add power

5.1 General

Prescribing multifocal contact lenses requires clinicians to consider the user's pupil diameter, how the lens conforms to the user's cornea, how the lens centres on the cornea, the inherent aberrations of the user's eye, how the user processes the variable optical power across their pupil, excess visual function, and the unique optical design of the multifocal lens as reflected in the manufacturers' fitting guides. Accounting for these design and manufacturing specificities and clinical practices, the exact labelled distance and add powers may exist over different regions of the contact lens for different designs. A regression equation, provided by the manufacturer, may be required to determine the label distance and label add power. The process of determining these regressions will vary with manufacturers. Regressions created using a focimeter or a wavefront sensor may be different.

5.2 Wavefront sensor

5.2.1 Wavefront instrument specification

The optical wavefront over the relevant optical zone shall be measured using an accurate and precise wavefront sensor (e.g. Shack Hartmann, Moiré deflectometer, phase-shifting Schlieren deflectometer, or other types of interferometers). The wavefront sensor (WFS) shall produce power profiles of the contact lens under test. In addition, the wavefront sensor shall be capable of outputting the average optical power over user-defined regions.

A key specification for any wavefront method is the converting of immersed effective power to in-air back vertex power. As described in 7.3.1.3, there are three recognized methods for this conversion.

5.2.2 Wavefront calibration

5.2.2.1 Wavefront calibration in-air

Calibration should be completed with calibration test pieces, known as test standards, with known nominal values. Calibration should occur with the test standards in-air. Minimum requirements for this purpose include four plus lenses and four minus lenses to cover the power ranges of the contact lenses to be measured. Consideration should be given to matching the range of test standards to the range of lenses and the intended test condition (in-air or immersed). Test standards shall be placed in calibrated cuvettes, as shown in Figure 1. Refer to 6.4.2 for additional information.

Calibration shall follow the steps outlined in ISO 18369-3:2017, Annex B, including following the manufacturer's instructions to calibrate the instrument.

NOTE Be careful to check with the manufacturer for the correct contact lens orientation for back vertex power measurement.

It is recommended to plot the power deviation versus the nominal standard power to better understand the shape (or form) of any bias.

5.2.2.2 Wavefront verification in-solution

5.2.3 Wavefront method of measurement

The following steps, given in Table 3, shall be followed to determine the base power and measured add power of refractive multifocal contact lenses.

Table 3 — Steps to determine the base power and measured add power of refractive multifocal contact lenses

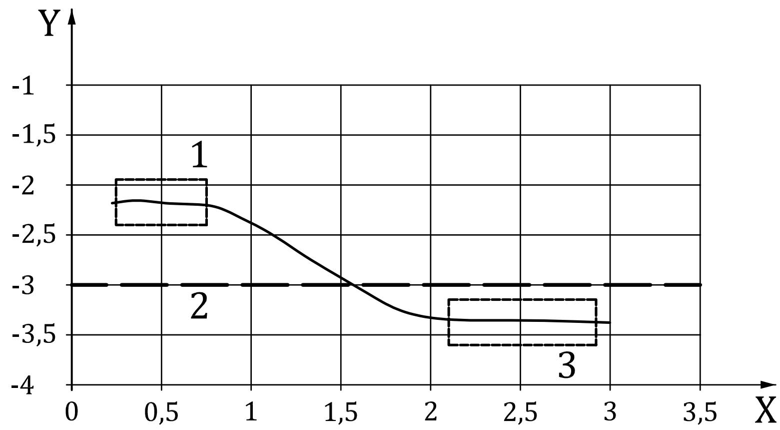
Step	Action
1	Measure the wavefront over the relevant optics zone using an accurate and precise wavefront sensor (e.g. Shack Hartmann, Moiré deflectometer, phase-shifting Schlieren deflectometer, other types of interferometers).
2	The manufacturer specifies two or more annular regions that will be used to determine the a) average most plus power, and b) average least plus power of the multifocal contact lens. Generally, the zones shall be as wide as possible to improve averaging but narrow enough to cover only the region of interest. The manufacturer shall provide, via professional services, the positions of the most plus and least plus annular zones.
3	Determine the average power over each region using the power profile or power map data derived from the measured optical wavefront.
4	The add power is the absolute value of the difference between the average most plus and average least plus powers. If necessary, a regression may be applied to correlate the measured add power with the label add power. If required, the manufacturer shall provide the regression formula, via Professional Services, to determine the label add power.
NOTE 1 The measured add power is a metric derived the power profile; and the measured add power may be different from the labeled add or the value listed in the fitting guide. NOTE 2 Additional independent average powers may need to be taken to meet ISO 18369-3 guidance for precision.	

5.2.4 Power profile examples

In the following examples, the location of the label power relative to the power profile does not equal the average Most Plus Power. The shape of the power profile is a degree of freedom for the manufacturer.

5.2.4.1 Centre-near progressive

Figure 1 shows the power profile of a centre-near, progressive multifocal contact lens. In this case the most and least plus zones are chosen to ensure the power does not change appreciably over each zone, but still contains the profile region of interest.



Key

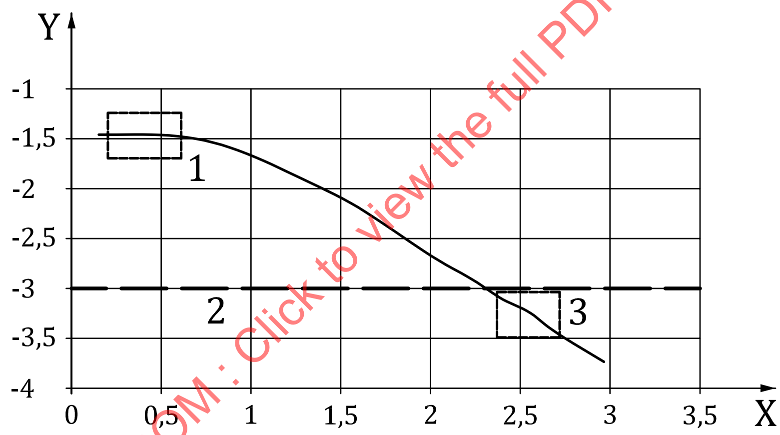
1 most plus

2 label power

3 least plus

Figure 1 — Example 1 power profile

Figure 2 shows a second example of a centre-near progressive contact lens.



Key

1 most plus

2 label power

3 least plus

Figure 2 — Example 2 power profile

5.2.4.2 Centre-distance progressive

Figure 3 shows the power profile of a centre-distance contact lens.

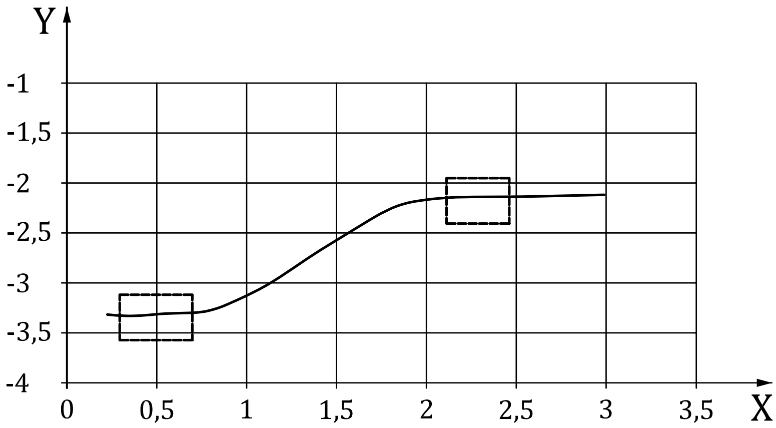
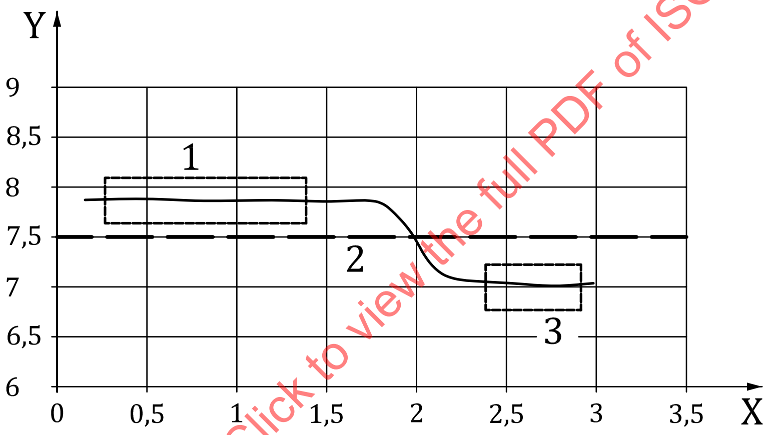


Figure 3 — Example 3 power profile

5.2.5 Bifocal contact lens

Figure 4 shows the measured power profiles for a centre-near, bifocal contact lens.



Key

1 most plus

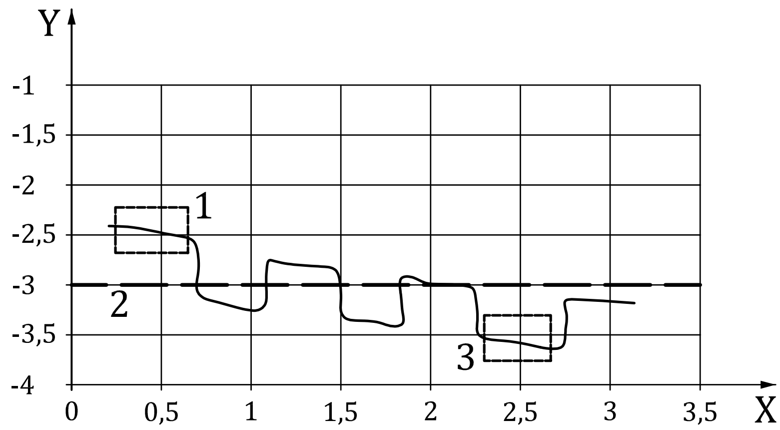
2 label power

3 least plus

Figure 4 — Centre-near, bifocal contact lens

5.2.5.1 Multi-Zone, bifocal contact lens

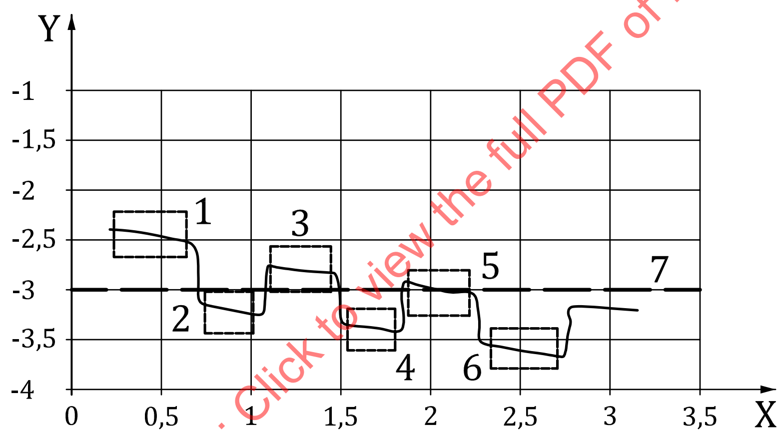
Figures 5 and 6 show the power profiles for a multi-zone, bifocal contact lens. In Figure 5, single most-plus and least-plus zones are defined, whereas in Figure 6, three most-plus and least-plus zones are defined. For Figure 6, the least-plus power would be the average of the power in the three bottom zones. The most-plus power would be the average of the three top zones.



Key

1 most plus
2 label power
3 least plus

Figure 5 — Multi-zone, bifocal power profile with two defined regions



Key

1 most plus 1
2 least plus 1
3 most plus 2
4 least plus 2
5 most plus 3
6 least plus 3
7 label power

Figure 6 — Multi-zone, bifocal power profile with six defined regions

5.3 Focimeter

5.3.1 Principle

A manually-focusing focimeter may be used to measure the most plus power and least plus power of a multifocal contact lens via the use of lens supports with various aperture geometries. The determination of such lens supports requires knowledge of the optical zones provided by the manufacturer. The manufacturer shall provide, via professional services, the positions of the most plus and least plus annular zones. The location and width of the focimeter aperture shall be chosen to correspond with the location of the most plus and least plus powers for each lens design. Multiple apertures may be required to measure add power across the desired power range.

5.3.2 Focimeter specification

5.3.2.1 Focimeter

The focimeter shall have a minimum range of -20,00 D to +20,00 D with a minimum measuring accuracy of ±0,06 D, and capable of manual focusing. Other focimeters may be used provided the readings derived are shown to be equivalent to those of a manually-focusing focimeter. A focimeter conforming to ISO 8598-1 can be used.

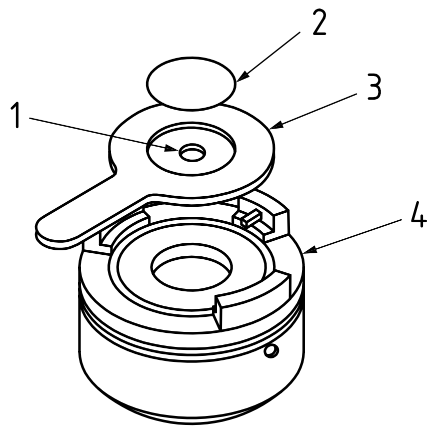
5.3.2.2 Focimeter lens supports/apertures

Focimeter supports allow for centration of the contact lens optic zone around the optical axis of the focimeter, correct placement of the contact lens back vertex relative to the measurement plane of the focimeter and transmission of light through a defined aperture geometry.

The supports and fixtures detailed in Figures 7 and 8 show one design type for such lens supports. Other support configurations can also be utilized (such as supports designed like ISO 18369-3:2017, 4.3.2.2).

Figure 7 shows three lens paddles with different aperture geometries. Figure 8 shows an adjustable paddle fixture that centres the paddles relative to the focimeter and allows for z-height adjustment.

Figure 7 — Picture of three annular aperture paddles



Key

1 aperture
2 contact lens
3 paddle
4 adjustable paddle stage

Figure 8 — Diagram of adjustable paddle stage, paddle and contact lens

5.3.3 Focimeter calibration

Instrument calibration shall be carried out to assure measuring accuracy to known standards using spherical test lenses with minimal spherical aberration as specified in ISO 9342-1. The label back vertex power of the calibration lenses shall be spaced to determine the measuring accuracy over a broad range of label back vertex powers. Minimum requirements for this purpose include four plus lenses and four minus lenses to cover the power range of the focimeter, e.g. −5,00 D; −10,00 D; −15,00 D; −20,00 D; +5,00 D; +10,00 D; +15,00 D; and +20,00 D. The actual back vertex powers of these test lenses shall be traceable to a national or International Standard. The certification error for these standards should be within ±0,03 D.

During the calibration, maintain the focimeter, lens support and lenses at a temperature of 20 °C to 25 °C.

Place each test lens centrally with its back surface against the appropriate lens stop and focus the focimeter to obtain the clearest possible image. Record the focimeter reading to the nearest 0,06 D or less. Take three independent readings and record the arithmetic mean. Differences between calculated and actual label back vertex power shall be used to construct a correction calibration curve, if the results fail to meet the calibration accuracy criteria.

NOTE The term “independent” means that the test lens is removed from the instrument and remounted between each reading.

5.3.4 Measurement of most plus and least plus power

A measurement of the most plus power and a measurement of the least plus power shall be undertaken.

Multiple independent readings may be taken to minimize measurement error. Alternate measurements between most plus and least plus powers when taking multiple readings to ensure consistency.

When measuring multiple times, take care that the lens is not distorted or damaged. Also, note the order of multiple measurements to confirm that there is no measurement trend that may be the result of lens distortion or damage.

5.3.4.1 Focimeter measurement of rigid lenses

Before making the measurement, rigid lenses shall be maintained at a temperature of 20 °C to 25 °C for at least 30 min.

Place the contact lens support for measurement of the most plus power onto the focimeter.

During the measurement, maintain the focimeter and contact lens support at a temperature of 20 °C to 25 °C.

Place the contact lens onto the contact lens support to properly position the back vertex and align the contact lens optic with the focimeter optical axis. It is important that the lens surfaces are clean and free of debris or solution.

Focus the focimeter to find the best image for the most plus power of the contact lens.

NOTE The progressive nature of multifocal contact lenses requires identifying the centre of the best focus region.

Repeat this process using the contact lens support for the least plus power of the contact lens.

5.3.4.2 Focimeter measurement of soft contact lenses

Equilibrate the soft contact lenses, see ISO 18369-1:2017, 3.1.1.21.

Place the contact lens support for measurement of the most plus power onto the focimeter.

During the measurement, maintain the focimeter and contact lens support at a temperature of 20 °C to 25 °C.

Blot the lens with a lint-free absorbent cloth or filter paper to remove surface liquid, then place it upon the contact lens support within 10 s to properly position the back vertex and align the contact lens optic with the focimeter optical axis.

Focus the focimeter to find the best image for the most plus power of the contact lens.

NOTE The progressive nature of multifocal contact lenses requires identifying the centre of the best focus region.

Repeat this process using the contact lens support for the least plus power of the contact lens.

6 Ring test results

6.1 Ring test objectives

The objective of this ring test was to determine the trueness (i.e. accuracy) and precision (i.e. gauge repeatability and reproducibility (GR & R)) of a proposed method for measuring the label and add power of multifocal contact lenses using a WFS and a manually-focusing focimeter.

The scope of this ring test consisted of the following:

— Verify the wavefront sensor and manually-focusing focimeter are calibrated over their respective measurement ranges;

— Determine the precision (GR & R) of measuring label and add power for the wavefront sensor and manually-focusing focimeter.

The results from this ring test will be used to determine the feasibility of implementing these new methods in future versions of ISO 18369-2 and ISO 18369-3.

6.2 Ring test background

A proposal for measuring multifocal add power was created by a subgroup of WG9 in 2015. The foundation of this proposal is to measure the average power over a most plus and least plus region of the lens. The measured add power is the difference between the average most plus and average least plus powers. If necessary, a regression may be applied to correlate the measured add power to the label add power.

Two methods of determining the most plus and least plus powers were identified. The first method used a wavefront sensor to generate a power profile. The two average powers were taken directly from the power profiles. The second method, employing a manually focusing focimeter, was also proposed. In this case, the average powers were determined using specially designed annual apertures that allow only the most plus and least plus regions to be measured.

To determine the capability (trueness and precision) of the proposed measurement method, a ring test was initiated using five companies/organizations (Bausch + Lomb, Alcon, CooperVision, Menicon, and China National Institute of Metrology). The China National Institute of Metrology withdrew from the ring test.

6.3 Ring test executive summary

The ring test protocol was executed in laboratories operated by the companies/organizations listed in Table 4. The protocol was executed using calibrated/qualified wavefront sensors and manually-focusing focimeters in accordance with the directives found in ISO 18369-3. For the remainder of the report, the ring test results for each company will be masked randomly as Lab 1, Lab 2, Lab 3, and Lab 4.

Table 4 — Participating companies/organizations

Company/Organization	Country	Completion
Bausch + Lomb	United Status	October, 2017
CooperVision	United Kingdom	August, 2018
Alcon	United States	November, 2018
Menicon Co., Ltd.	Japan	August, 2019

A summary of the test results shows that the wavefront sensor and focimeters used in the ring test were accurate compared to certified glass calibration standards (see Tables 5 and 6). The certification uncertainty estimates are taken from an internal Bausch+Lomb technical document. In addition, the GR&R tests (XBar/R) for wavefront sensors shows that the measurements are generally capable when using a target GR&R of 30 %. In some cases, averaging additional independent readings may be necessary to achieve a 30 % GR&R.

NOTE This target for the P/T ratio does not equal the amount of measurement error relative to the specification.

For manually-focusing focimeters, the GR&R results (XBar/R) shows a requirement for averaging additional independent measurement to achieve the target of 30 %. The comparison of the standard deviation to the tolerance exaggerates the impact of measurement error. Refer to Tables 7 and 8 for GR & R results.

6.3.1 WFS calibration verification using (13) certified low-power glass lenses

Table 5 — WFS calibration verification (accuracy)

Lens No.	Certified power D	Certification uncertainty D	Lab 1	Lab 2	Lab 3	Lab 4
1	-2,223 0	0,002	-0,50 %	-0,72 %	-0,04 %	0,31 %
2	-1,781 3	0,002	-0,86 %	-0,97 %	-0,46 %	0,32 %
3	-1,486 0	0,002	-0,88 %	-0,88 %	-0,60 %	0,33 %
4	-1,151 9	0,002	-1,12 %	-0,68 %	-1,12 %	0,01 %
5	-0,892 7	0,002	-0,87 %	-0,75 %	-1,05 %	-0,19 %
6	-0,593 7	0,002	-0,97 %	-0,46 %	-1,33 %	-0,12 %
7	-0,497 9	0,002	-0,78 %	-0,98 %	-1,16 %	0,22 %
8	-0,236 0	0,002	-3,37 %	-2,10 %	-2,03 %	-0,41 %
9	0,223 2	0,002	3,49 %	2,15 %	0,03 %	-0,54 %
10	0,446 1	0,002	2,89 %	0,65 %	0,21 %	-0,92 %

Table 5 *(continued)*

Lens No.	Certified power D	Certification uncertainty D	Lab 1	Lab 2	Lab 3	Lab 4
11	0,592 6	0,002	2,59 %	0,23 %	1,04 %	-0,62 %
12	0,889 7	0,002	1,27 %	0,14 %	0,71 %	-0,42 %
13	1,269 9	0,002	0,80 %	-0,15 %	0,45 %	-0,07 %

6.3.2 Focimeter calibration verification using (10) standard B+L calibration lenses

Table 6 — Focimeter calibration verification (accuracy)

Lens No.	Certified power D	Certification uncertainty D	Lab 1	Lab 2	Lab 3	Lab 4
1	-3,010	0,003	-0,33 %	1,00 %	-0,33 %	0,00 %
2	-5,001	0,002	-0,02 %	0,98 %	0,98 %	-0,02 %
3	-7,960	0,003	0,50 %	0,13 %	1,13 %	0,50 %
4	-11,900	0,004	0,84 %	-0,08 %	1,68 %	0,84 %
5	-15,810	0,005	0,41 %	-0,13 %	1,83 %	0,38 %
6	3,025	0,003	-0,83 %	-1,49 %	-0,83 %	-0,83 %
7	5,048	0,002	-0,95 %	-0,55 %	0,04 %	0,24 %
8	8,102	0,003	0,28 %	-0,27 %	-1,26 %	0,22 %
9	12,230	0,005	0,16 %	-0,08 %	-1,06 %	0,16 %
10	16,374	0,005	0,01 %	-0,02 %	-1,67 %	-0,02 %

6.3.3 WFS gauge repeatability and reproducibility (GR&R) using PV2 MF HA lenses

Table 7 — WFS GR&R (XBar/R method) using PV2 MF LA lenses

Lens region	Tolerance	Lab 1	Lab 2	Lab 3	Lab 4
Least Plus	±0,25 D	20 %	17 %	27 %	8 %
Most Plus	±0,25 D	40 %	46 %	35 %	15 %

6.3.4 Focimeter gauge repeatability and reproducibility (GR&R) using PV2 MF HA lenses

Table 8 — Focimeter GR&R (XBar/R method) using PV2 MF LA lenses

Lens region	Tolerance	Lab 1	Lab 2	Lab 3	Lab 4
Least Plus	±0,25 D	126 %	39 %	122 %	75 %
Most Plus	±0,25 D	124 %	43 %	189 %	146 %

NOTE Differences in the results shown in Table 8 is indicative of the manual nature of the test method. The nature of the method is such that light irradiance is reduced when testing multifocals compared with testing spherical lenses in accordance with ISO 18369-3. Furthermore, the introduction of additional apertures provided by the paddle increases the depth of focus of the projected image.

6.4 Calibration lens accuracy requirements

Recommendations are presented for allowable measurement errors when verifying the calibration of focimeters and wavefront sensors.

6.4.1 Focimeters

The spherical lens power tolerances from ISO 18369-2 are ±0,25 D and ±0,50 D for $|F'_L| \leq 10$ D and 10 D < $|F'_L| \leq 20$ D, respectively. Figure 10 contains a snippet of ISO 8598-1:2014, Table 1, which lists the maximum indication error on measured vertex power for various contact lens powers.

Applying the maximum indication error for general instruments to the certified power of the focimeter calibration lenses gives allowable measurement error as shown in Table 10. These are the values that will be used to determine if the focimeter calibration verification measurements are acceptable.

Table 9 — Maximum permissible indication error on measured vertex power for general purpose instruments (ISO 8598-1:2014, Table 1)

Values in dioptres (D)

Measuring range of vertex power		Maximum permissible indication error		
		Instruments with continuous scale	Digitally rounded instruments when set to increments of	
			0,25	0,12(5)[a]
<0 ≥ -5	>0 ≤ +5	±0,06	0,0	0,0
< -5 ≥ -10	> +5 ≤ +10	±0,09	0,0	0,12(5)
<-10 ≥ -15	> +10 ≤ +15	±0,12	0,0	0,12(5)
< -15 ≥ -20	> +15 ≤ +20	±0,18	±0,25	0,12(5)
< -20	> +20	±0,25	±0,25	±0,25

NOTE 1 Calibrating to tighter tolerances (e.g. 10 % of the product tolerance) will improve instrument equivalence and reduce possible differences between two instuments.

NOTE 2 The user should be aware that when a focimeter is set to read in steps of 0,01 D, the readings may not be true to this level of precision.

[a] The meaning of 0,12(5) is that the insturments has been set to 1/8th dioptre steps, displayed as 0,12 D.

Table 10 — Allowable measurement error for example focimeter calibration lenses

Sphere power D	Allowable measurement error ±D	 ±%
-3,00	0,06	2,00 %
-5,00	0,06	1,20 %
-8,00	0,09	1,13 %
-12,00	0,12	1,00 %
-16,00	0,18	1,13 %
3,00	0,06	2,00 %
5,00	0,06	1,20 %
8,00	0,09	1,13 %
12,00	0,12	1,00 %
16,00	0,18	1,13 %

6.4.2 Wavefront sensor low-power lenses

To avoid having to immerse the focimeter calibration lenses in packaging solution, a set of low-power glass lenses can be purchased and certified that have a range of powers comparable to the immersed focimeter calibration lenses (see Figure 9). This allows the calibration of a wavefront sensor to be verified with lenses in-air and without needing to accurately know the refractive index of the lens and solution.

The flatness of the cuvette's clear aperture shall not induce more than 0,008 D. The low-power standards shall be certified by the manufacturer to ensure required accuracy.

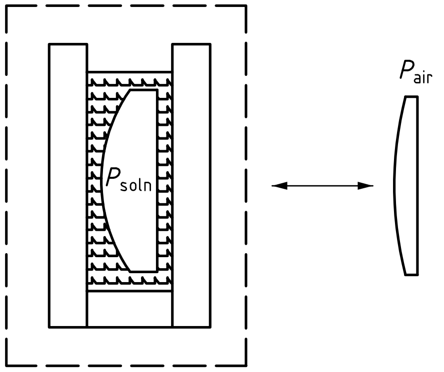


Figure 9 — Power of an immersed lens

To apply the measurement error assumptions made for focimeter calibration lenses, the power of a contact lens immersed in solution (P_{sol}) that is equal to the low-power in-air calibration lens (P_{air}) is determined. The allowable measurement errors for the focimeter calibration lenses can then be applied. Finally, the measurement errors for the low-power lenses can be calculated.

For this protocol, contact lens power measurements using a wavefront sensor were taken immersed in a cuvette filled with packaging solution (n = 1,336 15). The ratio of the in-air power to the in-solution power is given by Formula (1):

$$k = \frac{P_{air}}{P_{sol}} \cong \frac{(n_{lens} - 1)}{(n_{lens} - n_{sol})} \quad (1)$$

where

k is the ratio of in-air power to immersed power;

P_{air} is the in-air power;

P_{sol} is the immersed power;

n_{lens} is the index of refraction of the lens (n = 1,390);

n_{sol} is the index of refraction of the solution (n = 1,336).

If we assume that n_{lens} = 1,390 (high water content lens) and n_{sol} = 1,336, then k = 7,2. Referring to Table 9, first multiply the low-power lens powers by k, apply the tolerances from 6.4.1, and then divide by k. These values are the tolerances that will be used to verify the calibration of the wavefront sensor, see Table 11.

Table 11 — In-air accuracy estimates for example low-power lenses

Power D		Allowable measurement error		
Certified power (in-air)	**Contact lens equivalent**	**Contact lens equivalent** ±D	**In-air** ±D	**In-air** ±%
-2,223	-16,006	0,18	0,025	1,12 %
-1,781	-12,823	0,12	0,017	0,95 %
-1,486	-10,699	0,12	0,017	1,14 %
-1,152	-8,294	0,09	0,013	1,13 %
-0,893	-6,430	0,09	0,013	1,46 %
-0,594	-4,277	0,06	0,008	1,35 %
-0,498	-3,586	0,06	0,008	1,61 %

Table 11 *(continued)*

Power D		Allowable measurement error		
Certified power (in-air)	**Contact lens equivalent**	**Contact lens equivalent** ±D	**In-air** ±D	**In-air** ±%
-0,236	-1,699	0,06	0,008	3,39 %
0,223	1,606	0,06	0,008	3,59 %
0,446	3,211	0,06	0,008	1,79 %
0,593	4,270	0,06	0,008	1,35 %
0,890	6,408	0,09	0,013	1,46 %
1,270	9,144	0,09	0,013	1,02 %

7 Discussion

7.1 Ring test conclusions

— A summary of the test results shows that the wavefront sensor and focimeters used in the ring test were generally accurate (see 6.4) compared to certified glass calibration standards. Additional power measurements might be required to improve the accuracy.

— The GR&R tests (XBar/R) show that, for wavefront sensors, the measurements are generally capable when using a target GR&R of 30 %. In some cases, averaging additional independent readings will be necessary.

— For focimeters, the GR&R results (XBar/R) shows a need for averaging additional independent measurement to achieve the target of 30 %.

7.2 Ring test recommendations

— The method for measuring the multifocal add power should be considered in the next revision of ISO 18369-3 with the condition that averaging multiple independent measurements may be required to meet the GR&R target of 30 %. This consideration shall not start until the TS public review period has concluded.

— A multifocal add power tolerance that is clinically significant and practically achievable using high-volume manufacturing processes, should be considered in the next revision of ISO 18369-2. This consideration shall not start until the TS public review period has concluded.

— Requirements on accuracy should account for immersed and in-air conditions. Conditions can be coordinated by specifying a tolerance percentage across the measuring range.

7.3 Multifocal add-power measurement challenges

7.3.1 Immersed wavefront sensor measurement challenges

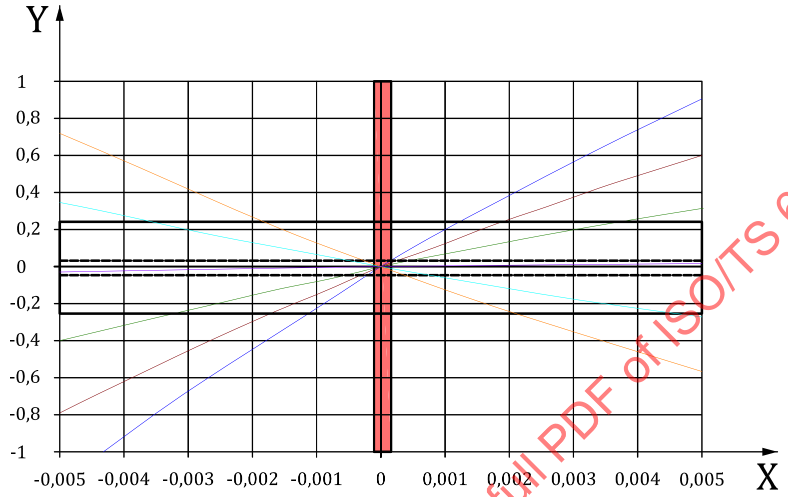
7.3.1.1 Refractive index (RI) accuracy

The ISO 18369-3 tolerance for contact lens RI is ±0,005; methods for measuring RI are discussed in ISO 18369-4. However, RI measurement accuracy of ±0,000 2 may be required for high-water lenses. Sphere power errors are greater as the refractive index (RI) of the lens approaches the RI of the measurement medium and the power of the lens increases. Figure 10 a) shows the required RI measurement capability for a high-water content contact lens (n_{lens} = 1,38). The six curves represent the error in sphere power measurements as a function of errors in the lens RI measurements for various contact lens sphere power values.

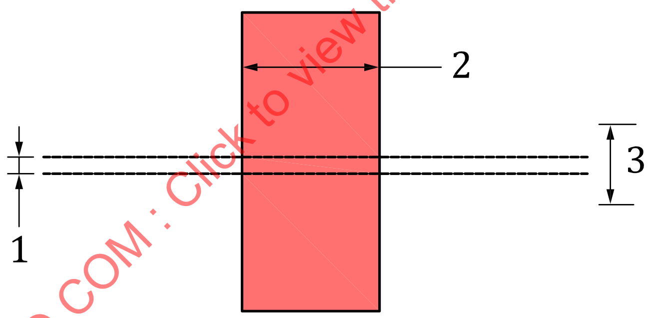
The sphere power tolerances from ISO 18369-2 (±0,25 D) are shown in the horizontal blue region of the graph (see Figure 10 b)). To appropriately mitigate the impact of refractive index errors, the measurement error for sphere power due to RI measurements should be 10 % of the total tolerance of ±0,25 D (the region defined by the horizontal dashed lines in Figure 10 b)).

The intersection of the extreme curves (−9,0 D and +6,0 D) with the dashed lines is used to estimate the required RI measurement capability. For this high-water content contact lens, the RI measurement capability is estimated to be approximately ±0,000 2.

Figure 11 shows the same analysis for a lower-water contact lens (n_{lens} = 1,42). In this case the RI measurement capability is estimated to be approximately ±0,000 5.



a) Error in sphere measurements versus error in refractive index for a high-water content contact lens



b) Expanded view of how refractive index capability was determined

Key

1 power tolerance/10

2 required RI capability

3 power tolerance

Figure 10 — Accuracy requirements for refractive index