BVLASER

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medical & aesthetic
devices manufacturer

13 YEARS

OPERATION MANUAL

CO2 Laser Machine

User Manual

LUME PRO

NANJING BV LASER S&T Co., Ltd.

Caution: Federal law restricts this device to sale by or on the order of a physician!

Contents

CAUTION

To ensure safe operation and continued usage over time, please read the following manual completely before operating this device. Keep this manual in a readily accessible area to be referred to at any time.

1. Introduction

- ☞ This manual describes how to use this machine safely.
- ☞ Review the manual carefully before operating this device. Carefully review proper maintenance procedures.
- ☞ All operators of this device must carefully study this manual to become familiar with the proper and safe operation of the device.

2. Indications of dangers, warnings, and cautions

To ensure the safe operation of the device and to prevent extraneous accidents from occurring, it is highly recommended that the contents of this manual are thoroughly studied and followed. This includes studying all warnings and provided signs, which detail the inherent danger when using this device.

Warning labels should be unobstructed and easily viewable.

Promptly replace all stained or detached labels with new labels.

Contact the BV LASER sales office when new labels are needed.

Symbols, signs, and/or signal words which attract the users' attention

DANGER **Indicates an immediate hazard to patients, operators, staff, or the device.**

WARNING **Indicates a potential hazard to patients, operators, staff, or damage to the device.**

CAUTION **Highlights errors to prevent unwarranted injury or damage to the device.**

Be sure to follow the instructions when you operate the device.

Use the device and/or maintenance device incorrectly, may lead to an electrical shock.

Indicates the possibility of exposure to hazardous laser radiation that could result in serious injury to the operator, patient, or staff.

Fire hazard. Take care to avoid flammable material.

Indicates prohibited actions.

Highlights a requirement that must be adhered to.

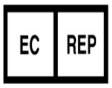
Be sure the electrical sources are properly grounded.

Wear eye protection.

Disconnect the main plug from an electrical outlet.

Refer to the user's manual.

Manufacturer



European authorized representative information

Production Date

EU product safety certification authority and code

B type application device

3. Indications For Use

The CO2 laser machine is used for human tissue vaporization, coagulation in dermatology and plastic surgery, general surgery, gynecology, podiatry, dental, and otorhinolaryngology.

Chapter 1 Introduction

1.1 Use of this Manual

The CO2 laser machine is designed to meet international safety and performance standards. Personnel operating the system must have a thorough understanding of the proper operation of the CO2 laser machine. This manual has been prepared to aid medical and technical personnel in the use and operation of the system. Do not operate the system before reading this manual and gaining a clear understanding of system operation. If any part of this manual is not clear, please contact your service representative for clarification.

The information provided in this manual is not intended to replace the professional training on the clinical use of the system. Please contact your service representative for current information on available training. For clinical information, refer to the Clinical Guide in this manual, which includes set up guidelines for each application.
This manual should always accompany the system and all operating personnel must know its location. Additional copies of this manual are available from BV LASER or your service representative.

1.2 Physician Responsibility

Federal (USA) law restricts the prescription of medical devices for sale by or on the order of a physician or properly licensed paranthe petitioner. The properly licensed practitioner will be responsible for the use and operation of the device and for all operator qualifications.BV LASER makes no representations regarding federal, state, or local laws or regulations that might apply to the use and operation of any medical device. The physician is responsible for contacting his or her local licensing agencies to determine any credential required by law for clinical use and the operation of the device.

1.3 Maintenance

The CO2 laser machine is a precision-based medical device that requires periodic routine maintenance, which must be performed by BV LASER authorized technician. Failure to adhere to the aforementioned maintenance guidelines will void all warranties, expressed and implied. Please contact BV LASER or your service representative for details.

1.4 Modification of the System

Unauthorized modification of the hardware, software, or specifications of the CO2 laser machine voids all warranties, expressed and implied. BV LASER takes no responsibility for the use or operation of such a modified device.

1.5 Resale Inspection

The CO2 laser machine is a precision, technical medical device. If any BV LASER device is resold by anyone other than an authorized sales representative, BV LASER offers a resale inspection by the BV L A S E R technician to assure that the device is working and by manufacturer specifications.
Using the deviceafter it has been resold and before it has been inspected is a misuse of the device.
This may result in injuriesand voids all warranties, expressed and implied.

BV LASER also offers service contracts and extended warranties for its devices. Please contact BV LASER or your service representative for more information about these services.

1.6 Abbreviations and Acronyms

"	Inches
℃	Degree(s) Centigrade/Celsius
℉	Degree(s) Fahrenheit
A	Ampere (s)
AC	Alternating current
CFR	Code of Federal Regulations
cm	Centimeter(s)
CW	Continuous wave
Hz	Hertz
IEC	International Electrotechnical Commission
IVF	*In vitro* fertilization
J	Joule(s)
J/ c ㎡	Joule(s) per square centimeter
Kg.	Kilogram(s)
Lbs.	Pound(s)
LCD	Liquid crystal display
LED	Light emitting diode
m	Meter(s)

mm	Millimeter(s)
msec	Millisecond
nm	Nanometers
OD	Optical density
Sec	Second(s)
SPF	Skin protection factor
V	Volt(s)
VAC	Volt(s) AC
W	Watt(s)

Chapter 2 Safety

2.1 Introduction

This chapter describes general safety issues regarding the use of the CO2 laser machine, with a special emphasis on optical and electrical safety.

The CO2 laser machine can emit high-intensity infrared laser radiation that can potentially cause serious damage to soft tissue, especially the eyes. Therefore, to avoid serious injury, all doors and windows in the treatment room should be properly equipped with high-density shading materials to protect them from inadvertent exposure. There must be warning signs outside the treatment room.

The CO2 laser machine focuses on two aspects: functionality and safety. This system is designed with a comprehensive safety inspection protocol that aims to reduce risk to the user and patient. Considering the high-intensity and energy output of the laser during operation, all relevant staff must abide by the mentioned precautionary measures. Before beginning operation, check whether applicable accessories are installed correctly, in addition, whether the power cord is fully intact. Finally, confirm that all pertinent staff is wearing goggles.

CAUTION

Federal law (USA) restricts this device to only be sold to or on the order of a physician or any practitioner licensed by the law of the state in which he or she practices or intends to use or order the device.

The CO2 laser machine operates at a wavelength of 10600nm. The system has been specially designed to minimize accidental exposure to hazardous radiation.

With proper operation and maintenance, trained and qualified medical practitioners can use the system safely. The supervising physician and all other personnel operating or maintaining the CO2 laser machine must be familiar with the safety information provided in this chapter.

The primary consideration should be for the safety of the patient, the physician, and other personnel. Patient safety is mainly assured with a well-trained staff and a well-laid out treatment room. Patient education is also important, including information about the nature of the treatment.

2.2 System Safety Measures

The CO2 laser machine is designed to maximize safety for both the patient and operating personnel. The following are some of the system's preventive safety measures.

2.2.1 Electrical Safety

Keep all covers and panels of the laser system closed because removing the covers creates a safety hazard.

Some components may remain a charge after the power supply has been turned off, so no part of the exterior housing should be removed, except by BV LASER authorized personnel.

The device is grounded through the grounding conductor in the power cable. This protective grounding is essential for safe operation.

WARNING

This product's protective earthing terminal has been marked under the relevant standards. Maintenance personnel should check whether the protective earthing wires having a good connection by the requirements before finishing debugging.

WARNING

To avoid the risk of electric shock, this device must only be connected to a supply main that is properly grounded.

Be sure to get familiar with the components and specifications of the instrument before use.

Do not perform maintenance work, which is not recommended in the user manual.

WARNING

Opening the exterior housing may expose the user to hazardous optical radiation and electrical voltage--even after the laser has been turned off.

Do not operate the device if the power cord is frayed or otherwise damaged.

Do not soak or spray the laser console, handle, or touch-screen in fluids because this can result in damage to the equipment and electrical shock.

Clean the touch screen only when the system is shut down and disconnected from the electrical power source.

A fuse, located on the service panel, protects the system by tripping when power overload occurs. To resume normal operation, built-in safety measures as following:

- Software checks of all safety-related hardware after the system is switched on.
- A watchdog cycle continuously monitors the operation of the system during operation.
- If an error occurs, the system displays a warning message to the operator and disables further operation.

A self-test of the electrical circuitry takes place after the system is turned on. The test circuits continuously monitor system operations during treatment.

2.2.2 Laser Safety

The fractional arm and handle are used to transmit laser to the treatment of parts.
An emergency shutoff button expedites the shutdown process when necessary. When pressed, it immediately shuts down system operation.

Laser emission (from the laser handle) is enabled only when the footswitch is pressed.

WARNING

Any laser-emitting device can cause injury if used improperly. Personnel who work with lasers must always be aware of the possible dangers and must take the proper safeguards as described in this manual.

2.3 The Operating Room

The operating room must be marked with signs warning that a high-intensity laser device is using. The sign provided with the CO2 laser machine is shown in Figure 2-1.

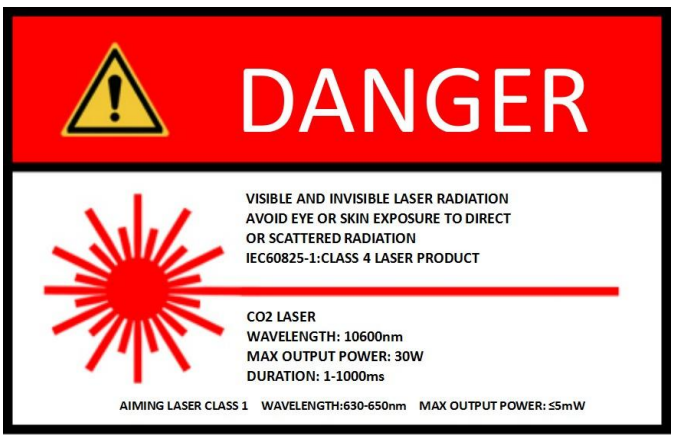


Figure 2-1: Operating Room Warning Sign

The operating room should not have any light-reflecting objects such as mirrors.

Only essential personnel who are properly trained and qualified in the safe operation of the CO2 laser machine should have access to the device.

Please ensure that all operating room personnel are familiar with the CO2 laser machine controls and can appropriately disable the system immediately when necessary.

2.4 General Precautions and Warnings

The following precautions and warnings must be observed to ensure safe use of the CO2 laser machine.

2.4.1 Precautions

- Physicians and clinicians should read this manual thoroughly before operating the machine.
- The lens of the handle must be kept clean at all times.

2.4.2 Warnings

- Only personnel authorized by BV LASER can service the CO2 laser machine. This includes making internal adjustments to the power supply, cooling system, optics, handles, etc.
- Please verify that the CO2 laser machine is wired for the appropriate electrical voltage of your country (110 VAC).
- Maintenance performed by the operator must only take place when the system is shut down and disconnected from the electrical power source. Performing maintenance procedures with the system powered-up can be hazardous to the operator and/or destructive to the system.
- Always turn off the system when it is not in use.
- Never leave the system unattended in **Ready** mode.
- Never allow untrained personnel to operate the system.
- Never press the footswitch unless the handpiece is safely aimed at a specific target.
- Never leave the system turned on, open, or unattended during system maintenance.

2.5 Warnings about Laser Exposure

2.5.1 Burn Hazards

Radiation emitted from the CO2 laser machine with a wavelength of 10600nm, is invisible to the human eye and can cause third-degree burns.

2.5.2 Direct and Reflected Eye Exposure Hazards

It is essential that all people (patient and medical personnel) present in the operating room during the operation protect their eyes with BV LASER recommended protective eyewear.

It is better to close their eyes during treatment even if wearing protective eyewear.

If the patient cannot wear the protective eyewear, fit the patient with opaque eye protection that completely blocks light from reaching the eyes.

If the treatment area is near the eyes (e.g. eyelids), protect the eyes with corneal shields.

WARNING	
	**CO2 laser radiation can cause serious eye damage even blindness. Do not treat eyebrows, eyelashes, or other areas within the bony area surrounding the eye. For maximum safety, the patient must wear metal eye goggles for all facial treatments.**

DANGER	
	**While operating the laser system, never look directly into the laser aperture at the distal end of the handpiece, even if you are wearing laser safety glasses. Please be aware that during normal operation, the nominal ocular hazard distance (NOHD) of the system is 10m.** **Never direct the laser beam at anything other than the intended treatment area. Stray laser light and its reflection are always a potential hazard and may cause serious eye injury.**

DANGER	
	**Eye safety precautions :** **Identify the operating room clearly by posting approved operating safety signs in prominent locations.** **Cover all windows to prevent the laser beam from escaping the operating room.** **Restrict access to the operating room when the device is in use. Allow access only to personnel who are trained in the operation of the device.** **Ensure that the footswitch is clean and working properly. Place the footswitch where it will not be confused or mistaken.**

2.5.3 Safety Eyewear

WARNING

CO2 laser radiation is hazardous to the human eye. All personnel must use safety eyewear that provides adequate protection (OD>5) at 10600nm radiation. Safety glasses and opaque eye protectors are supplied with the system. Additional protective eyewear can be ordered from your BV LASER **representative. For users outside the U.S., the appropriate standard may be EN 207, in which case the safety eyewear must have a protection class of L5.**

2.5.4 Explosions and Fire Hazards

The absorption of optical energy raises the temperature of the absorbing material. Take precautions to reduce the risk of igniting combustible materials in the treatment area.

The system is not suitable for use in the presence of flammable mixtures with air or oxygen.

If alcohol is used to clean and disinfect the CO2 laser machine, make it dry thoroughly before operating the system.

Flammable materials must be kept at a safe distance from the system.

DANGER

Do not operate in the presence of volatile solvents such as alcohol, gasoline, food, or other solvents.

Do not use any flammable substances such as alcohol or acetone in the preparation of the skin for treatment. If necessary, use soap and water to clean before treatment.

2.5.5 Voltage Hazards

The system utilizes 110VAC. To avoid personnel injury, do not operate the system before ensuring that the exterior panels are properly closed. Do not attempt to remove or disassemble the exterior panels.

Whenever system maintenance is performed, never leave the CO2 laser machine turned on, open, or unattended.

2.5.6 Grounding the System

The device is grounded through the grounding conductor in the power cable.

2.6 System Safety Features

The CO2 laser machine is equipped with many safety features. All operating room personnel should be familiar with the location and operation of these safety features.

2.6.1 Key switch

The key switch connects and disconnects electrical power to the system. Operation of the system is possible only with the key provided by BV LASER This prevents unauthorized use of the device.

Do not leave the device unattended with a key in it.

Verify that the system is inoperable when the key is removed.

2.6.2 Emergency Shut-Off Button

This red button is used for an emergency shutdown. When pressed, it immediately shuts off power to the entire system.

To release the emergency shut-off button, turn it clockwise. Otherwise, the system will remain off.

2.6.3 Cooling System

The device is equipped with a thermoelectric cooler and one fan to ensure the system’s cooling effect.

2.7 Equipment Classification and Compliance

The CO2 laser machine complies with the following standards:

- US Federal Performance Standards 21 CFR 1040.10 and 1040.11 for Class IV Laser Products
- IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety
- IEC 60601-1-2 Medical Electrical Equipment - Part 1: General Requirements for Safety; Electromagnetic Compatibility - Requirements and Tests (General)
- IEC 60601-2-22 Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Diagnostic, and Therapeutic Laser Equipment
- IEC 60825-1 Safety of Laser Products - Part 1: Equipment Classification, Requirements, and User's Guide

The CO2 laser machine should be installed and operated according to CAN/CSA-Z386-01: Laser Safety in the Health Care Facility.

In compliance with these standards, the system is equipped with:

- Key switch
- Emergency shut-off button

- Footswitch connector
- Proper labeling

In accordance with the regulations, a recommended routine inspection and maintenance schedule is provided in chapter 6: **Maintenance**.

2.7.1 Classification of the System according to IEC 60601-1

- **According to the method of protection against electric shock:** the system is Class II equipment.
- **According to the degree of protection against electric shock:** The light arm and laser handpiece are type B applied parts.
- This equipment is not suitable for use in presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

2.8 Device Labels

2.8.1 System Labels

The following **Warning**, **Certification,** and **Identification** labels adhere to the CO2 laser machine:

- Identification Label is affixed to the back of the device. This label contains the following information:
  - Manufacturer's details
  - Name and model number of the system
  - Assurance that the system complies with the US Federal Performance Standards
  - Serial number and date of manufacture
  - The system's electrical requirements
  - Caution: **US FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN**
  - Caution: **Read the User To guarantee proper ventilation, always keep the sides of the system at least 20" (0.5m) from the wall or from other potential obstructions to airflow.**
  - Laser emission warning label, including laser source type and radiation parameters, and indicating that the product is a Class IV device (see Figure 2-3 & Figure 2-4), located on the conspicuous upper position of the device.

Figure 2-3: Warning Label

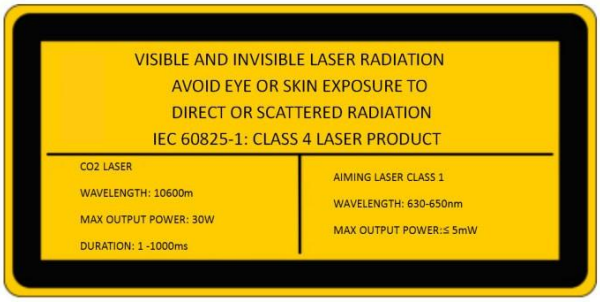


Figure 2-4: Warning Label

Electrical Requirement, located next to the power cable connection port.

Figure 2-5: Electrical Requirement

- ***Laser Emission Danger*** - warns against possible exposure to laser beam radiation.

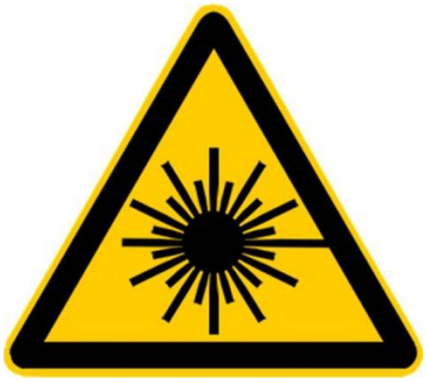


Figure 2-6: Laser Emission Danger Label

- Laser Aperture warning label, located near the tip of the handle:

Figure 2-7: Laser Aperture Warning Label on the Handpiece

Other informative labels placed around the system:

- Footswitch label: it is located on the service panel and marks the footswitch connection port

- The footswitch has a waterproof rating of IPX1.

2.8.2 Package Label

The following labels are attached to the shipping crate of the CO2 laser machine:

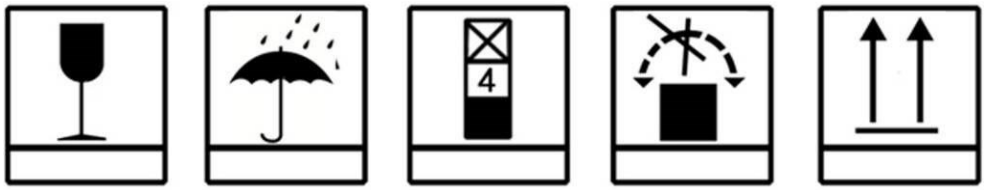


Figure 2-8: Shipping Crate Labels

Chapter 3 Installation

3.1 Introduction

The CO2 laser machine is designed for installation in a hospital or a clinic and requires minimal on-site preparation. When the CO2 laser machine is purchased, complete on-site installation, including initial system testing and calibration is to be performed by the purchaser. A full set of instructions is included in this manual.

Device delivery and installation are carried out by BV LASER authorized personnel. Personnel will provide the following service upon delivery:

- Unpack the system and position it in a pre-selected location
- Verify the integrity of the system and its components
- Connect system components (light arm, handles, foot switch,)
- Plug the system into a designated electrical outlet
- Test the system for functional operation of all components and software
- Coordinate the performance of an on-site safety inspection, if required

CAUTION

Any damage to the packaging found before opening the package should be reported to your BV LASER representative and the insurance carrier.

3.2 Equipment List

The CO2 laser system includes the following :

Picture	Description	Quantity
	Light arm	1

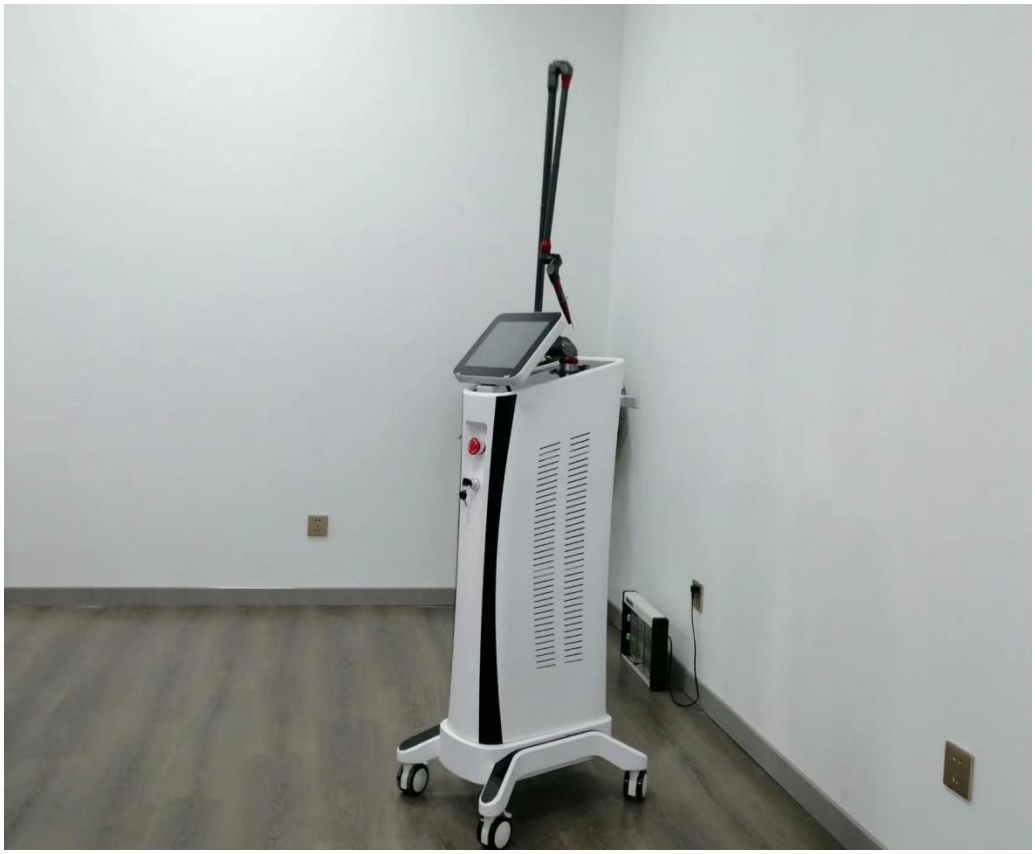
	Plastic clips	5
	Footswitch	1
	Protective glasses (Medical staff)	1
	Protective goggle (Patient)	1
	Power line	1
	Keys	2
	Handle	1

3.3 Facility Requirements

Before unpacking the system, ensure that the operating room meets the requirements described in the following sections.

3.3.1 Space and Positioning

Space should be allocated with adequate ventilation and free airflow. The working area for the system should be prepared according to the system dimensions presented in Figure 3-1. To guarantee proper ventilation, always keep the sides of the system at least 20" (0.5m) from the wall or from other potential obstructions to airflow.



3.3.2 Electrical Requirements

The system is factory pre-wired for the local line voltage, as ordered by the customer. Accordingly, the system will require a separate line supply of:

110 VAC ± 10%, 60 Hz, single phase

Power input lines should be free of transients, voltage, and current spikes, sags, and surges. Consequently, the CO2 laser's power line should not be shared with other heavy variable loads such as elevators, air conditioning systems, large motors, etc.

The system must be provided with a safe and reliable electrical environment. It must not be overloaded with electricity. Otherwise, it will cause the power supply circuit to burn out or even cause a fire. Avoid the

following problems: The power of the power strips cannot meet the requirements, wiring is confusing, the bad insulation of the circuit joint parts, improper handling of the joint parts, the capacity margin of the protection devices such as air switches, fuses, etc. are too small, the plugs in the power socket are loose, the power supply Socket connection wrong line, etc.

The system is grounded through the grounding conductor in the power cable that is plugged into the wall power outlet. Good grounding is essential for safe operation.

CAUTION

Verify that the CO2 laser machine is wired for the appropriate line voltage of your country (110 VAC).

The system should be connected to a separate power line with a separate Cutout Switch. BV LASER **cannot guarantee adequate performance unless the system is connected to a dedicated circuit.**

3.3.3 Environmental Requirements

Air Quality:

The system should be operated in a non-corrosive atmosphere. Corrosive materials such as acids can damage electrical wiring, electronic components, and the surfaces of optical components.

Air-borne dust particles should be kept to a minimum. Dust particles absorb light and heat up. Hot particles located on the optical lenses can damage them. Metallic dust is destructive to electrical equipment.

Temperature:

To ensure that the system performs optimally, maintain the following temperature and relative humidity levels:

- Operating Temperatures: 10℃~ 30℃ (50˚F~ 86˚F)
- Storage Temperatures: -4℃~ 55℃ (25˚F~ 131˚F)
- Transportation Temperatures: -4℃~ 55℃ (25˚F~ 131˚F)
- Operating Relative Humidity: ≤80%
- Storage Relative Humidity: ≤90%
- Transportation Relative Humidity: ≤90%

3.4 Installation

CAUTION

Frequent use can lead to overheating of the device. Therefore, it is recommended that an air conditioner be installed in the room where the system will be used.

3.4.1 Install light arm

Check the connector of the handle and make sure there are no other things dropped inside. Insert the light arm into its pedestal at the back of the screen. Make sure the connection is well done.

Figure 3-1

Figure 3-2

3.4.2 Install treatment head

Screw the connector onto the handpiece. Then, insert its treatment head into the light arm and screw it well.

Figure 3-3

3.4.3 Fix the tube and light arm

Use the three large clips to fix the tube and the thick part of the light arm and the two small clips to the thin part.

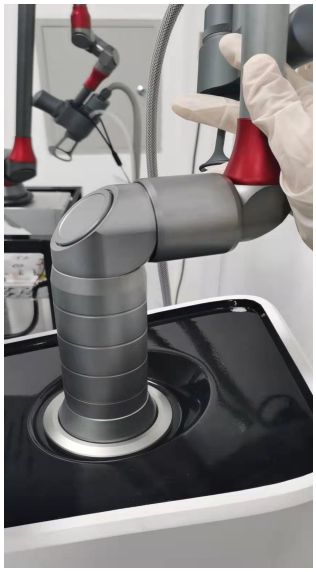


Figure 3-4

Figure 3-5

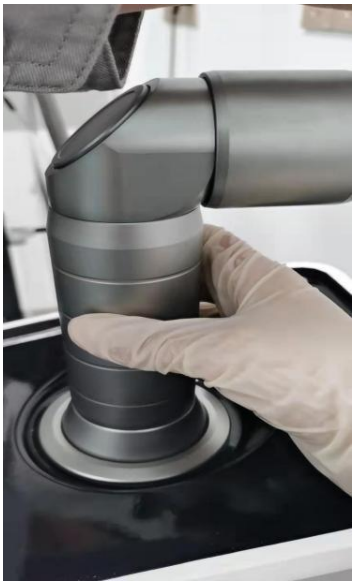


Figure 3-6

3.4.4 Install footswitch

Insert the foot switch into the slot beside the “water inlet” mouth and fix it by tightening the ring clockwise.

Figure 3-7

3.4.5 Install power line

Insert one end of the power line into the corresponding socket and the other end into the preset slot at the back of the host machine.

Chapter 4 System Description

4.1 Introduction

This chapter provides a detailed description of the CO2 laser machine. The description covers the system's main components, controls, functional subsystems, along with system parameters.

4.2 General System Description

CO2 laser machine has two modes, continuous mode and multi-pulse mode. It utilizes CO2 laser to vaporize and heat tissue.

During the treatment, the water in skin tissues absorbs laser energy and then vaporizes.

Laser parameters and other system features are controlled from the control panel on the console, which provides an interface to the system's micro-controller through an LCD touch-screen.

4.3 System Components and Controls

The CO2 laser machine consists of the following major components (see Figure 4-1):

1. The main console unit that incorporates the main CPU board, power supply modules, laser RF power supply, laser device, cooling system, aiming beam system, purging system, and a switching module.
2. Light arm with handpiece
3. Footswitch (not shown).

Figure 4-1: Major System Components

4.3.1 Main Console

The console unit incorporates the following system components:

4.3.1.1 Main CPU Board

This board controls the operation of the sub-systems in real-time. It incorporates an advanced microprocessor, memory chip, and both digital and analog interfaces.

4.3.1.2 Power Supply Modules

Two power supply modules deliver electrical power to the system's components:

- LME5C-S 420W DC25KV– delivers power to the laser power supply
- MSP-450-12 450W DC12V – delivers power to the cooling system

4.3.1.3 Laser power supply, laser device

The CO_2 laser is emitted by the CO2 laser power supply and laser device under the control of the main CPU board.

4.3.1.4 Cooling System

The cooling system consists of a water pump, thermoelectric cooler, fan, and water flow sensor. The cooling system starts automatically when the equipment is started.

4.3.1.5 Air Purging system

In order to prevent the optical element (inside handpiece) from being obscured by the plume produced in the process of treatment, the air purging system is activated when the system starts work.

4.3.2 Control Panel

The system control panel includes the following features (see Figure 4-1):

- **Emergency Shutoff Button** - this is a red, mushroom-like button designed for emergency shutdown of the system.

- **LCD Display Screen** - this touch-controlled screen provides information on the status and settings of the CO2 laser machine. The various screens of the display are described in detail in **Chapter 6 - Operating Instructions**.
- **Key Switch** - turns on the system when activated.

4.3.3 Service Panel

The service panel (see Figure 4-2) is located on the system's backside. It houses all the required controls and connections for the system:

- Power Socket
- Chain Safeguard
- Footpedal

Figure 4-2 Service Panel

CAUTION

To avoid overheating and system malfunction, do not block the airflow into the system.

4.3.4 Footswitch

The footswitch, shown in Figure 4-3, is connected to the system via the footswitch connection port on the service panel (see Figure 4-2). Laser emission occurs only when the footswitch is activated.

The footswitch is enabled only when the system is in **Ready** mode. Pressing the footswitch in **Standby** or any other mode will not activate the laser handpiece.

Fig 4-3 Footpedal

4.3.5 Handpiece

The handpiece is connected to the light arm, which is held by the operator. The handpiece consists of a focus lens, a handpiece body, and a discharge smoke interface.

The lens is used for focusing the light, the focal length is 50.8mm.

The handpiece body is the enclosure of the handpiece, which is used for being held by the operator.

The discharge smoke interface is used for connection with the air pump to blow out the smoke generated during operation.

Fig 4-4 Handpiece

4.4 User-Selectable Operating Parameters

The user may adjust system controls by setting values for the following parameters:

1. Power
2. Duration
3. Interval

For detailed instructions on setting the operating parameters, refer to **Chapter 5 - Operating Instructions**.

4.4.1 Pause in Operation

As a standard safety measure, whenever laser operation is not immediately required, the system should be set to **Standby** mode. If the operator leaves the room, the system should be turned off.

CAUTION

To stop laser operation, release the footswitch at any time.

WARNING

Any untrained and unauthorized personnel that change the parameter settings may adversely influence system operation.

4.5 System Specifications

Laser medium/energy source	CO_2		
Wavelength	10600nm		
Maximum Power	60W		
Work mode	Multi-Pulse, Continuous		
Mode Structure	TEM_{00}		
Beam delivery	7- joint light arm		
Light arm	1.36m		
Aiming Beam	Red diode laser (630~650nm, ≤5 mW)		
Spot size	0.5 mm(± 10%)		
Pulse Duration and Power	Multiple Pulse	(Duration)	1~1000ms
		(Interval)	1~1000ms
	Continuous Wave	1~30W	
Power calibration	Period of 1 year		
Clean Method	70% isopropanol		
Control system	Touch screen, footswitch		
Laser operation	Footswitch		

Cooling System	Water Cooling
Dimension(length*wide*high)	120 * 75 * 56cm(without light arm)
Weight	68kg

Chapter 5 Operation Instructions

5.1 Introduction

This chapter describes the operation instructions for the CO2 laser machine.

CAUTION

- **This system may only be operated by a licensed practitioner, according to the local laws in every state.**
- **A laser radiation warning sign, supplied with this system (see Figure 2-1), should be placed at the entrance to the operating room where the system is in use.**
- **Improper use or adjustment of this system may invalidate the system service warranty agreement. Please contact your authorized** BV LASER **distributor before attempting to use the system in any manner other than those specified in this manual.**

5.2 Error Detection

This system is equipped with self-testing software that continuously monitors system operation using watchdog software & circuitry.

The software continuously checks the system for any errors:

- The LCDs an error message and disables further operation.
- The audible indicator sounds an alarm signal which is longer than the normal light or laser emission signals.

In such a case where the system is shut down and restarted as a result of an error, refer to **Chapter 7 - Troubleshooting** - for further instructions if the issue persists.

5.3 Before Operation

1. Plug the line into the main power outlet.
2. Insert the key into the key switch.
3. Connect the footswitch to the service panel.
4. The patient and all personnel in the room should wear safety eyewear specific to the handle in use (see Chapter 2).
5. Install the fractional arm & handpiece and adjust the operating parameters according to the manufacturer's instructions.

5.4 During Operation

To operate the system:

1. Turn on the system.
2. Access the selection mode interface.
2. Access the treatment parameters and working interface.
3. Set the operating parameters.
4. Click the ready button.
5. Press the footswitch to initiate the operation of the laser.

WARNING

- **The CO2 laser machine emits an intense laser beam. Make sure that all personnel are protected against accidental exposure, either directly from the handpiece or indirectly from a reflective surface to the laser beam.**
- **To protect against eye damage and discomfort, make sure that everyone present in the room is wearing BV LASER recommended protective eyewear.**
- **Never look directly at the beam coming from the handpiece, even when wearing appropriate protective eyewear.**
- **Never point the handpiece so that it discharges into free space. Make sure that the handpiece is pointed at the treatment site during the actual treatment.**

5.4.1 Turning on the System

To turn on the CO2 laser machine:

1. The screen lights up and the system enters the initialization interface, as shown in Figure 5-1.

2. The screen lights up and the system enters the initialization interface. After 3 seconds when initialization process completed, the interface will enter into the mode selection automatically, as shown in Figure 5-1.

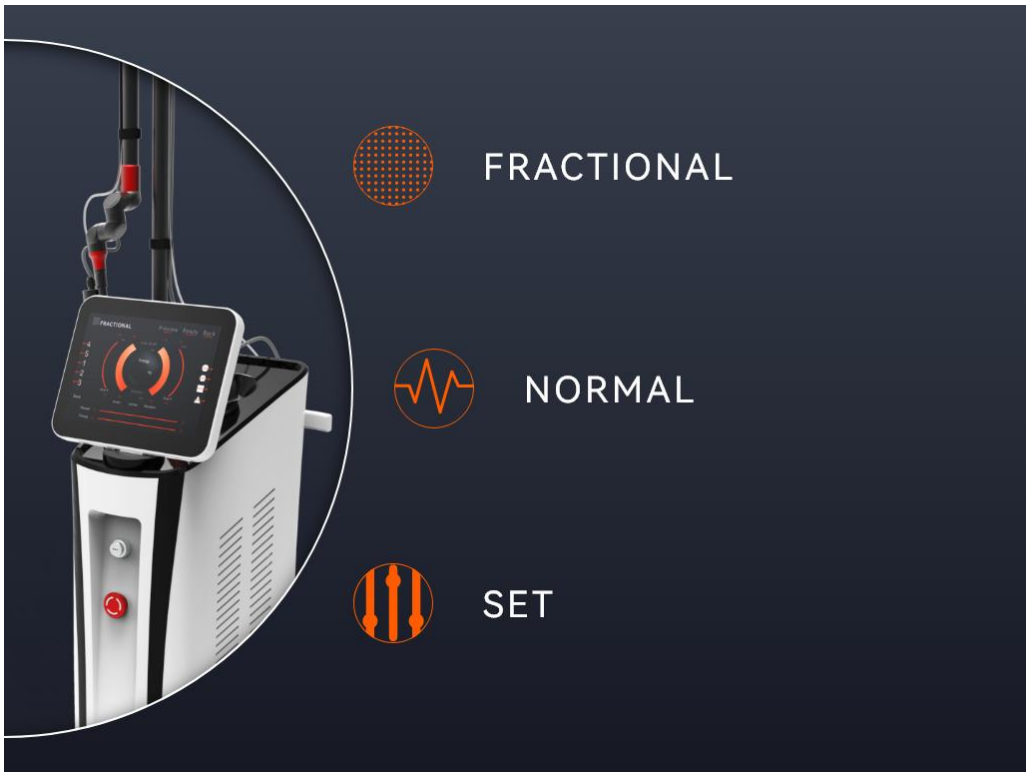


figure 5-1

3. Press the “FRANCTIONAL” button to enter into the treatment interface, as shown in Figure 5-2.

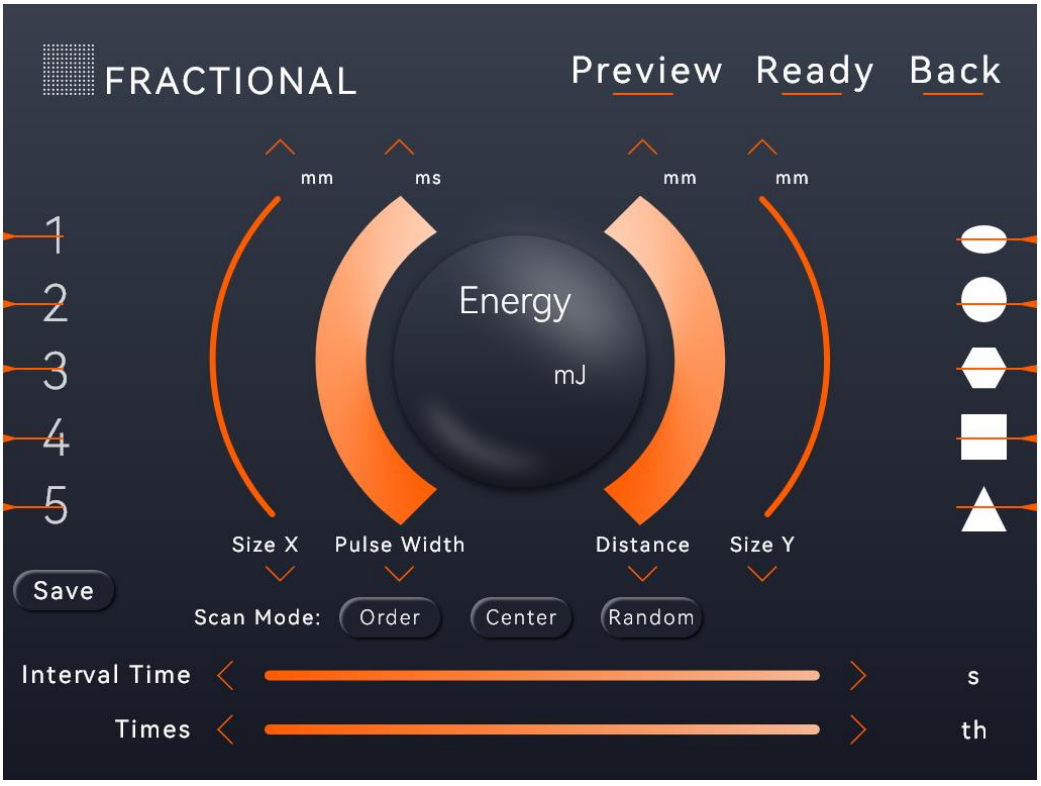
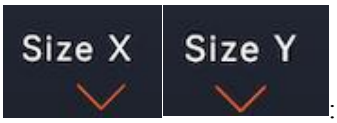
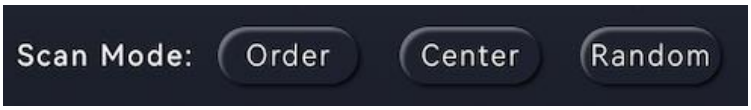


figure 5-2

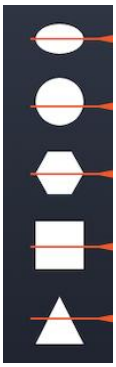
: Click the “Distance” button, the system adjust the distance of the light.



: Adjust the aspect ratio of graphics



： Beam scan pattern


： Selection of Scanned Graphics

： The energy density display box, which is the total energy per unit time divided by spot area. The display value of energy density is according to parameters of CO2 laser.

: Pulse width display and adjustment function box. This box shows the current set pulse duration, the shown pulse duration could be adjusted by “+” and “-“ key. The pulse duration adjustable range is 1~1000ms, the increment is 1ms. When the pulse duration is adjusted, the energy density value and output pulse waveform will be changed with it. The change of energy density is proportional to the pulse duration, the larger the pulse duration, the greater the energy density, the higher the high level of the output pulse waveform.

: Interval time is the time between pulses in multi-pulse mode. This box shows the current set interval time, the shown interval time could be adjusted by “+” and “-“. The interval time adjustable range is 1~1000ms, the increment is 1ms. When the interval time is adjusted, the energy density value and output pulse waveform will be changed with it. The change of energy density is inversely proportional to the interval time, the smaller the interval time, the greater the energy density, the higher the high level of the output pulse waveform.

: Preset Programs. This function consists of six buttons, which are 1 to 5 digital keys and a save key. The five numeric keys save five sets of laser parameters respectively. Before use, it has a set of preset parameters., Users can store their common parameters as needed, up to 5 groups. These five sets of parameters can be used or modified by the users and users can also store each set of parameters by clicking the save button.

: Standby / Ready the state button. In standby mode, the ready icon is green. When the button is pressed, the system sends a signal to the CO2 laser power supply, and the system will enter into the preparation mode. At the same time, the ready icon will turn to red. When the button is pressed in the ready mode, the system sends the a signal to the CO2 laser power supply, and the system will enter into the standby mode, then, the ready icon will turn to green.

: Return to the button. Press this button in the standby state, and the system returns to the mode selection interface; if the system is in a ready state, no action is made.

Text style	Corresponding prompt status
	The system is in the standby state, and the machine is running normally, and there is no alarm.
	The system is in a ready state, and the trigger can emit light normally.

4. Press the “NORMAL” button to enter into the treatment interface, as shown in Figure 5-3

Figure 5-3

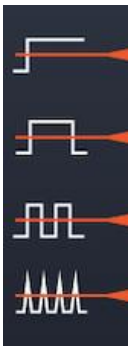
: The energy density display box, which is the total energy per unit time divided by spot area. The display value of energy density is according to parameters of CO2 laser.

: Pulse width display and adjustment function box. This box shows the current set pulse duration, the shown pulse duration could be adjusted by "+" and "-" key. The pulse duration adjustable range is 1~1000ms, the increment is 1ms. When the pulse duration is adjusted, the energy density value and output pulse waveform will be changed with it. The change of energy density is proportional to the pulse duration, the larger the pulse duration, the greater the energy density, the higher the high level of the output pulse waveform.

: Interval time is the time between pulses in multi-pulse mode. This box shows the current set interval time, the shown interval time could be adjusted by "+" and "-". The interval time adjustable range is 1~1000ms, the increment is 1ms. When the interval time is adjusted, the energy density value and output pulse waveform will be changed with it. The change of energy density is inversely proportional to the interval time, the smaller the interval time, the greater the energy density, the higher the high level of the output pulse waveform.

:Power display and adjustment function box. The box shows the current set power energy, the shown power energy could be adjusted by “+” and “-“ key. Its adjustable range is 1~60W and the increment is 1W. When the power is adjusted, the energy density value changes with it.

: Preset Programs. This function consists of six buttons, which are 1 to 5 digital keys and a save key. The five numeric keys save five sets of laser parameters respectively. Before use, it has a set of preset parameters., Users can store their common parameters as needed, up to 5 groups. These five sets of parameters can be used or modified by the users and users can also store each set of parameters by clicking the save button.


:Pulse mode. There are several modes that you can choose. Such as continuously,single pulse,multi pulse and ultra pulse.

: Standby / Ready the state button. In standby mode, the ready icon is green. When the button is pressed, the system sends a signal to the CO2 laser power supply, and the system will enter into the preparation mode. At the same time, the ready icon will turn to red. When the button is pressed in the ready mode, the system sends the a signal to the CO2 laser power supply, and the system will enter into the standby mode, then, the ready icon will turn to green.

: Return to the button. Press this button in the standby state, and the system returns to the mode selection interface; if the system is in a ready state, no action is made.

5.4.2 Setting Parameters

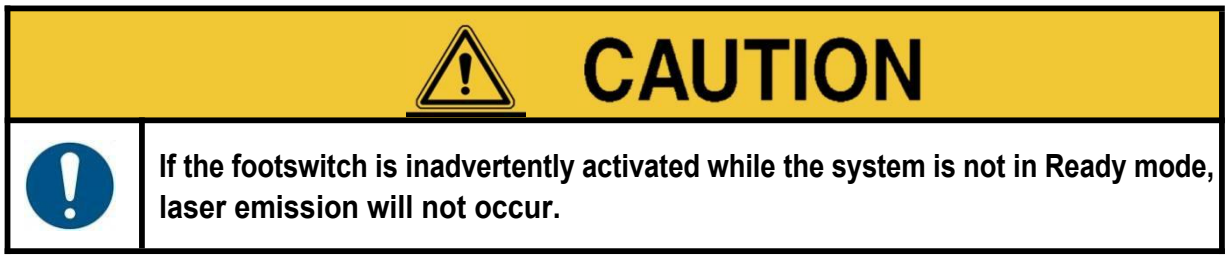
Operating parameters may be adjusted accordingly to the needs of the operation. The user-controlled operating parameters are:

- Power
- Pulse Width
- Distance

5.4.3 Initiating Laser Emission

To initiate laser emission

1. Point the laser handpiece to the treatment area and then press the footswitch.
2. Lasing is enabled only when the footswitch is activated.



3. The handpiece should not be in contact with the treated area during treatment.
4. To stop laser emission at any time, release the footswitch.

5.4.4 Pause in Operation

As a standard safety measure whenever laser emission is not immediately required, the system should be set to Standby mode. Before leaving the room, the operator should turn the system off as described in Section 5.5.

5.4.5 Changing Parameters during Operation

The Power, Duration, and Interval can be changed during system operation. To change the operating parameters perform the following:

1. Release the footswitch.
2. Change the operating parameters.
3. Return to **Ready** mode.

5.5 Turning the System Off

To turn off the system:

1. Set the system to **Standby** mode.
2. Turn the key Switch counter-clockwise a quarter of a turn.

3. Disconnect the power cable from the main power outlet.
4. Clean the handpiece (refer to Chapter 6: **Maintenance**).

CAUTION

To turn off the system in case of emergency, press the emergency shut-off button. To release the button, rotate the button clockwise until it pops up.

WARNING

To prevent unauthorized use of the system, do not leave the key in the key switch unattended.

5.6 Recommend Parameters

Fractional laser treatment parameters reference

Indications	Power (W)	Pulse width (ms)	Point spacing (mm)	Total energy (mj)	Number of scans (th)	Prompt after treatment effect	Duration of treatment(months)	How many times it works
Acne scarring	7-10	2.5	1.0	17.5	2th	Redness, swelling, exudate	1-2	After 2-3 times
Rejuvenation and firming	5-8	2.5	1.0	12.5	1th	Redness	2-3	After 5 times
Wrinkle removal	7-10	2.5	1.0	17.5	1th	Redness	2-3	After 5 times
Dilated pores	5-8	2.5	1.0	12.5	1th	Redness	2-3	After 5 times
Scar removal	10-15	2.5	1.0	17.5	2th	Redness, swelling, exudate	1-2	After 2-3 times
Hormonal dermatitis	4-8	2.5	1.0	12.5	1th	Micro reactions	1-2	After 5 times

Cutting therapeutic parametric parameters

Mode	Indications	Total energy (mj)	Power (W)	Pulse width (ms)	Intervein. (us)
	Pigmented nevi, various vegetations	NA	3-5	NA	NA
	Depressed/hypertrophic scars, acne pits	100-200	5-10	20	NA
	Pigmented nevi, genital warts	12.5-17.5	5-7	25	25
	Moles(smaller), flat warts, genital warts, cystic acne	5.0-15.0	5-15	1.0	25

Intimate treatment parameter reference

Indications	Point spacing. (mm)	Power (W)	Pulse width (ms)	Post-treatment reactions	Remarks
Vaginal tightening	0.6-0.8	5-10	1	No significant response	The interval is about 4 weeks
Pink vulva, tightening vaginal, pink areola	1.2-1.4	3-5	1	No significant response	The interval is about 4 weeks

Chapter 6 Electromagnetic emission and electromagnetic immunity

WARNING:

1. Avoid using this equipment adjacent to or stacking with other equipment because it could result in improper operation.

2. The use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this **CO2 Laser Machine BW-203B** could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation

3. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the **CO2 Laser Machine BW-203B**, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result

NOTE:

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), 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.

Guidance and manufacturer's declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS

<table>
<tr><th colspan="3">Guidance and manufacturer´s declaration – electromagnetic emission</th></tr>
<tr><td colspan="3">The CO2 Laser Machine + BW-203B is intended for use in the electromagnetic environment specified below. The customer or the user of CO2 Laser Machine + BW-203B should assure that it is used in such an environment.</td></tr>
<tr><td>Emissions test</td><td>Compliance</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>RF emissions

CISPR 11</td><td>Group 1</td><td>The CO2 Laser Machine + BW-203B uses RF energy only in its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions

CISPR 11</td><td>Class A</td><td rowspan="3">The CO2 Laser Machine + BW-203B is suitable for use in all establishments except domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions

IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations flicker emissions

IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacturer´s declaration – electromagnetic immunity			
The **CO2 Laser Machine + BW-203B** is intended for use in the electromagnetic environment specified below. The customer or the user of the **CO2 Laser Machine + BW-203B** should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	±8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	±2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be typical of a commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	0 % UT; 0,5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be typical of a commercial or hospital environment. If the user of the **CO2 Laser Machine + BW-203B** requires continued operation during power mains interruptions, it is recommended that the **CO2 Laser Machine + BW-203B** be powered from an uninterruptible power supply

	0 % UT; 250/300 cycle		or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE	U_T is the a. c. mains voltage before application of the test level.		

Guidance and manufacturer´s declaration – electromagnetic immunity – for EQUIPMENT and SYSTEM

Guidance and manufacturer´s declaration – electromagnetic immunity			
The **CO2 Laser Machine + BW-203B** is intended for use in the electromagnetic environment specified below. The customer or the user of the **CO2 Laser Machine + BW-203B** should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the **CO2 Laser Machine + BW-203B**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz	3V 150 kHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz	$= [\frac{3.5}{V_1}] P$ $= [\frac{12}{V_2}] P$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	3 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	$d = [\frac{3.5}{E_1}] P$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}] P$ 800 MHz to 2.7 GHz where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects, and people.

a. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

b. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM, and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **CO2 Laser Machine + BW-203B** is used exceeds the applicable RF compliance level above, the **CO2 Laser Machine + BW-203B** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the **CO2 Laser Machine + BW-203B**.

c. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM - for EQUIPMENT and SYSTEMS

Recommended separation distances between portable and mobile RF communications equipment and the CO2 Laser Machine + BW-203B

The **CO2 Laser Machine + BW-203B** is used in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **CO2 Laser Machine + BW-203B** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **CO2 Laser Machine + BW-203B** as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output of the transmitter W	Separation distance according to the frequency of the transmitter (m)			
	150 kHz to 80 MHz outside ISM and amateur radio bands $d = [\frac{3.5}{V_1}] P$	150 kHz to 80 MHz in ISM and amateur radio bands $[\quad] P$ V_2	80 MHz to 800 MHz $d = [\frac{3.5}{E_1}] P$	800 MHz to 2.7 GHz $d = [\quad] P$
0.01	0.12	0.20	0.035	0.07
0.1	0.38	0.63	0.11	0.22
1	1.2	2.00	0.35	0.70
10	3.8	6.32	1.10	2.21
100	12	20.00	35	70

For transmitters rated at a maximum output power not listed above the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Chapter 7 Maintenance

7.1 Introduction

This chapter contains maintenance instructions for the CO2 laser machine.

Routine maintenance is to only be performed by clinical staff unless otherwise specified. Additional maintenance procedures not mentioned within the contents of this chapter are to only be performed by BV LASER authorized technical personnel.

This device is designed to operate without any need for operator maintenance. However, the outer surfaces of the system should be kept clean for hygienic reasons and the handpiece should be cleaned between sessions to ensure positive treatment results.

DANGER

To avoid the risk of electric shock, pull out the power cord from the electrical outlet when performing maintenance duties.

Maintenance by the operator should be performed only when the system is shut down and disconnected from the main power source. Performing maintenance procedures with the system turned on may be hazardous to the operator and/or destructive to the system.

7.2 Periodic Service

The system should be periodically inspected and maintained to keep it in peak operating condition.

The following are recommended routine maintenance operations to be performed by BV LASER authorized technical personnel every 6 months:

- General system check
- Interior inspection, including cleaning of interior components
- Verification of laser beam power output to ensure optimal performance

WARNING

- **The interior of the system may be serviced only by BVLASER authorized technical personnel.**

7.3 Service Information

Please have the model number and serial number (printed on the identification label, located on the system's rear service panel) on hand when in communication with BV LASER authorized representatives.

WARNING

- **Unauthorized servicing or modification of this system, not described in this manual may expose the operator or patient to potential voltage and laser radiation hazards.**
- **Improper use or adjustment of this system may invalidate the service warranty agreement.**

Questions or problems should be referred to your BV LASER representative.

7.4 Routine Maintenance

Clinic staff should perform the following routine maintenance procedures regularly as per clinic protocol.

WARNING

- **Always turn the system off and unplug the power cable before performing maintenance procedures.**
- **The interior of the system or its components can only be serviced by BVLASER authorized technical personnel.**

7.4.1 Cleaning and Disinfecting the system panels

It is recommended to wipe the outer surface area clean with a soft cotton cloth swabbed in 70% alcohol.

7.4.2 Laser Handpiece

A preliminary inspection of the handpiece should be done daily. The inspection includes checking the tip of the handpiece. If the handpiece tip is dirty, it should be cleaned with a damp cotton cloth.

Following each day’s treatment, a soft cotton cloth swabbed in 70% alcohol should be used to disinfect the handpiece tip.

Chapter 8 Troubleshooting

8.1 Introduction

The CO2 laser machine is equipped with a self-monitoring system that continuously monitors system operations. If a system malfunction is detected, an error message will appear on the LCD.

The error will disable system operations and the operator should turn the system off using the key switch and the main switch.

The following troubleshooting table does not attempt to list all possible system failures. Any error not listed should be referred to BV LASER Service personnel.

WARNING

Do not attempt to open or disassemble the system panels.

8.2 Warranty

The system warranty period is one year.

CAUTION

Improper use or adjustment of the CO2 laser machine may invalidate the service warranty agreement. Please contact your authorized BV LASER **distributor before attempting to troubleshoot this system in any manner other than specified in this manual.**

8.2 Troubleshooting Guides

Table 8-1 lists some probable system malfunctions for which no messages are displayed. If the corrective actions listed in the table do not solve the problem, contact your BV LASER service representative.

The following troubleshooting guides do not attempt to list all possible system failures. Any fault not listed should be referred to your BV LASERservice representative.

If qualified technicians who benefit from users of BV LASER device can provide this equipment repair

service, BV LASER Company can provide circuit diagrams, component lists, graphical annotation, correction method, and information on repairable device parts for equipment.

Table 8-1: System Malfunctions Troubleshooting Guide

Symptoms	**Probable Causes**	**Corrective Actions**
The display does not work when the key switch is turned on.	1. Emergency shut-off button is engaged. 2. No main power supply. 3. The fuse is burned out. 4. Other unknown faults.	1. Turn off the system, turn the emergency shut-off button clockwise, and restart the system. 2. Check if the main power supply is present and if the power cable is well. 3. Replace the fuse. 4. Call BV LASER Service.
Laser emission is not initiated when the footswitch is pressed.	1. The system is in Standby mode. 2. The footswitch's cable is not connected to the service panel. 3. Other reasons other than those listed above	1. Switch the system to Ready mode. 2. Check the footswitch's cable connection. 3. Call BV LASER Service.
The output energy is reduced significantly.	1. The handpiece tip was polluted. 2. Other reasons	1. Clean the handpiece tip. 2. Call BV LASER Service.

Appendix A Clinical Guide

A.1 Introduction

This section is provided to aid professionals in the use of the CO2 laser machine. It adds to or reinforces information presented in the user's Manual concerning instructions for use, precautions, and warnings necessary to reduce the risk of injury. All operators must read the entire user's Manual before reviewing this appendix and before operating the system.

A.2 Training Requirements

The CO2 laser machine is designed to be operated only by personnel properly trained in its handling and use. All personnel who operate the system must read the user's Manual.

BV LASER provides in-service training for the CO2 laser machine. At the end of this in-service training, personnel is considered trained for the operation of the CO2 laser machine.

The physician is responsible for contacting the local licensing agencies to determine any credentials required by law for clinical use and operation of the device.

A.3 Intended Use and Indications

The CO2 laser machine is used for human tissue vaporization, coagulation in dermatology and plastic surgery, general surgery, gynecology, podiatry, dental, and otorhinolaryngology.

A.4 Contraindications

- Cancer; in particular, skin cancer
- Pregnancy (including IVF)
- Photosensitivity or use of Photosensitive medication and herbs for which 10600nm light exposure is contra-indicated
- Diseases that may be stimulated by light at 10600nm
- Prolonged exposure to sun or artificial tanning during the 3 to 4 weeks prior to treatment and post-treatment
- Active infection of herpes simplex in the treatment area
- History of keloid scarring

- Patients with fragile and dry skin
- Patients with hormonal disorders
- Patients using anticoagulants
- Epilepsy Patients
- Patients with history of coagulopathies
- Patients with communicable disease in the active stage and symptom appearance of HIV, tuberculosis, hepatitis.
- Patients with all kinds of Hemorrhagic disease.
- Patients with serious cardiovascular disease, such as, congenital heart disease (CHD)， acute myocarditis，atrial fibrillation，ventricular fibrillation.
- Patients with fever over 38℃.
- Patient with mental disorder, Kawasaki disease, hysteria, Late stage of cirrhosis1， hepatonecrosis.
- Pregnant women and teenagers.
- Patients with serious hypotension, hypertension, hypoglycemia, anemia.
- Female patients undergoing menstruation.
- Patients with perceptual disturbance and abnormal skin.

A.5 Adverse Effects of Treatment

The use of the CO2 laser machine is similar to the use of other laser-based technologies. Historically, traditional systems have demonstrated the ability to cause a certain degree of controlled and uncontrolled tissue damage. In addition, there are the following risks:

- Discomfort
- Severe or prolonged erythema (redness) and edema (swelling) within 2-24 hours of treatment that could last for several weeks.
- Irritation, itching, a mild burning sensation, or pain (similar to sunburn) may occur within 48 hours of treatment at the application site.
- Blisters, epidermal erosions, or peri-lesional hyperpigmentation or hypopigmentation may develop and remain evident for several weeks to months following treatment.
- Crusts
- **Scarring** or **keloid**.
- Bruising or purpura
- Eye damage from reflected or prolonged unprotected exposure to pulsed light or laser light. Protective goggles (appropriate to the wavelength) must be worn during all treatments to prevent

eye injury.

A.6 Eye Protection

- It is essential that all people present in the treatment room during the treatment (patient and medical personnel) protect their eyes by wearing BV LASER recommended protective eyewear.
- The eyewear should be of an optical density of 5 (OD>5).
- It is good practice to instruct the patient to close their eyes during treatment even when wearing protective eyeglasses.
- If the patient cannot wear the protective eyewear, fit the patient with opaque eye protection that completely blocks light from the eyes.
- If the treatment area is very close to the eyes (eg. eyelids), protect the eyes with corneal shields.

A.7 Optical Safety

- Guard against accidental exposure to light/laser emission.
- Never look directly at the laser emission from the laser handpiece or at any reflecting surface, even when wearing protective eyewear.
- Always set the system to **Standby** mode when there is a pause in treatment; this prevents inadvertent light/laser emission.
- Press the footswitch only when the beam is aimed at the target tissue under direct visualization.

A.8 Fire Safety

- Remove any hair from the treatment site. Use only drapes soaked in sterile water near the treatment area if required.
- Make sure a fire extinguisher (rated for electrical fires) is available at all times.
- Avoid the use of flammable tissue-prepping agents or allow the material to completely evaporate before using the laser.
- Do not use the laser in the presence of flammable, explosive anesthetic gases or oxygen.
- Any oxygen tubes present in the room should be of a light/laser-safe type.

A.9 Photography

It is recommended to take "before and after" photographs to document the treatment progress. These photographs provide objective evidence because many patients are not able to assess the progress of

treatment through gradual improvement.

Standard conditions and similar camera speed, flash, and focal distance should be used to photograph all patients. This consistency enables objective comparison of photos taken at different times.

A.10 Topical Anesthesia

Due to the unique capabilities and the DualChill Technique in the CO2 laser machine, the procedure can be administered without topical anesthesia. However, there may be patients who prefer to undergo the treatment using a topical anesthetic.

Topical anesthetics are generally applied for a while (up to 1 hour) before treatment. Be certain to remove all of the topical anesthetics before treatment.

A.11 Pre-Treatment

A.11.1 General

During the first visit, the physician (or an authorized staff member) should:

- Take a detailed patient medical history, including previous treatment modalities, and examine the dermatological condition for suitability of treatment with the CO2 laser machine.
- Exclude from treatment anyone who has had prolonged sun exposure or artificial tanning during the last 48 hours.
- Exclude from treatment anyone who is expecting to have prolonged sun exposure during the upcoming month.
- Patients with a history of herpes simplex in the treatment area should take preventive antiviral medication prior to treatment.
- Determine why the patient is seeking treatment and understand his/her expectations.
- Discuss treatment goals with the patient.

A.11.2 Counseling

During the first visit, the physician (or an authorized member of the staff) should:

Discuss the treatment with the patient

- The therapy may consist of multiple treatments given over several months.
- There may be some discomfort or pain associated with the treatment.
- Transient erythema/edema may appear immediately following the treatment.
- It may take a few months for the skin to fully recover.

- There is a risk of adverse reactions, such as redness, swelling, blistering, crusting, infection, pigmentary change, and scarring.

A.12 Treatment

Treatment can begin after the treatment parameters are selected.

WARNING

Delivering excessive energy to the treatment site can result in thermal damage to the skin, possibly leading to hypertrophy and/or atrophy and/or abnormal pigmentation.

Ensure that the patient is lying comfortably with eye protection in place. All personnel in the treatment room should wear appropriate eye protection as well. The operator should have good access to the treatment area and the controls of the CO2 laser machine.

1. Clean the skin to remove perfumes, cosmetics, and sunscreens.
2. For different treatment items, the operator sets the appropriate treatment parameters, including the working mode, power, duration, and interval.
3. Always perform a test spot to establish the cutaneous reaction when beginning treatment.
4. Carefully observe the reaction to the test spot.
5. If the laser pulse has the desired immediate endpoint, continue treatment with the same parameters.
6. Start treatment by activation of the footswitch.
7. Occasionally examine the treatment area for a change in skin color and morphological changes (erythema/edema).
8. If adverse skin effects occur, adjust the treatment parameters.

WARNING

The light emitted by the CO2 laser machine is capable of causing serious eye damage or blindness. For maximum safety, metal goggles must be worn by the patient for all facial treatments.

9. After treatment, it is recommended to cool the area immediately with a sterile cooling product.

A.13 Post-Treatment Care

The post-treatment care is applicable to all modes of CO2 laser machine.

Cold (not frozen) packs should be applied immediately post-treatment to cool the treatment area, reduce swelling and ease discomfort. Pre-chilled l0xl0 cm gauze pads, previously soaked with sterile saline or sterile water may be used.

Care should be taken to prevent trauma to the treated area for the first four or five days following the treatment: avoid hot baths, aerobic exercise, massage, etc.

- **Exposure to Sunlight** - patients should apply high-factor sun protection (SPF >30), and protect the treated area from exposure to direct sunlight for at least one month post-treatment. Tanning after treatment sessions may enhance melanin regeneration, which may result in hyper-pigmentation.
- **Makeup** - makeup is not generally recommended due to risk of infection and of makeup chemicals being absorbed or irritating the skin.
- **Other Post-Treatment Recommendations** - if the treatment site is exposed to dirt, it should be covered with a dressing for ten days. Patients should be advised not to participate in rough sports or similar activities for several days following the treatment until the skin returns to its normal condition.

A.14 Follow-Up

The measures presented below are only the manufacturer's recommendations for follow-up. They may serve as a basis for defining your treatment regimen.

- Patients should return for examination of the treatment site between six to eight weeks after treatment and additional treatment, if necessary.
- If no additional treatment is necessary, the patient should return for an additional re-examination three to four months later.
- If no change is noted, treatment parameters should be changed. With multiple treatments, increase the time intervals between treatment sessions (after the second one).
- Patients should be instructed to avoid sun exposure after and in between treatments.

A.15 Concluding Treatment

Determining when treatment should be concluded is left to the discretion of the professional staff, or the patient achieving satisfaction with the treatment results.

Manufacturer Information
Manufacturer: Nanjing BV LASER Laser S&T Co., Ltd..
Address: Nanjing Economic and Technological Development Zone (Liandong U Valley Science and Technology Innovation Park)

Appendix B Recycling Instructions

The main components of the equipment are metal and plastic components and circuit boards containing electronic components. Although there are no toxic and hazardous substances such as batteries and radioactive sources, when the equipment life is terminated and the equipment is scrapped, it is also necessary to seriously dispose of the equipment residue. First, avoid environmental pollution caused by improper handling, the salvage value can be recovered. It is recommended to dismantle and dispose by local recycling regulations for electronic products. If the user disassembles the solution by yourself, the following points should be noted:

1. Disassembly operations should be performed by professional and technical personnel with professional qualification certificates.
2. The device contains large-capacity capacitors and measures should be taken to avoid the risk of electric shock.
3. The metal parts of the equipment casing may scratch the operator. It is recommended to make necessary protection.
4. The disposal of dismantled products must be carried out in accordance with local laws and regulations.
5. The refinement of precious metals in circuit boards must be completed by qualified companies.

DANGER	
	**CO2 laser radiation can cause serious eye damage or blindness. Do not treat eyebrows, eyelashes, or other areas within the bony area surrounding the eye. For maximum safety, the patient must wear metal eye goggles for all facial treatments.**

WARNING	
	**While operating the laser system, never look directly into the laser aperture at the distal end of the handpiece, even if you are wearing laser safety glasses. Please be aware that during normal operation, the nominal ocular hazard distance (NOHD) of the system is 10m.** **Never direct the laser beam at anything other than the intended treatment area. Stray laser light and its reflection are always a potential hazard and may cause serious eye injury.**

WARNING

Eye safety precautions :

Identify the operating room clearly by posting approved operating safety signs in prominent locations.

Cover all windows to prevent the laser beam from escaping the operating room.

Restrict access to the operating room when the device is in use. Allow access only to personnel who are trained in the operation of the device.

Ensure that the footswitch is clean and working properly. Place the footswitch where it will not be confused or mistaken.

Waste Treatment

The scrapped therapeutic apparatus and lossy parts shall not be discarded randomly, and shall be disposed in strict accordance with the relevant provisions of the “EU Waste Treatment Policy”.

Manufacturer:

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