





# Introducing the new model in refractive surgery

# Alcon's next level of Personalized Precision<sup>1-3</sup>



1.Mrochen M, Bueler M, Donitzky C, Seiler T. Optical ray tracing for the calculation of optimized corneal ablation profiles in refractive treatment planning. J Refract Surg. 2008;24:S446-S451. 2. Kanellopoulos AJ, Maus M, Bala C, et al. International Multicenter, Myopic and Myopic Astigmatism Femto LASIK, Customized by Automated Ray-Tracing Ablation Profile Calculation: A Post market Study. Clin Ophthalmoly 2024;18:525-536 3. InnovEyes™ Sightmap Diagnostic Device User Manual 1089

Personalize



Wavelight plus

Measure

Deliver

SUMMARY

# wavelight plus

### Measure

### One device, multiple measurements<sup>1,4</sup>

# Personalize

Ray tracing creates a personalized ablation profile<sup>1,2,5</sup>

# Deliver

Go beyond the limits of 20/20 vision<sup>2-4\*</sup>

\*20/16 (82.5%) and 20/12.5 (44.8%) vision (and/or 98.1% of eyes with 20/20 vision

1.Mrochen M, Bueler M, Donitzky C, Seiler T. Optical ray tracing for the calculation of optimized corneal ablation profiles in refractive treatment planning. J Refract Surg. 2008;24:S446-S451. 2. Kanellopoulos AJ, Maus M, Bala C, et al. International Multicenter, Myopic and Myopic Astigmatism Femto LASIK, Customized by Automated Ray-Tracing Ablation Profile Calculation: A Post market Study. Clin Ophthalmoly 2024;18:525-536 3. He C, Bala C. Ray tracing guided myopic laser in situ keratomileusis - real world clinical outcomes. J Cataract Refract Surg. 2023;10-1097 4. InnovEyes<sup>TM</sup> Sightmap Diagnostic Device User Manual 1089. 4. Schumacher S, Seiler T, Cummings A, Maus M, Mrochen M. Optical ray tracingguided laser in situ keratomileusis for moderate to high myopic astigmatism. J Cataract Refract Surg. 5. Kanellopoulos AJ. Initial outcomes with customized myopic LASIK, guided by automated ray tracing optimization: A novel technique. Clin Ophthalmol. 2020;14:3955–3963 2012;38(1):28-34. doi:10.1016/j.jcrs.2011.06.032



Wavelight plus

Measure

Personalize Deliver

SUMMARY









### **PERSONALIZE: Ray Tracing Technology**<sup>1,2</sup> The Future of Refractive Personalization

The 3-dimensional model of the eye is created by:

Utilizing the exact measurements, the Ray-Tracing calculation continues to iterate the model by recalculating and tracing rays until the optimal ablation treatment profile is achieved.<sup>1</sup>



1.Mrochen M, Bueler M, Donitzky C, Seiler T. Optical ray tracing for the calculation of optimized corneal ablation profiles in refractive treatment planning. J Refract Surg. 2008;24:S446-S451. 2. Kanellopoulos AJ, Maus M, Bala C, et al. International Multicenter, Myopic and Myopic Astigmatism Femto LASIK, Customized by Automated Ray-Tracing Ablation Profile Calculation: A Post market Study. Clin Ophthalmoly 2024;18:525-536



### Going Further to Refine the Model<sup>1,2</sup>

Pre-Compensation Algorithm







The **ablation efficiency** of each laser pulse is simulated depending on its position on the measured cornea<sup>2</sup>



 Kanellopoulos AJ, Maus M, Bala C, et al. International Multicenter, Myopic and Myopic Astigmatism Femto LASIK, Customized by Automated Ray-Tracing Ablation Profile Calculation: A Post market Study. Clin Ophthalmol. 2024;18:525–536.
 Bueeler M, & Mrochen M. Computer program for ophthalmologic surgery. (U.S. Patent No. US20080033408A1).2008.





### **DELIVER: Maximized Outcomes**

The future of refractive surgery is about exceeding expectations<sup>1\*</sup>





+In a real-world private practice setting-200 patients (400 eyes).

1.He C, Bala C. Ray tracing guided myopic laser in situ keratomileusis - real world clinical outcomes. J Cataract Refract Surg. 2023;10-1097



Deliver

SUMMARY





### **DELIVER:** Set a High Standard in Refractive Outcomes<sup>1</sup>

99%

of patients would

decide to undergo the

procedure again<sup>1\*</sup>



of patients would recommend wavelight plus<sup>1\*</sup>

<sup>3</sup> Alcon data on file, 2021. RFP911-P001 Postmarket Study of Outcomes from WaveLight EX500 InnovEyes - V-RIM-0063613

\*In a clinical study; based on responses to the following questions:

- "Did you achieve the goals you had for LASIK surgery?"
  "If you could do it all over again, would you decide to have LASIK performed?"
  "Currently, how satisfied or dissatisfied are you with the result of your LASIK surgery"

PROWL questionnaire at 3 months post-op; n=106.

1.Kanellopoulos AJ, Maus M, Bala C, et al. International Multicenter, Myopic and Myopic Astigmatism Femto LASIK, Customized by Automated Ray-Tracing Ablation Profile Calculation: A Post market Study. Clin Ophthalmol. 2024;18:525-536.



**IPI & REFERENCES** 



of patients were completely or very satisfied with the result of their wavelight plus surgery<sup>1\*</sup>



### Refine the Model with **Personalized Precision** Measure. Personalize. Deliver.



Evaluates the entire optical system with One Device, Multiple Measurements<sup>3</sup> Accounts for corneal healing using a *Precompensation Algorithm*<sup>3,4</sup>

Simulates the optimal treatment model using *Ray Tracing* <sup>1,5</sup>

3

Yields the recommended **Personalized Treatment**<sup>1,3,4</sup>

1. InnovEyes<sup>TM</sup> Sightmap Diagnostic Device User Manual 1089 2. Bueler M, & Mrochen M. Computer program for ophthalmologic surgery. (U.S. Patent No. US20080033408A1). 2008. 3. Mrochen M, Bueler M, Donitzky C, Seiler T. Optical ray tracing for the calculation of optimized corneal ablation profiles in refractive treatment planning. J Refract Surg. 2008;24:S446-S451. 4. Kanellopoulos AJ, Maus M, Bala C, et al. International Multicenter, Myopic and Myopic Astigmatism Femto LASIK, Customized by Automated Ray-Tracing Ablation Profile Calculation: A Post market Study. Clin Ophthalmoly 2024;18:525-536. 5. Schumacher S, Seiler T, Cummings A, Maus M, Mrochen M. Optical ray tracing-guided laser in situ keratomileusis for moderate to high myopic astigmatism. J Cataract Refract Surg. 2012 Jan;38(1):28-34. doi: 10.1016/j.jcrs.2011.06.032. Epub 2011 Oct 26. PMID: 22033124.



Wavelight plus

Measure P

Personalize Deliver

SUMMARY

#### Important Product Information – WaveLight<sup>®</sup> Plus laser systems

**CAUTION:** Federal law restricts this device to sale by or on the order of a physician.

### DESCRIPTION AND CHARACTERISTICS:

The WaveLight<sup>®</sup> Plus laser systems is a non-contact ophthalmic diagnostic device designed to capture Scheimpflug images of the anterior segment of the eye, which includes the cornea, pupil, anterior chamber, and lens of the eye. Furthermore, it provides the axial dimensions of the eye using the technology of coherence interferometry. It can also measure the optical aberrations of the eye by applying Hartman-Shack wavefront technology

#### INDICATION:

The WaveLight® Plus laser systems is indicated for screening and diagnosis of adult patients who may undergo a customized photorefractive treatment with the WaveLight® Plus laser systems.

The WaveLight EX500 laser system in conjunction with WaveLight® Plus Sightmap is indicated for use in INNOVEYES Laser Assisted In-Situ Keratomileusis ("wavelight plus"1 LASIK) treatments:

- for the reduction or elimination of myopia or myopia with astigmatism, in eyes with spherical equivalent (SE) more than -1.00 and up to 9.00 diopters (D), with up to 8.00 D of spherical component (in minus cylinder format) and up to 3.00 D of astigmatic component at the spectacle plane, based on the INNOVEYES Sightmap Measured Refraction
- in patients with magnitude of the spherical equivalent (SE) difference between the Manifest Refraction (MRSE) and the Sightmap measured refraction SE being less than 0.75 D,
- in patients who are 18 years of age or older, and
- for patients with documentation of a stable manifest refraction defined as ≤ 0.5 D preoperative spherical equivalent shift over one year prior to surgery.

#### CONTRAINDICATIONS

If you have any of the following situations or conditions, it is not recommended to have an examination with the WaveLight® Plus laser systems.

Patients with open wounds and sores getting in contact with the head rest must not be examined.

There are no other known contraindications to the use of the WaveLight® Plus laser systems when used according to its approved indications.

#### TARGET PATIENT POPULATION:

The targeted patient population are patients which are selected for ophthalmic diagnosis consistent with the indications for use of the WaveLight<sup>®</sup> Plus laser systems.

#### INTENDED USERS:

The WaveLight® Plus laser systems may only be used by specially trained physicians, medical staff and optometrists who are well versed in its diagnostic abilities and possible dangers.

#### WARNINGS / PRECAUTIONS:

- Contact lens wearers must discontinue wearing hard or gas permeable lenses for at least 3 weeks and soft lenses for at least 1 week prior to examination.
- The examination takes place in a darkened room or with the help of a dark cloth covering the WaveLight® Plus laser systems and the patient's head.
- The patient must be able to sit in an upright and comfortable position.
- The patient must be able to fixate steadily.
- Patients should not wear makeup at the day of examination.
- Avoid using eye-drops before examination. It may impact the diagnostic results and should be reported to the surgeon.
- Taking medication with influence on the hormonal balance can affect the consistency of the cornea.
- Results may be influenced by pregnancy and nursing. Hormonal changes can affect the consistency of the cornea.
- This device can cause flammable materials to ignite or explode
- Use of the controls or adjustments or performance procedures other than those specified in the user manual may result in hazardous radiation exposure.

### MODE OF ACTION

The mode of action of the WaveLight® Plus laser systems is through the screening and diagnosis of anterior segment of the eye for planning custom refractive surgery treatments with the intent of improving vision.

### STORAGE CONDITIONS

Store at -10-55°C (14-131°F).





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