PARAGON VISION SCIENCES
*Paragon RG-4™ Fitting Reference Guide** & Certification Manual
2008

*This document is an abbreviated version and does not replace the FDA approved professional fitting guide. Lenses should not be fit until reading the full, FDA approved, version of this fitting guide which is available on our website.

Paragon RG-4™ Fitting Reference Guide

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 a 6-digit alpha numeric code.
        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.)

Figure 1-1: RG-4 lens with laser mark

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).

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Suggested Lens Diameters For The Specified Mean-K's

(These diameters will be automatically built into the lens order UNLESS specified otherwise.)

Mean K Reading	Suggested Lens Diameter
40.00D ~ 42.25D	11.2 mm
42.50D ~ 43.75D	10.8 mm
44.00D ~ 47.50D	10.4 mm
47.75D ~ 49.00D	10.0 mm

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. 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.

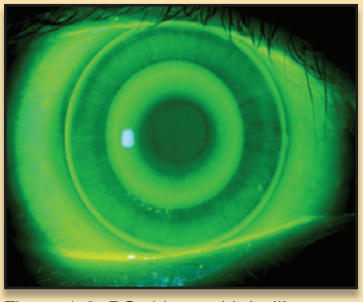

Figure 1-2: RG-4 lens with bull's eye pattern

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.

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- *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. 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.

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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.
        - 360° 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:

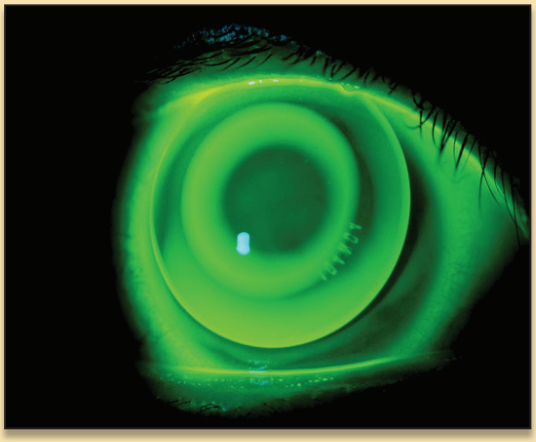

Figure 1-3: RG-4 lens with loose fit

- Excessive edge lift and excessive movement
- Incomplete alignment zone touch (not uniformly 360° 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)

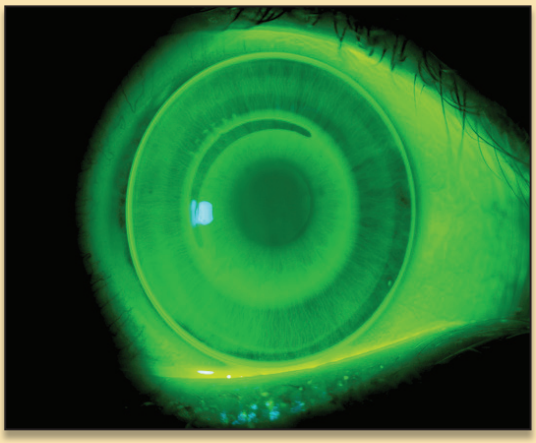

Figure 1-4: RG-4 lens with tight fit

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 fluoroscein 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 fluroescein pattern will be observed.

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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.

RG-4™ FITTING REFERENCE TABLE

Mean k/S.E	-1.50	-2.00	-2.50	-3.00	-3.50	-4.00	-4.50	-5.00
39.74 - 40.00	112A01	112A02	112A03	112A04	112A05	112A06	112A07	112A08
40.01 - 40.26	112B01	112B02	112B03	112B04	112B05	112B06	112B07	112B08
40.27 - 40.52	112C01	112C02	112C03	112C04	112C05	112C06	112C07	112C08
40.53 - 40.78	112D01	112D02	112D03	112D04	112D05	112D06	112D07	112D08
40.79 - 41.04	112E01	112E02	112E03	112E04	112E05	112E06	112E07	112E08
41.05 - 41.30	112F01	112F02	112F03	112F04	112F05	112F06	112F07	112F08
41.31 - 41.56	112G01	112G02	112G03	112G04	112G05	112G06	112G07	112G08
41.57 - 41.82	112H01	112H02	112H03	112H04	112H05	112H06	112H07	112H08
41.83 - 42.08	112I01	112I02	112I03	112I04	112I05	112I06	112I07	112I08
42.09 - 42.33	112J01	112J02	112J03	112J04	112J05	112J06	112J07	112J08
42.34 - 42.59	108K01	108K02	108K03	108K04	108K05	108K06	108K07	108K08
42.60 - 42.85	108L01	108L02	108L03	108L04	108L05	108L06	108L07	108L08
42.86 - 43.09	108M01	108M02	108M03	108M04	108M05	108M06	108M07	108M08
43.10 - 43.35	108N01	108N02	108N03	108N04	108N05	108N06	108N07	108N08
43.36 - 43.61	108O01	108O02	108O03	108O04	108O05	108O06	108O07	108O08
43.62 - 43.86	104P01	104P02	104P03	104P04	104P05	104P06	104P07	104P08
43.87 - 44.11	104Q01	104Q02	104Q03	104Q04	104Q05	104Q06	104Q07	104Q08
44.12 - 44.36	104R01	104R02	104R03	104R04	104R05	104R06	104R07	104R08
44.37 - 44.61	104S01	104S02	104S03	104S04	104S05	104S06	104S07	104S08
44.62 - 44.86	104T01	104T02	104T03	104T04	104T05	104T06	104T07	104T08
44.87 - 45.10	104U01	104U02	104U03	104U04	104U05	104U06	104U07	104U08
45.11 - 45.35	104V01	104V02	104V03	104V04	104V05	104V06	104V07	104V08
45.36 - 45.60	104W01	104W02	104W03	104W04	104W05	104W06	104W07	104W08
45.61 - 45.84	104X01	104X02	104X03	104X04	104X05	104X06	104X07	104X08
45.85 - 46.09	104Y01	104Y02	104Y03	104Y04	104Y05	104Y06	104Y07	104Y08
46.10 - 46.33	104Z01	104Z02	104Z03	104Z04	104Z05	104Z06	104Z07	104Z08
46.34 - 46.57	104ZA1	104ZA2	104ZA3	104ZA4	104ZA5	104ZA6	104ZA7	104ZA8
46.58 - 46.81	104ZB1	104ZB2	104ZB3	104ZB4	104ZB5	104ZB6	104ZB7	104ZB8
46.82 - 47.05	104ZC1	104ZC2	104ZC3	104ZC4	104ZC5	104ZC6	104ZC7	104ZC8
47.06 - 47.29	104ZD1	104ZD2	104ZD3	104ZD4	104ZD5	104ZD6	104ZD7	104ZD8
47.30 - 47.53	104ZE1	104ZE2	104ZE3	104ZE4	104ZE5	104ZE6	104ZE7	104ZE8
Over 47.53								

Color Coding	11.2 Diameter	10.8 Diameter	10.4 Diameter

RG4™
PARAGON HDS®100

Paragon RG-4™ Certification Test

Practitioner Name (MD/OD/Other):_____Practice Name:_____
Address:_____City/State/Zip:_____
Phone:_____Fax:_____ Email:_____
Lab of Choice:_____Topographer Brand:_____

Circle your answers below:

1. In corneal reshaping for myopia, the topographical changes (central corneal flattening and mid-peripheral steepening) originate:
   A. From the periphery towards the center.
   B. From the center towards the periphery.
   C. Corneal tissue does not actually change at all.

2. The laser mark ID code found in the Reference Table and on the Lens designates:
   A. Diameter, flat k & lens power B. Diameter, Mean k, Power
   C. Diameter, steep k & Sagittal depth D. Diameter & Power only

3. What is the main function of the reverse curve of a corneal reshaping lens?
   A. To allow for tissue fluid movement from the center to the periphery
   B. To aid in lens centration
   C. To provide adequate alignment of the base curve
   D. All of the above

4. What is the primary fitting function of the alignment curve in a corneal reshaping design?
   A. To re-distribute tissue fluid from the corneal center to the periphery.
   B. To aid in centration and stabilization in the lens fit.
   C. To provide the appropriate power curve.

5. What is the appropriate size of the treatment zone as result of successful corneal reshaping treatment?
   A. 2-3mm B. 3-4mm C. 4-5mm D. 5-6mm

6. What is the recommended limit to the amount of corneal with-the-rule astigmatism that should be attempted with the RG-4 lens?
   A. 1.00D B. 1.50D C. 0.75D D. 1.25D

7. What is the ideal Refraction-Over the Lens in an appropriate RG-4 fitting?
   A. -0.75D B. +0.75D C.Plano D.-4.00D

8. The following type of astigmatism will remain untreated after corneal reshaping treatment.
   A. With-the-rule B. Lenticular C.Against-the-Rule

9. Which of the following are contraindications for corneal reshaping?
   A. Lid Margin Disease B. Irregular Astigmatism
   C. Corneal Dystrophy D. All of the above

10. If an RG-4 lens is too loose, it is likely to:
    A. Correct too much myopia B. Decenter
    C. Create excessive bubbles in the reverse curve

11. The correct formula for achieving the desired mean K is:
    A. Steep K - Flat K / 2 B.Flat K + Steep K / 4
    C. Steep K - Flat K X 2 D.Flat K + Steep K /2

12. Assuming a well-centered lens with an appropriate treatment base curve, what lens adjustment will be needed if there is inadequate treatment?
    A. Increase lens diameter B. Increase lens power
    C. Decrease mean k D. Decrease lens diameter
    E. Either B or C

13. The following topography map would indicate that the RG-4 lens was decentered superiorly during overnight wear:
    A. The "Frown" pattern B. A central island pattern
    C. The "Smiley Face" pattern D. Inferior/Temporal steepening pattern

14. A persistent "Central Island" indicates the need to adjust the RG-4 lens in what way?
    A. Steepen the base curve radius B. Increase lens diameter
    C. Reduce mean k D. Increase Reverse Curve Radius

15. Before removal of the lenses after overnight wear, patients should be sure that the lenses are:
    A. Well centered B. Clean and free of coatings and films
    C. Moving freely and not adhered

16. To find the correct corneal spherical equivalent for the RG-4 lens selection, the following formula is used;
    A. Steep K – Flat K / 2 + spherical manifest
    B. Spherical manifest + ½ astigmatic manifest
    C. Flat K + Steep K /4 + spherical manifest
    D. Steep K – Flat K + spherical manifest

17. Excessive bubbles underneath a well-centered RG-4 lens typically indicate a lens with:
    A. A loose fitting lens B. Against-the-Rule Astigmatism
    C. Coated Lenses Surface D. A tight fitting lens

18. Corneal Topography can play a key role in the which of the following phases of corneal reshaping:
    A. Lens selection and design
    B. Patient follow-up and treatment management
    C. Patient pre-selection and baseline documentation
    D. All of the above

19. Select the patient with the clinical data indicating best candidacy for corneal reshaping?
    A. Ks 43.00@180/ 45.50 @ 090 Rx -3.00 -2.25 X 180
    B. Ks 41.00@145/ 43.50 @ 055 Rx -0.50 -1.50 X 145
    C. Ks 43.50@180/ 44.00 @ 090 Rx -3.25 -0.50 X 180
    D. Ks 44.00@175/ 44.00 @ 090 Rx -3.00 -1.25 X 180

20. When adjusting mean k for proper lens positioning, adjust the mean k by _____ in order to observe changes in the fluorescein pattern?,
    A. 1.00D B. 0.75D C. 0.50D D. 0.25D

Only practitioners who successfully complete the certification test are permitted to fit Paragon RG-4™ lenses for corneal reshaping. As with any medical device, only licensed practitioners may purchase Paragon RG-4 lenses.

Signature:_____State License #_____Date:_____

Option 1 _____ I wish to purchase the RG-4 31 lens diagnostic fitting set for $728.50.
Option 2 _____ I do not wish to purchase the RG-4 31 lens diagnostic fitting set but will order empirically through consultation services.
Option 3 _____ I am currently an Optometric student and not state licensed.

Fax completed test to 480-926-7369 / Questions 800-528-8279