15W Co₂LASER SURGICAL SYSTEM (2).

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TABLE OF CONTENTS

Safety Guidelines	
Preface	2
Warning	2
Operating Instructions Manual	
1. Operation Principle of the system	3
2. Name of the components	5
3. Pre- startup Preparations	6
4. Installation and adjustment	8
5. Operation Procedures	10
6. Protection and Alarm	12
7. Pilot Beam	13
8. Precautions	14
9. Maintenance	16
10. Accessories	17
Service Manu	
11. Troubleshooting Guide	20
12. Technical Specification	22
13. System Schematics	23
14. Warranty and Service	25
15. Warnings. Identification and Labels	26



Safety Guidelines

The following information is provided for the correct utilization of CO₂ 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 PC015-A series CO₂ 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 requirement 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 part2, 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 PC015-A series CO_2 laser surgical systems are designed according to accident prevention regulations, only a proper and careful use an guarantee safety. For effective precautions, please refer to chapter3..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.



Preface

The PC015- A CO₂ 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 latest 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.



1. Operation principle of the system

1. 1. Principle of CO2 laser surgical system

The CO₂ 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 CO₂ laser source.

1.2. System description

The PC015-A 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.CO₂ 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

1.3.1CO2 laser and compound light source

Sealed-off laser is selected. The active medium is a mixture of CO₂ and other compound gases. The compound light consists of sealed-off CO₂ laser tube, light intensity detector, diode laser and beam combiner. The beam combiner combines CO₂ laser beam and beam 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 ion 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 articulated arm at full extension is 110cm.



2. Name of the components

- 1. Articulated arm
- 2. Interlocks switch
- 3. Footswitch
- 4. Emergency stop button
- 5. Controlled panes





3. Pre-startup preparations

3.1. Upacking 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 6 small screws on 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-fryer to avoid short circuit or electric shock.

Never turn on power when the tank is empty.

Screwdriver screws





Pouring water





3.3.Checking power voltage

Ensure that the power voltage complies with the requirement of the instrument. Socket is in working order.

3.4.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.)



3.5.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





3.6.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 clock wisely by 90° , then the power supply is turned on, and the water pump and cooling fan are started up.





4.1 Articulated arm

CO₂ 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 install the articulated arm on the connector base and lock it tightly.

4.2 Adjustment of Co2 laser emission

4.2.1

Release the beam delivery arm and hold the alignment tube to the connector base. Align the laser beam to center of the alignment tube to enable the CO2 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. 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 up 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 CO₂ 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 key switch and turn on the power supply.

5.2. Function selection

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 REPT

The system is set to "repetation" state. The laser emit intermittently according to the pulse duration set previously when the footswitch is pressed.

5.3.3 SUPER PULSE

The system is set to "super pulse" state. Laser emits intermittently according to the setting super pulse duration when the footswitch is pressed. After the system is in "READY" state, if turned to the "STBY" state again, the specifications remain unchanged. At that time, the footswitch does not work.

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" $key(\blacktriangle)$ or "down" $key(\blacktriangledown)$ 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 "CONT" state, the digital reading of time will be "999".

b)When the system is in "REPT" state, the initial time is "0.05" second. The maximum is "1" second. The time range id from 0.05 to 1 second. Each press on the up/down key increased/decresess time by "0.01"s.

c)When the system is in "SUPER PULSE" state, the initial time display is "0.02" sec, (pulse duration).

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



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 alarm stops beeping..

6.2.Overheat protection

Prevent the instrument from being overheated: when the temperature of the circulating water is higher than 40°C, 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°C. 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 CO2 laser, a visible red diode laser emitting coaxially with CO2 laser is provided to help the operator locate laser beam conveniently. Press the key, the red light emit, and a green indicator flashes. Press the key again, the red light stops emitting, and the green indicator extinguishes.

8. Precautions

- **8.1** Never let the laser beam be directed to human eyes or healthy skin.
- 8.2 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.
- 8.3

 If 75%, alcohol is used to clean or sterilize relevant part of the instrument, don't use the instrument till the alcohol vaporizes. Never operate the instrument in the presence of flammable anesthetics.
- 8.4 In order to prevent the focus lens of the handpiece from being polluted and to keep a clear view of the surgical area, a smoke evacuator is recommended to the operator. The handpiece and focus lens must be cleaned every 3 months.
- 8.5

 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.
- 8.6 This instrument generates high voltages inside. No attempt should be made by non-professional to open the cabinet of the instrument to avoid electric shock resk.
- 8.7 If the instrument gives out abnormal smell or sound, stop operation at once. Cut off the power first before any inspection.

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



- **8.8** Keep the instrument in an environment with the temperature between 1°C~50°C and the relative humidity between 10%~80%.
- **8.9** Empty the water tank before transportation to prevent the laser tube from being frozen to break.
- 8.10 Don't leave around laser tube and the instrument recklessly when their service lives end. Recycle according to the local environment protection regulations.
- 8.11

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



9. Maintenance

The instrument generates hegh voltages within power supply and laser tube. Refer to professional personnel for maintenance to avoid electric shock.

9.2 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.

9.3 Cobinet 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.

9.4 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 of professional personnel.

9.5 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 specification to the original one (220V/2A) to avoid damage arising from unfit fuses.

9.6 Handpiece sterilization

Handpiece must be sterilized after use. Refer to chapter 8.3 for details.



10 Accessories

Operator's manual and service manual	1сору		
Articulated arm	1pc		
Power cable	1pc		
Footswitch	1pc		
Interlock key	2pcs		
Fuse 2pcs(spare	e parts)		
(Connecting wires recommended: 0.15*23)			
handpieces (see table below)			

Handpieces Accessories

DWG NO.	FIGURE
JH-DT-10	
JH-DT-11	
JH-DT-12	98
JH-DT-13	68
JH-DT-14	40
JH-DT-15	78



11. Troubleshooting Guide

Please refer to professional personnel for maintenance

efer 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.)	plugged. The emergency stop	
No laser beam emits out though the instrument seems running normally.		Insert the plug of footswitch 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.	instrument.Wait till the
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. CO ₂ laser is off the center.	or not working normally. No laser emits or	Refer to professional personnel for service.



Note: Operators are not allowed to adjust the components listed below:

Laser tube, articulated arm, diode pilot beam, microprocessor board.



12. Technical Specification

Laser Type Sealed off CO₂ laser

Laser Wavelength: 10.6 microns
Laser Mode: Low-valance mode

Output Power: 0~15W. cont adjustable

Focus Spot Diameter: 0.4mm
Divergence: 4mrad

Lens Focal Distance: F=100mm

Power Instability: ±10%

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 220V, 50Hz

(see supply circulating

water)

Input Power: 300VA

Environment Temperature: 5~40C° Relative Humidity: <80%

Weight (kg) 18kg Atomospheric pressure: 86.0kpa~106.0kpa

Warning up time: 5min

Electromagnetic requirement: No electromagnetice

Field interference

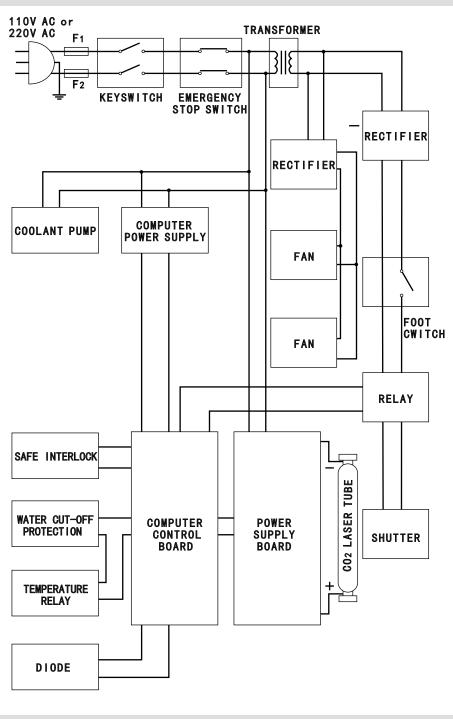
Other working conditions: No obvious vibration

or airflow

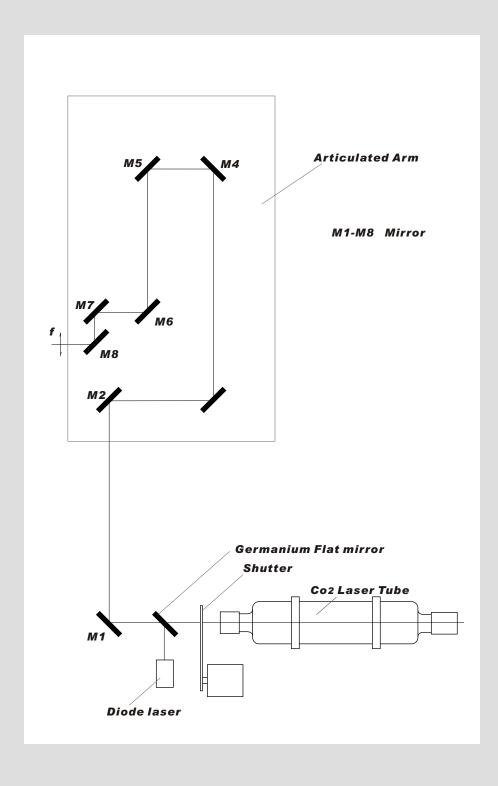
Specifications subject to change without notice



13. System schematics









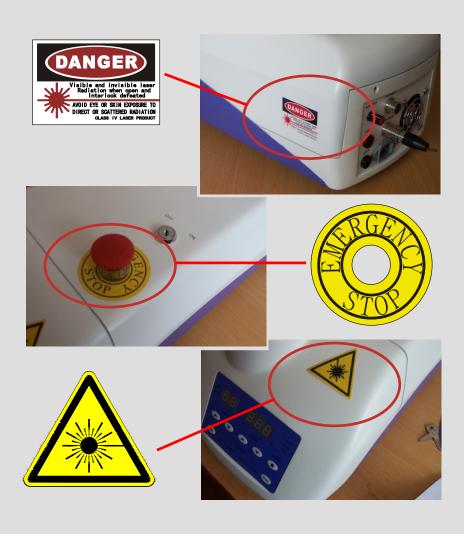
14. Warranty & Service

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 cause by improper use of the instrument, such as using unfitted power supply and wrong accessories, operating in a manner other than specified in this operators manual, 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 free and door-to-door service charge of professional personnel.



15. Warnings, Identification & Labels





Label Explanations

No	Symbol	Definition
Label 1		NOTICE! PLEASE SEE ACCOMPANYING DOCUMENTS
Label 2	*	TYPE B APPLIED PART
Label 3		PROTECTIVELY ERTH
Label 4	4	DANGEROUS VOLTAGE
Label 5	Visible and invisible laser Radiation when open and interlock defeated NAID EVE OR SKIM EXPOSURE TO DIRECT OR SOUTTERED AND IATION CLASS IV LASER PRODUCT	WARNING AND EXPLANATORY LABEL
Label 6		WARNING LABEL HAZARD SYMBOL
Label 7	LASER APEKTURE	LASER APEKTURE
Label8		FUSE
Label 9	Remote Control	REMOTE CONTROL PLUG
Label 10	Footswitsh	FOOTSWITCH PLUG



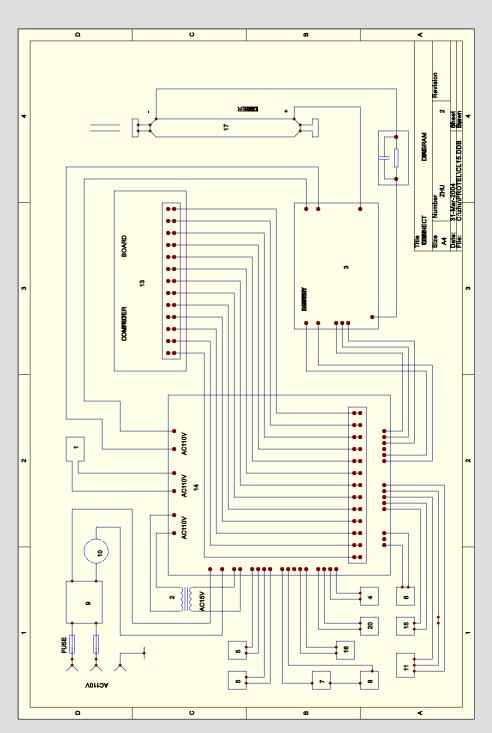
- 1. Water pump
- 2. Transformer
- 3. Power supply
- 4. Diode aiming beam
- 5. 12V fan
- 6. Aiming beam adjustment
- 7. Remote
- 8. Foot switch
- 9. Key switch
- 10. Emergency stop
- 11. Flow sensor
- 12.Watertank
- 13. Computer control

board

14. Computer control

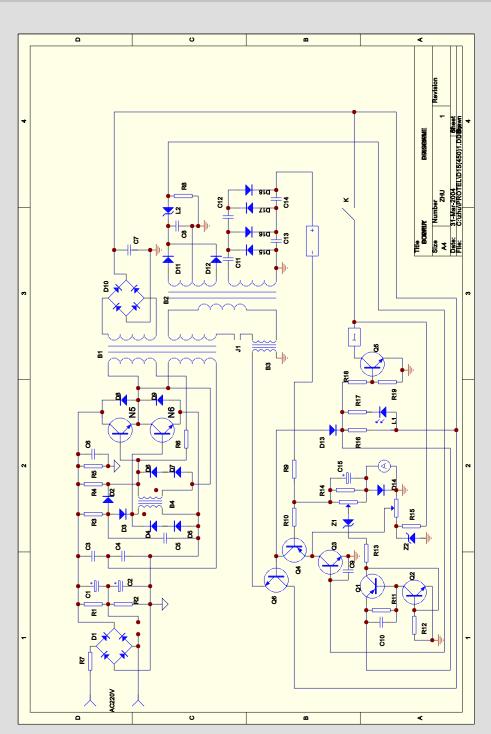
board power supply

- 15. Temperature sensor
- 16. Inter-lock switch
- 17. Laser tube
- 18. control switch
- 19. Current adjustment
- 20. Electric motor
- 21. AC110V-AC220V
- 22. AC15V input



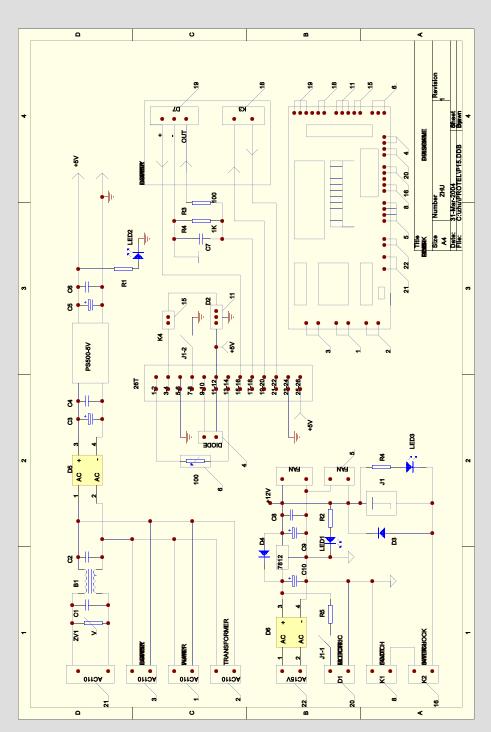


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