

This instrument is a kind of laser medical equipment, please read all the contents of this user manual seriously to insure that you can operate it correctly and safely. Please keep this manual well after reading for your reference.

Manual Version: V1.0 (The information is subject to change without prior notice).

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Part One Product Introduction

1 Components structure and functions

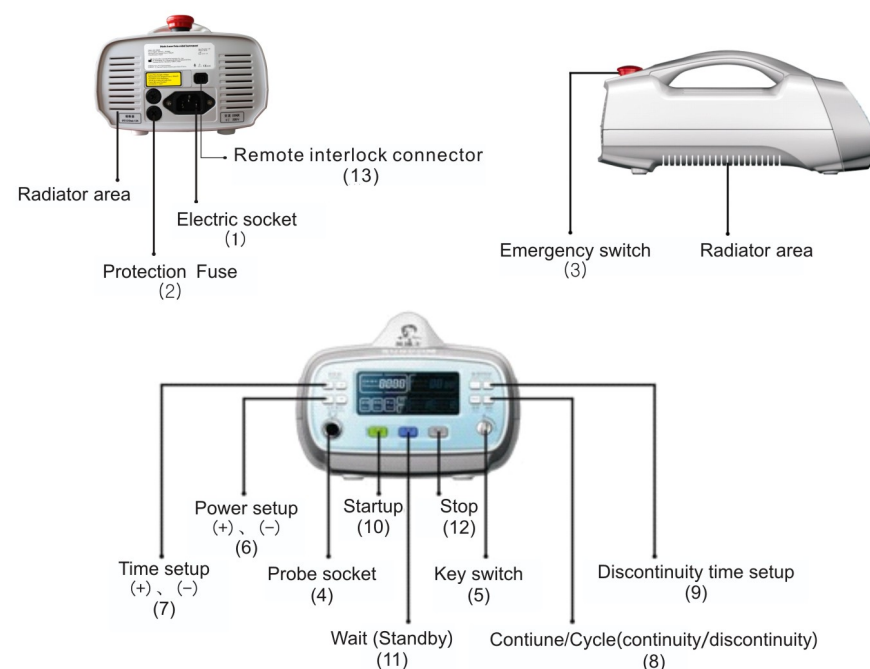
A) Mainframe: Achieve to control the main functions of the instrument by control panel (Pic. 1).

B) Probe: Touch and focus on pain location on human body for treatment. Used with probe holders (Pic.2).

C) Electrical power cable: To connect mainframe with outer electrical power supply (Pic.3).

D) Protective goggles: To protect the user or operator's eyes from laser injury (Pic. 4).

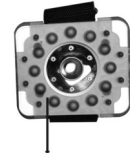
2 Instrument Diagram



Pic.1 Mainframe of Laser-Pain Relief Instrument



Pic. 2 Probe



Probe cover



Pic. 3 Electric power cable

Pic. 4 Protective goggles
(Wear before operations)

3 Instruction of Function Keys and Other Parts

- (1) Electric socket: AC230V、50/60Hz
- (2) Protection fuse: 1.5A
- (3) Emergency switch: In emergency, press the red button to cut off the power supply immediately.
- (4) Probe socket: Jack of probe line.
- (5) Key switch: Turn the key to the "ON" position and the supply of power connected, to the "OFF" position to cut off power supply.
- (6) Power setup button: Press the button under standby status to adjust the power between 10mW~500mW, 10mW for each time.
- (7) Time setup button: press the button under standby status to adjust the usage time between 30 seconds to 30 minutes, 30 seconds for each time.
- (8) Continuity/Discontinuity button: Press continuity button and discontinuity button in standby status, the output of laser would be continuous or discontinuous with the corresponding button pressed.
- (9) Continuity/Discontinuity time setup: Press the key in standby status, to adjust time between 1~9 seconds.
- (10) Start Key: Press the key in standby status, the instrument begins to emit laser.

(11) Standby: Press the key, the instrument would turn to ready status from standby status.

(12) Stop Key: Press the key in ready status, the instrument would turn to standby status. If you press stop key when the instrument is emitting laser, it would turn to standby status without output of laser.

(13) Remote interlock connector: Before you operating the instrument, you are required to make it connected, thus, the instrument can emit laser.

Part Two Specifications and Performance

1. Laser medium: GaAlAs – Semiconductor.
2. Laser classification: 3B
3. Safety classification: class I
4. Classification: Class IIa
5. The consumption of the product: 20 VA
6. Terminal laser output: Terminal output maximum for each probe of laser emitter: $500\text{mW} \pm 20\%$, the exit facula diameter of laser beam $\leq 10\text{mm}$.
7. Wavelength of probe central laser output: $810\text{nm} \pm 30\text{nm}$.
8. Beam divergence angle: $\phi_x = 0.26\text{ rad}$, $\phi_y = 0.78\text{ rad}$.
9. Laser output power instability St: $\leq 10\%$.
10. Probe peripheral laser wavelength: $650\text{nm} \pm 30\text{nm}$.
11. Time scope and precision: Time range is from 0 to 30 minutes, adjustable By 30seconds, time error should be less than $\pm 3\%$.
12. Operating and control functions
 - A) When machine is in standby mode, the operator can set up laser output power and treatment time, also can set up continuity or discontinuity status, discontinuity time can be set up in discontinuity status.
 - B) When machine is in ready mode, laser output power and treatment time can not be adjusted, the operator press start button and the machine would work with request of pre-setup.

C) When machine stops working at the end of planned time, laser emission stops with buzzing for indication of finish.

D) This machine can work in continuity and discontinuity status: Default start is in continuity; on discontinuity status, connection time defaults 2 seconds, disconnection time defaults 2 seconds.

13. Time control function

The operator can control working time by Time button, time range is from 0 to 30 minutes, adjustable by 30 seconds.
The time of discontinuity can be set up in discontinuity status, connection time (laser output working) can be adjusted from 1 to 9 seconds, disconnection (laser output pausing) time can be adjusted from 1 to 9 seconds.

14. Machine gross weight: 5.2 kg.

15. During appropriate operation, the nominal ocular hazard distance (NOHD) : rNOHD=2.3m

16. This machine should be operated under the environment with the following request:

- A) Ambient temperature: 5 °C ~ 40 °C .
- B) Relative humidity: no more than 80%.
- C) Electric power supply: 230V, 50Hz/60Hz.


















Part Three Application Range

Laser Pain-Relief Instrument is used as an adjuvant therapy for rheumatoid arthritis, osteoarthritis, acute and chronic pain, tissue repair and wound healing.

Part Four Contraindications

Patients who are suffering from thyroid disease, internal bleeding and cancer are prohibited to use this apparatus. This instrument should not be used on the eye, abdomen as well as lumbosacral location of pregnant women.

Part Five Label description

	Caution : Alert the user if you do not operate the instrument accordingly, personal injury or instrument damage would be occurred.		
	Attention ! Check the random file (This user manual) .		
			
Laser Radiation Mark	Irradiation Warning label	Laser Window label	
<div><p>Laser Pain-relief Instrument</p><p>Model: RG-300IB Power Supply: AC 230V 50/60Hz Maximal Laser Output Power: 500mW Classification: Class I</p><p> Shenzhen Raycome Health Technology Co., Ltd 3F, 51 Building, No. 5 Qiongyu Rd, Hi-tech Industrial Park, Nanshan district, Shenzhen, 518057, China</p><p> New Tech Development 21, Rue de Presles 93300 Aubervilliers France</p><p>Specification: 110 Power: 20 VA </p><p>   0482</p></div>			
Nameplate label			
	B Type Equipment		Manufacture
	EC Authorized Representative		Production Date
	Series Number		CE Mark Compliance with Directive 93/42/EEC of EU

Part Six Precaution and Warning

1. If you don't use the components or operate the instrument as requirements, radiation injury would occur.
2. This laser device emits NIR (Near Infrared), please absolutely avoid direct eye exposure.
3. Particular for prevention and protection of eye exposure.
 - Absolutely, do not use laser expose to eye directly.
 - The whole process of operation, user must wear protective goggles.
 - Start device after making sure the laser probe on the pain location appropriately to avoid accidental injury to eye when operating.
 - When irradiating on location close to eyes, the patients should close eyes and cover eyes with shelter things.
 - During appropriate operation, the NOHD (nominal ocular hazard distance) = 2.3M.
 - This set of device provides protective goggles (Laser Safety Glasses) for wavelength 810nm.
4. Because laser probe should touch human body during treatment process, the device must be used with set-up of protective earth for electric power.
5. Because laser probe comprises of optical system, it should be treated carefully and lightly without collision and falling for avoiding mechanical damage. The machine must be protected from heat and moisture.
6. Wipe the laser probe lens with clean cloth or mull to maintain the device effectively.
7. When the machine is moved from relative cold temperature(beyond 5~40℃) to room temperature place, do not start it up until the machine temperature gets close to the room temperature for avoiding malfunction.
8. It is not recommended for using flammable anaesthetic and oxidizable gas such as nitrous oxide and oxygen when operating. Some of materials such as cotton may be ignited by the high temperature during machine working. The solvents used for cleaning and sterilization of flammable solution should volatilize completely before machine operation for avoiding ignition danger.
9. Do not put anything over the machine, and take the key away from unoccupied machine.
10. The machine should be kept out of reach of children and pets when it is unoccupied.

11. On emergency condition, should use the manual emergency switch to stop laser output immediately (The emergency switch is with shape of red mushroom with a yellow circle on the below position). When the emergency was removed, turn on the switch to start it up again.

12. Do not use the Emergency Switch as normal switch under normal circumstance, otherwise, it will do harm to the maintenance.

13. The laser irradiation is prohibited on melanin for avoiding skin burn injury.

14. The device has been granted for delivery by strict testing and debugging. No user serviceable parts inside, do not attempt to disassemble the device or do not attempt repairs. In the event your device doesn't work, please contact with our company or Raycome Health distributors.

15. If the device and accessories meet the life span, please dispose it comply with the relevant local regulations, as well as processing the packaging materials.

Part Seven Installation and Operation

1. Installation

Take mainframe and accessories such as probes, probe wires, cables and laser protective goggles etc. out from packing box. User should connect probe, probe wires, cable with electrical outlet.

Caution:

- 1) Do treat laser probe carefully and lightly without collision and falling for avoiding mechanical damage because of optical system and laser material.
- 2) This instrument must be connected to a grounded outlet protection, if the outlet is not connected with ground wire, please do not use it.
- 3) In order to ensure your safety and the performance of the instrument, please kindly use the accessories attached.

2. Operation explanation

⚠ Caution: Please wear the goggles before operating.

1) Start Up: Turn the Key Switch to the ON position as clockwise rotation, LED screen display the boot screen, and boot into standby, the default mode is continuous working mode, setup default time as 3 minutes.



2) Chose Working Mode: By press continuity button [-] and discontinuity button [- -] to chose working mode, the screen would display the corresponding tag.



In the discontinuity working mode, working time can be adjusted from 1~9 seconds by pressing [Δ] button.



3) Adjust Working Time: Adjustable time is from 0-30 minutes, users can press time button [+ -] to adjust the treatment time according to personal needs.



4) Adjust Power: Default power is 200mW, and adjustable power is from 0~500mW, users can press Power button [+ -] to adjust power according to the personal needs.



5) After adjusting the power, please put the laser outlet of the probe to the treated area.



⚠ Caution: Please locate the probe after drying the treated area.

6) Working: Press standby button, the instrument goes into ready status, then, both working time and power can not be adjusted, press the start-up button, the instrument begins to emit laser.



7) Stop: Adjusted time is over, the instrument stops to output laser, and returns to the ready status, and the instrument would prompt users with intermittent sound signal. If you want to stop during the procedure of treatment, please press stop button, and the instrument would return to the ready status without laser output.



Caution: If you want to stop treatment in case of sudden emergency, put the Emergency Switch to shut down the instrument.

8) Shutdown: Turn the key switch to the off position as counterclockwise rotation, the instrument would turn off.



Caution: Please shut down the instrument regularly, do not pull the socket out directly to shut down the instrument, to avoid damage to the instrument.

Caution: After treatment, please remove the key from the key switch in order to protected against unqualified use.

Part Eight Power Calibration

Because the aging of the laser, the contaminate of laser system or otherwise, the actual output power value would be quite different from the display value, so that the instrument should be calibrated, generally once per year. Respectively, choose 200mW and 400mW to be low power and high power calibration in the range of laser output, to make sure the display power match with the actual power output. Ready, low power calibration, high power calibration and end are included in the process of calibration, as following:

Ready:

1. Put the laser emission window of the probe close to the power detector.
2. Hold on the Stop button and do not release.
3. Turn the Key Switch to the ' On ' position, and release the Stop button.
4. The display of the control panel should be '200', prompts that the low power calibration point is 200mW. The original value of the display window should be 'XXX', this is the low power calibration point of last time.

Low Power Calibration:

1. Press the Standby button, Startup button, laser output starts, begin to low power calibration.
2. Press the Power setup button to adjust the output power of the probe, until the display value is '200'mW, the number of the display is the value of the low power calibration. When pressing the Power setup button, the number of the display should be +1 or -1.

High Power Calibration:

1. Press the Standby button, Startup button, begin to high power calibration. The original value of the display window is '400',
2. The number of the display is the value of the high power calibration. When pressing the Power setup button, the number of the display should be +1 or -1.

End

Press the Standby button and Startup button, all the display value return to the initial status, this is the end of the calibration.

Part Nine Cleaning & Maintenance

Medicinal alcohol can be used to clean and maintain the probe cover and the outermost shell. To treat different patient, please disinfect the probe cover with medicinal alcohol (or 70% ethanol, or 70% isopropanol) to prevent cross-infection.

Caution:

- 1) Before cleaning, do shut down the instrument and disconnect the connection of the power cord socket.
- 2) When cleaning, do not let the liquid spill on the instrument and probe, kingly, please fully dry it after cleaning for reusing.

Part Ten Transportation and Storage

1. Transportation

This device can be transported by normal transport tool, however, please prevent from severe shock, vibration, too much rain and snow shower splash or insolation.

2. Storage

After being packed, the device should be stored in environment with relative humidity no more than 93%, ambient temperature from 5℃~40℃, good ventilation system and without corrosive gas.

Part Eleven Common Breakdown

The following form lists the common breakdown of this instrument may occur during the treatment. If you can not fix it after following the suggestions below, please do not hesitate to contact our after-sale service department.

NO.	BREAKDOWN	REASON	RESOLBENT
1	Can not start up	Power is not connected well	Check the power cable is connected or not
		Emergency switch pressed	Rotary the switch as the arrow
		Fuse disconnected	Replace the fuse with the same nominal value
2	No laser output	Probe cable not plugged in	Make sure the cable connected well with the mainframe
		Press Startup button in Standby status	When it is ready, press the startup button to emit laser.

Appendix A EMC

The treatment machine conforms to EMC standards IEC 60601-1-2:2007.



Caution:

1. Please use the recommended accessories, the inappropriate one's may cause the accretion of irradiation and reduction of anti-jamming performance.
2. The instrument should not be close to or stacked with other equipment when used, if necessary, please check the configuration of its operation. Portable and mobile communication device would affect the performance of the instrument, as the following tables: 1. 2. 3. 4

Table 1


Guidance and manufacturer's declaration - electromagnetic emissions		
The Laser Pain-Relief Instrument is intended for use in the electromagnetic environment specified below. The customer or the user of the Laser Pain-Relief Instrument should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions EN 55011	Group 1	The Laser Pain-Relief Instrument uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any
RF emissions EN 55011	Class B	The Laser Pain-Relief Instrument is suitable for use in all establishments , including domestic establishments and those directly connected to the public low- voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Table 2

Guidance and manufacturer's declaration - electromagnetic immunity			
The Laser Pain-Relief Instrument is intended for use in the electromagnetic environment specified below. The customer or the user of the Laser Pain-Relief Instrument 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	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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 %.
Electrical fast 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	± 1kV line(s) to line(s) ± 2kV line(s) to earth	± 1kV line(s) to line(s) ± 2kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) For 0.5 cycle 40 % UT (60 % dip in UT) For 5 cycles 70 % UT (30 % dip in UT) For 25 cycles <5 % UT (>95 % dip in UT) For 5 s	<5 % UT (>95 % dip in UT) For 0.5 cycle 40 % UT (60 % dip in UT) For 5 cycles 70 % UT (30 % dip in UT) For 25 cycles <5 % UT (>95 % dip in UT) For 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Laser Pain-Relief Instrument requires continued operation during power mains interruptions, it is recommended that the Laser Pain-Relief Instrument be powered from an uninterruptible power supply.

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Table 3

Guidance and manufacturer's declaration - electromagnetic immunity			
The Laser Pain-Relief Instrument is intended for use in the electromagnetic environment specified below. The customer or the user of the Laser Pain-Relief Instrument should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 TEST LEVEL	Compliance Level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the Laser Pain-Relief Instrument, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 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 metres (m) b. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
NOTE 1 At 80 MHz and 800 MHz, 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.			

- a 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 Laser Pain-Relief Instrument is used exceeds the applicable RF compliance level above, the Laser Pain-Relief Instrument should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Laser Pain-Relief Instrument.
- b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the Laser Pain-Relief Instrument			
The Laser Pain-Relief Instrument is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Laser Pain-Relief Instrument can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Laser Pain-Relief Instrument as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter M		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
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.			

Appendix B List

Before opening the package of the RG-300IB Laser Pain-Relief Instrument, please kindly count the items as the following list. If they can not meet the list, or you have further questions, please contact with our company or our agent.

No.	Item	Quantity
1	Mainframe	1
2	Key	2
3	Probe	1
4	Power Cable	1
5	Protective Goggles	1
6	User Manual	1
7	Operating diagram	1
8	Warranty \ Certificate	1