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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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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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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

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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.

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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.

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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.

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