### LASER CUSTOM ABLATIONS

<table>
<thead>
<tr>
<th>Company</th>
<th>Product</th>
<th>Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Alcon</strong></td>
<td><strong>LADARVision4000</strong></td>
<td>William T. Kelley, general manager, North America (949) 292-6477</td>
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<tr>
<td><strong>Asclepion-Meditec</strong></td>
<td><strong>MEL-70G and MEL-70 GX</strong></td>
<td>(877) 523-2784</td>
</tr>
</tbody>
</table>

### Specifications

- **Beam size, type and shape**: 0.8-mm Gaussian flying small-spot, 1.8 mm, 0.9 mm, flying spot, Gaussian
- **Laser repetition rate**: 55 to 60 Hz, 35 to 50 Hz
- **Average and peak fluence**: Average: 180 mJ/cm², Peak: 250 mJ/cm²
- **FDA-approved corrections and ranges**
  - Not yet cleared by FDA
- **Maximum optical zone diameter/taper**: 9 mm/2 mm
- **Ablation time for -8.00 -2.00 x 180 with 6.5-mm optical zone**: 85 seconds
- **Patient alignment**
  - A centration photo is taken to define the relationship between the limbal border and the undilated pupil, ensuring exact placement of the ablation. At the time of surgery, the motorized patient bed is moved in x, y and z axes to position patient.
  - Coaxial aiming beam
  - Optimal feedback through microscope
  - Multidirectional patient bed and microscope
- **How does surgeon verify that eye is centered?**
  - A centration photo is taken to define the relationship between the limbal border and the undilated pupil, ensuring exact placement of the ablation. The photo is then matched to the placement of the eye at the time of surgery.
- **How are adjustments made to patient position for ease of procedure and flap visualization?**
  If adjustments are necessary, the motorized patient bed can be moved in x, y and z axes. Also, auto in left, auto in right, and auto out buttons move the patient into the desired position. Micro-adjustments can also be made with a dial on the side of the laser.
- **Purchase price/what’s included/yearly maintenance costs/per-procedure fee**
  - Speak to your local Alcon Refractive Manager. Laser purchase includes clinical training and 1 year of service. Per-procedure fee: $150. $350,000. Annual maintenance contract: $35,000. No per-procedure fees.
  - All inclusive for 1-year (including gas)
  - All inclusive for 1 year; all inclusive (except gas) with service contract
- **Time it takes to get system delivered**
  - Per customer request
  - Typically 30 days
- **Availability of service, training**
  - Clinical training is provided to doctor and staff as part of laser purchase.
  - Regular service available throughout the world, either direct or through distributors; training courses held regularly
- **Machine dimensions**
  - 91” L x 34” W; recommended room size: 9’ x 13’
  - 235 cm X 80 cm X 75 cm
- **Evergreen upgrades?**
  - Periodic software upgrades have been installed free to date.
  - No charge for most upgrades; only major changes require payment
- **Approved aberrometer?**
  - Yes; Wavefront Sciences, Albuquerque, N.M.
- **Wavefront or topographic device used**
  - Hartmann Shack
- **Current status of custom ablation trials**
  - Ongoing
- **Range of refractive error being treated**
  - Custom ablations being performed at approximately 100 sites outside the U.S.; U.S. trials planned.
  - Set for -12D to +8D, but actual machine capability is -24D to +14D
- **Wavelength used in trials**
  - 670 and 820 nm
  - 193 nm
- **How many measurements are used over a 7-mm pupil?**
  - up to 200
  - 800
- **Reference point for aligning wavefront measurement and Tx**
  - Daytime line of sight
  - Line of sight
- **How much misalignment is allowed by the system?**
  - Accuracy required within 0.04 to 0.15 RMS um; +1% depending on Tx range.
  - N/A
- **Tracker type**
  - Laser radar
  - Video
- **Dilation required?**
  - Yes
  - No
- **Tracker sampling rate**
  - 4,000 times per second
  - N/A
- **Is the system closed or open loop?**
  - Closed-loop
  - Closed loop
- **Total latency from target measurement to laser pulse delivery**
  - 3 ms
  - 12 ms
- **Reference point for the tracking system?**
  - Pupil border. Pupil is dilated to paralyze it; tracker tracks the “frozen" pupillary border. If the image being tracked weren’t frozen, then accurate tracking cannot take place. This will become even more important with custom ablation.
  - Pupil or fixation ring
- **Maximum allowable Z-axis movement without affecting ablation profile**
  - +/-3 mm in Z axis
  - +/-5 mm
### Bausch & Lomb

**217A Excimer Laser**

- Ralph H. Thomas, Director of Refractive Marketing
- (909) 971-5277

- 2 mm, flying spot, modified Gaussian beam

- Laser parameters:
  - Wavelength: 193 nm
  - Spot size: 2.6 mm wide x 1.2 m deep x 1.5 M high

### LaserSight Technologies

**LaserScan LSX Laser System**

- (407) 678-9900 ext. 195

- Parameters:
  - Average: 0.8 to 1.0 mm
  - Super-Gaussian beam

### Nidek

**EC-5000 Excimer Laser System**

- (800) 223-9044, ext. 724

- Parameters:
  - Average: 0.69 mm/cm²
  - Average and peak: 140 mJ/cm²

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### Focus and Astigmatism

- Myopia up to -7D; astigmatism less than -3D

- 15-mm optical zone with transition zone of 3 mm

- Natural, undilated pupil. Active system tracks all pupil sizes independent of hydration or shape changes.

### Kaufman, M.D., et al.

- **Summary of Results**

- **1-year warranty included; covers parts and labor.**

- **Typically 2 to 4 weeks**

### Z-axes movement

- Z-axis movement won’t affect ablation profile; movement is observed during ablation.
**Company**

**WaveLight Laser Technologie AG**

**VISX**

**Product**

Allegretto Wave

STAR S3 ActiveTrak

**Contact Information**

+49-9131-6186-159

(408) 733-2020

**Beam size, type and shape**

0.95 mm, scanning spot laser, circular Gaussian beam profile

0.65-mm to 6.5-mm variable size circle. Other shapes for astig. and hyperopia Tx.

**Laser repetition rate**

200 Hz

10 Hz

**Average and peak fluence**

Average: 200 mJ/cm²  Peak: 400 mJ/cm²

Average and peak: 160 mJ/cm²

**FDA-approved corrections and ranges**

In U.S., device is investigational only. Studies ongoing.

PRK: myopia 0 to –12; myopic astig. 0 to –4D; hyperopia +1 to +6D; hyperopic astig. +0.5 to +3D; LASIK: myopia 0 to –14D; myopic astig. 0.5 to –3D; hyperopia +0.5 to +3D; hyperopic astig. 0 to +3D mixed astig., where cylinder less than or equal to –6D is greater than sphere, and cylinder and sphere have opposite signs.

**Maximum optical zone diameter/taper**

8-mm true optical zone with full refractive power, plus 1.0-mm transition zone

6.5 mm / 8.0 mm

**Ablation time for -8.00 -2.00 x 180 with 6.5-mm optical zone**

Approximately 49 seconds

50 seconds

**Patient alignment**

Patients' head firmly held with donut-shaped headrest. Optical alignment performed under microscope reticle using joystick. Fixation achieved using a fixation light coaxial to the laser beam. Visualization is excellent with a Zeiss operating microscope.

Sphinx position

**How does surgeon verify that eye is centered?**

Two angled distance measurement beams to verify focus and position. Patient stares at a green blinking focusing light. Purkinje reflexes used to confirm correct centration.

Patient fixation on the light, with feedback for alignment

**How are adjustments made to patient position for ease of procedure and flap visualization?**

Fine adjustments of the patient position are made using a joystick. Field illumination is provided using a white LED light source from multiple directions, providing a shadow and reflection-free view. An optional integrated Zeiss slit lamp is available, to permit high resolution verification of flap position and interface assessment.

Joystick moves bed in all three axes

**Purchase price/what's included/ yearly maintenance costs/per-procedure fee**

Not available in U.S.

$225,000 includes laser, patient chair, printer, accessory kit, surgeon stool, software license, 12-month limited warranty, lensometer, VisionKey Cards for PTK (Package of 10), Total Care Annual Service Agreement: $50,000. Various no-interest payment plans. Per-procedure service agreement available for $40 per procedure with $52,500/year cap. Customers who do not wish to purchase an all-inclusive service contract can purchase service and maintenance on a time and material basis. Per-procedure fee: $110.

**Maintenance included? What's covered and for how long?**

Laser not available in U.S. Internationally, maintenance is included during warranty. Comes with a 1-year manufacturer's warranty. Consumables excluded.

VISX warrants that each new laser will be free from defects in materials and workmanship for 12 months commencing on the date of initial installation of the STAR S3 when properly installed, maintained, and used for its intended purpose. During the warranty period VISX will, at its option, either repair or replace any equipment that does not conform to the foregoing warranty.

**Time it takes to get system delivered**

Laser not available in U.S. International delivery time is 4 to 8 weeks.

Variable

**Availability of service, training**

Laser not available in U.S. Internationally, basic and advanced training courses offered by WaveLight and Lumenis on a regular schedule. Extensive in-service training for surgeons and staff at laser installation. Included in purchase price: initial system operator and physician training not to exceed four system operators and five physicians.

**Machine dimensions**

Laser: 120 x 143 x 110 cm  Bed: 60 x 210 x 70 cm

Height: 59 in.; width: 50 in.; length: 80 in.

**Evergreen upgrades?**

Software and hardware updates provided during warranty period; upgrade packages for expanding Tx range or other applications offered as they become available.

No

**Approved aberrometer?**

Allegretto Wave Analyzer not for sale in U.S.

VISX WaveScan

**Wavefront or topographic device used**


VISX WaveScan

**Current status of custom ablation trials**

International studies ongoing. U.S. trials planned for later this year.

Phase III multicenter FDA trials

**Range of refractive error being treated**

Up to ~8D SEQ. Aberrometry measurements are possible for higher ranges.

Up to ~6.5D sphere, ~3D cylinder

**Wavelength used in trials**

660 nm with the Allegretto Wave Analyzer

785 nm

**How many measurements are used over a 7-mm pupil?**

Up to 98 dots out of a columnated grid pattern of 168 dots are used to display Zernike coefficients to the 6th order over a 7-mm pupil.

240

**Reference point for aligning wavefront measurement and Tx**

Pupil center, XY and Z coordinates used for the alignment of the patient's eye to the infrared camera. The software detects decelerations so corrections in the alignment can be made by the operator prior to capturing the image.

Patient alignment is over pupil center, as in wavefront. The exception would be angle-kappa, seen in some hyperopic patients.

**How much misalignment is allowed by the system?**

200 microns of deceleration when capturing the image with Allegretto Wave Analyzer

None. Wavefront data generated from exit pupil, which is used for alignment during the surgery.

**Tracker type**

Video-based, providing XY centration based on papillary margin detection.

VISX ActiveTrak. Video camera-based.

**Dilation required?**

No

No

**Tracker sampling rate**

200 Hz, synchronized with laser repetition rate

60 Hz

**If the system is closed or open loop?**

Closed loop

Not provided

**Total latency from target measurement to laser pulse delivery**

~8 ms

Not provided

**Reference point for the tracking system?**

The pupil center, derived from the intersection of the maximal X and Y diameter cords, is used for tracking. The ablation center can be adjusted by the surgeon using X and Y offsets, as desired.

Line of sight

**Maximum allowable Z-axis movement without affecting ablation profile**

+/- 1 mm

2 mm
COMMENTS FROM THE MANUFACTURERS

Alcon Summit Autonomous The LADARVision excimer laser system operates with the only FDA-approved laser radar eye tracker and the only eye tracker with FDA expanded claims that state laser ablation with the use of the tracker actually improves the accuracy of corneal shaping.

In addition to periodic software upgrades, many ergonomic improvements have been incorporated into the system, including two sources of enhanced lighting, a Zeiss microscope, a hinge ablation mask, a calibration arm, and a plume aspirator.

Asclepion-Meditec Although LASIK has been the dominant procedure for refractive corrections over the last several years, LASEK is rapidly increasing in popularity. Superior outcomes will eventually cause one procedure to be dominant over the other.

Bausch & Lomb The B&L Zyoptix system is combining the B&L 217A laser, which currently has unmatched FDA results, with not only a Zywave Schack-Hartmann aberrometer but also the Orbscan multidimensional corneal measurement system, which is the state-of-the-art in corneal topography. Trials in the United States have been completed for myopic patients. In addition, the Zywave system is widely available internationally, and thousands of customized ablation cases have been done by close to 150 installed systems. This has provided a large body of practical knowledge of the system in a “real-world” setting.

LaserSight Technologies LASEK for hyperopia with or without astigmatism and mixed astigmatism are under review by the FDA.

Nidek It’s worth noting that the EC-5000 does not need an eye tracker during standard LASIK procedures because of the dynamic rotating and overlapping delivery, or slit-scanning, system. Later, during custom ablation procedures, refractive outcomes can benefit from the use of an eye tracker because eye movements can cause an unprescribed ablation pattern, potentially resulting in under-corrections or induced astigmatism.

WaveLight Laser Technologie AG The Allegretto Wave Excimer Laser is a software-driven, flexible system. The laser does not rely on single-use masks, lenses and diaphragms to size and scan the treatment beam. The system allows for data input from a variety of sources, including manifest refraction data, as well as wavefront and topography-based data to optimize the treatment. Speed: The high repetition rate gives a very fast correction per diopter. This minimizes dehydration effects, flap shrinking and other outside influences. Precision: The Gaussian beam profile together with a small spot creates a smooth ablation pattern even for complicated treatments of higher-order aberrations. Better vision: The wavefront-optimized nomogram allows for large true optical zones and excellent mesopic vision after treatment. The whole system is designed to be quickly and easily set up and ready to use in a minimum of time. (Investigational device; not for sale in the United States.)

VISX The VISX WavePrint system incorporates both subjective and objective patient information into the platform. It uses diagnostic information taken from an initial WaveScan measurement to plan a treatment table for the ablation. This planned treatment is then ablated onto a plastic disk, the PreVue lens, and tested in trial lenses with the patient. Once a satisfactory result is achieved, the ablation is performed using the Star S3 laser, which features a three-dimensional tracker.

VISX is currently developing technology to replace the PreVue lens with adaptive optics, which uses a deformable mirror that is shifted to a pattern inverse to the patient’s wavefront. When an eye chart is displayed on this mirror, the patient sees the quality of his aberration-free vision, and is able to preview the postoperative results of the pending surgery. At this stage, the surgeon will be able to modify various Zernike terms to optimize the patient’s vision in the WaveScan unit, as well as in the final result. OM