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***MultiStar***  
*and*  
***MultiPulse***

APPLICATION MANUAL

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### **Important advice for the user:**

This manual provides therapeutic guidance to assist in practical therapeutic work with this laser. Therefore please make yourself familiar with the contents of this manual and pay special attention to hints concerning the safe operation of the instrument.

The specifications are subject to change; the manual is not covered by an update service.

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 judgement, „hands-on“ training with a skilled fellow clinician and personal experience.

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# Laser Safety

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## 1 Laser Safety

### 1.1 Precautions

For more than 35 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 60 825-1 and the European Medical Device Directive (93/42/EEC) in valid version 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 than expert personnel of Asclepion Laser Technologies GmbH. Attempted servicing of this device with the help of persons not authorised by Asclepion Laser Technologies GmbH may have lethal consequences and will immediately void any warranty.**

# Laser Safety

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## 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 practising 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 GmbH 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 GmbH, before you begin laser treatment.**

# Basics of Laser Technology

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## 2 Basics of Laser Technology

### 2.1 The Laser

Since MAIMAN invented the laser in 1960, it has established itself in all branches of science and technology. Today, modern medicine cannot be imagined without lasers. (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, the laser is a light source emitting a narrow, bundled beam. This beam is of a specific wavelength with its uniform waves propagating almost parallel (collimated), in phase (coherent) and with little divergence.

Lasers are available in the wavelength regions from ultraviolet to infrared; laser powers range from a few fractions of a milliwatt for medical applications to the kilowatt range for high-power lasers used in industry.

If laser excitation is continuous, the laser is referred to as continuous-wave laser (cw-mode, for instance, argon lasers). If the laser is excited by single pulses, the laser is called a pulsed laser (e.g. ruby laser). If the excitation energy is accumulated and then suddenly released, the laser is referred to as a q-switched laser (such as q-switched ruby laser).

### 2.2 Physical Background

Inside the laser, energy is pumped into an "active medium". This process is followed by forcing the medium to release the stored energy in the form of light. In the so-called resonator, this light is then bundled into a beam by means of mirrors.

The medium may be a gas (e.g. argon laser), a liquid (e.g. dye laser), a solid (e.g. ruby rod) or a laser diode.

Generally, a light wave is generated when an atom "drops" from the "excited" state, where it has a high energy level, to a lower-level state. The difference in energy between the two levels then corresponds to the energy of the emitted wave.

The generation of laser radiation requires a state in which there are more excited atoms in the active medium than atoms of a lower energy level. This kind of energy distribution is referred to as "inversion".

In a laser, emission is triggered artificially by letting a light wave of identical energy hit an atom. This is sufficient to stimulate the atom to emit its own wave of the same frequency. For this reason, this process is called "stimulated emission".

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The parallel bundled laser beam is generated by the resonator. In its simplest form, the resonator consists of two parallel mirrors with the laser medium in between. When many light waves are generated in the medium by emission, the mirrors will always reflect those waves back into the medium that are incident at right angles. The reflected waves will again hit excited atoms while passing once more through the medium thus generating more stimulated emission.

This process is continuing avalanche-like with the light beam becoming ever stronger. On one end of the resonator, the mirror used is a partially transmitting mirror serving to output the usable laser beam.

The way of pumping energy into the laser or "charging the laser up" depends on the active medium used. The major pumping techniques include the excitation by high-intensity light, which is also referred to as "optical pumping" (e.g. ruby laser), the excitation by an electrical gas discharge (e.g. argon laser) and the direct electrical pumping (diode laser).

## 2.3 Laser Safety

If applied improperly, laser light may cause damage.

The greatest potential hazard exists for the human eye as even very low powers may cause irreversible damage to the retina due the focusing effect of the eye lens.

The nature of injury largely depends on the wavelength of the laser light.

The applicable threshold values of laser power and energy are specified in complex tables.

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)

<b><u>Class 1</u></b>	accessible laser radiation is not hazardous
<b><u>Class 1M</u></b>	restricted to the spectral range between 302.5nm and 4000nm, possible danger, when using optics in the laser beam
<b><u>Class 2</u></b>	restricted to the spectral range between 400nm and 700nm non-hazardous because of eye lid reflex
<b><u>Class 2M</u></b>	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
<b><u>Class 3R</u></b>	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

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**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



**All laser types typically used in medical therapy are classified in the highest danger class (Class 4). These lasers require protection even against a diffusely reflected beam.**

Official regulations oblige the owner/operator of laser devices to take some precautions for their use. In addition, users of medical lasers must meet the requirements laid down in the Medical Device Directive (in Germany: Law on Medical Products).

These regulations, among others, prescribe the following precautions for medical applications:

- ?? Mark the laser area (i.e. the room where laser radiation is emitted) and the laser device by laser warning labels.
- ?? Avoid reflecting surfaces in the operating room.
- ?? Keep flammable substances away from the laser area or taking precautions to prevent that such substances catch fire.
- ?? Check devices, optical fibers, and beam delivery systems for visible defects.
- ?? Observe user's manual and application manual provided by the manufacturer; checking the necessary safety devices for proper function before beginning laser operation.
- ?? Power ON condition must be clearly visible on laser device and at the entrance to the laser area (warning lamp).
- ?? Users, patients, present personnel must wear appropriate laser safety goggles (actual version of EN 207, safety goggles for MultiStar / MultiPulse: D 10,600 nm L4). Prior to using protective eyewear, make sure it is in perfect condition.
- ?? Just before switching the laser on, warn all persons present in the laser area that the laser is about to be armed. Take necessary precautions to prevent the development and spreading of flammable gases and vapors (risk of explosion) in the laser area.
- ?? Provide for efficient evacuation of generated vapor (vaporization).
- ?? Protect handpieces (particularly their optical end faces) from contamination.
- ?? Use only those agents and methods for cleaning and disinfection approved by the manufacturer.
- ?? Perform annual briefings of personnel on safety issues.
- ?? Secure the laser device against inadvertent positional changes.



# Application

## 3 Application

### 3.1 Application Modes

The CO<sub>2</sub> laser beam may be emitted in the following modes:

**CONTINUOUS** (CW), **PULSED** (PW) and **SUPER PULSED** (SP)

**"CW"** (Continuous Wave) In this mode, laser emission does not change during a given period of time. That's why the time/power graph shows a straight line that is parallel with the time axis.

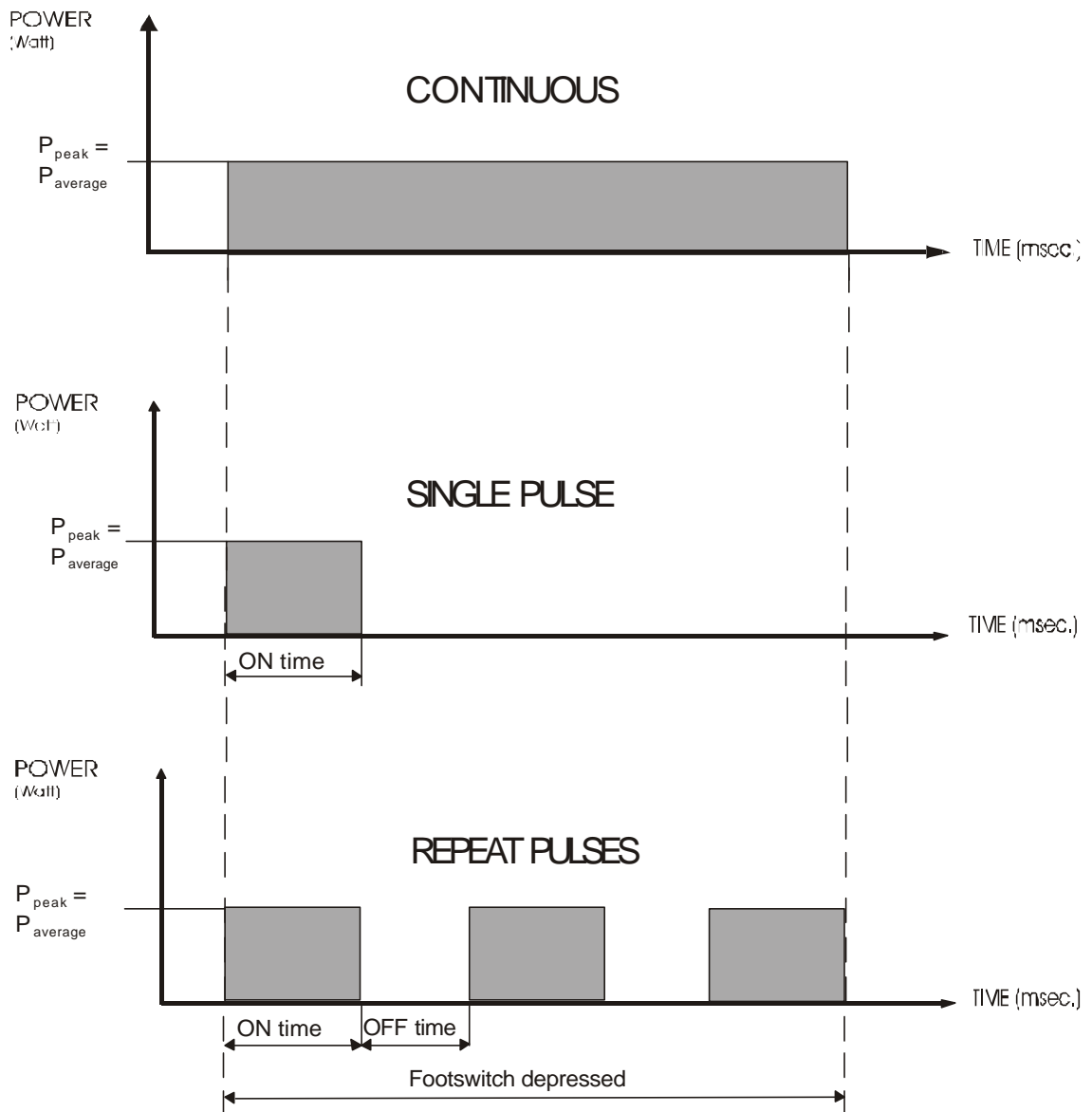
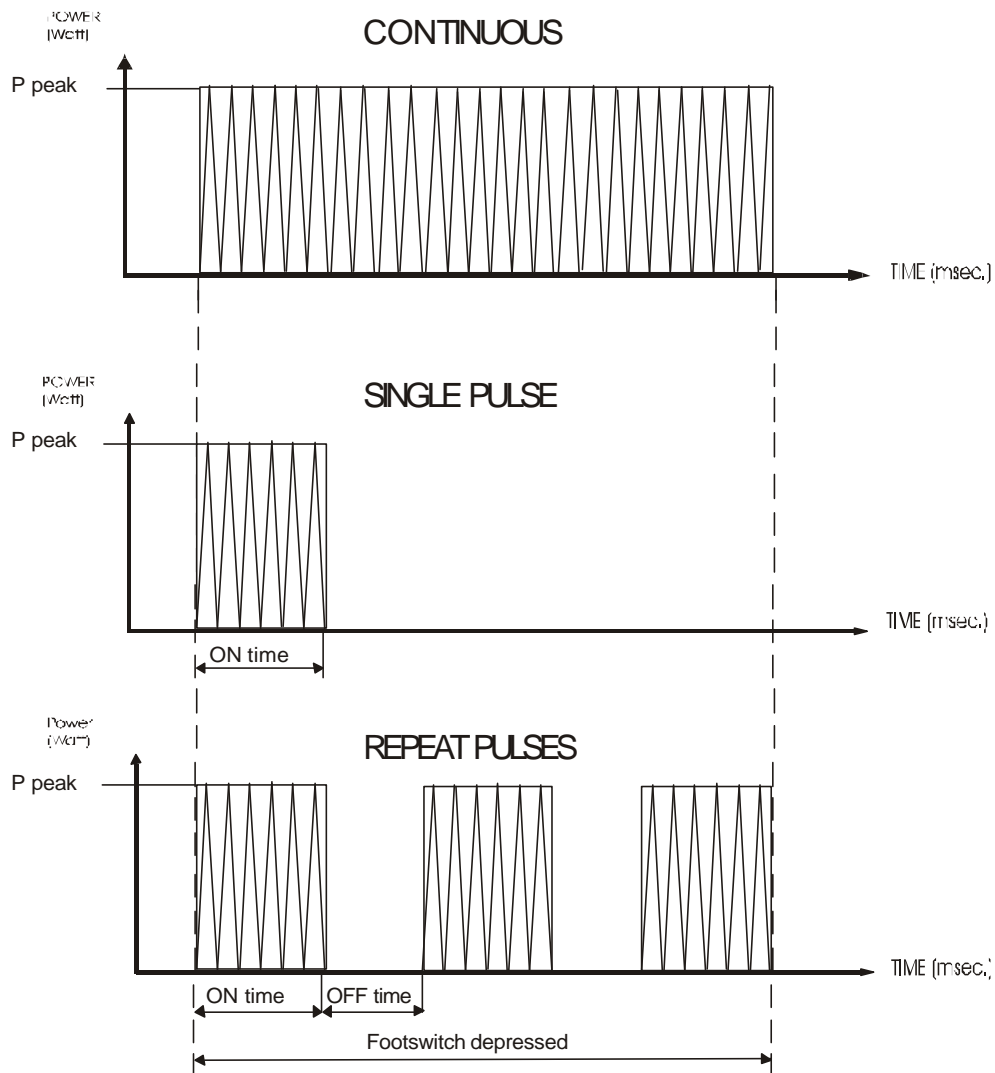


Fig. 1: Tissue exposure modes in CW mode

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**“SP” (SuperPulse)** A laser source is emitting in pulsed mode, if a pulse shape is generated over a given period of time. The energy of a single pulse corresponds to the area under the pulse curve.



*Fig. 2: Tissue exposure modes in Superpulse mode*

**“PW” (Pulsed Wave):** The system operates in pulsed mode using a fixed frequency. The power value will automatically be the last value set.

When you change the “Power” value, the system automatically changes the duty cycle: **the higher the power**, the higher is the duty cycle, and the effect on the patient is about the **same as in “CW”** mode (coagulation). **The lower the power**, the lower is the duty cycle, and the effect on the patient is about the **same as in “SP”** mode (vaporization). With this mode, it is possible to cover the effects on the patient between “CW” and “SP” modes.

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## 3.2 Tissue effects

The crucial parameter for treatment by laser devices such as the *MultiStar / MultiPulse* is the **power density**.

For that, the following mathematical relations apply:

$$\text{Power Density [Watt /cm}^2\text{]} = \text{Power [W]} / \text{Area [cm}^2\text{]}$$

$$\text{Power [Watt]} = \text{Energy [J = W x s]} / \text{Exposure Time [s]}$$

Due to its high absorption in water, the CO<sub>2</sub> laser is very well suitable for cutting and ablation of tissue in layers. The benefits provided by laser surgery include hemorrhage-free cutting of tissue with very small necrosis zones of max. 0.3 mm allowing blood vessels up to a size of 0.5 mm to be occluded.

The applied laser parameters, particularly the power density, are crucial for the interaction of radiation with tissue. The following tissue effects may arise:

Temperature	37 - 60 °C	60 - 65 °C	90 - 100 °C	Some hundred °C	
<b>Process</b>	Warming up	Denaturation of protein	Drying out Vaporization	Carbonization	Evaporation Burning
<b>Optical changes</b>	None	Whitish-gray coloration Increased scattering	Constant scattering	Black coloration Increased absorption	Development of smoke and gas
<b>Mechanical changes</b>	None	Relaxation	Shrinkage Dehydration	Strong mechanical damage	Ablation

Table 1\*: Thermal tissue effects

\*Source for table 1 to 4: "Angewandte Lasermedizin", H.-P. Berlien, G. Müller

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*Ecomed-Verlagsgesellschaft, 2000, ISBN 3-609-70510-8*

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Generally, for the ablation of tissue such a kind of drying is desirable where the temperature does not exceed 100 °C. For that, two processes are possible: vaporization for more superficial ablation and cutting for excision of tissue. The following parameters apply to these processes:

	Vaporization	Cutting
<b>Power density</b>	200 - 600 W/cm <sup>2</sup>	10,000 – 100,000 W/cm <sup>2</sup>
<b>Power</b>	4 - 10 W	5 - 25 W
<b>Spot size</b>	1 - 3 mm	0.1 – 0.2 mm
<b>Coagulation zone</b>	approx. 500 µm	approx. 100 µm

*Table 2\*: Comparison of parameters*

### 3.3 Indications

#### Indications for CO<sub>2</sub> lasers according to Berlien/Müller 12/99

Score	Indication	Feasibility
0	Contraindication	Impossible
1	Not recommendable	Hardly feasible
2	Usable if other techniques fail	Hardly feasible; may be used if there are no alternatives
3	Possible, competes with other techniques	Feasible
4	Good indication	Easily feasible
5	Absolute indication, other techniques not recommendable	Very well feasible

*Table 3\*: Legend to Table 4*

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INDICATION	SCORE
<b>Integumentary system</b>	
Condylomata acuminata	4/5
Mollusca	2/4
Verrucae	3/5
Epithelial dysplasia:	
<del>Leukoplakia</del>	4/5
<del>Morbus Bowen</del>	4/5
Benign skin tumors	4/5
Cutaneous/subcutaneous metastases (inoperable)	2/5
Basal cell epithelioma	2/5
Hypertrophic scars	2/5
Keloids:	
<del>telangiectatic</del>	
<del>capillary/hypertrophic</del>	
<del>fibrotic</del>	2/3
<b>Face and oral cavity</b>	
Epithelial dysplasia:	
<del>Leukoplakia</del>	3/5
<del>Carcinoma in situ</del>	2/5
Lingual tumors	3/3
Gingival hyperplasia	3/5
Partial velum resection	4/5
Tonsils:	
<del>Tonsillotomy</del>	3/4
<del>Tonsillectomie</del>	2/3

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<b>Upper respiratory tract</b>	
Recurrent nasal polyps	3/5
Turbinal cauterisation	3/5
Papillomatosis	4/5
Larynx polyp	3/5
Larynx tumor	4/5
Larynx stenoses:	
<del>2/2</del> Congenital	3/3
<del>2/2</del> Scarred	3/4
<b>Lower respiratory tract</b>	
Tracheal and bronchial fistulas (benign):	
<del>2/2</del> Congenital	2/4
<del>2/2</del> Scarred	3/4
<del>2/2</del> Granulomas	3/4
<del>2/2</del> Papillomas	3/4
<b>Gynecology</b>	
Condylomata acuminata	4/5
Epithelial dysplasia:	
<del>2/2</del> Morbus Paget	4/5
<del>2/2</del> Leukoplakia	4/5
<del>2/2</del> Morbus Bowen	4/5
<del>2/2</del> Cervical dysplasia	3/5
<del>2/2</del> Carcinoma in situ	2/5
Ectopic pregnancy:	
<del>2/2</del> Isthmic	3/5
<del>2/2</del> Ampullar	4/5
Peritubal adhesion	4/5



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Polycystic ovaries	3/3
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<b>Urology</b>	
Epithelial dysplasia:	
<del>4/4</del> Morbus Querat	4/4
<del>4/5</del> Morbus Paget	4/5
<del>4/5</del> Leukoplakia	4/5
<del>4/5</del> Morbus Bowen	4/5
Prostate:	
<del>4/5</del> BPH, transurethral, interstitial	4/5 (ITT)
<del>2/4</del> Carcinomas	2/4
Ureteral / urethral stenoses:	
<del>4/5</del> congenital	4/5
<del>3/5</del> acquired, benign	3/5
<del>3/5</del> acquired, malign	3/5
<b>Proctology</b>	
Anal stenoses	3/4
Anal ectropion	3/4
Anal mariscae	4/4
Anal fissures, excision	4/4
Condylomata acuminata	4/5
Hemorrhoidectomy	4/5
Pilonidal sinuses	4/5
<b>Oncology</b>	
Tumor resection:	
<del>4/4</del> Microsurgery	4/4
<del>4/4</del> Soft parts	4/4
Dysplasias	3/4

Table 4\*: Indications for CO<sub>2</sub> laser therapy

# Application

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## 3.4 Treatment recommendations\*

### 3.4.1 Vaporisation

Accessories:            Focusing handpiece  
                              Micromanipulator (Surgical microscope)

Laser parameter:    Power:                    8 – 10 – (20) W  
                              Spot diameter:        0.5 – 2 – (3) mm  
                              Exposure time:        0.1 – 0.2 s  
                              Interval time:         0.1 – 0.2 s

Indications:            Condylomata acuminata  
                              Verrucae  
                              Epithelial dysplasia  
                              Benign skin tumors  
                              Benign mucous membran tumors  
                              Larynx stenosis (congenital or aquired)

Recommendations:    Repeated passes, if necessary  
                              Smoke evacuation

# Application

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\*Source : *“Angewandte Lasermedizin”, H.-P. Berlien, G. Müller  
Ecomed-Verlagsgesellschaft, 2000, ISBN 3-609-70510-8*

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## 3.4.2 Vaporisation of an extended area

Accessories:            Focusing handpiece  
                              Micromanipulator (Surgical microscope)

Laser parameter:    Power:                    5 – 10 W  
                              Spot diameter:        0.5 – 1.5 mm  
                              Exposure time:        0.1 s  
                              Interval time:         0.1 s

Indications:            Condylomata acuminata  
                              Verrucae  
                              Epithelial dysplasia  
                              Benign skin tumors  
                              Benign mucous membran tumors

Recommendations:   Ablation depth depending on power density  
                              Repeated passes, if necessary  
                              Smoke evacuation

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## 3.4.3 Vaporisation of an extended area

Accessories: Scanner

Laser parameter: Power: 10 – 20 W  
Power: 5 – 7 W Superpulse mode  
Spot diameter: 0.5 – 1 mm  
Exposure time: according to scan frequency

Indications: Skin ablation  
Homogeneous superficial ablation of flat benign skin tumors  
Special indications of basaloma  
Special indications of scars  
Special indications of tattoos

Recommendations: Ablation depth depending on power density  
Repeated passes, if necessary  
Smoke evacuation

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## 3.4.4 Dissection

Accessories:            Focusing handpiece  
                              Micromanipulator (surgical microscope)

Laser parameter:    Power:                    5 – 10 W  
                              Spot diameter:        0.5 mm  
                              Exposure time:        0.1 – 0.2 s  
                              Interval:                0.1 – 0.2 s

Indications:            Surgery of benign and malign carcinoma  
                              Preparation of organs before resection:  
                                    Gall-bladder  
                                    Tonsils  
                                    Larynx polyps

Recommendations:   Spread tissue  
                              Vary exposure time according to desired coagulation zone  
                                    or use gas irrigation  
                              Maximum coagulation zone: 1,5 mm  
                              Smoke evacuation



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## 3.4.5 Scars

Accessories: Scanner (cw or short-pulsed)

Laser parameter: Power: 10 – 15 W  
Spot diameter: 0.5 mm  
Exposure time: 0.4 - 1 ms

Indications: Acne scars  
Hypertrophic scars  
Smoothing out of atrophic scars

Recommendations: Treatment in 2 to 3 passes according to area:  
Forehead 2 passes  
Cheeks 3 passes  
Refill deep scars with gel (i.e. Instillagel<sup>®</sup>)  
Follow-up treatment with hydrophil crème and  
Multiple compresses of black tea each day  
Smoke evacuation

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