innovation, inspiration... custom vision

iFIDELITY™

The 6 Elements of High Resolution Surgical Delivery

iFIDELITY™ is iVIS Technologies' industry leading, precision surgical ablation delivery system. Critical to custom vision surgery, iFIDELITY synthesizes 6 discrete elements to assure the accurate spatial delivery of the three-dimensional ablation profile to the cornea.

With legacy refractive surgical laser systems, only eyetracking speed was discussed as a metric of a refractive laser system's ability to improve the delivery accuracy of the planned treatment. iVIS sets a new standard in precision ablation delivery by looking not only at changes in translational eye position, but adding five important new technologies to assure that the entire ablation is accurately delivered. The iVIS Suite is the first and only system on the market today with this feature set.

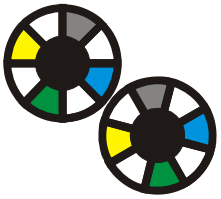
Definition

high fidelity \ high fi-del-i-ty\, *noun:*

1. the extremely high-quality reproduction of an effect (as sound or an image) that is very faithful to the original;
2. characterized by minimum distortion or error;
3. reproduced as near to the original as possible.

The term **high fidelity** has direct implications in refractive surgery. This describes accurate reproduction of the three dimensional ablation plan at its intended location. Multiple error sources, of which changes in eye position is only one, lead to a decrease in the precision of the ablation, i.e., decreased **fidelity** of the delivered ablation.

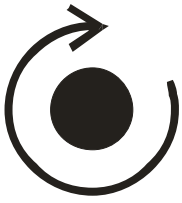
The optimum ablation profile is only an effective treatment with the desired visual outcomes, if the entire ablation plan is accurately reconstructed (complete volume and position) on the cornea. The iVIS Suite's high fidelity delivery system is controlled through a synthesis of six communicating subsystems of the iRES™ laser and its integrated data sources:



iDLIVE™ Ocular Features Registration

in-situ ocular identification and rotational registration

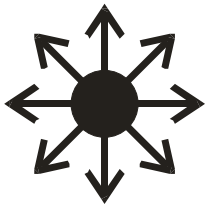
Utilizing detailed anterior segment data acquired from the Precisio tomographer, iDLIVE provide positive statistical identification ("ID") of preoperative diagnostic data to the operative eye, and automated in-situ operative rotational registration of the diagnostic data and ablation plan to the corresponding ocular features viewed by the laser's vision system. Rotational registration is widely considered to be the largest component of rotational alignment error.



iDLIVE™ Intra-Operative Rotational Eyetracking

cyclo-rotational tracking and compensation

iDLIVE provides the iRES laser with intra-operative rotational tracking and compensation for rotational eye and head position errors. iDLIVE provides continuous registration of the eye to the eye data package which includes corneal tomography, pupillometry, refractive data, and the ablation plan. Although intra-operative cyclotorsion may be smaller than the preoperative rotational registration compensation, it can contribute additional precision to the delivered surgery especially for complex irregular shapes.



iTRKR™

high-speed, synchronous eyetracking

The iRES laser features a state-of-the-art eyetracking system, developed exclusively for iVIS Technologies. This high-speed, synchronous eyetracking system eliminates the need for surgical field lighting obstructions required by other laser systems. iTRKR is simple to use, requires no pre-operative dilation and utilizes dynamic, intra-operative thresholding. This is an elegant solution to one source of ablation delivery error.

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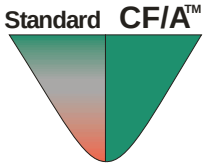
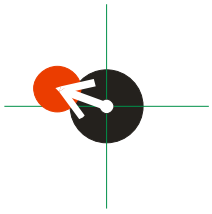
Constant Frequency per Area (CF/A)™



real-time attenuation of laser spot frequency per area

Uniquely, the iRES laser controls not only translational and rotational delivery precision, but leads the industry in controlling consistent fluence delivery per area to assure the precision of the ablation depth as well. Constant Frequency per Area ("CF/A") is iVIS Technologies' patent applied for technology that continuously varies pulse delivery frequency based upon the area being treated. This important feature improves fluence delivery consistency throughout the ablation profile. Older laser systems attempt to compensate for ablation rate variability induced by plume effect by adding additional pulses according to algorithms. This often requires the surgeon to both devise and maintain complex nomograms. This becomes much more unpredictable with complex and irregular custom ablation shapes. Effective delivery of constant pulse rate per area significantly improves the precision of energy delivery.

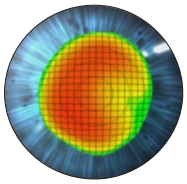
iControl™



intra-operative pupil dimension control

Routinely patients exhibit asymmetric pupil dilation. Uncompensated, the eyetracker will actively and variably decenter the ablation with the pupil centroid shift, thereby creating an eyetracked decentration that is often clinically undetected. The iRES laser's iControl feature utilizes detailed information on pupil size and position relative to the ablation plan. The iControl feature, by default, actively adjusts lighting intraoperatively to maintain the required pupil size and centroid that has been registered to the ablation plan's position on the cornea. Utilizing iControl, pupil centroid shifts from asymmetrical dilation that would normally be unaccounted for and erroneously included in the eyetracking compensations, are eliminated.

iVerify™



full-circle efficiency analysis of the intended surgical plan vs. achieved ablation

iVIS Technologies uniquely incorporates clinical verification of ablation delivery precision using key elements of the iVIS Suite. Utilizing the Precisio high definition tomographer and the ablation plan executed with the iRES laser, this process is easily incorporated into the post-operative follow-up utilizing a subtraction of the preoperative corneal elevation from the postoperative corneal elevation. This results in a differential that represents the tissue removed, or the *delivered ablation* map (inclusive of any biological and biomechanical responses). This *delivered ablation* map is then differentially compared to the ablation plan resulting in a three dimensional element, ideally of no volume, which represents the efficiency of ablation delivery and any biological / biomechanical responses. This is a remarkable tool for the surgeon to more fully understand even complex surgical solutions.

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