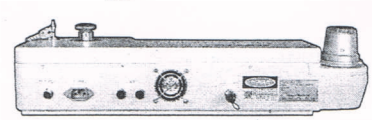
Model : ML015-CA



Western Surgical®

CO_2 LASER SURGICAL SYSTEM

USER MANUAL

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Safety Guidelines

The following information is provided for the correct utilization of CO_2 laser surgical system. The information includes not only the accident protection regulations the products comply with, but also the effective precautions regarding proper use of the products.

The safety regulations that ML series CO_2 laser surgical system comply with can be grouped under 3 categories:

1. Electric safety regulation
2. Laser radiation safety regulation
3. Electromagnetic radiation safety regulation

These safety regulations comply with the following standards set by IEC:

IEC 60601-1 1998+A1: 1991+A2:1995
Medical Electric Equipment Part 1: General Requirements for Safety

IEC 60601-1-2:2000
Medical Electric Equipment General Requirement for Safety
Collateral Standard :Electromagnetic Compatibility Requireme...
and Test

IEC 60601-1-4:2000
Medical Electric Equipment General Requirement for Safety
Collateral Standard: Programmable Medical Electric Equipment

IEC 60602-2-22:1995
Medical Electric Equipment Part 2, Specific Safety Requirement on Diagnosing and Treatment Laser Equipment

IEC 60825-1:2001
Radiation Safety for Laser Product, Equipment Classification, Requirement and User's Guidance.

IEC 1441:1997
Risk Analysis

Although ML series CO_2 laser surgical systems are designed according to accident prevention regulations, only a proper and careful use can guarantee safety. For effective precautions, please refer to chapter 3.4.5.8 and 9 in operator's manual.

The EMC performance of this system has been evaluated and is in compliance with EN 60601-1-2. Better use this system in an environment free of strong electromagnetic field.

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Preface

The ML015-CA CO_2 laser surgical system is an intelligent laser treatment instrument. This product is featured by compact structure, beautiful appearance, reliable performance, convenient operation and perfect safety. The technical specifications of the product have achieved the advanced international standard.

The instrument can be applied to general surgery, gynecology, otolaryngology, dermatology and cosmetology etc for different treatment such as cutting, vaporizing, cauterizing and solidifying. It can be used in ward and private clinics for its portability and compactness.

Warning

This instrument generates high voltages and laser radiation within the cabinet. Operators must pay much attention to safety during operation. Operation safety instructions are specified in this manual. Any improper use, adjustment or maintenance may cause laser radiation hazards or high-voltage electric shock.

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1. Operation Principle of the System

1.1. Principle of CO_2 Laser Surgical System

The CO_2 laser, with a specific wavelength of 10.6um can be absorbed by human body tissue (no matter what color the skin is)almost by 100%, with the laser slightly passing through the skin. It is the heat and electromagnetic effect of the laser that people use to conduct non-blood or less-blood cutting, cauterizing, gasification and accurate microsurgery. Most optical knives use CO_2 laser as light source.

1.2. System Description

The ML015-CA CO_2 laser surgical system is the latest microprocessor-controlled instrument based on a sealed-off CO_2 laser providing up to 15W output power on body tissue. It is easy and safe to operate.

1.3. Main Cabinet

1. CO_2 laser and compound light source
2. Switch source with high voltage and constant current
3. Main control panel
4. Cooling system
5. Footswitch
6. Articulated arm

1.3.1. CO_2 Laser and Compound Light Source

Sealed-off laser is selected. The active medium is a mixture of CO_2 and other compound gases. The compound light source consists of sealed-off CO_2 laser tube, light intensity detector, diode laser and beam combiner. The beam combiner combines CO_2 laser beam and diode laser beam coaxially and guides them into the articulated arm beam delivery system.

1.3.2. Switch Source with High Voltage and Constant Current

The instrument is equipped with a switching-mode power supply which converts input voltage to the high voltage required for laser emission. Compared with traditional source, it has a series of advantages, such as small volume, high efficiency and safety while increasing voltage.

1.3.3. Main Control Panel

The microprocessor-based main panel is used to control all functions by touching the thin film switch. Time and power are displayed digitally, which is clear and accurate.

1.3.4. Laser Cooling System

The laser cooling system is a closed circulating loop. The coolant (distilled water or ionn water) is circulated by a pump.

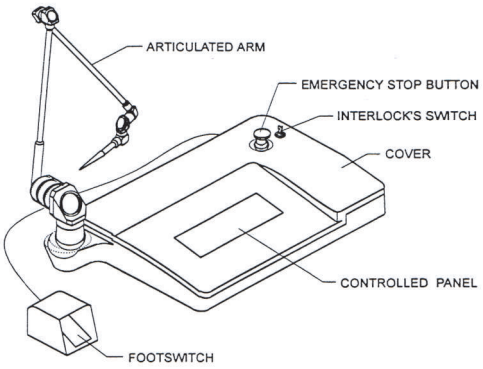
1.3.5. Footswitch

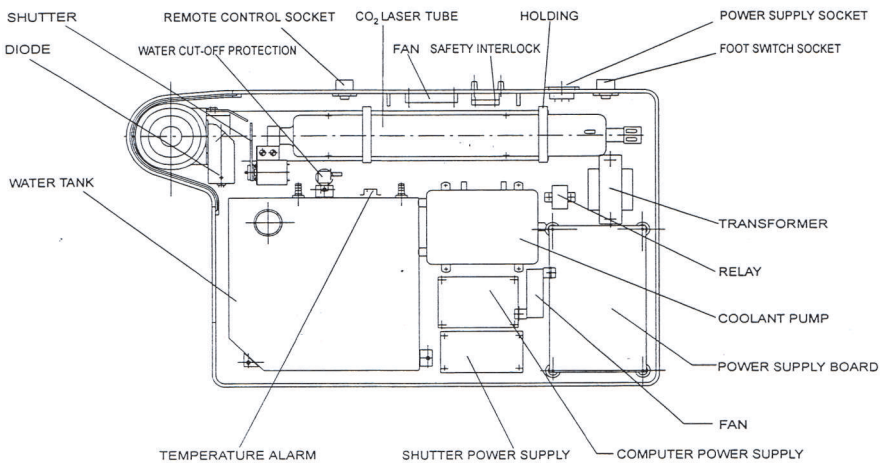
A footswitch is used to control laser output. When the footswitch is pressed, the shutter opens and laser emits from the articulated arm.

1.3.6. Articulated Arm

The laser beam delivery system consists of light-weight, spring-balanced, 7-joint articulated arm. The working radius of the articul ated arm at full extension is 110cm.

2. Name of the Components





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3. Pre-startup preparations

3.1. *Unpacking and Inspection*

After unpacking, please check to ensure that the instrument is not seriously damaged, circuit lines are well connected and accessories are available (see accessories list).

3.2. *Pouring Coolant*

Unscrew with a screwdriver 3 small screws on the back of the instrument, which are used to fix the upper cover. Open the upper cover and the cap of the water tank carefully and pour clean water (or distilled or ion water if available) into the tank through a hose (f5~f10mm)till it is full. Then close the cover. Don't open the cover recklessly unless for the sake of transportation. When filling water, be sure not to let the water overflow. If water overflows, wipe with dry cloth or dry it with an electric hair-dryer to avoid short circuit or electric shock.

Never turn on power when the tank is empty

3.3. *Remote Control Interlock*

Insert the remote-control interlock plug into the proper socket on the back of the instrument. Push in alignment of the notch until a tone is heard, which means a successful lockup.

3.4. *Checking Power Voltage*

Ensure that the power voltage complies with the requirement of the instrument.

3.5. *Connecting Power Cable*

Plug the two terminals of the power cable into the power input socket and the power socket. (Make sure the ground socket is in working order.)

3.6 *Footswitch Connection*

Plug the footswitch cable into the socket on the rear part of the instrument. Push in alignment of the notch until a tone is heard, which means a successful lockup.

3.7. *Temporary Start*

After several minutes of trial operation of the instrument, cut off the power supply temporarily.

4. Installation and Alignment

Insert the key into the hole of the lock on the panel and rotate clockwisely by 90°, then the power supply is turned on, and the water pump and cooling fan are started up.

4.1. *Articulated Arm*

Co_2 laser beam delivery arm consists of an alignment tube articulated arm, focusing tip, focus-setting tube, divergent physiotherapy head and a connector base. The connector base is fixed on the output terminal of the laser instrument. Usually the only thing required to do is to installthe articulated arm on the connector base and lock it tightly.

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4.2. Adjustment of CO_2 Laser Emission

4.2.1. Release the beam delivery arm and hold the alignment tube to the connector base. Align the laser beam to the center of the alignment tube to enable the CO_2 laser beam to travel along the axis of alignment tube. Start the instrument and choose the lowest output power (about 1W).Check light spot (such as double spots or double beams). Locate the laser spot at the end of the alignment tube with a piece of sulphuric acid paper while keeping on adjusting the system till laser beam travel through the entrance center of the alignment tube and emit from the end center of the alignment tube. Release the alignment tube and reinstall the delivery arm by screwing up tightly.

4.2.2. Generally, a focusing tip is used to for operation. As to large area cauterizing surgery, remove the focusing tip and install focus-setting tube and focus-setting tip to control beam spot.

4.3. Aligning Pilot Beam Adjust the red diode laser as the aforesaid method, till its laser spot converges with that of the CO_2 laser.

5. Operation Procedures

CAUTION: Any operation in a manner other than specified hereunder may cause the hazard of laser radiation.

5.1. Start main Power Supply Rotate the keyswitch and turn on the power supply.

5.2. Function Selection

5.2.1. STBY State Press function key "STBY" and the indicator illuminates, indicating the instrument is in "STBY" state. Set laser radiation parameters according to the need of operation.

5.3. Operation Mode Selection

5.3.1. CONT : The system is set to "continuous" state. The laser will emit continuously according to the duration the footswitch is pressed down.

5.3.2. SINGLE : The system is set to "single pulse" state. The laser emits once according to the pulse duration set previously when the footswitch is pressed once.

5.3.3. REPT : The system is set to "repetation" state. The laser emits intermittently according to the pulse duration set previously when the footswitch is pressed.

5.4. Power and Time Setting

5.4.1. Power Setting: The laser output power ranges from 0.5 to 15W. Adjust laser power by pressing the "up" key (▲) or "down" key (▼) under the display window.

Power Range (W)	*Power Setting Increment (W)*
0.5 ~ 1.0	0.1
1.0 ~ 10	0.5
10 ~ 15	1.0

5.4.2. Time Setting:

a). When the system is in "continuous " state, the digital reading of time will be "999".

b). When the system is in "pulse" or "repetition" state, the initial digital reading of time is "0.05" second. The maximum is "1" second. The time range is from 0.05 to 1 second. Each press of the "up"("down") key increases (decreases) the time by "0.01"s.

5.5. READY State **After the above setting, set the function key to READY state.**

5.5.1. When the instrument is set to "READY"state, the green alarm lamp (laser output indicator) flashes intermittently, indicating the laser is ready to emit (the buzzer doesn't beep). When the footswitch is pressed, the laser output shutter opens, laser beam emits, the alarming lamp illuminates steadily and the buzzer beeps. Then the laser works according to the parameters set previously.

5.5.2. When the instrument is in " READY" state, the operation keys of the system do not work when pressed. Before changing the mode of operation, switch the function key to "STBY" state first.

5.5.3. When the instrument is in "READY"state, if it is turned to "STBY" state again, the parameters remain unchanged, and the footswitch does not work.

6. Protection and Alarm

6.1. Indication of Coolant Circulation

When the water pump begins to work shortly after the power is turned on, the coolant doesn't circulate normally, with the indicator flashing and the buzzer beeping. After the coolant circulates normally and the warning device, which will alarm in case of no water, is connected, the indicator illuminates steadily and the alarm stops beeping.

6.2. Overheat Protection

Prevent the instrument from being overheated: when the temperature of the circulating water is higher than 40℃ , the indicator will flash and the buzzer will beep.
Before normal operation is restored, cut off power supply and wait till the temperature of cooling water goes down below 25 ℃. Then restart the instrument.
In case of the two aforesaid alarming states, if the footswitch is pressed, laser will not emit.

7.Pilot Beam

In view of the invisibility of the 10.6um CO_2 laser, a visible red diode laser emitting coaxially with CO_2 laser is provided to help the operator locate laser beam conveniently. Press the key, the red light emits, and a green indicator flashes. Press the key again , the red light stops emitting, and the green indicator extinguishes.

8.Remote Control Interlock

The instrument is provided with a remote control interlock function. Connect the terminal of remote control interlock at the rear part of the instrument to the interlock device(micro switch or photoelectric switch) in the operation room with wires. When the door of the operation room is opened, the interlock device is cut off automatically, and laser emission stops. When the door is closed, the interlock device is put through again. Press the function key to switch the instrument from "STBY" to "READY" state. Then the laser is ready to emit.
The installation of the interlock device is only limited to professional personnel.

9. Precautions

9.1. Never let the laser beam be directed to human eyes or healthy skin.

9.2. To prevent human eyes or skin from being hurt by the reflection of laser light, never allow the laser beam be directed to any smooth reflective surface, such as stainless steel device surface, mirror surface, etc.

9.3. If 75% alcohol is used to clean or sterilize relevant parts of the instrument, don't use the instrument till the alcohol vaporizes. Never operate the instrument in the presence of flammable anesthetics.

9.4. In order to prevent the focus lens of the handpiece from being polluted and to keep a clear view of the surgical area, a blower is recommended to the operator. The handpiece and focus lens must be cleaned every 3 months

9.5. The laser beam generated by this instrument is hazardous to eyes in the area within 35m from the instrument(when someone is staring directly at the laser). Operators must use safety eyewears when operating.

9.6. This instrument generates high voltages inside. No attempt should be made by non-professional personnel to open the cabinet of the instrument to avoid electric shock risk.

9.7. If the instrument gives out abnormal smell or sound, stop operation at once. Cut off the power first before any inspection.

The laser tube is made of glass. Handle with care to avoid damage.

9.8. Keep the instrument in an environment with the temperature between 1℃ ~ 50℃ and the relative humidity between 10%~ 80%.

9.9. Empty the water tank before transportation to prevent the laser tube from being frozen to break.

9.10. Don't leave around laser tube and the instrument recklessly when their service lives end. Recycle according to the local environment protection regulations.

9.11. To avoid improper use of the instrument, remove the key from the keyswitch and keep it properly when the instrument is not in use. The instrument generates high voltages within the power supply and laser tube. Please refer to professional personnel for maintenance to avoid electric shock.

9.12. Operation room should be equipped with a dust or fume exhauster, because the dust arising during operations may be mixed with biological tissue particles.

10. Maintenance:

10.1 High voltage hazard — The instrument generates high voltages within power supply and laser tube. Refer to professional personnel for maintenance to avoid electric shock.

10.2 Lens cleaning — The output power may drop slightly after the instrument has been put into use for half a year. This may be caused by the stained focus lens of the handpiece. Wipe the lens gently with moistened cotton ball once or twice. Be sure not to damage the lens.

10.3 Cabinet cleaning — If there is dirt on the cabinet, wipe gently with moistened cotton cloth and some detergent or toothpaste. Don't use over-wet cloth in case the water leaks into the inner part of the instrument, causing short circuit and damage. Please refer to chapter 9 for precautions

10.4 Power calibration — The practical laser output power and the preset panel power must be calibrated each year with standard laser power meter within validity period by trained or professional personnel.

10.5 Fuse Replacement — Open the fuse holder with a screwdriver and remove the original fuse. Before replacement, check and ensure the new fuse is identical in type and specifications to the original one (250V/3.1A) to avoid damage arising from unfit fuses.

10.6 Handpiece Sterilization — Handpieces must be sterilized after use. Refer to chapter 9.3 for details.

11. Accessories:

operator's manual and service manual		1 copy
articulated arm	LND-2C	1 pc
power cable	3VTJ2	1 pc
footswitch	FS-201 250V/10A	1 pc
footswitch key	2NO-2NC	2 pcs
fuse	type 616, 250V, 3.15A	2 pcs (spare parts)
remote control switch	V-156-1C25	1 pcs
(connecting wires recommended : 0.15 x 23)		
handpieces (see table below)		

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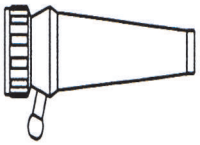
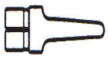
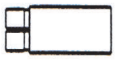
Handpieces Accessories

DWG NO.	NAME	FIGURE	APPLICATION	REMARKS
WQ-DT-01	handpiece handle		general purpose hanfpiece applied to surgery, and demartology	provided along with instrument
WQ-DT-02	acuminate handpiece			
WQ-DT-03	thimble			
WQ-DT-04	hooked handpiece			
WQ-DT-05	120° reflector handpiece		applied to E.N.T	Provided against purchase order
WQ-DT-06	90°reflector handpiece			
WQ-DT-07	long tubular thimble			
WQ-DT-08	ENT 120° reflector			
WQ-DT-09	ENT 90° reflector			
WQ-DT-10	ENT double side reflector			

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12. Troubleshooting Guide

Please refer to professional personnel for maintenance.

SYMPTOMS	*POSSIBLE CAUSES*	*ACTIONS*
After the main power is on, the panel does not light, the water pump does not work either. (When the water pump works, there are slight vibration and sound.)	The power plug has not beenproperly plugged. The emergency stop switch is pressed down.	Check the two plugs at the two ends of the power cable. Replug properly. Turn the red mushroom-shaped button of the emergency key in the indicated direction to have the emergency key connected.
No laser beam emits out though the instrument seems running normally.	The plug of the footswitch is not properly inserted. The setting of the control panel isn't suitable. When the instrument is used for the first time, after water is filled the cover is not closed tightly.The interlock keys are not pressed down. The joint of the articulated arm is loosened.	Insert the plug of foots witch tightly according to operator's manual. Set the panel again according to operator's manual. Close the cover and press the interlock keys. Screw the joint tightly .
No laser emits. The instrument alarms	The instrument has been working for too long and the coolant is too hot.	Stop running the instrument. Wait till the temperature of the cooling water goes down below 25℃, then restart the instrument.
The instrument makes big noise when running.	The instrument is not well-balanced.	Place the instrument on a stable and flat surface.
Red pilot beam doesn't converge or doesn't emit from the end of the tube. Co2 laser is off the center.	The articulated arm is either damaged inside or not workingnormally. No laser emits or output power drops significantly.	Refer to professional personnel for service.

Note:- Operators are not allowed to adjust the componnents listed below: laser tube, articulated arm, diode pilot beam, microprocessor board.

13. Technical Specifications

Laser Type:	Sealed off CO_2 laser
Laser Wavelength :	10.6 microns
Laser Mode :	Low-valance mode
Output Power :	0~15W. cont. adjustable
Focus Spot Diameter :	0.4mm
Divergence:	4 mrad
Lens Focal Distance :	f=100mm
Power Instability :	<610%
Pilot Beam :	red diode laser 0.1~5mW,
Delivery System :	spring-balanced 7-joint articulated arm
Operation and Control:	Touching switch, microprocessor-controlled
Working Modes	Continuous, single pulse, repeat pulse
Pulse Duration	0.05~1s
Display :	Power, time (digital display)
Cooling System :	Closed loop circulating water
Power Supply:	AC 230V, 50HZ (see supply entrance label)
Input Power :	300VA
Environment Temperature :	5~40 ℃
Relative Humidity :	< 80%
Dimensions (mm) :	360×610×120(mm)
Weight (kg) :	18kg
Atomospheric pressure:	86.0kpa~106.0kpa
Warming up time:	5min
Electromagnetic requirement:	no electromagnetic field interference
other working conditions:	no obvious vibration or airflow

Specifications subject to change without notice

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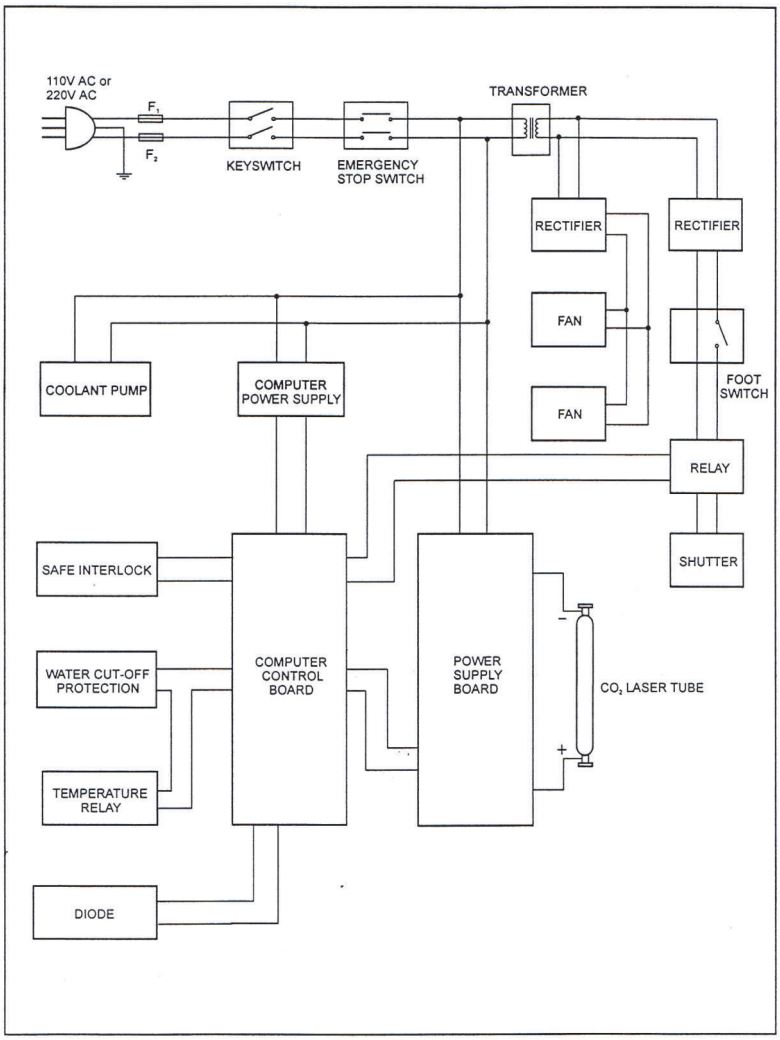
14. System schematics



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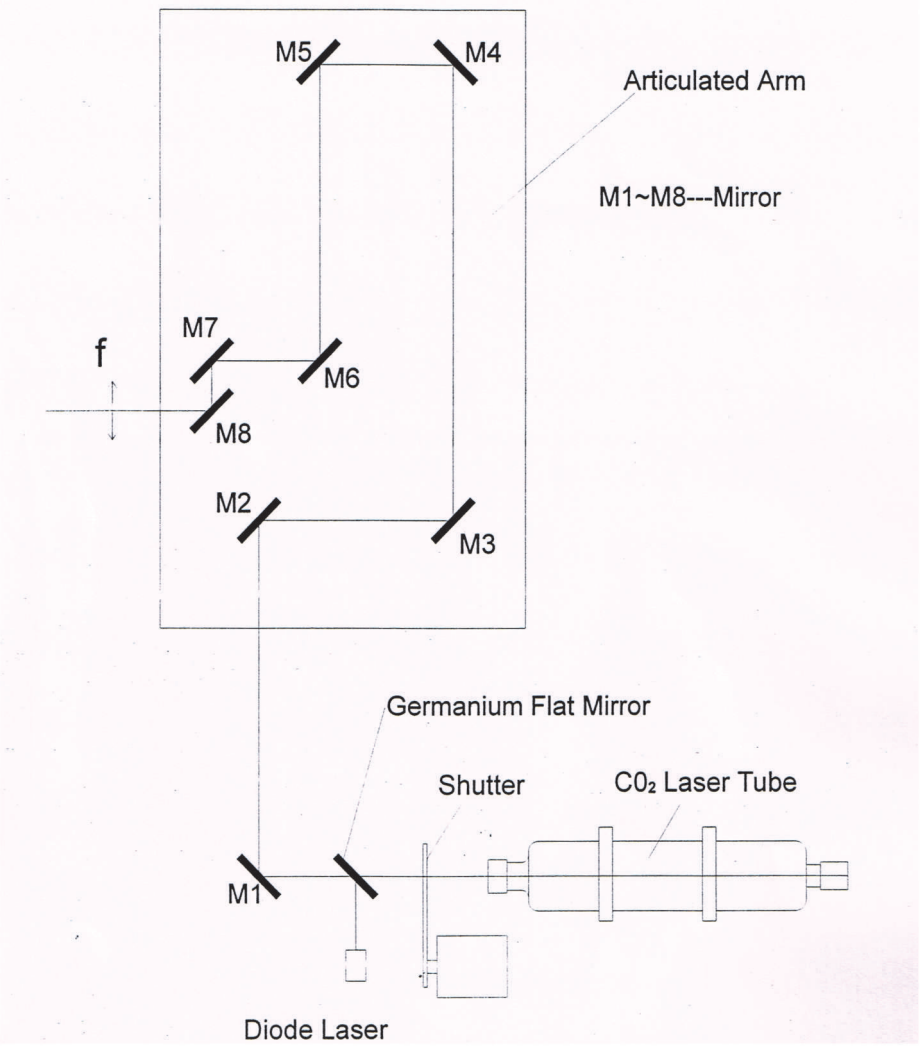

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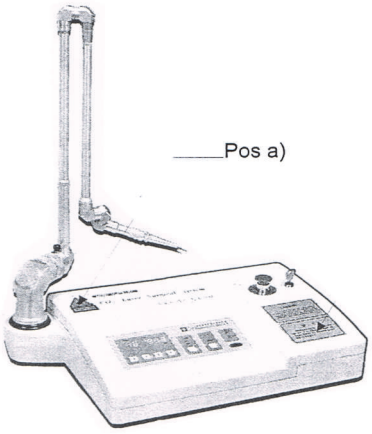
15. Warranty & service

The instrument is a well designed, user friendly laser surgical system with high quality. It performs perfectly under normal use and maintenance. Within a year from the date of purchasing, any damage caused by manufacturing or components defects can enjoy free repairing service.

Such service is valid only if the instrument is properly used. Any damage caused by improper use of the instrument , such as using unfitted power supply and wrong accesories, operating in a manner other than specified in this operator's mannul, damages caused by transportation, accidents, unauthorized installation or maintenance, etc., such free service will be invalid immediately. The free service does not include accessories, transportation fee and door-to-door service charge of professional personnel.

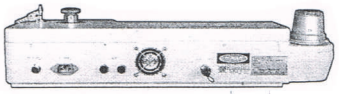
16. Warnings, Identification & Labels



Pos a)

Pos b)

Sticker pos.a)



Pos. C) Pos. D)

Sticker pos.c)

Sticker pos.d)

Sticker pos.b)

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Label Explanation

No.	Symbol	Definition
label 1		NOTICE! PLEASE SEE ACCOMPANYING DOCUMENTS.
label 2		TYPE B APPLIED PART
label 3		PROTECTIVELY EARTH
label 4		DANGEROUS VOLTAGE
label 5		WARNING AND EXPLANATORY LABEL
label 6		CAUTION
label 7		WARNING LABEL-HAZARD SYMBOL
label 8		MANUFACTURER & PRODUCT INFORMATION
label 9		AUTHORIZED EUROPEAN REP
label 10		LASER APERTURE
label 11		FUSE
label 12	Remote Control	REMOTE CONTROL PLUG
label 13	Foot switch	FOOTSWITCH PLUG

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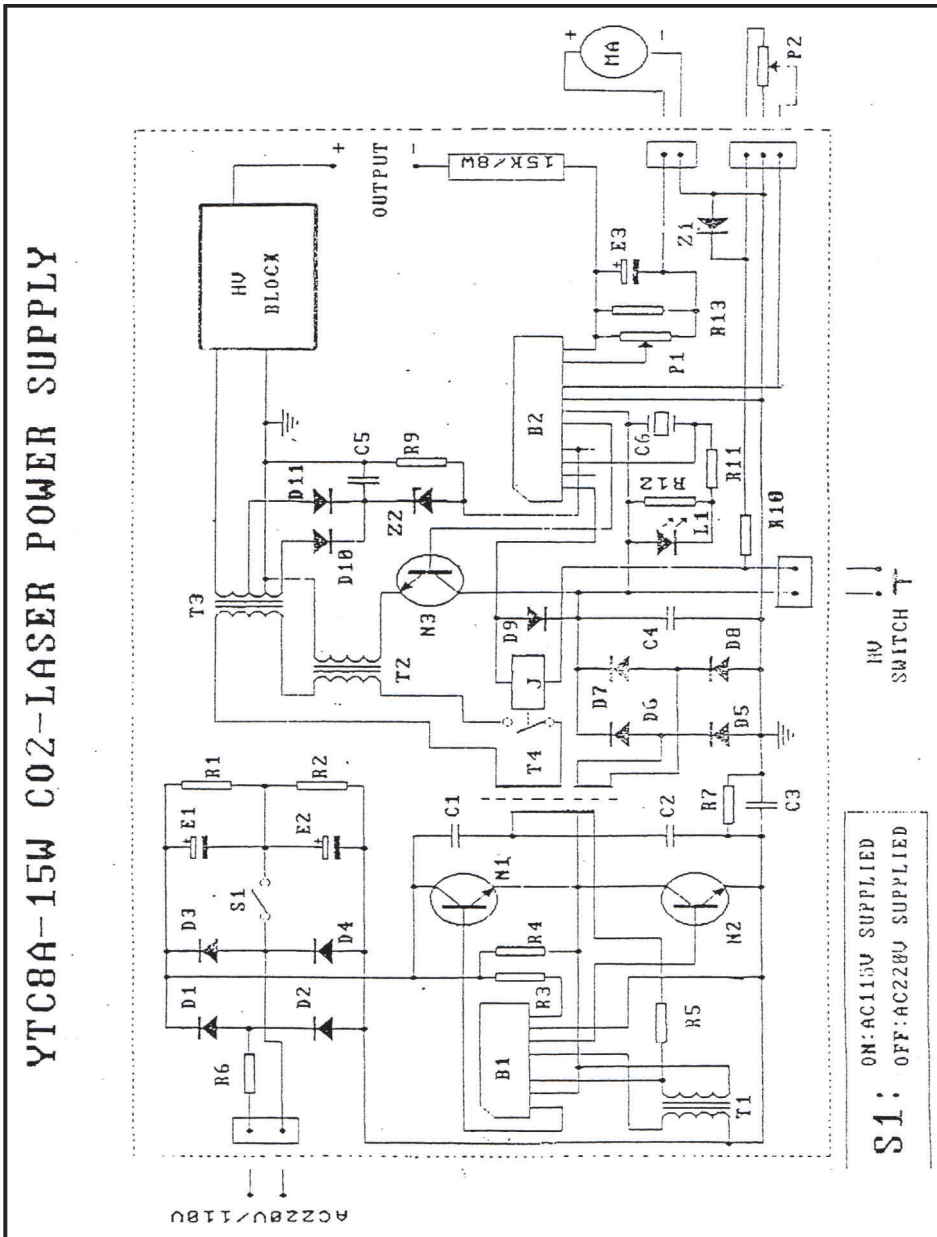
YTC8A-15W CO2-LASER POWER SUPPLY



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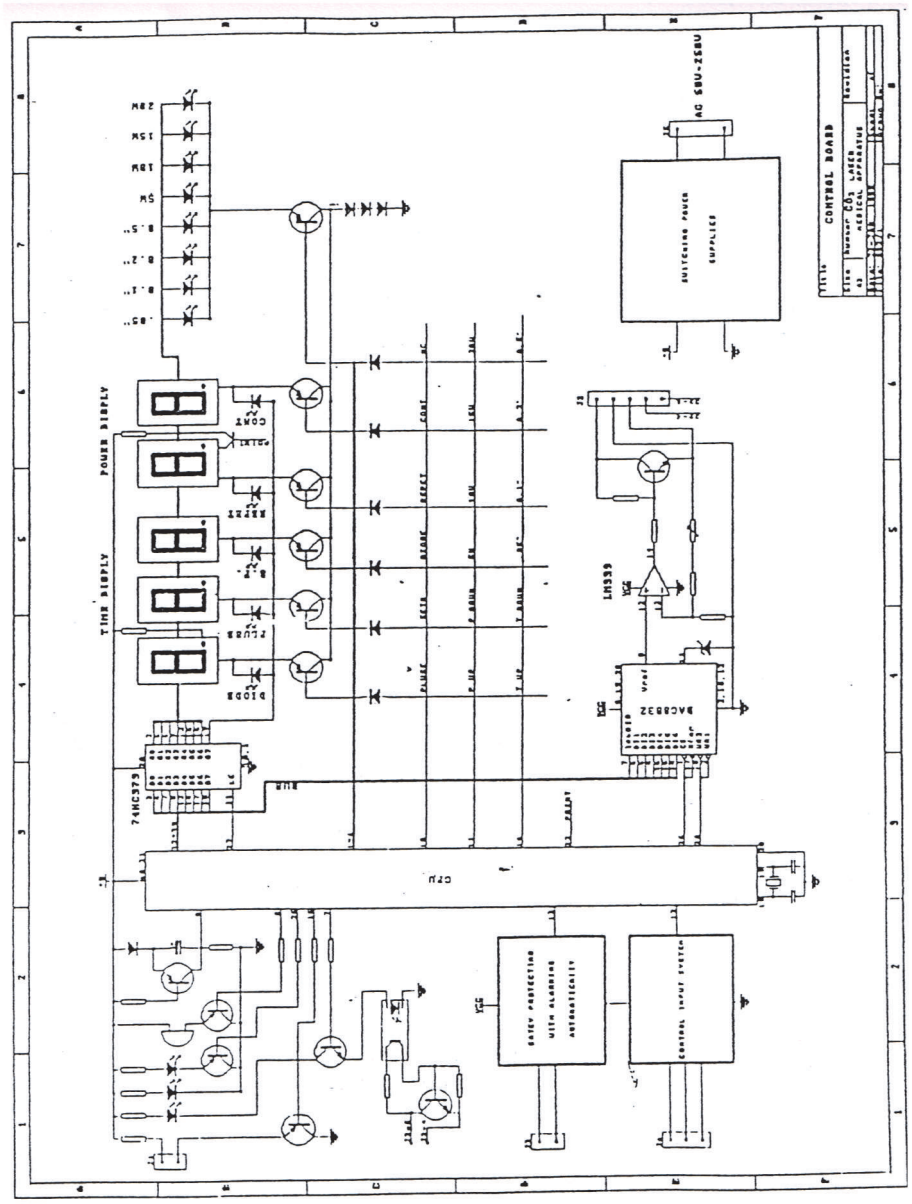

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Tel: 0086-21-62642623
Fax:0086-21-52827988
E-mail:swot@wonderful-sh.com
Website:http://wwwmwonderful-sh.com

Date of Installation	**Installed By**
Model No.	**Serial No.**
Warranty Period	
Name of Doctor & Address :	

Customer Sign. With Stamps

Marketed By: Western Surgical
Sign. With Stamps

No Claim Warranty :
1) Any Defect Througut Power Supply
2) Any Physical Damage
3) Under Warranty Standby Unit Not Provide
4) Under Warranty When Company Send Parts or Machine we Imidiat send to Buyer.

* Carrying Warranty at Rajkot only on site warranty not provided free of cost.
* Due to constant upgradation design, price and features are subject to change any time without prior notice.

OUR OTHER PRODUCTS RANGE

* Carrying Warranty at Rajkot only on site warranty not provided free of cost.
* Due to constant upgradation design, price and features are subject to change any time without prior notice.

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