General Lens Description

The Paragon RG-4 lens, for overnight corneal reshaping, is a traditional 4-curve lens design with an aspheric alignment zone to aid with stability and centration.

RG-4 has been designed precisely to accommodate the sagittal height of the cornea for effective reshaping. A typical fluorescein pattern should be a well-centered bull’s eye appearance with central and mid-peripheral compression zones, interlaced with a narrower tear circulation zone and a peripheral edge lift for tear supply.

A. Lens Specifications

- Lens type: 4-curve reverse geometry lens design
- Keratometric Range: 40.00D ~ 49.00D (in 0.25 D steps)
- Power Correction Range: up to -3.00D
- Corneal Cylinder Correction: up to -1.50D
- Lens Diameters: 10.0 ~ 12.4 mm (in 0.2 mm steps)
- Standard power over-correction in each lens is +1.25D
- Material: Paragon HDS® 100
- Plasma Treated
- Laser mark (figure 1-1) identification code (see Reference Table pg. 7)
  1. Lens identification codes are 6-digit alpha numeric codes.
     a. First 3 digits refer to **Lens Diameter**
     b. Fourth digit refers to the **Mean K** (Beginning with the Mean K range of 46.34D, the Mean K is represented by the fourth and fifth digits.)
     c. Final 2 digits refer to **Lens Corneal Spherical Equivalent Target Sphere Power**. This refers to the amount of patient sphere power we are attempting to correct. (Beginning with the Mean K range of 46.34D, the target sphere power is represented by the final digit only.)

*For example, Reference Table ID Code 108L04 refers to:*

- 108 = 10.8 Diameter.
- L = Mean K in the range of 42.60D – 42.85D.
- 04 = -3.00D (calculated corneal spherical equivalent).
Suggested Lens Diameters For The Specified Mean-K’s
(These diameters will be automatically built into the lens order UNLESS specified otherwise.)

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<tr>
<th>Mean K Reading</th>
<th>Suggested Lens Diameter</th>
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<td>40.00D ~ 42.25D</td>
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<td>42.50D ~ 43.75D</td>
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<td>44.00D ~ 47.50D</td>
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<td>47.75D ~ 49.00D</td>
<td>10.0 mm</td>
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B. Suggested Diagnostic Set

- 31 lenses
- Keratometric Range: 40.00D ~ 47.50D
- Target power: -3.00D

Step By Step Fitting Process For RG-4 Lenses
Using The Diagnostic Set

1. Determine the **Manifest Refraction** for the patient’s distance vision.
2. Determine the **Mean K** by averaging the flat and steep K measurements.
3. If corneal cylinder is present, calculate the corneal spherical equivalent. Corneal spherical equivalent is determined by calculating one-half of the difference between the steep and flat keratometric readings and adding that value to the sphere power. Always subtract the flat K reading from the steep K reading. No vertex correction of the power is required.
4. Select the initial diagnostic lens by selecting the diagnostic lens with the patient’s corresponding Mean K. Refer to the lens Reference Table (see page 7) for the proper lens identification code.
5. Place the lens on the eye and instill fluorescein.
6. Evaluate the following:
   a. Centration: A well centered lens is important.
   b. Does the fit present a bull’s eye pattern? The bull’s eye pattern should present (see figure 1-2):
      - No less than 4 mm of central applanation.
      - 1 - 2 mm of pooling in the reverse zone.
      - 360° of peripheral dark band in the alignment zone.
      - Sufficient edge lift, providing a combination of tear pumping and acceptable comfort.
   c. Movement: Generally, about .05 mm of movement is sufficient.

If the fitting criteria (centration, bull’s eye pattern, minimal movement and acceptable comfort) are achieved, then complete an over-refraction to determine the optimal prescription lens to order. The desired over-refraction is plano.

The Over-Refraction Is Completed As Follows:

1. If the over-refraction of the -3.00D diagnostic lens yields -1.00D, then order a lens with a target sphere of -4.00D with the Mean-K by providing this data or by providing the lens identification code from the Reference Table.
2. If the over-refraction yields +0.50D or less, make no lens change. Simply order a lens with the same parameters as the diagnostic lens.
3. If the over-refraction is +1.00D or more, select the appropriate power. For example, if the over-refraction is +1.00D (over the -3.00D diagnostic lens), the lens ordered should have a target sphere power of -2.00D with the patient’s Mean K.
Paragon RG-4™ Fitting Reference Guide

- NOTE: In some cases, reverse geometry lenses, for corneal reshaping, may have a tendency to experience peripheral seal-off which increases the possibility of corneal erosion if worn during waking hours. Therefore, it is not recommended that the RG-4 lenses be worn during waking hours.

Empirical Fitting (no diagnostic set)

There are two easy methods to fit RG-4 empirically:

A. Call your Authorized Lab Consultant or a Paragon Consultant with the following data:
   - Manifest Refraction.
   - Flat and Steep Keratometric Readings.

OR

B. Follow these simple instructions:

1. Determine the Manifest Refraction for the patient’s distance vision.
2. Determine the Mean K by averaging the flat and steep K measurements.
3. If corneal cylinder is present, calculate the corneal spherical equivalent. Corneal spherical equivalent is determined by calculating one-half of the difference between the steep and flat keratometric readings and adding that value to the sphere power. Always subtract the flat K reading from the steep K reading. No vertex correction of the power is required.
4. Order the lens providing the corneal spherical equivalent and the Mean K or by providing the lens identification code noted in the Reference Table.

For example,
IF:
   - Manifest refraction:  -2.50 – 0.75 x 180°
   - Keratometric Readings:  42.50D / 43.50D
     (K Reading presents 1.00D of corneal cylinder)

THEN:
   - Corneal Spherical Equivalent: -3.00D
     (-2.50 + ½ of difference in K readings)
   - Mean K: 43.00D
     (43.50D - 42.50D divided by 2 = 0.50D)
     (Add 0.50D to 42.50D = 43.00D)

Therefore, the prescription lens order would be
-3.00D with a Mean K of 43.00D
   OR
   Provide the Lens Code, 108M04.

This lens will be a 10.8 mm Diameter, -3.00D Target Sphere Power and a base curve to accommodate the 43.00D Mean K-reading. (Reference Table Lens ID Code, 108M04)

5. Upon receipt, place the lens on the eye and instill fluorescein.
6. Evaluate the following:
   a. Centration: A well centered lens is most important.
   b. Does the fit present a bull’s eye pattern? The bull’s eye pattern should present:
      • No less than 4 mm of central applanation.
      • 1 - 2 mm of pooling in the reverse zone.
      • 360º of peripheral dark band in the alignment zone.
      • Present sufficient edge lift providing a combination of tear pumping and acceptable comfort.
   c. Movement: Generally, about .05 mm of movement is sufficient.

If the fitting criteria (centration, bull’s eye pattern, minimal movement and acceptable comfort) are achieved, then complete an over-refraction to determine if you have a dispensable lens. The desired over-refraction is plano.

The over-refraction (over lens -3.00D, Mean K 43.00D) is completed as follows:

1. If the over-refraction of the initial lens ordered yields plano, then you have the dispensable lens.
   - If the over-refraction yields a -1.00D, then you must add this to the sphere power and order the lens.
     (Reference Table Lens ID Code, 108M06)
2. If the over-refraction yields +0.50D or less, make no lens change.
3. If the over-refraction is +1.00D or more, decrease the sphere power by +1.00D in your order.
   (Reference Table Lens ID Code, 108M02)

   • NOTE: In some cases, reverse geometry lenses for corneal reshaping may have a tendency, to experience peripheral seal-off which increases the possibility of corneal erosion if worn during waking hours. It is, therefore, not recommended that the RG-4 lenses be worn during waking hours.

Troubleshooting: Loose Fit (see figure 1-3)

Observations:

- Excessive edge lift and excessive movement
- Incomplete alignment zone touch (not uniformly 360º around)
- Superior and/or lateral decentration

Strategy:
- Select trial lens with a 0.50D steeper Mean K. Also adjust the lens sphere power to accommodate for the change in tear lens layer by adding ~ 0.50D.
  (See section on “Base Curve Adjustment Process” for adjustment.)

   • NOTE: If the new lens does not correct the observations, then:

   • Increase diameter of the new lens selected above by 0.40 mm. It is unnecessary to compensate Mean K or power when adjusting the diameter.
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For Example:
If initial trial fit lens, with a Mean K of 43.00D and corneal spherical equivalent of -3.00D, is too loose (Reference Table Lens ID Code, 108M04), add 0.50D to the Mean K and select a Mean K of 43.50D.

• **NOTE 1:** This 0.50D steepening will induce a +0.50D tear lens effect. To offset this effect, add -0.50D to the sphere. This will create a new prescription lens of 43.50D / -3.50D target sphere. (Reference Table Lens ID Code, 108O05).

• **NOTE 2:** If the lens selected in NOTE 1 does not correct the observations then select a lens with a 0.40 mm larger diameter as follows: 11.2D, 43.50D, -3.50D. (Please note: The ID code for this lens is outside the standard parameters and does NOT exist on the Reference Table.)

Troubleshooting: Tight Fit (see figure 1-4)

**Observations:**

• Insufficient edge-lift
• No movement
• Alignment zone being 360º tightly compressed on the cornea
• A centrally widened tear band and/or central pooling of fluorescein along with large bubble capture.

**Strategy:**

• Select trial lens with a 0.50D flatter Mean K. This base curve adjustment will induce a -0.50D tear lens effect. To accommodate this tear lens effect add +0.50D to the corneal spherical equivalent.

**NOTE:** If the new lens does not correct the observations, then:

• **Decrease** diameter by 0.40 mm of the new lens selected above. It is unnecessary to compensate mean K or power when adjusting the diameter.

For Example:
If initial trial fit lens, with a Mean K of 43.00D and corneal spherical equivalent of -3.00D is too tight (Reference Table Lens ID Code, 108M04), subtract 0.50D from the Mean K and select a Mean K of 42.50D.

• **NOTE 1:** This 0.50D flattening will induce a tear lens effect of -0.50D. To offset this effect, add +0.50D to the sphere. This will create a new prescription lens of 42.50D / -2.50D target sphere. (Reference Table Lens ID Code, 108K03).

• **NOTE 2:** If the lens selected in NOTE 1 does not correct the observations then select a lens with a 0.40 mm smaller diameter as follows: 10.4D, 42.50D, -2.50D. (Please note: The ID code for this lens is outside the standard parameters and does NOT exist on the Reference Table.)

**NOTE:** When adjusting the Mean K for proper positioning, two step changes (0.50D) will be required before changes in fluorescein pattern will be observed.
Determining Proper Lens Diameter

The appropriate diameter of the RG-4 is selected for you within the Fitting Program. If, however, there is a need to alter lens diameter, it is suggested that a lens is chosen that is 92-97% of the horizontal visible iris diameter (HVID).

Base Curve Adjustment Process

If a base curve adjustment is needed, then compensation is required for the tear lens layer in selecting the new corneal spherical equivalent. The adjustment is described below.

The rules used to compensate for the tear lens effect of the base curve changes in the RG-4 lens are the same as used for standard RGP lenses.

Rule 1: The selection of a 0.50D steeper Mean K induces a +0.50D tear lens effect. Therefore −0.50D should be added to the corneal spherical equivalent power in determining the new power and ordering the new prescription.

For example, if we add 0.50D to the initial mean K of 43.00D resulting in 43.50D, we must also add -0.50D to the corneal spherical equivalent of -3.00D, resulting in -3.50D.

Rule 2: The selection of a 0.50D flatter Mean K induces a -0.50D tear lens effect. Therefore +0.50D should be added to the corneal spherical equivalent power in determining the new power and ordering the new prescription.

For example, if we deduct 0.50D from the initial mean K of 43.00D resulting in 42.50D, we must also add +0.50D to the corneal spherical equivalent of -3.00D resulting in - 2.50D.

Dispensing And Follow-Up Visit

- The contact lenses should be inspected and cleaned thoroughly before dispensing.
- Lens insertion and removal and basic hygiene should be taught routinely. Wearers may add a drop of conditioning solution with head down posture to prevent air trapping in the base curve of the lenses.
- Tap water rinsing is prohibited.
- The wearing schedule should be 8-10 hours per night, for the first few days or even a few weeks, for the reshaping to stabilize. The maintenance wear of 6-8 hours per night may be sufficient to keep the vision clear thereafter.
- Daywear, or wearing lenses during waking hours, is NOT recommended.
- Only the anterior of the lens edge can be gently touched with a velveteen pad to relieve foreign body sensation. It is not recommended to modify or polish any posterior curvature of the lens.
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Color Coding

11.2 Diameter
10.8 Diameter
10.4 Diameter