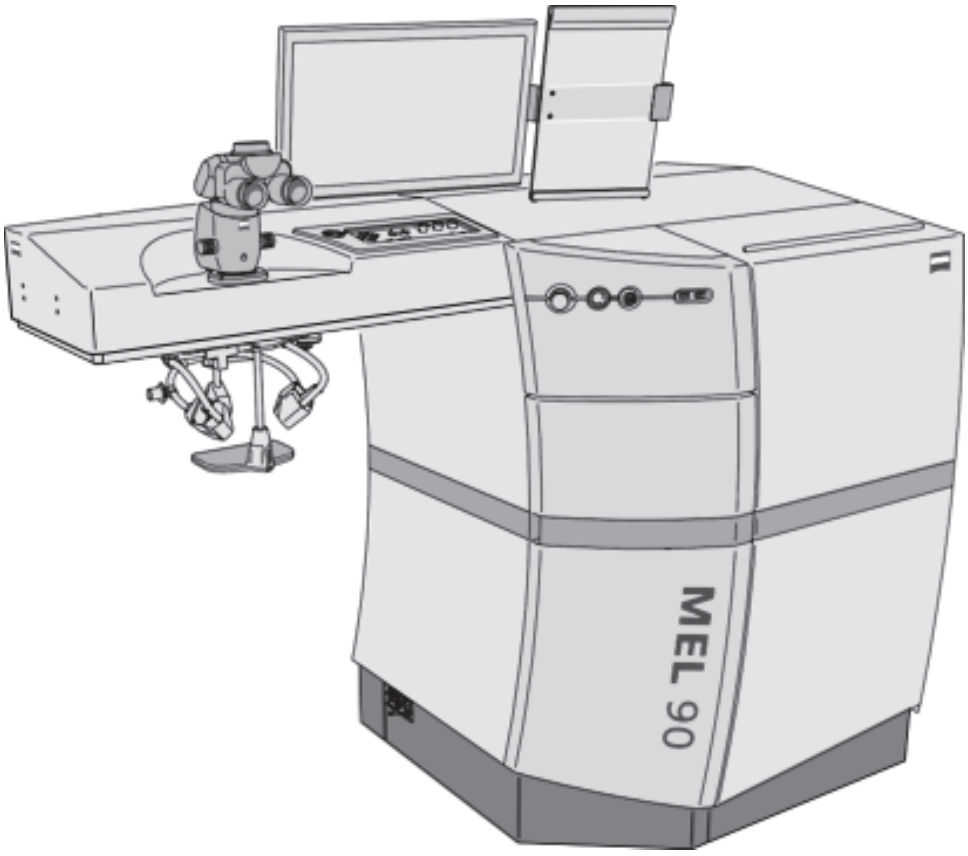
MEL 90

Laser-Assisted In Situ Keratomileusis (LASIK) for the correction of myopia and hyperopia with or without astigmatism and mixed astigmatism

PROFESSIONAL USE INFORMATION



ZEISS

Contents

Notes on the Professional Use Information

RESTRICTED DEVICE: U.S. Federal Law restricts this device to sale, distribution, and use by or on the order of a physician or other licensed practitioner.

Use of this device is restricted to practitioners who have been trained in its calibration and operation and who have knowledge of current therapy methods in refractive surgery and practical experience in corneal surgery.

This document (Professional Use Information) provides information concerning the intended clinical use of the ZEISS MEL 90. This manual must be used in conjunction with the MEL 90 user manual that provides general use information concerning system components, safety instructions, installation, maintenance, and troubleshooting for this device.

CAUTION

Carefully read all instructions prior to use. Observe all contraindications, warnings, and precautions noted in these instructions. Failure to do so may result in patient and/or user complications.

Purpose and availability of documents

This Professional Use Information booklet explains the safety precautions, functions, usage, and performance parameters of this option. In addition, the MEL 90 user manual should be observed which contains information on the operation of the device.

Correct operation of the device is imperative for its safe and successful function. You should therefore ensure that you are thoroughly familiar with this Professional Use Information booklet before setting up and using this option the first time.

The Professional Use Information booklet and other documents enclosed with this device should be kept accessible to users at all times to ensure that the information required for use of this product is readily available.

Questions and comments

If you have any questions or comments concerning this user manual or the device, please contact ZEISS customer service or your local dealer (Contact details see reverse).

Explanation of symbols used

The symbols used in this user manual refer to important safety information which may warn against possible health risks or fatal injuries and contain useful notes. Whenever you see these symbols, read the accompanying information carefully and observe all safety notes and information in this user manual and on device labels.

WARNING

Indicates a hazardous situation which may result in fatal or serious injury if the appropriate safety precautions are not heeded.

CAUTION

Indicates a situation in which special care should be exercised for the safe and effective use of the device.

☞ Information, hints and advice for a better understanding of the instructions to be observed in the operation of the device.

General Cautions

Reading this Professional Use Information document is not a substitute for the need to carefully study the MEL 90 user manual, or for the detailed training provided by ZEISS, nor does it release you from the obligation to update your own expertise in keeping up with the latest results of general research in the field of refractive surgery on a regular basis.

This device may only be set up, operated and used for the specified purpose. Observe all warnings, precautions, and contraindications as described in the Professional Use Information booklet and the MEL 90 user manual.

This device may only be installed, operated, used and maintained by persons who have been properly trained or who have the required knowledge and experience to do so.

Only accessories, including software, conforming to the requirements stated in this user manual may be used.

Use of the controls or settings in a manner other than described herein may result in exposure to dangerous radiation.

The light dosage from the illumination system is a product of light intensity and exposure time. In order to minimize radiation exposure, limit one of these parameters to the medically required level for observing the patient's eye. Exposure to light from this instrument when operated at maximum intensity will exceed the recommended maximum exposure (RME) of 2.2 J/cm², unless additional action is taken by the user to minimize exposure, after 8 min. The risk of retinal injury at an exposure of 2.2 J/cm² is not high, but because some patients may be more susceptible than others, caution is advised if this radiant exposure value is exceeded. However, because of a significant risk of injury at exposures exceeding 10 J/cm², the user should avoid exposures longer than 44 min.

Device description

MEL 90

The MEL 90 (see **Figure 1**) is designed for refractive surgery based on the ablation of corneal tissue achieved with a short pulse excimer laser having a wavelength of 193 nanometers. The laser head emits 4 to 7 nanosecond pulses (FWHM nominal pulse duration) with a repetition rate of 500 Hz. The MEL 90 is a spot-scanning laser that utilizes a Gaussian beam with a 0.7 mm spot diameter.

Figure 1. MEL 90 with patient supporting system LS Comfort 80 combi

The MEL 90 also contains an ablation debris removal system called the Cone for Controlled Atmosphere (CCA+). The CCA+ is an airflow system that ensures constant ablation debris removal from the beam path.

The MEL 90 is equipped with an active eye tracking system in order to be able to align the ablation spot to eye movements by determining the center of the pupil. To supply the eye tracker with illumination, the eye of the patient is illuminated by near-infrared (NIR) light which is not visible to patients. The system determines the pupil center from an infrared (NIR) image of the patient's eye, refreshed and processed at 1050 Hz.

A green laser (532 nm) light located inside the surgical microscope and centered on its optical axis serves as a fixation target for the patient. For ease of fixation, the laser is employed in a blinking mode at a frequency of 5Hz. The fixation light blinks during the entire surgery.

User control of the MEL 90 is implemented by a software application called the Operation Assistant (OPASS), which runs on the Main Control PC (operating system Windows 10) computer interface in order to provide the surgeon direct control over the preoperative data and an integrated application manual. The OPASS program allows the surgeon to import patient data and treatment plans, to input clinical data, and monitor the progress of the operation on a visual control panel. The Main Control PC transfers data to the Device Control (central control unit) of the excimer laser, which is fully independent and controls the operation of the excimer laser (note: the surgeon has no access to the Device Control).

The MEL 90 is equipped with a patient supporting system (LS Comfort 80 combi) for supporting and positioning the patient. The LS Comfort 80 combi includes motorized adjustment of the patient supporting surface.

The MEL 90 consists of the following major components:

Laser Arm	The Laser Arm contains the operating microscope, the debris removal system (called CCA+), the galvanometric scanners, the eye tracking camera, a portion of the optical system, the control panel and the laser arm interface.
Laser Unit	The excimer laser unit consists of the high voltage power supply, the solid state pulser circuit, the laser discharge trigger unit, and control interface board. The communication with the Device Control is done fiber-optically via the laser interface, which also optically controls the trigger unit. The laser head is provided with premix gas by the gas handling system.
Optics	The optics form the excimer raw beam and guide it to the treatment plane by means of a beam shaper, two lenses, and different mirrors, so that a well-defined beam of Gaussian shape emerges. A vacuum pump is used to evacuate air present in the beam path; this function is initiated automatically when the laser is started.
Device Control	The Device Control with laser control software (called POLO) provides the control of the whole laser system. It performs the following tasks: execution of the treatment (i.e. triggering of the laser head), monitoring and setting of the scanner position, control of the blower and the debris removal, communication with user interface software (called OPASS), execution of the gas management system functions, and energy control via high voltage setting and energy measuring.
Control Panel	The control panel provides control of the distance lasers (which are used for correct height adjstment of the patient's eye), the white light illumination, and the eyetracker parameters.
Eyetracker	A fast eyetracker unit ensures alignment of the laser beam to the eye of the patient in the working plane (2D eye tracking). It is comprised of a 1050 Hz infrared camera, an infrared LED illumination system (830 nm) and a separate control computer.
Operating Microscope	An operating stereomicroscope (OPMI) allows the surgeon to observe the patient's eye during the treatment.
Illumination System	An LED ring light consisting of 72 single visible light LEDs arranged in an annular pattern is mounted at the laser exit aperture for illumination of the operating area (maximum irradiance in treatment plane is 2.0 mW/cm²). In addition, there is a satellite illumination system (two visible light LEDs) mounted on the CCA+ unit to allow grazing-angle illumination of the patient's eye (maximum irradiance in treatment plane is 1.2 mW/cm²).
Gas Handling System	The gas handling system consists of a laser gas (premix) bottle, pipes, valves, pressure sensors, vacuum pump, filters (halogen), and pressure reducers. The central control unit performs an automatic gas change on user request. The bottles are placed inside the device.

CCA+ Debris Removal	A blower and suction unit called CCA+ debris removal provides a controlled environment at the patient's eye by removing the debris. It is mounted on a swivel arm (the entire component is referred to as the CCA+ unit), and also carries the infrared illumination. The CCA+ unit can be moved away when not in use.
Patient Supporting System	A motor-driven patient supporting system (LSC 80 combi) is movable in all 3 dimensions (X-, Y- and Z-directions). In addition, the patient headrest can be moved in the Z-direction and can be tilted in a dorsal and ventral direction. The bed can be swung out manually for easy exit of the patient.
Slit Lamp (optional)	The slit lamp produces an evenly illuminated field in front of a reflecting prism, the geometry and color of which can be varied by the use of apertures and filters. The slit lamp has a 6V (10W) halogen bulb, a slit width of 0.15 mm to 0.75 mm, and a slit height and illumination field size of 2 mm to 12 mm (continuous).

If the MEL 90 is operated in conjunction with VISUMAX 600/800, the system uses the LS Comfort 80 combi as joint patient supporting system.

If the MEL 90 is operated in conjunction with VisuMax, the MEL 90 system also uses the patient supporting system of the VisuMax.

The MEL 90 can be connected to the local clinic network and to the Zeiss FORUM patient image and data management system.

MEL 90 Laser Specifications:

Laser Type	Argon Fluoride Excimer Laser
Laser Wavelength	193 nm
Laser Spot Size (FWHM diameter)	0.7 mm ± 0.1 mm
Laser Pulse Duration (FWHM)	4 to 7 nanoseconds
Laser Head Repetition Rate	500 Hz
Fluence (at the treatment area)	> 150 mJ/cm² (peak)
Range of Ablation Diameter	Up to 9.2 mm (optical zone of 6.0 to 7.0 mm, diameter including a transition zone: up to 2.2 mm). The laser has a maximum ablation diameter of up to 10 mm.
Eyetracker, tracking frequency	1050 Hz
Working distance	190 mm ± 0.1 mm

Installation Requirements	Please refer to the Instructions for Use for restrictions, tolerances or other requirements established regarding room air circulation, clearance between the laser room walls, and distance between the laser and other electronic or radiation-producing medical equipment.
The software versions in the laser system are as follows:	a. OPASS Software version 4.3.4 b. Main Control PC Operating System: Image Version 4, Windows 10 c. POLO Software version 4.1.1.65 d. Eyetracker Firmware version 1.0.0.135 e. Software Package Gate Control version 1.1.2.

This laser is locked out for treatments outside the set approved and accepted under flagged warning treatment parameters.

Indications, contraindications, warnings, precautions, and potential risks

Indications for use

The MEL 90 is indicated for use in primary Laser-Assisted in situ Keratomileusis (LASIK) treatments for the reduction or elimination of:

- Myopia less in magnitude than -10.00 D sphere (in minus-cylinder notation), with and without cylinder up to -4.00 D, when MRSE is less in magnitude than -10.00 D;
- Hyperopia up to +4.00 D sphere (in plus-cylinder notation), with and without cylinder up to +3.00 D, when MRSE is up to +5.00 D; and
- Mixed astigmatism with cylinder from >1.00 D up to 4.00 D;

in patients who are 18 years of age or older with documentation of stable manifest refraction over the past year as demonstrated by a change in MRSE within +/- 0.50 D.

Contraindications

MEL 90 LASIK procedure is contraindicated in patients with:

- a residual stromal bed thickness that is less than 250 microns from the corneal endothelium;
- abnormal corneal topographic findings, e.g. keratoconus, pellucid marginal degeneration;
- severe dry eye;
- active eye infection or inflammation;
- recent herpes eye infection or problems resulting from past infection;
- active autoimmune disease or connective tissue disease;
- uncontrolled diabetes;
- uncontrolled glaucoma.
- who are pregnant or nursing.

Warnings

There is reasonable evidence to believe that there may be increased risk for serious adverse consequences if LASIK surgery is performed in patients with the following conditions, and therefore use of the MEL90 LASIK procedure is not recommended for patients with:

- controlled autoimmune or connective tissue disease;
- controlled diabetes;
- immunocompromised status (weakened immune system) due to medication or a disease condition, e.g., immunosuppressive therapy, such as corticosteroids, or AIDS;
- a history of Herpes simplex or Herpes zoster keratitis;
- controlled glaucoma;
- a history of taking isotretinoin (Accutane®);
- epithelial basement membrane dystrophy;
- amblyopia;
- moderate or mild symptoms of dry eye;
- difficulty following directions or who are unable to fixate;

and for patients who:

- take medication that have dry eyes as side effect;
- participate in activities that could damage the LASIK flap, including contact sports.

☞ In addition, please consult medical literature and recommendations of professional associations in your country.

Precautions

The safety and effectiveness of the MEL 90 LASIK procedure have NOT been established for patients:

- with refractive error outside the range in the approved indications for use;
- with a difference between cycloplegic and manifest refractions of greater than or equal to 0.75 D spherical equivalent in the eye to be treated;
- with central corneal thickness of less than 480 microns in the eye(s) to be treated;
- that are hyperopic with white-to-white distance <11.5 mm;
- with a family history of thinning of the cornea due to keratoconus, pellucid marginal degeneration, or other conditions that may cause ectasia;
- with large mesopic pupils, greater than the optical zone size, as evaluated under mesopic conditions;
- with previous corneal or intraocular surgery, or trauma to the intended ablation zone;
- with a history of strabismus;
- with iris problems including, but not limited to, coloboma and previous iris surgery compromising proper eye tracking;
- history of keloid formation;
- with active ophthalmic disease or abnormality (including, but not limited to, symptomatic blepharitis (e.g. ocular rosacea), recurrent corneal erosion, neovascularization >1 mm from limbus);
- with elevated intraocular pressure (IOP), ocular hypertension or being followed for possible glaucoma (glaucoma suspect);
- with severe allergies and eye rubbing;
- taking medications likely to affect wound healing including, but not limited to, antimetabolites;
- taking hormone replacement therapy or antihistamines who may experience delayed re-epithelialization of the cornea following surgery;
- taking the medication Amiodarone hydrochloride (Cordarone®);
- taking the medication sumatriptan succinate (Imitrex®);
- more than 12 months after surgery.
- with media problems (corneal, lens, and/or vitreous opacities including, but not limited to, cataract);
- with a history of uveitis;

Patient selection precautions

All patients must be given the opportunity to read and understand the Patient Information Booklet and to have all questions answered to their satisfaction prior to giving consent for the MEL 90 LASIK procedure. Consideration should be given to the following in determining the appropriate patients for the procedure:

- Complete examination, including but not limited to cycloplegic evaluation, must be performed. Preoperative corneal mapping is essential to exclude any topographical abnormalities, such as keratoconus. The lens must be evaluated, especially in older patients, to assure that nuclear sclerosis or any other lens opacity is not present prior to laser surgery. Indirect ophthalmoscopy through a dilated pupil is essential to rule out any retinal pathology.
- To obtain accurate and stable refractive information, contact lens wearers must be examined after a sufficient period of not wearing contact lenses. Additional precautions should be taken for rigid gas permeable or hard contact lens wearers with respect to stable central keratometry readings. Refractive stability is considered to be a change of ≤ 0.50 D in both MRSE as compared to the baseline measurements.
- Evaluation of the optic nerve and measurement of intraocular pressure are necessary to rule out glaucoma. If elevated intraocular pressure and/or evidence of glaucomatous damage are found, topical steroids should only be used with careful medical supervision, or the patient should not undergo refractive surgery.
- Pachymetry must be performed to obtain a baseline central corneal thickness measurement to assure that the combination of the planned corneal flap thickness and the planned ablation depth will not approach closer than 250 microns to the corneal endothelium.
- The patient should be without known major psychological disorders.
- The patient should be evaluated for any known sensitivity to planned concomitant medication.
- The patient should be able to lie flat without difficulty and fixate steadily for the procedure.
- The patient should be clearly informed of all alternatives for the correction of his/her refractive error including, but not limited to, spectacles, contact lenses, and other refractive surgeries, prior to consenting for the procedure.
- Due to the importance of managing patient expectations in elective refractive surgery, it is recommended that the physician:
  - convey realistic expectations to the prospective patient;
  - ensure patient comprehension of the risks and benefits at the start of the informed consent process;
  - discuss with patients how having the MEL 90 LASIK procedure may affect the future interpretation of intraocular pressure measurements; patients should be instructed to inform future eye care providers that they have had a refractive procedure to correct their refractive error;
  - discuss the risk of decreased contrast sensitivity potentially affecting activities under low-light conditions;
  - provide a patient information card that has eye measurements from before the procedure. Patients can keep this card to help their doctor calculate the lens implant power should they need to have future cataract surgery; a form for the necessary information is available on the internet.

Procedure-related precautions

Preoperative evaluation for dry eye should be performed. This may be particularly important for patients who have been contact lens intolerant because of symptoms of dryness. Patients should be advised of potential for worsening of symptoms associated with dry eye syndrome post-LASIK surgery.

The effect of LASIK on visual performance under poor lighting conditions have not been fully characterized. It is possible that following LASIK treatment, patients will find it more difficult to see in conditions such as very dim light, rain, snow, fog, or glare from bright lights at night. Visual performance possibly could be worsened in patients with large pupil sizes.

Intraocular pressure is more difficult to interpret after LASIK because of the resulting corneal thinning. Patients should be informed that they should tell future eyecare professionals that they have had LASIK.

Future intraocular lens calculations for cataract surgery may be affected by LASIK. The surgeon should give the patient a patient information card that has eye measurements from before the LASIK surgery. Patients should be advised to keep this card and give it to their future cataract surgeon.

Prior to surgery, prospective patients should be provided with a copy of the Patient Information Brochure for this product and informed of the possible risks and benefits associated with its use.

Potential risks

The potential risks associated with the MEL 90 LASIK procedure include, but are not limited to:

- Loss of best spectacle corrected visual acuity (BSCVA);
- Over-correction or under-correction;
- Increase in refractive cylinder;
- Difficulty with night driving or other low light tasks;
- Headache or eyestrain due to imbalance between the eyes;
- Worsening of patient complaints such as glare, halos, starbursts, hazy or blurred vision, distortion, double or ghost images, fluctuation of vision, focusing difficulty, difficulty with depth perception, light sensitivity, grittiness, and ocular pain/soreness;
- Dry eye;
- Ptosis;
- Increase in IOP;
- Conjunctivitis;
- Discomfort or pain; potentially including chronic eye pain that is resistant to therapy referred to as neuropathic corneal pain;
- Iritis;
- Corneal haze/scar/infection/inflammation/infiltrate/ulcer/epithelial defect/epithelium in the interface/ edema/decompensation/striae or microstriae/ectasia;
- Perforated, miscreated, or melting of the flap;
- Treatment interruption, difficult flap lifting with tissue damage, ocular penetration;
- Retinal detachment/posterior vitreous detachment/vascular accidents.

For further discussion of adverse events and complications that occurred during the course of the clinical trial, refer to the section *Clinical Results.*

Alternative Treatment Options

Alternatives to the LASIK procedure available to a patient might include spectacle correction (glasses), contact lenses, surgery with another FDA approved laser using Photo Refractive Keratectomy (PRK), LASIK, Small Incision Lenticule Extraction (SMILE), or a lens implant surgically placed inside the eye. You should discuss with your patient whether they are a candidate for these procedures as well as the risks/benefits of each alternative. Furthermore, for this discussion important information about these alternative procedures is available at the following websites (accessed June 2023):

- FDA
  http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/SurgeryandLifeSupport/LASIK/default.htm
- NEI
  https://www.nei.nih.gov/learn-about-eye-health/eye-conditions-and-diseases/refractive-errors
- AAO
  http://www.aao.org/eye-health/treatments/lasik
- FTC
  https://www.consumer.ftc.gov/articles/0062-basics-lasik-eye-surgery#lasikbasics

Clinical results

ZEISS conducted a pivotal clinical study to assess the safety and effectiveness of the ZEISS MEL 90 for patients who are 18 years of age or older with stable refractive errors up to -10.00 D of myopia with and without cylinder up to -4.00 D, hyperopia up to +5.00 D with and without cylinder up to +4.00 D, and mixed astigmatism up to 4.00 D in magnitude with spherical equivalent from -11.00 D through +5.00 D.

Study design

This was a prospective, multi-center, single-armed, unmasked clinical study. Subjects were followed for 12 months postoperatively. Retreatments were not allowed during the study.

Follow-up examinations were scheduled at 1 day, 1 week, 1 month, 3 months, 6 months, 9 months, and 12 months, as follows:

Preoperative Evaluation:	Day -60 to Day -1
Operative Evaluation:	Day 0, day of surgery
Postoperative Day 1:	Day 1
Postoperative Week 1:	Days 5 to 9
Postoperative Month 1:	Days 21 to 35 (Weeks 3 to 5)
Postoperative Month 3:	Days 70 to 98 (Weeks 10 to 14)
Postoperative Month 6:	Days 147 to 182 (Weeks 21 to 26)
Postoperative Month 9:	Days 245 to 301 (Weeks 35 to 43)
Postoperative Month 12:	Days 330 to 420 (Months 11 to 14)

The results for visual acuities are presented in logMAR acuity scores, with 0.0 logMAR equivalent to 20/20 Snellen, and 0.3 logMAR equivalent to 20/40 Snellen.

The key effectiveness variables for the study were:

- Refractive Predictability: MRSE and MRCYL within ± 1.00 D and ± 0.50 D of the intended refractive outcome at the point at which stability is established.
- Uncorrected Distance Visual Acuity: UCDVA of 0.3 logMAR or better at the point at which stability is established.

For eyes treated for myopia or hyperopia with astigmatism and mixed astigmatism eyes, the following effectiveness variables were also reported:

- Vector analysis: the absolute value of the intended refractive correction (|IRC|) vector, the absolute value of the surgically induced refractive correction (|SIRC|) vector, absolute value of the error vector (|EV|), correction ratio (CR), error ratio (ER) pooled and stratified by baseline magnitude of cylinder.
- Predictability: the percentage of eyes achieving MRCYL within ± 1.00 D of the intended outcome, and within ± 0.50 D of the intended outcome at the point at which stability is established.

Refractive stability was also evaluated according to the guidance. Stability was considered to have been achieved at the latter of two postoperative refractions performed at least 3 months apart or at 3 months after surgery when compared with the 1-month interval, if all of the stability criteria were met. These criteria were as follows:

- At least 95% of the treated eyes should have a change ≤ 1.00 D of MRSE, MRCYL, and vector cylinder at the latter of two postoperative refractions performed at least 3 months apart or at 3 months after surgery when compared with the 1-month interval;
- The mean rate of change in MRSE, MRCYL, and vector cylinder, as determined by paired analysis, is ≤ 0.5 D per year 0.04 D/month) over the same time period;
- The mean rate of change of MRSE, MRCYL, and vector cylinder decreases monotonically over time, with a projected asymptote of zero or a rate of change attributable to normal aging;

- The 95% confidence interval for the mean rate of change includes zero or a rate of change attributable to normal aging;
- Stability will be confirmed at least 3 months after the stability time point by a statistically adequate subgroup.

The key safety variables for the study were:

- Decrease in Best Corrected Distance Visual Acuity (BCDVA):
  - In eyes with preoperative BCDVA 0.0 logMAR or better, the percentage of eyes with BCDVA worse than 0.3 logMAR at the postoperative interval at which stability is established were calculated.
  - Percentage of eyes with BCDVA loss ≥ 10 letters from baseline at the point at which stability is established were calculated.
- Induced Manifest Refractive Astigmatism: The percentage of eyes with induced manifest refractive cylinder of > 2.00 D of absolute cylinder at the postoperative interval at which stability is established were calculated.
- Incidence of Adverse Events: The rate of each type of adverse event, by the proportion of subject and eyes, were summarized.

Inclusion and exclusion criteria

Enrollment in the study was limited to subjects who met the following inclusion criteria:

- Male or females must be at least 18 years of age.
- Myopia up to -10.00 D with and without cylinder up to -4.00 D, or hyperopia up to +5.00 D with and without cylinder up to +4.00 D, or mixed astigmatism up to 4.00 D in magnitude; with spherical equivalent from -11.00 D through +5.00 D.
- Intended treatment targeted for emmetropia in the eye(s) to be treated.
- Stable refraction (within ± 0.50 D), as determined by MRSE for a minimum of 12 months prior to surgery, verified by consecutive manifest refractions and/or medical records or glasses prescription history in the eye(s) to be treated.
- A difference between cycloplegic and manifest refractions of < 0.75 D spherical equivalent in the eye(s) to be treated.
- For myopes, an uncorrected distance visual acuity (UCDVA) of 0.3 logMAR or worse in the eye(s) to be treated; for hyperopes and mixed astigmatism, difficulty maintaining UCDVA of 0.3 logMAR, as evidenced by the need for constant contact lens wear or spectacle wear in the eye(s) to be treated.
- Best corrected distance visual acuity (BCDVA) of at least 0.0 logMAR in the eye(s) to be treated.
- Must be willing to discontinue use of contact lenses for at least 2 weeks (for hard lenses) or 3 days (for soft lenses) prior to the preoperative examination, and through the day of surgery in the eye(s) to be treated.
- Contact lens wearers must demonstrate a stable refraction (within ±0.5 D), as determined by MRSE, on two consecutive examinations at least 1 week apart, in the eye(s) to be treated after discontinuing contact lens use for at least 2 weeks (for hard lenses) or 3 days (for soft lenses) prior to baseline examination.
- Central corneal thickness of at least 480 microns in the eye(s) to be treated.
- Willing and able to return for scheduled follow-up examinations.
- Able to follow study instruction in English.

Patients were not permitted to enroll in the study if they met any of the following exclusion criteria:

- Anticipated residual stromal bed thickness < 250 microns in the eye(s) to be treated.
- Fellow eye BCDVA worse than 0.3 logMAR.

- Abnormal corneal topographic findings, e.g. keratoconus, pellucid marginal degeneration in either eye.
- History of or current anterior or posterior segment pathology, including cataracts in the eye(s) to be treated.
- Planned treatment for monovision.
- History of any of the following medical conditions, or any other condition that could affect wound healing: collagen vascular disease, autoimmune disease, immunodeficiency diseases, endocrine disorders (including, but not limited to unstable thyroid disorders), lupus, rheumatoid arthritis, diabetes (regardless of type, duration, severity or control); active ophthalmic disease or abnormality (including, but not limited to, symptomatic blepharitis, recurrent corneal erosion, severe dry eye syndrome or symptoms, neovascularization > 1 mm from limbus), retinal detachment/repair, clinically/visually significant lens opacity, clinical evidence of trauma, corneal opacity within the central 9 mm and visible on topography, at risk for developing strabismus, or with ocular hypertension, intraocular pressure (IOP) >21 mmHg at screening or evidence of glaucoma or propensity for narrow angle glaucoma.
- Residual, recurrent, active ocular or uncontrolled eyelid disease, corneal scars or other corneal abnormality such as recurrent corneal erosion or severe basement membrane disease in the eye(s) to be treated.
- Ophthalmoscopic signs of progressive or unstable myopia or keratoconus suspect in either eye.
- Irregular or unstable (distorted/not clear) corneal mires on central keratometry images in either eye.
- History of ocular herpes zoster or herpes simplex keratitis in either eye.
- Difficulty following directions or unable to fixate.
- For hyperopes, clinically measurable strabismus or amblyopia in the eye(s) to be treated.
- For hyperopes, white-to-white less than or equal to 11.5 mm as measured by corneal topography in the eye(s) to be treated.
- For hyperopes, slit lamp examination demonstrating potentially occludable angle as judged by the investigator in the eye(s) to be treated.
- Previous intraocular or corneal surgery of any kind in the eye(s) to be treated, including any type of surgery for either refractive or therapeutic purposes.
- History of steroid-responsive rise in intraocular pressure, glaucoma, or preoperative IOP > 21 mmHg in either eye.
- Immunocompromised or requires chronic systemic corticosteroids or other immunosuppressive therapy that may affect wound healing.
- History of or has a current, clinically significant major psychiatric disorder (e.g., major depressive disorder, psychosis, schizophrenia).
- Subjects with known sensitivity to planned study concomitant medications.
- Enrollment in another drug or device clinical study within the prior 3 months.
- Subjects who are pregnant, lactating, or of child-bearing potential and not practicing a medically approved method of birth control.

Further, fellow (second) eyes of patients undergoing simultaneous, bilateral treatment were not enrolled in the study if they met any of the following exclusion criteria:

- Flap complications during the first eye's surgery such as a free cap, partial flap, thin flap, or irregular flap.
- Epithelial defect exceeding 2 mm x 2 mm in dimension.
- Severe blepharospasm in the first eye that may have prevented or impeded the completion of the keratectomy and/or the laser ablation procedure.
- Poor subject cooperation with instructions for the first eye's surgery and/or poor subject fixation on the laser fixation target.

- Aborted LASIK procedure in the first eye or PRK was performed in the first eye because LASIK was not possible.

Results and data analysis

Demographics and baseline parameters

A total of 836 eyes of 418 subjects were enrolled in the study between 1 October 2019 and 24 April 2024; of these, 714 eyes of 358 subjects were treated at 9 investigational sites. Two subjects had unilateral treatments. Of the 714 eyes receiving treatment, 358 eyes underwent treatment for myopia with or without astigmatism (myopia cohort), 221 eyes underwent treatment for hyperopia with or without astigmatism (hyperopia cohort) and 135 eyes underwent mixed astigmatism treatment (mixed astigmatism cohort).

A summary of demographic information for all treated subjects is provided in **Table 1**, with stratification by subjects treated for each cohort; myopia, hyperopia, and mixed astigmatism.

Subjects ranged in age from 18 to 63 years, with a mean age of 35.7 years for all treated eyes. The distribution of females and males enrolled in the study was essentially even for the total population; however, in the hyperopia cohort, more females (55.6%) than males (44.4%) were enrolled and treated in the study and in the mixed astigmatism cohort, more males (59.7%) than females (40.3%) were treated. The majority of subjects were Caucasian (91.9%).

TABLE 1
DEMOGRAPHICS FOR ALL TREATED SUBJECTS BY TREATMENT COHORT

		Myopia		Hyperopia		Mixed Astigmatism		Total	
		N (%)		N (%)		N (%)		n/N (%)	
Gender	Male	88/183	(48.1%)	52/117	(44.4%)	46/77	(59.7%)	177/358	(49.4%)
	Female	95/183	(51.9%)	65/117	(55.6%)	31/77	(40.3%)	181/358	(50.6%)
Race	White	167/183	(91.3%)	109/117	(93.2%)	71/77	(92.2%)	329/358	(91.9%)
	Black	4/183	(2.2%)	6/117	(5.1%)	1/77	(1.3%)	11/358	(3.1%)
	Asian	8/183	(4.4%)	0/117	(0.0%)	0/77	(0.0%)	8/358	(2.2%)
	Other	4/183	(2.2%)	2/117	(1.7%)	5/77	(6.5%)	10/358	(2.8%)
Ethnic	Hispanic or Latino	13/183	(7.1%)	8/117	(6.8%)	10/77	(13.0%)	28/358	(7.8%)
	Not Hispanic or Latino	170/183	(92.9%)	109/117	(93.2%)	67/77	(87.0%)	330/358	(92.2%)
Age (years)	Mean (SD)	33.1 (7.5)		39.9 (11.5)		35.3 (9.1)		35.7 (9.6)	
	Median	32.0		42.0		35.0		34.0	
	Min, Max	19, 63		18, 62		20, 57		18, 63	
Age Category	18 to < 22	9/183	(4.9%)	5/117	(4.3%)	6/77	(7.8%)	18/358	(5.0%)
	22 and older	174/183	(95.1%)	112/117	(95.7%)	71/77	(92.2%)	340/358	(95.0%)

Abbreviations: SD=Standard Deviation.

Note: Of 418 Subjects enrolled, 417 were assigned to cohorts, and 358 treated. 19 had OD and OS assigned to a different cohort (8 were assigned to myopia and mixed astigmatism and 11 to hyperopia and mixed astigmatism). Therefore, the number of subjects in tables of the 3 cohorts will sum to more than the number of subjects in the overall table.

Note that only treated subjects are summarized.

Tables 2.1 and 2.2 show the distribution of baseline manifest refraction sphere (MRSPH) and cylinder (MRCYL) for all treated eyes, with stratification by subjects treated for each cohort; myopia, hyperopia, and mixed astigmatism. For these tables, the baseline refraction is represented in minus cylinder form for all cohorts. As a result, 11 eyes in the hyperopia cohort have a MRSPH greater than +5.00 D in minus cylinder form; however, these same eyes are within the treatment range of +5.00 D MRSPH when represented in plus cylinder form.

Mean manifest refraction sphere at baseline for all treated eyes was -1.17 D, with a range of -10.00 D to +6.25 D. By cohort, the mean MRSPH was -4.65 D, +2.97 D and +1.26 D for the myopia, hyperopia and mixed astigmatism cohorts, respectively.

TABLE 2.1
PREOPERATIVE MANIFEST REFRACTION SPHERE (MRSPH)
FOR ALL EYES BY TREATMENT COHORT

Cohort	Myopia Eyes		Hyperopia Eyes		Mixed Astigmatism Eyes		Total Eyes	
	N (%)		N (%)		N (%)		N (%)	
-10.00 to -9.01 D	26/358	(7.3%)					26/714	(3.6%)
-9.00 to -8.01 D	28/358	(7.8%)					28/714	(3.9%)
-8.00 to -7.01 D	26/358	(7.3%)					26/714	(3.6%)
-7.00 to -6.01 D	29/358	(8.1%)					29/714	(4.1%)
-6.00 to -5.01 D	42/358	(11.7%)					42/714	(5.9%)
-5.00 to -4.01 D	38/358	(10.6%)					38/714	(5.3%)
-4.00 to -3.01 D	45/358	(12.6%)					45/714	(6.3%)
-3.00 to -2.01 D	47/358	(13.1%)					47/714	(6.6%)
-2.00 to -1.01 D	48/358	(13.4%)					48/714	(6.7%)
-1.00 to -0.01 D	25/358	(7.0%)					25/714	(3.5%)
0.00 D	4/358	(1.1%)	0/221	(0.0%)	0/135	(0.0%)	4/714	(0.6%)
+0.01 to +1.00 D			15/221	(6.8%)	77/135	(57.0%)	92/714	(12.9%)
+1.01 to +2.00 D			50/221	(22.6%)	26/135	(19.3%)	76/714	(10.6%)
+2.01 to +3.00 D			55/221	(24.9%)	23/135	(17.0%)	78/714	(10.9%)
+3.01 to +4.00 D			48/221	(21.7%)	9/135	(6.7%)	57/714	(8.0%)
+4.01 to +5.00 D*			42/221*	(19.0%)			42/714	(5.9%)
+5.01 to +6.00 D*			10/221*	(4.5%)			10/714	(1.4%)
+6.01 to +7.00 D*			1/221*	(0.5%)			1/714	(0.1%)
N	358		221		135		714	
Mean (SD)	-4.64 (2.74)		+2.97 (1.31)		+1.26 (0.99)		-1.17 (4.12)	
Median	-4.50		3.00		+1.00		0.00	
Min, Max	-10.0, 0.00		+0.75, +6.25		+0.25, +3.50		-10.0, +6.25	

Abbreviations: SD=Standard Deviation.
*Shaded cells: Treatment of > +4.00 D sphere (in plus-cylinder notation) will present a flagged warning to the user indicating that correction of these powers is outside the range of the approved indications for use.

As shown in **Table 2.2**, the mean manifest refraction cylinder at baseline for all enrolled eyes was -1.300 D, with a range of - 4.00 D to 0.00 D. The range of baseline MRCYL was the same for the myopia and hyperopia cohorts (- 4.00 D to 0.00 D), with a mean MRCYL of -1.002 D and -0.988 D, respectively. The mixed astigmatism cohort had a mean MRCYL of -2.602 D (range -4.00 D to -0.75D).

TABLE 2.2
PREOPERATIVE MANIFEST REFRACTION CYLINDER (MRCYL)
FOR ALL EYES BY TREATMENT COHORT

Cohort	Myopia Eyes		Hyperopia Eyes		Mixed Astigmatism Eyes		Total Eyes	
	N (%)		N (%)		N (%)		N (%)	
-3.01 to -4.00 D*	24/358	(6.7%)	12/221*	(5.4%)	51/135	(37.8%)	87/714	(12.2%)
-2.01 to -3.00 D	34/358	(9.5%)	26/221	(11.8%)	39/135	(28.9%)	99/714	(13.9%)
-1.01 to -2.00 D	65/358	(18.2%)	29/221	(13.1%)	30/135	(22.2%)	124/714	(17.4%)
-1.00 D**	25/358	(7.0%)	23/221	(10.4%)	13/135**	(9.6%)	61/714	(8.5%)
-0.75 D**	44/358	(12.3%)	29/221	(13.1%)	2/135**	(1.5%)	75/714	(10.5%)
-0.50 D***	37/358	(10.3%)	26/221	(11.8%)	0/135***	(0.0%)	63/714	(8.8%)
-0.25 D***	37/358	(10.3%)	18/221	(8.1%)	0/135***	(0.0%)	55/714	(7.7%)
0.00 D***	92/358	(25.7%)	58/221	(26.2%)	0/135***	(0.0%)	150/714	(21.0%)
N	358		221		135		714	
Mean (SD)	-1.002 (1.048)		-0.988 (1.040)		-2.602 (0.992)		-1.300 (1.210)	
Median	-0.75		-0.75		-2.75		-1.00	
Min, Max	-4.00, 0.00		-4.00, 0.00		-4.00, -0.75		-4.00, 0.00	

Abbreviations: SD=Standard Deviation.
Shaded cells:
* Treatments of hyperopia with cylinder magnitude > 3.00 D through 4.0 D will present a flagged warning to the user indicating that correction of these powers is outside the range of the approved indications for use.
** Treatments of mixed astigmatism with cylinder miagnitude up to 0.50 D will be locked out.
*** Treatments of mixed astigmatism with cylinder magnitude > 0.50 D through 1.00 D will present a flagged warning to the user indicating that correction of these powers is outside the range of the approved indications for use.

Accountability

Of the 836 eyes of 418 subjects enrolled, 382 eyes of 195 subjects were assigned to the myopia cohort, 293 eyes of 154 subjects to the hyperopia cohort, and 157 eyes of 89 subjects to the mixed astigmatism cohort. Four eyes were not assigned: two (2) eyes of 1 subject and 2 fellow eyes of 2 subjects due to screen failure of the primary eye.

Of all enrolled eyes, 122 were not treated. Of those, 98 eyes of 49 subjects and 1 eye each of 2 subjects were excluded from the study based on failure to meet inclusion criteria or meeting exclusion criteria; 8 subjects (16 eyes) withdrew consent; and 3 subjects (6 eyes) were discontinued by the investigator.

As a result, 714 eyes of 358 subjects were treated,of which 358 eyes of 183 subjects received treatment for myopia, 221 eyes of 117 subjects for hyperopia, and 135 eyes of 77 subjects for mixed astigmatism.

Over the course of the postoperative follow-up, greater than 92% accountability was achieved at all scheduled visits through Month 12, except Months 3 and 6 (**Table 3**). At the Month 6 visit, percent accountability for all available eyes within window was 89.3% and percent accountability for all available eyes completing visits whether within window or out of window was 96.6%. The exam cut-off for inclusion in analyses for this report was April 24, 2024; therefore, a small number of eyes were still active at the time of this report. With 6 eyes active at Month 12, the percent accountability for all available eyes within window was 96.0% and percent accountability for all available eyes completing visits whether within window or out of window was 96.6%.

TABLE 3 - POSTOPERATIVE ACCOUNTABILITY FOR ALL EYES

N=714 Eyes		Day 1	Week 1	Month 1	Month 3	Month 6	Month 9	Month 12
Available for analysis	In or Out of Window	712 (99.7%)	700 (98.0%)	686 (96.1%)	684 (95.8%)	684 (95.8%)	666 (93.3%)	674 (94.4%)
	In Window	712 (99.7%)	694 (97.2%)	654 (91.6%)	638 (89.4%)	632 (88.5%)	650 (91.0%)	670 (93.8%)
	Out of Window	0 (0.0%)	6 (0.8%)	32 (4.5%)	46 (6.4%)	52 (7.3%)	16 (2.2%)	4 (0.6%)
Active		0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	6 (0.8%)
Discontinued		2 (0.3%)	2 (0.3%)	4 (0.6%)	4 (0.6%)	6 (0.8%)	8 (1.1%)	10 (1.4%)
Lost to follow-up		0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	10 (1.4%)	16 (2.2%)
Missed visit	Missing	0 (0.0%)	12 (1.7%)	24 (3.4%)	26 (3.6%)	22 (3.1%)	28 (3.9%)	8 (1.1%)
	Missing or Out of Window	0 (0.0%)	18 (2.5%)	56 (7.8%)	72 (10.1%)	74 (10.4%)	44 (6.2%)	12 (1.7%)
% Accountability*	In or Out of Window	712 / 712 (100.0%)	700 / 712 (98.3%)	686 / 710 (96.6%)	684 / 710 (96.3%)	684 / 708 (96.6%)	666 / 704 (94.6%)	674 / 698 (96.6%)
	In Window	712 / 712 (100.0%)	694 / 712 (97.5%)	654 / 710 (92.1%)	638 / 710 (89.9%)	632 / 708 (89.3%)	650 / 704 (92.3%)	670 / 698 (96.0%)
	Out of Window	0 / 712 (0.0%)	6 / 712 (0.8%)	32 / 710 (4.5%)	46 / 710 (6.5%)	52 / 708 (7.3%)	16 / 704 (2.3%)	4 / 698 (0.6%)

* % Accountability = Available for Analysis / (Treated - [Discontinued + Active])

The accountability for each of the treatment cohorts is shown below in **Tables 3.1 to 3.3**.

For the myopia cohort of 382 enrolled eyes, 358 were treated. Twenty-four of the eyes were not treated, 20 based on failure to meet inclusion criteria or meeting exclusion criteria; 4 eyes (2 subjects) withdrew consent.

For hyperopia cohort of 293 enrolled eyes, 221 were treated. Seventy-two (72) of the eyes were not treated, 62 eyes based on failure to meet inclusion criteria or meeting exclusion criteria; 6 eyes (3 subjects) withdrew consent; and 4 eyes (2 subjects) were discontinued by the investigator.

For the mixed astigmatism cohortof the 157 enrolled eyes,135 were treated. Twenty-four of thee eyes were not treated, 20 due to not meeting Inclusion/Exclusion Criteria; 6 eyes (3subjects) due to the withdrawal of consent; and 2 eyes (1 subject) was discontinued by the investigator.

For all three cohorts, when considering eyes within window, greater than 90% accountability was for all visits through Month 12, except Month 6 for the myopia cohort and Months 3 and 6 for the hyperopia cohort. Accountability for eyes whether within or out of window exceeded 95% for the myopia and mixed astigmatism cohorts. For the hyperopia cohort, accountability for eyes whether within or outside of window was at least 93% for all visits, except for Month 9 where accountability was 88.5% due to a higher number of missed visits at this exam. Each cohort had two (2) eyes still active at the Month 12 visit.

TABLE 3.1 - POSTOPERATIVE ACCOUNTABILITY FOR ALL MYOPIA COHORT EYES

N=358 Eyes		Day 1	Week 1	Month 1	Month 3	Month 6	Month 9	Month 12
Available for analysis	In or Out of Window	356 (99.4%)	353 (98.6%)	340 (95.0%)	345 (96.4%)	342 (95.5%)	347 (96.9%)	348 (97.2%)
	In Window	356 (99.4%)	352 (98.3%)	329 (91.9%)	321 (89.7%)	307 (85.8%)	339 (94.7%)	345 (96.4%)
	Out of Window	0 (0.0%)	1 (0.3%)	11 (3.1%)	24 (6.7%)	35 (9.8%)	8 (2.2%)	3 (0.8%)
Active		0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.6%)
Discontinued		2 (0.6%)	2 (0.6%)	2 (0.6%)	2 (0.6%)	2 (0.6%)	2 (0.6%)	2 (0.6%)
Lost to follow-up		0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (1.1%)	4 (1.1%)
Missed visit	Missing	0 (0.0%)	3 (0.8%)	16 (4.5%)	11 (3.1%)	14 (3.9%)	5 (1.4%)	2 (0.6%)
	Missing or Out of Window	0 (0.0%)	4 (1.1%)	27 (7.5%)	35 (9.8%)	49 (13.7%)	13 (3.6%)	5 (1.4%)
% Accountability*	In or Out of Window	356 / 356 (100.0%)	353 / 356 (99.2%)	340 / 356 (95.5%)	345 / 356 (96.9%)	342 / 356 (96.1%)	347 / 356 (97.5%)	348 / 354 (98.3%)
	In Window	356 / 356 (100.0%)	352 / 356 (98.9%)	329 / 356 (92.4%)	321 / 356 (90.2%)	307 / 356 (86.2%)	339 / 356 (95.2%)	345 / 354 (97.5%)
	Out of Window	0 / 356 (0.0%)	1 / 356 (0.3%)	11 / 356 (3.1%)	24 / 356 (6.7%)	35 / 356 (9.8%)	8 / 356 (2.2%)	3 / 354 (0.8%)

Subject (01-074) experienced a seizure prior to undergoing treatment with the MEL 90. As the procedure was not completed, the subject was discontinued due to the unrelated medical event.

* % Accountability = Available for Analysis / (Treated - [Discontinued + Active])

TABLE 3.2 - POSTOPERATIVE ACCOUNTABILITY FOR ALL HYPEROPIA COHORT EYES

N=221 Eyes		Day 1	Week 1	Month 1	Month 3	Month 6	Month 9	Month 12
Available for analysis	In or Out of Window	221 (100.0%)	213 (96.4%)	219 (99.1%)	210 (95.0%)	210 (95.0%)	193 (87.3%)	199 (90.0%)
	In Window	221 (100.0%)	213 (96.4%)	205 (92.8%)	193 (87.3%)	202 (91.4%)	189 (85.5%)	199 (90.0%)
	Out of Window	0 (0.0%)	0 (0.0%)	14 (6.3%)	17 (7.7%)	8 (3.6%)	4 (1.8%)	0 (0.0%)
Active		0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.9%)
Discontinued		0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	3 (1.4%)	5 (2.3%)
Lost to follow-up		0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.9%)	6 (2.7%)	11 (5.0%)
Missed visit	Missing	0 (0.0%)	8 (3.6%)	2 (0.9%)	11 (5.0%)	8 (3.6%)	19 (8.6%)	4 (1.8%)
	Missing or Out of Window	0 (0.0%)	8 (3.6%)	16 (7.2%)	28 (12.7%)	16 (7.2%)	23 (10.4%)	4 (1.8%)
% Accountability*	In or Out of Window	221 / 221 (100.0%)	213 / 221 (96.4%)	219 / 221 (99.1%)	210 / 221 (95.0%)	210 / 220 (95.5%)	193 / 218 (88.5%)	199 / 214 (93.0%)
	In Window	221 / 221 (100.0%)	213 / 221 (96.4%)	205 / 221 (92.8%)	193 / 221 (87.3%)	202 / 220 (91.8%)	189 / 218 (86.7%)	199 / 214 (93.0%)
	Out of Window	0 / 221 (0.0%)	0 / 221 (0.0%)	14 / 221 (6.3%)	17 / 221 (7.7%)	8 / 220 (3.6%)	4 / 218 (1.8%)	0 / 214 (0.0%)

* % Accountability = Available for Analysis / (Treated - [Discontinued + Active])

TABLE 3.3 - POSTOPERATIVE ACCOUNTABILITY FOR ALL MIXED ASTIGMATISM COHORT EYES

N=135 Eyes		Day 1	Week 1	Month 1	Month 3	Month 6	Month 9	Month 12
Available for analysis	In or Out of Window	135 (100.0%)	134 (99.3%)	127 (94.1%)	129 (95.6%)	132 (97.8%)	126 (93.3%)	127 (94.1%)
	In Window	135 (100.0%)	129 (95.6%)	120 (88.9%)	124 (91.9%)	123 (91.1%)	122 (90.4%)	126 (93.3%)
	Out of Window	0 (0.0%)	5 (3.7%)	7 (5.2%)	5 (3.7%)	9 (6.7%)	4 (3.0%)	1 (0.7%)
Active		0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.5%)	2 (1.5%)
Discontinued		0 (0.0%)	0 (0.0%)	2 (1.5%)	2 (1.5%)	3 (2.2%)	3 (2.2%)	3 (2.2%)
Lost to follow-up		0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
Missed visit	Missing	0 (0.0%)	1 (0.7%)	6 (4.4%)	4 (3.0%)	0 (0.0%)	4 (3.0%)	2 (1.5%)
	Missing or Out of Window	0 (0.0%)	6 (4.4%)	13 (9.6%)	9 (6.7%)	9 (6.7%)	8 (5.9%)	3 (2.2%)
% Accountability*	In or Out of Window	135 / 135 (100.0%)	134 / 135 (99.3%)	127 / 133 (95.5%)	129 / 133 (97.0%)	132 / 132 (100.0%)	126 / 130 (96.9%)	127 / 130 (97.7%)
	In Window	135 / 135 (100.0%)	129 / 135 (95.6%)	120 / 133 (90.2%)	124 / 133 (93.2%)	123 / 132 (93.2%)	122 / 130 (93.8%)	126 / 130 (96.9%)
	Out of Window	0 / 135 (0.0%)	5 / 135 (3.7%)	7 / 133 (5.3%)	5 / 133 (3.8%)	9 / 132 (6.8%)	4 / 130 (3.1%)	1 / 130 (0.8%)

* % Accountability = Available for Analysis / (Treated - [Discontinued + Active])

Key safety outcomes

The safety analyses include eyes in the Safety Population, defined as "eyes with attempted LASIK (successful or aborted after initiation of flap)." The Safety Population includes all 714 eyes treated in the study. This section presents key safety outcomes, BCDVA, adverse events and patient-reported outcomes.

The results for visual acuities are presented in logMAR acuity scores, with 0.0 logMAR equivalent to 20/20 Snellen, and 0.3 logMAR equivalent to 20/40 Snellen.

Key safety outcomes at the last available visit for each of the 714 eyes in the Safety Population are summarized in **Table 4**. No study subject presented with a loss of ≥ 2 lines BCDVA or with BCDVA worse than 0.3 logMAR at the last available visit. One subject **(Subject 08-001 OS)** presented with increased manifest refractive astigmatism > 2.00 D at the last available visit, this subject had a user transcription error which led to the wrong treatment axis.

Regarding loss of ≥ 2 lines BCDVA at any point during the study, there were 4 study eyes at Week 1, 3 eyes at Month 1, and 1 eye at Month 3 with this degree of loss. These are further presented and discussed below (**Table 5**). One of these cases, the right eye of one patient in the hyperopia cohort, was related to a flap melt associated with epithelium in the interface at approximately 3-months postoperatively with loss of slightly over 2 lines of BCDVA. This required a secondary surgical intervention (SSI) in order to remove the ingrowth to help prevent permanent reduction in acuity. After this SSI, the acuity started to gradually improve, and by the 6-month visit BCDVA was less than 1 line worse than baseline.

TABLE 4
KEY SAFETY OUTCOMES AT LAST AVAILABLE VISIT FOR ALL EYES IN SAFETY POPULATION

Key Safety Outcome	Myopia n/N (%)	Hyperopia n/N (%)	Mixed Astigmatism n/N (%)	Total n/N (%)
Loss of ≥ 2 lines BCDVA	0/358 (0%)	0/221 (0%)	0/135 (0%)	0/714 (0%)
Loss of > 2 lines BCDVA	0/358 (0%)	0/221 (0%)	0/135 (0%)	0/714 (0%)
BCDVA worse than 0.3 logMAR	0/358 (0%)	0/221 (0%)	0/135 (0%)	0/714 (0%)
BCDVA worse than 0.3 logMAR if 0.0 logMAR or better preoperatively	0/358 (0%)	0/221 (0%)	0/135 (0%)	0/714 (0%)
Increased manifest refractive astigmatism > 2.00D	0/358 (0%)	0/221 (0%)	1/135 (0.7%)	1/714 (0.1%)

The primary safety outcomes for the study were defined in the protocol as:

- the percentage of eyes with preoperative BCDVA 0.0 logMAR or better with BCDVA worse than 0.3 logMAR at timepoint of refractive stability;
- the percentage of eyes with BCDVA loss ≥ 10 letters from baseline at the point of refractive stability;
- The percentage of eyes with induced manifest refractive cylinder of > 2.00 D of absolute cylinder at the timepoint of refractive stability;
- The rate of each type of adverse event, by the proportion of subject and eyes.

Stability was determined at the 6-months postoperative visit (see section "Stability of MRSE"). **Table 4.1** summarizes the results for the primary safety outcomes for all eyes and for each treatment cohort separately. The results on adverse events are summarized further below (**Table 6** and **Tables 6.1 to 6.3**) At the timepoint of refractive stability, one eye, which had been treated for myopia, experienced a transient loss of BCDVA ≥2 lines. As described above, one eye presented with increased manifest refractive astigmatism > 2.00 D due to a treatment on the wrong axis. The eye was retreated before the 3-month visit; the 1 Month data showing induced astigmatism has been carried through to all visits for safety analysis.

TABLE 4.1
PRIMARY SAFETY OUTCOMES AT 6 MONTHS FOR ALL EYES IN SAFETY POPULATION

Key Safety Outcome	Myopia n/N (%)	Hyperopia n/N (%)	Mixed Astigmatism n/N (%)	Total n/N (%)
Loss of ≥ 2 lines BCDVA	1/342 (0.3%)	0/210 (0%)	0/133 (0%)	1/685 (0.2%)
BCDVA worse than 0.3 logMAR if 0.0 logMAR or better preoperatively	1/342 (0.3%)	0/210 (0%)	0/133 (0%)	1/685 (0.2%)
Increased manifest refractive astigmatism > 2.00D	0/342 (0%)	0/210 (0%)	1/133 (0.8%)	1/685 (0.2%)

Data for subject 08-001 OS Month 1 was carried forward through all post-operative visits for safety analysis.

Preservation of BCDVA

The gain and loss of BCDVA from baseline across visits for the full cohort is presented in **Table 5.**

At Week 1, 11.1% (78/700) of eyes experienced a loss in BCDVA of 1 line or more, with the majority of those eyes (10.6%, 74/700) having a loss in BCDVA of one line. At Month 6, 5.3% (36/685) of eyes had a loss in BCDVA of 1 line or more, with one eye in the myopic cohort experiencing a loss of greater than 2 lines of BCDVA (**Table 5.1)**. The proportion of eyes with a loss of 1 line of BCDVA decreased to 3.1% (21/675) at Month 12, with no eyes experiencing a loss greater than 1 line at this final visit.

Regarding the key safety outcome of loss of 2 or more lines of BCDVA, five eyes experienced such loss temporarily at 1 month postoperatively or later. Three eyes are in the myopia cohort and two eyes in the hyperopia cohort; no eyes in the mixed astigmatism cohort had a loss of 2 or more lines of BCDVA.

Gains in BCDVA were consistently higher than losses in BCDVA for every visit from Month 1 through the end of the study. Specifically, at Month 6, 20.6% (141/685) of eyes had a gain of 1 or more line of BCDVA compared to 5.3% (36/685) of eyes with a loss of 1 or more lines of BCDVA.

TABLE 5
CHANGE IN BEST CORRECTED VISUAL ACUITY FOR ALL EYES IN SAFETY POPULATION

	Day 1 n (%)		Week 1 n (%)		Month 1 n (%)		Month 3 n (%)		Month 6 n (%)		Month 9 n (%)		Month 12 n (%)		Unsched.[3] n (%)	
Lost > 2 lines (>10 letters)	19	(2.7%)	3	(0.4%)	2	(0.3%)	1	(0.2%)	1	(0.2%)	0	(0%)	0	(0%)	4	(8.3%)
Lost 2 lines (10 letters)	12	(1.7%)	1	(0.1%)	1	(0.2%)	0	(0%)	0	(0%)	0	(0%)	0	(0%)	0	(0%)
Lost 1 line (5-9 letters)	85	(11.9%)	74	(10.6%)	36	(5.3%)	24	(3.5%)	35	(5.1%)	19	(2.9%)	21	(3.1%)	2	(4.2%)
Unchanged (< 5 letters)	516	(72.5%)	518	(74.0%)	519	(75.7%)	526	(76.9%)	508	(74.2%)	504	(75.6%)	488	(72.3%)	39	(81.3%)
Gained 1 line (5-9 letters)	76	(10.7%)	102	(14.6%)	117	(17.1%)	118	(17.3%)	129	(18.8%)	125	(18.7%)	152	(22.5%)	3	(6.3%)
Gained 2 lines (10 letters)	4	(0.6%)	2	(0.3%)	9	(1.3%)	13	(1.9%)	5	(0.7%)	12	(1.8%)	10	(1.5%)	0	(0%)
Gained > 2 lines (>10 letters)	0	(0%)	0	(0%)	2	(0.3%)	2	(0.3%)	7	(1.0%)	7	(1.1%)	4	(0.6%)	0	(0%)
Not Reported	0		12		24		26		22		28		8			
Total with Data[1]	712		700		686		684		685		667		675		48	
On Study[2]	712		712		710		710		706		694		682			

Percentages are based on non-missing counts.
[1] Data for subject 08-001 OS Month 1 was carried forward through all post-operative visits
[2] On-study represents the number of eyes not discontinued, LTF, or active at that visit.
[3] Note that for eyes with more than one interim visit, the worst logMAR value was selected
Outlined rows represent results associated with safety.

The gain and loss of BCDVA at Month 6, stratified by treatment cohort, is presented in **Table 5.1**. Both the myopia and mixed astigmatism cohorts show a higher proportion of eyes with a gain of 1 or more line of BCDVA compared to the proportion of eyes with a loss of 1 or more lines of BCDVA. The hyperopia cohort shows a more even distribution of gain and loss of 1 or more lines of BCDVA.

TABLE 5.1
CHANGE IN BEST CORRECTED VISUAL ACUITY AT MONTH 6
STRATIFIED BY TREATMENT COHORT FOR ALL EYES IN SAFETY POPULATION

	Myopia Cohort n (%)	Hyperopia Cohort n (%)	Mixed Astigmatism n (%)	Total n (%)
Lost > 2 lines (>10 letters)	1 (0.3%)	0 (0%)	0 (0%)	1 (0.2%)
Lost 2 lines (10 letters)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Lost 1 line (5-9 letters)	11 (3.2%)	19 (9.1%)	5 (3.8%)	35 (5.1%)
Unchanged (< 5 letters)	246 (71.9%)	162 (77.1%)	100 (75.2%)	508 (74.2%)
Gained 1 line (5-9 letters)	76 (22.2%)	27 (12.9%)	26 (19.6%)	129 (18.8%)
Gained 2 lines (10 letters)	3 (0.9%)	1 (0.5%)	1 (0.8%)	5 (0.7%)
Gained > 2 lines (>10 letters)	5 (1.5%)	1 (0.5%)	1 (0.8%)	7 (1.0%)
Not Reported	14	8	0	22
Total with Data	342	210	133	685
On Study[1,2]	356	218	132	706

[1] Data for subject 08-001 OS Month 1 was carried forward through all post-operative visits. Note: Month 3 through Month 12 data includes 1 additional eye "with data" than "on study" due to this additional data point.
[2] On-study represents the number of eyes not discontinued, LTF, or active at that visit.
Outlined rows represent results associated with safety.

Adverse Events

Over the course of the study, 84 eyes of 59 subjects experienced one or more adverse events, for a total of 106 events. The adverse events consisted of intraoperative and postoperative events, with three (3) serious adverse events and three (3) secondary surgical interventions reported. These events are presented in **Table 6** (for all eyes, followed by **Tables 6.1 to 6.3** for each treatment cohort) and further described in the sections following the table. There were twenty-one (21) intraoperative adverse events. Only one of these events, interface debris, occurred at a rate above 1.0%, with 15 events for 14 eyes (2.0%, 14/714). The remaining intraoperative adverse events occurred at an incidence rate of less than 1.0%.

There were two (2) postoperative adverse events which occurred at a 1.0% incidence or greater. These events were 23 events for 20 eyes for a patient complaint of dry eye (2.8%, 20/714) and 9 events for 8 eyes for epithelium in the interface (1.1%, 8/714). The remaining postoperative adverse events occurred at an incidence rate of less than 1.0%. There were three serious adverse events in the postoperative course for a flap melt, retinal detachment, and a seizure resulting in hospitalization.

Three secondary surgical interventions were performed for epithelial ingrowth removal, for retreatment of an incorrect treatment axis, and for a scleral buckle procedure for retinal detachment. No unanticipated adverse device effects (UADEs) were reported.

TABLE 6 - ADVERSE EVENTS (AEs) FOR ALL EYES

	Subjects with --------- 1 or More AE ----- ----		Eyes with --------- 1 or More AE ----- ----		Events
Adverse Events	**n/N**	**%**	**n/N**	**%**	**#**
One or More of Any Adverse Event	59/358	16.5%	84/714	11.8%	106
Intraoperative Adverse Events					
Interface debris	10/358	2.8%	14/714	2.0%	15
Flap is not of the size and shape as initially intended	1/358	0.3%	1/714	0.1%	1
Flap misaligned	1/358	0.3%	1/714	0.1%	1
Flap tear	1/358	0.3%	1/714	0.1%	1
Free cap	1/358	0.3%	1/714	0.1%	1
Hinge tissue ablated	1/358	0.3%	1/714	0.1%	1
Treatment was on wrong Axis	1/358	0.3%	1/714	0.1%	1
Procedure interruption due to seizure	1/358	0.3%	2/714	0.3%	2
Postoperative Adverse Events					
Clinical signs and subjective symptoms reported by the patient consistent with dry eye	13/358	3.6%	20/714	2.8%	23
Epithelium in the interface	6/358	1.7%	8/714	1.1%	9
Diffuse lamellar keratitis (Grade 2 or less)	6/358	1.7%	6/714	0.8%	6
Corneal edema between 1 week and 1 month after the procedure	2/358	0.6%	4/714	0.6%	4
Corneal striae	3/358	0.8%	4/714	0.6%	4
Conjunctivitis, allergic	2/358	0.6%	3/714	0.4%	3
Corneal abrasion	3/358	0.8%	3/714	0.4%	3
Conjunctivitis, viral	1/358	0.3%	2/714	0.3%	2
Epithelium in the interface with loss of 10 letters or more of BCDVA	1/358	0.3%	1/714	0.1%	2
MGD (Meibomian Gland Dysfunction)	1/358	0.3%	2/714	0.3%	2
Posterior Vitreous Detachment (PVD)	1/358	0.3%	2/714	0.3%	2
Transient light sensitivity syndrome (TLSS)	1/358	0.3%	2/714	0.3%	2
Vitreous syneresis	1/358	0.3%	2/714	0.3%	2
Anterior uveitis	1/358	0.3%	1/714	0.1%	1
Chemical splash in eye	1/358	0.3%	1/714	0.1%	1
Conjunctival laceration	1/358	0.3%	1/714	0.1%	1
Corneal dryness	1/358	0.3%	1/714	0.1%	1
Corneal edema at 1 month or later	1/358	0.3%	1/714	0.1%	1
Decrease in BCDVA ≥ 10 letters not due to irregular astigmatism at ≥ 3 months	1/358	0.3%	1/714	0.1%	1
Epithelial defect	1/358	0.3%	1/714	0.1%	1
Foreign body	1/358	0.3%	1/714	0.1%	1
Foreign body sensation	1/358	0.3%	1/714	0.1%	1
IOP increase of > 10 mmHg above baseline on 2 consec. exams or IOP > 30 mmHg on 2 consec. exams	1/358	0.3%	1/714	0.1%	1
Irregular flap margin	1/358	0.3%	1/714	0.1%	1
Loss of BCDVA	1/358	0.3%	1/714	0.1%	1
Metallic foreign body	1/358	0.3%	1/714	0.1%	1
Serious Adverse Events					
Melting of the flap	1/358	0.3%	1/714	0.1%	1
Retinal detachment	1/358	0.3%	1/714	0.1%	1
Seizure	1/358	0.3%	1/714	0.1%	1
Secondary Surgical Interventions					

	Subjects with --------- 1 or More AE ----- ----		Eyes with --------- 1 or More AE ----- ----		Events
Adverse Events	**n/N**	**%**	**n/N**	**%**	**#**
Epithelial ingrowth removal	1/358	0.3%	1/714	0.1%	1
Retreatment	1/358	0.3%	1/714	0.1%	1
Scleral buckle	1/358	0.3%	1/714	0.1%	1

AEs are sorted by descending frequency of events.
Note: Of 418 Subjects enrolled, 417 were assigned to cohorts, and 358 treated, 19 had OD and OS assigned to a different cohort (8 were assigned to myopia and mixed astigmatism and 11 to hyperopia and mixed astigmatism). Therefore, the number of subjects in tables of the 3 cohorts will sum to more than the number of subjects in the overall table.

TABLE 6.1 - ADVERSE EVENTS (AES) FOR ALL MYOPIC EYES

	Subjects with --------- 1 or More AE ----- ----		Eyes with --------- 1 or More AE ----- ----		Events
Adverse Events	**n/N**	**%**	**n/N**	**%**	**#**
One or More of Any Adverse Event	32/183	17.5%	46/358	12.8%	58
Intraoperative Adverse Events					
Interface debris	9/183	4.9%	13/358	3.6%	14
Procedure interruption due to seizure	1/183	0.5%	2/358	0.6%	2
Postoperative Adverse Events					
Diffuse lamellar keratitis (Grade 2 or less)	6/183	3.3%	6/358	1.7%	6
Clinical signs and subjective symptoms reported by the patient consistent with dry eye	5/183	2.7%	6/358	1.7%	9
Corneal striae	3/183	1.6%	4/358	1.1%	4
Epithelium in the interface	3/183	1.6%	4/358	1.1%	4
Corneal abrasion	2/183	1.1%	2/358	0.6%	2
Conjunctivitis, allergic	1/183	0.5%	2/358	0.6%	2
Corneal edema between 1 week and 1 month after the procedure	1/183	0.5%	2/358	0.6%	2
Posterior Vitreous Detachment (PVD)	1/183	0.5%	2/358	0.6%	2
Vitreous syneresis	1/183	0.5%	2/358	0.6%	2
Anterior uveitis	1/183	0.5%	1/358	0.3%	1
Corneal edema at 1 month or later	1/183	0.5%	1/358	0.3%	1
Decrease in BCDVA ≥ 10 letters not due to irregular astigmatism at ≥ 3 months	1/183	0.5%	1/358	0.3%	1
Epithelial defect	1/183	0.5%	1/358	0.3%	1
Irregular flap margin	1/183	0.5%	1/358	0.3%	1
Loss of BCDVA	1/183	0.5%	1/358	0.3%	1
Serious Adverse Events					
Retinal detachment	1/183	0.5%	1/358	0.3%	1
Seizure	1/183	0.5%	1/358	0.3%	1
Secondary Surgical Interventions					
Scleral buckle	1/183	0.5%	1/358	0.3%	1

AEs are sorted by descending frequency of events.
Note: Of 418 Subjects enrolled, 417 were assigned to cohorts, and 358 treated, 19 had OD and OS assigned to a different cohort (8 were assigned to myopia and mixed astigmatism and 11 to hyperopia and mixed astigmatism). Therefore, the number of subjects in tables of the 3 cohorts will sum to more than the number of subjects in the overall table.

TABLE 6.2 - ADVERSE EVENTS (AEs) FOR ALL HYPEROPIC EYES

	Subjects with --------- 1 or More AE ----- ----		Eyes with --------- 1 or More AE ----- ----		Events
Adverse Events	**n/N**	**%**	**n/N**	**%**	**#**
One or More of Any Adverse Event	16/117	13.7%	23/221	10.4%	32
Intraoperative Adverse Events					
Flap tear	1/117	0.9%	1/221	0.5%	1
Free cap	1/117	0.9%	1/221	0.5%	1
Hinge tissue ablated	1/117	0.9%	1/221	0.5%	1
Interface debris	1/117	0.9%	1/221	0.5%	1
Postoperative Adverse Events					
Clinical signs and subjective symptoms reported by the patient consistent with dry eye	5/117	4.3%	9/221	4.1%	9
Epithelium in the interface	3/117	2.6%	4/221	1.8%	5
Conjunctivitis, viral	1/117	0.9%	2/221	0.9%	2
Epithelium in the interface with loss of 10 letters or more of BCDVA	1/117	0.9%	1/221	0.5%	2
Transient light sensitivity syndrome (TLSS)	1/117	0.9%	2/221	0.9%	2
Chemical splash in eye	1/117	0.9%	1/221	0.5%	1
Conjunctival laceration	1/117	0.9%	1/221	0.5%	1
Conjunctivitis, allergic	1/117	0.9%	1/221	0.5%	1
Corneal abrasion	1/117	0.9%	1/221	0.5%	1
Foreign body sensation	1/117	0.9%	1/221	0.5%	1
Metallic foreign body	1/117	0.9%	1/221	0.5%	1
Serious Adverse Events					
Melting of the flap	1/117	0.9%	1/221	0.5%	1
Secondary Surgical Interventions					
Epithelial ingrowth removal	1/117	0.9%	1/221	0.5%	1

AEs are sorted by descending frequency of events.
Note: Of 418 Subjects enrolled, 417 were assigned to cohorts, and 358 treated, 19 had OD and OS assigned to a different cohort (8 were assigned to myopia and mixed astigmatism and 11 to hyperopia and mixed astigmatism). Therefore, the number of subjects in tables of the 3 cohorts will sum to more than the number of subjects in the overall table.

TABLE 6.3 - ADVERSE EVENTS (AEs) FOR ALL MIXED ASTIGMATISM EYES

	Subjects with --------- 1 or More AE ----- ----		Eyes with --------- 1 or More AE ----- ----		Events
Adverse Events	**n/N**	**%**	**n/N**	**%**	**#**
One or More of Any Adverse Event	11/77	14.3%	15/135	11.1%	16
Intraoperative Adverse Events					
Flap is not of the size and shape as initially intended	1/77	1.3%	1/135	0.7%	1
Flap misaligned	1/77	1.3%	1/135	0.7%	1
Treatment was on wrong Axis for OS	1/77	1.3%	1/135	0.7%	1
Postoperative Adverse Events					
Clinical signs and subjective symptoms reported by the patient consistent with dry eye	3/77	3.9%	5/135	3.7%	5
Corneal edema between 1 week and 1 month after the procedure	1/77	1.3%	2/135	1.5%	2
MGD (Meibomian Gland Dysfunction)	1/77	1.3%	2/135	1.5%	2
Corneal dryness	1/77	1.3%	1/135	0.7%	1
Foreign body	1/77	1.3%	1/135	0.7%	1

	Subjects with --------- 1 or More AE ----- ----		Eyes with --------- 1 or More AE ----- ----		Events
Adverse Events	**n/N**	**%**	**n/N**	**%**	**#**
IOP increase of > 10 mmHg above baseline on 2 consec. exams or IOP > 30 mmHg on 2 consec. exams	1/77	1.3%	1/135	0.7%	1
Secondary Surgical Interventions					
Retreatment	1/77	1.3%	1/135	0.7%	1

AEs are sorted by descending frequency of events. Wilson 95% confidence interval is rounded to 1 decimal place. For eye, dependence within the subject is ignored.
Note: Of 418 Subjects enrolled, 417 were assigned to cohorts, and 358 treated, 19 had OD and OS assigned to a different cohort (8 were assigned to myopia and mixed astigmatism and 11 to hyperopia and mixed astigmatism). Therefore, the number of subjects in tables of the 3 cohorts will sum to more than the number of subjects in the overall table.

Patient reported outcomes

The Patient Reported Outcomes (PRO) instrument used in the IDE clinical study consisted of the Patient Reported Outcomes with LASIK (PROWL) questionnaire with accompanying photographs, and 2 of the 3 domains of the Ocular Surface Disease Index (OSDI). Study subjects self-administered the PRO instrument directly to reduce the potential for bias from an interviewer. Assessment of visual symptoms is shown in **Table 7** for all cohort subjects for all visits and **Table 7.1** for subjects at Month 6 stratified by treatment cohort.

Preoperatively, symptom prevalence with or without correction was experienced by 70.4% (252/358) of subjects. All symptoms were reported at a rate higher than 30%, with starbursts indicated as the most prevalent symptom (55.9%, 200/358). Symptom prevalence decreased to 41.1% (140/341) at Month 6, including reports of starbursts, that decreased to 33.4% (114/341).

Only 22.5% (65/289) of subjects developed any type of symptom at Month 6. Subjects are included in this category if they experienced some or even no symptoms preoperatively and then experienced a particular symptom or symptoms postoperatively that was not present preoperatively. At Month 6, 18.5% (36/195) and 19.5% (29/149) of subjects indicated the development of halos or starbursts, respectively.

A greater proportion of subjects experienced resolution of a symptom or symptoms postoperatively. Subjects are included in this category if they experienced one or more symptoms preoperatively and then any or all of these symptoms were not present postoperatively. At Month 6, 82.4% (196/238) of subjects had resolution of any type of symptom. The highest resolution proportion was seen for double images and glare at 83.6% (92/110) and 77.1% (101/131), respectively.

Preoperatively, 44.4% (159/358) of subjects reported difficulty performing activities due to symptoms. The reports of difficulty dropped to 24.9% (85/341) at Month 6. Importantly, the report of very or extreme difficulty performing activities was 9.8% (35/358) preoperatively, primarily due to the glare (4.5%; 16/358) and starbursts (5.0%; 18/358). Postoperatively, a significant decrease in the reports of very or extreme difficulty was seen, with only 2.1% (7/341)subjects at Month 6 reporting these levels of difficulty performing tasks after surgery.

Subjects were also asked to assess whether they were bothered by their symptoms. Preoperatively, 57.0% (204/358) reported bothersome symptoms, which decreased to 32.8% (112/341) at Month 6. The report of very or extremely bothersome symptoms was 19.6% (70/358) of subjects preoperatively, mostly due to starbursts (14.8%; 53/358). As seen with reports of difficulty, postoperatively, less subjects (2.9%; 10/341) reported this level of bother by their symptoms, again mostly driven by starbursts (1.8%; 6/341).

TABLE 7
PROWL VISUAL SYMPTOMS FOR ALL SUBJECTS IN SAFETY POPULATION

Symptom Information	PreOp n/N	PreOp (%)	Month 3 n/N	Month 3 (%)	Month 6 n/N	Month 6 (%)	Month 9 n/N	Month 9 (%)	Month 12 n/N	Month 12 (%)
Symptom Prevalence[1]										
Any type of symptom	252/358	(70.4%)	164/341	(48.1%)	140/341	(41.1%)	120/331	(36.3%)	130/338	(38.5%)
Double images	117/358	(32.7%)	17/341	(5.0%)	28/341	(8.2%)	17/331	(5.1%)	18/338	(5.3%)
Glare	140/358	(39.1%)	56/341	(16.4%)	47/341	(13.8%)	38/331	(11.5%)	46/338	(13.6%)
Halos	156/358	(43.6%)	101/341	(29.6%)	84/341	(24.6%)	74/331	(22.4%)	79/338	(23.4%)
Starbursts	200/358	(55.9%)	134/341	(39.3%)	114/341	(33.4%)	101/331	(30.5%)	107/338	(31.7%)
Symptom Development[1,2]										
Any type of symptom			74/288	(25.7%)	65/289	(22.5%)	52/281	(18.5%)	56/286	(19.6%)
Double images			6/229	(2.6%)	10/231	(4.3%)	6/228	(2.6%)	3/230	(1.3%)
Glare			20/208	(9.6%)	17/210	(8.1%)	14/203	(6.9%)	16/206	(7.8%)
Halos			42/193	(21.8%)	36/195	(18.5%)	26/187	(13.9%)	29/189	(15.3%)
Starbursts			43/151	(28.5%)	29/149	(19.5%)	31/147	(21.1%)	32/148	(21.6%)
Symptom Resolution										
Any type of symptom			201/240	(83.8%)	196/238	(82.4%)	195/230	(84.8%)	199/237	(84.0%)
Double images			101/112	(90.2%)	92/110	(83.6%)	92/103	(89.3%)	93/108	(86.1%)
Glare			97/133	(72.9%)	101/131	(77.1%)	104/128	(81.3%)	102/132	(77.3%)
Halos			89/148	(60.1%)	98/146	(67.1%)	96/144	(66.7%)	99/149	(66.4%)
Starbursts			99/190	(52.1%)	107/192	(55.7%)	114/184	(62.0%)	115/190	(60.5%)
Any reported difficulty performing activities due to symptoms										
Any type of symptom	159/358	(44.4%)	97/341	(28.4%)	85/341	(24.9%)	68/331	(20.5%)	74/338	(21.9%)
Double images	73/358	(20.4%)	13/341	(3.8%)	16/341	(4.7%)	10/331	(3.0%)	14/338	(4.1%)
Glare	94/358	(26.3%)	35/341	(10.3%)	27/341	(7.9%)	22/331	(6.6%)	23/338	(6.8%)
Halos	87/358	(24.3%)	54/341	(15.8%)	40/341	(11.7%)	39/331	(11.8%)	42/338	(12.4%)
Starbursts	121/358	(33.8%)	73/341	(21.4%)	64/341	(18.8%)	52/331	(15.7%)	60/338	(17.8%)
Very or extreme difficulty performing activities due to symptoms										
Any type of symptom	35/358	(9.8%)	3/341	(0.9%)	7/341	(2.1%)	2/331	(0.6%)	2/338	(0.6%)
Double images	15/358	(4.2%)	1/341	(0.3%)	3/341	(0.9%)	0/331		0/338	
Glare	16/358	(4.5%)	1/341	(0.3%)	0/341		0/331		0/338	
Halos	9/358	(2.5%)	1/341	(0.3%)	2/341	(0.6%)	0/331		1/338	(0.3%)
Starbursts	18/358	(5.0%)	3/341	(0.9%)	3/341	(0.9%)	2/331	(0.6%)	2/338	(0.6%)
Any reported bothersome symptoms										
Any type of symptom	204/358	(57.0%)	122/341	(35.8%)	112/341	(32.8%)	92/331	(27.8%)	97/338	(28.7%)
Double images	81/358	(22.6%)	15/341	(4.4%)	24/341	(7.0%)	15/331	(4.5%)	16/338	(4.7%)
Glare	117/358	(32.7%)	46/341	(13.5%)	40/341	(11.7%)	29/331	(8.8%)	35/338	(10.4%)
Halos	112/358	(31.3%)	68/341	(19.9%)	63/341	(18.5%)	55/331	(16.6%)	57/338	(16.9%)
Starbursts	162/358	(45.3%)	100/341	(29.3%)	86/341	(25.2%)	73/331	(22.1%)	86/338	(25.4%)
Very or extremely bothersome symptoms										
Any type of symptom	70/358	(19.6%)	12/341	(3.5%)	10/341	(2.9%)	12/331	(3.6%)	12/338	(3.6%)
Double images	29/358	(8.1%)	3/341	(0.9%)	4/341	(1.2%)	5/331	(1.5%)	4/338	(1.2%)
Glare	29/358	(8.1%)	2/341	(0.6%)	1/341	(0.3%)	2/331	(0.6%)	0/338	
Halos	21/358	(5.9%)	4/341	(1.2%)	3/341	(0.9%)	3/331	(0.9%)	4/338	(1.2%)
Starbursts	53/358	(14.8%)	8/341	(2.3%)	6/341	(1.8%)	6/331	(1.8%)	7/338	(2.1%)

[1] The symptom was considered present if it was experienced either with or without optical correction

[2] Analysis includes only patients with no symptom of the relevant type preoperatively who completed the questionnaire at the postoperative visit.

At stability, symptoms as measured using the PROWL visual symptom scoring system 6 months postoperatively were present among 41.1% (140/341) of all subjects, with a lower proportion seen in the myopia cohort (31.0%; 54/174), as seen in **Table 7.1**. The overall proportion of subjects that experienced improvement in visual symptoms from baseline to Month 6 was greater than the proportion of subjects who experienced worsening of visual symptoms, with 82.4% (196/238) of subjects experiencing resolution versus 22.5% (65/289) experiencing development. Resolution was very similar across all treatment groups, while development of symptoms was highest in the hyperopia cohort (35.3%; 30/85). The presence of very or extreme difficulty with symptoms was low for all treatment cohorts at 3.6% or less. The level of bothersome symptoms as very or extreme was similarly low at 6.4% (7/110) in the hyperopia cohort and 3.9% (3/76) in the mixed astigmatism cohort. Among these few eyes, starbursts were the most prevalent source of bothersome symptoms.

Table 7.1
PROWL VISUAL SYMPTOMS AT MONTH 6
STRATIFIED BY TREATMENT COHORT FOR ALL SUBJECTS IN SAFETY POPULATION

Symptom Information		Myopia Cohort		Hyperopia Cohort		Mixed Astigmatism		Total	
		n/N	(%)	n/N	(%)	n/N	(%)	n/N	(%)
Symptom Prevalence[1]									
	Any type of symptom	54/174	(31.0%)	57/110	(51.8%)	36/76	(47.4%)	140/341	(41.1%)
	Double images	6/174	(3.4%)	17/110	(15.5%)	6/76	(7.9%)	28/341	(8.2%)
	Glare	24/174	(13.8%)	15/110	(13.6%)	9/76	(11.8%)	47/341	(13.8%)
	Halos	33/174	(19.0%)	32/110	(29.1%)	23/76	(30.3%)	84/341	(24.6%)
	Starbursts	45/174	(25.9%)	45/110	(40.9%)	28/76	(36.8%)	114/341	(33.4%)
Symptom Development[1,2]									
	Any type of symptom	24/153	(15.7%)	30/85	(35.3%)	14/68	(20.6%)	65/289	(22.5%)
	Double images	4/134	(3.0%)	5/60	(8.3%)	2/51	(3.9%)	10/231	(4.3%)
	Glare	7/108	(6.5%)	7/64	(10.9%)	4/48	(8.3%)	17/210	(8.1%)
	Halos	14/103	(13.6%)	16/65	(24.6%)	8/40	(20.0%)	36/195	(18.5%)
	Starbursts	11/82	(13.4%)	13/47	(27.7%)	5/28	(17.9%)	29/149	(19.5%)
Symptom Resolution									
	Any type of symptom	93/113	(82.3%)	68/83	(81.9%)	49/56	(87.5%)	196/238	(82.4%)
	Double images	38/40	(95.0%)	38/50	(76.0%)	21/25	(84.0%)	92/110	(83.6%)
	Glare	49/66	(74.2%)	38/46	(82.6%)	23/28	(82.1%)	101/131	(77.1%)
	Halos	52/71	(73.2%)	29/45	(64.4%)	21/36	(58.3%)	98/146	(67.1%)
	Starbursts	58/92	(63.0%)	31/63	(49.2%)	25/48	(52.1%)	107/192	(55.7%)
Any reported difficulty performing activities due to symptoms									
	Any type of symptom	35/174	(20.1%)	36/110	(32.7%)	18/76	(23.7%)	85/341	(24.9%)
	Double images	5/174	(2.9%)	8/110	(7.3%)	4/76	(5.3%)	16/341	(4.7%)
	Glare	11/174	(6.3%)	11/110	(10.0%)	6/76	(7.9%)	27/341	(7.9%)
	Halos	16/174	(9.2%)	17/110	(15.5%)	9/76	(11.8%)	40/341	(11.7%)
	Starbursts	27/174	(15.5%)	27/110	(24.5%)	12/76	(15.8%)	64/341	(18.8%)
Very or extreme difficulty performing activities due to symptoms									
	Any type of symptom	1/174	(0.6%)	4/110	(3.6%)	2/76	(2.6%)	7/341	(2.1%)
	Double images	1/174	(0.6%)	1/110	(0.9%)	1/76	(1.3%)	3/341	(0.9%)
	Glare	0/174		0/110		0/76		0/341	
	Halos	0/174		2/110	(1.8%)	0/76		2/341	(0.6%)
	Starbursts	0/174		2/110	(1.8%)	1/76	(1.3%)	3/341	(0.9%)
Any reported bothersome symptoms									
	Any type of symptom	44/174	(25.3%)	49/110	(44.5%)	24/76	(31.6%)	112/341	(32.8%)
	Double images	6/174	(3.4%)	14/110	(12.7%)	5/76	(6.6%)	24/341	(7.0%)
	Glare	19/174	(10.9%)	14/110	(12.7%)	8/76	(10.5%)	40/341	(11.7%)
	Halos	27/174	(15.5%)	25/110	(22.7%)	14/76	(18.4%)	63/341	(18.5%)
	Starbursts	36/174	(20.7%)	35/110	(31.8%)	17/76	(22.4%)	86/341	(25.2%)
Very or extremely bothersome symptoms									
	Any type of symptom	1/174	(0.6%)	7/110	(6.4%)	3/76	(3.9%)	10/341	(2.9%)
	Double images	1/174	(0.6%)	2/110	(1.8%)	1/76	(1.3%)	4/341	(1.2%)
	Glare	0/174		1/110	(0.9%)	0/76		1/341	(0.3%)
	Halos	0/174		3/110	(2.7%)	0/76		3/341	(0.9%)
	Starbursts	0/174		5/110	(4.5%)	2/76	(2.6%)	6/341	(1.8%)

a The symptom was considered present if it was experienced either with or without optical correction

b Analysis includes only patients with no symptom of the relevant type preoperatively who completed the questionnaire at the postoperative visit.

*Total is based on subject response; subjects with eyes in different cohorts will be represented twice.

The PROWL questionnaire includes 2 of 3 of the subscales of the Ocular Surface Disease Index (OSDI) questionnaire, "dry eye symptoms" and "environmental triggers". The PRO used in this IDE included the same 2 subscales. Study subjects were asked to grade five (5) symptoms of light sensitivity, grittiness, ocular pain or soreness, blurred vision and poor vision experienced during the week prior to the study visit. Additionally, subjects were asked to grade the impact of three (3) environmental triggers, including windy conditions, low humidity and air-conditioned environments during the week prior to the study visit. The eight questions across the two subscales were combined to form a single score for assessment of dry eye symptoms and environmental triggers.

Each subject's dry eye symptoms and environmental trigger score was further categorized as normal (0-12), mild (13-22), moderate (23-32), and severe dry eye disease (33-100). The original OSDI questionnaire contains more questions (12 vs. 8), therefore, the results in this study may not reflect dry eye symptoms as well as the full OSDI questionnaire. The results in **Table 8** may over- or underestimate the true number of subjects in each category. As shown in Table 8, for the full cohort of subjects, the proportion of subjects with moderate symptoms decreased from 9.2% (33/358) at baseline to 4.4% (15/341) at Month 6 and severe symptoms decreased from 7.8% (28/358) to 4.1% (14/341) at Month 6. The proportion of subjects categorized as "normal" increased from 60.6% (217/358) to 73.3% (250/341) at Month 6 and slightly improved through Month 12.

TABLE 8
OCULAR SURFACE DISEASE INDEX (OSDI) CATEGORIES FOR ALL SUBJECTS IN SAFETY POPULATION

	Preoperative		Month 3		Month 6		Month 9		Month 12	
Dry Eye Symptom and Environmental Trigger Score										
Normal	217/358	(60.6%)	232/341	(68.0%)	250/341	(73.3%)	255/331	(77.0%)	269/338	(79.6%)
Mild	80/358	(22.3%)	76/341	(22.3%)	62/341	(18.2%)	54/331	(16.3%)	48/338	(14.2%)
Moderate	33/358	(9.2%)	16/341	(4.7%)	15/341	(4.4%)	12/331	(3.6%)	5/338	(1.5%)
Severe	28/358	(7.8%)	17/341	(5.0%)	14/341	(4.1%)	10/331	(3.0%)	16/338	(4.7%)
Categories for score: normal (0-12), mild (13-22), moderate (23-32), and severe dry eye disease (33-100)										

Key effectiveness outcomes

The effectiveness outcomes are presented for the Treated Eye Population, which includes all eyes with a successful LASIK procedure. The primary effectiveness outcomes for the study were defined in the protocol as:

- the percentage of eyes with MRSE within ± 1.00 D and ± 0.50 D of the intended refractive outcome at timepoint of refractive stability;
- the percentage of eyes with UCDVA of 0.3 logMAR or better at timepoint of refractive stability;
- the percentage of eyes with MRCYL within ± 1.00 D and ± 0.50 D of the intended refractive outcome at timepoint of refractive stability.

Key effectiveness outcomes in terms of UDVA and MRSE are presented in **Table 9** for all treated eyes (n=714) and **Table 9.1** for eyes stratified by treatment cohort, including primary effectiveness outcomes in the shaded rows. Primary effectiveness outcomes in terms of MRCYL are presented in the section on "Accuracy of the astigmatic correction" in **Tables 14 and 14.1**.

At Month 6, the point at which refractive stability was achieved, 98.7% (676/685) of eyes had UCDVA of 0.3 logMAR or better; the results for the individual treatment cohorts are shown in **Table 6.1**. The uncorrected visual acuity outcomes in this study, specifically the proportion of eyes with UCDVA of 0.3 logMAR or better, exceeded the target for the study (85% UCDVA of 0.3 logMAR or better).

Greater than 97% of the study eyes in the Treated Eye Population were within ± 1.00 D of the attempted MRSE at all study visits from Month 1. At Month 6, 98.0% (671/685) and 89.8% (615/685) of eyes were

within ± 1.00 D and ± 0.50 D of the attempted MRSE, respectively. The results for the individual treatment cohorts are shown in **Table 6.1**. Predictability of the MRSE correction in this study was excellent with the proportion of eyes within ± 0.50 D and ± 1.00 D of attempted MRSE correction at all visits exceeding the study's endpoint target of 50% within ± 0.50 D and 75% within ± 1.00 D.

TABLE 9
SUMMARY OF KEY EFFECTIVENESS VARIABLES FOR ALL EYES IN TREATED EYE POPULATION

	Day 1 n/N (%)	Week 1 n/N (%)	Month 1 n/N (%)	Month 3 n/N (%)	Month 6 n/N (%)	Month 9 n/N (%)	Month 12 n/N (%)
UCDVA -0.1 logMAR or better	157/712 (22.1%)	163/700 (23.3%)	205/686 (29.9%)	207/684 (30.3%)	243/684 (35.5%)	232/666 (34.8%)	259/674 (38.4%)
UCDVA 0.0 logMAR or better	379/712 (53.2%)	385/700 (55.0%)	431/686 (62.8%)	488/684 (71.4%)	488/684 (71.4%)	489/666 (73.4%)	511/674 (75.8%)
UCDVA 0.1 logMAR or better	539/712 (75.7%)	552/700 (78.9%)	587/686 (85.6%)	617/684 (90.2%)	616/684 (90.1%)	600/666 (90.1%)	616/674 (91.4%)
UCDVA 0.2 logMAR or better	641/712 (90.0%)	637/700 (91.0%)	647/686 (94.3%)	668/684 (97.7%)	663/684 (96.9%)	651/666 (97.8%)	662/674 (98.2%)
UCDVA 0.3 logMAR or better	682/712 (95.8%)	670/700 (95.7%)	669/686 (97.5%)	677/684 (99.0%)	**676/684 (98.8%)**	662/666 (99.4%)	668/674 (99.1%)
MRSE ± 0.25 D of Attempted	461/712 (64.8%)	420/700 (60.0%)	457/686 (66.6%)	496/684 (72.5%)	520/684 (76.0%)	502/666 (75.4%)	507/674 (75.2%)
MRSE ± 0.50 D of Attempted	599/712 (84.1%)	564/700 (80.6%)	590/686 (86.0%)	608/684 (88.9%)	**614/684 (89.8%)**	597/666 (89.6%)	597/674 (88.6%)
MRSE ± 1.00 D of Attempted	693/712 (97.3%)	674/700 (96.3%)	668/686 (97.4%)	674/684 (98.5%)	**670/684 (98.0%)**	655/666 (98.4%)	667/674 (99.0%)
MRSE ± 2.00 D of Attempted	708/712 (99.4%)	698/700 (99.7%)	683/686 (99.6%)	683/684 (99.9%)	684/684 (100%)	666/666 (100%)	674/674 (100%)

Primary effectiveness outcomes are highlighted in light gray and bolded at Month 6, the point of stability.

Table 9.1 provides the key effectiveness outcomes at Month 6 for the three treatment cohorts. For the myopia cohort, 98.8% (338/342) of eyes had UCDVA of 0.3 logMAR or better and 98.8% (338/342) and 93.0% (318/342) of eyes were within ± 1.00 D and ± 0.50 D, respectively. In the hyperopia cohort, 98.1% (206/210) of eyes had UCDVA of 0.3 logMAR or better and 96.7% (203/210) were within ± 1.00 D MRSE. Only one outcome, the proportion of eyes within ± 0.50 D MRSE, showed a lower proportion in the hyperopia cohort (82.9%; 174/210) than the myopia or mixed astigmatism cohort at Month 6. The mixed astigmatism cohort experienced 100% (132/132) of eyes UCDVA of 0.3 logMAR or better and 97.7% (129/132) and 92.4% (122/132) of eyes were within ± 1.00 D and ± 0.50 D MRSE, respectively.

TABLE 9.1
SUMMARY OF KEY EFFECTIVENESS VARIABLES AT MONTH 6
STRATIFIED BY TREATMENT COHORT IN TREATED EYE POPULATION

	Myopia Cohort n/N (%)	Hyperopia Cohort n/N (%)	Mixed Astigmatism n/N (%)	Total n/N (%)
UCDVA -0.1 logMAR or better	168/342 (49.1%)	31/210 (14.8%)	44/132 (33.3%)	243/684 (35.5%)
UCDVA 0.0 logMAR or better	295/342 (86.3%)	102/210 (48.6%)	91/132 (68.9%)	488/684 (71.4%)
UCDVA 0.1 logMAR or better	324/342 (94.7%)	175/210 (83.3%)	117/132 (88.6%)	616/684 (90.1%)
UCDVA 0.2 logMAR or better	334/342 (97.7%)	200/210 (95.2%)	129/132 (97.7%)	663/684 (96.9%)
UCDVA 0.3 logMAR or better	**338/342 (98.8%)**	**206/210 (98.1%)**	**132/132 (100%)**	**676/684 (98.8%)**
MRSE ± 0.25 D of Attempted	283/342 (82.8%)	131/210 (62.4%)	106/132 (80.3%)	520/684 (76.0%)
MRSE ± 0.50 D of Attempted	**318/342 (93.0%)**	**174/210 (82.9%)**	**122/132 (92.4%)**	**614/684 (89.8%)**
MRSE ± 1.00 D of Attempted	**338/342 (98.8%)**	**203/210 (96.7%)**	**129/132 (97.7%)**	**670/684 (98.0%)**
MRSE ± 2.00 D of Attempted	342/342 (100%)	210/210 (100%)	132/132 (100%)	684/684 (100%)

Primary effectiveness outcomes are highlighted in light gray and bolded at Month 6, the point of stability.

Key effectiveness outcomes stratified by preoperative MRSE

Tables 10.1 through 10.3 show stratification of the key effectiveness outcomes by preoperative MRSE for each treatment cohort.

As shown in **Table 10.1,** differences in the three levels of acuity from 0.1 logMAR or better UCDVA and below are seen in the myopia cohort, driven by the lower proportions seen in the small subset of subjects with -10.00 D to -11.00 D refractive corrections. For the primary effectiveness outcomes of UCDVA 0.3 logMAR or better and MRSE within ± 1.00 D of attempted MRSE, the results are comparable across the myopic correction stratification groups. However, for the primary effectiveness outcome of MRSE within ± 0.50 D there was a slightly lower proportion of eyes that achieved this level in the higher refractive corrections.

TABLE 10.1
SUMMARY OF KEY EFFECTIVENESS VARIABLES AT MONTH 6 FOR ALL MYOPIC EYES IN TREATED EYE POPULATION STRATIFIED BY PREOPERATIVE MRSE (D)

	-11.00 to -10.00 n/N (%)	-9.99 to -9.00 n/N (%)	-8.99 to -8.00 n/N (%)	-7.99 to -7.00 n/N (%)	-6.99 to -6.00 n/N (%)	-5.99 to -5.00 n/N (%)
UCDVA -0.1 logMAR or better	2/13 (15.4%)	9/29 (31.0%)	6/25 (24.0%)	8/23 (34.8%)	26/44 (59.1%)	18/44 (40.9%)
UCDVA 0.0 logMAR or better	8/13 (61.5%)	24/29 (82.8%)	19/25 (76.0%)	16/23 (69.6%)	37/44 (84.1%)	37/44 (84.1%)
UCDVA 0.1 logMAR or better	11/13 (84.6%)	28/29 (96.6%)	22/25 (88.0%)	21/23 (91.3%)	39/44 (88.6%)	43/44 (97.7%)
UCDVA 0.2 logMAR or better	12/13 (92.3%)	29/29 (100%)	23/25 (92.0%)	23/23 (100%)	41/44 (93.2%)	43/44 (97.7%)
UCDVA 0.3 logMAR or better	13/13 (100%)	29/29 (100%)	24/25 (96.0%)	23/23 (100%)	42/44 (95.5%)	43/44 (97.7%)
MRSE ± 0.25 D of Attempted	9/13 (69.2%)	22/29 (75.9%)	17/25 (68.0%)	19/23 (82.6%)	35/44 (79.6%)	39/44 (88.6%)
MRSE ± 0.50 D of Attempted	11/13 (84.6%)	26/29 (89.7%)	19/25 (76.0%)	22/23 (95.7%)	41/44 (93.2%)	41/44 (93.2%)
MRSE ± 1.00 D of Attempted	13/13 (100%)	28/29 (96.6%)	24/25 (96.0%)	23/23 (100%)	43/44 (97.7%)	44/44 (100%)
MRSE ± 2.00 D of Attempted	13/13 (100%)	29/29 (100%)	25/25 (100%)	23/23 (100%)	44/44 (100%)	44/44 (100%)

	-4.99 to -4.00 n/N (%)	-3.99 to -3.00 n/N (%)	-2.99 to -2.00 n/N (%)	-1.99 to -1.00 n/N (%)	-0.99 to 0.00 n/N (%)	Total n/N (%)
UCDVA -0.1 logMAR or better	25/42 (59.5%)	17/32 (53.1%)	32/48 (66.7%)	22/36 (61.1%)	3/6 (50.0%)	168/342 (49.1%)
UCDVA 0.0 logMAR or better	40/42 (95.2%)	30/32 (93.8%)	45/48 (93.8%)	33/36 (91.7%)	6/6 (100%)	295/342 (86.3%)
UCDVA 0.1 logMAR or better	41/42 (97.6%)	31/32 (96.9%)	48/48 (100%)	34/36 (94.4%)	6/6 (100%)	324/342 (94.7%)
UCDVA 0.2 logMAR or better	42/42 (100%)	31/32 (96.9%)	48/48 (100%)	36/36 (100%)	6/6 (100%)	334/342 (97.7%)
UCDVA 0.3 logMAR or better	42/42 (100%)	32/32 (100%)	48/48 (100%)	36/36 (100%)	6/6 (100%)	338/342 (98.8%)
MRSE ± 0.25 D of Attempted	38/42 (90.5%)	26/32 (81.3%)	42/48 (87.5%)	30/36 (83.3%)	6/6 (100%)	283/342 (82.8%)
MRSE ± 0.50 D of Attempted	41/42 (97.6%)	31/32 (96.9%)	48/48 (100%)	32/36 (88.9%)	6/6 (100%)	318/342 (93.0%)
MRSE ± 1.00 D of Attempted	41/42 (97.6%)	32/32 (100%)	48/48 (100%)	36/36 (100%)	6/6 (100%)	338/342 (98.8%)
MRSE ± 2.00 D of Attempted	42/42 (100%)	32/32 (100%)	48/48 (100%)	36/36 (100%)	6/6 (100%)	342/342 (100%)

Shaded cells: Treatment of -10.00 through -11.00 D MRSE will present a flagged warning to the user indicating that correction of these powers is outside the range of the approved indications for use.

Table 10.2 provides the comparison of key effectiveness outcomes for the hyperopia cohort. There are differences in the three levels of acuity from 0.1 logMAR or better UCDVA and below and ± 0.25 D MRSE predictability outcomes, driven by the lower proportions seen in the subsets of subjects with higher hyperopic refractive corrections. For the primary effectiveness outcomes of UCDVA 0.3 logMAR or better and MRSE within ± 0.50 D of attempted MRSE, the results are almost similar between the hyperopic correction stratification groups. For the primary effectiveness outcome of MRSE within ± 1.00 D of attempted MRSE, the results do show differences, driven by the lower proportion seen in the moderately high hyperopic corrections.

TABLE 10.2
SUMMARY OF KEY EFFECTIVENESS VARIABLES AT MONTH 6 FOR ALL HYPEROPIC EYES IN TREATED EYE POPULATION STRATIFIED BY PREOPERATIVE MRSE (D)

	+0.01 to +1.00 n/N (%)	+1.01 to +2.00 n/N (%)	+2.01 to +3.00 n/N (%)	+3.01 to +4.00 n/N (%)	+4.01 to +5.00 n/N (%)	Total n/N (%)
UCDVA -0.1 logMAR or better	12/25 (48.0%)	14/59 (23.7%)	3/57 (5.3%)	1/44 (2.3%)	1/25 (4.0%)	31/210 (14.8%)
UCDVA 0.0 logMAR or better	22/25 (88.0%)	41/59 (69.5%)	19/57 (33.3%)	12/44 (27.3%)	8/25 (32.0%)	102/210 (48.6%)
UCDVA 0.1 logMAR or better	25/25 (100%)	54/59 (91.5%)	47/57 (82.5%)	32/44 (72.7%)	17/25 (68.0%)	175/210 (83.3%)
UCDVA 0.2 logMAR or better	25/25 (100%)	57/59 (96.6%)	54/57 (94.7%)	41/44 (93.2%)	23/25 (92.0%)	200/210 (95.2%)
UCDVA 0.3 logMAR or better	25/25 (100%)	58/59 (98.3%)	56/57 (98.3%)	44/44 (100%)	23/25 (92.0%)	206/210 (98.1%)
MRSE ± 0.25 D of Attempted	22/25 (88.0%)	42/59 (71.2%)	31/57 (54.4%)	21/44 (47.7%)	15/25 (60.0%)	131/210 (62.4%)
MRSE ± 0.50 D of Attempted	24/25 (96.0%)	53/59 (89.8%)	43/57 (75.4%)	34/44 (77.3%)	20/25 (80.0%)	174/210 (82.9%)
MRSE ± 1.00 D of Attempted	25/25 (100%)	59/59 (100%)	54/57 (94.7%)	40/44 (90.9%)	25/25 (100%)	203/210 (96.7%)
MRSE ± 2.00 D of Attempted	25/25 (100%)	59/59 (100%)	57/57 (100%)	44/44 (100%)	25/25 (100%)	210/210 (100%)

As shown in **Table 10.3,** differences were seen in the three levels of acuity from 0.1 logMAR or better UCDVA and below for the mixed astigmatism cohort. The differences seen at the two highest acuity levels were likely driven by the higher proportions seen in the subset of subjects with -0.99 to 0.00 MRSE refractive corrections. For the primary effectiveness outcomes of UCDVA 0.3 logMAR or better and MRSE within ± 0.50 D and ± 1.00 D of attempted MRSE, the point estimates are comparable across the mixed astigmatism correction stratification groups.

TABLE 10.3
SUMMARY OF KEY EFFECTIVENESS VARIABLES AT MONTH 6 FOR ALL MIXED ASTIGMATISM EYES IN TREATED EYE POPULATION STRATIFIED BY PREOPERATIVE MRSE (D)

	-1.00 to -2.00 n/N (%)	0.00 to -0.99 n/N (%)	+0.01 to +0.99 n/N (%)	+1.00 to +2.00 n/N (%)	Total n/N (%)
UCDVA -0.1 logMAR or better	5/17 (29.4%)	31/63 (49.2%)	7/36 (19.4%)	1/16 (6.3%)	44/132 (33.3%)
UCDVA 0.0 logMAR or better	8/17 (47.1%)	53/63 (84.1%)	20/36 (55.6%)	10/16 (62.5%)	91/132 (68.9%)
UCDVA 0.1 logMAR or better	11/17 (64.7%)	59/63 (93.7%)	34/36 (94.4%)	13/16 (81.3%)	117/132 (88.6%)
UCDVA 0.2 logMAR or better	17/17 (100%)	63/63 (100%)	34/36 (94.4%)	15/16 (93.8%)	129/132 (97.7%)
UCDVA 0.3 logMAR or better	17/17 (100%)	63/63 (100%)	36/36 (100%)	16/16 (100%)	132/132 (100%)
MRSE ± 0.25 D of Attempted	13/17 (76.5%)	54/63 (85.7%)	25/36 (69.4%)	14/16 (87.5%)	106/132 (80.3%)
MRSE ± 0.50 D of Attempted	16/17 (94.1%)	58/63 (92.1%)	33/36 (91.7%)	15/16 (93.8%)	122/132 (92.4%)
MRSE ± 1.00 D of Attempted	17/17 (100%)	62/63 (98.4%)	35/36 (97.2%)	15/16 (93.8%)	129/132 (97.7%)
MRSE ± 2.00 D of Attempted	17/17 (100%)	63/63 (100%)	36/36 (100%)	16/16 (100%)	132/132 (100%)

Postoperative UCDVA versus preoperative BCDVA

Achievement of a level of UCDVA equal to or better than preoperative BCDVA for the full cohort is presented in **Table 11.** Across the full cohort, greater than 50% of eyes achieved this level from Month 6 through the end of the study. The best outcomes were among the myopia cohort, with 67.3% (230/342) achieving an equivalent or better UCDVA at Month 6 than preoperative BCDVA. The hyperopic cohort had the lowest proportion of subject eyes achieving this level (32.4%; 68/210) and the mixed astigmatism cohort was just slightly worse than the myopia cohort at 48.5% (64/132) at Month 6.

TABLE 11
POSTOPERATIVE UCDVA EQUAL OR BETTER THAN PREOPERATIVE BCDVA FOR ALL EYES IN TREATED EYE POPULATION

	Day 1	Week 1	Month 1	Month 3	Month 6	Month 9	Month 12
All Cohort Eyes							
n/N (%)	263/712 (36.9%)	260/700 (37.1%)	334/686 (48.7%)	353/684 (51.6%)	362/684 (52.9%)	372/666 (55.9%)	399/674 (59.2%)
Myopia Cohort							
n/N (%)	175/356 (49.2%)	172/353 (48.7%)	229/340 (67.4%)	223/345 (64.6%)	230/342 (67.3%)	223/347 (64.3%)	237/348 (68.1%)
Hyperopia Cohort							
n/N (%)	54/221 (24.4%)	44/213 (20.7%)	57/219 (26.0%)	71/210 (33.8%)	68/210 (32.4%)	82/193 (42.5%)	84/199 (42.2%)
Mixed Astigmatism Cohort							
n/N (%)	34/135 (25.2%)	44/134 (32.8%)	48/127 (37.8%)	59/129 (45.7%)	64/132 (48.5%)	67/126 (53.2%)	78/127 (61.4%)

UCDVA better or equal to Preoperative BCDVA is defined as UCDVA logMAR being exactly equal to or smaller than BCDVA.

Accuracy of MRSE

Mean MRSE and accuracy of the intended correction for the Treated Eye population through the postoperative course is presented in **Table 12**.

At least 97.4% of the study eyes were within ± 1.00 D of the attempted MRSE at all study visits from Month 1 through the end of the study. The proportions of eyes within ± 0.50 D and ± 0.25 D of the attempted MRSE were 86.0% (590/686) and 66.6% (457/686) at Month 1, respectively. At Month 6, 98.0% (670/684), 89.8% (614/684), and 76.0% (520/684) of eyes were within ± 1.00 D, ± 0.50 D, and ± 0.25 D of the attempted MRSE.

There were no reports of MRSE over- or undercorrection by > 2.00 D at Month 6 or later. A small number of eyes presented with an over- or undercorrection of MRSE by > 1.00 D at Month 6 or later, the majority of which were transient in nature.

TABLE 12
ACCURACY OF MRSE -- ATTEMPTED VS ACHIEVED FOR ALL EYES IN TREATED EYE POPULATION

MRSE Deviation	PreOp n (%)	Day 1 n (%)	Week 1 n (%)	Month 1 n (%)	Month 3 n (%)	Month 6 n (%)	Month 9 n (%)	Month 12 n (%)
N	714	712	700	686	684	684	666	674
Mean	-1.820	-0.167	-0.237	-0.193	-0.153	-0.128	-0.141	-0.114
Median	-1.125	0.000	-0.125	-0.125	0.000	0.000	0.000	0.000
Min, Max	-10.75, 5.00	-2.50, 0.88	-2.63, 1.00	-2.88, 1.00	-2.50, 1.25	-1.63, 1.50	-1.75, 1.25	-1.75, 1.25
± 0.25 D		461 (64.8%)	420 (60.0%)	457 (66.6%)	496 (72.5%)	520 (76.0%)	502 (75.4%)	507 (75.2%)
± 0.50 D		599 (84.1%)	564 (80.6%)	590 (86.0%)	608 (88.9%)	**614 (89.8%)**	597 (89.6%)	597 (88.6%)
± 1.00 D		693 (97.3%)	674 (96.3%)	668 (97.4%)	674 (98.5%)	**670 (98.0%)**	655 (98.4%)	667 (99.0%)
± 2.00 D		708 (99.4%)	698 (99.7%)	683 (99.6%)	683 (99.9%)	684 (100%)	666 (100%)	674 (100%)
Overcorrected > 1.00 D		15 (2.1%)	22 (3.1%)	17 (2.5%)	9 (1.3%)	9 (1.3%)	5 (0.8%)	2 (0.3%)
Overcorrected > 2.00 D		3 (0.4%)	2 (0.3%)	3 (0.4%)	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)
Undercorrected > 1.00 D		4 (0.6%)	4 (0.6%)	1 (0.2%)	1 (0.2%)	5 (0.7%)	6 (0.9%)	5 (0.7%)
Undercorrected > 2.00 D		1 (0.1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Primary effectiveness outcomes are highlighted in light gray and bolded at Month 6, the point of stability.

Mean MRSE and change in MRSE stratified by treatment cohort at Month 6 are shown in **Table 12.1**. The three cohorts show similar outcomes in terms of achieved MRSE within ± 1.00 D; with lower proportions of hyperopic eyes achieving ± 0.50 D or ± 0.25 D.

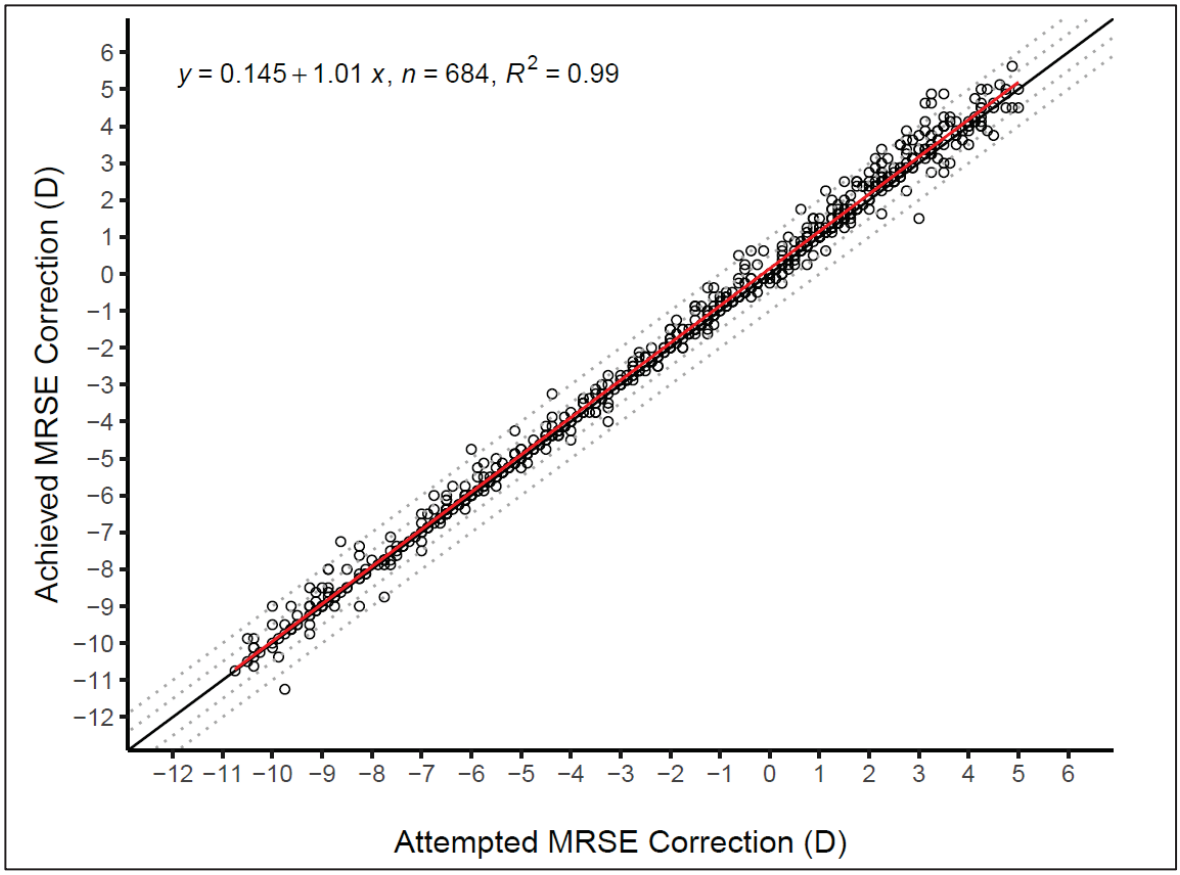
TABLE 12.1
ACCURACY OF MRSE -- ATTEMPTED VS ACHIEVED AT MONTH 6
STRATIFIED BY TREATMENT COHORT IN TREATED EYE POPULATION

MRSE Deviation	Myopia Cohort n (%)	Hyperopia Cohort n (%)	Mixed Astigmatism n (%)	Total n (%)
± 0.25 D	283 (82.8%)	131 (62.4%)	106 (80.3%)	520 (76.0%)
± 0.50 D	**318 (93.0%)**	**174 (82.9%)**	**122 (92.4%)**	**614 (89.8%)**
± 1.00 D	**338 (98.8%)**	**203 (96.7%)**	**129 (97.7%)**	**670 (97.9%)**
± 2.00 D	342 (100%)	210 (100%)	132 (100%)	684 (100%)
Overcorrected > 1.00 D	1 (0.3%)	6 (2.9%)	2 (1.5%)	9 (1.3%)
Overcorrected > 2.00 D	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Undercorrected > 1.00 D	3 (0.9%)	1 (0.5%)	1 (0.8%)	5 (0.7%)
Undercorrected > 2.00 D	0 (0%)	0 (0%)	0 (0%)	0 (0%)
N	342	210	132	684
Mean	-0.090	-0.199	-0.113	-0.127
Median	0.000	-0.125	0.000	0.000
Min, Max	-1.38, 1.50	-1.63, 1.50	-1.13, 0.50	-1.63, 1.50

Primary effectiveness outcomes are highlighted in light gray and bolded at Month 6, the point of stability.

Figure 2 shows the linear correlation between the attempted and the achieved MRSE for the Treated Eye Population at the point of stability (i.e. Month 6). For the full cohort, the slope of the correlation is 1.01, the intercept is 0.145 D and the relationship is highly correlated at $R^2 = 0.99$, showing the high accuracy of the MRSE correction.

FIGURE 2
ATTEMPTED VERSUS ACHIEVED MRSE AT THE POINT OF STABILITY (6 MONTHS) FOR ALL EYES IN TREATED EYE POPULATION



Stability of MRSE

Table 13 presents the change in MRSE between pairwise sequential postoperative visits and the cohort of eyes that had every postoperative visit from 1 to 6 months (6-month consistent cohort). Stability of MRSE was identified at the 3- to 6-month postoperative interval and was confirmed at the subsequent 6- to 9-month interval for the Treated Eye Population. For the 3- to 6-month interval 99.4% (656/660) eyes experienced ≤ 1.00 D change in MRSE. At the 6- to 9-month interval 99.9% (655/656) experienced ≤ 1.00 D change in MRSE.

For the Treated Eye Population, the mean rate of change in MRSE per month was no greater than 0.008 D from the 3- to 6-month interval through the end of the study, well below the 0.04 D/month specified in ANSI Z80.11-2012. The 95% confidence interval for the mean rate of change in MRSE between visits was near zero for all visit intervals following the Month 3 visit in both populations. The mean change of MRSE did not show a monotonic trend over time, however, rates varied only minimally around zero, with a rate of less than 1/100th of a diopter for all intervals from Month 3 to Month 12. With the very small 95% confidence intervals around the mean rate of change in MRSE between visits near zero, there was essentially no change in MRSE across all postoperative visits.

TABLE 13
STABILITY OF MANIFEST REFRACTION SPHERICAL EQUIVALENT (MRSE) FOR PAIRWISE SEQUENTIAL VISITS AND 6-MONTH CONSISTENT COHORT FOR ALL EYES

		Between 1 and 3 Months	Between 3 and 6 Months	Between 6 and 9 Months	Between 9 and 12 Months
Pairwise sequential visits					
Eyes within 0.5 D Change	n/N 95% CI	622/660 (94.2%) (92.2%, 95.8%)	634/660 (96.1%) (94.3%, 97.3%)	639/656 (97.4%) (95.9%, 98.4%)	650/660 (98.5%) (97.2%, 99.2%)
Eyes within 1.0 D Change	n/N 95% CI	654/660 (99.1%) (98.0%, 99.6%)	656/660 (99.4%) (98.5%, 99.8%)	655/656 (99.9%) (99.1%, 100.0%)	660/660 (100%) (99.4%, 100%)
Change between Visits	N	660	660	656	660
	Mean (SD)	0.035 (0.289)	0.023 (0.259)	-0.014 (0.221)	0.024 (0.182)
	95% CI	0.013, 0.057	0.003, 0.043	-0.032, 0.003	0.010, 0.038
Change per Month	N	660	660	656	660
	Mean (SD)	0.018 (0.145)	0.008 (0.086)	-0.005 (0.074)	0.008 (0.061)
	95% CI	0.007, 0.029	0.001, 0.014	-0.011, 0.001	0.003, 0.013
Change per Year	N	660	660	656	660
	Mean (SD)	0.211 (1.735)	0.092 (1.034)	-0.058 (0.886)	0.096 (0.729)
	95% CI	0.079, 0.344	0.013, 0.172	-0.126, 0.010	0.041, 0.152
6-month consistent cohort					
Eyes within 0.5 D Change	n/N 95% CI	603/638 (94.5%) (92.5%, 96.0%)	612/638 (95.9%) (94.1%, 97.2%)	601/618 (97.3%) (95.6%, 98.3%)	608/618 (98.4%) (97.0%, 99.1%)
Eyes within 1.0 D Change	n/N 95% CI	633/638 (99.2%) (98.2%, 99.7%)	634/638 (99.4%) (98.4%, 99.8%)	617/618 (99.8%) (99.1%, 100.0%)	618/618 (100%) (99.4%, 100%)
Change between Visits	N	638	638	618	618
	Mean (SD)	0.032 (0.284)	0.023 (0.262)	-0.015 (0.226)	0.022 (0.185)
	95% CI	0.010, 0.054	0.003, 0.044	-0.033, 0.003	0.007, 0.036
Change per Month	N	638	638	618	618
	Mean (SD)	0.016 (0.142)	0.008 (0.087)	-0.005 (0.075)	0.007 (0.062)
	95% CI	0.005, 0.027	0.001, 0.015	-0.011, 0.001	0.002, 0.012
Change per Year	N	638	638	618	618
	Mean (SD)	0.192 (1.704)	0.093 (1.049)	-0.060 (0.903)	0.087 (0.742)
	95% CI	0.059, 0.324	0.012, 0.175	-0.131, 0.011	0.028, 0.145

A Wilson confidence interval, which ignores dependence between eyes, is provided for responder endpoints. The confidence intervals are provided for this outcome based on the requirements of ANSI Z80.11. The confidence interval can not be the basis for statistical inference.

Results for the myopia and mixed astigmatism cohorts essentially mirror those for the full study cohort, with the point of refractive stability identified at the 3- to 6-month postoperative interval and confirmed at the subsequent 6- to 9-month interval. The mean rates of MRSE changes observed from Month 3 and later are very close to zero, indicating essentially no change in MRSE across all postoperative visits for these cohorts. The point estimates for the hyperopia cohort show a greater rate of mean MRSE change in the early postoperative interval (0.072 D between Month 1 and 3), lowering to 0.024 D between Month 3 and 6 consistent with typical healing after hyperopic treatment.

Accuracy of the astigmatic correction

Table 14 summarizes three parameters for the MRCYL correction outcomes; accuracy within ± 0.25 D, ± 0.50 D and ± 1.00 D, deviation from target in terms of mean MRCYL and percent reduction in MRCYL. **Table 14.1** provides the MRCYL point estimates stratified by treatment cohort at Month 6. The calculation of the percent reduction per eye was performed by dividing the achieved by the attempted MRCYL correction individually for each eye and then calculating the mean and standard deviation for these ratios. As the mean percent reduction in MRCYL does not take into account the presence of a change in axis for individual eyes, these values alone cannot be interpreted as an undercorrection.

The percentage of eyes with a magnitude of MRCYL within ± 1.00 D was increased from 45.3% (254/564) preoperatively to 97.8% (526/538) at Month 6. After a large reduction of mean MRCYL from baseline (-1.646 ± 1.133 D cylinder) to the Week 1 visit (-0.264 ± 0.418 D cylinder), there was no appreciable change in mean MRCYL over the remaining postoperative course for the Treated Eyes population. Mean MRCYL was -0.215 ± 0.335 D at Month 6. The mean percent reduction in MRCYL for the full cohort was -81.0 ± 45.0% at Month 6.

TABLE 14
DEVIATION FROM TARGETED CYLINDER CORRECTION AND PERCENT REDUCTION IN MRCYL FOR EYES TREATED FOR ASTIGMATISM IN TREATED EYES POPULATION

	PreOp	Day 1	Week 1	Month 1	Month 3	Month 6	Month 9	Month 12
Within ± 0.25 D	55 (9.8%)	410 (73.0%)	384 (69.6%)	384 (71.2%)	397 (73.5%)	397 (73.8%)	381 (72.4%)	394 (73.9%)
Within ± 0.50 D	118 (20.9%)	503 (89.5%)	477 (86.4%)	483 (89.6%)	486 (90.0%)	**477 (88.7%)**	468 (89.0%)	478 (89.7%)
Within ± 1.00 D	254 (45.0%)	554 (98.6%)	538 (97.5%)	526 (97.6%)	527 (97.6%)	**526 (97.8%)**	514 (97.7%)	517 (97.0%)
Absolute Deviation from Target (D):								
N	564	562	552	539	540	538	526	533
Mean	-1.646	-0.210	-0.264	-0.246 (	-0.214 (	-0.215 (	-0.221 (	-0.216 (
Median	-1.250	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Min, Max	-4.00, -0.25	-2.00, 0.00	-5.50, 0.00	-5.50, 0.00	-2.00, 0.00	-2.00, 0.00	-2.00, 0.00	-2.00, 0.00
Percent Reduction in MRCYL (D):								
N		562	552	539	540	538	526	533
Mean		-82.0	-77.2 (	-78.9	-81.5	-81.0	-78.7	-79.8
Median		-100.0	-100.0	-100.0	-100.0	-100.0	-100.0	-100.0

Primary effectiveness outcomes are highlighted in light gray and bolded at Month 6, the point of stability.

As shown in **Table 14.1**, mean MRCYL was -0.154 D, -0.281 D and -0.256 D for eyes treated for astigmatism in the myopia, hyperopia and mixed astigmatism cohorts, respectively, at Month 6. The percentage of eyes with a magnitude of MRCYL within ± 1.00 D was 98.8% (249/252) at Month 6 in the myopia cohort; a slightly higher proportion than seen in the hyperopia (96.8%) or mixed astigmatism cohorts (97.0%). The percent reduction in MRCYL was -85.3%, -65.0% and -91.4% for eyes treated for astigmatism in the myopia, hyperopia and mixed astigmatism cohorts, respectively, at Month 6.

TABLE 14.1
DEVIATION FROM TARGETED CYLINDER CORRECTION AND PERCENT REDUCTION IN MRCYL AT MONTH 6 STRATIFIED BY TREATMENT COHORT FOR EYES TREATED FOR ASTIGMATISM IN TREATED EYES POPULATION

	Myopia Cohort	Hyperopia Cohort	Mixed Astigmatism	Total
Within ± 0.25 D	206 (81.7%)	102 (66.2%)	89 (67.4%)	397 (73.8%)
Within ± 0.50 D	**234 (92.9%)**	**130 (84.4%)**	**113 (85.6%)**	**477 (88.7%)**
Within ± 1.00 D	**249 (98.8%)**	**149 (96.8%)**	**128 (97.0%)**	**526 (97.8%)**
Absolute Deviation from Target (D):				
N	252	154	132	538
Mean	-0.154	-0.281	-0.256	-0.215
Median	0.000	-0.125	0.000	0.000
Min, Max	-1.50, 0.00	-2.00, 0.00	-1.75, 0.00	-2.00, 0.00
Percent Reduction in MRCYL (D):				
N	252	154	132	538
Mean	-85.3	-65.0	-91.4	-81.0
Median	-100.0	-96.7	-100.0	-100.0

Primary effectiveness outcomes are highlighted in light gray and bolded at Month 6, the point of stability.

Effectiveness of the low astigmatic correction

The effectiveness of low MRCYL correction in myopic and hyperopic eyes with the MEL 90 was reported by providing eyes with ≤ 0.50 D MRCYL treated with a low cylinder correction versus treated with a spherical correction. Eyes with MRCYL confirmed by objective measurement were treated with a low cylinder correction (confirmed cylinder). Eyes with MRCYL that was not confirmed by objective measurement were treated with a spherical correction based on MRSE (unconfirmed cylinder).

In the myopia cohort, 74 eyes with confirmed low cylinder were compared to 49 eyes with unconfirmed low cylinder. For hyperopia, 44 eyes with confirmed low cylinder were compared to 35 eyes with unconfirmed low cylinder.

Table 15 presents the point estimates of results for untreated and treated low cylinder in myopic and hyperopic eyes by means of deviation from the target from 0.00 D cylinder. In the myopia cohort, a greater percent reduction in MRCYL at Month 6 was seen for the treated low cylinder (-79.3%) than the untreated low cylinder (-20.8%) eyes. The treated low cylinder eyes decreased from a baseline -0.375 D mean cylinder to -0.075 D mean cylinder at Month 6; while the untreated low cylinder eyes had a minimal change from -0.293 D mean cylinder at baseline to -0.213 D mean cylinder at Month 6.

The percent reduction of MRCYL for the hyperopia eyes was less pronounced at Month 6 for the treated low cylinder (-25.0%) compared to the myopic eyes, but showed the same trend compared to the untreated low cylinder (-18.2%) eyes. The treated low cylinder eyes decreased from a baseline -0.398 D mean cylinder to -0.256 D mean cylinder at Month 6; while the untreated low cylinder eyes had a change from -0.300 D cylinder at baseline to -0.227 D cylinder at Month 6.

Table 15
DEVIATION FROM TARGETED CYLINDER CORRECTION AND PERCENT REDUCTION IN MRCYL FOR MYOPIC AND HYPEROPIC EYES WITH LOW CYLINDER FOR PER PROTOCOL POPULATION

	Myopia Cohort				Hyperopia Cohort			
	Untreated (Unconfirmed ≤ 0.50 D Cyl)		Treated (Confirmed ≤ 0.50 D Cyl)		Untreated (Unconfirmed ≤ 0.50 D Cyl)		Treated (Confirmed ≤ 0.50 D Cyl)Cyl)	
	Preop	Month 6	Preop	Month 6	Preop	Month 6	Preop	Month 6
Within ± 0.25 D	40 (81.6%)	37 (78.7%)	37 (50.0%)	63 (90.0%)	29 (82.9%)	24 (72.7%)	18 (40.9%)	29 (69.0%)
Within ± 0.50 D	49 (100%)	44 (93.6%)	74 (100%)	69 (98.6%)	34 (97.1%)	29 (87.9%)	44 (100%)	35 (83.3%)
Within ± 1.00 D	49 (100%)	47 (100%)	74 (100%)	70 (100%)	35 (100%)	32 (97.0%)	44 (100%)	41 (97.6%)
Absolute Deviation from Target (D):								
N	49	47	74	70	35	33	44	42
Mean	-0.293	-0.213	-0.375	-0.075	-0.300	-0.227	-0.398	-0.256
Median	-0.250	-0.250	-0.375	0.000	-0.250	0.000	-0.500	0.000
Min, Max	-0.50, -0.25	-1.00, 0.00	-0.50, -0.25	-0.75, 0.00	-0.75, -0.25	-1.50, 0.00	-0.50, -0.25	-1.25, 0.00
Percent Reduction in MRCYL (D):								
N		47		70		33		42
Mean		-20.8		-79.3		-18.2		-25.0
Median		-26.5		-100.0		-100.0		-100.0

Unconfirmed Cylinder was not treated for Cylinder. A 'target' of 0.0 was assumed for the calculation of outcome..

Stability of MRCYL

The change in MRCYL between consecutive visits is presented in **Table 16** for pairwise sequential visits as well as for eyes with available data at every postoperative visit from Month 1 to Month 6 (6-month consistent cohort).

For both the Pairwise Sequential and Consistent Cohort, the mean change in MRCYL was < 0.04 D per month for all intervals. The mean change of MRCYL varied only minimally around zero. The proportion of eyes with a change in MRCYL between visits within 1.00 D was at least 99.4% for all intervals.

Results for the myopia cohort essentially mirror those for the full study cohort, with the point of refractive stability identified at the 3- to 6-month postoperative interval and confirmed at the subsequent 6- to 9-month interval. Both the hyperopia and mixed astigmatism cohorts show stability of MRCYL identified at the 1- to 3-month postoperative interval and confirmed at the subsequent 3- to 6-month interval.. The proportion of eyes with a change in MRCYL between visits within ±1.00 D was at least 99.6%, 98.7% and 99.2% for the myopia, hyperopia and mixed astigmatism cohorts, respectively, for all intervals.

TABLE 16
STABILITY OF MANIFEST REFRACTION CYLINDER FOR PAIRWISE SEQUENTIAL VISITS AND 6-MONTH CONSISTENT COHORT FOR ALL COHORT EYES TREATED WITH ASTIGMATISM

		Between 1 and 3 Months	Between 3 and 6 Months	Between 6 and 9 Months	Between 9 and 12 Months
Pairwise sequential visits					
Eyes within 0.5 D Change	n/N 95% CI	511/519 (98.5%) (97.0%, 99.2%)	508/519 (97.9%) (96.2%, 98.8%)	508/519 (97.9%) (96.2%, 98.8%)	510/523 (97.5%) (95.8%, 98.5%)
Eyes within 1.0 D Change	n/N 95% CI	518/519 (99.8%) (98.9%, 100.0%)	516/519 (99.4%) (98.3%, 99.8%)	518/519 (99.8%) (98.9%, 100.0%)	523/523 (100%) (99.3%, 100%)
Change between Visits	N	519	519	519	523
	Mean (SD)	0.020 (0.227)	-0.008 (0.227)	-0.008 (0.230)	0.000 (0.197)
	95% CI	0.001, 0.040	-0.027, 0.012	-0.028, 0.012	-0.017, 0.016
Change per Month	N	519	519	519	523
	Mean (SD)	0.010 (0.114)	-0.003 (0.076)	-0.003 (0.077)	0.000 (0.066)
	95% CI	0.000, 0.020	-0.009, 0.004	-0.009, 0.004	-0.006, 0.006
Change per Year	N	519	519	519	523
	Mean (SD)	0.121 (1.364)	-0.031 (0.908)	-0.031 (0.921)	-0.002 (0.787)
	95% CI	0.004, 0.239	-0.109, 0.048	-0.110, 0.049	-0.070, 0.066
6-month consistent cohort					
Eyes within 0.5 D Change	n/N 95% CI	492/499 (98.6%) (97.1%, 99.3%)	488/499 (97.8%) (96.1%, 98.8%)	473/484 (97.7%) (96.0%, 98.7%)	467/480 (97.3%) (95.4%, 98.4%)
Eyes within 1.0 D Change	n/N 95% CI	499/499 (100%) (99.2%, 100%)	496/499 (99.4%) (98.2%, 99.8%)	483/484 (99.8%) (98.8%, 100.0%)	480/480 (100%) (99.2%, 100%)
Change between Visits	N	499	499	484	480
	Mean (SD)	0.026 (0.223)	-0.007 (0.229)	-0.011 (0.236)	0.001 (0.200)
	95% CI	0.007, 0.046	-0.027, 0.014	-0.032, 0.010	-0.017, 0.019
Change per Month	N	499	499	484	480
	Mean (SD)	0.013 (0.111)	-0.002 (0.076)	-0.004 (0.079)	0.000 (0.067)
	95% CI	0.003, 0.023	-0.009, 0.005	-0.011, 0.003	-0.006, 0.006
Change per Year	N	499	499	484	480
	Mean (SD)	0.156 (1.335)	-0.026 (0.917)	-0.045 (0.942)	0.004 (0.802)
	95% CI	0.039, 0.274	-0.107, 0.055	-0.130, 0.039	-0.068, 0.076

A Wilson confidence interval, which ignores dependence between eyes, is provided for responder endpoints.
The confidence intervals are provided for this outcome based on the requirements of ANSI Z80.11. The confidence interval can not be the basis for statistical inference.

Vector Analysis

The vector analysis summary for the three treatment cohorts at stability (Month 6) is shown in **Table 17**. The astigmatic vectors for "intended refractive correction" (IRC) and "surgically induced refractive correction" (SIRC) incorporate both the magnitude and axis of the cylinder into the vector. The "error vector" (EV) is equal to the vector difference between SIRC and IRC, while the "correction ratio" (CR) is the ratio of |SIRC|/|IRC|.

For both the myopic and hyperopic eyes treated for astigmatism, the mean CR was greater than 1, with 1.03 ± 0.25 for the myopia cohort and 1.13 ± 0.60 for the hyperopia cohort. The mixed astigmatism cohort had a CR of 0.98 ± 0.10 at Month 6. In the stratifications by preoperative MRCYL, the mixed astigmatism cohort showed values very slightly lower than 1.0. Both the myopia and hyperopia cohorts showed values larger than 1.0 in the low cylinder bins and values lower than 1.0 in one of the higher cylinder bins. Note, that

according to Bullimore et al. (2015) the values lower than 1.0 for small correction may not be interpreted as undercorrections, as this is a methodological artifact, which is more pronounced if the variation of the astigmatism is higher, which is indeed the case for hyperopia compared to myopia (compare the |EV| for the lowest cylinder corrections). The overall mean |EV| was lowest for the myopia cohort (0.17 ± 0.26) and highest and similar for the hyperopia cohort (0.29 ± 0.36) and mixed astigmatism cohort (0.30 ± 0.35). The ER was lowest for the mixed astigmatism cohort (0.10 ± 0.11) and highest in the hyperopia cohort (0.35 ± 0.68).

TABLE 17
VECTOR ANALYSIS SUMMARY AT STABILITY (MONTH 6)
FOR COHORT EYES TREATED WITH ASTIGMATISM IN TREATED EYES POPULATION

Preoperative Cylinder	N	|IRC| (Mean ± SD)	|SIRC| (Mean ± SD)	|EV| (Mean ± SD)	CR (Mean ± SD)	ER (Mean ± SD)
Full Cohort						
All Eyes	564	1.65 (1.13)	1.64 (1.11)	0.23 (0.32)	1.05 (0.37)	0.20 (0.44)
>0.0 to ≤ 0.5 D	118	0.38 (0.13)	0.45 (0.25)	0.14 (0.27)	1.21 (0.70)	0.41 (0.84)
>0.5 to ≤ 1.0 D	136	0.86 (0.12)	0.88 (0.27)	0.18 (0.26)	1.02 (0.31)	0.21 (0.32)
>1.0 to ≤ 2.0 D	124	1.57 (0.31)	1.58 (0.35)	0.15 (0.23)	1.01 (0.15)	0.10 (0.17)
>2.0 to ≤ 3.0 D	99	2.61 (0.28)	2.57 (0.36)	0.27 (0.26)	0.99 (0.09)	0.10 (0.10)
>3.0 to ≤ 4.0 D	87	3.59 (0.29)	3.50 (0.45)	0.53 (0.44)	0.98 (0.12)	0.15 (0.12)
Myopia Cohort						
All Eyes	266	1.35 (1.01)	1.34 (0.99)	0.17 (0.26)	1.03 (0.25)	0.16 (0.33)
>0.0 to ≤ 0.5 D	74	0.38 (0.13)	0.41 (0.17)	0.07 (0.17)	1.09 (0.36)	0.21 (0.52)
>0.5 to ≤ 1.0 D	69	0.84 (0.12)	0.85 (0.23)	0.16 (0.24)	1.01 (0.26)	0.19 (0.30)
>1.0 to ≤ 2.0 D	65	1.56 (0.32)	1.59 (0.34)	0.13 (0.21)	1.02 (0.16)	0.09 (0.16)
>2.0 to ≤ 3.0 D	34	2.55 (0.25)	2.46 (0.32)	0.22 (0.21)	0.96 (0.06)	0.08 (0.08)
>3.0 to ≤ 4.0 D	24	3.54 (0.27)	3.55 (0.48)	0.52 (0.39)	1.01 (0.13)	0.15 (0.11)
Hyperopia Cohort						
All Eyes	163	1.34 (1.00)	1.39 (0.97)	0.29 (0.36)	1.13 (0.60)	0.35 (0.68)
>0.0 to ≤ 0.5 D	44	0.40 (0.12)	0.52 (0.33)	0.25 (0.36)	1.41 (1.02)	0.75 (1.13)
>0.5 to ≤ 1.0 D	52	0.86 (0.13)	0.90 (0.33)	0.24 (0.31)	1.06 (0.40)	0.28 (0.38)
>1.0 to ≤ 2.0 D	29	1.59 (0.29)	1.61 (0.40)	0.25 (0.30)	1.01 (0.19)	0.17 (0.23)
>2.0 to ≤ 3.0 D	26	2.57 (0.31)	2.60 (0.41)	0.30 (0.27)	1.02 (0.10)	0.12 (0.10)
>3.0 to ≤ 4.0 D	12	3.60 (0.34)	3.28 (0.34)	0.71 (0.60)	0.92 (0.15)	0.19 (0.16)
Mixed Astigmatism Cohort						
All Eyes	135	2.60 (0.99)	2.53 (1.02)	0.30 (0.35)	0.98 (0.10)	0.10 (0.11)
>0.0 to ≤ 0.5 D	0					
>0.5 to ≤ 1.0 D	15	0.97 (0.09)	0.92 (0.15)	0.04 (0.13)	0.96 (0.13)	0.04 (0.13)
>1.0 to ≤ 2.0 D	30	1.60 (0.29)	1.54 (0.31)	0.10 (0.16)	0.97 (0.09)	0.06 (0.10)
>2.0 to ≤ 3.0 D	39	2.68 (0.27)	2.64 (0.34)	0.28 (0.28)	0.99 (0.10)	0.11 (0.11)
>3.0 to ≤ 4.0 D	51	3.61 (0.28)	3.53 (0.46)	0.50 (0.41)	0.98 (0.11)	0.14 (0.11)

Notes: N is based on IRC; Ns may be smaller for other columns due to missing data at point of stability.
Notes: IRC=Intended refractive correction; SIRC=Surgically induced refractive correction; EV=Error vector; CR=Correction ratio; ER=Error ratio.

Patient Reported Outcomes for Satisfaction

The main goal of LASIK with the MEL 90 is to reduce or eliminate the need for spectacles or contact lenses. As shown in **Table 18**, satisfaction with outcomes was high, with 92.7% (316/341) of all subjects indicating they were completely or very satisfied with the result of their LASIK surgery at Month 6.

TABLE 18
PATIENT REPORTED OUTCOMES FOR SATISFACTION AT MONTH 6 BY TREATMENT COHORT FOR ALL SUBJECTS IN SAFETY POPULATION

	Myopia Cohort		Hyperopia Cohort		Mixed Astigmatism		Total*	
	n/N	(%)	n/N	(%)	n/N	(%)	n/N	(%)
Q 6. In general, how satisfied or dissatisfied are you with your present vision?								
Completely satisfied	135/174	77.6%	41/110	37.3%	45/76	59.2%	208/341	61.0%
Very satisfied	32/174	18.4%	48/110	43.6%	20/76	26.3%	97/341	28.4%
Somewhat satisfied	6/174	3.4%	14/110	12.7%	8/76	10.5%	26/341	7.6%
Somewhat dissatisfied	1/174	0.6%	1/110	0.9%	1/76	1.3%	3/341	0.9%
Very dissatisfied	0/174		5/110	4.5%	1/76	1.3%	6/341	1.8%
Completely dissatisfied	0/174		1/110	0.9%	1/76	1.3%	1/341	0.3%
Q 36. Currently how satisfied or dissatisfied are you with the result of your LASIK surgery?								
Completely satisfied	140/174	80.5%	50/110	45.5%	46/76	60.5%	223/341	65.4%
Very satisfied	25/174	14.4%	51/110	46.4%	20/76	26.3%	93/341	27.3%
Somewhat satisfied	6/174	3.4%	5/110	4.5%	6/76	7.9%	16/341	4.7%
Somewhat dissatisfied	2/174	1.1%	1/110	0.9%	2/76	2.6%	4/341	1.2%
Very dissatisfied	0/174		1/110	0.9%	1/76	1.3%	2/341	0.6%
Completely dissatisfied	1/174	0.6%	2/110	1.8%	1/76	1.3%	3/341	0.9%
Q 43. If you could do it all over again would you decide to have LASIK performed?								
Yes, I would decide to have it again, because of my result.	163/174	93.7%	100/110	90.9%	66/76	86.8%	312/341	91.5%
Yes, I would decide to have it again, despite my result.	10/174	5.7%	9/110	8.2%	8/76	10.5%	26/341	7.6%
No, I would not decide to have it again, because of my result.	1/174	0.6%	0/110		1/76	1.3%	2/341	0.6%
No, I would not decide to have it again, despite my result.	0/174		1/110	0.9%	1/76	1.3%	1/341	0.3%
Q 44. Would you recommend LASIK surgery to a friend or family member?								
Yes, I would decide to have it again, because of my result.	164/174	94.3%	102/110	92.7%	67/76	88.2%	316/341	92.7%
Yes, I would decide to have it again, despite my result.	10/174	5.7%	8/110	7.3%	8/76	10.5%	24/341	7.0%
No, I would not decide to have it again, because of my result.	0/174		0/110		1/76	1.3%	1/341	0.3%
No, I would not decide to have it again, despite my result.	0/174		0/110		0/76		0/341	

*Total is based on subject response; subjects with eyes in different cohorts will be represented twice.

Surgical planning and procedures

Please refer to the MEL 90 Instructions for Use.

Technical data

Characteristics of laser radiation	
Laser source:	ArF excimer laser
Laser class:	4 (according to IEC 60825-1:2001/2007/2014)
Energy:	1.00 ± 0.15 mJ
Wavelength:	193 nm
Half beam divergence:	35 mrad ± 20 %
Repetition rate:	500 Hz
Pulse width:	4 to 7 ns
Beam dimensions:	0.7 mm FWHM diameter, Gaussian profile
Treatment area:	max. 10 mm x 10 mm
Energy density at the eye:	> 150 mJ/cm^2
Safety distance (NOHD):	13.6 m (100 s exposure time)

Specifications of pressurized components	
Gas cylinder (excimer laser gas)	
Volume:	max. 11 liters
Pressure:	max. 14.7 MPa (147 bar)
Gas:	ArF with max. 0.2 % fluorine
F The material safety data sheet can be ordered via the service hotline of Carl Zeiss Meditec AG.	
High pressure circle	
Volume:	max. 0.012 liters
Pressure:	max. 15 MPa (150 bar)
Gas:	ArF with max. 0.2 % fluorine
Low pressure circle including laser tube:	
Volume:	max. 2.3 liters
Pressure:	max. 850 kPa (8.5 bar)
Gas:	ArF with max. 0.2 % fluorine

Surgical microscope specifications	
Magnification:	0.4x, 0.6x, 1.0x, 1.6x, 2.5x
Eyepieces:	10x

Eyetracking specifications	
Active Eyetracker; high speed:	1050 fps

Slit lamp illumination specifications (optional parts)	
Halogen bulb:	6 V, 10 W, PG22 (product number 000000-0120-703)
Slit images:	narrow slit, wide slit, circular field

Signal inputs and outputs
1 x co-observer HDMI video output, not isolated
1 x connector for remote interlock
1 x DVI/DP port, not isolated
4 x USB, not isolated
1 x network connector, RJ45 socket, isolation specified for at least 4 kV and according to IEC 60601-1
1 x EMERGENCY STOP/EMERGENCY LASER STOP interface
1 x port for foot switch
1 x Interlock port for patient supporting system
1 x RS232 interface

Mechanical characteristics	
MEL 90 basic unit dimensions:	L x W x H: 1.63 m x 0.73 m x 1.48 m to 1.70 m
MEL 90 basic unit weight including gas cylinder:	295 kg

Abbreviations/Glossary

ArF	Argon Fluoride
BCDVA	Best corrected distance visual acuity
BSCVA	Best spectacle corrected visual acuity
CCA+	Cone for Controlled Atmosphere
CR	Correction ratio
D	Diopter
Deg	Degree
ER	Error ratio
EV	Error vector
FWHM	Full width half maximum
Hz	Hertz
IRC	Intended refractive correction
IOP	Intraocular pressure
LASIK	Laser Assisted in-situ Keratomileusis
LogMAR	Logarithm of Minimum Angle of Resolution
µm	Micrometer, micron
mJ	Milli Joule
mm	Millimeter
mmHg	Millimeters of mercury
MRCYL	Manifest refraction cylinder
MRSE	Manifest refraction spherical equivalent
MRSPH	Manifest refraction sphere
NIR	Near-infrared
nm	Nanometer
ns	Nanosecond
OPASS	Operation assistant software
OSDI	Ocular Surface Disease Index
PRK	Photorefractive keratectomy
PRO	Patient reported outcomes
PROWL	Patient Reported Outcomes with LASIK
RME	Recommended maximum exposure
SIRC	Surgically induced refractive correction
SMILE	Small Incision Lenticule Extraction
UCDVA	Uncorrected distance visual acuity

Figures/Tables

Index

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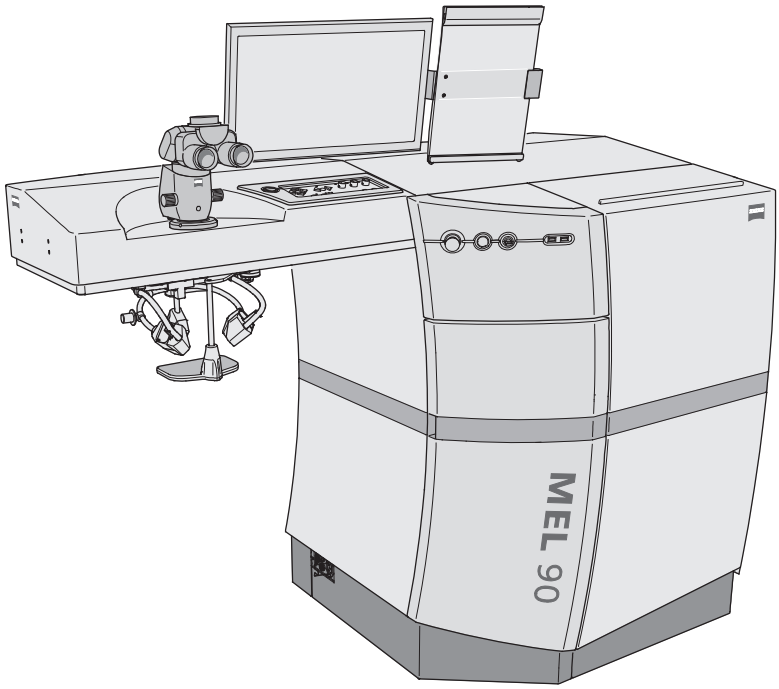
000000-2179-684-ProfUseInf-MEL 90
LASIK-en-US-211124
MEL 90

MEL 90

Instructions for use



Contents

Notes on the instructions for use

Purpose and availability of the documentation

These instructions for use describe the safety precautions, functions, usage, performance parameters and care and maintenance measures for the MEL 90.

Correct operation of the system is imperative for its safe and successful function. You should therefore ensure that you are thoroughly familiar with these instructions for use before setting up and using the MEL 90 for the first time.

The instructions for use and other documentation enclosed with the MEL 90 should be kept accessible to users at all times to ensure that the information required for using the MEL 90 is readily available.

Carefully read all instructions prior to use. Observe all contraindications, warnings, and precautions.

Questions and comments

If you have any questions or comments concerning these instructions for use or the MEL 90, please contact ZEISS Service or your local dealer. (Contact details see reverse.)

Regardless of any national legislation which may apply, any shortcomings regarding the identity, quality, resilience, reliability, safety, effectiveness or performance of this medical product should be reported to the manufacturer.

Explanation of symbols used

The symbols used in these instructions for use refer to important safety information which may warn against possible health risks or fatal injuries and contain useful notes.
Whenever you see these symbols, read the accompanying information carefully and observe all safety notes and information in these instructions for use and on device labels.

WARNING

Indicates a hazardous situation which could result in death or serious injury if the appropriate safety precautions are not heeded.

CAUTION

Indicates a hazardous situation which could result in minor or moderate injury if the appropriate safety precautions are not heeded.

CAUTION - PROPERTY DAMAGE

Indicates possible property damage if the appropriate safety precautions are not heeded.

☞ Information, hints and advice for better understanding of the instructions to be observed in the operation of the device.

Notes on safety and security

Responsibilities and duties of the responsible organization

Operating personnel

The device may be operated only by properly instructed and trained persons.

Restrict access to the device to authorized operating personnel.

Ensure that the operating personnel have been trained and instructed.

- Caution: Federal law restricts this device to sale by or on the order of a physician.
- This device shall only be installed, operated, used and maintained by persons who have the necessary training, knowledge and experience. Please also adhere to the national qualification guidelines applicable in your country.

Notification to manufacturers and authorities

If a serious incident affecting the user, patient or another person occurs in connection with this medical device, the responsible organization or person responsible must report this incident to the manufacturer or seller of the medical product.
The responsible organization or person must report serious incidents to their competent authority. In all other countries, comparable rules apply where national legislation so requires.

Responsibilities of the User

ZEISS explicitly advises to change the password of the "Administrator" application user when logging in for the first time.

ZEISS explicitly advises using a complex password (up to 12 characters, upper and lower case, numbers and special characters) to enhance security and safeguard against password cracking and brute-force attacks.

The passwords should be changed regularly.

Network integration

The device can be included into an Ethernet network to perform the following applications:

- Print
- DICOM® Export/Import

- File export to a shared network drive
- Export of system diagnostic data

The device has an integrated galvanic isolation (4 kV isolation voltage) at the network interface (**5**, Fig. 10, page 35). An additional external galvanic isolation is therefore not necessary.

CAUTION - GENERAL HAZARDS

Connect the device only to private networks which are protected from public networks (the internet) by measures which meet the latest technical requirements (e.g. firewalls).

The connection of the MEL 90 to a clinic or practice network must be carried out by trained ZEISS personnel.

The Ethernet cable used for the connection to a clinic or practice network must conform to the following specifications:
- length max. 5 m,
- double-shielded cable,
- at least CAT 7.

Network addresses and port numbers must be specified by the responsible IT system administrator.
The DICOM® (Digital Imaging and Communication in Medicine) standard is the international standard for medical images and related information (ISO 12052). It defines the formats for medical images that can be exchanged together with the relevant data for clinical use in the required quality.
For detailed information, please refer to ZEISS DICOM® Conformance Statement, www.zeiss.com/dicom.

ZEISS advises that for the secure software and data use as well as import/export of treatment planning data and results within the healthcare delivery organization's network, the user must ensure that
- digital data are transmitted in encrypted form using a tunneled system as transmitting sensitive patient data poses a risk to data protection
- the connection of the product to the clinic network and product patches and updates installation is to be carried out by trained ZEISS personnel.
- software or updates are not installed by the customer to ensure intended use and protect against malware
- before attaching any external media (e.g., USB stick) to the device, these media are to be scanned with current antivirus and antimalware programs

- patients' data entered or imported with the default refraction values displayed for MEL 90 are verified for correctness

In the event of a suspected cybersecurity incident, disconnect the device, take it out of service and contact the Carl Zeiss Meditec service for further investigation and application of immediate measures.
The detection of suspected cybersecurity incidents may include:

- unexpected behavior,
- recurring errors, freeze or crash of the application,
- known issues on the network environment,
- infection on an USB drive that is/has been connnected to the device.

Connection of MEL 90 in combination with VisuMax

CAUTION - GENERAL HAZARDS

MEL 90, VisuMax, Ethernet switch and printer may only be connected directly or via a network consisting exclusively of devices approved for this purpose by Carl Zeiss Meditec AG. It is not permitted to connect the devices to a clinic, practice or public network.

Connection of MEL 90 in combination with VISUMAX 600/800 (in regions approved)

CAUTION - GENERAL HAZARDS

MEL 90 and/or VISUMAX 600/800 may be connected to a clinic or practice network which is secured by suitable protective measures (IEC 80001-1 provides instructions on how to address these risks).

Hazards arising from connecting the device to a clinic or practice network

WARNING - RISK FROM DEVICE OPERATION

Before connecting the device to a network, observe the following safety measures to prevent injury or damage:

- The user (or IT manager) is responsible for ensuring that no malicious software (e.g. computer viruses) are transmitted to the device via the network connection.
- Protect the network by using suitable safeguards (e.g. firewalls) against unauthorized access.

☞ Ensure a data transmission rate of 1 Gbit/s (Fast Ethernet) and the conformity of your network configuration with internet protocol IPv4 so that patient data can be exported to your network reliably, safely and error-free.

CAUTION - SENSITIVE DATA/PATIENT HAZARD

Connecting the device to a clinic or practice network which includes other devices could lead to risks for patients, users and third parties.
The integrated protective measures may not protect against as yet unknown methods of attack.

The responsible organization should determine, analyze, evaluate and manage these risks by taking appropriate measures.
(IEC 80001-1 includes instructions to address these risks.)

- Observe the maintenance and inspection intervals that are specified in these instructions for use. This also brings the configuration of the protective software up to date.

Similarly, subsequent changes to the clinic or practice network can lead to new risks and therefore require additional analysis:

- Changes to the clinic or practice network configuration
- Connection of additional elements in the clinic or practice network
- Removal of elements from the clinic or practice network, update or upgrade of devices that are connected to the clinic or practice network

The configuration and network settings should only be changed by a network administrator with experience.

Protect the system and patient data from unauthorized use. Please also observe the nationally applicable laws and regulations for the protection of sensitive data.

Package check list

The following parts are supplied with the MEL 90 basic device (including power cable 2.4 m and network cable 5 m):

- Documentation set
- Foot switch including 2.8 m cable (ASA-Schalttechnik type FM1 SS2 F4 U)
- Dummy plug (remote interlock/remote door interlock)
- Document holder
- Fluence test paper (test card set)
- Magnet for fluence test plate, 5 pieces
  (permanent magnet L/D = 20/12 mm width a/f)
- Adapters for sterilizable caps 12 mm
  (to be mounted onto the rotary/push buttons for illumination control)

Available device combinations

- MEL 90 in combination with ZEISS VisuMax
- MEL 90 in combination with ZEISS VISUMAX 600/800

Country-specific information and labels

Classification/Manufacturer's declaration

WARNING - GENERAL HAZARDS

This device may only be set up, operated and used for the specified purpose and in accordance with national regulations, applicable industry standards and occupational safety and accident prevention regulations. Any modifications or maintenance work should also comply with these.

This declaration shall be rendered invalid if changes are made to the product without the manufacturer's authorization.

Indications for use

The MEL 90 is indicated for use in primary Laser-Assisted in situ Keratomileusis (LASIK) treatments for the reduction or elimination of:

- Myopia less in magnitude than -10.00 D sphere (in minus-cylinder notation), with and without cylinder up to -4.00 D, when MRSE is less in magnitude than -10.00 D;
- Hyperopia up to +4.00 D sphere (in plus-cylinder notation), with and without cylinder up to +3.00 D, when MRSE is up to +5.00 D; and
- Mixed astigmatism with cylinder from >1.00 D up to 4.00 D;

in patients who are 18 years of age or older with documentation of stable manifest refraction over the past year as demonstrated by a change in MRSE within +/- 0.50 D.

-

Contraindications

MEL 90 LASIK procedure is contraindicated in patients with:

- a residual stromal bed thickness that is less than 250 microns from the corneal endothelium;
- abnormal corneal topographic findings, e.g. keratoconus, pellucid marginal degeneration;
- severe dry eye;
- active eye infection or inflammation;
- recent herpes eye infection or problems resulting from past infection;
- active autoimmune disease or connective tissue disease;
- uncontrolled diabetes;
- uncontrolled glaucoma;
- who are pregnant or nursing.

Warnings

There is reasonable evidence to believe that there may be increased risk for serious adverse consequences if LASIK surgery is performed in patients with the following conditions, and therefore use of the MEL90 LASIK procedure is not recommended for patients with:

- controlled autoimmune or connective tissue disease;
- controlled diabetes;
- immunocompromised status (weakened immune system) due to medication or a disease condition, e.g., immunosuppressive therapy, such as corticosteroids, or AIDS;
- a history of Herpes simplex or Herpes zoster keratitis;
- controlled glaucoma;
- a history of taking isotretinoin (Accutane®);
- epithelial basement membrane dystrophy;
- amblyopia;
- moderate or mild symptoms of dry eye;
- difficulty following directions or who are unable to fixate;

and for patients who:

- take medication that have dry eyes as side effect;
- participate in activities that could damage the LASIK flap, including contact sports.

☞ In addition, please consult medical literature and recommendations of professional associations in your country.

Precautions

The safety and effectiveness of the MEL 90 LASIK procedure have NOT been established for patients:

- with refractive error outside the range in the approved indications for use;
- with a difference between cycloplegic and manifest refractions of greater than or equal to 0.75 D spherical equivalent in the eye to be treated;
- with central corneal thickness of less than 480 microns in the eye(s) to be treated;
- that are hyperopic with white-to-white distance <11.5 mm;
- with a family history of thinning of the cornea due to keratoconus, pellucid marginal degeneration, or other conditions that may cause ectasia;
- with large mesopic pupils, greater than the optical zone size, as evaluated under mesopic conditions;
- with previous corneal or intraocular surgery, or trauma to the intended ablation zone;
- with a history of strabismus;
- with iris problems including, but not limited to, coloboma and previous iris surgery compromising proper eyetracking;
- history of keloid formation;
- with active ophthalmic disease or abnormality (including, but not limited to, symptomatic blepharitis (e.g. ocular rosacea), recurrent corneal erosion, neovascularization >1 mm from limbus);
- with elevated intraocular pressure (IOP), ocular hypertension or being followed for possible glaucoma (glaucoma suspect);
- with severe allergies and eye rubbing;
- taking medications likely to affect wound healing including, but not limited to, antimetabolites;
- taking hormone replacement therapy or antihistamines who may experience delayed re-epithelialization of the cornea following surgery;
- taking the medication Amiodarone hydrochloride (Cordarone®);
- taking the medication sumatriptan succinate (Imitrex®);
- more than 12 months after surgery.
- with media problems (corneal, lens, and/or vitreous opacities including, but not limited to, cataract);
- with a history of uveitis.

Additional Precautions

Preoperative evaluation for dry eye should be performed. This may be particularly important for patients who have been contact lens intolerant because of symptoms of dryness. Patients should be advised of potential for worsening of symptoms associated with dry eye syndrome post-LASIK surgery.

The effect of LASIK on visual performance under poor lighting conditions have not been fully characterized. It is possible that following LASIK treatment, patients will find it more difficult to see in conditions such as very dim light, rain, snow, fog, or glare from bright lights at night. Visual performance possibly could be worsened in patients with large pupil sizes.

Intraocular pressure is more difficult to interpret after LASIK because of the resulting corneal thinning. Patients should be informed that they should tell future eyecare professionals that they have had LASIK.

Future intraocular lens calculations for cataract surgery may be affected by LASIK. The surgeon should give the patient a patient information card that has eye measurements from before the LASIK surgery. Patients should be advised to keep this card and give it to their future cataract surgeon.

Prior to surgery, prospective patients should be provided with a copy of the Patient Information Brochure for this product and informed of the possible risks and benefits associated with its use.

Potential risks

The potential risks associated with the MEL 90 LASIK procedure include, but are not limited to:

- Loss of BSCVA;
- Over-correction or under-correction;
- Increase in refractive cylinder;
- Difficulty with night driving or other low light tasks;
- Headache or eyestrain due to imbalance between the eyes;
- Worsening of patient complaints such as glare, halos, starbursts, hazy or blurred vision, distortion, double or ghost images, fluctuation of vision, focusing difficulty, difficulty with depth perception, light sensitivity, grittiness, and ocular pain/soreness;
- Dry eye;
- Ptosis;
- Increase in IOP;
- Conjunctivitis;
- Discomfort or pain; potentially including chronic eye pain that is resistant to therapy referred to as neuropathic corneal pain;
- Iritis;
- Corneal haze/scar/infection/inflammation/infiltrate/ulcer/epithelial defect/epithelium in the interface/ edema/decompensation/striae or microstriae/ectasia;
- Perforated, miscreated, or melting of the flap;
- Treatment interruption, difficult flap lifting with tissue damage, ocular penetration;
- Retinal detachment/posterior vitreous detachment/vascular accidents.

☞ In addition, please consult medical literature and recommendations of professional associations in your country.

Disposal of the product

Disposal of consumables

Dispose of the fluence test paper as ordinary domestic waste.

Dispose of used filters and hoses as medical waste.

Observe local waste disposal regulations.

☞ Keep packing material in the event of a relocation or repair.
If you would like to dispose of the original packing material, send it in for recycling via a recognized collection system.

Disposal of the medical product

CAUTION - CHEMICAL HAZARDS DUE TO DISPOSAL OF ENVIRONMENTALLY HAZARDOUS SUBSTANCES

The device contains electronic components and batteries (lithium) which are harmful to the environment if they are not disposed of properly.
Dispose of the device and integrated batteries correctly in accordance with national legislation.

CAUTION - BIOLOGICAL HAZARDS DUE TO INFECTION

Removed corneal tissue may contain viable and potentially infectious particles.
Dispose of this material according to current guidelines for biological tissue.

In accordance with national regulations at the time at which the product was brought onto the market, the product specified on the consignment note is not to be disposed of via the domestic waste disposal system or communal waste disposal facilities.

For more information on disposing of the device, contact the ZEISS contact person in your country.

You can find the ZEISS contact person for your country on the Internet at the following website: www.zeiss.com/med.

If you resell the device or its components inform the buyer that the device is to be disposed of in accordance with the currently applicable regulations.

External labels on the MEL 90

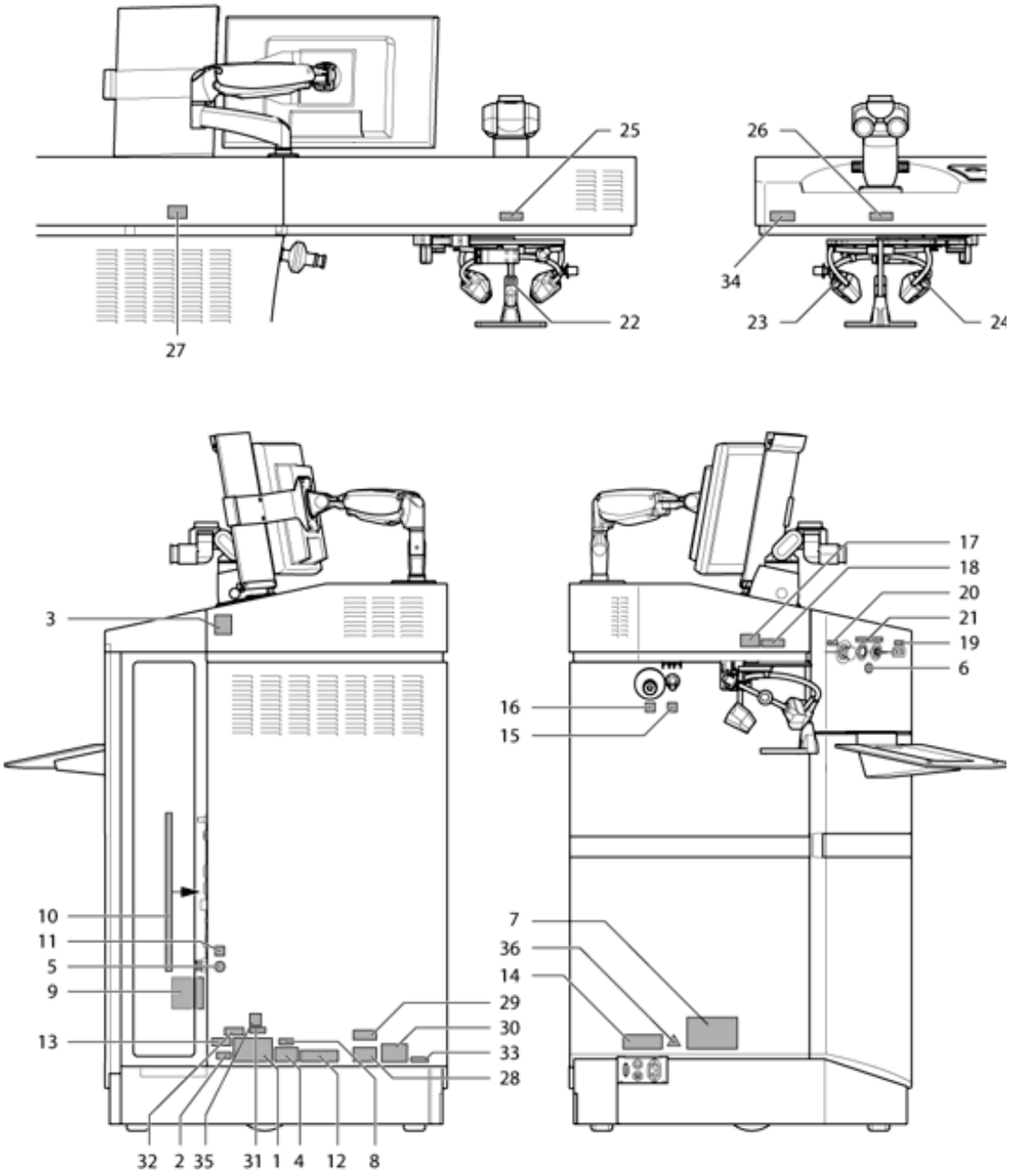
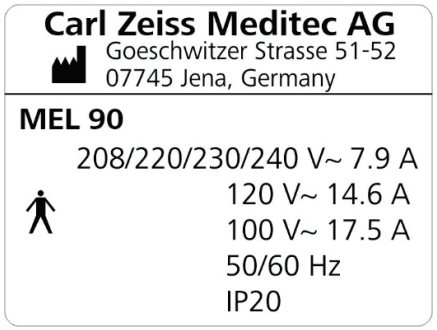
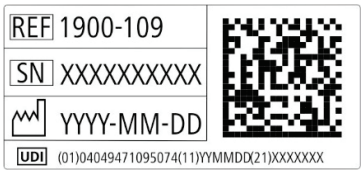
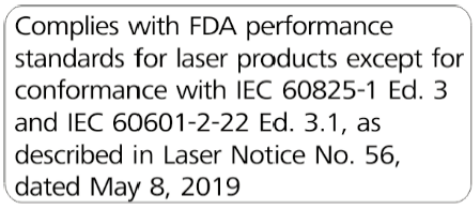
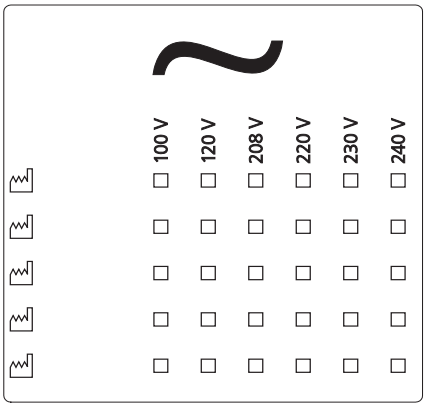
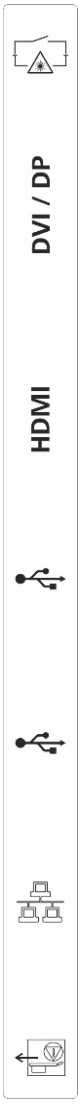
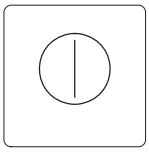
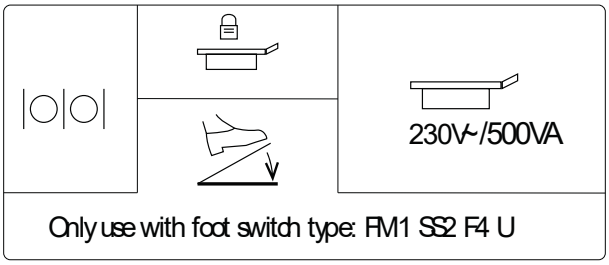
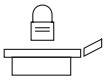
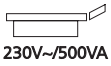


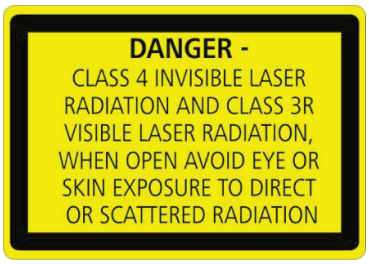
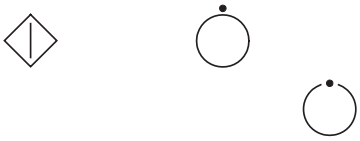
Fig. 1 Warning and information labels on the device

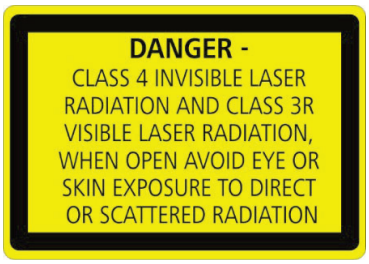
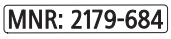
Item	Labeling	Explanation
1		MEL 90 type plate Manufacturer Applied parts type B conforming to IEC 60601 AC voltage
2		Identification label with unique device identification code (Unique device identification label) REF Catalog/part number SN Serial number Date of manufacture UDI Unique device identification code (data matrix and plain text)
3		Device identification code (data matrix, serial number and device name)
4		CSA certification mark
5		Information label "Disconnect device from the power supply before opening"

Item	Labeling	Explanation
6		Information label “Observe instructions for use”
7		Laser Class 4 warning label
8		Certification according to 21 CFR 1010.2 and Laser Notice 56.
9		Voltage supply setting AC voltage Setting date

Item	Labeling	Explanation
10		"Connection plate" label Remote interlock DVI/DP output (non-insulated, observe IEC 60601-1, for connection of external devices) Co-observer HDMI output (non-insulated, observe IEC 60601-1, for connection of external devices) USB port (non-insulated, observe IEC 60601-1, for connection of external devices) USB port (non-insulated, observe IEC 60601-1, for connection of external devices) Network port (insulated, conforming to IEC 60601-1, for connection of external devices or to the clinic/practice network) EMERGENCY STOP/EMERGENCY LASER STOP interface (to be connected when using the ZEISS VisuMax® device combination)

Item	Labeling	Explanation
11		Label "Main switch"
12	Not applicable	Not applicable
13		Label with MEL 90 device weight
14		"Patient supporting system connector panel" sign  "RS 232 port"  "Patient supporting system interlock"  "Connection for foot switch"  "Patient supporting system power supply"
15	1	Screen-printed text "Port 1, CCA+ unit" (suction system)
16	2	Screen-printed text "Port 2, CCA+ unit" (compressed air unit)

	Labeling	Explanation
17		Laser Class 4 warning label "Warning prior to opening housing"
18		Warning label "Laser radiation"
19		Screen-printed text "USB port"
20		Label "EMERGENCY STOP for moving the patient supporting system and EMERGENCY LASER STOP for the laser"
21		Screen-printed text "**Start**" button and "Key switch"
22		Label "Port 1, CCA+ unit" (suction unit)
23		Label "Port 2, CCA+ unit" (compressed air unit)
24		Label "Port 2, CCA+ unit" (compressed air unit)
25		Warning label "Laser radiation"
26		Warning label "Laser radiation"

Item	Labeling	Explanation
27		Laser Class 4 warning label "Warning prior to opening housing"
28	intentionally left blank	intentionally left blank
29	intentionally left blank	intentionally left blank
30	intentionally left blank	intentionally left blank
31	intentionally left blank	intentionally left blank
32	intentionally left blank	intentionally left blank
33		Label with part no.
34	intentionally left blank	intentionally left blank
35		Label for marking the device as a medical device
36		Warning label for power outlet to patient supporting system.

External labels of the fluence test card set

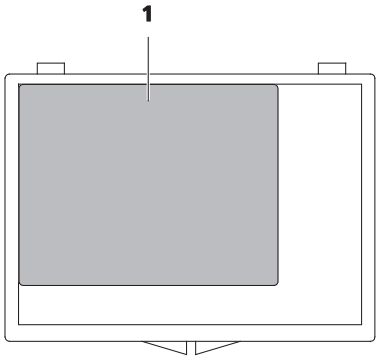
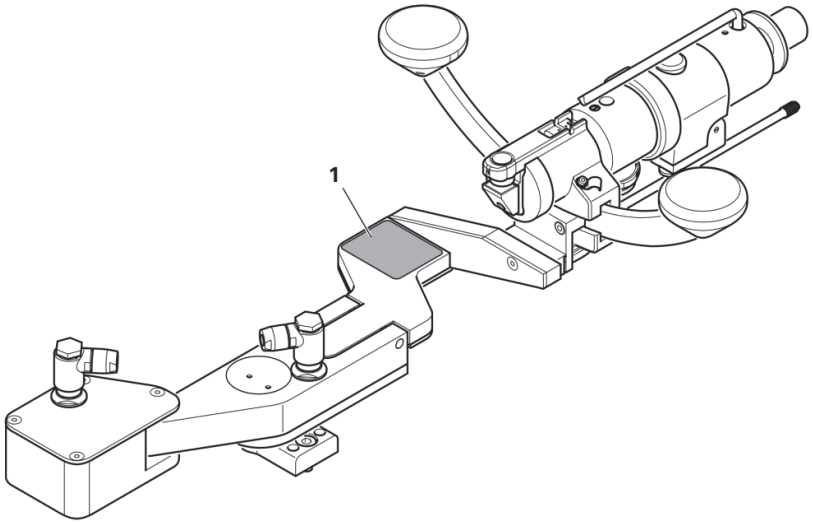


Fig. 2 Fluence test card set type plate

Item	Labeling	Explanation
1	**Carl Zeiss Meditec AG** Goeschwitzer Strasse 51-52 07745 Jena, Germany **Fluence Test Card Set** REF 320817-0201-350 -40°C +70°C 10 % 75 % 500 hPa 1060 hPa CE 0297 (01)04049471100013(17)YYMMDD	Fluence test card set type plate Manufacturer Catalog/part number Permitted temperature range: -40°C to +70°C Permitted air humidity range: 10 % to 75 % Permitted air pressure range: 500 hPa to 1060 hPa Protect from heat (sunlight) Protect from moisture EU conformity symbol with identification number of notified body Unique device identification code (data matrix and plain text) with expiry date

External labels of the HSL MEL 80 hand-held slit lamp (optional)



1 Type plate

Fig. 3 HSL MEL 80 hand-held slit lamp

Item	Labeling	Explanation
1	Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 07745 Jena, Germany HSL MEL 80 YYYY-MM-DD REF 1231-430 SN XXXXXXX CE 0297	HSL MEL 80 type plate Manufacturer Date of manufacture REF Catalog/part number SN Serial number Disposal advice for EU CE 0297 EU conformity symbol with identification number of notified body

Performance specifications

Functional description

MEL 90 by Carl Zeiss Meditec AG was developed for use in refractive surgery based upon corneal tissue ablation using a short-pulsed excimer laser with a wavelength of 193 nm.

The laser source emits pulses of a few nanoseconds and a repetition rate as specified in the technical data.

The MEL 90 is a spot scanning laser with a Gaussian treatment laser beam.

The MEL 90 is equipped with a CCA+ system (Cone for Controlled Atmosphere). This patented airflow system ensures the steady removal of biological debris from the beam path above the patient's eye.

The MEL 90 is equipped with an active Eyetracker. The eye of the patient is illuminated by IR light in order to be able to determine and calculate the center of the pupil.

A green light which is generated by a fixation laser and centered onto the optical axis within the OPMI surgical microscope serves as a fixation aid for the patient. In order to facilitate fixation, the fixation lamp flashes throughout the operation.

The MEL 90 is operated via the OPASS software (Operation Assistant) running on a Windows-based PC. The OPASS software includes an onscreen help feature which offers users support in using the software. Using this software the user is able to enter clinical data and to monitor the treatment progress on a display. The Windows PC and OPASS will transfer all edited data to the control computer, a PC which has been designed for laser control.

The MEL 90 is equipped with a patient supporting system (LS Comfort 80 combi) for supporting and positioning the patient. The patient supporting system is a treatment table with motorized adjustment of the patient supporting surface.
If the MEL 90 is operated in conjunction with VISUMAX 600/800, the system uses the LS Comfort 80 combi as joint patient supporting system.
If the MEL 90 is operated in conjunction with VisuMax, the system also uses the patient supporting system of the VisuMax.

Service life

WARNING - GENERAL HAZARDS

The development, production and maintenance of this device, together with associated risks, are based on an expected service life of eight years, assuming that the device is serviced at the specified intervals.

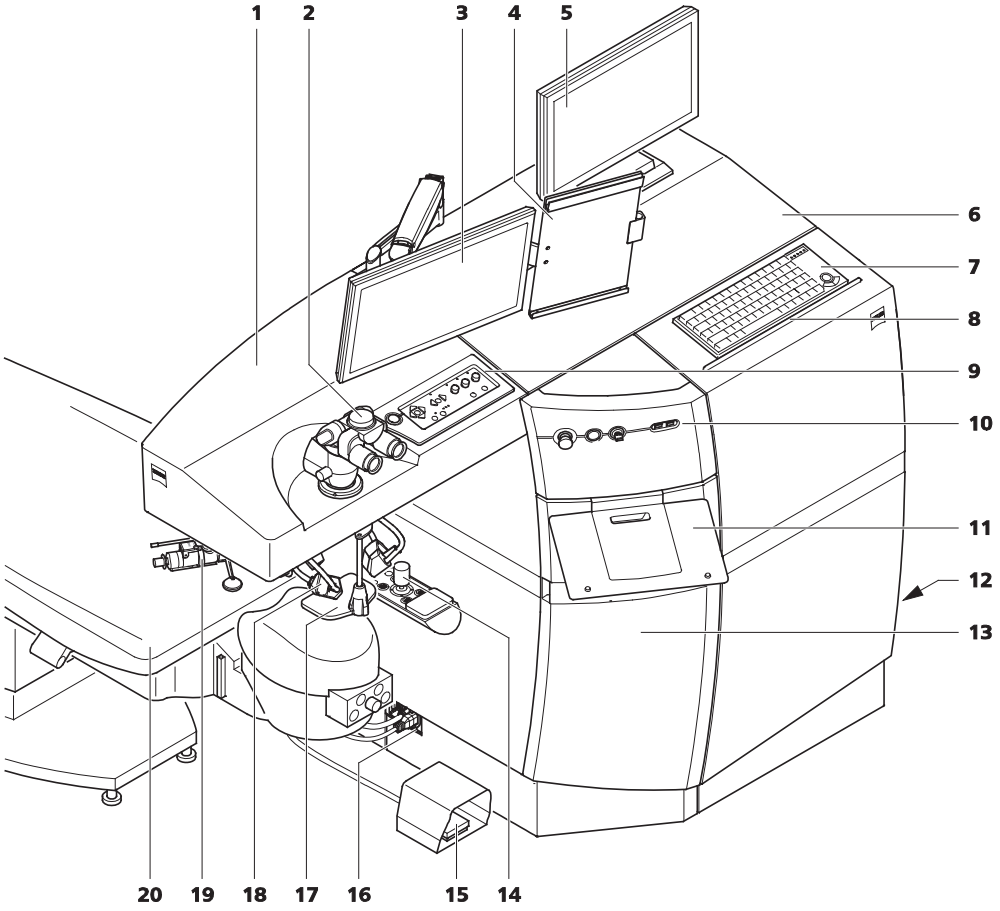
Modifications to the product or failure to follow the manufacturer's instructions may substantially reduce the expected service life and significantly increase the risks associated with the use of this device.

It is the responsibility of the institution operating this product to follow the manufacturer's instructions and to decide on the risk/benefit ratio upon expiration of the expected service life or maintenance and inspection intervals specified by the manufacturer.

Description of the device

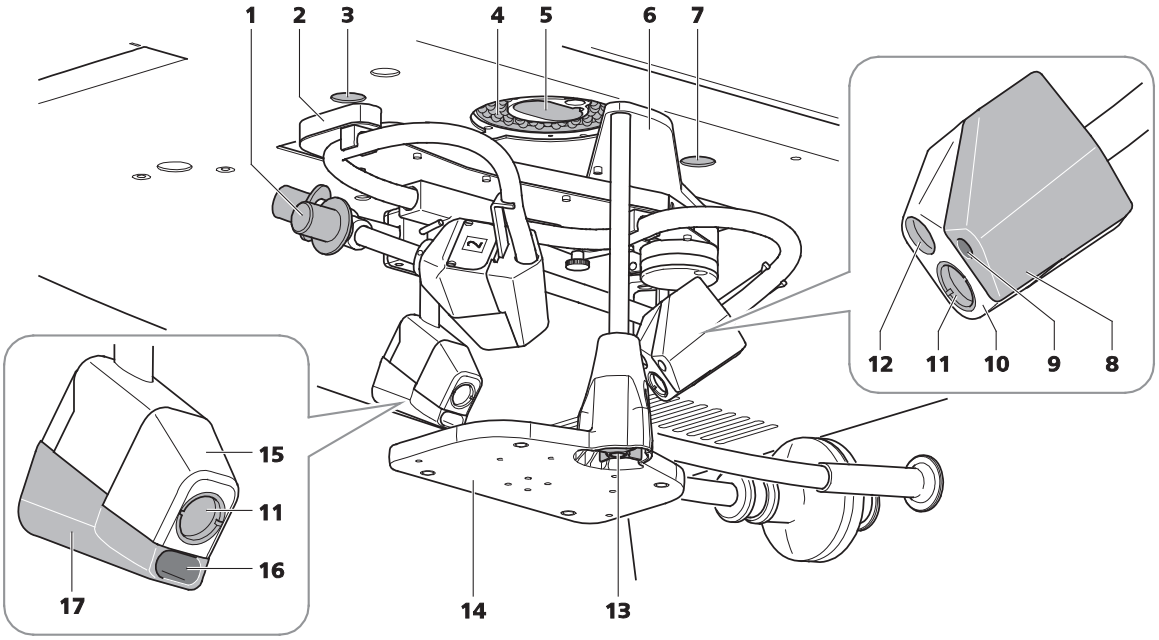
This medical device is not equipped with applied parts which are protected against the effect of defibrillators

Device configuration and components



1 Laser arm
2 OPMI pico surgical microscope
3 Touchscreen monitor
4 Document holder
5 Additional monitor (optional)
6 Basic unit
7 External keyboard (optional)
8 Rest support for external keyboard
9 Control panel (laser arm)
10 Control panel (basic unit)
11 Rest for external keyboard (optional)
12 Connector panel and main switch
13 Door of CCA+ unit
14 Control unit of patient supporting system
15 Foot switch
16 Connector panel of the patient supporting system
17 Fluence test plate
18 CCA+ unit (suction and compressed air unit)
19 Hand-held slit lamp (optional)
20 Patient supporting system (LS Comfort 80 combi)

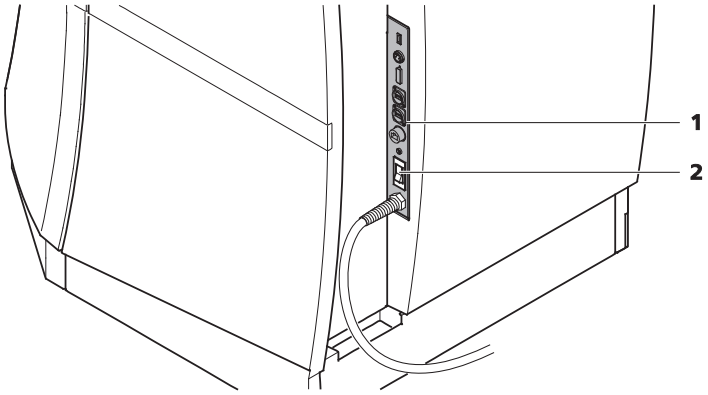
Fig. 4 System overview



1 Handles for swiveling the CCA+ unit
2 Swivel arm of CCA+ unit
3 Aperture of left distance laser
4 White light ring illumination
5 Laser exit aperture
6 Swivel arm of fluence test plate
7 Aperture of right distance laser
8 Compressed air unit head (right side, left side mirror image)
9 Opening of compressed air unit of CCA+ unit
10 Satellite illumination head (right side, left side mirror image)
11 IR illumination for Eyetracker
12 Satellite illumination for operating area illumination
13 Wing screw for adjusting height of fluence test plate (± 3 mm)
14 Fluence test plate
15 IR illumination head for Eyetracker
16 Opening of suction unit of CCA+ unit
17 Head of suction system

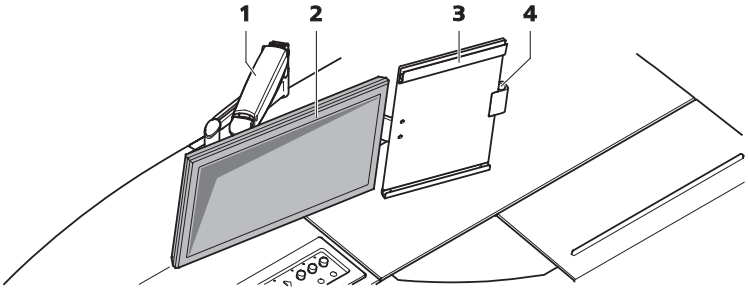
Fig. 5 Laser aperture, CCA+ unit and fluence test plate

Control elements and displays



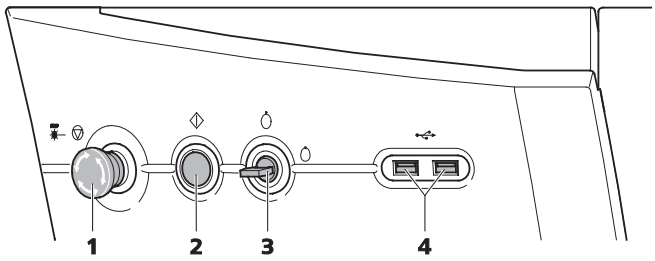
1 MEL 90 connector panel
2 Main switch **<Device On/Off>** (switch lit green = device switched on)

Fig. 6 Main power switch on MEL 90 connector panel



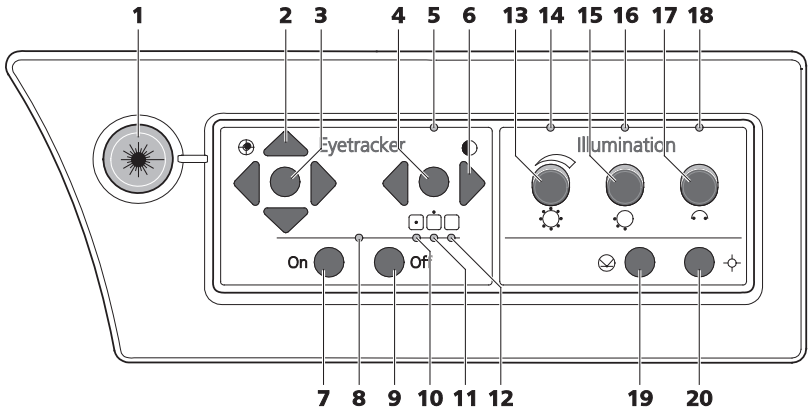
1 Swivel arm
2 Touchscreen monitor
3 Document holder
4 Pen slot on document holder

Fig. 7 Touchscreen monitor



1 **<EMERGENCY STOP/EMERGENCY LASER STOP>** button
2 **<Start>** button
3 Key switch
4 USB ports (2 ports)

Fig. 8 Control panel on basic unit



1 Laser warning lamp

Eyetracker:

2 <**Manual offset**> arrow buttons (for adjusting offset of detected center of pupil to actual center of treatment)

3 **<Home>** button (laser beam returns to calculated center)

4 **<Automatic threshold on/off>** button

5 Status LED (LED lit when automatic function on)

6 **<Lower threshold>** left arrow button
<**Raise threshold**> right arrow button (both only when automatic function switched off)

7 **<Eyetracker On>** button (turns the Eyetracker on)

8 Status LED, green (LED on = Eyetracker is active)

9 **<Eyetracker Off>** button (deactivates the Eyetracker)

10 Status LED, green (LED lights up = pupil inside hot zone)

11 Status LED, yellow (LED lights up = pupil outside hot zone)

12 Status LED, yellow (LED lights up = pupil not detected)

Ring illumination

13 **<Ring illumination on/off>** rotary/push button
(for switching ring illumination on/off and for adjusting the brightness)

14 Status LED (LED lit when ring illumination on)

15 **<Segment ring illumination>** rotary/push button

16 Status LED (LED lit when segmentation on)

Satellite illumination:

17 **<Satellite illumination on/off>** rotary switch
(levels: off, left, right, both lamps)

18 Status LED (LED lit when satellite illumination on)

Distance lasers:

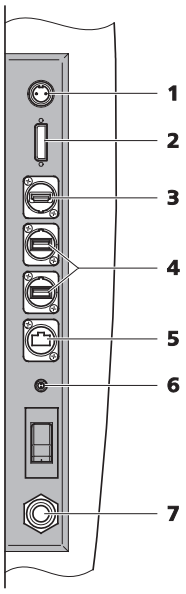
19 <**Distance laser on/off**> button (for both distance lasers)

Aiming beam:

20 **<Aiming beam on/off>** button

Fig. 9 Control panel on laser arm

Ports and connection of parts



1 Connector for remote interlock (see section *Remote interlock*, page 73)

2 DVI/DP output
(connection for co-observer monitor for OPASS operation and co-observer image, see section *Assistance monitor*, page 136)
The monitor output can be technically designed as DVI or DP.

3 Co-observer HDMI video output
(connection for a co-observer monitor for HD co-observer image, see section *Co-observer monitor*, page 137)

4 USB ports (2x, see section *Assistance monitor*, page 136 and *External keyboard*, page 138)

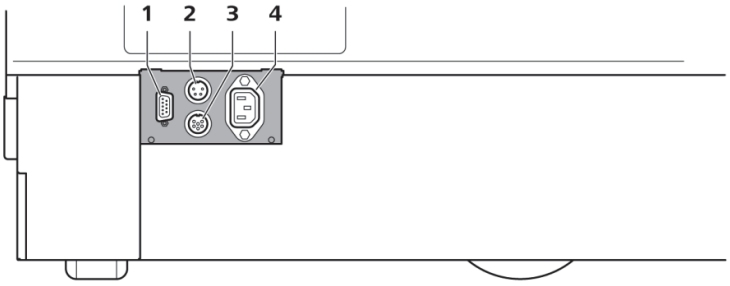
5 Network connector (Ethernet port) for VisuMax (see page 70), for printer (see page 135) or for clinic/practice network (see page 7 and following).

6 EMERGENCY STOP/EMERGENCY LASER STOP interface for VisuMax (see page 70)

7 Power cable including safety plug (connection to power supply with protective ground connector)

Fig. 10 MEL 90 connector panel and main power switch

☞ The network connection may only be configured and connected by trained ZEISS personnel. Observe the safety instructions on page 7 following and on page 135.



1 Not used

2 Interlock connection for patient supporting system (only the cables supplied with the LS Comfort 80 combi patient supporting system may be used)

3 Connection for foot switch FM1 SS2 F4 U

4 LS Comfort 80 combi patient supporting system power supply (only the cables supplied with the LS Comfort 80 combi patient supporting system may be used)

Fig. 11 Connector panel for patient supporting system and foot switch

Laser beam guidance

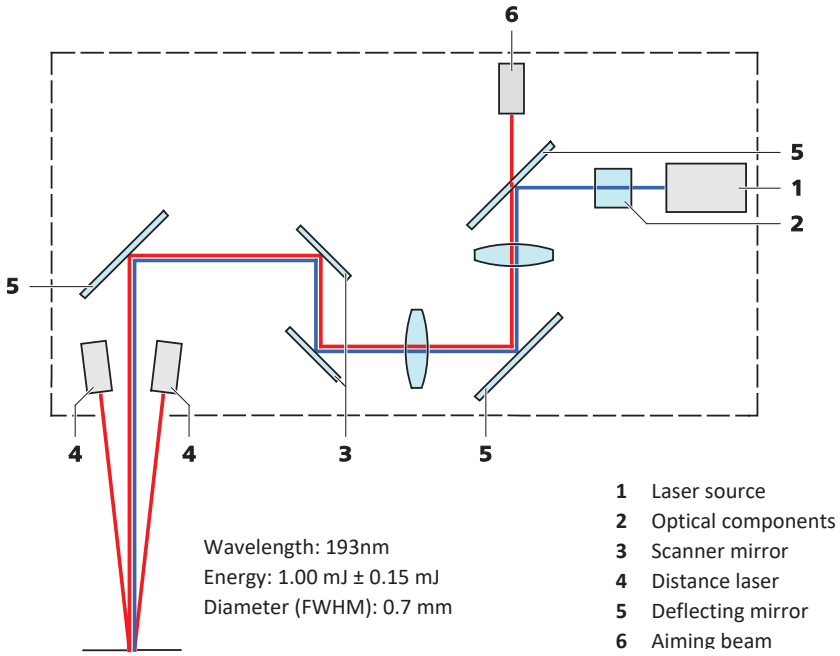


Fig. 12 Laser beam guidance

Expected position of patient and patient environment

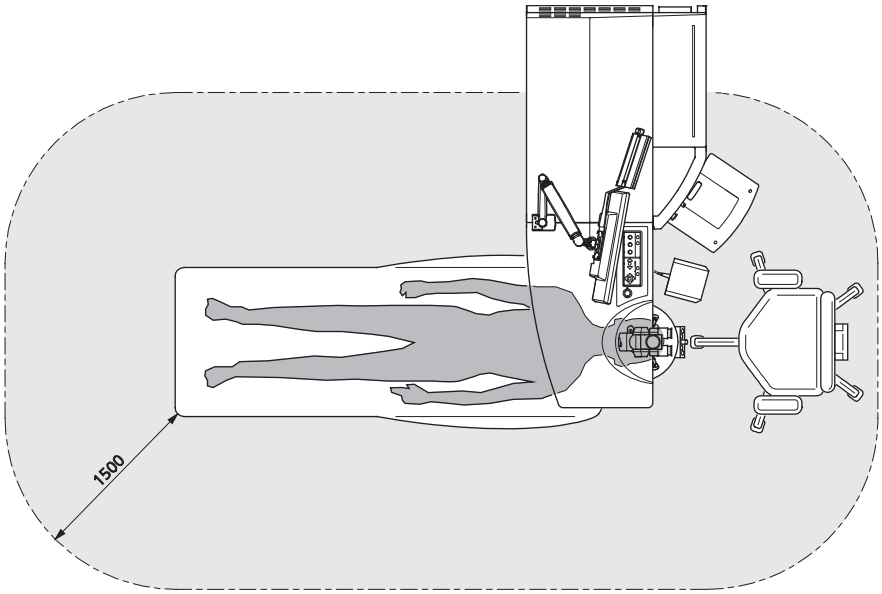


Fig. 13 Expected position of patient and patient environment

Installation

Transport

WARNING - GENERAL HAZARDS

This device may only be transported and re-installed by persons who have been authorized by the manufacturer.

Installation, assembly and first-time operation

WARNING - GENERAL HAZARDS

This device may only be installed by trained ZEISS personnel.

If the altitude of the installation site specified in the technical data is exceeded, this increases the probability of short circuiting across air and leakage distances and thus of acceptable current levels being exceeded.

The device may not be set up, operated, used or serviced in ambient conditions other than those prescribed (see section *Technical data* from page 139 and *Electromagnetic compatibility* from page 150).

WARNING - THERMAL ENERGY RISK

Fire or explosion hazard exists if the laser exit aperture is used in the presence of flammable materials, solutions or gases or in an oxygen-enriched environment.

Some materials saturated with oxygen, for example cotton, can be ignited at the high temperatures that occur when the laser device is used according to its intended use.

The solvents of adhesives and flammable solutions used for cleaning and disinfection should be given time to evaporate before the laser device is used.

Attention should also be paid to the fact that gases can ignite.

The device is not suitable for use in an environment enriched with oxygen (e.g. with a combustible mix of anesthetic, cleaning or disinfection agents with air, oxygen or nitrous oxide).

WARNING - RISK FROM ELECTRIC ENERGY

The electrical installation must conform to IEC 60364-7-710 or the applicable national regulations. This includes the integration of a ground fault circuit interrupter (GFCI).

This device may only be connected to a power supply network that is equipped with a protective ground conductor to avoid the risk of electrical shock.

Before connecting the power cable to the mains socket, check that the power cable is suitable for the connection, in particular the protective conductor connection. There are regional differences in the design of power supply sockets.

The device must always be installed so that the power cable is accessible and can be removed at any time.

Extension cables and/or portable multiple sockets may not be used.

The patient supporting system may only be connected to the power connection of the device.

WARNING - RISK FROM ELECTRIC ENERGY

If the MEL 90 is combined with the VisuMax or with the VISUMAX 600/800, each device should be connected to the power supply via separate sockets. It is not permitted to supply the power from a multisocket strip because this could exceed the limit values for ground leakage current.

WARNING - ELECTRIC HAZARD DUE TO IMPROPER SYSTEM INSTALLATION

Incorrect installation may cause higher leakage currents or an electric shock.
Non-medical electrical products are not allowed to be used in the patient environment (at a distance of 1.5 meters from the patient).

The device necessarily requires a patient supporting system for its use. It may also be necessary to combine other non-medical devices such as printers or external monitors with the device.

When combined with other devices, safety is only ensured if the normative requirements for medical systems are complied with (the system requirements of and IEC 60601-1 must be observed).

Anyone connecting additional equipment to medical electrical devices is considered to be a system configurer and as such is responsible for compliance of the system with the local legal and normative requirements for ME systems.

Local laws take precedence over the above normative requirements.

In the following, components are listed as they are intended by the manufacturer for combination with the device.

ME SYSTEM with patient supporting system:

If the device is combined with a patient supporting system which is not distributed by Carl Zeiss Meditec AG, the distributor is responsible for its safety.
When selecting a patient supporting system, observe the minimum requirements in sections *Installation* and following and *Patient supporting system* and following and contact ZEISS Service if necessary.

ME SYSTEM with external monitor:

An external monitor can be connected to the device.
When selecting an appropriate external monitor, observe the minimum requirements in sections *Installation*, page 37 and following and *Additional monitors*, page 136 and following and contact ZEISS Service if necessary.

ME SYSTEM with printer:

A printer can be connected to the device.
When selecting an appropriate external printer, observe the minimum requirements in sections *Installation*, page 37 and following and *Printer*, page 135 and following and contact ZEISS Service if necessary.

CAUTION - GENERAL HAZARDS

MEL 90 and/or VISUMAX 600/800 may be connected to a clinic or practice network which is secured by suitable protective measures

(IEC 80001-1 provides instructions on how to address these risks) (see *Network integration*, page 7 and following).

CAUTION - GENERAL HAZARDS

MEL 90, VisuMax, Ethernet switch and printer may only be connected directly or via a network consisting exclusively of devices approved for this purpose by Carl Zeiss Meditec AG. If MEL 90 and VisuMax are connected with each other, a connection to a clinic network, a practice network or a public network is not allowed.

CAUTION - TRIPPING HAZARD

Inappropriately laid cables represent an increased risk of tripping and falling.
Always route cables in such a manner that they do not obstruct your work.

CAUTION - RISK FROM DEVICE OPERATION

The area below the laser arm must be free of drafts to ensure proper functioning of the CCA+ unit.

Dust, water vapor or organic substances (e.g. vapor from floor coverings) in the air will cause over- or undercorrection.

If installing in a newly decorated or renovated room, allow at least four weeks to elapse after the decoration work before using the device.

CAUTION - TRAPPING POINT

If the specified minimum distances are not observed, body parts may be trapped.
Make sure that the minimum distances for installation are met.

☞ We recommend the use of an air-conditioning system to ensure the required ambient conditions are maintained. The room air should be replaced every hour.

☞ To preclude interruptions to surgery, we recommend using an uninterruptible power supply.

☞ For reasons of safety, it is recommended that the device be connected to an individually fused, grounded power outlet.

Daily startup

WARNING - GENERAL HAZARDS

Prior to using the device, the user must ensure that it is in good condition and fully functioning. Furthermore, the user must follow the instructions for use and adhere to other safety-relevant information or maintenance instructions enclosed. This also applies to all medical products and parts to be used together with the device, including software and other objects.

Do not place any objects on the device, in particular in the area above the patient.

The following inspections must be carried out each working day prior to use:

- Visual inspection of the housing, components, labels, instructions for use, parts and the power cable to ensure that they are present and intact.
- Visual inspection of ventilation slots

If parts are missing or damage is visible, the device should be taken out of service and ZEISS Service informed.

The following inspections must be carried out prior to each treatment:

- Fluence test

If an error occurs after starting the system or after switching on the device with the key switch, or the display fails to light up, the device must be shut down and ZEISS Service informed.

Do not allow access to the device to persons of age 16 years or less.

Keep the key to your device in a safe place inaccessible to unauthorized persons.

WARNING - RISK FROM RADIATION ENERGY

Caution - Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

Exposure of the skin and eyes to direct and scattered radiation (except for treatment of the target eye) must be prevented by taking suitable measures. Laser safety goggles (at least protection class IR LB4, 193 nm and protection level D LB8, 193 nm, conforming to DIN EN 207 and ANSI Z87.1) must be worn if the laser warning lamp on the device is illuminated.

The laser hazard area should be as small as possible and demarcated by suitable screens. Unauthorized persons should be prevented from entering the laser hazard area. The number of persons in the laser hazard area must be kept to a minimum.

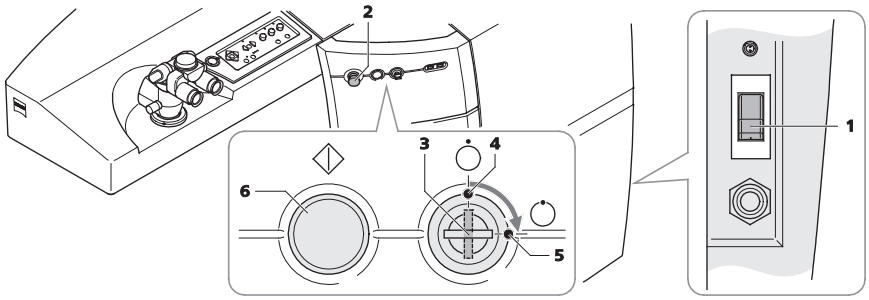
Warning signs must be placed at the entrance to the laser hazard area.

A warning lamp must be installed at the entrance door indicating when the laser is in operation.

The laser hazard area must be clearly demarcated and marked as such during laser operation.

All objects within the laser hazard area, including the floor, should have diffusely reflecting surfaces or be covered with diffusely reflecting material. Only use medical instruments in the laser beam path which are shaped or surface-finished to prevent hazardous reflection.

Switching the device on



1 Main power switch on MEL 90 connector panel
2 **<EMERGENCY STOP/EMERGENCY LASER STOP> button**
3 Key switch
4 Position of key switch **<Off>**
5 Position of key switch **<On>** (**Standby** mode)
6 **<Start>** button **(Laser operation** mode)

Fig. 14 Switching the device system on

- Switch on the entire equipment system (MEL 90 and patient supporting system) by pressing the main switch (**1**, Fig. 14, page 43).

The green control lamp in the main switch indicates that the system is powered up.

- Check that the **<EMERGENCY STOP/EMERGENCY LASER STOP>** button (**2**, Fig. 14, page 43) is not activated; do so by rotating it anticlockwise. It will pop out if it was pushed in.
- Turn the key switch (**3**, Fig. 14, page 43) from **Off** (**4,** Fig. 14, page 43) to **On** (**5**, Fig. 14, page 43).

The device is now in **Standby** mode; the laser cannot be operated yet.

After a short interval the **Login** dialog of the OPASS software will appear on the monitor.

☞ If the device is only turned on at the key switch, the PC will only start in **Standby** mode with the OPASS software. Patient data and configuration settings (e.g. administration of treatment licenses) can now be edited.

Patients cannot be treated in **Standby** mode (no laser operation).

- For treatment (**laser operation** mode), besides turning on the key switch you must also push the **<Start>** (**6**, Fig. 14, page 43) button.

Log in as a user

- The title bar shows the title of the **Login** dialog.
- Under **User name** select your user name and enter your password in the **Password** field.
  Then tap the **Login** button in the menu bar.

☞ During the first start you can only log in as administrator. As administrator, you may enter further user accounts at any time.

☞ ZEISS explicitly advises using a complex password (up to 12 characters, upper and lower case, numbers and special characters) to enhance security and safeguard against password cracking and brute-force attacks.

During login and afterwards in the **Welcome** main dialog, the progress of the warm-up phase will be displayed.
The warm-up phase lasts about 10 minutes.

After logging in, the **Welcome** main dialog opens (Fig. 15, page 46). When the warm-up phase is complete, all functions in the OPASS, other than those buttons which are greyed out, are available.

Information on the OPASS software can be obtained in section *OPASS software* from page 74 and in the integrated onscreen help.

Call up the onscreen help using the **Integrated onscreen help** icon in the toolbar, top right.

Once you have finished with the onscreen help, close the Help window using the **Back** button.

Use the **Switch off device** icon to switch off the device.

Use the **Cancel the current operation** icon to cancel the current operation. The system will return to the **Welcome** main dialog.

The onscreen keyboard is disabled.
Use this icon to enable the onscreen keyboard. The virtual keyboard is displayed as soon as an input field is selected.

The onscreen keyboard is enabled.
Use this icon to disable the onscreen keyboard and hide the virtual keyboard.

In case of a forgotten user password, the administrator can log in to the OPASS administrator and navigate to “Configuration” then “User”, edit the user's data and set a new temporary password. The user can login by means of this temporary password and must change the password in this session.

On the third failed login to the OPASS administrator account due to a wrong password, a password reset dialog is displayed which shows a request key. The administrator needs to contact service hotline of Carl Zeiss Meditec AG, present this key and will receive a validation key. After entering the correct validation key into the password reset dialog the admistrator password will be reset to the factory setting.
After this the administrator should set a new personal password.

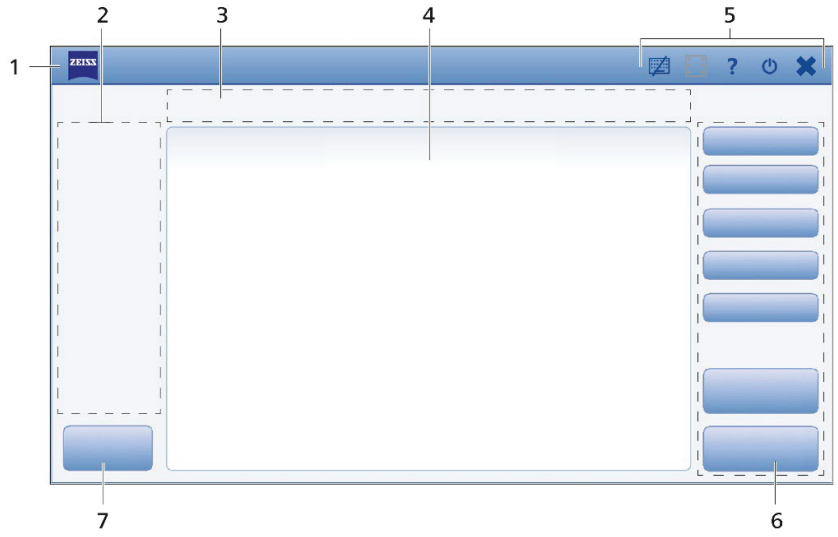
User interface layout

The layout of the user interface is described as follows.

The information column (**2**, Fig. 15, page 46) and the information bar (**3**, Fig. 15, page 46) show the data of the user, the patient and the treatment.

All settings required for conducting the treatment are made in the work area (**4**, Fig. 15, page 46). These are made via various dialogs and lists. Status messages and information regarding the device and the treatment are also shown here.

You can access all the OPASS software functions via the toolbar (**5**, Fig. 15, page 46) or the menu bar (**6**, Fig. 15, page 46).



1 Title bar

2 Information column
(shows information on user, patient and treatment)

3 Information bar
(shows information regarding the patient and the relevant eye)

4 Work area (depending on content: information field, list or dialog box)

5 Toolbar with icons

6 Menu bar (access to all OPASS software functions)

7 Button to log off or return to the previous dialog

Fig. 15 User interface layout

The eye to be treated is highlighted in the information bar. There are two display options:			
right eye (oculus dexter)			left eye (oculus sinister)

Main dialog

The **Welcome** main dialog of the OPASS software will be displayed after logging in. When the warm-up phase is complete, all functions in the software, other than those buttons which are greyed out, are available.

The menu bar of the main dialog shows the following icons.

The **Gas change** button opens the **Gas change** dialog.
Here the information on the last gas change is displayed and a new gas change can be started.

The **Patient management** button opens the **Patient management** dialog.
Patient data records can be selected, found, created, edited or deleted and the appropriate treatments can be managed here.

The **Configuration** button opens the **Configuration Settings** dialog.
Various presettings for the screen layout, access, functionality and treatment can be made here. The language settings can also be made in this dialog.

The **Refractive treatment** button opens the **Refractive treatment Select patient** dialog.
Here a patient data record can be selected and the treatment can be started.

The **Logoff** button opens the **Logoff** dialog.

Language setting

The language can be set in the **Configuration Settings** dialog.

To change the language setting, proceed as follows:

- Use the **Configuration** icon in the **Welcome** main dialog. The **Configuration Settings** dialog will be displayed.
- In the work area, you will find the **Localization** work field.
- Select the desired language for the user interface in the **Language** selection field.

Function test

Fluence test

CAUTION - RISK FROM DEVICE OPERATION

Perform a fluence test:

- after setting up the device, to check the functioning of the laser. Ensure that the distance lasers and aiming beam are correctly positioned.
- after each gas change, to allow the laser to adjust for the current status of the excimer laser gas.
- after changing the energy settings.
- after energy deviations.
- after canceling a fluence test.
- prior to each treatment.

The MEL 90 excimer laser possesses an energy control system which maintains constant pulse energy over multiple treatments. In order to reduce the probability of energy deviations, a fluence test must be performed prior to each treatment.

The **Fluence test** dialog opens after selecting the patient and the treatment.

Before treatment can be carried out, the fluence test must be successfully completed.

1 Decrease the target energy value
2 Increase the target energy value
3 Opens the Gas change dialog
4 Completion of successful fluence test
5 Opens the dialog window active in the previous work step
6 Discontinues or ends the fluence test
7 Starts the fluence test (in conjunction with the foot switch)

Fig. 16 **Fluence** test dialog

The **Fluence test** icon is shown in the work area of the selected treatment method.

Tap the **Fluence test** icon in the **Refractive treatment Parameters** dialog to open the **Fluence test** dialog.
The patient and treatment have already been selected when tapping the **Fluence test** icon.

The **Fluence test** work area shows the following icons.

The **Decrease** icon reduces the target energy value.

The **Increase** icon increases the target energy value.

The **Cancel** icon interrupts or ends the fluence test.

The **Test** icon starts the fluence test. The fluence test is initiated by pressing the foot switch.
It may be necessary to repeat the test several times in order to obtain the optimum fluence value.

The fluence test menu bar shows the following icons.

The **Gas change** icon opens the **Gas change** dialog.
It provides information on the last gas change, the number of gas changes performed on this device and the current cylinder pressure. It initiates the gas change and delivers various status information.

The **OK** icon concludes the successful fluence test.

The **Back** icon (left menu bar) closes the **Fluence test** dialog.
The dialog which was active in the previous step will open again.

A special test paper is used to calibrate the energy density at the treatment site. The number of laser shots required can be used as a measure of energy density.

☞ The relationship between ablation rates on the test paper and on the human cornea has been determined empirically.

- The test involves firing a laser pulse onto the closed shutter to adjust the energy of the laser. After a short pause, the upper and the lower segments of a circular area are ablated different numbers of times. The fluence is correctly adjusted if the upper segment remains grey and a complete green semicircle is visible in the lower segment of the circle (see Fig. 17, page 52).
- The center of the circular area is marked by a series of laser shots. At the end of the fluence test, the aiming beam spot must point to the center of this spot.

CAUTION - RISK FROM DEVICE OPERATION

At the end of the fluence test, the aiming beam spot must point to the center of this spot. If the aiming beam points to a spot significantly removed from the center of this spot, contact ZEISS Service.

- Single spots are produced on the left and right above the circular area. The left spot is exposed to twice as many laser shots as the right spot.

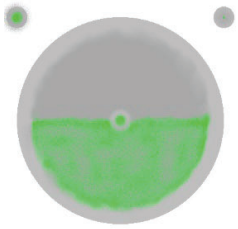
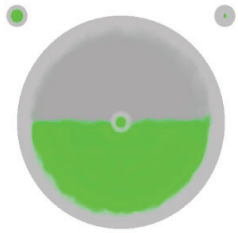
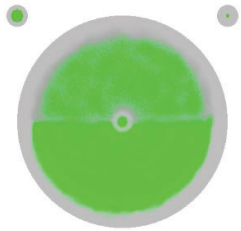
	The fluence is too low. • Increase the target energy value by tapping **+ Increase** (**2,** Fig. 16, page 49)
	Optimum setting • The fluence setting does not need to be changed.
	The fluence is too high. • Reduce the target energy value by tapping **– Decrease** (**1,** Fig. 16, page 49).
Geometrical anomalies	Scanner function is impaired. • Please contact the authorized customer service or ZEISS Service.

Fig. 17 Possible ablation images of the fluence test for fluence assessment

WARNING - RISK FROM DEVICE OPERATION

If the test paper displays a geometry which differs from that shown in Fig. 17, do not perform treatment. Contact ZEISS Service.

CAUTION - RISK FROM DEVICE OPERATION

The fluence test paper has a limited lifetime. Do not use after the expiry date (refer to reverse side).

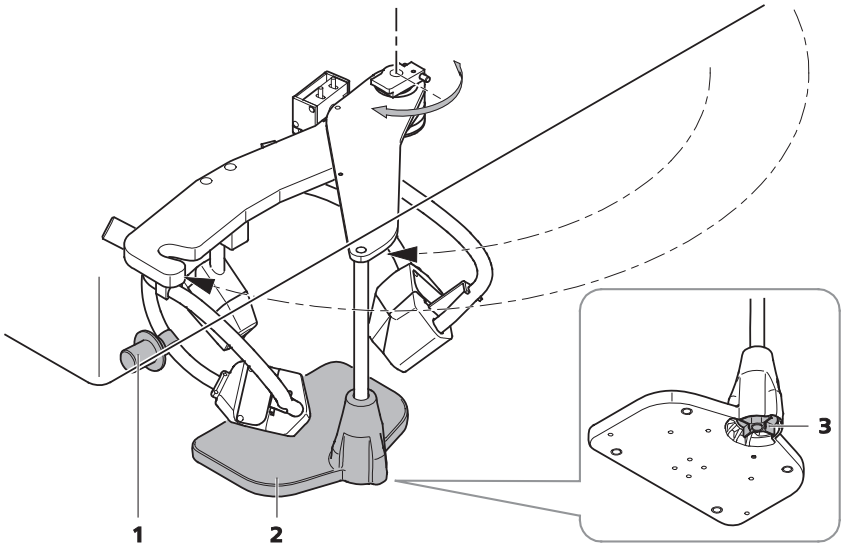
Unpacking or touching the fluence test paper can crease or soil the surface.

- Before use, check the paper for dirt or deformation
- Only touch the fluence test paper by the edge or the green area
- Make sure that the metallic surface in the lower area is homogeneous and has a reference pattern.

If the optimal shot pattern for the energy setting cannot be achieved, contact ZEISS Service.

To perform a fluence test, proceed as follows:

- Tap the **Fluence test** button. The **Fluence test** dialog will open (Fig.16, page 49).
- Swivel the CCA+ unit into place. Check the correct connection of the hoses. Loose hoses are not permitted.
- Swivel the fluence test plate into place.



1 Handle for swiveling the CCA+ unit
2 Fluence test plate
3 Wing screw for adjusting height of fluence test plate (± 3 mm)

Fig. 18 CCA+ unit with fluence test plate in operating position

- Apply the test paper. Move the fluence test paper so that an area with an intact aluminum coating is situated beneath the light spots of the distance laser. Fix it with magnets such that the beam path is not obstructed.
- Switch on the distance lasers on the control panel (**19**, Fig. 9, page 34).
(Refer to section *Distance lasers and aiming beam* on page 59)
- Check the two focus points using the surgical microscope. Adjust the height of the fluence test plate using the height adjustment (**3**, Fig. 18, page 54) until the two points coincide. Turn the wing screw; clockwise to raise, and counterclockwise to lower the fluence test plate.
- To activate the fluence test, tap on the **Test** button (**7**, Fig. 16, page 49)

- Now press the foot switch of MEL 90 (**15**, Fig. 4, page 31) and keep depressed throughout the fluence test.
- If the ablation image deviates from the "optimum setting" (Fig. 17, page 52) the target energy value (and therefore the fluence) must be adjusted using the **- Decrease** or **+ Increase** buttons.
- Move the fluence test paper so that an area with an intact aluminum coating is situated beneath the light spots of the distance laser.
- Repeat the test by tapping the **Fluence test** button and depressing the foot switch.

☞ It may be necessary to repeat the test several times in order to obtain the optimum fluence value.

- After completing the fluence test, tap the **OK** button (**4**, Fig. 16, page 49)
- Tap the **Cancel** button (**6**, Fig. 16, page 49) if the energy is not sufficient for a successful fluence test and a message prompting you to change the gas is displayed.
- Swivel the fluence test plate back after completing the fluence test.
- Swivel the CCA+ unit into place.

☞ Because the aiming beam follows the same optical path through the beam delivery system as the therapy beam, it represents a good method for checking that the beam delivery system is undamaged.

If the aiming beam spot does not appear in the working plane of the beam delivery system, if the intensity of the spot is weak or if it has a diffuse appearance, this may indicate that the beam delivery system is damaged or is not operating correctly.

If the laser is not used for longer periods, the gas lifetime and laser head life span will be reduced. We recommend to change gas once every two weeks and to perform at least two LASIK treatments with -8D on a sheet of paper afterwards.

Operation of the device

WARNING - GENERAL HAZARDS

The responsible organization should only operate this device if the manufacturer or another person authorized by the manufacturer has:

- subjected the device to a functional check at its place of installation and
- instructed the person nominated by the responsible organization on the correct handling, use and operation of the medical product in accordance with the instructions for use and other safety-relevant information and maintenance instructions included, and on its permitted use with other medical products, objects and parts.

Persons who are not authorized to use the device may not be left unattended at or in the vicinity of the device.

WARNING - MECHANICAL ENERGY HAZARD

Keep an eye on all automatic and manual movements of the patient supporting system.

If there is a risk of crushing, stop the patient supporting system movement by moving the joystick or pressing the **<EMERGENCY STOP/EMERGENCY LASER STOP>** button.

Remove the patient from the patient supporting system.
You may have to use the mechanical release on the head rest of the patient supporting system.

Ensure that the patient is not wearing any loose items (e.g. clothing, hand bag, jewelry) that could be trapped between moving parts.

Patients with long hair should wear a hair net.

WARNING - RISK OF ELECTRIC SHOCK

The operator should not touch the patient and the connectors of the device simultaneously.

If the patient's head touches the CCA+ unit the movement of the patient supporting system is interrupted by an internal collision sensor.

☞ Activating the **<EMERGENCY STOP/EMERGENCY LASER STOP>** button stops the movement of the patient supporting system and turns off the laser. The power supply of the MEL 90 remains active and the device is in **Standby** mode.

- Switch off the device. Turn the key switch (**1**, Fig. 29, page 113) from **On** (**2**, Fig. 29, page 113) to **Off** (**3**, Fig. 29, page 113).
  (See section *Shutting off the entire* system, page 113)
- Open the **<EMERGENCY STOP/EMERGENCY LASER STOP>** switch by turning it counterclockwise. You can now restart the device (see section *Switching the device on*, page 43).

WARNING - RISK FROM RADIATION ENERGY

Caution - Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure

Exposure of the skin and eyes to direct and scattered radiation (except for treatment of the target eye) must be prevented by taking suitable measures. Laser safety goggles (protection class at least IR LB4, 193 nm and protection level D LB8, 193 nm conforming to EN 207 and ANSI Z87.1) must be worn if the laser warning lamp on the device is illuminated.

The laser hazard area should be as small as possible and demarcated by suitable screens. Unauthorized persons should be prevented from entering the laser hazard area. The number of persons in the laser hazard area must be kept to a minimum.

Warning signs must be placed at the entrance to the laser hazard area.

A warning lamp must be installed at the entrance door indicating when the laser is in operation.

The laser hazard area must be clearly demarcated and marked as such during laser operation.

All objects within the laser hazard area, including the floor, should have diffusely reflecting surfaces or be covered with diffusely reflecting material. Only use medical instruments in the laser beam path which are shaped or surface-finished to prevent hazardous reflection.

WARNING - RISK FROM RADIATION ENERGY

The light dosage from the illumination system is a product of light intensity and exposure time. In order to minimize radiation exposure, limit one of these parameters to the medically required level for observing the patient's eye.

Please note that some national authorities require that

- the accident insurance authority responsible and the occupational health authority be notified about the operation of laser systems prior to their first use;
- the expert for the system be appointed laser protection representative for the operation of laser systems in writing;
- the laser areas of laser systems be clearly demarcated and marked as such during laser operation, and in enclosed spaces that the operation of laser systems is signaled at the entrances to the laser areas by means of laser warning signs;
- minors must not be employed in laser areas where laser systems are operated.

The laser hazard area is the area in which the maximum permissible exposure (MPE) may be exceeded. This includes areas into which the laser beam may unintentionally be deflected by a reflecting surface.

The physician is not required to wear protective eyewear when observing the area to be treated through the microscope.

Touchscreen monitor

The OPASS software, the display of the Eyetracker video image and the display of status and error messages are all operated via the touchscreen monitor (**2**, Fig. 7, page 33).

You can adjust the position of the monitor using the swivel arm (**1**, Fig. 7, page 33) to meet your ergonomic requirements.

The monitor does not need to be switched on separately. Turning the key switch to **On** (**5**, Fig. 14, page 43) also turns on the monitor.

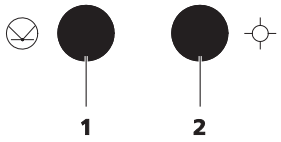
The onscreen keyboard is disabled. You can enable the onscreen keyboard via the icon button.

If the onscreen keyboard is enabled, it will be displayed when selecting an input field.

Furthermore, a numerical keyboard is displayed when selecting numerical input fields. This includes also keys to increase or decrease values in coarse (double arrow) and fine (single arrow) steps.

Distance lasers and aiming beam

- Press the button (**1**, Fig. 19, page 59) on the control panel to switch the distance lasers on or off.
- Press the button (**2**, Fig. 19, page 59) on the control panel to switch the aiming beam on or off.



1 **<Distance laser on/off>** button
2 **<Aiming beam on/off>** button

Fig. 19 Buttons for distance lasers and aiming beam

☞ The aiming beam turns on automatically once the Eyetracker is activated and/or the foot switch operated.

Operating area illumination

WARNING - RISK FROM RADIATION ENERGY

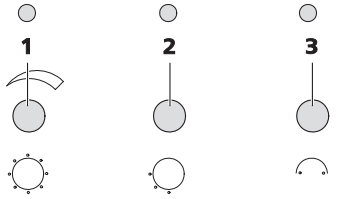
Cautionary statement in accordance with ANSI Z80.36:

CAUTION: - The light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater is the risk of ocular damage. Exposure to light from this instrument when operated at maximum intensity will exceed the recommended maximum exposure (RME) of 2.2 J/cm², unless additional action is taken by the user to minimize exposure, after 8 min. The risk of retinal injury at an exposure of 2.2 J/cm² is not high, but because some patients may be more susceptible than others, caution is advised if this radiant exposure value is exceeded. However, because of a significant risk of injury at exposures exceeding 10 J/cm², the user should avoid exposures longer than 44 min.

The MEL 90 excimer laser is equipped with a white light ring illumination system mounted at the laser exit aperture for illumination of the operating area. The ring illumination can also be operated in individual segments. This option allows improved visibility of contours in the operating plane due to selective shadow cast.

In addition, there is a satellite illumination system mounted on the CCA+ unit which allows grazing-angle illumination of the patient's eye. This is particularly helpful when centering the eye, as it allows better visualization of the pupil.

The illumination systems are controlled using the rotary/push buttons on the **Illumination** section of the control panel (see Fig. 20, page 60).



1 Rotary/push button **<Ring illumination on/off>**
2 Rotary/push button **<Segment ring illumination>**
3 Rotary button **<Satellite illumination on/off>**

Fig. 20 Rotary/push buttons for operating area illumination

Switching the ring illumination on and off

- Press the rotary/push button (**1**, Fig. 20, page 60) to switch on ring illumination. Press the switch again to turn off ring illumination.
- Rotate the switch to adjust the brightness.

  The LED located above the switch indicates whether the illumination ring power is on.

Segmenting the ring illumination

- Press the rotary/push button (**2**, Fig. 20, page 60) to switch the ring illumination segments on or off.

The LED located above the switch indicates whether segmentation is on.

- Rotate the switch to rotate the segmented illumination.
- Press and rotate the switch simultaneously to increase or decrease the number of illuminated segments.
-

Switching the satellite illumination on and off

- Turn the rotary switch (**3**, Fig. 20, page 60) clockwise to switch on the satellite illumination system.
  - Either the left, right or both lamps can be switched on (level 0: off, level 1: left lamp, level 2: right lamp, level 3: both lamps).
  - If at least one of the lamps is on, this will be indicated by the LED located above the rotary switch.
- Turn the rotary switch (**3**, Fig. 20, page 60) counterclockwise to switch off the satellite illumination system.

Eyetracker

The Eyetracker is used to track the eye and guide the laser beam during treatment.

The Eyetracker locates the pupil, calculates its geometric center and sends the coordinates of the center point to the scanner. To avoid being dependent upon the ambient lighting the Eyetracker works in the infrared range. The eye is illuminated for the Eyetracker with infrared light. The infrared illumination system is located on the CCA+ unit. No Eyetracker video image will therefore be seen on the monitor until the CCA+ unit is swiveled into the operating position.

To assist the Eyetracker in identifying the pupil, the grey scales of the black and white camera image are made darker or lighter above a defined threshold. This threshold is adjusted to achieve maximum contrast between the pupil and the iris. The pupil is visible as a black hole.

The Eyetracker of the MEL 90 employs an auto threshold system which dynamically adjusts to changing conditions on the eye during treatment. The auto threshold function is activated automatically when the CCA+ unit is swiveled into the operating position.

The Eyetracker continuously directs the laser beam onto the calculated center point of the pupil. If this does not coincide with the desired center of

treatment, the position can be adjusted by means of an offset which can be set manually. The Eyetracker adjusts for this offset when correcting for eye movement. The center of ablation is marked by a red cross. If the limbus was detected successfully at the start of treatment its geometrical center will be marked with white cross hairs.

If after successful limbus detection there is "pupil center shift" as the treatment progresses, this is automatically corrected.

A blue square is displayed in the video image of the Eyetracker to show the permissible or accepted area (hot zone). The pupil must be within the admissible range (hot zone) before the Eyetracker can be activated. Defining such a small zone minimizes the risk of incorrect corrections due to parallax errors.

The Eyetracker is operated using the **Eyetracker** controls on the control panel (see Fig. 21 to Fig. 24, page 63 to page 64).

The tracking status is indicated by a number of LEDs and by text information on the monitor.

☞ Avoid any irradiation of the working plane by additional IR radiation sources or the sun.

☞ The Eyetracker can also be operated without the video display. The video window is simply an additional display option.

Tracking function status is indicated by the status LEDs on the control panel. The most essential factor is that the patient's eye is within the admissible or acceptable range (hot zone) of the operating area.

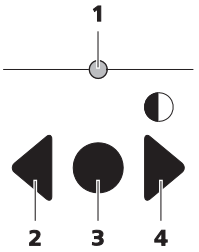
Automatic threshold adjustment

The round **<Automatic threshold on/off>** button (**3**, Fig. 21, page 63) is used to manually switch on or off the automatic threshold setting.

The status LED lights up green (**1**, Fig. 21, page 63) when the automatic threshold setting is on.

When the automatic threshold setting is off, the arrow buttons (**4** and **2**, Fig. 21, page 63) can be used to raise or lower the threshold.

The threshold is displayed top right in the Eyetracker video image.



1 Green status LED
(LED lights up = automatic function is switched on)
2 **<Decrease threshold>** button
3 **<Automatic threshold on/off>** button
4 **<Increase threshold>** button

Fig. 21 Automatic threshold adjustment

☞ Swiveling in the CCA+ unit activates the automatic threshold setting.

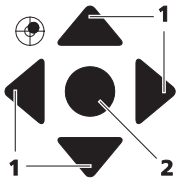
Offset adjustment

With the Eyetracker switched on, the center of the pupil and the center of the treatment are congruent.

Using the arrow buttons (**1**, Fig. 22, page 63) the center of treatment can, however, be shifted manually in relation to the center of the pupil (manual offset in direction of arrow).

Tap the **<Home>** button (**2**, Fig. 22, page 63) to delete this offset.

Set offset values are automatically deleted at the end of each treatment.



1 **<Manual offset>** arrow buttons
2 **<Home>** button

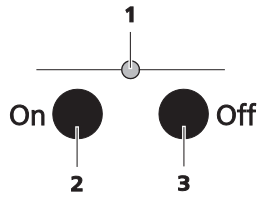
Fig. 22 Offset adjustment

Activating the Eyetracker

Use the **<On>** button (**2**, Fig. 23, page 64) to turn on the Eyetracker. This means that the Eyetracker correction data which have been collected in the background since the CCA+ unit has been swiveled in are now actively added to the scanner data.

The green LED (**1**, Fig. 23, page 64) is illuminated when the Eyetracker is active.

Use the **<Off>** button (**3**, Fig. 23, page 64) to deactivate the Eyetracker. The green LED will be extinguished and the pupil coordinates will no longer be transferred to the scanner.



1 Green status LED
(LED lit = Eyetracker activated)
2 **<On>** button (activate Eyetracker)
3 **<Off>** button (deactivate Eyetracker)

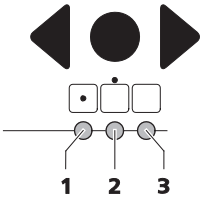
Fig. 23 Activating/deactivating the Eyetracker

☞ If the Eyetracker has not yet been activated, the following warning message will be displayed on the monitor screen after tapping the **Ready** button: "Switch on the Eyetracker".

Activate the Eyetracker, then tap **OK** in the warning message.

If you wish to work without using the Eyetracker, tap the **<Off>** button (**3**, Fig. 23, page 64).

Eyetracker status display



1 Green LED = Pupil inside hot zone
2 Yellow LED = Pupil outside hot zone
3 Yellow LED = Pupil not detected

Fig. 24 Eyetracker status display

Pupil is inside hot zone, tracking OK

The green LED (**1**, Fig. 24, page 64) on the status display will be illuminated.

The pupil is inside the hot zone.

Pupil has been found, but is outside the hot zone

The yellow LED (**2**, Fig. 24, page 64) on the status display will be illuminated.

The operation will be interrupted and a warning message will be displayed on the monitor screen.

Maneuver the patient's eye back into the hot zone and tap **Resume** in the warning message. The operation can then be continued.

The Eyetracker has lost or failed to find the pupil

Both yellow LEDs (**2** and **3**, Fig. 24, page 64) on the status display will be illuminated.
The operation will be interrupted and a warning message will be displayed on the monitor screen.

Maneuver the patient's eye back into the hot zone and tap **Resume** in the warning message. The operation can then be continued.

If the right yellow LED (**3**, Fig. 24, page 64) flashes, the Eyetracker is defective. Please contact ZEISS Service.

Eyetracker operating procedure

Step 1

Position the patient's eye in the center of the operating area using the field of view of the microscope as a guide.

Step 2

Swivel the CCA+ unit into the operating position.

- The automatic threshold setting is activated.
- Once the Eyetracker has found the pupil, the threshold value remains largely constant, with only slight adjustments being made for changing ambient conditions (e.g. shadows, opacity of the pupil during the treatment).
- The green LED (**1**, Fig. 24, page 64) on the status display must be illuminated.
- The cross hairs in the Eyetracker video image must follow the pupil.
- Ensure that the pupil is at the center of the hot zone. The yellow LED (**2**, Fig. 24, page 64) on the status display must not be illuminated.
- The automatic threshold setting can also be deactivated using the **<Automatic Threshold On/Off>** (**3**, Fig. 21, page 63) button.

The threshold can then be adjusted manually using the arrow buttons (**2** and **4**, Fig. 21, page 63). This may be necessary if the Eyetracker fails to detect the pupil automatically due to poor contrast.

Step 3

Activate the Eyetracker using the **<On>** button (**2**, Fig. 23, page 64).

The Eyetracker status LED (**1**, Fig. 23, page 64) must be illuminated. The aiming beam must be visible in the center of the pupil and must follow the movement of the pupil.

Step 4

Where the center of treatment is not the geometric center of the pupil, use the offset control buttons (**1**, Fig. 22, page 63) to move the aiming beam to the actual center of ablation. To reset the aiming beam to its original position, press the **<Home>** button (**2**, Fig. 22, page 63).

Once the Eyetracker has been configured, the ablation can be carried out (refer to section *RSTP - Recommended standard treatment procedures (frequently used functions)* from page 77).

Step 5

Activate the laser by tapping the **Ready** button in the current dialog on the monitor screen and press the foot switch.

☞ If the Eyetracker has not yet been activated, the following warning message will be displayed on the monitor screen after tapping **Ready**: "Switch on the Eyetracker". This warning can be confirmed as soon as the Eyetracker has been activated.

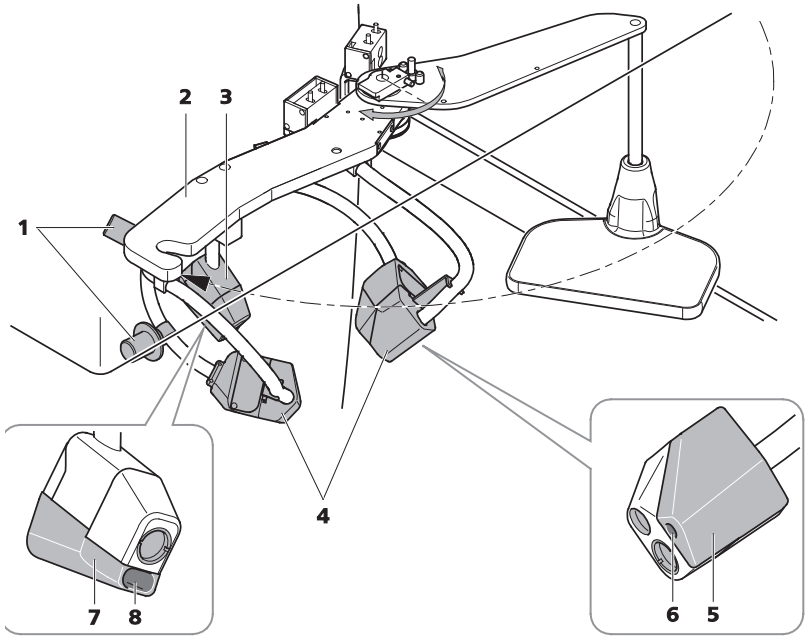
CCA+ unit

The CCA+ unit ensures a constant atmosphere around the eye during treatment.

The unit consists of a compressed air system (**4**, Fig. 25, page 67) which uses a directed airflow to rapidly remove ablation products from the ablation zone, and an extraction system (**3**, Fig. 25, page 67) to extract the ablation products, minimizing unpleasant odors during laser treatment.

In addition, the satellite illumination for the operating area illumination (see page 60) and the IR illumination for the Eyetracker (see page 61) are mounted on the CCA+ unit.

☞ An internal collision sensor is integrated in the CCA+ unit. This interrupts the elevation of the patient supporting system as soon as the patient's head displaces the CCA+ unit.



1 Swivel arm handles
2 Swivel arm
3 Suction system
4 Compressed air system
5 Head of compressed air unit (right side, left side mirror image)
6 Opening of compressed air system
7 Head of suction system
8 Opening of suction system

Fig. 25 CCA+ unit

- Swivel the CCA+ unit into the operating position before carrying out a fluence test or the actual laser treatment.
- Ensure that the CCA+ unit clicks firmly into place in the operating and parked positions.
- Always use the swivel arm handles (**1**, Fig. 25, page 67) provided for the purpose to maneuver the CCA+ unit.

☞ The handle caps are removable and can be sterilized (see section *Sterilization*, page 126 and following).

In the suction unit and the compressed air unit there is a filter which can be changed easily by the user.

CAUTION - BIOLOGICAL HAZARDS

Caution – Laser fume and/or plume may contain viable tissue particulates.

It is recommended to wear a facemask to reduce the absorption of particles.

CAUTION - GENERAL HAZARDS

To prevent the growth of bacteria and fungi, replace the filters and hoses monthly, even if they do not appear to be contaminated (refer to section *Maintenance*, page 120 and following).

- Dispose of used filters and hoses as medical waste. Observe local waste disposal regulations.

OPMI pico surgical microscope

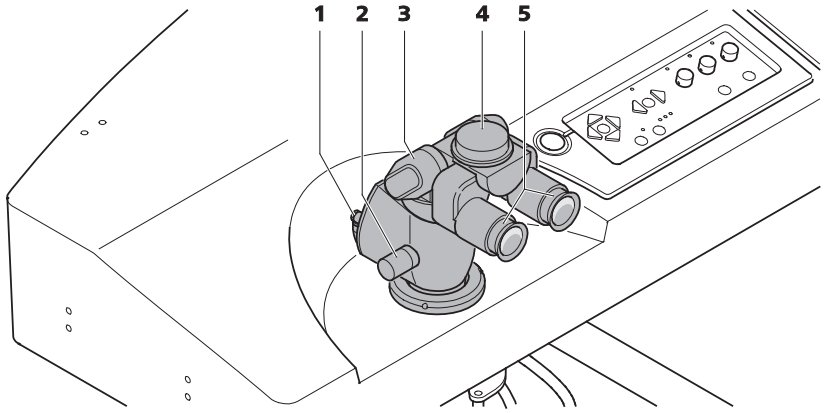
An OPMI pico with swivel-type binocular tube is used with the MEL 90.

- Adjust the swivel-type binocular tube (3, Fig. 26, page 69) to a comfortable position.
- Adjust the appropriate interpupillary distance with the rotary knob (**4**, Fig. 26, page 69) on the top of the binocular tube.

Located on each side of the microscope body, there are rotary knobs (**2**, Fig. 26, page 69) with magnification steps (5 steps: 0.4 to 2.5).

Select the appropriate magnification during treatment in accordance with the RSTP - Recommended standard treatment procedures (frequently used functions), page 77.

The eyepieces (**5**, Fig. 26, page 69) can be adjusted to your refractive power by turning the knurled wheel. The eyecups can be turned out for optimum adjustment of the field of view.



1 Plug for co-observer camera
2 Rotary knob, magnification changer
3 Tiltable tube
4 Interpupillary distance adjustment
5 Eyepieces

Fig. 26 OPMI pico surgical microscope

☞ The co-observer camera of the OPMI pico is connected to the back of the OPMI.

You will not normally need to remove this plug (**1**, Fig. 26, page 69). However, if you do need to remove or insert it, the device must be switched off before doing so to avoid damage to the camera electronics.

Patient supporting system

LS Comfort 80 combi patient supporting system

WARNING - GENERAL HAZARDS

Only use the patient supporting system supplied by Carl Zeiss Meditec AG. It includes safety systems which operate in conjunction with the MEL 90 excimer laser only.

WARNING - MECHANICAL ENERGY HAZARD

Observe the movements of the LS Comfort 80 combi.
If there is a risk of crushing for the patient, stop the patient supporting system movement by moving the joystick or pressing the EMERGENCY STOP/EMERGENCY LASER STOP button. Remove the patient from the patient support after pressing the EMERGENCY STOP/EMERGENCY LASER STOP button (if necessary, use the mechanical release on the head rest of the patient supporting system).
Ensure that no parts of the body are trapped between the patient supporting system and the basic device.

Ensure that the patient is not wearing any loose objects (e.g. clothing, hand bag, jewelry) that could be trapped between moving parts.

When swiveling the patient supporting system, make sure that no persons are within the swiveling range of the patient supporting system.

☞ Observe the weight limit of the patient supporting system.

The LS Comfort 80 combi is a treatment table with motorized adjustment of the patient supporting surface.

Instructions for operating the patient supporting system and notes on safety are provided in the relevant instructions for use.

An interlock system is incorporated to prevent the patient supporting system from moving during laser treatment by locking it in position.

Complete movement of the patient supporting system is only possible when the CCA+ unit is in its parking position.

If the CCA+ unit is folded in, the travel range is restricted to within narrow limits (Interlock I is active).

If the foot switch is activated to carry out treatment or if the sensors on the CCA+ unit (**18**, Fig. 4, page 31) or the optional hand-held slit lamp (**19**, Fig. 4, page 31) are triggered by removing the components, the patient supporting system will be completely locked (Interlock II is active).

Patient supporting system in combination with ZEISS VisuMax®

The VisuMax must be installed by a service employee authorized by Carl Zeiss Meditec AG.

CAUTION - CHEMICAL HAZARDS

The coating on the platform for the combination of the MEL 90 with the VisuMax contains natural rubber.
In case of an intolerance to natural rubber, avoid touching the coating.

☞ In combination with the ZEISS VisuMax devices, observe the weight limit of the patient supporting system.

The MEL 90 and VisuMax devices are equipped with a patient supporting system which is used by both devices during treatment. The patient supporting system has 3 pivoting positions (VisuMax, entry/exit and MEL 90, see Fig. 39, page 144 and Fig. 40, page 145).

For treatment using the MEL 90 excimer laser, the VisuMax unit must be switched on to supply power to the patient supporting system. If the MEL 90 is switched off and the patient supporting system is in the treatment position beneath the MEL 90, the patient supporting system cannot be swiveled out.

Instructions for operating the patient supporting system and notes on safety are given in the instructions for use of the patient supporting system.

Instructions for operating VisuMax and notes on safety are given in the instructions for use of the VisuMax.

Functioning of the movement locks of the EMERGENCY STOP/EMERGENCY LASER STOP system and the data transfer in connection with ZEISS VisuMax

CAUTION - GENERAL HAZARDS

Only EMERGENCY STOP/EMERGENCY LASER STOP and Ethernet cables supplied with VisuMax shall be used.

When the unit is operated in conjunction with the ZEISS VisuMax, the action of the movement lock protection mechanisms depends on the device to which the patient supporting system is assigned.

When the unit is operated in the VisuMax position, the safety functions apply as described in the VisuMax instructions for use.

When used in the MEL 90 position, the movement locks apply as described for the combination with the LS Comfort 80 combi patient supporting system.

In combination with ZEISS VisuMax the EMERGENCY STOP/EMERGENCY LASER STOP systems are connected. Activating one of the two EMERGENCY STOP/EMERGENCY LASER STOP systems causes movement of the patient supporting system to be locked (Interlock II is active).

As an additional function, patient planning data can be transferred from the MEL 90 system to the VisuMax system. Please contact ZEISS Service if you wish to use this function.

LS Comfort 80 combi patient supporting system in combination with ZEISS VISUMAX 600/800

☞ In combination with the ZEISS VISUMAX 600/800 devices, observe the weight limit of the patient supporting system.

VISUMAX 600/800 must be installed by a service employee authorized by Carl Zeiss Meditec AG.

The MEL 90 and VISUMAX 600/800 system is equipped with a patient supporting system which is used by both devices during treatment. The patient supporting system has 2 pivoting positions (VISUMAX 600/800 entry/exit and MEL 90, see Fig. 41, page 146).
For treatment in combination with VISUMAX 600/800, MEL 90 must be switched on to supply power to the patient supporting system. If the MEL 90 is switched off and the patient supporting system is in the treatment position beneath the VISUMAX 600/800, the patient supporting system cannot be swiveled out.

Instructions for operating the patient supporting system and notes on safety are given in the instructions for use of the patient supporting system.

Instructions for operating the VISUMAX 600/800 and notes on safety are given in the instructions for use of the VISUMAX 600/800.

Functioning of the movement locks of the EMERGENCY STOP/EMERGENCY LASER STOP system and the data transfer in connection with ZEISS VISUMAX 600/800

CAUTION - GENERAL HAZARDS

Only EMERGENCY STOP/EMERGENCY LASER STOP cables supplied with VISUMAX 600/800 may be used.

When the device is operated in conjunction with the ZEISS VISUMAX 600/800, the action of the movement lock protection mechanisms depends on the device to which the patient supporting system is assigned.

When the device is operated in the VISUMAX 600/800 position, the safety functions apply as described in the VISUMAX 600/800 instructions for use.

When used in the MEL 90 position, the movement locks apply as described for the combination with the LS Comfort 80 combi patient supporting system.

In combination with the ZEISS VISUMAX 600/800 the EMERGENCY STOP/LASER EMERGENCY STOP systems are connected. Activating one of the two EMERGENCY STOP/LASER EMERGENCY STOP systems causes movement of the patient supporting system to be locked (Interlock II is active).

Remote interlock

The device has a connection for a remote-controlled safety interlock (remote interlock, **2**, Fig. 10, page 35).

When delivered, a plug is inserted in the remote interlock connection. If the MEL 90 is to be operated without a remote interlock, this plug remains inserted.

If the MEL 90 is to be operated with the interlock, please contact the authorized ZEISS Service for support.

When using the remote interlock, any ongoing treatment with the MEL 90 will be interrupted as soon as the door of the treatment room is opened. After closing the door and confirming the displayed message, the treatment can be continued.

☞ The use of the remote interlock may interrupt the treatment.

☞ When the device is operated in combination with the ZEISS VisuMax, the remote interlock must be connected additionally via a separate line.

OPASS software

General information

The OPASS software, together with the integrated PC with Windows® operating system and the monitor with touch function constitute the MEL 90 user interface. The **Welcome** main dialog is used to access all software functions.

Information on the software version can be obtained by tapping the ZEISS logo in the title bar, top left.

This section describes only the basic operation of the software. Further information on using the OPASS software or on troubleshooting can be found in the integrated online help function.

☞ There are a number of warning messages which may be displayed on the monitor of the MEL 90 computer. These messages must be acknowledged by the user.

Integrated onscreen help

The OPASS software includes an onscreen help feature which offers users support in using the software. Use the integrated onscreen help to obtain information on the individual functions, input options or status messages.

Use the **Integrated onscreen help** icon in the toolbar, top right, to call up the Integrated onscreen help.

If the integrated onscreen help is no longer needed, close the open help page by tapping the **Back** button.

☞ Please note that the integrated onscreen help makes no reference to medical or technical issues.

If you have any questions, please contact ZEISS Service or your local dealer.

Onscreen keyboard

If the onscreen keyboard is enabled, it will be displayed when selecting an input field.

Furthermore, a numerical keyboard is displayed when selecting numerical input fields. This includes also keys to increase or decrease values in coarse (double arrow) and fine (single arrow) steps.

It is always possible to enter data using an external keyboard (if connected) even if the onscreen keyboard is enabled.

Dialog boxes

If you want to set parameter values, select options or enter information, you must use the dialog boxes provided. Fig. 27, page 75 shows different field variants which can arise in the dialog boxes (and list fields) of the OPASS software.

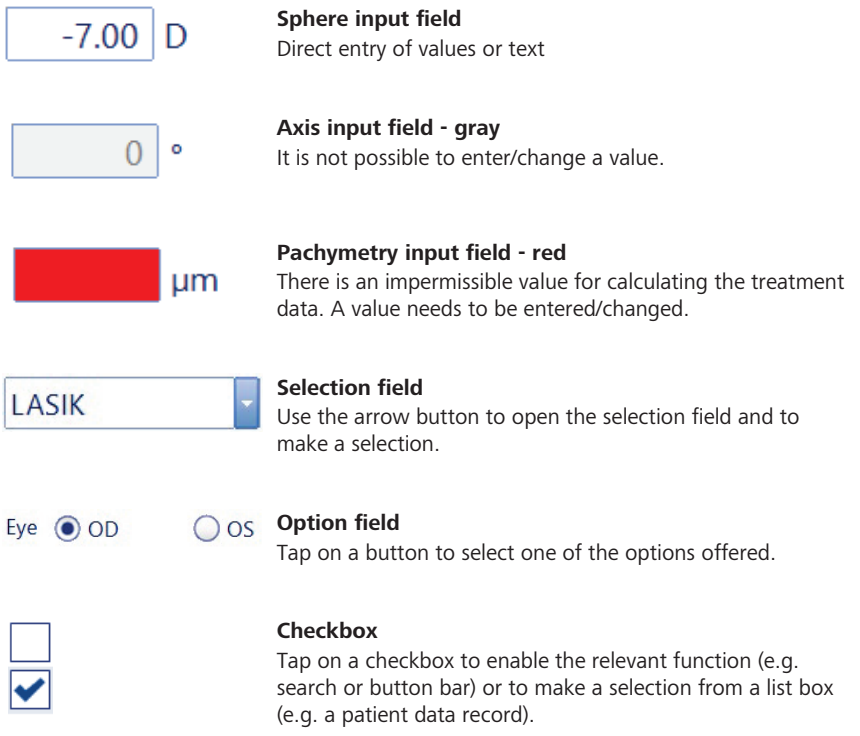


Fig. 27 Field variants in dialog boxes

Warning messages

- On leaving the approved treatment area a message appears on the screen without a warning symbol.
- On leaving the possible treatment area a message appears on the screen without a warning symbol. It is not possible to continue the treatment, as all relevant buttons of the OPASS software can no longer be selected in this case.
- If the treatment can be carried out on the basis of calculating the treatment data with one of the set parameters, however injury to the patient cannot be excluded, this is signaled by a yellow warning symbol with explanatory text. The user can continue the treatment at his/her own risk.
- A yellow warning symbol with explanatory text (Fig. 28, upper section, page 76) is displayed before a possible release of laser radiation and during the actual emission of laser radiation.

  In **Laser ready** mode the excimer laser emission can be triggered by operating the foot switch. The noise of the excimer laser can be heard, and the **Emission** display is shown in the screen (see Fig. 28, lower section, page 76).

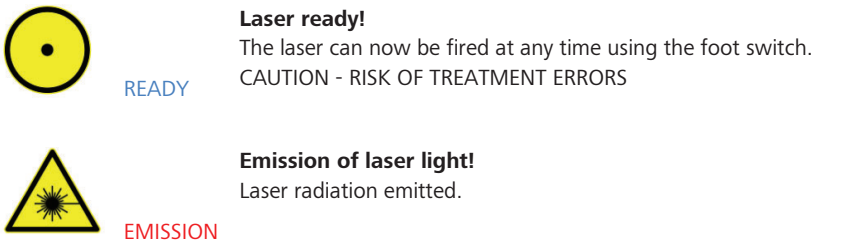


Fig. 28 Laser radiation warning messages

- After the energy adjustment phase the shutter will be opened. The laser warning lamp (**1**, Fig. 9, page 34) on the device will be turned on.

RSTP - Recommended standard treatment procedures (frequently used functions)

General remarks

National hygiene regulations must be observed for all work on a patient's eye.

CAUTION - GENERAL HAZARDS

Guide the patient when entering and leaving the operating area to avoid accidents due to stumbling.

Position the aiming beam as carefully as possible on the area to be treated. Because the aiming beam follows the same optical path through the laser beam delivery system as the therapy beam, it represents a good method for checking that the laser beam delivery system is undamaged. If the aiming beam spot at the distal end of the laser beam delivery system is not visible, is weak or appears diffuse, it may indicate damage to or improper function of the laser beam delivery system.

You should also check that a distributed pulse pattern can be seen through the microscope during ablation. If only a horizontal or vertical line or a single point is seen in the center, this may indicate that one or both scanner mirrors are not moving. Treatment must be aborted in this case.

When planning treatment, allow for measurement uncertainty in the diagnostic procedure for determining treatment parameters.

Cutting a flap with a femtosecond laser may result in temporary bubble formation in the stromal bed. This could affect the functioning of the Eyetracker.

There are different ways of achieving successful refractive surgery.

Nonetheless, Carl Zeiss Meditec AG has compiled a list of recommended treatment procedures. This is the result of information from numerous experienced surgeons and reflects many years of experience in the field of refractive surgery. This list will enable the physicians to perform the treatment with high-quality results in the interest of their patients.

We therefore recommend using the standard treatment procedures. If alternative procedures are used, a detailed comparison with the operator's own clinical data should be carried out.

In cooperation with our clinical researchers, we are constantly developing these recommendations whenever new methods or findings replace or supplement existing procedures.

These recommendations have been optimized for the MEL 90 excimer laser and may therefore differ from your experiences with other laser devices from Carl Zeiss Meditec AG or other manufacturers.

Reading these recommendations is not a substitute for carefully studying the complete documentation for this device or for detailed training provided by Carl Zeiss Meditec AG, nor does it release you from the obligation to update your own expertise in keeping with the latest results of general research in the field of refractive surgery.

Preparing the device and patient for treatment

1. **Patients who want to undergo refractive surgery** should be checked for their suitability according to section *Contraindications*, page 14.
2. **Patient expectations.** It is recommended that physicians assess how realistic patients' expectations are. It may be helpful to present statistical clinical information.
3. **Refraction.** Despite constant improvement in autorefractors and aberrometers, we recommend that the surgeon (or an appropriately trained person) determine the refraction of the patient themselves. To determine the subjective refraction, "fogging" techniques and/or duochrome tests should be used to repress accommodation. In particular, we recommend additional determination of the cycloplegic refraction for non-presbyopic, hyperopic patients. This also offers an opportunity to examine the posterior eye segment. In order to record any possible cyclotorsion it is recommended in case of astigmatism > 1.5 D to mark the horizontal axis of the patient while the patient is sitting.
4. **Pupil size.** The pupil size should be determined according to established standard methods. This helps in determining the optical zone to be corrected and the associated ablation depth.
5. **Pachymetry.** Multiple readings should be taken in the central area of the cornea in order to find the thinnest point (the use of average values is not advisable). The minimum value should be used to determine the patient's suitability for LASIK treatment. It is generally accepted that for LASIK treatments, the residual corneal thickness following flap cut and ablation should be no less than 250 µm.
6. **Patient consent.** The patient should be provided with written material on risks and side effects in advance of the surgery. The consent form must be signed in accordance with local regulations.
7. **Contact lenses** can lead to deformation of the surface of the cornea. It is therefore recommended that contact lens wearers do not wear their contact lenses for a certain period before

treatment. The period required depends on the type of contact lens used, the frequency of their use and the length of time for which contact lenses have been worn. The table below can be used as a guideline.

	Type	Removal before surgery
Soft lenses	Spherical	at least 72 hours
	Continuous wear or toric	at least one week
Hard lenses	Toric	1 month per 10 years of wear
	Gas permeable	
	Genuine hard lenses (PMMA)	

8. **Refraction check.** It is recommended that the surgeon personally checks the patient's refraction on the day of the treatment. This provides two measurements of refraction from two different visits, which may aid in assessing the effect of contact lenses or in verifying the original refraction measurement. Similarly, this enables minor modifications to be made and verifies the identity and refraction values of the patient on whom the treatment is about to be carried out. The corneal vertex distance must be taken into account when determining the refraction. Lighting conditions should be standardized. The patients should be refractioned for the best-corrected visual acuity (NB. 50 % of the average population have a best-corrected visual acuity of above 1.0 (20/20 or 6/6)).

LASIK treatment with microkeratome

1. Perform at least the following examinations prior to surgery and document the results:
   - Examination of the corneal topography by means of computer-assisted videokeratoscopy
   - Check of uncorrected and corrected visual acuity, as necessary, if accommodation has been dispensed with
   - Measurement of intraocular pressure
   - Measurement of the mesopic pupil diameter (0.05 lux to 50 lux)
   - Measurement of aniseikonia in anisometropy and determination of tolerance of the planned correction by contact lens trial
   - Examination of the anterior and posterior segments of the eye with medically dilated pupil
   - Measurement of corneal thickness (pachymetry) by optical method in a central range of at least 6 mm
   - Exclusion of medical contraindications
2. Ensure that the prescribed environmental conditions are adhered to (stable 18 °C to 24 °C, stable < 50 % humidity, refer to section *Technical data*, page 139). Check that there are no drafts in the working plane.
3. Perform a fluence test (see Fig. 17, page 52).
4. Check the patient's personal details (name, date of birth and which eye is to be treated).
5. Compare the refraction values entered with the values in the patient's medical records.
6. Verify that the optical zone corresponds to the pupil size.
7. Check that the residual stromal thickness is at least 250 µm. (Note: Residual stromal thickness is calculated as the difference of measured value of corneal thickness (pachymetry value) minus flap thickness minus ablation depth).
8. Center the patient - ensure that the head is properly centered and positioned (no lateral flexion of the head). The patient must be lying so that s/he is not straining (the neck muscles) when the eye is in the correct position. The patient should not cross his/her legs. If necessary, use the knee roll provided.
9. Ask the patient to focus on the green fixation light while you bring the two red distance lasers into coincident position (height adjustment/Z-axis).

10. Move the patient in the XY plane until you have centered the distance lasers over the entry pupil.

☞ Both distance lasers should be left running throughout the procedure. This makes it easier to ensure that the cornea remains vertically beneath the laser (XY position) and at the right height (Z-axis).

11. Apply an anesthetic to the eye being treated according to the manufacturer's recommendation.
12. Cover the other eye if necessary.
13. Dry lachrymal fluid from the eyelids (otherwise the adhesive film may fail to adhere properly).
14. Mask the eyelids. Ensure that neither the eyelids nor the film are in the way.
15. Ensure that the adhesive film does not come into contact with the cornea.

☞ The use of a closed lid retractor may make the use of adhesive film unnecessary and also restricts the entry of meibomian secretions.

16. Insert the eye lid retractor and open slowly. Ensure that you have good access to the treatment area, ideally with the iris in the center of the palpebral fissure.
17. Mark the cornea asymmetrically (e.g. with gentian violet), including the central 6 mm zone (should flap irregularities occur in the center).

☞ Points **18** to **19** refer specifically to the use of a mechanical microkeratome. If using a femtosecond laser, please observe the manufacturer's instructions.

☞ Position the hinge in nasal or superior direction as the air flow of the CCA+ unit on the eye is directed to the inferior position.

18. Attach the suction ring or the microkeratome on eye to be treated. Check for proper centering. Where possible, center the ring on the visual axis, rather than on the center of the pupil. This is particularly important for patients with a large kappa angle.
19. Perform the flap cut following the manufacturer's recommendations for the microkeratome used.

20. After the flap cut, with the patient fixating on the flashing fixation light, move the patient supporting system into a position in which the two distance lasers overlap on the cornea at the center of the pupil. This ensures that the cornea is horizontally beneath the laser beam.
21. Inspect the flap cut created and the cornea before proceeding with the treatment.
22. Swivel the CCA+ unit into place. This will usually start the Eyetracker's auto threshold system (if not, this can be started manually).
23. Switch off the ring illumination (this makes observation of the pupil during ablation more difficult) and turn on the CCA+ unit's satellite illumination.
24. Set the magnification to 1.6x.
25. Switch on the Eyetracker. If the eye to be treated is correctly positioned and the pupil is correctly detected by the Eyetracker, the aiming beam will be directed to the center of the entrance pupil. Check the aiming beam positioning using the microscope.
26. The treatment center can now be changed manually. To do this, change the position of the aiming beam using the arrow keys of the manual offset setting. Ensure that the eye to be treated is correctly positioned and that the patient fixates the flashing fixation light during the adjustment procedure.
27. Switch off the Eyetracker. The aiming beam will move to the side.
28. Set the magnification to 1.0x.
29. Now swivel out the CCA+ unit to have better access to the eye to be treated.

30. Recheck the position of the patient, in particular the patient's head (avoid rotation).
31. Place a damp, sterile swab on the hinge of the opened flap. We do not recommend the use of ring-shaped swabs, as this can affect limbus tracking.
32. Open the flap in a single movement, exerting as little tensile force as possible. Place the flap on the damp, sterile swab.
33. Start a 15 second countdown (stopwatch or timer).
34. Check the degree of hydration.
    If necessary, correct the degree of hydration of the open stroma with a suitable lint-free swab. Pay particular attention to a homogeneous degree of hydration over the entire area of the expected ablation.
35. Swivel the CCA+ unit back into the operating position. Make sure that the detected pupil is in the hot zone of the Eyetracker and switch the Eyetracker back on. Make sure that the aiming beam is in the determined position. Instruct the patient to fixate the flashing cloud of the fixation light for the duration of the laser treatment.
36. Recheck the parameter settings. Tap **Ready**.
37. Inform the patient of the noise which will be produced by the laser.
38. It may be necessary to protect the rear of the flap and the hinge from the laser using a dry swab (do not hold the swab in the area of the stroma). Hold the patient's head with your other hand.
39. You can resume the laser treatment by pressing the laser foot switch again.

CAUTION - RISK FROM DEVICE OPERATION

You should observe the progress of the ablation continuously through the surgical microscope in order to be able to react to any unforeseen hazards.

40. For larger ablations in particular (myopia > 5 D or hyperopia > 2 D) you should ensure that the cornea moisture remains consistent. If necessary, interrupt the ablation and re-dry the cornea at the hinge.

☞ The progress bar shows the progress of the treatment procedure. The control computer will automatically stop lasering after the correction program is finished. The treatment can be interrupted by releasing the foot switch. To resume the treatment, simply re-operate the foot switch.

After releasing the foot switch the treatment can be aborted by tapping **Abort**. A message will be displayed asking if you really wish to abort the treatment. If you select no, you can continue the treatment. The treatment cannot be resumed if you confirm that you wish to abort the treatment.

CAUTION - RISK FROM DEVICE OPERATION

If the treatment is interrupted, the aiming beam will return to the center of the treatment area selected prior to commencing the treatment. If this fails to occur, the treatment must be aborted.

41. Talk to the patient during the ablation. Ensure that the distance lasers overlap in the center of the pupil by holding the head in an appropriate position. Small deviations in height (+/- one beam diameter separation) are acceptable. Where possible, the ablation should be carried out without interruption.
42. Tell the patient to continue to look at the flashing cloud. Your assistant or surgery nurse should read out the percentage progress so the patient knows how much longer he/she is required to concentrate.

☞ If the Eyetracker loses the pupil or the pupil moves out of the hot zone during treatment, the treatment will be interrupted automatically.

The treatment can be resumed by tapping **Resume** once the pupil has been relocated or after deactivating the Eyetracker.

43. When the ablation is complete, swivel the CCA+ unit back to the parked position and switch on the ring illumination.
44. Reposition the flap as atraumatically as possible (avoid pulling and bending).
45. Irrigate under the flap using a 27 gauge anterior chamber cannula. Irrigate thoroughly (in order to remove all debris) but briefly (in order to avoid hydration). This helps ensure that the flap sits well with a minimal edge gap. Irrigate with 2 ml of solution for 1 to 2 seconds.
46. Replace the flap before the irrigating solution has completely disappeared from the interface by stroking with a wet swab. The corneal markings must be correctly aligned (the edge gap can change as a result of asymmetrical swelling during irrigation).
47. If you are using the optional hand-held slit lamp, set it to the highest magnification and check that the interface is clean and that the corneal markings are aligned. (If necessary, use the segmenting facility of the ring lamp to check that the flap is correctly positioned.)
48. Ask the patient to continue to look at the fixation light while you prepare to treat the second eye:
    1. Print out the treatment protocol for the first eye, if necessary.
    2. Bring up the parameters for the second eye.
    3. Prepare and check the microkeratome for the second eye.
49. Ensure that the flap is in the desired position and is securely attached to the stroma.
50. Remove the lid retractor slowly, while carefully holding the eyelids still. Remind the patient not to screw up his/her eyes.
51. Carefully remove the adhesive film/covering.
52. Ask the patient to blink, then recheck the flap position.
53. If you intend to treat the second eye, bandage the eye.
54. Go to number 4 to treat the second eye, if necessary.
55. After treatment of the patient, remove the adhesive film/covering from the treated eye or both eyes.
56. If you are not using the optional hand-held slit lamp: take the patient to a slit lamp. Visualizing the flap with the microscope, check that the interface is clean and check the flap position. Minor dislocations can be corrected under slit lamp illumination using a sterile triangular swab.

57. Take the patient to the recovery area, where he/she should wait for 20 minutes with his or her eyes closed.
58. Give the patient instructions regarding post-operative care, in particular the use of eye pads overnight.
59. Discharge the patient and the person accompanying him/her. Ask the patient to keep his/her eyes closed as much as possible until the first follow-up appointment on the following day.

WARNING - MECHANICAL ENERGY HAZARD

If you use the MEL 90 in combination with the VisuMax, walk the patient over the edge of the platform and through the surgical area upon getting off the patient supporting system.

Femtosecond laser LASIK (in combination with a ZEISS femtosecond laser)

Treatment Pack is available in sizes S, M and L. Each Treatment Pack is labeled with the according size.

Further information on the application of Treatment Pack may be found in the instructions for use for corresponding ZEISS femtosecond laser.

WARNING - MECHANICAL ENERGY HAZARD

Keep an eye on all automatic and manual movements of the device.

If there is a risk of crushing for the patient, stop the patient supporting system movement by moving the joystick or pressing the EMERGENCY STOP/EMERGENCY LASER STOP button. Remove the patient from the patient support after pressing the EMERGENCY STOP/EMERGENCY LASER STOP button (if necessary, use the mechanical release on the head rest of the patient supporting system).

Ensure that no parts of the body are trapped between the patient supporting system and the basic device.

Ensure that the patient is not wearing any loose items (e.g. clothing, hand bag, jewelry) that could be trapped between moving parts. Patients with long hair should wear a hair net.

CAUTION - GENERAL HAZARDS

Explain to the patient the benefits, contraindications,
mode of operation and risks associated with the treatment.

Femto-LASIK (with ZEISS VisuMax)

☞ If using another femtosecond laser, please observe the manufacturer's instructions. The following RSTPs are exclusively for the use of Femto-LASIK with ZEISS VisuMax.

1. Perform a comprehensive examination, including the retina. Enquire about the working conditions of your patient, e.g. night driving.
2. Check the refraction yourself or ask an experienced person to do so. To determine the subjective refraction, "fogging" techniques and/or duochrome tests should be used to repress accommodation. In particular, we recommend determining the cycloplegic refraction for non-presbyopic, hyperopic patients. This also makes it possible to examine the fundus of the eye.
3. Measure the pupil diameter using a recognized standard procedure. This serves to determine the treatment diameter and the associated ablation depth.
4. Measure the thickness of the cornea at its thinnest point using a recognized standard procedure.

☞ When measuring with a pachymeter, please always consider the accuracy specifications of the manufacturer, especially for further calculations such as the residual stromal thickness.

5. Check the treatment diameter. Ideally, the postoperative effective optical zone should be adapted to the mesopic pupil diameter.

CAUTION - RISK FROM DEVICE OPERATION

Observe all contraindications cited in the literature of professional medical associations and in the relevant laws in force in your country.

6. Check the refraction immediately before treatment.
7. Ensure that the ambient conditions satisfy the requirements (see section *Installation* in the VisuMax laser keratome Ophthalmo-surgical laser instructions for use).
8. Start the VisuMax laser keratome and prepare for treatment according to the instructions for use.

9. Enter or retrieve patient data and treatment planning at the VisuMax and MEL 90 and check.
    - Select the mode of treatment.
    - Select eye (OS/OD).
    - Enter and check the treatment parameters for the eye to be treated.
10. Set the microscope: magnification 1.0x. Swivel the patient supporting system into the entry/exit position.
11. Bring the patient into the operation room.
12. Lay the patient on the patient supporting system, which is in its entry position, so that the eye can easily be brought into exactly the desired position.
13. Apply an anesthetic to the eye being treated according to the manufacturer's recommendation.
14. Verify the data for the patient and eye to be treated, e.g. by talking to the patient.
15. Swing the patient supporting system into the observation position.

WARNING - RISK FROM RADIATION ENERGY

The light dosage from the illumination system is a product of light intensity and exposure time. In order to minimize radiation exposure, limit one of these parameters to the medically required level for observing the patient's eye.

While the optical radiation safety of VisuMax has been demonstrated in isolation for a maximum observation time of 900 seconds, it has not been evaluated for the potential subsequent overlap of light sources when used in connection with other devices, such as excimer laser systems.

16. Prepare the operating area, e.g. by draping with a sterile self-adhesive surgical sheet and fold it back so that the eyelashes and edge of the eyelid are completely covered.
17. Set the microscope: magnification 0.6x.
18. Insert the lid speculum. A lid speculum with suction is recommended.
19. Open the lid speculum as wide as the patient can tolerate. Fine align the patient supporting system so that the iris is in the center of the palpebral fissure.

CAUTION - RISK FROM DEVICE OPERATION

If you use corneal markers, use only IR-transparent marking ink.

Check that the marking is not visible in IR illumination.

20. Mark the cornea non-symmetrically using gentian violet, if necessary.

CAUTION - RISK FROM DEVICE OPERATION

Ensure that no liquid is allowed to enter the vacuum system.

21. Irrigate the corneal surface thoroughly to remove any residual meibomian secretions or other particles.
    Remove any excess of liquid on the cornea and the surrounding area where the suction of Treatment Pack is to be applied.
    The surface should be moist but not wet.
22. Start the treatment routine in the software by selecting patient/eye mode on the right hand touch screen monitor and follow the steps of the treatment wizard.

CAUTION - BIOLOGICAL HAZARDS

The current hygiene recommendations of the medical associations must be observed in all procedures on the patient's eye. Do not remove the sterile Treatment Pack from its wrappings until immediately before use. Take precautions to ensure that it remains sterile. Use Treatment Pack only if it is wrapped in its original packing in a sterile environment. Do not use Treatment Pack if it has passed its use-by date (printed on the wrapping) or if its wrapping is damaged.

Examine the wrappings of Treatment Pack to ensure there is no damage before removing it. Do not use Treatment Pack if you are not certain that it is sterile.

CAUTION - GENERAL HAZARDS

Use only Treatment Pack which is expressly approved by Carl Zeiss Meditec AG.

23. Remove the sterile Treatment Pack from its wrappings.

CAUTION - RISK FROM DEVICE OPERATION

Do not use a contacting agent.

The optical attributes of the contact glass change as a result of the operation, meaning that it may not be re-used.

24. Position the sterile contact glass on the laser aperture and connect the filter of Treatment Pack to the control panel. The hose must connect the filter with the contact glass. The contact glass will be under suction pressure. Please ensure that the complete Treatment Pack is sterile!

WARNING - MECHANICAL ENERGY HAZARD

Upon connection of Treatment Pack you will be asked via the graphical user interface to perform an excursion test. When testing the excursion by lifting the treatment objective, the latter must travel smoothly. If you feel that the treatment objective does not move freely, shut down the laser keratome and contact ZEISS Service.

25. Re-check the preparations for surgery.
26. Press the **<Start>** button to move the patient supporting system into treatment position.
    The controls move the patient supporting system automatically into the treatment position. You can stop the movement with the joystick any time. The automatic motion will stop as the eye approaches the contact glass on the treatment objective.
27. Ask the patient to fixate upon the green fixation light and use the surgical microscope to inspect the patient's eye.

WARNING - RISK FROM RADIATION ENERGY

The light dosage from the illumination system is a product of light intensity and exposure time. In order to minimize radiation exposure, limit one of these parameters to the medically required level for observing the patient's eye.

While the optical radiation safety of VisuMax has been demonstrated in isolation for a maximum observation time of 900 seconds, it has not been evaluated for the potential subsequent overlap of light sources when used in connection with other devices, such as excimer laser systems.

28. Position the patient's eye by moving the patient supporting system so that the visual axis is exactly in the center of the contact glass and the eye meets the contact glass. When the eye is approaching the contact glass, the reflection of the treatment illumination should be in the center of the observation area.
    Use the joystick to maneuver the patient supporting system.
    Observe all patient supporting system movements and repeatedly check the positions of the eye and contact glass in the microscope or on the left-hand monitor.
    Use the concentric circles of the ocular reticle in the surgical microscope for centering the pupil.
    On the left of the monitor, the reflection of the flashing green fixation light indicates the center of treatment.
29. Switch on the vacuum suction and allow the eye to be sucked onto the contact glass.

CAUTION - RISK FROM DEVICE OPERATION

Ensure that the size of the connected Treatment Pack corresponds to the planned treatment diameter size in the graphical user interface. If the Treatment Pack is too small, an incomplete incision may result.

Carefully check the surgical parameters and do not begin laser treatment until all parameters are correct. If surgery is performed with incorrect parameters, there is a risk of over or undercorrection.

Take special care to ensure exact alignment of the patient's eye. Manual alignment errors cannot be corrected by the laser keratome. These errors may impact the treatment results. Encourage the patient to cooperate in achieving optimum results.

CAUTION - RISK FROM DEVICE OPERATION

If the suction ring is too large, it may cause suction pressure on the conjunctiva. Suction on the conjunctiva owing to incorrect size of Treatment Pack may result in premature loss of suction. Total surgery time (centering, suction time) should be kept as short as possible, as there is otherwise a risk of suction loss. Ensure that conditions which may distract the patient (background noise, other activities in the surgery) are kept to a minimum while the eye is under suction.

The formation of bubbles at the periphery of the suction zone is an indication of imminent suction loss. Bear in mind that slight movements of the pupil may occur without any movement of the cornea.

Encourage the patient to lie as still as possible.

☞ The system changes to **Ready** mode upon activation of the vacuum suction.

The laser beam is triggered by pressing the foot switch.

30. Check again for proper centering and suction.

CAUTION - RISK FROM DEVICE OPERATION

Observe the entire surgical procedure through the surgical microscope. The process must be stopped immediately if the size and position of the incision deviate from the intended treatment. This may otherwise result in treatment errors.

Do not perform surgery if the incisions are incorrectly positioned!

For possible post-surgery use the Restart mode or consult medical literature for further treatment options.

Bear in mind that slight movements of the pupil may occur without any movement of the cornea.

31. Press the foot switch to start the treatment.

- Keep the switch depressed until the treatment has been completed.
  The laser treatment runs automatically.
- Release the foot switch to pause surgery.
- Press the foot switch again to resume the treatment.

☞ If surgery is paused, a message will appear on the display.

- Observe the entire surgical procedure through the surgical microscope.
- If either the extent or position of the incision deviate from the intended treatment, stop the procedure immediately by releasing the foot switch.
- The operation is aborted by releasing the vacuum suction (press <**suction on/off>** button on control panel).

☞ If the treatment is interrupted by loss of suction we recommend using the functions automatically offered by the device for continuing or resuming laser therapy.

- At the end of the operation a message will appear in the information box of the **Treatment** dialog. In the event of abortion, safety queries and messages will appear.

32. Move the patient supporting system into the observation position to inspect the laser treatment result.
33. Remove the sterile self-adhesive surgical sheet.
34. Go to number 10 to treat the second eye, if necessary.
35. Remove and dispose of the used Treatment Pack.
36. Shut down the surgery management software:
    Tap on **Finish**.
    The main software dialog will open again. It is now ready for the next operation.
37. Ensure that the prescribed environmental conditions are adhered to (stable 18 °C to 24 °C, stable < 50 % humidity, refer to section *Technical data*, page 139). Check that there are no drafts in the working plane of MEL 90.
38. Retrieve the saved treatment planning for the eye to be treated.
39. Perform a fluence test (see section *Fluence test*, page 48).
40. Swivel the patient supporting system into the treatment position of the MEL 90.
41. Compare the refraction values entered with the values in the patient's medical records.
42. Verify that the optical zone corresponds to the pupil size.
43. Check that the residual stromal thickness is at least 250 µm.
    (Note: Residual stromal thickness is calculated as the difference of measured value of corneal thickness (pachymetry value) minus flap thickness minus ablation depth).

44. Center the patient - ensure that the head is properly centered and positioned (no lateral flexion of the head). The patient must be lying so that s/he is not straining (the neck muscles) when the eye is in the correct position. The patient should not cross his/her legs. If necessary, use the knee roll provided.
45. Ask the patient to focus on the green flashing light while you bring the two red distance lasers into coincident position (height adjustment/Z-axis).
46. Move the patient in the XY plane until you have centered the distance lasers over the pupil.

☞ Both distance lasers should be left running throughout the procedure. This makes it easier to ensure that the cornea remains vertically beneath the laser (XY position) and at the right height (Z-axis).

47. Cover the other eye if necessary.
48. Dry lachrymal fluid from the eyelids (otherwise the adhesive film may fail to adhere properly).
49. Mask the eyelids. Ensure that neither the eyelids nor the film are in the way.
50. Ensure that the adhesive film does not come into contact with the cornea.

☞ The use of a closed lid retractor may make the use of adhesive film unnecessary and also restricts the entry of meibomian secretions.

51. Insert the eye lid retractor and open slowly. Ensure that you have good access to the treatment area, ideally with the iris in the center of the palpebral fissure.
52. Tell the patient that he/she should fix on the green flashing light.
53. Turn the patient's head to a natural, relaxed position.
54. With the patient fixing on the flashing fixation lamp, move the patient supporting system into a position in which the two distance lasers overlap on the cornea at the center of the pupil. This ensures that the cornea is horizontally beneath the laser beam.
55. Inspect the flap cut created and the cornea before proceeding with the treatment. Bubbles generated during the femtosecond laser incision could have an adverse effect on the function of the Eyetracker. Remove them according to the current standard, if necessary.
56. Swivel the CCA+ unit into place. This will usually start the

Eyetracker's auto threshold system (if not, this can be started manually).

57. Switch off the ring illumination (this makes observation of the pupil during ablation more difficult) and turn on the CCA+ unit's satellite illumination.
58. Set the magnification to 1.6x.
59. Switch on the Eyetracker. If the eye to be treated is correctly positioned and the pupil is correctly detected by the Eyetracker, the aiming beam will be directed to the center of the pupil. Check the aiming beam positioning using the microscope.

☞ Cutting a flap with a femtosecond laser may result in temporary bubble formation in the stromal bed. This could affect the functioning of the Eyetracker.

60. The treatment center can now be changed manually. For this purpose, the position of the aiming beam can be changed with the arrow keys of the manual offset setting. Make sure that the eye to be treated is correctly positioned and that the patient fixates the flashing fixation light during the adjustment procedure.
61. Switch off the Eyetracker. The aiming beam will move to the side.
62. Swivel the CCA+ unit out of surgery position.
63. Set the magnification to 1.0x.
64. Recheck the position of the patient, in particular the patient's head (avoid rotation).
65. Place a damp, sterile swab on the hinge of the opened flap. We do not recommend the use of ring-shaped swabs, as this can affect limbus tracking.
66. Open the flap in a single movement, exerting as little tensile force as possible. Place the flap on the damp, sterile swab.
67. Start a 15 second countdown (stopwatch or timer).
68. Check the degree of hydration.
    If necessary, correct the degree of hydration of the open stroma with a suitable lint-free swab. Pay particular attention to a homogeneous degree of hydration over the entire area of the expected ablation.
69. Swivel the CCA+ unit into place.
    This will usually start the Eyetracker's auto threshold system (if not, this can be started manually).

70. Make sure that the detected pupil is in the hot zone of the Eyetracker and switch the Eyetracker back on. Make sure that the aiming beam is in the determined position. Instruct the patient to fixate the flashing cloud of the fixation light for the duration of the laser treatment.
71. Recheck the parameter settings. Tap **Ready**.
72. Inform the patient of the noise which will be produced by the laser.
73. It may be necessary to protect the rear of the flap and the hinge from the laser using a dry swab (do not hold the swab in the area of the stroma). Hold the patient's head with your other hand.
74. You can resume the laser treatment by pressing the laser foot switch again.

CAUTION - RISK FROM DEVICE OPERATION

You should observe the progress of the ablation continuously through the surgical microscope in order to be able to react to any unforeseen hazards.

75. For larger ablations in particular (myopia > 5 D or hyperopia > 2 D) you should ensure that the cornea moisture remains consistent. If necessary, interrupt the ablation and re-dry the cornea at the hinge.

The progress bar shows the progress of the treatment procedure. The control computer will automatically stop lasering after the correction program is finished. The treatment can be interrupted by releasing the foot switch. To resume the treatment, simply re-operate the foot switch. After releasing the foot switch the treatment can be aborted by tapping **Abort**. A message will be displayed asking if you really wish to abort the treatment. If you select no, you can continue the treatment. The treatment cannot be resumed if you confirm that you wish to abort the treatment.

CAUTION - RISK FROM DEVICE OPERATION

If the treatment is interrupted, the aiming beam will return to the center of the treatment area selected prior to commencing the treatment. If this fails to occur, the treatment must be aborted.

76. Talk to the patient during the ablation. Ensure that the distance lasers overlap in the center of the pupil by holding the head in an appropriate position. Small deviations in height (+/- one beam diameter separation) are acceptable. Where possible, the ablation should be carried out without interruption.
77. Tell the patient to continue to look at the "flashing cloud". Your assistant or surgery nurse should read out the percentage progress so the patient knows how much longer he/she is required to concentrate.

If the Eyetracker loses track of the pupil during the treatment or the pupil leaves the hot zone, the control computer will interrupt the treatment. The treatment can be resumed by tapping **Resume** once the pupil has been relocated or after deactivating the Eyetracker.

78. When the ablation is complete, swivel the CCA+ unit back to the parked position and switch on the ring illumination.
79. Reposition the flap as atraumatically as possible (avoid pulling and bending).
80. Irrigate under the flap using a 27 gauge anterior chamber cannula. Irrigate thoroughly (in order to remove all debris) but briefly (in order to avoid hydration). This helps ensure that the flap sits well with a minimal edge gap. Irrigate with 2 ml of solution for 1 to 2 seconds.
81. Replace the flap before the irrigating solution has completely disappeared from the interface by stroking with a wet swab. The corneal markings must be correctly aligned (the edge gap can change as a result of asymmetrical swelling during irrigation).
82. If you are using the optional hand-held slit lamp, set microscope to the highest magnification and check that the interface is clean and that the corneal markings are aligned. (If necessary, use the segmenting facility of the ring lamp to check that the flap is correctly positioned.)

83. Ask the patient to continue to look at the fixation lamp while you prepare to treat the second eye.

- Print out the treatment protocol, if necessary.
- Bring up the parameters for the second eye.

84. Ensure that the flap is in the desired position and is securely attached to the stroma.
85. Remove the lid retractor slowly, while carefully holding the eyelids still. Remind the patient not to screw up his/her eyes.
86. Carefully remove the adhesive film/covering.
87. Ask the patient to blink, then recheck the flap position.
88. If you intend to treat the second eye, bandage the eye.
89. Go to number 41 to treat the second eye, if necessary.
90. After treatment of the patient, remove the adhesive film/covering from the treated eye or both eyes.
91. If you are not using the optional hand-held slit lamp: take the patient to a slit lamp. Check that the interface is clean and check the flap position. Minor dislocations can be corrected under slit lamp illumination using a sterile triangular swab.
92. Take the patient to the recovery area, where he/she should wait for 20 minutes with his or her eyes closed.
93. Give the patient instructions regarding post-operative care, in particular the use of eye pads overnight.
94. Discharge the patient and the person accompanying him/her. Ask the patient to keep his/her eyes closed as much as possible until the first follow-up appointment on the following day.

WARNING - MECHANICAL ENERGY HAZARD

Walk the patient over the edge of the platform upon getting off the patient supporting system.

Femto-LASIK (with ZEISS VISUMAX 600/800)

If using another femtosecond laser, please observe the manufacturer's instructions. The following RSTPs are exclusively for the use of Femto-LASIK with ZEISS VISUMAX 600/800.

1. Perform a comprehensive examination, including the retina (enquire about the working conditions of your patient, e.g. night driving).
2. Check the refraction yourself or ask an experienced person to do so. To determine the subjective refraction, "fogging" techniques and/or duochrome tests should be used to repress accommodation. In particular, we recommend determining the cycloplegic refraction for non-presbyopic, hyperopic patients. This also makes it possible to examine the fundus of the eye.
3. Measure the pupil diameter using a recognized standard procedure. This serves to determine the treatment diameter and the associated ablation depth.
4. Measure the thickness of the cornea at its thinnest point using a recognized standard procedure.

When measuring with a pachymeter, please always consider the accuracy specifications of the manufacturer, especially for further calculations such as the residual stromal thickness.

5. Check the treatment diameter (ideally, the postoperative effective optical zone should be adapted to the mesopic pupil diameter).

CAUTION - RISK FROM DEVICE OPERATION

Observe all contraindications cited in the literature of professional medical associations and in the relevant laws in force in your country.

6. Check the refraction immediately before treatment.
7. Ensure that the ambient conditions satisfy the requirements (see section Installation in the VISUMAX 600/800 instructions for use).
8. Start the VISUMAX 600 or VISUMAX 800.
9. Check the patient data and the treatment planning for the eye to be treated and select "Treat" on the planning screen of the device.

10. Bring the patient into the treatment room.
11. Lay the patient on the patient supporting system.
12. Apply an anesthetic to the eye being treated according to the manufacturer's recommendation.
13. Position the patient's head using the patient positioning device. Use the side view camera video and the corresponding overlay on the planning screen to check the correct position of the patient head.
14. Prepare the operating area, e.g. by draping with a sterile self-adhesive surgical sheet and fold it back so that the eyelashes and edge of the eyelid are completely covered.
15. Insert the led speculum. We recommend a closed lid speculum with suction.
16. Open the lid speculum as wide as the patient can tolerate. Ensure that you have good access to the treatment area, ideally with the iris in the center of the palpebral fissure.

CAUTION - RISK FROM DEVICE OPERATION

If you use corneal markers, use only IR-transparent marking ink.

Check that the marking is not visible in IR illumination.

17. Mark the cornea non-symmetrically using gentian violet.

CAUTION - RISK ARISING FROM INCORRECT OPERATION

Ensure that no liquid is allowed to enter the vacuum system.

18. Irrigate the corneal surface thoroughly to remove any residual meibomian secretions or other particles. Remove any excess of liquid on the cornea and the surrounding area where the suction of Treatment Pack is to be applied. The surface should be moist but not wet.
19. Swivel the laser arm into the operating position.
20. Verify the data for the patient and eye to be treated, e.g. by talking to the patient or by using the Surgical Timeout Checklist on the treatment screen.
21. Select the eye to be treated on the treatment screen (OD/OS).
22. Check and confirm the treatment parameters for the eye to be treated.

23. Move the laser objective in the laser arm to its working position by turning the joystick of the laser arm until you are prompted on the treatment screen to attach Treatment Pack.

CAUTION - RISK ARISING FROM INCORRECT OPERATION

Carefully check the treatment parameters and do not begin laser treatment until all parameters are correct. If surgery is performed with incorrect parameters, there is a risk of over or undercorrection.

Take special care to ensure exact alignment of the patient's eye. Manual alignment errors cannot be corrected by the laser keratome. These errors may impact the treatment results. Encourage the patient to cooperate in achieving optimum results.

24. Remove the sterile Treatment Pack from its wrappings.

CAUTION - GENERAL HAZARDS

Use only Treatment Pack which is expressly approved by Carl Zeiss Meditec AG.

CAUTION - BIOLOGICAL HAZARDS

The current hygiene recommendations of the medical associations must be observed in all procedures on the patient's eye. Do not remove the sterile Treatment Pack from its wrappings until immediately before use. Take precautions to ensure that it remains sterile. Use Treatment Pack only if it is wrapped in its original packing in a sterile environment. Do not use Treatment Pack if it has passed its use-by date (printed on the wrapping) or if its wrapping is damaged.

Examine the wrappings of Treatment Pack to ensure there is no damage before removing it. Do not use Treatment Pack if you are not certain that it is sterile.

CAUTION - RISK ARISING FROM INCORRECT OPERATION

Do not use a contacting agent.

The optical attributes of the contact glass change as a result of the operation,

meaning that it may not be re-used.

25. Position the sterile contact glass on the laser aperture and connect the filter of Treatment Pack to the vacuum connection. The hose must connect the filter with the contact glass. The contact glass will be under suction pressure. Please ensure that the complete Treatment Pack remains sterile!

26. Re-check the preparations for surgery.
27. Use the laser arm joystick to position the laser arm over the eye to be treated. Ensure that the eye to be treated is approximately in the center of the live image display of the treatment screen.
28. Ask the patient to fixate upon the green fixation light and use the live image display of the treatment screen to inspect the patient's eye.

WARNING - RISK FROM RADIATION ENERGY

The light dosage from the illumination system is a product of light intensity and exposure time. In order to minimize radiation exposure, limit one of these parameters to the medically required level for observing the patient's eye.

While the optical radiation safety of VISUMAX 600/800 has been demonstrated in isolation for a maximum observation time of 900 seconds, it has not been evaluated for the potential subsequent overlap of light sources when used in connection with other devices, such as excimer laser systems.

29. Pay attention to anatomical conditions that could lead to contact of the contact glass with the patient, except in the limbal area. To avoid accidental nose contact, tilt the patient head so that the patient's eye rotates laterally within the eyelid gap. Make sure that the limbus is not covered by the eyelid retractor, outer eyelid angle or tear film meniscus.
30. Position the laser arm so that the visual axis of the eye to be treated is exactly in the center of the contact glass and the eye meets the contact glass.
    When approaching, the treatment illumination reflex should be in the center of the live image display of the treatment screen.

    Use the laser arm joystick to position the laser arm. Observe all movements of the laser arm and constantly check the position of the patient eye in relation to the contact glass on the treatment screen.

    Use the aiming devices (overlay) of the live image display to center on the planned treatment center. The reflection of the green flashing fixation light represents the treatment center.
31. Switch on the vacuum suction and allow the eye to be sucked onto the contact glass.

CAUTION - RISK FROM DEVICE OPERATION

Ensure that the size of the connected Treatment Pack corresponds to the planned treatment diameter size in the graphical user interface. If it is too small, this may result in an incomplete incision.

Carefully check the surgical parameters and do not begin laser treatment until all parameters are correct. If surgery is performed with incorrect parameters, there is a risk of over or undercorrection.

Take special care to ensure exact alignment of the patient's eye. Manual alignment errors cannot be corrected by the laser keratome. These errors may impact the treatment results. Encourage the patient to cooperate in achieving optimum results.

CAUTION - ABORTION OF TREATMENT

If the suction ring is too large, it may cause suction pressure on the conjunctiva. Suction on the conjunctiva owing to incorrect size of Treatment Pack may result in premature loss of suction. Total surgery time (centering, suction time) should be kept as short as possible, as there is otherwise a risk of suction loss. Ensure that conditions which may distract the patient (background noise, other activities in the surgery) are kept to a minimum while the eye is under suction.

The formation of bubbles at the periphery of the suction zone is an indication of imminent suction loss. Bear in mind that slight movements of the pupil may occur without any movement of the cornea.

Encourage the patient to lie as still as possible.

☞ The system changes to READY mode upon activation of the vacuum suction. The laser beam is triggered by pressing the foot switch.

32. Check again for proper centering and suction.

CAUTION - RISK BY TREATMENT ERRORS

Observe the entire treatment on the treatment screen. The process must be stopped immediately if the size and position of the incision deviate from the intended treatment. This may otherwise result in treatment errors.

Do not perform surgery if the incisions are incorrectly positioned!

For possible post-surgery use the Restart mode or consult medical literature for further treatment options.

Bear in mind that slight movements of the pupil may occur without any movement of the cornea.

33. Press the foot switch to start the treatment.

- Keep the switch depressed until the treatment has been completed. The laser treatment runs automatically.
- Release the foot switch to pause surgery if necessary.
- Press the foot switch again to resume the treatment.

☞ If surgery is paused, a message will appear on the treatment screen.

- Observe the entire treatment on the treatment screen.
- The laser pulses are applied and end by performing a flap side cut. Advise the patient that the fixation light will disappear but that he/she has to maintain fixation. Do not change the head position of the patient during laser treatment.
- A pressure sensor in the device automatically compensates for slight movements of the treatment objective in the z-axis. Lateral movements of the patient head can be prevented by gently touching the patient head with your hands.
- If either the extent or position of the incision deviate from the intended treatment, stop the procedure immediately by releasing the foot switch.
- The treatment is aborted by releasing the vacuum suction (suction button on laser arm joystick).

☞ If the treatment is interrupted by loss of suction we recommend using the functions automatically offered by the device for continuing or resuming laser therapy.

When the laser treatment is completed, the device automatically releases the eye suction. After releasing the eye suction, the eye is automatically undocked by lifting the device head to a safe distance.

In the event of treatment abortion, safety queries and messages will appear.

CAUTION - MECHANICAL HAZARD FROM FALLING CONTACT GLASS

If you click the **Detach** button, the contact glass will fall off the laser objective and may fall on the patient's open eye.

Hold the contact glass holder before pressing the **Detach** button and then remove the contact glass from the patient environment.

34. Detach Treatment Pack to finish treatment.
    - Hold the contact glass holder by the tube connection.
    - Press the **Detach** button on the treatment screen and remove the contact glass from the laser objective.
    - Turn the vacuum connection of the Treatment Pack half a turn counterclockwise and pull it off the vacuum connection of the laser arm.
35. Examine the result of the laser treatment.
36. Return the patient's head back to a natural, relaxed position so the patient is relaxed.
37. Remove the lid speculum and sterile self-adhesive surgical sheet.
38. Go to step 14 of these RSTPs to treat the other eye or go to step 20.
39. Swivel the laser arm to the resting position.
40. Remove and dispose of the used Treatment Pack.
41. Finish the treatment sequence of the software: tap on **Finish**.

    The main software dialog will open again. It is now ready for the next operation.

42. Ensure that the prescribed environmental conditions are adhered to (stable 18 °C to 24 °C, stable < 50 % humidity, refer to section *Technical data*, page 139). Check that there are no drafts in the working plane of MEL 90.
43. Retrieve the saved treatment planning for the eye to be treated.
44. Perform a fluence test (see section *Fluence test*, page 48).
45. Swivel the patient supporting system into the treatment position of the MEL 90.
46. Compare the refraction values entered with the values in the patient's medical records.
47. Verify that the optical zone corresponds to the pupil size.
48. Check that the residual stromal thickness is at least 250 µm. (Note: Residual stromal thickness is calculated as the difference of measured value of corneal thickness (pachymetry value) minus flap thickness minus ablation depth).
49. Center the patient - ensure that the head is properly centered and positioned (no lateral flexion of the head). The patient must be lying so that s/he is not straining (the neck muscles) when the eye is in the correct position. The patient should not cross his/her legs. If necessary, use the knee roll provided.
50. Ask the patient to focus on the green flashing light while you bring the two red distance lasers into coincident position (height adjustment/Z-axis).
51. Move the patient in the XY plane until you have centered the distance lasers over the pupil.

☞ Both distance lasers should be left running throughout the procedure. This makes it easier to ensure that the cornea remains vertically beneath the laser (XY position) and at the right height (Z-axis).

52. Cover the other eye if necessary.
53. Dry lachrymal fluid from the eyelids (otherwise the adhesive film may fail to adhere properly).
54. Mask the eyelids. Ensure that neither the eyelids nor the film are in the way.
55. Ensure that the adhesive film does not come into contact with the cornea.

☞ The use of a closed lid retractor may make the use of adhesive film unnecessary and also restricts the entry of meibomian secretions.

56. Insert the eye lid retractor and open slowly. Ensure that you have good access to the treatment area, ideally with the iris in the center of the palpebral fissure.
57. Tell the patient that he/she should fix on the green flashing light.
58. Turn the patient's head to a natural, relaxed position.
59. With the patient fixing on the flashing fixation lamp, move the patient supporting system into a position in which the two distance lasers overlap on the cornea at the center of the pupil. This ensures that the cornea is horizontally beneath the laser beam.
60. Inspect the flap cut created and the cornea before proceeding with the treatment. Bubbles generated during the femtosecond laser incision could have an adverse effect on the function of the Eyetracker. Remove them according to the current standard, if necessary.
61. Swivel the CCA+ unit into place. This will usually start the Eyetracker's auto threshold system (if not, this can be started manually).
62. Switch off the ring illumination (this makes observation of the pupil during ablation more difficult) and turn on the CCA+ unit's satellite illumination.
63. Set the magnification to 1.6x.
64. Switch on the Eyetracker. If the eye to be treated is correctly positioned and the pupil is correctly detected by the Eyetracker, the aiming beam will be directed to the center of the pupil. Check the aiming beam positioning using the microscope.

Cutting a flap with a femtosecond laser may result in temporary bubble formation in the stromal bed. This could affect the functioning of the Eyetracker.

65. The treatment center can now be changed manually. For this purpose, the position of the aiming beam can be changed with the arrow keys of the manual offset setting.
    Make sure that the eye to be treated is correctly positioned and that the patient fixates the flashing fixation light during the adjustment procedure.
66. Switch off the Eyetracker. The aiming beam will move to the side.

67. Swivel the CCA+ unit out of surgery position.
68. Set the magnification to 1.0x.
69. Recheck the position of the patient, in particular the patient's head (avoid rotation).
70. Place a damp, sterile swab on the hinge of the opened flap. We do not recommend the use of ring-shaped swabs, as this can affect limbus tracking.
71. Open the flap in a single movement, exerting as little tensile force as possible. Place the flap on the damp, sterile swab.
72. Start a 15 second countdown (stopwatch or timer).
73. Check the degree of hydration.
    If necessary, correct the degree of hydration of the open stroma with a suitable lint-free swab. Pay particular attention to a homogeneous degree of hydration over the entire area of the expected ablation.
74. Swivel the CCA+ unit into place.
    This will usually start the Eyetracker's auto threshold system (if not, this can be started manually).
75. Make sure that the detected pupil is in the hot zone of the Eyetracker and switch the Eyetracker back on. Make sure that the aiming beam is in the previously defined position. Instruct the patient to fixate the flashing cloud of the fixation light for the duration of the laser treatment.
76. Recheck the parameter settings. Tap **Ready**.
77. Inform the patient of the noise which will be produced by the laser.
78. It may be necessary to protect the rear of the flap and the hinge from the laser using a dry swab (do not hold the swab in the area of the stroma). Hold the patient's head with your other hand.
79. You can resume the laser treatment by pressing the laser foot switch again.

CAUTION - RISK FROM DEVICE OPERATION

You should observe the progress of the ablation continuously through the surgical microscope in order to be able to react to any unforeseen hazards.

80. For larger ablations in particular (myopia > 5 D or hyperopia > 2 D) you should ensure that the cornea moisture remains consistent. If necessary, interrupt the ablation and re-dry the cornea at the hinge.

The progress bar shows the progress of the treatment procedure. The control computer will automatically stop lasering after the correction program is finished. The treatment can be interrupted by releasing the foot switch. To resume treatment, re-operate the foot switch. After releasing the foot switch the treatment can be aborted by tapping **Abort**. A message will be displayed asking if you really wish to abort the treatment. If you select no, you can continue the treatment. The treatment cannot be resumed if you confirm that you wish to abort the treatment.

CAUTION - RISK FROM DEVICE OPERATION

If the treatment is interrupted, the aiming beam will return to the center of the treatment area selected prior to commencing the treatment. If this fails to occur, the treatment must be aborted.

81. Talk to the patient during the ablation. Ensure that the distance lasers overlap in the center of the pupil by holding the head in an appropriate position. Small deviations in height (+/- one beam diameter separation) are acceptable. Where possible, the ablation should be carried out without interruption.

82. Tell the patient to continue to look at the "flashing cloud". Your assistant or surgery nurse should read out the percentage progress so the patient knows how much longer he/she is required to concentrate.

If the Eyetracker loses track of the pupil during the treatment or the pupil leaves the hot zone, the control computer will interrupt the treatment. The treatment can be resumed by tapping **Resume** once the pupil has been relocated or after deactivating the Eyetracker.

83. When the ablation is complete, swivel the CCA+ unit back to the parked position and switch on the ring illumination.
84. Reposition the flap as atraumatically as possible (avoid pulling and bending).
85. Irrigate under the flap using a 27 gauge anterior chamber cannula. Irrigate thoroughly (in order to remove all debris) but briefly (in order to avoid hydration). This helps ensure that the flap sits well with a minimal edge gap. Irrigate with 2 ml of solution for 1 to 2 seconds.
86. Replace the flap before the irrigating solution has completely disappeared from the interface by stroking with a wet swab. The corneal markings must be correctly aligned (the edge gap can change as a result of asymmetrical swelling during irrigation).
87. If you are using the optional hand-held slit lamp, set the microscope to the highest magnification and check that the interface is clean and that the corneal markings are aligned. (If necessary, use the segmenting facility of the ring lamp to check that the flap is correctly positioned.)
88. Ask the patient to continue to look at the fixation lamp while you prepare to treat the second eye.
    - Print out the treatment protocol, if necessary.
    - Bring up the parameters for the second eye.
89. Ensure that the flap is in the desired position and is securely attached to the stroma.
90. Remove the lid retractor slowly, while carefully holding the eyelids still. Remind the patient not to clench his/her eyes.
91. Carefully remove the adhesive film/covering.
92. Ask the patient to blink, then recheck the flap position.
93. If you intend to treat the second eye, bandage the first eye.
94. Go to number 46 to treat the second eye, if necessary.
95. After treatment of the patient, remove the adhesive film/covering from the treated eye or both eyes.

96. If you are not using the optional hand-held slit lamp: take the patient to a slit lamp. Check that the interface is clean and check the flap position. Minor dislocations can be corrected under slit lamp illumination using a sterile triangular swab.
97. Take the patient to the recovery area, where he/she should wait for 20 minutes with his or her eyes closed.
98. Give the patient instructions regarding post-operative care, in particular the use of eye pads overnight.
99. Discharge the patient and the person accompanying him/her. Ask the patient to keep his/her eyes closed as much as possible until the first follow-up appointment on the following day.

WARNING - MECHANICAL ENERGY HAZARD

If you use the MEL 90 in combination with the VisuMax, walk the patient over the edge of the platform and through the surgical area upon getting off the patient supporting system.

Shutting down

Brief pause in use

During brief periods of non-use the user should log out in the main **Welcome** dialog using the **Logoff** button (bottom left).

The entry of a password will be required to resume operation.

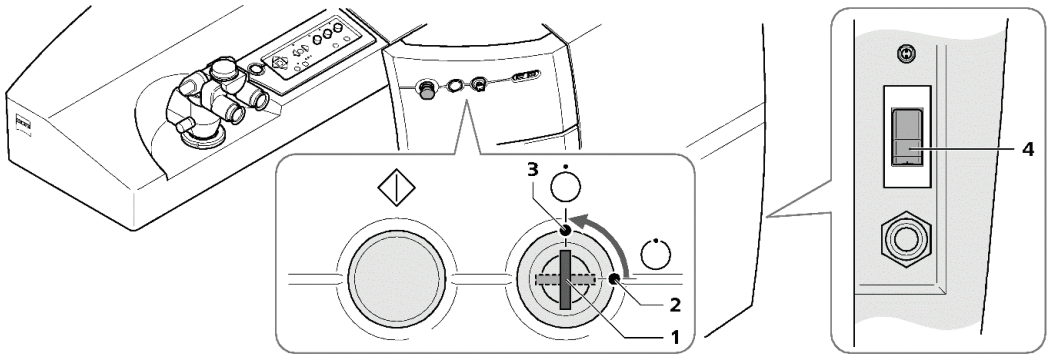
Shutting off the entire system

- To close the software, tap the **Switch off device** icon at the top right in the toolbar.
- Confirm the safety check "Do you really want to switch off the device?" by clicking on **Yes**.

The OPASS software will close and Windows® will shut down.

- Wait until the screen has gone blank then switch off the device by turning the key switch (**1**, Fig. 29, page 113) from **On** (**2**, Fig. 29, page 113) to **Off** (**3**, Fig. 29, page 113).
- Remove the key switch from the device to prevent its use by unauthorized persons.
- Switch on the entire equipment system (MEL 90 and patient supporting system) by pressing the main switch (**4**, Fig. 29, page 113).
  The green control lamp in the main switch indicates that the system is powered up.

When switched off, both poles (phase and neutral) of the MEL 90 should be disconnected from the power supply.



1 Key switch
2 Position of key switch **<On>**
3 Position of key switch **<Off>**
4 Position of main power switch **<Off>**

Fig. 29 Switching the device system off

Shutting down in the event of a technical failure

WARNING - GENERAL HAZARDS

If this device does not perform as described in these instructions for use, please carry out the following measures:

1. Turn the key switch to **<Off>** (**3**, Fig. 29, page 113) (some parts are still live).
2. Turn off the entire system using the main switch (**4**, Fig. 29, page 113).
3. Unplug the power plug from the mains.
   To completely disconnect the MEL 90 from the power supply, the power supply connector must be unplugged from the mains socket.
4. Ensure that the system cannot be put back into operation.
5. Inform the person authorized by the manufacturer that maintenance work needs to be carried out on the system.

Shutting down in the event of unintended mechanical movement and unintended laser radiation

WARNING - GENERAL HAZARDS

If the device makes unintended movements or applies unintended laser radiation, carry out the following measures:

Press the **<EMERGENCY STOP/EMERGENCY LASER STOP>** button (**1**, Fig. 8, page 33) immediately.

2. Turn the key switch to **<Off>** (**3**, Fig. 29, page 113) (some parts are still live).
3. Turn off the entire system using the main switch (**4**, Fig. 29, page 113).
4. Unplug the power plug from the mains.
   To completely disconnect the MEL 90 from the power supply, the power supply connector must be unplugged from the mains socket.
5. Ensure that the system cannot be put back into operation.
6. Inform the person authorized by the manufacturer that maintenance work needs to be carried out on the system.

Procedure and shutdown in case of fluorine emission

WARNING - CHEMICAL HAZARDS

The device contains compressed fluorine. If a pungent odor is perceived,

- ventilate the room thoroughly,
- bring everyone in the room into safety,
- use protective clothing.

Contact the manufacturer immediately. For further information, e.g. the currently valid hazard materials datasheet, please contact the supplier of the excimer laser gas.

First aid measures

General information

Symptoms of poisoning can occur after several hours, therefore medical observation is necessary for at least 48 hours after the accident.

Lie the affected person down and cover.

In case of respiratory distress, provide oxygen therapy.

Inhalation

Ensure that the patient has sufficient fresh air; lie him/her down.

Refer for medical treatment.

If the patient stops breathing, provide resuscitation bag or respirator.

Skin contact

Wash contaminated areas thoroughly with water.

Acid burns should be treated immediately, otherwise this could delay the healing of the wounds.

Eye contact

In case of contact with eyes, rinse carefully with plenty of water and refer for medical treatment.

Notes for the physician

Symptoms

The following symptoms can occur: unconsciousness, coughing, breathing difficulty, dizziness.

Risks

Risk of pulmonary edema.

Treatment

Rinse local chemical burns immediately with water (1-3 liters) for at least 30 minutes. If water is not available, rinse with milk.[1] Treat chemical burns by a local injection with calcium gluconate solution. In case of pulmonary irritation, use dexamethasone dosage aerosol as initial treatment.

[1] Akute Verätzung am Auge (Acute cauterization on the eye). S1-Leitlinie der Deutschen Ophthalmologischen Gesellschaft e.V. (DOG) und des Berufsverbands der Augenärzte Deutschlands e.V. (BVA) ((S1 guideline of the German Ophthalmological Society and the professional association of ophthalmologists in Germany). AMWF registry No. 045-018; 31.12.2020

Soleimani M, Naderan M. Management Strategies of Ocular Chemical Burns: Current Perspectives, Clin Ophthalmol 2020:14 2687-2699

Sharma M, et al. Treatment of acute ocular chemical burns. Surv Ophthalmol 2018; 63: 214-235

Fire fighting measures

Suitable extinguishing media

Adapt extinguishing measures to suit the environment.

Dry chemical agent

Unsuitable extinguishing agents for safety reasons

Water

Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases

Hydrogen fluoride (HF)

Special protective equipment for fire fighting

In the presence of combustion or carbonization gases, any firefighting, rescue and clearing up activities should be undertaken only with heavy-duty respiratory equipment.

Additional information

Cool any gas cylinder by spraying with water.

Maintenance and care

WARNING - GENERAL HAZARDS

The system may only be opened, put into operation, modified and repaired by the manufacturer's customer service technicians (trained ZEISS personnel). If in doubt, insist on seeing the written authorization or contact Carl Zeiss Meditec AG directly.

The manufacturer is not liable for damage caused by unauthorized tampering with the device. Such actions will render any warranty claims invalid.

All procedures for adjusting, cleaning, sterilization and disinfection listed in the accompanied documentation must be performed.

After installation and after modifications of the installation during the operative lifetime of the device the operator must ensure compliance with the IEC 60601-1 standard.

There are a number of warning messages which may be displayed on the monitor of the MEL 90 computer. These messages must be acknowledged by the user.

Troubleshooting

Turn off the device immediately if it emits smoke, sparks or strange noises. Label the device as defective and call ZEISS Service.

The device contains compressed fluorine. Should a pungent smell be perceived, ventilate the room thoroughly. Get everyone in the room to safety. Notify ZEISS Service immediately.

For further information, e.g. the currently valid hazard materials datasheet, please contact ZEISS Service.

In the event of an electric shock, pull the plug immediately and label the device as defective. Do not use the device until it has been repaired and certified by ZEISS Service.

Internal components remain energized even after the device has been switched off with the key switch. Use the main power switch (**2**, Fig. 6, page 33) on the connector panel of the MEL 90 to switch off the complete system. The device must be unplugged to disconnect it completely from the power supply.

Localizing faults
Generating a system diagnosis file

The device has a function for generating a system diagnosis file.
This service log file can help in remote diagnostics to take the appropriate action if the device is not functioning properly.

To generate an incident report, proceed as follows:

- Start the device using the key switch. Wait until the OPASS software **Login** dialog appears on the monitor.
- Press the **<Start>** (**6**, Fig. 14, page 43) button.
- Wait until the warm up of the laser is complete.
- Insert the USB drive into one of the USB ports (**4**, Fig. 8, page 33).
- Under **User name** in the **Login** dialog (see page 44) select your user name and enter your password in the **Password** field. Then tap **Login**.
- Tap the **Configuration** button in the main dialog of the OPASS software.
- Tap the Incident report button in the Configuration Settings menu.
- Enter information on the problem which has occurred in the **Configuration Incident report** dialog.
- Select the USB drive as the destination drive.
- 
- Tap the **Create report** button and wait until the incident report has been saved on the USB drive.
- Send the ***.IRF** file to Service & Support Refractive Lasers (support.refractivelaser@zeiss.com).

Automatic energy system warning messages

The actual laser energy value should not normally deviate by more than a few percent. This difference should only exceed this amount briefly during the adjustment phase (max. 1 minute) or during operation.

If the actual energy value deviates from the target value by more than 10 %, a warning message will be displayed on the monitor.

If this value deviates from the target value by more than 20 %, the fluence test will be interrupted. If you wish to continue the fluence test tap **Next** in the following safety check. Contact ZEISS Service for telephone support, if necessary.

If the energy value deviates from the target value by more than 30 %, you will not be able to continue the treatment.

If the difference between actual and target energy values during the energy adjustment phase is constantly too high and the gas lifetime display is approaching 0 %, change the gas then check whether the automatic energy system subsequently functions correctly.

Gas change warning message

If the automatic energy system is almost at the limit of the permitted range, a message will be displayed on the monitor prompting you to carry out a gas change.
You will be able to finish the current treatment, but should carry out a gas change before starting the next treatment.

To initiate the automatic gas change, tap on **Gas change** on the **Welcome** main dialog.

The progress of the gas change is shown by markings (ticks) in the boxes in front of the listed parts and by the progress bars.

☞ The gas change alters the performance parameters of the laser, meaning that a fluence test needs to be carried out after every gas change.

Fuses

A thermal safety cutout is integrated into the MEL 90 electrical supply. If this cutout is triggered, the device is disconnected from the power supply.

Wait for approximately two minutes before switching on the device again.

If the safety cutout is triggered repeatedly, please contact ZEISS Service.

Maintenance

User maintenance

The user is responsible for carrying out the following:

- Visual inspection for damage prior to switching the device on
- Fluence test
- Replacing the filter when device is switched off

CAUTION - BIOLOGICAL HAZARDS

Caution, laser flue gases may contain viable tissue particles. Please adhere to the following replacement intervals.

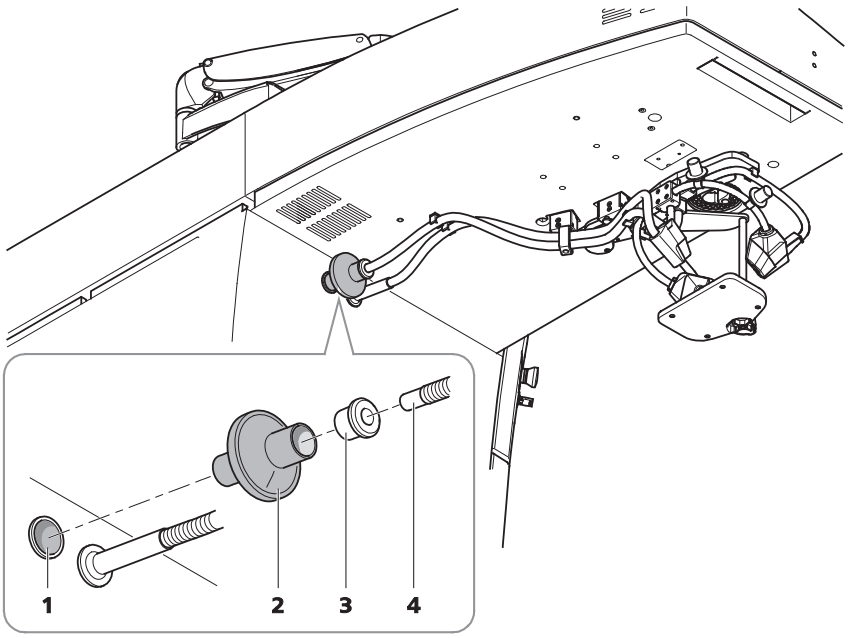
Replacing the compressed air filter

The MEL 90 laser is equipped with CCA+ smoke extraction technology. To prevent the development of foci of bacteria and fungi, replace the filters (and hoses) monthly even if they appear not to be contaminated.

- The compressed air filter (**2**, Fig. 30, page 121) is located outside the device beneath the laser arm.
- Remove the hose and hose adapter (**4** and **3**, Fig. 30, page 121) from the filter.
- Pull the old compressed air filter out of the filter fitting (**1**, Fig. 30, page 121) and insert a new one.

Use the compressed air filter from the Carl Zeiss Meditec AG "Filter and hose set" (see section *Optional parts*, page 130).

- Replace all the external hoses visible beneath the laser arm (see section *Replacing the hoses*, page 123) with new ones.



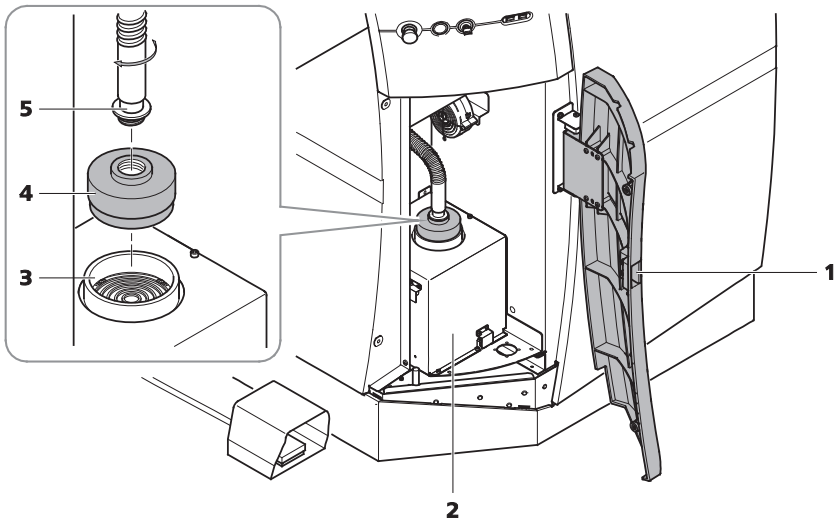
1 Filter fitting for compressed air filter
2 Compressed air filter
3 Hose adapter
4 Compressed air circuit hose

Fig. 30 Replacing the compressed air filter

Replacing the suction filter

- To change the suction filter open the door of the CCA+ unit (**1**, Fig. 31, page 122) at the front of the basic unit.
- Pull the suction filter (**4**, Fig. 31, page 122) and hose from the filter fitting (**3**, Fig. 31, page 122) of the suction unit (**2**, Fig. 31, page 122).
- Twist the hose adapter (**5**, Fig. 31, page 122) off the filter.
- Twist a new filter onto the hose adapter and replace it in the opening of the suction unit.

Use the suction filter from the Carl Zeiss Meditec AG "Filter and hose set" (see section *Optional parts*, page 130).



1 Door of CCA+ unit
2 Suction unit
3 Filter fitting for suction filter
4 Suction filter
5 Hose adapter with hose

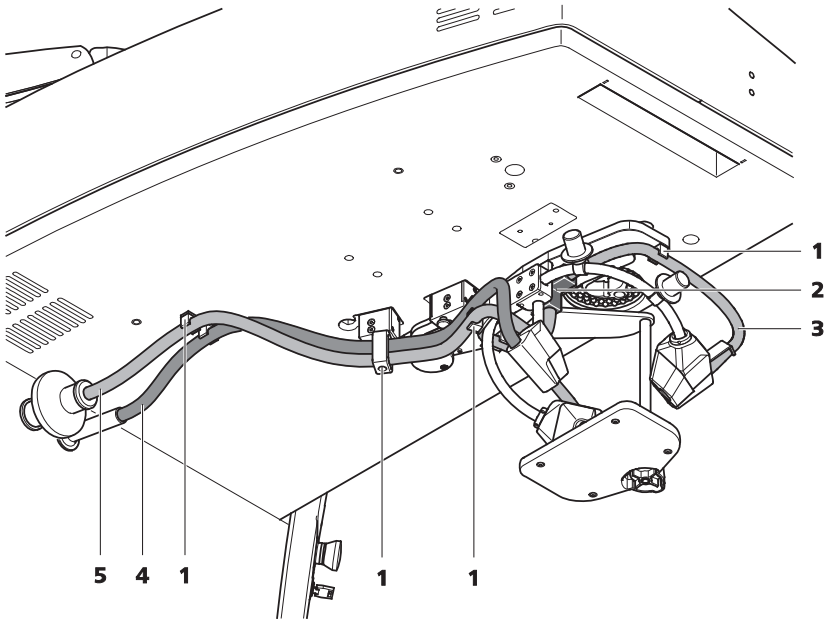
Fig. 31 Replacing the suction filter

Replacing the hoses

- Pull all hoses out of their respective connections - if this was not already done during the filter change.
- Release the hoses from the hose holders (**1**, Fig. 32, page 123) and take the distributor (**2**, Fig. 32, page 123) out of its holder (two holding pins).
- Replace all the external hoses visible beneath the laser arm (**3**, **4**, **5**, Fig. 32, page 123) and the distributor (**2,** Fig. 32, page 123) with new hoses and a new distributor.

Only use the hoses and the distributor (T-piece) from the Carl Zeiss Meditec AG "Filter and hose set" (see section *Optional parts*, page 130).

- When connecting the hoses note the labels on the connections and use the hose holders.



1 Hose holders (six hose clamps and a hose eyelet)
2 Distributor (Tee)
3 Compressed air circuit hose - short (2x)
4 Suction circuit hose - long (1x)
5 Compressed air circuit hose - long (1x)

Fig. 32 Replacing the hoses

Maintenance by ZEISS Service

In some countries there are inspection intervals for pressurized components. After a service life of the MEL 90 of five years, please contact ZEISS Service to replace the gas system of the MEL 90 if necessary.

Upon request, Carl Zeiss Meditec AG will provide the service technicians with electric circuit diagrams, component lists, descriptions, calibration instructions and other information to support the repair of device components which can be repaired by service technicians.

Changing the gas cylinder

Gas cylinder and gas filter replacement may only be performed according to the currently valid instructions of ZEISS Service.

Cybersecurity Maintenance

A special component - the Gate Control - connects the MEL 90 device to the site network and provides protection against network-based cybersecurity threats. To prevent cybersecurity events, the MEL 90 Gate Control software should be updated whenever Carl Zeiss Meditec AG issues software updates or patches for the Gate Control component. All software updates or patches are installed only by trained ZEISS personnel.

Care and cleaning

CAUTION - BIOLOGICAL HAZARDS

National disinfecting regulations must be observed in the choice of disinfectants and disinfection procedures.

Contaminated parts with which the patient has come into contact during the treatment should be cleaned with a disinfectant approved for the purpose.

The disinfectant manufacturer's instructions for use and exposure time must be observed.

CAUTION - RISK FROM DEVICE OPERATION

Protect all optical exits (laser aperture and surgical microscope tube) against contamination and avoid touching optical exits.

CAUTION - RISK FROM DEVICE OPERATION

Please note that the vapors of some cleaning agents and disinfectants (especially agents containing alcohol) reduce the laser radiation transmission.

CAUTION - PROPERTY DAMAGE

Use only disinfectants approved by the manufacturer for the treatment of plastics and painted metal surfaces.

The surface of the device is resistant to the following mixtures of substances:

- 70 % isopropyl alcohol
- 2 % glutaraldehyde
- 0.2 % didecyldimethylammonium chloride
- in demineralized water

The surface of the device is resistant to the following mixtures of substances:

- Dismozon®

For disinfectants with a different composition, damage to the device cannot be excluded.

Do not use any aggressive or abrasive cleaning agents.

The product has not been tested for resistance to UV rays. Repeated or permanent exposure to UV rays may result in color or mechanical changes.

☞ Do not use acetone and acetone-based cleaning agents to clean the devices, as they could damage the surfaces.

Sterilization

The following are provided to avoid cross contamination between user and patient:

- sterilizable adapters for control elements (these must be sterilized by the user before use) and
- disposable products as sterile coverings.

CAUTION - BIOLOGICAL HAZARDS

The adapters should be sterilized before use, taking national and facility regulations into account.

Sterilizable adapters

Overview and use

Designation	Use	Supplier
Sterilizable caps 12 mm	Push and turn switch for ring illumination Rotary switch for satellite illumination	Carl Zeiss Meditec AG[2]
Sterilizable caps 22 mm	OPMI magnification changer	Carl Zeiss Meditec AG[2]
Cap 12D x 30[1]	CCA+ unit Optional hand-held slit lamp	Carl Zeiss Meditec AG[2]
Instrument protective cap	Optional hand-held slit lamp	Carl Zeiss Meditec AG[2]

[1] Caps on CCA+ and optional hand-held slit lamp are included with the MEL 90.
[2] Please contact ZEISS Service or your local dealer.

General information

CAUTION - BIOLOGICAL HAZARDS

Sterilizable parts should be sterilized in compliance with the accompanying documentation.

The sterilizable adapters are delivered in unsterile condition.

The sterilizable adapters can be sterilized in an autoclave. Heat sterilization should be performed as follows:

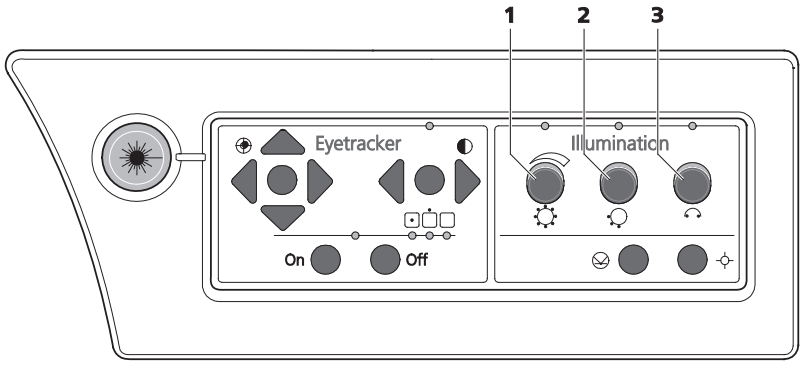
Sterilization time (time of exposure at sterilization temperature):
at least 5 minutes at 132 °C/134 °C

Detailed information on sterilization of the sterilizable caps can be found in the "Preparing resterilizable products" instructions for use of the sterilizable caps used.

When attaching the sterilizable adapter to the MEL 90, the user must be sterile and ensure that unsterile areas are not touched directly.

Sterilizable cap 12 mm

The adapters for knobs and push and turn switches for use with the sterilizable caps are supplied with the device and can be installed by ZEISS Service if required.

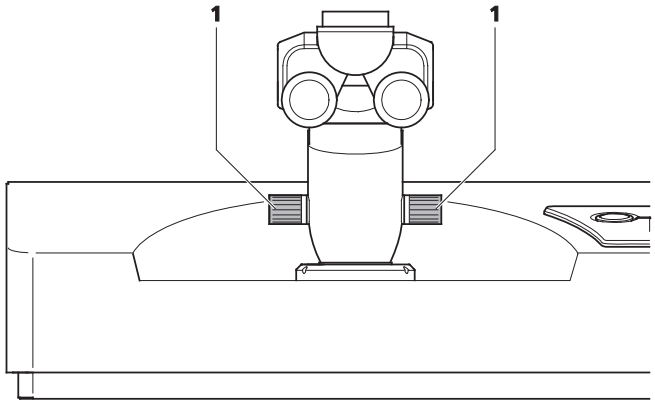


1 Sterilizable cap 12 mm for rotary/push button for the ring illumination
2 Sterilizable cap 12 mm for rotary/push button for segmenting the ring illumination
3 Sterilizable cap 12 mm for satellite illumination rotary switch

Fig. 33 Sterilizable caps on the control panel (laser arm)

Sterilizable cap 22 mm

Two sterilizable 22 mm caps are used for each magnification changer of the OPMI pico.

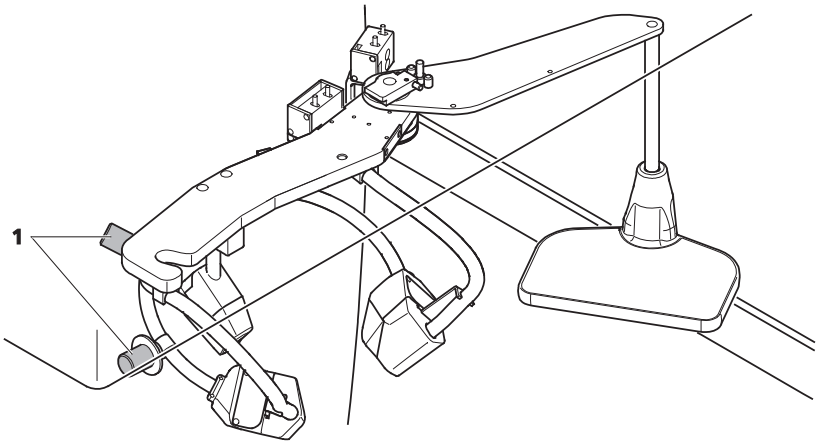


1 22 mm sterilizable caps for magnification changer (right and left)

Fig. 34 Sterilizable caps on OPMI pico

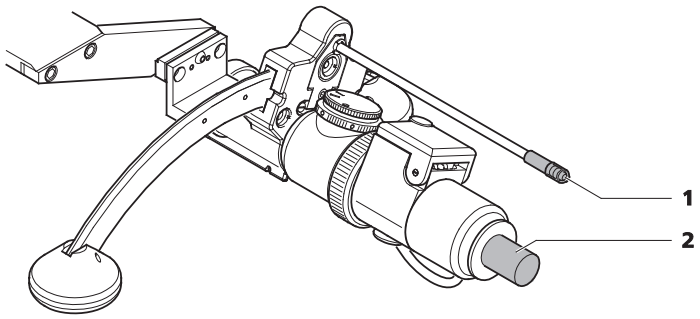
Cap 12D x 30

12 mm sterilizable caps can also be used instead of the 12D x 30 caps on the CCA+ unit and the optional hand-held slit lamp.



1 Caps for swivel arm grip

Fig. 35 Caps on the CCA+ unit



1 Instrument protective cap
2 Cap

Fig. 36 Caps on the optional hand-held slit lamp

Instrument protective cap

The upper locking handle of the hand-held slit lamp is covered by an instrument-protective cap (**1**, Fig. 36, page 129).

Sterile covers

We recommend to use a sterile cover for the external MEL 90 PC keyboard.

When attaching a sterile cover to the MEL 90, the user must be sterile and ensure that unsterile areas are not touched directly.

Modifications

This device must not be changed without approval of the manufacturer.

Safety inspections

WARNING - GENERAL HAZARDS

The responsible organization must ensure that this medical product is subjected to a safety inspection once a year. Safety inspections may only be performed by personnel authorized by the manufacturer.

Optional parts

WARNING - GENERAL HAZARDS

The medical products related to the device, related parts including software and other related objects may only be operated and used if they have been approved by the manufacturer or if they are specified in these instructions for use, taking the indication for use and the safety of patients, users, employees and third parties into consideration.

Anyone who connects additional devices to the signal inputs or outputs is creating a medical device system and must ensure that it conforms to the system requirements of IEC 60601-1.

The use of parts with the device via portable multiple sockets is not permitted.

Do not install any electrically operated optional parts within the patient environment that do not comply with IEC 60601-1.

The following parts can be used with the MEL 90:

- Hand-held slit lamp
- External keyboard, English
- Keyboard holder
- Touchscreen monitor 18.5"/1366x768 (use supplied power supply unit)
- Part for external monitor
- Adapter set for combination with VisuMax
- Sterilizable adapters (see page 126, section *Sterilizable adapters*)
- Sterile covers (see page 129, section *Sterile covers*),

A complete, up-to-date list of parts can be obtained from ZEISS Service or your local dealer.

Consumables

- Bulbs for hand-held slit lamp (halogen lamps)
- Filter and hose set
- Fluence test paper (test card set)

A complete, up-to-date list of parts can be obtained from ZEISS Service or your local dealer.

Hand-held slit lamp

WARNING - RISK FROM RADIATION ENERGY

Cautionary statement in accordance with ANSI Z80.36:

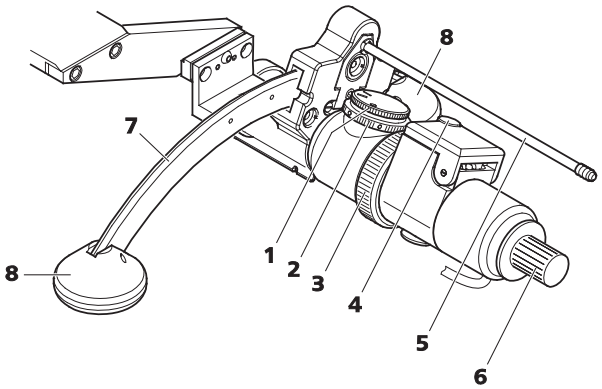
CAUTION: - The light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater is the risk of ocular damage. Exposure to light from this instrument when operated at maximum intensity will exceed the recommended maximum exposure (RME) of 2.2 J/cm², unless additional action is taken by the user to minimize exposure, after 1.3 min. The risk of retinal injury at an exposure of 2.2 J/cm² is not high, but because some patients may be more susceptible than others, caution is advised if this radiant exposure value is exceeded. However, because of a significant risk of injury at exposures exceeding 10 J/cm², the user should avoid exposures longer than 6.0 min.

Operating principle

The illumination unit produces an evenly illuminated field approximately 8 cm in front of a reflecting prism, the geometry and color of which can be varied by the use of apertures and filters.

Apertures:	Slit aperture/pinhole aperture
Filters:	Red-free filter (green filter) excitation filter for fluorescence (blue filter)

Illumination unit



1 Slit width selector knob (narrow, wide, free aperture)

2 Filter wheel for inserting filters (blue filter, green filter, no filter)

3 Knurled ring for adjusting the diameter of the field of illumination or the slit length

4 Knurled screw for opening the lamp cover
5 Lever for unlocking the hand-held slit lamp (with protective cap)
6 Handle (with sterilizable cap)
7 Guide rail
8 Impact protection (2x)

Fig. 37 Hand-held slit lamp (optional)

Operation

☞ An internal collision sensor is integrated in the hand-held slit lamp. This interrupts the elevation of the patient supporting system as soon as the patient's head displaces the hand-held slit lamp.

- Using the handle (**6**, Fig. 37, page 132), swivel the slit lamp under the microscope. The hand-held slit lamp will be automatically switched on.

☞ The examination distance is determined by the working plane of the laser.

- Select a slit or circular luminous field by turning the knob (**1**, Fig. 37, page 132) to the desired mark (narrow slit, wide slit, circular field).
- Select the slit length or the diameter of the field of illumination by turning the knurled ring (**3**, Fig. 37, page 132).

☞ To avoid unwanted reflections, the smallest possible illumination field size should be selected.

- Select the required filter using the filter wheel (**2**, Fig. 37, page 132).

Blue dot:	Blue filter
Green dot:	Green filter
White dot:	No filter

☞ The colored dot of the selected filter points in the direction of the patient.

- Adjust the angle between the observation and illumination direction:
  - Release the guide rail clamp by pressing the lever (**5**, Fig. 37, page 132) towards the handle.
  - With the lever held in the pressed position, adjust the angle between the observation and illumination directions.
  - Release lever at desired angle.
    The illumination unit is secured in this position.

- The slit lamp will be automatically switched off when swiveled back.

Replacing the halogen bulb

WARNING - RISK FROM ELECTRIC ENERGY

Do not replace the halogen lamp while a patient is on the patient supporting system. This is to prevent you from accidentally touching the patient and the lamp contacts simultaneously.

CAUTION - THERMAL ENERGY RISK

There is a risk of burns if the bulb is replaced immediately after bulb failure! Allow the lamp to cool, or use heat-proof gloves.

Use only halogen lamps with product number 000000-0120-703. Do not use other bulbs!

To avoid contamination, do not touch the glass body.

To replace the halogen bulb, proceed as follows:

- Switch off the device and disconnect the power cable.
- Unscrew the knurled screw (**4**, Fig. 37, page 132) and swing up the lamp cover.
- Remove the defective bulb by the base.
- Holding the lamp by the base, insert the new bulb into the fitting so that the locating pins engage in the groove.
- Replace the lamp cover and tighten the knurled screw (**4**, Fig. 37, page 132).

Check the illumination after lamp replacement:

- Swivel the slit lamp into position.
- Close the field aperture using the knurled ring (**3**, Fig. 37, page 132).
- Hold a sheet of white paper directly in front of the light aperture. The projected filament image should be positioned horizontally in the light aperture and completely fill the reflecting prism.

Printer

The printer must be installed by trained ZEISS personnel.

CAUTION - BIOLOGICAL HAZARDS

The printer must conform to the relevant hygiene standards of the place where located.

Only a PostScript-compatible network printer with PostScript Level 3 and 10/100 BASE-TX interface may be used.

Further information on printer operation may be found in the instructions for use for the printer.

Connecting the system to a network printer available in a clinic or practice network

CAUTION - GENERAL HAZARDS

MEL 90 and printer may be connected via a network, which is protected from the outside by suitable protective measures (IEC 80001-1 includes instructions on addressing these risks) (see *Network integration*, page 7 and following).

The Ethernet cable used must conform to the following specifications:

- length max. 5 m,
- double-shielded cable,
- at least CAT 7.

Connecting a printer to the MEL 90 and VisuMax combination

CAUTION - GENERAL HAZARDS

MEL 90, VisuMax, Ethernet switch and printer may only be connected directly or via a network consisting exclusively of devices approved for this purpose by Carl Zeiss Meditec AG. It is not permitted to connect the device to a clinic, practice or public network.

The printer must be connected via an Ethernet switch conforming to the following specifications:

- 10/100 BASE-TX-standard,
- local approval (e.g. CE, CSA, UL).

We recommend a "Cisco Series 100" Ethernet switch type.

The Ethernet cable used must conform to the following specifications:

- length max. 5 m,
- double-shielded cable,
- at least CAT 7.

Additional monitors

Assistance monitor

Only the assistance or co-observer monitor (see section *Optional parts*, page 130) may be used. Use of a different monitor can cause the device to malfunction.

The are two usage options if an extra assistance monitor is used:

Assistance monitor for OPASS operation (clone mode)

The OPASS software and the treatment procedure is shown on the touchscreen monitor and on the assistance monitor.

Assistance monitor for co-observer image (extended mode)

In this variant the OPASS software is shown on the touchscreen monitor with the treatment procedure whereas the assistance monitor shows the co-observer image of the OPMI pico.

Once the treatment starts, the co-observer image appears on the assistance monitor. After leaving the **Report** dialog, the co-observer image is discontinued.

- The assistance monitor is connected via the DVI/DP output (**2**, Fig. 10, page 35) and one of the USB ports (**4**, Fig. 10, page 35) to the connector panel of the MEL 90.
- For details on the power supply see section *Technical data*, page 139.

CAUTION - GENERAL HAZARDS

The assistance monitor may only be operated using the respective power supply unit.

Co-observer monitor

A monitor (not provided by Carl Zeiss Meditec AG) can be connected via HDMI to display the HD co-observer image.

The OPASS software is shown on the touchscreen monitor with the treatment procedure whereas the co-observer monitor shows the HD co-observer image of the OPMI pico.

Once the treatment starts, the co-observer image appears on the co-observer monitor. After leaving the **Report** dialog, the co-observer image is discontinued.

The monitor is connected via the HDMI co-observer video output to the connector panel of the MEL 90 (**3**, Fig. 10, page 35).

WARNING - RISK FROM ELECTRIC ENERGY

If connecting the co-observer monitor via HDMI to MEL 90, ensure a safe isolation (4 kV in accordance with IEC 60601-1).

Anyone who connects additional devices to the signal inputs or outputs is creating a medical device system and must ensure that it conforms to the system requirements of IEC 60601-1.

WARNING - RISK FROM ELECTRIC ENERGY

The use of parts with the device via portable multiple sockets is not permitted.

Do not install any electrically operated optional parts within the patient environment that do not comply with IEC 60601-1.

The HDMI cable used must conform to the following specifications:

- length max. 3 m
- double-shielded and foil shield cable
- copper-shielded plugs

Keyboard holder

Using the optional keyboard holder (**11**, Fig. 4, page 31) an external keyboard can be positioned ergonomically within the reach of the user.

- The door of the CCA+ unit (**13**, Fig. 4, page 31) must be opened to mount the keyboard holder.
- Slot the keyboard into the recesses on the top edge of the door and then close the door again.

External keyboard

The external keyboard (**7**, Fig. 4, page 31) can be used optionally for operating the OPASS software.

The external keyboard can either be placed on the rest edge (**8**, Fig. 4, page 31) of the basic unit or on the optional keyboard holder (**11**, Fig. 4, page 31).

- It is connected via one of the USB ports on the control panel of the basic unit (**4**, Fig. 8, page 33) or to the connector panel of the MEL 90 (**4**, Fig. 10, page 35).

Technical data

Characteristics

Essential performance
The essential performance feature is the accuracy of energy and positioning of the laser treatment radiation in relation to the patient's eye. The patient supporting system should not move during treatment.
The essential performance feature is documented by a correct fluence test.
An essential performance feature is a feature that is required to achieve freedom from unreasonable risks.

☞ Short voltage interruptions may lead to functional failures.
To avoid this we recommend an independent power supply.

Characteristics of laser radiation	
Laser source:	ArF excimer laser
Laser class:	4 (according to IEC 60825-1:2001/2007/2014)
Energy:	1.00 ± 0.15 mJ
Wavelength:	193 nm
Half beam divergence:	35 mrad ± 20 %
Repetition rate:	500 Hz
Pulse width:	4 to 7 ns
Beam dimensions:	0.7 mm FWHM diameter, Gaussian profile
Treatment area:	max. 10 mm x 10 mm
Energy density at the eye:	> 150 mJ/cm^2
Safety distance (NOHD):	13.6 m (100 s exposure time)

Specifications of other radiation sources	
Aiming beam:	Laser class 1 according to IEC 60825-1: 2007/2014
Distance lasers:	Laser class 1 according to IEC 60825-1: 2007/2014
Fixation laser:	Laser class 1 according to IEC 60825-1: 2007/2014
Ring illumination:	Group 2 according to Z80.36:2021
Satellite illumination:	Group 2 according to Z80.36:2021
Infrared illumination:	Group 2 according to Z80.36:2021

Specifications of pressurized components	
Gas cylinder (excimer laser gas)	
Volume:	max. 11 liters
Pressure:	max. 14.7 MPa (147 bar)
Gas:	ArF with max. 0.2 % fluorine
☞ The material safety data sheet can be ordered via the service hotline of Carl Zeiss Meditec AG.	
High pressure circle	
Volume:	max. 0.012 liters
Pressure:	max. 15 MPa (150 bar)
Gas:	ArF with max. 0.2 % fluorine
Low pressure circle including laser tube:	
Volume:	max. 2.3 liters
Pressure:	max. 850 kPa (8.5 bar)
Gas:	ArF with max. 0.2 % fluorine

Surgical microscope specifications	
Magnification:	0.4x, 0.6x, 1.0x, 1.6x, 2.5x
Eyepieces:	10x

Eyetracking specifications	
Active Eyetracker; high speed:	1050 fps

Slit lamp illumination specifications (optional parts)	
Halogen bulb:	6 V, 10 W, PG22 (product number 000000-0120-703)
Slit images:	narrow slit, wide slit, circular field

Signal inputs and outputs
1 x co-observer HDMI video output, not isolated
1 x connector for remote interlock
1 x DVI/DP port, not isolated
4 x USB, not isolated
1 x network connector, RJ45 socket, isolation specified for at least 4 kV and according to IEC 60601-1
1 x EMERGENCY STOP/EMERGENCY LASER STOP interface
1 x port for foot switch
1 x Interlock port for patient supporting system
1 x RS232 interface

Mechanical characteristics	
MEL 90 basic unit dimensions:	L x W x H: 1.63 m x 0.73 m x 1.48 m to 1.70 m
MEL 90 basic unit weight including gas cylinder:	295 kg

Installation requirements

Requirements for electrical installation	
Power supply:	100 V AC ± 10 %; 50/60 Hz; 17.5 A
	120 V AC ± 10 %; 50/60 Hz; 14.6 A
	208/220/230/240 V AC ± 10 %; 50/60 Hz; 7.9 A
Overvoltage category of the mains supply (according to IEC 60664-1):	II
The electrical installation conforming to IEC 60364-7-710 or the applicable national regulations.	
Protection of the electrical circuit by circuit breaker of the building and earth-leakage circuit-breaker	
Power output for patient supporting system:	230 V AC; 500 VA

Assistance monitor: Requirements for electrical installation	
Power supply:	100 V to 250 V AC; 50/60 Hz; 1.5 A to 0.75 A

Requirements for the installation area	
Footprint including standard patient supporting system:	L x W: 3.28 m x 3.03 m
Footprint including VisuMax 180°:	L x W: 4.50 m x 3.79 m
Footprint including VisuMax 90°:	L x W: 3.92 m x 3.94 m
Footprint including VISUMAX 600/800:	L x W: 4.58 m x 3.06 m
Clearance between wall and rear of the device:	at least 20 cm
Clearance between patient supporting system and fixed installation:	in extreme positions at least 25 cm

Installation site

All figures in the illustrations below are given in "mm".

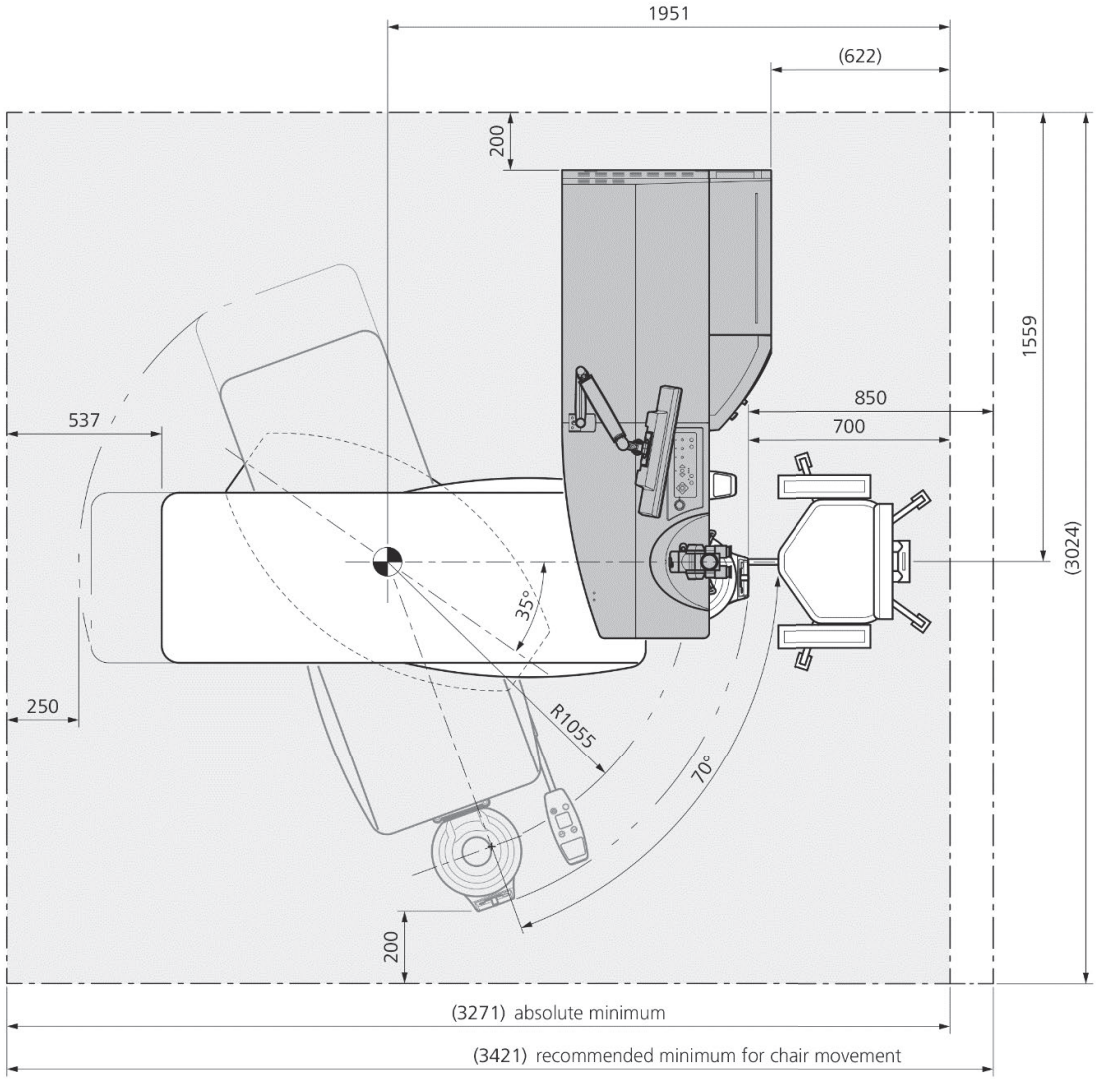


Fig. 38 Space requirements of the MEL 90

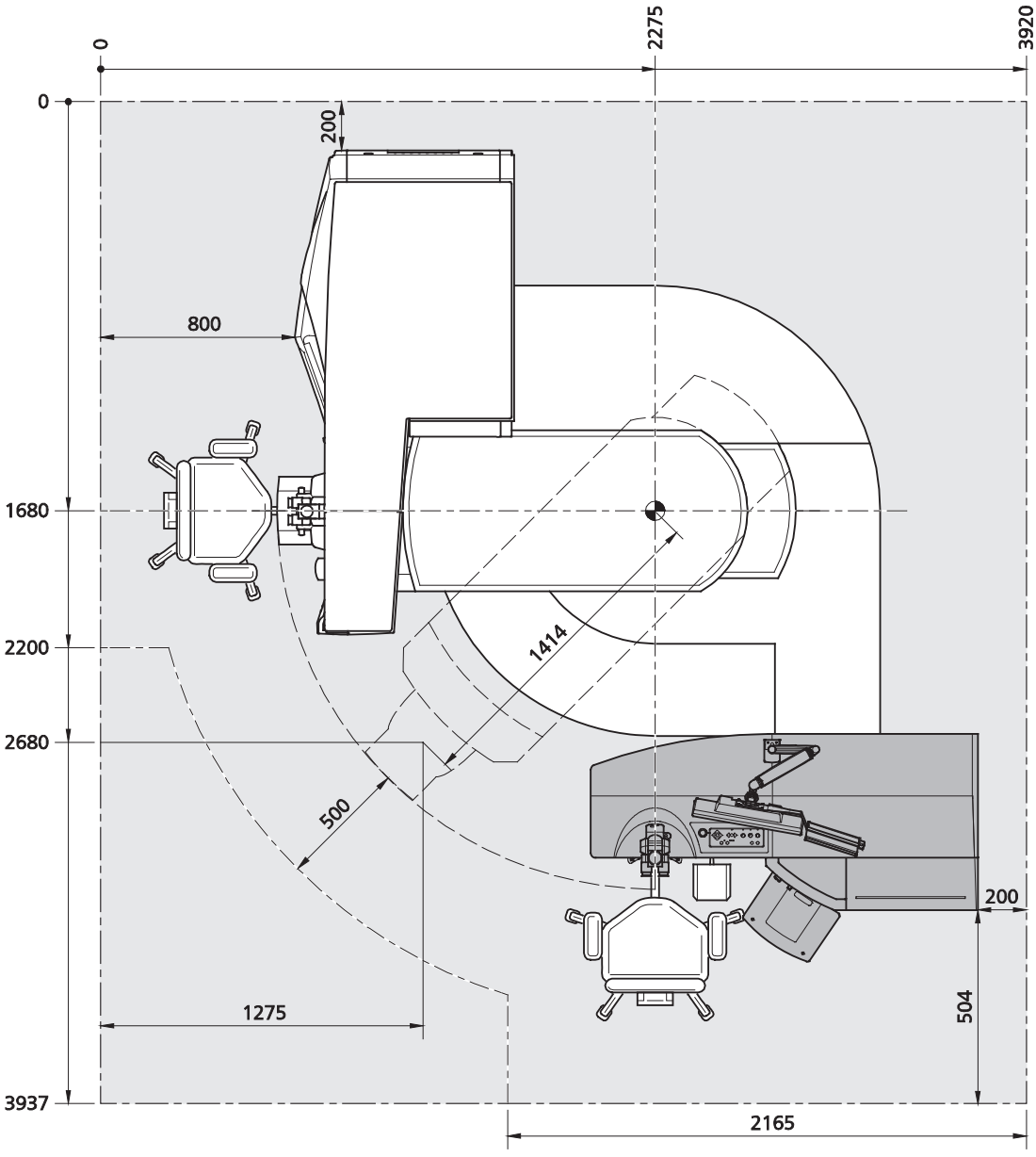


Fig. 39 Space requirements of the MEL 90 and VisuMax device system 90°

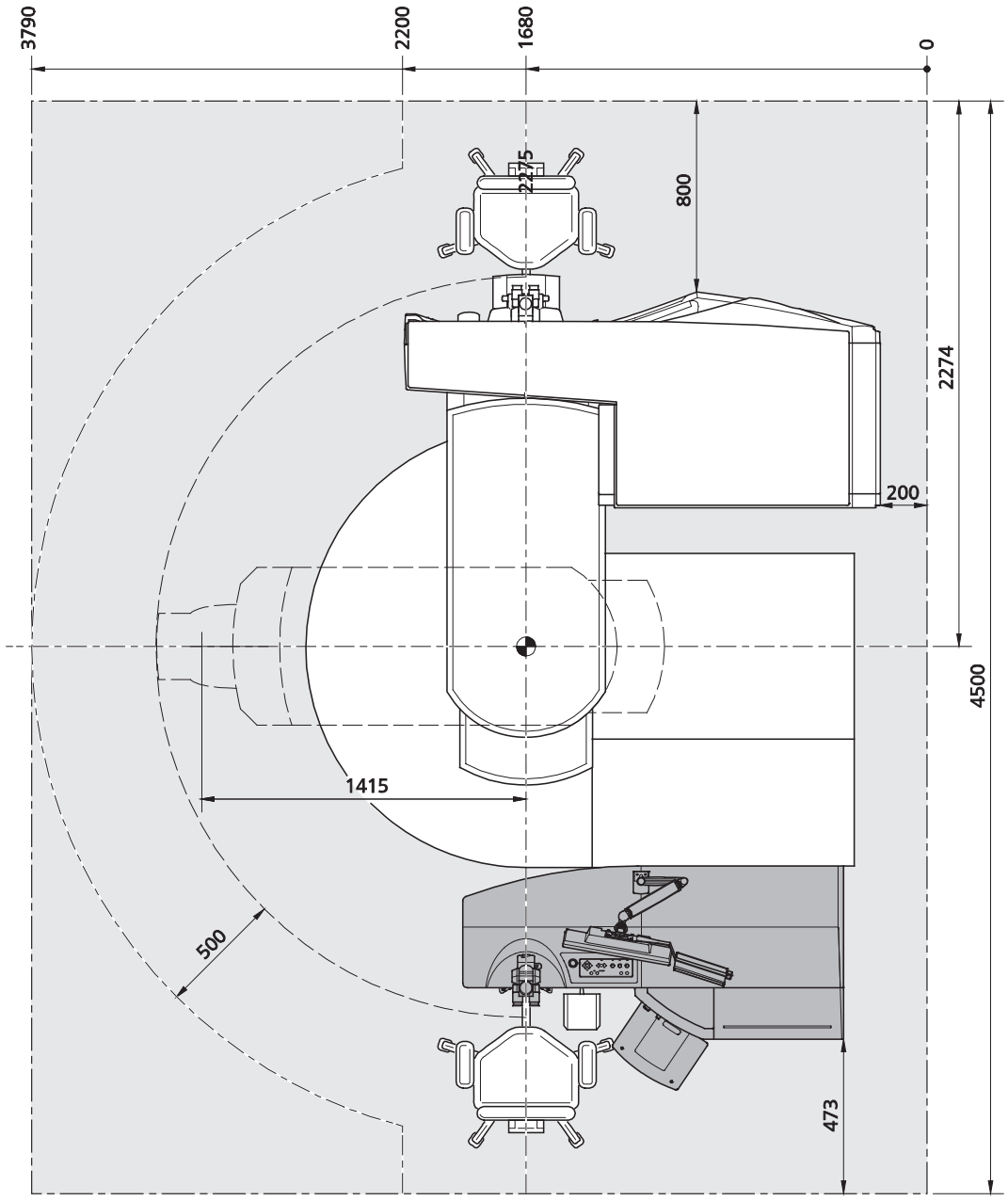


Fig. 40 Space requirements of the MEL 90 and VisuMax device system 180°

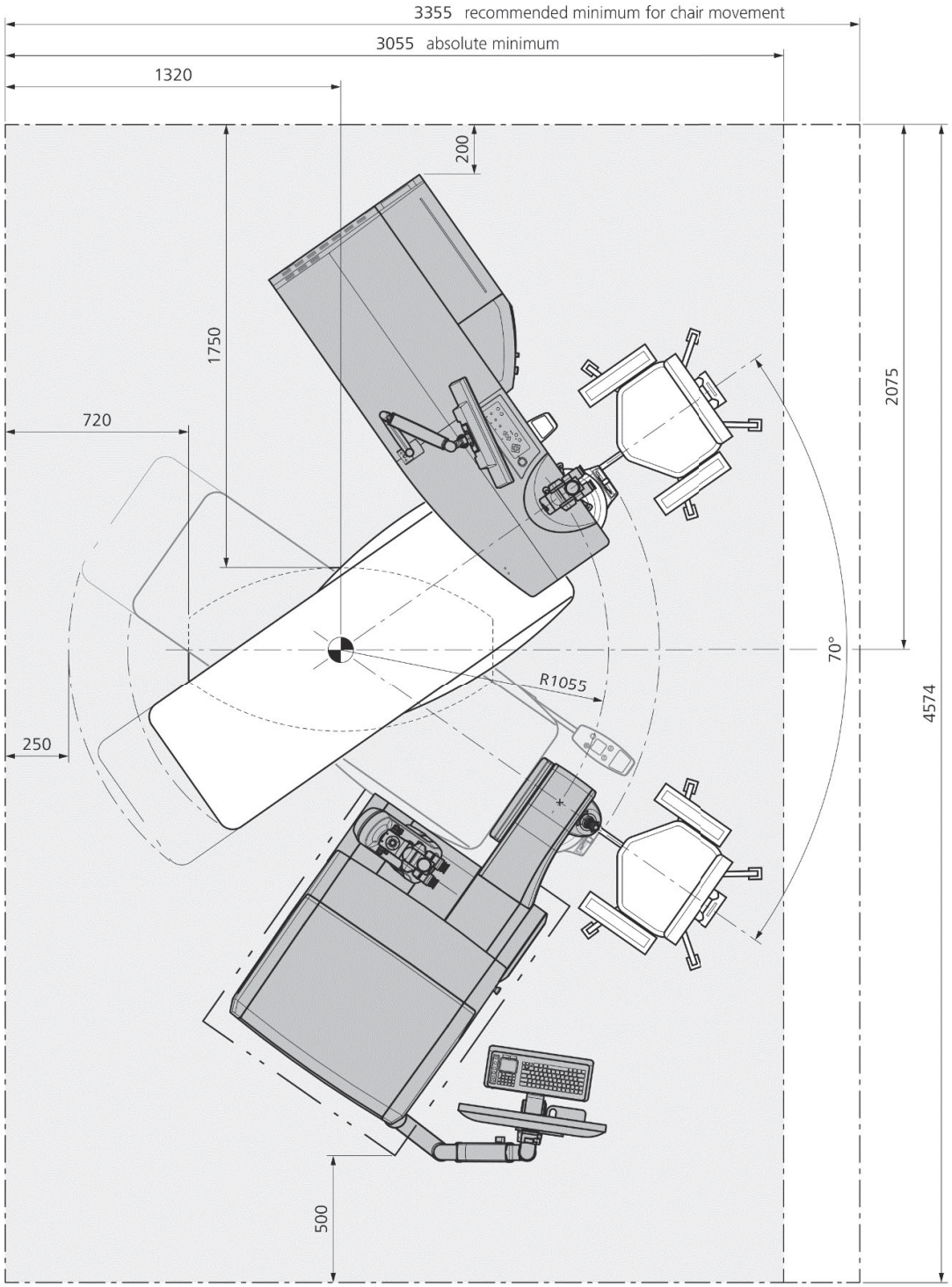


Fig. 41 Space requirements of the MEL 90 and VISUMAX 600/800 device system

Ambient conditions for intended use	
Temperature:	+18 °C to +24 °C, tolerance during treatment is < 1 °C
Relative humidity:	< 50 %, tolerance during treatment is < 1 %
Altitude:	< 3000 m (atmospheric pressure range: 700 hPa – 1060 hPa) In combination with ZEISS VisuMax or ZEISS VISUMAX 600/800 devices, please note the altitude of ZEISS VisuMax or ZEISS VISUMAX 600/800

Ambient conditions for on site storage	
Temperature:	+15 °C to +30 °C
Relative humidity:	< 50 %
Air pressure:	500 - 1060 hPa

Ambient conditions for external storage and transport in original packaging	
Temperature:	-15 °C to +40 °C
Relative humidity:	< 95 %
Air pressure:	500 - 1060 hPa

Classification

Type of protection against electric shock:	Protection class I
Degree of protection against electric shock:	Type B applied part
Ingress protection rating against penetration by water and solids:	IP 20
Approved sterilization and disinfection methods:	Wipe down and disinfect the application parts following the instructions in the section *Care and cleaning*, page 124
Protection rating for application in the presence of combustible mixtures of anesthetic, air, oxygen or nitrous oxide:	Medical device that is not suitable for operation with combustible mixtures of anesthetic, air, oxygen or nitrous oxide.
Transport specifications:	Fixed installation (can only be transported by ZEISS Service)

Thresholds of adjustment ranges

The approved range is listed in chapter Indications for use, page 13.
Furthermore, the following limitations apply:

Repetition rate 500 Hz (LASIK)

Myopia

Diameter of optical zone [mm]	**Myopia** [D] **(sphere)**	**Myopic astigmatism** [D] **(cylinder)**	**Further limitation** [D]
6.0 to 6.62	0 to -10	0 to -4	MRSE to -11*
6.63 to 7.0	0 to -10	0 to -4	sphere + cylinder to -11

*Treatment of -10.00 through -11.00 D spherical equivalent will present a flagged warning to the user indicating that correction of these powers is outside the range of the approved indications for use.

Hyperopia

Diameter of optical zone [mm]	**Hyperopia** [D] **(sphere)**	**Hyperopic astigmatism** [D] **(cylinder)**	**Further limitation** [D]
6.0 to 7.0	0 to +5	0 to +4	MRSE to +5*

*Treatment of > +4.00 D sphere (in plus-cylinder notation) will present a flagged warning to the user indicating that correction of these powers is outside the range of the approved indications for use.
Treatment of > +3.00 D through +4.0 D cylinder will present a flagged warning to the user indicating that correction of these powers is outside the range of the approved indications for use.

Mixed astigmatism

Diameter of optical zone [mm]	**Mixed astigmatism** [D] **(sphere)**	**Mixed astigmatism** [D] **(cylinder)**	**Further limitation** [D]
6.0 to 7.0	0 to +4	> 0.5 to 4	|cylinder| ≥ |sphere| *

*Treatment of mixed astigmatism with cylinder > 0.50 D through 1.00 D will present a flagged warning to the user indicating that correction of these powers is outside the range of the approved indications for use.

☞ The specified parameter ranges are only accessible under the most favorable parameter combination. Additional limitations and inter-parameter dependencies can reduce the adjustable range.

Electromagnetic compatibility

Special precautionary measures apply to this device with regard to electromagnetic compatibility (EMC). To avoid electromagnetic disturbances which may have serious impact on the patient or the user, the device may only be installed, operated and serviced in accordance with the instructions for use and using the components supplied by Carl Zeiss Meditec AG.

Ambient conditions for intended use

MEL 90 is intended for use in professional healthcare facilities with regard to electromagnetic compatibility. These include in particular hospitals and medical practices, including those connected to the public power supply (e.g. in residential areas).

MEL 90 is not intended for operation in the following environments:

- Home health care (e.g. residential accommodation, nursing homes)
- Outdoor environments
- Other special environments (e.g. military facilities, heavy industry, facilities for medical treatment or diagnosis with high-power devices. These include in particular high-frequency surgical devices, short-wave therapy equipment and MRI devices.)

CAUTION - RISK DUE TO ELECTROMAGNETIC INTERFERENCE

With the exception of devices intended for this use by Carl Zeiss Meditec AG, using MEL 90 in direct proximity to other devices or together with other devices should be avoided as this could result in faulty operation. If it is nonetheless necessary to operate the device in the afore mentioned manner, the devices should be observed to check intended operation of the arrangement used.

CAUTION - GENERAL HAZARDS

The use of parts, all types of transducers and cables not specified in these instructions for use or not sold by Carl Zeiss Meditec AG as replacement parts may result in higher electromagnetic emissions or reduced immunity of the device and thus in faulty operation.

Replacement cables may only be purchased at Carl Zeiss Meditec AG.

Portable HF communications equipment (including peripheral devices such as antenna cable and external antennas) should not be used within a radius of 30 cm to MEL 90, including cables specified by the manufacturer. Otherwise, deterioration in the performance of the MEL 90 is to be anticipated.

Optional information technology parts (e.g. printers, additional monitors) which are connected to the medical device must be class B conforming to CISPR 22 or comparable devices.

A list of the removable parts can be found in section *Package check list*, page 12.

☞ No regular inspections or maintenance are required in order to maintain electromagnetic compatibility (EMC).
If obvious damage to the device is detected (e.g. housing or cables), contact ZEISS Service. It may be possible that a medical device having a damage still can be operated, but increased emission and/or decreased immunity may arise.

The following guideline applies only to parts specified for and delivered with the device from Carl Zeiss Meditec AG.

Guidance and manufacturer's declaration - electromagnetic emissions	
The MEL 90 is intended for use in the electromagnetic environment specified below. The customer or the user of the MEL 90 should assure that it is used in such an environment	
Emissions test	**Compliance**
HF emissions CISPR 11	Group 1
HF emissions CISPR 11	Class A
Harmonic emissions as per IEC 61000-3-2	Class A
Voltage fluctuations/flicker according to IEC 61000-3-3	Compliant

Note: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Guidance and manufacturer's declaration - electromagnetic immunity		
The MEL 90 is intended for use in the electromagnetic environment specified below. The customer or the user of the MEL 90 should assure that it is used in such an environment		
Electromagnetic immunity tests	**IEC 60601 test level**	**Compliance level**
Electrostatic discharge (ESD) as per IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air
Fast transient/burst immunity as per IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to ground	±1 kV line(s) to line(s) ±2 kV line(s) to ground
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T for 1/2 cycle 0 % U_T for 1 cycle 70 % U_T for 25/30 cycles 0 % U_T for 250/300 cycles	0 % U_T for 1/2 cycle 0 % U_T for 1 cycle 70 % U_T for 25/30 cycles 0 % U_T for 250/300 cycles
Power frequency 60 Hz magnetic field as per IEC 61000-4-8	30 A/m	30 A/m
Note: U_T is the AC voltage supply before application of the test levels.		
Proximity magnetic fields as per IEC 61000-4-39	65 A/m 134.2 kHz 7.5 A/m 13.56 MHz	65 A/m 134.2 kHz 7.5 A/m 13.56 MHz

Guidance and manufacturer's declaration - electromagnetic immunity		
The MEL 90 is intended for use in the electromagnetic environment specified below. The customer or the user of the MEL 90 should assure that it is used in such an environment		
Electromagnetic immunity tests	**IEC 60601 test level**	**Compliance level**
Conducted HF IEC 61000-4-6	3 $V_{effective\ value}$ 150 kHz to 80 MHz	3 V
	6 $V_{effective\ value}$ ISM bands[a]	6 V
Radiated HF disturbances as per IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m
Radiated HF disturbances from near fields of wireless communication devices as per IEC 61000-4-3	27 V/m 380 MHz to 390 MHz	27 V/m
	28 V/m 430 MHz to 470 MHz, 800 MHz to 960 MHz, 1.7 GHz to 1.99 GHz, 2.4 GHz to 2.57 GHz	28 V/m
	9 V/m 704 MHz to 787 MHz 5.1 GHz to 5.8 GHz	9 V/m

Note 1: At 80 MHz and 800 MHz the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is influenced by absorption and reflection by structures, objects and persons.

Note 3: 5G cellular interference testing for common high-band frequencies above 5.8 GHz has not been performed.

Note 4: Immunity testing against interference from high-band 5G cellular, WPT (wireless power transfer), NFC (near field communication), Electrosurgical, Electrocautery, Diathermy, X-ray, Metal Detectors, EAS (electronic article surveillance) and MRI devices has not been performed.

Note 5: The MEL 90 is not intended for use in the vicinity of high-power / high-frequency medical devices for treatment or diagnosis, such as Electrosurgical, Electrocautery, Diathermy, X-ray and MRI devices.

[a] The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

Abbreviations/Glossary

CCA	Cone for controlled atmosphere
CISPR	Comité international special sur les perturbations radioelectrique (International commission for electromagnetic interference)
D	Diopter
DP	Display port
DVI	Digital Visual Interface
EMC	Electromagnetic compatibility
EN	European Standard
Fig.	Figure
FWHM	Full width half maximum
HF	High frequency
IEC	International Electrotechnical Commission
LASIK	Laser(-assisted) in situ keratomileusis
LED	Light emitting diode
ME system	Medical electrical system
MPE	Maximum permissible exposure
NOHD	Nominal Ocular Hazard Distance (safety distance from laser source)
OD	Oculus dexter (right eye)
OPASS	Operation assistant (device software of MEL 90)
OS	Oculus sinister (left eye)
PC	Personal computer
PMMA	Polymethyl methacrylate
RSTP	Recommended standard treatment procedures
UMDNS	Universal Medical Device Nomenclature System
USB	Universal serial bus (standard interface for PC peripherals)

Figures

List of pictograms

Icons	
Blue	Icon is enabled and can be selected.
Grey	Icon is disabled and cannot be selected.

General icons		
Icon	**Designation**	**Description**
	**Onscreen keyboard is disabled**	Enable onscreen keyboard
	**Onscreen keyboard is enabled**	Disable onscreen keyboard
	**Enable video recordings**	Start of video recording
	**Disable video recording**	Stop video recording
	**Enable onscreen help**	Showing onscreen help
	**Switch off the device**	Switch off the device
	**Cancel current process**	Cancel current process and return to main dialog
	**Log in**	Enable access to user interface
	**Log off**	Log off the current user
	**Back**	Open the previous dialog
	**OK; Ready; Start**	Confirm or enable input made

Welcome main dialog		
Icon	**Designation**	**Description**
	**Gas change**	Open "Gas change" dialog and start gas change
	**Patient management**	Open, find, create, edit or delete patient records and administer the associated treatments.
	**Configuration**	Make various presettings for the screen layout, access, functionality and treatment
	**Refractive treatment**	Select the patient data record and start the fluence test

Warning messages	
 READY	**Laser ready!** The laser can now be fired at any time using the foot switch. CAUTION - RISK OF TREATMENT ERRORS
 EMISSION	**Emission of laser beams!** Laser beams are released.

Patient management		
Icon	**Designation**	**Description**
	**New**	Create personal data of a new patient
	**Edit**	Edit personal data of the currently selected patient
	**Delete**	Delete a data record or several data records selected from a list
	**USB export/Export treatment data**	Export selected patient data records to an external drive
	**Print list**	Print the current (filtered) list
	**Refractive treatment**	Select a patient data record and start treatment
	**Treatment data**	Select the eye to be treated and the type of treatment

Patient management Treatment data		
Icon	**Designation**	**Description**
	**Start**	Start data export to the root directory of the selected destination drive

Patient management Details Opens on selecting the **Treatment data** dialog		
Icon	**Designation**	**Description**
	**Print/Print report**	Print a report
	**Save**	Save the patient data record with all entries made

Patient details (working area)	
Enter the patient data and values, separately for OD (right eye) and OS (left eye).	
OD	Enter the patient data and values for the right eye (oculus dexter)
OS	Enter the patient data and values for the left eye (oculus sinister)

Configuration (User)		
Icon	**Designation**	**Description**
	**Settings**	Return to the "Settings" dialog from other dialogs of Configuration
	**User data**	Create and edit user data
	**Licenses**	Add treatment licenses
	**Incident report**	Create a report file for the documentation of an incident.
	**Data management**	Specify the destination directory for data back-up and review the destination directory for data export
	**Apply**	Apply all changes and information entered

Fluence test

Open Fluence test in the **Refractive treatment Parameters** dialog.

Icon	Designation	Description
	**Zero line**	Align the patient's eye or the microscope eyepiece (cross hairs)
	**Fluence test**	Open the "Fluence test" dialog Patient and treatment are selected prior to this
	**Gas change**	Open the "Gas change" dialog
	**Decrease**	Reduce the energy target value
	**Increase**	Increase the energy target value
	**Test**	Start the fluence test (in conjunction with the foot switch)
	**Cancel**	Cancel the fluence test
	**OK**	Completion of successful fluence test

Eye selection

The eye to be treated is highlighted in the information bar.
Select the eye to be treated prior to each treatment.
There are two display options:

right eye (oculus dexter) 

left eye (oculus sinister)

 **Refractive treatment**		
Icon	**Designation**	**Description**
Refractive treatment **Select patient**		
	**Patient management**	Management of patient data records and corresponding treatments
	**Unknown patient**	Carry out a refractive treatment without previously selecting a patient data record
	**Treat patient**	Opens the "Refractive treatment" (Select eye) dialog to select the eye to be treated; it is required to select a patient
Refractive treatment **Report**		
	**Next eye**	Opens the "Refractive treatment" (Select eye) dialog to select the eye to be treated
	**Next patient**	Opens the "Refractive treatment" (Select patient) dialog to search and select a patient data record for further treatment

Configuration Service and Administrator		
Icon	**Designation**	**Description**
Configuration Service (Log in as Service)		
	**Settings**	Selection of language and network settings
	**Network symbol**	Parameters of network configuration
	**Licenses**	Add treatment licenses
	**Service**	Settings for patient export, gas change, data handling and audio settings
	**Service address**	Include contact data for device service.
Configuration Administrator (Log in as administrator)		
	**Settings**	Language selection
	**User**	Create, edit and delete user accounts
	**Patient databases**	Manage databases; Create, edit and delete databases; Assign databases to a user
	**License account**	Manage licenses; Create a license account and assign to a user

Keyword index

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