MCL 30
Dermablate

Skin Ablation with the Er:YAG Laser System

APPLICATION MANUAL

1624 99 004 – 05 03

Important advice for the user:

This Manual provides therapeutic guidance to assist in practical therapeutic work with this laser. The information contained herein reflects the state of the art technology in this field. The editor will assume no liability for errors which, despite adequate care and attention, cannot be ruled out entirely. The user alone bears full responsibility for actions performed in conjunction with this Manual.

This is no substitute for clinical judgment, „hands-on“ training with a skilled fellow clinician and personal experience.

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1 Laser Safety Instructions

1.1 Precautions

For nearly 40 years, lasers have been used in medical applications. Given the large number of successful treatments carried out with a laser, the number of incidents is disproportionately low. Regardless of this, one should never underestimate the attention required for working with laser devices. Negligent handling of laser radiation may cause serious injuries to the user and the patient.

The radiation emitted by a laser device is very intense. It may create hazards even at some distance from the physical laser outlet opening. Incorrect use of laser radiation may result in major eye injuries or burns to body tissue.

In the event of non-compliance with the instructions in this Application Manual, the laser may become a source of potential danger for the doctor, patient or third party. Therefore, this manual describes how to operate the laser as a medical device.

The decision on whether this laser is suited for a given medical application and which treatment method should be selected for this application is the responsibility of the attending physician alone. Under no circumstances should a laser treatment be performed when there is the slightest doubt about the appropriate operating conditions of this device.

Generally, the national Accident Prevention Regulation for laser radiation applications, the European standard EN 60 825 and the Law on Medical Products (MPG) are applicable to operation of this laser device.

The use of control elements or the performance of adjustment or treatment procedures in any other way than described in this Application Manual may release dangerous laser radiation.

Under no circumstances should the protective shielding be removed!

The wheeled cabinet unit of the laser may not be opened by anyone other that expert personnel of Asclepion Laser Technologies GmbH. Attempted servicing of this device with the help of persons not authorised by Asclepion Laser Technologies may have lethal consequences and will immediately void any warranty.

1.2 Important Considerations before First Treatment

The purpose of this Application Manual is to provide special application advice for the operation of this laser. It should be understood that such advice can in no way be considered to replace intensive studies of technical literature, personal experience obtained under the supervision of expert personnel and critical considerations in every single case.

On the other hand, it is necessary to assist "Newcomers" and those who do not work with the system regularly by supportive guidance.

For this reason, we recommend the study of current literature and contact with privately practicing physicians who work with this kind of laser equipment, in order to familiarize oneself with the methods that use a laser, before proceeding with the treatment of patients.

We will gladly assist you in establishing contacts with other users. Asclepion Laser Technologies field/sales personnel servicing your area can provide you with full details.

Check yourself if you have really understood the way the laser and the body tissue interact, the relationships between the individual application parameters and the applied technique, and the principles of laser safety.

If you have the slightest doubt, consult one or more colleagues with practical experience and/or application engineers of Asclepion Laser Technologies, before you begin laser treatment.

2 Introduction - Laser Technology Background

2.1 The Laser

Ever since its invention by MAIMAN in 1960, the laser has established itself in all branches of science and technology, and modern medicine can no longer be imagined to exist without it. (First dermatological application by Goldmann in 1963).

Laser is the acronym for „**L**ight **A**mplification by **S**timulated **E**mission of **R**adiation“.

What is typical of a laser? From a practical point of view, a laser is a light source which emits a beam of tightly bundled light. This light beam has a defined wavelength, and its uniform waves propagate with little divergence, i.e. they are nearly parallel (collimated) and in phase (coherent).

Lasers exist for wavelength ranges from ultraviolet to infra-red, laser power may vary from a few fractions of a milliwatt for medical applications to the kilowatt range for heavy-duty lasers applied in industry.

Laser set-ups with continuous excitation source are referred to as continuous wave lasers (cw-mode, for example, argon lasers). If excitation is achieved by single pulses, the term is pulsed laser (such as ruby lasers). By the accumulation and sudden release of the excitation energy, one is able to obtain Q-switched operation mode
(e.g. Q-switched ruby laser).

2.2 Physical Background

Inside the laser, energy is introduced into an "active medium". Next, the medium is forced to release its stored energy in the form of light. In a so-called resonator with mirrors, this light is then bundled into a beam.

The medium can be a gas (e.g. argon gas within a tube), a liquid (e.g. dye fluid) or a solid state laser (e.g. ruby rod, diode).

Generally, a light wave is formed when an atom in "excited" state where it contains a substantial amount of energy "drops" to another state with less energy. The difference in energy between the two levels then corresponds to the energy of the emitted wave.

For a laser beam to be created, there must be more atoms in excited state in a given active medium than atoms of a lower energy level. An energy distribution of this kind is referred to as an "inversion".

In a laser, emission is triggered artificially by hitting an atom with a light wave of consistent energy. This is sufficient to incite the atom to emit its own wave of the same frequency. Accordingly, this process is called "stimulated emission".

The parallel bundled laser beam is formed by a resonator. In its simplest form, a resonator consists of two parallel mirrors enclosing the laser medium. When a number of light waves are induced in the medium as a result of emission, the two mirrors will always reflect those waves back to the medium, which are incident at right angles. The reflected waves again hit excited atoms during their next round-trip in the resonator and excite these in turn.

This is an avalanche-like, ongoing process and the light beam becomes stronger and stronger. Typically, a partly transparent mirror is used on one of the two sides to serve as an output coupler for the required part of the laser beam.

How to pump the energy into the laser, i.e. how to "charge it up", depends on the type of active medium selected. The standard pump procedures are based on excitation by very intensive light also referred to as "optical pumping" (e.g. ruby laser), excitation of an electrical gas discharge (e.g. argon laser) and direct electrical pumping (diode laser).

2.3 Laser Safety

Unqualified use of laser light may cause damage.

The greatest potential hazards exist for the human eye. Even lowest power levels are capable of causing irreversible damage to the retina because the eye lens has a focusing effect.

The nature of potential injuries essentially depends on the wavelength of the laserlight.

To determine which threshold values are applicable in terms of power and energy, comprehensive tables need to be consulted.

For better convenience, a classification according to the potential risk of injury was introduced for laser devices. This classification can easily be used to identify the degree of danger posed by the laser radiation of a particular laser device [EN 60 825-1 (Nov. 2001), (internat. IEC 60 825-1)].

Short version: (details see documents above)

Class 1	accessible laser radiation is not hazardous
Class 1M	restricted to the spectral range between 302.5nm and 4000nm, possible danger, when using optics in the laser beam
Class 2	restricted to the spectral range between 400nm and 700nm non-hazardous because of eye lid reflex
Class 2M	restricted to the spectral range between 400nm and 700nm non-hazardous because of eye lid reflex possible danger, when using optics in the laser beam
Class 3R	restricted to the spectral range between 302.5nm and 4000nm, direct view into the laser beam is normally dangerous, the risk is lower than class 3B

Class 3B	direct view into the laser beam is normally dangerous, observation of diffuse reflections from laser beam are usually non-hazardous
Class 4	even diffusely reflected laser beam is hazardous for the human eye and sometimes for the skin, danger of fire or explosion is possible
Class 4	Accessible laser radiation is very hazardous for the human eye and hazardous for the skin. Even diffusely scattered radiation may pose a threat. Laser radiation may create danger of fire or explosion.

All laser types typically used in dermatotherapy qualify for the maximum danger class (class 4) and require protection even from a diffusely reflected beam.

According to official regulations, a number of protective measures are required today for the operation of lasers. For medical users, the Law on Medical Products applies additionally.

These regulations prescribe (among others) the following precautions for medical laser applications:

- Marking of the laser area (typically the room in which laser operation takes place) and laser device by laser warning labels.
- Absence of reflecting surfaces in the operating room.
- Inflammable materials must be kept away from the laser area or precautions taken to prevent ignition of such materials.
- Checking of laser device, optical fibers, and handpieces for visible defects.
- Observance of instructions contained in the Operator Manual and the Application Manual of manufacturer; checking safety devices for proper function before beginning laser application.
- Power ON condition must be clearly visible at the laser device and at the access points to the laser area (red warning light).
- Suitable protective eyewear (EN 207, safety goggles with OD 4 -**o**ptical **d**ensity- for the wavelength of this laser) must be worn (by user, patient, personnel). Make sure that eyewear is in proper condition before putting it on.
- Warn all persons present in the laser area before turning the laser on, prevent formation and spreading of flammable gases or vapors (danger of explosion) in the laser area.
- Provide efficient exhaust facility for emerging vapors (vaporization).
- Protect handpieces (particularly optical end faces) from contamination.
- Use only those agents and techniques for cleaning and disinfection as specified by the manufacturer.

- Annual safety briefing of personnel.
- Laser must be secured against accidental positional changes.

3 Application Parameters

<u>Technical Data</u>	***MCL 30 Dermablate***
Type of laser:	Er:YAG laser, Laser Class 4
Wavelength:	2.94 µm
Pulse length:	≤ 1 ms
Spot sizes and Fluences:	1,0 mm: 8 – 100 J/cm² 2,0 mm: 2 – 40 J/cm² 3,0 mm: 2 – 20 J/cm² 4,0 mm: 2 – 12 J/cm² 5,0 mm: 2 – 7 J/cm² 6,0 mm: 2 – 5 J/cm²
Frequencies:	1; 4; 8; 10; 15 Hz in Normal Mode
Average Power:	20 Hz in Thermal Mode max. 12 W
Aiming Beam:	635 nm diode, 1 mW
Beam Delivery:	Articulated mirror arm with VarioTEAM handpiece
Display:	LCD Display
Operation:	Touch Screen
Cooling:	Internal Cooling Circuit

Application Parameters

3.1 Wavelength

Since the wavelength of the Er:YAG laser (2.94 µm) corresponds to the absorption maximum of water, the laser energy is almost completely absorbed in water (absorption coefficient = 12.500 cm^{-1}).

Given that water accounts for approximately 77% of the total content of human skin, this optimum absorption creates ideal conditions for the ablative effect of the Er:YAG laser.

When the energy density reaches a certain value (ablation threshold), the water inside the tissue vaporizes suddenly and thus drags off the tissue. The vaporized water escapes with ultrasonic speed, which is characterized by a special sound (bang).

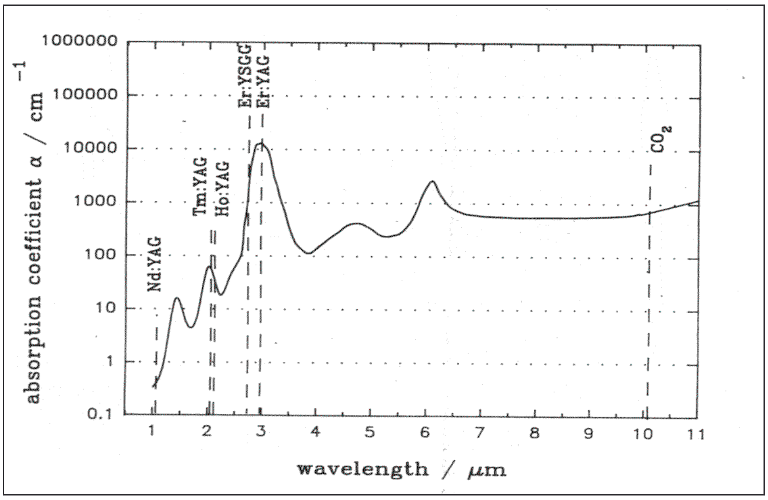


Fig. 1: Absorption in water as a function of wavelength

3.2 Exposure time

Besides energy density and wavelength, the extent of thermal damage also depends on the exposure time.

The MCL 30 Dermablate has a pulse time of approximately 400 µs. This time is clearly shorter than the thermal relaxation time of tissue. Thus, even with high repetition rates, there is no spreading of heat in the tissue.

The zone of thermal necrosis is max. 30 - 50 µm in ablation with the Er:YAG laser.

3.3 Variable parameters: spot size, frequency, energy density

In practice, frequencies and spot diameters will be chosen to permit a fast, high-precision therapy, depending on the indication.

Frequency:

- For the treatment of an extended lesion the frequency, i.e. the repetition rate of laser pulses, is freely selectable depending on application and personal experience.
  A frequency suitable for manual handpiece guidance is, for instance, 8 Hz.
- When treating small lesions, the frequency of the MCL 30 Dermablate can be set to

  1 Hz thus avoiding overtreatment of the lesion.
- In the Thermal mode the frequency is firmly set to 20 Hz, which leads to rapid heating of tissue by subablative pulses.

Spot Size:

The spot size is mainly determined by the indication. Small spot sizes are selected for the ablation of small lesions (e.g. syringomas) or for flattening the edge of an acne scar. For the treatment of extensive indications it is advisable to use a medium to large spot size.

When selecting the largest spot sizes consider that the energy density (energy per spot area) should still be sufficient to achieve the therapeutic effect (see Section 3.4 „Energy density„).

As the spot size may slightly change with energy, it is advisable to check the exact spot size on the photographic paper whenever you change the energy (see User's Manual).

3.3.1.1.1 Energy density

= Energy per area = Fluence

The energy density is the most important parameter to achieve the desired therapeutic effect. As the spot size is contained in the area with its square (area = π x radius²), a change in spot size has a much greater effect on energy density than a change in energy adjustment.

The following mathematical relations apply:

$$\text{Energy density [J/cm}^2\text{]} = \frac{\text{Energy [J]}}{\text{Area [cm}^2\text{]}} = \frac{127 \times \text{Energy [J]}}{(\text{Spot size in mm})^2}$$

The energy density is displayed on the screen as FLUENCE.

The energy density determines the depth of ablation. With Er:YAG lasers, it is directly proportional to ablation depth, i.e. the ablation depth increases linearly with energy density. This is true both for a single laser pulse as well as for multiple pulses fired onto the same skin area.

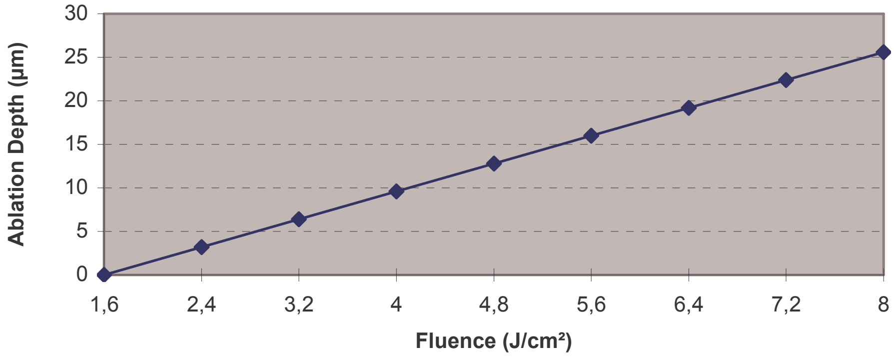


Fig. 2: Ablation depth as a function of energy density

It has been found in clinical practice that optimal results can be achieved by applying medium energy densities (approx. 4 - 10 J/cm²) (for dermatological applications).

We recommend an energy density of **4 J/cm²** for the first applications.
In general, an energy density of **4 - 10 J/cm²** is appropriate for most of the indications.

It must be considered that ablation only starts above a defined threshold (ablation threshold). In literature, this threshold is specified with approx. **1.6 J/cm²**. Energy densities less than 1.6 J/cm² heat up tissue and may lead to thermal damages. They may also be applied intentionally to achieve a superficial hemostasis.

To achieve this, the user can switch to the thermal mode of the MCL 30 Dermablate. Then the laser emits subablative pulses (energy density = 1 J/cm²) with a high frequency (F = 20 Hz). These energy densities are not sufficient to ablate tissue, therefore the energy brought in remains as heat in the tissue.

4 Guidelines for Therapy

This section contains practical guidelines for using Er:YAG lasers. They are of course no substitute for in-depth study of the literature, gathering personal experience under supervision, and critical judgment. However, these guidelines should prove useful as an aide-mémoire for novices and practitioners who do not use the Er:YAG laser regularly.

Before treating extensive regions, trial therapy should first be performed on a carefully selected test area to assess the result.

By means of trial therapy it is possible to judge the risk of scarring, the wound healing and the risk of post inflammatory pigmentation changes. On the other hand the patient can make himself familiar with the way the lesion will be treated.

4.1 Indications

The MCL 30 Dermablate laser is intended for coagulation, vaporization, ablation or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery), oral surgery and in ophthalmology (skin around the eyes).

The following dermatological lesions have been treated successfully for several years:

- Acne scars
- Becker's nevi
- Café-au-lait spots
- Elastosis cutis
- Epidermal nevi (soft)
- Exophytic scars (flat scars, not keloids)
- Lentigines (simplex, senilis)
- Nevi spili
- Sebaceous adenomas
- Stepped scars (e.g. camouflage of skin graft borders)
- Syringomas
- Wrinkles („Skin Resurfacing„)
- Xanthelasmas

4.2 General comments for treatment

The Er:YAG laser allows for the superficial ablation of the skin with minimal thermal effect. The resulting good visualization of the area of treatment allows the physician to be the ultimate judge of depth parameters.

With the Er:YAG laser undesirable side effects, such as pigmentation changes or scarring, can be minimized, as ablation only occurs within the epidermis. The melanocytes and papillary blood vessels are not ablated.

To make use of the advantages of the Er:YAG laser it is recommended to work with pulse energies just above the ablation threshold (e.g. 4 J/cm²). Thus, the user controls depth penetration. Repeated treatment can enhance surgical results to an optimal effect. Treatment with higher energy level can damage tissue. Thus, an optimal effect is more easily obtained by repeated treatment with lower energy levels.

As ongoing clinical studies show, the success of Er:YAG treatment results from:

1. Removing and sculpturing of tissue during treatment
2. Softening and smoothing of tissue during wound healing
3. Collagen neogenesis during the first year post-op.

Tissue Effects:

- If the energy density is extremely low, there is no visible effect on tissue but thermal effects can be done.
- Excessively low energy densities (below the ablation threshold) result in the desiccation of the tissue (whitish discoloration) and limit the subsequent ablation effect. However, superficial coagulation is possible.
- Homogeneous ablation is a sign that the energy density is correct.
- Excessively high energy densities result in premature capillary bleeding or inhomogeneous ablation.

4.3 Treatment Preparation

Smoke evacuation:

During the treatment with the Erbium laser, a distinct dust and smoke formation must be expected due to the photo-ablation. The particles and aerosols being emitted are evacuated through the handpiece of the MCL 30 Dermablate near to the place of origin. The integrated smoke evacuator has special filters to detain the particles and to emit clean air. Without a smoke evacuator the optical part of the handpiece can be damaged due to the deposition of the particles.

Anesthesia:

In general, local anesthesia is required, if more than one pass with the recommended energy density is applied. The local anesthesia should be varied according to the depth of treatment. There are several forms to choose from: surface anesthesia, applied topically and occlusively (EMLA) or infiltration anesthesia (aminoamides, aminoester) that is injected intradermally or subcutaneously. It is also possible to apply infiltration anesthesia topically after the ablation of epidermis.

Wound care:

Anti-inflammatory dressings (erythromycin) together with a basic ointment serve as a basis for rapid wound healing.

Complete re-epithelialization is usually finished after 7 to 10 days.

4.4 Techniques:

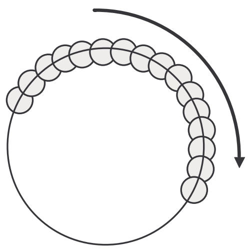
<u>Smooth skin lesions</u> can be ablated by applying over-lapping laser spots to the area to be treated.

The overlapping best adapted to the beam profile is 10 to 20 % of the spot diameter. Of course, it is possible to work with a higher overlap but it has to be taken into consideration that energy densities summarize in the overlapped areas. Lower pulse energies have to be selected in this case. We do not recommend to overlap less than 10% since ablation may be not as regular as usual.

<u>Uneven skin lesions</u> can be treated by smoothing the entire treatment area and then flattening the edges of wrinkles or other lesions in a second pass.

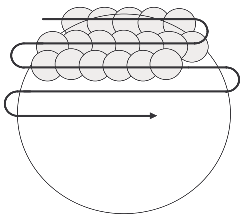
Guidelines for Therapy

Circular technique



- Use overlap technique **to flatten edges** of lesion (e. g. acne scars)
- Sponge debris off with NaCl solution
- Continue therapy until desired result is achieved
- If necessary, control bleeding by applying a moist dressing (e.g. hydrocolloid, PVP-I ointment, petrolatum gauze)

Paintbrush technique:

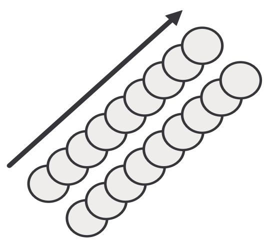


- Paintbrush technique for **extensive lesions** (e.g. lentigines)
- Important (!): sponge debris off from time to time with NaCl solution to assess result
- Continue therapy until no more lesion (e.g. pigment) is visible
- If necessary, control bleeding by applying a moist dressing (e.g. hydrocolloid, PVP-I ointment, petrolatum gauze)

Single spot technique:

- Single technique for **single lesions** (e.g. syringomas)
- Important (!): sponge debris off from time to time with NaCl solution to assess result
- If necessary, control bleeding by applying a moist dressing (e.g. hydrocolloid, PVP-I ointment, petrolatum gauze)

Overlap technique:



- Use overlap technique **to flatten edges** of lesions (e. g. wrinkles)
- Sponge debris off with NaCl solution
- Continue therapy until desired result is achieved
- If necessary, control bleeding by applying a moist dressing (e.g. hydrocolloid, PVP-I ointment, petrolatum gauze)

4.5 Clinical Protocol

Preparation of patient

- Remove cosmetics (thoroughly!)
- Disinfect skin
- Give local anesthetic, e.g. 0.5-1.0% mepivacaine,
- Optional: EMLA cream, 1 hour prior to treatment under occlusion
- Fit laser goggles

Therapy parameters

Spot diameter	Recommended Energy density
1.0 mm – 6,0 mm	4 J/cm² - 10 J/cm² for ablating the lesion 2 J/cm² - 3 J/cm² for flattening the edges

Aftercare

- Change dressing regularly until healing is complete
- Sunscreen post-therapeutically (sun blocker, factor > 15, approx. 12 weeks)

Notes

- Trial therapy is advisable to assess probable final result
- Instruct patient not to touch any scabs
- Final result assessable 6-10 weeks after therapy
- Minor erythema may exist for up to 6 months
- Scarring may occur if treatment depth extends beyond the papillary dermis (punctuate bleeding)

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