



AESCULAP[®]

MEDITEC



Application Manual

Version 2.2 – 12/99

MEL 70 *G-Scan*

Excimer Laser for application in corneal surgery

Software version PC V 2.2 as of December 1999
Master computer version 2.2 as of December 1999

AESCULAP-MEDITEC GMBH
PRÜSSINGSTRASSE 41
07745 JENA
GERMANY

EXCIMER HOTLINE:

Phone: +49 36 41/65 22 78

Fax: +49 36 41/65 21 21

Index

1	Safety Instructions.....	6
1.1	Precautionary measures	6
1.2	Significant advice for the first treatment	7
1.3	General PRK contraindications	8
1.4	General guidelines for the selection of patients	9
1.5	LASIK treatment.....	9
1.6	General Complications.....	10
2	PRK treatment	11
2.1	The opportunities of PRK treatment.....	11
2.1.1	PRK myopia	11
2.1.2	PRK hyperopia.....	13
2.2	Activation of the laser.....	14
2.2.1	Initial heating phase and gas exchange.....	15
2.3	The Main Menu	16
2.4	Data input for PRK treatment	18
2.4.1	Input of patient data	18
2.4.2	The OP-Assistant.....	19
2.4.3	The fluence test	20
2.5	Preparation of the laser.....	21
2.6	Preparation of the patient.....	23
2.7	The eye tracker	25
2.8	Centration with the MEL 70 G-Scan using the Artificial Limbus Ring.....	27
2.8.1	Centre of Pupil	27
2.8.2	Purkinje Reflex.....	27
2.9	The treatment session	28
2.10	Termination of the program.....	29
2.11	Switching off of the laser.....	29
2.12	Follow-up treatment (proposal)	30
2.12.1	Immediate postoperative treatment.....	30
2.12.2	Postoperative treatment until complete re-epithelialisation	30
2.12.3	Postoperative treatment after complete re-epithelialisation	31
3	LASIK treatment.....	32
3.1	The opportunities of LASIK treatment.....	32
3.1.1	LASIK myopia	32
3.1.2	LASIK hyperopia	33
3.2	Activation of the laser.....	34
3.2.1	Initial heating phase and gas exchange.....	35
3.3	The main menu	36
3.4	Data input for LASIK treatment	38
3.4.1	Input of patient data	38
3.4.2	The OP-Assistant.....	39

3.4.3	The fluence-test.....	40
3.5	Preparation of the laser	41
3.6	Preparation of the patient	44
3.7	The eye tracker.....	45
3.8	Centration with the MEL 70 G-Scan using the Artificial Limbus Ring.....	47
3.8.1	Centre of Pupil	47
3.8.2	Purkinje Reflex.....	47
3.9	The treatment session	48
3.10	Termination of the program	49
3.11	Switching off of the laser.....	49
3.12	Follow-up treatment (proposed).....	49
4	PTK-Shaping	50
4.1	Applications	50
4.2	Activation of the laser	50
4.2.1	Initial heating phase and gas exchange.....	51
4.3	The Main Menu.....	52
4.4	Data input for PTK Shaping treatment.....	54
4.4.1	Input of patient data	54
4.4.2	The OP-Assistant.....	55
4.4.3	The fluence test	56
4.5	Preparation of the laser	57
4.6	Preparation of the patient	60
4.6.1	The treatment session	61
4.7	Termination of the program	61
4.8	Switching off of the laser.....	61
4.9	Postoperative treatment (proposed)	62
5	PTK-Spot	63
5.1	Applications	63
5.2	Activation of the laser	63
5.2.1	Initial heating phase and gas exchange.....	64
5.3	The Main Menu.....	65
5.4	Program input for PTK Spot treatment.....	67
5.4.1	The patient data menu.....	67
5.4.2	The OP-Assistant.....	68
5.5	Preparation of the laser	69
5.6	Treatment of recurrent erosion	70
5.6.1	Preparation of the patient	70
5.6.2	The treatment session	70
5.6.3	Postoperative treatment.....	71
5.6.4	Results.....	71
5.7	Treatment of pterygia.....	72
5.7.1	Preparation of the patient	72
5.7.2	The treatment session	72

Index

5.7.3	Results	73
5.8	Termination of the program.....	73
5.9	Switching off of the laser.....	73
6	Topographic treatment.....	74
6.1	Application	74
6.2	Activation of the laser.....	74
6.2.1	Initial heating phase and gas exchange.....	75
6.3	The Main Menu	76
6.4	Program entry for topographic treatment	77
6.4.1	The OP Assistant.....	78
6.4.2	The fluence test	79
6.5	Preparation of the laser.....	80
6.6	Preparation of the patient.....	83
6.6.1	Procedure for PRK.....	83
6.6.2	Procedure for LASIK	84
6.7	The eye tracker	85
6.8	Centration with the MEL 70 G-Scan using the Artificial Limbus Ring.....	87
6.9	The treatment session	88
6.10	Termination of the program.....	89
6.11	Switching off of the laser.....	89
6.12	Post-operative treatment.....	89
7	Appendix.....	90
7.1	Bases for software operation	90
7.1.1	Use of a pointer device	90
7.1.2	Use of a dialog box	90
7.2	The configuration menu	91
7.3	Patient management (data base).....	92
7.3.1	Create/edit patient.....	93
7.3.2	Search patient.....	94
7.4	Failure indicator	95
7.4.1	Unexpected interruption of a treatment session.....	95
7.5	Cleaning instructions.....	95
7.6	MEL 70 G-Scan general view	96

1 Safety Instructions

The following symbols are used throughout the application manual to indicate hazards and special advice.



Warning advice for possible accident and injury hazards



Warning advice for possible technical damage

1.1 Precautionary measures

Lasers have been employed for medical purposes for more than three decades. Only a very small number of incidents have occurred in comparison to the large number of successful treatments. Nevertheless, one should never allow the necessary attention to slacken when using laser devices. Any careless handling of laser beams may result in serious injuries in both user and patient.

Lasers emit a very intensive radiation which may be hazardous even at quite some distance from the laser outlet aperture proper. Inappropriate application may result in burns of body tissue and damage at optical equipment.

The non-observance of the instructions for use and the application manual may constitute a potential source of hazards for both the attending physician and the patient. This present application manual describes the application and operation of the MEL 70 *G-Scan* Excimer Laser as a medical device.

The decision on the suitability of the device and the selection of the method of treatment is the exclusive responsibility of the attending physician. It is indispensable to conduct an energy test prior to each treatment session.



On no account any treatment may be administered when there is the slightest doubt at the proper functioning of the device!

Safety Instructions



The employment of control elements as well as adjustments or the giving of a treatment in a different form than described in the present application manual may result in a release of hazardous laser radiation!



The cover of the device must not be removed under any circumstances. The laser device may only be opened by qualified technical personnel of the company AESCULAP-MEDITEC!

Any attempt at performing maintenance activities at the device by personnel which has not been commissioned by AESCULAP-MEDITEC will result in the immediate cessation of our warranty obligation!



Persons with heart-pacemakers are required to keep a distance of 2 metres from the MEL 70 *G-Scan*!

1.2 Significant advice for the first treatment

This present Application Manual for the MEL 70 *G-Scan* is deemed to be merely a guideline for the performance of the first treatment steps and shall facilitate the familiarisation with treatments by means of an Excimer Laser. It can by no means be a substitute for on-site instructions on the device given by a qualified AESCULAP-MEDITEC staff. The treatment of the first patient should only be performed under supervision of an authorised AESCULAP-MEDITEC representative.

Our recommendation for every user is to study the current literature on this topic and to establish contacts with clinics which are equipped with the described device in order to familiarise themselves with the methods of treatment employing an Excimer Laser, before they start their independent treatment of patients.

AESCULAP-MEDITEC will be happy to help you making contact with other MEL 70 *G-Scan* users. In addition, we should like to offer you continued support by our specialists during your operations over a longer period of time. Please, turn to our responsible field officer if you request further information.

1.3 General PRK contraindications

A photorefractive keratectomy (PRK) by means of an Excimer Laser should only be conducted after a careful definition of the indications.

Patients to which one or more entries in the below list apply should not be subjected to a PRK surgery procedure:

- Progressive myopia or keratoconus.
- Residual, chronic or active ophthalmic diseases or corneal anomalies (with the exception of refractive anomalies in both eyes), such as iritis, uveitis, keratitis sica, blepharitis or a cataract with an essential visus impact.
- The regular taking of medication which cause a disturbance of the wound healing process, such as corticosteroids from antimetabolites or implanted hormones, such as Norplant.
- Immunosuppression
- Corneal neo-vascularisation up to 1 mm to the ablation zone.
- An augmentation of the spherical or cylindrical portions in an existing refraction by more than 0.5 dioptries/year since a first examination.
- Previous corneal operations or injuries in the ablation zone.
- Any system disease which causes a disturbance of the wound healing process, such as a systemic connective tissue disease, diabetes and serious atopy.
- Vascillating medium-level keratometry indications with irregular meridian marks or corneal photographs with interrupted central rings.
- Patients with large pupil diameters (in excess of 7 mm).
- Female patients who are or soon intend to become pregnant.

Please, refer to the topical literature for further contraindications!

Safety Instructions

1.4 General guidelines for the selection of patients

The ideal patients, particular for any new user, are deemed to be patients with a moderately severe myopia who cannot or do not want to wear spectacles for professional or personal reasons and who do not regard contact lenses as an alternative solution. On principle, also anisometropia is a well-suited indication.

The patient should be at least twenty years of age. Children should be, if at all, subjected to PRK surgery only in exceptional cases.

1.5 LASIK treatment

The LASIK (Laser In-situ Keratomileusis) software differs from the PRK software in many aspects:

- LASIK allows for the correction of considerably higher refractive visual defects than PRK; the limits which had been set for PRK have been extended to make an adjustment up to a max. of -24 D possible, however, without considering the clinical relevance.
- LASIK does not remove tissue from the surface (hence the Bowman's membrane will be left unaffected) but at the stromal level. The ablation values in this region are differing and, hence, the nomograms (i.e. the deviations in the program in relation to the theoretical formula) will differ from the PRK nomograms.

In addition to the above difference LASIK entails quite a number of new factors which may have an impact on the refraction results. Such factors include, for instance, the thickness of the 'flap', the moistening during the incision and hence the moistening of the stromal bed, the drying of the stromal bed (with a triangular swab); even the very brand of the microkeratome may play a role.

However, all the above factors could not be considered in the software system since they cannot be expressed in numeric terms.

The aforesaid is the reason why every new user should commence the application of this treatment method with a small number of patients with individual corrective values and, if need be, use the obtained results to modify the program selection for the subsequent cases. Thus every user will gradually develop their own nomograms.

Nevertheless, the currently available AESCULAP-MEDITEC Software is particularly well suited for new users, provided that the below recommendations are adhered to:

- In spite of the fact that a greater level of sterility during hand washing and the disinfection of equipment parts is urgently required, such should not be done immediately prior to the operation or in the operating theatre since the released alcoholic gases will absorb a large amount of the Excimer Laser light. The latter is a frequent reason for uncontrolled, defective corrections.
- The software is programmed with the patient's eye-glass refraction values.

1.6 General Complications

LASIK and PRK are known to cause the following complications in some single cases:

- glare
- haze
- halos
- decreased night vision
- regression

PRK

2 PRK treatment

2.1 The opportunities of PRK treatment

2.1.1 PRK myopia

The myopia programs are designed to perform corrections of myopia of a maximum total of -12 D with or without astigmatism.

An optical zone from 4.0 mm to 7.0 mm may be selected. The larger the optical zone the more the risk of a postoperative glare sensitivity will be reduced. However, the ablation centre depth will increase with a larger diameter of the optical zone.

We recommend to use an optical zone of 6 mm for corrective surgery procedures up to -6 D.

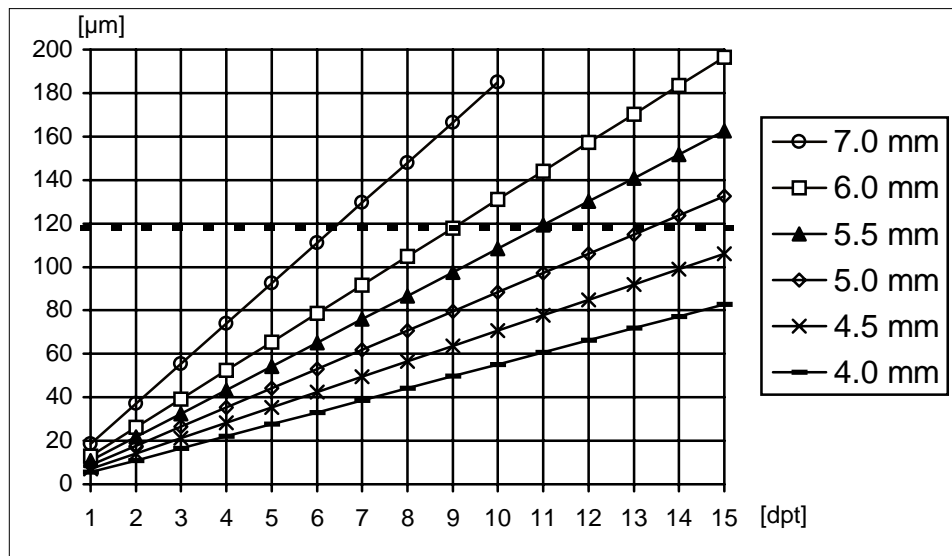


Fig. 1: Ablation centre depth as a function of the optical zone diameter

As a rule, the **subjective spectacles refraction values** are used as the basis for the data input. These values are directly input into the OP Assistant.

Exclusively **negative values** are to be used (e.g. $-2 -2 \times 45^\circ$).

On principle, it is recommended to conduct an examination with a cornea topography system in order to be sure that the patient does not suffer from asymmetric astigmatism or an early stage of keratoconus.

In case of patients who are presbyopic or are likely to soon become presbyopic it should be considered whether a low level of residual myopia could be left untreated.

The current subjective refraction is also adjusted in the OP Assistant during any re-treatments. The refraction should be stable over a period of not less than six months.

Caution should be exercised when treating dry eyes or post-keratoplasty cases since there the degree of hydration and the healing progress may differ from case to case. We recommend for such cases a more conservative approach with an undercorrection of 20 per cent.



Do not try and combine different myopia programs in order to achieve so-called multipass treatments! The in-built nomogram is bound to cause severe overcorrections.



The correction of more than -6 D of astigmatism can result in reduced contrast sensitivity, increased blurring, undercorrection and regression.

PRK

2.1.2 PRK hyperopia

The hyperopia programs are employed in corrections of hyperopias and hyperopic, symmetrical astigmatisms **totalling not more than +8 dioptres**.

The treatment diameter (the optical zone plus the transition zone) is 9.0 mm for all programs.

As a rule, the **subjective spectacles refraction values** are used as the basis for any data input. These values are directly input into the OP Assistant. This applies also to angles.

The refractometry shall be performed with utmost care, in particular with young patients and, if possible, in a state of cycloplegia.

Exclusively positive values are to be used (e.g. sph +3 / cyl. +2 × 45°).

On principle, it is recommended to conduct an examination with a cornea topography system in order to be sure that the patient does not suffer from asymmetric astigmatism or an early stage of keratoconus.



Do not try and combine different hyperopia programs in order to achieve so-called multipass treatments! The in-built nomogram is bound to cause severe overcorrections.



The correction of more than +6 D of astigmatism can result in reduced contrast sensitivity, increased blurring, undercorrection and regression.

2.2 Activation of the laser

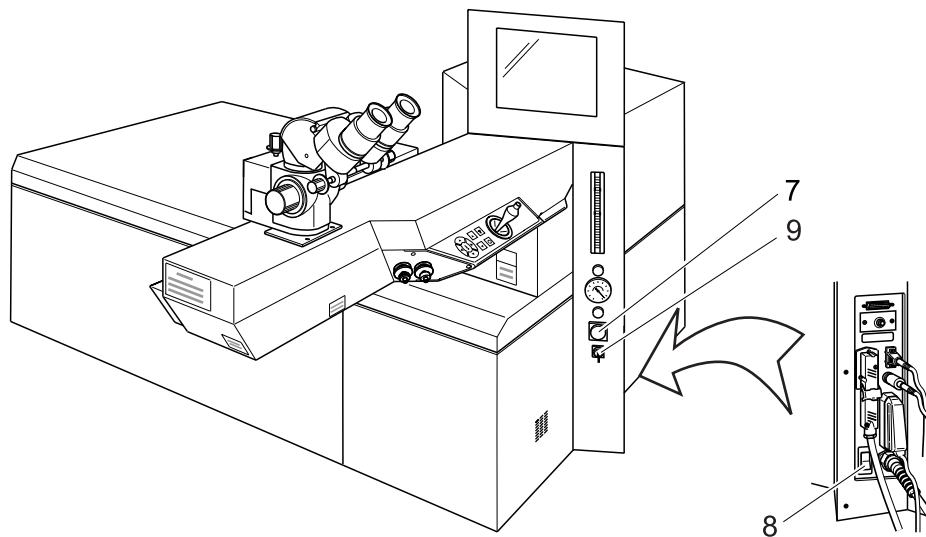


Fig. 2: MEL 70 *G-Scan* switch

Unlock the EMERGENCY OFF switch (7)

Switch on the main switch (8), the green light in the switch lights up.

Turn the key switch (9) fully to the right, the key will automatically return to centre position.

After approx. 30 seconds the menu of the initial heating phase will appear on the screen.

2.2.1 Initial heating phase and gas exchange

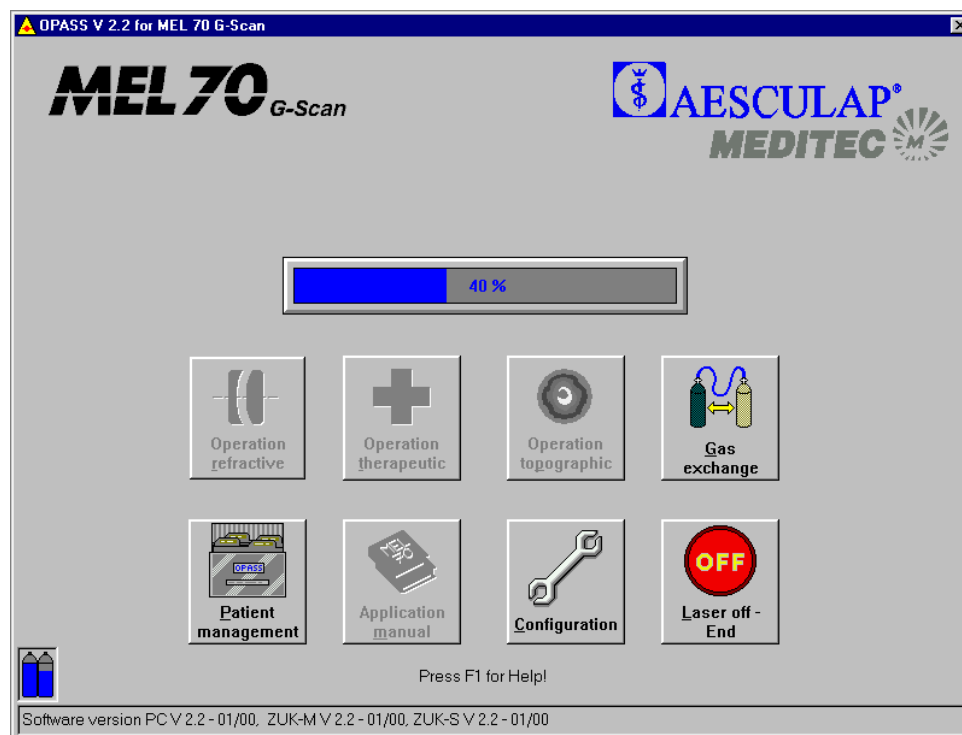


Fig. 3: Menu Initial heating phase

The laser requires a period of six minutes to heat up to the necessary operating temperature. A progress indicator will advise you of the status of the initial heating phase. The symbols with a grey background **cannot** be selected during this period.

In order to perform an automatic gas exchange click the symbol “Gas exchange” during the initial heating phase. The gas exchange takes approx. five minutes. Confirm the gas exchange with clicking “Yes”. Another progress indicator will advise you of the status of the gas exchange.

A filling level indicator of the gas cylinders is located at the left bottom corner of the screen. If one of the cylinders is empty, please, notify your hotline officer so that the cylinder will be replaced during the next service cycle.

The state bar is located at the lower screen margin. Situation-related reports and the currently used software version are displayed in this box.

Following the initial heating phase the main menu will appear on the screen.

2.3 The Main Menu

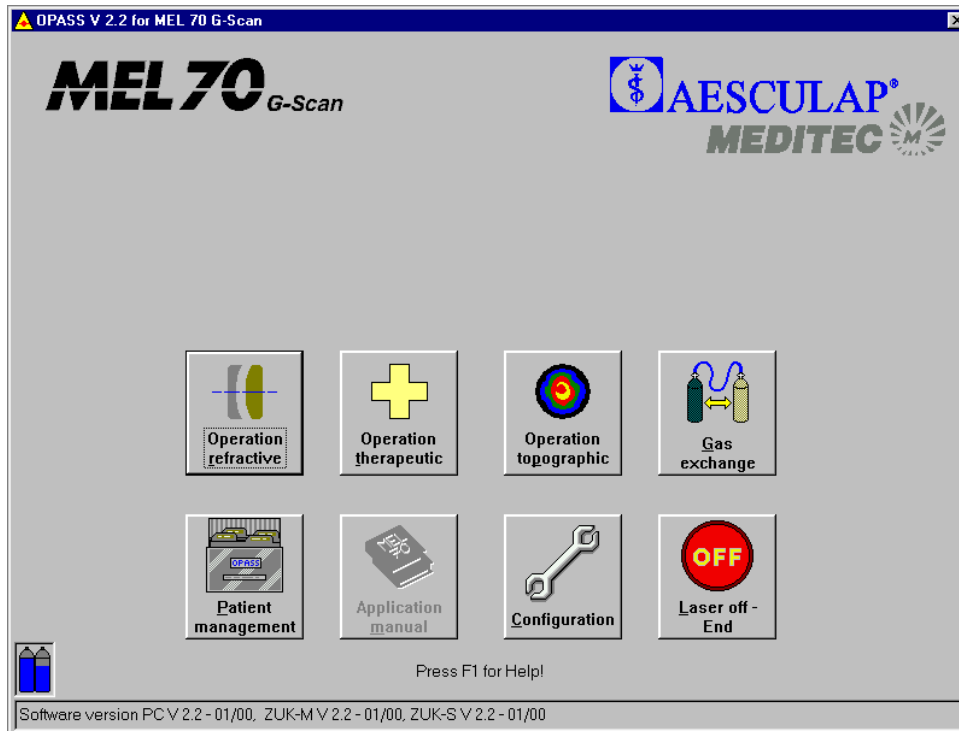


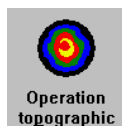
Fig. 4: The main menu for PRK



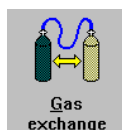
Click on this symbol in order to perform a refractive operation.



Click on this symbol in order to perform a therapeutic treatment (PTK Shaping or PTK Spot treatment). (cf. Chapters 4 and 5).

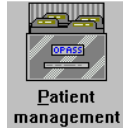


Click on this symbol in order to perform a topographic operation (cf. Chapter 6).



Click on this symbol in order to perform an automatic gas exchange (duration approx. five minutes). The gas exchange may be conducted during the initial heating phase.

PRK



Click on this symbol in order to open the patient management (cf. Appendix).



Click on this symbol in order to open the application manual.



Click on this symbol in order to perform the configuration adjustments. Here you may input the data of your clinic or select the printer for the journal printout (cf. Appendix).

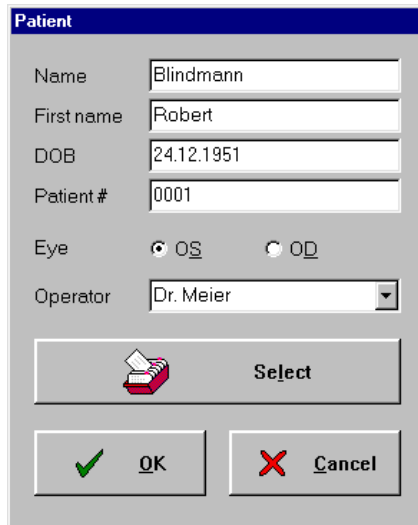


Click on this symbol in order to terminate the computer program and switch off the laser. You should not switch off the laser until the message "YOU MAY NOW SWITCH OFF THE COMPUTER" appears on the screen.

2.4 Data input for PRK treatment

Select the option “Operation refractive” from the main menu by mouse click.

2.4.1 Input of patient data



The screenshot shows a dialog box titled "Patient" with the following fields and controls:

- Name: Blindmann
- First name: Robert
- DOB: 24.12.1951
- Patient #: 0001
- Eye: OS OD
- Operator: Dr. Meier (dropdown menu)
- Buttons: Select (with printer icon), OK (with green checkmark), Cancel (with red X)

Fig. 5: Menu Patient Data

To begin with, input the patient data and the name of the operating surgeon. Mark whether the left or the right eye is to be treated. You may either enter the data directly into the input field or select a patient from the patient database.

When you click on „Select“ with the left mouse key, the list of patients entered previously in the PATIENT MANAGEMENT screen opens (for details of PATIENT MANAGEMENT, see annex). These entries are printed in the operation journal.

Confirm the correct entry with “OK”.

The “Cancel” pushbutton takes you back to the main menu.

PRK

2.4.2 The OP-Assistant

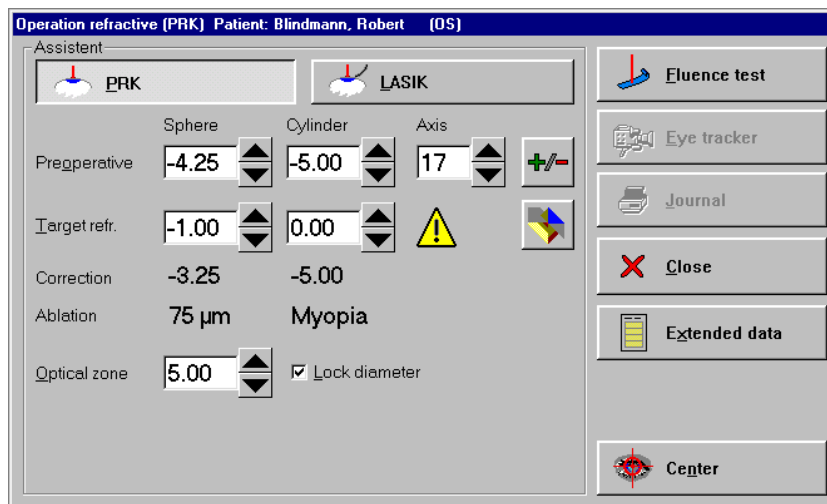


Fig. 6: The OP-Assistant


Select the treatment method PRK from the menu.

Input the preoperative **subjective spectacles refraction values** directly into the OP Assistant. In some cases it may be desirable to undercorrect the patient. In order to do so, enter the desired target refraction (by clicking on the scroll arrows with the left mouse key you will modify the value in 0.25 D steps, by clicking with the right mouse key you will modify the value by 1 D). The OP Assistant will automatically calculate and display the correction in the appropriate field.

In the case of a “false” mixed astigmatism (e.g., $-4 + 2 \times 10^\circ$):

By clicking on the “Diagram” symbol you will get a graphical representation of the working ranges. The red arrow indicates the preoperative refraction, the green arrow the target refraction. You can close the diagram by clicking on the button with the hook.

In the event that the preoperative values are outside of the valid working ranges the refractive error cannot be completely corrected, i.e. a residual sphere or a residual cylinder will result (the red arrow in the diagram is outside of the coloured range, the green arrow is not in the zero point).

In this case the program suggests a $-/+$ calculation (Click , Fig. 6, $\rightarrow -2 -2 \times 180^\circ$).

After inputting the refraction data, the optical zone can be varied but the thickness of the cornea should be observed.

2.4.3 The fluence test

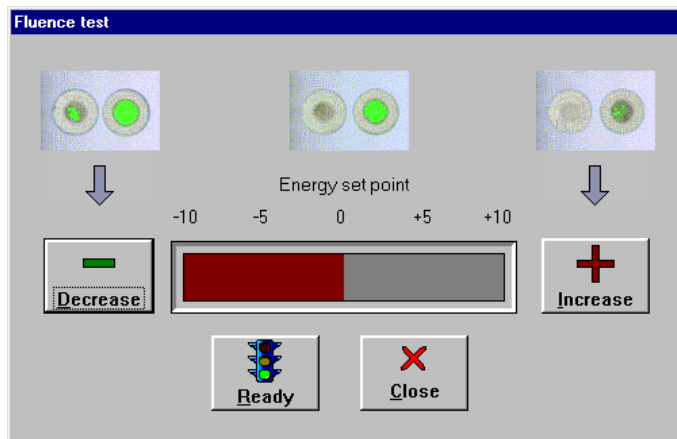


Fig. 7: Menu fluence test

By clicking on the pushbuttons “High” or “Low” you may increase or decrease the energy set point.

You start the fluence test by operating the pushbutton “Ready”.

Clicking on the pushbutton “Close” will abort the fluence test.

PRK

2.5 Preparation of the laser

Height adjust your operating chair.

Switch on the ring-shaped lamp (11) and check the ocular adjustment.

Swivel the laser arm and switch on the distance control laser (12).

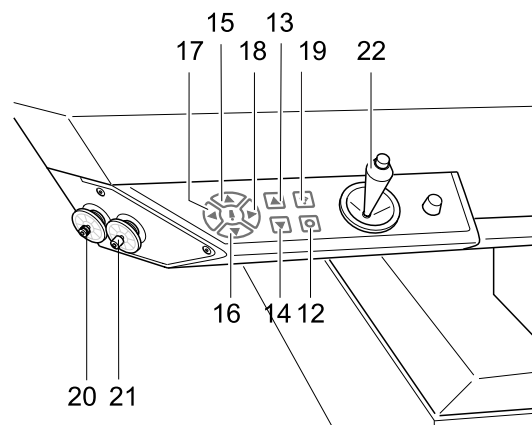


Fig. 8: Control Panel Laser Arm

Position the patient bed together with the blue test base at the appropriate height. The two focusing points require to be brought into an overlapping position. Operate the below keys on the operating panel of the laser arm towards this end:

Height adjustment	higher	(13)	deeper	(14)
Horizontal alignment	forward	(15)	backward	(16)
	to left	(17)	to right	(18)

Put a piece of test paper onto the blue test base.

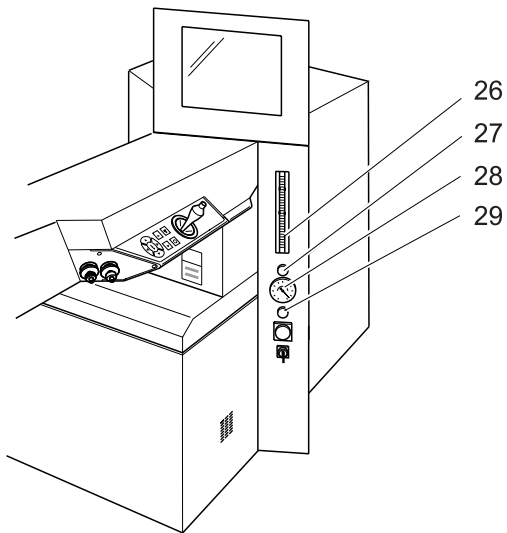


Fig. 9: Control panel

Click on the pushbutton “Ready” in the menu of the fluence test.



Now the laser may be actuated by means of the right-hand foot pedal!

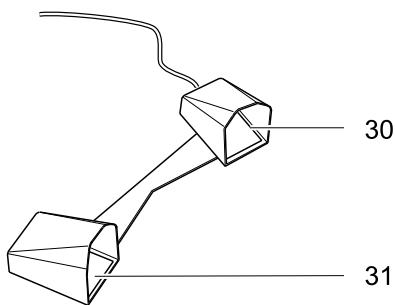


Fig. 10: Foot pedal

PRK

Place the red target beam with the joystick (22) onto a free area of the test paper.

Now make the fluence test as described in the Instruction Manual.

Following the successfully completed test, click on the pushbutton “OK” and turn the laser arm to the side.



**Only continue after a successfully completed fluence test!
A faulty fluence value will result in false treatment.**

Repeat this procedure with each new patient.

Remove the blue test base.

2.6 Preparation of the patient

Thirty minutes prior to the laser treatment a topical anaesthetic (e.g. Novesine, Kerakain) and Pilocarpin shall be administered.

If required, a sedative agent (e.g. Diazepam) shall be given.

The minus cylinder axis of the patient is marked on, e.g., the sclera, with a colour pen. (Alternatively, the patient may be temporarily placed under the surgery microscope with the test frame put on).

The height adjustment is carried out by means of the focusing laser.

The head of the patient is aligned horizontally as much as possible, so that the pupil is at the centre of the eye-slit when the patient looks into the surgery microscope.

When **treating astigmatisms** the reticule of the ocular by turning is adjusted to the 0° axis of the patient. (It may be necessary to temporarily reduce the magnification of the surgery microscope in order to make the angle marks visible when a test frame is used).

An eyelid speculum is to be placed between the eyelids (preferably of the Barraquer type).

Ask the patient to fixate on a green LED and mark the optical centre (centre of the entry pupil) with an eye cannula.

Attach the ring marker and turn by 20° to 30° under slight pressure.

Recommended ring markers:

Myopia	always 1 mm larger than the treatment zone
Hyperopia	9.0 mm ring marker

Perform abrasion of the epithelium by means of a 'Hockey' knife (when treating pure astigmatisms: extend the abrasion area in the axis of the minus cylinder by approx. 9.5 mm).

Repeat marking the optical centre (centre of the entry pupil) with an eye cannula.

Re-check the working distance by means of the distance control laser (combine points). Subsequently, switch off the distance control laser.

PRK

2.7 The eye tracker

An active eye tracker will follow the patient's eye movements during the treatment and, if need be, the laser beam will be traced accordingly. The suction ring of the flue gas extraction installation serves as the object for the tracker. This ring needs to be attached first (as much centred as possible).

Click on the pushbutton "Eye Tracker" in the menu of the OP Assistant.

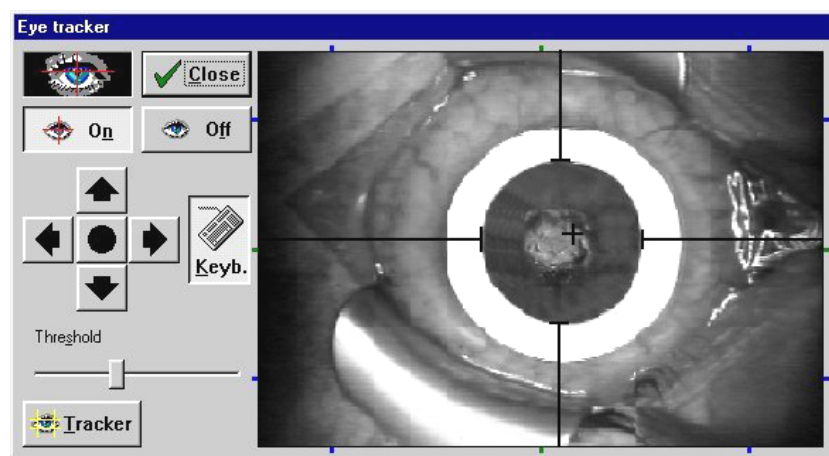


Fig. 11: Menu Eye Tracker

The menu of the eye tracker will open. This window remains open during the treatment session and enables you to make different adjustments and check the functioning of the tracker. A video image of the eye tracker is displayed on the right, while the left shows the configuration pushbuttons.

Activate the eye tracker by clicking on the pushbutton "On". The tracker status indicator is located above the latter pushbutton. If the eye is displayed against a black background, the object was recognised by the eye tracker. If the object was not recognised the background will remain grey. In the latter case, check the below items:

- Has the eye tracker been switched on?
- Is the pupil still in the HOT ZONE?
The HOT ZONE is the area where the laser follows the patient eye movement. If the pupil leaves the HOT ZONE the sequence of shots is automatically interrupted until the pupil is again in the area of this zone. In such case reposition the head of the patient in such a way that the eye is at the centre of the camera image.

When the eye tracker is switched on you will see a graticule in the video image. This graticule will be automatically placed in the object centre. However, since the optical axis is not always in the object centre you have the opportunity to modify this setting. You can change the position of the graticule by clicking with the right mouse key on the arrow keys on the left of the video image. The right mouse key will move the graticule in larger steps. Click the round pushbutton in the centre in order to readjust the graticule to the geometrical centre.

You can also move the graticule with the arrow keys. The keyboard button must be enabled for this.

You can adjust different parameters of the video image, such as brightness, contrast, etc., by clicking on the “Video” pushbutton.

The eye tracker is switched off by clicking on the “Off” pushbutton.

The eye tracker window is closed by clicking on the “Close” pushbutton.



When the eye tracker is switched off the laser beam will not be automatically traced, i.e. any eye movements will not be compensated!

PRK

2.8 Centration with the MEL 70 G-Scan using the Artificial Limbus Ring

2.8.1 Centre of Pupil

- Input patient data
- Perform fluence test
- Have the patient look at the green LED
- Use a blunt cannula/marker to set centre of abrasion
- Press ready
- Use ring marker to set area of abrasion
- Remove epithelium
- Again have the patient look at the green LED (move bed or head if necessary)
- Again use cannula/marker to set centre of ablation (centre of the entrance pupil)
- Press 'eye tracker' button (the joystick will be deactivated)
- Apply limbus ring in a way that the aiming beam sits roughly on your mark
- Set aiming beam to your mark on the cornea by using the mouse or keypad
- Start ablation

2.8.2 Purkinje Reflex

- Input patient data
- Perform fluence test
- Press center to set the red HeNe beam in the center of microscope
- Have the patient look at the red HeNe beam
- Use a blunt cannula/marker to set centre of abrasion
- Press ready
- Use ring marker to set area of abrasion (put joystick aside)
- Remove epithelium

- Again have the patient look at the red HeNe beam (move bed or head if necessary, joystick must be centred!)
- Press 'eye tracker' button (the joystick will be deactivated)
- Reposition patient, have him look straight
- Apply limbus ring in a way that it is lying horizontal
- Align aiming beam by using the mouse or keypad that you can see the Purkinje reflex
- Start ablation

2.9 The treatment session

When you press the „Center“ button the target beam of the laser will always be in the center of the surgical microscope in whatever position the joystick may be. In this way the target beam instead of the fixation light can be used for centering.

Check the values which have been adjusted in the Assistant.

Click on the “Ready” pushbutton in the OP Assistant.

Actuate the right foot pedal and keep it depressed.

A progress indicator will display the progress of the treatment. By clicking on the “Cancel” pushbutton the treatment may be discontinued following the release of the foot pedal.

After the termination of the correction program the OP Assistant will automatically interrupt the laser triggering. The treatment is interrupted by releasing the foot pedal and may be resumed by actuating the pedal again.

PRK

2.10 Termination of the program

By clicking on the “PROTOKOLL” pushbutton you will receive a print-out of the surgery data via the connected printer.

You may return to the main menu by clicking on the “OK” pushbutton.

In order to treat further patients, commence again in the main menu and follow the instructions in the applications manual.

2.11 Switching off of the laser

In order to switch off the laser click on the “OFF Laser off – End” and confirm the switch-off by clicking on the pushbutton “Yes”.

Wait for the message “NOW YOU MAY SWITCH OFF THE COMPUTER” appears on the screen.

Turn the key switch (9) fully to the left.

Switch off the main switch (8) (the green light in the switch will go out).

2.12 Follow-up treatment (proposal)

2.12.1 Immediate postoperative treatment

Immediately following the surgery the below medicines shall be applied to the eye:

- Tobradex eye-drops (Alcon) 1 drop or a topical antibiotic (e.g. Gentamicin)
- Voltaren eye-drops (CibaVision Oph), 1 drop

Therapeutical soft bandage contact lenses may be applied following large corrections. The below lens types are recommended for use:

- Acuvue (Johnson and Johnson), (9.1–14.4, 8.4–14.0, 8.8–14.0), or
- New Vu (Ciba), (8.4–14.0, 8.8–14.0)

Examine the patient by means of a slit lamp and check the fit of the contact lenses. In case of excessive slipping the lens should be placed again into its correct position. If the lens is fitting well there is no need to use an eye-patch.

Alternatively to the use of contact lenses, Gentamicin ointment and an eye dressing may be applied.

2.12.2 Postoperative treatment until complete re-epithelialisation

Ask the patient to come to your surgery everyday for follow-up visits. Pass on to the patient a sheet of instructions with detailed instructions for their behaviour following the surgery.

Remove the soft bandage contact lenses if they have slipped or if the epithelium fails to cover up within the anticipated period of time.

Administer Tobradex eye-drops 4 times per day until the epithelium has healed (alternatively, give a topical antibiotic).

Administer Voltaren eye-drops 3 times per day on the day of the surgery, 2 times per day on the first and second postoperative day, then stop administering them. Do not use these drops longer than for two postoperative days.

PRK

If the re-epithelialisation is delayed remove the soft bandage contact lenses and apply an eye dressing. Remove the eye dressing at least three times a day for the application of the eye drops. In case that an analgesic medication is required, we recommend e.g. Tylenol N° 3 or Mepergan Forte (Meperidine Promethazine).

2.12.3 Postoperative treatment after complete re-epithelialisation

Stop the application of the antibiotic agent and, if need be, switch to steroids (Fluormetholon 0.1 %, Alcon), 4 times per day during the first month, 3 times per day during the second month, 2 times per day during the third month, once in the morning for the next two weeks, then discontinue the application.

In the event that the patient requires a lubricant, use solutions without preservatives, e.g. Refresh Plus. In the event that the patient requires an ointment as lubricant, use Refresh Plus PM ophthalmic ointment (Allergan Inc).

3 LASIK treatment

3.1 The opportunities of LASIK treatment

3.1.1 LASIK myopia

The myopia programs are designed to perform corrections **of up to a theoretical value of -24 D** without and with astigmatism.

An optical zone from 4.0 mm to 6.0 mm may be selected. The larger the optical zone the more the risk of a postoperative glare sensitivity will be reduced. However, the ablation centre depth will increase with a larger diameter of the optical zone.

As a rule, we recommend to use the largest possible treatment diameter. However, for higher corrections the diameter of the optical zone should be reduced in order to prevent too large ablation depths.

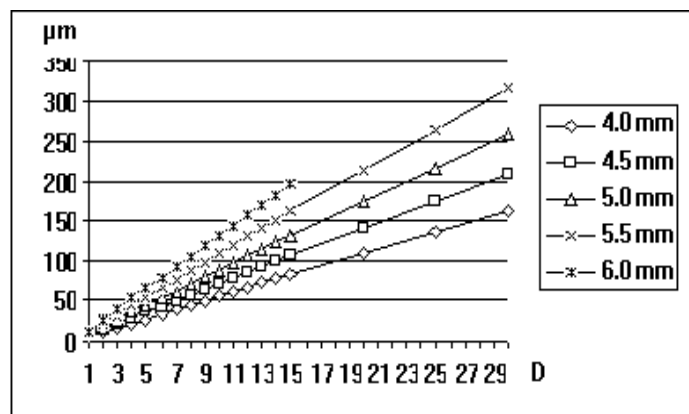


Fig. 12: Ablation centre depth for different optical zone diameters {µm}; theoretical values

As a rule, the **subjective spectacles refraction values** are used as the basis for the data input. These values are directly input into the OP Assistant. Alternatively, in case of cylinders <1 D the spherical equivalent can also be input.

Exclusively **negative values** are to be used (e.g. $-10 -10 \times 20^\circ$).



Do not try and combine different myopia programs in order to achieve so-called multipass treatments! The in-built nomogram is bound to cause severe overcorrections.

On principle, it is recommended to conduct an examination with a cornea topography system in order to be sure that the patient does not suffer from asymmetric astigmatism or an early stage of keratoconus.

In case of patients who are presbyopic or are likely to soon become presbyopic it should be considered whether a low level of residual myopia could be left untreated.

3.1.2 LASIK hyperopia

The hyperopia programs are employed in corrections of hyperopias and hyperopic, symmetrical astigmatisms **totalling not more than +16 dioptres**.

The treatment diameter (the optical zone plus the transition zone) for all programs is 9 mm

As a rule, the **subjective spectacles refraction values** are used as the basis for any data input. These values are directly input into the OP Assistant. This applies also to angles.

The refractometry shall be performed with utmost care, in particular with young patients and, if possible, in a state of cycloplegia.

Exclusively **positive values** are to be used (e.g. sph +3/cyl. +2 $\times 45^\circ$).



Do not try and combine different hyperopia programs in order to achieve so-called multipass treatments! The in-built nomogram is bound to cause severe overcorrections.

On principle, it is recommended to conduct an examination with a cornea topography system in order to be sure that the patient does not suffer from asymmetric astigmatism or an early stage of keratoconus.

3.2 Activation of the laser

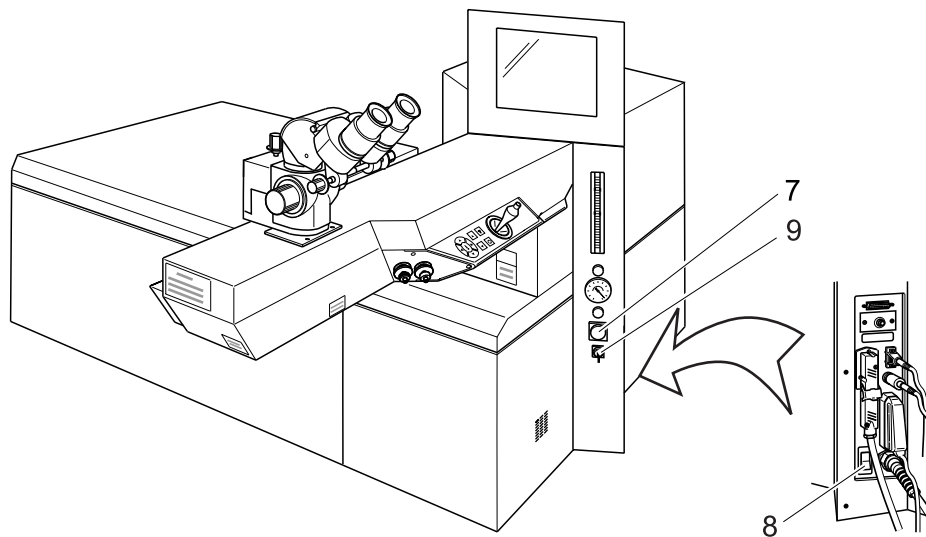


Fig. 13: MEL 70 G-Scan switch

Unlock the EMERGENCY OFF switch (7).

Switch on the main switch (8), the green light in the switch lights up.

Turn the key switch (9) fully to the right, the key will automatically return to centre position.

After approx. 30 seconds the menu of the initial heating phase will appear on the screen.

3.2.1 Initial heating phase and gas exchange

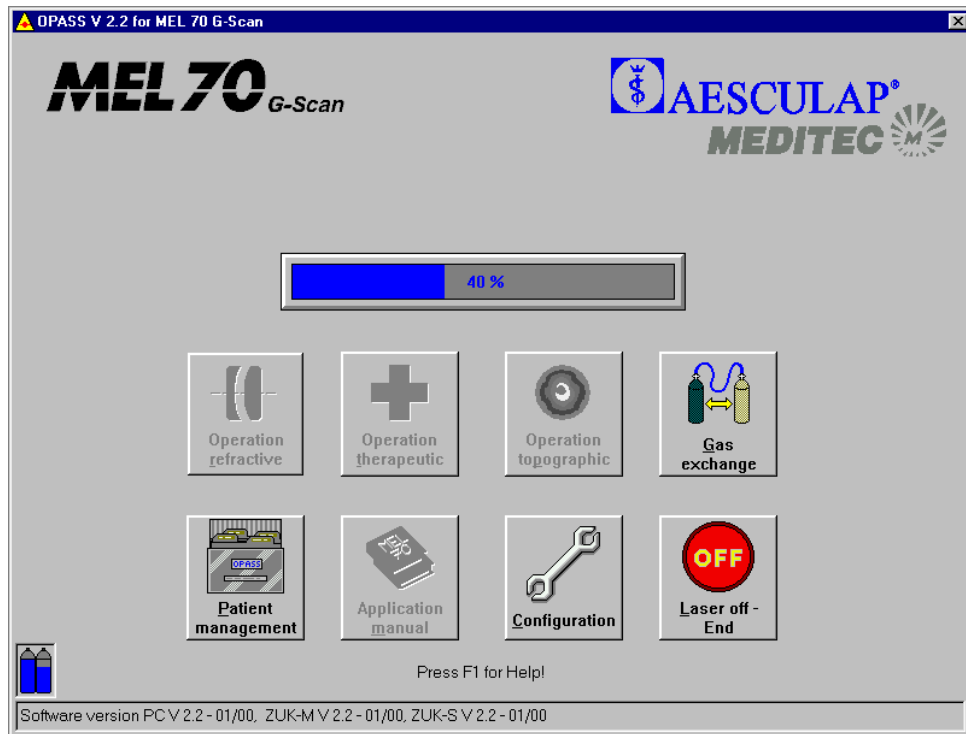


Fig. 14: Menu Initial heating phase

The laser requires a period of six minutes to heat up to the necessary operating temperature. A progress indicator will advise you of the status of the initial heating phase. The symbols with a grey background **cannot** be selected during this period.

In order to perform an automatic gas exchange click the symbol “Gas exchange” during the initial heating phase. The gas exchange takes approx. five minutes. Confirm the gas exchange with clicking “Yes”. Another progress indicator will advise you of the status of the gas exchange.

A filling level indicator of the gas cylinders is located at the left bottom corner of the screen. If one of the cylinders is empty, please, notify your hotline officer so that the cylinder will be replaced during the next service cycle.

The state bar is located at the lower screen margin. Situation-related reports and the currently used software version are displayed in this box.

Following the initial heating phase the main menu will appear on the screen.

3.3 The main menu

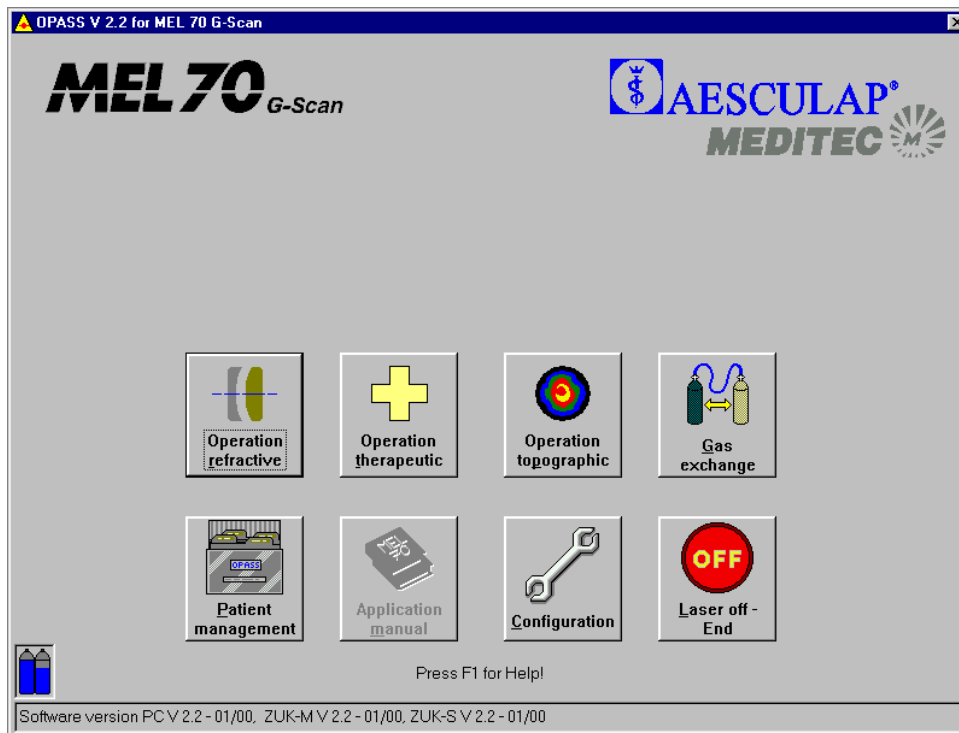


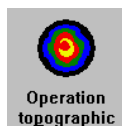
Fig. 15: Main menu LASIK



Click on this symbol in order to perform a refractive operation.



Click on this symbol in order to perform a therapeutic treatment (PTK Shaping or PTK Spot treatment). (cf. Chapters 4 and 5).



Click on this symbol in order to perform a topographic operation (cf. Chapter 6).



Click on this symbol in order to perform an automatic gas exchange (duration approx. five minutes). The gas exchange may be conducted during the initial heating phase.



Click on this symbol in order to open the patient management (cf. Appendix).



Click on this symbol in order to open the application manual.



Click on this symbol in order to perform the configuration adjustments. Here you may input the data of your clinic or select the printer for the journal printout (cf. Appendix).

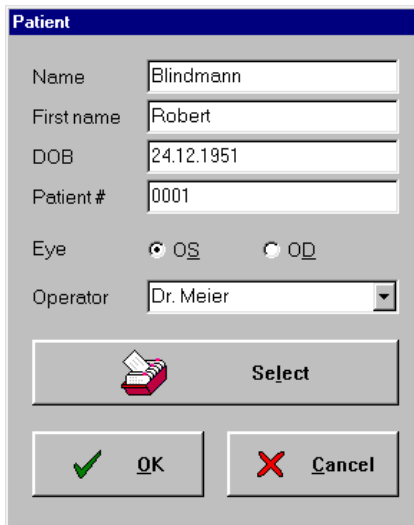


Click on this symbol in order to terminate the computer program and switch off the laser. You should not switch off the laser until the message "YOU MAY NOW SWITCH OFF THE COMPUTER" appears on the screen.

3.4 Data input for LASIK treatment

Select the treatment option “Operation refractive” from the main menu by mouse click.

3.4.1 Input of patient data



The screenshot shows a dialog box titled "Patient" with the following fields and controls:

- Name: Blindmann
- First name: Robert
- DOB: 24.12.1951
- Patient #: 0001
- Eye: OS OD
- Operator: Dr. Meier (dropdown menu)
- Buttons: Select (with a printer icon), OK (with a green checkmark), and Cancel (with a red X).

Fig. 16: Menu Patient Data

To begin with input the patient data and the name of the operating surgeon. Mark whether the left or the right eye is to be treated. You may either enter the data directly into the input field or select a patient from the patient database.

When you click on „Select“ with the left mouse key, the list of patients entered previously in the PATIENT MANAGEMENT screen opens (for details of PATIENT MANAGEMENT, see annex). These entries are printed in the operation journal.

Confirm the correct entry with “OK”.

The “Cancel” pushbutton takes you back to the main menu.

3.4.2 The OP-Assistant

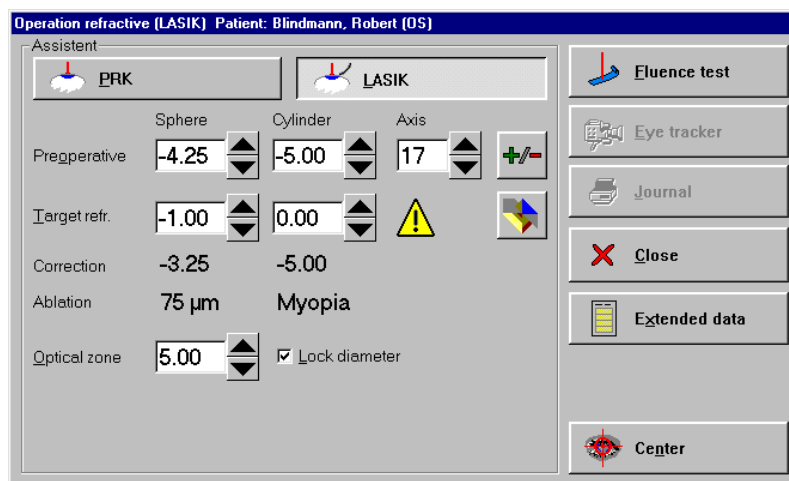


Fig. 17: Menu Operations-Assistant LASIK


Select the treatment method LASIK from the menu.

Input the preoperative **subjective spectacles refraction values** directly into the OP Assistant. In some cases it may be desirable to undercorrect the patient. In order to do so, enter the desired target refraction (by clicking on the scroll arrows with the left mouse key you will modify the value in 0.25 D steps, by clicking with the right mouse key you will modify the value by 1 D). The OP Assistant will automatically calculate and display the correction in the appropriate field.

In the case of a “false” mixed astigmatism (e.g., $-4 + 2 \times 10^\circ$):

By clicking on the “Diagram” symbol you will get a graphical representation of the working ranges. The red arrow indicates the preoperative refraction, the green arrow the target refraction. You can close the diagram by clicking on the button with the hook.

In the event that the preoperative values are outside of the valid working ranges the refractive error cannot be completely corrected, i.e. a residual sphere or a residual cylinder will result (the red arrow in the diagram is outside of the coloured range, the green arrow is not in the zero point).

In this case the program suggests a $-/+$ calculation (click , Fig. 17, $\rightarrow -2 -2 \times 180^\circ$).

After inputting the refraction data, the optical zone can be varied but the thickness of the cornea should be observed.

3.4.3 The fluence-test

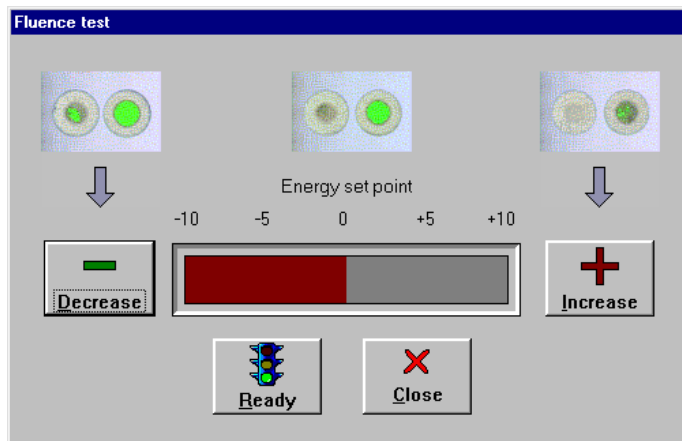


Fig. 18: Menu fluence test

By clicking on the pushbuttons “High” or “Low” you may increase or decrease the energy set point.

You start the fluence test by operating the pushbutton “Ready”.

Clicking on the pushbutton “Close” will abort the fluence test.

LASIK

3.5 Preparation of the laser

Height adjust your operating chair.

Switch on the ring-shaped lamp (11) and check the ocular adjustment.

Swivel the laser arm and switch on the distance control laser (12).

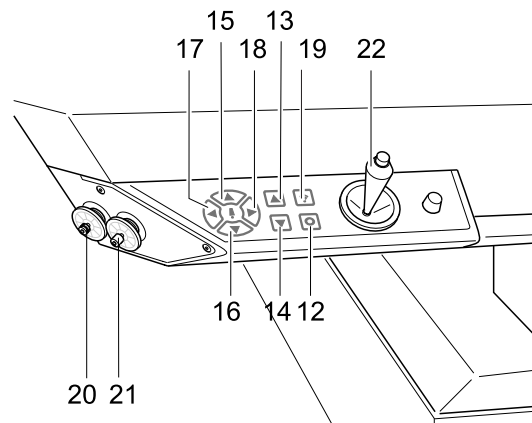


Fig. 19: Control Panel Laser Arm

Position the patient bed together with the blue test base at the appropriate height. The two focusing points require to be brought into an overlapping position. Operate the below keys on the operating panel of the laser arm towards this end:

Height adjustment	higher	(13)	deeper	(14)
Horizontal alignment	forward	(15)	backward	(16)
	to left	(17)	to right	(18)

Put a piece of test paper onto the blue test base.

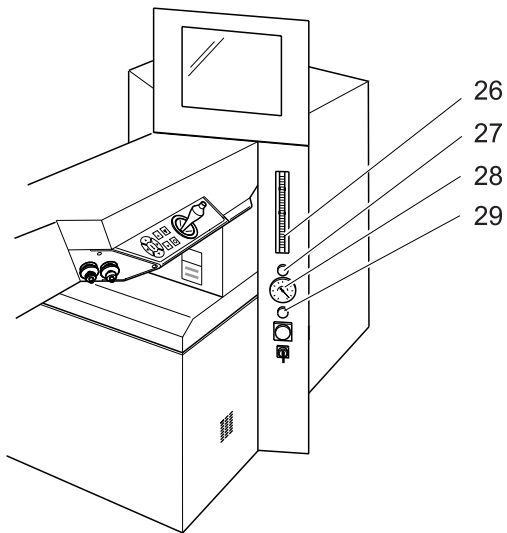


Fig. 20: Control panel

Click on the pushbutton “Ready” in the menu of the fluence test.



Now the laser may be actuated by means of the right-hand foot pedal.

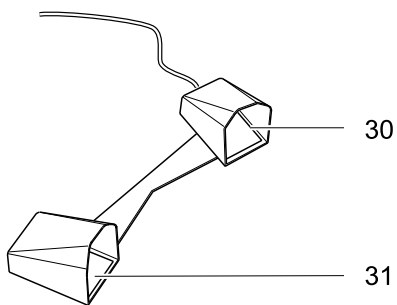


Fig. 21: Foot pedal

Place the red target beam with the joystick (22) onto a free area of the test paper.

Now make the fluence test as described in the Instruction Manual.

Following the successfully completed test, click on the pushbutton “OK” and turn the laser arm to the side.



**Only continue after a successfully completed fluence test!
A faulty fluence value will result in false treatment.**

Repeat this procedure with each new patient.

Remove the blue test base.

3.6 Preparation of the patient

Thirty minutes prior to the laser treatment a topical anaesthetic (e.g. Novesine, Kerakain) and Pilocarpin shall be administered.

If required, a sedative agent (e.g. Diazepam) shall be given.

The minus cylinder axis of the patient is marked on, e.g., the sclera, with a colour pen. (Alternatively, the patient may be temporarily placed under the surgery microscope with the test frame put on).

The height adjustment is carried out by means of the focusing laser.

The head of the patient is aligned horizontally as much as possible, so that the pupil is at the centre of the eye-slit when the patient looks into the surgery microscope.

Cover with sterile sheets the area around the eye and head of the patient.

An eyelid speculum is to be placed between the eyelids (preferably of the Barraquer type).

When **treating astigmatisms** the reticule of the ocular by turning is adjusted to the 0° axis of the patient.

Ask the patient to fixate on a green LED and mark the optical centre (centre of the entry pupil) with an eye cannula.

Make the lamellar cut according to the guidelines of your microkeratome. The flap should have a size of not less than 8.5 mm in diameter.

Remove the suction ring of the microkeratome.

Remove excessive lacrimal fluid from the conjunctival sac by means of a swab/wick and dry the corneal stroma by means of a spatula ('Hockey' knife). If required, dry the hinge of the flap with a triangular swab.

Repeat the marking the optical centre (centre of the entry pupil) with an eye cannula.

Re-check the working distance by means of the distance control laser (combine points). Subsequently, switch off the distance control laser.

LASIK

3.7 The eye tracker

An active eye tracker will follow the patient's eye movements during the treatment and, if need be, the laser beam will be traced accordingly. The suction ring of the flue gas extraction installation serves as the object for the tracker. This ring needs to be attached first (as much centred as possible).

Click on the pushbutton "Eye Tracker" in the menu of the OP Assistant.

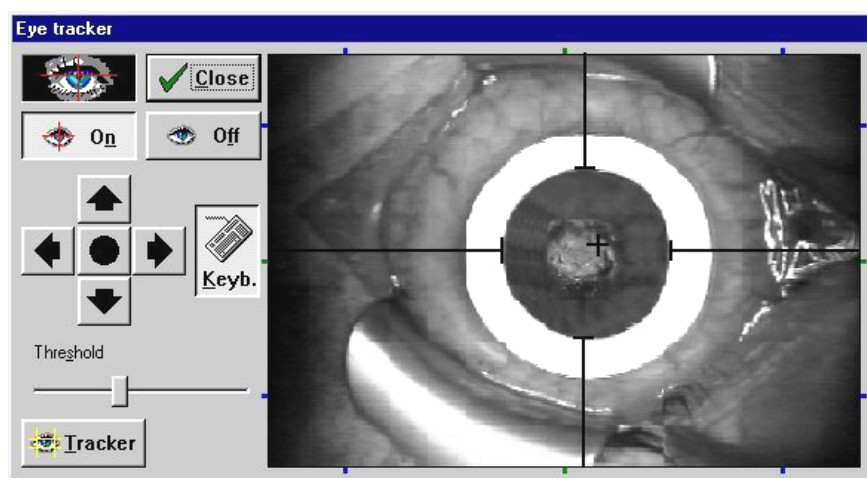


Fig. 22: Menu eye tracker

The menu of the eye tracker will open. This window remains open during the treatment session and enables you to make different adjustments and check the functioning of the tracker. A video image of the eye tracker is displayed on the right, while the left shows the configuration pushbuttons.

Activate the eye tracker by clicking on the pushbutton "On". The tracker status indicator is located above the latter pushbutton. If the eye is displayed against a black background, the object was recognised by the eye tracker. If the pupil was not recognised the background will remain grey. In the latter case, check the below items:

- Has the eye tracker been switched on?
- Is the pupil still in the HOT ZONE?
The HOT ZONE is the area where the laser follows the patient eye movement. If the pupil leaves the HOT ZONE the sequence of shots is automatically interrupted until the pupil is again in the area of this zone. In such case reposition the head of the patient in such a way that the eye is at the centre of the camera image.

When the eye tracker is switched on you will see a graticule in the video image. This graticule will be automatically placed in the object centre. However, since the optical axis is not always in the object centre you have the opportunity to modify this setting. You can change the position of the graticule by clicking with the right mouse key on the arrow keys on the left of the video image. The right mouse key will move the graticule in larger steps. Click the round pushbutton in the centre in order to readjust the graticule to the geometrical centre.

You can also move the graticule with the arrow keys. The keyboard button must be enabled for this.

You can adjust different parameters of the video image, such as brightness, contrast, etc., by clicking on the “Video” pushbutton.

The eye tracker is switched off by clicking on the “Off” pushbutton.

The eye tracker window is closed by clicking on the “Close” pushbutton.



When the eye tracker is switched off the laser beam will not be automatically traced, i.e. any eye movements will not be compensated!

LASIK

3.8 Centration with the MEL 70 G-Scan using the Artificial Limbus Ring

3.8.1 Centre of Pupil

- Input patient data
- Perform fluence test
- Press ready
- Perform keratome cut
- Apply limbus ring roughly centred
- Open flap
- Have the patient look to the green LED
- Use cannula/marker to set centre of ablation (centre of pupil)
- Press 'eye tracker' button (the joystick will be deactivated)
- Set aiming beam to your mark on the cornea by using the mouse or keypad
- Protect flap with a wet sponge from the nasal side in case of a cylindrical ablation around the zero degree axis (classical flap) or 90 degrees (down-up flap), respectively
- Start ablation



Caution

Stop every once in a while to verify eyetracker centration and to dry the stromal bed.

3.8.2 Purkinje Reflex

- Input patient data
- Perform fluence test
- Press ready
- Perform keratome cut
- Press 'eye tracker' button (the joystick will be deactivated)
- Apply limbus ring in a way you can see the Purkinje reflex
- Open flap

- Reposition aiming beam by using the mouse or keypad to find again the Purkinje reflex
- Protect flap with a wet sponge from the nasal side in case of a cylindrical ablation around the zero degree axis (classical flap) or 90 degrees (down-up flap), respectively
- Start ablation



Caution

Stop every once in a while to verify eyetracker centration and to dry the stromal bed.

3.9 The treatment session

When you press the „Center“ button the target beam of the laser will always be in the center of the surgical microscope in whatever position the joystick may be. In this way the target beam instead of the fixation light can be used for centering.

Check the values which have been adjusted in the Assistant.

Click on the “Ready” pushbutton in the OP Assistant.

Actuate the right foot pedal and keep it depressed.

A progress indicator will display the progress of the treatment. By clicking on the “Cancel” pushbutton the treatment may be discontinued following the release of the foot pedal.

After the termination of the correction program the OP Assistant will automatically interrupt the laser triggering. The treatment is interrupted by releasing the foot pedal and may be resumed by actuating the pedal again.

LASIK

3.10 Termination of the program

By clicking on the “PROTOKOLL” pushbutton you will receive a print-out of the surgery data via the connected printer.

You may return to the main menu by clicking on the “OK” pushbutton.

In order to treat further patients, commence again in the main menu (Chapter 3.3) and follow the instructions in the applications manual.

3.11 Switching off of the laser

In order to switch off the laser click on the “OFF Laser off - End” and confirm the switch-off by clicking on the pushbutton “Yes”.

Wait for the message “NOW YOU MAY SWITCH OFF THE COMPUTER” appears on the screen.

Turn the key switch (9) fully to the left.

Switch off the main switch (8) (the green light in the switch will go out).

3.12 Follow-up treatment (proposed)

Put the flap back into the stromal bed. If required, the flap may be moistened with BSS and cleaned before being put back. There must be no epithelium cells remain under the flap.

Wait for some two to five minutes until the flap has slightly dried and is fixed to the stroma. Use a sponge for drying and also for pressing the wound edges into the stromal bed.

Confer to the current literature for further postoperative treatment.

4 PTK-Shaping

4.1 Applications

The PTK Shaping program is designed to remove corneal scars near the surface up to a max. depth of approx. 100 μm .

The treatment diameter for all programs is max. 6 mm, the linear transition zone is max. 7 mm and the total ablation is max. 9 mm.

4.2 Activation of the laser

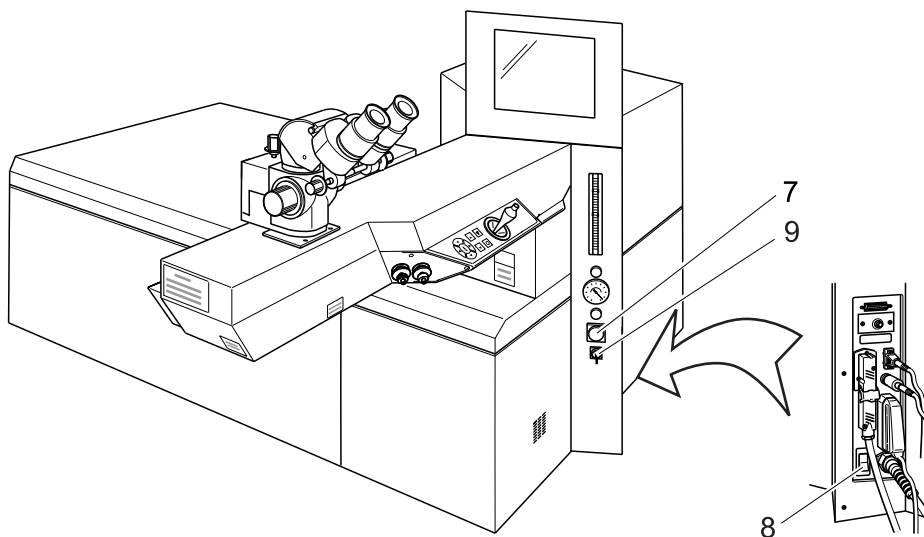


Fig. 23: MEL 70 *G-Scan* switches

Unlock the EMERGENCY OFF switch (7.)

Switch on the main switch (8), the green light in the switch lights up.

Turn the key switch (9) fully to the right, the key will automatically return to centre position.

After approx. 30 seconds the menu of the initial heating phase will appear on the screen.

PTK-Shaping

4.2.1 Initial heating phase and gas exchange

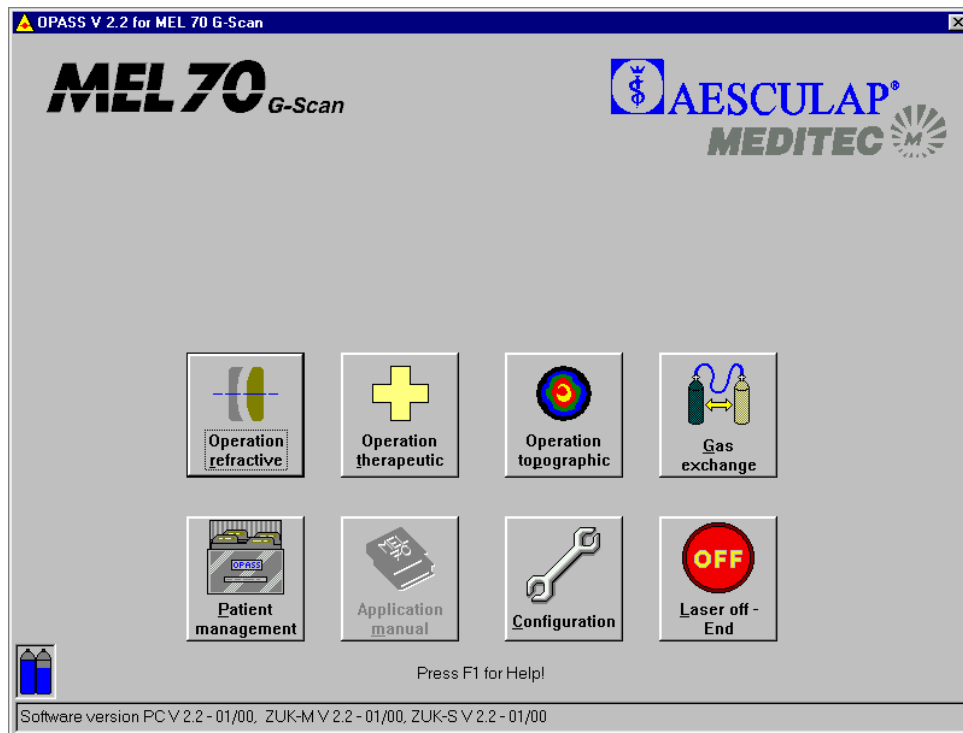


Fig. 24: Menu Initial heating phase

The laser requires a period of six minutes to heat up to the necessary operating temperature. A progress indicator will advise you of the status of the initial heating phase. The symbols with a grey background **cannot** be selected during this period.

In order to perform an automatic gas exchange click the symbol “Gas exchange” during the initial heating phase. The gas exchange takes approx. five minutes. Confirm the gas exchange with clicking “Yes”. Another progress indicator will advise you of the status of the gas exchange.

A filling level indicator of the gas cylinders is located at the left bottom corner of the screen. If one of the cylinders is empty, please, notify your hotline officer so that the cylinder will be replaced during the next service cycle.

The state bar is located at the lower screen margin. Situation-related reports and the currently used software version are displayed in this box.

Following the initial heating phase the main menu will appear on the screen.

4.3 The Main Menu

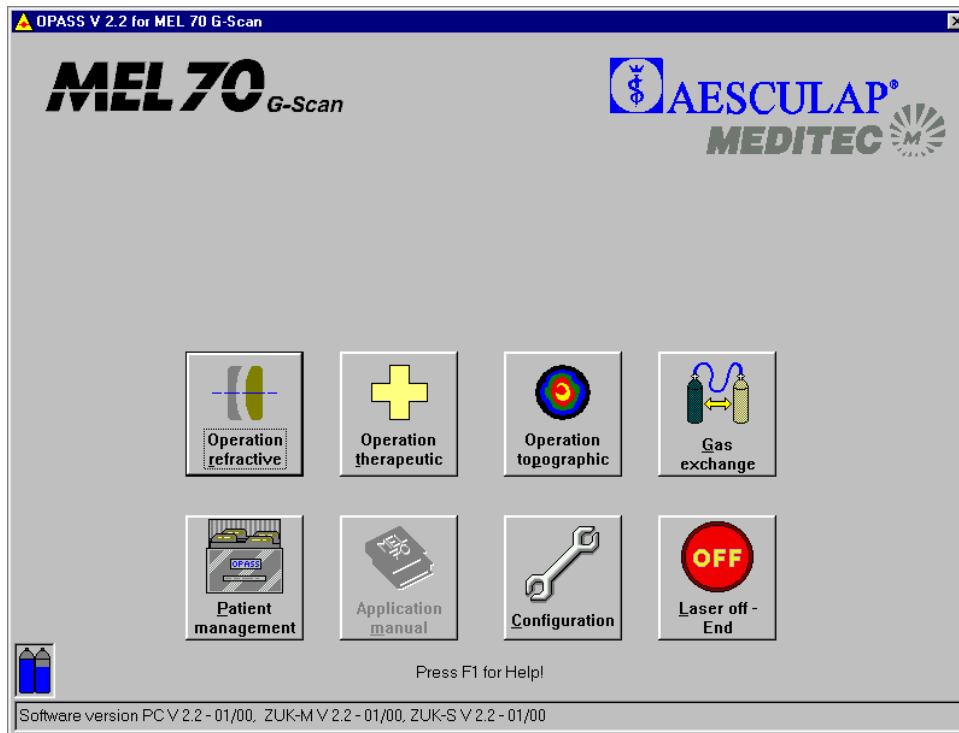


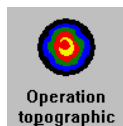
Fig. 25: The Main Menu PTK-Shaping



Click on this symbol in order to perform a refractive operation.



Click on this symbol in order to perform a therapeutic treatment (PTK Shaping or PTK Spot treatment).



Click on this symbol in order to perform a topographic operation (cf. Chapter 6).



Click on this symbol in order to perform an automatic gas exchange (duration approx. five minutes). The gas exchange may be conducted during the initial heating phase.

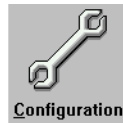
PTK-Shaping



Click on this symbol in order to open the patient management (cf. Appendix).



Click on this symbol in order to open the application manual.



Click on this symbol in order to perform the configuration adjustments. Here you may input the data of your clinic or select the printer for the journal printout (cf. Appendix).

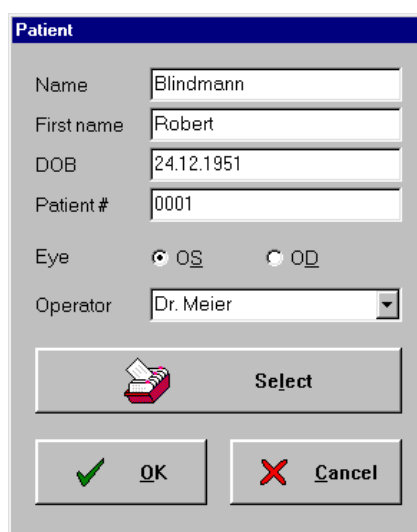


Click on this symbol in order to terminate the computer program and switch off the laser. You should not switch off the laser until the message "YOU MAY NOW SWITCH OFF THE COMPUTER" appears on the screen.

4.4 Data input for PTK Shaping treatment

Select the treatment method “Operation therapeutic” from the main menu by mouse click.

4.4.1 Input of patient data



The screenshot shows a dialog box titled "Patient" with the following fields and controls:

- Name: Blindmann
- First name: Robert
- DOB: 24.12.1951
- Patient #: 0001
- Eye: OS OD
- Operator: Dr. Meier (dropdown menu)
- Buttons: Select (with a printer icon), OK (with a green checkmark), and Cancel (with a red X).

Fig. 26: Menu Patient Data

To begin with input the patient data and the name of the operating surgeon. Mark whether the left or the right eye is to be treated. You may either enter the data directly into the input field or select a patient from the patient database.

When you click on “Select” with the left mouse key, the list of patients entered previously in the PATIENT MANAGEMENT screen opens (for details of PATIENT MANAGEMENT, see annex). These entries are printed in the operation journal.

Confirm the correct entry with “OK”.

The “Cancel” pushbutton takes you back to the main menu.

PTK-Shaping

4.4.2 The OP-Assistant

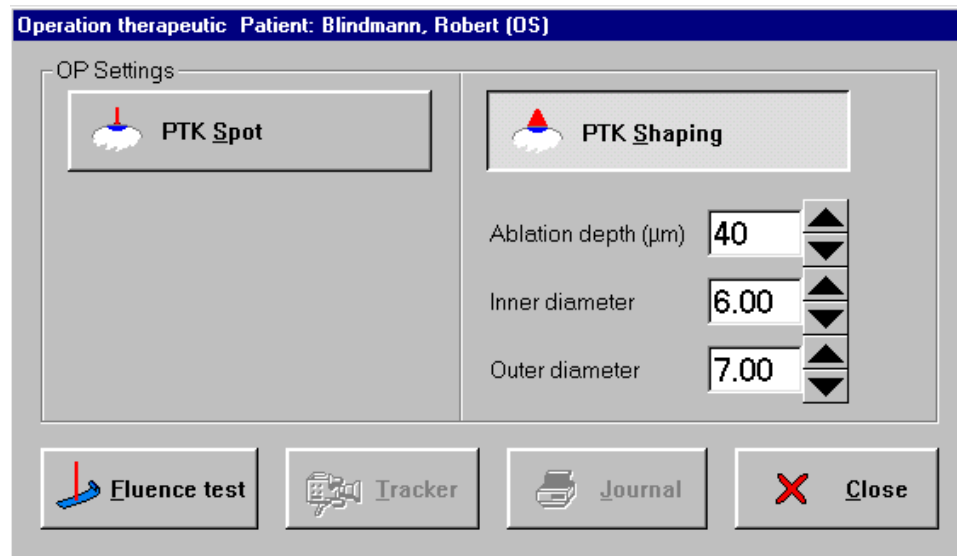


Fig. 27: Menu Operations-Assistant for PTK-Shaping

Select the treatment method “PTK Shaping” from the OP menu.

Input the desired ablation depth. Depending on the relevant ablation depth a transition zone from 7 mm to 6 mm or 5 mm will result. In the process the edges of the ablation zone will be rounded.

Following the completion of the input, click on the pushbutton “Fluence Test”.

The pushbutton “Close” will take you back to the main menu.

4.4.3 The fluence test

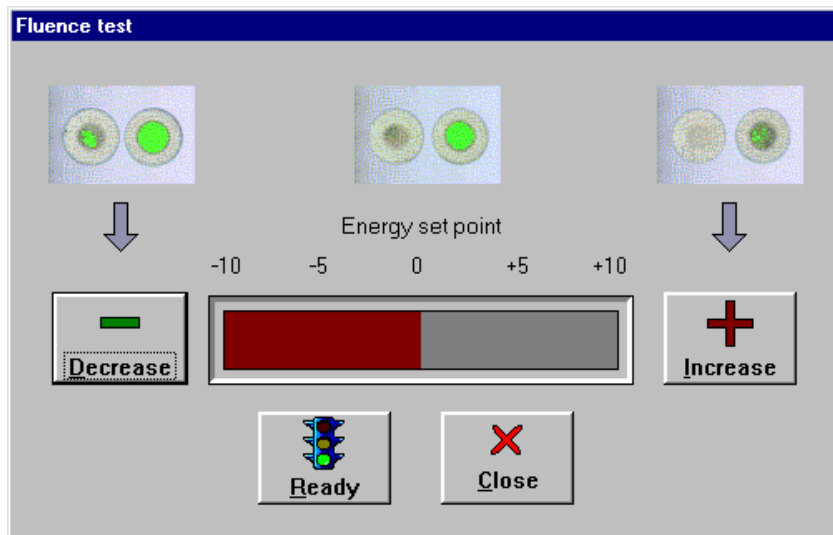


Fig. 28: Menu fluence-test

By clicking on the pushbuttons “High” or “Low” you may increase or decrease the energy set point.

You start the fluence test by operating the pushbutton “Ready”.

Clicking on the pushbutton “Close” will abort the fluence test.

PTK-Shaping

4.5 Preparation of the laser

Height adjust your operating chair.

Switch on the ring-shaped lamp (11) and check the ocular adjustment.

Swivel the laser arm and switch on the distance control laser (12).

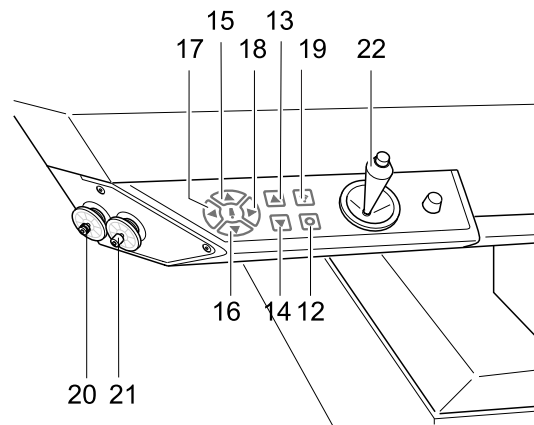


Fig. 29: Control panel laser arm

Position the patient bed together with the blue test base at the appropriate height. The two focusing points require to be brought into an overlapping position. Operate the below keys on the operating panel of the laser arm towards this end:

Height adjustment	higher	(13)	deeper	(14)
Horizontal alignment	forward	(15)	backward	(16)
	to left	(17)	to right	(18)

Put a piece of test paper onto the blue test base.

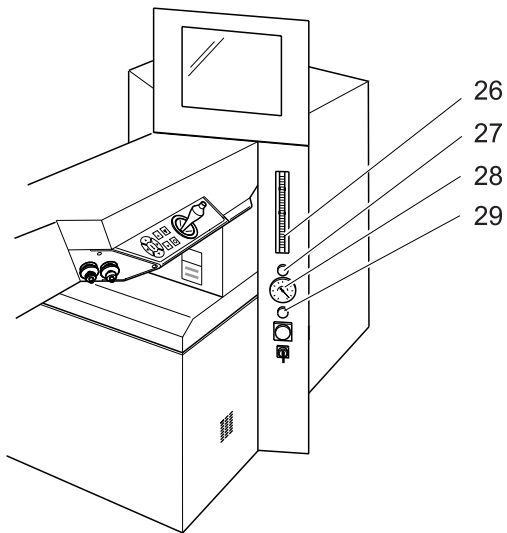


Fig. 30: Control panel

Connect the blue hose for the flue gas extraction suction to the laser arm (2) and the PRK suction ring (blue marking). Adjust the value for the flue gas extraction to maximum at the flow meter (26).

Click on the pushbutton “Ready” in the menu of the fluence test.



Now the laser may be actuated by means of the right-hand foot pedal.

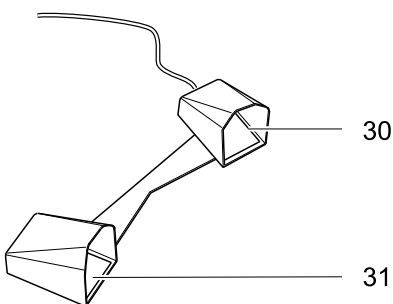


Fig. 31: Foot pedal

PTK-Shaping

Place the red target beam with the joystick (22) onto a free area of the test paper.

Now make the fluence test as described in the Instruction Manual.

If required, modify the energy set point in the fluence test menu by clicking on the pushbuttons “stronger” or “weaker”. Repeat the test by operating again the pushbutton “Ready” in the fluence test menu.



**Only continue after a successfully completed fluence test!
A faulty fluence value will result in false treatment.**

Following the successfully completed test, click on the pushbutton “OK” and turn the laser arm to the side.

Remove the blue test base and lower the patient bed.

Connect the red hose for mask fixation to the laser arm (2) and to the suction ring (red marking). Shortly tap on the left foot pedal (31) in order to switch on the mask fixation and check its correct functioning with your thumb or by squeezing the red hose. Adjust the vacuum (28) to approx. -0.4 bar by means of the red turning button (29).

Switch off the mask fixation by shortly tapping on the foot pedal.

Disinfect the suction ring by wiping it with 70 % alcohol – or rather, use another suction ring that has been steam sterilised.

Repeat this procedure with each new patient.

4.6 Preparation of the patient

Thirty minutes prior to the laser treatment a topical anaesthetic (e.g. Novesine, Kerakain or 0.5 % Proparacaine) and Pilocarpin shall be administered.

If required, a sedative agent (e.g. Diazepam) shall be given.

The height adjustment is carried out by means of the focusing laser.

The head of the patient is aligned horizontally as much as possible, so that the pupil is at the centre of the eye-slit when the patient looks into the surgery microscope.

An eyelid speculum is to be placed between the eyelids (preferably of the Barraquer type).

Ask the patient to fixate on a green LED and mark the optical centre (centre of the entry pupil) with an eye cannula.

Attach the ring marker, diameter 8.5 mm, and turn by 20° to 30° under slight pressure.

Perform the abrasion of the epithelium by means of a 'Hockey' knife.

Repeat marking the optical centre (centre of the entry pupil) with an eye cannula.

Re-check the working distance by means of the focusing laser (combine points). Subsequently, switch off the focusing laser.

PTK-Shaping

4.6.1 The treatment session

Check the values which have been adjusted in the Assistant.

Click on the “Ready” pushbutton in the OP-Assistant.

Actuate the right foot pedal and keep it depressed.

A progress indicator will display the progress of the treatment. By clicking on the “Cancel” pushbutton the treatment may be discontinued following the release of the foot pedal.

After the termination of the correction program the OP Assistant will automatically interrupt the laser triggering. The treatment is interrupted by releasing the foot pedal and may be resumed by actuating the pedal again.

4.7 Termination of the program

By clicking on the “PROTOKOLL” pushbutton you will receive a print-out of the surgery data via the connected printer.

You may return to the main menu by clicking on the “OK” pushbutton.

In order to treat further patients, commence again in the main menu and follow the instructions in the applications manual.

4.8 Switching off of the laser

In order to switch off the laser click on the “OFF Laser off – End” and confirm the switch-off by clicking on the pushbutton “Yes”.

Wait for the message “NOW YOU MAY SWITCH OFF THE COMPUTER” appears on the screen.

Turn the key switch (9) fully to the left.

Switch off the main switch (8) (the green light in the switch will go out).

4.9 Postoperative treatment (proposed)

Remove the eyelid speculum.

Administer an antibiotic ointment (e.g. Gentamicin).

Give analgesic medication for the first postoperative day (e.g. Valoron N).

Apply an eye dressing for two to three days with daily follow-up checks of the healing process, again administer an antibiotic ointment.

PTK-Spot

5 PTK-Spot

5.1 Applications

In the PTK Spot mode corneal tissue may be manually removed at great accuracy. The laser will be controlled with a joystick during the surgery.

It depends on the individual decision whether the treatment will consist of the ablation of part of the epithelium, of epithelial or stromal tissue or even of a perforation like in Excimer Laser keratoplasty.

5.2 Activation of the laser

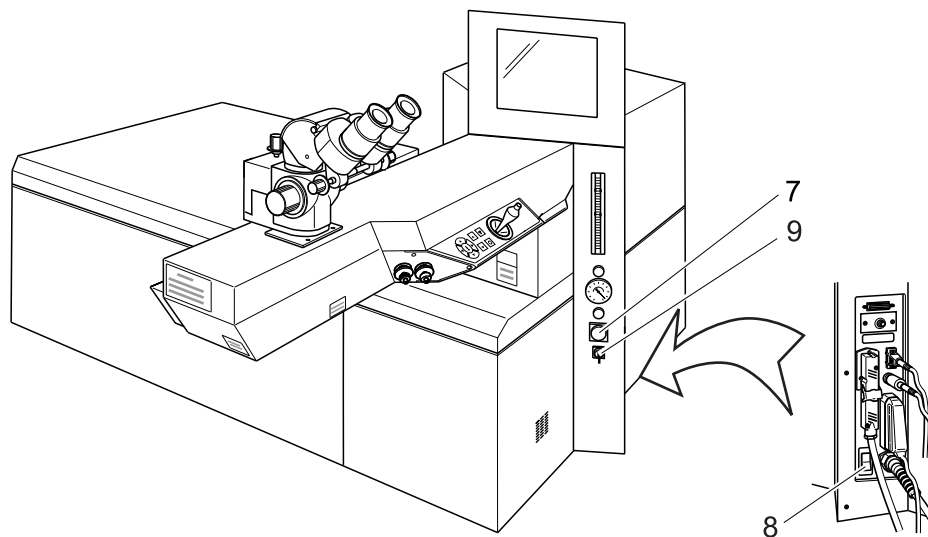


Fig. 32: MEL 70 G-Scan switches

Unlock the EMERGENCY OFF switch (7.)

Switch on the main switch (8), the green light in the switch lights up.

Turn the key switch (9) fully to the right, the key will automatically return to centre position.

After approx. 30 seconds the menu of the initial heating phase will appear on the screen.

5.2.1 Initial heating phase and gas exchange

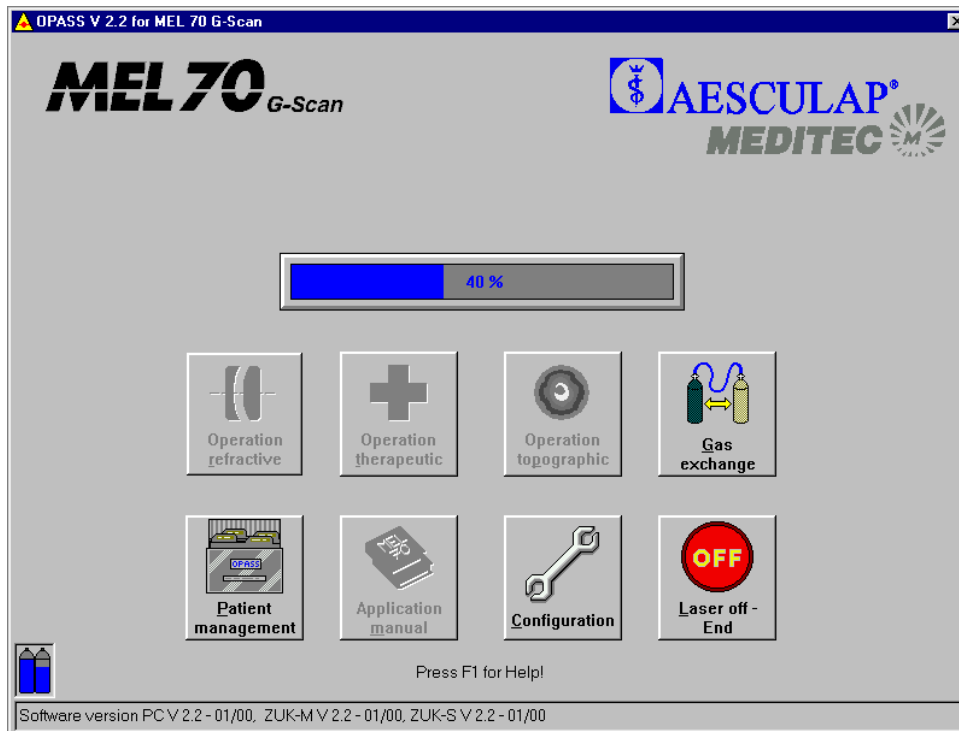


Fig. 33: Menu Initial Heating Phase

The laser requires a period of six minutes to heat up to the necessary operating temperature. A progress indicator will advise you of the status of the initial heating phase. The symbols with a grey background **cannot** be selected during this period.

In order to perform an automatic gas exchange click the symbol “Gas exchange” during the initial heating phase. The gas exchange takes approx. five minutes. Confirm the gas exchange with clicking “Yes”. Another progress indicator will advise you of the status of the gas exchange.

A filling level indicator of the gas cylinders is located at the left bottom corner of the screen. If one of the cylinders is empty, please, notify your hotline officer so that the cylinder will be replaced during the next service cycle.

The state bar is located at the lower screen margin. Situation-related reports and the currently used software version are displayed in this box.

Following the initial heating phase the main menu will appear on the screen.

5.3 The Main Menu

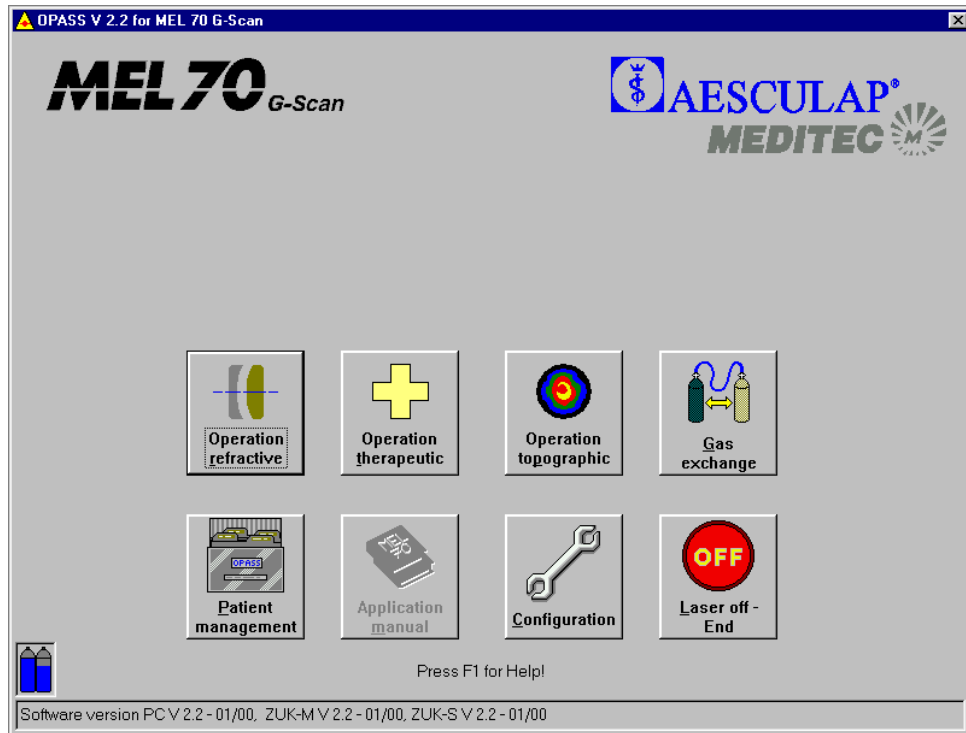


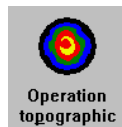
Fig. 34: The Main Menu PTK-Spot



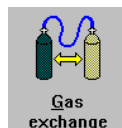
Click on this symbol in order to perform a refractive operation.



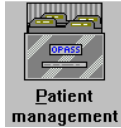
Click on this symbol in order to perform a therapeutic treatment (PTK Shaping or PTK Spot treatment).



Click on this symbol in order to perform a topographic operation (cf. Chapter 6).



Click on this symbol in order to perform an automatic gas exchange (duration approx. five minutes). The gas exchange may be conducted during the initial heating phase.



Click on this symbol in order to open the patient management (cf. Appendix).



Click on this symbol in order to open the application manual.



Click on this symbol in order to perform the configuration adjustments. Here you may input the data of your clinic or select the printer for the journal printout (cf. Appendix).



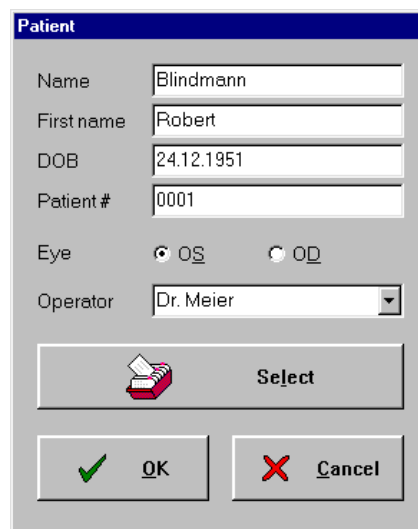
Click on this symbol in order to terminate the computer program and switch off the laser. You should not switch off the laser until the message "YOU MAY NOW SWITCH OFF THE COMPUTER" appears on the screen.

PTK-Spot

5.4 Program input for PTK Spot treatment

Select the treatment method “Operation therapeutic” from the main menu by mouse click.

5.4.1 The patient data menu



The screenshot shows a dialog box titled "Patient" with the following fields and controls:

- Name: Blindmann
- First name: Robert
- DOB: 24.12.1951
- Patient #: 0001
- Eye: OS OD
- Operator: Dr. Meier (dropdown menu)
- A "Select" button with a printer icon.
- Two buttons at the bottom: "OK" with a green checkmark and "Cancel" with a red X.

Fig. 35: Menu Patient Data

To begin with input the patient data and the name of the operating surgeon. Mark whether the left or the right eye is to be treated. You may either enter the data directly into the input field or select a patient from the patient database.

When you click on “Select” with the left mouse key, the list of patients entered previously in the PATIENT MANAGEMENT screen opens (for details of PATIENT MANAGEMENT, see annex). These entries are printed in the operation journal.

Confirm the correct entry with “OK”.

The “Cancel” pushbutton takes you back to the main menu.

5.4.2 The OP-Assistant

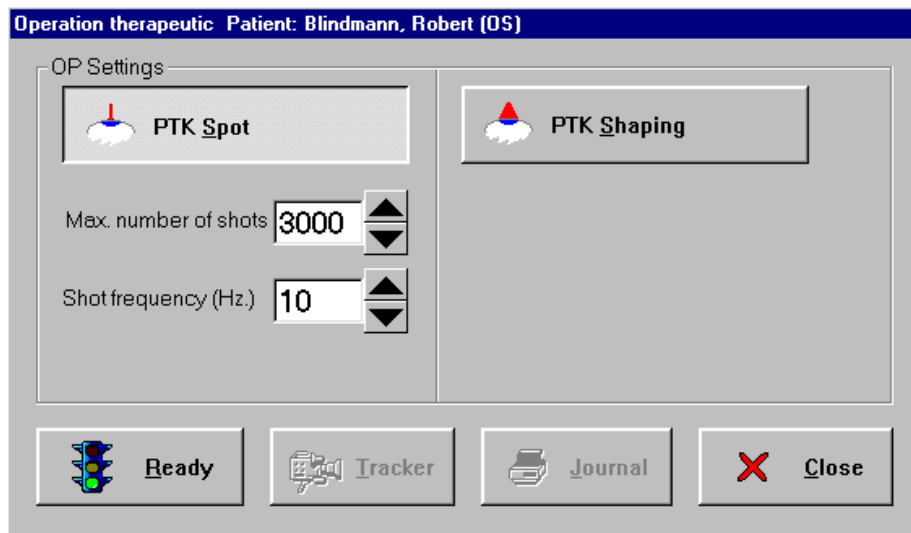


Fig. 36: The Operations -Assistant PTK-Spot

Select the treatment method “PTK Spot” from the OP menu.

Input the maximum number of shots (the shot sequence of the laser will be interrupted when this max. number is reached) and the frequency of shots (number of laser pulses per second)

The pushbutton “Close” will take you back to the main menu.

PTK-Spot

5.5 Preparation of the laser

Height adjust your operating chair.

Switch on the ring-shaped lamp (11) and check the ocular adjustment.

Swivel the laser arm and switch on the distance control laser (12).

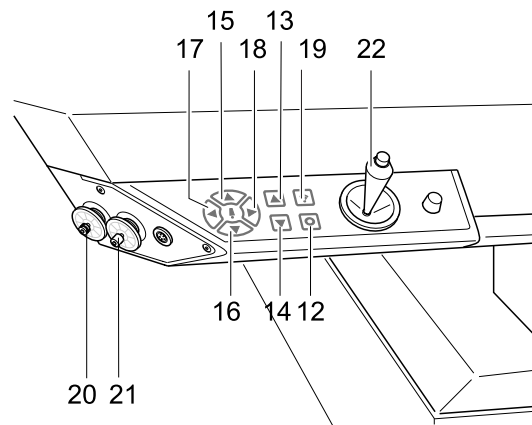


Fig. 37: Control panel laser arm

Position the patient bed together with the blue test base at the appropriate height. The two focusing points require to be brought into an overlapping position. Operate the below keys on the operating panel of the laser arm towards this end:

Height adjustment	higher	(13)	deeper	(14)
Horizontal alignment	forward	(15)	backward	(16)
	to left	(17)	to right	(18)

Click on the pushbutton "Ready".



Now the laser may be actuated at any time by means of the right-hand foot pedal.

5.6 Treatment of recurrent erosion

5.6.1 Preparation of the patient

Administer a topical anaesthetic (e.g. Novesine, Kerakain).

Fluorescin may be used to mark the area of the cornea which is to be subjected to Excimer Laser treatment.

Place an eyelid speculum.

5.6.2 The treatment session

The Excimer Laser is used to “knock tight” the loose epithelium. In order to do so, about 10 μm –20 μm of the epithelium are ablated. This ablation depth should not be exceeded, so as to avoid any damage at the Bowman’s membrane.

The laser spot will be controlled with a joystick (22).

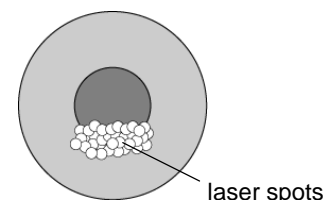
The total number of required laser impulses is relatively low. Under normal circumstances and depending on the size of the area to be treated 50–150 laser impulses will suffice. The ablation depth **of one pulse** is 1.5 μm . This is the reason why not more than 10 laser pulses may be directed at any one specific spot.

Adjust the number of shots at 150 shots.

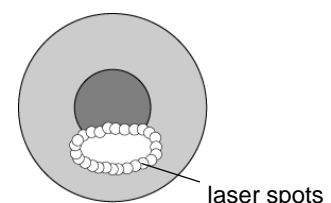
Adjust the frequency at 3–5 Hz.

The procedure during the treatment depends on the individual clinical characteristics:

In case of a *closed erosion* (without an epidermolysis) a laser ablation is performed which is evenly distributed across the whole affected area.



In case of an extended erosion with a partially detached or only loosely attached epithelium, first loose remnants of the epithelium are removed with a triangular swab. Subsequently, the marginal zones of the erosion are treated with the laser spot.



PTK-Spot

Actuate the right foot pedal (30) and keep it depressed.

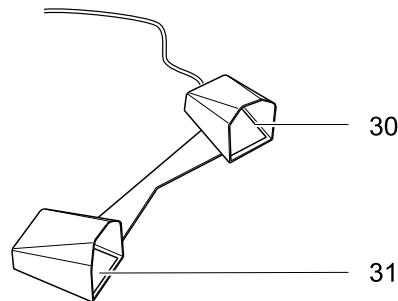


Fig. 38: Foot pedal

A progress indicator will display the progress of the treatment. By clicking on the “Cancel” pushbutton the treatment may be discontinued following the release of the foot pedal.

After the termination of the correction program the OP Assistant will automatically interrupt the laser triggering. The treatment is interrupted by releasing the foot pedal and may be resumed by actuating the pedal again.

5.6.3 Postoperative treatment

The patient will have to wear an eye dressing for twelve hours. Apply a topical antibiotic for three days and artificial lacrimal fluid during the following four weeks.

5.6.4 Results

Re-epithelialisation at a fast rate.

Three days after the operation the re-epithelialisation is completed and the patient is free from pain.

The relapse rate is significantly lower in comparison to conventional treatment methods.

5.7 Treatment of pterygia

5.7.1 Preparation of the patient

Administer a topical anaesthetic (e.g. Novesine, Kerakain).

Remove the pterygium in the conventional way (e.g. by means of scissors or 'Hockey' knife).

The haemorrhage will be stopped either by cauterisation or coagulation by means of an Argon laser.

The Excimer Laser is employed to smooth the rough surface of the cornea.

5.7.2 The treatment session

Adjust the number of shots at 3000 shots.

Adjust the frequency at 10–20 Hz.

The procedure during the treatment depends on the individual clinical Characteristics:

Click on the pushbutton "Ready" in the OP Assistant.

The cornea requires to be kept dry during the treatment, use e.g. triangular swabs for this purpose. This is necessary since any bleeding or weeping would prevent the ablation of the tissue.

As a rule, there are several thousand laser ablations required before a smooth surface is achieved.

Actuate the right foot pedal (30) and keep it depressed.

A progress indicator will display the progress of the treatment. By clicking on the "Cancel" pushbutton the treatment may be discontinued following the release of the foot pedal.

After the termination of the correction program the OP Assistant will automatically interrupt the laser triggering. The treatment is interrupted by releasing the foot pedal and may be resumed by actuating the pedal again.

PTK-Spot

5.7.3 Results

Re-epithelialisation at a fast rate.
Excellent healing of the wound.

5.8 Termination of the program

By clicking on the “PROTOKOLL” pushbutton you will receive a print-out of the surgery data via the connected printer.

You may return to the main menu by clicking on the “OK” pushbutton.

In order to treat further patients, commence again in the main menu and follow the instructions in the applications manual.

5.9 Switching off of the laser

In order to switch off the laser click on the “OFF Laser off – End” and confirm the switch-off by clicking on the pushbutton “Yes”.

Wait for the message “NOW YOU MAY SWITCH OFF THE COMPUTER” appears on the screen.

Turn the key switch (9) fully to the left.

Switch off the main switch (8) (the green light in the switch will go out).

6 Topographic treatment

6.1 Application

Fundamentally all PRK and LASIK treatments can be made with the topography link. In particular, this treatment mode can be used for repairing decenterings, irregularities and asymmetries. For more detailed information, please refer to the “T.O.S.C.A. Workstation” user’s manual.

6.2 Activation of the laser

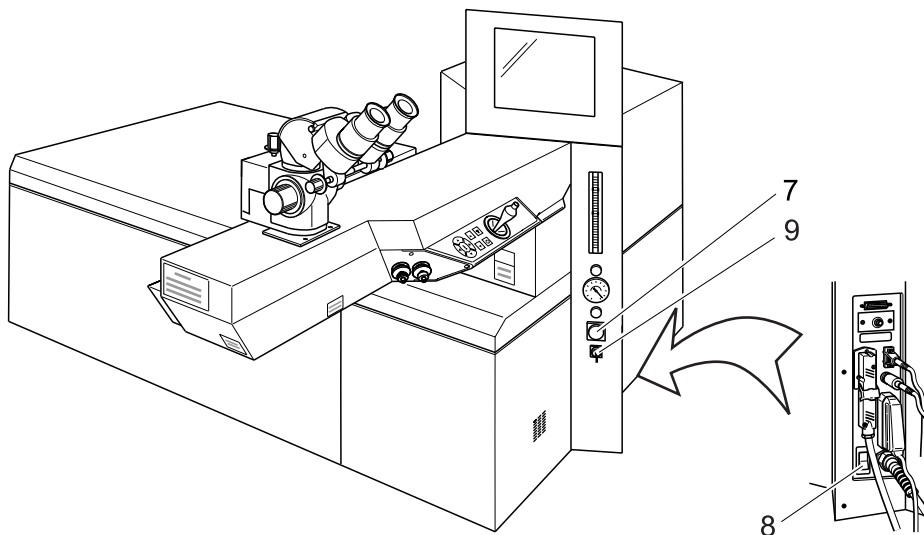


Fig. 39: MEL 70 *G-Scan* switch

Unlock the EMERGENCY OFF switch (7)

Switch on the main switch (8), the green light in the switch lights up.

Turn the key switch (9) fully to the right, the key will automatically return to centre position.

After approx. 30 seconds the menu of the initial heating phase will appear on the screen.

Topographic treatment

6.2.1 Initial heating phase and gas exchange

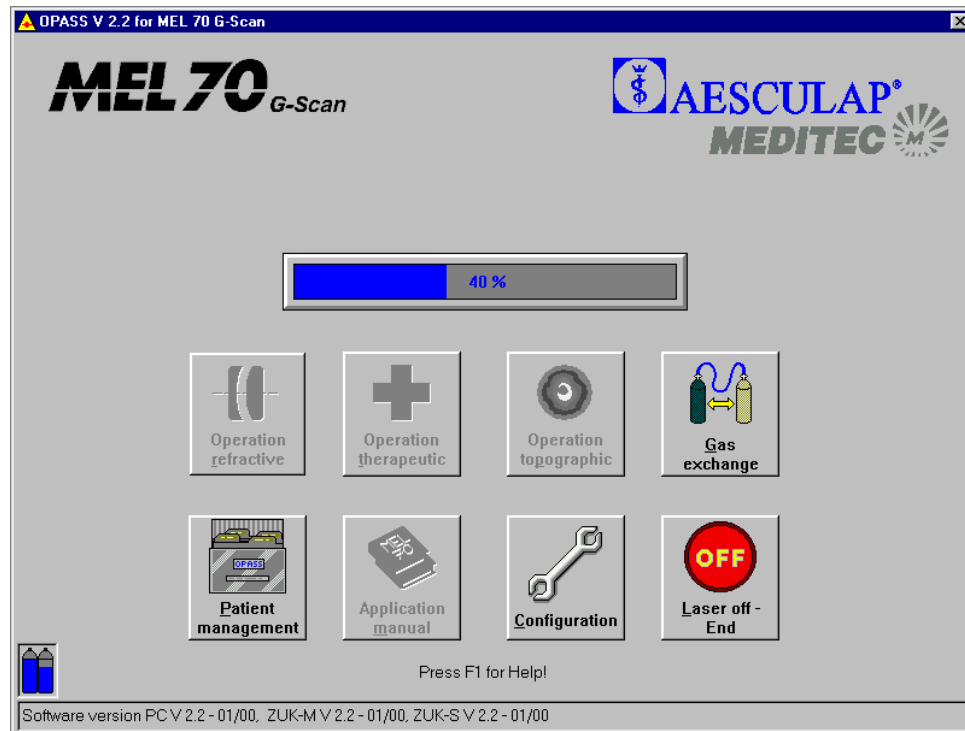


Fig. 40: Menu Initial heating phase

The laser requires a period of six minutes to heat up to the necessary operating temperature. A progress indicator will advise you of the status of the initial heating phase. The symbols with a grey background **cannot** be selected during this period.

In order to perform an automatic gas exchange click the symbol “Gas exchange” during the initial heating phase. The gas exchange takes approx. five minutes. Confirm the gas exchange with clicking “Yes”. Another progress indicator will advise you of the status of the gas exchange.

A filling level indicator of the gas cylinders is located at the left bottom corner of the screen. If one of the cylinders is empty, please, notify your hotline officer so that the cylinder will be replaced during the next service cycle.

The state bar is located at the lower screen margin. Situation-related reports and the currently used software version are displayed in this box.

Following the initial heating phase the main menu will appear on the screen.

6.3 The Main Menu

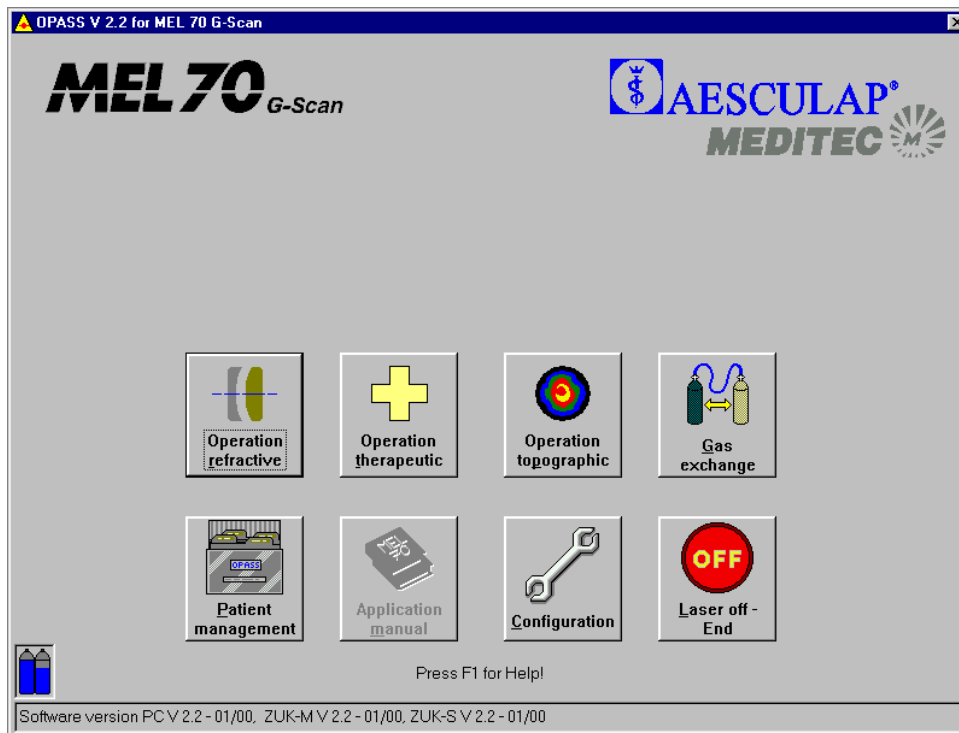


Fig. 41: Topographic treatment main menu



Click on this symbol in order to perform a refractive operation.



Click on this symbol in order to perform a therapeutic treatment (PTK Shaping or PTK Spot treatment). (cf. Chapters 4 and 5).



Click on this symbol in order to perform a topographic operation.



Click on this symbol in order to perform an automatic gas exchange (duration approx. five minutes). The gas exchange may be conducted during the initial heating phase.

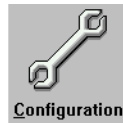
Topographic treatment



Click on this symbol in order to open the patient management (cf. Appendix).



Click on this symbol in order to open the application manual.



Click on this symbol in order to perform the configuration adjustments. Here you may input the data of your clinic or select the printer for the journal printout (cf. Appendix).



Click on this symbol in order to terminate the computer program and switch off the laser. You should not switch off the laser until the message "YOU MAY NOW SWITCH OFF THE COMPUTER" appears on the screen.

6.4 Program entry for topographic treatment

The topographic treatment is carried out on the basis of the patient's data obtained from a corneal topographic system.

The corneal topographic system stores all patient data on a ZIP disk.

Start the program. Load the ZIP disk with the patient data in the ZIP drive of the PC and select "Operation topographic" from the main menu.

The patient data are now transferred to a directory of the data base and deleted on the ZIP disk.

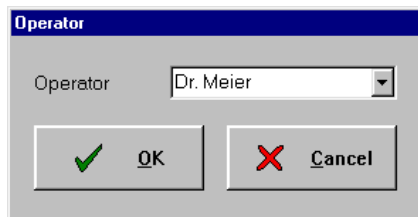


Fig. 42: Operator menu

Enter the operator's name and confirm your entry with "OK". The „OPERATION BASED ON TOPOGRAPHY“ menu opens.

Klicking "Cancel" returns you to the main menu.

6.4.1 The OP Assistant

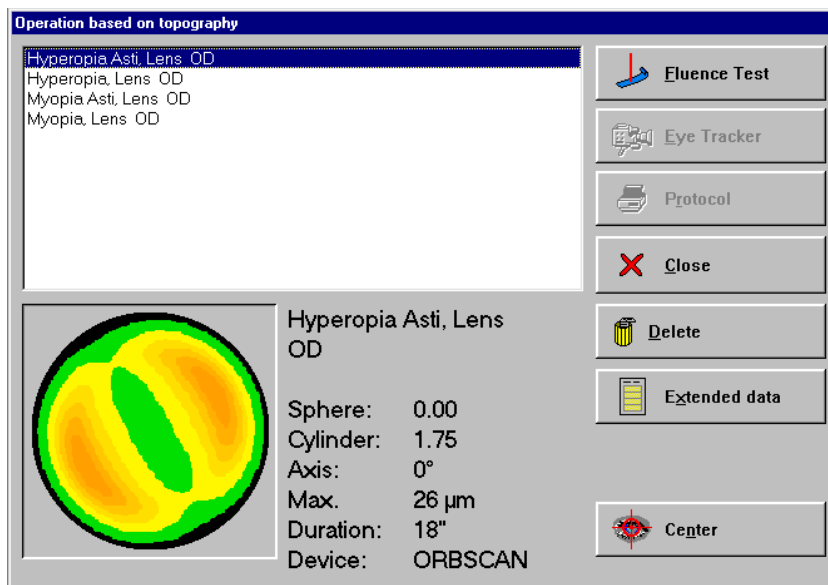


Fig. 43: Operation Based on Topography operation assistant menu

Select the patient for treatment from the patient list. The selected data record is highlighted blue.

The click on the "Fluence Test" button. The FLUENCE TEST menu opens.

You can view additional patient data by clicking on the "Extended data" button.

Topographic treatment

You can delete a data record from the patient list by clicking on “Delete”.

Clicking “Close” returns you to the main menu.

6.4.2 The fluence test

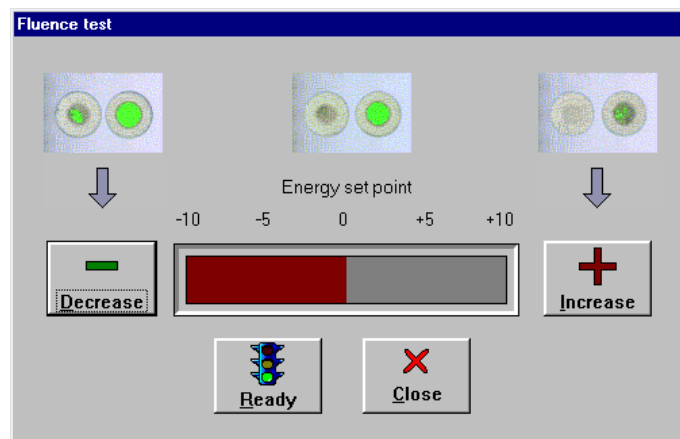


Fig. 44: Menu fluence test

By clicking on the pushbuttons “High” or “Low” you may increase or decrease the energy set point.

You start the fluence test by operating the pushbutton “Ready”.

Clicking on the pushbutton “Close” will abort the fluence test

6.5 Preparation of the laser

Height adjust your operating chair.

Switch on the ring-shaped lamp (11) and check the ocular adjustment.

Swivel the laser arm and switch on the distance control laser (12).

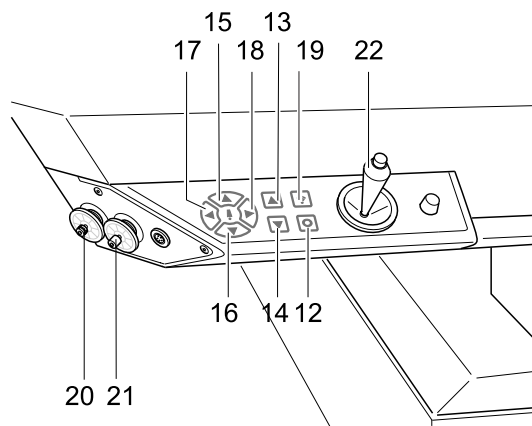


Fig. 45: Control Panel Laser Arm

Position the patient bed together with the blue test base at the appropriate height. The two focusing points require to be brought into an overlapping position. Operate the below keys on the operating panel of the laser arm towards this end:

Height adjustment	higher	(13)	deeper	(14)
Horizontal alignment	forward	(15)	backward	(16)
	to left	(17)	to right	(18)

Topographic treatment

Put a piece of test paper onto the blue test base.

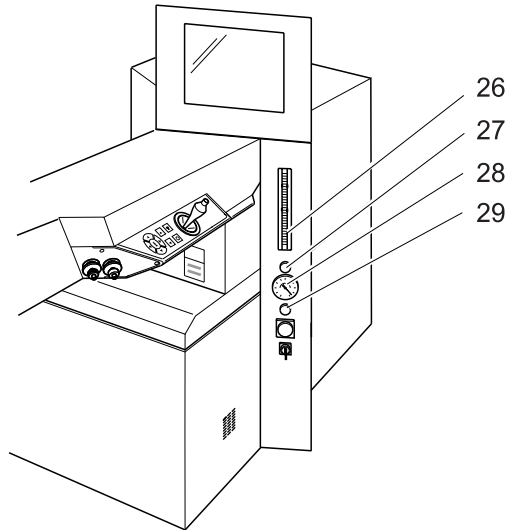


Fig. 46: Control panel

Connect the blue hose for the flue gas extraction suction to the laser arm (2) and the PRK suction ring (blue marking). Adjust the value for the flue gas extraction to maximum at the flow meter (26).

Click on the pushbutton “Ready” in the menu of the fluence test.



Now the laser may be actuated by means of the right-hand foot pedal.

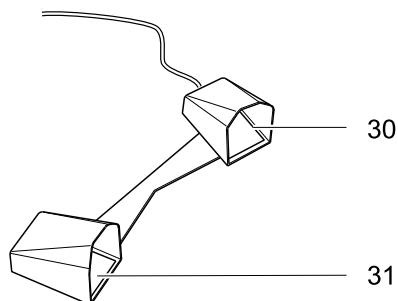


Fig. 47: Foot pedal

Place the red target beam with the joystick (22) onto a free area of the test paper.

Now make the fluence test as described in the Instruction Manual.

Following the successfully completed test, click on the pushbutton “OK” and turn the laser arm to the side.



Danger

**Only continue after a successfully completed fluence test!
A faulty fluence value will result in false treatment.**

Repeat this procedure with each new patient.

Remove the blue test base.

Topographic treatment

6.6 Preparation of the patient

Thirty minutes prior to the laser treatment a topical anaesthetic (e.g. Novesine, Kerakain) and Pilocarpin shall be administered.

If required, a sedative agent (e.g. Diazepam) shall be given.

The minus cylinder axis of the patient is marked on, e.g., the sclera, with a colour pen. (Alternatively, the patient may be temporarily placed under the surgery microscope with the test frame put on).

The height adjustment is carried out by means of the focusing laser.

The head of the patient is aligned horizontally as much as possible, so that the pupil is at the centre of the eye-slit when the patient looks into the surgery microscope.

Cover with sterile sheets the area around the eye and head of the patient.

An eyelid speculum is to be placed between the eyelids (preferably of the Barraquer type).

When **treating astigmatisms** the reticule of the ocular by turning is adjusted to the 0° axis of the patient.

Ask the patient to fixate on a green LED and mark the optical centre (centre of the entry pupil) with an eye cannula.

6.6.1 Procedure for PRK

Attach the ring marker and turn by 20° to 30° under slight pressure.

Recommended ring markers:

Myopia	always 1 mm larger than the treatment zone
Hyperopia	9.0 mm ring marker

Perform abrasion of the epithelium by means of a 'Hockey' knife (when treating pure astigmatisms: extend the abrasion area in the axis of the minus cylinder by approx. 9.5 mm).

Repeat marking the optical centre (centre of the entry pupil) with an eye cannula.

Re-check the working distance by means of the distance control laser (combine points). Subsequently, switch off the distance control laser.

6.6.2 Procedure for LASIK

Make the lamellar cut according to the guidelines of your microkeratome. The flap should have a size of not less than 8.5 mm in diameter.

Remove the suction ring of the microkeratome.

Remove excessive lacrimal fluid from the conjunctival sac by means of a swab/wick and dry the corneal stroma by means of a spatula ('Hockey' knife). If required, dry the hinge of the flap with a triangular swab.

Repeat the marking the optical centre (centre of the entry pupil) with an eye cannula.

Re-check the working distance by means of the distance control laser (combine points). Subsequently, switch off the distance control laser.

Topographic treatment

6.7 The eye tracker

An active eye tracker will follow the patient's eye movements during the treatment and, if need be, the laser beam will be traced accordingly. The suction ring of the flue gas extraction installation serves as the object for the tracker. This ring needs to be attached first (as much centred as possible).

Click on the pushbutton "Eye Tracker" in the menu of the OP Assistant.

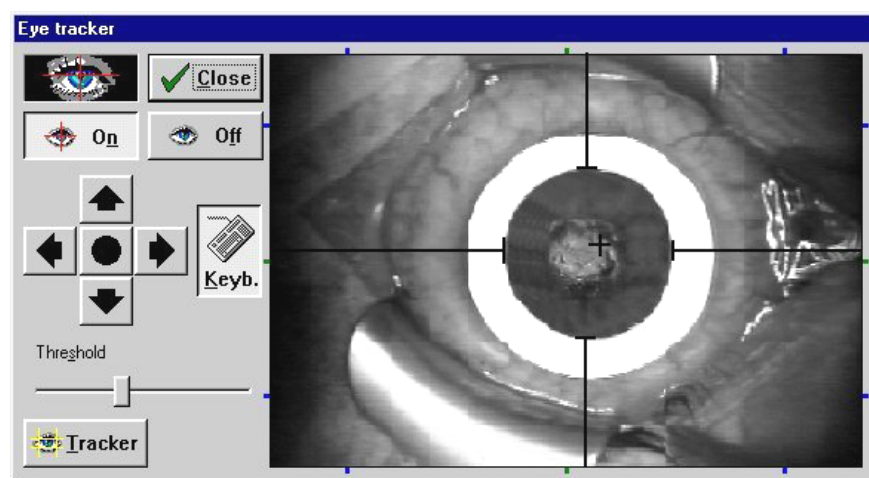


Fig. 48: Menu eye tracker

The menu of the eye tracker will open. This window remains open during the treatment session and enables you to make different adjustments and check the functioning of the tracker. A video image of the eye tracker is displayed on the right, while the left shows the configuration pushbuttons.

Activate the eye tracker by clicking on the pushbutton "On". The tracker status indicator is located above the latter pushbutton. If the eye is displayed against a black background, the object was recognised by the eye tracker. If the pupil was not recognised the background will remain grey. In the latter case, check the below items:

- Has the eye tracker been switched on?
- Is the pupil still in the HOT ZONE?
The HOT ZONE is the area where the laser follows the patient eye movement. If the pupil leaves the HOT ZONE the sequence of shots is automatically interrupted until the pupil is again in the area of this zone. In such case reposition the head of the patient in such a way that the eye is at the centre of the camera image.

When the eye tracker is switched on you will see a graticule in the video image. This graticule will be automatically placed in the object centre. However, since the optical axis is not always in the object centre you have the opportunity to modify this setting. You can change the position of the graticule by clicking with the right mouse key on the arrow keys on the left of the video image. The right mouse key will move the graticule in larger steps. Click the round pushbutton in the centre in order to readjust the graticule to the geometrical centre.

You can also move the graticule with the arrow keys. The keyboard button must be enabled for this.

You can adjust different parameters of the video image, such as brightness, contrast, etc., by clicking on the “Video” pushbutton.

The eye tracker is switched off by clicking on the “Off” pushbutton.

The eye tracker window is closed by clicking on the “Close” pushbutton.



When the eye tracker is switched off the laser beam will not be automatically traced, i.e. any eye movements will not be compensated!

Topographic treatment

6.8 Centration with the MEL 70 G-Scan using the Artificial Limbus Ring

PRK

Centre of Pupil

- Input patient data
- Perform fluence test
- Have the patient look at the green LED
- Use a blunt cannula/marker to set centre of abrasion
- Press ready
- Use ring marker to set area of abrasion
- Remove epithelium
- Again have the patient look at the green LED (move bed or head if necessary)
- Again use cannula/marker to set centre of ablation (centre of the entrance pupil)
- Press ‘eye tracker’ button (the joystick will be deactivated)
- Apply limbus ring in a way that the aiming beam sits roughly on your mark
- Set aiming beam to your mark on the cornea by using the mouse or keypad
- Start ablation

Purkinje Reflex

- Input patient data
- Perform fluence test
- Press center to set the red HeNe beam in the center of microscope
- Have the patient look at the red HeNe beam
- Use a blunt cannula/marker to set centre of abrasion
- Press ready
- Use ring marker to set area of abrasion (put joystick aside)
- Remove epithelium
- Again have the patient look at the red HeNe beam (move bed or head if necessary, joystick must be centred!)

LASIK

Centre of Pupil

- Input patient data
- Perform fluence test
- Press ready
- Perform keratome cut
- Apply limbus ring roughly centred
- Open flap
- Have the patient look to the green LED
- Use cannula/marker to set centre of ablation (centre of pupil)
- Press ‘eye tracker’ button (the joystick will be deactivated)
- Set aiming beam to your mark on the cornea by using the mouse or keypad
- Protect flap with a wet sponge from the nasal side in case of a cylindrical
- ablation around the zero degree axis (classical flap) or 90 degrees (down-up flap), respectively
- Start ablation



Caution

Stop every once in a while to verify eyetracker centration and to dry the stromal bed.

Purkinje Reflex

- Input patient data
- Perform fluence test
- Press ready
- Perform keratome cut
- Press ‘eye tracker’ button (the joystick will be deactivated)
- Apply limbus ring in a way you can see the Purkinje reflex
- Open flap
- Reposition aiming beam by using the mouse or keypad to find again the Purkinje reflex

PRK

- Press ‘eye tracker’ button (the joystick will be deactivated)
- Reposition patient, have him look straight
- Apply limbus ring in a way that it is lying horizontal
- Align aiming beam by using the mouse or keypad that you can see the Purkinje reflex
- Start ablation

LASIK

- Protect flap with a wet sponge from the nasal side in case of a cylindrical ablation around the zero degree axis (classical flap) or 90 degrees (down-up flap), respectively
- Start ablation



Caution

Stop every once in a while to verify eyetracker centration and to dry the stromal bed.

6.9 The treatment session

When you press the “Center” button the target beam of the laser will always be in the center of the surgical microscope in whatever position the joystick may be. In this way the target beam instead of the fixation light can be used for centering.

Check the values which have been adjusted in the Assistant.

Click on the “Ready” pushbutton in the OP Assistant.

Actuate the right foot pedal and keep it depressed.

A progress indicator will display the progress of the treatment. By clicking on the “Cancel” pushbutton the treatment may be discontinued following the release of the foot pedal.

After the termination of the correction program the OP Assistant will automatically interrupt the laser triggering. The treatment is interrupted by releasing the foot pedal and may be resumed by actuating the pedal again.

Topographic treatment

6.10 Termination of the program

By clicking on the “PROTOKOLL” pushbutton you will receive a print-out of the surgery data via the connected printer.

You may return to the main menu by clicking on the “OK” pushbutton.

In order to treat further patients, commence again in the main menu (Chapter 3.3) and follow the instructions in the applications manual.

6.11 Switching off of the laser

In order to switch off the laser click on the “OFF Laser off - End” and confirm the switch-off by clicking on the pushbutton “Yes”.

Wait for the message “NOW YOU MAY SWITCH OFF THE COMPUTER” appears on the screen.

Turn the key switch (9) fully to the left.

Switch off the main switch (8) (the green light in the switch will go out).

6.12 Post-operative treatment

Please refer to chapters PRK (2.12) and LASIK (3.12).

7 Appendix

7.1 Bases for software operation

7.1.1 Use of a pointer device




The operating principle of a mouse or another pointer device is that you first point at an element on the screen and subsequently click one of the mouse keys in order to perform an action at the aforementioned element.

If the pointer is pointed at the desired element or the desired area you may perform the following actions:

- *Clicking:* Depress the left mouse key shortly once and let go again.
- *Double-clicking:* Depress the left mouse key shortly twice and let go again.
- *Double-clicking with right mouse key:* Depress the right mouse key shortly once and let go again. A context menu will be overlaid.
- *Dragging:* If you want to move a window to another position, point at the title bar. Keep the left mouse key depressed and drag the window into the desired position.

7.1.2 Use of a dialog box

A dialog box is displayed when you want to input information or defined options. The following types of options may be used in dialog boxes:

-  Extends the list of options. Click on the desired element.
-  Selects always but one option. The circle will be filled when an option has been chosen.
-  Activates one or more setting. A hook will be overlaid when a setting has been activated.

Appendix

7.2 The configuration menu

You may perform different configuration adjustments in this dialog.

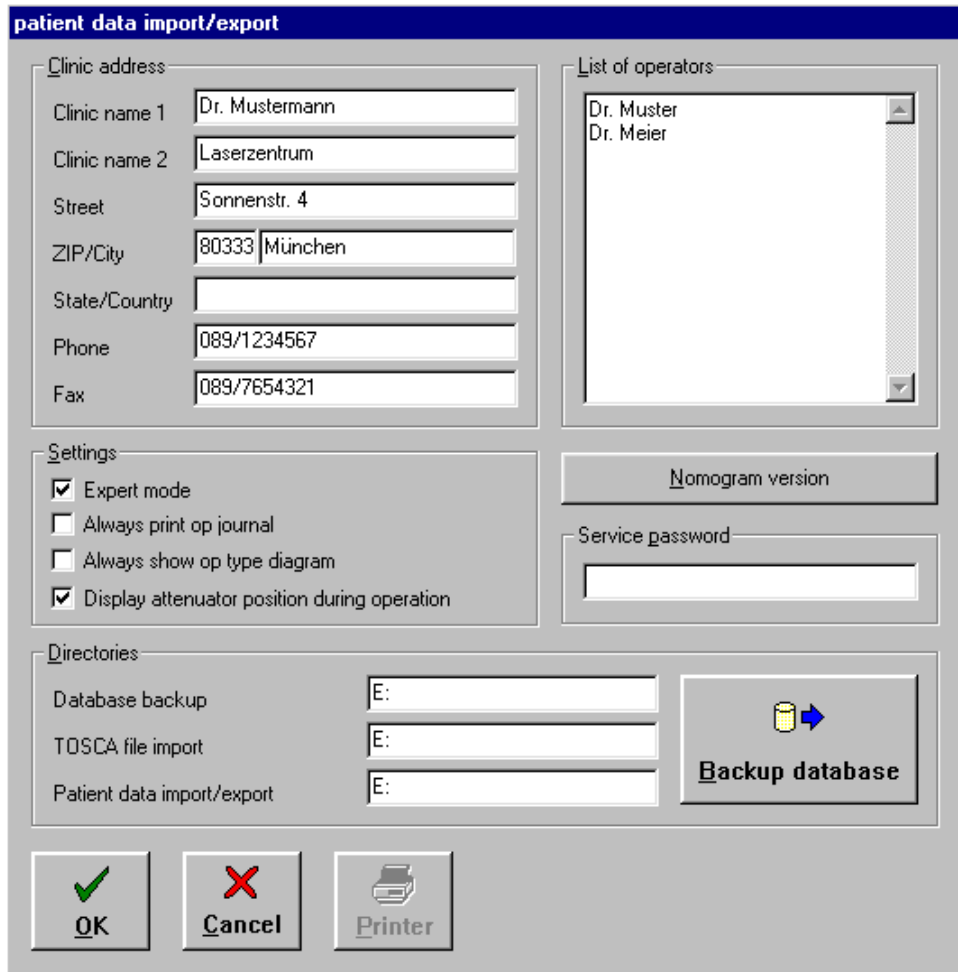


Fig. 49: The Configuration menu

Enter into, or, if need be, modify in the pushbutton CLINIC ADDRESS the data of your surgery.

Enter the names of the doctors treating patients with the Excimer laser in the LIST OF OPERATORS. This list appears in the patient data menu and in the patient management when the treating doctor's name is selected.

You can make various settings in the SETTINGS dialog section. If the expert mode is selected you have access to the integrated data base.

In the DIRECTORIES section you define the directories in which data is saved, T.O.S.C.A. data is imported and the import or export of patient data occurs.

The pushbutton SERVICE PASSWORD is reserved for the service engineer. You must not make any entries in this field.

By clicking the pushbutton PRINTER you may choose a new printer or modify printer adjustments and also any new printer will be configured under Windows 95.

7.3 Patient management (data base)

You can optimize the clinic organization with the patient management functionality by defining a patient list prior to surgery. The data entered there can be viewed in a list in the patient data menu before to the operation is performed on the patient.

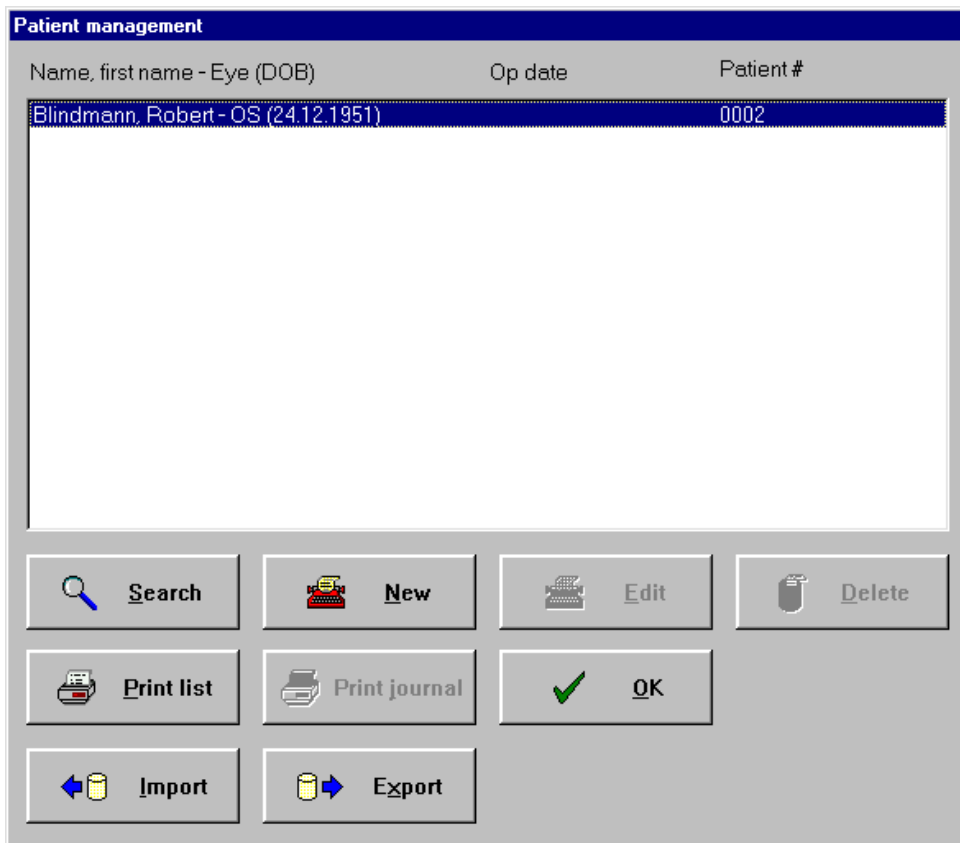


Fig. 50: Patient Management menu

Appendix

Klick on “New” to create a new patient data record in the data base.

Klick on “Edit” if you want to change or add data to the patient data record.

You can search for a patient or a patient group in the patient data base by entering various search words and clicking on the “Search” button.

You can delete the (blue) highlighted data record from the patient data base by clicking on “Delete”.

You can print out the patient list by clicking on “Print list”.

The operation journal of a patient is printed with a click on “Print journal”.

You can import patient data with a click on “Import”. Clicking on “Export” exports patient data.

When all patients have been entered, close the patient management by clicking on “OK”.

7.3.1 Create/edit patient

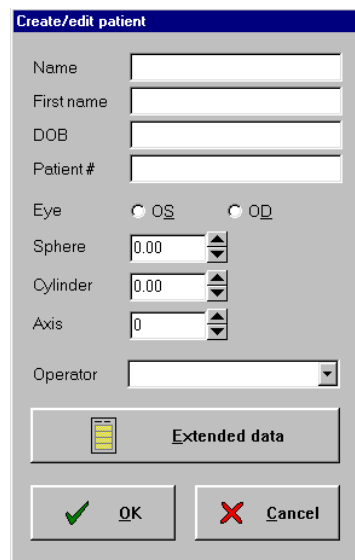
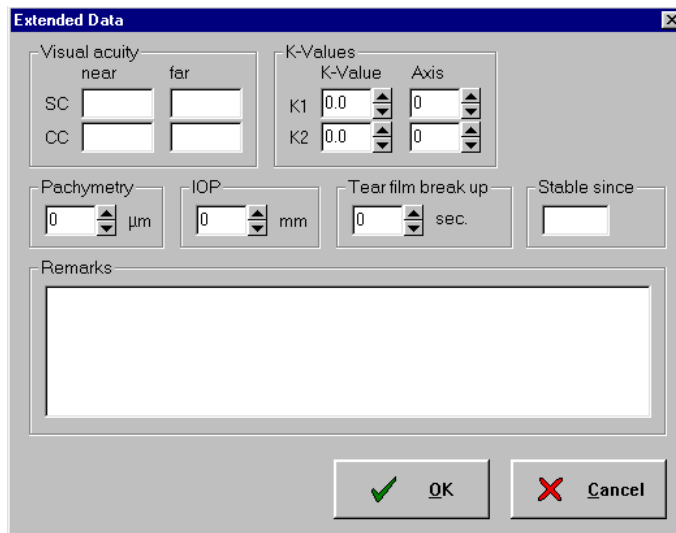


Fig. 51: Patient Management menu

Enter the patient data and the subjective spectacle refraction in the dialog section and select the treating doctor from the list of operators.

By clicking on “Extended data” you open the “Extended data” menu.



Extended Data

Visual acuity
near far

SC

CC

K-Values
K-Value Axis

K1 0.0 0

K2 0.0 0

Pachymetry µm

IOP mm

Tear film break up sec.

Stable since

Remarks

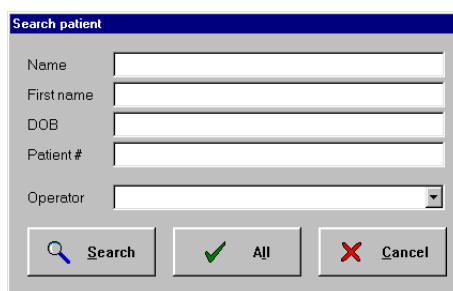
Fig. 52: Extended Data Menu

You can extend the patient data by entering additional data and values in these fields.

Confirm your entries with “OK”.

Press “Cancel” to exit the menu without saving the entries in the patient list. The program takes you back to the CREATE/EDIT PATIENT menu.

7.3.2 Search patient



Search patient

Name

First name

DOB

Patient #

Operator

Fig. 53: Search Patient menu

Appendix

Enter the patient data you know in the SEARCH PATIENT section.

Clicking on “Search” displays a list of all patients satisfying the search criteria.

Clicking on “All” displays a list of all patients.

Click on “Cancel” to exit the menu. The program returns you to the “Patient Management” menu.

7.4 Failure indicator

7.4.1 Unexpected interruption of a treatment session

In any case the patient will receive a proportional correction (10 %, 30 %, etc.).

7.5 Cleaning instructions

The suction ring may be cleaned with every usually applied method - alcohol, steam or gas. It is of particular importance to see to it that the small holes for the flue gas extraction and mask fixation are clean. Remove any foreign particles from these holes with a suitable needle.

The surface of the laser may be cleaned by wiping with a moist (not a wet!) cloth and disinfected with a disinfection agent.

The control buttons of the surgery microscope can be removed and steam sterilised.

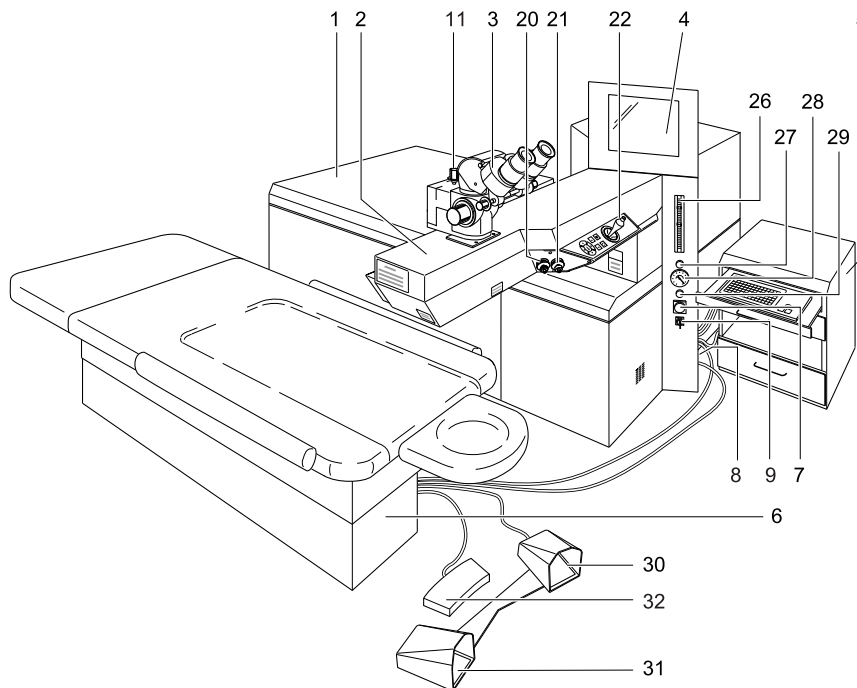
7.6 MEL 70 G-Scan general view


Fig. 54: MEL 70 G-Scan general view

1	Basic device	17	Key move patient bed to the left
2	Laser arm	18	Key move patient bed to the right
3	Surgery microscope	19	Key reset the patient bed
4	Screen	20	Hose connection debris removal
5	Roll-front cabinet with PC keyboard	21	Hose connection mask fixation
6	Patient bed	22	Joystick
7	Emergency Off switch	25	Suction ring
8	Main switch	26	Flow meter debris removal
9	Key switch	27	Rotary switch debris removal
11	Dimming control ring lamp surgery microscope	28	Vacuum indicator
12	Switch distance control laser	29	Rotary switch vacuum adjustment
13	Key move patient bed upwards	30	Right foot pedal release laser shot
14	Key move patient bed downwards	31	Left foot pedal mask fixation
15	Key move patient bed forwards	32	Foot pedal move patient bed upwards/downwards
16	Key move patient bed backwards		