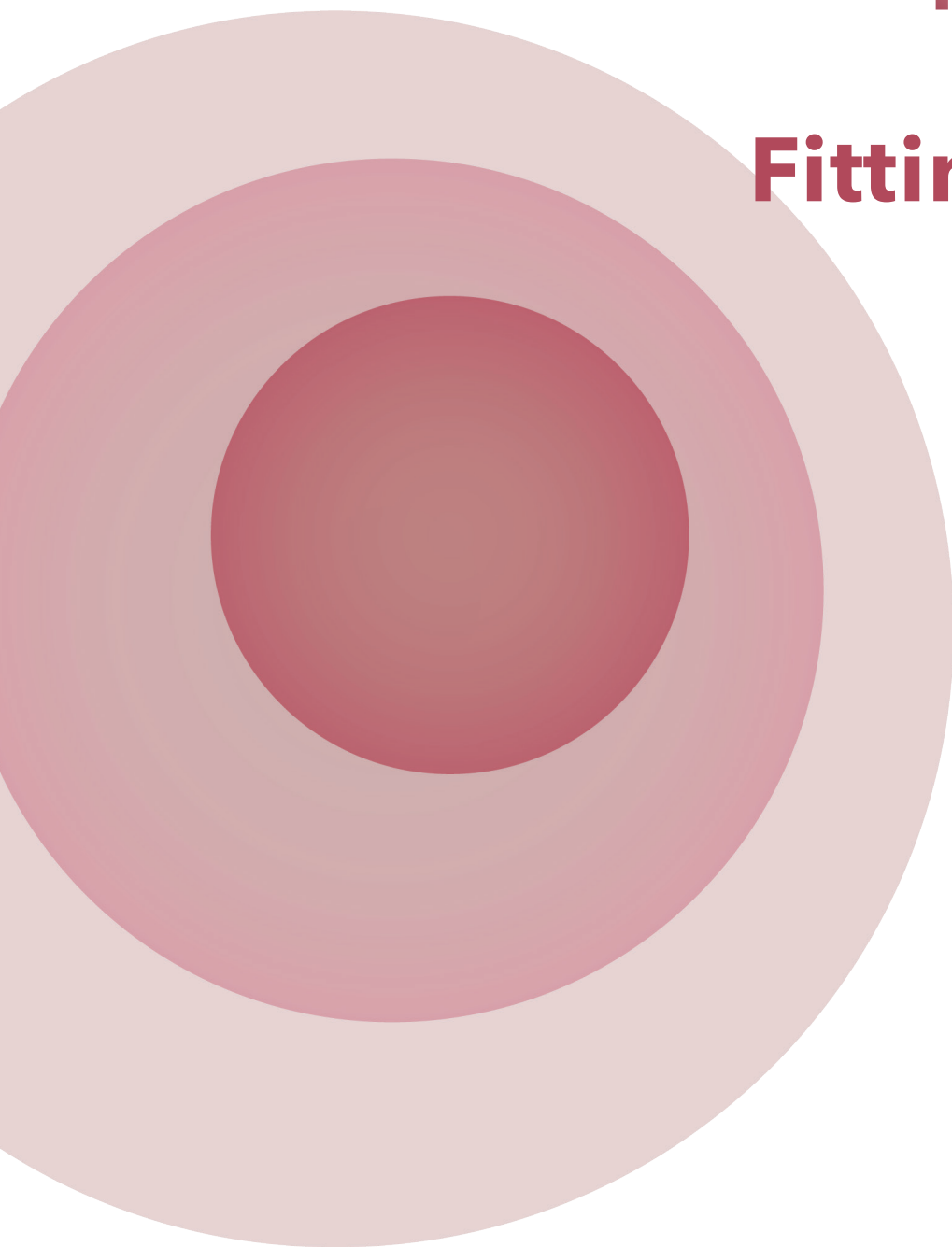


Menicon Time XL

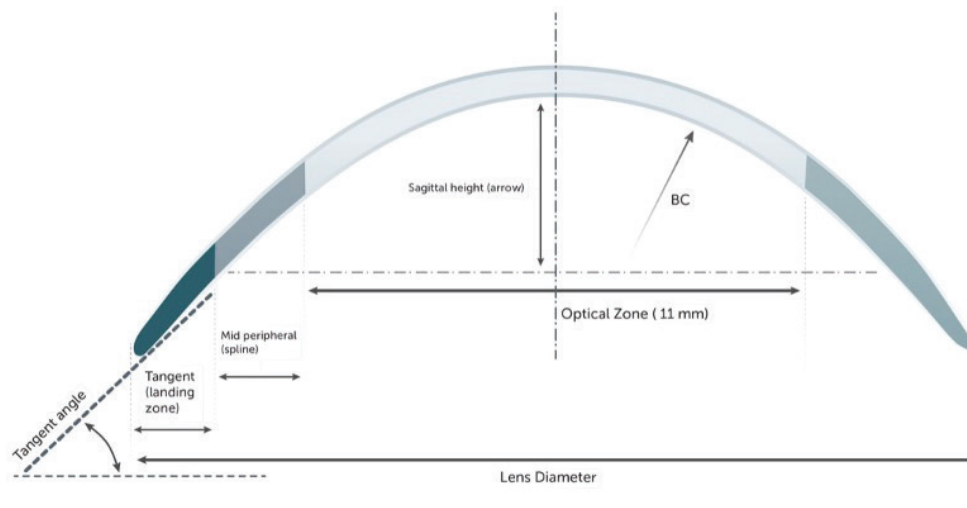
Fitting Guide



Getting to know the design

The Menicon Time XL lens is an innovative mini-scleral lens design. It is the first mini-scleral lens that has been produced with a bitangential periphery. Research shows that the shape of the limbus and the sclera is typically linear and not curved.¹ Furthermore, in 95% of cases, the scleral surface is toric and not spherical. The bitangential design of Menicon Time XL optimizes the pressure distribution of the lens on the sclera to improve the patient's comfort which allows for longer daily use.^{2,3}

Two important innovations were combined for maximum comfort and optimum performance of the Menicon Time XL lens. The lens periphery is produced linearly and torically (bitangential). The toric periphery of the lens can be precisely controlled in both flat and steep meridians to better align with the sclera for a simple and stable fit. The toricity is limited to just the periphery of the lens as the back surface geometry of the optical zone is spherical. If necessary, the front of the Menicon Time XL optical zone can be manufactured with a corrective cylinder.



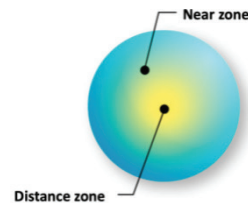
Lens parameters

Sagittal height	2600 µm to 5500 µm (100 µm steps)
Tangent. Flat and Steep meridians	Both meridians are available from 28° to 50° (2° steps)
Base curve	7.40 to 9.40mm (0.20mm steps)
Diameter	14.00 to 17.50mm (0.50mm steps)
Power	-30.00D to +35.00D (0.25D steps)
Material	Menicon Z: $Dk\ 163 \times 10^{-11}(\text{cm}^2/\text{sec})$ [$\text{mLO}_2/(\text{mL} \times \text{mmHg})$] Optimum Extreme: $Dk\ 125 \times 10^{-11}(\text{cm}^2/\text{sec})$ [$\text{mLO}_2/(\text{mL} \times \text{mmHg})$]
Handling tint	Menicon Z: Clear Optimum Extreme: Clear and blue
Wearing type	Daily wear
Recommended replacement	Yearly
Additional options	Multifocal design, Aberration Control (AC) and Limbal Clearance Factor (LCF)
Cylinder	-0.75D to -5.00D (0.25D steps)
Axis	1° to 180° (1° steps)

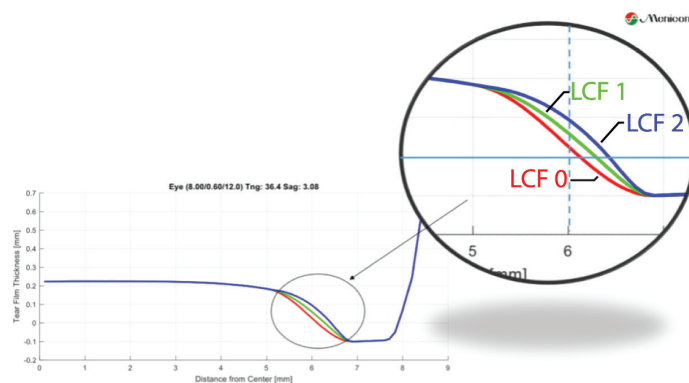
Additional options:

Multifocal

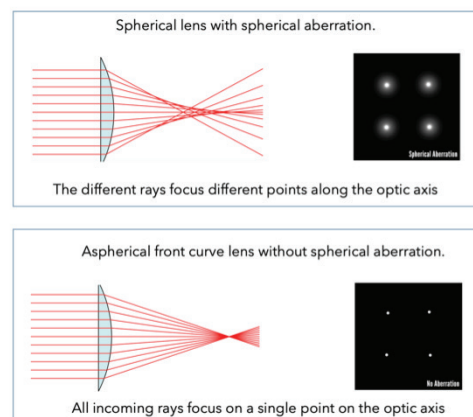
- The **Menicon Time XL Multifocal** is based on a simultaneous vision design with a progressive addition power increasing from centre to periphery in the optical zone. This allows clear near vision without compromising distance vision.



- **Limbal clearance factor (LCF):** Menicon Time XL design includes an option to increase the lens clearance to provide extra space at the limbal transition area. It is available as two variations: LCF 1 and LCF 2



- **Aberration control (AC):** Menicon Time XL design includes an aspherical front surface to minimise residual higher order aberrations (primarily spherical aberration). When using AC, the aspherical front provides constant power across the entire optical zone. This is particularly suitable for more extreme powers and can also improve vision in low light, such as in the evening or in a dark room.



Please note that the Multifocal Menicon Time XL design incorporates AC as standard. For the regular Menicon Time XL design, both aberration control (AC) and limbal clearance factor (LCF) are additional options that are available upon request.

Fitting objective and diagnostic set

Menicon Time XL is designed to fully vault the cornea and limbus and rest on the sclera. Although an initial assessment can be made after at least 30 minutes of lens wear, an optimal fitting is achieved when the following characteristics are observed usually after a few hours of lens wear:

- Pressure is distributed equally with no visible conjunctival vessel blanching
- Central corneal clearance of approximately 200 μm
- Limbal clearance of approximately 100 μm , with a minimum of 50 μm

Diagnostic set configuration

The Menicon Time XL diagnostic set consists of 16 diagnostic lenses with a diameter of 16.0 mm, a base curve of 8.4 mm, and plano power. Four different sagittal heights (in μm) are available: 3400, 3600, 3800 and 4000. All lenses feature a toric periphery with toricity expressed in tangent angles. The difference in the toricity of all the fitting lenses is 6° . All lenses are clearly marked with the sagittal height and tangent values on the lens.



Example: 3800 36-42

3800 = sagittal height

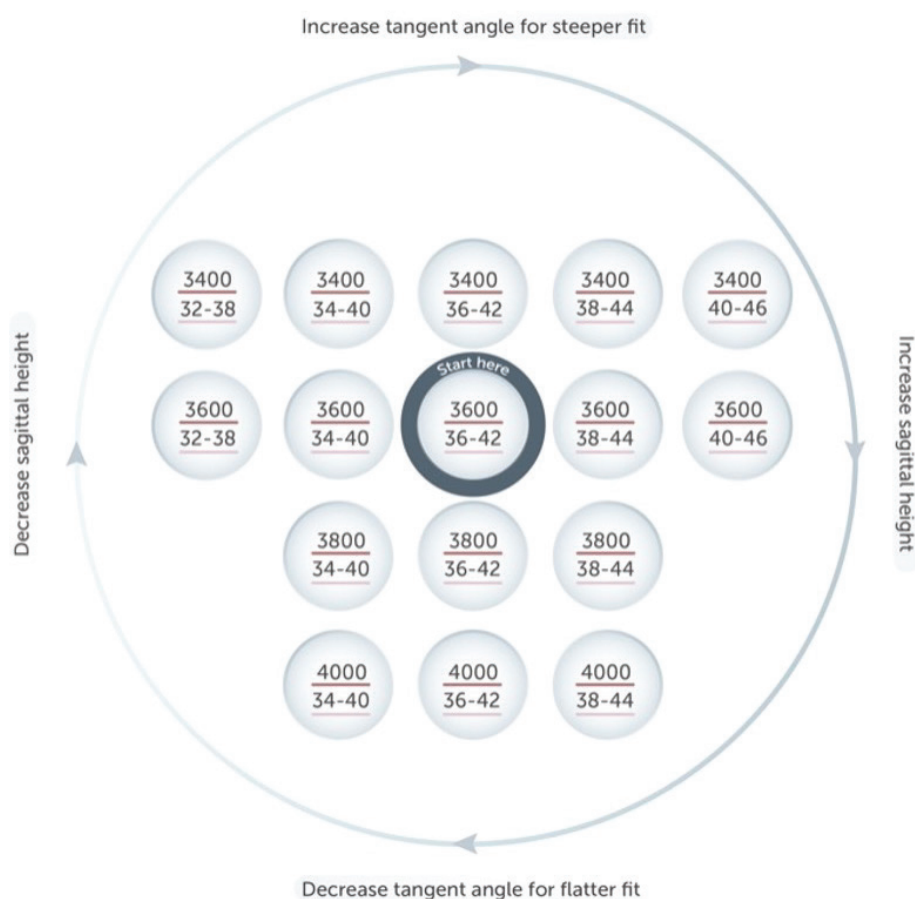
36° = tangent of flat meridian

42° = tangent of steep meridian

Step by step fitting procedure

Step 1

Selecting a diagnostic lens



You can choose the first diagnostic lens in one of two ways:

1. Use Easyfit Desktop to determine the first diagnostic lens
2. Choose a lens based on experience

1. Use Easyfit Desktop to determine the first diagnostic lens

To determine the diagnostic lens, import the patient's topography images into Easyfit Desktop. The system uses the corneal topography measurements to estimate the scleral height and to recommend the best sagittal height and tangent combination to place on eye.

2. Choose a lens based on experience

The most common sagittal height is 3600 μm . As with other scleral lenses, the sagittal height will vary per eye and per corneal condition. A patient with keratoconus may have a deeper corneal profile and require a more significant increase in sagittal height when compared to a normal eye. For

patients who have undergone a corneal transplant or refractive surgery, a lower height may be required. The corneo-scleral profile can be assessed with a slit lamp examination. If uncertain, start with sagittal height 3600 and tangents 36/42 for keratoconus and transplants, or sagittal height 3400 and tangents 36/42 for regular corneas.

Corneal profile	Sagittal height	Usage percentage
Shallow	3000 to 3300 μm	10%
Normal	3400 to 3800 μm	75%
Deep	3900 to 4100 μm	10%
Very Deep	4200 to 4400 μm	5%

Scleral profile	Flat meridian	Usage percentage
Flat profile	28-32	8%
Normal profile	34-38	80%
Steep profile	40-50	12%

Step 2

Assessing the lens diameter

The diameter of 16.0 mm in the diagnostic set is suitable for most patients with an average to small cornea. The lens diameter must extend roughly 1.5 to 2.5 mm beyond the limbus or be 3.0 to 5.0 mm larger than the horizontal visible iris diameter (HVID). The lenses are available in a range of diameters from 14.0 to 17.5 mm in increments of 0.5 mm.

If the patient requires a different lens diameter than the standard 16.0 mm from the diagnostic set, the desired diameter can be entered when ordering the lens. Be sure to take this into account when continuing to assess the diagnostic lens.

Step 3

Assessing the tangent

Assess the lens in primary gaze. In all meridians check the tangent alignment with the sclera by looking for conjunctival vessel blanching or excessive edge lift. If vessel blanching near the lens edge is observed, the tangent is too tight/steep so the tangent angle needs to be reduced (flattened) in the corresponding meridian. If excessive edge lift is observed (blanching near the limbus, too much shadow at the lens edge, fluorescein flows too easily under the lens edge, the tangent is too loose/flat so the tangent angle needs to be increased (steepened) in the corresponding meridian. Avoid making the patient look in other gazes to assess the tangents as the lens can mislocate and lead to incorrect assessments. It is better to pull the eyelids up and down while in primary gaze to assess the tangents in all positions.

For a tight (too steep) tangent → decrease the number of degrees (flatter)
 For a loose (too flat) tangent → increase the number of degrees (steeper)

Example 1



Image 1

Lens edge is too tight.
 Conjunctival vessel blanching near the lens edge. Decrease the tangent by 2°.



Image 2

Lens edge is too tight.
 Conjunctival vessel blanching from the lens edge and extending inwards. Decrease the tangent by 4°.

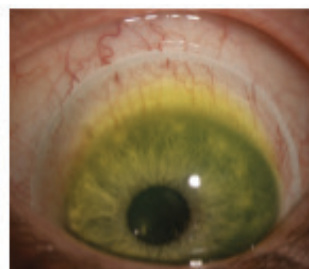


Image 3

Extreme edge tightness around the entire lens edge. Decrease the tangent by 6°.

Example 2

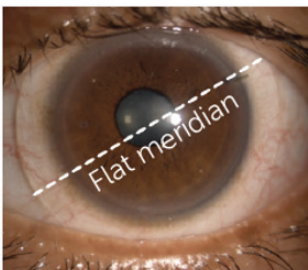


Image 1*

Excessive edge lift on the flat meridian: Edge lift shadow on sclera. Increase the tangent by 2° in the flat meridian.

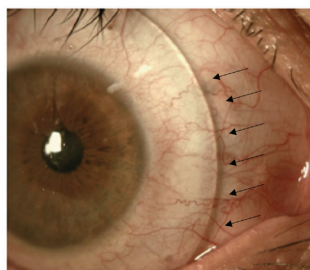


Image 2*

Excessive edge lift on both meridians: edge lift shadow visible on sclera. Increase the tangent in both meridians.

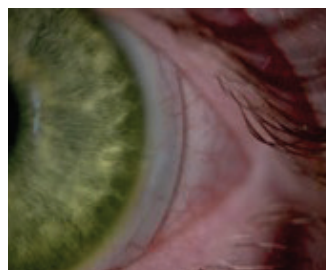
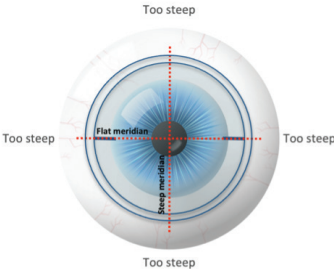
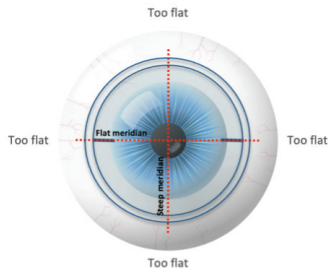
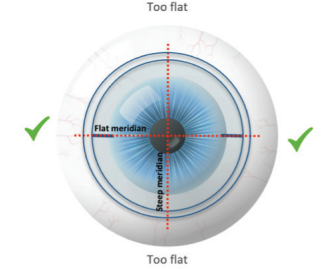
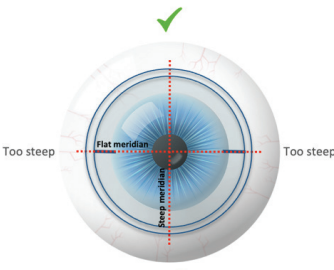


Image 3

Blanching close to the limbus is the sign of a very flat tangent. Increase the angle by 4°.

* Shadow is not that easy to assess and depend on the light orientation. In case of a doubt it is better to steepen the tangents until you get a blanching and to validate the previous tangent angle.

Also putting some fluorescein at the lens edge to observe how easy is the flow will help to assess how flat is the periphery.

Observation		Advice
Vessel Blanching The lens edges in both meridians are too steep (too tight).		Decrease the tangents by 4° in both meridians. Example Flat meridian: from 36° to 32° Steep meridian: from 42° to 38°
Edge lift and/or blanching close to the limbus on sclera. Lens edges in all meridians appear too flat (too loose).		Increase the tangents by 4° in both meridians. Example Flat meridian: from 38° to 42° Steep meridian: from 44° to 48°
Edge lift and/or blanching close to the limbus on sclera. Lens edges are too flat (too loose) in the steep meridian and ideal in the flat meridian.		Do not change the tangent in the flat meridian. Increase the tangent in the steep meridian by 4° . Example Flat meridian: tangent remains 36° Steep meridian: from 42° to 46°
Vessel Blanching Lens edges are too steep (too tight) in the flat meridian and correct in the steep meridian.		Decrease the tangent in the flat meridian by 4° and do not change the tangent in the steep meridian. Example Flat meridian: from 38° to 34° Steep meridian: tangent remains 44°

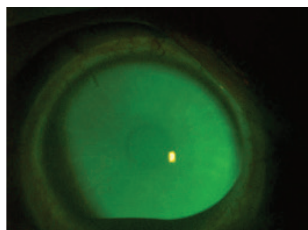
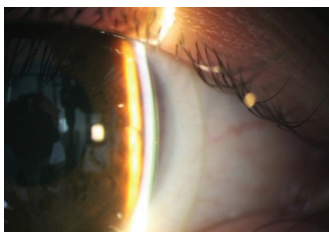
Step 4

Assessing the limbal clearance

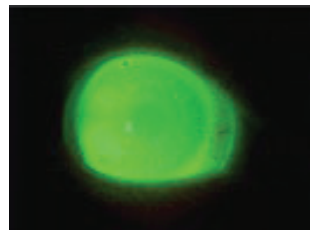
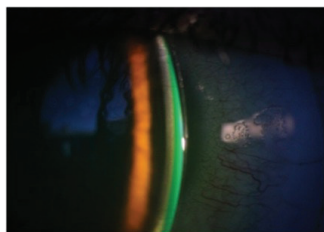
Assess the limbal clearance with fluorescein, as shown below, or by using white light or an OCT. It is important that the lens does not make contact with the limbus. Ideal limbal clearance is about 100 μm but this amount may vary circumferentially. If the tangent and the sagittal height are correct, the limbal clearance can be adjusted by changing the base curve.

In the event of pressure or clearance of less than 50 μm , it is important to re-assess the landing zone. A smaller limbal clearance will be observed if the tangent is flat. An increase in the tangent should lead to the ideal limbal clearance.

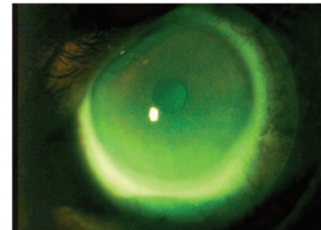
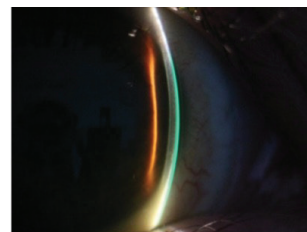
Check the landing zone before you change the base curve.
Increase the tangent by 2° if you see an edge that lifts away from the sclera.



Pressure in the limbal area. Flatten base curve.



Too much clearance in the limbal area. Steepen base curve.



Ideal clearance in the limbal area. Maintain base curve.

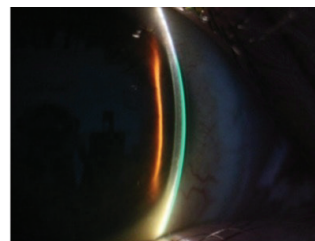
Tip: Changes to the base curve should always be accompanied by a change in lens power. Change to a Flatter Base Curve = positive lens power compensation; Change to a Steeper Base Curve = negative lens power compensation

Step 5

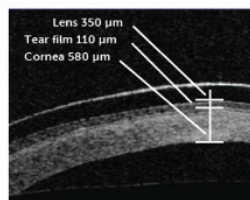
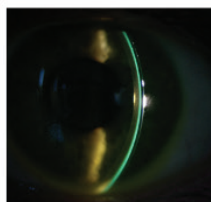
Assessing central clearance

Assess the clearance at the highest point of the cornea using an optical section with fluorescein and white light or an OCT of the anterior segment. The ideal central clearance is approximately 350 μm at insertion and 200 μm after the lens has settled (30 minutes ~ a few hours of wearing). For reference, the diagnostic lens has a thickness of 350 μm . The central clearance can be adjusted by increasing or decreasing the sagittal height of the lens. Increase the sagittal height of the lens by a corresponding amount if there is too little central clearance.

Tip: The central clearance can be estimated by comparing the thickness of the lens (350 μm at plano) with the tear reservoir below the lens. This can be evaluated with a slit lamp by moving a narrow slit of light spanning from limbus to limbus at an angle of 45°. If the clearance is too high, it is more difficult to insert the lenses without creating air bubbles. For eyes where debris often accumulates on the lens, a shallower sagittal height should be selected. Greater sagittal height may be necessary for eyes that are sensitive to progressive ectasia.

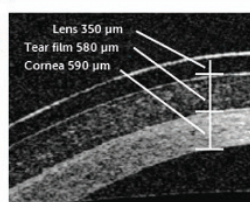
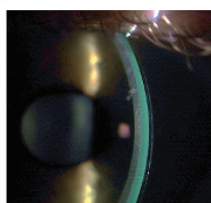


Too little clearance



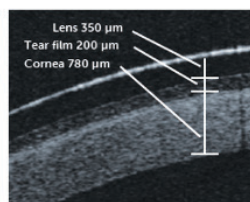
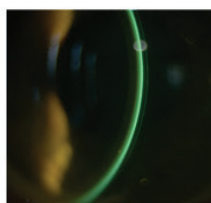
Increase the sagittal height if central clearance is too low

Too much clearance



Decrease the sagittal height if central clearance is too high

Ideal clearance



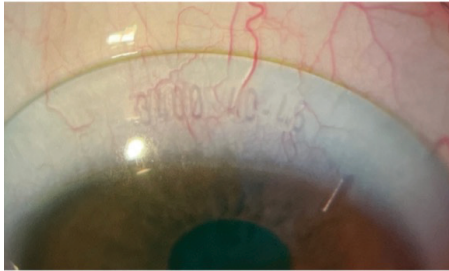
No changes required

Tip: When one or both of the tangent angles are modified, this changes the distribution of pressure under the lens and will also have consequences for the central clearance.

Step 6

Determining lens power

Perform an over-refraction after the eye has adjusted to the optimum diagnostic lens. The power of the diagnostic trial lens is plano. Menicon Time XL is a non-rotationally symmetric lens that stabilises across the flat meridian which is identified with marks.



Tip: All diagnostic and toric lenses have marks aligned with the flattest meridian.

Determine the position of the marks. If the lens is correctly fitted, the orientation of the marks will be stable and remain in a constant position.

To compensate the cylinder axis for the orientation of the flattest meridian, note the axis location of the marks and the axis of the over-refraction. Subtract the mark axis from the over-refraction axis. If the resulting number is positive, that is the cylinder axis to order (see example). If the resulting number is negative, subtract that absolute value from 180° and that is the axis to order (see formula).

Formula

Over-refraction axis - laser mark axis = +X

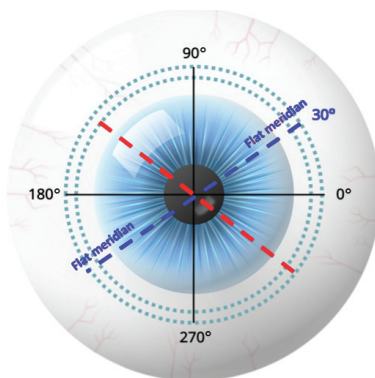
X = cylinder axis for lens order;

Over-refraction axis - laser mark axis = -X

180 - X = cylinder axis for lens order;

Example

Mark settles at 30°



To compensate for the axis misalignment from 180°:

- Laser mark: 30°
- Over-refraction is -1.00 -1.00 x 140°
- $140^\circ - 30^\circ = 110^\circ$
- Order: -1.00 -1.00 x 110°

Tip: The final lens power can be easily calculated with Easyfit Desktop

Troubleshooting

Observation	Recommendation
Tight lens fit: vessel blanching, compression or tight edge in landing zone in either the flat or the steep meridian	Mild: decrease the tangent in the specific meridian by 2° (60 µm). Moderate: decrease the tangent in the specific meridian by 4° (120 µm). Note: changing the tangent in one meridian will not automatically change the tangent in the opposite meridian.
Vessel blanching is circular (around the entire lens)	Light: decrease the tangent in both meridians by 2° (60 µm). Moderate: decrease the tangent in both meridians by 4° (120 µm).
Loose lens fit: Too much edge lift or scleral standoff or too much movement and/or blanching close to the limbus	Mild: increase the tangent in the specific meridian by 2° (60 µm). Moderate: increase the tangent in the specific meridian by 4° (120 µm). Note: changing the tangent in one meridian will not automatically change the tangent in the opposite meridian.
Excessive movement	Increase the diameter if the tangent looks good and the lens moves too much.
Too much central clearance	Decrease the sagittal height to achieve a clearance of 200-250 µm.
Too little central clearance	Increase the sagittal height to achieve a clearance of 200-250 µm.
Good central clearance, but limbus too tight.	If after checking diameter and tangents (the steepest that don't create blanching) are correct and if applying the flattening of the base curve standard option is still INSUFFICIENT to increase the limbal clearance you can use the additional option of Limbal Clearance Factor (LCF).
Mid-peripheral or limbal clearance is too thin or too deep	Increase or decrease the base curve respectively and adjust lens power. The ideal limbal clearance is 100 µm.
Cylindrical over-refraction	Determine the position of the mark, order a front toric lens.

Observation	Recommendation
Visual fluctuations	Check surface quality (wettability and deposits) and lens stability. Decrease the sagittal height and/or increase the diameter, check lens stability. The application of aberration control (AC) can also offer a solution for extreme powers and in low light.
Lens surface deposits	Use suitable cleaning solutions. Use a protein remover if the secretion consists of protein. Check and treat ocular causes (GPC, MGD). Change the lens material if the cleaning system is not effective.
Vision is blurry	Perform an over-refraction to identify any remaining astigmatism. Order a front-toric lens as needed. Record the lens rotation in degrees during follow-up visits to keep track of the lens stability over time.
Debris in tear layer	Remove the lens, then clean and rinse it if vision is blurred. Improve the tangent alignment in order to prevent debris from collecting under the lens. Check and treat ocular causes (GPC, MGD). Optimize lens solutions. Rinse the eye with saline solution or other rinsing solution before inserting the lens. Reduce central clearance.
Inferior decentration	Minor decentration is acceptable. First, check the sagittal lens height is not too high, then check the vertical scleral fit and the tangent alignment. Next, increase the diameter.
Air bubbles under the lens	Reinsert lens to eliminate "insertion bubbles". Constant, central air bubbles may signify excessive sagittal lens height. Decrease the sagittal lens height. Constant air bubbles in the mid-periphery may signify a base curve that is too flat. Steepen the base curve. The appearance of air bubbles after correct insertion may indicate a tangent that is too flat.
Lens discomfort	Initial lens insertion will cause some awareness, but lenses should not feel uncomfortable. Check edge lift. Increase the tangent in the specific meridian that may need changes. Check the central clearance. Increase the sagittal height if the clearance is too low.

Lens care

To keep Menicon Time XL lenses in optimal condition it is important to clean the lenses thoroughly every day.

We recommend cleaning with a multipurpose solution like MeniCare Pure (or MeniCare Plus) in the morning after removing them and storing them in a clean lens case with a fresh dose of MeniCare Pure (or MeniCare Plus).

If needed, we also recommend the use of SPRAY & CLEAN as an extra cleaner against oily (lipid) deposits.

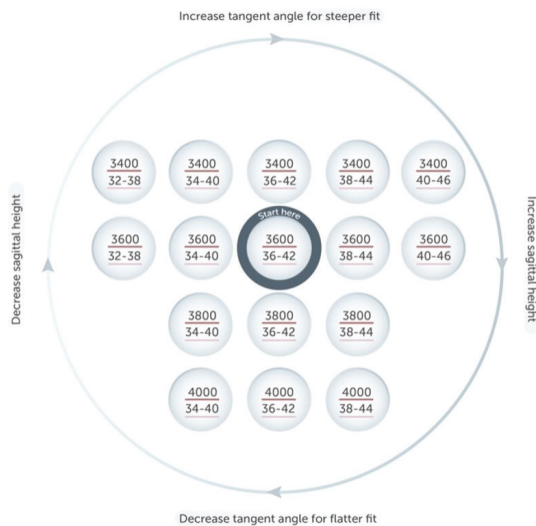
Regardless of the daily cleaning solution used, we always recommend a deep cleaning with Menicon Progent regularly. Menicon Progent is an intensive cleaner and very effective in removing any invisible residual deposits that may remain on Menicon Time XL lenses.

Proper lens maintenance is essential for optimal lens performance and comfortable, safe lens wear.

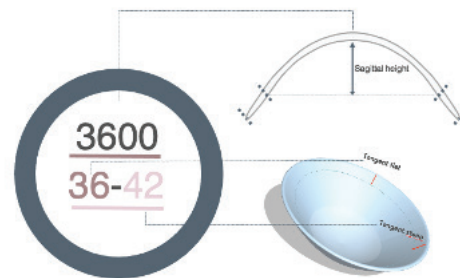
For trial lens management, please visit the Menicon website for additional guidance about caring for your trial sets in the Hygienic Management of Multipatient Use of Rigid Gas Permeable Trial Lenses guide.



Menicon Time XL diagnostic set



Example: 3600 32-38



3600 = sagittal height
 32° = tangent of flat meridian
 38° = tangent of steep meridian

Radius	8.4 mm
Diameter	16 mm
Height difference at the edge	0.18 mm (180 micron)
Power	0 dpt
Material	Optimum Extreme (blue)
Marking	Laser marks in the flat meridian
Marking Length	1.0 mm and 1.5 mm from edge
Engraving	Code/Material/Order number

References

1. Van der Worp E, Graf T, Caroline PJ. Exploring beyond the corneal borders. Contact Lens Spectrum 2010; 25 (6):26-32.
2. Van der Worp E. A Guide to Scleral Lens Fitting (monography online). Pacific University Common Knowledge: Books and Monographs. 2010. Available at: <http://commons.pacificu.edu/cgi/viewcontent.cgi?article=1003&context=mono>. Consulted on 13 June 2013.
3. Visser, Medical Applications and Outcomes of Bi-tangential Scleral Lenses. Optometry and Vision Science VOL. 90. No.10, October 2013.

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Menicon
Time XL



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