

lateral exposure. The American Optical spectacle-type safety glasses, or equivalent, provide ample protection. Safety eyewear is not required when viewing through a microscope, colposcope or endoscope, as the glass lenses of these instruments provide sufficient protection.

2.5 Patient Safety

For enhanced patient safety, perform the following safety procedures:

1. surround the surgical area with wet towels.
2. Make sure that safety eyewear is available to the patient, if conscious.
3. For facial surgery, completely cover the patient's eyes with moistened eye pads.

2.6 Exposure and Fire Hazard

Do not operate the unit in the presence of volatile substances (or flammable anesthetics) such as alcohol, gasoline or solvents.

2.7 High Voltage Hazard

The SYKON CO2 laser systems generates high voltages within the main case. To avoid injury, do not attempt to remove or disassemble any panels. Only Multimage s.r.l authorized technical person may service the unit.

2.8 Using the Proper Power Receptacle and Plug

Use only the power receptacle and plug specified for your unit.

Use only a power receptacle and plug that are in good condition.

Use only a hospital grade plug and a correctly matched power receptacle.

To remove the power cord from the receptacle, hold it by the plug.

Never pull on the power cord to remove the plug from the receptacle.

2.9 Water proof of foot switch

IPX5 Class Foot switch is perfectly protected against any possible vibration. Water Proof is secured in any direction under the condition of 3m distance, 12.5L/min, 30 kpa, in 3 min. Do not use in any excess conditions.

2.10 Grounding the Unit

The unit is grounded through the grounding conductor in the power cord.

Good grounding is essential for safe operation. To ensure grounding reliability, always plug the power cord into a properly wired hospital grade power receptacle.

Additional grounding can be provided by using the external ground connection point(see 3.4).

2.11 Fuse Replacement

The user may replace a line fuse that is located beside the power cord connection on the auxiliary panel. To avoid fire hazard, use only the fuse specified for your unit. Replacement fuse must be identical in type, voltage rating and current rating to the original fuse.

(Warning : Before removing a fuse, turn off the key switch, remove the power cord from the ac outlet.)

2.12 Compliance with International Standards

The SYKON CO2 laser systems complies with: U.S Federal Performance Standards 21 CFR 1040.10 and 21 CFR 1040.11 for Class IV laser products

European Directive 93/42/EEC Concerning Electromagnetic Compatibility.

The SYKON CO2 laser system is designed to comply with the IEC601-1 Standard for safe Use of Electromedical Equipment, the IEC 825-1 Safety of Laser Products – Equipment Classification Requirement, and the User's Guide for Class IV Laser Products.

In compliance with these standards, the SYKON CO2 laser systems incorporates an emission indicator, a CO2 laser beam shutter, a power display, a master key switch and proper labeling.

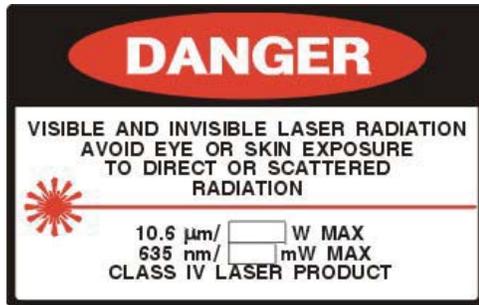
The systems also incorporates an input power transformer that ensures a leakage current of less than 150 μ A.

In accordance with these regulations, a recommended routine inspection and maintenance schedule is provided in the maintenance chapter of this manual.

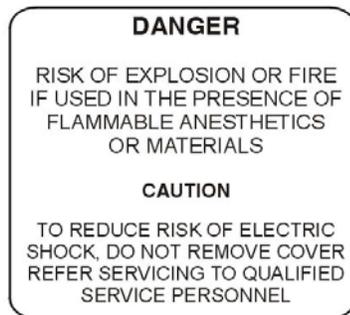
2.13 Warning and Identification

The important labels affixed to the unit. These include:

1. Laser emission danger label – warning against possible exposure to laser radiation and specifying the types of laser present.



2. Non-interlocked warning label-warning against.
 - a. Risk of explosion if used in the presence of volatile substances.
 - b. Possible electrical shock when cover is removed.
 - c. Possible radiation exposure.



3. Attention label – instructing the user to use only the tab to lift the articulated arm.



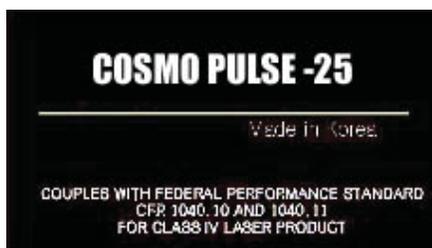
4. Electric shock warning label – warning user to properly ground the unit, and against opening the unit’s cover.



5. Identification label – noting unit model number, serial number, electrical requirements, date of manufacture and address.



6. Certification label – assuring that the unit complies with U.S. Federal Performance Standards.



7. Laser aperture warning label – indicating laser beam exit location.



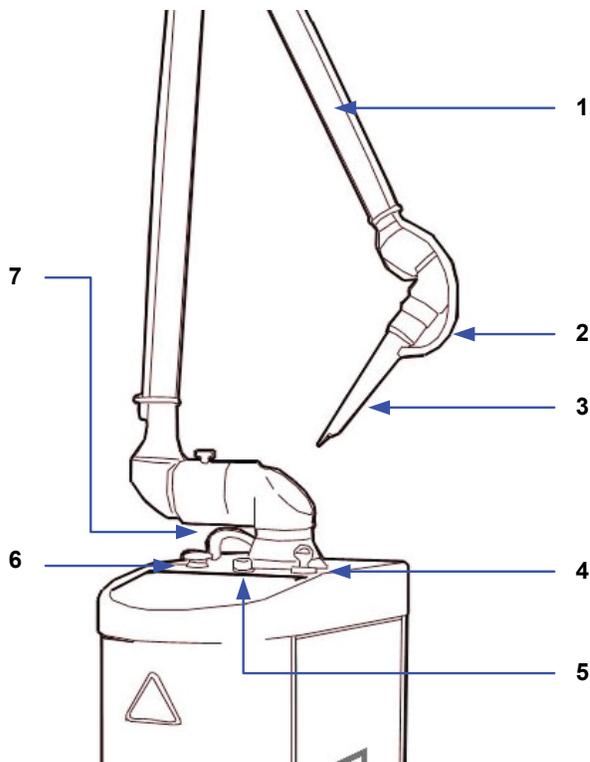
System Description

3.1 General

The following is a description of the SYKON CO2 laser systems controls, indicators and connection points according to location.

3.2 Main Cabinet and Articulated Arm

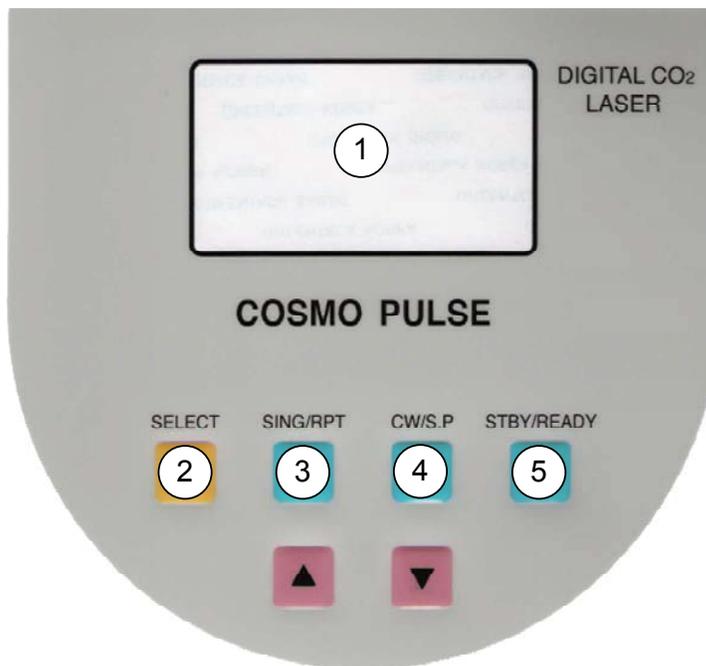
Refer to figure as below for items 1 through 7.



1. **7-Joint Articulated Arm** – laser and aiming beam comes out through this arm
2. **Air Hose** – the air flows through this hose to the handpiece
3. **Handpiece** - recommended using Alcohol for cleaning
4. **Main S/W** - when the master “**I**” position, power is supplied to the unit. Turning the key counter clockwise to the “**O**” position turns off the unit. The key should be removed whenever the unit is left unattended
5. **Emergency S/W** - emergency Power down.
6. **Aiming beam control Knob** – adjust the brightness of aiming beam(red light)
7. **Air Flow Connection** - connection point for attaching the silicone tube to the compressed air flow system.

3.3 Control Panel

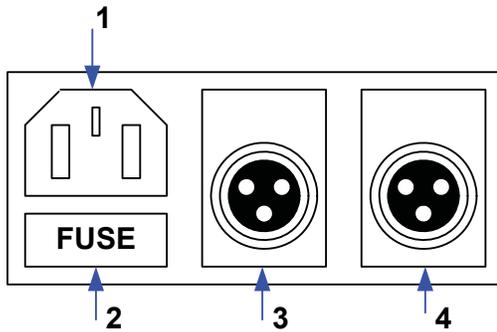
Refer to figure as below for items 1 through 5.



1. **Display panel** : LCD display panel
2. **SELECT** : move powers, emission modes and times by cursor on display.
3. **SING/RPT** : set single , repeat, continuous of emission mode.
4. **CW/S.P** : set cw(continuous wave) and SP(Super and Pulse)
5. **STBY / RDY** : stand by / ready position.

3.4 Rear Panel

Refer to figure as below for items 1 to 5.



1. **Line Connection** – connection point for the AC power cord
2. **Line Fuses** – installation point for line fuse.
3. **Door Interlock** - connection point for an external remote interlock switch.
4. **Foot S/W Connection** – Connection point for footswitch cable.

3.5 System specifications

1. Outputs

Laser : Seales-off, DC-excited CO2 Laser

Wavelength : 10.6microns,infrared

Mode Structure : TEM₀₀ (Gaussian)

Power on tissue :

Continuously adjustable power on tissue in the following ranges:

CW : 1 ~ 30W

SUPERPULSE : Average power range : 0.5~ 7W

Peak power : ~ 200W in 0.1 ~ 7W range

(energy for stapedectomy: 12mJ)

Aiming Beam :

Diode Laser 635nm / 1mw (Class II)

Spot Size :

From 0.1mm, focused at 50mm working distance, to 6.7mm,
fully defocused at 400mm working distance.

Delivery System :

Lightweight, aluminum pipe, 7 JOINT ARTICULATED ARM

2. Operation and Control

Microprocessor-based, soft-touch control panel.

3. Input

Electrical Power : 230Vac 50/60Hz, ±10%, according to order

Cooling System : Closed circuit with water

Air Flow system : Provides air flow at the surgical accessory

4 Physical

Dimensions :

Width : 180 mm

Depth : 290 mm

Height : 1120 mm

BASE : 380mm X 480mm

Weight : 45Kg

Delivery System :

Working radius at full arm extension – 1200 mm (s' = 1700mm)

Horizontal rotation of delivery system – 360°

Completely foldable for storage in the articulated arm compartment at rear of unit

5. Standard Accessories

Handpiece Set : Focusing handpiece assembly for 100mm or 50mm working distance

3.6 Environment conditions

Operation temperatures	15°C ~ 30°C
Storage temperatures	0°C ~ 55°C
Relative humidity - operating	up to 80%
Relative humidity - storage	up to 90%