JENA SURGICAL
LASER AT YOUR SIDE

MULTIPULSE PRO DUO

USER MANUAL

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JenaSurgical is a brand by the manufacturer
Asclepion Laser Technologies GmbH.

CE 0123

WARNING

This device is designed to meet international safety and performance standards. Personnel operating the device must have a thorough understanding of the proper operation of the device.

Therefore, this user manual must be studied carefully before using the device and all warnings and instructions are to be observed during its operation.

Release date: 24.11.2021

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1 Glossary

The following symbols and abbreviations may be used on the MultiPulse device and/or in this manual.

Symbols and abbreviations

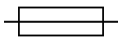
CE	Declaration of Conformity to Medical Device Directive 93/42/EEC
	Symbol for “Date of Manufacture”
	Symbol for “Manufacturer”
	Electrical protection degree type B
I	Electrical protection type
~	Symbol of alternating current
	Symbol of a fuse
	Warning on system discarding (Directive 2002/96/EC)
	Refer to the Instructions for Use
REF	Catalogue number
SN	Serial number
NOHD	Nominal Ocular Hazard Distance
ON/OFF	Use/Pause: intermittent use cycle

Table 1 Units of measurement

J	Joule - unit of energy
mJ	millijoule - 1,000 mJ=1J
nm	nanometer - unit of laser wavelength, 1000 nm=1µm
µm	micrometer - 1,000,000µm=1m
s	second - unit of time
µs	microsecond - 1,000,000 µs=1 s
ns	nanosecond - 1,000 ns = 1 µs
Hz	Hertz (cycles per second) - unit of frequency
A	ampere - unit of electrical current
VA	volt ampere - unit of absorbed electrical power
V~	unit of alternating voltage
Pa	Pascal - unit of measure of atmospheric pressure
kg	Kilogram - unit of mass
W	Watt - unit of power

2 Introduction

2.1 The MultiPulse PRO DUO system

The MultiPulse PRO DUO system is a 10,600 nm Carbon Dioxide (CO_2) laser device delivering a maximum power of 60 W.

It is scientifically known that the 10,600 nm wavelength is mostly absorbed by water; this characteristic makes it particularly suitable for soft tissue surgery.

CO_2 laser surgery is recognized as being minimally invasive and highly effective, as proven by hundreds of scientific articles over the last twenty years regarding surgery and microsurgery with this type of laser in various disciplines.

The MultiPulse PRO DUO system is designed to deliver the CO_2 laser beam through articulated arm (handpieces and scanning unit) or alternatively through a hollow fiber.

The use with the scanning unit is indicated for layer-by-layer char-free ablation, enhancing the safety of the treatment with more uniform, accurate and controllable impact such as ablative and fractional skin “resurfacing”.

The scanner technology can also be coupled with MicroSpot micromanipulators for ENT, microsurgical, gynaecological and neurosurgical applications. This is achieved with the use of a HiScan Surgical scanner.

Another miniaturized scanner, EndoScan, can be connected to the MultiPulse PRO DUO system. This scanning unit is suited mainly for gynaecological applications, both colposcopic and laparoscopic procedures, as well as other surgical applications requiring quick ablation.

2.2 About the Manual

The MultiPulse PRO DUO Operator’s Manual provides operators with the following information about the system:

- Indications for use,
- Safety,
- System description,
- Installation,
- Use of the system,
- Scanning units,
- Clinical Applications,
- Faults and troubleshooting,
- Maintenance and
- Accessories.

Before using the system for the first time, please familiarize yourself with the information and instructions in this manual. This is essential to ensure an effective and optimal use of the system, to avoid damage to persons or to the device, and to obtain good results from treatments.

In compliance with the standards about usability IEC/EN 62366-1 and EN 60601-1-6, this manual is the necessary material for training about the primary operating functions of this equipment.

In this manual, different colors are used to highlight warnings:

- Warnings on a grey background with a yellow triangle are remarks concerning safety.

Operators must read and follow all the remarks.

CAUTION

The use of controls or adjustments, or performance of procedures other than those specified herein may result in hazardous laser radiation exposure (IEC 60825-1).

Important information

Figures in this manual are purely indicative and may be subject to changes.

2.3 Symbols in the user manual

The following symbols are used to inform of the residual risks due to any shortcomings of the protection measures adopted or to other possible dangers:

WARNING

This symbol indicates a possible danger for an individual's life and health. Non-compliance with these instructions can cause serious danger to health, including life-threatening injuries.

CAUTION

This symbol indicates a possible dangerous situation.

Failure to obey these instructions can cause injuries and equipment damage.

The following symbols are used to give instructions on operating the device:

Important information

This symbol indicates important information about the proper use of the device. Failure to obey these instructions can cause damage to property or malfunctions of the device or its surroundings.

Tip

This symbol indicates practical tips and particularly useful information that enables the user to use all the features of the device to best effect.

2.4 Copyright

The specifications are subject to change due to further technical development. Contact the Technical Service of Asclepion Laser Technologies GmbH or your local distributor to get latest information.

3 Intended use

The MultiPulse PRO DUO system with its accessories is a medical device intended for:

- Incision, excision, ablation, vaporization and coagulation of soft tissue, including intraoral tissues in the medical specialties of aesthetics (dermatology and plastic surgery).
- Incision, excision, ablation, vaporization and coagulation of soft tissue in open and endoscopic surgery in the medical specialties otolaryngology (ENT), gynecology, general surgery, thoracic surgery, podiatry, orthopedics, genitourinary and dental and oral surgery.
- Incision, excision, ablation, evaporation and coagulation of soft body tissue in open surgery in the field of neurosurgery.

CAUTION

The MultiPulse PRO system must not be used for applications other than those specified above.
Asclepion Laser Technologies GmbH is not responsible for direct or side effects resulting from use of the system differing from the intended use specified above.

CAUTION

The use of laser treatment for pregnant women or children is NOT recommended because there do not exist clinical studies for these patients.

WARNING

When using the device in open Neurosurgery, the applied parts of the device NEVER be used in direct contact with the patient. This could lead to serious health consequences, including death.

WARNING

The scan units of the MultiPulse PRO device comply with degree of protection B. When combined with an endoscope, the REF 04366003A direct coupler (see chapter 15 Accessories) must be used between the scanner and the endoscope. Only this ensures the electrical safety of the combination.
Asclepion Laser Technologies GmbH is not responsible for direct or indirect injuries or death resulting from use of the device in conjunction with an endoscope.

3.1 Requirements for the user

The device can only be used by physicians having gained specific expertise in all such disciplines and medical applications the device is intended and used for, in addition to adequate training and experience in the type of treatment to be carried out in the particular case.

The user/operator must also ensure, under his/her own sole responsibility, that he/ she fulfils the requirements and qualifications required by laws and current local regulations enabling to operate the device according to its specific indications for use.

To ensure a safe and effective use of the medical device, the user is recommended to attend an adequate previous training on the clinical and technical operations of the system, as well as on laser safety standards and precautions.

WARNING

The laser emissions from the device can cause thermal changes to tissue structures.

Nobody other than a practicing physician or under the responsibility of a practicing physician (hereinafter referred to as user for simplification) may use the device.

Active medical products may only be applied by users who are adequately qualified to do so, based on their professional training background, expert knowledge and practical experience.

It is expressly pointed out that the device may be used only by persons who have been instructed in its operation and confirmed their attendance on the training course by signing the Medical Device Logbook.

4 Disclaimer

This manual is not intended to be a complete guide to the use of the system. Asclepion Laser Technologies recommends that all users first seek training that includes, but is not limited to, the following aspects of operation:

- Basic Laser Energy Physics
- Laser Safety
- Tissue Interaction
- Operating Procedures
- System Set-Up Procedures
- Potential Hazards

Asclepion Laser Technologies shall not be liable nor responsible of the safety and performance in the following cases:

- if the system is not used in compliance with health and safety rules and regulations in force;
- if the precautions and instructions contained in the present manual are not observed;
- if the system is not used by qualified and trained personnel;
- if the installation, any modification, recalibration or maintenance are not performed by qualified personnel authorised by Asclepion Laser Technologies;
- if the environment in which the system is located and used does not conform with all electrical, laser, etc. safety prescriptions specified by the applicable international and local regulations and international guidelines in force.

Asclepion Laser Technologies is not liable for direct or indirect effects arising out, in connection with or resulting from the application or use of the system, which are not a direct consequence of design or manufacturing defects of the device or parts thereof.

The manufacturer shall not be responsible of the success of the treatment.

Asclepion Laser Technologies reserves the irrevocable right to provide, upon written request, maintenance personnel authorised by the same, with electrical diagrams, components lists, adjustment instructions and any information relating to the parts of the system which are considered to be repairable.

5 Premises

The following instructions must be scrupulously observed.

5.1 Delivery – Inspection of goods received

Unless otherwise agreed between the manufacturer and the customer, the delivery of the goods shall be ex works (INCOTERMS 2000) even if it has been expressly agreed that the transport or part thereof shall be the responsibility of the manufacturer on the customer's behalf.

Upon delivery, all risks inherent to the system shall be transferred to the customer.

Therefore, any damage to the system during transport shall be to the customer's account.

It shall be the customer's responsibility to inspect upon delivery and in the presence of the carrier, the integrity and condition of the goods received; to verify correspondence between the goods delivered and those described in the transport documentation; to immediately bring to the carrier's attention any divergence and/or damage noticed.

5.2 Working environment

The environment in which the device is located and operated must be suitable and comply with the relative legal requirements and regulations in force, applicable also to the associated systems, concerning the use and storage thereof in complete safety to persons and objects.

The operation, workplace health and safety measures and any other activities shall be the exclusive responsibility of the relevant person(s) in charge and must be performed in compliance with local laws and Regulations and, where applicable, in compliance with European Directives (Council Directive 89/391/EEC and subsequent).

5.3 Responsibilities

The manufacturer shall guarantee the conformity of the product with EC safety and hygiene requirements according to the applicable Directives. The use of the system shall be the exclusive responsibility of the operator who shall be obliged to apply the necessary and adequate diligence and skills. The manufacturer shall be responsible in terms of and within the exclusive scope of current regulations applicable to the production and marketing of medical devices.

The manufacturer shall not be responsible for unfavourable consequences resulting from installation, use or maintenance which does not comply with the instructions in the present manual or resulting from failure by the user to apply the care, precautionary measures and safety regulations necessary to avoid such consequences.

5.4 Laser Safety Officer

We recommend prior consultation of the IEC 60825-8 Safety of laser products, Part 8: Guidelines for the safe use of laser beams on humans (2006-12, Second edition), which is a guideline on how to apply laser safety in medical practices. In accordance with Point 3.1 of the abovementioned guidelines, we recommend that a Laser Safety Officer be appointed and a precise definition of the relative responsibilities established.

6 Safety

This section provides a short recap of the current safety standards taken into account for the design and manufacturing of the MultiPulse PRO DUO system.

This section also covers specific safety features designed to minimize potential hazards.

6.1 General safety

The MultiPulse PRO DUO system is compliant with, but not limited to the following standards:

- European Council Directive 93/42/EEC on medical devices.
- European Council Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE).
- European Council Directive 2011/65/EU on RoHS.
- **Standard EN ISO 14971** - Medical devices - Application of risk management to medical devices.
- **Standard EN 60601-1** - Medical electrical equipment Part 1: General requirements for basic safety and essential performance.
- **Standard EN 60601-1-2** - Medical electrical equipment – Part 1: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility – Requirements and tests.
- **Standard IEC 60601-2-22** - Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.
- **Standard EN 60601-1-6** - Medical electrical equipment – Part 1: General requirements for basic safety and essential performance - Collateral standard: Usability.
- **Standard EN 62366-1** - Medical devices – Application of usability engineering to medical devices.
- **Standard EN 60825-1** - Safety of laser products - Part 1: Equipment classification and requirements.
- **Standard EN ISO 10993-1**- Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
- **Standard EN ISO 15223-1** - Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements.
- **Standard EN 1041** - Information supplied by the manufacturer of medical devices.

Classification:

- According to Directive 93/42/EEC, the MultiPulse PRO DUO system is a **Class IIb** device and possesses **CE 0123** certification.
- According to Standard EN 60601-1, the MultiPulse PRO DUO system is classified as **"Class I**" regarding type of electrical protection, and "**type B**" regarding degree of electrical protection.
- According to Standard EN 60825-1, the MultiPulse PRO DUO system is **Class 4**.

6.2 Precautionary measures

Even if the MultiPulse PRO DUO system has been designed and manufactured according to the prescribed safety standards, only a correct and proper use can ensure full safety.

WARNING

No modification of this equipment is allowed.
Do not modify this equipment without written authorization of Asclepion Laser Technologies GmbH (EN 60601-1).

CAUTION

The user is directly responsible for the correct identification of the area to be treated and for the correct positioning of the handpiece.

6.3 Optical hazard

The MultiPulse PRO DUO system emits a visible/invisible beam of intense energy that can cause serious injury to the eye and skin from direct or indirect contact with the beam. Accordingly, please adhere to the following precautions to minimize eye injuries in operators, assisting personnel and patients:

- All persons in the room during treatment must wear protective eyewear. See next paragraph for protective eyewear specifications.

CAUTION

- Never look directly into the handpiece, into the fiber or into apertures labelled “laser aperture”, even while wearing protective eyewear.
- Limit entry to the treatment room to only those who assist in treatment and are trained in the use of the equipment.
- Do not view the direct or scattered laser radiation with any other optical instruments than those authorized by the manufacturer.

CAUTION

- Direct the activated laser only at the intended area of treatment.
- Remove any metal object such as watches, rings, necklaces and similar items from the operating area and, if possible, do not use reflective instruments or materials.

Reflective objects could intercept the laser beam causing a deflection to an area other than the intended treatment area.

Many surfaces that may seem opaque can actually reflect the CO_2 or diode laser emission wavelength.

- Place the system in Standby mode when not in use (when in Standby mode, the beam cannot be inadvertently switched on).
- Ensure that all trained personnel assisting in the treatment know how to shut down the system in the case of an emergency.
- **Always remove the key from the switch when the system is switched off, and keep it in a safe place.**

6.3.1 Protective eyewear specifications

Safety glasses must comply with the European Standard EN 207 “Personal eye-protection equipment - Filters and eye-protectors against laser radiation (laser eye-protectors)”.

The degree of protection has been calculated taking into consideration the worst-case scenario in terms of power/energy and laser spot dimensions.

The standard EN 207 suggests calculating the degree of protection for the protective eyewear by considering a direct intra-beam viewing, 100 mm from the handpiece, with exposure time of 5 s. However, the presence of visual and acoustic warnings in the system and the nature of application, allows us to consider, as a more realistic condition, the viewing of the beam diffused by the tissue at a distance of 300 mm from the handpiece with exposure time 1 s.

The specifications for the safety glasses are then as follows:

• Direct intra-beam viewing, 100 mm distance, 5 s exposure time:

  – CO_2 laser radiation: OD≥4 @ 10600 nm, DLB5 ILB5 @ 10600 nm

  – Aiming diode laser radiation: OD≥1 @ 635 nm;

• Diffused beam viewing, 300 mm distance, 1 s exposure time:

  – CO_2 laser radiation: OD≥3 @ 10600 nm, DLB4 ILB4 @ 10600 nm

Contact your local agent or Asclepion Laser Technologies GmbH for information on where to find this type of eyewear.

CAUTION

- As a safety precaution, eyes must not be exposed to direct laser radiation, even if protected by glasses.
- Always check that you are wearing the right goggles: make sure that the wavelength of the source you are using is marked on the lens or frame.

6.4 Electrical Hazard

The MultiPulse PRO DUO system uses high voltages internally. Do not open the protective panels unless you are trained and authorized to do so.

CAUTION

- To avoid the risk of electric shock, this device must only be connected to supply mains with protective earth.
  If the integrity of the environment’s electrical system - and in particular of the protective earth - is not reliable for safety, do not connect the device to the mains socket until the safety conditions are restored (EN 60601-1).
- The treatment must immediately be stopped in case of leaks of liquid from the cooling circuit. In this event, do not use the system and immediately call technical assistance.

CAUTION

It is recommended to avoid the presence of liquid in proximity of the device.

6.5 Biological Hazard

CAUTION

The laser smoke presents a possible biological hazard. Ablated tissue from the patient is contained in the smoke.

Laser smoke may contain viable particles. The use of a laser smoke evacuator is recommended (EN 60601-2-22).

6.6 Fire Hazard

When the laser beam comes into contact with an exterior surface, this surface absorbs energy. This raises the surface temperature, whether the surface is skin, hair, clothes, or any flammable substance. Accordingly, operators must take the following precautions in order to prevent a fire:

- Use non-flammable substances for uses such as anaesthesia, preparing soft tissue for treatment, and cleaning or disinfecting instruments.
- Be especially careful with the use of oxygen. Oxygen accelerates both the severity and the extent of fire.
- Store the bare minimum of combustible materials in the treatment room. If treatment requires the use of a combustible material, such as gauze, first soak it in water.
- Prevent singeing or burning when treating an area with hair by wetting the area with water or saline before beginning treatment.
- Always keep a small fire extinguisher and water in the treatment room.

CAUTION

Never use inflammable gas as a gas shield.
The use of flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen should be avoided.
Some materials may be ignited by the laser equipment when saturated with oxygen, such as cotton wool.
Solvents for adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used. It is also important to beware of the danger of ignition of endogenous gases (EN 60601-2-22).

6.7 Radio Frequency Interference

The MultiPulse PRO DUO system complies with standard EN 60601-1-2.

It requires special EMC precautions and must be installed according to EMC information provided in this manual - see Appendix. Portable and Mobile RF communications equipment can affect the MultiPulse PRO DUO system.

WARNING

Medical devices are subject to specific precaution measures concerning the electromagnetic compatibility (EMC). The device emits low levels of electromagnetic radiation that may have an effect on devices that do not comply with the standard. Unintended settings at these devices could be the result of such an effect. Please observe the notes of the manufacturer's EMC declaration in the Appendix when installing and operating the device.

WARNING

The device may be influenced by devices that do not comply with the standard indicated above. The result may be unintended settings. Therefore, switch off cellular phones and similar equipment before putting the laser device into operation.

WARNING

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING

The MultiPulse PRO DUO system should not be used in proximity of other equipment. If this is necessary, however, make sure the MultiPulse PRO system operates correctly in the stacked configuration.

6.8 Essential Performances

The following functions are Essential Performances, i.e. performances necessary to keep risk within acceptable limits:

- The ability of the system to prevent any unwanted laser emission,
- the ability of the system to stop laser emission as soon as the footswitch is released and
- the ability of the system to maintain the laser output power during treatment within ± 20 % with respect to the set value.
- ability of the system to perform emission only from the selected source.

Any degradation or loss of Essential Performance would be indicated by a failure on the display, and the device emission would be immediately interrupted.

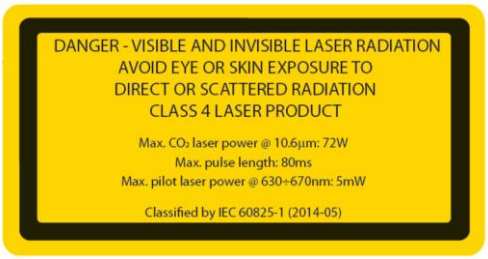
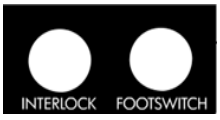
6.9 Safety Labels

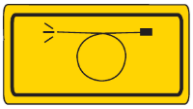
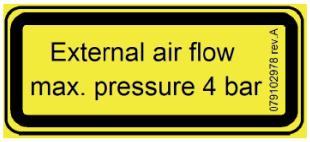
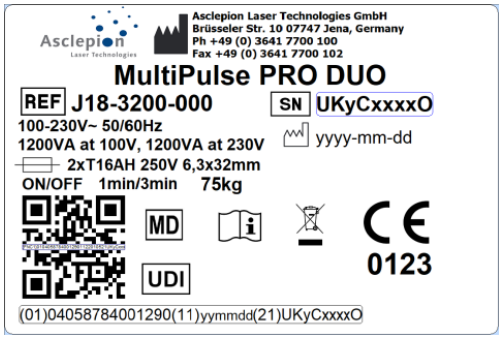
The MultiPulse PRO DUO system comes complete with the safety labels shown below.

Important information

All labels must be kept in their own position, in good condition and promptly replaced if damaged.

Meaning of the safety labels

	**Label 1** Emission of laser radiation.
	**Label 2** Label for the aperture that emits laser radiation.
	**Label 3** Warning regarding danger of the exposure to laser radiation. CO_2 laser source specifications.
	**Label 4** Warning regarding danger of exposure to laser radiation when panels are removed from the chassis.
	**Label 5** Warning. The operator is advised to read the operator's manual carefully before using the system.
	**Label 6** Label for the emergency switch used to turn the system off promptly.
	**Label 7** Label for the connections on the rear panel (interlock and footswitch).

	**Label 8** Warning when connecting/disconnecting the scanning unit.
	**Label 9** Electrical protection degree type B.
	**Label 10** Potential equalization connector label.
	**Label 11** Label for the key switch.
	**Label 12** Warning regarding the system disposal.
	**Label 13** Identification of the fiber delivery system for CO_2 laser radiation.
	**Label 14** Label for the aperture that emits laser radiation.
	**Label 15** Specification for pressure of external air flow.
	**Label 16** Pushing prohibited
	**Label 17** Type plate

6.9.1 Placement of safety labels

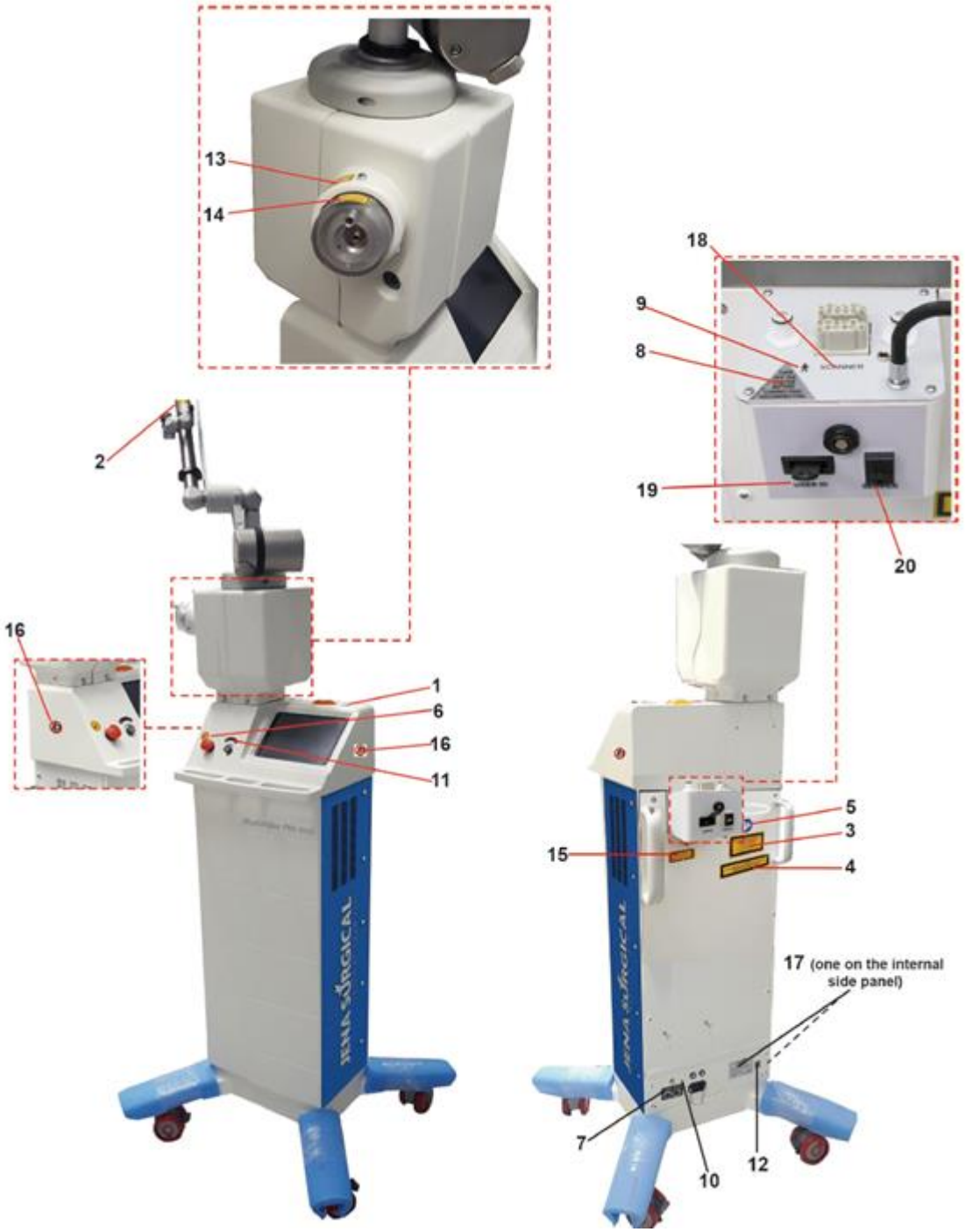


Figure 1 - Position of the safety labels

7 System description

The operator interacts directly with the following external parts of the system.

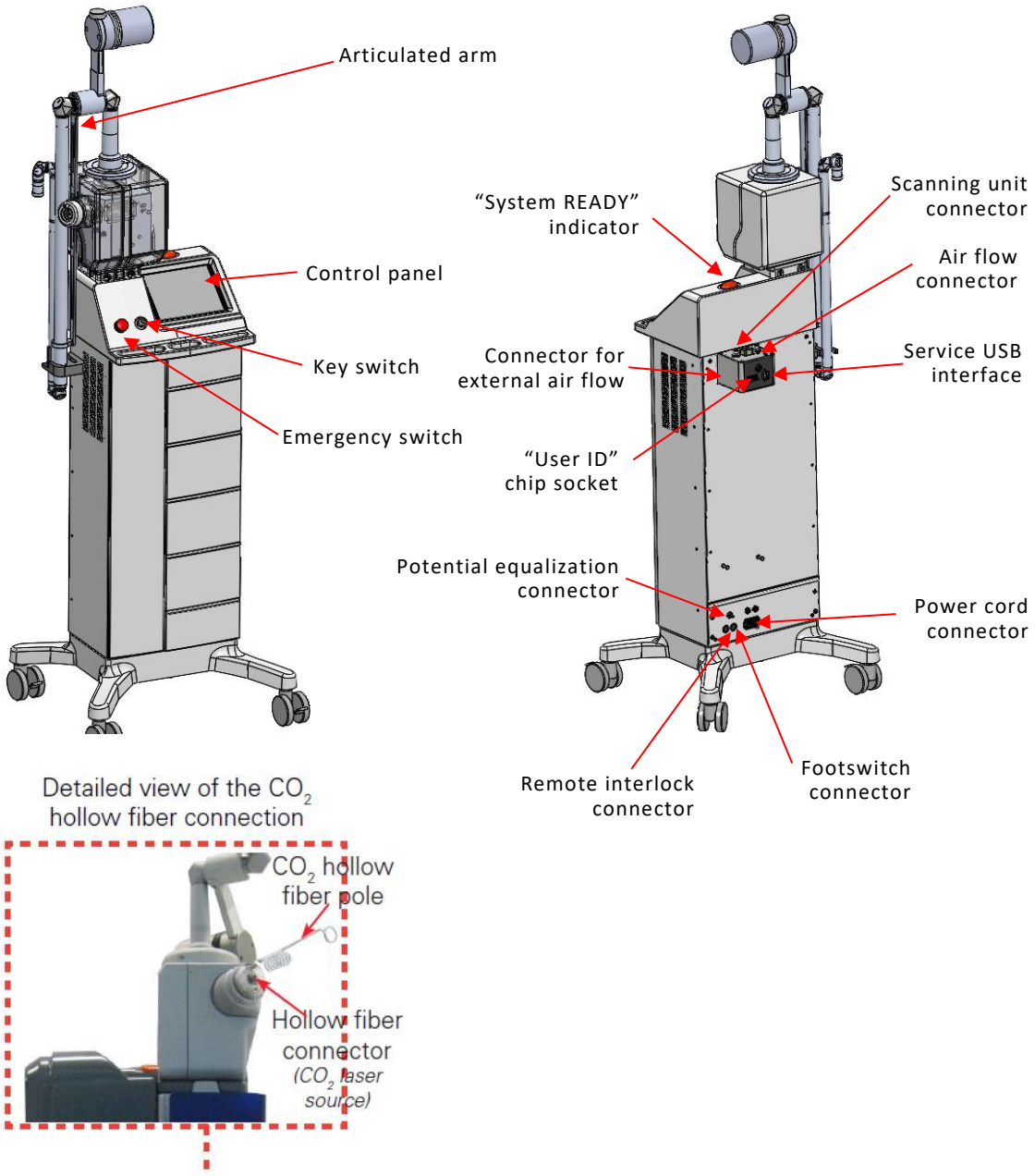


Figure 2 - System's main external components

7.1 Control and signal devices

7.1.1 System switches

The power supply to the system is controlled through the three switches described below. Please refer to Figure 2 for their positions on the device.

Key Switch

Use the key switch to turn the system on and off.

It is a double-throw switch (O-I) with a removable safety key (only in the O position).

To turn the system on, insert the key and turn the key switch to “I”; to turn the system off after normal operation, turn the key to “O”.

The key switch can be used to turn the system on only if the emergency switch is not engaged.

CAUTION

The key must always be removed when the system is turned off and must be safely kept by authorized personnel only.

Emergency Switch

The emergency switch immediately shuts the system down.

It must only be used in emergency circumstances when it is necessary for the operator to immediately stop laser emission.

To shut the system down, push the switch button in. To reset the switch, rotate it and pull it outwards.

Important information

Do not use the emergency switch to turn the system on and off under normal circumstances.

7.1.2 Footswitch

When the system is in READY mode, begin laser emission by pressing the footswitch, which is an electrical switch intended to be set up on the floor and operated by foot. The footswitch is normally disabled as a precautionary measure: in this case, when the footswitch is pressed, a warning message is displayed on screen and a warning sound is produced.

7.1.3 Potential Equalization Connector

The potential equalization connector is located on the bottom of the rear panel. Connecting a potential equalization cable between this connector and a suitable grounded connection in the operating room offers additional grounding protection for the system (potential equalization).

7.1.4 Internal buzzer

The system is equipped with an internal buzzer that sounds an acoustic signal in the following cases:

- To warn the operator that an incorrect action has been performed - for instance, the footswitch is pressed when disabled.

- When a laser treatment is in progress – the CO_2 source is switched on, the footswitch is enabled and pressed, the shutter is open and the correct effective power is delivered- a sound is produced every 1 s. This timed sound helps the operator to "keep track" of the treatment time.
- If a laser treatment is in progress - the CO_2 source is switched on, the footswitch is enabled and pressed, the shutter is open and an incorrect effective power is delivered - five sounds are produced every 1 s. This increased timed sound warns the operator that an incorrect effective power delivery has been detected, i.e. the real CO_2 output power level does not match the power level set on the control power.

7.1.5 "SYSTEM READY" indicator light

The "SYSTEM READY" indicator light (see Figure 2) is lit when laser emission is enabled.

7.1.6 Active CO_2 delivery system indicators

These indicators show which CO_2 delivery mode is active:

- When the articulated arm delivery system has been selected, the indicator which encircles it will illuminate blue.
- When the hollow fiber delivery system has been selected, the indicator which encircles the fiber connector will illuminate blue.

7.1.7 Control panel

The control panel allows the operator to control the system: from here he/she can select the status of the system and treatment parameters.

It is composed of a back-lit touch screen which the operator uses to send commands by gently pressing the required controls/parameters on the screen.

7.2 CO_2 Laser Delivery Accessories

7.2.1 Articulated arm

The CO_2 laser radiation is delivered to the treatment area through the handpieces or the scanning units. The handpieces shown in Figure 4, Figure 5 and Figure 6 and the scanning units (see chapter 11 "Scanning units") are attached to the distal end of the articulated arm.

The articulated arm is an optical assembly that delivers beam laser radiation. It is made up of seven mirrors placed on rotating knuckles: the mechanical accuracy of the articulated arm allows the CO_2 laser beam to travel inside it and along its axis however the arm is oriented.

The field of action of the articulated arm covers a radius of approximately 80 cm, the transfer efficiency of power is greater than 85 %. The loss of 15% is balanced by a suitable calibration of the internal power meter.

CO_2 Handpieces

A wide range of handpieces are available for the MultiPulse PRO DUO system, with different spot sizes and high performances in specific fields of application.

The system can be equipped with a handpiece body housing different lens assemblies (1.5", 2", 4", 7" and collimated, please refer to Figure 4).

Additionally, both 5" handpiece and 8" handpiece are available: each of them consists of a handpiece body (and lens assembly) with interchangeable handpiece tips. The 5" handpiece is equipped with tips that are either straight, straight with backstop, or with mirror to deflect the laser at 90° and 120°; the 8" handpiece includes a straight tip and straight with backstop (please refer to Figure 5 and Figure 6).

CAUTION

If the 8" handpiece is connected to the EndoScan unit, the user has not to select scanning figures larger than 60 %.

Important information

The term "spot size" refers to the diameter of the laser beam (and therefore the diameter of the circular area exposed to laser radiation) when the handpiece is held perpendicular to the surface being treated and the laser beam is in the focal point.
The spot of the collimated handpiece is approximately 2.0 mm. The handpiece is attached to the distal end of the articulated arm.

In order to avoid dust and particles from depositing on the optics during laser operation, an air flow is provided by an internal pump.

The air intake connector on the handpiece is connected to the relative outlet connector located on the rear of the system by a black plastic PVC tube. See chapter 8.5 for details on the connections.

CAUTION

Never disconnect the black tube during system operation.

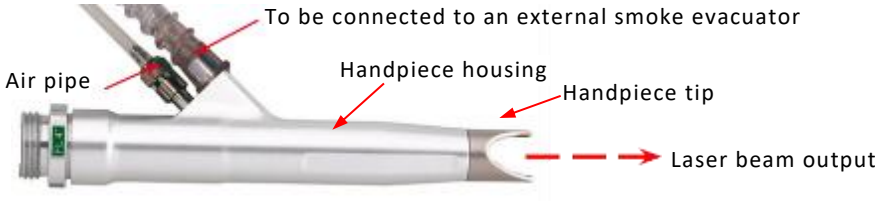


Figure 3 - Laser handpiece

It is also possible to connect the handpiece to an external smoke evacuator through a flexible hose. The connection hose of the smoke evacuator can be supported by the plastic clamps set up along the articulated arm (see Figure 16).

CAUTION

"As the aiming beam passes down the same delivery system as the working beam it provides a good method of checking the integrity of the laser delivery system. If the aiming beam is not present at the distal end of the delivery system, its intensity is reduced, or it looks diffused, this is a possible indication of a damaged or not properly working system" (IEC 60601-2-22).

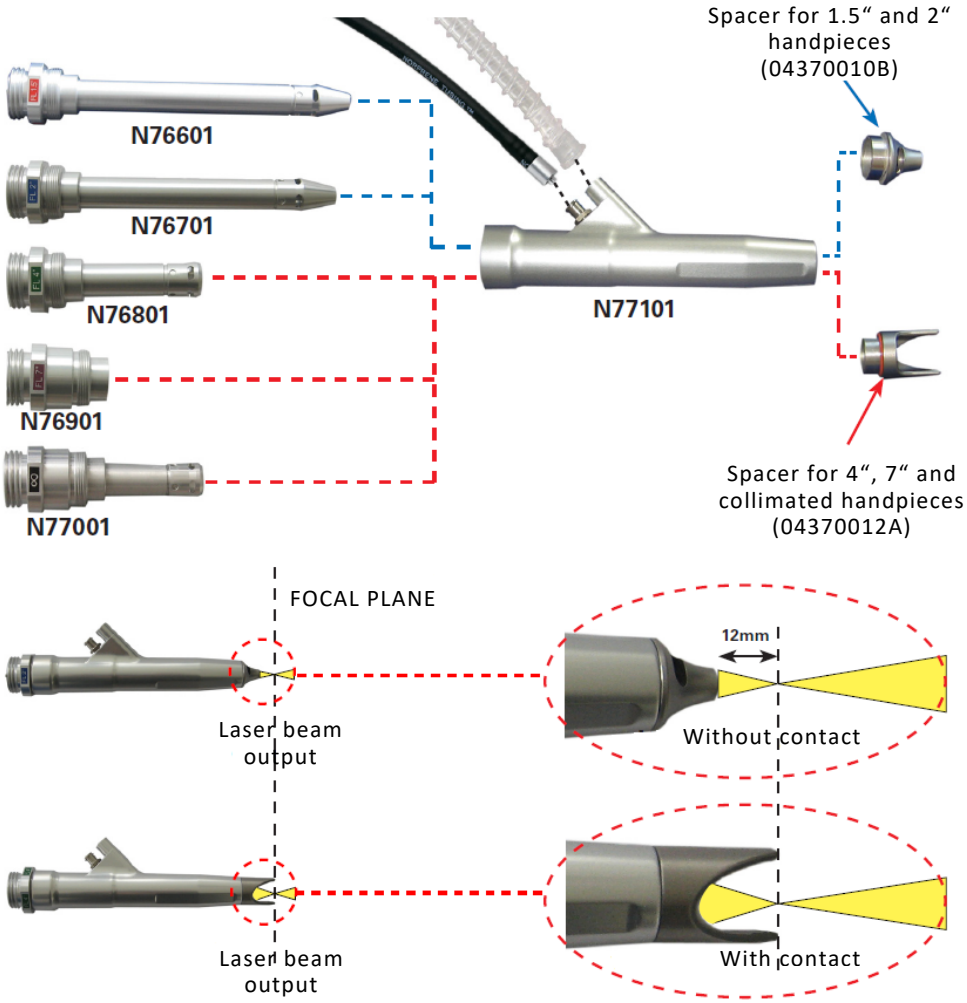


Figure 4 - Assembly of the handpieces

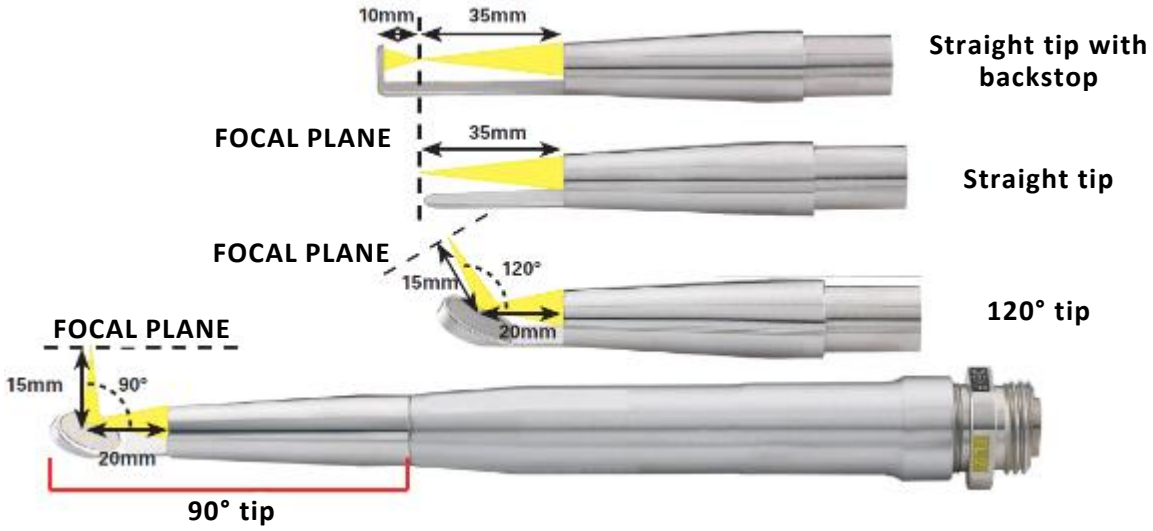


Figure 5 - 5" handpiece and spacers

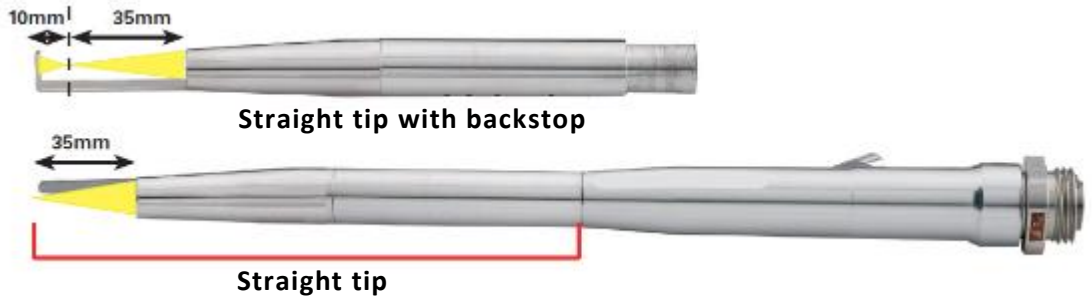


Figure 6 - 8" handpiece and spacers

Changing lens assembly

To change the lens assembly, disconnect the air pipes from the handpiece barrel, then unscrew the handpiece from the articulated arm.

Unscrew the lens that is currently assembled on the handpiece and srew in the new one.

Re-attach the air purge tube and the smoke evacuator tube (if included).

Important information

Please pay attention to insert the lens assembly you want really to use: the focal length is marked on the holder itself!

Changing handpiece spacers

Handpiece spacers can be easily changed by removing the end of the handpiece itself and inserting the new spacer.

Use the narrow spacer for the 1.5" and 2" handpieces, the open one for the 4", 7" and collimated handpieces. 5" and 8" handpieces have their own spacers.

Changing handpiece tips

Handpiece tips can be easily changed by unscrewing the end of the handpiece itself and screwing on the new tip.

CO_2 handpieces for dental applications

The handpieces shown in Figure 7 and Figure 8 can be provided for the CO_2 laser source to be used for dental applications for the treatment of soft tissues.

The handpieces consist of the handpiece body and interchangeable handpiece apertures.

The 4" handpiece (Figure 7) comes with three different apertures: a straight aperture to transmit the laser beam in line with the handpieces axis, and two apertures with a mirror to deflect the laser by 105° or 120°. Moreover, the straight and 105° apertures can be used with removable tips to work in contact with the tissue.

The 2" handpiece (Figure 8) includes three apertures: two straight apertures (either contact or non-contact type) that transmits the laser beam in line with the handpieces axis, and an aperture with a mirror to deflect the laser by 120°.

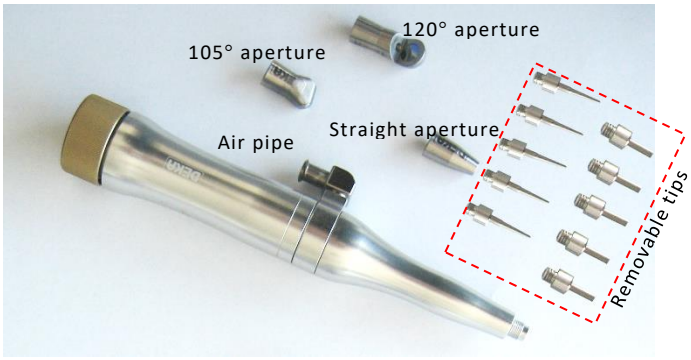


Figure 7 - 4" dental handpiece (N81501)

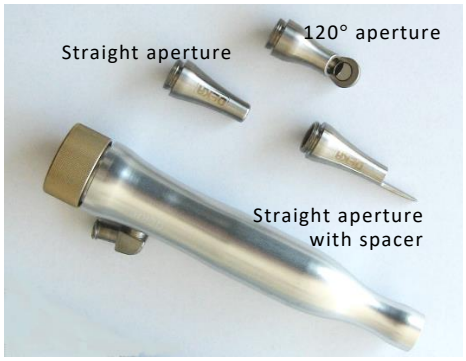


Figure 8 - 2" dental handpiece (N81601)

Changing handpieces

To change handpieces, disconnect the air purge tubing from the handpiece body.

Unscrew the handpiece from the articulated arm, screw on the new handpiece and connect the air purge tubing.

Changing handpiece aperture

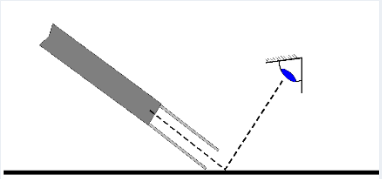
The handpiece aperture is easily changed by unscrewing the final part of the handpiece itself and screwing the new aperture.

Changing contact tips

Pull on the tip to remove and push the new tip into the hole located at the end of the aperture until it stops.

CAUTION

The handpiece must always be held perpendicularly to the surface under treatment and the spacer must always be in contact with the surface itself.
The operator must always keep in mind that the skin may reflect a high percentage of the energy received. Positioning the handpiece as shown in the figure below is not only incorrect, but may also be very dangerous if safety goggles are not worn!



7.2.2 CO_2 hollow fiber (waveguide)

The CO_2 laser beam can be delivered also through a hollow fiber (waveguide) to allow easier delivery of laser energy to the target tissue.

The fiber available for MultiPulse PRO DUO is a **sterile disposable** 500 µm fiber with SMA-905 connector and a length of 2 m.

All optical components, especially optical fibers, must be treated with extreme care and protected from dust and contamination. Store the fibers at room temperature in the transport packaging and protect them from any damage.

Only if these requirements are met, the sterility of the fibers is ensured until the expiry date specified on the sterile packaging.

WARNING

The sterile fiber has to be handled only under sterile conditions, otherwise any usage in the human body is contraindicated.

Please note instructions in user manual of the sterile fiber!

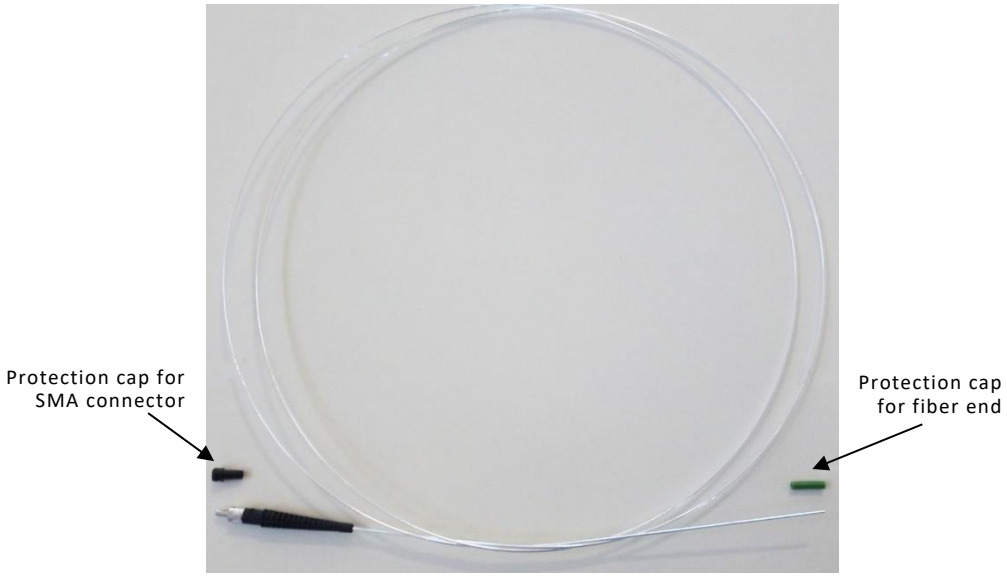
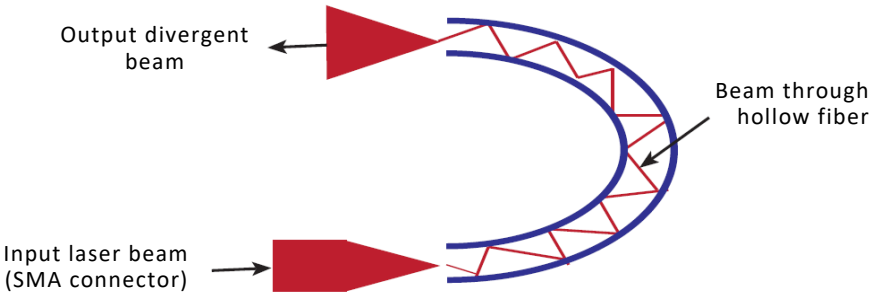


Figure 9 - CO_2 hollow fiber



Important information

When operating with the fiber, always ensure that purge air is flowing through the fiber port and fiber prior to laser beam emission (please refer to chapter 8.3 and 10.3.2).

Please refer to the proper fiber's instruction guide for complete description, maintenance procedures and technical specifications.

CAUTION

- The fiber is designed to be used in a non-contact mode. Keep inadvertent contact with the tissue and fiber tip to a minimum.
- Always use the minimum laser power setting for a given procedure. Minimize the amount of bending of the fiber to avoid damage to the fiber or handpiece.
- Fiber damage can occur when using a laser at a high-power level or at an extreme bending radius for long lasing time periods.

7.2.3 Applied parts

The following accessories are applied parts:

- all CO_2 handpieces (see Figure 4, Figure 5, Figure 6): type B applied parts;
- "HiScan Surgical" (see Figure 41): type B applied part;
- "EndoScan" (see Figure 48): type B applied part;
- "HiScan DOT" (see Figure 52): type B applied part;
- hollow fiber: type B applied part.

8 Installation

Remove the device from its packaging, position it on a horizontal surface and lock the front wheels by using the locking system provided on them, so that it is stable.

Conserve the packaging in case it is necessary to repack the device for future transport or storage.

Check that the items listed in Chapter 15 “Accessories” are included inside the box together with the device.

Important information

Before first use the device has to be installed by a person being qualified and authorized by Asclepion Laser Technologies to do so.

CAUTION

Located inside the accessories case, there is a temperature recorder. Upon receipt of shipment inspect the temperature indicator. If it is red (see picture below), before installing and using the device, contact the Technical Assistance Service.

8.1 System requirements

8.1.1 Space requirements

The MultiPulse PRO DUO device must be properly located in order to guarantee an adequate ventilation for the rear side of the laser system, where the fan is located.

Make sure that adequate space is available in the working area to guarantee a proper use of the device. The MultiPulse PRO DUO system has the following dimensions and weight:

Table 2 Dimensions and weight

Height	174 cm (with folded articulated arm)
Width	66 cm
Depth	59 cm
Weight	75 kg

8.1.2 Electrical requirements

Please consider the following electrical requirements before installing the system:

- Make sure the socket is efficiently earthed,
- the MultiPulse PRO DUO system unit should not share a power line with other heavy power-load equipment. The system should be on a separate power line with a separate circuit breaker,

- the MultiPulse PRO DUO system should not be used near other equipment. If this is necessary, observe the system to verify normal operation in the stacked configuration in which it will be used and,
- the MultiPulse PRO DUO system should be placed in that way that unintentionally disconnecting the device from power line is not possible.

Important information

The system must be connected directly to a wall outlet. The system should not be connected neither to an uninterruptible power supply (UPS) nor to an electronic phase advancer nor to an insulation transformer.

8.1.3 Environmental requirements

Follow these environmental requirements to properly maintain the system:

- Keep the air free of corrosive substances, such as salts and acids. These pollutants may damage electrical wirings.
- Keep dust particles to a minimum. Dust particles can cause damage to the system.
- Do not place the system near heat sources.
- Observe the following temperature, humidity and pressure requirements:

Table 3 Operating and environmental conditions

Operating temperature	From 15 °C to 35 °C
Operating humidity	From 20 % to 80 % non-condensing
Atmospheric pressure	From 700 hPa to 1,060 hPa

Table 4 Transport and storage conditions

Storage and transport temperature	From 5 °C to 50 °C
Storage and transport humidity	From 10 % to 90 %
Atmospheric pressure	From 700 hPa to 1,060 hPa

8.1.4 Working area

The MultiPulse PRO DUO system is a class 4 laser device and must be used in a proper working area according to international and local requirements.

Prepare the working area following at least the instructions indicated below:

- Mark the treatment room clearly to prevent unexpected entry during treatment. The label shown below (provided with the accessories) must be placed on the external part of each entrance to this area in order to indicate the presence of a laser source inside.

Figure 10 - Door safety label

- Cover windows and other openings in the treatment room to prevent the inadvertent escape of laser light.

CAUTION

Remove any metal objects such as watches, rings, necklaces and similar items from the operating area and, if possible, do not use reflective instruments or materials.

- Ensure that all trained personnel assisting in the treatment room are able to shut down the system in case of emergency.
- Always remove the key from the switch when the system is deactivated and keep it in a safe place.

CAUTION

All persons in the room must wear protective eyewear during treatment. Limit entry to the treatment room only to those who assist in treatment and are trained in the use of the equipment.

- The interlock socket may be used as an additional precautionary measure. See chapter 8.6.

8.2 Installation

Proceed as follows:

- Insert the key into the key switch located on the front: the key can only be inserted in the “O” position, i.e. with the system switched off. Do not turn the key to the “I” position;
- make sure the emergency switch is in the upwards position;
- connect the external interlock network to the socket marked “INTERLOCK”; if there is no external interlock network, connect the interlock connector supplied with the accessories (see also chapter Accessories).
- connect the footswitch to the socket marked “FOOTSWITCH”.

Important information

The contacts of the interlock and footswitch sockets must never be connected to the mains otherwise the system should be seriously damaged. Connect these sockets only as specified in this paragraph.

- Connect the mains cable (provided with the system) to the proper socket located on the rear side of the system.
- Connect the other end of the mains cable to a wall outlet.

Important information

The mains plug is intended as the disconnecting device for this equipment.

- Make sure that the mains plug is always reachable.
- Make sure the wall outlet is properly grounded.
- Make sure that the mains specifications are met.

8.2.1 Installing counterweight for the articulated arm

At system first installation, the counterweight of the articulated arm must be installed. Proceed as follows (please refer to following figures):

- first, if not present, install the support rod of the counterweight following the steps illustrated below:

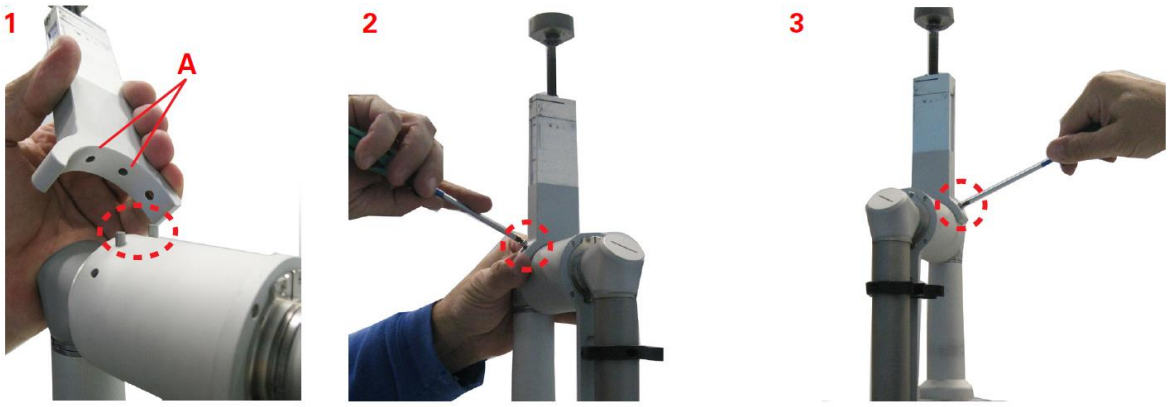


Figure 11 - Installation of support rod

Important information

When installing the support rod, pay attention to put the two central holes on it (A in step 1, Figure 11) onto the proper pins of the articulated arm (highlighted by the dotted line in step 1).

- Assemble the heaviest component, **paying attention to put this first component on the opposite side of the articulated arm** (as shown in Figure 12, step 1) and to insert the special washer of the articulated arm into the groove of the counterweight.

CAUTION

Be very careful while handling the counterweight as it is very heavy: if it falls, it can injury someone or damage the equipment.

- Install the second component which allows to fix the counterweight: insert the special washer of the articulated arm into its groove and screw it using the provided 5mm Allen wrench.

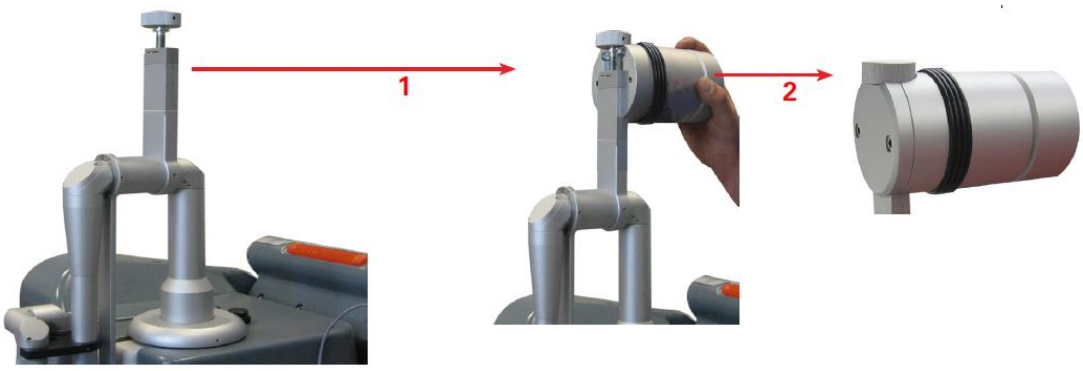


Figure 12 - Installation of the articulated arm's counterweight

Important information

The counterweight and its support rod have always to be removed for long distance transport.

To remove them, put the articulated arm in its resting position and reverse the steps in this paragraph.

To move the articulated arm to the working position, remove it from its resting position and act on the adjusting knob in order to balance the counterweight according to the accessory connected to the articulated arm. Turn the knob up to reach a position around the mark "HiScan" if a scanner is connected (without micromanipulator), around the mark "Freehand" if a handpiece is connected.

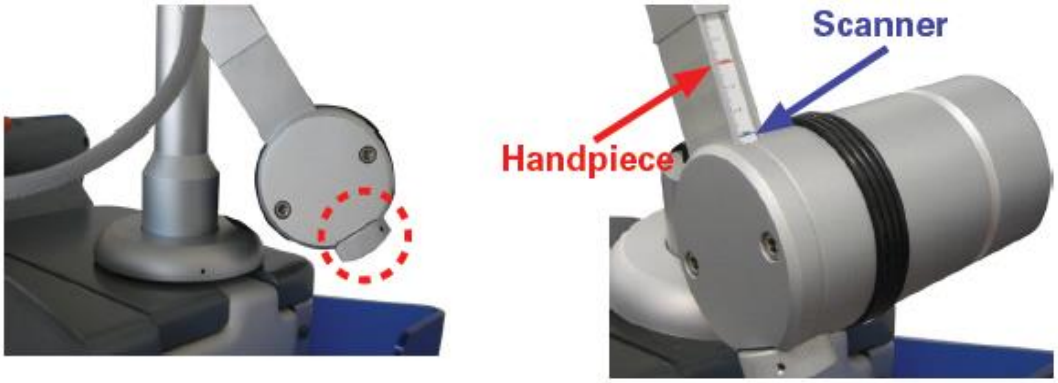
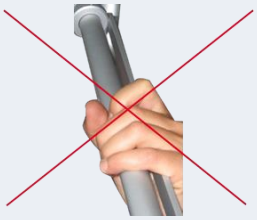


Figure 13 - Adjusting counterweight

To place again the articulated arm in its resting position, rotate it slightly outwards and fold it so as to leave the counterweight upward. Secure the arm using the provided clamp on the system.

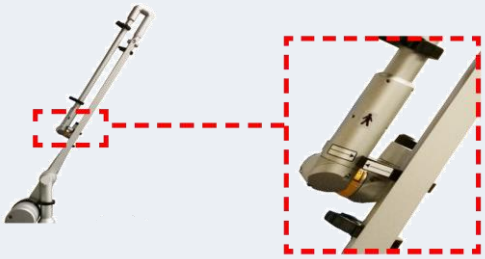
Important information

Avoid to apply any force to the support cantilever of the articulated arm. Do not grip the arm as shown in the picture below.



Important information

To return the arm to its proper resting position, please take care that the two arrows shown in the following figure are aligned.



8.3 CO_2 hollow fiber connection

To connect the hollow fiber to the system, first install the fiber pole, then remove the cap which prevents the fiber from damage *(do not touch the fiber input with any object whatsoever!)* and insert the fiber SMA connector into the socket on the upper side of the system (Figure 14) and secure the connector nut avoiding to force it.

Let the fiber pass through the passing hole of the fiber pole.

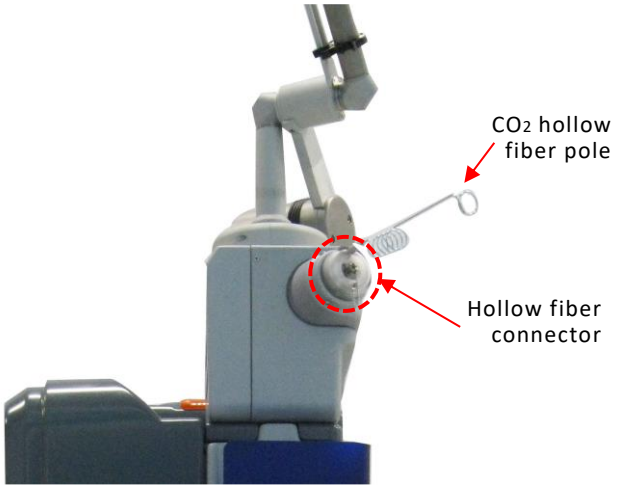


Figure 14 - CO_2 hollow fiber connection

Important information

- • Before operating ensure that air flow is present at fiber's output: enter the User menu, select the fiber delivery system, put the air flow "continuous", press READY (please refer to chapter 10.3.2) and verify that the flow is present and no alarm appears on display.
- • Ensure that the fiber is properly connected to the SMA connector on the system and that the connector itself is not loose.
- • Ensure that the antibacterial filter is clean (please refer to chapter 14.1.6).

Important information

- Use only fiber optic authorized by the Manufacturer: please refer to Chapter 15 “Accessories”.
- Always switch off the CO_2 laser source before removing the fiber.
- **The fiber optic is fragile. Never bend it or wind it in close circles.**
- **Always remove the fiber before transporting the system.**
- Be always sure the fiber optic can be moved freely during treatment without getting entangled.
- The surface of the fiber optic connector must never touch, or be touched by objects which could damage it: any damage to this surface may decrease the transmission rate and therefore lead to poor performances.
- **When the fiber is disconnected from the system, always put the proper cap on the SMA connector side to protect it and to prevent the entry of dust inside.**
- Either during treatment or when the system is turned off, do not lay the fiber on the floor or anywhere it may be bent or trampled on.
- Always use the provided fiber pole and holder to hang the fiber optic (see Figure 14).

8.4 User ID chip

The MultiPulse PRO DUO system is provided with a "User ID" chip which allows the user to enter the "personal" database of user-defined treatments: see chapter 10.5 for details.

Insert the chip into its socket (see Figure 2), making sure that the metal part goes into the narrow side.

If the inserted "User ID" chip is recognized by the system, the icon highlighted in Figure 15 will appear in the Free Hand menu.

Figure 15 - "User ID" icon in the Free Hand Menu

8.5 Air flow connections

The MultiPulse PRO DUO system is equipped with an internal pump which produces a continuous air flow to prevent dust and particles from depositing on the optics during laser operations.

The air flow outlet connector (highlighted in the Figure 16) can be found on the rear side of the MultiPulse PRO DUO system: an internal connection links the air pump to this connector.

Figure 16 - Airflow connector on system

A black tube is provided to connect this outlet connector to the inlet connector on the handpiece (see Figure 3). Always check that the black tube is properly connected to both connectors.

Important information

Always check that the black tube is properly connected to both connectors.

Important information

Use the proper plastic holders placed on the articulated arm to position the air tube and, if present, the hose for the smoke evacuator; use the larger housing for the scanning unit cable. See the Figure 17.

Figure 17 - Tube holder on articulated arm

An antibacterial filter is present on the air flow path both towards the articulated arm and the CO_2 fiber: always ensure that the antibacterial filter is clean (please refer to chapter 14.1.6).

As an option, the system can also be connected to an external air flow source: the connector available on the rear side of the MultiPulse PRO DUO system (see Figure 18) is for medical-grade compressed air.

The user can select the source of the air flow ("internal" or "external") from the CO_2 fiber user menu: please refer to chapter 10.3.2.

Figure 18 - External air flow connector on system

8.6 Remote interlock

The interlock socket may be used as an additional precautionary measure to stop emissions in case a specific external event occurs.

For instance, all the doors leading to the system operating area can be provided with series-connected micro-switches (normally closed). In this case the opening of any of these doors results in an “INTERLOCK” alarm message so laser emission is immediately stopped.

To connect an external interlock chain, the interlock connector supplied with the accessories can be used.

Open the connector as shown in the following figures.

Important information

Note that there is a jumper between contacts 1 and 2 (set by factory).

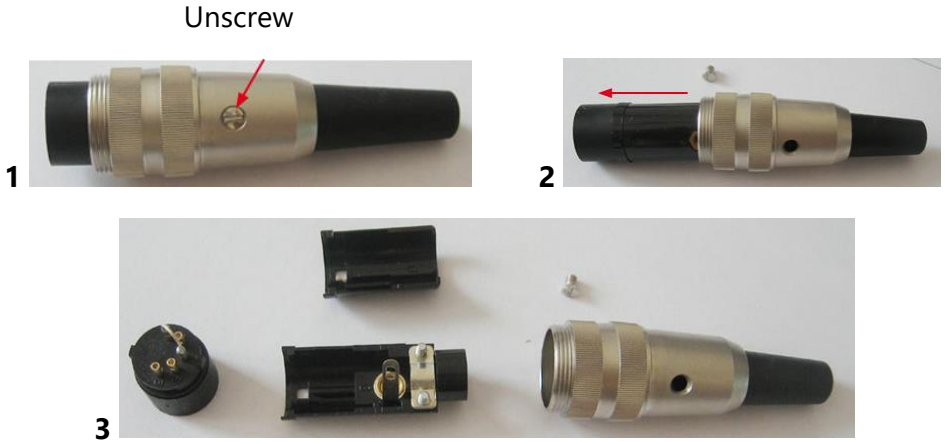


Figure 19 - How to open the interlock connector

To use an external interlock chain, proceed as follows:

- remove the jumper between the contacts 1 and 2;
- connect these contacts to the external network. Note that the interlocks must be normally closed in order to let the laser system operate otherwise an INTERLOCK fault is stated and the system is stopped.

No voltage level should be applied to the contacts of the interlock connector.

If no external interlock network is set up, the interlock connector provided with the system (accessories) must be connected to the interlock socket in order to disable interlock fault detection.

8.7 Moving/transporting the device

The device is susceptible to misalignment if not handled properly. It should never be banged, jolted, dropped, turned upside down, tilted or knocked.

Before moving/transporting the system, disconnect all accessories (handpieces, mains cable, footswitch, and interlock connector), **fold the articulated arm**, and pack the accessories in their appropriate cases.

8.7.1 Moving the device

To move and guide the system, unblock the rotating wheels and use the handle located on the front of the system, making sure to move the system at a slow pace. Do not use the rear cord wrap to transport the system.

Inclines

When moving the system up or down inclines, always travel in line with the slope. The system should never be moved diagonally or directly across an incline. Doing so may result in loss of control of the system and damage to the system or injury may result.

Thresholds

When moving the system over a threshold, and if necessary due to the height of the threshold, firmly grasp the front handle and pull the system forward until the front wheels cross the threshold. Depending on the height of the threshold, a slight lift using the front handle may be necessary to get the front wheels started over the threshold. Continue pulling the system forward slowly until the rear wheels cross the threshold. Rapidly moving the system across a threshold can result in system instability resulting in damage to the laser system and/or possible injury.

8.7.2 Transporting the device

When transporting the system by vehicle, store it in its own packaging, if possible, or secure it with a strap or structural support with the wheels locked inside the vehicle, making sure not to bump or press the articulated arm. The system should be protected from the strap using padding or blankets.

Important information

Do not transport the device tilted or lying down.

9 Technical specifications

General specification:

Model Code (REF)	MultiPulse PRO DUO: J18-3200-000
Mains voltage	100-230 V~ 50/60 Hz
Absorbed electric power	1,200 VA (max)
Fuses	2xT16 A 250 V 6.3x32 mm
Electrical protection degree	B
Electrical protection type	I
Laser class	4
Dimensions	66 cm x 174 cm x 59 cm (W x H x D) with folded articulated arm
Weight	75 kg
Use/Pause ON/OFF	Intermittent: 1 min use, 3 min pause
Degree of Protection Against Ingress of Water (IP Classification according to IEC 60529)	IPX0

The MultiPulse PRO DUO system is equipped with a CO_2 laser source, which emits an infrared beam, and an aiming laser source, which emits a visible red beam.

CO_2 laser source emission specifications:

Type	Value	
Wavelength	10,600 nm ± 400 nm	
Laser type	CO_2 - sealed off RF excited	
Average power at handpiece output	0.1 - 60 W	
Maximum laser output	72 W	
Laser beam delivery system	7-mirror articulated arm	
Output mode	TEM_{00}	
Divergence of laser beam full angle d63 (i.e., at 63 % of output power) - handpiece output	1.5" handpiece	70 mrad
	2" handpiece	52 mrad
	4" handpiece	26 mrad
	5" handpiece	20 mrad
	7" handpiece	12 mrad
	8" handpiece	11 mrad
	Collimated handpiece	3.2 mrad

Type	Value	
Diameter of laser beam d63 (i.e., at 63% of output power) - handpiece output	15" handpiece	0.125 mm
	2" handpiece	0.155 mm
	4" handpiece	0.267 mm
	5" handpiece	0.325 mm
	7" handpiece	0.489 mm
	8" handpiece	0.530 mm
	Collimated handpiece	15 mm
Diameter of laser beam d_{86} *(i.e., at 86 % of output power)* - handpiece output	2 mm (collimated handpiece)	
CO_2 hollow fiber inner diameter	500 µm	
CO_2 hollow fiber outer diameter	1040 µm	
CO_2 hollow fiber length	2 m	
Divergence at CO_2 hollow fiber's output (full angle d_{86} - *i.e., at 86% of output power)*	56±10 mrad	
Maximum power at CO_2 hollow fiber's input	40 W	
Power stability over 1 hour	Better than 20 %	
MPE	1 kW/m^2	
Nominal Ocular Hazard Distance (NOHD)	29 m 100 m (with collimated handpiece) 8 m (with hollow fiber)	

CO_2 aiming laser source emission specifications:

Type	Value
Wavelength	635 nm
Maximum output power (source output)	4 mW
Output mode	Circular
Divergence (source output)	0.6 mrad
Diameter (source output)	18 mm
Laser class	3R
Relative position with CO_2 source	Coaxial
Nominal Ocular Hazard Distance (NOHD)	15 m

Operating features:

Type	Value
Aiming Beam	Visible. Selectable intensity between 1 % and 100 %; with 2 % step between 2 % and 10 %, with 10 % step between 10 % and 100 %.
Operating modes	• **CW mode**: the average output power can be selected from 0.5 W to 60 W, limited to 40 W when CO_2 hollow fiber is selected. • **UP mode**: the average output power can be selected from 0.5 W to 60 W, limited to 40 W when CO_2 hollow fiber is selected. The frequency can be set from 300 Hz to 800 Hz, and the pulse duration from 0.5 µs to 1 ms. • **SP mode**: the average output power can be set from 0.1 W to 15 W. The frequency can be set from 5 Hz to 100 Hz, and the pulse duration from 0.06 to 86 ms. • **DP mode**: the average output power can be set from 0.2 W to 15 W. The frequency can be set from 5 Hz to 100 Hz. The pulse duration can be set from 0.6 to 86 ms. • **HP mode**: the average output power can be set from 0.1 W to 8 W. The frequency from 5 Hz to 100 Hz, and the pulse duration from 0.5 µs to 1 ms.
Exposure modes	Continuous exposure mode or timed exposure mode. Timed exposure mode allows operation in both single and repeated exposure. When the timed exposure mode is selected, the exposure time can be selected between 0.01 s and 0.9 s. When repeated exposure mode is selected the "T.OFF" time can be set between 0.1 s and 5 s.

9.1 Accuracy of the provided values

The accuracy of all the values mentioned in this manual is reported in the outcome of the MultiPulse PRO DUO development project and documented in the technical documentation of the device.

10 System operation

10.1 System start-up

Insert the key into the key selector and turn it to the “**I**” position. The system will run a self-test during which time “System check” will appear on the introductory screen.

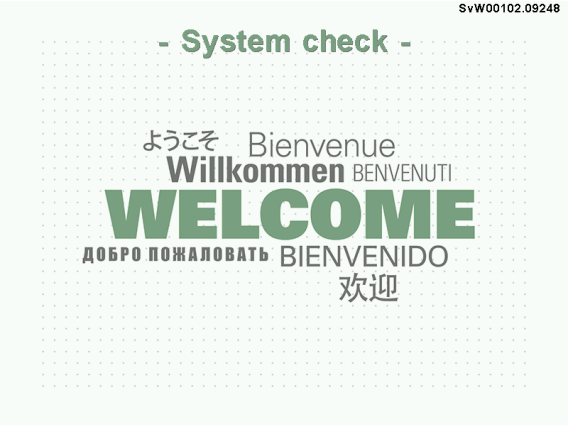


Figure 20 - Start-up screen with "System Check"

Important information

During the self-test phase, the SYSTEM READY indicator light on the top cover of the system and the LED on the control panel will flash. This notifies the user that the system is operating correctly. It is advisable to ensure that the light flashes during this phase. Otherwise, call the Technical Assistance Service.

Once the internal check is finished, any detected problem will appear in the “SYSTEM FAULT” menu: refer to the “Troubleshooting” section for possible solutions to the problem; otherwise an introductory warning will appear.

Figure 21 - Start-up screen with introductory warning

CAUTION

The operator and all personnel in the operating area are always required to wear protective eyewear when operating.

Never look directly into the handpiece or into apertures labelled “LASER APERTURE”, even when wearing protective eyewear.

Once the "OK" key has been pressed, the CO_2 User menu will appear.

Figure 22 - CO_2 User menu

The various keys at the bottom of the screen, which are common to all system menus, are described below:

	Press this key to go to Favorite menu
	Press this key to go to the Home menu
	Press this key to go back to the previous screen
	Press this key to select Database mode
	Press this key to go to the Set-up menu
	Press this key for information

Keys are greyed out if the related option is temporarily disabled.

The system automatically selects the following status:

- “STAND BY” mode;
- Footswitch disabled;
- Aiming, exposure, emission and scanning parameters: last used values for that delivery system.

10.2 Management of the selected source

'STAND BY'/'ON' key

The 'STAND BY'/'ON' key allows to switch the selected source off/on.

When it is light green, the key is disabled;

When it is bright green, the key is enabled to switch on the source;

When it is orange, the selected source is ON and it can be switched off by pressing the key itself.

'READY' key

The 'READY' key enables the footswitch in order to avoid unwanted emissions from occurring if it is accidentally pressed when the source is switched on.

The operator is advised to use the READY option to disable the footswitch as a precautionary measure, while selecting the parameters.

Emission is enabled if both the light in the READY key and the SYSTEM READY indicator light on the top cover of the system are steady.

'EMISSION' LED

The "EMISSION" LED is below the "READY" key and, when it is on, this means that emission is in progress.

10.3 User mode for CO_2 source

The "User" mode allows the user full control of the emission parameters by "manually" selecting the emission mode, the pulse configuration as well as the power/frequency levels., based on the required treatment and the user's own experience.

After start-up screen, a selection screen is displayed which allows to select the CO_2 delivery system among handpieces ("Free Hand" option) or hollow fiber ("FIBER" option) or the connected scanning unit, if any.

The following paragraphs describe the operating modes for the "Free Hand" and "Fiber" options. *For the description of all the available scanning units, please refer to the relevant Section of this Operator's Manual (Chapter 11 "Scanning units").*

10.3.1 CO_2 Free Hand mode

Power

The two POWER selection keys are used to increase or decrease and display the power level. The range of available values changes according to the selected emission mode. Please refer to the description of the emission modes in this paragraph.

Frequency

The FREQUENCY area displays the laser emission frequency; the FREQUENCY selection keys can be used to set the frequency between 5 Hz and 100 Hz. *These keys only appear when the SP, DP or HP emission mode is selected.*

Emission mode

The "EMISSION MODE" key allows the user to select the emission mode between "CW", "SP", "UP", "DP" or "HP".

CW mode

Laser emission is continuous: the CO_2 laser source is enabled for emission as long as it is switched on, so it provides a constant output power level, as selected by the operator according to the required treatment.

The POWER selection keys allow the user to set the power value between 0.5 W and 60 W.

SP mode

In SP mode the CO_2 laser source is pulsed. The operator can select the frequency – i.e. the number of times the source is switched on and off per second - and the power value.

The FREQUENCY selection keys allow the user to set the frequency value between 5 Hz and 100 Hz; the POWER selection keys allow the user to set the power value between 0.1 W and 15 W.

DP mode

In DP mode the CO_2 laser source is pulsed. The operator can select the frequency - i.e. the number of times the source is switched on and off per second - and the power value.

The frequency range changes according to the selected power value, as shown in the Table below.

Table 5 Power and Frequency selection in DP mode

Power	Allowed values for the "Frequency" parameter
0.2 W	5 Hz
0.2 W < P ≤ 0.3 W	up to 10 Hz
0.4 W ≤ P < 3 W	up to 20 Hz
3 W ≤ P < 4W	up to 50 Hz
4 W ≤ P < 5 W	up to 80 Hz
5 W ≤ P ≤ 15 W	up to 100 Hz

UP mode

In UP mode the CO_2 laser source is pulsed. The system sets an optimal frequency while the output power level must be set by the operator according to the required treatment.

The POWER selection keys allow the user to set the power value between 0.5 W and 60 W.

HP mode

In HP mode the CO_2 laser source is pulsed. The operator can select the frequency - i.e. the number of times the source is switched on and off per second - and the power value.

The FREQUENCY selection keys allow the user to set the frequency value between 5 Hz and 100 Hz; while the POWER selection keys allow the user to set the power value between 0.1 W and 8 W.

Exposure

The MultiPulse PRO DUO system allows the user to control the exposure time during a laser treatment by acting on the CO_2 shutter.

The selected exposure mode is displayed on the screen in the "Exposure mode" area. Press this area to change the exposure mode.

There is a choice of exposure modes:

• Continuous - **"Contin."** on the screen -;
• Timed single exposure - **"Single"** on the screen -;
• Timed repeated exposures - **"Repeat."** on the screen -.

Note that it is possible to change the emission mode - CW/SP/UP/DP/HP - regardless of the selected exposure mode.

In **continuous exposure mode "Contin."**, the exposure time is controlled entirely by the operator by acting on the footswitch: as long as the footswitch is held pressed down, the shutter is open and, accordingly, laser emission occurs.

When the **single exposure mode "Single"** is enabled and the footswitch is pressed down, the system opens the shutter and keeps it open only for the selected exposure time. Once the selected exposure time is over, the shutter closes automatically regardless of whether the footswitch is still held pressed down.

If the operator wants to perform a new exposure, he/she has to release the footswitch and then press it down again.

The system allows the user to select an exposure time between 0.01 s and 0.9 s by acting on the two arrows next to the "T.ON" value. The minimum available "T.ON" value depends on the selected frequency as reported in the following Table.

Table 6 Minimum available TON according to selected frequency

Frequency	5 Hz	10 Hz	20 Hz	50 Hz	80 Hz	100 Hz
Min.T.ON	0.10 s	0.05 s	0.03 s	0.01 s	0.01 s	0.01 s

Figure 23 - Exposure mode selection

When the **timed repeated exposures mode** is enabled and the footswitch is pressed, the MultiPulse PRO DUO system opens the shutter and keeps it open for the selected exposure time.

Once the selected exposure time is over, the shutter is automatically closed and, if the footswitch is still pressed down, the system waits out the selected "T.OFF" time. The shutter will then open again and a new exposure will be carried out. This sequence is repeated continuously as long as the footswitch is held down.

The system allows the user to set the exposure time between 0.01 s and 0.9 s by acting on the two arrows next to the "T.ON" value and to set the "T.OFF" time between 0.1 s and 5 s. The minimum available "T.ON" value depends on the selected frequency as reported in Table 6.

Total Energy and Total Time

The system displays the energy delivered and the time elapsed since the last resetting.
When the system is turned on, these counters are set to zero, and then increase during treatment. By pressing the “RESET” option is pressed, the “TOTAL ENERGY” and “TOTAL TIME” values are cleared.

Aiming source

The two"  " icons in the "Aiming" area adjust the intensity of the aiming beam between 1 % and 100 % (2 % increments between 2 % and 10 %, 10 % increments for the remaining values).

It is also possible to switch the aiming beam off during the laser procedure by pressing the "**Dowl**" ("Diode off while lasing") option. Set the "Dowl" option to ON to have a clear view of the treatment area and to clearly distinguish the treated tissues during the procedure.

CAUTION

CO_2 aiming beam intensities higher than 60 % require an optical protection as indicated in chapter 6.3.1. The system displays a warning icon next to the selected value (if higher than 60%).

Scanning unit

Press the area displaying the type of scanning unit currently connected to the system in order to switch it on.

The screen displays a message warning the operator that the delivery system selection has been changed; the operator is also reminded to check the scanning unit connections.

10.3.2 CO_2 "Fiber" user mode

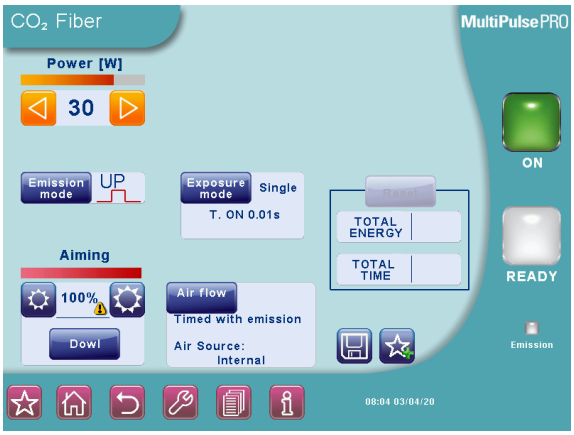


Figure 24 - CO_2 Fiber user mode

Power

The two POWER selection keys are used to increase or decrease and display the power level. The range of available values changes according to the selected emission mode. Please refer to the description of the emission modes in this paragraph.

Important information

Always use the minimum laser power setting for a given treatment.

Fiber damage can occur when using a laser at a high power level or at an extreme bending radius for long lasing time.

Important information

The actual output power level from the CO_2 fiber is lower than the selected one, with a typical transmission between 60 % and 70 %, mainly due to two factors:

- Loss of attenuation in the CO_2 fiber: the laser energy transmitted along the fiber is reduced due to radiation dispersion and absorption inside the fiber itself. The attenuation effect increases when the fiber is bent or wound during use.
- Contamination of the CO_2 fiber: the distal tip of the fiber can partially (or completely) clog up with the residues of burns and/or blood.

Frequency

The FREQUENCY area displays the laser emission frequency; the FREQUENCY selection keys can be used to set the frequency between 5 Hz and 100 Hz. *These keys only appear when the SP, DP or HP emission mode is selected.*

Emission mode

The "EMISSION MODE" key allows the user to select the emission mode between "CW", "SP", "UP", "DP" or "HP".

CW mode

Laser emission is continuous: the CO_2 laser source is enabled for emission as long as it is switched on, so it provides a constant output power level, as selected by the operator according to the required treatment.

The POWER selection keys allow the user to set the power value between 0.5 W and 40 W.

SP mode

In SP mode the CO_2 laser source is pulsed. The operator can select the frequency - i.e. the number of times the source is switched on and off per second - and the power value.

The FREQUENCY selection keys allow the user to set the frequency value between 5 Hz and 100 Hz; the POWER selection keys allow the user to set the power value between 0.1 W and 15 W.

DP mode

In DP mode the CO_2 laser source is pulsed. The operator can select the frequency - i.e. the number of times the source is switched on and off per second - and the power value.

The frequency range changes according to the selected power value, as shown in Table 5.

UP mode

In UP mode the CO_2 laser source is pulsed. The system sets an optimal frequency while the output power level must be set by the operator according to the required treatment.

The POWER selection keys allow the user to set the power value between 0.5 W and 40 W.

HP mode

In HP mode the CO_2 laser source is pulsed. The operator can select the frequency - i.e. the number of times the source is switched on and off per second - and the power value.

The FREQUENCY selection keys allow the user to set the frequency value between 5 Hz and 100 Hz; while the POWER selection keys allow the user to set the power value between

Exposure

The MultiPulse PRO DUO system allows the user to control the exposure time during a laser treatment acting on the CO_2 shutter.

The selected exposure mode is displayed on the screen in the "Exposure mode" area. Press this area to change the exposure mode.

There is a choice of exposure modes:

• continuous - "**Contin**." on the screen -;

• timed single exposure - "**Single**" on the screen -;

• timed repeated exposures - "**Repeat.**" on the screen -.

Note that it is possible to change the emission mode - CW/SP/UP/DP/HP - regardless of the selected exposure mode .

In **continuous exposure mode "Contin."**, the exposure time is controlled entirely by the operator by acting on the footswitch: as long as the footswitch is held pressed down, the shutter is open and, accordingly, laser emission occurs

When the **single exposure mode "Single"** is enabled and the footswitch is pressed down, the system opens the shutter and keeps it open only for the selected exposure time. Once the selected exposure time is over, the shutter closes automatically regardless of whether the footswitch is still held pressed down.

If the operator wants to perform a new exposure, he/she has to release the footswitch and then press it down again.

The system allows the user to select an exposure time between 0.01 s and 0.9 s by acting on the two arrows next to the "T.ON" value. The minimum available "T.ON" value depends on the selected frequency as reported in Table 6.

When the **timed repeated exposures mode** is enabled and the footswitch is pressed, the MultiPulse PRO DUO system opens the shutter and keeps it open for the selected exposure time.

Once the selected exposure time is over, the shutter is automatically closed and, if the footswitch is still pressed down, the system waits out the selected "T.OFF" time. The shutter will then open again and a new exposure will be carried out. This sequence is repeated continuously as long as the footswitch is held down.

The system allows the user to set the exposure time between 0.01 s and 0.9 s by acting on the two arrows next to the "T.ON" value and to set the "T.OFF" time between 0.1 s and 5 s. The minimum available "T.ON" value depends on the selected frequency as reported in Table 6.

Air flow

Press the "**Air flow**" area in the CO_2 Fiber user menu to choose an air flow mode for the CO_2 fiber.

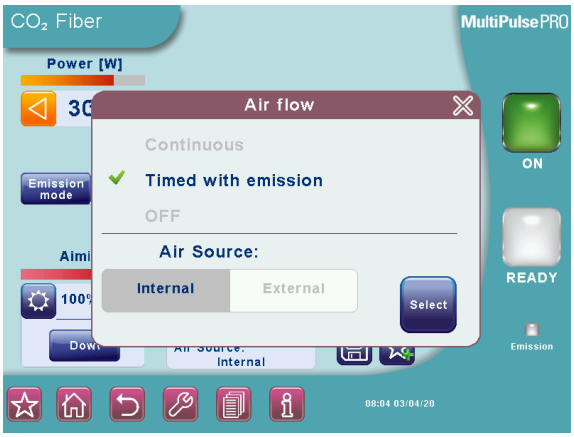


Figure 25 - "Air flow" menu for CO_2 Fiber

First of all, select whether the source of the air flow for the fiber is internal ("**Internal**" option in the menu) or external ("**External**" option in the menu) air. The system includes a compressor that can supply filtered (through an antibacterial filter) internal air.

As an option, an external air supply (e.g. a pressurized tank) can be connected to the system. Please refer to chapter 8.5 for details about connections.

Then, it is possible to set the air flow mode to "**Continuous**" (i.e. the air flows continuously when the system is in READY status), "**Timed with emission**" (i.e. the air flows when the CO_2 laser source is operating) or "**OFF**" (no air flow).

Important information

To avoid damage to the delivery system, if the "**OFF**" option is set, the maximum power value allowed by the system is 10 W.
When working with the internal air flow, the power selection is limited to 30 W.

Important information

- Before starting procedure, ensure that the air flow is present at the delivery system output.
- The antibacterial filter must be inspected before each use and must be replaced periodically. The filter life depends on the frequency and conditions of use. If the filter is dirty or if you notice a decrease in the air flow, it must be replaced.

CAUTION

- Use medical-grade compressed air.
- During intrauterine laser surgery, do not use air to purify the fiber or for insufflation. Otherwise an air embolus could occur.
- During laser function, pressurized purification air comes out from the fiber opening. To reduce the risk of air embolism, do not bring the opening into contact with a blood vessel or vascular tissue.

CAUTION

• To avoid damage to the CO_2 fiber and to the delivery system, connect an external source of pressurized air if fiber bending radius is less than 45 mm.

• The external air flow must have a pressure between 3 bar and 4 bar.

Aiming source

The two"  " icons in the "Aiming" area adjust the intensity of the aiming beam between 1 % and 100 % (2 % increments between 2 % and 10 %, 10 % increments for the remaining values).

It is also possible to switch the aiming beam off during the laser procedure by pressing the "**Dowl**" ("Diode off while lasing") option. Set the "Dowl" option to ON to have a clear view of the treatment area and to clearly distinguish the treated tissues during the procedure.

CAUTION

CO_2 aiming beam intensities higher than 60 % require an optical protection as indicated in chapter 6.3.1. The system displays a warning icon next to the selected value (if higher than 60%).

Total Energy and Total Time

The system displays the energy delivered and the time elapsed since the last resetting.
When the system is turned on, these counters are set to zero, then they increase during treatment.
If the “RESET” option is pressed, the “TOTAL ENERGY” and “TOTAL TIME” values are cleared.

10.4 Favorite menu

In the CO_2 Free Hand menu, the  icon allows the user to access a list of user-defined favorite treatment parameters. Selecting a favorite parameter set offers the convenience of quickly loading the most used parameter values.

To save a favorite parameter set, first select the desired parameter values in the CO_2 Free Hand menu and then press the  icon; the system displays the following popup:

Figure 26 - 'Add to favorites' menu

Press one of the empty rows to select it (the row will be highlighted with a blue background) and then the Save icon  : the system displays a summary of selected parameter values.

Figure 27 - Summary of parameter values to be saved

If the values are not correct, press '**No**' and modify them, otherwise press '**Yes**' and insert a name for the favorite parameter set: a keyboard will appear to allow the user to enter the information.

On the keyboard, note that the "  " icon allows the user to switch from upper case to lower case, while the "  " icon allows the user to enter special characters. Press the Save icon to save the set of parameters in the list of favorite parameter sets.

To load one of the parameter sets previously saved amongst the favorites, press the  icon in the bottom of the screen: the system displays the list of saved favorite parameter sets. Press the desired row (the row will be highlighted with a blue background), then:

- press the row again to display a summary of the saved parameters or
- press the "USE THESE DATA" key to load that set of parameters.

Figure 28 - Loading a parameter set from list of favorite parameter sets

Important information
After a favorite parameter set is loaded, any changes made to individual parameter values will not be displayed by the system.

10.5 Database mode

The "Database" mode contains sets of stored treatment parameters (i.e., treatment description, delivery system, phototype, fluence and pulse configuration) both preset and user-defined; it offers the convenience of saving important parameters that can be set automatically.

To enter this mode, the user must press the area with the name of the treatment category he/she wants to select from the CO_2 Free Hand menu, or using the  key common to all system menus.

Figure 29 - Database mode

For example, by pressing the "ENT" area, it is possible to display the list of all treatments stored in the "ENT" category.

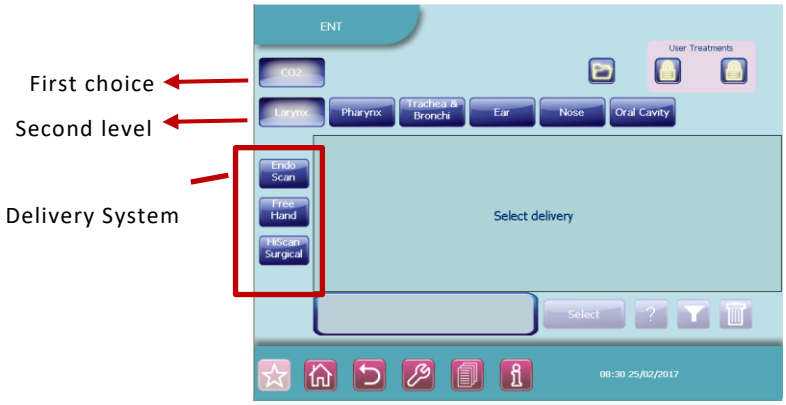


Figure 30 - ENT treatments

Proceed as described below.

The first selection to be made is the type of source (only one selection at a time is allowed). If a given source is not available, the relevant key is disabled.

When a source has been selected, the system enables the corresponding keys on the second level, i.e. the procedure where at least one treatment is available.

Depending on the selected option, all available delivery systems are enabled: the user must select the one (by pressing the corresponding area) for which he/she wants to see the related treatments.

The system displays all the available treatments for the selected parameters.

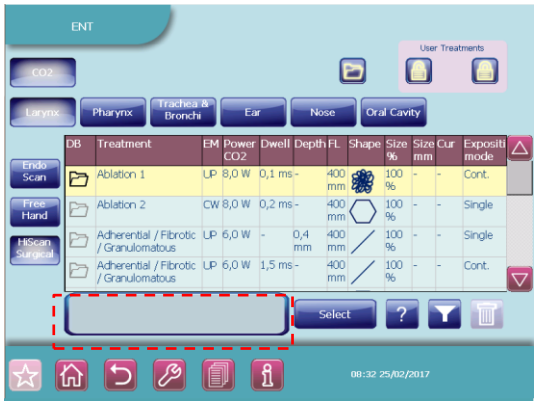


Figure 31 - List of available treatments

If the list of treatments does not fit on one page, two arrows appear on the right side to allow the user to scroll through the treatments list.

Each row in the table corresponds to an available treatment; the system provides the following information for each treatment:

- database type: preset (identified by ), user-defined public (identified by ) and user-defined personal (identified by ).

If the user wishes to see only one type of treatment, he/she must press the relative key: e.g. to view preset treatments, press "  ". The "preset" treatments are factory settings and cannot be modified by the user.

Important information

The treatment parameters in the preset “database” menu are purely illustrative of the available treatment modes and are not prescriptive and/or more favorable for treatments in practice. These parameters are pre-set at the factory on the basis of values commonly used by operators and indicated in scientific medical literature at the current state of the art on the date of delivery of the device. Given that these values are purely indicative, they are not intended to replace or influence in any way the diligence, caution and skills of the operator. It is the physician’s exclusive responsibility to select the appropriate treatment protocol for each patient based on an adequate check-up and individual case history.
Asclepion Laser Technologies GmbH will not be held liable for use of the pre-set values in the “Database” menu.

The system also allows the user to save his/her treatments in both "public" and "personal" databases. The former is always available to view and edit stored treatments; the latter user-defined database can only be accessed if the "User ID" chip is inserted in its connector on the system.

- treatment name and emission parameters: emission mode, power and/or frequency, scanning parameters (if required).
- it is possible to add notes about the selected treatment (both preset and user defined) by pressing the area highlighted in Figure 31: a keyboard will appear to enter information.

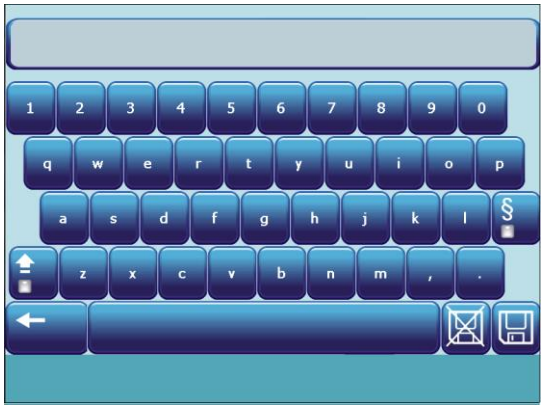


Figure 32 - Keyboard

Note that the "  " key allows the user to switch from upper case to lower case, while the "  " key allows the user to enter special characters.

The "  " icon is pressed to save changes; the "  " is pressed to close the window without saving changes.

- It is also possible to carry out a "search" in the treatments database: the user can press the "  " icon to set up a filter on the list of treatments and select the ones he/she wishes to view.

Figure 33 - Database filter

Multimedia Tutorials

For preset treatments, information about the selected treatment is available: the "  " key displays the "Multimedia for treatment" screen with information about the treatment and, for certain treatments, also a multimedia area with access to photos and videos.

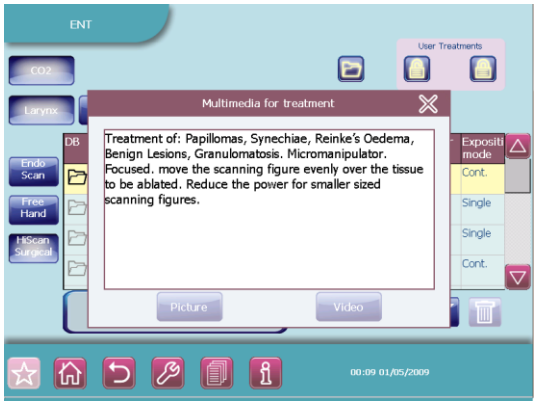


Figure 34 - Info about the selected treatment

If available, press the 'Video' key and then select the desired video tutorial. The video player interface appears.

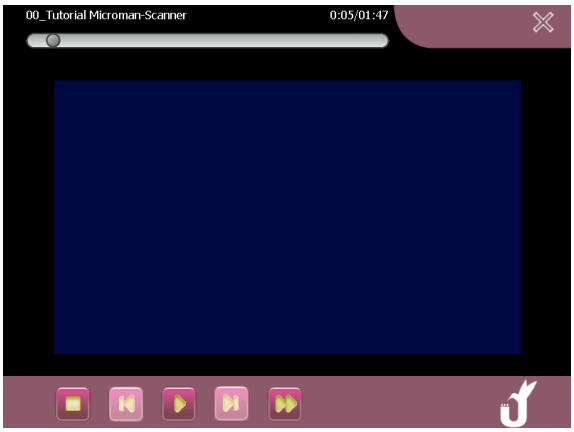


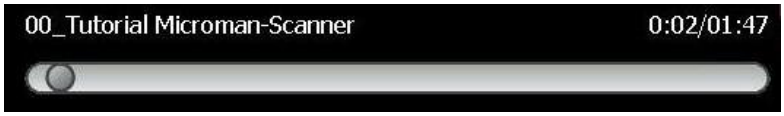
Figure 35 - Example of tutorial

Use the options described in the table below to manage video playback:

	Press this key to stop the video
	Press this key to play the video
	Press this key to pause the video
	Press this key to fast forward the video
	Press this key to return to the previous video (if present)
	Press this key to advance to the next video (if present)

In the upper part of the screen a grey bar indicates the video progress.

Above the bar, the system displays the name of the video and the video progress relative to the total video duration.



Press on any point of the bar to quickly jump to a specific point of the video from that particular second.

By pressing the video progress in the upper right corner, the user can alternate between visualizing the video progress relative to the total video duration or relative to the remaining video duration.

How to select a treatment

- The user must press the row associated with the treatment he/she wishes to select: the row will turn yellow.
- The user must press the "**Select**" key: the selected treatment will be set on the device. The type of database, the treatment category, the treatment name and the phototype (if applicable) are displayed at the top of the CO_2 Free Hand menu.

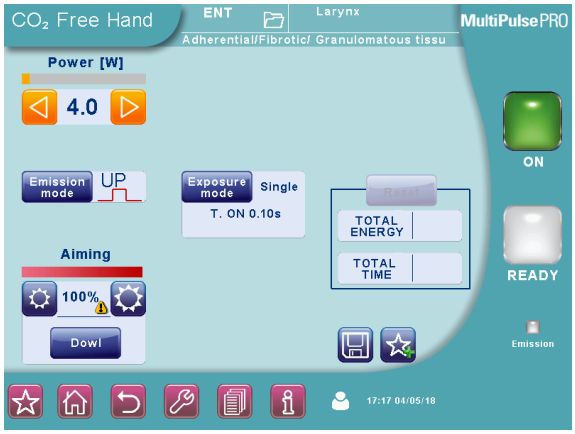


Figure 36 - Treatment selected in the Free Hand menu

Important information

Once the selected treatment has been set in the Free Hand menu, if the user edits a saved parameter, the system will mark the edited parameter with "*" and will allow the saved value to be restored by pressing the "Restore" key (displayed at the top of the screen when a parameter is changed).
It is not possible to edit or delete preset treatments, whereas both operations are allowed on user-defined treatments.

How to delete a user-defined treatment

- Press the row associated with the treatment the user wishes to delete.
- Press the "  " icon and confirm.

How to save a user-defined treatment

- Enter "Free Hand" mode and select the emission configuration that the user wishes to save.
- Press the "  " icon: the system displays the menu shown in Figure 37.

Figure 37 - How to save a treatment

- Select the treatment category, the type of user-defined database (public or personal) where the user wishes to save the treatment and the type of procedure.
- Press the "Treatment" area to choose the treatment name. It is possible to choose a name from the ones already available or type in a new name by pressing on the area highlighted in Figure 38.

Figure 38 - Treatment name

A "keyboard" will appear to allow the user to enter information.

- It is also possible to add notes about the treatment by pressing the "**Note**" field.
- Press the "  " icon to save: the new treatment parameters will be saved and displayed in the treatments database.

10.6 Set up menu

The Set up menu allows the user to set the time and date on the system, choose the background colour of the screen, select the language, and other options. To enter this menu press "  ".

Figure 39 - "Set up" menu

From this menu the user can:

- Choose between a 12 h and 24 h time format and a dd/mm/yy, mm/dd/yy, or yy/ mm/dd date format; to change a parameter, press the relative area and use the corresponding arrows.
- Enable/disable the keys sound.
- Adjust the volume of the internal buzzer: press the "+" and "-" keys to adjust the level and the "TEST" key to test the selected level.
- Select the time for automatic system switch off between 2 and 20 minutes by pressing "  ": if the system is left unused for the selected amount of time, it will automatically switch off the laser source in order to extend the service life of the internal components.
- Change the background color.
- Change the language.
- Choose an air flow mode for the handpiece by pressing "  ": continuous (i.e. the air flows continuously when the system is in READY status), and timed with emission (i.e. the air flows when the CO_2 laser source is operating).

If any parameters are edited, the "  " icon will appear to allow the user to save changes.

10.7 CO_2 power calibration procedure

The MultiPulse PRO DUO system is equipped with an internal power meter that measures the real output power level of the CO_2 laser source.

The power evaluation and calibration procedure starts and runs continuously when the CO_2 source is switched on.

When the CO_2 source is switched on and every time the power level is changed, the system displays the flashing message "POWER EVALUATION" on the screen in order to warn the operator that a power evaluation and calibration procedure for that power level is in progress.

During this procedure, the footswitch is automatically disabled so that no laser emission can be performed.

Important information

Note that if READY mode is selected, the system will only restore this mode once the procedure is finished.

The procedure is intended to verify the real power level provided by the CO_2 laser source and ensure it matches the power level selected by the operator. At the end of the procedure, the "POWER EVALUATION" message disappears. The following two conditions are possible:

- Either the real power level matches the selected power level or the procedure succeeds in making them match: no further messages appear and the system is ready to operate;
- The real power level does not match the selected power level AND the procedure fails to make them match: in this case, a double warning sound is set off and the real power level currently available flashes on the screen for about 5 s as a warning to the operator. After 5 s, this value stops flashing and it is considered as the effective treatment power level.

Once the calibration procedure has been carried out, the MultiPulse PRO DUO system starts monitoring the real power level in order to detect power fluctuations.

If the real power level changes and no longer matches the value displayed on the screen, the system will react as follows:

- If a laser treatment is in progress, i.e. the footswitch is pressed down and as long as it is held down, the new power level will appear on the screen in black characters on a white background, and the internal buzzer will beep 5 times per seconds - instead of 1 beep per second - as a warning to the operator; If the power mismatch is recovered, the old power level will appear on the screen in standard characters and timed buzzer beeping will back to one beep per second.
- if no laser treatment is in progress, two warning beeps will sound and the new power level will flash on the screen for about 5s as a warning to the operator. After 5 s, this value will stop flashing and will then be considered as the new effective treatment power level.
- if the detected output power is outside of the regulatory limits with respect to the nominal output, emission will stop immediately and the system will set off a HIGH POWER or a LOW POWER alarm - see Section “Troubleshooting”.

10.8 System shutdown

To shut the system down in normal (non-emergency) conditions, proceed as follows:

- **Press the “STAND BY” key on the control panel;**
- Turn the key in the key switch to the “O” position;
- Remove the key and keep it in a safe place.

In emergency conditions, press the emergency switch - see “System description” section.

11 Scanning units

The MultiPulse PRO DUO system can be equipped with different scanning units which can be connected to the articulated arm to provide high performance in specific fields.

The scanning units are listed below:

- "HiScan Surgical" for microsurgery applications
- "EndoScan" for endoscopic surgical and microsurgical applications
- "HiScan DOT" for fractionated skin resurfacing or traditional skin resurfacing

Important information

The "HiScan DOT" is purchasable only in combination with HiScan Surgical and/or Endoscan scanner

11.1 Installation of the scanning unit

Proceed as follows to install a scanning unit:

- **Switch the system off;**
- Remove the handpiece from the articulated arm, if it is connected;
- Remove the protection cap (if present) and screw the scanning unit onto the articulated arm;
- Connect the scanning unit cable to the connector on the rear panel, being careful to fit the plug on the cable into the relative socket;

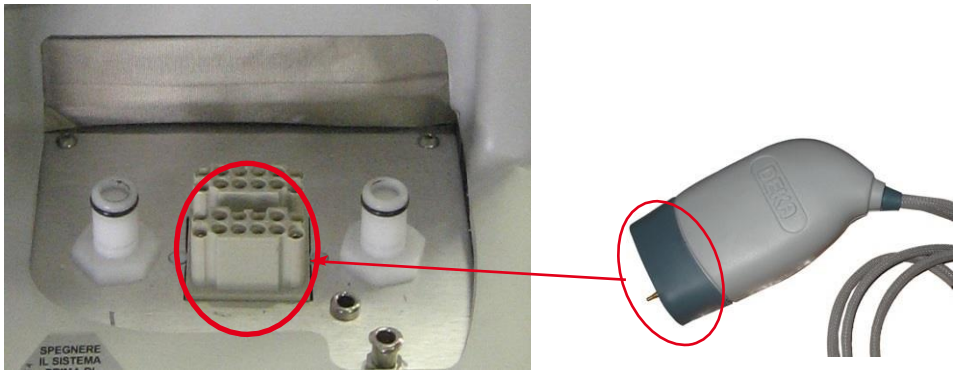
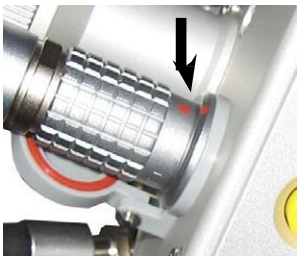


Figure 40 - Scanning unit connection

- **only if it is not already connected**, connect the other end of the cable to the scanning unit: insert the connector so that its red dot lines up with the red dot on the connector on the unit, as shown in the example here;
- Connect the air flow tube for the scanning head to the air tube on the articulated arm.



Important information

When the scanning unit is not connected to the system, place the protection cap back on it.
Each scanning unit has its own box: be very careful not to mix up the box of one unit with another. If possible, do not disconnect the cable from the scanning head.

Important information

- The scanning cable must be connected/disconnected with the system switched off (the key switch must in the 'O' position).
- **Do not disconnect the scanning head from its cable unless it is absolutely necessary: if it is necessary to remove the scanner, disconnect its cable from the system.**

Once a scanning unit is connected, the MultiPulse PRO DUO system automatically detects it and allows the user to switch it on from the control panel. The currently connected unit is highlighted on the CO_2 Free Hand menu.

11.1.1 Info menu

By pressing the ' info' icon in the bottom of the screen, the system displays general information about Asclepion Laser Technologies GmbH, in addition to the number of frames scanned by the connected scanner.

Scanning Info

The system displays further information about scanning, i.e. the total scanning time and energy, based on to the selected parameters.

11.2 Use of the HiScan Surgical unit

One of the optional scanning units for the MultiPulse PRO DUO system is the HiScan Surgical.

The external HiScan Surgical unit can be used with EasySpot Hybrid micromanipulator. Please refer to the Operator's Manual of the micromanipulator for its description and use.

Figure 41 - HiScan Surgical unit

Important information

The HiScan Surgical is generally provided already connected to the Micromanipulator: please do not disconnect the two units, if possible. If the two units are disconnected, screw the connector of the HiScan Surgical unit, marked as **(A)**, onto the micromanipulator; connect the Micromanipulator cable to its connector on the HiScan unit **(B)**.

To verify that the two units are correctly assembled, perform an emission on a tongue depressor selecting the "hexagon" shape and verifying that the scanning is performed horizontally from top to bottom.

To switch the HiScan Surgical unit on, if installed correctly, press the "HiScan Surgical" area on the CO_2 main menu. The screen will appear as shown in the figure below:

Figure 42 - User menu when HiScan Surgical unit is on

Shapes of the scanning pattern

The scanning unit can generate five types of patterns: line, spiral, ellipsoid motion on a circular surface, arc of a circle up to a complete circle, and hexagon (in "normal" or "interlaced" scan mode).

Touch the relative icon in the "**Shape**" area to select a scanning shape.

Important information

The HiScan Surgical unit moves the red aiming beam along the outline of the selected scanning area. This function allows the user to immediately check the characteristics - shape and size - of the scanning area.

A brighter spot on an angle of the hexagon shape indicates the scanning starting point.

CAUTION

The ellipsoid motion on a circular surface does not provide a uniform delivery of energy to the tissue. Accordingly, the "depth" displayed on the screen is an average of the depths of ablated tissue involved in the entire scanning; moreover, this motion must be carried out at a high scanning speed, moving the laser beam over the tissue, to achieve the best ablation results.

According to the selected shape, the system enables/disables the parameters described in the following paragraphs.

Scanning mode

It is possible to select two different types of scanning **ONLY for the "hexagon" scanning shape**:

- **"Normal"** scan mode
  When this scan mode is selected, the area is treated by scanning lines from left to right and from right to left, starting from the first line at the top, to the last line on the bottom.
- **"Interlaced"** scan mode
  When this scan mode is selected, the area is treated by scanning the odd numbered lines first, followed by the even numbered lines. Once the odd numbered lines have been scanned from the top to the bottom, the even lines are scanned from the bottom to the top. Use of the interlaced scan mode is advisable for reducing thermal effects during treatment.

To select either one or the other scan mode, press the "**Scan Mode**" area (this area is displayed only when the "hexagon" shape has been selected).

Size of the scanning pattern

The **"Size"** option allows the user to change the size of the scanning area:

- for all shapes except for spiral, the size is displayed both as a percentage of the maximum available scanning area (i.e. 6.3 mm at 400 mm focal length) and as size in mm (according to the selected focal length);
- the diameter of the spiral pattern is displayed in mm and can be selected from 0.3 mm to 1.1 mm (increments of 0.1 mm).

This parameter is available for all scanning shapes and can be edited in one of the following ways:

- by pressing **"Size"** in the User menu and acting on the arrows of the **"Select Dimension"** menu;
- by using the **red key** on the scanning head – see Figure 41;
- by using the remote control (central position) on the micromanipulator joystick. The size of the scanning area changes when the remote control key is released. "SCAN OFF" mode is enabled by keeping this key pressed down for more than 4 s. See the Micromanipulator Operator's Manual.

"Curving" parameter

If the "arc of circle" shape is selected, the "**Curving**" parameter is enabled in the User menu.

The two arrows in this area allow the user to change this parameter, i.e. the extension of the selected arc.

Figure 43 - "Curving" parameter

Its value is expressed as ratio between the arc covered by the scanning and the maximum available extension, i.e. the entire circumference. By way of example, the pictures below illustrate arcs of circles with their corresponding values in the "Curving" parameter.

The "Curving" parameter is NOT available for the other scanning shapes.

Rotation of the scanning patterns

The selected scanning shape can be rotated in one of the following ways:

- by using the two yellow keys on the scanning head - see Figure 41-;
- by turning the key of the remote control on the micromanipulator joystick. See the *Micromanipulator Operator's Manual*.

The selected scanning shape can be rotated also during emission: see the description of "ROWL" parameter in par. "Settings" on page 65.

Emission mode

The **"Emission mode"** area alternately selects and displays either **CW** or **UP** emission mode.

In CW mode and UP mode the POWER selection keys allow the user to set the power value between 0.5 W and 60 W.

Exposure mode

The selected exposure mode is displayed on the screen in the **"Exposure mode"** area; touch this area to open the screen which allows the user to change the exposure mode.

Figure 44 - Exposure mode selection

One of three exposure modes can be selected by touching the relative area:

- continuous - "**Contin.**" on the screen -;
- timed single exposure - "**Single**" on the screen -;
- timed repeated exposures - "**Repeat.** " on the screen -.

Note that the emission mode - CW/UP - can be changed regardless of the selected exposure mode.

In **continuous exposure mode**, the exposure time is controlled by the operator by acting on the footswitch: as long as the footswitch is held pressed down, the shutter is open and, accordingly, laser emission occurs and the scanning unit repeats the selected pattern.

In this mode, it is also possible to select a finite number of scanning's ("**Pass**" parameter on the screen): in this case, laser emission stops as soon as the selected number is reached. Otherwise, when the symbol  is highlighted (infinite pass), the emission is entirely controlled by the operator.

It is possible to change the "**Pass**" parameter by acting on the two arrows. The User menu displays the depth of ablated tissue for each scanning and total depth once all the selected scans are completed.

When the **single exposure mode** is enabled and the footswitch is pressed down, the system opens the shutter and keeps it open only for the time of one complete scanning. Once this time is over, the shutter closes automatically regardless of whether the footswitch is still down. If the operator wants to perform a new exposure, he/she must first release the footswitch and then press it down again.

When the **timed repeated exposures mode** is enabled and the footswitch is pressed, the system opens the shutter and performs scanning sequences as long as the footswitch is held down. Once a single scanning is complete, the shutter closes automatically and then, if the footswitch is still down, the system waits out the selected "Delay" time; after this time the shutter opens again and a new scanning is performed. This sequence is repeated continuously as long as the footswitch is held down.

Use the arrow keys to change the "**Delay**" time between two scanning's from 0.1 s to 3 s (increments of 0.1 s).

Scanning modes

The HiScan Surgical system allows the operator to use two different operating modes available in the "**MODE**" area of the User menu: the "Depth mode" and the "Power mode".

In "**Depth mode**", the operator can act directly on two parameters: **emission power** and **cutting depth**. According to the selected values for these two parameters and according to the selected focal length, the system automatically calculates the required energy density (fluence). The "Depth" parameter can be changed within the range of 0.2 mm and 2 mm by acting on the two arrows.

Important information

In *continuous exposure mode*, the "depth" selection is disabled.

Using "**Power mode**" (*please refer to the User menu shown in Figure 42 where this mode is selected*), the operator can act directly on two parameters: the **emission power** and the **dwell time** of the laser beam on a scanning point; according to the selected values for these two parameters and according to the selected focal length, the system automatically calculates the required energy density (fluence) and therefore the cutting depth on tissue: this last parameter is displayed on the User menu.

Important information

If, according to the selected dwell time and power value, the resulting depth is greater than 2mm, the system does not display this value and a warning icon will appear next to the dwell time.

Important information

Tissue ablation depth is strictly connected to the treated tissue type and characteristics, therefore the "Depth" parameter is provided on the screen purely as an indication.

Power selection

The "**Power**" selection keys allow the user to change the power value up to 60 W when CW emission mode is selected; also up to 60 W when UP emission mode is selected.

Disabling scanning

If an area requires treatment without scanning, select the "point" shape in the "SHAPES" area of the User menu (without unscrewing the scanning head). The "point" will be highlighted in red and the selection of scanning parameters will be disabled: the operator will only be able to edit power value, emission mode, exposure mode and focal length.

The scanning can also be disabled by keeping the red key on the scanning head pressed down for a few seconds (or the central key of the remote control on the micromanipulator joystick) until the red aiming beam stops at the center of the scanning area. Laser will be emitted to this point.

Figure 45 - "No Scan" mode

When "**No Scan**" mode is set, the system displays a warning message reminding the user that it is necessary to move the laser beam manually in order to avoid dangerous overexposure. Accordingly, the user can enable an acoustic signal of warning that the "No Scan" status is set: this acoustic warning continues until scanning mode is enabled again.

Important information

When the "No Scan" mode is selected, footswitch works in continuous way.

Aiming source

The intensity of the aiming beam from 1% to 100% (step: 2% between 2% and 10%, step: 10% for the other values).

It is also possible to switch off the aiming beam while lasing: press the "Aiming" area and select the "Dowl" ("Diode Off while Lasing") option. Set the "Dowl" option on to have a clear view of the operating field and well distinguish the ablated tissues during treatment.

CAUTION

CO_2 aiming beam intensities higher than 60% require an optical protection as indicated in chapter 6.3.1. The system displays a warning icon next to the selected value (if higher than 60%).

Scanning Info

The system displays further info about scanning that is the total scanning time and energy according to the selected parameters.

"Free hand" mode

It is always possible to go back to "Free Hand" mode by pressing the "**Free Hand**" area: the systems will ask the user to confirm this choice.

Settings

The "**Settings**" window allows the user to access the options needed to set the scanning system correctly and to enable the "Rowl" option.

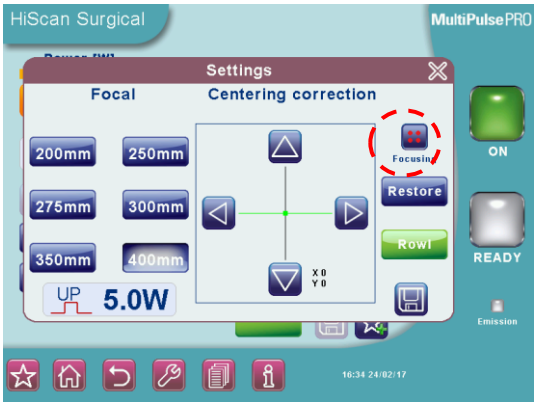


Figure 46 - "Settings" option

Rowl

The "Rowl" (Rotating on While Lasing) option allows the operator to activate the rotation of the selected scanning shape during laser emission.

The "Rowl" function key is present in the settings windows, when the option is activated the "Rowl" label is shown near the "Settings" key in the User menu.

Important information

This option is automatically disabled every time the system is switched off.

Focal

The "**Focal**" option allows the operator to "inform" the system about the focal length set on the micromanipulator.

Touch the relative area to select the operating focal length of the microscope, then press "" to confirm the choice.

CAUTION

Be very careful to select the correct focal length, as this parameter is required by the system to calculate the scanning area and the cutting depth.
The selected focal length must be the same of the working focal length set on the microscope on which the focus of the micromanipulator was adjusted.

Focusing and centering the laser beam

The "**Focusing**" area (highlighted in Figure 46) provides the correct sequence of operations to carry out before using the scanning system.

This operation must be carried out on the operating microscope or colposcope; when it has been completed, at a given focus length (e.g. in ENT, 400 mm for laryngeal surgery, and 300 mm for middle ear surgery), the focus lock will prevent any other adjustments to the focus point, to avoid repeating this operation with every procedure.

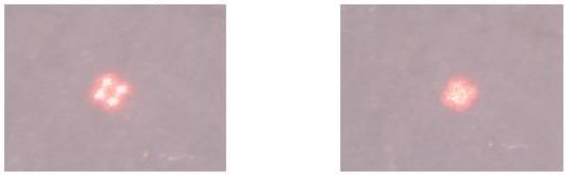
The beam must be focused with the microscope set at this maximum magnification.

Proceed as follows:

1. Wear safety goggles!
2. Attach the micromanipulator, together with the scanner, onto the microscope or colposcope and connect the assembly to the laser system;
3. turn the laser system on and set the aiming beam intensity at 2%;
4. set the microscope-colposcope at maximum magnification;
5. before moving the focus lock, the focusing ring must be up to the beat (i.e. the white arrow has to line up with "F" label, as shown here to the side);
6. Change the focus lock by moving the retainer in the direction of the "open padlock" icon;

Figure 47 - Focus lock retainer

7. enter the "Settings" menu;
8. focus the laser beam: the user must be able to clearly see four red dots through the microscope.



9. Always test the fine focus of the CO_2 laser: press the area highlighted in Figure 46 once ("**Test emission**" will appear under the key instead of "Focusing") and perform an emission on a tongue depressor (also refer to the *Micromanipulator Operator's Manual*).

10. Move the retainer in the direction of the "closed padlock" icon.

CAUTION

If the CO_2 beam spot and the aiming beam spot do not match (i.e. if they do not overlap), please call the Technical Assistance Service.

Important information

The focus of the aiming beam is the same focus of the CO_2 laser beam; nevertheless, it is recommended to fine tune the CO_2 laser focus by emitting single pulses on a target such as a wooden tongue depressor or using alumina (also refer to the *Micromanipulator Operator's Manual)*.

Important information

The focal distances marked on the micromanipulator provide an approximate indication of the position required to achieve a given focal length as, depending on the type of microscope, it may differ slightly from the point shown by the marking.

Only once the laser beam has been focused, perform the laser beam centering operation.

This adjustment allows the user to fine tune laser beam centering. It must not replace the alignment procedure of the articulated arm, however it can be used when minor adjustments are required prior to a treatment, in order to enter the most critical accessories perfectly, such as micromanipulators or laparoscopes.

CAUTION

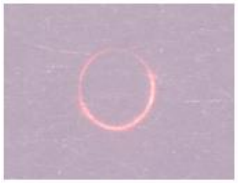
Before starting the surgical procedure the user is required to ensure that the red aiming beam and the CO_2 beam are coaxial and that the laser radiation is delivered correctly.
Whit microsurgery procedures this check must be performed through the microscope and the micromanipulator, with the system in its operating setup; the user must not change the operating setup during the surgical procedure.

Proceed as follows:

- Enter the "Settings" menu and press the area highlighted in Figure 46 until "Centering" appears.
- If the circle is clear and uniform, centering is correct and it is not necessary to perform further operations.

OK

- If the aiming beam produces clearly non-uniform shapes



NO

NO

press the arrow keys in the "Settings" menu to manage the horizontal and vertical movements of the laser beam along the two axes;

Important information

It is also possible to control the horizontal and vertical movement of the laser beam along the two axes in the following ways:

- press either the red key on the scanning head or the central key of the remote control on top of the micromanipulator joystick to switch between the "x" and "y" axes;
- press either the two yellow keys on the scanning head or the right-left keys of the remote control on top of the micromanipulator joystick to move the beam.

IMPORTANT

The green dots in the “Centering correction” area are not an absolute reference for centering (they must not be positioned on the intersection of the axes to center the laser beam!) as they only represent how much the centering has been corrected with respect to the factory setting position of the galvanometers.

- In order to check the centering accuracy, the system allows the user to switch the laser source on and perform a laser emission on a target surface using preset parameters with the circular shape.
- At the end of the centering procedure, press the "  " icon on "Centering correction" to confirm.

Important information

Assuming that the laser arm is aligned correctly, the "**Restore**" option is very important in order to return to the initial position. This option may be useful if the operator "loses" the beam during the centering procedures.

CAUTION

If the user performs the centering correction procedure without saving the new settings (i.e., he/she switches the system off before exiting the "Centering correction" menu), at the next system start-up a warning message will appear: the user is required to perform the centering procedure again before operating the scanning unit.

11.2.1 HiScan Surgical alarms

Hi-Scan

This fault is related to problems with the HiScan Surgical unit. Try to reset the fault display. Call the technical assistance service if the fault persists.

HS KEYB

There are three keys on the scanning head. The system detects a fault if one of these keys is pressed down while the HiScan Surgical unit is on. Try to reset the fault display. Call the technical assistance service if the fault persists.

HS galvo driver

The system detects a fault if the mirrors inside the HiScan Surgical unit are not working properly. If this fault appears when the HiScan Surgical unit is switched on, check all the connections with the scanning unit. Try to reset the fault display. Call the technical assistance service if the fault persists.

HS points maker

This fault is related to problems with the software of the HiScan Surgical unit.

Try to reset the fault display. Call the technical assistance service if the fault persists.

EEPROM Factory Centering/EEPROM User Centering

These faults are related to problems with the centering procedure data storage. When it affects the factory setting, call the technical assistance service; when it affects the user setting, repeat the centering procedure and, if the problem persists, call the technical assistance service.

11.3 Use of the EndoScan unit

An additional external scanning unit called EndoScan is available among system accessories - optional - shown in Figure 48.

EndoScan can be used with either a long focal handpiece (4" or longer), EasySpot micromanipulator, or a laparoscope.

Figure 48 - EndoScan unit

Important information

When installed, the micromanipulator must be screwed onto the connector of the EndoScan unit marked **(A)**; the remote control, if included, must be connected to the connector marked **(B)**.

To switch the EndoScan unit on, if installed correctly, press the "EndoScan" area in the CO_2 main screen. The screen will appear as shown in the figure:

Figure 49 - User menu with EndoScan unit on

Shape
The scanning unit can generate two types of patterns:

Surface mode

A circular surface area is covered, using a composed ellipsoid motion. In this scanning mode, using UP emission mode, the user achieves more delicate ablations.

Perimeter mode

The focused laser beam moves in a circular motion. In this scanning mode the laser becomes a sort of "milling cutter" that ablates a layer of tissue with every motion.

It is possible to stop the scanning motion at any time and switch to steady spot, by simply pressing the dedicated button in the center of the touch screen.

Important information

The EndoScan unit moves the red aiming beam along the selected scanning area. This function allows to immediately check the characteristics – shape and dimensions - of the scanning area.

Size of the scanning pattern
The "**Size**" option allows the user to change the size of the scanning area (displayed as a percentage of the maximum available scanning area, i.e. 6.3mm x 6.3mm at 400mm focal length).

Important information

- Once the power level has been set, tissue ablation rates increase as scanning pattern sizes decrease.
- When the EndoScan unit is connected to the laparoscopic coupler, the user must not select scanning area sizes over 30%.
- When the EndoScan unit is connected to an 8" CO_2 handpiece, the user must not select scanning area sizes over 60%.

Emission mode

The "**Emission mode**" area alternately selects and displays either CW or UP emission mode.

Please refer to chapter 10.3.1 for details on the emission mode.

Exposure mode

The system allows the user to control the exposure time during a laser treatment.

The selected exposure mode is displayed on the screen in the "Exposure" area. Touch this area to change the exposure mode.

There is a choice of three exposure modes:

- continuous - "**Contin**." on the screen -;
- timed single exposure - "**Single**" on the screen -;
- timed repeated exposures - "**Repeat**. " on the screen -.

Note that it is possible to change the emission mode - CW/UP – regardless of the selected exposure mode.

In **continuous exposure mode**, the exposure time is controlled entirely by the operator by acting on the footswitch: as long as the footswitch is held pressed down, the shutter is open and, accordingly, laser emission occurs and the scanning unit repeats the selected pattern.

When the **single exposure mode** is enabled and the footswitch is pressed down, the system opens the shutter and keeps it open only for the time of one complete scanning. Once this time is over, the shutter closes automatically regardless of whether the footswitch is still down. If the operator wants to perform a new exposure, he/she must first release the footswitch and then press it down again.

When the **timed repeated exposures mode** is enabled and the footswitch is pressed, the system will open the shutter and perform a series of scans for as long as the footswitch is held down.

Once a single scan has been carried out the shutter will close automatically. If the footswitch is still pressed down, the system will wait out the selected "Delay" time. The shutter will then open again automatically and a new scan will be carried out. This sequence is repeated continuously as long as the footswitch is held down. Use the arrow keys to change the "delay" time between two scans within the range of 0.1 s and 3 s (increments of 0.1 s).

Power

The "**Power**" selection keys allow the user to change the power value up to 60 W.

Dwell Time

Only with the circular scanning pattern, is possible for the user to apply the "Dwell Time" parameter, i.e. the length of time that the laser beam remains on a scanning point, within a range of 100 µs and 1000 µs.

"No Scan" scanning mode

Touch the "**No Scan**" option in the "Shapes" area to select this scanning mode: this area will turn red, while all scanning parameters will be disabled except for the emission mode. Scanning can also be disabled by keeping the central key on the scanning head pressed down for a few seconds (or the central key of the remote control on the micromanipulator joystick) until the red aiming beam stops at the center of the scanning area. The laser pulse will be performed on this point.

If "No Scan" scanning mode is selected, the system will emit a steady laser beam, without scanning.

Aiming source

The intensity of the aiming beam from 1% to 100% (step: 2% between 2% and 10%, step: 10% for the other values).

It is also possible to switch off the aiming beam while lasing: press the "Aiming" area and select the "Dowl" ("Diode Off while Lasing") option. Set the "Dowl" option on to have a clear view of the operating field and well distinguish the ablated tissues during treatment.

CAUTION

CO_2 aiming beam intensities higher than 60% require an optical protection as indicated in chapter 6.3.1. The system displays a warning icon next to the selected value (if higher than 60%).

"Free hand" mode

It is always possible to go back to the "Free Hand" mode by pressing the "**Free Hand**" area: the systems will ask the operator to confirm this choice.

Scanning Info

The system displays further info about scanning that is the total scanning time and energy according to the selected parameters.

Adjusting laser beam focus and centering

The "**Centering correction**" option allows the user to adjust laser beam focus and centering.

This adjustment allows the user to fine tune laser beam centering. It must not replace the alignment procedure of the articulated arm, however, it can help when minor adjustments are required prior to a treatment, in order to enter the most critical accessories perfectly, such as micromanipulators or laparoscopes. Using the micromanipulator, when this procedure has been completed, at a given focus length (e.g., 400mm for laryngeal surgery), the focus lock will prevent any other adjustments to the focus point, to avoid repeating this operation at every procedure. If the EndoScan is used together with a laparoscope, please refer to chapter 11.3.1.

CAUTION

Before starting the surgical procedure the user is required to ensure that the red aiming beam and the CO_2 beam are coaxial and that the laser radiation is delivered correctly.

With microsurgery procedures this check must be performed through the microscope and the micromanipulator, with the system in its operating setup; the user must not change the operating setup during the surgical procedure.

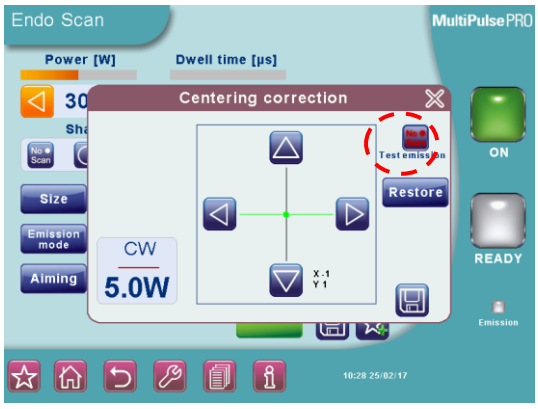


Figure 50 - EndoScan centering correction

Proceed as follows:

1. **Wear safety goggles!**
2. Attach the micromanipulator, together with the scanner, onto the microscope or colposcope head and connect the assembly to the laser system;
3. turn the laser system on and set the aiming beam intensity at 2%;
4. set the microscope-colposcope at maximum magnification;
5. before moving the focus lock, the focusing ring must be up to the beat (i.e. the white arrow has to line up with "F" label, as shown here to the side);

6. Change the focus lock by moving the retainer in the direction of the "open padlock" icon;

Figure 51 - Focus lock retainer

7. enter the "Centering correction" menu and ensure the focus is correct by performing an emission on a tongue depressor (also refer to the *Micromanipulator Operator's Manual*);

FOCUSED LASER BEAM DEFOCUSED LASER BEAM

8. move the retainer in the direction of the "closed padlock" icon.

CAUTION

If the CO_2 beam spot and the aiming beam spot do not match (i.e. if they do not overlap), please call the Technical Assistance Service.

Important information

The focus of the aiming beam is the same focus of the CO_2 laser beam; nevertheless, it is recommended to fine tune the CO_2 laser focus by emitting single pulses on a target such as a wooden tongue depressor or using alumina.

Important information

The focal distances marked on the micromanipulator provide an approximate indication of the position required to achieve a given focal length as, depending on the type of microscope and on the micromanipulator connection, it may differ slightly from the point shown by the marking.

Only once the laser beam has been focused, perform the laser beam centering operation.

Proceed as follows:

- Enter the "Centering correction" menu and press the area highlighted in Figure 50 until "**Centering**" appears.
- If the circle is clear and uniform, centering is correct and it is not necessary to perform further operations.

OK

- If the aiming beam produces clearly non-uniform shapes

NO

NO

press the arrow keys in the "Centering correction" menu to manage the horizontal and vertical movements of the laser beam along the two axes;

Important information

It is also possible to control the horizontal and vertical movement of the laser beam along the two axes in the following ways:

- press either the red key on the scanning head or the central key of the remote control on top of the micromanipulator joystick to switch between the "x" and "y" axes;
- press either the two yellow keys on the scanning head or the right-left keys of the remote control on top of the micromanipulator joystick to move the beam.

IMPORTANT

The green dots in the “Centering correction” area are not an absolute reference for centering (they must not be positioned on the intersection of the axes to center the laser beam!) as they only represent how much the centering has been corrected with respect to the factory setting position of the galvanometers.

- In order to check the centering accuracy, the system allows the user to switch the laser source on and perform a laser emission on a target surface using preset parameters with the circular shape.
- At the end of the centering procedure, press the "  " icon on "Centering correction" to confirm.

Important information

Assuming that the laser arm is aligned correctly, the "**Restore**" option is very important in order to return to the initial position. This option may be useful if the operator "loses" the beam during the centering procedures.

CAUTION

If the user performs the centering correction procedure without saving the new settings (i.e., he/she switches the system off before exiting the "Centering correction" menu), at the next system start-up a warning message will appear: the user is required to perform the centering procedure again before operating the scanning unit.

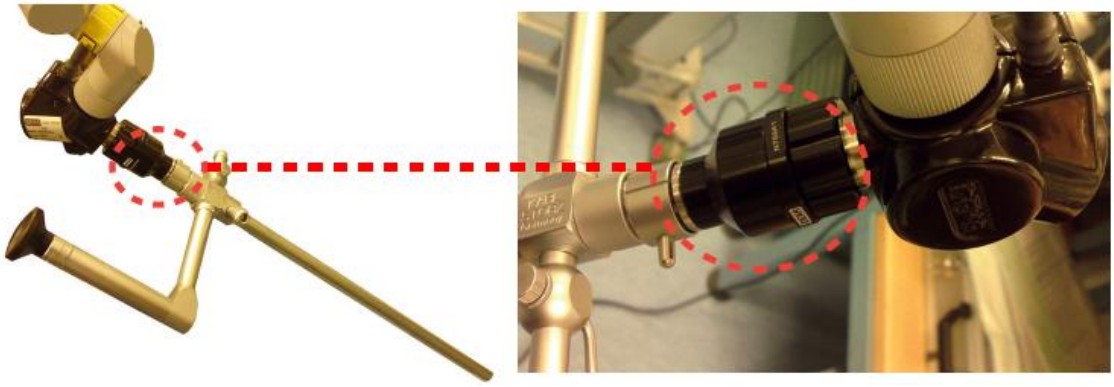
11.3.1 Laparoscopy

Correct centering must be checked every time the laparoscope is connected to the EndoScan unit.

Important information

The following instructions refer to the laparoscope most commonly used for CO_2 laser laparoscopic surgery i.e., the STORZ model with integrated working channel and optics, recommended by the Manufacturer to optimize surgical performance. The same precautions can be applied to all other laparoscopes used.

1. Ensure that all connections are secured and tight.



2. Before starting the surgery, verify the centering in the menu in the EndoScan screen. Enter the "Centering correction" menu and press the area highlighted in Figure 50 until **"Centering Laparo"** appears and point the tracking beam on a white target, or even on the floor.
3. The laser beam is centered when the “circle” is complete (not an arc of circle). You can center the beam both from the display or by using the button on the scanner (C) in Figure 48, up and down to move the beam and in the middle to change the correction axes).

Important information

The movement of the scanner's mirror may not correspond to the direction of the axes, as it depends on the position of the scanner itself; if so, move the beam by simply directing it as required.

4. If you do not see the circle or a part of it, press “Restore”: this will bring the beam back to its default centering position, which corresponds to a system whose arm is well-aligned. If you still do not see at least a portion of the circle after pressing the “Restore” button, please contact the technical assistance service.

IMPORTANT!
The two green spots on the axes are not an absolute centering reference (they must not be positioned on the axes intersection to center the laser beam!), they are simply the correction entity with respect to the default position of the galvanometer. Contact the technical assistance service if these spots are very distant from the center during the centering operation.

5. Upon centering the beam, confirm its adjustment by pressing "  ".

WARNING
Always connect the CO_2 insufflation tube in the patient not at the trocar but at the dedicated inlet of the laparoscope's working channel. This way, the passage of the focused laser beam will not be affected by fumes and air heating in the working channel, thereby ensuring an optimal use.

The following figure shows the focused beam.

11.3.2 EndoScan alarms

EndoScan

This fault is displayed on the "SYSTEM FAULT" menu if the MultiPulse PRO DUO system detects problems with the EndoScan unit. Make sure that the scanning unit is properly connected. Try to reset the fault display; call the technical assistance service if the fault persists.

EEPROM Factory Centering/EEPROM User Centering

These faults are related to problems with the centering procedure data storage.

When it affects the factory setting, call the technical assistance service; when it affects the user settings, repeat the centering procedure and, if the problem persists, call the technical assistance service.

11.4 Use of the HiScan DOT unit

An additional external scanning unit called HiScan DOT is available among the optional system accessories. The HiScan DOT unit shown in Figure 52, allows the user to achieve high performance "skin resurfacing" treatments.

Figure 52 - HiScan DOT-Unit

Skin resurfacing can be achieved using the HiScan DOT unit, in two different ways: in "**DOT**" scanning mode the area of skin is treated in dots: the operator can set the distance between dots, delivering laser power to localized points, without exposing the surrounding tissues to laser radiation (see Figure 53, right). This mode guarantees an effective procedure, less trauma and quicker healing. The "DOT" mode is effective in terms of photo rejuvenation, the treatment of "acne" scars and skin "photo aging" therapy.

In "**STANDARD RESURFACING**" mode the entire area is treated by scanning in lines, from left to right and from right to left, starting from the first line at the top to the last line on the bottom (see Figure 53, left); this mode is highly effective, providing substantial ablative action, though requiring a longer recovery period.

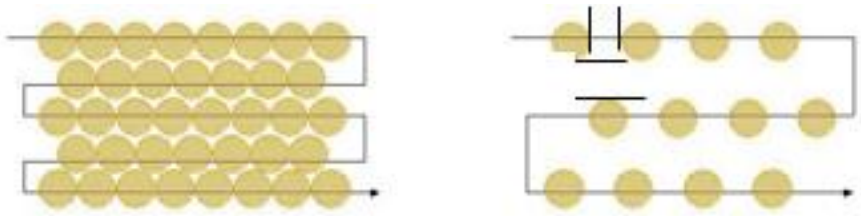


Figure 53 – „STANDARD RESURFACING“ and „DOT“ scanning modes

To activate the HiScan DOT unit, when installed correctly, press the "HiScan DOT" on the CO_2 main menu. The screen pictured below will appear.

Figure 54 – DOT scanning mode

Power

The "**Power**" selection keys allow the user to select a power value of up to 60 W *when SP and DP emission modes are selected*; up to 40W *when HP emission mode is selected*.

Dwell time

The scanning "**dwell time**", i.e. the length of the HiScan emission, can be selected between 100 µs and 2,000 µs (at increments of 100 µs).

Spacing

The "**Spacing**" parameter, i.e. the "distance" between the scanning dots, can be selected between 0 to 2,000 µm (at increments of 50 µm).

This parameter is not available with the "STANDARD RESURF." option.

Shape and size of the scanning area

The scanning head allows the user to move both the aiming beam and the CO_2 laser beam, according to a pattern with a certain shape and size selected by the operator in the following way:

- using the three keys located on the left part of the screen:
  the **Shape** area allows the user to change the shape of the scanning area, selecting from: point, line, parallelogram, hexagon, triangle, square, ellipse and annular ring;
  the **Size** key allows the user to change the size of the scanning area (shown as a percentage of the maximum available scanning area, i.e. 15 mm x 15 mm;
  the **Ratio** key allows the user to change the height-width ratio of the scanning area.

Important information

The HiScan DOT unit moves the red aiming beam along the outline of the selected scanning area. This function allows the user to immediately check the characteristics - shape and size - of the scanning area.

Aiming beam intensity

The intensity of the aiming beam can be set between 1% and 100% (increments of 2 % between 2 % and 10 %, 10 % increments for the remaining values).

It is also possible to switch the aiming beam off during laser treatment: press "Aiming" and select the "Dowl" ("Diode off while lasing") option.

Set the "Dowl" option ON to have a clear view of the treatment area and to clearly distinguish the treated tissues during the procedure.

CAUTION

CO_2 aiming beam intensities higher than 60 % require an optical protection as indicated in chapter 6.3.1. The system displays a warning icon next to the selected value (if higher than 60 %).

Smart Stack

It is possible to select and edit the "**Smart Stack**" parameter which manages the number of pulses delivered consecutively by the system on the same "dot".

This value can be set between 1 to 5 by pressing "Smart Stack" by the number of pulses the user wishes to set.

For example, if a value of "1" is set, the system will perform only one pulse on every single dot, while a value of "3" will provide three pulses on a single dot, before moving onto another spot/dot. In theory, this scanning mode (i.e. Stack 3) should have the same effect on tissues as three consecutive scanning applications, however it has the advantage of ensuring greater overlapping by emitting three pulses over the same dot.

CAUTION

Nevertheless, this mode also causes the energy factor on the tissue to multiply.

For this reason, if the "Stack" value is greater than "1", the selected number is highlighted in red as a warning to the operator.

This parameter is not available with the "STANDARD RESURF" option.

Scan mode

It is possible to select a scan mode from Normal, Interlaced or SmartTrack, by simply touching the "**Scan mode**" area.

"Normal" scan mode

When this scan mode is selected, the area is treated by scanning lines from left to right and from right to left, starting from the first line at the top, to the last line on the bottom.

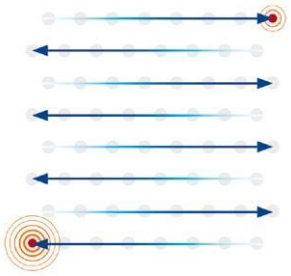


Figure 55: Example of "Normal" scan mode

"Interlaced" scan mode

When this scan mode is selected, the area is treated by scanning the odd numbered lines first, followed by the even numbered lines. Once the odd numbered lines have been scanned from the top to the bottom, the even lines are scanned from the bottom to the top.

Use of the interlaced scan mode is advisable for reducing thermal effects during treatment.

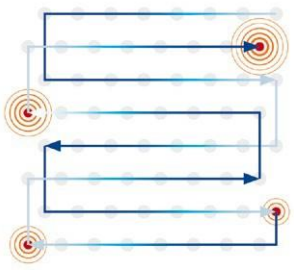


Figure 56: Example of "Interlaced" scan mode

"SmartTrack" scan mode

When this scan mode is selected, the area is treated by scanning dots in random order: this minimizes the risk of tissue overheating, and therefore thermal damage.

This scan mode is not available with the "STANDARD RESURF." option.

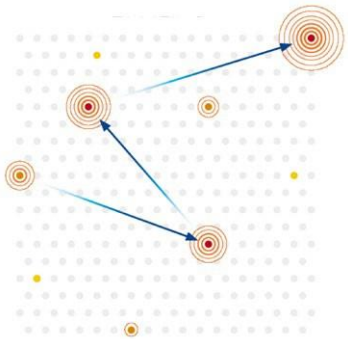


Figure 57: Example of "SmartTrack" scan mode

Exposure mode

The system allows the user to control scanning exposure time.

Press the "**Exposure mode**" key to open the screen where the exposure mode can be changed.

Two exposure modes are available by pressing the relevant areas:

- Single scanning ("Single" on the screen);
- Timed repeated scanning ("Repeat." on the screen).
- **Single scanning**
  When the single exposure mode is enabled and the footswitch is pressed, the system opens the shutter and keeps it open only for the duration of one complete scan. Once this time is over, the shutter closes automatically, whether the footswitch is still pressed or not. If the operator wants to perform a new exposure, he/she must release the footswitch and then press it down again.
- **Timed repeated scanning mode**
  When this mode is enabled and the footswitch is pressed, the system opens the shutter and performs scanning sequences as long as the footswitch is held down. Once a single scan is complete, the shutter closes automatically and then, if the footswitch is still pressed, the system waits out the selected "Delay" time; after this time the shutter opens again and a new scan is performed. This sequence is repeated continuously as long as the footswitch is held down. Use the arrow keys to change the "**Delay**" time between scans from 0.1 s to 5 s (increments of 0.1 s).

Figure 58 - "Exposure" mode selection

Emission mode

An emission mode can be selected from **DP**, **HP** and **SP** modes.

In SP mode and DP mode the POWER selection keys allow the user to set the power value between 0.5 W and 60 W. In HP mode the POWER selection keys allow the user to set the power value between 0.5 W and 40 W.

CAUTION

For the same amount of time selected for pulse length, the amount of energy released by the system in DP mode is greater than the energy released in SP mode, because of a different pulse shape.
Moreover, with equal power values, the energy released in HP mode is different (and can be much higher) from the other modes.

Always check the value of the released energy as it is the indicator of the thermal effect on the tissue.

Scanning info

The system displays additional information about the scanning: the value - according to the selected parameters - of the energy released on each scanning point ("Pulse Energy"), the fluence (energy density) and the percentage of treated surface ("Density").

"STANDARD RESURF." mode

By selecting the "**STANDARD RESURF**." option, the "DOT ON" scanning mode is disabled and the "traditional" scanning mode is enabled: *this means that the emission mode is continuous and cannot be changed; moreover, the "Spacing" parameter, the "Smart Stack" option and the "SmartTrack" scanning mode are no longer available.*

Figure 59 - Standard resurfacing scanning mode

When the "STANDARD RESURF." mode is running, the "DOT" option allows the user to go back to "DOT" scanning mode.

"Free hand" mode

It is always possible to go back to the "Free Hand" mode by pressing the "Free Hand" key: the system will ask the operator to confirm this choice.

11.4.1 HiScan DOT alarms

Hi-Scan

This fault is related to problems with the HiScan DOT unit.

Try to reset the fault display.

Call the Technical Assistance Service if the fault persists.

HS galvo driver

The system reports a fault if the mirrors inside the HiScan DOT unit are not working properly.

If this fault is reported when the HiScan DOT is switched on, check all the connections with the scanning unit.

Try to reset the fault display. If it persists call the Technical Assistance Service.

HS points maker

This fault is related to problems with the software of the HiScan DOT unit.

Try to reset the fault display. If it persists call the Technical Assistance Service.

12 Clinical applications

This section discusses the clinical applications of the system in general terms; it is not intended to be an exhaustive clinical manual.

CAUTION

The MultiPulse PRO system must not be used for applications other than those specified above.
Asclepion Laser Technologies GmbH is not responsible for direct or side effects resulting from use of the system differing from the intended use specified above.

12.1 CO_2 laser surgery

WARNING

When using the device in open Neurosurgery, the applied parts of the device NEVER be used in direct contact with the patient. This could lead to serious health consequences, including death.

WARNING

The use of laser treatment for pregnant women or children is NOT recommended because there do not exist clinical studies for these patients.

WARNING

The scan units of the MultiPulse PRO DUO device comply with degree of protection B. When combined with an endoscope, the REF 04366003A direct coupler (see chapter 15 “Accessories”) must be used between the scanner and the endoscope. Only this ensures the electrical safety of the combination.
Asclepion Laser Technologies GmbH is not responsible for direct or indirect injuries or death resulting from use of the device in conjunction with an endoscope.

The CO_2 laser is the laser of choice in most medical fields, thanks to its optical property of being absorbed mainly by water. It has excellent tissue cutting properties with very little lateral tissue damage (approximately 50 µm, with ultrapulsed systems and scanners).

Carbon dioxide (CO_2) radiation has a wavelength of 10,600 nm in the invisible far infrared region. As CO_2 radiation is invisible, a visible (typically red) aiming beam laser is superimposed precisely on to the path of the CO_2 beam.

CO_2 radiation reaches the accessories by passing through an articulated arm with internal mirrors, typically 7 mirrors.

In surgical practice, the MultiPulse PRO DUO CO_2 laser can be used with handpieces of different focal lengths and spots, or with scanning units and micromanipulators. Use with micromanipulators provides a coaxial delivery of energy for laser surgery using operating microscopes. Thus, its range of clinical application is extended considerably, allowing for an increasingly refined use of the laser. Using the zoom on the micromanipulator, the focal point can be changed and set on the surgical operating plane. The operator must therefore know how to focus and work with accessories equipped with zoom, especially electronic scanners, which provide the best results when combined with a perfectly focused laser, when performing photoablation.

Also refer to the Micromanipulator Operator's Manual.

12.1.1 Contraindications

There are no known contraindications for the use of the system, with the exception of the general contraindications of standard surgery.

Generally, contraindications regarding the use of carbon dioxide laser include inadequate view of the area requiring treatment due to anatomic considerations (e.g. prolapsing lateral vaginal sidewall, the anatomical conformation of the larynx) and inadequate physician training or experience.

12.1.2 Side effects

Complications, though rare, can occur depending on the anatomical area or the surgical procedure.

Generally speaking, they involve: bleeding, swelling, discomfort or moderate pain, abnormal healing, adhesions.

The patient must understand the importance of pre-treatment and post-treatment instructions, and that failure to comply with these instructions may increase the probability of complications.

Both bacterial and viral infections are potential side effects if proper clinical precautions are not observed; these precautions are related to the type of surgical procedure.

12.1.3 Precautions

- Do not use the laser if the aiming and treatment beams do not coincide.
- Spot size and laser energy are controlled separately. When using smaller spot sizes, as in excision procedures, the operator must remember that the energy density is greater. Laser parameters should be applied with extreme caution until the user has an excellent understanding of the biological interaction between laser energy and tissue.
- The beam must be moved manually to control ablation depth.
- Plastic instruments such as speculums or eye shields can melt upon impact with a laser beam. Use only stainless steel surgical instruments designed specifically for laser use.
- If necessary, the area around the target site can be protected with wet towels or gauze sponges or laser beam backstops. Ensure that sponges do not dry out!
- Be especially careful with the use of oxygen. Oxygen accelerates both the severity and the extent of fire. Always refer to the protocols regarding anaesthesia in force in the hospital where the laser system is used.
- Use non-flammable substances for uses such as anaesthesia, preparing soft tissue for treatment, and cleaning or disinfecting instruments.
- The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used.
- Store the bare minimum of combustible materials in the treatment room. If treatment requires the use of a combustible material, such as gauze, first soak it in water.
- Prevent singeing or burning when treating an area with hair by wetting the area with water or saline before beginning treatment Attention should also be drawn to the danger of ignition of endogenous gases. When procedures are performed in the perianal area, moistened sponges should be inserted into the rectum.
- Always use laser-resistant, cuffed, and flexible stainless steel endotracheal tubes. The endotracheal tube cuff can be filled with saline to protect it from inadvertent penetration. The saline can be dyed with Methylene blue so that evidence of cuff-penetration by the laser will promptly appear on the surrounding gauze sponges.

- The endotracheal tube and the tissues behind the target area can be further protected by placing wet sponges or gauze to absorb laser energy. A piece of wet gauze or gel foam must always be inserted behind the vocal folds to act as a backstop for the laser beam, and protect both the endotracheal tube and other anatomic structures.
- If ventilation via endotracheal intubation cannot be avoided, the use of laser-safe tubes is mandatory in order to avoid damage to the airways by endotracheal fire. Normally, during laser operation, it is advisable to keep the concentration of inspiratory oxygen low in order to avoid the risk of endotracheal ignition and fire. Please refer to the anaesthesiological protocols of the hospital.

12.1.4 Pre-treatment Recommendations

At the time of the initial visit, the physician should determine the suitability of the laser treatment and inform the patient of the treatment.

CAUTION

If using the laser with micromanipulator, before starting starting the surgical procedure the physician has the responsibility to check if the CO_2 laser beam is properly focused at the microscope's operative working distance and to check the coaxiality between the red aiming beam and CO_2 beam.

The physician has not to change the microscope's working distance after the focusing operation and/or during the surgical procedure.

CAUTION

Be very careful to select the correct focal length, as this parameter is required by the system to calculate the scanning area and the cutting depth.

The selected focal length must be the same as the operating focal length set on the microscope, which used as the basis for focusing the micromanipulator.

Do not change the microscope operating distance after the focusing operation has been carried out and/or during the surgical procedure.

12.1.5 Treatment Recommendations

Adjust the maximum operating field for the joystick using the relative adjustment screw before starting the procedure, in such a way that the beam does not exceed the operating view of the microscope.

This ensured that the laser beam will never leave the visual field, avoiding the risk of it being “lost” by the operator.

12.1.6 Post-treatment Recommendations

Important information

After each treatment session, physicians must advise their patients on proper care of the treated area according to the surgical discipline or procedure.
The patient must contact the physician if there is any indication of infection (redness, tenderness or pus).

12.2 Dermatology

12.2.1 Examination and contraindications in dermatology

- Sun and UV lamp exposure: avoid prior to (at least 1 month), during and after treatment.
- Apply SPF50 sunblock before and after the treatment.
- Be careful in case of drugs:
  - Anticoagulants (this can cause persistent erythema),
  - Retinoids,
  - Photo-sensitizers
- The treatment is contraindicated for patients who have recently undergone an exfoliation treatment, surgical treatments such as lifting and any patient with past skin disorders, including cheloids.
- Subjects with a history of Herpes may be prescribed antiviral prophylaxis a few days before the treatment.
- Subjects with dark photo types (III-VI) should follow a pre-operative protocol to help prevent post-inflammatory hyperpigmentation (PIH), beginning a few days prior to treatment.
- The doctor, based on the treatment results, may consider prescribing antibiotic drugs.
- Prior to commencing treatment, a skin test should be performed on a small area so that the doctor can ascertain whether the treatment will injure the skin.
- When using CO_2 laser radiation only, do not wet either the skin or the electrodes;
- Moreover, do not use the electrode sheaths.

12.2.2 Side Effects

For dermatological application side effects are mild to moderate pain during the treatment, burning sensation, bleeding and mild to moderate posttreatment erythema and oedema that resolve in few days. Adverse effect such as burn may result from improper use or excessive energy.

12.2.3 Pre-treatment

Cleaning the skin

Before starting treatment, the area concerned must be cleansed of any impurities that could interact with or obstruct the CO_2 sources.

Remove any make up, lotions, deodorants or ointments with a gentle soap, then rinse with plenty of water.

Photographic examination

Photographs taken to document the patient throughout all of the various phases of treatment make it possible to monitor its effectiveness. In order to ensure the best photographic quality it will be necessary to standardize shots in the aim of reproducing the patient's position and the lighting conditions.

12.2.4 Post-treatment care in dermatology

Operations carried out with CO_2 laser devices generate abrasion or ablation of the skin which require daily care of the wound.

The aim is to achieve healing, prevent the formation of scabs in the middle and on the inner edges of the treated area, and thus guarantee an adequate cleanliness and softness.

In order to reduce the oedema and the inflammation that may occur following fractional skin resurfacing, we recommend applying cool compresses or wet gauzes cooled using the Cryo6 air jet to the skin, immediately after treatment. The post-treatment routine involves medicating the area by gently cleaning the skin, applying cold packs, which must always be carried out using sterile gauze and a physiological solution. The patient must re-apply an emollient and/or antibiotic and enzymatic ointment every time, especially after cleaning and showers. This procedure must be repeated 3-4 times per day until clinical healing begins (typically 4-7 days). At this point, a normal skin-care moisturizer and sunblock protection can be applied (for 2-5 months, depending on skin photo type and environmental conditions).

It is advisable to wait for 1 day before having a shower (avoid hot water on the treated area until healing is complete).

Avoid exposure to the sun for at least 2 weeks.

The use of moisturizing and emollient lotions is suggested without any time limitations: it helps maintaining the uniform and compact aspect of the new skin.

13 Troubleshooting

This section describes the faults detected by the system and provides a troubleshooting guide for a number of problems that can be identified and solved by the operator.

13.1 Managing faults in the system

The MultiPulse PRO DUO system is able to detect faults that may be dangerous either for the subject undergoing treatment or for the system itself.

As soon as one of these conditions is detected, the system automatically switches to safety mode: shutter closed, source turned off (STAND BY), footswitch disabled. The SYSTEM FAULT menu immediately appears on the screen.

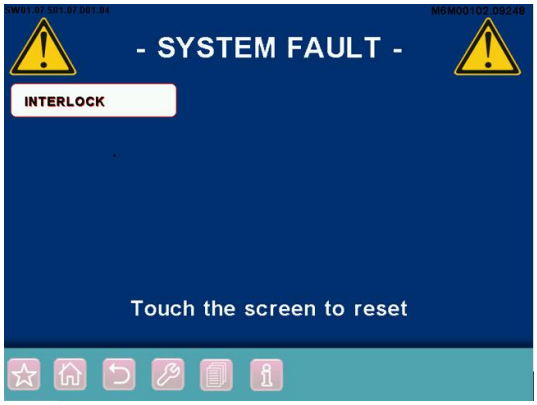


Figure 60: " SYSTEM FAULT" menu

The MultiPulse PRO DUO system only displays the currently detected faults - i.e. the figure illustrates the detection of an INTERLOCK fault.

Moreover, once a fault is detected, the system will continue to display the message, even if the fault is solved: this allows the operator to record any detected faults, and possibly notify the Technical Assistance Service.

13.2 Descriptions of Faults

Possible faults and appropriate actions are described in detail below.

Interlock

This fault appears if the INTERLOCK system detects an open circuit.

If the INTERLOCK feature is attached to an external interlock device, make sure the door is closed, that the external interlock device is running and that the cable from the external interlock device is plugged into the INTERLOCK socket on the system.

If there is no external interlock device, make sure the INTERLOCK connector (provided with the system accessories) is plugged into the INTERLOCK socket. Reset the fault display. Call Technical Service if this fault persists.

Temperature

This fault is displayed if the temperature of the cooling fluid inside the CO_2 laser source or the temperature of the high voltage power supply unit gets too high.

Do not turn the system off in order to allow the cooling fluid to cool down.

Wait approximately 2 minutes, and then press any key to reset the fault display. Call Technical Service if this fault persists.

Shutter

This fault is displayed if the detected shutter position does not match the expected shutter position. Press any key to reset the fault display.

Call Technical Service if this fault persists.

High voltage

This fault is displayed if the internal high voltage power supply unit is not working properly.

Press any key to reset this fault display, then switch the laser source back on again. Call Technical Service if this fault persists.

Flow

This fault is displayed if the flow of the cooling circuit is low.

Press any key to reset the fault display.

Call Technical Service if this fault persists.

Only Asclepion Technical Assistance Service or skilled personnel authorized by Asclepion can service the cooling circuit.

High power/Low power

These two faults are detected if the power evaluation procedure detects an incorrect output power level.

The "High power"/"Low power" warning appears in the SYSTEM FAULT menu in the same location as "High current" alarm.

Read chapter 10.7 carefully. Reset the fault display, then try to switch the laser source back on again in order to perform the power evaluation procedure again.

Call the Technical Assistance Service if the fault persists.

EEPROM/Data Memory

These faults are reported if an internal memory component is not working properly.

It can be generated on system start-up or when the CO_2 laser source is switched off - STAND BY key pressed.

These faults are not critical in terms of system performance but may cause problems regarding the management of treatment programs, i.e. the system might lose the changes made by the operator to the treatment programs.

Try to reset the fault display, if it persists call the Technical Assistance Service.

CO_2 PS TEMP

This fault is reported if the temperature reading of the power supply for the CO_2 source is outside of the operating range.

Try to reset the fault. If the fault persists, call the technical assistance service.

CO_2 Power Supply

This fault condition is reported if the system detects problem with the CO_2 power supply.

Try to reset the fault display, if it persists call the Technical Assistance Service.

CO_2 DUTY

This fault is reported if the system detects an internal fault generated by the CO_2 power source.

Try to reset the fault display, if it persists call the Technical Assistance Service.

Flip Mirror

This fault condition is stated if the system detects a wrong positioning of the flip mirror which directs the CO_2 laser beam on the articulated arm/fiber.

Try to reset the fault condition, if it persists call the technical assistance service.

High Fiber Temperature

This fault condition is stated if CO_2 fiber temperature is too high (>50°C on the fiber coupling).

Try to reset the fault condition, if it persists call the technical assistance service.

Air Pressure

This fault condition is displayed if the air pressure at CO_2 fiber output is insufficient. Verify that all the air pipes (both the ones of the antibacterial filter and, if present, the one of the external air flow) are properly connected. Press any key to reset the fault display. Call Technical Service if this fault persists.

FIBER

This fault condition is displayed if the CO_2 fiber is not properly connected to the system.

Connect the fiber or check the fiber connection. Press any key to reset the fault display. Call Technical Service if this fault persists.

13.3 Warnings

If the system detects any power fluctuations, the power level on the screen may appear in yellow rather than red characters once calibration is complete. If a laser treatment is in progress when this occurs, the rate of the warning tone will increase. These two conditions are warnings, not faults. The system will not go into standby and the operator can continue the laser treatment.

13.4 Troubleshooting

Below is a brief troubleshooting guide to solving a number of problems that can be identified and solved by the operator.

The system will not turn on

- Make sure that the mains cable is properly plugged in and the mains voltage/current values match system specifications.
- Check if the key switch and the emergency switch are positioned correctly.

Nothing happens when the footswitch is pressed

- Make sure that the system is in OPERATE state - see the "SYSTEM DESCRIPTION" section.
- Make sure the footswitch is connected correctly to the relative connector – see the "SYSTEM DESCRIPTION" section.

Poor laser emission or no laser emission from the handpiece

- Call the Technical Assistance Service.

The aiming beam and CO_2 beam are not coaxial

- Make sure the articulated arm is installed correctly.
- The problem may be due to a misalignment of the articulated arm: call the Technical Assistance Service.

The power displayed after calibration is different from the selected power.

- The system cannot provide the selected power. Read chapter 10.7 carefully.

The system does not detect the connected scanning unit

- Make sure the scanning unit is connected correctly. Read the relative Sections carefully.

For any further problems, contact your local agent or:

Asclepion Laser Technologies GmbH

Bruesseler Str. 10

07747 JENA

Germany

Phone: +49 (0) 3641 / 7700 - 411

Fax: +49 (0) 3641 / 7700 - 402

E-mail: **service@asclepion.com**

14 Maintenance

14.1 Ordinary maintenance

With regular maintenance, safety testing, calibration and application of the instrument under normal conditions, the MultiPulse PRO DUO has a lifetime of 5 years.

CAUTION

Always turn off the system and disconnect it from the mains before performing maintenance.

14.1.1 Laser Care and Handling

Asclepion advises the operator to periodically clean and disinfect the exterior of the laser system in the following manner:

- Clean the exterior of the laser with mild soap and water.
- Use a soft cloth for cleaning and disinfecting.
- When necessary, disinfect the exterior parts of the equipment with hospital-grade disinfectant.

Precautions

- Be careful not to let the detergent penetrate cavities or openings of the device;
- Do not use chemical solvents and/or abrasive detergents;
- Do not use alcohol to clean the surface of the screen.

CAUTION

When operating the handpiece/scanner on the area to be treated, verify that their outer surface is not too warm: overheating means that the handpiece/ scanner is not working properly or has not been reprocessed correctly.

14.1.2 Reprocessing reusable parts

The following reusable parts must be reprocessed after use:

- CO_2 handpieces
- Spacers
- Fiber pole passing hole
- Stripper for CO_2 hollow fiber *(for the cutter, please refer to the proper instruction)*

Limitations on reprocessing:

Repeated processing has minimal effect on these components. End of life is normally determined by wear and damage due to use.

Important information

The articulated arm can be wrapped in sterile cloth during use, however, always avoid wrapping it too tightly to prevent mechanical stress. Asclepion Laser Technologies GmbH can provide an 18x300 sterile cloth.

Important information

Use support systems and/or containers for transportation in compliance with ISO 11607-1 and 11607-2 standards.

Proper handling and reprocessing of reusable parts before use on patients must be carried out in strict observance of the steps described below:

A) Start cleaning the reusable parts as soon as possible after use.
B) Wear heavy-duty rubber gloves, a plastic apron, eye protection, and mask during reprocessing.
C) Separate disposable parts from reusable ones.
D) **Pre-cleaning at the point of use.**
Prior to carrying out a thorough cleaning, remove any visible residues.

A deep container, e.g. a bucket, containing a wire-mesh basket can be filled with tap water between 22 °C and 43 °C and enzymatic detergent (a protease formula that dissolves proteins), as Endozime® AW Triple Plus with APA.

This detergent must be used in accordance with manufacturer instructions (e.g. dilution/concentration, temperature, water properties, soak time).

It must also have the following characteristics:

- non-abrasive
- low-foaming
- free-rinsing
- biodegradable
- nontoxic in the specified dilution of use.

The parts are placed in the wire basket, agitated for 3-5 minutes, and then lifted out. The basket is overturned onto a table or tray in order to separate the items prior to cleaning, packing and autoclaving.

E) **Disassembly of the reusable parts**
Disassemble the items as described in the relative Sections.

F) **Thorough cleaning**
Thoroughly cleaning the parts being reprocessed allows all foreign material (dirt and organic matter) to be removed, and must accordingly precede all sterilisation procedures.

If any instruments or other items have not been cleaned, sterilisation may not be effective, as microorganisms trapped in organic material may survive sterilisation.

Steps for thorough cleaning

1. Soak the instruments in a container deep enough to contain the number of items, filled with a solution of tap water between 22 °C and 43 °C and the same enzymatic detergent used for pre-cleaning (step D).

2. Scrub the items vigorously, with the brush provided with the accessories, to completely remove all foreign material. Hold items under the surface of the water while scrubbing and cleaning to avoid splashing.

3. Be sure to brush inside grooves and joints where organic material can collect and remain lodged.

4. Flush through lumens with an adapted water jet.

5. Rinse items for 2-3 minutes thoroughly under tap water to remove all traces of detergent. Please observe the suggested rinse time as it ensures that any residues remaining on the item do not exceed the safety levels.

6. Inspect items visually to confirm that they are clean. If any visible debris remains, repeat steps 2-4.

7. Let the cleaned device dry at room temperature until is completely dried.

Important information

Only reprocessing instructions reported above have been validated and have to be followed by the user. Automatic cleaning has not been validated.

G) Sterilisation

The following protocol is recommended for steam sterilisation:

1. Place each part in an individual sterilisation pouch. Pouches should be large enough to hold items without forcing the pouch seals.

2. Arrange all wrapped items inside the chamber of the autoclave in such a way that allows steam to circulate freely. DO NOT STACK.

3. Follow manufacturer instructions for autoclave operation.

Set the autoclave parameters as follows, according to the type of autoclave:

1) Pre-vacuum cycle: 132 °C or 134 °C, 4 minutes, minimum drying time: 5 minutes.
2) Pre-vacuum cycle: 134 °C, 3 minutes, minimum drying time: 5 minutes.
3) Gravity cycle: 132 °C, 10 minutes, minimum drying time: 5 minutes.

Important information

The autoclave should be checked at each use to make sure it is functioning properly. Follow manufacturer instructions whenever possible, as maintenance varies depending on the type of autoclave.

H) Post-processing handling

Do not store packed items until they cool to room temperature.

Store items in accordance with the following guidelines:

Store items in a closed, dry, cabinet at a moderate temperature and low humidity, in an area that is not subject to heavy traffic.

A wrapped pack can be considered sterile as long as it remains intact and dry.

When in doubt about the sterility of a pack, consider it contaminated and re- sterilize the items.

Reassemble the items before use, following the previously described steps in reverse order (step C).

Inspection and Function Testing:

- All parts: visually inspect for damage and wear (i.e. breakage, deformation, crack, scratch). For probes with mirror: check for damage that may affect the mirror reflectivity (deformation, scratch, matte surface)
- Connections (i.e. handpiece with articulated arm/scanner, probe with handpiece/ scanner, cannula with handpiece): check for compromised connection between parts (hard to connect, loose connection)
- Aiming beam: check for spread beam, non-visible beam.

In case one or more of the above listed criticalities arises, do not use the subject component.

14.1.3 CO_2 hollow fiber care

Read carefully the instructions enclosed with the fiber.

14.1.4 Inspecting, cleaning and disinfecting the scanning units

Before and after each use, inspect the scanning unit for dirt or damage. Failure to clean, or cleaning the equipment inadequately, can alter the efficiency of the system. Proceed as follows:

- Switch the system off and disconnect the scanning unit from the laser system before inspection/cleaning/disinfecting.
- To clean and disinfect the external surface of the scanning unit, use a cloth moistened with hospital grade disinfectant. Do not use disinfectants containing peracetic acid or chlorine to clean of the components of the scanning unit.
- Dry with a clean cloth. Do not use the scanning unit until its surface is completely dry, i.e. the disinfectant solution is fully evaporated.

Checking and cleaning the focalisation lenses

Before every operation, and with the laser system switched off, it is advisable to inspect the lens and, if necessary, to clean it.

The focalisation lens is housed inside the scanning head and is accessed by disconnecting the spacers from the scanning head.

It can be cleaned with optical paper soaked in acetone and disinfected with optical paper soaked in isopropyl alcohol 70 %. Never wet the lens with water. Allow time for the alcohol to dry.

If the lens appears to be damaged, contact the Technical Assistance Service immediately.

14.1.5 Emergency switch and interlock

Check the correct working of the emergency switch and of the interlock network once a month.

14.1.6 Antibacterial filter check and cleaning

The antibacterial filter must be inspected before each use and must be replaced periodically.

The filter life depends on the frequency and conditions of use. If the filter is dirty or if you notice a decrease in the air flow, it must be replaced.

To replace it, disconnect the two plastic pipes and connect the new filter: place the filter's face with the "IN" label pointed towards the IN connector on the system.

14.1.7 Fuses check and replacement

If the MultiPulse PRO DUO cannot be turned on, fuses should be checked. The fuses are located above the mains plug on the rear side of the system.

Proceed as follows:

- Always turn off the system and disconnect the mains cable before checking or replacing the fuses.
- Unscrew the damaged fuses and replace them with fuses of the same kind.
- Try to turn on the system again; if it still cannot be turned on, call the Technical Assistance Service.

Figure 61 - Main fuses

14.2 Disposing of the system

In compliance with European Commission Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE) and state regulations in force, please do not dispose of this equipment in any location other than designated collection centres.

You can also contact your local Asclepion dealer to arrange sending the equipment back to the manufacturer.

14.3 Maintenance to be carried out by skilled personnel

The following maintenance procedures should be carried out in order to ensure system reliability. The safety check should be carried out in compliance with the relevant national legally regulations, as amended, and include at least the tests mentioned below:

- laser source inspection - visual inspection of laser device and accessories;
- footswitch/shutter check;
- internal power meter inspection and calibration;
- electric insulation check;
- cooling circuit check - refill or exchange if necessary.

The cooling fluid used in the MultiPulse PRO DUO system is bidistilled water.

All of these maintenance procedures must be carried out at least once every year by qualified personnel authorised by Asclepion Laser Technologies.

Tip

Upon request, the manufacturer will provide to authorized service technicians a service Manual containing circuit diagrams, component parts lists, descriptions, calibration instructions, and other technical information not contained in this User Manual, to assist appropriately qualified technical staff to perform maintenances and repairs, where possible. In this context, “authorized technicians” and “appropriately qualified technical staff” mean staff that attended a manufacturer’s service training course on this device and that was authorized to repair it.

Additional information

The user must write in the Machine LogBook (delivered with the machine) each maintenance performed on the machine. Necessary condition to access the warranty conditions from the manufacturer is the fulfilment of all the maintenances and their communication in written to the producer (copy of the LogBook).

15 Accessories

Name	Code	Quantity
Interlock connector	N21901	1
Footswitch	E094B1 E06301 (optional)	1
System key	--	2
Mains cable	--	1
Safety labels	See chapter 6.9	1 set
Door safety labels	079101200	2
Operator's Manual	See code on the footer	1
CO_2 laser safety glasses for physician	070100077	2
Aiming beam protective eyewear	070100078	2
Laser safety eyewear for patient	070100054	1
CO_2 laser safety glasses for physician for direct beam exposure	070100047	optional
Aiming beam protective eyewear	070100056	optional for 70100047
"USER ID" chip	iBM103U	1
5mm Allen wrench	041100082	1
Accessories case	070400110	1
Low temperature recorder	030600866	1
CO_2 hollow fiber pole	04364170A	1
CO_2 hollow fiber holder	04244152B	1
Fiber pole passing hole	04244070A	1
CO_2 500µm hollow fiber 2m SMA 905 SingleUse (5x)	HAF005001	optional
CO_2 500µm hollow fiber 2m SMA 905 PluriUse (1x)	HAF005003	optional
CO_2 hollow fiber cutter	070002090	optional
CO_2 hollow fiber stripper	070001567	optional
1.5" handpiece *including* 1.5" focal assembly Handpiece body Spacer Handpiece case	F26301 N76601 N77101 04370010B 070400108	optional
2" handpiece *including* 2" focal assembly Handpiece body Spacer Handpiece case	F26401 N76701 N77101 04370010B 070400108	optional
4" handpiece *including* 4" focal assembly Handpiece body Spacer Handpiece case	F26501 N76801 N77101 04370012A 070400108	optional

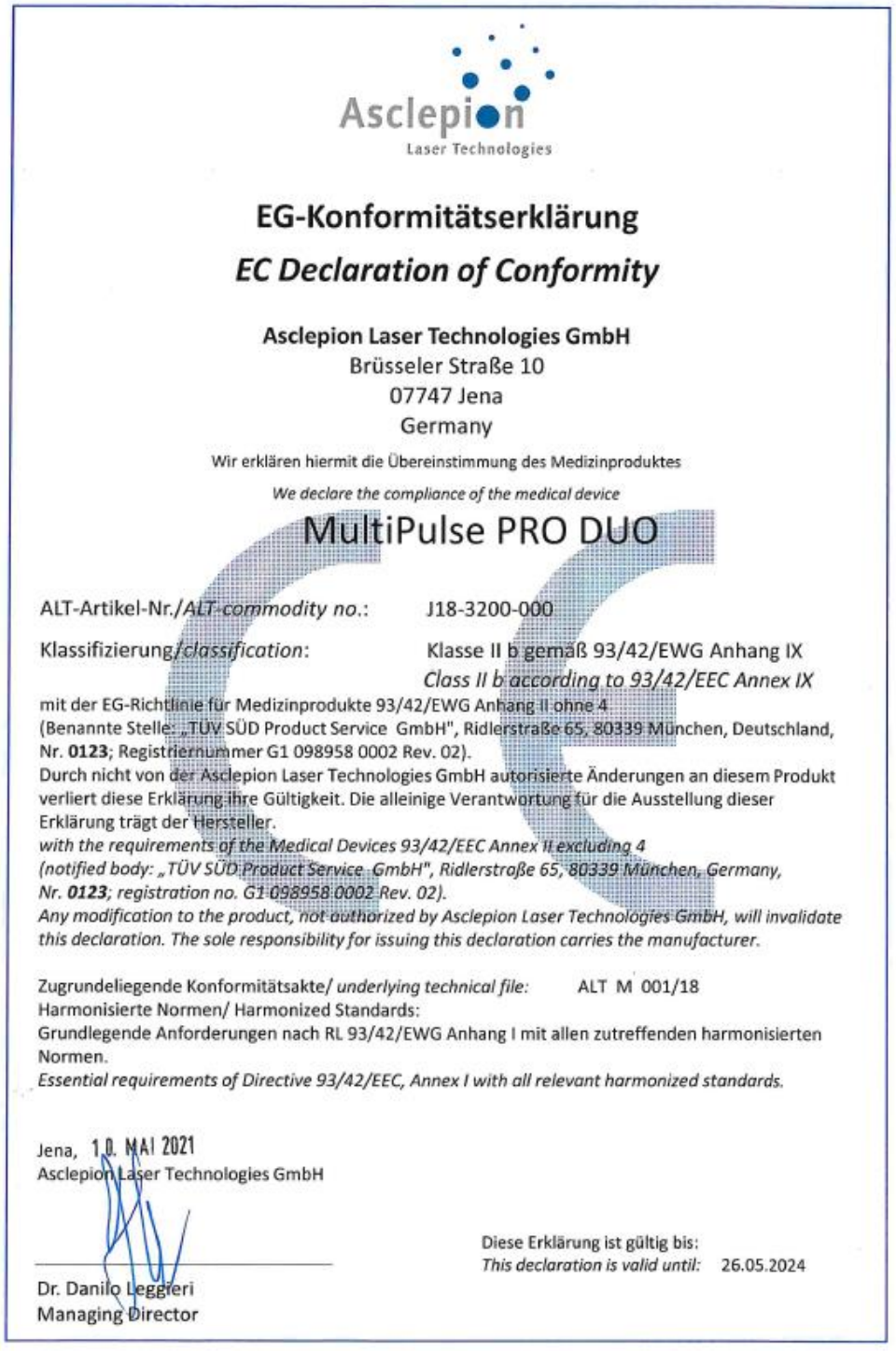
Name	Code	Quantity
5" handpiece	F28001	
including		
5" focal assembly	N77801	
Handpiece body	N78001	
Straight tip	04370017B	optional
Tip with backstop	04370018B	
90° tip	N83101	
120° tip	N83001	
Handpiece case	070400120	
7" handpiece	F26601	
including		
7" focal assembly	N76901	optional
Handpiece body	N77101	
Spacer	04370012A	
Handpiece case	070400108	
8" handpiece	F28101	
including		
8" focal assembly	N77901	
Handpiece body	N78401	optional
Straight tip	04370022B	
Tip with backstop	04370023B	
Handpiece case	070400121	
Collimated handpiece	F26701	
including		
Collimated focal assembly	N77001	optional
Handpiece body	N77101	
Spacer	04370012A	
Handpiece case	070400108	
HiScan DOT unit	F269B1	
including		optional
HiScan DOT head	E109R1	
HiScan DOT cable	W00457	
HiScan Surgical unit	F27001	
including		
HiScan Surgical head	E165A1	optional
HiScan cable	N74801	
Remote control	N64501	
EndoScan unit	F26801	
including		
EndoScan head	N77501	optional
EndoScan cable	N74901	
Remote Control	N64501	
EasySpot Hybrid Micromanipulator	N183F1	optional
EasySpot Micromanipulator	N183G1	optional
2" dental handpiece for CO_2 source (FL 2")	N81601	
including		
120° tip	N81901	Optional
straight tip with spacer	04375014A	
straight tip	04375015A	

Name	Code	Quantity
4" dental handpiece for CO_2 source (FL 4")	N81501	
including		
120° tip	N81801	
105° tip	N81701	Optional
Straight tip	04375011A	
Tapered Perio tip	04255044A	
Straight Perio tip	04255049A	
Endonasal probes kit 86mm	F27901	Optional
including		
Handpiece for endonasal probes	N34601	1
Hollow flexible waveguide 86 mm	N76501	2
Straight endonasal probe 86 mm	04283016A	2
90° endonasal probe 86 mm	04283018B	2
Accessories for laparoscopy:		
400 mm focal for laparoscope	N759A1	
300 mm focal for laparoscope	N75901	Optional
Direct Coupler	04366003A	
Connection for STORZ laparoscope	04366004A	
Option handpieces for CO_2 hollow fiber		
Fiber Handpiece 14 ga, 340 mm, 20° Bend, Spatula Tip	070600006	Optional
Fiber Handpiece 14 ga, 340 mm, 20° Bend	070600007	Optional
Fiber Handpiece 14ga, 400 mm, Rigid, Spatula Tip	070600008	Optional
Fiber Handpiece 230 mm 14 ga, Straight, Spatula Tip	070600009	Optional
Fiber Handpiece 386 mm, 14 ga, 75.1 mm bend, Rigid, 30.7 mm Bend at Tip	070600010	Optional
Fiber Handpiece 290 mm, 14 ga, Straight, Spatula Tip	070600011	Optional
Fiber Handpiece 190 mm, 14 ga, Straight, Spatula T	070600012	Optional
Fiber Handpiece 230 mm, 14ga 35 Degree Bend, Spatula Tip	070600013	Optional
Fiber Handpiece 240 mm, 14 ga, 35 Degree Bend, 30.7 mm Radius Tip	070600014	Optional
Fiber Handpiece 190 mm 14 ga, 35 Degree Bend and Spatula	070600015	Optional
Fiber Handpiece 190 mm 14 ga, 35 Degree Bend, 30.7R	070600016	Optional
Fiber Handpiece 60 mm 14 ga, 15 Degree Bend, Spatula Tip	070600017	Optional
Fiber Handpiece 130 mm 14 ga, 15 Degree Bend, 30.7R Spatula Tip	070600018	Optional
Fiber Handpiece 14 ga, 90 mm, Malleable	070600019	Optional
Fiber Handpiece 14 ga, 140 mm, Malleable	070600020	Optional
Fiber Handpiece 14 ga, 240 mm, Malleable	070600021	Optional
Fiber Handpiece 14 ga, 300 mm, Malleable	070600022	Optional
Fiber Handpiece 14 ga, 60 mm, straight tip	070600023	Optional
Fiber Handpiece 14 ga, 180 mm, straight tip	070600024	Optional
Fiber Handpiece 14 ga, 60 mm, straight, curved tip	070600025	Optional
Fiber Handpiece 14 ga, 140 mm, straight, curved tip	070600026	Optional

Name	Code	Quantity
Fiber Handpiece 14 ga, 180 mm, straight, curved tip	070600027	Optional
Fiber Handpiece 14 ga, 240 mm, bent, curved tip	070600028	Optional
Fiber Handpiece 14 ga, 140 mm, bent, straight tip	070600029	Optional
Fiber Handpiece 14 ga, 240 mm, bent, straight tip	070600030	Optional

16 Declaration of Conformity

This is an exemplary figure. The original certificate can be requested from Asclepion Laser Technologies GmbH.



Asclepion
Laser Technologies

EG-Konformitätserklärung

EC Declaration of Conformity

Asclepion Laser Technologies GmbH
Brüsseler Straße 10
07747 Jena
Germany

Wir erklären hiermit die Übereinstimmung des Medizinproduktes

We declare the compliance of the medical device

MultiPulse PRO DUO

ALT-Artikel-Nr./*ALT-commodity no.*: J18-3200-000

Klassifizierung/*classification*: Klasse II b gemäß 93/42/EWG Anhang IX
Class II b according to 93/42/EEC Annex IX

mit der EG-Richtlinie für Medizinprodukte 93/42/EWG Anhang II ohne 4
(Benannte Stelle: „TÜV SÜD Product Service GmbH", Ridlerstraße 65, 80339 München, Deutschland, Nr. **0123**; Registriernummer G1 098958 0002 Rev. 02).
Durch nicht von der Asclepion Laser Technologies GmbH autorisierte Änderungen an diesem Produkt verliert diese Erklärung ihre Gültigkeit. Die alleinige Verantwortung für die Ausstellung dieser Erklärung trägt der Hersteller.
with the requirements of the Medical Devices 93/42/EEC Annex II excluding 4
*(notified body: „TÜV SÜD Product Service GmbH", Ridlerstraße 65, 80339 München, Germany, Nr. **0123**; registration no. G1 098958 0002 Rev. 02).*
Any modification to the product, not authorized by Asclepion Laser Technologies GmbH, will invalidate this declaration. The sole responsibility for issuing this declaration carries the manufacturer.

Zugrundeliegende Konformitätsakte/ *underlying technical file:* ALT M 001/18
Harmonisierte Normen/ Harmonized Standards:
Grundlegende Anforderungen nach RL 93/42/EWG Anhang I mit allen zutreffenden harmonisierten Normen.
Essential requirements of Directive 93/42/EEC, Annex I with all relevant harmonized standards.

Jena, 10. MAI 2021
Asclepion Laser Technologies GmbH

Dr. Danilo Leggieri
Managing Director

Diese Erklärung ist gültig bis:
This declaration is valid until: 26.05.2024

Appendix: EMC manufacturer's declaration

Electromagnetic emissions

The MultiPulse PRO DUO is intended for use in the electromagnetic professional healthcare facility environment specified below. The customer or the user of the MultiPulse PRO DUO system should assure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic environment
RF Emission CISPR 11	Group 1	The MultiPulse PRO DUO system uses RF energy only for its internal function. Therefore, its RF emission are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emission CISPR 11	Class A	The emission characteristics of MultiPulse PRO DUO system make it suitable for use in industrial areas and hospitals. If it is used in a residential environment, this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment
Harmonic emissions IEC 61000-3-2	NA*	
Voltage fluctuation/ flicker emissions IEC 61000-3-3	Complies	

* Professional use P>1 kW

Electromagnetic immunity

The MultiPulse PRO DUO system is intended for use in the professional healthcare facility environment specified below. The customer or the user of the MultiPulse PRO DUO system should assure that it is used in such an environment

Immunity test	Test level acc. IEC 60601-1-2/ Compliance level	Electromagnetic environment
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV , ± 4 kV , ± 8 kV , ± 15 kV air	Floors should be wood, concrete, or ceramic tiles. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV 100 kHz repetition frequency	Mains power quality should be that of a typical commercial and/or hospital environment.
Surges IEC 61000-4-5	± 1 kV differential-mode ± 2 kV common mode	Mains power quality should be that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage fluctuations of power supply input lines IEC 61000-4-11	UT=0 %, 0.5 cycle (0, 45, 135, 180, 225, 270 and 315°) UT=0 %; 1 cycle and UT=70 %; 25/30 cycles, single phase: at 0° UT=0 %; 250/300 cycles	Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50 or 60 Hz) magnetic field IEC 61000-4-8	30 A/m	The magnetic field strength should be at levels typical for commercial and/or hospital environments.

The MultiPulse PRO DUO system is intended for use in the professional healthcare facility environment specified below. The customer or the user of the MultiPulse PRO system should assure that it is used in such an environment.

<table>
<tr><th>Immunity test</th><th>Test level acc.
IEC 60601-1-2</th><th colspan="3">Electromagnetic environment guidelines</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 V_{rms}
150 kHz ÷ 80 MHz</td><td colspan="3">WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the MultiPulse PRO DUO) including cables specified by the manufacturer.
Otherwise, degradation of the performance of this equipment could result.</td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz ÷ 2.7 GHz</td><td colspan="3">WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the MultiPulse PRO DUO) including cables specified by the manufacturer.
Otherwise, degradation of the performance of this equipment could result.</td></tr>
<tr><td rowspan="19">Proximity field from wireless transmitters
IEC 61000-4-3</td><td colspan="2">Test frequency [MHz]</td><td>Immunity test level [V/m]</td><td rowspan="19">WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the MultiPulse PRO DUO) including cables specified by the manufacturer.
Otherwise, degradation of the performance of this equipment could result.</td></tr>
<tr><td colspan="2">385</td><td>27</td></tr>
<tr><td colspan="2">450</td><td>28</td></tr>
<tr><td colspan="2">710</td><td rowspan="3">9</td></tr>
<tr><td colspan="2">745</td></tr>
<tr><td colspan="2">780</td></tr>
<tr><td colspan="2">810</td><td rowspan="3">28</td></tr>
<tr><td colspan="2">870</td></tr>
<tr><td colspan="2">930</td></tr>
<tr><td colspan="2">1720</td><td rowspan="3">28</td></tr>
<tr><td colspan="2">1845</td></tr>
<tr><td colspan="2">1970</td></tr>
<tr><td colspan="2">2450</td><td>28</td></tr>
<tr><td colspan="2">5240</td><td rowspan="3">9</td></tr>
<tr><td colspan="2">5500</td></tr>
<tr><td colspan="2">5785</td></tr>
</table>

CABLES AND ACCESSORIES WITH WHICH COMPLIANCE TO EN 60601-1-2 EMC REQUIREMENTS IS CLAIMED	
Interlock connector	N21901
Foot switch	E094B1 / E06301
Mains cable	021300051
1.5" handpiece	F26301
2" handpiece	F26401
4" handpiece	F26501
5" handpiece	F28001
7" handpiece	F26601
8" handpiece	F28101
Collimated handpiece	F26701
HiScan Surgical	F27001
EndoScan unit	F268B1
500 µm CO2 hollow fiber	–
Micromanipulator	N183F1/G1

NOTE

The use of accessories, transducers and cable other that those above specified may increase electromagnetic emission and decrease electromagnetic immunity.